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STATE-OF-THE-ART REVIEW

Application of Balloon-Expandable Transcatheter Heart Valve in Bicuspid Aortic Valve

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ABSTRACT

Bicuspid aortic valve (BAV) remains challenging in transcatheter aortic valve replacement (TAVR) because of unfavorable anatomy. New-generation balloon-expandable valve (BEV) appears to be a valid alternative to surgery, especially in some Asian countries with a higher prevalence of BAV. This tutorial review summarizes current thinking about how to plan and implant BEV in BAVs using versatile techniques. First, the authors depict the main morphological characteristics of BAVs and their effects on the TAVR procedure. Next, the authors provide preprocedural analysis on sizing, obtaining the optimal deployment projection, and how to simplify valve-crossing. Finally, the authors provide step-by-step guidance on how to deploy the BEVs with evolved iterations in terms of specific anatomies, calcified annulus, and giant annulus. (JACC: Asia 2021;1:147–161) © 2021 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Bicuspid aortic valve (BAV) is the most common congenital cardiac disorder, with an estimated incidence of 1%-2% in the general population (1). Although surgical intervention is, for anatomical reasons, widely considered to be the first-line treatment for BAV, clinical trials have demonstrated the comparable outcomes of new-generation transcatheter heart valves (THVs) in BAV vs tricuspid aortic valve (TAV) (2). With a higher prevalence of BAV in some Asian countries, BAV accounted for 47.5% of the overall population described in the first Chinese transcatheter aortic valve replacement (TAVR) trial (3). Given that TAVR was recently recommended in a younger population and in all surgical risk categories in current guidelines, the number of eligible BAV patients may increase considerably. Since the end of 2020, the Sapien 3 valve (Edwards Lifesciences) has been available commercially in China, and a balloon-expandable valve (BEV) has become a valid alternative THV in TAVR. New-generation BEV has been studied retrospectively in BAV with a lower incidence of paravalvular leak (PVL) and permanent pacemaker implantation (PPI) when compared with self-expanding valves (SEVs) (4). In this tutorial review, we describe our current versatile techniques to plan and implant BEV in BAVs.

BAV CHARACTERISTICS IN AN ASIAN POPULATION

Sievers et al (5) provide a systematic classification of BAVs. According to the presence and number of raphes, BAVs are classified into type 0 without raphe,

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ABBREVIATIONS AND ACRONYMS

AV = aortic valve

BAV = bicuspid aortic valve

BEV = balloon-expandable valve

MDCT = multidetector computed tomography

ODP = optimal deployment projection

PVL = paravalvular leak

SEV = self-expanding valve

TAV = tricuspid aortic valve

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

type 1 with 1 raphe, and type 2 with 2 raphes. Additionally, based on the spatial position of the raphe, type-1 BAVs are divided into L-R (fusion of the left-right coronary cusps), R-N (fusion of the right-noncoronary cusps), and L-N (fusion of the left-noncoronary cusps); type-0 BAVs are divided into coronary cusp fusion and mixed cusp fusion (6). Type-1 L-R accounts for 70% BAVs in Western countries, whereas type-0 BAV is more common among Chinese patients who underwent TAVR, presenting in 50%-73% (7-9). The characteristics of the raphe are critical; a heavily calcified raphe or commissure has a hostile impact on THV expansion and orientation.

Despite no clear correlation of the BAV phenotypes with clinical outcomes, a heavily calcified raphe and extensive calcification have been associated with higher rates of aortic root injury, PVL, and mortality (4). Importantly, a 3-fold excess of leaflet calcium was shown in Chinese TAVR patients compared with Western patients in all aortic valve (AV) types (3).

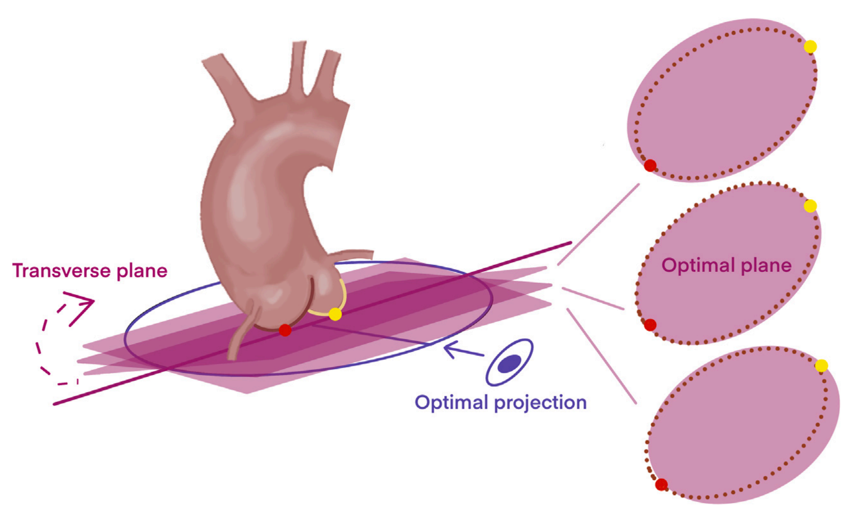
The dimensions of the AV complex are usually larger in BAV than in TAV, increasing the likelihood of sizing incompatibility and THV malposition (10). In a similar manner, BAV presenting with pure isolated aortic regurgitation—accounting for 10%-15% of BAV patients and always associated with dilated annulus (1)—has generally not been considered suitable for TAVR because of increased risk for valve embolization and PVL in the absence of calcification.

SIZING

In TAVR, "sizing" can be defined as the choice of the prosthesis within a range of available sizes to ensure that it is best accommodated into the native aortic root with minimal risk of complications. This sizing is dependent on the observation of anatomy-device interaction and represents one of the most important predictors of a successful procedure (11). As an in-depth understanding of aortic root anatomy has become pivotal over the past few decades (12), imaging techniques have garnered growing attention because they allow more precise measurements of the annulus and aortic root for a proper definition of the spatial orientation of the AV complex.

