Clinical and Imaging Requirements for TAVI

Transcatheter aortic valve implantation is an alternative treatment for patients with severe aortic stenosis who are at high surgical risk or are considered inoperable.

BY ITSIK BEN-DOR, MD; GABRIEL MALUENDA, MD; RON WAKSMAN, MD; LOWELL F. SATLER, MD; GABY WEISSMAN, MD; NELSON PUIG; AND AUGUSTO D. PICHARD, MD

In the last decade, transcatheter aortic valve implantation (TAVI) techniques have shown to be feasible and effective alternative therapies for high-risk patients with severe aortic stenosis. Preprocedural evaluation of patients for TAVI is crucial so as to select the patients who will benefit the most and have the procedure done safely. After determining appropriate operative risk, the interventionist needs to determine the anatomical suitability. Imaging before TAVI provides important information on aortic stenosis severity, aortic valve anatomy, aortic annular dimensions, and peripheral vascular anatomy, key issues to accurately select the prosthesis size and the procedural approach (transfemoral vs transapical). In this article, we focus on risk assessment of potential candidates for TAVI and on multimodality imaging before TAVI using the balloon-expandable Edwards Sapien valve (Edwards Lifesciences, Irvine, CA).

CLINICAL RISK ASSESSMENT FOR PATIENT SELECTION

TAVI is intended for use in symptomatic patients with severe calcific aortic stenosis requiring aortic valve replacement who are at high risk for open chest surgery due to comorbid conditions and for patients who are inoperable. As a general principle, the selection of candidates for TAVI and performance of the procedure require the cooperation of a multidisciplinary team including a cardiologist, cardiothoracic and vascular surgeons, an imaging specialist, and anesthesiologists. Quantification of aortic stenosis severity relies mainly on echocardiographic Doppler techniques: aortic valve area < 1 cm² (< 0.6 cm²/m²) or mean gradient > 40 mm Hg. In patients with depressed left ventricular function, a low-pressure transaortic gradient is commonly observed. In this situation, accurate differentiation between true and pseudo severe aortic stenoses is assessed with dobutamine stress echocardiography. In addition, the anatomy and morphology of the aortic valve is evaluated by echocardiography. The presence of a bicuspid valve is a contraindication for TAVI owing to a high likelihood of asymmetric deployment of the prosthesis. Defining high-surgical-risk patients is not simple. A Society of Thoracic Surgeons (STS) risk score > 10 and/or a logistic EuroSCORE > 20 are most often used to define high risk. The STS score has been shown to underestimate the true mortality rate after cardiac surgery, but it more closely reflects the operative and 30-day mortality rates for the highest-risk patients having aortic valve replacement. The EuroSCORE overestimates the mortality risk of aortic valve replacement, and this overestimation is greatest in high-risk patients. Therefore, high-risk patients for TAVI cannot be selected based on the EuroSCORE because it lacks discrimination and center-specific calibration.

Patients can be at very high-operative-mortality risk and yet have low scores; however, equal scores for two patients do not necessarily imply equal risk. There are
numerous comorbidities not captured in the EuroSCORE and STS scoring systems, such as porcelain aorta, chest wall radiation, chest wall deformity, previous sternotomy, highly compromised respiratory function, frailty, and cirrhosis. There have been attempts to quantify frailty index and to correlate frailty index with outcome; however, the analysis of frailty is particularly difficult and is often not quantifiable. Clinical judgment of experienced cardiac surgeons plays a key role in assessing the operative mortality rate in these cases.

Currently available validated risk score systems have not captured the “nonoperable” patient. Defining inoperability is complicated and often requires the consensus of several surgeons. It is important to emphasize that scoring systems are not intended to be used as substitutes for clinical decision making. Clinical judgment must also play a key role in the patient selection process, and risk scores should be used as adjuvant guidance for clinical decision making. TAVI for high-risk populations is aimed at patients whose comorbidities, such as porcelain aorta, will not interfere with normal recovery after aortic valve implantation. However, patients who are bedridden or have a life expectancy of < 12 months and patients with severe tricuspid regurgitation with fluid retention should not undergo this procedure. Patients must be in stable condition before the procedure. Those in decompensate heart failure with severely depressed left ventricular function should undergo medical optimization and balloon valvuloplasty to allow for improvement of their ventricular function, along with stress echocardiography to assess the myocardial contractility reserve.

