

Aortic Annular Sizing for Transcatheter Aortic Valve Replacement Using Cross-Sectional 3-Dimensional Transesophageal Echocardiography

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- Objectives** This study compared cross-sectional three-dimensional (3D) transesophageal echocardiography (TEE) to two-dimensional (2D) TEE as methods for predicting aortic regurgitation after transcatheter aortic valve replacement (TAVR).
- Background** Data have shown that TAVR sizing using cross-sectional contrast computed tomography (CT) parameters is superior to 2D-TEE for the prediction of paravalvular aortic regurgitation (AR). Three-dimensional TEE can offer cross-sectional assessment of the aortic annulus but its role for TAVR sizing has been poorly elucidated.
- Methods** All patients had severe symptomatic aortic stenosis and were treated with balloon-expandable TAVR in a single center. Patients studied had both 2D-TEE and 3D imaging (contrast CT and/or 3D-TEE) of the aortic annulus at baseline. Receiver-operating characteristic curves were generated for each measurement parameter using post-TAVR paravalvular AR moderate or greater as the state variable.
- Results** For the 256 patients studied, paravalvular AR moderate or greater occurred in 26 of 256 (10.2%) of patients. Prospectively recorded 2D-TEE measurements had a low discriminatory value (area under the curve = 0.52, 95% confidence interval: 0.40 to 0.63, $p = 0.75$). Average cross-sectional diameter by CT offered a high degree of discrimination (area under the curve = 0.82, 95% confidence interval: 0.73 to 0.90, $p < 0.0001$) and mean cross-sectional diameter by 3D-TEE was of intermediate value (area under the curve = 0.68, 95% confidence interval: 0.54 to 0.81, $p = 0.036$).
- Conclusions** Cross-sectional 3D echocardiographic sizing of the aortic annulus dimension offers discrimination of post-TAVR paravalvular AR that is significantly superior to that of 2D-TEE. Cross-sectional data should be sought from 3D-TEE if good CT data are unavailable for TAVR sizing. (J Am Coll Cardiol 2013;61:908-16) © 2013 by the American College of Cardiology Foundation

Significant paravalvular aortic regurgitation (PVAR) occurs after transcatheter aortic valve replacement (TAVR) in >10% of patients (1). This group (2), and others (3), have

demonstrated that cross-sectional contrast computed tomography (CT) derived measurements of the aortic annulus offer greater discriminatory value for post-TAVR PVAR than conventional two-dimensional (2D) measurements using transesophageal echocardiography (TEE). However, because of renal dysfunction in a population with a significant burden of comorbidities, contrast CT is often not an option.

Three-dimensional TEE (3D-TEE) can also provide immediate cross-sectional information on the aortic annulus, but its clinical value for TAVR sizing remains unclear. This study, therefore, has 2 goals: to determine the value of the 3 measurement techniques for predicting PVAR

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after TAVR, and to define clinically relevant sizing parameters that can be applied to practice.

Methods

Patient population, assessment, and procedure. All patients had severe symptomatic aortic stenosis and were treated with balloon-expandable TAVR (Edwards Sapien/Sapien XT, Edwards Lifesciences, Irvine, California) in a single center. Patients studied had both 2D-TEE and 3D imaging (electrocardiography-gated CT or 3D-TEE) of the aortic annulus available at baseline (Fig. 1). The TEE was performed using the iE33 xMATRIX echocardiography system (Philips Ultrasound, Philips Medical Systems, Bothell, Washington), which has 3D-TEE capabilities, and built-in quantitative analysis software (QLab, Philips Ultrasound, Bothell, Washington). An electrocardiography-gated cardiac contrast CT study was only performed if the renal function was considered satisfactory by the treating physician. Available 3D data (CT or 3D-TEE QLab) were analyzed by different investigators, blinded during data collection to the measurements of each other, to prosthesis size, and to the outcomes of the TAVR procedure. The X-plane (simultaneous biplane 2D-TEE) cross-sectional measurements were prospectively made, with avoidance of non-coaxial cuts (Fig. 2). QLab allows greater control of the coaxiality, employing 2 planes (coronal and sagittal) to generate an orthogonal axial cross-section retrospectively as an offline multiplanar analysis of a 3D volume (Fig. 1); this can also be obtained online, prospectively, using the same software. The methodology for multislice CT image acquisition and analysis has been previously described (2); details are available in the online Appendix. Presence of left ventricular outflow tract calcium was determined qualitatively by contrast or noncontrast CT in all patients.

Annular sizing for TAVR. Sizing for TAVR was made at the operator's discretion, using data from all available imaging modalities, with a prospective knowledge of cross-sectional CT dimensions after May 2011. Traditional cutoffs for annular size by 2D-TEE measurement (D_{2D-TEE}) have been previously described (2). As parameters for 3D-TEE sizing were unclear during the study, 3D-TEE did not influence the final decision for device size. All aortic annular measurements (2D-TEE, CT, 3D-TEE) were made in midsystole.

Post-TAVR paravalvular aortic regurgitation. Post-TAVR PVAR was assessed in line with contemporary guidelines (4), with periprocedural TEE examinations reviewed retrospectively. This was performed by 1 of 2 physician readers experienced in the assessment of TAVR echocardiograms, blinded to the periprocedural TEE report, CT and 3D-TEE measurements, and clinical and angiographic data.

