# Validation of Transesophageal Echocardiographic In Vitro Measurements for Bioprosthetic Aortic Valves: Implications for Percutaneous Valve-in-Valve Therapy

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*Background:* Percutaneous valve-in-valve therapy has become an important treatment option for failing bioprosthetic heart valves. Accurate assessment of valve internal diameter (ID) is essential for effective and safe treatment. These data may not be available in an individual patient, or the manufacturer-supplied dimensions may be incorrect because they do not allow for the space occupied by valve leaflet material.

*Methods:* In total, 2,332 two-dimensional and three-dimensional transesophageal echocardiographic in vitro measurements were performed using both Philips iE33 and GE Vivid E9 systems with a range of system settings on 53 bioprosthetic valves in all available sizes. Two-dimensional echocardiographic ID measurements were made in two orthogonal planes at the level of the sewing ring, and similar three-dimensional measurements were generated from multiplane reconstructions. They were compared with both manufacturer-supplied valve ID (MID) and the true ID (TID) measured with Hegar dilators.

*Results:* Both the iE33 and the Vivid 9 provided comparable valve ID measurements. TID was statistically significantly smaller than MID ($P < .001$). All echocardiographic measurements were closer to TID than to MID. Two-dimensional measurements were closest to TID because of higher spatial resolution.

*Conclusions:* Transesophageal echocardiographic valve ID measurements compare well with TID, which is overestimated by MID. These findings have potentially important implications for valve-in-valve procedures because an inaccurate measurement of TID might lead to the wrong choice of implanted valve. (J Am Soc Echocardiogr 2016;29:267-75.)

*Keywords:* Valve-in-valve implantation, Failed aortic bioprosthesis, Ultrasound imaging, Internal diameter measurement

Moderate or severe heart valvular diseases are most common in patients >75 years of age, and they are likely to become more common because of the aging population.[1] Surgical valve replacement is the gold standard treatment in selected symptomatic patients. In the context of native aortic valve stenosis and very high-risk subjects, not suitable for conventional open heart surgery, transcatheter aortic valve replacement (TAVR) may be a valuable alternative treatment.[2-5] Percutaneous valve-in-valve (VIV) therapy with TAVR is a less invasive approach for treating failing bioprosthetic heart valves (BV). Several successful VIV interventions have already been performed,[6-9] showing that the procedure is a valid additional treatment option for a failing BV. Transesophageal echocardiography (TEE) is critical in the assessment of the aortic valve for TAVR and for VIV, especially in patient selection, monitoring during the procedure, and detecting complications. A key factor in the success of these new, noninvasive procedures is accurate measurement of the internal dimensions of the failing valve to determine the correct implant size. The size of an implantable TAVR valve is predetermined by the internal diameter (ID) of the preexisting valve, which is different for each manufacturer, and it is measured below the intra-annular portion of the valves.[10] TEE is the most appropriate and widely used imaging modality to assess failing BVs.[11] Therefore, in this study, we evaluated with TEE in vitro the most commonly used aortic bioprostheses.

Our hypothesis was that the manufacturer-supplied ID (MID) was greater than the true ID (TID) and that ID measurements made with TEE using contemporary ultrasound systems would correlate well with TID. To test this hypothesis, we compared ID measurements

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| Abbreviations |
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| **BV** = Bioprosthetic heart valve |
| **ID** = Internal diameter |
| **MID** = Manufacturer-supplied internal diameter |
| **TAVR** = Transcatheter aortic valve replacement |
| **TEE** = Transesophageal echocardiography |
| **TID** = True internal diameter |
| **3D** = Three-dimensional |
| **2D** = Two-dimensional |
| **VIV** = Valve-in-valve |

performed using TEE in vitro from two different ultrasound vendors with MID and TID.

## METHODS

### Valve Characteristics and Imaging Modality

We analyzed in vitro 53 new and unused aortic bioprosthesis in the most commonly used available sizes: Perimount ($n = 7$), Magna ($n = 1$), Carpentier Edwards standard ($n = 7$), Mosaic ($n = 5$), Biocor ($n = 5$), Biocor Supra ($n = 5$), Aspire ($n = 5$), Soprano ($n = 3$), Trifecta ($n = 6$), Hancock ($n = 5$), and Mitroflow ($n = 4$). In total, we performed 2,332 two-dimensional (2D) and three-dimensional (3D) TEE in vitro measurements using both Philips iE33 (Philips Medical Systems, Best, The Netherlands) and GE Vivid E9 (GE Healthcare, Little Chalfont, United Kingdom) systems with a range of system settings. TEE in vitro was performed for each aortic bioprosthesis. An iE33 echocardiographic system with an X7-2t Live 3D transesophageal echocardiographic transducer with 2- to 7-MHz operating frequency and a Vivid E9 6 TC multiplane phased-array transesophageal echocardiographic transducer with a 3- to 8-MHz operating frequency probe were used. Both systems enable real-time 3D TEE, as well as simultaneous imaging in two orthogonal planes (Live xPlane [Philips] and Multi-D [GE]) and conventional 2D multiplane TEE.

