

Validation of a Novel Software Tool for Automatic Aortic Annular Sizing in Three-Dimensional Transesophageal Echocardiographic Images



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Background: Accurate aortic annulus (AoA) sizing is crucial for transcatheter aortic valve implantation planning. Three-dimensional (3D) transesophageal echocardiography (TEE) is a viable alternative to the standard multidetector row computed tomography (MDCT) for such assessment, with few automatic software solutions available. The aim of this study was to present and evaluate a novel software tool for automatic AoA sizing by 3D TEE.

Methods: One hundred one patients who underwent both preoperative MDCT and 3D TEE were retrospectively analyzed using the software. The automatic software measurements' accuracy was compared against values obtained using standard manual MDCT, as well as against those obtained using manual 3D TEE, and intraobserver, interobserver, and test-retest reproducibility was assessed. Because the software can be used as a fully automatic or as an interactive tool, both options were addressed and contrasted. The impact of these measures on the recommended prosthesis size was then evaluated to assess if the software's automated sizes were concordant with those obtained using an MDCT- or a TEE-based manual sizing strategy.

Results: The software showed very good agreement with manual values obtained using MDCT and 3D TEE, with the interactive approach having slightly narrower limits of agreement. The latter also had excellent intra- and interobserver variability. Both fully automatic and interactive analyses showed excellent test-retest reproducibility, with the first having a faster analysis time. Finally, either approach led to good sizing agreement against the true implanted sizes (>77%) and against MDCT-based sizes (>88%).

Conclusions: Given the automated, reproducible, and fast nature of its analyses, the novel software tool presented here may potentially facilitate and thus increase the use of 3D TEE for preoperative transcatheter aortic valve implantation sizing. (*J Am Soc Echocardiogr* 2018;31:515-25.)

Keywords: Aortic valve sizing, 3D transesophageal echocardiography, Fully automatic analysis, Interactive analysis, Transcatheter aortic valve implantation

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Abbreviations

3D = Three-dimensional
AoA = Aortic annulus
AS = Aortic stenosis
AV = Aortic valve
BA = Bland-Altman
CV = Coefficient of variation
FA = Fully automatic
IA = Interactive analysis
ICC = Intraclass correlation coefficient
LOA = Limits of agreement
LVOT = Left ventricular outflow tract
MDCT = Multidetector row computed tomography
STJ = Sinotubular junction
TAVI = Transcatheter aortic valve implantation
TEE = Transesophageal echocardiography
THV = Transcatheter heart valve

Acquired aortic stenosis (AS) is the most common valvular heart disease in the elderly.¹ In recent years, transcatheter aortic valve implantation (TAVI) has become an effective and widely used treatment option for patients with severe AS and high operative risk,^{1,2} with recent studies finding it viable for intermediate-risk patients as well.³ Because no direct access exists during the intervention, sizing of the transcatheter heart valve (THV) must rely on preoperative measurement of anatomic variables of the diseased valve. Accurate preoperative measurement of the aortic annulus (AoA) using imaging⁴⁻⁶ is therefore key to prevent procedural complications.⁵⁻⁷

Although two-dimensional imaging modalities, such as two-dimensional transthoracic echocardiography and transesophageal echocardiography (TEE), were originally considered the standard for such assessment, it is now largely accepted that three-dimensional (3D) imaging techniques, namely, 3D TEE and multidetector row computed to-

graphy (MDCT), should be used instead.^{4,5,7,8} Such 3D-based measures, such as AoA area and perimeter, were shown to present superior accuracy and reproducibility, even more when considering the elliptical shape of the annulus.^{5,7-9} Although MDCT is at most centers the modality of choice for this cross-sectional AoA measurement,^{8,9} its use is not without limitations, with concerns being raised in patients at risk for contrast-induced nephropathy or in the presence of imaging artifacts.^{6,10,11} As a result, 3D TEE is usually used as a radiation- and contrast-free alternative,^{9,10} with some centers specializing in echocardiography and even using it as the primary preoperative modality.