Statistical analysis. Statistical analyses were made using SPSS software (PASW, version 18.0, SPSS, Chicago, Illinois) and SAS software (version 9.2, SAS Institute, Cary, North Carolina). Normality of distributions for continuous

variables was tested using the Shapiro-Wilks test, and data analyzed appropriately thereafter (Online Appendix).

Receiver-operating characteristic (ROC) curves were generated using post-TAVR paravalvular AR moderate or greater as the principal endpoint (state variable) and 2D-TEE, CT, and 3D-TEE as the dependent variables (Online Appendix). The method of deLong et al. (5) was used for direct comparisons of the discriminatory value of 1 modality to another. The ROC-derived upper cutoffs for sizing corresponded to the highest sum of sensitivity and specificity for prediction of PVAR (see Online Appendix). Undersizing by 3D cross-sectional measurements was also assessed in a multivariable binary logistic regression model for PVAR greater than mild (see Online Appendix).

Results

Study population. Baseline 2D-TEE and cross-sectional imaging of the aortic annulus (electrocardiography-gated contrast CT or 3D-TEE) was available in 256 patients, included in this analysis (Online Fig. 1). Regarding procedural complications, 6 (2.3%) had >1 prosthesis implanted in the aortic position (emergent valve-in-valve), 5 (2.0%) had valve embolization, and 3 (1.2%) had device malpositioning resulting in significant paravalvular regurgitation (all 3 high malpositioning).

Correlation of 3D-TEE and CT. Reliability assessment of aortic annular measurements by cross-sectional CT and 3D-TEE measurements showed excellent reproducibility (Online Appendix). There was a moderate correlation between dimension obtained by 3D-TEE (QLab) and CT (Table 1), but QLab measurements were smaller than the corresponding cross-sectional CT measurements. The eccentricity index (orthogonal maximal over minimal dimension) was greater by CT (1.22 ± 0.11) than by 3D-TEE (1.16 ± 0.12 ; $p < 0.001$). The relative differences between modalities were greater for area than for perimeter and D_{mean} (Table 1).

ROC curve analyses for predicting paravalvular regurgitation and determining evidence-based sizing parameters. For the patients studied, PVAR moderate or greater occurred in 26 of 256 (10.2%). In ROC curve analyses (Table 2, Figs. 3 and 4), CT-derived parameters had the greatest discriminatory value for PVAR. A statistical comparison of areas under the curve of various measurement parameters to ΔD_{2D-TEE}

Abbreviations and Acronyms

AR	= aortic regurgitation
CI	= confidence interval
CT	= computed tomography
LVEF	= left ventricular ejection fraction
OR	= odds ratio
PAVR	= paravalvular aortic regurgitation
ROC	= receiver-operating characteristic
TAVR	= transcatheter aortic valve replacement
TEE	= transesophageal echocardiography
TTE	= transthoracic echocardiography
2D	= two-dimensional
3D	= three-dimensional

