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The Use of Computed Tomography Prior to TAVR: Prediction and Prevention of Complications and Impact on Outcomes

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Abstract Cardiac CT is increasingly being utilized as an essential component of the work-up for transcatheter valve replacement. The article reviews the most contemporary published literature on the strengths of cardiac CT for predicting and minimizing adverse procedural outcomes, including aortic annular rupture, paravalvular leak, conduction disturbance, and coronary obstruction.

Keywords Aortic stenosis · TAVR · Paravalvular regurgitation · Transcatheter heart valve · Aortic annulus · Device sizing

Introduction

Transcatheter aortic valve replacement (TAVR) has been rapidly adopted by the medical and surgical community as a treatment strategy for severe symptomatic aortic stenosis in patients considered to be at high risk for conventional surgical aortic valve replacement [1–3]. There is a growing body of literature demonstrating its long term efficacy and safety in severe aortic valve stenosis [3, 4•, 5•]. While initially the role of multidetector computed tomography (MDCT) was confined to the assessment of vascular access to help mitigate the risk of vascular injury and to help provide guidance to the proceduralist, it is being increasingly recognized that MDCT, through its isotropic voxels, high spatial resolution, and multiplanar capabilities can provide important information regarding the aortic root and annulus allowing for the opportunity to improve on clinical outcomes.

This article is part of the Topical Collection on *Cardiac Computed Tomography*

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Annular Sizing Background

Unlike surgical valve replacement, where it is possible to directly measure the size of the aortic annulus in vivo, TAVR requires accurate and reproducible noninvasive imaging to size the annulus and aortic root in advance of the procedure to guide the selection of an appropriately sized prosthesis, and to help mitigate the risk of paravalvular regurgitation, annular rupture and prosthesis malposition/embolization.

The 2 procedural complications that have attracted the most clinical attention have been paravalvular regurgitation and annular rupture: the former because it is relatively common and has been consistently shown to be a strong predictor of poor medium to long term outcome, and the latter because while rare, it is catastrophic and frequently fatal. As experience grows, the goal has been to find an appropriate prosthesis sizing algorithm that balances the need to place a prosthesis large enough to minimize paravalvular regurgitation while ensuring that the valve selected is not so large that the risk of annular rupture is unacceptably elevated. These complex imaging requirements have resulted in a push for the integration of advanced 3-dimensional imaging, which allows for a more granular assessment of the annulus and surrounding anatomic structures.

At the initial stages of the development and adoption of TAVR, 2D echocardiography was utilized to estimate aortic annulus diameter and guide prosthesis selection. It has since been recognized that there is a tendency for 2D echocardiographically-derived measurements to systematically underestimate the size of the annulus. This is largely due to the noncircular geometry of the annulus rather than measurement error itself. The noncircular configuration of the annulus has been known for some time by anatomists but

had been underappreciated by the TAVR community owing to the limitations of 2-dimensional imaging. Three-dimensional imaging techniques show that the in vivo aortic annulus is an ellipsoid structure, with dimensions and eccentricity that are dynamic over the cardiac cycle (Figs. 1 and 2). Transesophageal echocardiography (TEE) 2D based measurements measure the "diameter" of this ovoid structure by transecting it in a single imaging plane, traditionally in the parasternal long axis, or equivalent TEE plane, transecting the ellipse largely through its short axis and leading to a systematic underestimation of annular size [6–11]. The use of an implicit circular assumption in calculating annulus area using $A=(\pi d/2)2$ for the echocardiographically calculated area causes a similar underestimation of annular area.

A number of different MDCT measurements have been proposed for the assessment of the annular geometry once the plane of the virtual annular ring has been defined. The first is simply to measure the long and short diameters of the annular ellipse and calculate the mean diameter. The obvious issue with this method is that the degree of eccentricity of the annulus is highly variable. The second method is to use the perimeter, while the third method is to use the planimetry-derived cross sectional annular area [12, 13•]. The literature suggests that, although it may be more dynamic than perimeter over the course of the cardiac cycle [14], the advantage of using area as a measurement is that it has been consistently been shown to be the most reproducible measure [14, 15•, 16].

