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BRIEF REPORT

Direct Assessment of Normal Mechanical Mitral Valve Orifice Area by Real-Time 3D Echocardiography

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A reliable method for the assessment of the mitral valve (MV) area is essential for the management of patients with a prosthetic MV. In this study, we assess the feasibility of 3-dimensional (3D) echocardiography to directly measure the mechanical MV orifice area in both an in vitro study of prosthetic valve function under controlled-flow conditions as well as in a clinical imaging protocol. The 3D anatomic diastolic area (ADA) and 3D color Doppler diastolic area were compared with a manufacturer-defined geometric orifice area (GOA) and Doppler-derived effective orifice area (EOA) for normal mechanical MVs (Fig. 1).

METHODS

In vitro study. A pulsatile circulatory loop was developed in our laboratory and previously described in detail (1,2). In brief, the setup consists of an inflow conduit leading to a flow chamber representing the left atrium, a valve orifice containing a mechanical mitral prosthesis, a receiving chamber simulating the left ventricle, and an outflow conduit, along with ultrasound imaging windows. The modular imaging chamber permits assessment of multiple valve sizes under tailored hemodynamic flow conditions. For each St. Jude Medical mechanical MV (St. Jude Medical, St. Paul, Minnesota) size tested (23, 25, and 31 mm), we assessed 3 different pulsatile inflow volumes (range 51 to 97 ml/beat) at a rate of 72 beats/min. A 3.5-MHz (S3) Doppler transducer (iE33, Philips Medical Systems, Andover, Massachusetts) was used to assess transorifice flow. The Doppler-derived EOA was calculated as stroke volume divided by the time-velocity integral through the mitral prosthesis. 3D live and 3D full-volume color Doppler (7-beat stitch) images were acquired (X3 transducer, Philips Medical Systems) and then analyzed offline using a QLAB workstation (version 6, Philips Medical Systems). An average of 3 measurements was recorded for each imaging modality. All off-line measurements were performed by 2 observers blinded to valve size and the manufacturer-defined GOA.

Clinical study. Patients scheduled to undergo clinically indicated transesophageal echocardiography (TEE) or prosthetic MV implantation (intraoperative TEE) were approached for study participation. Patients with prosthesis malfunction or coexisting aortic regurgitation of more than mild severity were excluded. Thirty-five consecutive patients with a prosthetic MV were approached for the study. Ten patients were excluded due to moderate to severe paravalvular regurgitation (n = 2), partial leaflet obstruction (n = 1), bioprosthetic mitral valve (n = 3), and insufficient 3D TEE image quality (n = 4). Prosthetic valve type and size were obtained from the patient's valve information card, the operative report, or the valve manufacturer's implant database. The research protocol was approved by the institutional review board, and all participants provided written consent.

2-dimensional and 3D transesophageal echocardiographic image acquisition. TEE was performed using an X7-2t transducer (iE33, Philips Medical

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Systems). Peak and mean mitral gradients were measured from continuous wave mitral inflow Doppler. Live 3D (zoom mode), 3D full-volume (4-beat stitch), and 3D color Doppler (7-beat stitch) image data were acquired from the mid-esophageal view. Gain settings were optimized to minimize dropout of visible prosthetic leaflet and annular surfaces. Color Doppler velocity baseline and write priority settings were not adjusted. Data were transferred to an off-line analysis system (QLAB version 6, Philips Medical Systems) and stored. 3D image data were subsequently analyzed by 2 independent observers blinded to the 2-dimensional (2D) Doppler data, prosthetic valve size, and the manufacturer-defined GOA.

3D data analysis. The mitral orifice area was measured from 3 consecutive mid-diastolic frames and then averaged. The following protocol was used to define the diastolic valve area. First, 2 orthogonal long-axis imaging planes were defined through the prosthetic valve. Then the short axis of the open prosthetic valve was identified by adjustment of the "slider" data cropping feature within the short-axis image tile (Fig. 2) (Online Video 1). A true short-axis slice through the mid portion of the prosthesis was confirmed by any-plane rotation of the volume-rendered image tile (Fig. 2D). The inner circumference of the visible short-axis area was then manually traced at the mid-level of the open prosthesis. As shown in Figure 2C, the bileaflet disk area was not excluded from the area measured. In addition, the internal valve diameter was measured from the short-axis view. The same image cropping and measurement methods were also applied to 3D color Doppler datasets used for the in vitro and clinical imaging studies (Online Video 2).