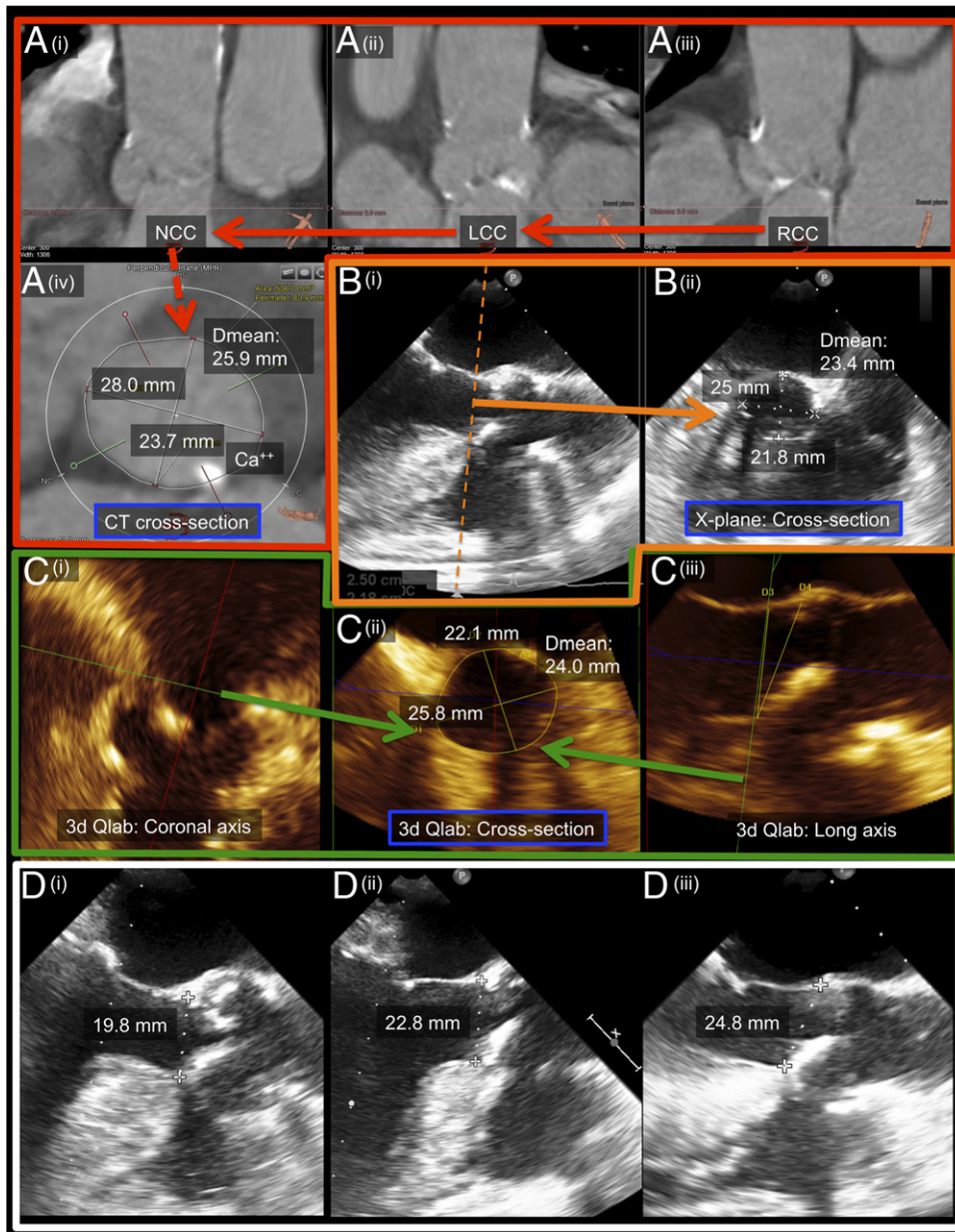


Figure 1 Methodology of Cross-Sectional Imaging

Measurements by (A) computed tomography (CT): red arrows demonstrate the creation of a cross-section (iv) derived from a basal plane that touches the base of each leaflet cusp (i–iii), (B) X-plane: orange dotted line indicates plane of cross-section from a long axis view (i) with orange arrow pointing to derived cut (ii), and (C) QLab (Philips Ultrasound, Bothell, Washington): green arrows indicate co-axial alignment of a cross-section (ii) using coronal (i) and long (iii) axes, are shown. (D) Heterogeneity of measurements by conventional hinge-point-hinge-point 2-dimensional transesophageal echocardiography (2D-TEE) was observed. Parameters indicate appropriate sizing for a 26-mm Sapien/Sapien XT prosthesis (Edwards Lifesciences, Irvine, California). LCC = left coronary cusp; NCC = noncoronary cusp; RCC = right coronary cusp.

showed significantly greater areas for both $\Delta D_{\text{mean(QLab)}}$ ($p = 0.031$) and $\Delta D_{\text{mean(CT)}}$ ($p < 0.0001$) (Fig. 4).

There were 3 cases with malpositioning (high implantation, with the lowest part of the stent frame above the aortic annulus) and significant PVAR. After exclusion of these cases from the analysis, D_{mean} by cross-sectional CT and 3D-TEE remained significant predictors of PVAR moderate or greater (area under the curve 0.81, 95% CI: 0.71 to

0.90, $p < 0.001$ for ΔD_{mean} by CT; area under the curve 0.68, 95% CI: 0.52 to 0.84, $p = 0.048$ for ΔD_{mean} by 3D-TEE).

For each sizing parameter, a cutoff was set that corresponded to the highest sum of sensitivity and specificity for the prediction of PVAR moderate or greater (Table 2), generating evidence-based sizing parameters that differed for each imaging modality (Table 3). Using the cutoffs for

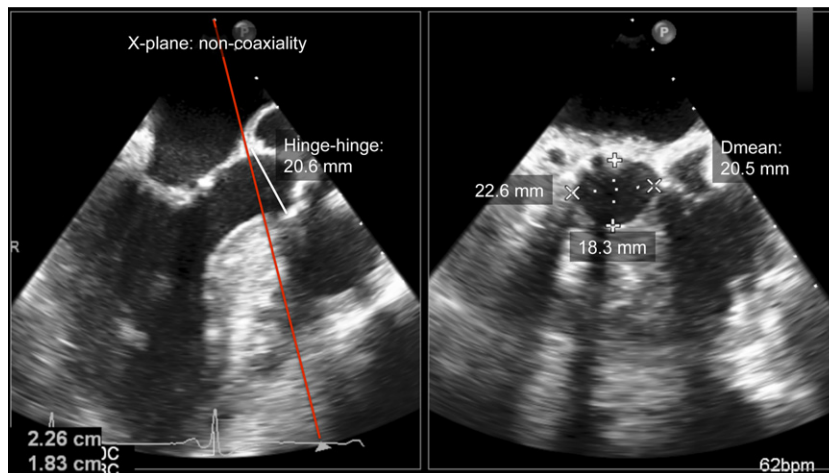


Figure 2 Potential Non-Coaxial Cross-Section by X-Plane

Non-coaxiality of the cross-section of the long-axis plane (left) can generate a skewed cut that can generate a distorted short-axis/axial cut (right), leading to inaccurate measurements.