**ACCESS SITE PERIPHERAL ANATOMY**

Adequate vascular access is one of the most important determinants of procedural success and/or complications. The 22- and 24-F sheaths used for delivery of the 23- and 26-mm Edwards Sapien valves require minimum vessel diameters of 7 and 8 mm, respectively. The 18- and 19-F sheaths used for delivery of 23- and 26-mm Sapien XT valves require minimum vessel diameters of 6 and 6.5 mm, respectively. Ideally, the minimal lumen diameter should exceed the diameter of the delivery system. However, in the absence of extensive calcification, bulky atheroma, or severe tortuosity, short segments of relatively compliant arteries 1 to 2 mm smaller in diameter than the intended sheath can often be safely cannulated. Three imaging modalities are available to evaluate the access vessels: angiography, contrast-enhanced computed tomography (CT), and intravascular ultrasound (IVUS).

**ANGIOGRAPHY**

Abdominal aortography produces excellent images. Digital subtraction angiography allows for the same or better images with a smaller amount of contrast (10–15 mL) (Figure 1A). Vessel diameters are measured with quantitative coronary angiography and a reference marker pigtail catheter. Excess vessel tortuosity can prevent the large sheath from advancing to the abdominal aorta. Three-dimensional (3D) CT displays are rotated to best define tortuosity. Tortuosity without calcification that is straightened by a wire does not preclude the procedure (Figure 1B and 1C). Tortuosity with marked calcification does not allow the advancement of the large sheaths. Calcification is often not well-appreciated by angiography. We have seen many cases in which the iliofemoral angiogram showed adequate vessels for percutaneous access, whereas the CT revealed severe calcification, thereby making us reject the patient for transfemoral access.

**COMPUTERIZED TOMOGRAPHY**

A detailed CT analysis is very important and can predict possible access problems. The CT images are displayed in longitudinal, 3D, and axial views. Noncontrast CT is very important for quantifying the amount of calcification in both longitudinal and axial views (Figure 2A). The cursor is moved millimeter by millimeter, looking
for areas of significant calcification. Significant calcification, especially in long segments, does not allow straightening. Severe calcification at the bifurcation of the internal and external iliac arteries is of special concern because this area has no yield for expansion or movement; the internal iliac anchors the bifurcation into the pelvis. Concentric calcification can cause significant problems when advancing or retrieving the delivery sheath.

We routinely obtain the contrast-enhanced CT scan using a 4-F pigtail catheter placed in the abdominal aorta, which is left in place after catheterization. The injector is loaded with 20 mL of contrast plus 60 mL of saline. The injection is performed at 4 mL/s for 10 seconds (10 mL of contrast). This technique produces better pictures than standard intravenous contrast and helps preserve renal function in this older patient population with critical aortic stenosis.

The vessel diameter is carefully assessed in longitudinal and axial views. We routinely place the cursor in the abdominal aorta and lower it millimeter by millimeter to get exact measurements throughout the entire length of the vessel considered for access (Figure 2B). Occasionally, the longitudinal images appear to have an adequate minimum diameter, but the axial views do not.

There are some pitfalls that must be taken into account when analyzing CT images. Exact vessel diameter measurements require that the cursor is perpendicular to the longitudinal axis of the vessel, which must be adjusted for each segment of the iliofemoral arteries (Figure 2C). Blooming must be brought to a low level to perform adequate measurements of the vessels and to quantify the extent of calcification because it can falsely lower the apparent lumen diameter. The dimensions can change significantly after correction (Figure 2D).

**IVUS**

IVUS of the iliofemoral vessels is useful when there is discrepancy in the results of angiography and CT. IVUS is an excellent way to measure vessel diameter but does not allow for good analysis of calcification (Figure 3).

### ABdominal and Thoracic Aorta, Ascending Aorta, and Aortic Arch

The abdominal aorta usually has an adequate diameter for the large sheath. Occasionally, CT has shown segments of significant narrowing with severe calcification in the abdominal aorta, which excludes the patient from transfemoral access (Figure 4A).

Patients with extensive atherosclerosis of the aorta or large mobile protruding aortic atheromas (Figure 4B and 4C) are at high risk for a neurological event during the procedure; those with porcelain aorta are included in this group. Atherosclerotic material can also be dis-

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**Figure 2.** Noncontrast CT scan showing severe calcification (A). The axis of the red line must be perpendicular to the vessel to obtain accurate vessel dimensions (B). High-level blooming (left panel) distorts vessel diameter measurement and evaluation of calcium severity; low-level blooming (right panel) allows for precise measurements (C). IVUS analysis of the iliofemoral vessels (D).

