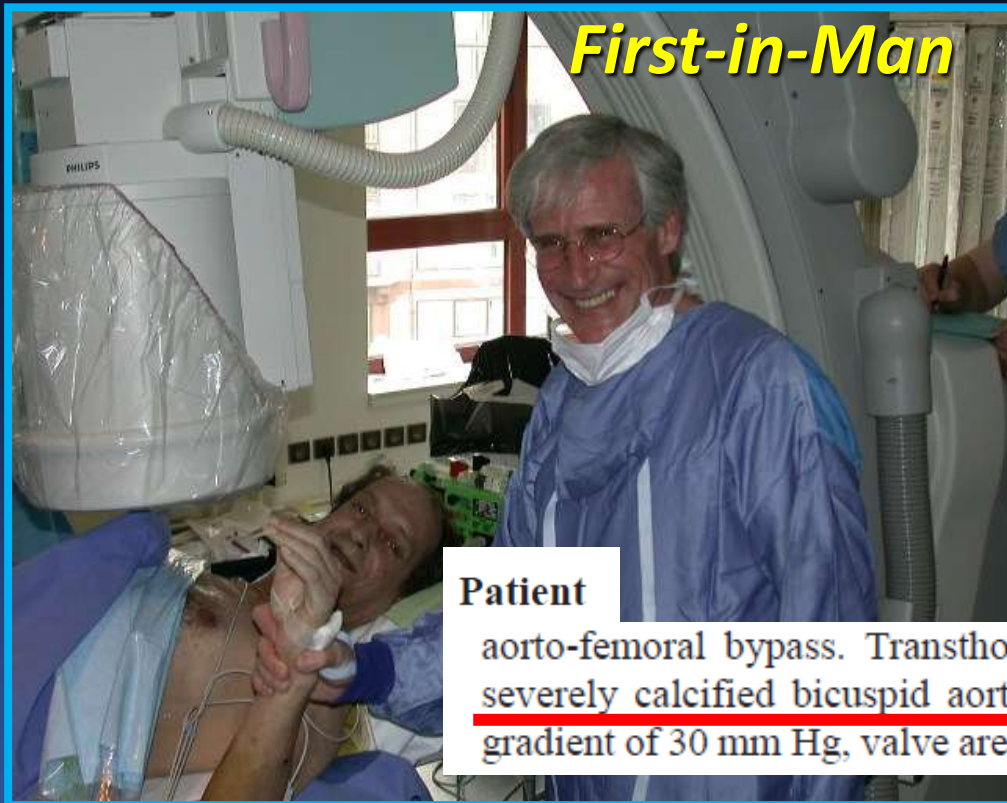


TAVR for Bicuspid AS: Optimal Sizing & Valve Selection

Jung-Min Ahn, MD

Division of Cardiology, University of Ulsan College of Medicine,
Heart Institute, Asan Medical Center, Seoul, Korea

First-In-Man TAVR was done in *Bicuspid AV*



57 years old

Cribier A, et al. Circulation. 2002;106:3006-3008

Bicuspid AV is **Very Common**

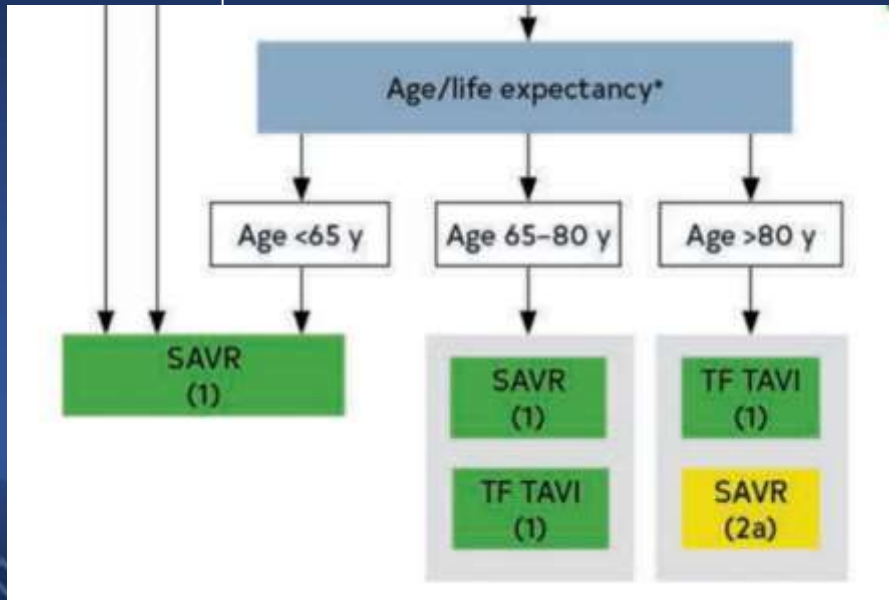
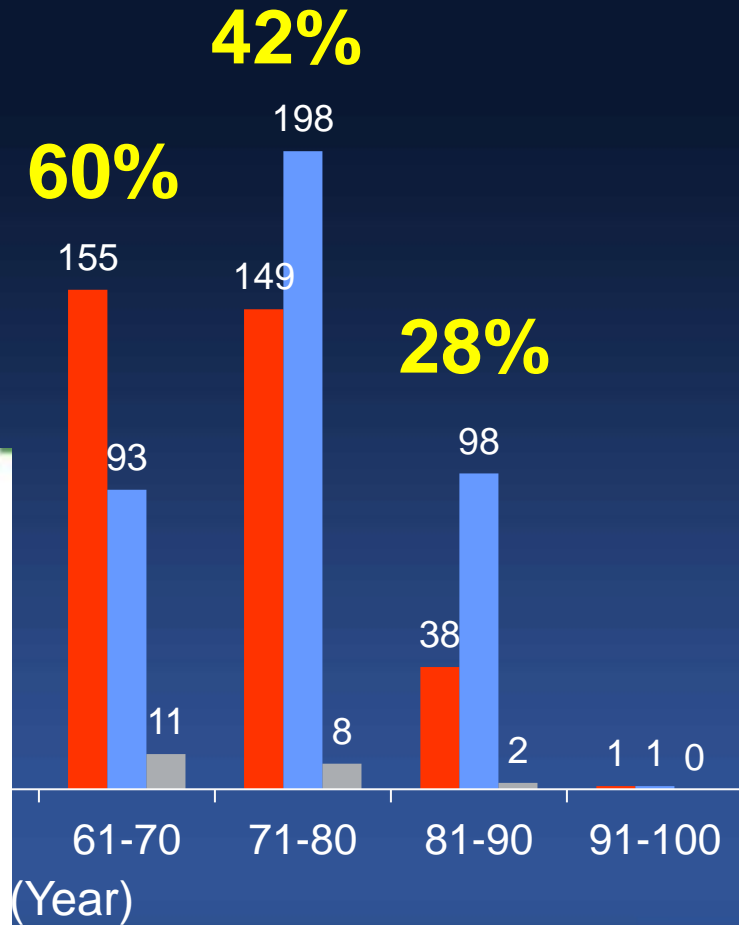
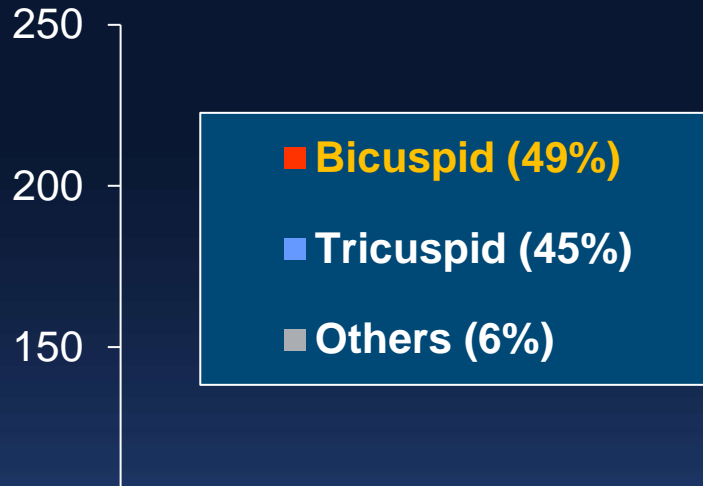
- **1-2%** of the General Population
- **>33%** Have Serious Complications*
- **Aortic Stenosis** Is The Most Frequent Complication

*Valve Complication (AS, AR, infection),
Vascular Complication (Medial Degeneration, Aneurysm, Dissection)

Fedak P W et al. Circulation. 2002;106:900-904

Incidence of Bicuspid AV in isolated AVR

584 men and 348 women from USA (Baylor University)

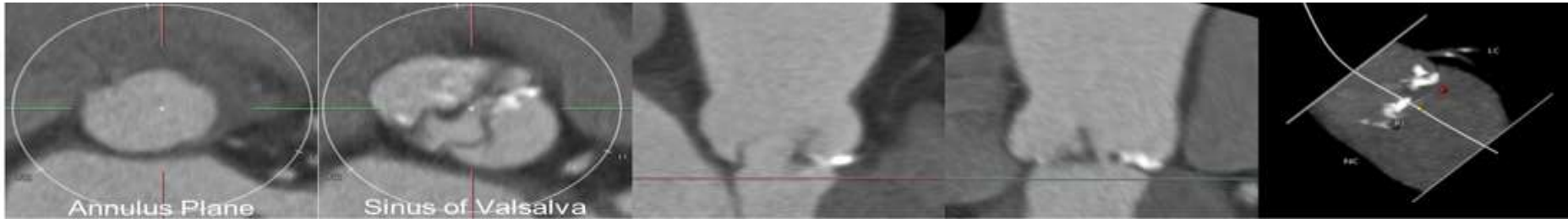


Journal of the American College of Cardiology 2005;111:920-925



Concerns of Bicuspid AS TAVR

Small Calcification



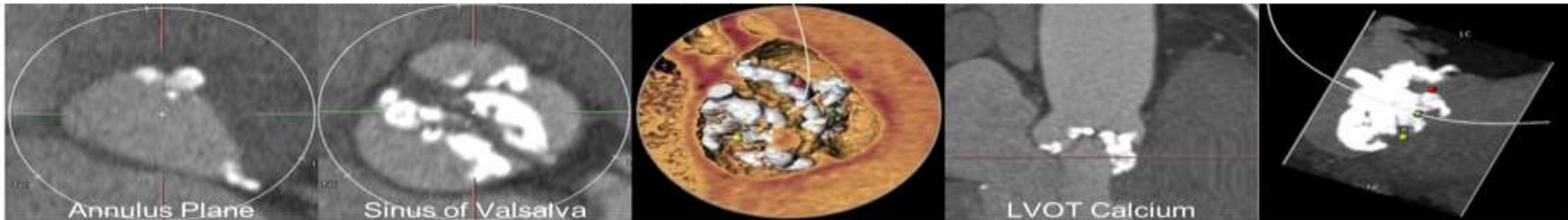
Anatomical Concern

- Annular eccentricity
- Asymmetrical heavy valve calcification
- Unequally-sized leaflets
- Calcified raphe
- Concomitant aortopathy
- Lack of Standardized Annulus Measurement