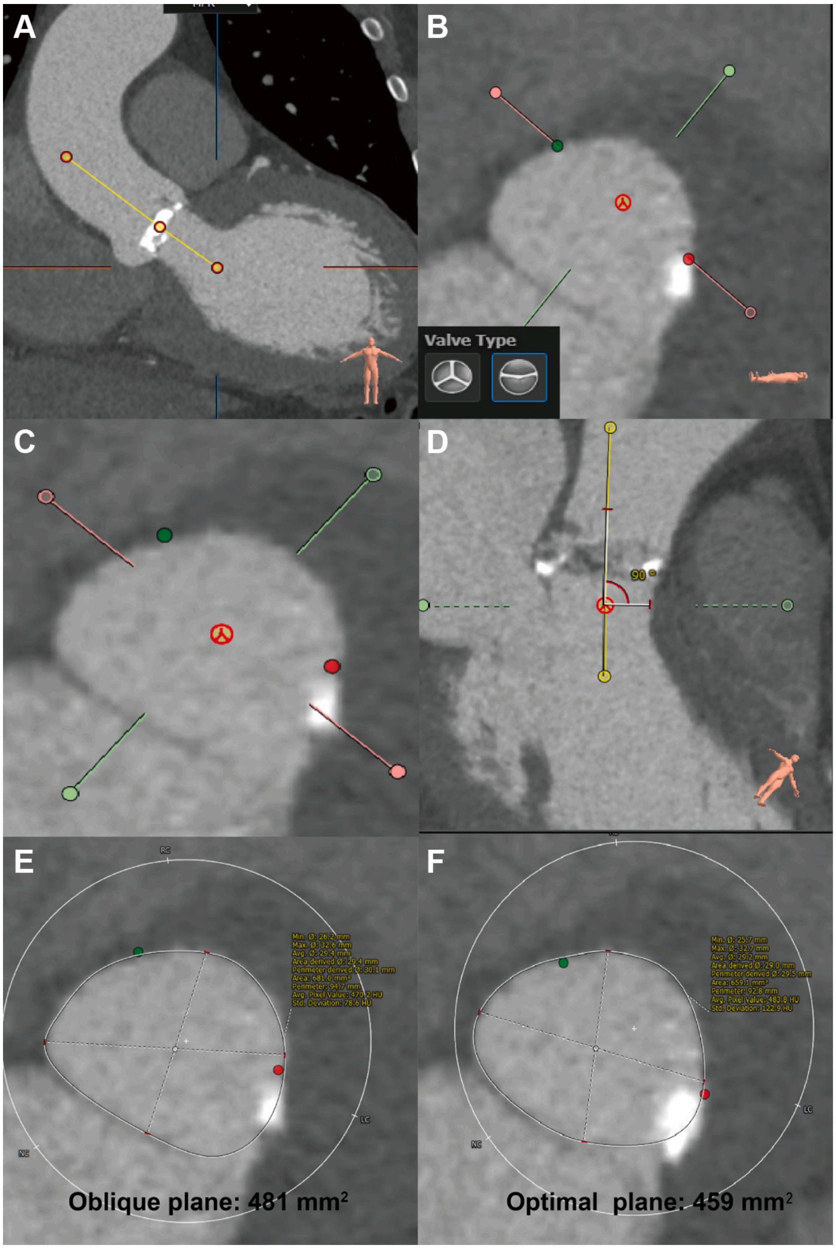
The AV annulus typically represents the tightest part of the aortic root and is defined as a virtual ring with 3 anatomical anchor points at the base of each of the attachments of the aortic leaflets. The size of a THV traditionally relied on the dimensions of the aortic annulus during systole, with the native leaflets and their hinge points providing the first resistance and anchoring force to the prosthesis (11). To date, multidetector computed tomography (MDCT) imaging plays a pivotal role to perform sizing and provides a detailed and reliable description of the aortic root anatomy.

FIGURE 1 Reconstruction Principle in Type-0 Bicuspid Aortic Valve



Schematic representation of the type-0 bicuspid aortic root. After reconstruction using 2 hinge points, a series of measurements are made through different angulations of the transverse plane. The optimal plane is defined as the plane with the smallest annulus dimension. The optimal projection is defined to obtain the farthest distance between the 2 hinge points.

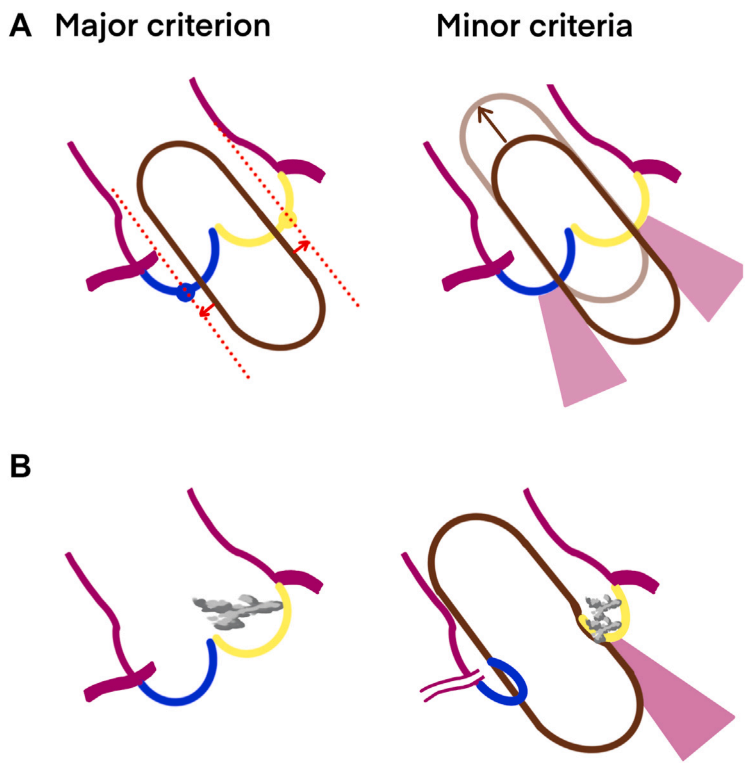
FIGURE 2 **Semiautomatic Approach to Obtain Optimal Annular Plane**



(A) Place the **yellow central line** in the aortic root manually. **(B)** Select the type-0 bicuspid aortic valve model and determine the 2 hinge points of the cups. **(C)** Rotate the **crosshairs** to obtain the shortest dimension in the transverse plane. **(D)** Centralize the **yellow line** in the sagittal plane to obtain a perpendicular plane with the shortest dimension. **(E and F)** The smallest annular area is obtained compared with the other larger oblique plane.

In BAVs, selection of the size of the THV can be challenging. The BAV annulus often has an elliptical shape and relatively larger size compared with TAV and is more like to exhibit eccentric calcification. The AV complex shape (from the annulus to the leaflet tips) could be nontubular, flared, or tapered, suggesting that the narrowest dimensions and point of highest resistance of the AV complex may be located above the annulus, at the commissural level.

FIGURE 3 **Balloon Sizing**



(A) In all aortic valve types, the anatomical relationship between the sinus hinge points and the balloon serves as the major criterion to decide the THV size, whereas contrast backflow and the movement of the balloon serve as the minor criteria. **(B)** In BAV, balloon sizing serves as a THV simulator. In cases with a heavily calcified annulus, the balloon could shift to the less-calcified side. Excessive THV shift during placement could result in coronary artery occlusion (especially in shallow sinus width and longer leaflet length), PVL, and aortic root injury.
BAV = bicuspid aortic valve; THV = transcatheter heart valve; PVL = paravalvular leak

THV underexpansion is frequently observed in BAV with an associated 11%-dimension decrease (10). This underexpansion in BAV is of utmost importance because it may potentially hamper THV durability or even promote leaflet thrombosis. Therefore, we stress the need for refined sizing policies to select the appropriate prosthesis size, and procedural technique modification to obtain the maximum expansion achievable in given bicuspid anatomy.

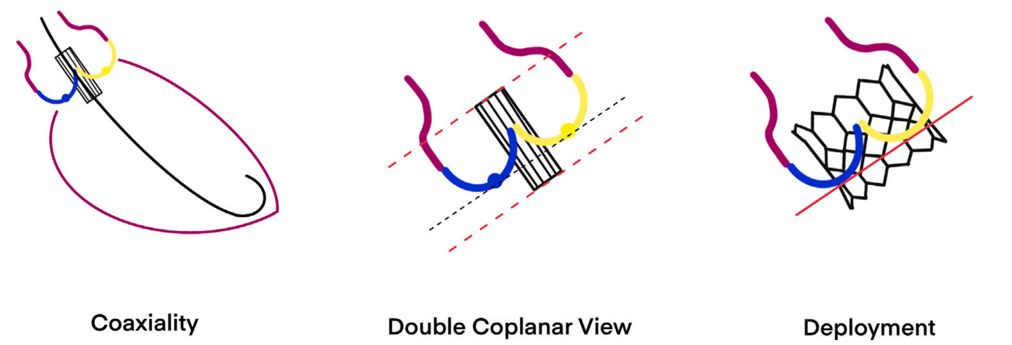
TYPE 0: RECONSTRUCTION PRINCIPLE. Reliable identification of the optimal annular plane is the key to size the annulus accurately in type-0 BAVs. Given that it is impossible to reconstruct the annular plane using only 2 anatomical hinge points, additional reconstruction criteria should be given to obtain the optimal annular plane (OAP). The overall reconstruction principle is as follows: after aligning the transverse plane with 2 hinge points, obtain the smallest annulus dimension as the optimal annular plane among the series of oblique planes. After obtaining the OAP, optimal deployment projection is determined by the farthest distance between the 2 hinge points (**Figure 1**).

