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Impact of Three-Dimensional Transesophageal Echocardiography on Prosthesis Sizing for Transcatheter Aortic Valve Implantation

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Objectives: To compare aortic annulus diameters obtained by 3D transesophageal echocardiography (TEE) with 2D-TEE and the impact on prosthesis size selection in transcatheter aortic valve implantation (TAVI). Background: In TAVI the aortic annulus diameter determines prosthesis size. The ideal modality for annulus assessment has not been defined yet. Methods: Annulus diameters in 2D-TEE (long-axis view) and in 3D-TEE (long-axis view in multiple-plane-reconstruction) were compared in consecutive patients with aortic stenosis screened for TAVI. Prosthesis size was selected according to industry guidelines, integrating data from 3D-TEE, angiography and computed tomography. The percentage of cases in which 2D-TEE and 3D-TEE correctly predicted final prosthesis size was calculated. Results: Forty-nine patients were studied (Age 80 ± 5, 39% male, logistic EuroScore 17 ± 11%). Annulus diameters from 2D- and 3D-TEE correlated (r = 0.808, P < 0.0001). Mean diameters were significantly larger on 3D- vs. 2D-TEE (23.4 ± 2.2 vs. 22.1 ± 2.6 mm, P < 0.001) with a mean difference of 1.2 mm (limits of agreement: −1.8 to 4.3). The interobserver variability of 2D- and 3D-TEE was 3.5 ± 5.6% and 0.9 ± 5.1%, respectively. Thirty-nine patients underwent TAVI (27 CoreValve™, 12 Edwards Sapien™). The procedure was successful in 37 (95%) patients. Postprocedural regurgitation was none or mild in 89% of the cases with no severe insufficiency. Final prosthesis size was correctly predicted by 2D-TEE in 67% while in 80% by 3D-TEE. Overall, 3D-TEE suggested a different prosthesis size in 26% of all cases compared to 2D-TEE. Conclusions: Aortic annulus measurement by 3D-TEE yields significantly larger diameters than 2D-TEE. This impacts prosthesis size selection in a considerable percentage of cases.

Key words: cardiac imaging; aortic stenosis; multiple plane reconstruction

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has emerged as a valid therapy option for patients with aortic stenosis deemed at high risk for conventional surgery [1,2]. In the majority of patients, two access routes, the transfemoral [2,3], and the transapical approach [4], have been used and procedural results from registries and first randomized trials are encouraging [5–7].

For successful implantation, appropriate patient screening is an important task for the interdisciplinary TAVI team. Crucial for this process is the correct selection of the prosthesis size based on measurements of the aortic annulus.

To date, there is no gold standard for the measurement of the aortic annulus in TAVI. Several imaging modalities have been used for that purpose, mainly transthoracic (TTE) and transesophageal echocardiography

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Additional Supporting Information may be found in the online version of this article.

Conflict of interest: Nothing to report.

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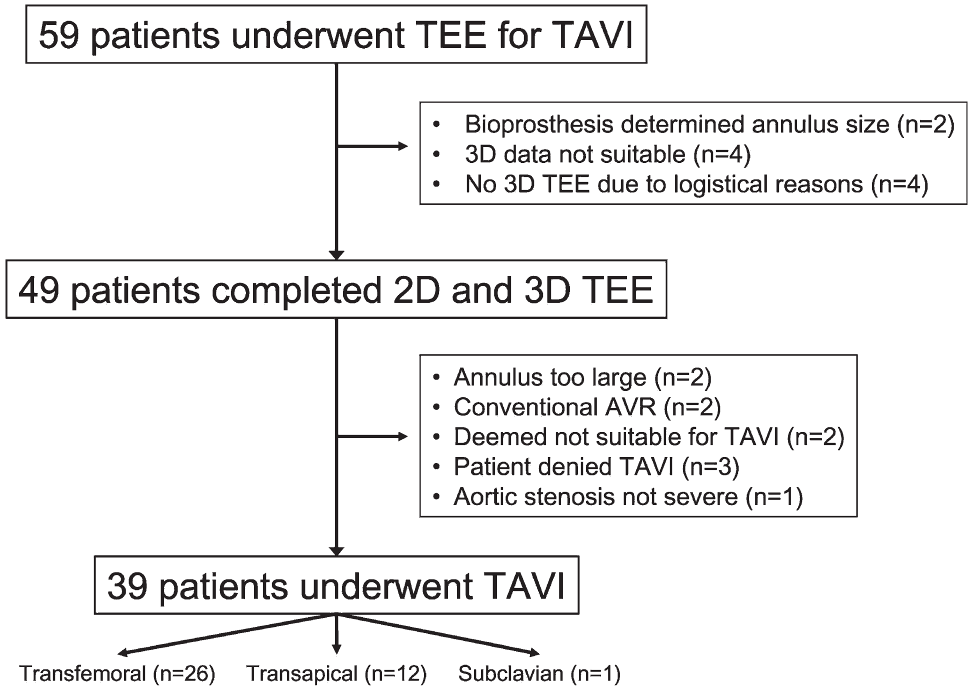