Procedural Concern

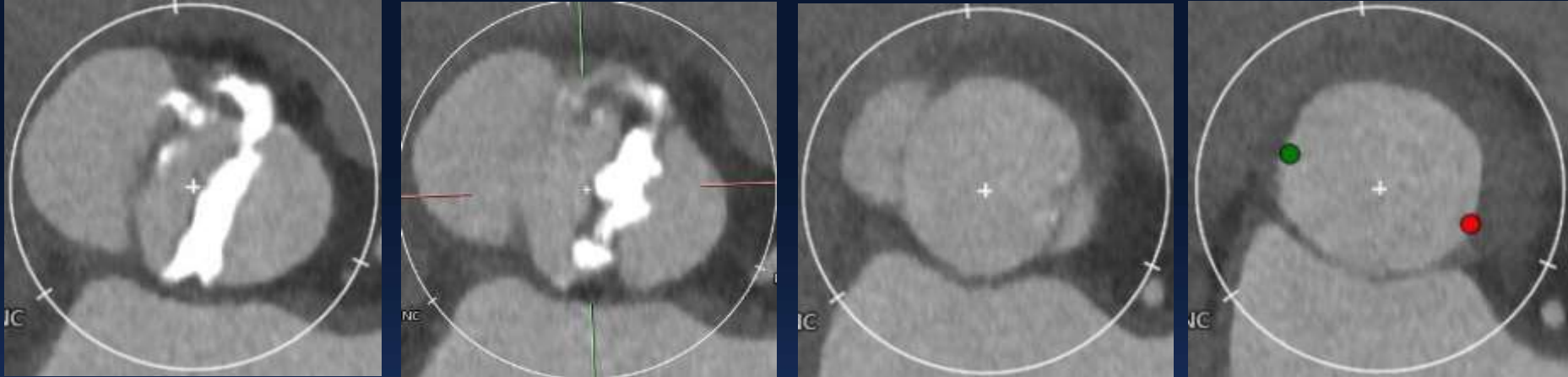
- Elliptical deployment
- Impaired Bioprosthesis Durability
- Residual Aortic Regurgitation
- Annulus Rupture
- Coronary Obstruction
- Aortic Complication

LVOT Calcification



Case: M/79 with Bicuspid AS

Annulus Plane



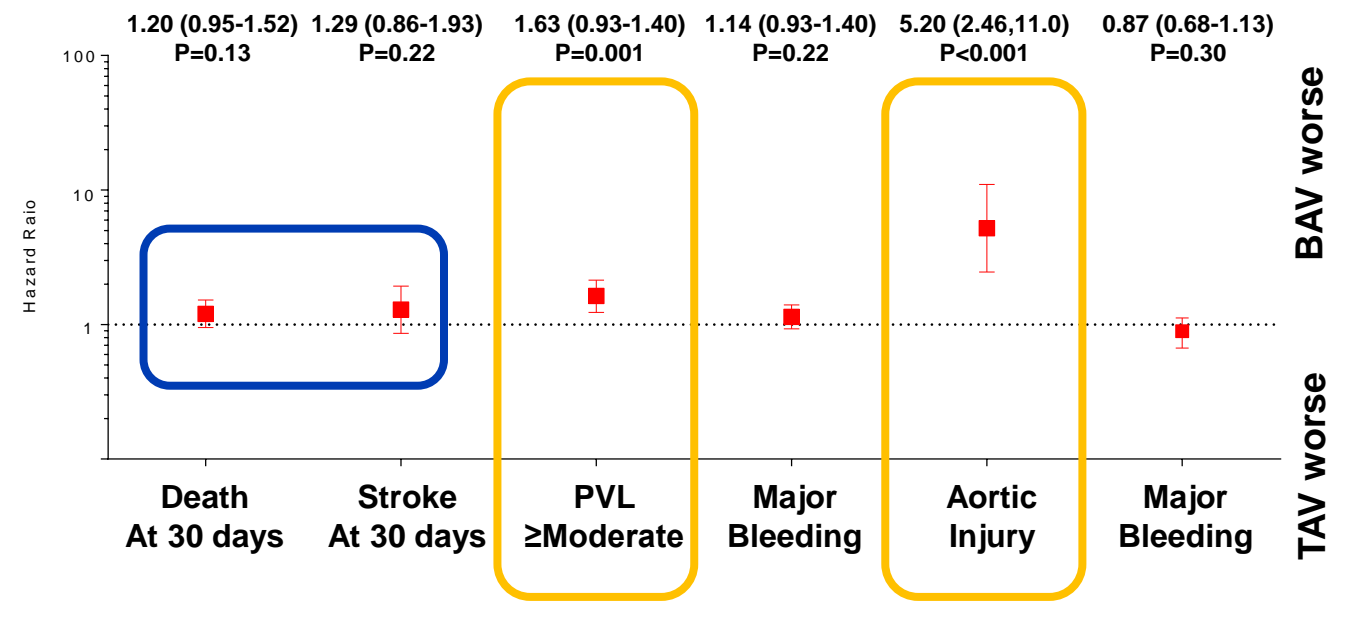
Practical Issues

- Feasible?
- Which Type of Valves?
- How To Select Optimal Size?
- Pre- and Post Balloon?
- Device Underexpansion
- Associated Aortopathy

	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 ²⁶	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																		3 (4%)
Liu XB ³¹	2015	15																		1 (6.7%)
Watanabe Y ³³	2015	11																		1 (4.0%)
Arai T ³⁵	2017	10																		N/A
Sannino A ³⁸	2017	88																		0
Yoon SH ⁷	2017	546																		2 (2.3%)
Liao YB ²¹	2018	87																		27 (3.7%)
Aalaei-Andabillil SH ³⁷	2018	32																		8 (3%)
De Biase C ³⁹	2018	83																		16 (2.9%)
Kim WK ³⁹	2018	144																		10 (1.8%)
Nagaraja V ⁴⁰	2018	359																		3 (3.1%)
Xiong TY ²²	2018	67																		4 (2%)
Mangleri 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	

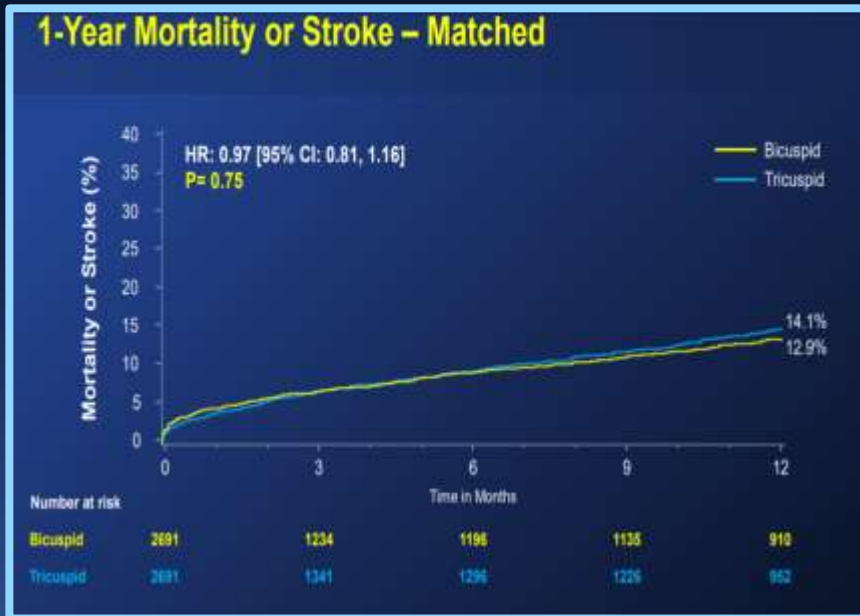
12,462 Patients From 18 Studies

Bicuspid vs. Tricuspid



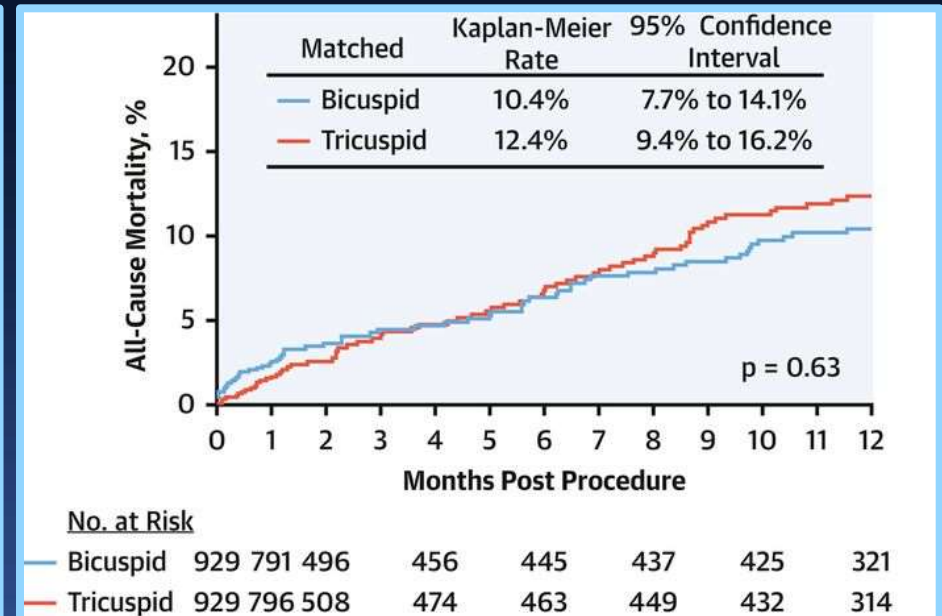
STS/ACC TVT Registry

Sapien 3



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

Evolut R

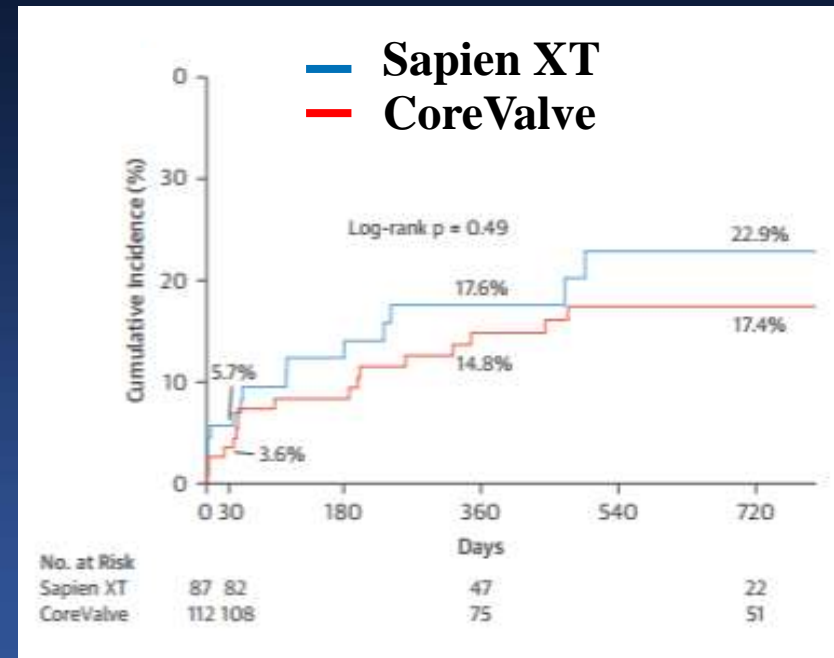
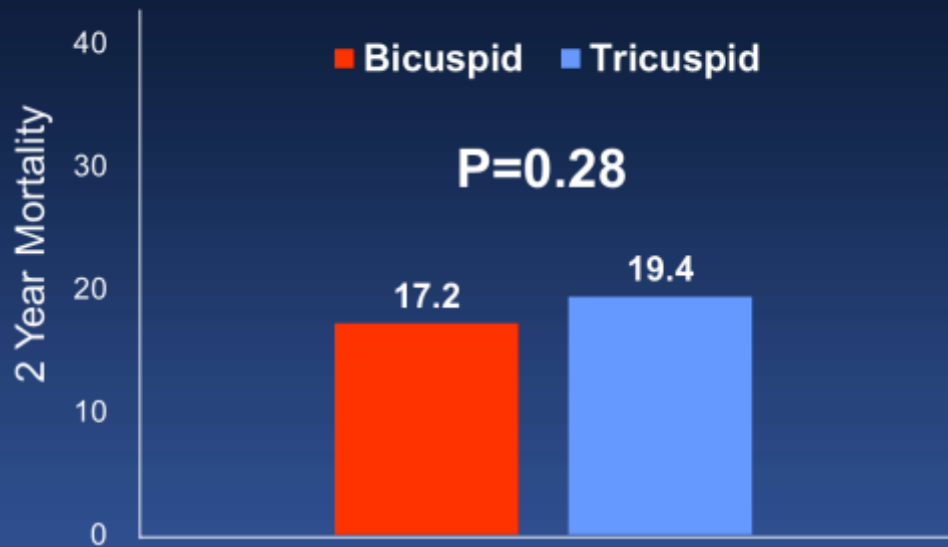


