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Computed Tomography Imaging Prior to Transcatheter Aortic Valve Replacement

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Abstract Transcatheter aortic valve replacement (TAVR) has emerged as an effective and lower risk treatment option for patients with severe aortic stenosis deemed to be too high risk for surgical replacement. Careful pre-procedural evaluation of aortic annular geometry is pertinent for appropriate transcatheter aortic valve sizing in such patients with three-dimensional datasets provided by multi-detector computed tomography (MDCT) proven to be superior in aortic annular evaluation. Moreover, MDCT plays an important role in the assessment of annular calcification associated with aortic root complications, as well as, the identification of patients at increased risk of coronary occlusion and the determination of co-planar angulations used for valve deployment during the TAVR procedure. In this review, we discuss the rationale for aortic annular assessment prior to TAVR using MDCT with a particular focus on transcatheter aortic valve sizing.

Keywords Transcatheter aortic valve replacement · Computed tomography imaging · Calcific aortic stenosis

Introduction

Calcific aortic stenosis (AS) continues to represent a significant burden on the healthcare system especially as the population continues to age [1]. It has been long established that clinical deterioration is rapid once symptoms develop with very poor survival rates reported for medically treated severe symptomatic AS [2]. Accordingly, the 2014 American Heart Association/American College of Cardiology Guidelines for the Management of patients with valvular heart disease recommend surgical intervention once symptoms develop in the clinical setting of hemodynamically severe AS [3]. Unfortunately, many elderly patients with severe AS are frail and burdened by multiple medical co-morbidities, which places them at high surgical risk. Medical therapy alone in such patients is not only associated with increased mortality but also significant morbidity, as patients are debilitated by AS-related symptoms and require more frequent hospitalization. In the past decade, transcatheter aortic valve replacement (TAVR) has emerged as an alternative, effective, and lower-risk treatment option for this cohort.

Following the first successful transvenous implantation over 10 years ago [4], clinical efficacy of TAVR has been repeatedly demonstrated, initially in observational cohort studies [5, 6] and subsequently in the form of prospective randomized controlled trials [7, 8, 9•]. The placement of aortic transcatheter valves (PARTNER) trial was the first randomized trial demonstrating clinical efficacy using the balloon-expandable Sapien valve system (Edwards Lifesciences, Irvine, CA). In the PARTNER 1B arm, patients deemed to be too high risk for surgery were randomized to either TAVR or standard therapy (including balloon valvuloplasty). At 1 year, TAVR was associated with reduced overall mortality as well as improved symptoms compared to standard therapy, although patients in the TAVR group had higher major stroke and vascular complication rates [7]. In PARTNER A, TAVR was shown to be non-inferior to surgery among patients with severe AS who were considered high operative risk but still surgical

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candidates [8]. More recently, the efficacy of the self-expandable core valve system (Medtronic, Minneapolis, MN) was also demonstrated in a prospective randomized controlled trial comparing surgery to TAVR among high-risk patients [9•]. TAVR with both balloon-expandable and self-expandable valves has therefore proven to be an effective treatment option for patients with severe AS deemed to be at high surgical risk.

Multi-detector Computed Tomography in Patients Undergoing TAVR

Pre-procedural multi-detector computed tomography (MDCT) imaging in TAVR patients was, until recently, primarily concerned with the assessment of the peripheral vessels ('aorto-ilio-femoral vasculature') to identify patients potentially at increased risk of vascular complications. In this regard, contrast-enhanced MDCT of the aorto-ilio-femoral vasculature is performed to identify patients with reduced luminal caliber relative to femoral sheath diameter, arterial tortuosity, and arterial calcification, particularly circumferential or 'horse-shoe' calcification within the distal vessels. The identification of high-risk vascular anatomy using MDCT permits pre-procedural identification of patients in whom consideration of alternative access (transapical, transaxillary or transaortic) is necessary. Peripheral vascular evaluation is therefore an important focus of the Society of Cardiovascular CT (SCCT) guidelines for MDCT before TAVR [10].

