

Intravascular ultrasound assessment of the actual transcatheter heart valve dimensions among patients treated for a right ventricular outflow tract insufficiency after surgical reconstruction

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Introduction: Transcatheter heart valve (THV) deployment can be used to treat right ventricular outflow tract (RVOT) insufficiency, but it is unknown whether manufacturers' predicted THV dimensions correspond with actually measured.

Purpose: To compare valve frame nominal dimensions predicted by the manufacturers' charts (Melody or Edwards SAPIEN [ES] 3) versus actual dimensions assessed using intravascular ultrasound (IVUS) with Visions PV.035 Digital Catheter (Philips) offering an imaging field of 60mm.

Methods: IVUS recordings were made post-THV deployment in 6 pts (median age 33 [20–44] yrs, 3 ♀, all with Tetralogy of Fallot) who had undergone prior corrective surgery (4 transannular patch, 1 bioprosthetic valve or 1 pulmonary homograft), but who presented with significant RVOT insufficiency. IVUS-visualized homograft cross-sections were perpendicular to its long axis. Offline volumetric measurements included the inner-THV dimension for a total of 16 evenly spaced cross-sections along the THV length. Assessed were THV inner-frame diameters (minimal and maximal), cross-sectional areas, and cross-sectional area of the visual orifice area identified at the coaptation site (Fig. 1). Each THV (1 Melody [Ø 22mm,

28mm nominal length] and 5 ES3 [1Ø 23mm, 18mm height; 4 Ø 29mm, 22.5mm height]) was implanted after pre-stenting using stents of 36, 39, or 48mm length, deployed on a 24mm (n=1) or 30mm (n=4) balloon-in-balloon catheter.

Results: Overall, 96 paired cross-sections were analyzed. Actual THV inner area was 95%±20% of that predicted. However, minimum THV inner diameter was smaller, but maximal inner diameter exceeded those predicted (Table 1). The ratios of measured-to-predicted minimal and maximal THV inner diameters were 97%±11% and 112%±13%, respectively, with a measured max/min inner THV frame diameter ratio of 1.16±0.13. However, the ratio of max/min lumen diameter measured at the coaptation site was of 1.11±0.11 signifying low eccentricity. Visual orifice area measured 364.3±87.6 mm², and was 65%±8% of the measured inner THV area.

Conclusions: After balloon-expandable THV implantation to treat RVOT insufficiency, there are differences in dimensions between actually measured vs predicted by manufacturers' charts. IVUS allows online tomographic insight into the actual THV frame dimensions and the substantially smaller, but circular orifice area.

Table 1. Comparison of nominal versus actual measurements

	Nominal dimension predicted by the manufacturers' charts (n=96 cross-sections)	Actual dimension assessed with IVUS (n=96 cross-sections)	p-value
Inner THV cross-sectional area (mm ²)	603.5±146.7	556.5±116.0	<0.001
Minimal inner THV diameter (mm)	27.5±3.6	24.7±3.2	<0.001
Maximal inner THV diameter (mm)	27.5±3.6	28.5±3.3	<0.001

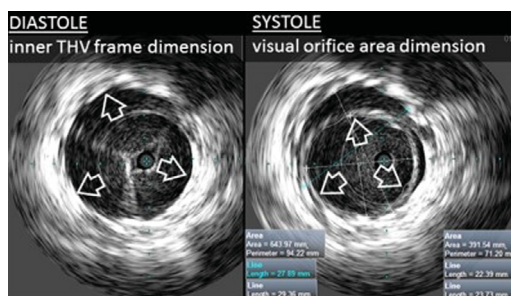


Figure 1. IVUS visualization