JACC CVI 2020 May 23;S1936-8798(20)30763-9

Valve Type

2 Year Mortality of TAVR

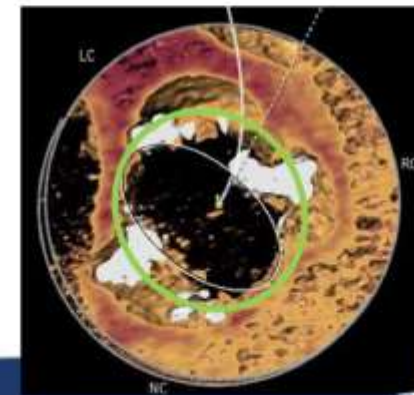
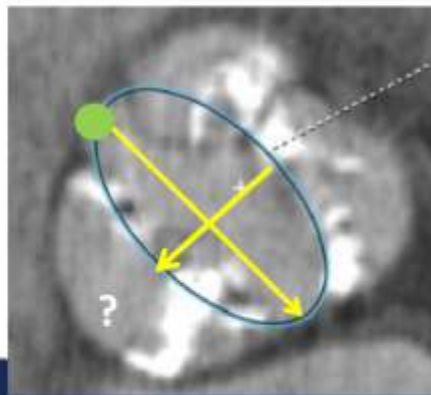
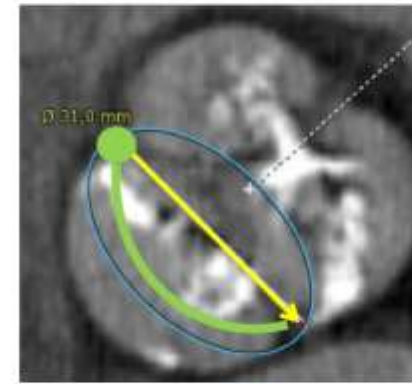
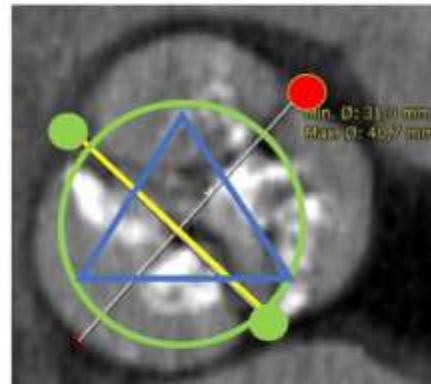
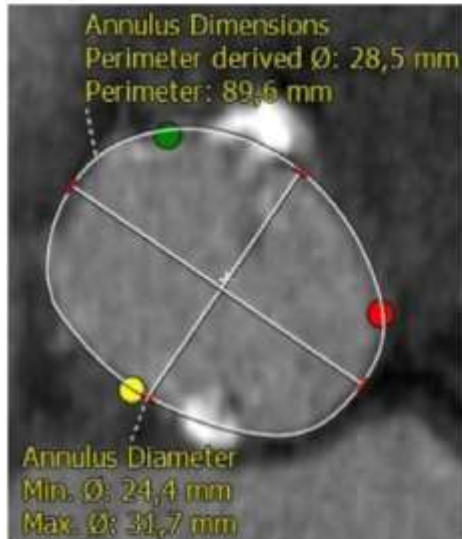
Higher Aortic Root Injury
➔ Balloon Expandable
Higher PVL
➔ Self Expandable



Yoon SH, et al. J Am Coll Cardiol. 2017 2017 Mar 15. pii: S0735-1097(17)36041-2

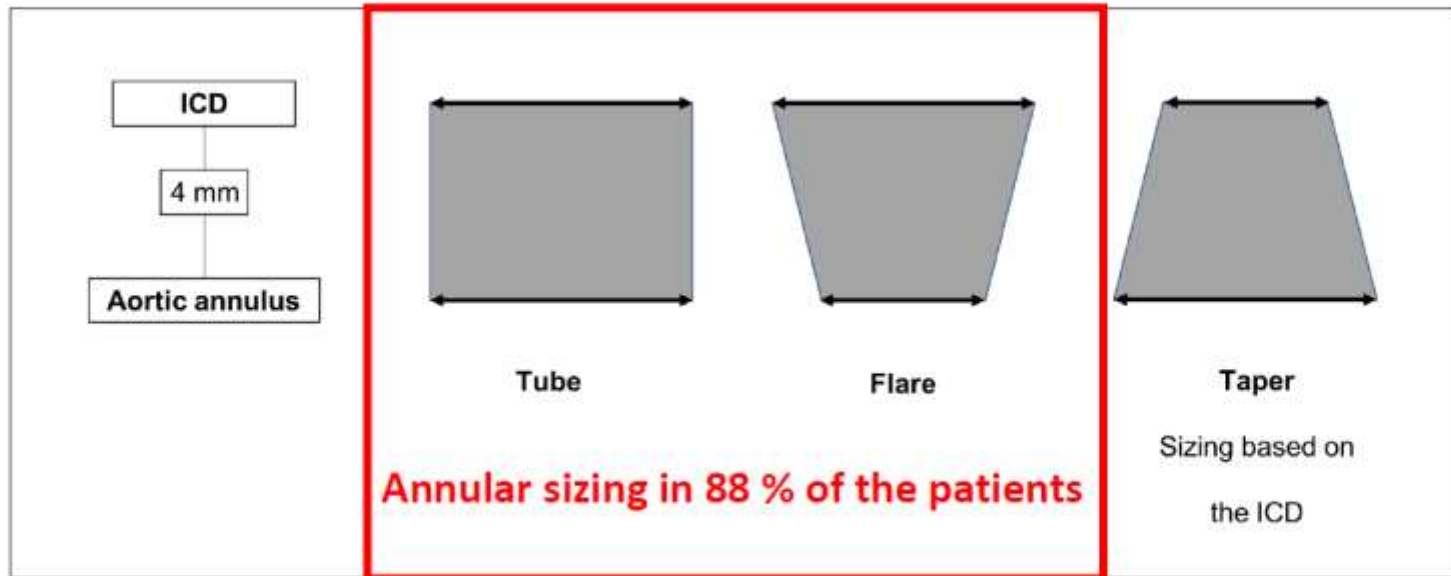
Device Sizing

Various sizing methodologies are proposed for TAVR in BAV



Device Sizing

Sizing according to the landing zone configuration



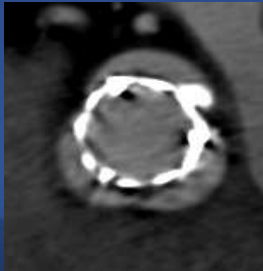
BABARD Registry (N=96, S3 65, Lotus 10, Evolut R 21)