More recently, MDCT has played an additional role in the pre-procedural evaluation of TAVR patients, namely assessment of the aortic root, particularly with regards to appropriate transcatheter heart valve (THV) sizing. Given its three-dimensional capabilities supported by its isotropic voxels, MDCT has been shown to provide important and reproducible information regarding the geometry of the commonly non-circular aortic annulus, as well as, a detailed assessment of the aortic root. The goal of MDCT in this setting is to help reduce the risk of TAVR-associated complications including paravalvular aortic regurgitation (PAR), coronary occlusion, aortic root rupture or hematoma, and device embolization. Assessment of aortic annular dimensions; the extent and nature of aortic annular and sub-annular calcification; coronary ostium height; sinus of Valsalva (SoV) dimensions and estimation of angulation planes for angiography are important components of the pre-procedural MDCT that contribute to lower rates of procedure-related complications.

Clinical Importance of Appropriate Device Sizing Using MDCT

Device sizing in TAVR is performed pre-procedurally because, unlike surgical aortic valve replacement, the aortic root cannot be directly visualized at the time of TAVR. Appropriate device sizing is crucial in order to avoid TAVR-associated complications due to 'over-sizing' including aortic root hematoma and/or rupture [11]; and similarly, due to 'under-sizing' including PAR [12] or, less commonly, device embolization. PAR is more frequently observed following TAVR compared to the other complications of patient-prosthesis mismatch, with mild or greater PAR occurring in 25 % of patients following TAVR in one study [13]. PAR is observed more frequently following TAVR compared to surgical aortic valve replacement and is associated with significant morbidity and mortality [14, 15, 16•]. Appropriate device sizing is therefore primarily targeted at minimizing the risk of post-implantation PAR.

The primary mechanism of PAR following TAVR is thought to be incomplete apposition between the device and the surrounding annular structures due to under-sizing. This was initially related to THV under-sizing owing to limitations imposed by two-dimensional imaging of the anatomically complex aortic annulus using echocardiography and aortic root angiography.

The aortic annulus is defined as the plane that bisects the nadirs of the aortic cusps (Fig. 1). Importantly, the geometrical configuration of the annular ring more closely resembles an oval rather than a circle and therefore the diameter obtained by direct calipers using a two-dimensional imaging modality is significantly dependent upon the plane obtained and likely to underestimate annular dimensions.

Three-dimensional datasets, primarily those obtained by MDCT, have been shown to overcome the pitfalls of two-dimensional imaging. Initial studies comparing MDCT and two-dimensional echocardiography suggested significant inter-modality differences in the acquired measurements. This was primarily due to the non-circular configuration of the annulus, which was previously underappreciated by two-dimensional echocardiography. Not surprisingly, when MDCT-based sizing was retrospectively applied in patients that underwent transesophageal echocardiography (TEE)-based sizing; a change in the device size selected was observed in many patients. These discrepancies were seen most commonly in patients who experienced greater than mild PAR. Multiple retrospective studies demonstrated that MDCT could more accurately predict the development of PAR post-implantation than two-dimensional echocardiography [17–21]. In one study, annular measurements obtained by MDCT including mean annular diameter and annular area were the best predictors of PAR in patients undergoing TAVR with a balloon-expandable (Sapien XT) valve [21]. In that study, patients with a device that produced annular over-sizing by $\geq$1 mm in diameter or $\geq$10 % by annular area had a significantly lower rate of moderate-severe PAR. Based on these observations, the same investigators

