Bicuspid TAVR:
All the Technical Issues and Data
From Asan Medical Center

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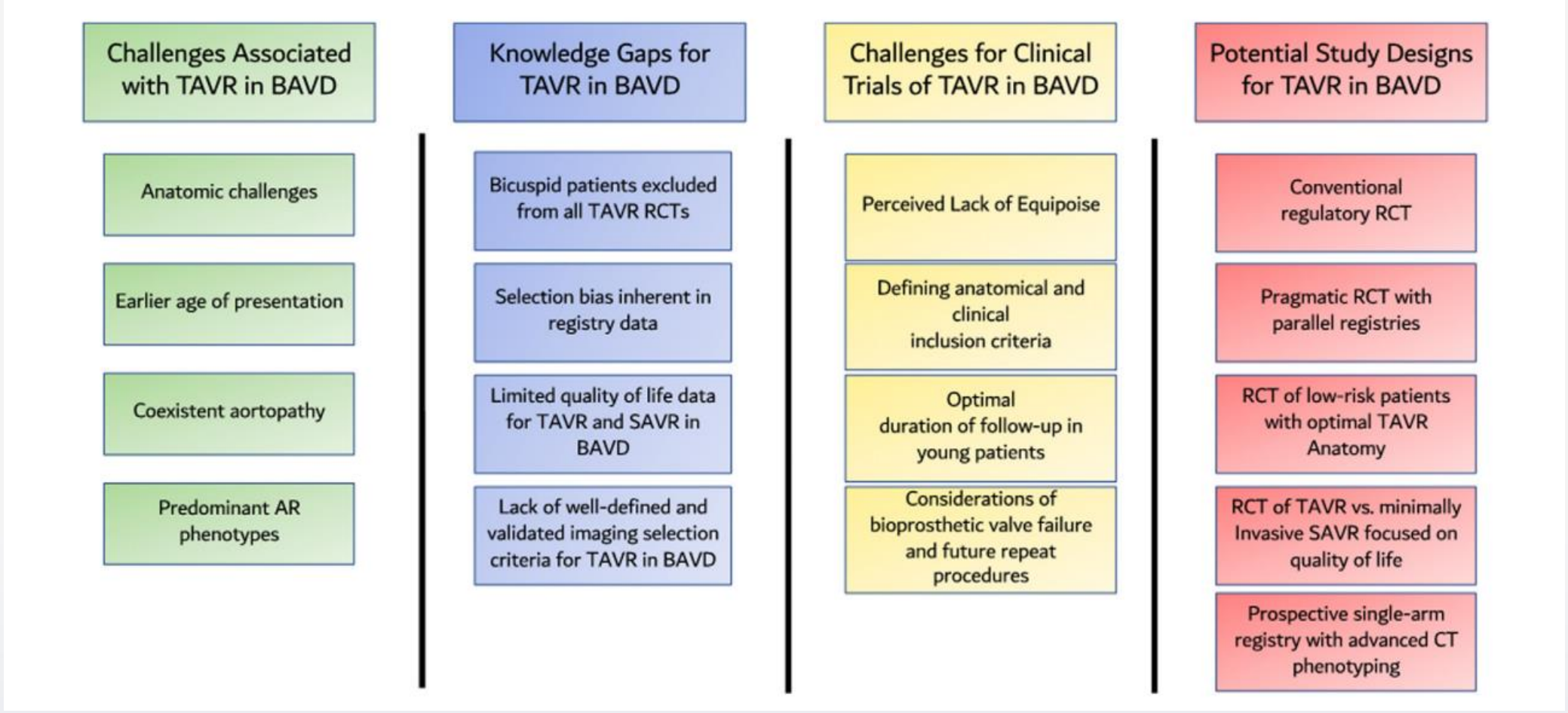
Current Considerations and Future Directions for Clinical Research in Bicuspid AS



Yousif Ahmad, and David Cohen et al. Structural Heart Volume 7, Issue 1, January 2023, 100102

Clinical and Anatomical Challenges

Clinical factors

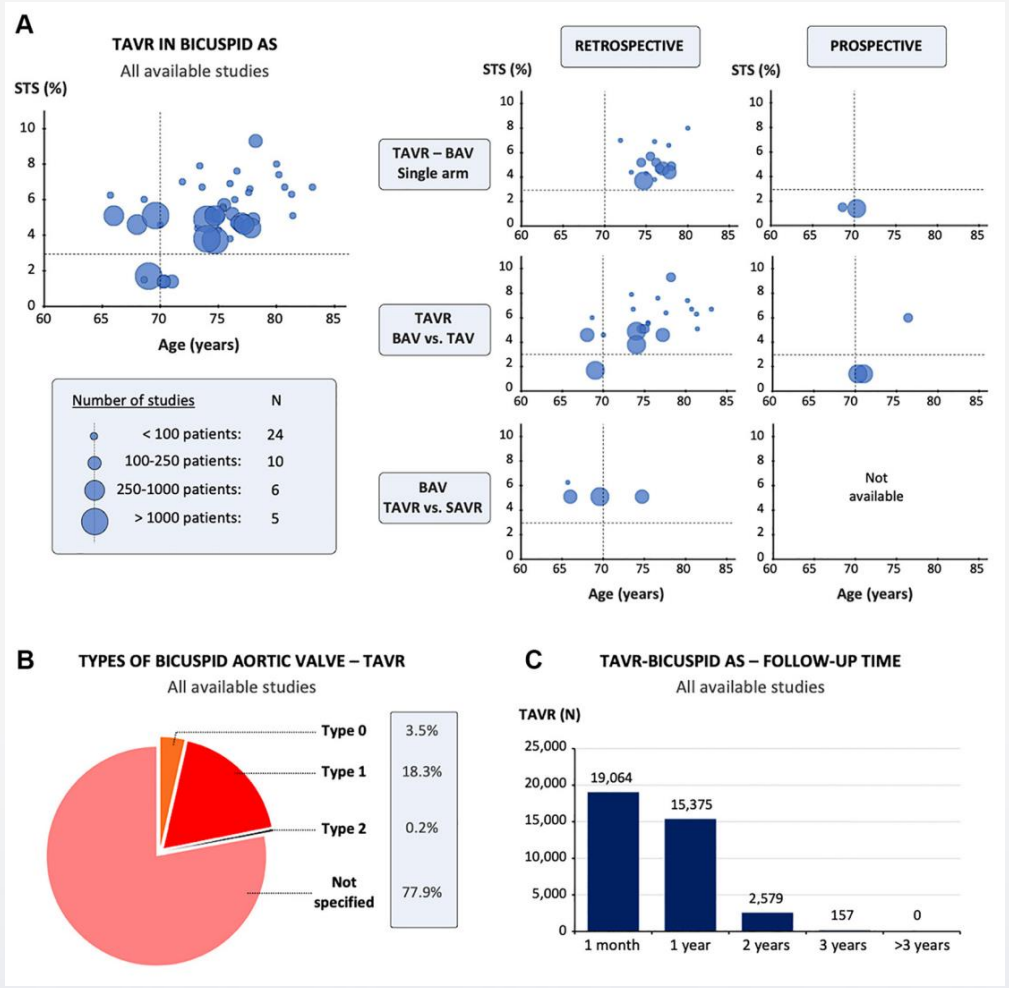
- Patients present at younger age (longer subsequent lifetime with an aortic prosthesis)
- Presence of concomitant aortopathy
- More likely to present with predominant aortic regurgitation or mixed aortic valve disease with insufficient calcification for device anchoring

Anatomic factors

- Larger annuli (sometimes outside the recommended range for treatment with commercial transcatheter heart valves)
- Increased cusp calcification, which is often bulky and asymmetrical, and not infrequently extends into the aortic annulus
- Eccentric, nontubular shape of aortic valve complex (tapered or flared)
- Presence of calcified raphe(s)
- Increased frequency of coronary anomalies (including left-dominant coronary circulation, anomalous coronary takeoffs)
- Longer leaflets with increased frequency of calcified leaflets (predisposing to coronary occlusion with TAVR)
- Increased frequency of horizontal aorta
- Aortic root and ascending aorta dilation

Yousif Ahmad, and David Cohen et al. Structural Heart Volume 7, Issue 1, January 2023, 100102

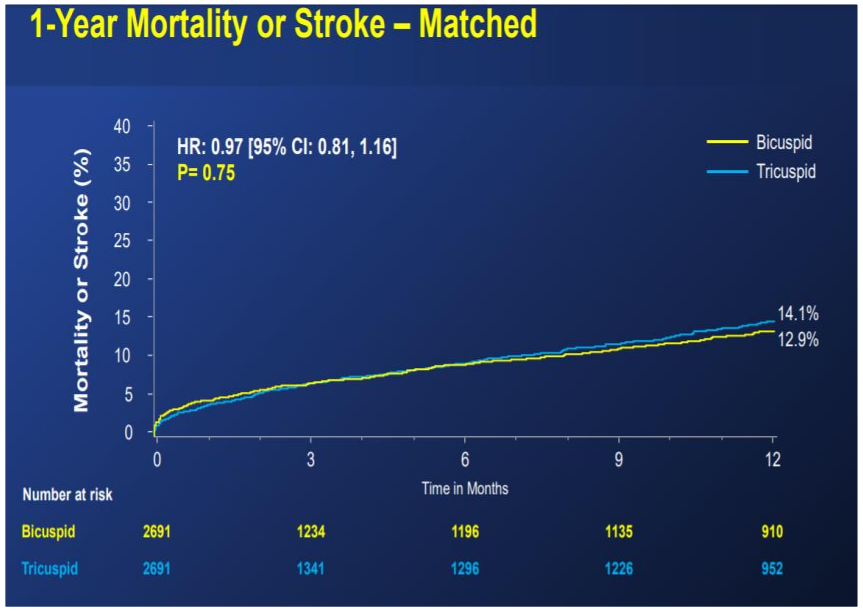
Available Evidence on TAVR in BAV Stenosis