D_{mean} , sensitivity appeared similar for cutoffs defined by ΔD_{2DTEE} , $\Delta D_{mean(QLab)}$, and $\Delta D_{mean(CT)}$ (88.5%, 84.6%, and 84.2%, respectively). However, specificity was better for both cross-sectional measures than for 2D-TEE (for CT data, specificity for cutoffs from $\Delta D_{mean(CT)}$ vs. ΔD_{2D-TEE} = 70.6% vs. 21.8%, $p < 0.0001$; for 3D-TEE, specificity for cutoffs from $\Delta D_{mean(QLab)}$ vs. ΔD_{2D-TEE} = 55.0% vs. 17.6%, $p < 0.0001$). Only 104 patients had both CT and 3D-TEE data, and only 6 of these had PVAR moderate or greater, limiting the statistical validity of direct comparisons of CT and 3D-TEE data; however, specificity for cutoffs from $\Delta D_{mean(CT)}$ versus $\Delta D_{mean(QLab)}$ = 69.4% versus 55.1% ($p = 0.020$).

Reassignment of sizing based on evidence-based parameters. Of patients with available cross-sectional CT data, 91 of 216 (42.1%) were undersized by $D_{mean(CT)}$ parameters, leading to a large proportion with size reassignment if these parameters had been strictly adhered to (Online Fig. 2). Of those with available cross-sectional 3D-TEE data, 73 of 144 (50.7%) were undersized by $D_{mean(QLab)}$ parameters.

Although choice of bioprosthesis was generally undersized by 2D-TEE relative to the cross sectional measures, there were many cases of the converse, with down-sizing of prosthesis choice with adherence to cross-sectional measures (Fig. 5, Online Fig. 2). Indeed, undersizing by 2D-TEE appeared nondiscriminatory for PVAR moderate or greater (Online Table 1). This was in comparison to a 7.3-fold excess of PVAR moderate or greater for undersizing by CT-derived D_{mean} and a 11.7-fold excess for undersizing by 3D-TEE (QLab)-derived D_{mean} parameters (Online Table 1).

Multivariable analysis for the prediction of significant paravalvular PVAR. Details are available in the Online Appendix. This analysis showed undersizing by cross-sectional measures to be an independent predictor of PVAR (OR: 3.24, 95% CI: 1.56 to 6.71, $p = 0.002$), along with presence of left ventricular outflow tract calcium (OR: 2.38, 95% CI: 1.08 to 5.23, $p = 0.031$) and male sex (OR: 3.26, 95% CI: 1.49 to 7.12, $p = 0.003$). Where there was undersizing by CT cross-sectional

Table 1 Correlations and Differences Between Similar Measurements Made by Cross-Sectional CT* and 3D-TEE (n = 104)

Variable	r	p Value (for Correlation)	Paired Difference: CT–3D-TEE (95% CI)	p Value (for Difference)	Percentage Difference (SD)
D_{max} , mm	0.62	<0.001	2.35 (1.86–2.84)	<0.001	10.35 (11.52)
D_{min} , mm	0.60	<0.001	0.85 (0.45–1.26)	<0.001	4.63 (10.09)
D_{mean} , mm	0.69	<0.001	1.59 (1.22–2.00)	<0.001	7.48 (8.80)
Area, cm^2	0.69	<0.001	0.45 (0.32–0.58)	<0.001	12.89 (16.87)
Perimeter, mm†	0.72	<0.001	4.94 (3.85–6.03)	<0.001	7.30 (7.98)

*Cross-sectional computed tomography (CT) 3mensio (3mensio Medical Imaging, Bilthoven, the Netherlands) images. †Perimeters derived by exporting 3-dimensional transesophageal echocardiography (3D-TEE) QLab (Philips Ultrasound, Bothell, Washington) images to Osirix (Pixmeo Sarl, Geneva, Switzerland [perimeter data not available within QLab]). Percentage difference = $[(CT \text{ dimension}/3D-TEE \text{ dimension}) - 1] \times 100$. The percentage difference (over-estimation) for area by CT relative to 3D-TEE was significantly greater than the difference for perimeter ($p < 0.001$) and for D_{mean} dimension ($p < 0.001$), but the percentage difference by perimeter and D_{mean} dimension did not differ significantly ($p = 0.656$). The percentage difference by CT relative to 3D-TEE was greater for the major dimension than for the minor dimension ($p = 0.001$).

CI = confidence interval.

Table 2 ROC Curve Analysis for Multiple Baseline Systolic 3D and 2D CT and Echocardiographic Measures of Aortic Annulus

Variable	n	AUC for Δ or Ratio (95% CI)	p Value	Upper Cutoff for Δ or Ratio	Sensitivity (%)	Specificity (%)
2D echocardiography						
Δ_{2D-TEE}	256	0.52 (0.40–0.63)	0.75	–3.3	88.5%	20.9%
Δ_{2D-TTE}	211	0.44 (0.32–0.56)	0.33	–4.1	56.5%	34.6%
3D-TEE (X-plane)						
Δ_{max} (X-plane)	84	0.66 (0.45–0.75)	0.17	1.7	57.1%	80.5%
Δ_{min} (X-plane)	84	0.61 (0.33–0.86)	0.34	–2.65	71.4%	71.4%
Δ_{mean} (X-plane)	84	0.66 (0.42–0.90)	0.16	–0.35	57.1%	83.1%
3D-TEE (QLab)						
Δ_{max} (QLab)	144	0.71 (0.59–0.83)	0.013	–0.35	84.6%	51.9%
Δ_{min} (QLab)	144	0.58 (0.42–0.74)	0.34	–3.65	61.5%	55.7%
Δ_{mean} (QLab)	144	0.68 (0.58–0.81)	0.036	–1.88	84.6%	55.0%
Area annulus/area THV _(QLab)	144	0.64 (0.51–0.77)	0.10	0.86	69.2%	53.4%
Perimeter annulus/perimeter THV _(QLab) *	144	0.64 (0.51–0.76)	0.10	0.94	69.2%	55.7%
Cross-sectional CT						
Δ_{max} (CT)	216	0.82 (0.74–0.90)	<0.001	3.75	73.7%	80.0%
Δ_{min} (CT)	216	0.71 (0.58–0.83)	0.003	–1.25	52.6%	83.8%
Δ_{mean} (CT)	216	0.82 (0.73–0.90)	<0.001	0.35	84.2%	70.6%
Area annulus/area THV _(CT)	216	0.79 (0.69–0.90)	<0.001	1.02	84.2%	73.1%
Perimeter annulus/perimeter THV _(CT)	216	0.82 (0.73–0.91)	<0.001	1.04	84.2%	75.1%