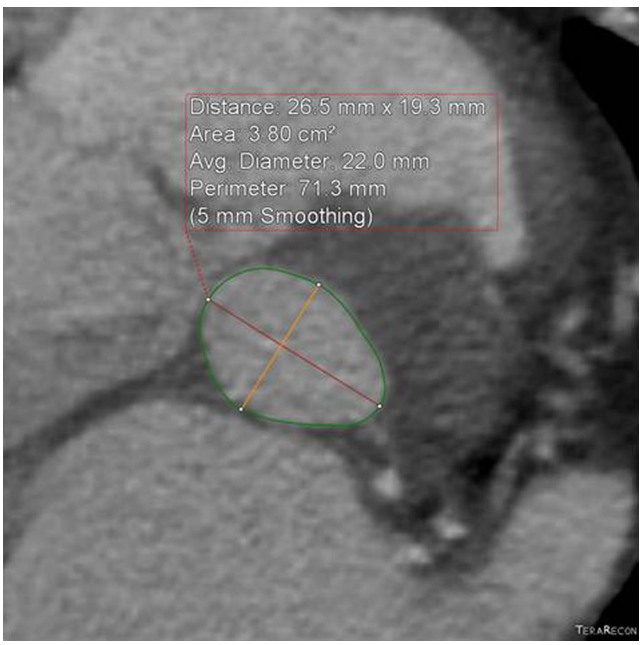


Fig. 1 Ellipsoid aortic annulus with CT measurements: long diameter 26 mm, short diameter 19 mm and area 380 mm^2 leading to recommendation to implant 23 mm valve. TEE derived measurements were an annular diameter 19 mm and would have suggested using 20 mm rather than 23 mm prosthesis, possibly leading to significant undersizing and paravalvular leak

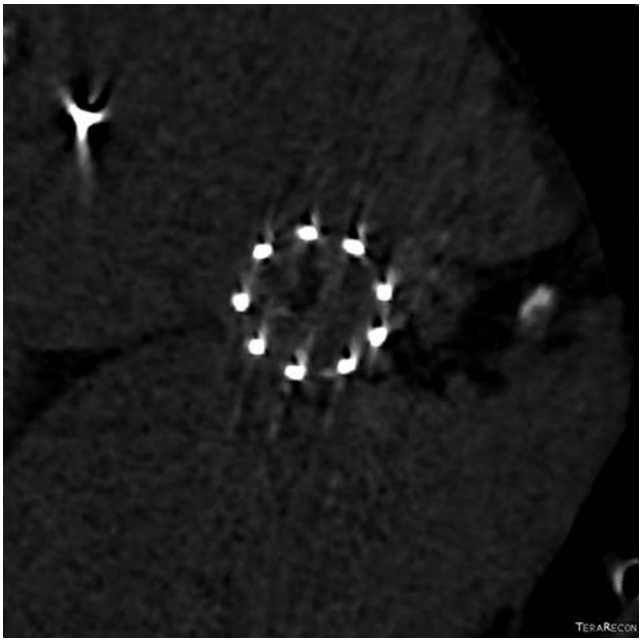


Fig. 2 Noncontrast post-TAVI CT demonstrating the ellipsoid annulus becoming circular following the deployment of a balloon-expandable valve

Four-dimensional computed tomography of the aortic annulus in the beating heart has shown that it is a dynamic structure across the cardiac cycle, becoming more circular and less eccentric in systole, driven largely by an increase in the short axis diameter, with a corresponding increase in overall cross-sectional area. The systolic increase in area varies from 6 % in normal subjects, to 10 %–15 % in those with calcific valves [14]. It is, therefore, recommended that MDCT measurements of area are made during systole when area is maximal. Our group has previously shown that using an area based sizing algorithm that 20 % of patients would have had a smaller valve size selected if diastolic measurements were used instead of systolic ones [13•].

Others have suggested that the annular perimeter is a more appropriate measure for valve selection and annular sizing owing to greater stability across the cardiac cycle [14, 17]. This remains a topic significant debate with discordance between phantom and patient studies [14, 18]. In addition, care must be taken when using perimeter measurements of the annulus owing to inconsistent integration of smoothing algorithms on workstation platforms resulting in artificially enlarged perimeter measurements.