Operators may choose manual measurement to reconstruct the OAP accurately in type-0 BAV using multiplanar reconstruction software, as we described previously (13). Additionally, we describe a simplified technique to obtain an approximate OAP in 3mensio Valves version 10.1 (Pie Medical Imaging) (**Figure 2**).

Manual MDCT sizing:

1. Align the coronal and sagittal planes with the aortic root.
2. Identify 1 of the hinge points and position the crosshairs.
3. Tilt the sagittal plane line to locate and intersect the second hinge point.
4. Tilt the transverse plane around the hinge point line to identify the smallest annulus dimensions.

FIGURE 4 **"Double Coplanar View" in Type-0 BAV**



Schematic illustration of the "Double coplanar view" with the alignment of both the native valve and the prosthetic valve. Coaxiality of BEV with the left ventricular outflow tract, annulus, and aortic root should be obtained when the guidewire is placed in the apex (right anterior oblique 30° view). The parallax of the inflow end and the outflow end should be eliminated **(red lines)**. BAV = bicuspid aortic valve; BEV = balloon-expandable valve.

Semiautomatic sizing in 3mensio Valves (based on centerline):

1. Aligning the axis with the aortic root manually.
2. Choose the type-0 BAV measurement option.
3. Identify the hinge point of the 2 cusps.
4. Rotate the transverse plane crosshairs to identify the smallest dimension (usually perpendicular with 2 hinge points).
5. Aligning the axis again in the smallest dimension.
6. Get the approximate optimal plane

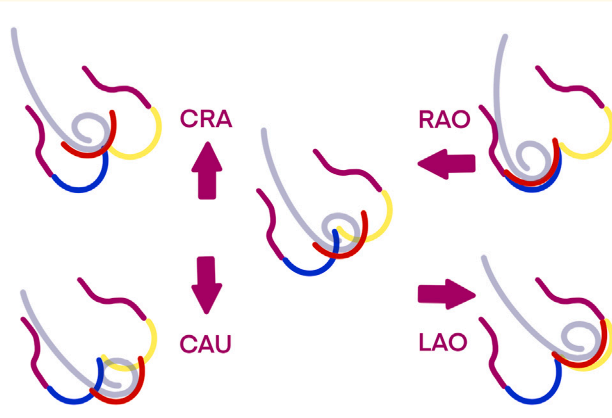
TYPE 1: RECONSTRUCTION PRINCIPLE. The type-1 BAV annulus can be reconstructed as with TAV using 3 anatomical cusps. However, the type-1 BAV complex could be tapered by presenting with 1 heavily calcified raphe. In this nontubular BAV complex shape, supra-annular sizing 4 mm above the annular plane has been suggested, considering the narrowest dimensions and highest resistance of the BAV complex at the commissural level. Despite frequent prosthesis underexpansion observed in BAV, annular-based sizing remains accurate in BAV with minimal oversizing (10,14). Additionally, MDCT measurements cannot reflect the mechanical characteristics of the AV complex; in particular, it cannot reveal whether the supra-annular structure can be opened to the same size as the annulus. These shortcomings led us to develop an intraprocedural balloon sizing in BAV.

INTRAPROCEDURAL BALLOON SIZING. Balloon sizing plays an indispensable role given the difficulty in the reconstruction of type-0 BAV and tapered or flared complex shape of type-1 BAV. One major criterion and 2 minor criteria could be used to select the subsequent THV size as follows (15):

- Major: the anatomical relationship between the sinus hinge points and the balloon.
- Minor: contrast backflow and the movement of the balloon.

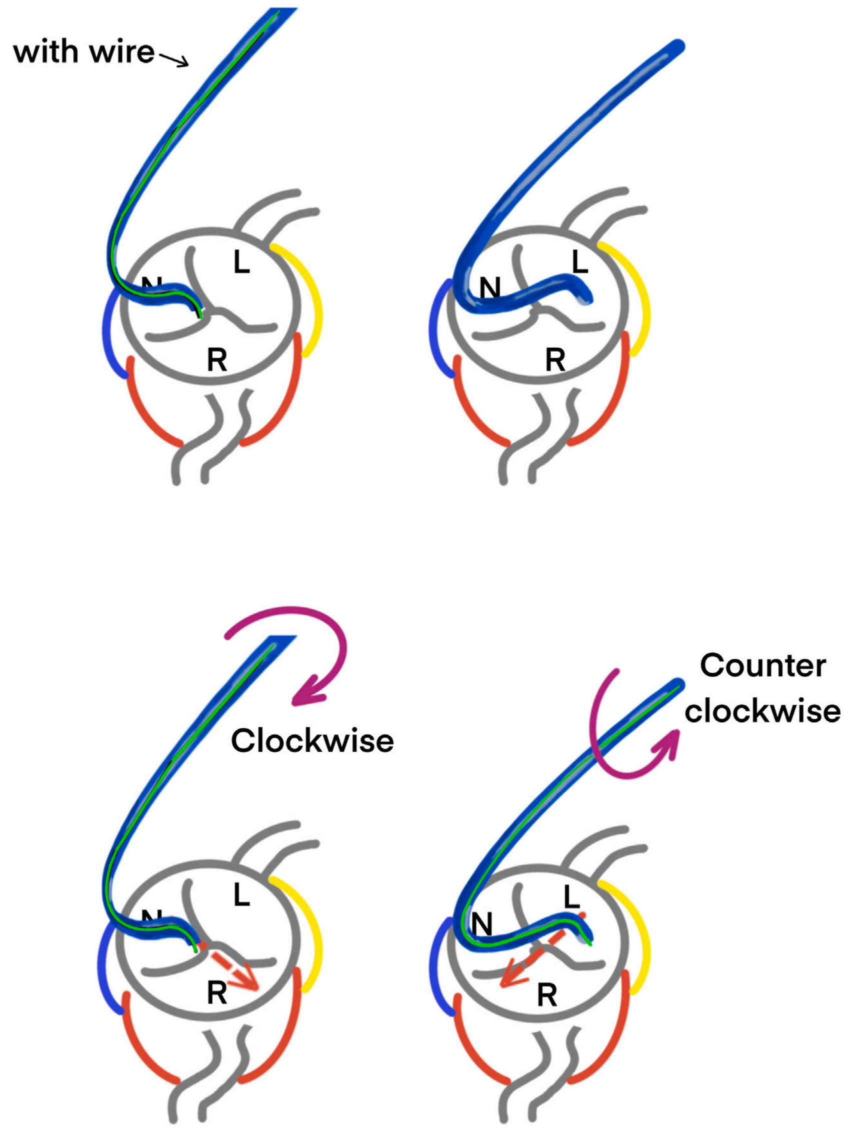
In BAV, balloon sizing gives additional information about the impact of the raphe with severe and asymmetric calcification. In the case of asymmetric calcification, the valve deploys asymmetrically, often being pushed to the side with less calcification. Balloon sizing, a simulated deployment, can predict the risk of coronary artery occlusion, PVL,

FIGURE 5 **"Follow the Right Cusp Rule"**



Schematic illustration of the "follow the right cusp" to optimize the ODP in type-1 BAV. C-arm rotation direction is consistent with the position of the RCC based on the other hinge points **(purple arrows)**. CAU = caudal; CRA = cranial; L = left coronary cusp; LAO = left anterior oblique; N = noncoronary cusp; R = right coronary cusp; RAO = right anterior oblique.