Fig. 1. Patient flow chart. Reasons for exclusion of patients from 3D-TEE analysis and from TAVI.

(TEE) [8]. Because of the complex anatomy of the aortic valve [9], modalities allowing for three-dimensional (3D) assessment of the aortic annulus are of great potential value. For that purpose, especially multislice computed tomography (MSCT) has been used with good results [10–12].

3D-TEE becomes increasingly available and also allows for 3D reconstructions but lacks radiation or contrast administration. Data on how aortic annulus measures assessed by 3D-TEE compare with 2D-TEE measurements are scarce and the impact on the choice of prosthesis size for TAVI has not been evaluated.

Thus, the aim of the present study was to compare aortic annulus measurements of 2D- and 3D-TEE and to evaluate the impact of 3D-TEE on prosthesis size selection for TAVI.

MATERIALS AND METHODS

Study Population

We studied 59 consecutive patients with severe aortic stenosis undergoing TEE as part of TAVI screening from October 2009 to January 2011. 10 patients were excluded from the comparison of 2D- and 3D-TEE. The logistic EuroScore [13] of the remaining patients was calculated and clinical baseline characteristics were recorded. The reasons for exclusion are shown in Fig. 1. Of these, four patients were excluded due to insufficient 3D data quality (two cases due to stitching artifacts because of atrial fibrillation, two cases because annulus calcification precluded valid measures of the aortic annulus). Of the remaining 49 patients, 39 underwent TAVI after completed screening. The reasons for not undergoing TAVI are displayed in Fig. 1. All patients underwent diagnostic coronary angiography with additional angiography of the aortic arch and of the iliac vessels as part of our TAVI screening protocol. MSCT was performed in 39% (19/49) of the patients in order to further evaluate the access route, if considered necessary. Since no ECG-gated MSCT was available, we did not perform annulus sizing with this modality. All patients signed informed consent for the diagnostic and therapeutic procedures.

Echocardiographic Examinations

Echocardiographic examinations were performed by two experienced echocardiographers following the recommendations of the American Society of Echocardiography using a commercially available ultrasound system (IE33, Philips, Best, The Netherlands).

TTE was performed using a S5 probe and left ventricular ejection fraction and mean transaortic gradient was obtained.

TEE was performed using a commercially available ultrasound system (IE33, Philips, Best, The Netherlands) with a multiplanar probe allowing for 2D and 3D imaging (X7-2t). In the mid-esophageal position at 110–135° a long axis view of the aortic valve was obtained. The aortic valve area was assessed by direct planimetry in 50–70°.

After 2D examinations, 3D data sets were acquired, manually adjusting depth and optimizing gain and compression during 3–5 cardiac cycles.

2D-TEE and 3D-TEE Measurements of the Aortic Annulus Diameter

In 2D-TEE, aortic annulus diameter was measured in midsystole in the 110–135° long-axis view at the insertion of the leaflets using the zoom mode (Fig. 2). Measurements were averaged from 3 to 5 beats.

3D data sets were evaluated offline on commercially available software (QLab Philips, Best, The Netherlands) using multiple plane reconstruction. In short, two orthogonal planes parallel bisecting the aortic valve in the long axis were manually adjusted. The third orthogonal transverse plane was set bisecting the aortic annulus at the insertion points of all three aortic cusps as the short-axis view. Aortic annulus diameter was measured in midsystole as the largest possible diameter in the idealized 3-chamber view using plane correction in the short axis plane (Fig. 2). Measurements were averaged from three measurements. In our laboratory, the evaluation of 3D-TEE data for TAVI screening takes less than 5 min in the vast majority of cases.