2D echocardiography. 2D and Doppler transthoracic echocardiography was performed within 24 h of TEE using a 3.5-MHz probe and a commercially available ultrasound system (iE33, Philips Medical Systems). The stroke volume was derived as the product of the cross-sectional area of the left ventricular outflow and time-velocity integral of flow. Mitral inflow velocity through the prosthetic valve was recorded with continuous wave Doppler from the apical window. The Doppler-derived EOA was calculated using the continuity equation (EOA = stroke volume/time-velocity integral) through the mitral prosthesis by continuous wave Doppler (3).

Reproducibility analysis. Intraobserver variability was assessed using repeated measurements performed by the same observer 3 months later, whereas interobserver variability was evaluated in a random selection of 15 patients by repeated analysis by a second observer, blinded to the results of all previous measurements. The percentage of variability was defined from the absolute difference between repeated measurements divided by the average of the 2 measurements.

Statistical analysis. Hemodynamic characteristics and summary echocardiographic data were summarized as mean ± SD (range). The Pearson correlation coefficient was used to assess the relationship between the mean 3D ADA, 3D color Doppler area, Doppler-derived EOA, and manufacturer-defined GOA. Pairwise multiple-comparison method (Holm-Sidak) was used to assess for analysis of variance. A p value <0.05 was considered statistically significant.

RESULTS

The 3D anatomic diastolic valve area was not different by live 3D zoom or 3D full-volume (stitched) imaging methods (p = NS) in the in vitro or clinical study. Acquisition of 3D TEE images added approximately 2 min to the standard TEE protocol per patient; the time required for complete analysis of each 3D dataset by an experienced observer was approximately 4 min.

In vitro study. A comparison of the diastolic valve area for each valve size studied in vitro is presented in Figure 3. The mean 3D ADA, 3D color Doppler area, and Doppler EOA for the 23-mm valve (GOA 2.6 cm^2) were 2.4 cm^2, 1.8 cm^2, and 1.6 cm^2, respectively; for the 25-mm valve (GOA 3.1 cm^2), the measured areas were 3.0 cm^2, 2.6 cm^2, and 2.0 cm^2, respectively, and for the 31-mm valve (GOA 5.18 cm^2), the measured areas were 4.0 cm^2, 3.2 cm^2, and 2.6 cm^2, respectively. For each valve size, the 3D ADA was the largest, whereas EOA by the continuity equation was the smallest. The 3D color Doppler area was of an intermediate value. Changes in flow rates did not affect either anatomic or color Doppler area measurements by 3D echocardiography (correlations: r = 0.55, p = NS and r = 0.66, p = NS, respectively).

Clinical study. The clinical characteristics and baseline echocardiographic measures of the 25 patients with normal mechanical MV function are shown in Table 1. Atrial fibrillation was present in 4 patients. Mechanical valve sizes ranged from 23 to 31 mm.

ABBREVIATIONS AND ACRONYMS

2D = 2-dimensional
3D = 3-dimensional
ADA = anatomic diastolic area
EOA = effective orifice area
GOA = geometric orifice area
MV = mitral valve
TEE = transesophageal echocardiography

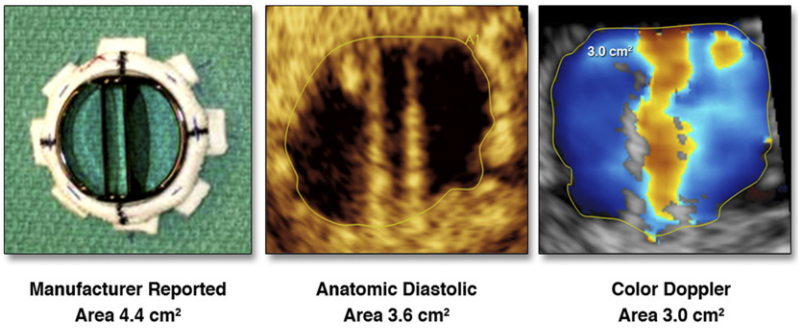

Figure 1. Planimetry Tracing of Diastolic Areas

Manual tracing of the inner prosthetic valve circumference of 29 mm St. Jude mechanical valve was used to define the 3-dimensional (3D) live anatomic diastolic area and color Doppler diastolic area. The mitral inflow area was recorded from 3 consecutive mid-diastolic frames for all 3D modalities.

All patients demonstrated normal transprosthetic gradients (mean 4.5 ± 2 mm Hg; range 2 to 10 mm Hg). Mild paravalvular regurgitation was noted in 5 patients.