FIGURE 6 Valve-Crossing Basic Technique



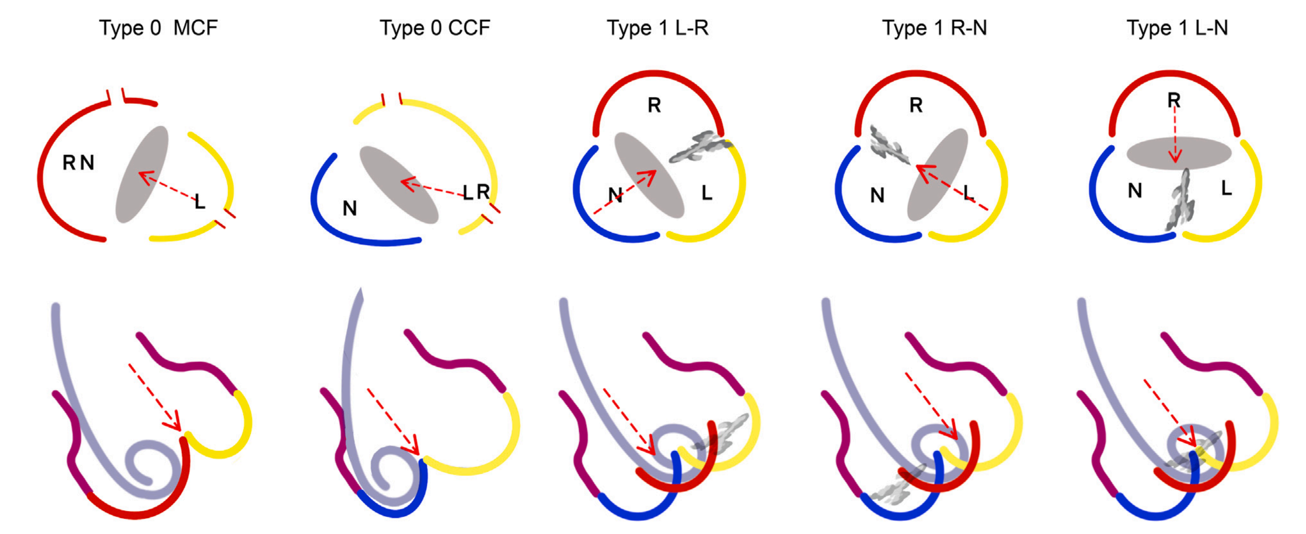
(Top) Schematic illustration of the valve crossing starting cusp. AL-1 with wire starts in the NCC, whereas AL-1 without wire starts in the LCC. **(Bottom)** Schematic illustration of the rotation course. Clockwise rotation of AL-1 goes from NCC to LCC/RCC, whereas counterclockwise rotation of AL-1 goes from LCC to NCC/RCC. AL-1 = Amplatz 1; LCC = left coronary cusp; NCC = noncoronary cusp; RCC = right coronary cusp; other abbreviations as in Figure 5.

asymmetric valve deployment, and annular rupture (Figure 3).

OPTIMAL DEPLOYMENT PROJECTION

Despite the "cusp-overlap" view recently becoming the preferred optimal deployment projection (ODP) for SEVs, the standard 3-cusp view is still considered the gold standard deployment projection for BEVs. Due to abnormal geometrical conformation and unequal-sized leaflets, alignment of the cusp in BAV can be difficult. The predicted angiographic projection angles, by bringing the 2 or 3 hinge points (Type-0 or -1 BAV) in 1 plane, may be inaccurate. Therefore, additional fluoroscopic tools could optimize the computed tomography (CT)-predicted ODP.

FIGURE 7 Valve-Crossing Course and Prediction Point



(Top) Schematic illustration of the valve crossing course **(red arrows)** in type-0 and -1 BAVs. **(Bottom)** Schematic illustration of the predicted crossing point **(red arrows)** with maximum likelihood. BAV = bicuspid aortic valve; CCF = coronary cusp fusion; LR = left-right coronary fused cusp; MCF = mixed cusp fusion; RN = right-noncoronary fused cusp; other abbreviations as in Figure 5.

TYPE-0 BAV: "DOUBLE COPLANAR VIEW". It should be noted that coplanar view alignment is not possible in "purely" BAV with only 2 anatomical cusps. In this case, a "Double coplanar view" alignment of both the native valve and the prosthetic valve could serve as the ODP. Precisely, after the nadirs of the 2 cusps are aligned, the BEV stent frame should be also coaxially aligned with the inflow end and the outflow end without the parallax of the BEV frame. Additionally, coaxiality of the BEV with the left ventricular outflow tract, annulus, and aortic root must be maintained via an apex-positioned stiff wire (Figure 4).

TYPE-1 BAV: "FOLLOW THE RIGHT CUSP RULE". In type-1 BAVs, "Follow the right cusp rule" could serve as a fine adjustment of CT-predicted ODP. Place an angled pigtail catheter in the right coronary cusp (RCC) and align it in 1 line between the left coronary cusp (LCC) and noncoronary cusp (NCC) (Figure 5) (16).

CROSSING TECHNIQUE

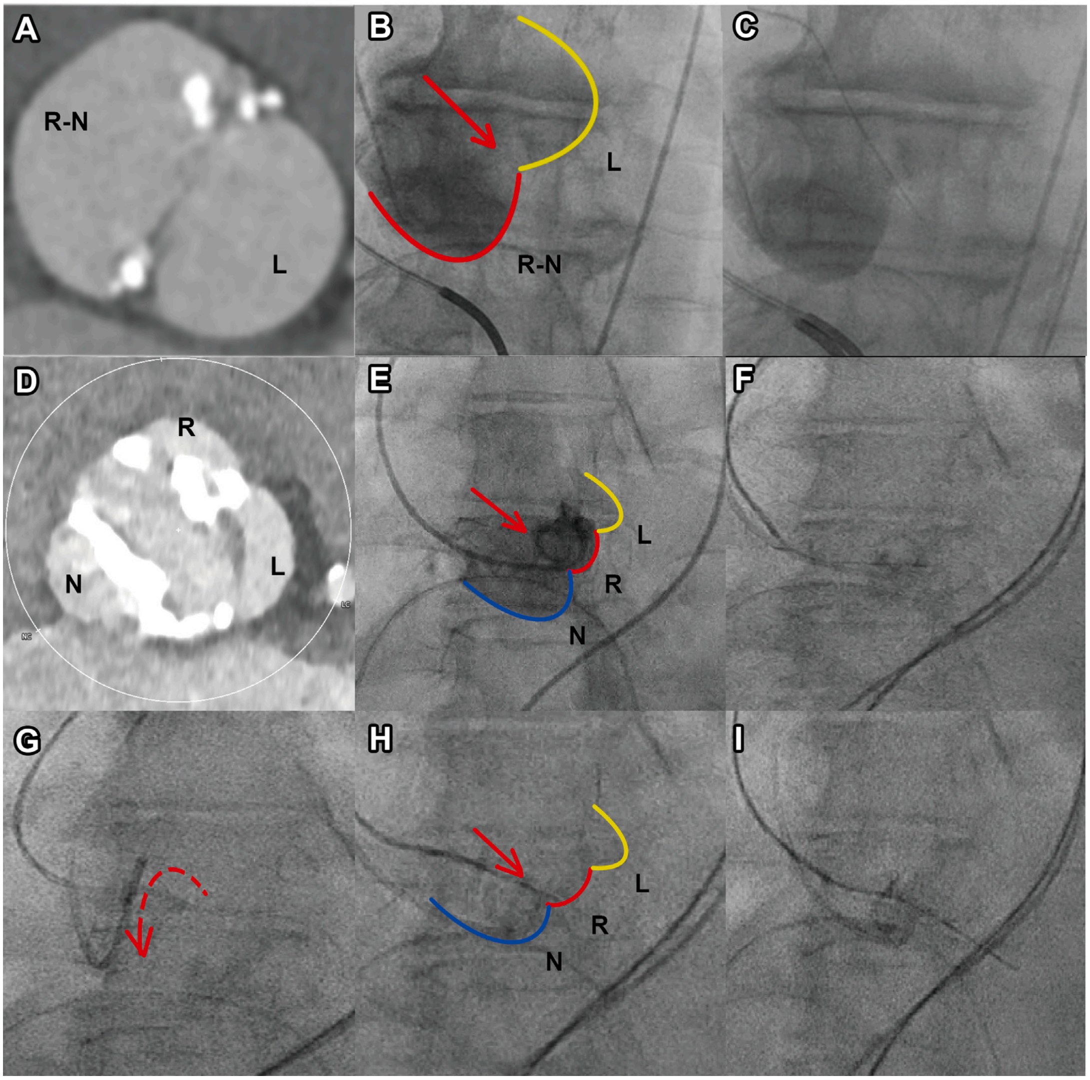
BASIC TECHNIQUE IN TAV. Starting from the ODP based on the "right cusp rule," the Amplatz 1 (AL-1) catheter with a normal, straight 0.035-inch wire inside usually points toward the anatomically posteriorly located NCC. From here, rotate the AL-1 catheter clockwise slowly to move the straight wire in small steps toward the valve opening, and observe to which cusp the wire jumps. If toward the RCC, the commissure and the predicted valve opening will be in the middle between the hinge points of LCC and RCC. If toward the LCC, the predicted valve opening will be in the middle between the hinge points of NCC and LCC. Repeat these steps until the wire crosses the AV and drops into the left ventricle (16-19). Alternatively, you can start from the LCC and rotate the AL-1 counterclockwise.