JACC Cardiovasc Interv. 2023 Jul 10;16(13):1682-1687

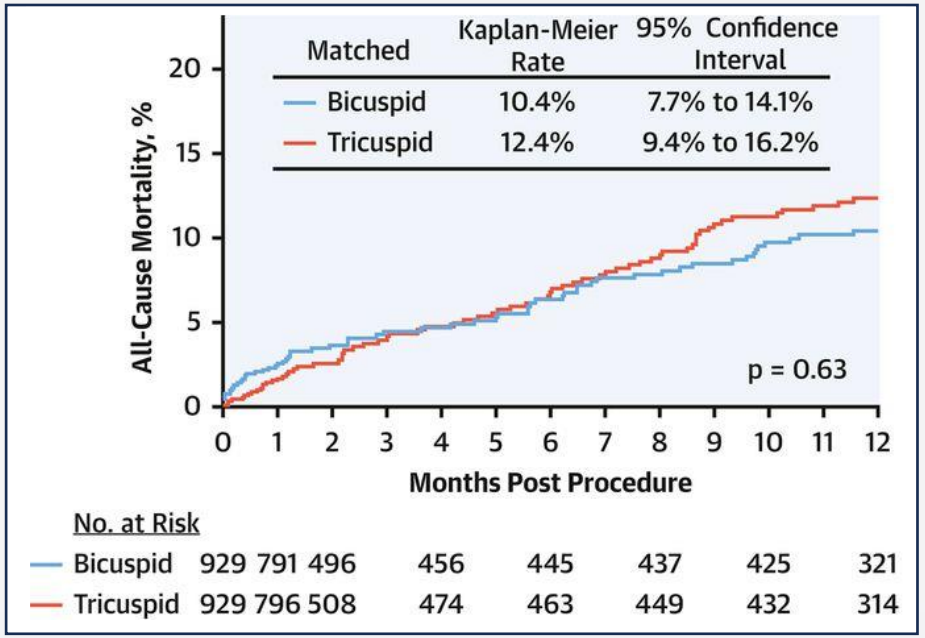
STS/ACC TVT Registry

Sapien 3



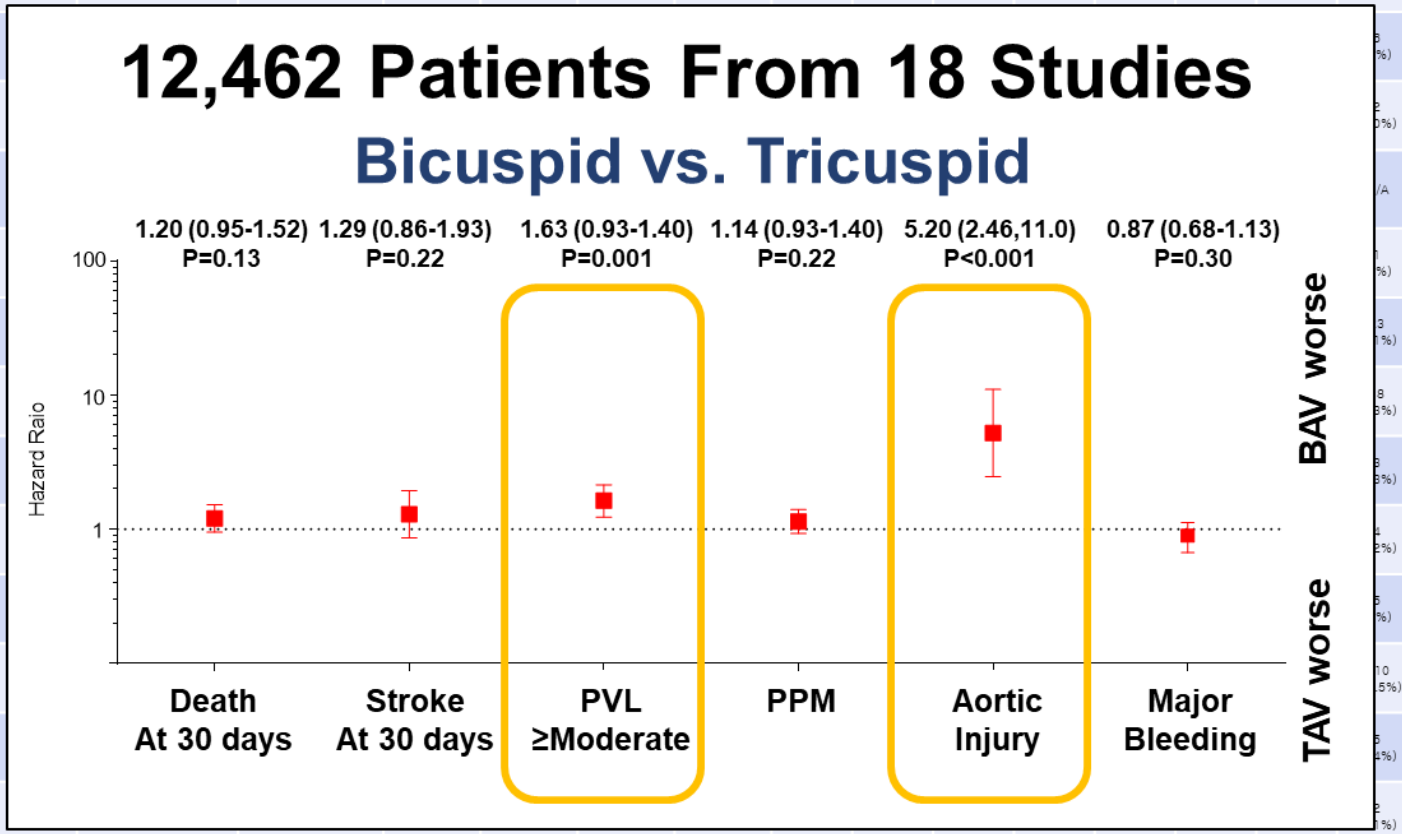
JAMA 2019 Jun 11;321(22):2193-2202

Evolut R



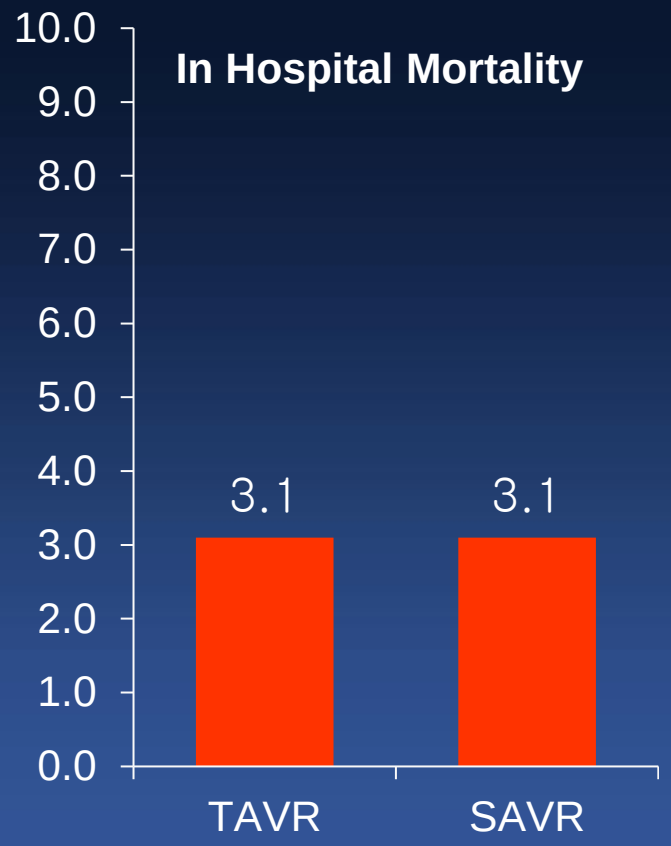
JACC CVI 2020 May 23;S1936-8798(20)30763-9

	Year	Number		Age		Male		PVL ≥ Moderate		PPM		Aortic root injury*		Major Bleeding		Mortality at 30 days		Stroke at 30 days	
		BAV	TAV	BAV	TAV	BAV	TAV	BAV	TAV	BAV	TAV	BAV	TAV	BAV	TAV	BAV	TAV	BAV	TAV
Hayashida K[25]	2013	21	208	82.0±7.0	83.2±6.5	12 (57.1%)	111 (53.4%)	0	2 (1.0%)	3 (14.3%)	15 (7.2%)	0	3 (1.4%)	1 (4.8%)	9 (4.3%)	1 (4.8%)	17 (8.2%)	N/A	N/A
Bauer T[27]	2014	38	1357	80.7±6.6	81.8±6.2	17 (44.7%)	570 (42.0%)	10 (25%)	204 (15%)	6 (17%)	475 (35%)	1 (2.6%)	5 (0.4%)	N/A	NA	4 (11%)	149 (11%)	0	41 (3%)
Costopoulos C[28]	2014	21	447	76.7±7.1	79.8±7.4	12 (57.1%)	212 (47.4%)	0	11 (3%)	3 (14%)	67 (15%)	2 (10%)	N/A	4 (19%)	90 (20%)	3 (16%)	67 (15%)	0%	5 (1.0%)
Kochman J[29]	2014	28																0	3 (4%)
Liu XB[31]	2015	15																1 (6.7%)	1 (4.0%)
Watanabe Y[33]	2015	11																N/A	N/A
Arai T[35]	2017	10																0	0
Sannino A[36]	2017	88																2 (2.3%)	27 (3.7%)
Yoon SH[7]	2017	546†																16 (2.9%)	10 (1.8%)
Liao YB[21]	2018	87																1 (1.1%)	0
Aalaei-Andabili SH[37]	2018	32																2 (6.3%)	3 (3.1%)
De Biase C[38]	2018	83																0	1 (0.6%)
Kim WK[39]	2018	144																N/A	N/A
Nagaraja V[40]	2018	359†																10 (2.8%)	20 (5.6%)
Xiong TY[22]	2018	67																N/A	N/A
Mangieri A[41]	2018	54	658	80±5.3	82.1±4.3	21 (38.9%)	420 (63.9%)	4 (7.4%)	9 (3.1%)	5 (9.2%)	57 (8.6%)	0	0	2 (3.7%)	34 (5.1%)	2 (3.7%)	17 (2.8%)	4 (7.4%)	12 (1.8%)
Tchetche D[42]	2019	101	88	78.2±10.1	83.1±5.7	66 (65.3%)	41 (46.6%)	21 (20.8%) ‡	11 (12.5%) ‡	13 (13%)	12 (14%)	N/A	N/A	11 (11%)	4 (4.5%)	0	3 (3.4%)	2 (2%)	0
Makkar RR	2019	2691†	2691†	73±10	73±11	1623 (60.3%)	1655 (61.5%)	36/1711 (2.1%)	43/1782 (2.4%)	245 (9.1%)	202 (7.5%)	16 (0.6%)	3 (0.1%)	3 (0.1%)†	3 (0.1%)†	70 (2.6%)	67 (2.5%)	65 (2.4%)	43 (1.6%)
Summary estimates		4396	8066	77.3 (75.3–79.3) §	79.0 (77.0–81.0)														
				Standard Difference −0.19 (−0.29– −0.09), P<0.001				OR 1.63 (1.23–2.14) P=0.001		OR 1.14 (0.93–1.40) P=0.22		OR 5.20 (2.46–11.0) P<0.001		OR 0.87 (0.68–1.13), P=0.30		OR 1.20 (0.95–1.52) P=0.13		OR 1.29 (0.86–1.93) P=0.22	



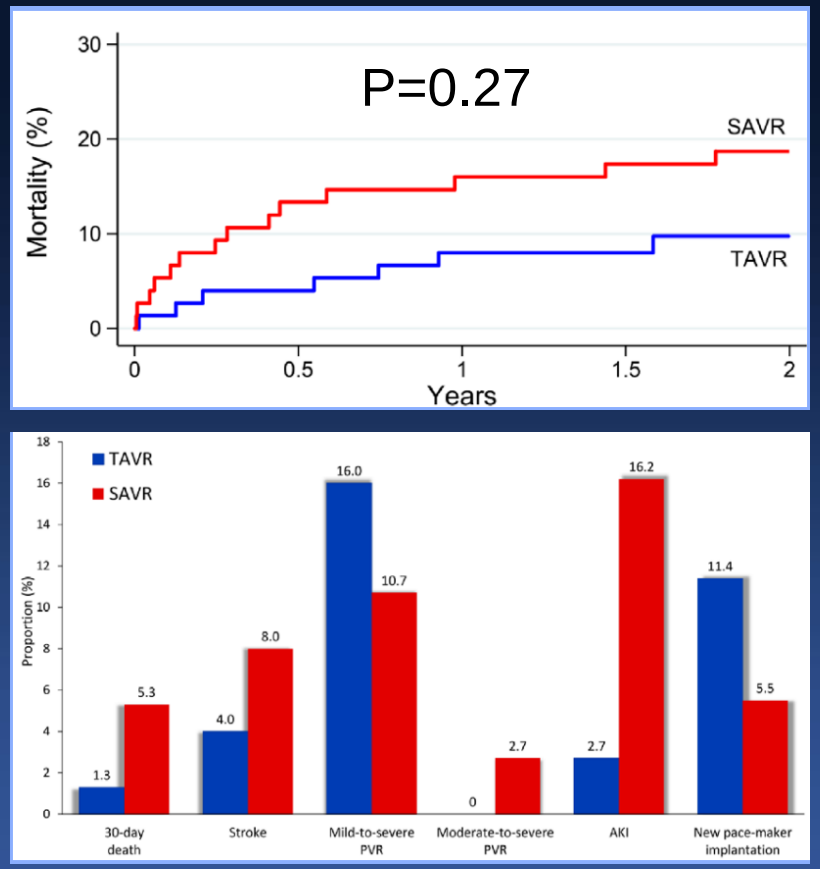
TAVR vs. SAVR in Bicuspid AS

NIS Data-base (USA)



JACC Cardiovasc Interv . 2019;12(18):1811-1822.