It additionally needs to be understood that there are important mechanistic differences in the way that balloon-expandable and self-expanding valves impact the annulus when they are deployed. The balloon-expandable devices lead to an almost uniformly circular annulus following the procedure, "forcing" a geometric change of the annular shape from oval to circle [19], with an increase in area with relative preservation of perimeter with oversizing. The self-expanding

valves in contrast, conform to the native annulus shape, and thus, oversizing leads to an increase in both perimeter and area. For this reason, different geometric approaches might be preferable for different valve types (Figs. 3–6).

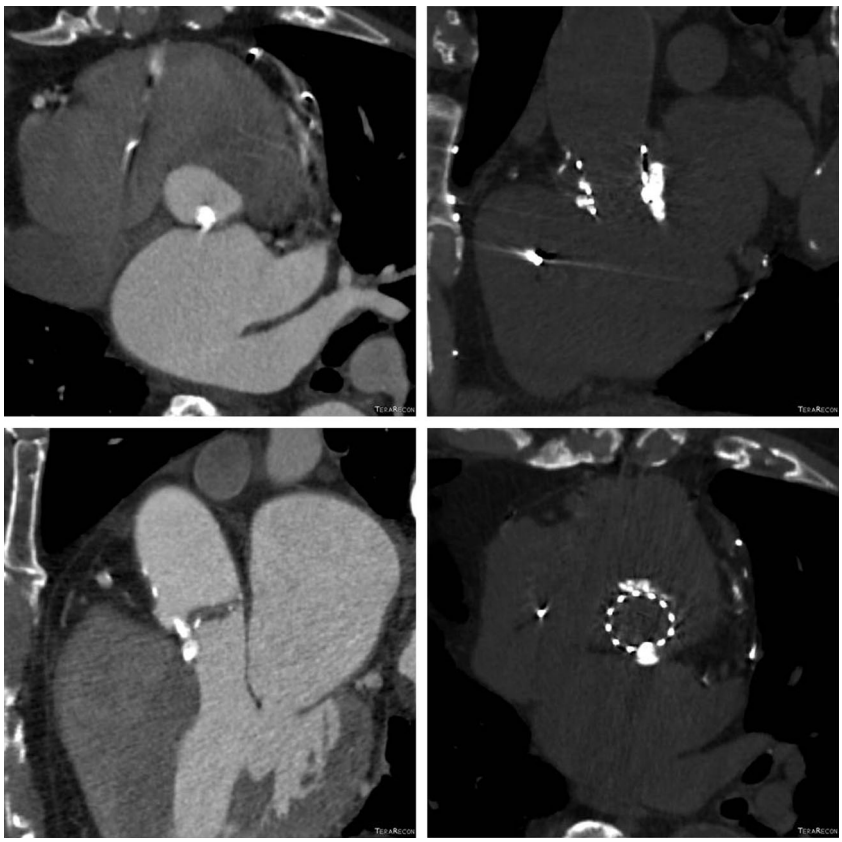
We believe that the current data supports the routine use of annular area to guide sizing due to its robust reproducibility and proven efficacy in minimizing paravalvular leak, particularly when implanting balloon-expandable valves [13•].

Paravalvular Regurgitation, Annular Rupture, and Prosthesis Sizing

Paravalvular aortic regurgitation (PAR) was fairly common in the PARTNER A and B, with at least moderate PAR seen in 12.9 % vs 0.9 % of patients at 30 days in PARTNER A when compared with the surgical arm, and 6.8 % vs 1.8 % at 12 months [20]. In PARTNER B, the 30-day and 12-month rates of at least moderate PAR were 11.8 % and 10.5 %, respectively [21]. Importantly, the presence and degree of PAR appears to have important prognostic implications, with even mild PAR being a predictor of late mortality in the PARTNER 2-year follow-up [22]. TAVR literature is increasingly recognizing that PAR is one of the more important sequelae of TAVR in terms of long term outcome, and much recent effort has been applied to the development of strategies to mitigate PAR [23–25].