Anatomy-based alternatives can be selected as follows (Figure 6):

1. Starting cusp: the AL-1 with a straight wire goes toward the outer curve of the aorta to the NCC side, whereas when pulling the wire back, the AL-1 goes to the LCC side.
2. Rotation course: clockwise rotation of AL-1 goes from NCC to LCC/RCC side and counterclockwise rotation goes from LCC to NCC/RCC
3. Alternative materials: Amplatz 2 (AL-2), right Judkins (JR-4), Pigtail, and Glidewire.

In BAV, the eccentric AV leaflets and calcified raphes can make these steps more challenging and time-consuming. Predefining the AV anatomy on the pre-TAVR CT and the predicted valve opening under fluoroscopy could be more efficient (Figures 7 and 8) (20).

FIGURE 8 Anatomy-Base Prediction for Valve-Crossing Point



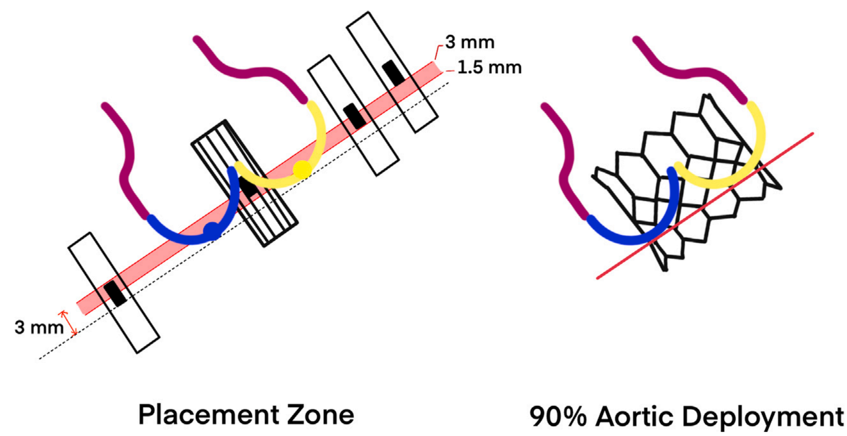
Type 0 CCF **(A to C)** and type-1 L-R **(D to I)** are illustrated separately. **(A)** Fused right and noncoronary cusp was determined in pre-TAVR CT. **(B)** The pigtail was placed in the fused cusp and the predicted crossing point was on the right side of the pigtail. **(C)** The straight wire went across the valve at the predicted point. **(D)** A raphe between RCC and NCC was determined in pre-TAVR CT. **(E)** The pigtail was placed in the RCC and the prediction point was on the right side of the pigtail. **(F)** Tried to cross the valve at the predicted crossing point. **(G)** Pigtail jumped out of the small RCC. **(H)** The pigtail was placed in NCC with stableness and the predicted point changed to the right side of the pigtail. **(I)** The straight wire crossed the valve at the predicted point. BAV = bicuspid aortic valve; RN = right-noncoronary fused cusp; TAVR = transcatheter aortic valve replacement; other abbreviations as in Figures 5 to 7.

PREDICTING THE CROSSING POINT IN TYPE-0 BAV. Usually, it is better to start at the LCC side and rotate counterclockwise or pull back the AL-1 in small steps. The tip of the AL-1 can be more easily placed toward the LCC when the wire is pulled back and the AL-1 is not straightened. It is also helpful to observe the location of the transvalvular jet. The crossing point is in the middle of the hinge points of the 2 cusps.

PREDICTING THE CROSSING POINT IN TYPE-1 BAV. Start with the AL-1 in the predefined single cusp based on the CT and rotate toward the fused cusp:

1. L-R: start NCC and rotate clockwise; the crossing point is in the middle of NCC and RCC.
2. R-N: start LCC and rotate counterclockwise; the crossing point is in the middle of LCC and RCC.

FIGURE 9 High Deployment



Schematic illustration of high deployment in BAV. A "high," 90% aortic deployment can be achieved by placing the middle marker of the deployment balloon slightly (one-half to 1 length of the 3-mm long marker) above the annulus. BAV = bicuspid aortic valve.

3. L-N: start RCC and rotate counterclockwise; the crossing point is in the middle of the annulus.

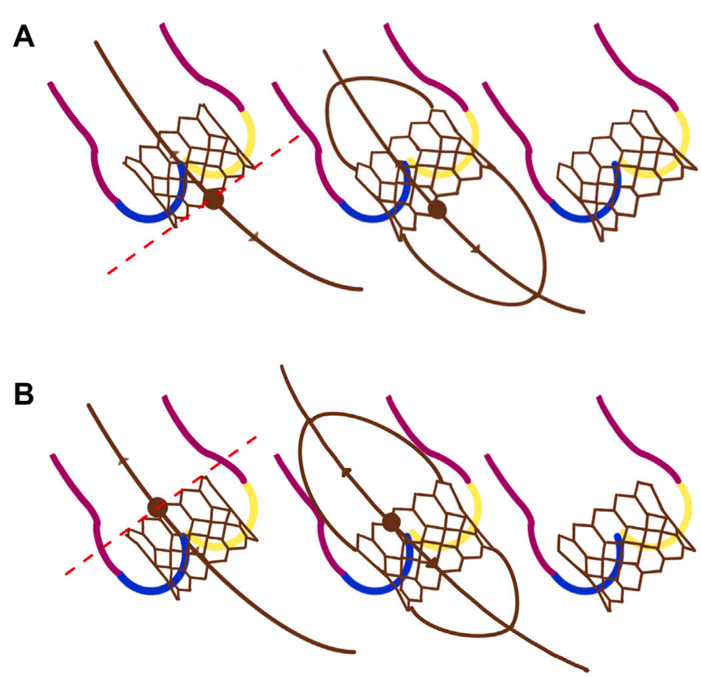
HEAVY CALCIFICATION

The calcification is usually heavier in BAV than TAV, with more eccentricity and asymmetry. The presence of a calcified raphe and asymmetrical morphology of the AV complex might hamper the optimal expansion of the THV stent frame. The raphe, located between the RCC and LCC, may induce conduction disturbances given an increasing contralateral compression force toward the NCC. Additionally, a higher incidence of aortic rupture in BEV than SEV remains a concern. Several techniques could be used to minimize the risk of PVL, aortic rupture, and PPI in heavily calcified BAV.