TAVI Procedures

After completion of screening, including angiography and in selected cases MSCT, 42 patients were deemed suitable for TAVI according to the interdisciplinary consensus by the TAVI team. Since three of these patients rejected the procedure, 39 finally underwent TAVI. TAVI was performed either via the transfemoral approach (subclavian approach in one case) using the selfexpandable CoreValve™ prosthesis (Medtronic, Irvine, CA) or the transapical approach using the balloon expandable Edwards SAPIEN™ or SAPIEN XT™ prosthesis (Edwards Lifesciences, Irvine, CA). Procedures were performed in the catheterization laboratory under general anesthesia using fluoroscopy and in the case of transapical TAVI under additional TEE guidance.

Prosthesis Size Selection

The decision on the final prosthesis size for each patient was based on 3D-TEE measurements of the aortic annulus according to the manufacturers' recommendations integrating angiographic and, when available, MSCT information (e.g., amount of calcification, distance of coronary ostiae).

At the time of the study, the Edwards-SAPIEN™ valve was available in two sizes, 23 and 26 mm. A 23-mm prosthesis was assigned if the aortic annulus diameter was ≥18 and≤21 mm, a 26-mm was implanted if the annulus diameter was >21 and ≤25 mm.

The CoreValve™ prosthesis is currently available in two sizes, 26mm and 29mm. A 26-mm prosthesis was assigned, if the annulus diameter was ≥20 and ≤23 mm. A 29-mm prosthesis was implanted if the annulus diameter was >23 and ≤27 mm.

Statistical Analysis

Continuous data are expressed as the mean ± standard deviation and were compared using Students *t*-test for paired data. For comparisons between 2D-and 3D-TEE data and for interobserver variability, Pearson's correlations and the Bland-Altman method [14] were used. In 22 randomly selected patients, the interobserver variability was assessed for the annulus diameter measurements in 2D-TEE and 3D-TEE.

Statistical significance was considered for a two-tailed p-value <0.05. The SPSS statistical package (version 13.0, SPSS Inc., Chicago, Illinois) was used.

RESULTS

Baseline Characteristics

The clinical and echocardiographic characteristics of the entire study population ($n = 49$) is displayed in Table I. Mean age was 80 ± 5 years and 19 patients (39%) were male. The mean logistic EuroScore was 17 ± 11%. All but one patient had a tricuspid aortic valve. Mean aortic valve area was 0.72 ± 0.15 cm^2 with a mean transaortic gradient of 48 ± 16 mm Hg. Left ventricular ejection fraction was 35–50% in 20% of the patients and three patients (6%) had a left ventricular ejection fraction <35%.

Comparison of 2D-TEE and 3D-TEE

There was a good correlation between 2D- and 3D-TEE measurements of the aortic annulus diameter ($r = 0.808$; $P < .0001$). Mean aortic annulus diameters were significantly larger on 3D-TEE compared with 2D-TEE (23.4 ± 2.2 vs. 22.1 ± 2.6 mm, $P < 0.001$). The Bland-Altman plot for the two modalities shows a mean difference of aortic annulus diameters of 1.2 mm with limits of agreement between −1.8 and 4.3 mm (Fig. 3).

The interobserver variability for aortic annulus measurements using 2D- and 3D-TEE was 3.5 ± 5.6% and 0.9 ± 5.1%, respectively. Figure 3 displays the correlations between the 2 observers. The Bland-Altman plot for the interobserver variability shows a mean difference of aortic annulus diameters for 2D-TEE of −0.7 mm (limits of agreement between −3.1 to 1.6mm) and of −0.2 mm (limits of agreement between −2.4 and 2.0 mm) for 3D TEE (Fig. 3).