There is a growing body of data to show that the integration of MDCT derived measurements of annular area (as opposed to 2D echo based diameter) into prosthesis selection with a goal of moderate oversizing, leads to significant decreases in the incidence of PAR without an unacceptable rise in annular rupture rates.

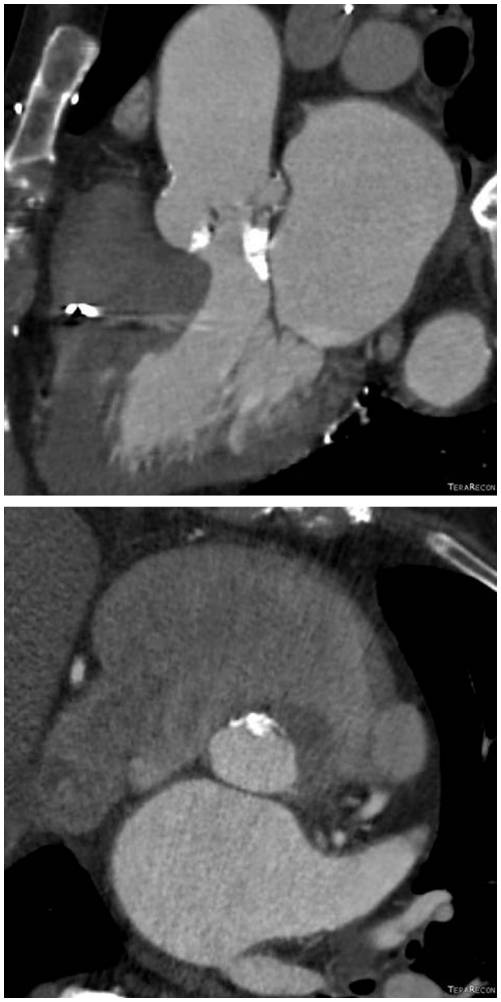
Data from the past 2 years has demonstrated that, in addition to procedural factors, annular and prosthesis sizing are the strongest predictors of PAR. Further prospective data has shown that CT derived area measurements outperform TEE derived diameter estimates in minimizing postprocedural PAR. Willson et al demonstrated in 2012 via a multicenter retrospective analysis that relative prosthesis undersizing is the strongest predictor of moderate or severe PAR, with percentage oversizing of MDCT derived area a stronger predictor than percentage oversizing of TEE derived diameter. Importantly, this paper also demonstrated that MDCT-derived 3D measurements are robustly reproducible over multiple readers across multiple centers and vendor platforms [13•]. Jilaihawi's single-center 2012 paper showed similar results, and proceeded to the introduction of a prospectively studied CT guided algorithm for which worse than mild PAR was reduced from 21.9 % to 7.5 % compared with the previously utilized TEE-guided algorithm [16].



Figs. 3–6 Ellipsoid aortic annulus with bulky 7 mm calcified nodule in LVOT. Figure 6 shows that following TAVI with a balloon-expandable valve, the annulus has assumed a more circular shape except for where the stent apposes the calcified nodule

Further support for the routine use of MDCT-based annular assessment came from data published in 2013 from a prospective multicenter trial performed by our group exclusively using Sapien XT valves, showing a reduction in greater than mild PAR from 12.8 % with echo-guided sizing alone to 5.3 % (P=0.03) with MDCT-guided sizing. Similarly, no cases of severe PAR were seen in the MDCT-guided group, compared with an incidence of 4.5 % in the echo-guided arm. The rate of annular rupture was low at 0.8 % in both groups, suggesting that the modest oversizing aimed for did not increase rupture rates [26•].

Although it is an infrequent complication and the numbers are small, it has been shown that annular rupture is associated with a more significant degree of prosthesis oversizing with balloon expandable prostheses. In 2012, Blanke et al described 3 patients with contained annular rupture post-TAVR. All 3 cases of annular injury presented were in the setting of extreme annular oversizing of >20 %. Importantly, the annular measurement on which oversizing was based was a diameter which is the equivalent of >40 % annular oversizing by area. Interestingly, all 3 underwent rupture adjacent to the left coronary sinus, and the authors have hypothesized that this represents the point of greatest structural weakness within the aortic root [27]. Building upon this data; we recently put together a large multicenter registry of patients who underwent pre-TAVR MDCT and experienced contained/uncontained annular injury. A total of 31 cases were caliper matched to patients who did not experience injury with the results showing that excessive annular area oversizing, particularly in the setting of moderate/ severe left ventricular outflow tract calcification results in a significantly elevated hazard for rupture. This growing data showing that modest oversizing helps reduce the burden of PAR without heightening the risk of annular injury [28•] (Figs. 7 and 8).



