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Assessment of the Geometric Interaction Between the Lotus Transcatheter Aortic Valve Prosthesis and the Native Ventricular Aortic Interface by 320-Multidetector Computed Tomography

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ABSTRACT

OBJECTIVES This study sought to assess the geometric interaction between the Lotus Valve System transcatheter aortic prosthesis (Boston Scientific, Natick, Massachusetts) and the native aortoventricular interface using multidetector computed tomography (MDCT).

BACKGROUND The interaction between transcatheter aortic valve prostheses and native anatomy is variable, although potentially predictable. The Lotus transcatheter device uses a novel mechanical means of expansion, the effect of which on native anatomic geometry has not previously been described.

METHODS Forty patients treated with the Lotus prosthesis were enrolled. The patients underwent 320-MDCT imaging before and after implantation. Prosthesis dimensions and relevant interaction parameters, including circularity and expansion, were assessed. The degree of paraprosthetic regurgitation (PAR) and prosthesis gradient were measured by transthoracic echocardiography at the same time points.

RESULTS The mean baseline annular eccentricity index (EI) was 0.21 ± 0.06 and left ventricular outflow tract EI was 0.31 ± 0.09. The deployed prostheses had high rates of circularity with a mean EI across all device segments of 0.06 ± 0.04. In noncircular device deployment, an EI >0.1 was identified in 25% of prostheses and was associated with greater native annular eccentricity at baseline compared with circular devices (0.24 ± 0.04 vs. 0.19 ± 0.06; p = 0.01). The median percent of expansion was 97.5 ± 3.8% in the inflow portion of the prosthesis. Twenty-five percent of prostheses were <90% expanded in at least 1 segment with a numerical, but not statistically significant, association between oversizing and underexpansion. No correlation was found between device underexpansion and the mean transprosthesis gradient or between noncircularity and PAR.

CONCLUSIONS The Lotus prosthesis results in nearly full device expansion and circularization of the native basal plane. Awareness of the anatomic interaction between this unique device and the native architecture may help in the formulation of appropriate device-specific sizing algorithms. (J Am Coll Cardiol Intv 2015;8:740-9) © 2015 by the American College of Cardiology Foundation.

Transcatheter aortic valve replacement (TAVR) has gained widespread acceptance as a treatment for suitably selected high- and extreme-risk patients with symptomatic severe aortic stenosis. An increasing number of devices are entering research and clinical practice, often with unique features designed to reduce recognized complications, improve efficacy, and increase ease of use.

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Successful TAVR relies on accurate pre-procedural imaging to appropriately size the transcatheter prosthesis. Improved pre-procedural sizing, including the use of 3-dimensional multiple detector computed tomography (MDCT)-based screening, has contributed to a reduction in complications such as paraprosthetic aortic regurgitation (PAR) (1–3), pacing requirement (4), device embolization, and annular injury (5).

Although much focus has been on 3-dimensional pre-procedural assessment, equally important in ensuring procedural efficacy and safety is an awareness of the interaction that a given TAVR device might have with the native anatomy. Self-expanding prostheses such as the CoreValve (Medtronic, Minneapolis, Minneapolis), when positioned in a noncircular native annulus, tend to remain slightly eccentric (6). Balloon-expandable prostheses, however, such as the SAPIEN valve (Edwards Lifesciences, Irvine, California) tend to circularize even an eccentric native annulus (7,8).

Awareness of this variability in device-annulus interaction is important in determining what degree of prosthesis oversizing is efficacious yet safe. Deploying a device of slightly larger area or perimeter than the native annulus, i.e., oversizing, has been used with the current generation of devices to ensure device stability and help minimize PAR (1). This approach must be balanced against overdistention of the annulus and outflow tract with an increased risk of annular injury and/or pacing requirement. Oversizing may equally result in an underexpanded or noncircular prosthesis, which may, in turn, lead to accelerated valve wear.

The interaction of the Lotus Valve System (Boston Scientific, Natick, Massachusetts) with its unique expansion and locking mechanism (9) (**Figure 1A**) with the native annulus has not previously been described. Description and quantification of this relationship will help in the development of appropriate sizing algorithms for this novel device.

METHODS

POPULATION. Forty patients undergoing TAVR using the Lotus Valve System at our cardiac center were prospectively enrolled. All patients were being treated for symptomatic severe aortic stenosis and had been deemed to be at high surgical risk by the institution's heart team. An independent case review committee reviewed all cases before acceptance into the trial. All patients met the previously reported inclusion and exclusion criteria for the Boston Scientific REPRISE (Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus Valve System) trials (10). This study formed a single-center substudy within the REPRISE trials. Ethics approval was obtained from the institutional Human Research Ethics Committee.

ABBREVIATIONS AND ACRONYMS

EI = eccentricity index

LVOT = left ventricular outflow tract

MDCT = multidetector computed tomography

PAR = paraprosthetic aortic regurgitation

TAVR = transcatheter aortic valve replacement

IMAGING. All subjects underwent retrospectively electrocardiography-gated, 320-MDCT imaging of the aortic root before device implantation. Twenty-five patients subsequently underwent imaging at 32.7 ± 1.2 days, and 15 patients underwent imaging at 384.5 ± 11.4 days after implantation. All scans were performed on a Toshiba Aquilion One 320-detector row scanner (Toshiba Medical Systems, Otawara, Japan). No heart rate control was used. Seventeen scans were performed using prospective electrocardiographic gating with a temporal window between 75% and 85% of the R-R interval, whereas 23 scans used a retrospective (full R-R interval) window. Collimation was individualized to achieve a z-axis that encompassed the entire aortic root. The slice thickness was 0.5 mm. The gantry rotation speed was 275 ms per rotation, the tube voltage was 100 to 120 kV, and the tube current individualized to body habitus.

MDCT ANALYSIS. Pre-procedural imaging. All scans were analyzed using the 3Mensio Structural Heart analysis program, version 7 (3Mensio, Bilthoven, the Netherlands) and the Vitrea Fx workstation (Vital Images, Minneapolis, Minnesota).

The aortic valve basal plane was defined as the short-axis plane through the nadir of each coronary cusp. The minimal diameter (D_{min}), maximal diameter (D_{max}), perimeter, and area were measured in this short axis. The circularity of the basal plane was expressed as the eccentricity index [$EI = 1 - (D_{min}/D_{max})$]. This metric was previously demonstrated to correlate with post-procedural aortic regurgitation (3).

The left ventricular outflow tract (LVOT) was assessed in the short-axis 4 mm below the basal plane, perpendicular to the center line. Minimal and maximal diameters, perimeter, and area were measured at this level, with the eccentricity expressed as the EI. The sinus of Valsalva width, perimeter, and area were measured at the widest point of the sinus. The height of each coronary sinus was measured from the basal plane to the sinotubular junction in a stretched multiplanar image. The coronary artery heights were measured from the basal plane to the lowest border of each coronary ostia in a stretched multiplanar image. The angulation of the aortic valve plane was measured in relation to the horizontal plane.