**Figure 3.** Iliac analysis by CT using a 4-F pigtail catheter with axial cuts for precise diameter measurement.
placed from the aortic valve itself or from the peripheral vessels and embolized to the brain, resulting in ischemic stroke. Careful advancement of the retroflex delivery system around the arch and the RetroFlex 3 (with a cone at the tip) (Edwards Lifesciences) can help prevent the mobilization of aortic plaques. Nonetheless, the incidence of clinically silent peri-interventional cerebral embolic lesions after TAVI is very high (up to 85%), but clinical significance is much lower at approximately 3%. We routinely externally compress both common carotid arteries while advancing the RetroFlex/valve assembly around the arch. Embolic protection devices are currently under development and might lower the risk of stroke.

Aortic aneurysms usually present no problem when advancing the catheters and valve, but their presence increases the risk of plaque or thrombus dislodgment. Thoracic or abdominal aortic grafts pose no problem in advancing the delivery system, but aortoiliac grafts, especially with a long iliac limb, do not allow the large sheath to advance. Even if the diameter appears adequate, it will wrinkle when the sheath is advanced and lock any movement. In cases of severe peripheral disease or large aortic atheroma, it is better to change the strategy to the transapical approach. CT images of the chest are helpful to plan the transapical procedure, allowing for visualization of the relationship of the apex to the chest wall and for evaluating the angle of approach to the left ventricular outflow tract.
There are several important characteristics of the aortic root and ascending aorta that must be considered. A very uncoiled aorta with the aortic valve in a vertical position (Figure 4D) precludes the ability to deliver the valve to the desired position. These cases are often excluded from the transfemoral approach. The valvular plane where the three aortic sinuses are aligned is commonly defined with fluoroscopy (Figure 5A) and CT images (Figure 5B) of the aortic valve and root for planning the best projection for valve delivery. Preprocedural contrast-enhanced CT imaging of the aortic root allows for the prediction of x-ray angiographic planes and contributes to planning the transcatheter aortic valve implantation. It also reduces fluoroscopy time and the amount of contrast needed.11

CT images enable us to anticipate the best insertion site of the delivery device if a transapical TAVI is planned (Figure 6). Heavy calcification of the aortic valve facilitates positioning of the percutaneous valve but has an increased risk of embolization. This may also cause problems for full and symmetric expansion of the valve and may increase the likelihood of paravalvular regurgitation. In severely calcified aortic valves, the deployment of the valve may be less optimal with more oval- or triangular-shaped deployed frames.12 Moderate postprocedural aortic regurgitation is more frequent with larger aortic valve annulus and more calcified native valves13 and is related to prosthesis/annulus incongruity.14 Device landing-zone calcification (ie, the left ventricular outflow tract) shows significant correlation to paravalvular leak15 and pacemaker implantation after TAVI.16

The aortic annulus is defined as a virtual ring with three anatomical anchor points at the nadir of each of the attachments of the three aortic leaflets. Measurement of aortic annulus diameter (Figure 5C and 5D) before the procedure is crucial to avoid serious complications such as prosthesis migration and to minimize the risk of significant paravalvular leakage after prosthesis implantation. The annulus size will determine which valve size to use: 23- and 26-mm models are now available for annular sizes of 18 to 21 mm and 22 to 25 mm, respectively. At present, no gold standard method to measure the aortic valve annulus has been established.

Most centers are using transesophageal echocardiography (TEE) for annulus sizing with good clinical results. Measuring the annulus by transthoracic echocardiography (TTE) usually underestimates annulus size compared with TEE, with a mean difference of 1.36 mm.17 In cases that will possibly require a 26-mm valve and have borderline iliac size, the interventionist must perform TEE before the percutaneous valve procedure to ensure that the 23-mm valve will be sufficient. Two-dimensional echocardiography may not be the ideal approach because only one dimension of the aortic valve annulus is measured.

The aortic valve annulus has an oval shape with the coronal diameter larger than the sagittal diameter. Magnetic resonance imaging and CT have shown to be more accurate than TEE to measure the aortic valve annulus using perioperative measurements as the reference; TEE underestimates the aortic valve annulus.18 Planimetric aortic valve annular measurement by 3D TEE has the best agreement with CT annular measurement; two-dimensional measurement underestimates annular size.19 A study that investigated the potential