The FinnValve Registry

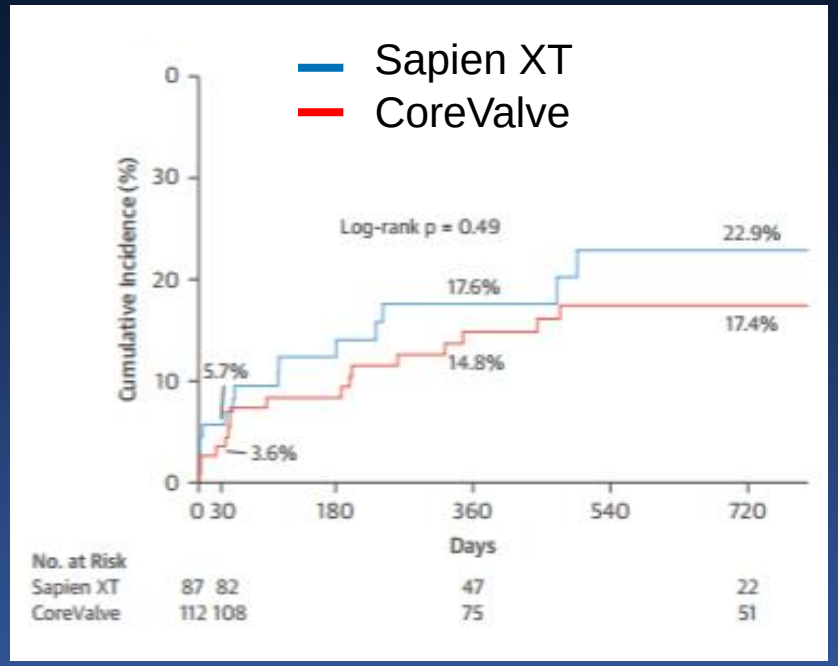


Clinical Research in Cardiology (2021) 110:429–439

SEV vs. BEV

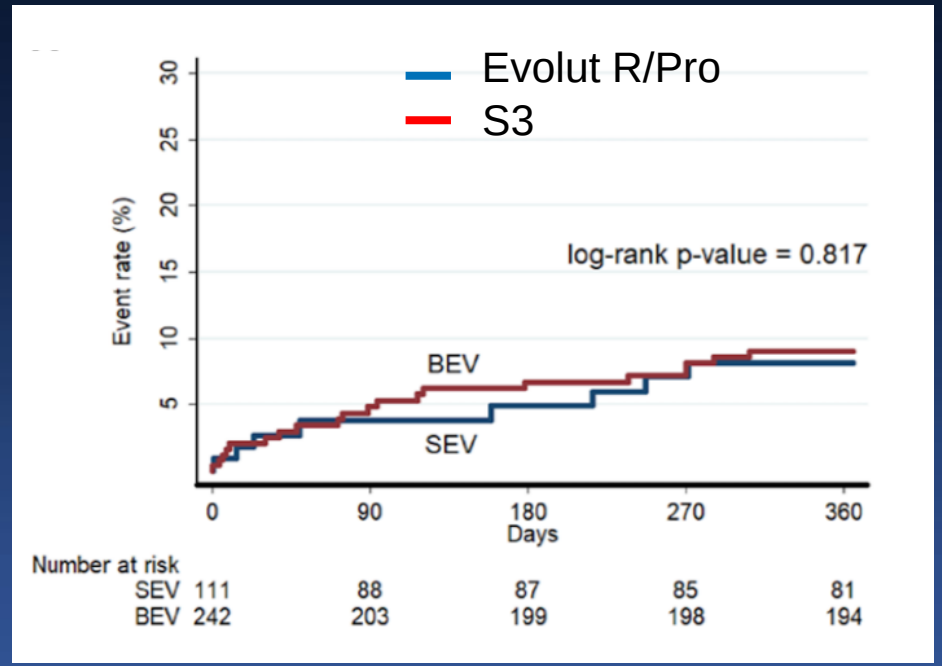
All Cause Mortality

The Bicuspid TAVR Registry



J Am Coll Cardiol 2016;68:1195–205

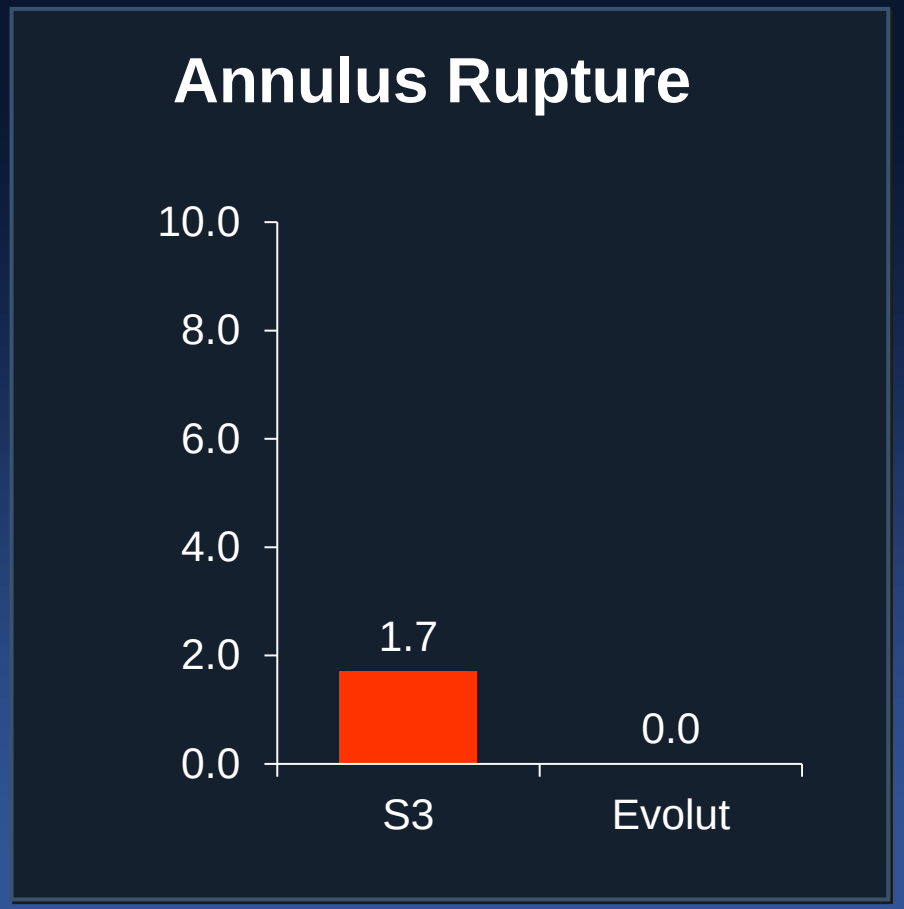
The BEAT Registry

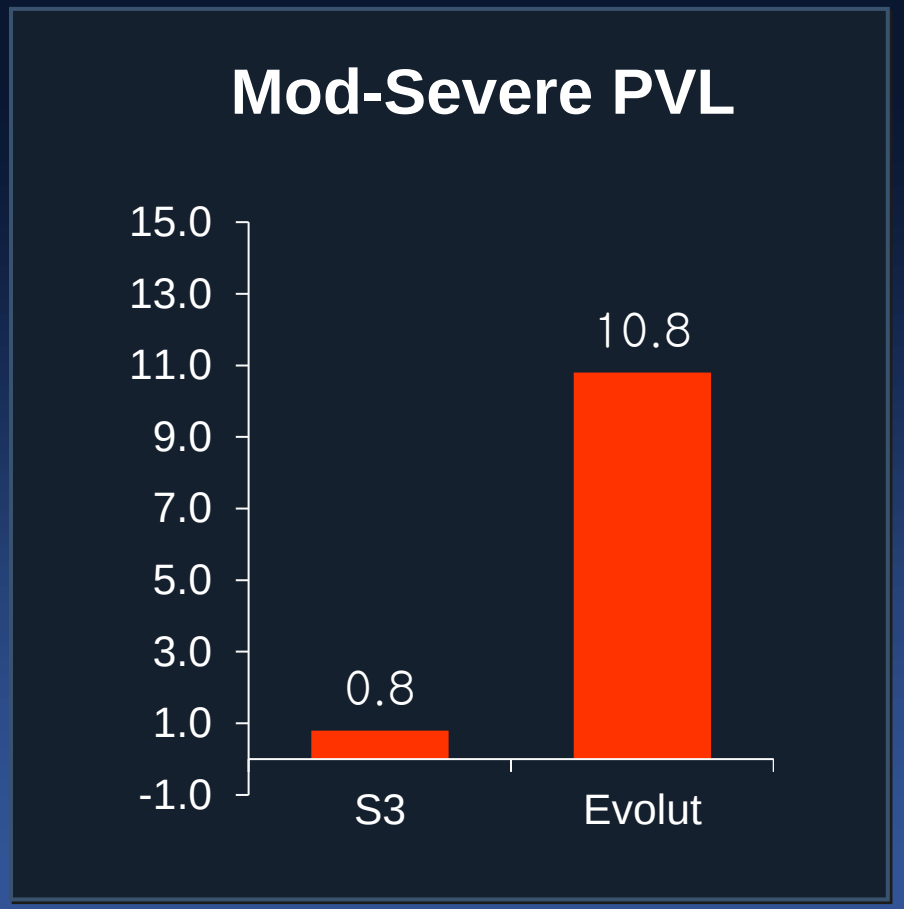


Circ Cardiovasc Interv. 2020;13:e008714

S3 vs. Evolut R/PRO

The BEAT Registry

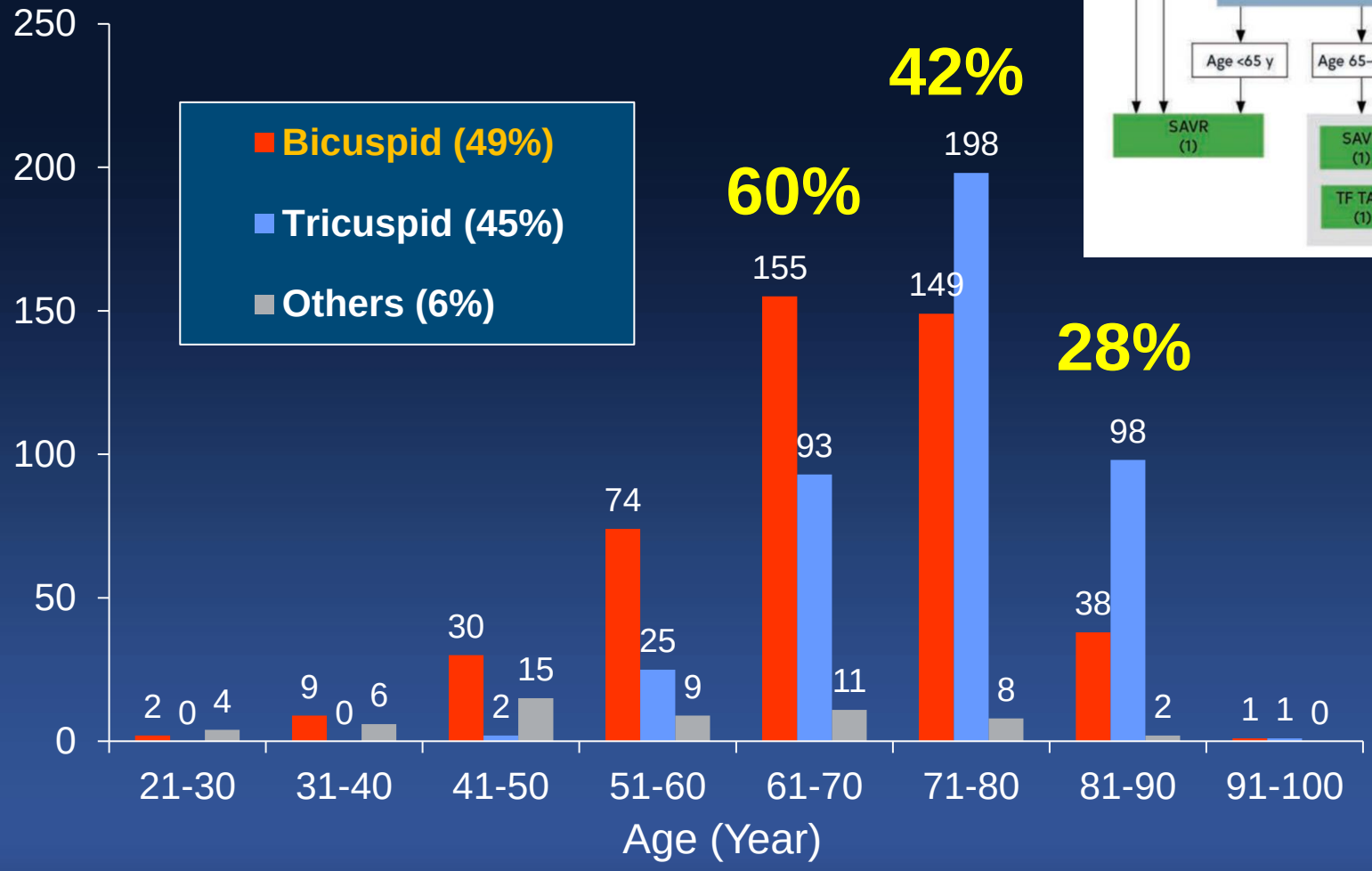


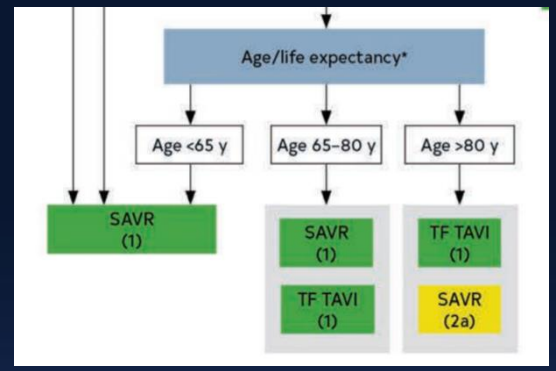


Circ Cardiovasc Interv. 2020;13:e008714

Incidence of Bicuspid AV in isolated AVR

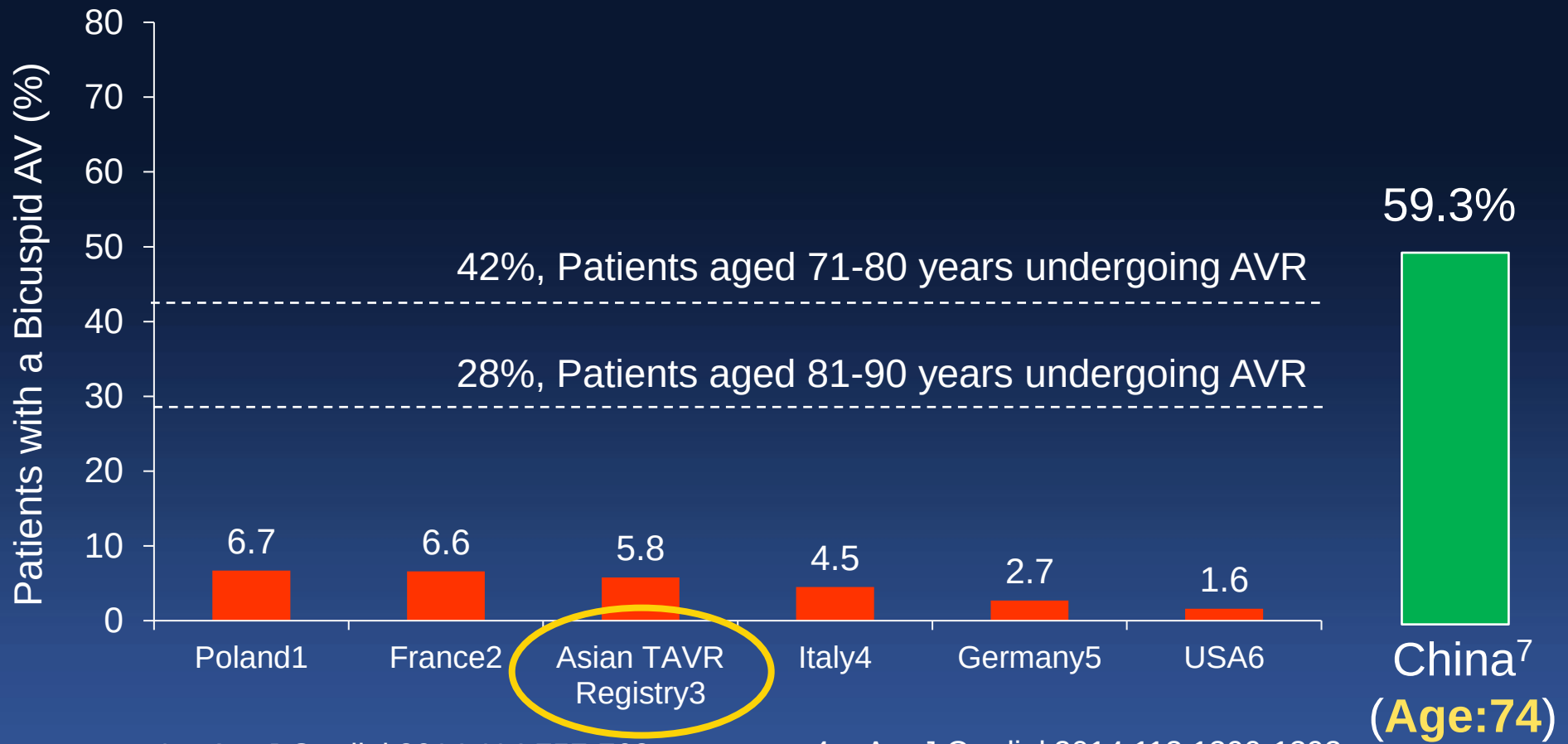
584 men and 348 women from USA (Baylor University)





William Roberts, Circulation 2005;111:920-925

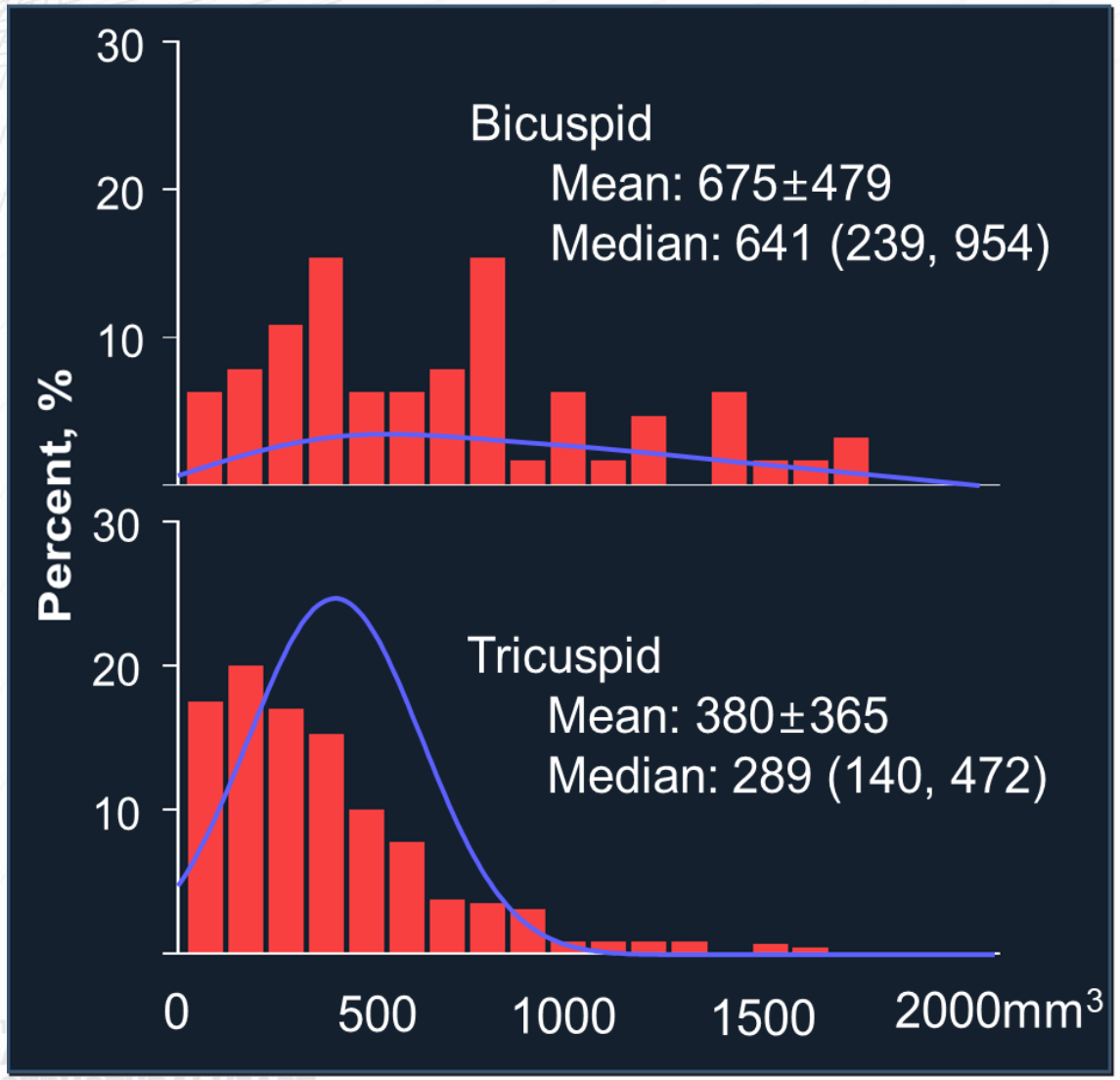