Post-transcatheter aortic valve replacement paravalvular regurgitation moderate or greater is the outcome measure. The receiver-operating characteristic (ROC) curve derived upper cutoffs for device sizing based on each parameter are shown. *Perimeters derived by exporting QLab (Philips Ultrasound, Bothell, Washington) images to Osirix (Pixmeo Sarl, Geneva, Switzerland [perimeter data not available within QLab]).

AUC = area under the curve; TEE = transesophageal echocardiography; THV = transcatheter heart valve; TTE = transthoracic echocardiography; 2D = 2-dimensional; other abbreviations as in Table 1.

measures, $\Delta_{mean(CT)}$ was considerably larger in males (median 1.20 mm, interquartile range: 0.75 to 2.00 mm) than in females (median 0.6 mm, interquartile range: 0.2 to 1.6 mm), indicating a greater degree of undersizing in males ($p = 0.008$).

Discussion

Most importantly, the present study demonstrates that cross-sectional measurements from 3D-TEE provide more accurate information than 2D-TEE for the performance of TAVR, with superior discrimination of post-TAVR PVAR. This information is highly relevant to case selection for TAVR and to the success of the procedure itself. Prostheses appropriately sized by ROC-curve-directed cross-sectional 3D-TEE (D_{mean}) parameters had an incidence of significant PVAR of only 1.4% relative to 10.3% in those appropriately sized by 2D-TEE (Online Table 2). Cross-sectional 3D-TEE using QLab can be performed rapidly in the catheterization laboratory before choice of valve prosthesis and carries a similarly high sensitivity for the prediction of PVAR to the present gold standard of cross-sectional CT, with a reasonable specificity intermediate between CT and 2D-TEE.

A recent study by Gripari et al. (6) studied cross-sectional 3D-TEE in 135 patients undergoing balloon-expandable TAVR. The investigators made the important observation that the 3D-TEE “area cover index” before TAVR ($1 - [\text{annulus area} / \text{prosthesis nominal area}]$) was an independent predictor of PVAR. The questions arising from this paper were how cross-

sectional 3D-TEE data compare to CT data and how this information can be practically applied to sizing, the foci of the present study.

We demonstrated cross-sectional 3D-TEE measurements to be smaller than those obtained by cross-sectional CT. This observation is important, as the application of 3D cross-sectional TEE measurements to sizing cutoffs originally defined by cross-sectional CT parameters could lead to gross prosthesis undersizing and the potential for even more PVAR.

Our data are consistent with those of Tsang et al. (7), who compared cross-sectional measurements by 3D-TEE, CT, and cardiac MRI in an ex-vivo cadaveric phantom imaging model. They found that, although well correlated, cross-sectional D_{mean} measurements by CT were on average 1.3 mm larger and 3D-TEE measurements were 1.3 mm smaller than cardiac MRI measurements, which were closer to the true dimensions. Similarly, Ng et al. (8) demonstrated a 9.6% underestimation of annular cross-sectional areas by 3D-TEE compared to CT, which is in line with the 12.89% underestimation we observed (Table 1).

The present limitations of cross-sectional 3D echocardiography. In contrast to QLab 3D-TEE, software for CT analysis is highly evolved for the purposes of TAVR. Moreover, QLab software does not provide perimetric data on traced annular cross-sections, meaning that this information is presently unavailable prospectively. These issues may be rectified in future by the focused application of this technology to the purpose of aortic valvar complex assessment for TAVR.

