Feasibility, Accuracy, and Reproducibility of Aortic Annular and Root Sizing for Transcatheter Aortic Valve Replacement Using Novel Automated Three-Dimensional Echocardiographic Software: Comparison with Multi–Detector Row Computed Tomography

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Background: In transcatheter aortic valve replacement (TAVR), multi–detector row computed tomography (MDCT) is currently the standard imaging modality for correct prosthesis sizing, despite risks of radiation and contrast-induced renal injury. Three-dimensional (3D) transesophageal echocardiography (TEE) has been proposed as a potential alternative imaging technique, and recently, automated 3D transesophageal echocardiographic software (Aortic Valve Navigator [AVN], an unreleased prototype from Philips) has been developed for assessment of the aortic annulus and root. The aim of this study was to assess the feasibility, accuracy, and reproducibility of AVN measurements in TAVR candidates by performing a comparison with MDCT.

Methods: In 150 patients with severe, symptomatic aortic stenosis referred for TAVR, data on aortic annular and root dimensions prospectively acquired using 3D TEE and MDCT were retrospectively analyzed. Image quality on 3D TEE and the duration of analysis with AVN were recorded, as well as the aortic valve Agatston score on MDCT.

Results: Data were obtained using 3D TEE and MDCT in 100% of patients for aortic annular dimensions and in 89% for aortic root dimensions. The mean duration of analysis using AVN was 4.2 ± 1.0 min, but it was significantly shorter with better 3D echocardiographic image quality and lower Agatston score on MDCT. Correlation of measurements between 3D TEE and MDCT was good to excellent for all anatomic locations (sinotubular junction mean diameter, $R = 0.71$; sinus of Valsalva mean diameter, $R = 0.87$; aortic annular mean diameter, $R = 0.75$; aortic annular perimeter, $R = 0.83$; aortic annular area, $R = 0.91$), with low inter- and intraobserver variability (intraclass correlation coefficient ≥ 0.93 and $r \geq 0.90$ for all locations). Comparison based on conventional prosthesis sizing charts yielded excellent agreement in prosthesis size choice ($\kappa = 0.90$).

Conclusions: New automated 3D transesophageal echocardiographic software allows accurate modeling and reproducible quantification of aortic annular and root dimensions with high feasibility. An excellent correlation between measurements with AVN and MDCT and agreement in prosthesis sizing suggests the use of AVN in clinical practice as potential alternative to MDCT before TAVR. (J Am Soc Echocardiogr 2017;■:■-■.)

Keywords: Three-dimensional echocardiography, Aortic annulus, Transcatheter aortic valve replacement, Multidetector computed tomography

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In patients with symptomatic severe aortic stenosis (AS) who are deemed ineligible or at high risk for surgery, transcatheter aortic valve replacement (TAVR) has rapidly become the current treatment of choice.[1,2] Early TAVR experience has demonstrated the prognostic impact of complications due to inaccurate prosthesis sizing, such as paravalvular regurgitation and, less frequently, annular rupture or valve embolization. Therefore, preimplantation prosthesis sizing is considered key for procedural success and will gain even further importance as indications for TAVR expand in the near future toward an intermediate-risk population.[3] Currently, multi–detector row computed tomography (MDCT) is the three-dimensional (3D) imaging technique of choice for aortic annular measurement and therefore for prosthesis sizing. However, this technique has its limitations in both the elderly population because of contrast nephrotoxicity and in the

Abbreviations

3D = Three-dimensional

AS = Aortic stenosis

AVC = Aortic valve calcification

AVN = Aortic Valve Navigator

HU = Hounsfield unit

ICC = Intraclass correlation coefficient

LV = Left ventricular

LVOT = Left ventricular outflow tract

MDCT = Multi–detector row computed tomography

MPR = Multiplanar reconstruction

STJ = Sinotubular junction

SV = Sinus of Valsalva

TAVR = Transcatheter aortic valve replacement

TEE = Transesophageal echocardiography

younger population because of radiation risks. Three-dimensional transesophageal echocardiography (TEE) is a valuable alternative to MDCT.[4-7] Data from both MDCT and 3D TEE are commonly analyzed manually and require advanced expertise to accurately measure the aortic annulus. Automated 3D echocardiographic software based on adaptive analytics algorithms may help standardize the measurement, reducing the time of analysis and maximizing accuracy and reproducibility, as has been shown for postprocessing tools for MDCT.[8,9] Prototype software for automated aortic annular and root sizing (Aortic Valve Navigator [AVN]; Philips Medical Systems, Andover, MA) has been recently developed, allowing reconstruction of an aortic root model from 3D transesophageal echocardiographic images. The aims of this study were (1) to assess the feasibility and reproducibility of automated 3D transesophageal analysis of the aortic annulus and root, (2) to assess the accuracy of automated 3D transesophageal analysis by comparison with measurements obtained with MDCT, and (3) to evaluate the impact on transcatheter valve prosthesis choice using automated 3D transesophageal analysis.