Frequency of Bicuspid AV in TAVR Registry



1. Am J Cardiol 2014;114:757-762
2. Am J Cardiol 2012;110:877-883
3. JACC Cardiovasc Interv 2016;9:926-33
4. Am J Cardiol 2014;113:1390-1393
5. Am J Cardiol 2014;113:518-521
6. JAMA 2013;310:2069-2077
7. Catheter Cardiovasc Interv. 2017;89(S1):528-533.

Calcium: Amount And Morphology

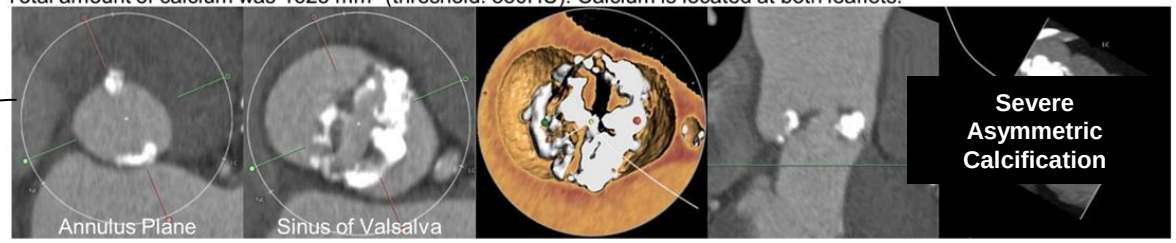
ASAN TAVR Registry



Higher Risk

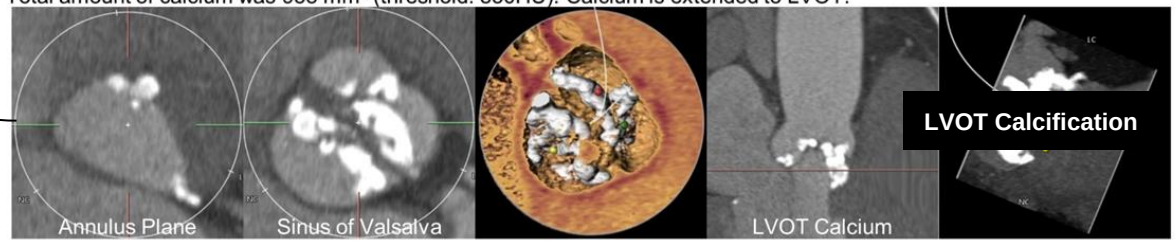
Case 1
Total amount of calcium was 65 mm³ (threshold: 850HU). There was only small amount of calcium.

Case 2
Total amount of calcium was 1625 mm³ (threshold: 850HU). Calcium is located at both leaflets.

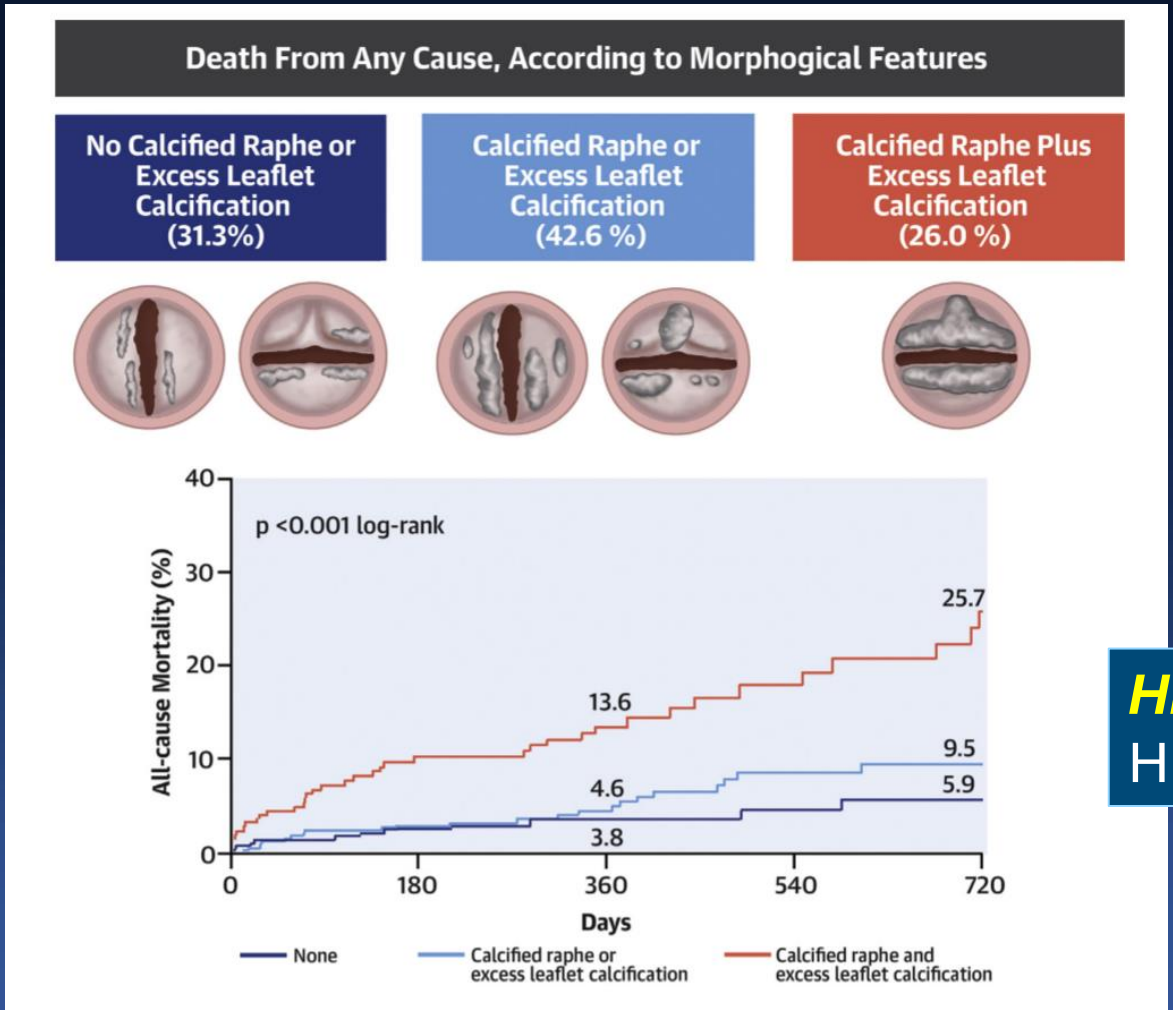


Case 3
Total amount of calcium was 380 mm³ (threshold: 850HU). Calcified raphe is observed between right and left coronary cusp.