### Methodology

A metal bowl lined with a soft, thick cloth to minimize reverberation artifacts was filled with water and stood for 24 hours to allow degasification. A purpose-built frame was attached to the bowl and supported the transesophageal echocardiographic probe so that the transducer surface was under the water facing downward and approximately 5 cm above the valves that were placed on the cloth at the bottom of the bowl (Figure 1). This essentially provided an in vitro simulation of midesophageal imaging of an aortic bioprosthesis. On the Philips iE33 system, Live xPlane imaging was used to obtain two orthogonal 2D views of the valves. We performed the measurements using simultaneous orthogonal planes because we believe that most operators would use this mode to check the orientation of the 2D scan planes relative to the prosthetic valve sewing ring plane. The 2D line density is the same as nonsimultaneous imaging. In all cases, the frame rate was >30 Hz, which we believe is quite adequate, assuming the patient is not tachycardic. The planes were adjusted to intersect the midpoint of the valve. Therefore, measurements were made from the edge of the strongest (brightest) and most consistent echo signal, ignoring the softer (darker) signals inside the valve ring. Images were acquired using three different system settings, resolution, general, and penetration, maintaining overall gain power at 60%. These settings are equivalent to high, medium, and low fundamental. Three-dimensional mode data sets were acquired using the 3D zoom modality in fundamental mode with the overall gain power maintained at 50% for penetration, general, and resolution modes. A second 3D data set was obtained for each valve using

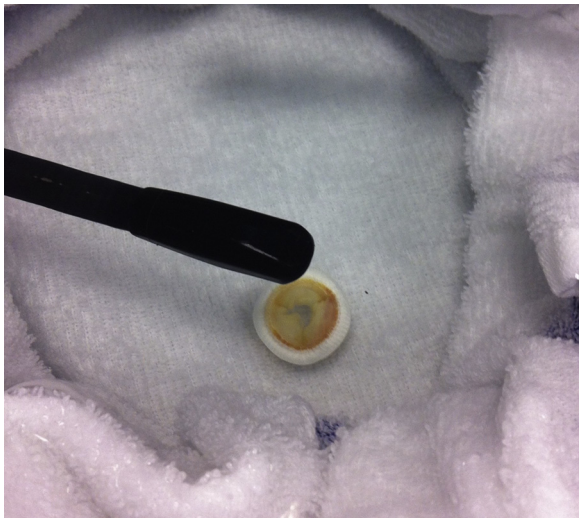

**Figure 1** Experimental setup of water tank. This is an image of the in vitro setup with a transesophageal echocardiographic probe suspended above a BV in a water tank lined with toweling to minimize reverberation artifacts.

resolution mode, with overall gain at 60% and a high volume rate, to determine the impact of lowering line density and hence spatial resolution. All 3D and four-dimensional zoom data sets were obtained in single-beat mode to replicate the in vivo situation in which this would be used to avoid stitching artifacts.

All valves were also imaged with a GE Vivid E9 BT12 machine. Multi-D was used and is comparable with Live xPlane imaging on the Philips system. We acquired images using three different frequencies, 8, 6, and 4 MHz, which are comparable with the Philips resolution, general, and penetration modes, maintaining overall gain power at −20 dB. We also used the four-dimensional zoom modality. Initially, data sets were obtained using frequencies of 8, 6, and 4 MHz, with a low volume rate. Then we acquired further images using a frequency of 8 MHz with a high frame rate, which again lowers the line density and, potentially, the spatial resolution.

The internal surface of the valve sewing ring was determined to be the most appropriate and likely landing zone for a VIV implant. The valve sewing ring is the narrowest internal dimension of the valve and is the point chosen by all operators performing this procedure to be the best landing zone for the implant. It is relatively easy to visualize this point on TEE and is analogous to the virtual aortic annulus used as a landing zone during TAVR procedures. Therefore, 2D echocardiographic ID measurements were made for the Philips iE33 machine in Live xPlane at the level of the sewing ring using Xcelera software (R3.2L1 SP2 3.2.1.712-2011) (Figure 2); 3D echocardiographic ID measurements, made at the same level, were generated using the manufacturer's software (QLAB version 9-3DQ) (Figure 3). Multiplane reconstruction from the 3D data sets was used to facilitate geometrically oriented measurements of the internal dimensions of the sewing rings using three orthogonal and perpendicular axes. Equivalent 2D and 3D echocardiographic ID measurements were also made at the same level of the sewing ring using analysis software on the GE Vivid E9 (version 112.2013) (Figures 4 and 5). Two experienced operators performed the ID measurements on the iE33, and a third experienced operator performed the ID measurements on the Vivid E9. All 2D and 3D echocardiographic measurements of the anatomic ID were compared with the MID and the TID. MID