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State-of-the-Art Paper

Effect of Valve Design on the Stent Internal Diameter of a Bioprosthetic Valve

A Concept of True Internal Diameter and Its Implications for the Valve-in-Valve Procedure

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The goal of this study was to provide a measurement of the true internal diameter (ID) of various surgical heart valves (SHV) to facilitate the valve-in-valve (VIV) procedure. During a VIV procedure, it is important to choose the right of the transcatheter heart valve (THV). Most users use the stent ID of an SHV to select the appropriate THV size. Echocardiography and computed tomography measurements are not yet standardized for measuring the ID of a variety of SHVs. Hence, we measured the true ID of SHV to assess the effect of valve design on the stent ID. Thirteen types of stented and 3 types of stentless valves were evaluated. True ID measurements were obtained using calipers and Hegar dilators. These were compared with the stent ID measurements. Fluoroscopy was used to confirm the impact of SHV designs on the true ID. Caliper measurements were found to be inaccurate and are hence not recommended. Hegar dilator measurements revealed a trend of reduction in stent ID. Porcine valves were most affected by their design, with reduction in the stent ID by at least 2 mm; pericardial valves with leaflets sutured inside the stent had the stent ID reduced by at least 1 mm, and SHV with leaflets sutured outside the stent had no effect on stent ID. In the majority of SHV designs, there is a reduction in the stent ID as a result of leaflet tissue. This is important in borderline sizes to avoid problems associated with oversizing and also to confirm suitability for the VIV procedure in the smaller label sizes of SHV. (J Am Coll Cardiol Intv 2014;7:115–27) © 2014 by the American College of Cardiology Foundation

Transcatheter aortic valve implantation (TAVI) has established itself as an accepted therapy for inoperable and high-risk patients with calcific aortic stenosis (1). Clinical need has led to the use of this technology in treating degenerated bioprosthetic surgical heart valves (SHV) to avoid redo open heart surgery (2). Multiple reports of valve-in-valve (VIV) procedures have appeared in the literature over the last 2 years, with substantial experience being acquired in treating a degenerated SHV in the aortic and mitral positions, and lesser experience in treating degenerated SHV in pulmonary and tricuspid positions (2–11).

This therapy area continues to grow rapidly because VIV treatment appears promising when compared with a redo open heart operation, due to its less invasive nature. One of the important determinants of immediate and long-term success of this novel treatment is choosing the right size of the transcatheter heart valve (THV) for a given SHV type and size. In a native aortic valve, measurements are performed at the level of the aortic annulus to determine the size of the THV (12). When performing a VIV procedure, the majority of current users use the stent internal diameter (ID) of an SHV to select the appropriate THV size (2–5). However, the SHV design may have an impact on this measurement because of the leaflet tissue mounted within the stent frame. We evaluated the effect of valve design on stent ID and discuss the

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concept of the true ID of an SHV, which is the relevant ID for the VIV procedure. We also briefly discuss sizing considerations for a VIV procedure in the aortic versus the mitral position.

Methods

Thirteen types of stented and 3 types of stentless aortic SHV of all sizes were obtained from various manufacturers (Table 1, Fig. 1). The 3 types of stentless aortic SHV studied were those implanted as aortic roots (Fig. 2). Stentless valves, which are implanted in a subcoronary position within a native aortic root, were excluded because they essentially behave like native aortic valves and take up the dimensions of the root in which they are implanted (Fig. 2).

Stent ID. We have previously published the stent ID of all SHV along with other dimensions (13). The industry standard when reporting the stent ID is the ID of the stent frame when covered with fabric or pericardium but without the valve leaflets (Fig. 3).

Abbreviations and Acronyms

CE = Carpentier-Edwards
CT = computed tomography
ID = internal diameter
SHV = surgical heart valve(s)
TAVI = transcatheter aortic valve implantation
THV = transcatheter heart valve(s)
VIV = valve-in-valve

True ID. True ID was defined as the ID of the inflow of the SHV.