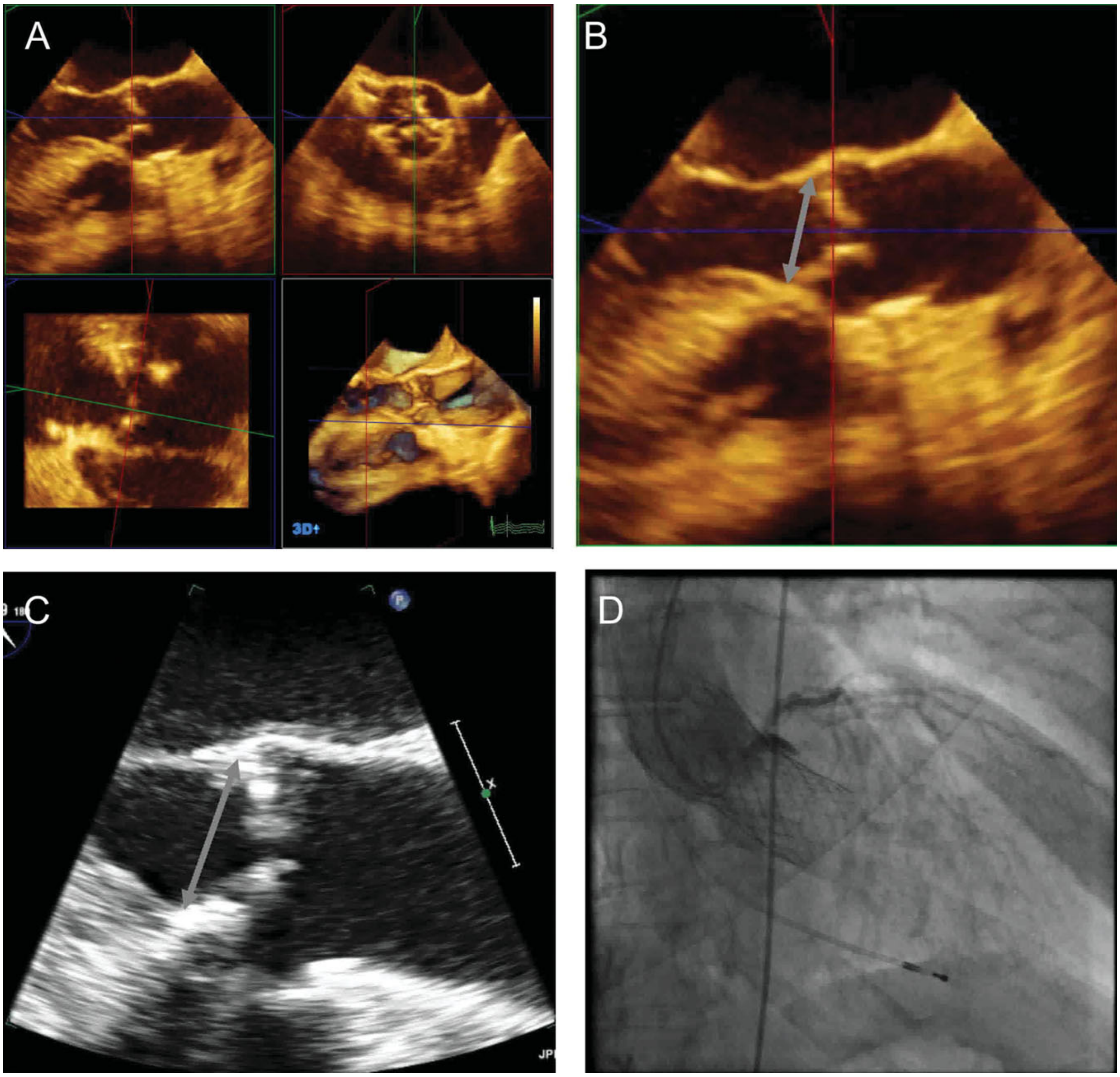

Fig. 2. Measurement of the aortic annulus diameter. Panel A shows the multiple plane reconstruction of the aortic valve using 3D-TEE. Two orthogonal planes divide the aortic valve along the long axis. These were adjusted manually to fit optimally (left upper and lower panel). In the third orthogonal transverse plane (right upper panel), the largest possible diameter for the idealized long axis view (panel B) is manually adjusted. Aortic annulus diameter was measured in midsystole as the largest possible diameter in the idealized long axis view (panel B). In 2D-TEE (panel C), aortic annulus diameter was measured at the insertion of the leaflets in midsystole from the 120° to 140° long-axis view. Panel D shows an example of a successfully implanted CoreValve™ prosthesis with no relevant paravalvular leakage. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Procedural Outcome and Impact of 3D TEE on Prosthesis Sizing

Of the entire study population, 39 underwent TAVI by the transfemoral approach using the CoreValve™ prosthesis ($n = 26$) or by the transapical approach using the Edwards SAPIEN™ or SAPIEN XT™prosthesis ($n = 12$). The subclavian access using the CoreValve™ prosthesis was utilized in one patient. The clinical and echocardiographic parameters of these patients are displayed in Supporting Information Table I.