BALLOON SIZING. Intraprocedural balloon sizing plays a crucial role in heavily calcified BAV. As discussed earlier, the balloon shifts to the "weaker side" and predicts how the THV deployment will occur, indicating the risk of annular rupture. Therefore, we recommend intraprocedural balloon sizing in every BAV case, especially in heavily calcified BAVs, for sizing "simulated deployment" and mechanical opening with unhampered THV deployment afterwards.

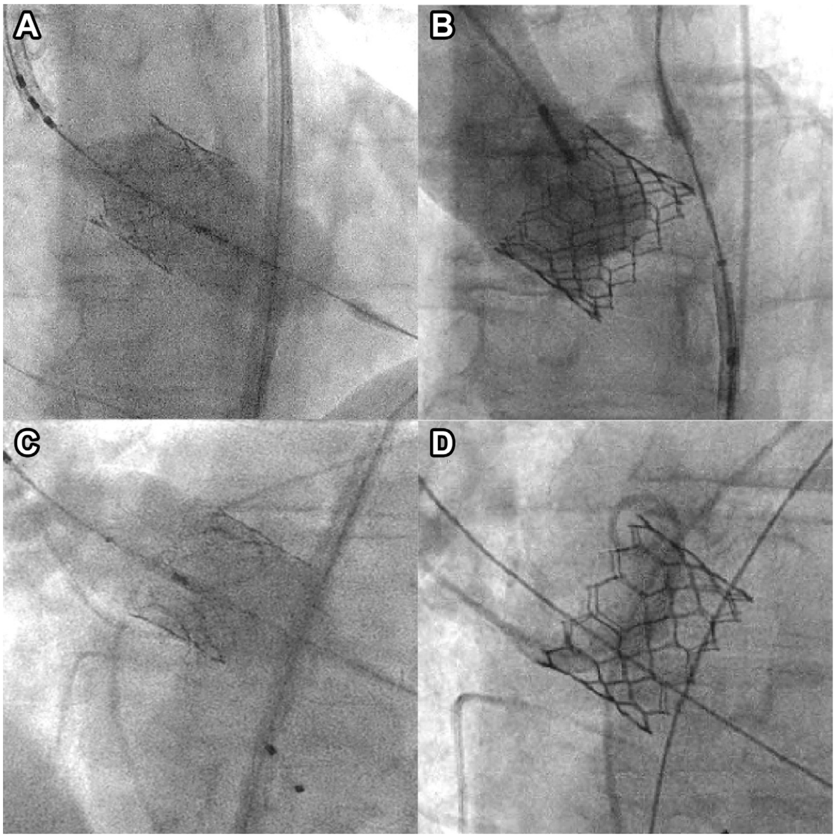
In terms of balloon size, the overall principle is using the same size of the smaller THV of choice. For example, if the annular dimension is 23.5 mm, a possible THV could be the 23-mm Sapien 3 THV or 26-mm Sapien 3 THV. The smaller THV of choice would

FIGURE 10 "Flare the Inflow" and "Flare the Outflow" Techniques



(A) Schematic illustration of the "flare the inflow" technique: place the middle marker and open the deployment balloon toward the ventricular end of the BEV frame **(red line)**. A better sealing of the BEV skirt prevents PVL without increasing the risk of annular rupture. **(B)** Schematic illustration of the "flare the outflow" technique by aligning the middle marker of the deployment balloon at the height of BEV outflow **(red line).** A better anchoring of the valve to avoid migration/embolization can be achieved. BAV = bicuspid aortic valve; BEV = balloon expandable valve; PVL = paravalvular leak; THV = transcatheter heart valve.

FIGURE 11 **"Flare the Inflow" and "Flare the Outflow" Techniques: Angiographic Examples**



Examples of "flare the inflow" **(A)** and "flare the outflow" techniques **(B).**

be 23 mm; accordingly, a 23-mm balloon should be used for balloon sizing, which "simulates an implantation of a 23 mm Sapien 3." Notably, the size of balloon should be smaller than the average diameter of the annulus. Edwards balloons with nominal volume filling are recommended because of their precise and consistent dimensions.

PLACEMENT HEIGHT. In BAV, an implantation height of 90% aortic is preferred. This strategy reduces the risk of valve migration toward the ventricle, the overhang of usually long native leaflets into the valve, and PPI. Also, the results regarding PVL are often superior, and the direct pressure on the annulus is potentially less. To achieve the high position, the middle marker of the deployment balloon should be placed slightly (one-half to 1 length of the 3-mm marker) above a line in between the 2 or 3 hinge points of the cusps. The final implantation height also depends on the predicted deployment and foreshortening of the BEV frame (Figure 9).

The Sapien 3 frame consists of 5 rungs and 12 cells, where the upper cells are larger contributing to different foreshortening in the inflow and outflow portion of the frame. Given that intentional underexpansion or overexpansion of Sapien 3 will result in different foreshortening of the inflow portion, adjusting the placement height slightly higher or lower immediately before deployment assists in achieving the optimal implant depth and reduces the incidence of PPI (21,22).

STEPWISE DEPLOYMENT. **"Underfilling trial".** Aortic injury or rupture is an uncommon but devastating complication in TAVR. Depending on anatomical factors (CT and balloon sizing), for the treatment of severe calcified valves we would recommend to start with less volume in the deployment balloon. An "underfilling trial" strategy could be taken as follows: 1) intentional underexpansion of Sapien 3 (eg, underfilling 2 mL) during deployment in a severely calcified BAV; and 2) decision on whether it requires a postdilatation with nominal filling volume based on the residual space in the annulus and the possibility of optimizing the BEV frame (23,24).

The amount of underfilling depends on the selected Sapien 3 valve size. A good concept in our opinion would be: Sapien 3 20 mm: start with 1 mL less; Sapien 3 23 mm: start with 1-2 mm less; and Sapien 3 26 and 29 mm: 1-3 mm less.

"Flare the inflow". The "Flare the inflow" technique could enhance the "outer skirt" of Sapien 3 to prevent PVL. The postdilatation emphasized on the inflow end of THV could also enhance structural performance maintaining circularity without applying additional pressure on the calcified annulus. Specifically, for postdilatation, place the deployment balloon toward the inflow with the middle marker placed at the ventricular end of the THV frame; the flared inflow THV frame could enhance the "outer skirt" sealing (**Figures 10A and 11**).

It should be noted that these techniques provide a structured approach to achieve optimal results in difficult anatomy. Hereby, we provide examples with different outcomes of balloon sizing (annular dimension in the "gray zone") to demonstrate our stepwise deployment in heavily calcified BAVs (**Figure 12**).

For an experienced team, a "single rapid-pacing strategy" could achieve similar results. For example, for a heavily calcified BAV, with an annulus-measurement of mean 27 mm, we would prepare a 29-mm Sapien 3 with nominal volume (33 mL). The deployment would be done stepwise during 1 rapid pacing run. The first operator observes the valve deployment under fluoroscopy and the second operator, while inflating the balloon, stops at –2 mL and gives additional volume (–1 mL or nominal volume) under guidance of the first operator. The decision of how much volume is added depends on the operator's understanding of the relationship between the THV and annulus. If the THV cannot deploy toward the calcified raphe and shifts toward the opposite side, there is a risk of annular injury, especially once it touches the hinge point of the cusp, and inflation should be stopped immediately. In addition, the deployment volume depends on the resistance that the second operator feels in the syringe while inflating the balloon. A good communication between the first and second operator is essential to successfully using this strategy (Video 1).