Caliper measurements. An attempt was made to obtain the ID measurements with the use of a Vernier caliper (Fig. 4). The caliper was introduced through the inflow of the SHV, and measurements were obtained with minimal distortion. At least 2 measurements were obtained for each SHV, and 3 operators independently measured all sizes of each type of SHV.

Hegar dilator measurements. We used Hegar dilators with increments of 0.5 mm to measure the true ID. The Hegar dilator has a conical tip; thus, it can be easily introduced within an SHV (Fig. 5) from the valve inflow. The main body of the dilator is a perfect circle in cross section and, hence, gives an exact diameter. Measurements were performed using incremental sizes of Hegar dilators, and the largest size of the dilator that could be placed within an SHV was noted for each SHV (Fig. 5). Measurements were performed by 3 operators independently.

Confirmation of hypotheses using fluoroscopy. SHV are essentially of 3 types depending upon the leaflet material and placement of the leaflets: 1) porcine valve with leaflets sutured inside of the stent; 2) pericardial valve with bovine pericardial leaflets sutured inside of the stent; and 3) pericardial valve with bovine pericardial leaflets sutured outside of the stent. To assess the effects of valve design on the stent ID, 1 SHV of each type with a radio-opaque stent frame was chosen. These were the Carpentier-Edwards (CE) standard, Perimount (Edwards Lifesciences, Irvine, California), and Trifecta (St. Jude Medical, St. Paul, Minnesota), respectively. A CoreValve THV (Medtronic, Minneapolis, Minnesota) was implanted within each of these, and the degree of separation between the radio-opaque stent frame and the CoreValve stent frame (inflow portion) was observed; this essentially is the difference between the stent ID and the true ID.

Results

True ID measurement with calipers. Because the SHV can be easily distorted with the lateral push of the caliper arms, there was a large variability in these measurements (from 0.5 to 2 mm) (Fig. 4). This was particularly true for SHV designs such as the CE porcine valve, which has an asymmetric leaflet structure (Fig. 4) and lacks a complete polymer/metal ring at the base of its frame. This was also observed with the stentless valves because they lack a rigid base. An attempt was made to obtain measurements without distorting the valve, but the interoperator variability was still large; thus, we did not use this method for measurement of the true ID.

True ID measurement with Hegar dilators. STENTED AORTIC SHV. The true ID was smaller than the stent ID in the majority of SHV (Table 2). There was no interoperator variability found in the Hegar dilator measurements except for the CE porcine valve, where 0.5-mm variability was noticed only in the larger sizes for the reasons mentioned in the preceding text. In these cases, we have taken the largest measurement for analysis. We found the following trends in the reduction of the true ID depending on the design of the SHV:

1. Porcine SHV: The porcine valve leaflets are always sutured inside of the stent frame, and the true ID is at least 2 mm less than the stent ID (Fig. 6A). Examples: Hancock II (Medtronic), Mosaic (Medtronic), Aspire (Vascutek, Inchinnan, United Kingdom), CE porcine standard, CE porcine S.A.V. (Edwards Lifesciences), Epic/Biocor (St. Jude Medical), and Epic/Biocor Supra (St. Jude Medical).
2. Pericardial SHV with leaflets sutured inside of the stent: The effect of the pericardial leaflets was less than that of the porcine leaflets, and the difference between true ID and stent ID was 1 mm (Fig. 6B). Examples: Perimount (Edwards Lifesciences), Perimount 2700 (Edwards Lifesciences), Magna/Magna Ease (Edwards Lifesciences), and Soprano (Sorin, Milan, Italy).
3. Pericardial SHV with leaflets sutured outside of the stent: Because the leaflets were sutured outside of the stent, the stent ID and the true ID were similar (Fig. 6C). Examples: Mitroflow (Sorin) and Trifecta.

STENTLESS AORTIC SHV. Although there is variability between various manufacturers, the true ID was always smaller than the labeled size (which corresponds to the root diameter) (Table 2).

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