

TAVI in Bicuspid Aortic Valves

An overview of the current data and technical considerations for transcatheter intervention in bicuspid aortic valves.

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Transcatheter aortic valve implantation (TAVI) has become the gold standard for inoperable and high-risk patients. It is often proposed for elderly intermediate-risk patients and seems promising in low-risk patients.¹⁻⁴ Although several challenges remain for TAVI, one of the main challenges is how to deal with bicuspid aortic valves (BAVs). BAVs are the most common congenital valvular abnormality, observed in an estimated 0.5% to 2% of the general population and up to 20% of octo- and nonagenarians undergoing aortic valve surgery.⁵ Patients with BAVs are regularly excluded from major randomized trials and registries, although recent initiatives have confirmed the feasibility of TAVI in inoperable and high-risk patients with BAVs.⁶ Foreseeing the treatment of younger and lower-risk patients, we can expect a greater proportion of BAVs in the TAVI population. This article reviews current data on TAVI for BAVs and describes the main technical considerations for this procedure.

DIAGNOSING BICUSPID AORTIC VALVES

Diagnosing a BAV is not an easy process and often combines transthoracic echocardiography,

multidetector CT (MDCT), and sometimes transesophageal echocardiography. The most frequently used surgical classification, described by Sievers and Schmidtke,⁷ is according to the leaflet distribution and the presence and number of raphe, with type 0, type 1, and type 2 as the three major types (Figure 1). More recently, Jilaihawi et al proposed an MDCT-based classification identifying three morphologies: (1) the tricommissural or functional type, in which one commissure is completely fused between two equal cusps; (2) the bicommissural raphe type, in which two cusps are fused by a fibrous or calcified ridge; and (3) the bicommissural nonraphe type, in which both leaflets are of equal surface without any raphe.⁸ Whatever classification is considered, a multimodality diagnostic approach is necessary.

SIZING

There is no consensus on the appropriate methodology for BAV sizing. Various techniques have been proposed: annulus-based sizing, supra-annular tracing, measuring the intercommissural distance (ICD), and balloon sizing (Figure 2). In the BAVARD registry,⁹ we retrospectively captured the sizing ratios utilized

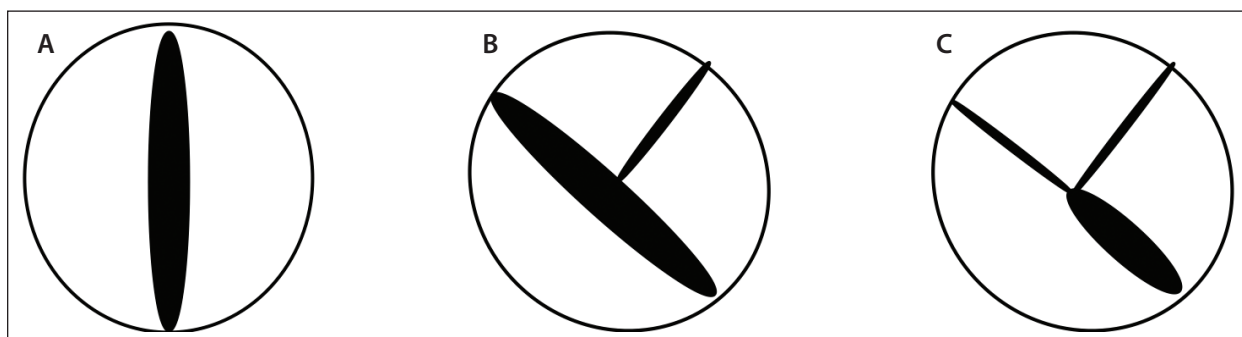


Figure 1. Sievers and Schmidtke classification of BAV anatomy: type 0 (A), type 1 (B), type 2 (C).

