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Proper Sizing Takes into Consideration of Annular and Supra-annular Planes and Calcium Distribution Can Improve Outcomes of TAVR with Both BEV and SEV



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Disclosure

• Proctor of Edwards, Medtronic, Boston Scientific, and Abbot





Outcomes After TAVR in Bicuspid Versus Tricuspid Anatomy

Between January 1, 2000, and April 1, 2020, 17 studies and 181,433 patients undergoing TAVR were included, of whom 6,669 (3.6%) had BAV were studied.

Montalto et al. J Am Coll Cardiol Intv 2021;14:2144–2155



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Both SEV and BEV work in TAVR for BAS, but.....

ORIGINAL ARTICLE

Balloon Versus Self-Expandable Valve for the Treatment of Bicuspid Aortic Valve Stenosis Insights From the BEAT International Collaborative Registry

- Balloon-expandable valves have higher gradients when used in bicuspid anatomies and a trend toward a higher rate of annular ruptures.
- Self-expandable valves have higher rate of residual moderate-to-severe perivalvular regurgitation.

Mangieri et al. Circ Cardiovasc Interv. 2020;13:e008714. DOI: 10.1161/CIRCINTERVENTIONS.119.008714





Bicuspid Aortic Valve Anatomy and Relationship with Devices (BAVARD method) New players for size and position in Bicuspid

ICD @ 4mm above annulus is the major (longest) axis

- Annulus/orifice
- Intercommissural diameter
- Bicuspid shape





Calcified raphe and excess leaflet calcification were associated with increased risk of complications & mortality

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Bicuspid Aortic Valve Morphology and Outcomes After Transcatheter Aortic Valve Replacement

Contemporary devices were implanted:

- Sapien 3 [Edwards Lifesciences],
- Evolut R/Evolut R Pro [Medtronic],
- Acurate [Boston Scientific],
- Lotus/Edge [Boston Scientific], or
- Portico [Abbott Structural Heart]

Calcification matters !!

CENTRAL ILLUSTRATION Death From Any Cause According to Morphological Features Death From Any Cause, According to Morphogical Features No Calcified Raphe or **Calcified Raphe or Calcified Raphe Plus Excess Leaflet** Excess Leaflet **Excess Leaflet** Calcification Calcification Calcification (31.3%)(42.6 %) (26.0 %) 40 p < 0.001 log-rank Mortality (%) All-cause **I** 13.6 9.5 10-5.9 4.6 3.8 180 360 540 720 Days Calcified raphe or Calcified raphe and excess leaflet calcification excess leaflet calcification Yoon, S.-H. et al. J Am Coll Cardiol. 2020;76(9):1018-30

(Top) Schematic presentations of various bicuspid aortic valve morphology. Bicuspid aortic valve with no morphological features (calcified raphe or excess leaflet calcification), either, or both of these features. (Bottom) All-cause mortality according to the morphological features. Event rates were calculated with the use of Kaplan-Meier methods and were compared with the log-rank test.



Calcification of R-L fusion raphe in type 1 BAS may cause asymmetrical THV expansion, resulting in higher rate of PPI

Structural Heart 8 (2024) 100227 **Dense Calcification** b a in the R-L raphe RCC LCC Tricuspid Tricuspid Valve Mitral NCC Valve Valve **TAVR Prothesis** Mitral Valve **Central Fibrous Body AV Bundle AV Bundle**

Figure 3. Potential mechanism of higher rate of pacemaker in BAV. (a) Aortic valve complex in a BAV Sievers 1 configuration with R-L fusion with calcium. (b) The asymmetrical TAVR expansion resulting from resistant calcific raphe and leaflet fusion may compress the non-coronary cusp toward the conduction fiber pathway along the central fibrous body.

Abbreviations: BAV, bicuspid aortic valve, TAVR, transcatheter aortic valve replacement.

A. Kalra et al.



The Wei's comprehensive sizing method for BAV @ CHGH



Min. diameter (shortest distance from leading edge of the leaflet calcification to the aortic wall) -- B

In 2016, Our team found that extensive calcification is common in bicuspid valves, and it is usually asymmetrically distributed.

of membranous septum

Application of Wei's method in BEV for Bicuspid AV







Balloon sizing in cases with borderline annular size/heavy calcification/coronary issues!



Balloon sizing can predict the risk of coronary artery occlusion, PVL, asymmetric valve deployment, annular rupture, and the impact of the severe asymmetric calcification.



In the case of asymmetric calcification, the valve deploys asymmetrically, often being pushed to the side with less calcification.

Aim high to avoid conduction

disturbance if no coronary issues.