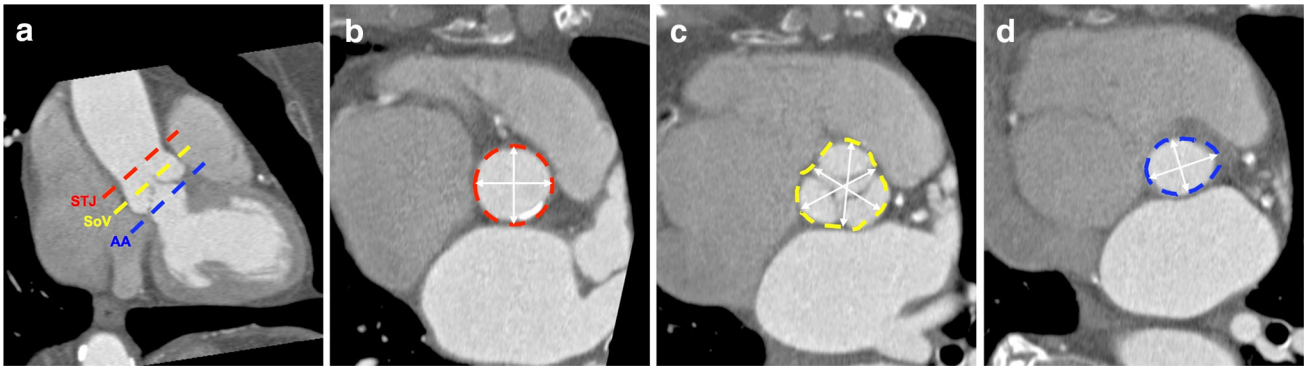

Fig. 1 Anatomy of the aortic root. Oblique sagittal image of the aortic root (**a**) is shown with the approximate levels of the sinotubular junction (STJ), sinuses of Valsalva (SoV) and aortic annulus (AoA). Double-oblique axial images (**b–d**) demonstrating differences in geometrical configuration at each level of the aortic root

developed a sizing algorithm (with a target of 10–15 % oversizing by annular area) and demonstrated that retrospective application of this algorithm led to improved prediction of PAR compared to TEE [20]. In a prospective study, the implementation of a similar algorithm based on modest oversizing (annular area over-sizing by 5–10 %) using the balloon-expandable Sapien XT resulted in a lower incidence of their primary study endpoint (mild or greater PAR) [22••]. Additionally, the algorithm also resulted in reduction of the secondary combined endpoint of in-hospital death, aortic annulus rupture, or severe PAR, although this was driven by lower rates of severe PAR. More recently, the retrospective application of MDCT derived perimeter-based sizing has also been shown to be predictive of PAR in patients treated with the self-expandable CoreValve who were originally sized using TEE [23]. These data highlight the superiority of three-dimensional measurements from MDCT in measuring annular dimensions and guiding device sizing in comparison with two-dimensional methods. It should be noted that recent studies have also tested the ability of three-dimensional echocardiography (3DE) in overcoming the weaknesses of two-dimensional imaging. Multiplanar reformats analogous to those used in MDCT can be reconstructed using 3DE and have been shown to permit accurate measurement of annulus size [24]. While some studies have shown MDCT to be superior to 3DE in predicting PAR [25], equivalent performance between modalities was more recently demonstrated [26]. Therefore, while MDCT is generally the preferred modality for aortic annular assessment in TAVR patients, it is reasonable to consider 3DE in patients where MDCT is not possible including patients with renal dysfunction or factors associated with poor MDCT image quality.

Data Acquisition and Aortic Annulus Measurements for Device Sizing

With regards to CT protocols for annular assessment in TAVR patients, guidelines issued by the SCCT provide useful recommendations for data acquisition in this setting. High spatial resolution images of the aortic root with minimal motion artifact are required to permit accurate measurements [10]. Specific protocols will vary depending on the institution and available scan platform. Typically, scanners with 64-slice detector widths are utilized in which case two acquisitions are performed. First, an ECG-gated acquisition of the cardiac field of view (carina to the inferior cardiac surface) is obtained following intravenous contrast administration to assess the aortic valve and aortic root; second, a non-gated scan of the thorax and abdomen (lung apices to lesser trochanters) is immediately performed to assess the remaining aorta and ilio-femoral vasculature without further contrast administration. The aortic root acquisition is performed during held respiration with either 'prospective' or 'retrospective ECG-gating with tube modulation' and a slice thickness of $\leq$1.0 mm is reconstructed. Importantly, if multiphasic data are available, the systolic images are utilized for annular measurements as prior studies have demonstrated larger annular dimensions during systole compared to diastole [27]. The change in annular dimensions during the cardiac cycle appears to predominantly affect annular area and minimal diameter measurements (annular configuration becomes less eccentric during systole) [28]. The contrast bolus is administered using either 'bolus-tracking' or 'test-bolus' methods depending on the CT scanner. While the risk of radiation dose is less of a concern due to the older age of TAVR patients, contrast dose is a more important consideration owing to the frequent observation of co-existing renal impairment in this cohort and the propensity to develop renal dysfunction following TAVR, which is associated with poor outcomes [29]. Efforts to reduce contrast-related nephrotoxicity including administration of a smaller total dose in patients with impaired renal function must be weighed against the risks of obtaining poor images that may affect accurate pre-TAVR assessment.