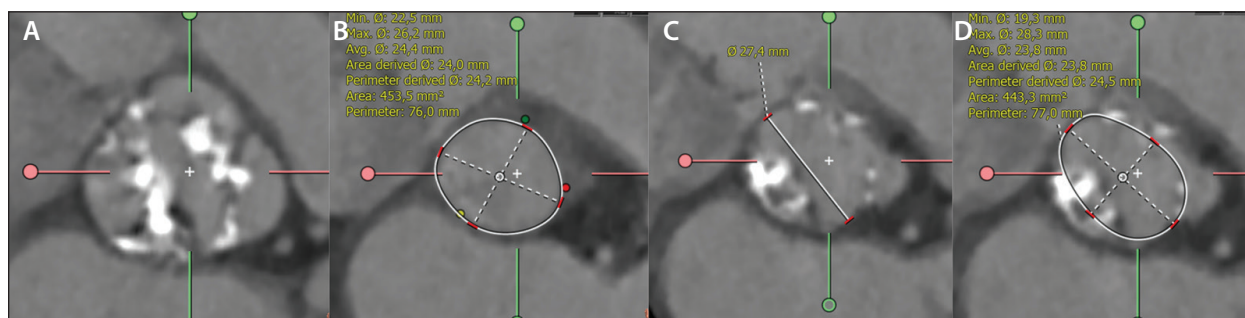


Figure 2. Sizing methodologies for TAVI in BAVs: Sievers type 1L/R (bicommissural raphe type) bicuspid valve (A); aortic annulus-based sizing (B); ICD 4 mm above the aortic annulus (C); supra-annular tracing (D).

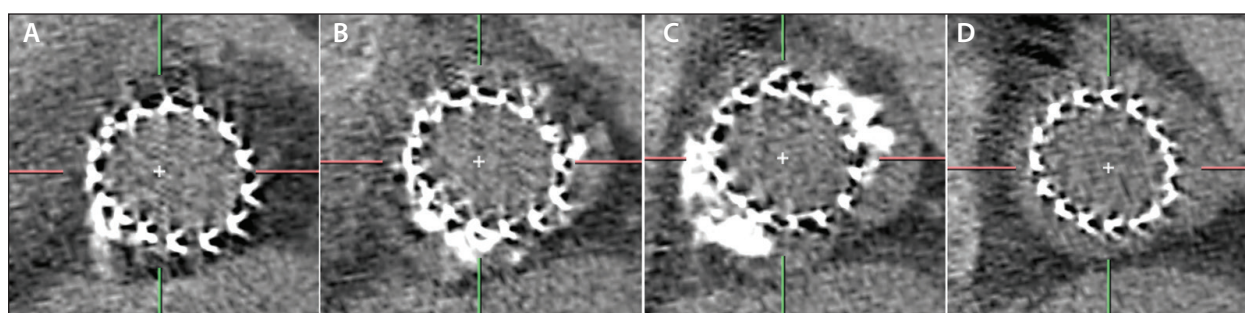


Figure 3. Post-TAVI MDCT evaluation of a type 1 BAV, demonstrating adequate circularity of a new-generation TAVI device: annular level (A); 4 mm above the aortic annulus (B); 8 mm above the aortic annulus (C); 12 mm above the aortic annulus (D).

in contemporary practice and proposed both the dimension of the aortic annulus and the ICD, considering the lower value as the reference for prosthesis size choice. Both the annulus and ICD (4 mm above the annulus) are reproducible measurements, but supra-annular tracing is prone to inter- and intraobserver differences. According to the BAVARD registry, the aortic annulus dimensions are relevant in almost 90% of cases. The ICD should be used in the remaining patients with tapered configurations. In a tapered configuration, the ICD provides a smaller dimension than the aortic annulus, and it is used for sizing in order to decrease the risk of aortic root injury generated by an aggressive oversizing. When using the annular mean perimeter-derived diameter as the reference, the average oversizing ratio was 3% to 5%, in contrast to a 1:1 ratio when utilizing the ICD.

Finally, balloon sizing may be used in borderline cases, but MDCT-based sizing remains the gold standard. Balloon sizing aims to identify the location of a balloon waist, evaluate sealing, and, in cases with a high risk of coronary obstruction, evaluate sealing and the movements of calcified nodules toward the coronary ostia. A balloon is sized according to the aortic annulus and the supra-annular dimensions and

aortography is performed during full inflation. Small sizing ratio differences exist between self-expanding, balloon-expandable, and mechanically expanded platforms, and these were also captured in the BAVARD registry.

CLINICAL OUTCOMES

Initial reports on TAVI in BAV using first-generation devices demonstrated the feasibility of the procedure but were burdened by high rates of malposition, the need for a second TAVI device, and residual paravalvular regurgitation.⁶ More contemporary reports that focused on new-generation TAVI devices shared common findings: similar clinical outcomes (particularly mortality and stroke) were observed between patients with tricuspid valves and BAVs at midterm follow-up.^{9,10} New-generation TAVI devices with repositionable and/or sealing features allow more accurate placement and less residual paravalvular regurgitation as compared to first-generation prostheses.¹¹ In a large collaborative registry, Yoon et al reported comparable cumulative all-cause mortality rates between patients with BAV stenosis and patients with tricuspid aortic valve stenosis at 2-year follow-up (17.2% vs 19.4%, respectively; $P = .28$).¹⁰