The prosthetic MV was adequately visualized, and 3D image quality was diagnostic with live 3D and 3D color Doppler images obtained in all patients. The mean GOA was 3.9 ± 0.8 cm^2 and the mean 3D ADA was 3.1 ± 0.7 cm^2. The 3D color Doppler diastolic area was smaller at 2.5 ± 0.6 cm^2, whereas Doppler-derived EOA was the smallest and averaged 2.1 ± 0.6 cm^2. The Doppler-derived EOA could not be calculated for 3 patients due to inadequate left ventricular outflow tract images or poor pulsed-wave Doppler quality.

The mean 3D ADA was smaller, but correlated well with the GOA (3.1 ± 0.7 cm^2 vs. 3.9 ± 0.8 cm^2; $r = 0.83$, $p < 0.001$) (Fig. 4A). The 3D color Doppler area showed modest correlation with the GOA (2.5 ± 0.6 cm^2; $r = 0.69$, $p < 0.001$) (Fig. 4B). For all patients, the Doppler-derived EOA was the smallest area measure and demonstrated a weak but statistically significant correlation with the GOA (2.1 ± 0.6 cm^2; $r = 0.51$, $p = 0.044$) (Fig. 4C). There was a strong correlation between the 3D measured valve internal diameter and the manufacturer valve internal diameter ($r = 0.89$, $p < 0.001$).

Reproducibility. For repeated measures of 3D anatomic diastolic area, the interobserver and intraobserver variability was 8 ± 7% and 5 ± 3%, respectively. For repeated measures of the 3D color Doppler diastolic area, the interobserver and intraobserver variability was 8 ± 4% and 7 ± 3%, respectively.

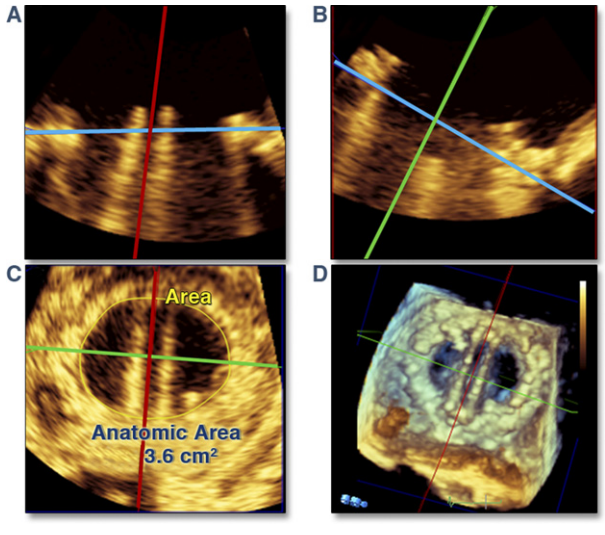

Figure 2. Measurement of 3D Anatomic Diastolic Area

Two orthogonal long-axis imaging planes were defined **(A,B)** through the prosthetic valve, and the true short axis through the mid-portion of the open prosthetic valve was identified **(C)**, and confirmed by any-plane rotation of the volume-rendered tile **(D)**. See Online Video 1.

DISCUSSION

The evaluation of prosthetic heart valve function has long been a clinical challenge. This report is the first to describe the use of matrix 3D TEE to provide a single direct measurement of the anatomic area or EOA of St. Jude Medical valves under normal flow conditions. Our results demonstrate 3 key findings. First, direct measurement of the anatomic area by 3D TEE is feasible and reproducible. Second, the anatomic area by 3D TEE correlates well with the manufacturer's GOA but with consistent underestimation bias. Third, the 3D color

Doppler area is a relatively simple and reproducible measure of the effective diastolic flow area.

Direct valve area assessment. Only 1 previous study described a possible role for 3D TEE in the quantitative examination of the prosthetic valve area (4), and there are no published reports of the relationship between the 3D color Doppler diastolic area and the GOA or Doppler-derived EOA. We performed 3D color Doppler assessment of the valve area and were able to provide the first comparison of a directly measured 3D effective diastolic flow area and a direct measurement of the 3D ADA.

The GOA is derived from the internal valve diameter of the prosthesis and is measured in vitro by the valve manufacturer. In both our in vitro and clinical imaging studies, we observed that the 3D ADA is smaller than the reported GOA for all valves (Figs. 3 and 4). This discrepancy is likely due to limitations in the spatial resolution of the 3D imaging methods.