Figs. 7 and 8 Extensive calcification of the posterior LVOT. This may denote an increased risk of annular rupture, and these "high-risk annuli" could influence a decision to opt for a smaller or underfilled valve in cases where the annulus area is borderline (the "grey-zone" between 2 different prosthesis sizes)

Our experience has been that optimal results with the Sapien XT valve were seen by aiming for 5 %–10 % oversizing by area of the prosthesis to native annulus. (NB: it is important to note that our proposed percentage oversizing algorithm is based on area measurements of the annulus and, therefore, must be applied to such). Oversizing the annular perimeter by the same degree would result in a significantly greater degree of annular stretch. A 5 %–10 % oversize by perimeter yields a proportionately higher degree of area oversizing of approximately 10 %–20 % and may represent an unacceptably high risk of annular rupture. The newer Sapien 3 valve, which has a side-skirt which may help to further reduce PAR, is currently under investigation, and may allow for less oversizing, although current sizing guidelines with this device are speculative, awaiting further outcomes data.

Our current sizing protocol based on annulus area for the Sapien XT valve is provided in Table 1.

A recent review paper by Kasel et al gave Sapien XT sizing recommendations that incorporated MDCT-derived mean annular diameter, area and perimeter to adjudicate prosthesis selection [29]. These sizing recommendations can be found in Table 2.

An equivalent prospective trial demonstrating an advantage to MDCT-guided annular sizing with self-expanding valves has not yet been published, although experts within the field do indeed advocate using MDCT over echocardiography for sizing, with a similar aim of moderate oversizing of valve relative to native annulus [30]. Given the differences in valve design and the higher risk of PAR but essentially absent risk of rupture with self-expanding valves has led to the recommendation of a greater degree of annular oversizing with the self-expanding valve platform of 10 %–20 % by perimeter or approximately 20 %–40 % by area [30].

Suggested sizing guidelines for the Corevalve are found in Table 3.

Table 1 Proposed MDCT area sizing for the Sapien XT valve

Annular area mm^2	20 mm valve % oversizing	23 mm valve % oversizing	26 mm valve % oversizing	29 mm valve % oversizing
230	(NR)			
240	30.9UF (NR)			
250	25.7UF			
260	20.8UF			
270	16.4			
280	12.2			
290	8.3			
300	4.7			
310	1.3	(NR)		
320	-1.9 (NR)	29.8UF		
330		25.9UF		
340		22.2UF		
350		18.7		
360		15.4		
370		12.3		
380		9.3		
390		6.5		
400		3.9	(NR)	
410		1.3	29.5UF (NR)	
420		-1.1 (NR)	26.4UF	
430			23.5UF	
440			20.7UF	
450			18.0	
460			15.4	
470			13.0	
480			10.6	
490			8.4	
500			6.2	
510			4.1	(NR)
520			2.1	27.0 (NR)
530			0.2	24.6UF
540				22.3UF
550				20.1UF
560				17.9
570				15.9
580				13.9
590				12.0
600				10.1
610				8.3
620				6.5
630				4.8
640				3.2
650				1.6
660				0.1
670				NR

NR not recommended, *UF* with underfilling.