To measure annular dimensions for THV sizing, the annulus is first reconstructed using multiplanar reformats

(Fig. 2). Typically, a plane approximating the annulus is obtained by adjusting the cross-hairs in sagittal and coronal views. Further adjustments are then made in these now oblique planes until the annulus, defined by the plane that bisects the nadirs of the aortic cusps, is identified in the double-oblique axial plane. This is confirmed by scrolling in the double-oblique axial images to ensure that the aortic cusps appear and disappear simultaneously. The annulus is then planimetered to determine annular area and perimeter. Average annular diameter can be derived from the planimetered area ($D_{\text{Area}} = 2 \times \sqrt{(\text{Area}/\pi)}$) or perimeter ($D_{\text{Perimeter}} = \text{Perimeter}/\pi$) assuming a circular configuration of the annulus (Fig. 2). Maximal and minimal diameters can also be obtained by direct caliper measurement with reporting of the average value. Multiple studies have demonstrated reproducibility of these measurements [30–32]. While some authors have suggested improved reproducibility with area and others with perimeter, it has been shown that interobserver agreement in prosthesis size recommendation is significantly improved when all three measurements are considered in formulating a "consensus result" [31].

Principles of Device Sizing Based on MDCT Derived Annular Measurements

While the annulus can be reproducibly reconstructed in most TAVR patients and dimensions obtained with high accuracy using MDCT, the subsequent selection and sizing of the device need to be individualized for the patient. Importantly, sizing will vary depending on the device selected as discussed below. It must also be noted that for some patients, annular dimensions may fall outside of the range of available valve sizes (Edwards Sapien: 20-, 23-, 26- and 29-mm; CoreValve: 23-, 26-, 29- and 31-mm), particularly in elderly women with severe AS who are known to have smaller aortic annulus and left ventricular outflow tract dimensions compared to males [33].

THV sizing in the prospective study of the Sapien XT (balloon-expandable) valve involved modest over-sizing (5–10 % by annulus area with an acceptable range of 1–20 %). This degree of over-sizing resulted in significantly improved clinical outcomes, particularly with regards to the incidence of clinically important PAR [22••]. Accordingly, device sizing using this valve has predominantly used annulus area-based 'modest over-sizing.' In cases where the annulus size falls between available device sizes, the use of the larger device is generally recommended with under-inflation of the filling balloon to result in a device size that is between the deployed device and the device one size below. This is generally recommended if the fully deployed device is likely to result in ≥20 % over-sizing by annulus area with the balloon-expandable Sapien XT. In cases of 'adverse aortic root features' such as sub-annular calcification or a shallow SoV, under-inflation of the device is recommended at a lower threshold (when full deployment is expected to result in ≥15 % over-sizing). It is important to note that with the introduction of the new generation balloon-expandable Sapien 3, sizing algorithms will need to be further redefined to account for any differences resulting from the new prosthesis design.

For the self-expandable CoreValve, perimeter-based sizing algorithms have been largely based on manufacturer recommendations. As discussed earlier, perimeter-based sizing was shown in a retrospective study to improve the prediction of PAR in patients undergoing TAVR with the CoreValve [23]. The subsequent demonstration of improved clinical outcomes in patients receiving the CoreValve in a prospective randomized controlled trial [9•] suggests that, assuming the operators adhered to the manufacturers recommendations, perimeter-based THV