Case 4
Total amount of calcium was 958 mm³ (threshold: 850HU). Calcium is extended to LVOT.



Calcification Morphology and Outcomes



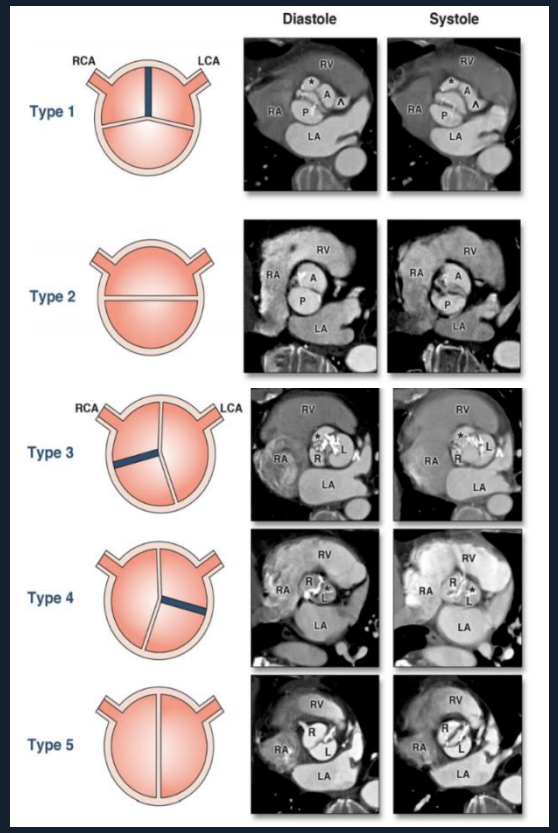
Severe AV calcification

Higher Aortic Root Injury
Higher PVL

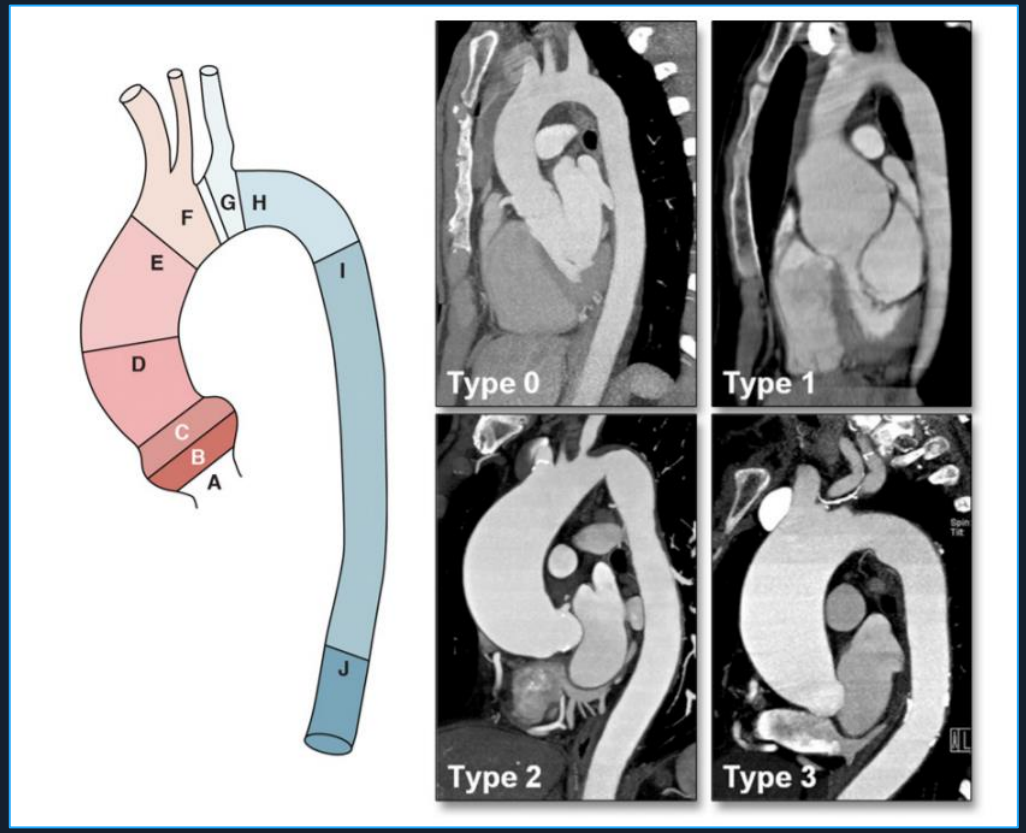
J Am Coll Cardiol. 2020;76(9):1018–30

Spectrum of BAV Disease

Aortic Valve Morphology

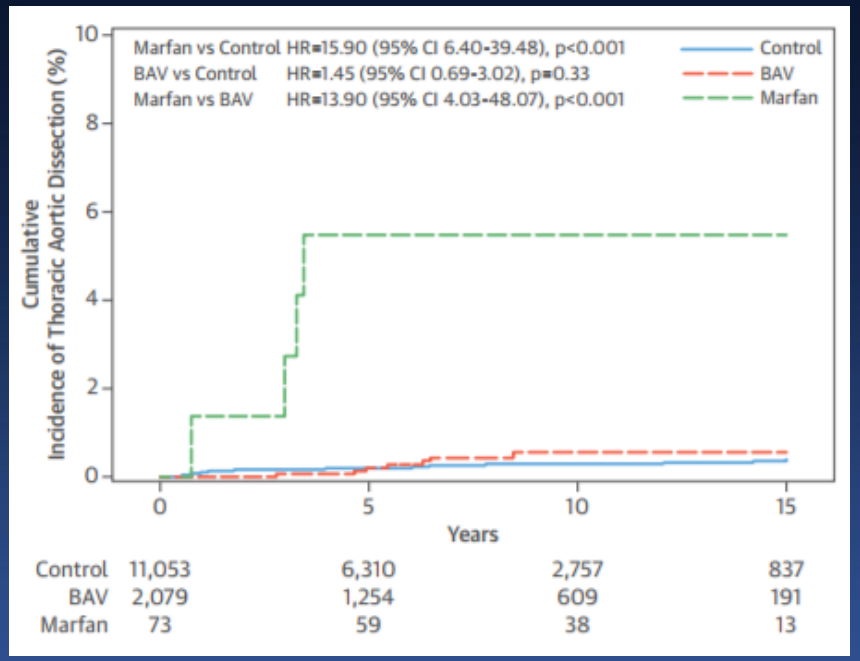


Combined Aortopathy



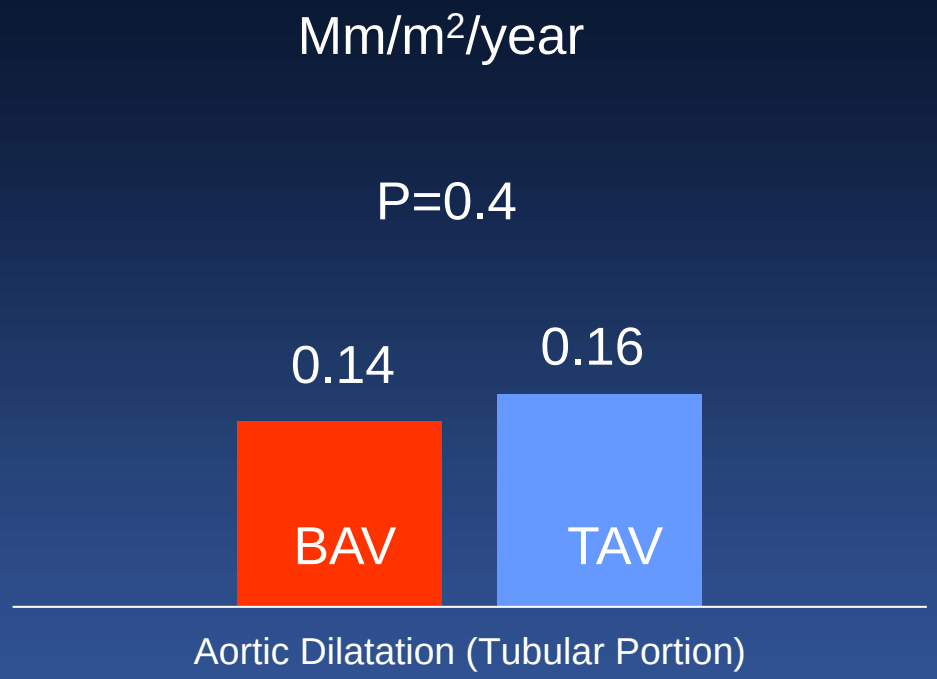
BAV Aortopathy

Risk Aortic Dissection After SAVR



Itagaki S et al. JACC 2015 Jun 9;65(22):2363-9

Rate of Ao Dilatation After SAVR



Kim YG et al. 2012 Dec;98(24):1822-7

Bicuspid aortopathy does not require earlier surgical intervention

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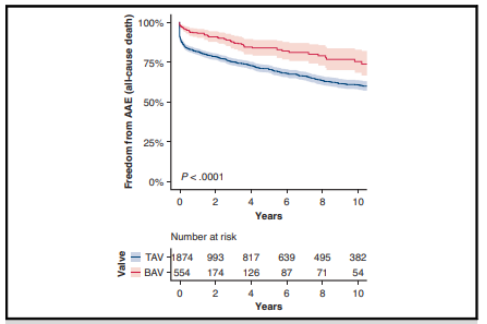
ABSTRACT

Objectives: Guidelines for surgical correction of patients with ascending thoracic aortic aneurysm (ATAA) with a bicuspid aortic valve (BAV) have oscillated over the years. In this study, we outline the natural history of the ascending aorta in patients with BAV and trileaflet aortic valve (TAV) ATAA followed over time, to ascertain if their behavior differs and to determine if a different threshold for intervention is required.

Methods: Aortic diameters and long-term complications (ie, adverse aortic events) of 2428 patients (554 BAV and 1874 TAV) with ATAA before operative repair were reviewed. Growth rates, yearly complication rates, event-free survival, and risk of complications as a function of aortic size were calculated. Long-term follow-up and precise cause of death granularity was achieved via a comprehensive 6-pronged approach.

Results: Aortic growth rate in patients with BAV vs TAV ATAA was 0.20 and 0.17 cm/year, respectively ($P = .009$), with the rate increasing with increasing aortic size. Yearly adverse aortic events rates increased with ATAA size and were lower for patients with BAV. The relative risk of adverse aortic events exhibited an exponential increase with aortic diameter. Patients with BAV had a lower all-cause and ascending aorta-specific adverse aortic events hazard. Age-adjusted 10-year event-free survival was significantly better for patients with BAV, and BAV emerged as a protective factor against type A dissection, rupture, and ascending aortic death.

Conclusions: The threshold for surgical repair of ascending aneurysm with BAV should not differ from that of TAV. Prophylactic surgery should be considered at 5.0 cm for patients with TAV (and BAV) at expert centers. (J Thorac Cardiovasc Surg 2023;■:1-10)



BAV-ATAA patients have better adverse-event-free survival than TAV-ATAA patients.