Device Sizing

Annulus Sizing

S3

Don't Do
Oversizing Too
Much, ~5%

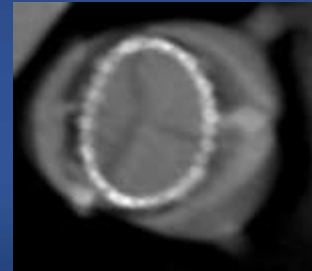


BE “remodels”
the annulus

Supra-annulus Sizing

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

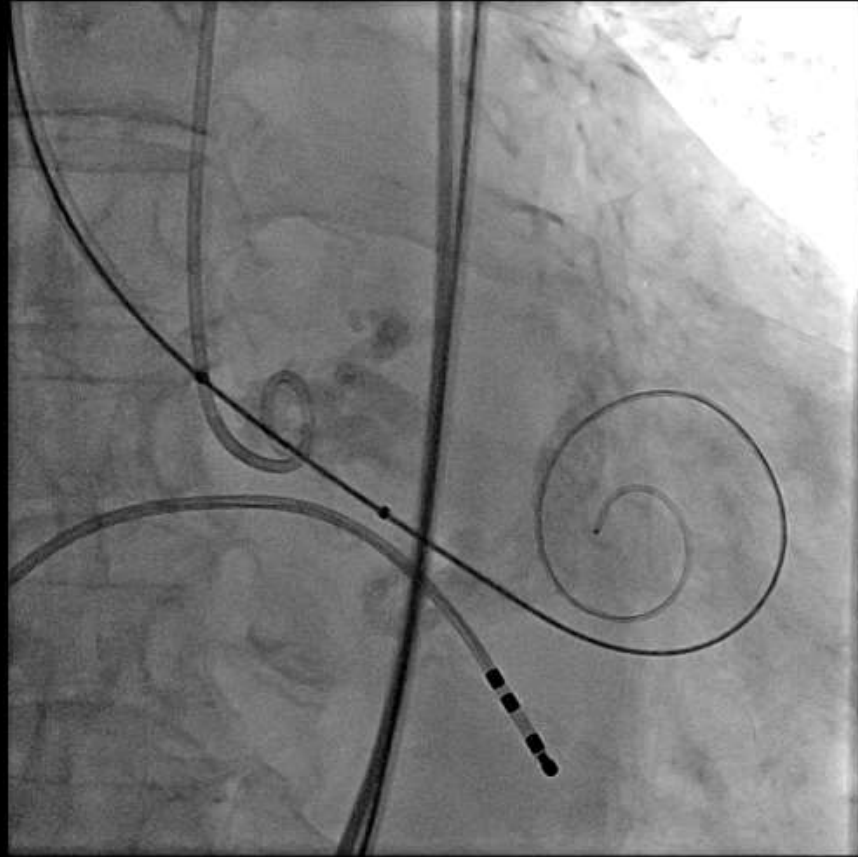
Evolut R/Lotus



The annulus
“remodels” SE

Balloon Aortic Valvuloplasty

More Often in Bicuspid AS

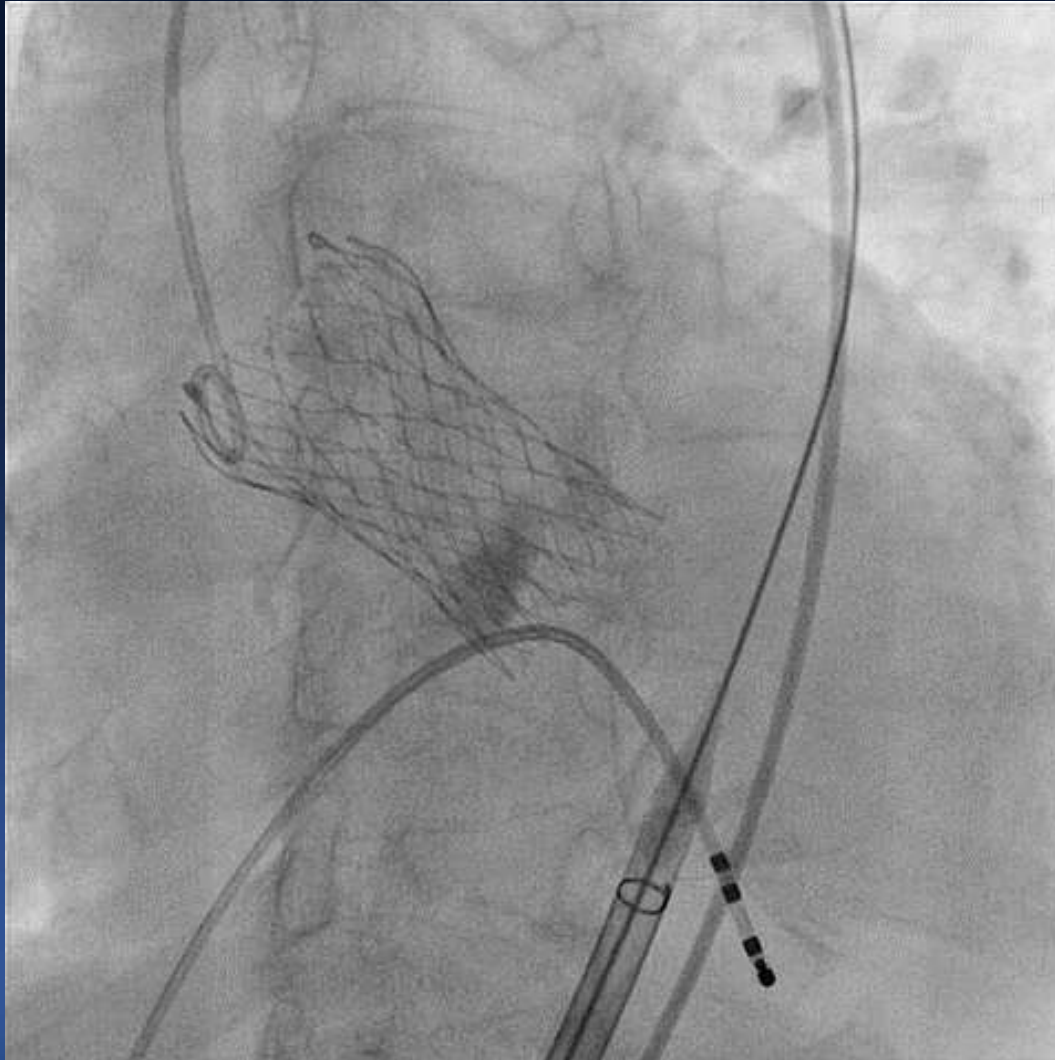


Goal

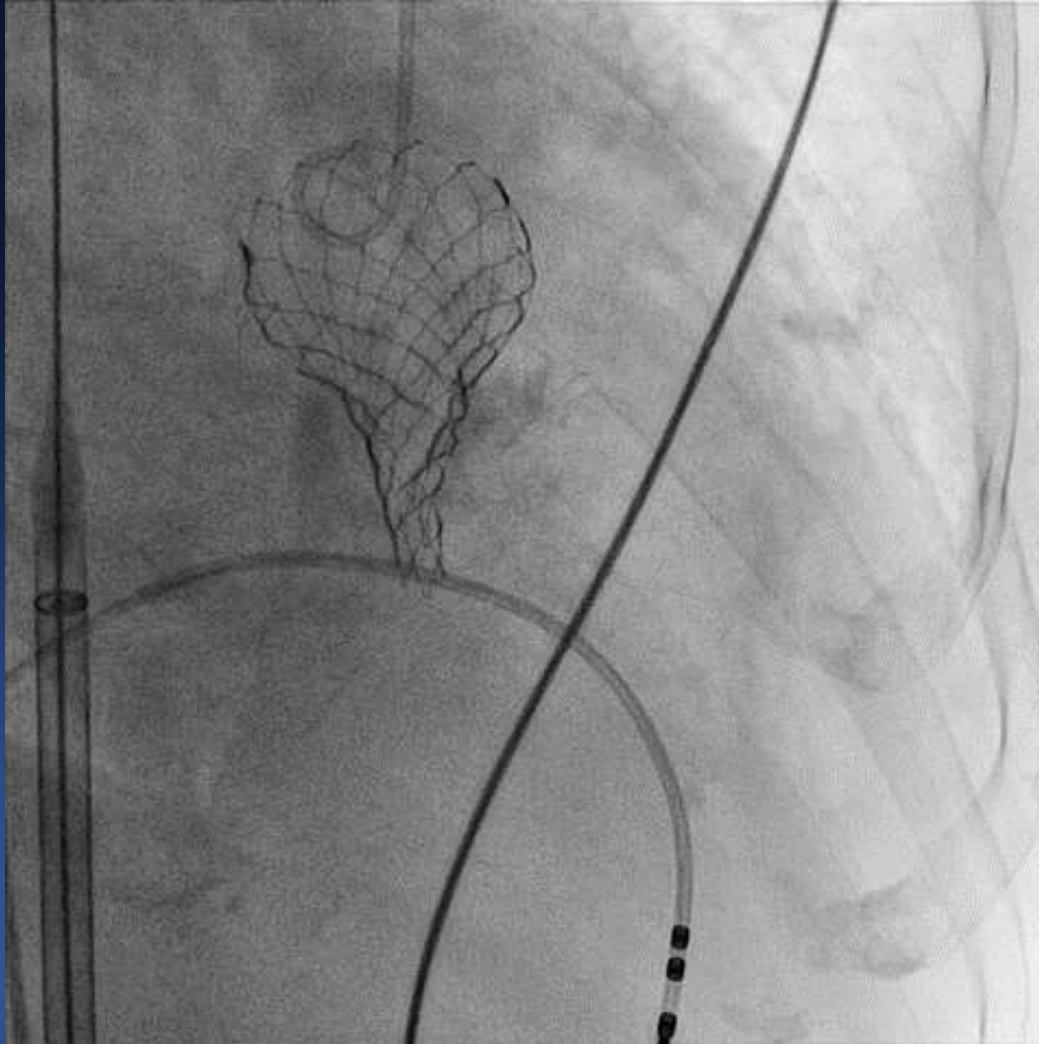
- 1) To facilitate device delivery
- 2) To confirm the device size
- 3) To assess the risk of coronary obstruction

To avoid the risk of aortic complex injury, relatively small balloon should be selected based on the CT measurement of aortic valve complex.

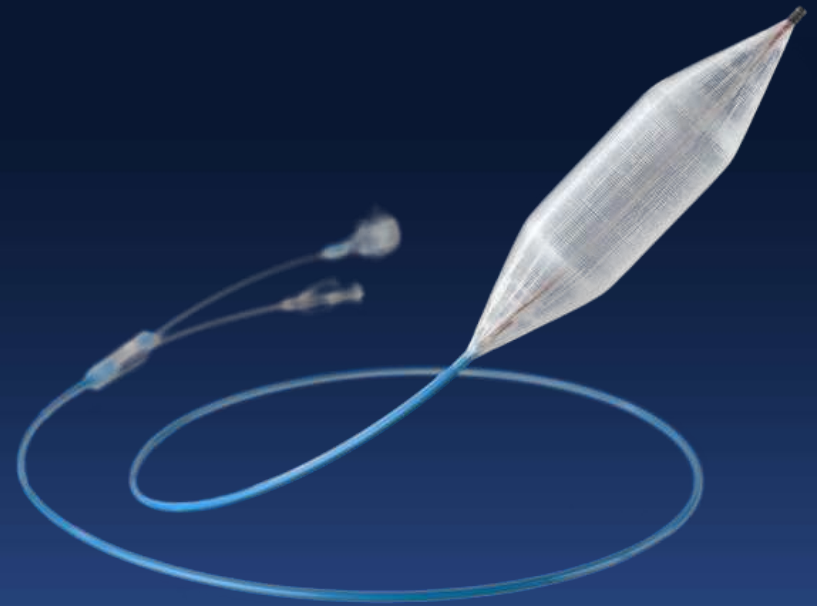
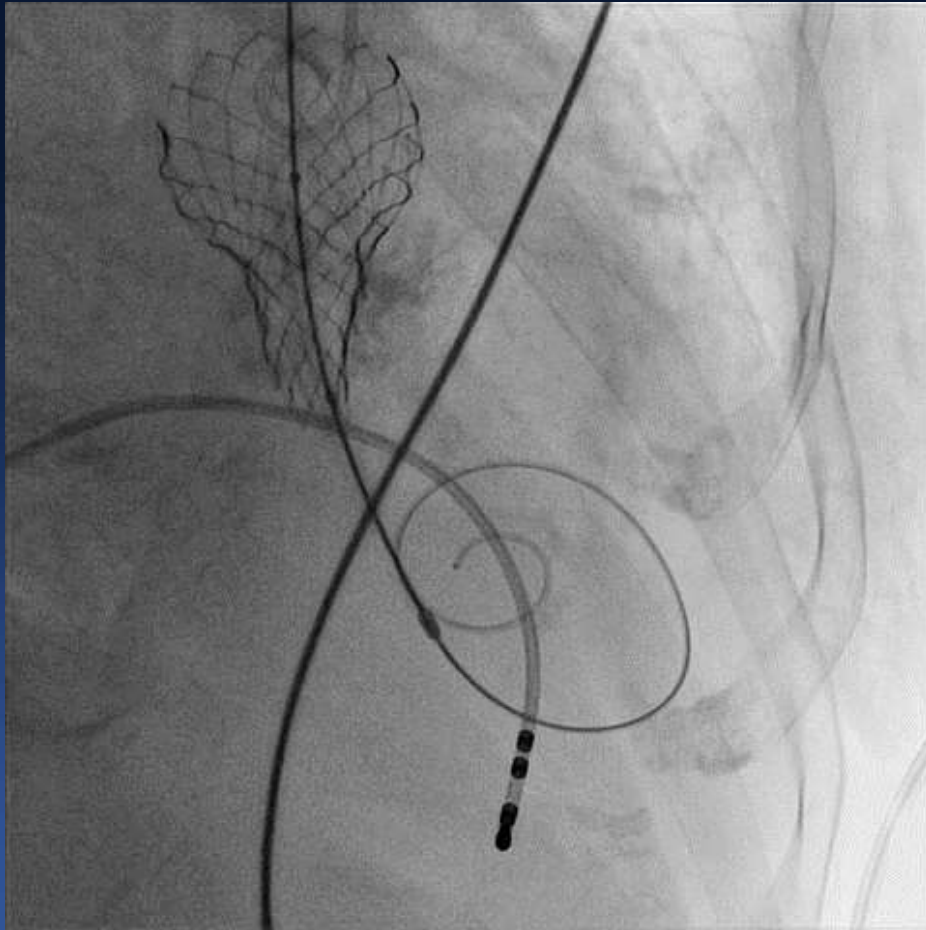
Post-Implantation