Compared with 3D ADA, the color Doppler–derived area was consistently smaller. In the clinical study, there was no significant difference between the average 3D color Doppler diastolic area and the Doppler-derived EOA. It is well recognized that the EOA is often smaller than the GOA for both native and prosthetic valve flow (5,6). This study is the first to investigate the relationship between a direct measurement of the EOA by 3D color Doppler and other measures of valve function. The data presented (Fig. 4B) show a significant correlation between the 3D color Doppler–derived area and the GOA but an increasing discrepancy as valve size increases. It was previously reported that there is less discrepancy between the EOA and GOA with smaller prosthetic valves, with the explanation that smaller valves use the potential flow area more completely than do large valves (7). Overall, our in vitro and clinical data support the concept that a measure of the short-axis color Doppler area represents an effective area rather than a geometric flow area.

Doppler-derived EOA. The Doppler-derived EOA is a measure of the physiological area occupied by blood flow and not the true anatomic area of the prosthesis. As such, the EOA, not GOA, determines the mitral diastolic gradient. Although the EOA is a more reliable index of prosthetic MV function than measurement of the mean gradient alone, it is important to note that the higher velocity across the smaller central orifice (relative to the larger outside orifices) of bileaflet prosthetic valves results in underestimation of the continuity equation–derived EOA (3,7). Furthermore, the Doppler-measured EOA of the prosthetic MV is a composite of several measurements and geometric assumptions that may each be prone to error.

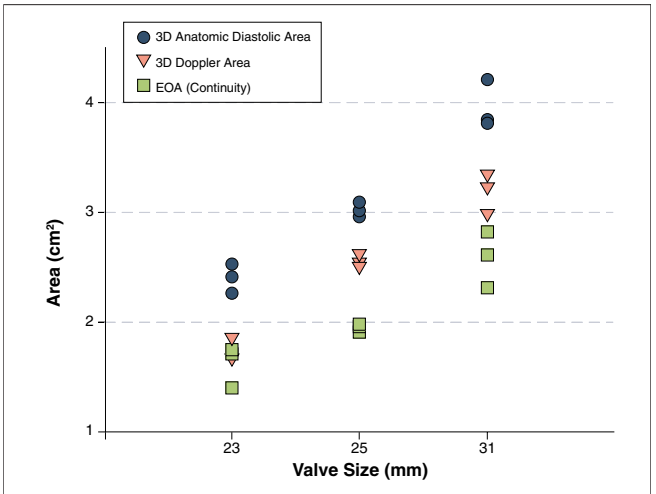

Figure 3. Valve Area Measurements by Different Methods in the In Vitro Study

Three valves of different sizes studied under different flow conditions. For each valve, the 3-dimensional (3D) anatomic diastolic area was the largest, whereas the effective orifice area (EOA) by the continuity equation was the smallest; 3D color Doppler was intermediate.

The simplicity of the directly measured 3D area assessment is reflected in the observer variability. We report 8% interobserver variability and 5% intraobserver variability, which compares favorably with the respective 15% and 9% repeated-measures variability reported for the Doppler-derived EOA of mechanical MVs (7).

Clinical implications. We examined the St. Jude Medical prosthesis because it is the most com-

Table 1. Patient Characteristics and Echocardiographic Data

	Mean ± SD	Range
Age, yrs	62 ± 17	21–86
Female, n (%)	14 (56)	—
Heart rate, beats/min	72 ± 13	54–100
BSA, m^2	1.9 ± 0.3	1.4–2.5
Ejection fraction, %	55 ± 14	27–71
SV_{LVOT}, ml	68 ± 17	44–108
Mean gradient, mm Hg	4.5 ± 2.4	2–10
TVI_{mitral}, cm	33 ± 7	23–46
EOA by continuity equation, cm^2	2.1 ± 0.6	1.2–3.2
EOA, indexed to BSA, cm^2/m^2	1.1 ± 0.3	0.7–1.8

BSA = body surface area; EOA = effective orifice area; LVOT = left ventricular outflow tract; SV = stroke volume; TVI = time-velocity integral.