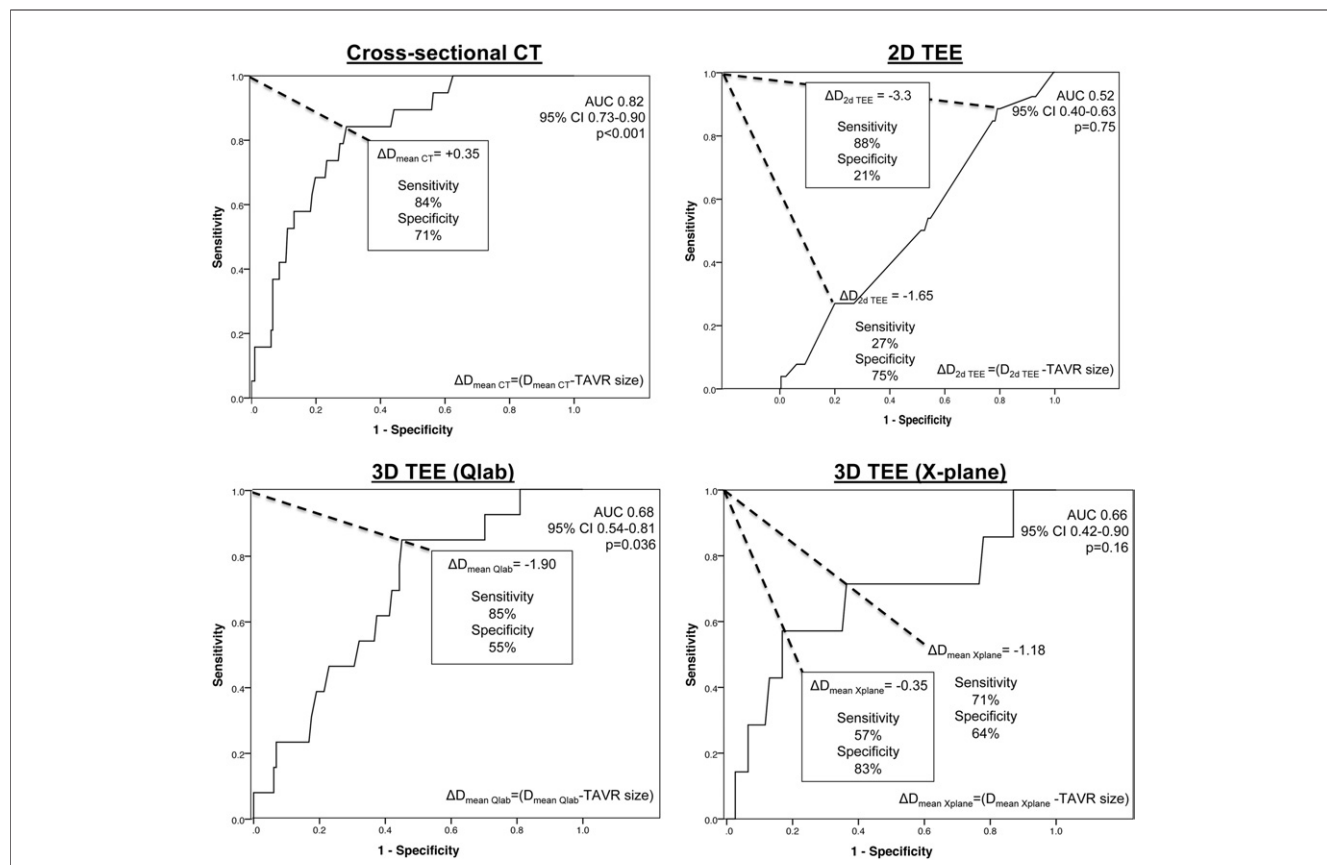


Figure 3 Prediction of Significant PVAR

Receiver-operating characteristic (ROC) curve analysis for prediction of paravalvular aortic regurgitation (PVAR) moderate or greater by measures derived from the multiple imaging parameters are shown with the imaging modality used as the predictive variable indicated for each panel. (Refer to text for further details.) AUC = area under the curve; CI = confidence interval; CT = computed tomography; TAVR = transcatheter aortic valve replacement; TEE = transesophageal echocardiography; 2D = 2-dimensional; 3D = 3-dimensional.

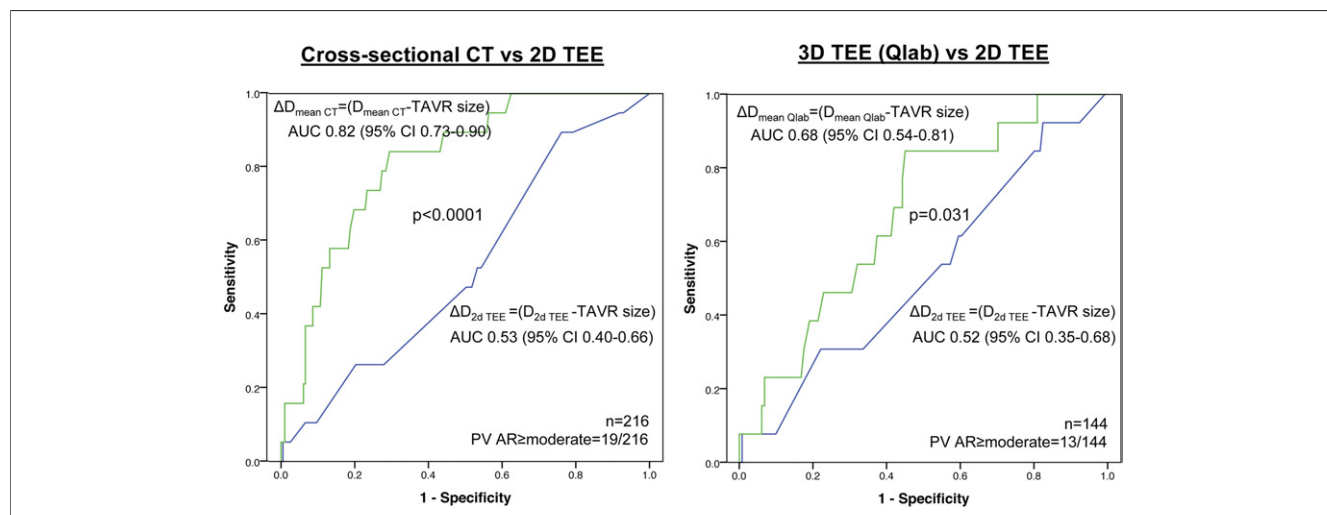


Figure 4 Comparison of Predictive Value for PVAR of Cross-Sectional CT and 3D-TEE Compared to 2D-TEE