RAO Projection



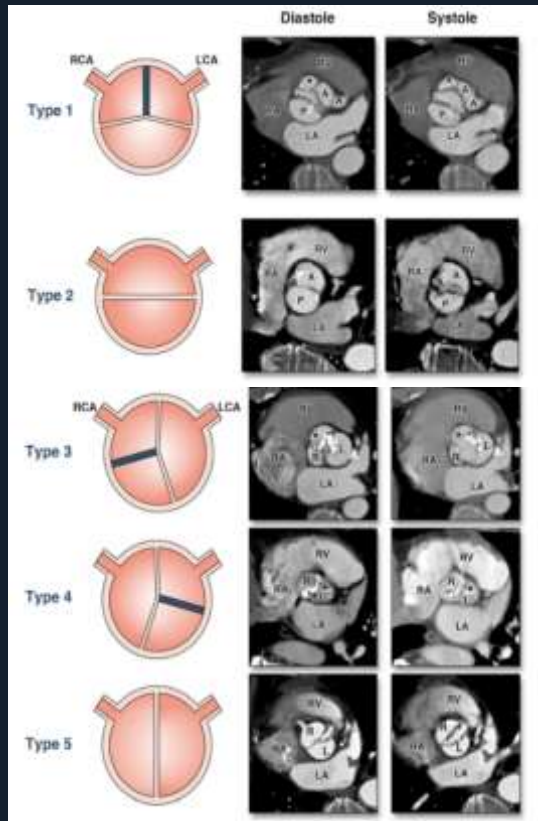
Post-Ballooning



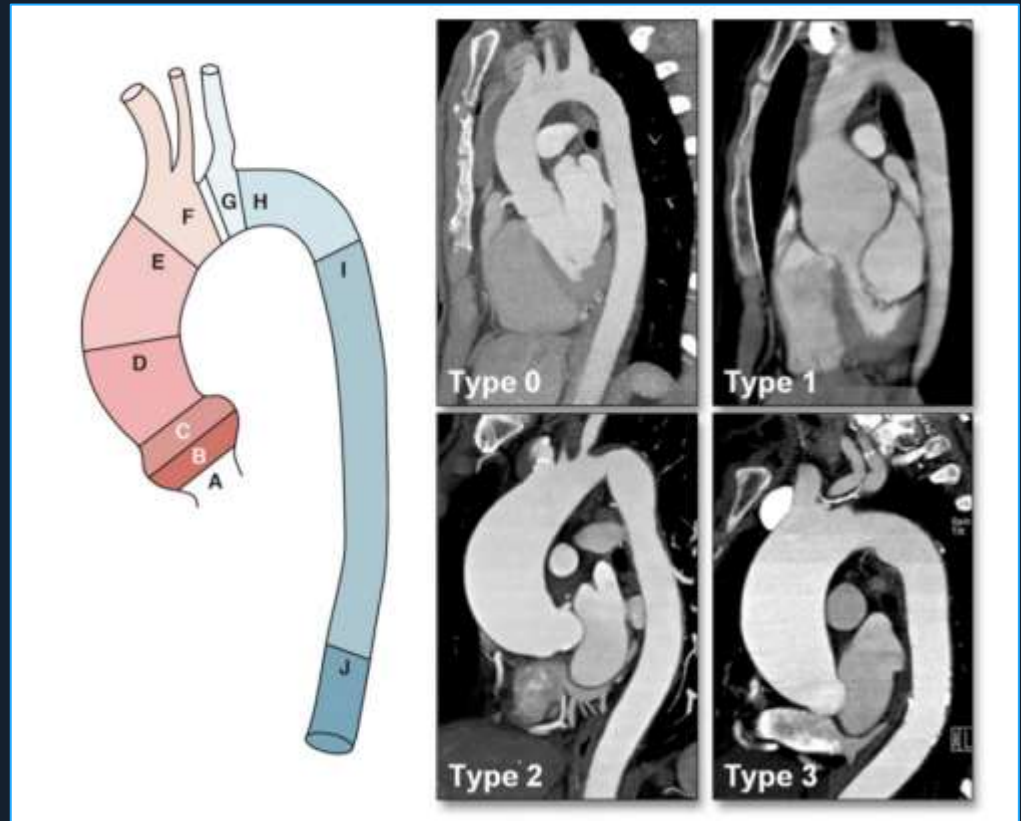
**ATLAS[®] PTA Dilatation Catheter
(20 mm x 4 cm)**

Spectrum of BAV Disease

Aortic Valve Morphology



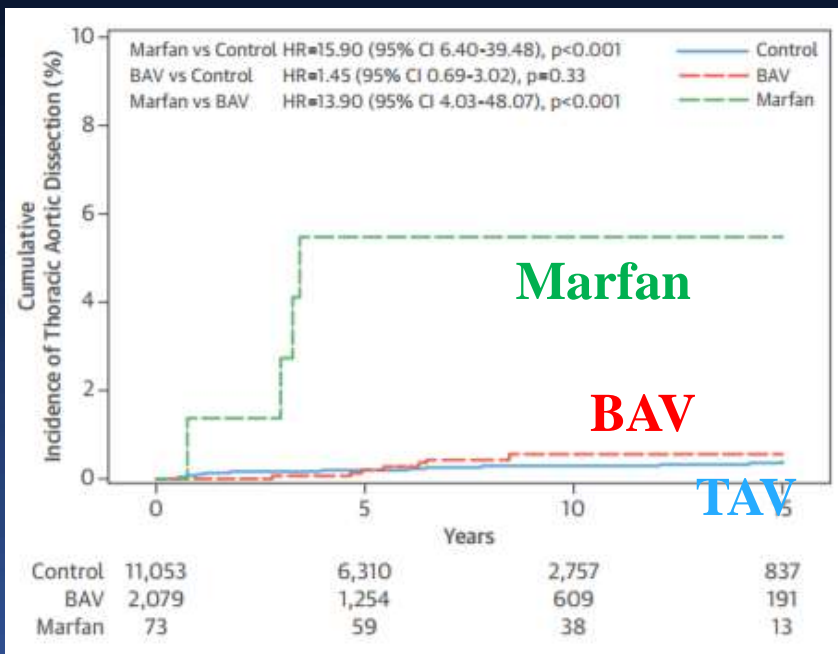
Combined Aortopathy



Kang JW, Song JK et al. *JACC: Cardiovascular Imaging* 2013 Feb;6(2):150-61

BAV Aortopathy

Risk Aortic Dissection After SAVR



Rate of Ao Dilatation After SAVR

Mm/m²/year

P=0.4

0.14

0.16

BAV

TAV

Aortic Dilatation (Tubular Portion)