The procedural data are displayed in Table II. One periprocedural death occurred due to pump failure in a

TABLE I. Clinical and Echocardiographic Characteristics of the Entire Study Population

	$n = 49$
Clinical characteristics	
Age (years)	80 ± 5
Male sex (%)	19 (39)
Logistic EuroScore (%)	17 ± 11
Diabetes (%)	24 (49)
Hypertension (%)	34 (69)
Hypercholesterolemia (%)	9 (18)
Previous valve surgery (%)	2 (4)
Previous CABG (%)	10 (20)
Coronary artery disease (%)	20 (41)
Previous cancer (%)	8 (16)
Previous myocardial infarction (%)	6 (12)
Previous stroke (%)[a]	5 (10)
Renal insufficiency (%)[b]	15 (31)
Chronic obstructive pulmonary disease (%)[c]	7 (14)
Pacemaker (%)	8 (16)
NYHA class III+ (%)	40 (82)
Echocardiography	
Left ventricular ejection fraction	
>50%	36 (74)
50–35%	10 (20)
<35%	3 (6)
Mean transaortic gradient (mm Hg)	48 ± 16
Maximal transaortic gradient (mm Hg)	79 ± 25
Pulmonary artery pressure (mm Hg) ($n = 39$)	41 ± 12
Tricuspid aortic valve (%)	48 (98)
Aortic valve area (cm^2)	.72 ± .15
Aortic annulus diameter in 2D TEE (mm)	22.1 ± 2.6
Aortic annulus diameter in 3D TEE (mm)	23.4 ± 2.2

[a]Severely affecting ambulation or day-to-day functioning.
[b]Serum creatinine >200 μmol/L preoperatively.
[c]Long-term use of bronchodilators or steroids for lung disease.
CABG, coronary artery bypass graft; NYHA, New York Heart Association; TEE, transesophageal echocardiography.

patient with a logistic EuroScore of 53.7% despite of a well-functioning implanted prosthesis. Conversion to open heart surgery was required in one case due to perforation of the ventricular wall. A veno-arterial extracorporeal circulation due to hemodynamic instability after valve implantation was used in four cases. In one case, no prosthesis could be implanted and the procedure was abandoned after valvuloplasty. In total, procedural success was achieved in 37 (95%) patients. Postprocedural regurgitation was none or mild (0–1) in 89% of cases (33 of 37 patients) and severe regurgitation (>2+) did not occur in any patient.

The final prosthesis size for implantation was selected integrating information from 3D-TEE, angiographic and MSCT data. Supporting Information Tables IIA and B show the assigned prosthesis sizes according to aortic annulus diameters by 2D- and 3D-TEE. Final prosthesis size was different from the predicted size in 33% of cases (13/39) with 2D-TEE and in 21% of cases (8/39) with 3D-TEE. Compared to 2D-TEE guidance for prosthesis size selection, the use of 3D-TEE changed prosthesis size selection in 10 (26%) of the patients.

DISCUSSION

This study shows that considerable differences between measures of the aortic annulus obtained by 3D-TEE versus 2D-TEE are present with larger measures being obtained with 3D-TEE. This divergence results in a different prosthesis size selection in a considerable percentage of cases and transforms thus into an important clinical decision.

Measurement of the Aortic Annulus Diameter—Different Modalities—Different Diameters

To date, no gold standard for the exact measurement of the aortic annulus diameter for TAVI exists. Especially for TAVI, this measure is of utmost importance to correctly select the size of the prosthesis. Erroneous measurements can lead to serious or even fatal consequences during implantation, such as embolization of the prosthesis or rupture of the aortic annulus. Therefore the need for a simple, fast, cost effective, and, most importantly, accurate modality for the assessment of the aortic annulus exists.

So far several diagnostic modalities for this purpose, such as transthoracic echocardiography, TEE, MSCT or angiography, exist. Mostly, a combination of several of these modalities is used in order to combine both, high spatial resolution and 3D-reconstruction. However, important factors are not only cost and workload issues for the preparation of the patient for TAVI, but also inherent limitations of the methods used. These limitations include issues such as heavy calcification of the aortic valve and of the aortic annulus.

Echocardiography is widely available, free of ionizing radiation and contrast administration and moreover is routinely used for diagnostic purposes, thus representing the ideal modality for prosthesis size selection in TAVI. Transthoracic echocardiography has been used for prosthesis sizing in TAVI and has consistently yielded smaller values and a larger interobserver variability compared to 2D-TEE [10,12].