Receiver-operating characteristic (ROC) curves with state variable paravalvular aortic regurgitation (PVAR) moderate or greater and independent variable of $\Delta D_{\text{mean(CT)}}$ (left) and $\Delta D_{\text{mean(Qlab)}}$ (right), respectively, compared to $\Delta D_{2d \text{ TEE}}$ are shown. Both have significantly greater areas under the curves (AUC), and hence, significantly greater predictive value for PVAR than 2-dimensional transesophageal echocardiography (2D-TEE) measures of the aortic annulus. CI = confidence interval; CT = computed tomography; TAVR = transcatheter aortic valve replacement; 3D-TEE = 3-dimensional transesophageal echocardiography.

Evidence Basis		Device Sizing			
Prosthesis					
Diameter, mm	20	23	26	29	
Area, cm ²	3.14	4.15	5.31	6.61	
Perimeter, mm	62.8	72.3	81.7	91.1	
3D-TEE (QLab)					
D _{mean} , mm	15.1–18.1	18.1–21.1	21.1–24.1	24.1–27.1	
Area, cm ²	1.96–2.71	2.71–3.59	3.59–4.58	4.58–5.70	
Perimeter, mm	50.4–59.3	59.3–68.2	68.2–77.1	77.1–86.0	
Cross-sectional CT					
D _{mean} , mm	17.3–20.3	20.3–23.3	23.3–26.3	26.3–29.3	
Area, cm ²	2.31–3.20	3.20–4.23	4.23–5.40	5.40–6.72	
Perimeter, mm	55.6–65.4	65.4–75.2	75.2–85.0	85.0–94.8	
2D-TEE					
Manufacturer-directed sizing, mm	16–19	18–22	21–25	24–27	

PVAR = paravalvular aortic regurgitation; other abbreviations as in Tables 1 and 2.

Study limitations. Advances in CT imaging (such as dual energy, high pitch, and helical methods) are now available; these techniques were not utilized in this study but may greatly reduce the volume of contrast required for cross-sectional imaging of the aortic annulus using

CT. Nevertheless, 3D-TEE is an alternative imaging method for cross-sectional imaging of the aortic annulus that avoids the need for contrast and is thus desirable, particularly if there is significant renal dysfunction (Fig. 6).