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

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

Associated BAV Aortopathy

Higher Surgical Risk
Very Old Age



TAVR

Lower Surgical Risk

Aortic root and Ascending Aorta Size
> 5.0-5.5cm*

Yes



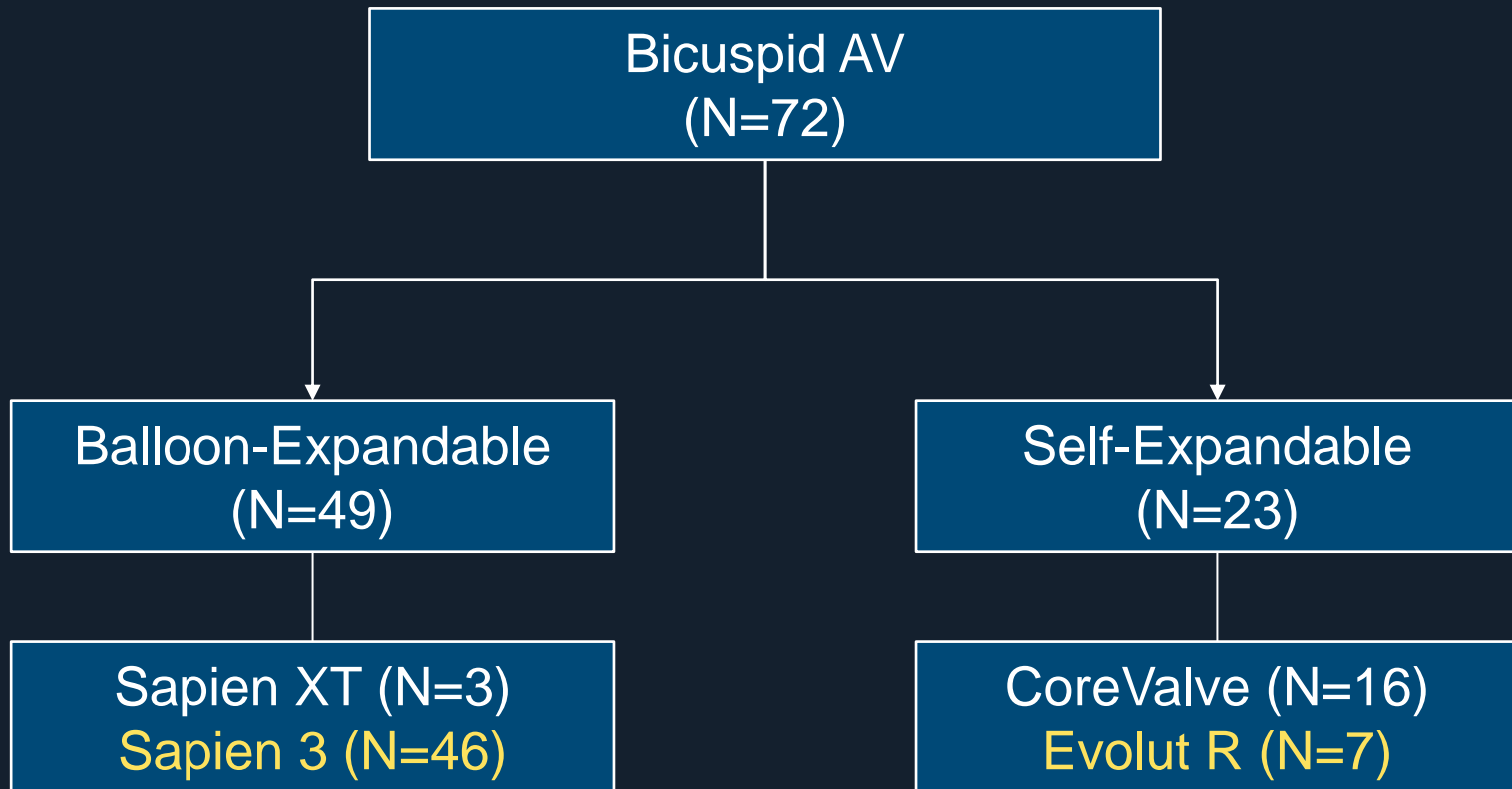
SAVR +
Aorta Surgery

No

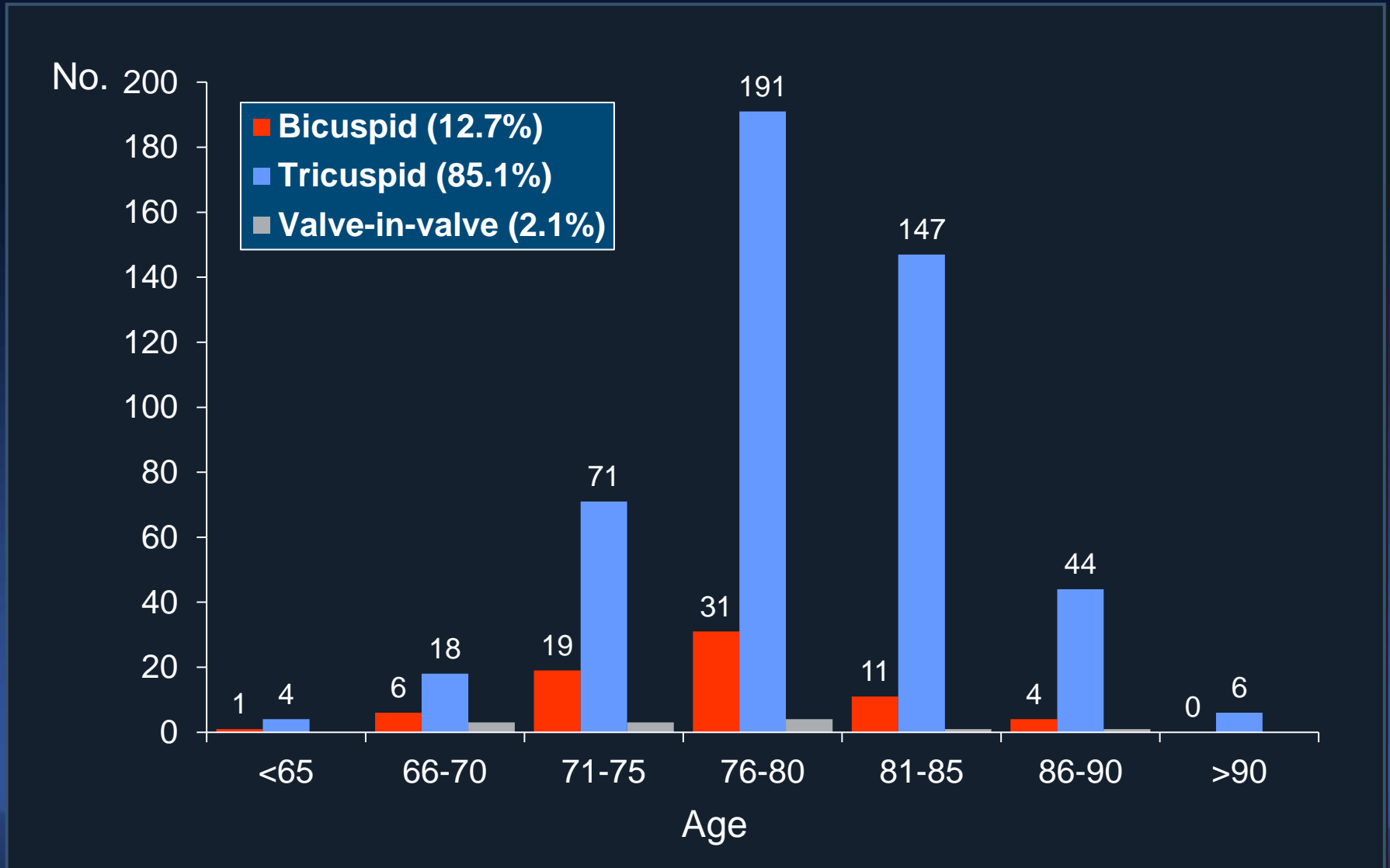


Consider TAVR
If Indicated

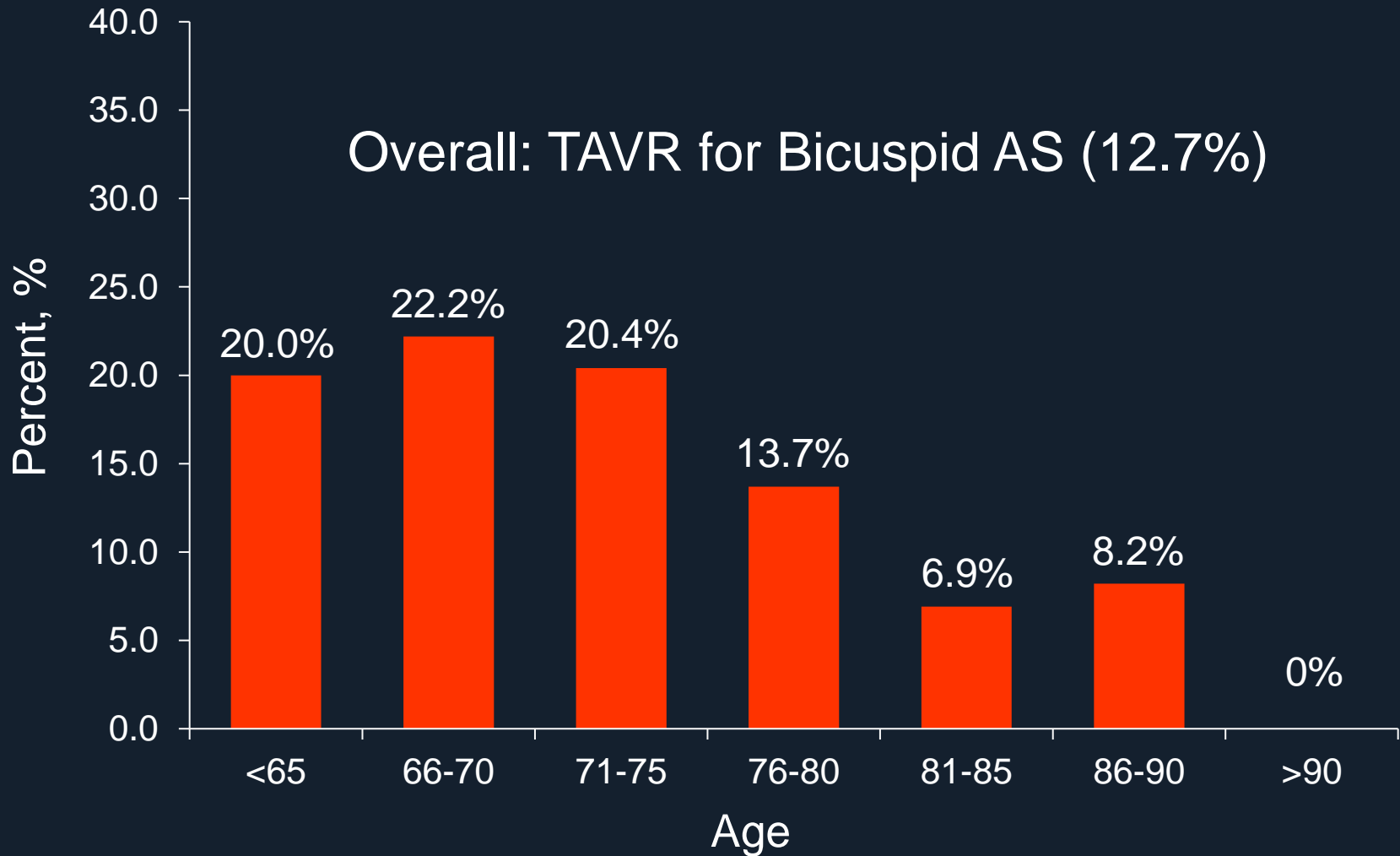
ASAN TAVR Registry (2011-2019)



Age Proportion of TAVR for Bicuspid AS



Proportion of TAVR for Bicuspid AS



Type of Bicuspid AV*

Type 0 24%



AP type=6



LR type=11

Type 1 76%
1 Raphe



LR fusion=46



RN fusion=6



NL fusion=1

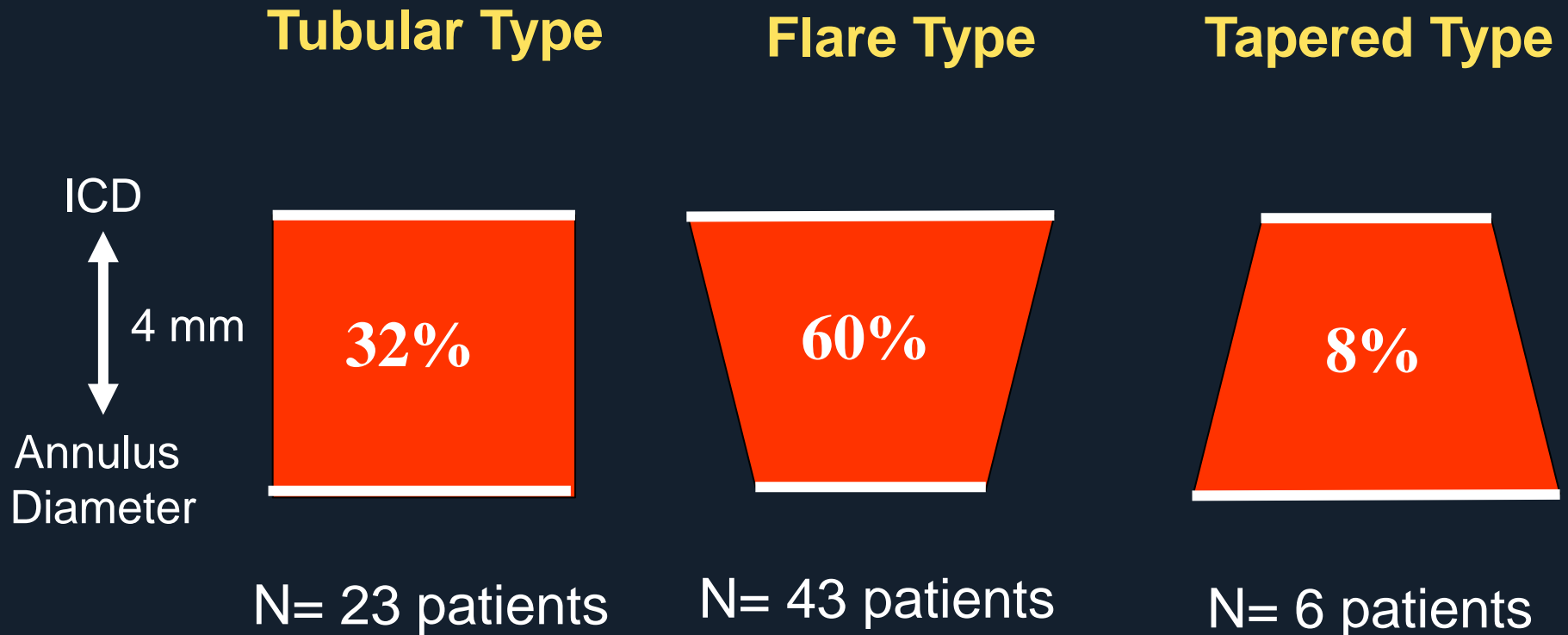
Type 2
2 Rapses



Type 2=0

*Sievers HH et al. J Thorac Cardiovasc Surg 2007;133:1226-33.