CENTRAL MESSAGE

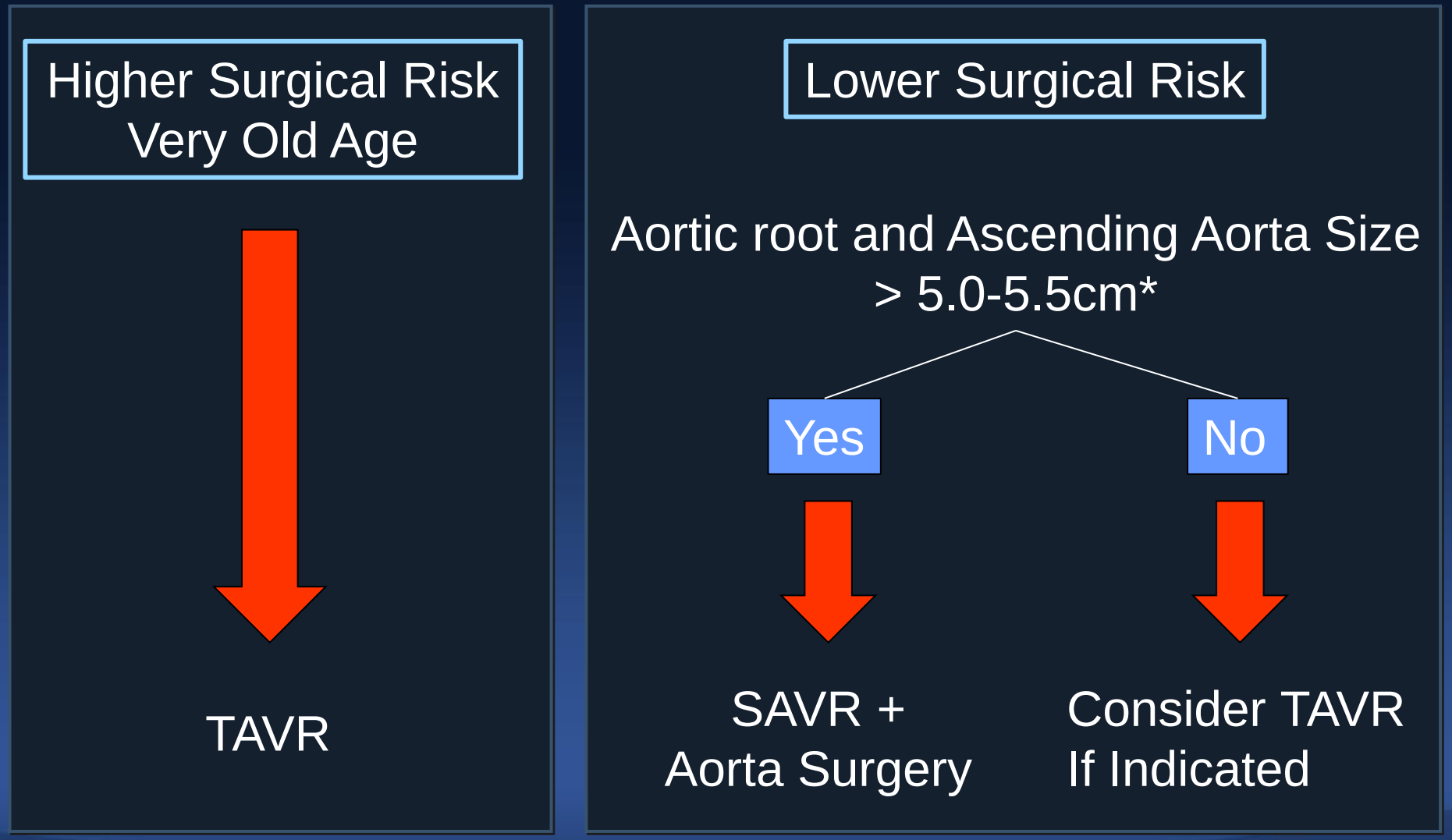
The threshold for prophylactic surgical repair of ATAA in the setting of a bicuspid aortic valve should not differ from that of a trileaflet aortic valve-associated ATAA.

PERSPECTIVE

Guidelines for surgical correction of ATAA in the setting of a BAV have ranged from an aggressive sub-5 cm threshold to >5.5 cm. This study outlines natural history of BAV and TAV related ATAAs over time, revealing that the intervention threshold should not differ between groups, and that prophylactic surgery should be considered at 5.0 cm in both groups to afford protec-

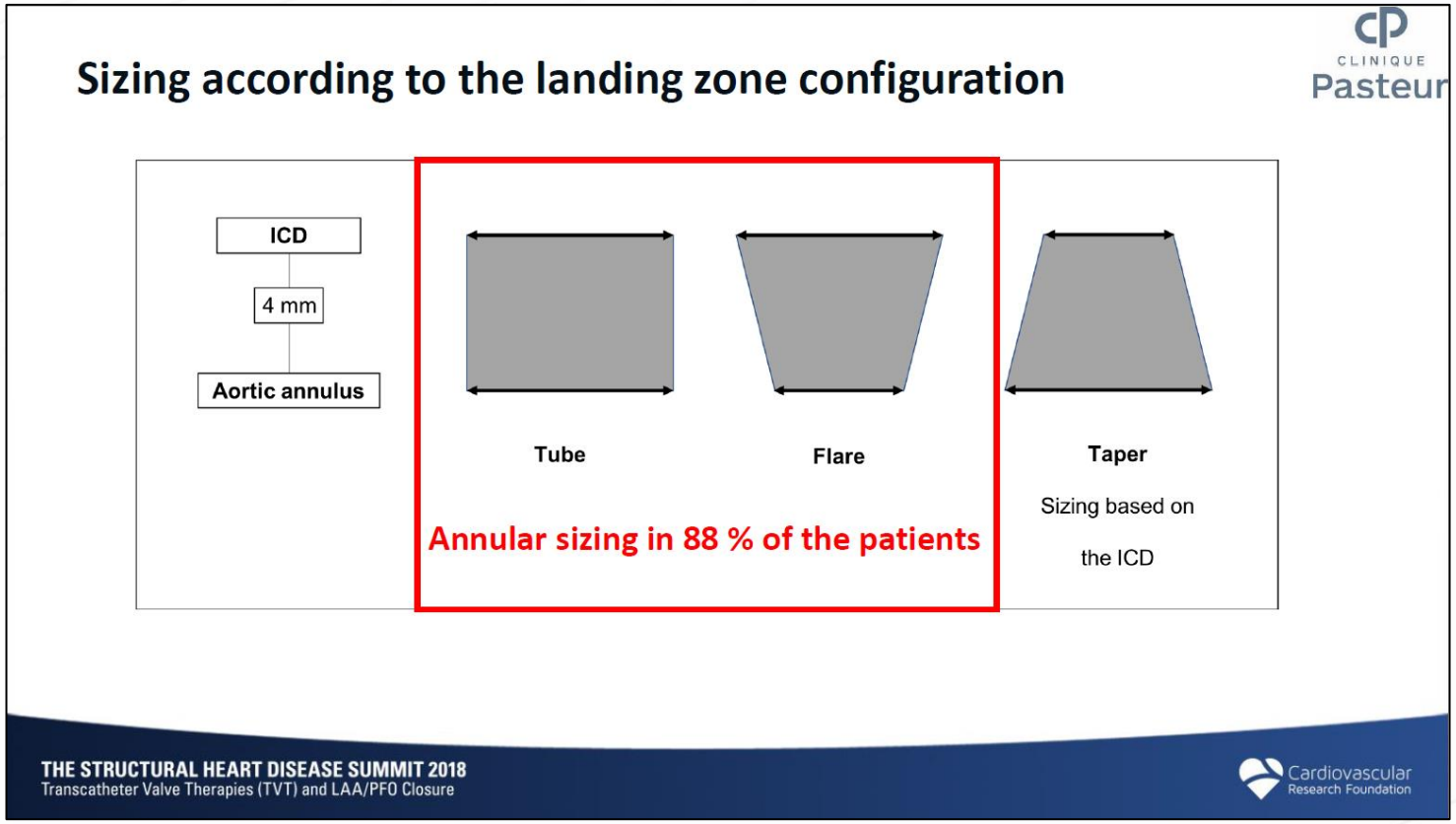
THOR

BAV Aortopathy



*JACC 2016 Surgery for Aortic Dilatation in Patients With Bicuspid Aortic Valves

Device Sizing



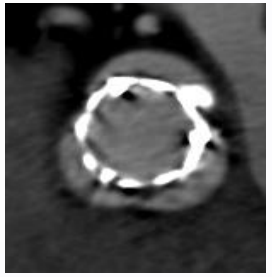
Circulation: Cardiovascular Interventions. 2019;12

Device Sizing

Annulus Sizing

S3

Don’t Do Oversizing Too Much

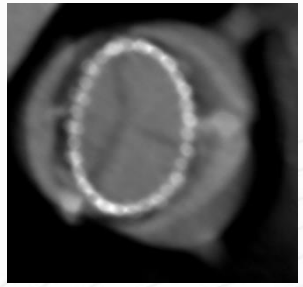


BE “Remodels” the Annulus

Supra-annulus Sizing

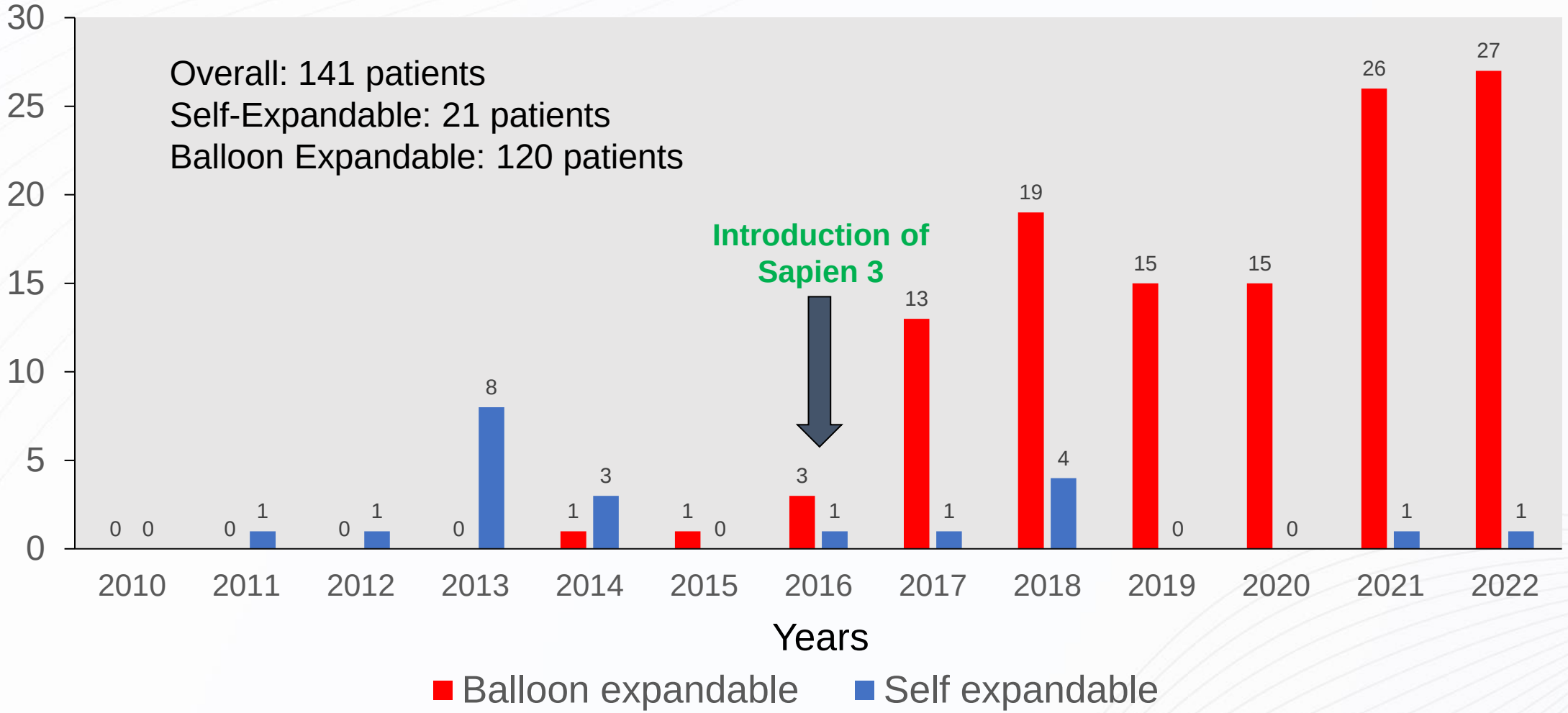
Evolute

- Sequential balloon sizing
- Intercommissural distance
- LIRA method
- CASPER method