FIGURE 12 Workflow in Heavily Calcified BAVs

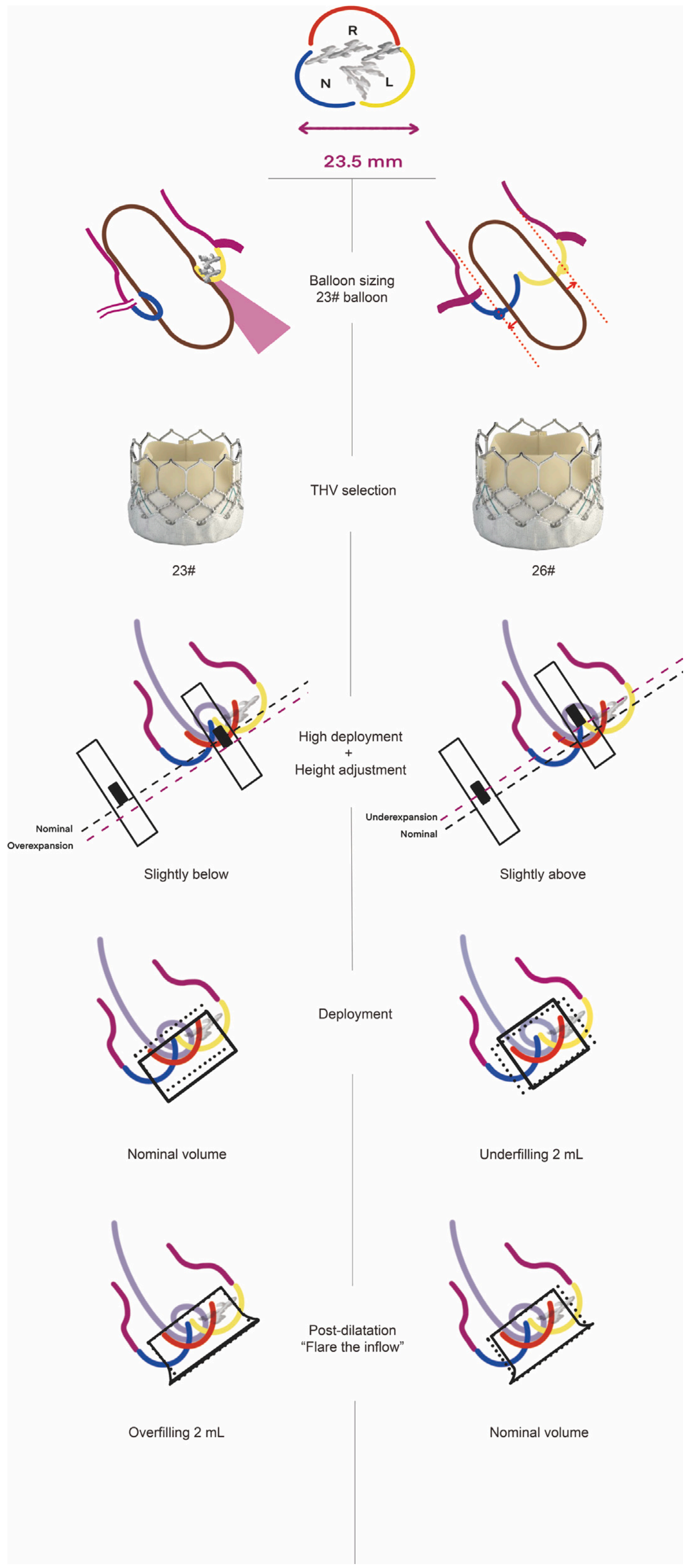


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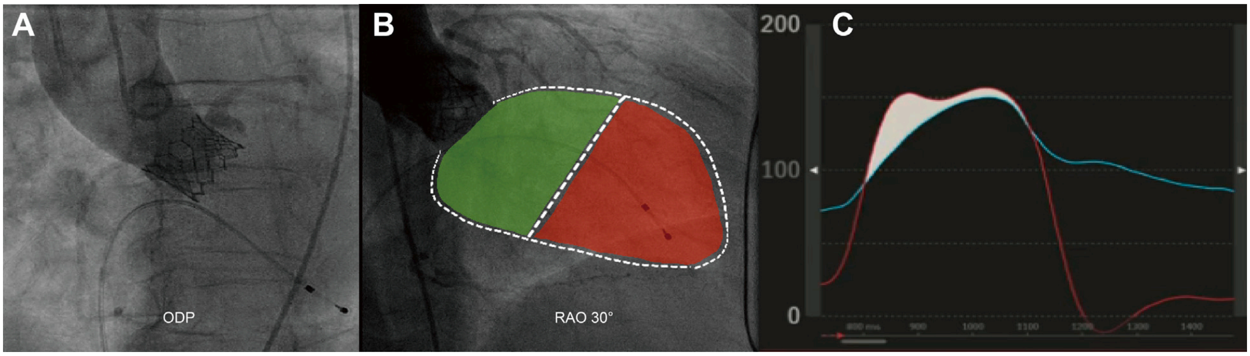
FIGURE 13 Fluoroscopy-Guided Evaluation



(A) Coaxial assessment of placement and relevant PVL in ODP. **(B)** PVL assessment RAO 30° in case of relevant PVL. The density of contrast in the **red zone** shows a more than mild insufficiency; the contrast in the **green zone** shows trivial or mild insufficiency. **(C)** Gradient assessment by pull back pigtail technique.

GIANT ANNULUS

The dimensions of all components of the AV complex are often larger in BAV than in TAV, increasing the likelihood of having an annulus size outside of the covering range of commercial THVs. We previously described the concept of overexpanding and overfilling the Sapien 3 THV to safely accommodate annulus sizes substantially larger than the commercially recommended range (21). Although Sapien 3 was originally not designed for overexpansion, the new frame geometry with a higher frame height and longer leaflets allows the Sapien 3 to be overexpanded to accommodate larger annulus sizes without causing significant central aortic insufficiency. Specifically, we recommended overfilling 2-4 mL to nominal volume 33 mL of the 29-mm Sapien 3 to treat giant annulus of 31-mm mean diameter (area 740 mm^2) and above. Given that the burst pressure of the deployment balloon is limited, more than 4 mL of additional volume should be used with caution.

The giant annulus might increase the risk of THV malposition and migration. The "Flare the outflow" technique may secure valve anchoring, obtain proper sealing, and prevent THV migration. We recommend postdilation by positioning the deployment balloon toward the outflow with the middle marker placed at the aortic end of the THV frame. The flared outflow end of the THV frame could ensure the anchoring of the valve (**Figures 10B and 11**).

FIGURE 12 Continued

Schematic illustration of workflow in heavily calcified BAVs in the "gray zone" annular dimension of 23.5 mm. With different strategies after balloon sizing, smaller (23 mm) THV or bigger THV (26 mm) could be chosen. **(Left)** A 23-mm Sapien 3 is deployed with intentional overexpansion. Place the marker of deployment balloon directly on top of the annulus line **(red line)** and deploy the BEV with nominal filling volume. In case of PVL, "flare the inflow" with additional 2 mL for postdilatation to achieve overexpansion without giving additional pressure on the annulus. **(Right)** A 26-mm Sapien 3 is deployed with intentional underexpansion. Place the marker of deployment balloon 3 mm above the annulus line **(red line)**. Intentional underfilling of the deployment-balloon with 2 mL less than nominal volume. Post-dilate—"flare the inflow"—with nominal volume to prevent PVL without giving additional pressure on the annulus. In contrast, a **dashed black rectangle** shows the standard deployment and standard post-dilatation.
BAV = bicuspid aortic valve; PVL = paravalvular leak.