Type of Bicuspid AV*



Tubular type: perimeter derived annulus diameter/ICD ratio 0.99-1.1

Tapered type: perimeter derived annulus diameter/ICD ratio >1.1

Flared type: perimeter derived annulus diameter/ICD ratio <0.99

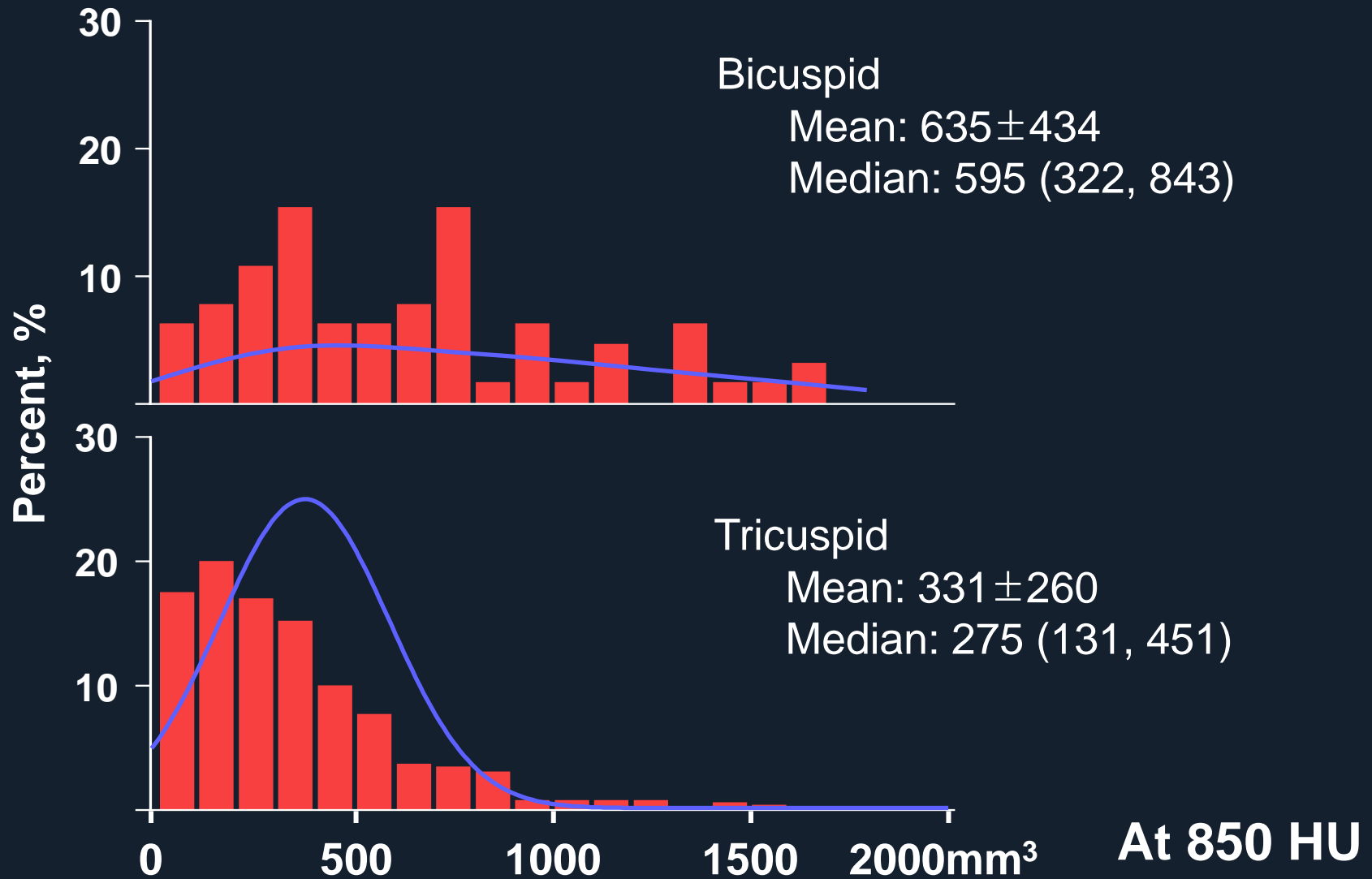
Baseline Characteristics

	Bicuspid AS (N = 72)	Tricuspid AS (N = 493)	P value
Age	77.0±5.4	79.2±5.2	0.001
Gender (Male)	68.2%	47.3%	0.001
NYHA Class III/IV	31.8%	43.0%	0.08
Logistic EuroSCORE	9.7±8.4	15.2±12.1	<0.001
STS score	2.7±1.5	4.3±3.3	<0.001
Diabetes Mellitus	18.2%	32.3%	0.02
Hypertension	59.1%	81.5%	<0.001
Previous Stroke	15.2%	12.2%	0.49
Peripheral Vascular Disease	3.0%	5.5%	0.31
Previous PCI	13.6%	30.0%	0.005
Previous CABG	0%	6.1%	0.04
LVEF, %	59.0±9.9	58.5±11.2	0.84

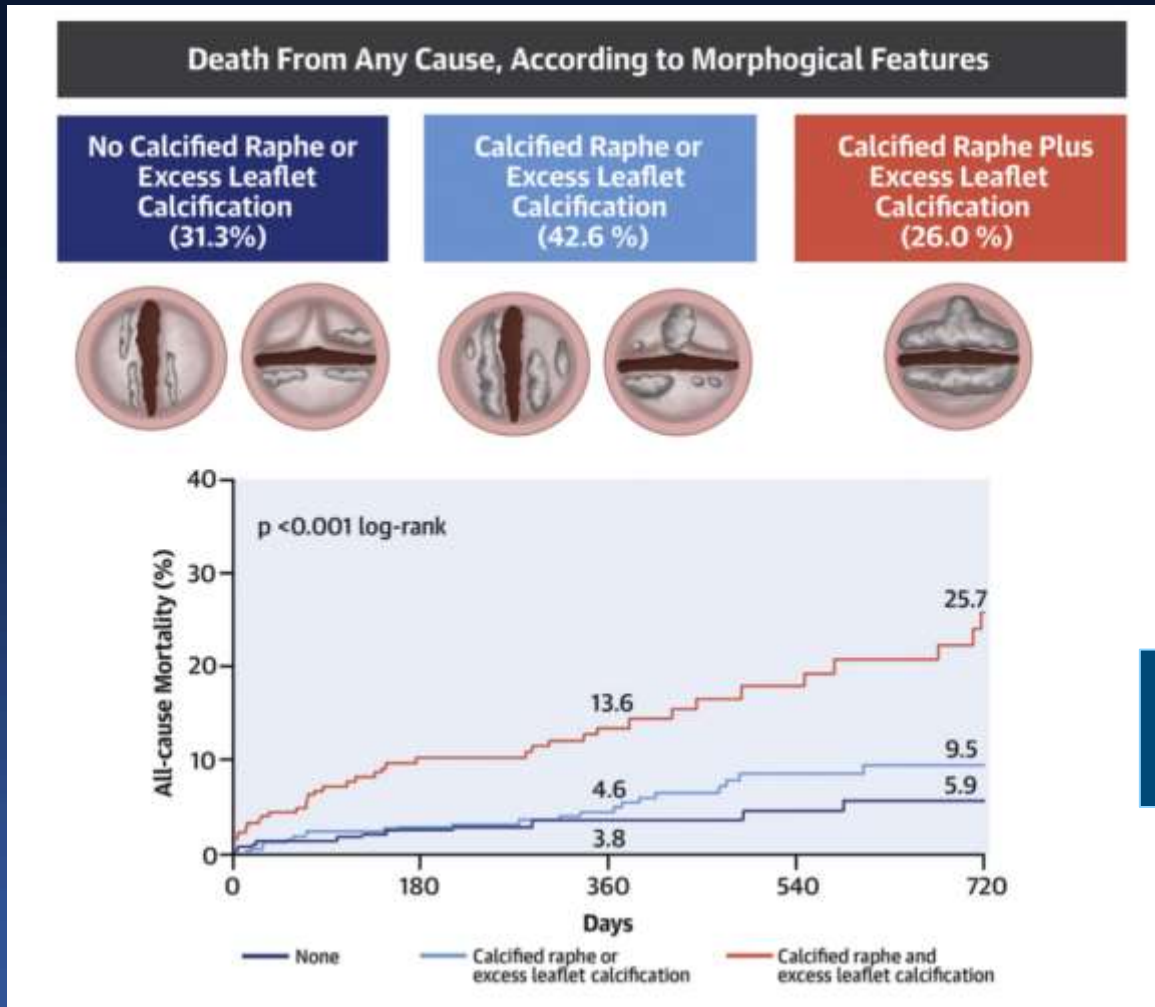
CT Measurement

	Bicuspid AS (N = 72)	Tricuspid AS (N = 493)	P value
Annulus Dimensions			
Area, mm ²	513±101	430±83	<0.001
Perimeter, mm	81.5±8.2	75.0±7.0	<0.001
Mean diameter, mm	25.7±2.6	23.6±2.3	<0.001
Sinus of Valsalva area, mm ²	1004±207	796±179	<0.001
LVOT Area, mm ²	486±122	410±107	<0.001
LM Height, mm	15.2±3.6	12.8±2.4	<0.001
RCA Height, mm	18.7±5.9	16.7±3.1	0.001