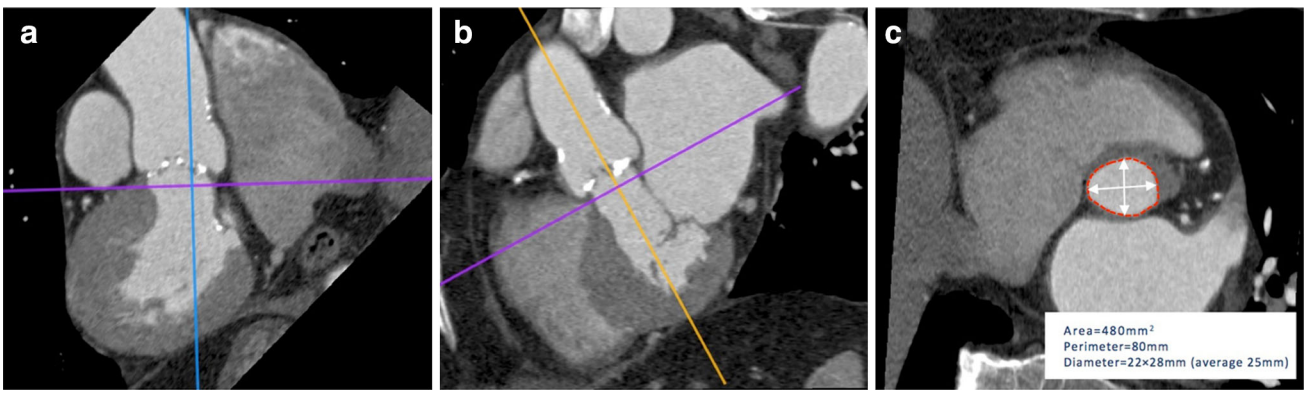

Fig. 2 Measurement of aortic annular dimensions for THV sizing. Multiplanar reformats are used with adjustment of the cross-hairs in the oblique coronal (**a**) and oblique sagittal (**b**) views until a double-oblique cross-sectional plane bisecting the nadirs of the aortic cusps is achieved. The aortic annulus is subsequently planimetered for calculation of annular area, perimeter, and diameter (**c**)