Table 2 Alternate balloon expandable sizing algorithm integrating perimeter measurements

Recommended Sapien XT valve size	23 mm	26 mm	29 mm
CT derived mean diameter (mm)	19–22	22–23	23–25
CT area (mm^2)	300–380	380–415	415–490
CT perimeter (mm)	60–69	69–72	72–85

The Sapien XT is only currently available in 4 sizes: 20 mm, 23 mm, 26 mm, and 29 mm. There are certain ranges of annular size, which we regard as "grey zones" in which it remains unclear as to whether the optimal strategy is to place an underfilled large prosthesis, or an overfilled small prosthesis. Within these regions of uncertainty, a fully deployed larger valve may represent an unacceptably high risk of annular rupture, and while balloon underfilling may mitigate this risk somewhat, there are theoretical concerns about the long term durability of a prosthesis that has not been optimally expanded during deployment. Barbanti et al recently published a proof of concept study showing good initial clinical outcomes employing a formalized balloon underfilling strategy for borderline annuli [31]. This is an important study as it is the first to prospectively record the degree and impact of prespecified balloon underfilling on procedural outcomes and complications.

While undersizing has historically been considered the biggest driver of PAR and modest prosthesis oversizing is emerging as a central strategy toward reducing its incidence, it remains clear that it is in fact multifactorial and that other anatomic and procedural features can also contribute [24, 32–34]. In particular, the extent and location of calcification within the valve, annulus, and aorta have been shown to be predictive of PAR [33, 34]. The mechanism is felt to relate to eccentric and noncompliant outcroppings of calcium that prevent complete apposition of the prosthesis to the wall of the left ventricular outflow tract and/or the complete expansion of the prosthesis. In 2013, Feuchtner and colleagues studied 94 patients implanted with both Sapien and Corevalves, both the degree of annular calcification and the presence of eccentric "protruding" calcification greater than 4 mm in size were predictive of moderate to severe PAR [34].

Coronary Obstruction

Periprocedural coronary obstruction is a rare complication of TAVR caused by displacement of the native coronary leaflets over the coronary ostia. It presents with persistent severe hypotension and is associated with a high mortality. MDCT may be able to identify high-risk patients prior to commencing the TAVR procedure [35, 36].

In a recent review of 6668 patients from an international multicenter registry, 44 cases (0.66 %) of acute coronary

Table 3 Proposed CT sizing algorithm for the self expanding corevalve. Modified from Mylotte et al. [30]

	23 mm Corevalve	26 mm Corevalve	29 mm Corevalve	31 mm Corevalve
Area (mm^2)	254–314	314–415	415–572	531–660
Perimeter (mm)	56.5–62.8	62.8–72.3	72.3–84.8	81.6–91.1

obstruction were identified, and their pre-TAVR MDCT scans were analyzed at a central core lab and compared with a 'no coronary obstruction' matched control group of 345 patients. The majority of cases of obstruction (88.6 %) involved the left coronary ostium and all but 1 case were as a result of displacement of a native leaflet over the ostium. The remaining case was secondary to a sheared off valve cusp migrating into the coronary artery. The complication was more frequently observed in women, balloon-expanded valves, and with valve-in-valve procedures. Procedural mortality was 15.9 %, and 30-day mortality was 40.9 % [37•].

The following MDCT features were associated with an increased risk of coronary obstruction:

- smaller aortic annulus size
- smaller sinus diameter
- smaller sinotubular junction diameter
- lower annular plane to left main ostium height

Mean left main height was 11 mm (10 mm in women) in those with coronary obstruction, compared with 13 mm in controls. Eighty percent of those with obstruction had a left main height <12 mm [37•]. This was an interesting finding considering that the manufacturer (Medtronic) recommends 14 mm as a cutoff for left main height, while ACC/AATS/SCAI/STS published guidelines suggest a cutoff of 10 mm. The right coronary ostial height is usually greater than that of the left main height in most patients, and right coronary obstruction has been only rarely observed.

Sinus of Valsalva dimensions also appears to be a factor, with the majority of patients developing obstruction having narrow aortic roots. Sixty-four percent of those with obstruction had a sinus diameter of <30 mm. We consider that a left main height greater than 12 mm and sinus diameter greater than 30 mm would correspond with a lower risk of obstruction, particularly in males and in procedures being performed on native valves. Severity of valve calcification does not appear to correlate with risk of obstruction [37•].