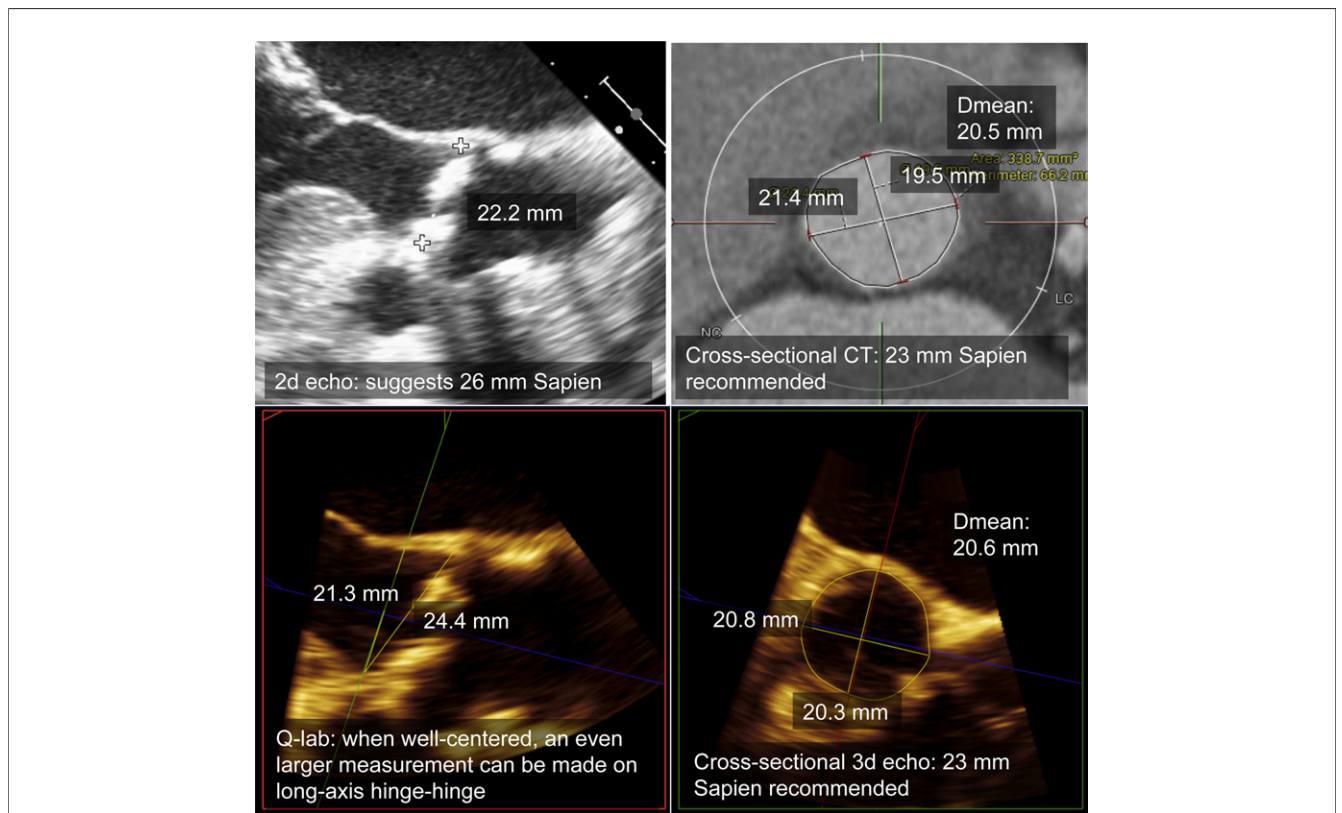


Figure 5 Prospective Application of Cross-Sectional Measures to Down-Size Choice of Prosthesis

(Top left) Hinge-point-hinge-point 2-dimensional transesophageal echocardiography (2D-TEE) resulted in an over-estimated choice of prosthesis. (Bottom left) Annular dimension could have been further over-estimated had the plane been well centered (QLab (Philips Ultrasound, Bothell, Washington) 2D image). A 23-mm prosthesis was implanted in accordance with the (top right) cross-sectional computed tomography (CT) and (bottom right) cross-sectional 3D-TEE, with paravalvular aortic regurgitation (PVAR) grade zero.

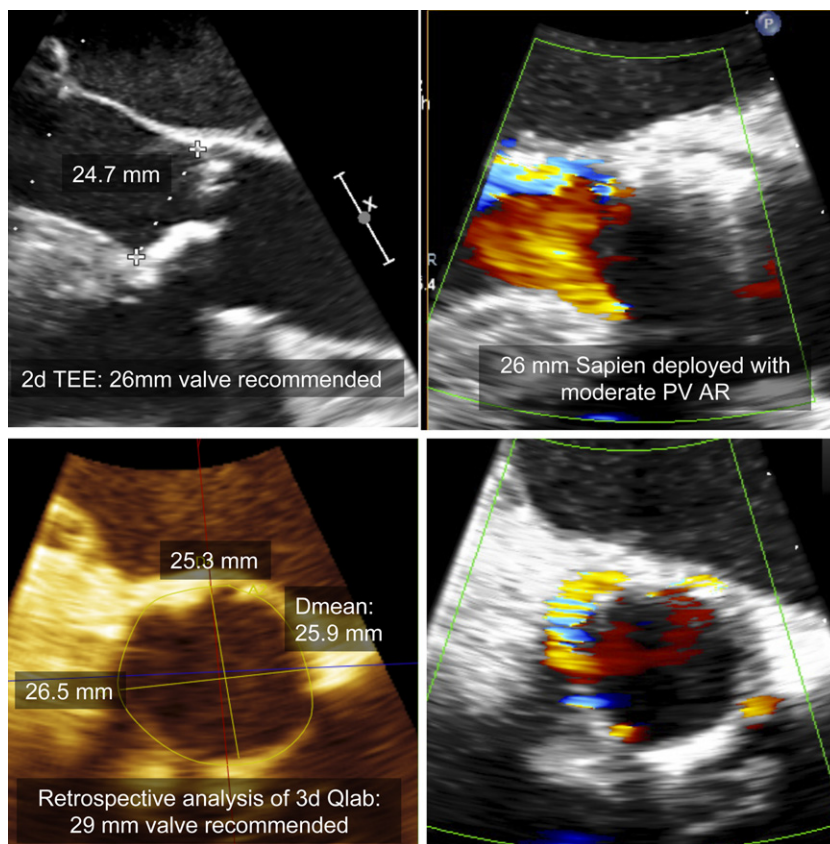


Figure 6 Retrospective Review of 3D-TEE Data in Patient Who Could Not Have Contrast CT

Aortic annular imaging of a patient with renal failure in whom contrast computed tomography (CT) was not performed, and prosthesis size was decided by conventional 2-dimensional transesophageal echocardiography (2D-TEE) parameters (top left). A 26-mm prosthesis was implanted, and there was moderate paravalvular aortic regurgitation (PVAR) as seen in the long-axis view (top right) and short-axis view (bottom right). A retrospective analysis of the 3D-TEE Qlab (Philips Ultrasound, Bothell, Washington) data showed parameters suggesting that a 29-mm prosthesis would have been more appropriate (bottom left).

Conclusions

Avoidance of paravalvular regurgitation is fundamental to the success of TAVR. Adherence to sizing parameters defined by cross-sectional 3D-TEE is associated with a lower incidence of PVAR than conventional 2D-TEE cutoffs, and should be used for balloon-expandable TAVR sizing if good cross-sectional CT data are unavailable.

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Key Words: computed tomography ■ paravalvular aortic regurgitation ■ 3D echocardiography ■ transcatheter aortic valve implantation ■ transcatheter aortic valve replacement.

 **APPENDIX**

For a supplemental Methods section, and a table and figures, please see the online version of this article.