Because 3D-based AoA measurements rely on the correct identification of the cross-sectional plane that intersects the hinge point of each aortic valve (AV) cusp using a multiplanar reconstruction,^{5-7,9} manual analysis of 3D data sets is time consuming and complex, prone to both intra- and interobserver variability.¹¹⁻¹³ Thus, the development of automatic tools to extract these measurements has the potential to shorten analysis time while reducing the variability among experts. Although several commercial automated solutions exist for MDCT-based analysis,¹³⁻¹⁵ only a few are available for 3D TEE.¹⁵⁻¹⁸

Recently, our group proposed a novel, fully automatic (FA) framework for AV sizing based on 3D transesophageal echocardiographic data sets for TAVI planning,^{19,20} which was later embedded in custom noncommercial software, Speqle3D (KU Leuven, Leuven, Belgium).²¹ The latter allows integrated analysis and visualization of the results, with the user able to interact throughout the measurements' extraction process. Although the framework was originally demonstrated to be accurate and robust against manual quantification on 3D transesophageal echocardiographic images, significantly reducing variability and analysis time, its accuracy was never assessed

against MDCT-based measuring and THV sizing. Thus, in this study, we sought to perform such a comparison, while validating the feasibility and reproducibility of the measurements taken with this novel software tool. The software's performance was further compared against a manual assessment from 3D transesophageal images. Finally, because the user can choose to perform a FA analysis or interact with it, both approaches were assessed and contrasted.

METHODS

Study Population

In the present study, high-risk or inoperable patients with symptomatic, severe AS who underwent TAVI at the St. Vinzenz-Hospital (Cologne, Germany) from August 2014 to September 2017 were retrospectively reviewed to identify those who underwent both preprocedural MDCT and 3D TEE. Among the 115 patients evaluated, 107 fulfilled these criteria and were thus further assessed. Of these, six patients were excluded because of inadequate preprocedural MDCT. No patients were excluded from imaging analysis on the basis of 3D transesophageal echocardiographic image quality or spatial-temporal resolution. As a result, 101 patients were enrolled in this study. All patients gave written informed consent before undergoing TAVI. Table 1 presents the clinical and echocardiographic characteristics of the study population.

THV Sizing and AV Implantation

On the basis of a thorough preoperative planning performed by a team of expert cardiologists and cardiothoracic surgeons, patients underwent transfemoral implantation of a balloon-expandable Edwards SAPIEN 3 THV (99 patients; Edwards Lifesciences, Irvine, CA) or a self-expandable Medtronic CoreValve Evolut R THV (two patients; Medtronic, Minneapolis, MN), of one of the three available sizes. At that time point, the experts' team used AoA measurements from the available imaging modalities for THV sizing. In borderline cases (i.e., measurements between the manufacturer's recommendations for two THV sizes),⁶ other clinical factors, such as gender, body size, and amount and location of calcifications were also considered.²² Overall, 23-, 26-, and 29-mm THVs were implanted in 44, 36, and 21 patients, respectively. All implantations were successfully performed, with the exception of one patient in whom the intervention was canceled because of increased risk for vessel rupture as a result of a too narrow iliofemoral artery.

Image Acquisition

Multidetector Row Computed Tomography. MDCT was performed according to guideline recommendations,¹² using a multidetector 64-channel scanner (Discovery CT750 HD; GE Healthcare, Waukesha, WI). In short, the protocol included a prospective electrocardiographically triggered scan of the aortic root and heart acquired during a single inspiratory breath-hold. Tube potential and current were determined on the basis of patients' body habitus. A timing bolus protocol was used to determine optimal contrast transit time. All images were reconstructed in an early diastolic phase using a soft tissue convolution kernel.

Echocardiography. All patients underwent preprocedural TEE (Vivid E9 or E95 with 4V-D transducer; GE Healthcare). Besides two-dimensional standard imaging, the echocardiographic study included at least one 3D image of the AV and root acquired from a midesophageal position using the 3D zoom mode (i.e., displaying a

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