Conduction Disturbance

Significant conduction disturbance requiring the implantation of a permanent pacemaker system is a not infrequent complication of TAVR. Anatomically, the atrioventricular node is located adjacent to the left ventricular outflow tract just below the level of the aortic annulus. Deployment of a prosthesis, either with a balloon-expandable or self-expanding system, stretches the annulus and can cause direct trauma to the Bundle of His or the left bundle branch within the membranous septum. As the left bundle is the anatomically more vulnerable structure, it is unsurprising that a preprocedure right bundle branch block has been identified as one of the strongest predictors of a postprocedural requirement for pacing [38].

The incidence of high-grade atrioventricular block is higher following TAVR than surgical valve replacement, and appears to be higher with self-expanding systems compared with balloon-expanding, with rates from reported series varying from 0 %–27 % with balloon-expandables to 19 %–49 % with self-expanding [38]. Variation in thresholds at different centers to proceed to implanting pacemakers may explain the wide reported ranges, but the overall trend is for more conduction block with Corevalves. Differences in the structural properties of the 2 prostheses, in particular the height and pre-annular extent of the Corevalve, as well as differences in applied radial force, may account for the difference in rates of conduction block. An impairment of atrioventricular conduction is detectable in most patients following Corevalve implantation, with the level of compression probably the atrioventricular node or His bundles [39]. A persistent and new-onset left bundle branch block postprocedure is a strong predictor of the development of high-grade block, and probably represents mechanical injury to the left bundle branch [38].

The role that MDCT may be able to play in anticipating and preventing conduction disturbances is less well-defined than with paravalvular regurgitation and annular rupture, and there is certainly no published evidence that prosthesis sizing helps to mitigate risk, although there is an association between the use of larger prostheses and a higher incidence of pacemaker requirement. There are data that increased interventricular septal thickness, small left ventricular outflow tract diameter, mitral annular and left ventricular outflow tract calcification, and increased thickness of the noncoronary leaflet may all increase risk.

Multiple groups have demonstrated that there are some procedural factors that can increase risk, and in particular that both an excessively high or low position of the prosthesis can increase risk [38]. MDCT is well-suited to assessing prosthesis position postprocedure. Although at present TAVR is performed using a combination of TEE and fluoroscopic guidance, MDCT fluoroscopic fusion imaging tools may in the future help to assist the operator in correct prosthesis

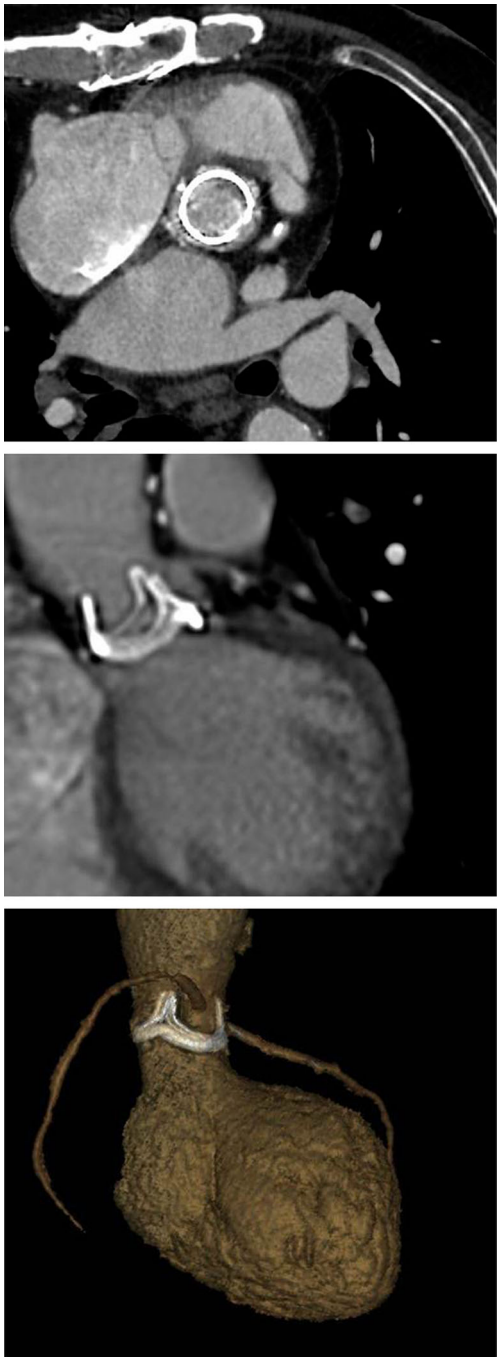
placement in much the way that they currently play a significant role in the procedural electrophysiology world.