Since the aortic annulus is a complex structure [9,15], a 3D-reconstruction for a comprehensive assessment of the anatomy is desirable. Mostly, this has been performed using MSCT. Several studies have compared aortic annulus measures by MSCT with those derived from echocardiography and aortography and have consistently shown that MSCT yielded larger diameters and possesses a higher reproducibility compared to these modalities [10,12]. Nevertheless, when using

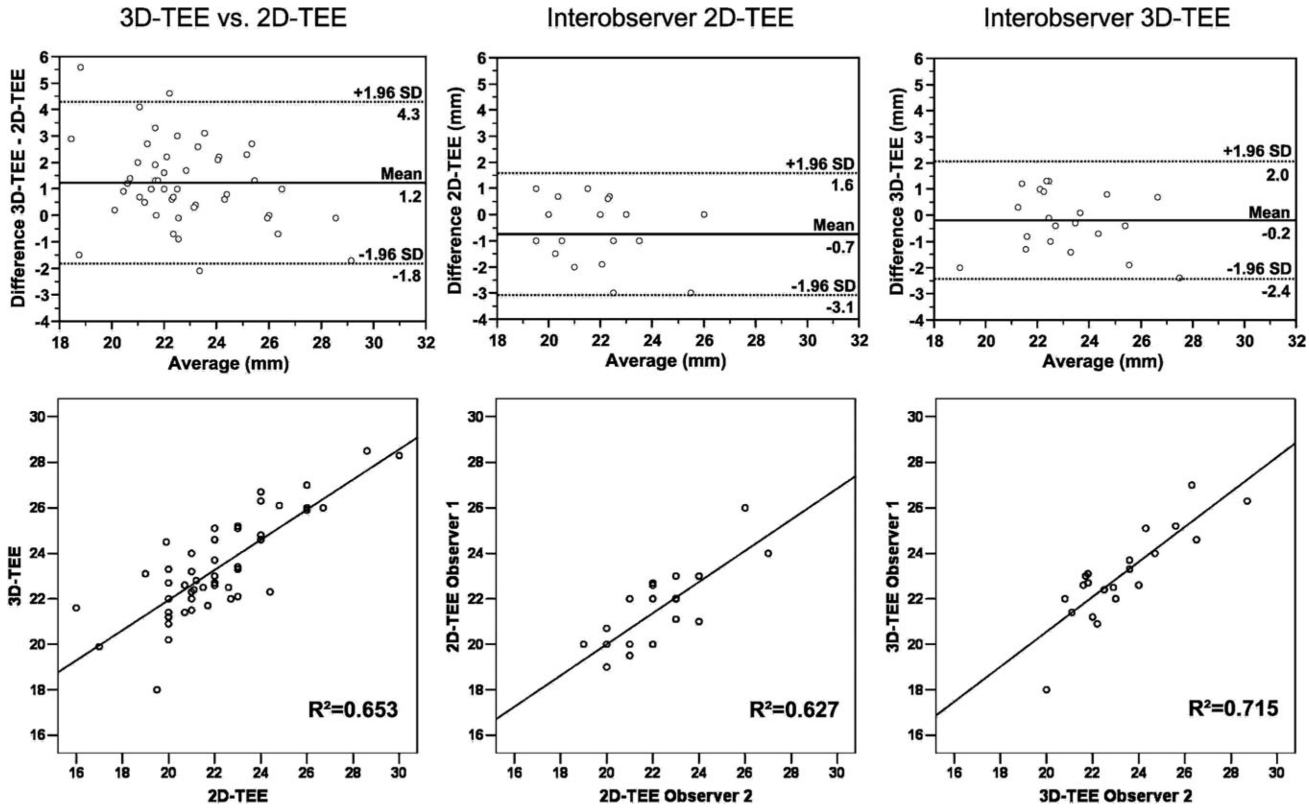

Fig. 3. Agreement between 2D and 3D TEE and interobserver variability of 2D and 3D TEE data. Linear regression analysis and Bland-Altman plots for 3D-TEE versus 2D-TEE and interobserver variability of 2D-TEE and 3D-TEE.