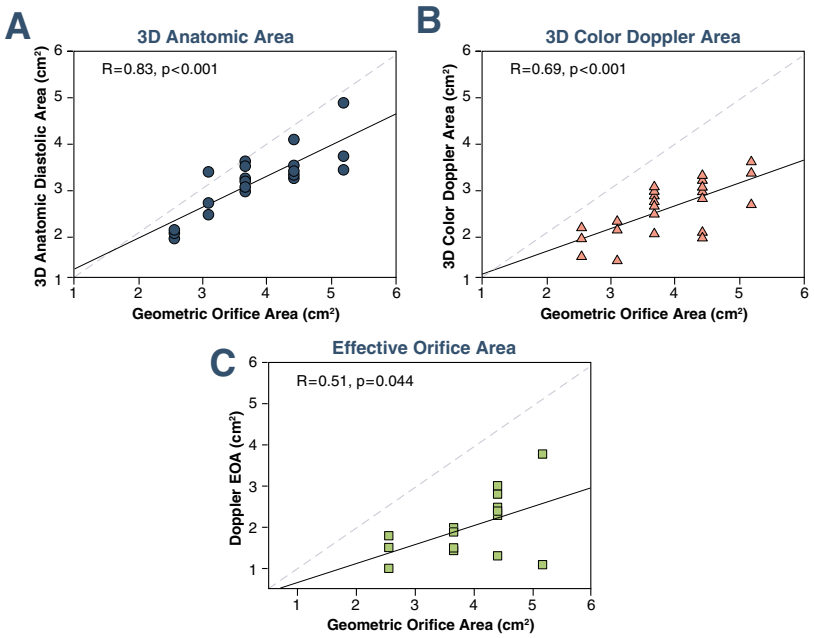

Figure 4. Area Measurements Compared With Manufacturer's Orifice Area

Relationship between manufacturer geometric orifice area and the 3D anatomic diastolic area **(A)**, 3D color Doppler area **(B)**, and EOA by continuity equation **(C)**. Abbreviations as in Figure 3.

monly implanted prosthetic valve worldwide (3) and because its hydrodynamic flow profile is complex. We anticipate that the area measurement techniques that we describe are likely to be applicable to other types of prosthetic valves. In this initial study, we did not enroll patients with valve dysfunction to assess the performance of 3D area measures in this important population. One area for application of these novel measures is in the identification of patients with prosthesis-patient mismatch. A direct 3D measurement of the anatomic and color Doppler valve area in these patients would be helpful, particularly when the valve size is not known. Another application of this method is for suspected prosthetic valve obstruction, as shown in Figure 5. In this clinical example, 3D TEE demonstrated leaflet obstruction. 3D color Doppler confirmed no diastolic flow through the medial half of the valve and a reduced color Doppler area, highlighting the potential value of 3D echocardiography (Online Video 3). Because our clinical study included only patients with normal MVs, it is important to validate our findings in a cohort of patients with abnormal prosthetic valve function and other types of prostheses.

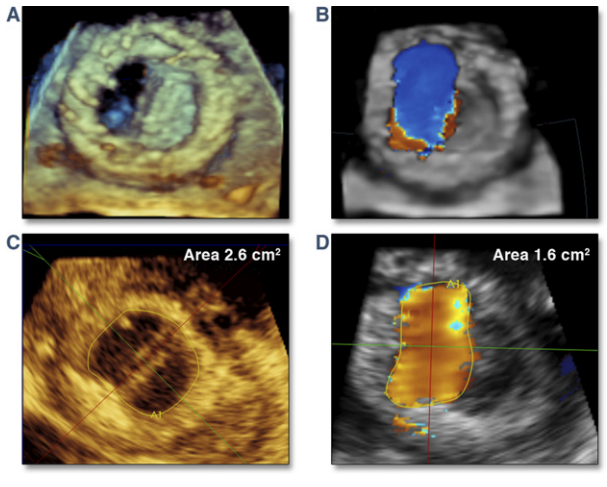

Figure 5. Abnormal Mechanical Valve Function

3D transesophageal echocardiography depicts a 27-mm St. Jude Medical valve (manufacturer's geometric orifice area, 3.7 cm^2) with partial leaflet obstruction. The right-side leaflet does not open **(A)**; see Online Video 2. 3D color Doppler demonstrates asymmetrical diastolic flow through only the left side of the prosthesis **(B)**. 3D anatomic diastolic area measured at the midpoint of the prosthesis appears normal **(C)**. 3D color Doppler diastolic area appears markedly reduced **(D)**, consistent with the reduced Doppler EOA (0.7 cm^2) and increased Doppler mean gradient (12 mm Hg). See Online Video 3. Abbreviation as in Figure 3.

CONCLUSIONS

Direct measurement of the mechanical MV orifice area by 3D echocardiography is feasible and simple and correlates well with manufacturer-reported area. 3D color Doppler can be used to

rapidly assess prosthetic valve function and to provide a direct measurement of the EOA, and may therefore be an important adjunct to the clinical evaluation of prosthetic valve function.

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Key Words: color Doppler ■ effective orifice area ■ prosthetic mitral valve ■ 3D echocardiography.

APPENDIX

For supplementary videos and their legends, please see the online version of this article.