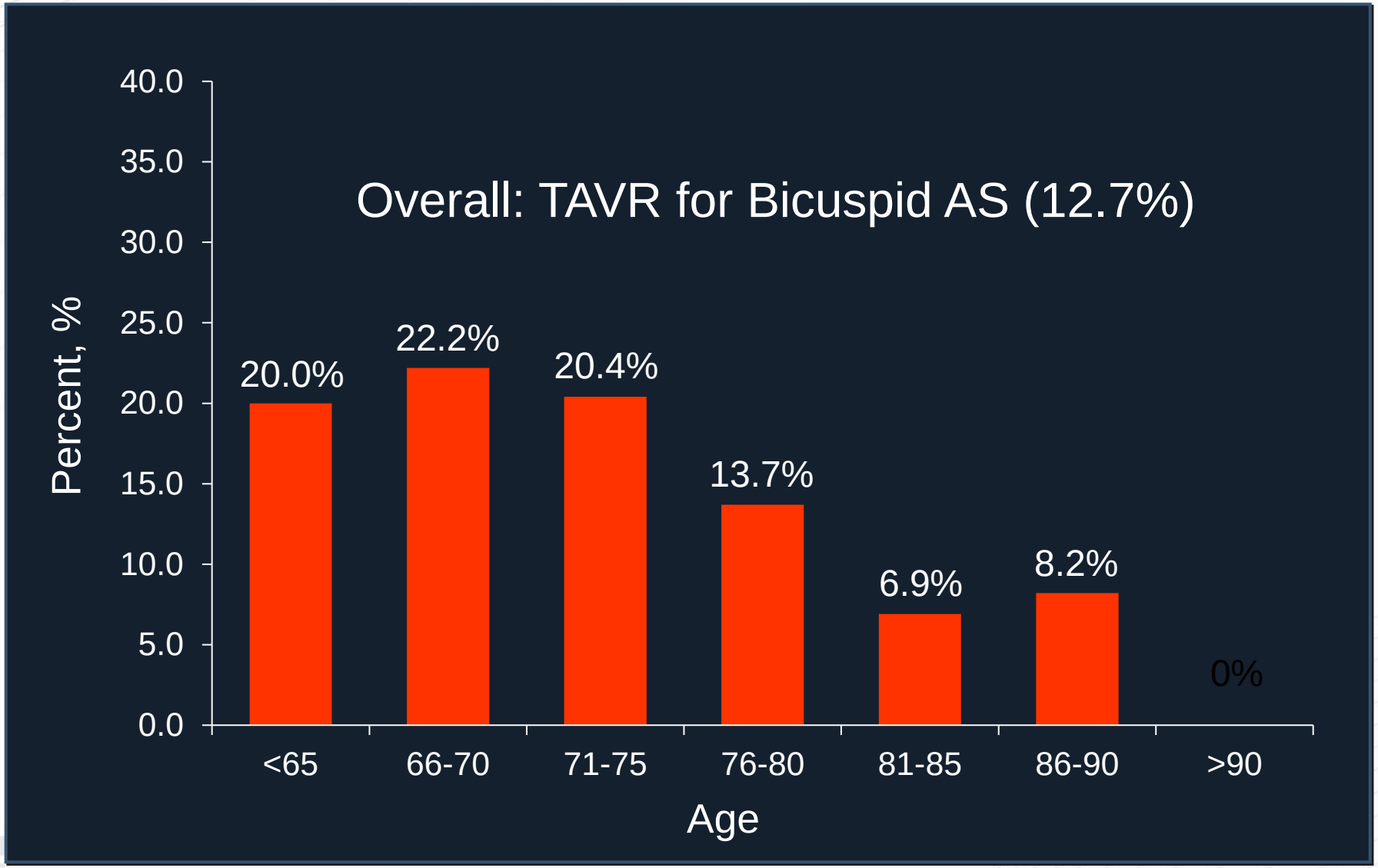
The annulus “remodels” SE

AMC Favors Sapien 3 For Bicuspid AS



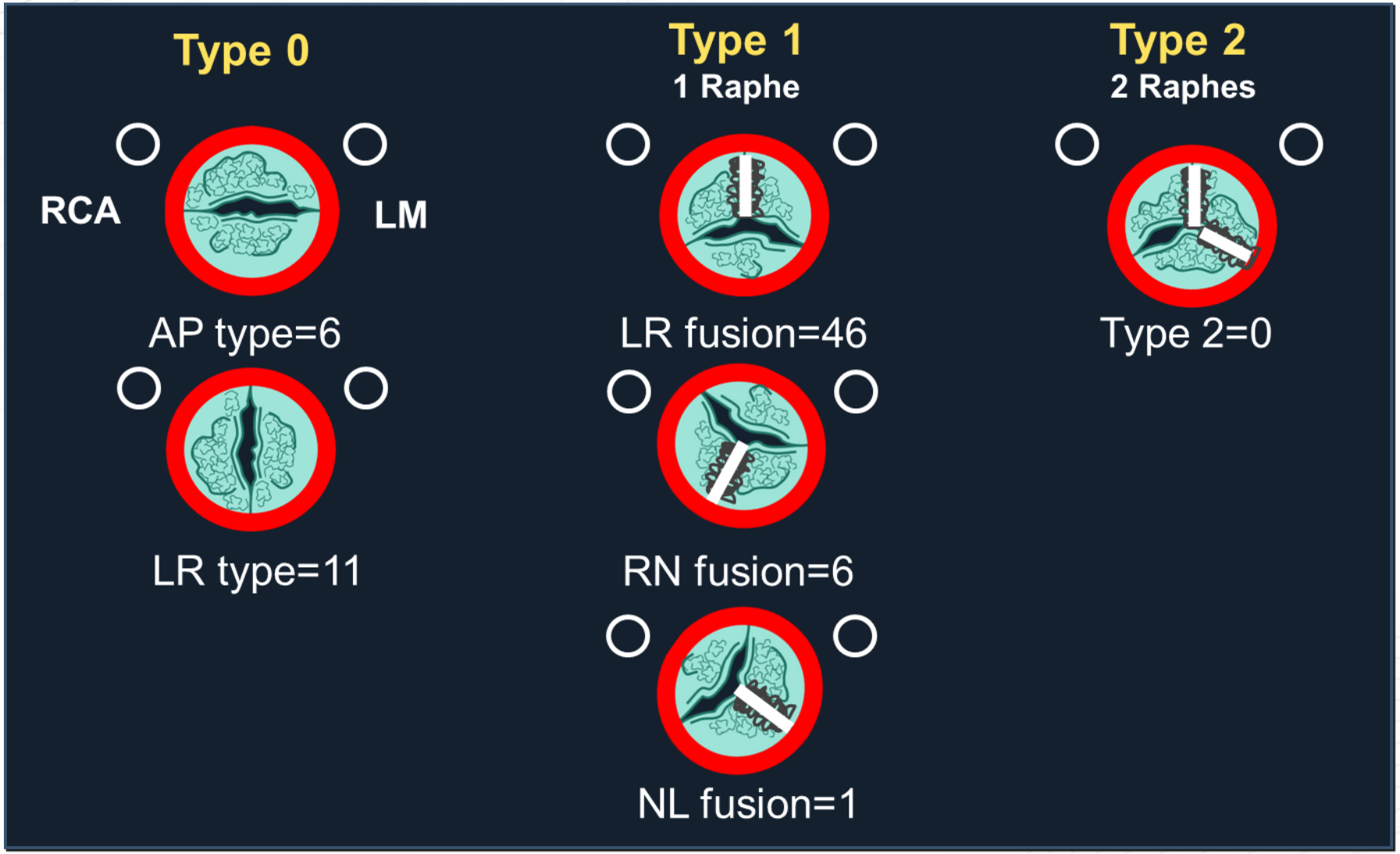
* 5 Lotus valves were excluded in this figure.

Proportion of TAVR for Bicuspid AS



ASAN TAVR Registry

Type of Bicuspid AV



ASAN TAVR Registry

Procedural and In-Hospital Outcomes of TAVR with S3

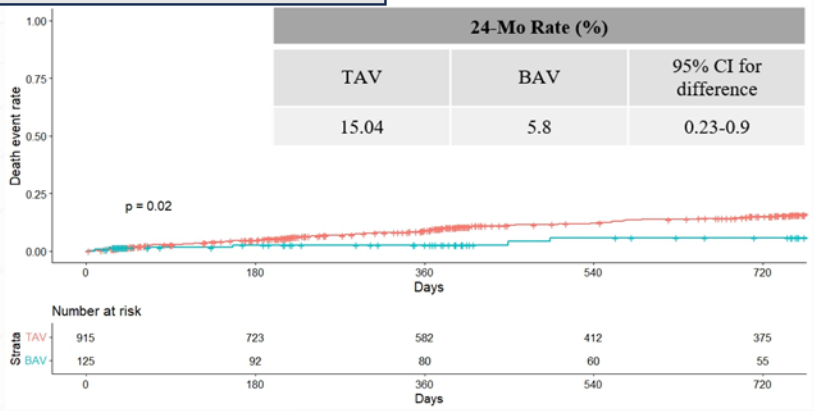
	Unadjusted cohort			Propensity score-matched cohort		
	Tricuspid	Bicuspid		Tricuspid	Bicuspid	
	(N=915)	(N=125)	p-value	(N=125)	(N=125)	p-value
Pre-balloon valvuloplasty	383 (41.9%)	93 (74.4%)	<0.001	66 (52.8%)	93 (74.4%)	<0.001
Post-balloon valvuloplasty	272 (29.7%)	49 (39.2%)	0.041	40 (32%)	49 (39.2%)	0.291
Procedural death	3 (0.3%)	0 (0.0%)	1.000	0 (0%)	0 (0%)	1.000
Conversion to operation	7 (0.8%)	0 (0.0%)	1.000	1 (0.8%)	0 (0%)	1.000
PPM insertion in-hospital	55 (6.0%)	8 (6.4%)	1.000	6 (4.8%)	8 (6.4%)	0.783
PCC insertion	13 (1.4%)	2 (1.6%)	0.699	3 (2.4%)	2 (1.6%)	1.000
Coronary obstruction	3 (0.3%)	0 (0.0%)	1.000	0 (0%)	0 (0%)	1.000
Annular rupture	2 (0.2%)	0 (0.0%)	1.000	1 (0.8%)	0 (0%)	1.000
PVL ≥ moderate at discharge	8 (0.9%)	5 (4.0%)	0.013	1 (0.8%)	5 (4.0%)	0.213