Valve-in-Valve

An emerging issue within the TAVR field is that of "valve-in-valve" (ViV) procedures, in which a TAVR is performed within a previously implanted bioprosthesis, obviating the need for a redo sternotomy. The role of MDCT in ViV remains somewhat undefined in a fashion similar to MDCT in in the broader TAVR field in 2009/2010. The technical issues facing MDCT in ViV are even more challenging since the acquired images can be difficult to interpret and assess owing to partial volume averaging effects from metallic structures within the failing valvular prosthesis. Furthermore, once a surgical bioprosthesis is in position, the effective annulus becomes effectively fixed in size and geometry compared with a native annulus. It may be that sizing can be guided by the known dimensions of the prosthesis, although there is a great deal of variability in exactly what dimensions are quoted from vendor to vendor (for example–inner orifice diameter, vs diameter of sewing ring). In 2013, Bapat et al attempted to address this issue with a comprehensive publication, in which the stent internal and external diameters, sewing ring diameter, and profile heights for bioprostheses from all vendors have been measured ex vivo and collated, along with fluoroscopic appearances [40]. These in vitro tests are essential to better understand the relationship of the sewing ring and internal diameter of the stents. This is important to understand the design of the various bioprostheses to allow for appropriate sizing and to contain the risk of coronary occlusion.

Registry data from the first few hundred cases performed has demonstrated that while annular rupture and paravalvular leak do not appear to be a major issue, ViV does bear an increased risk of coronary occlusion over TAVR on native valves. In the initial published registry data of 202 patients, ostial coronary obstruction was seen in 3.5 %. The other main procedural complications that were observed are initial device malposition, and high postprocedural gradient [41•] (Figs. 9–11).

The area in which MDCT may have the most utility in planning for ViV cases is in the for identification of patients at high risk of coronary artery obstruction, which was identified in this series as being a significantly higher risk than in TAVR of native valves. Further analysis of the ongoing international ViV registry may produce further insights into the anatomic features that predispose to obstruction.



Figs. 9–11 Imaging work up for a "valve-in-valve" TAVI. The annulus is perfectly circular, although the true inner diameter is uncertain, owing to blooming artifact from the dense stent structure. Left main ostial height is very low corresponding to a high risk of coronary obstruction. Figures 10 and 11 demonstrates the height of the valve posts relative to the ostium. This case was performed with prophylactic wiring and delivery of an undeployed stent into the left main coronary artery. The left main ostium indeed became obstructed following deployment of the valve, and flow was restored with bail-out stenting of the left main ostium with good results

Recommendations

MDCT evaluation prior to TAVR is now routine unless contraindications exist. Imaging of the aortic root should be ECG-gated and include the systolic phase with slice thickness less than 1 mm. For the measurement of the aortic annular dimensions a plane should be created,

which aligns with the 3 most caudal attachments of the aortic cusps (the so-called "virtual ring".) Short and long diameters, area, and circumference should be measured, preferably in systole. Mention should also be made of presence and extent of calcification of the annulus and outflow tract. Coronary ostial height is of value to the proceduralist, particularly in valve-in-valve cases, as is optimal fluoroscopic angle [42].

The role of MDCT in procedural planning for TAVR has exponentially grown since the early days of the procedure to move beyond the assessment of vascular access to providing a comprehensive 3-dimensionial understanding of the aortic root anatomy. The superiority of this modality over 2-dimensional echocardiography in guiding prosthesis sizing and improving outcomes is now well established, and as the literature available grows, so too does our understanding of the complex interplay between patient anatomy, hemodynamics and procedural success.

Compliance with Ethics Guidelines

Conflict of Interest Adam Berger declare that he has no conflict of interest.

Dr. Leipsic is a consultant for Edwards Lifesciences and provides CT Core Laboratory Services for Edwards Lifesciences as well.

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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