Figure 6. CT analysis of the left ventricle in relation to the aorta and the aortic valve annular plane to plan the transapical approach (A). The left ventricular apex is identified, and the optimal insertion point at the intercostal space is identified (B). Color tagging of the left and right ventricles in axial projection and relation to sternum (C).
The heights of the Edwards Sapien valves are 14.5 and 16 mm for the 23- and 26-mm devices, respectively. The distance between the aortic annulus and the coronary ostia is reported by Tops et al\textsuperscript{22} to have a large variability and is independent of patient height. The mean distance between the ostium of the right coronary artery and the base of the sinus of Valsalva is usually higher than the left coronary ostium (17.2 ± 33 mm vs 14.4 ± 2.9 mm). There is wide variation ranging from 7.1 to 22.7 mm. In almost 50% of the cases, the distance between the coronary ostium and the annulus was smaller than the left coronary leaflet length, which may increase the risk of coronary occlusion during TAVI. In patients with calcific aortic stenosis, the aortic root may show a longitudinal remodeling, and the distance between the aortic annulus and coronary ostia may decrease.\textsuperscript{23} It is important to evaluate the length between the inferior aspect of the annulus and the inferior aspect of the lowest coronary ostium for subsequent prosthetic aortic valve implantation (Figure 5E). The distal two-thirds of the stent are uncovered to allow for coronary perfusion if the prosthetic stent covers the coronary ostia, and coronary intervention, if needed, is feasible.\textsuperscript{24}

In a case of low left main coronary artery origin, it is recommended to obtain an aortogram during balloon valvuloplasty to determine if the aortic leaflet could obstruct the left main coronary artery ostium. The risk factors for coronary occlusion include high implant, long left coronary ostium, and long leaflet with bulky calcified nodules.

**LEFT VENTRICULAR ANATOMY AND FUNCTION AND OTHER COEXISTENCES**

Evaluation of left ventricular dimensions and function is a part of preprocedural screening of TAVI candidates. The presence of intracardiac thrombus is a contraindication for a TAVI procedure; previous apical myocardial infarction and apical wall thinning may contraindicate the transapical approach owing to the high risk of left ventricle tearing and pseudoaneurysm formation. In addition, the coronary arterial anatomy should be evaluated by coronary angiography because the presence of significant coronary artery disease not amenable for percutaneous intervention may be a relative contraindication for TAVI.

Severe organic mitral regurgitation should be an exclusion criterion for TAVI. To evaluate how much the mitral regurgitation could be secondary to critical aortic stenosis, the interventionist can perform aortic valvuloplasty and see the results in the following weeks. In many patients, the left ventricular function improves, and the mitral regurgitation diminishes significantly after valvuloplasty.\textsuperscript{25} Patients with mild or moderate mitral regurgitation do well with TAVI, and the degree of mitral regurgitation usually improves significantly.

In patients with marked hypertrophy of the septum or sigmoid septum, accurate positioning of the percutaneous valve may be hampered; during balloon inflation, the lack of space may squeeze the balloon toward the aorta before the stent/valve opens, and the valve will rise up, thereby increasing the risk of misplacement or even embolization. To avoid this, we mount the valve lower in the balloon; this technique has resulted in less or no motion of the stent/valve during deployment. Dynamic subvalvular obstruction may lead to severe hypotension when the valvular obstacle is relieved.

**SUMMARY**

Detailed, precise screening is the key to TAVI success. Patients are selected based on their high surgical risk or inoperability. Due to the large delivery system, careful evaluation of the peripheral vascular anatomy is indispensable. Because this is the most common cause of morbidity/mortality, we recommend angiography and high-quality CT in all patients. To determine the potential risk of neurological events, it is important to know the amount of atherosclerosis and plaque in the aortic arch and ascending aorta. Measuring the aortic annulus diameter is key to selecting the correct prosthesis size and is very important in preventing paravalvular leak or valve migration. The relationship among the aortic annulus, left coronary leaflet, and left coronary ostium is important. Assessment of all these components is necessary for preprocedural planning of access approach, valve sizing, and deployment.

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Itsik Ben-Dor, MD, is with the Department of Interventional Cardiology at the Washington Hospital Center in Washington, DC. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Gabriel Maluenda, MD, is with the Department of Interventional Cardiology at the Washington Hospital Center in Washington, DC. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Ron Waksman, MD, is Professor of Medicine, Georgetown University, and Director of Experimental Angioplasty & New Technologies at the Washington Hospital Center in Washington, DC. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Lowell F. Satler, MD, is Professor of Medicine, Georgetown University, and Director of the Catheterization Labs at the Washington Hospital Center in Washington, DC. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Nelson Puig is Senior Cardiovascular Technician of the catheterization labs at the Washington Hospital Center in Washington, DC. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Augusto D. Pichard, MD, is Professor of Medicine, Georgetown University, and Director of the Catheterization Labs at the Washington Hospital Center in Washington, DC. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Dr. Pichard may be reached at (202) 877-5975; guspichard@gmail.com.