ASAN TAVR Registry

Clinical Outcomes of TAVR with S3

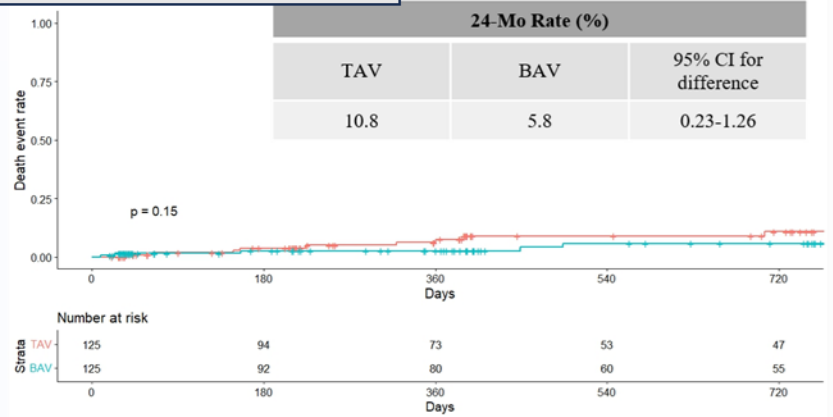
Mortality in Unmatched Cohort

24-Mo Rate (%)		
TAV	BAV	95% CI for difference
15.04	5.8	0.23-0.9



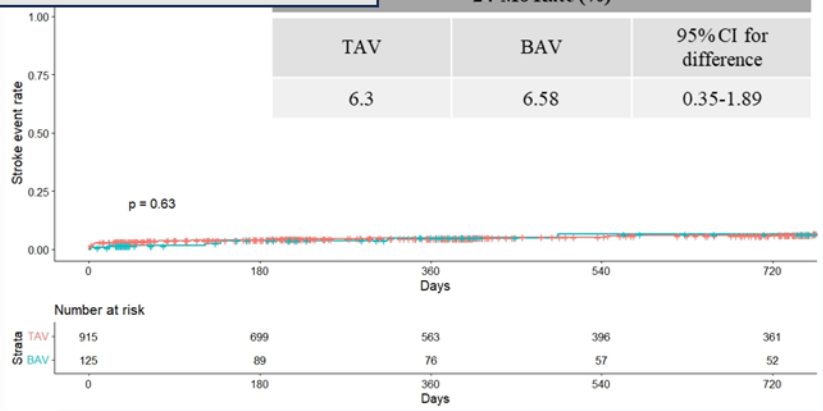
Mortality in Matched Cohort

24-Mo Rate (%)		
TAV	BAV	95% CI for difference
10.8	5.8	0.23-1.26



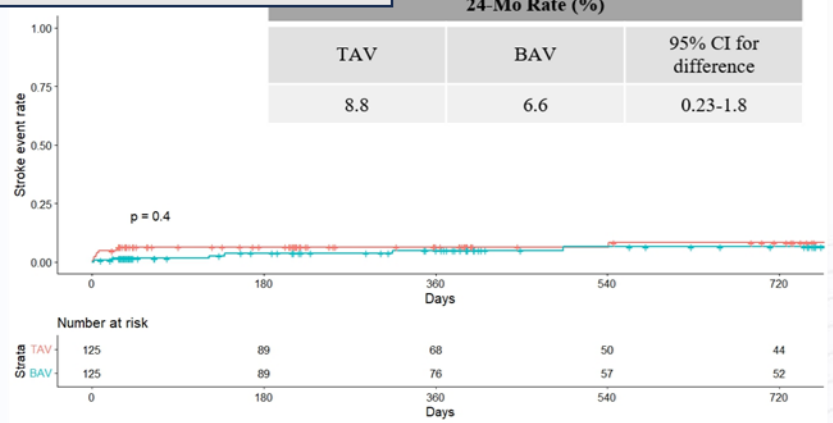
Stroke in Unmatched Cohort

24-Mo Rate (%)		
TAV	BAV	95% CI for difference
6.3	6.58	0.35-1.89



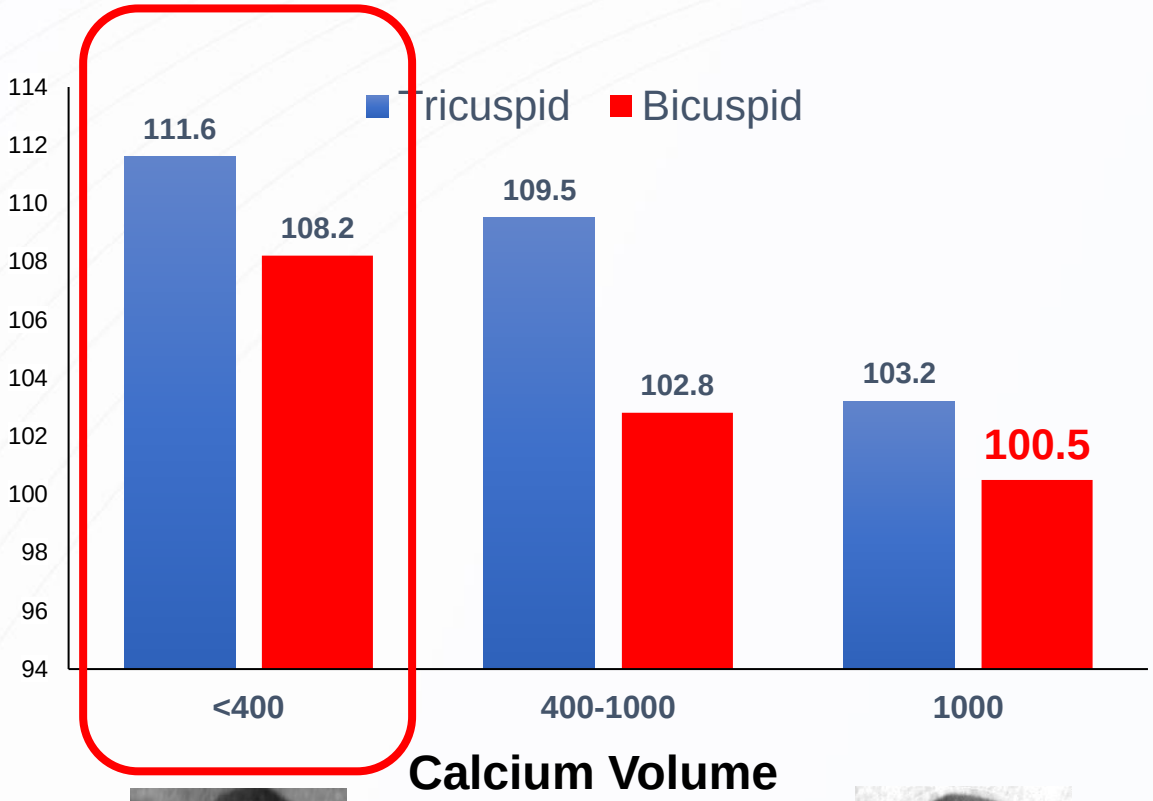
Stroke in Matched Cohort

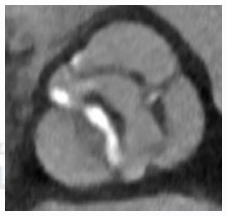
24-Mo Rate (%)		
TAV	BAV	95% CI for difference
8.8	6.6	0.23-1.8

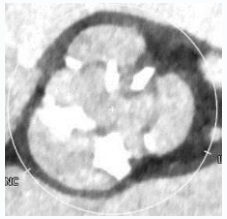


ASAN TAVR Registry

Initial S3 Oversizing By Calcium Volume





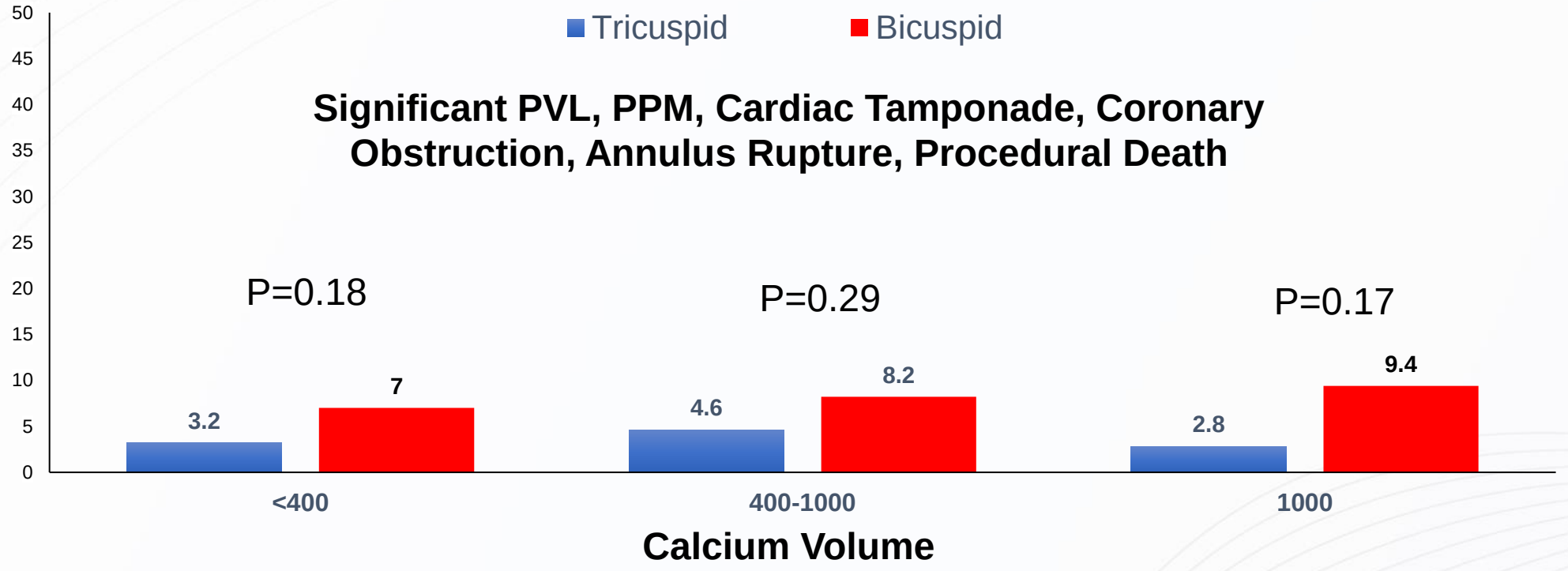


- *Bicuspid AS*
- *Heavy Calcification*
- *High Risk Morphology*

0 % or less Oversizing

ASAN TAVR Registry

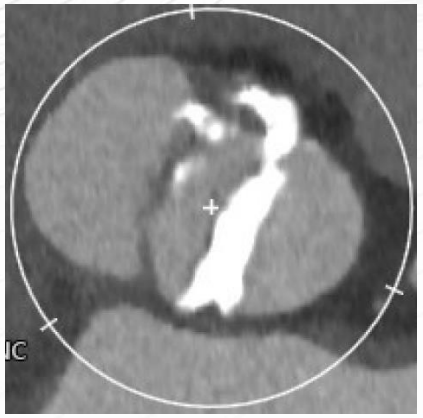
Procedural Complications By Calcium Volume



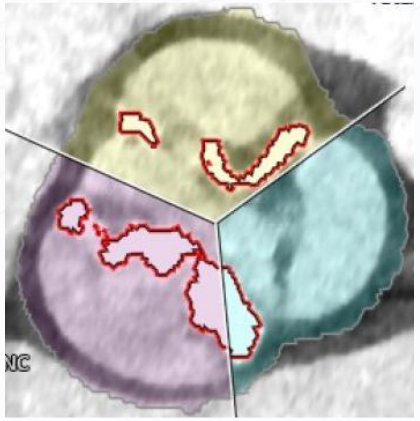
ASAN TAVR Registry

Undersizing is Effective and Safe

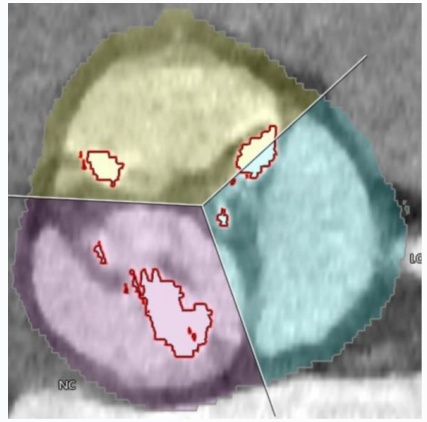
Annulus Area
589 mm²

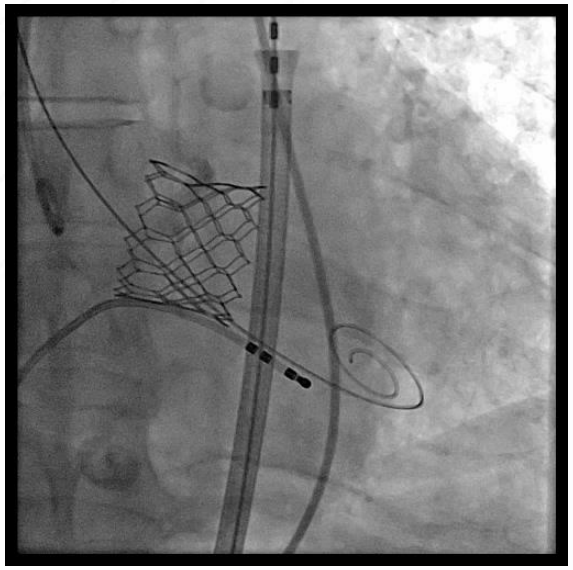


500 mm²

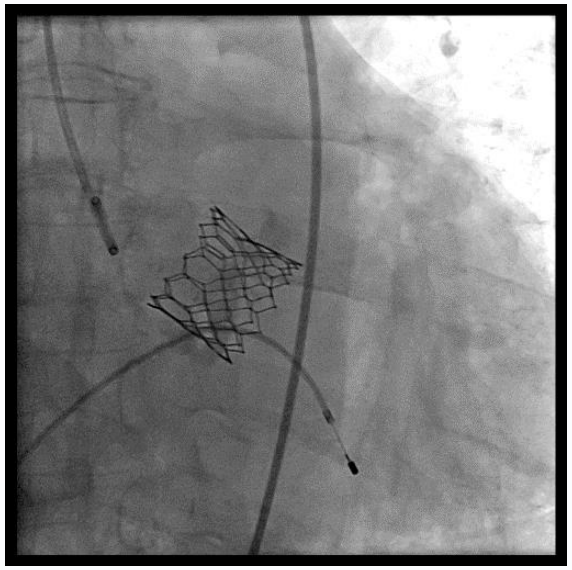


710 mm²

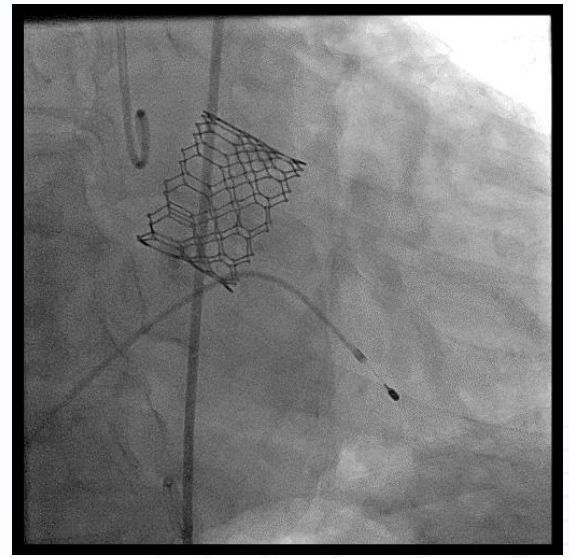




S3 29mm with -3cc Underfill
(2% Oversizing)



S3 26mm with 2 cc underfilling
(4% Undersizing)



S3 29mm
(9% Undersizing)

Conclusion

1. Bicuspid AS has distinct clinical and phenotypical characteristics: younger age, more severe AV calcification, and associated aortopathy.

2. The incidence of paravalvular leakage is increased compared to tricuspid aortic valve cohorts undergoing TAVR.

3. Caution should be exercised regarding aortic injury.

4. TAVR for bicuspid AS is not associated with an excess risk of mortality and stroke.

5. S3 implantation on bicuspid AV is not significantly different from S3 implantation on tricuspid AV.

6. However, there is a need to establish criteria for selecting patients with bicuspid AS who can be successfully treated with TAVR, similar to the Echo-Score used for rheumatic MS.