A more recent report even demonstrated similar ellipticity and prosthesis-patient mismatch in those with tricuspid aortic valve stenosis and BAV stenosis who underwent TAVI with new-generation devices. The main difference resides in the 10% rate of systematic underexpansion of TAVI devices implanted in BAVs, which may explain the higher pacemaker rates observed after TAVI in BAVs—particularly with balloon-expandable platforms, in which a 23.5% post-implantation pacemaker rate has been described.¹² Significant oversizing may prevent foreshortening of balloon-expandable devices, while also applying excessive forces on the conduction system of self-expanding platforms. These considerations highlight the need for further refinement of sizing ratios for BAVs. The BIVOLUTX registry will prospectively explore the clinical outcomes and CT findings of patients with a BAV treated with self-expanding platforms (NCT03495050).

TECHNICAL CONSIDERATIONS

An optimal angiographic working projection can be easily derived using dedicated MDCT software. The selected view should provide the following information: annular plane, coaxiality of the TAVI device, and location of heavy calcification. Predilatation is useful for complementary sizing in borderline cases, and it is also recommended prior to TAVI for BAVs. The aim is to open the aortic leaflets, which are usually heavily calcified in BAVs, to prepare for accurate device insertion and deployment. We usually choose a balloon size equal to the baseline minor diameter of the aortic annulus, as measured by MDCT.

In regard to the landing zone, there has been a passionate debate on the optimal implant depth. In contemporary practice, a higher implantation plane is targeted for BAVs than for tricuspid valves to provide better anchoring and sealing, but devices should still be deployed across the aortic annulus. In the BAVARD registry, the average implant depth was 3 mm for all TAVI devices. Landing the device across the aortic annulus also allows for possible additional postdilatation to ensure adequate circularity (theoretically associated with improved leaflet function—a potential surrogate for durability) (Figure 3). A view orthogonal to valve deployment should be systematically

obtained to identify stent frame underexpansion. If postdilatation is undertaken, then balloon size should match the minor axis of the aortic annulus and, if needed, be equal to the mean perimeter-derived diameter of the aortic annulus. Finally, the motion of the calcified nodules should be monitored carefully during balloon inflation to prevent injury to the sinuses of Valsalva.

CONCLUSION

BAVs are one of the last frontiers of TAVI. Knowledge of this disease has to be improved, with specific reference to optimal sizing methodology, deployment techniques, and long-term outcomes. ■

1. Gilard M, Eltchaninoff H, Donzeau-Gouge P, et al. Late outcomes of transcatheter aortic valve replacement in high-risk patients: the FRANCE-2 registry. *J Am Coll Cardiol*. 2016;68:1637–1647.
2. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2016;374:1609–1620.
3. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients [published online March 17, 2019]. *N Engl J Med*.
4. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients [published online March 17, 2019]. *N Engl J Med*.
5. Siu SC, Silversides CK. Bicuspid aortic valve disease. *J Am Coll Cardiol*. 2010;55:2789–2800.
6. Mylotte D, Lefevre T, Søndergaard L, et al. Transcatheter aortic valve replacement in bicuspid aortic valve disease. *J Am Coll Cardiol*. 2014;64:2330–2339.
7. Sievers HH, Schmidtke C. A classification system for the bicuspid aortic valve from 304 surgical specimens. *J Thorac Cardiovasc Surg*. 2007;133:1226–1233.
8. Jilaihawi H, Chen M, Webb J, et al. A bicuspid aortic valve imaging classification for the TAVR era. *JACC Cardiovasc Imaging*. 2016;9:1145–1158.
9. Tchétché D, de Biase C, van Gils L, et al. Bicuspid aortic valve anatomy and relationship with devices: the BAVARD multicenter registry. *Circ Cardiovasc Interv*. 2019;12:e007107.
10. Yoon SH, Bleiziffer S, De Backer O, et al. Outcomes in transcatheter aortic valve replacement for bicuspid versus tricuspid aortic valve stenosis. *J Am Coll Cardiol*. 2017;69:2579–2589.
11. Tchétché D, Van Mieghem NM. New-generation TAVI devices: description and specifications. *EuroIntervention*. 2014;10(suppl U):U90–100.
12. Perlman GY, Blanke P, Dvir D, et al. Bicuspid aortic valve stenosis: favorable early outcomes with a next-generation transcatheter heart valve in a multicenter study. *JACC Cardiovasc Interv*. 2016;9:817–824.

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