TABLE II. Procedural Data

	$n = 39$
Procedural success (%)	37 (95)
Procedural related death (%)	1 (3)
Peak-to-peak gradient before (mm Hg) ($n = 26$)	43 ± 21
Peak-to-peak gradient after (mm Hg) ($n = 22$)	4 ± 3
Procedural time (min)	88 ± 31
Post-procedural regurgitation (>1) ($n = 37$)	4 (11)
Conversion to surgery (%)	1 (3)
Use of extracorporeal circulation (%)	4 (10)
Valve-in-valve (%)	1 (3)

MSCT as a sizing modality one has to keep in mind that manufacturers' recommendations are based on echocardiographic measures. Indeed, one study showed, that up to 38% of patients would not have been eligible for the procedure, if screening would have been based on MSCT [12]. This reflects the difficulty in determining the ideal modality for prosthesis sizing.

3D-TEE in TAVI

3D-TEE becomes increasingly available, but up to date has mainly been used for intraprocedural guidance in TAVI [16,17]. Data on the use of 3D-TEE for patient screening in TAVI, how it compares to 2D-TEE and how it impacts prosthesis size selection are scarce.

A recent study showed larger intraoperative aortic root dimensions by 3D-TEE versus 2D-TEE but this study did not assess aortic annular diameters nor addressed the issue of prosthesis size selection [18].

The present study confirms the finding that 3D-TEE measures of aortic anatomy yield larger values and extends these findings, by showing that a 3D-TEE-based TAVI screening is feasible for prosthesis sizing. In our study we found a non negligible difference in aortic annulus measures assessed with 3D-TEE compared to 2D-TEE with a clear trend towards larger measures with 3D-TEE. This difference impacted prosthesis size selection in a considerable amount of patients (26%). The procedural results obtained by a 3D-TEE guided approach are excellent and can be compared with other series.

The additional use of 3D-TEE for prosthesis size selection offers several advantages over 2D-TEE use alone. First, with minimal extra effort (i.e., with the same probe) important additional information can be obtained in the same examination. Second, 3D-TEE data can be evaluated offline by an experienced TAVI physician. This issue may be of logistic importance as with the expected rising number of TAVI procedures, images can be created by an echocardiographer not familiar with TAVI and later be evaluated by a TAVI specialist. The excellent interobserver variability shown in this study also advocates the use of 3D-TEE for prosthesis sizing. Thirdly, the use of multiple plane reconstruction assures ideal angulations of the best plane for the assessment of the largest aortic annulus diameter possible, potentially of benefit in order to avoid paravalvular leakage by selecting larger prostheses.

Theoretically, it should be possible to achieve the same aortic annulus measures with both 2D-and 3D-TEE, nevertheless the multiplanar reconstruction of 3D images assures sizing in the largest plane possible. This issue is more difficult with 2D images since the 2D long-axis view of the aortic annulus may not bisect the center of the annulus, resulting in an underestimation of the annulus diameter as shown in our study. This is also reflected by a smaller interobserver variability with 3D-TEE compared with 2D-TEE.

Prosthesis Size Selection

Prosthesis size selection for TAVI is a complex issue not only involving echocardiographic measurements, but also the review of angiographic and MSCT data. Several factors have an impact on prosthesis size selection. Most importantly, especially in the case of borderline annulus diameters, the degree of calcification determines whether to oversize or to undersize the selected prosthesis. In these cases, a final decision on the prosthesis size cannot be made only considering mere annulus diameter as can be found in the recommendations of the manufacturer, but instead a comprehensive assessment of the individual findings in each patient is warranted. In our series of patients, this problem, especially in the case of borderline annuli diameters, becomes evident as in 21% of the patients a different prosthesis size than suggested by 3D-TEE was implanted. This highlights the importance of a multimodal assessment of the aortic valve for TAVI [19].

Limitations

This study has several limitations. First, it represents a limited experience of a single center for the use of 3D-TEE for prosthesis size selection in TAVI and was not designed to determine any superiority of one of the two modalities in terms of procedural outcome or minimization of paravalvular leakage. However, it has to be regarded as advantageous that two individuals performed all 3D-TEE examinations, minimizing possible technical/operator-related differences. Secondly, the potential usefulness of 3D-TEE to reconstruct virtual orthogonal planes was not evaluated since the aim of this study was to investigate a straightforward approach of prosthesis sizing in the long axis view as recommended by the manufacturers.

CONCLUSIONS

This study demonstrates the feasibility and very good reproducibility of 3D-TEE for the assessment of aortic annulus diameters in the preparation for TAVI. It further shows a considerable difference between aortic annulus measures obtained by 3D-TEE versus 2D-TEE. Larger measures of aortic annulus diameters were obtained with 3D-TEE. This difference translates into important clinical decisions by change of prosthesis size selection in a considerable percentage of cases.

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