METHODS

Population Characteristics

We retrospectively included 150 patients with severe AS who underwent TAVR, applying the following exclusion criteria: (1) lack of or inadequate preprocedural MDCT ($n = 23$), (2) lack of intraprocedural 3D TEE or imaging performed using an ultrasound system from another vendor ($n = 134$), and (3) valve-in-valve procedures ($n = 18$). Selection criteria for TAVR were the presence of severe AS, defined by mean aortic valve gradient ≥ 40 mm Hg or aortic valve area ≤ 1 cm^2.[10] Eligibility for TAVR was decided in a heart team discussion and mainly for those patients deemed too high risk or having contraindications for cardiac surgery. The need for patient written informed consent was waived by the institutional review board of the Leiden University Medical Center after approval of this retrospective analysis of clinically acquired data.

Transthoracic Echocardiography

Comprehensive two-dimensional transthoracic echocardiography was performed before TAVR using a commercially available ultrasound system (Vivid; GE Vingmed Ultrasound, Horten, Norway). Valve morphology, AS severity, stroke volume, and left ventricular (LV) function were measured according to the European Association of Cardiovascular Imaging and American Society of Echocardiography standards.[10] Specifically, LV end-diastolic and end-systolic volumes and LV ejection fraction were calculated using the Simpson biplane method. Stroke volume was indexed to body surface area.

Three-Dimensional Transesophageal Echocardiography

Acquisition of 3D transesophageal echocardiographic images was performed intraprocedurally using a commercially available ultrasound system (iE33 and EPIQ7; Philips Medical Systems) and transesophageal probe (X7-2t). Using 3D zoom mode with adjustment of lateral and elevation width, 3D images of the whole aortic valve apparatus were obtained, including the LV outflow tract (LVOT), the aortic root, and the ascending aorta. Image quality was recorded in all patients and graded as follows: 1 = poor, 2 = fair, 3 = good, 4 = very good, and 5 = excellent.

The 3D transesophageal echocardiographic images of the aortic annulus and root were subsequently analyzed using a prototype of dedicated software that allows automated modeling of the aortic annulus and aortic root in a multistep, predefined work flow. The software provides several measurements of the aortic root (LVOT, aortic annulus, sinus of Valsalva [SV], and sinotubular junction [STJ]), which can be preselected before the analysis. The following measurements were collected for the purpose of this study: aortic annular area, aortic annular maximum and minimum diameter, aortic annular perimeter, SV mean diameter, and STJ mean diameter. The mean aortic annulus diameter was calculated as the average of the maximum and minimum diameters. Figure 1 highlights the key steps of the software work flow.

After selection of the 3D transesophageal echocardiographic Digital Imaging and Communications in Medicine file, an automated algorithm orients the multiplanar reconstruction (MPR) images as requested (Figures 1A and 1B). After manual frame selection (in an early systolic phase), the user can place two reference markers ("AA: Ascending Aorta" or "LVOT") to facilitate interpretation of the images and eventually further adjust the MPRs. The software uses built-in algorithms to automatically define three virtual aortic valve annular points in each MPR, which can be confirmed by the user (Figures 1C−1E). The MPR in the transverse view automatically adjusts to the plane containing the three points, followed by an automated generation of the annulus contour. After approval of the annular contour, the software automatically initiates the LVOT contour at a plane parallel to the aortic annular plane and offset 5 mm into the left ventricle. The same steps are then followed to generate the SV and STJ contours in their respective planes.

If deemed necessary by the user, the software allows adjustment of the obtained contours using two different approaches (Figure 2). The first approach comprises manual regional adjustment of the contour by altering the position of the automated points. The second approach comprises global contour scaling ("slider") with a user-predetermined amount (or "offset"). Users can define this specific offset by determining the difference in measurements (or "bias") between 3D echocardiography and MDCT in a group of their own patients. Both approaches can also be combined to further improve contour tracing. Finally, after generating an aortic root model with the four different contours (aortic annulus, LVOT, SV, and STJ), the software allows the user to select from a variety of TAVR devices, allowing a 3D overlay of the device superimposed on the generated aortic root model (Figure 1F). An instantaneously generated and detailed list of the performed measurements is provided by the