Bicuspid AS (BEV case 1)

Circle method 23 mm S3

BAVARD method 23 mm S3



Daniel Blackman et al. Cardiol Ther. 2021

Didiet T et al. Circinterventions. 2019;12: 2007107

²¹⁷ TCTAP2024



Bicuspid AS (BEV case 1)

Wei's Comprehensive method

(28.9 + 17.3)/2 = 23.1cm





BAVARD (ICD 4mm) method may over-estimated supra-annular size → overlook some "true taper configuration"







Anchoring

Optimization

Bicuspid AS (BEV Case 2)

26mm S3 -2cc

• 72 y/o male

- CAD s/p CABG and complex PCI with ICMP and moderate LVDF,
- Critical AS with AVA 0.8 cm², MPG 40mmHg
- STS score 12.9% (extreme high risk for surgery)

Excessive calcification at leaflets, annulus and LVOT





Wei's method = 24.5mm

TAVR + occluders for heavily calcified bicuspid AS

TAVR with a 26mm Sapien 3 valve, underfill 2cc



TAVR + occluders for heavily calcified bicuspid AS

Min: 172

Post-dilatation with 26mmS3 (underfill 1cc)



TAVR + occluders for heavily calcified bicuspid AS

7 months later, the patient came back with severe PVL (two jets) and HFrEF 28% (45% before TAVR) \rightarrow 2 occluders (ADO II 3-6 and VPII 9-12) successfully deployed



Applying the Wei's method in BEV and SEV for Bicuspid AS

- The primary end-point was device success rate and procedural outcomes.
- The complementary approach of supra-annular sizing to conventional annular sizing method (Wei's Method) developed by our team were used in providing guidance to perform TAVR in BAV patients.







Application of Wei's method in SEV for Bicuspid AV

Valve Size Selection	Evolut™ PRO Bioprosthesis			Evolut™ R Bioprosthesis
Avoid aggressive oversizing !				
Cusp overlap view !		XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	AS	
Aim high !				
Optimization !	23 mm	26 mm	29 mm	34 mm
	18-20 mm	20-23 mm	23-26 mm	26-30 mm
Annulus Perimeter †	56.5-62.8 mm	62.8-72.3 mm	72.3-81.7 mm	81.7-94.2 mm
Sinus of Valsalva Diameter (Mean)	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva Height (Mean)	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm
Oversizing Percentage	-12%	0%	11%	30%

+Annulus Perimeter = Annulus Diameter x π

NOTE: Evolut[™] PRO valve size selection is identical to Evolut[™] R valve size selection criteria

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Bicuspid AS (SEV Case 1)

Final Valve Size : 29 mm E-PRO 1st Post-dilated : Nucleus 20/40 mm 2nd Post-dilated : True-Flow 24/35 mm





Min. Ø: 26.0 mm Max. Ø: 32.1 mm Avg. Ø: 29.0 mm Area derived Ø: 28.8 mm Perimeter derived Ø: 29.0 mm Area: 650.8 mm² Perimeter: 91.3 mm

Pø=29mm







Bicuspid AS (SEV Case 2)

Valve Size : 25 mm Post dilated BC (1): Nucleus 22/40mm Final outcome: AR = MildPPG = 12 mmHgPPM = NoneAVA = 2.0 cm2





Annulus Dimensions **Pø=21.8mm** Min. Ø: 18.4 mm Max. Ø: 24.9 mm Avg. Ø: 21.6 mm Area derived Ø: 21.4 mm Perimeter derived Ø: 21.8 mm Area: 360.4 mm² Perimeter: 68.4 mm Adult Ech X8-2t 76Hz 6.9cm 124 180 2D 53% C 50 P Off HGen © ₽______R 2.7 5.4 Adult Echo X8-2t 76Hz 6.9cm 0 124 180 2D 53% C 50 P Off HGen P 2.7 5.4 PAT T: 37.0C TEE T: 38.7C

30.0



LC

TIS0.2

Outcomes of TAVR with BEV or SEV for bicuspid AS, sized by the Wei's method

	Balloon-expandable valves (N=43)	Self-expanding valves (N=32)	P value			
Bicommissural, non-raphe or type 0, n (%)	17 (40)	17 (40) 14 (44)				
Bicommissural, raphe or type 1, n (%)	25 (58)	17 (53)	0.843			
Tricommissural or type 2, n (%)	1 (2)	1 (3)	0.999			
Asymmetrical distribution of calcium, n(%)	33 (77)	30 (94)	0.095			
Presence of calcified raphe>4mm, n (%)	18 (42)	10 (31)	0.482			
Tapered configuration, n (%)	7 (16)	9 (28)	0.340			
THV 23mm or smaller, n (%) No	patient experienced annular rup	oture ^{3 (9)}	0.003			
THV 26-27mm, n (%)	17 (40)	6 (19)	<0.05			
THV 29mm or larger, n (? Similar device success rates and rates of moderate-to-severe PVL <0.05						
Device success, n (%)	40 (93)	30 (94)	0.999			
mean PG > 20mmHg, n (%)	1 (2)	0 (0)	0.609			
Although the mean post-TAVR trans-AV PG was significantly higher among patients treated with BEV versus SEV, the estimated aortic valve area was similar in both groups						
No differences in the rate of permanent pacemaker implant were observed, even though the implantation depth was significantly shorter in BEV versus SEV						
Implantation depth, mm	2.26 ± 1.20	3.91 ± 2.47	0.001			
Permanent pacer implantation, n (%)	2 (5)	3 (9)	0.731			

Identify the "true taper configuration" is the key !!

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Conclusion

- The presence of a calcified raphe and excess leaflet calcification, and associated technical challenges for the TAVR procedure, is the most import determinant of procedural and clinical outcomes in bicuspid AS.
- A comprehensive sizing method (Wei's method) sized both supraannular and annular dimensions to identify the high-risk "TAPER" configuration, composes about 20% of bicuspid AS, so as to avoid aggressive oversizing and complications, is strongly recommended.
- The Our study confirms that proper sizing with the Wei's method is useful in providing guidance to perform safer THV implantation with similar device success rates of both BEV and SEV.