FLUOROSCOPY-GUIDED IMPLANTATION AND EVALUATION

As minimalistic TAVR under fluoroscopic-guidance is accepted in most leading centers, TAVR can be done safely and effectively under conscious sedation without using intraprocedural transesophageal echocardiography (25).

After BEV deployment in the ODP, for assessment of the THV position and relation to the coronary ostia, a root angiogram (10 mL of contrast with a flow of 10 mL/s) is performed.

The angiographic assessment of the functional result is done in an adjusted ODP, where the parallax of BEV frame is eliminated. After removal of the guidewire, we give 20 mL of contrast with a flow of 15 mL/s over a pigtail, which is placed 1 cm above the

CENTRAL ILLUSTRATION Algorithm for Balloon-Expandable Valve in BAV

BAVs
Heavily Calcified
Large Annulus

↓

Balloon Sizing
Size = Possible Smaller THV
Size < Annular Diameter

↓

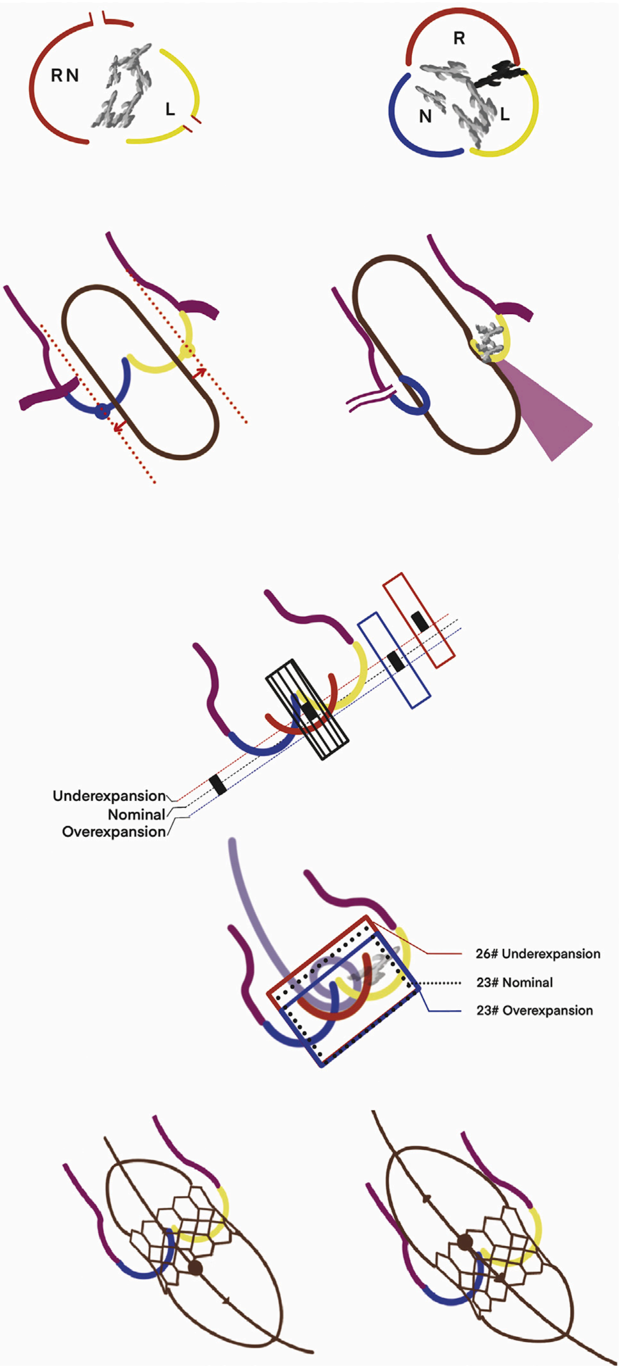
Placement
High Placement:
1/2 Marker Above
Height Adjustment:
Overexpansion - Annulus
Underexpansion - 1 Marker Above

↓

Deployment
Overexpansion - Smaller THV
Underexpansion - Bigger THV

↓

Post-Dilatation
Flare the Inflow: Avoid PVL
Flare the Outflow: Avoid Embolism



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Schematic guidance of the implantation of balloon-expandable valve in bicuspid aortic valve (BAV): computed tomography-based anatomy understanding, balloon sizing, placement height choice, deployment strategy, and postdilatation. PVL = paravalvular leak; THV = transcatheter heart valve.

BEV. Only in the case of more than trace PVL do we perform a second injection (30 mL of contrast with a flow of 20 mL/s.) in a right anterior oblique 30° view in a previously described technique to understand if the PVL is more than mild. If the density of contrast reaches the lower part of the left ventricle and the density is the same as in the aortic root, more than mild PVL is likely. TTE can be used for further assessment (19). In addition, in every case we measure a pull back gradient. (**Figure 13**). In cases with more than mild PVL, the mechanism of the insufficiency and treatment—postdilatation with additional volume or the "flare the inflow" technique—has to be discussed.

POSTPROCEDURAL TREATMENT

In practical guidelines, for patients with a bioprosthetic TAVR, aspirin 75 to 100 mg daily is reasonable in the absence of other indications for oral anticoagulants, and 3-6 months of added clopidogrel 75 mg may be reasonable. In the POPular (antiPlatelet therapy fOr Patients undergoing Transcatheter Aortic Valve Implantation) trial, aspirin alone was associated with less incidence of bleeding and the composite of bleeding or thromboembolic events than aspirin and clopidogrel. Compared with TAV, a higher incidence of thrombosis was observed in patients receiving a BEV for treatment of BAV stenosis (J. Michel, unpublished data, May 2021). After bicuspid TAVR, 3-month anticoagulation, followed by a lifelong aspirin 100 mg, should be discussed in younger patients without contraindication and low bleeding risk. Compared to the other regions of the world, a higher risk of bleeding was observed in East Asians. It is hard to draw a generalized anticoagulation strategy in Asian BAV, and special evaluation to stratify the bleeding risk is mandatory.

FUTURE DIRECTIONS

The **Central Illustration** summarizes the algorithm for BEV in BAV. TAVR is now the gold standard for patients at high or intermediate risk. However, BAV is still deemed as favorable anatomy for surgery because BAV was excluded from previous landmark randomized controlled trials. Recently, a large observational study from the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) registry compared 5,412 BAV patients to 165,547 TAV patients, which showed slightly lower procedural success (96.0% vs 96.7%; $P = 0.004$) and higher incidence of equal or greater than moderate PVL (4.7% vs 3.5%; $P < 0.001$) in BAV patients (26). Evidence from randomized controlled trials on TAVR in BAV patients are still scarce, especially in an Asian population. With additional safe and efficient techniques and new-generation THVs, comparable outcomes of BAV vs TAV with BEV are eagerly to be defined in large multicentric prospective cohorts.

HIGHLIGHTS

- There is growing concern to treat BAV patients in TAVR procedures.
- Versatile BEV shows high performance in all types of BAV.
- Anatomy-based analysis and procedural iteration enable BEV's feasibility and safety in BAV.
- Tailored THV and techniques might achieve a comparable result when compared with TAV.

CONCLUSIONS

BAV continues to be one of the major challenges for TAVR, especially in some Asian countries with a higher prevalence. New-generation BEV has been studied retrospectively in BAV with higher performance. Versatile techniques applied to BEV could treat anomaly, heavily calcified, larger annular BAVs safely, which were considered ineligible in TAVR because of high risk of PVL, coronary artery obstruction, PPI, and aortic rupture. Using a combination of the versatile techniques for BEV implantation, comparable results could be achieved in BAV compared with TAV.

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KEY WORDS aortic stenosis, balloon-expandable valve, bicuspid aortic valve, transcatheter aortic valve replacement, transcatheter heart valve

APPENDIX For a supplemental video, please see the online version of this paper.