Valve Calcification Volume



Calcification Morphology and Outcomes



Severe AV calcification



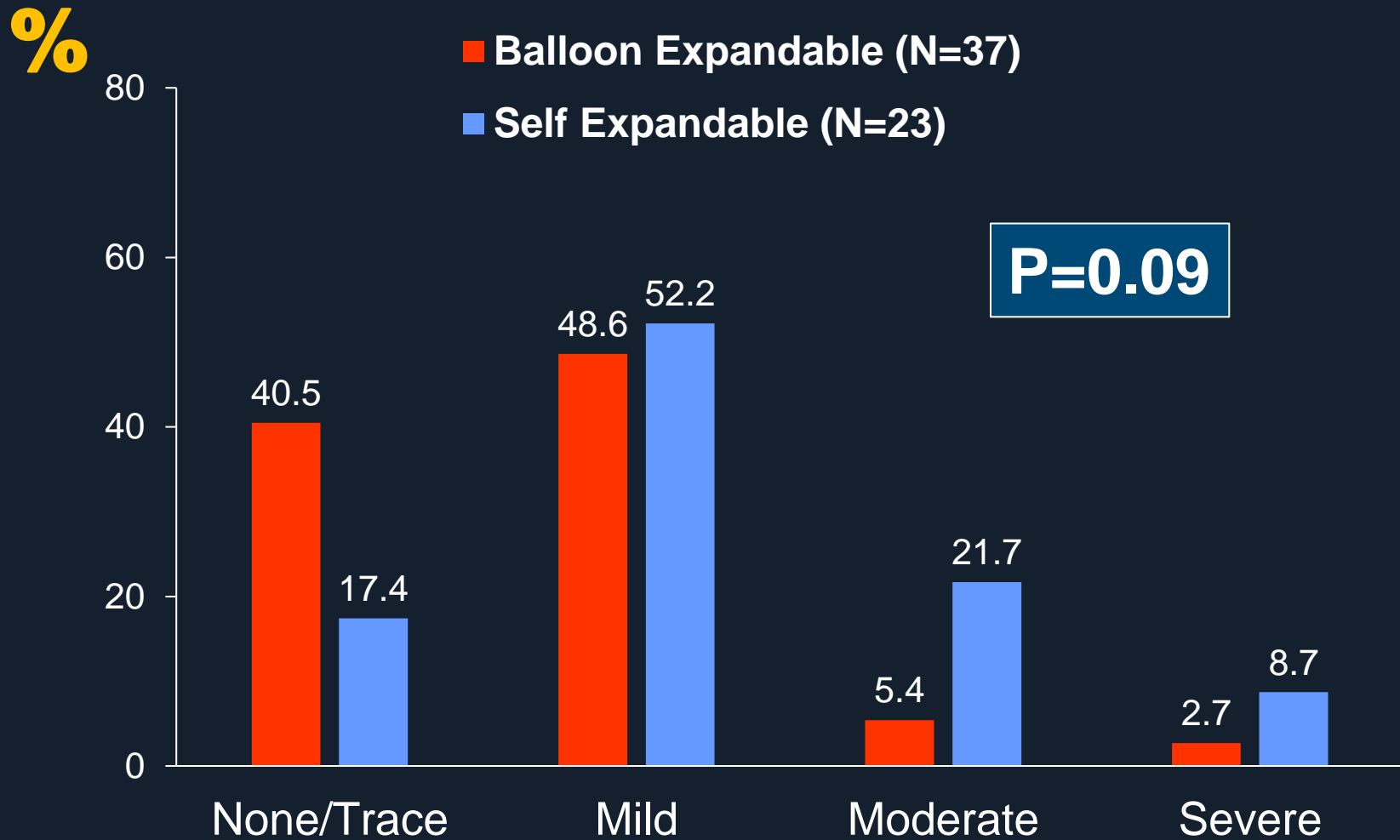
Higher Aortic Root Injury
Higher PVL

J Am Coll Cardiol. 2020;76(9):1018–30

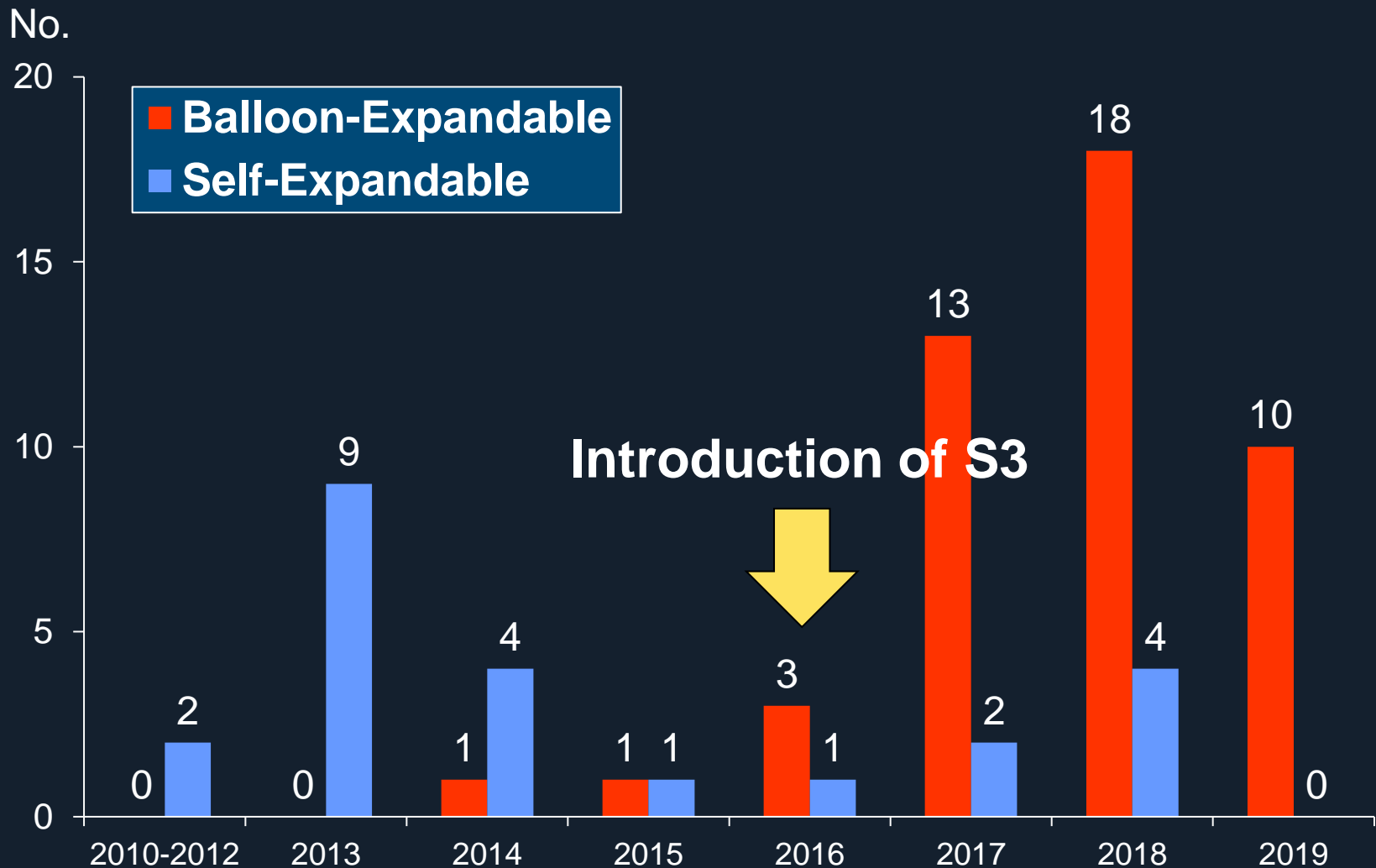
Procedural Outcomes

	Bicuspid AS (N = 72)	Tricuspid AS (N = 493)	P value
Pre-Balloon Valvuloplasty	63 (87.5%)		
Conversion To Surgery	3 (4.2%)	3 (0.6%)	0.006
	Annular rupture: 1 Wire perforation: 1 Valve migration: 1		
Coronary Obstruction	0%	4 (0.8%)	0.58
Annular Rupture	1 (1.4%)	1 (0.2%)	0.24
	Sapien XT: 1		
Second Valve Implantation	2 (2.8%)	11 (2.2%)	0.51
	CoreValve: 2		
New Permanent Pacemaker	7 (11.3%)	41 (9.2%)	0.61
	CoreValve: 2 Evolut R: 2 Sapien 3: 3		
PVL ≥ Moderate	10 (16.7%)	35 (7.9%)	0.055

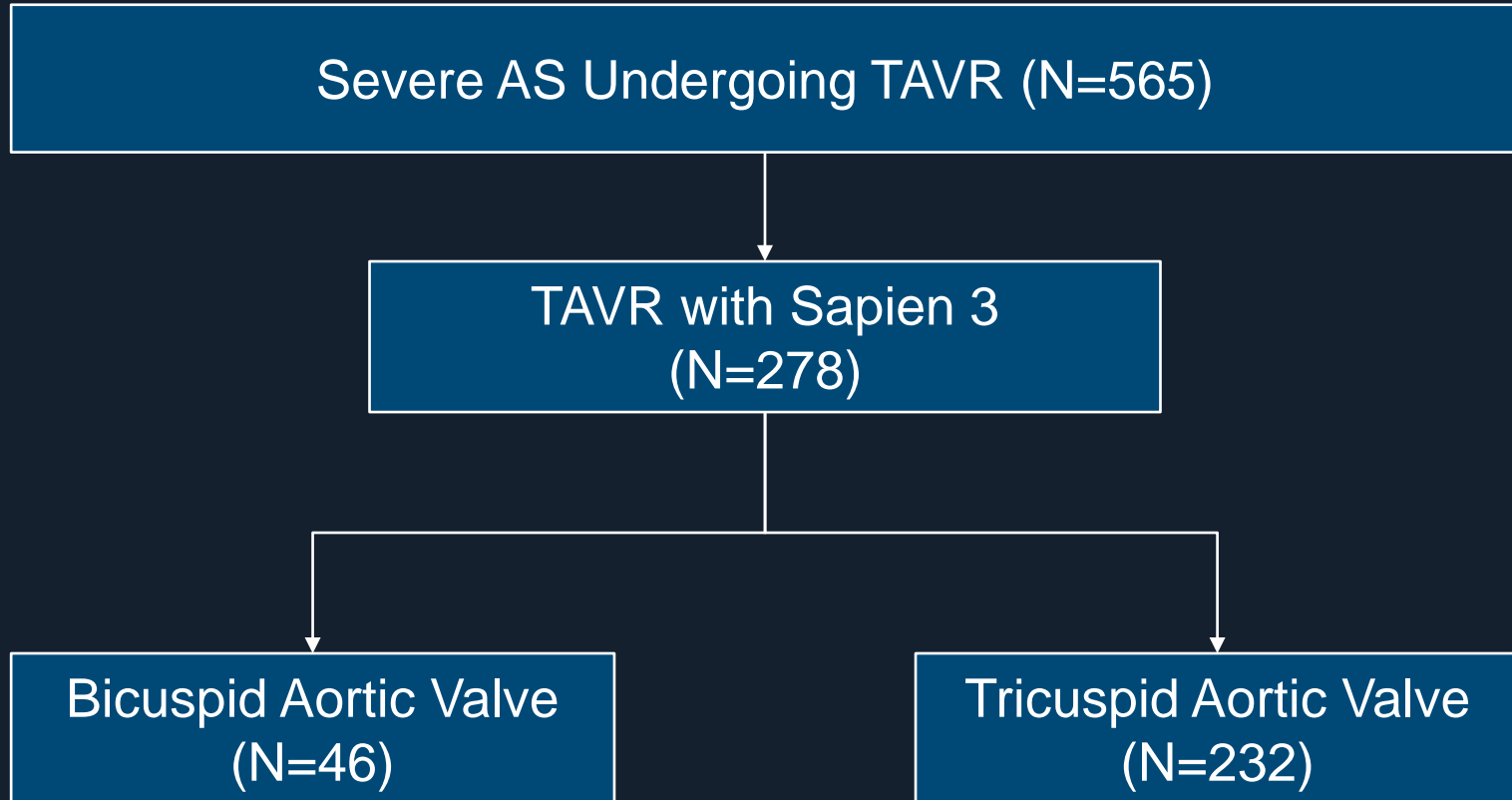
Para-Valvular Leakage



Heart Valve for Bicuspid AS



ASAN TAVR Registry



Procedural Outcomes

Sapien 3 Cohort

	Bicuspid AS (N = 46)	Tricuspid AS (N = 232)	P
Valve Oversizing to annulus, %	107.6±7.7	113.4±6.1	<0.001
Pre-Balloon Valvuloplasty	38 (82.6%)	119 (51.3%)	<0.001
Conversion To Surgery	1 (2.2%)	0%	0.17
	Valve migration: 1		
Coronary Obstruction	0%	3 (1.3%)	0.58
Annular Rupture	0%	1 (0.4%)	0.84
Second Valve Implantation	0%	0%	NA
New Permanent Pacemaker	3 (6.5%)	11 (4.7%)	0.42
PVL ≥ Moderate	4 (8.7%)	4 (1.7%)	0.03
	Valve migration: 1 Raphe calcification: 3		
Post-dilation	22 (47.8%)	79 (34.1%)	0.08

Optimal TAVR for Bicuspid AV

- We need more experiences.
- Case selection is important
- The incidence of paravalvular leakage is increased compared to tricuspid aortic valve cohorts undergoing TAVR, particularly with self-expandable device. Aortic injury should be considered in TAVR with balloon-expandable device.
- TAVR for bicuspid AS is not associated with excess mortality.
- The selected patients with bicuspid AV stenosis would be a candidate of TAVR with better devices.
- **Don't Do Oversizing in S3, ~5%**