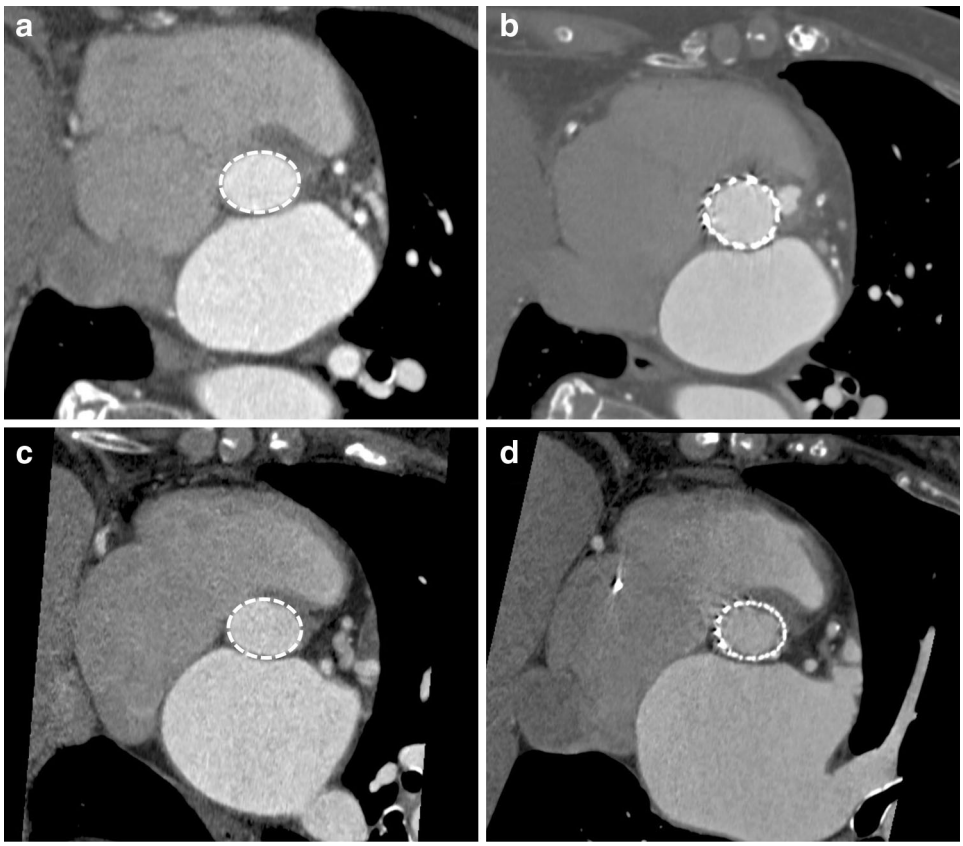

Fig. 3 Change in annular geometry following TAVR. The *oval-shaped* native aortic annulus (**a**, **c**) adopts a more *circular* configuration following TAVR using a balloon-expandable valve (**b**) compared to a self-expandable valve (**d**)

sizing is appropriate for this valve. Accordingly, THV sizing for patients receiving the CoreValve is primarily undertaken using annulus perimeter.

An important consideration in device sizing based on MDCT annular measurements is the change in the geometric configuration of the annulus following TAVR. In patients receiving a balloon-expandable valve, the oval-shaped native annulus often becomes circular in configuration, whereas deployment of a self-expandable valve results in less change to annular geometry (Fig. 3). Balloon-expandable valves therefore result in a more significant increase in annular area following TAVR compared to self-expandable valves, particularly in patients with an eccentric native annulus and this needs to be considered in deciding on the degree of annular over-sizing. Unlike area, the degree of annular perimeter change following TAVR is expected to be less significant; however, the availability of planimetry tools with smoothing algorithms that provide reliable perimeter measurements has been limited until recently and investigators have therefore primarily used annular area for THV sizing. It should be noted that the degree of over-sizing is dependent upon the annular measurement chosen with percentage over-sizing by area being significantly greater than that calculated using perimeter measurements [34].

Additional Imaging Considerations Prior to TAVR

Apart from annular size, additional factors may also affect device selection. In particular, the presence and extent of annular and/or sub-annular calcification is important as this may increase the risk of aortic root rupture particularly protruding sub-annular nodular calcium [35•]. In such patients, the risk of PAR is increased irrespective of how appropriate the device size is [36•, 37] and therefore an approach that involves aggressive over-sizing should be avoided and a compromise between excessive PAR and an increased risk of aortic root rupture is required. Qualitative assessment of aortic root calcification including site and severity as well as the identification of nodular calcification is an important component of MDCT prior to TAVR.

Coronary artery occlusion is a highly feared, albeit uncommon, complication of device deployment during TAVR that is associated with increased mortality [38]. The left coronary artery is more frequently affected owing to its closer proximity to the annular plane compared to the right coronary artery. The identification of patients at risk of this complication is important so that the operator may employ strategies thought to lower the risk. In an observational registry study, coronary height and decreased SoV dimensions were associated with increased risk of coronary

occlusion compared to a matched control group [38]. The majority of patients that developed coronary occlusion had a coronary height <12 mm and SoV dimension <30 mm. Accordingly, measurement of the perpendicular distance between coronary artery ostium and annular plane and SoV dimensions in an orthogonal plane is routinely performed in patients undergoing MDCT prior to TAVR.

A final component of the MDCT assessment of the aortic root prior to TAVR is the estimation of angulation planes for angiography. MDCT has been shown to reduce procedure time and lower contrast and radiation dose by guiding the operator to the angulations likely to provide a co-planar view of the annulus [39].

Conclusions

Appropriate device sizing is crucial in patients undergoing TAVR to minimize the risk of complications due to patient-prosthesis mismatch, particularly PAR. Three-dimensional datasets provided by MDCT (or 3DE if MDCT is not possible) allow accurate measurement of annular dimensions and are preferred over two-dimensional imaging modalities. Device sizing needs to be individualized and while primarily driven by annular dimensions, consideration of other patient-specific factors especially native annular geometry and annular or sub-annular calcification; as well as device-specific factors is crucial in selecting the most appropriate device.

Compliance with Ethics Guidelines

Conflict of Interest Dr. Christopher Naoum declares no potential conflicts of interest. Dr. Jonathon Leipsic and Dr. Philipp Blanke serve as consultants and provide corelab CT services for Edwards Lifesciences.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance

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