TAVR for Bicuspid AV: Practical Tips and Tricks for Optimal sizing and Positioning

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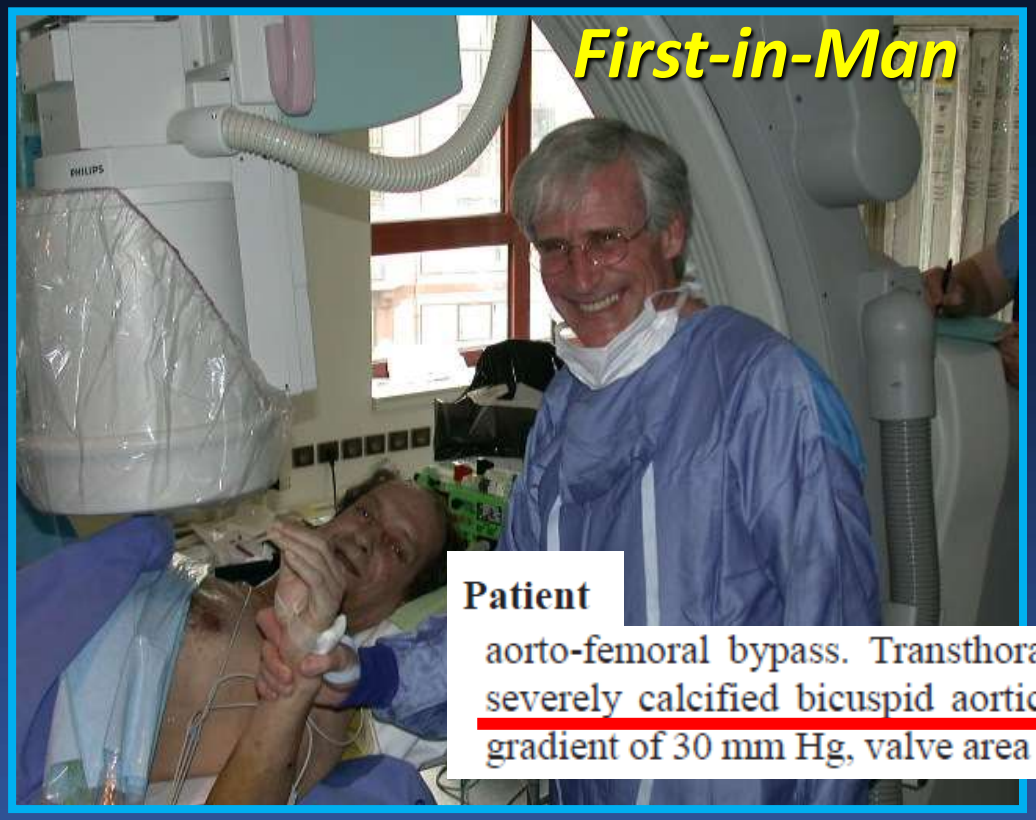
First-In-Man TAVR was done in *Bicuspid AV*
By Balloon Expandable Valve



57 years old

Patient

aorto-femoral bypass. Transthoracic echocardiography indicated a severely calcified bicuspid aortic valve with a mean transvalvular gradient of 30 mm Hg, valve area 0.6 cm^2, and ejection fraction 14%.

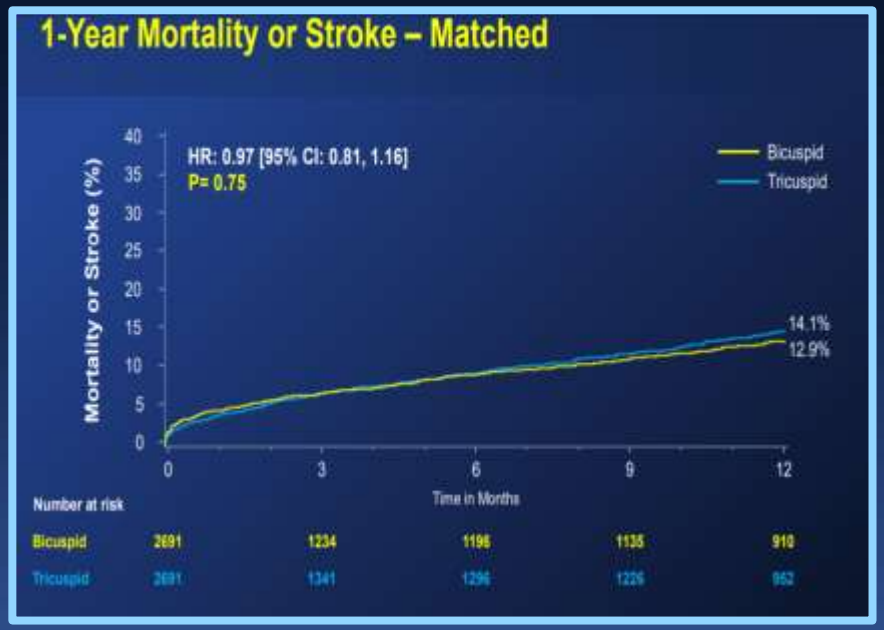
Cribier A, et al. Circulation. 2002;106:3006-3008

TAVR Trials

	STS Score	Age
Inoperable Population		
PARTNER IB Trial (*2010*)	11.6	83
High Risk Population (>8)		
PARTNER IA Trial (*2011*)	11.8	84
CoreValve US Pivotal Trial (*2014*)	**7.4**	**83**
Intermediate Risk Population (4-8)		
PARTNER II Trial (*2016*)	5.8	82
Low Risk Population (<4)		
NOTION Trial (*2015*)	3.0	79
PARTNER III (*2019*)	1.9	73
Evolut Low Risk Trial (*2019*)	1.9	74

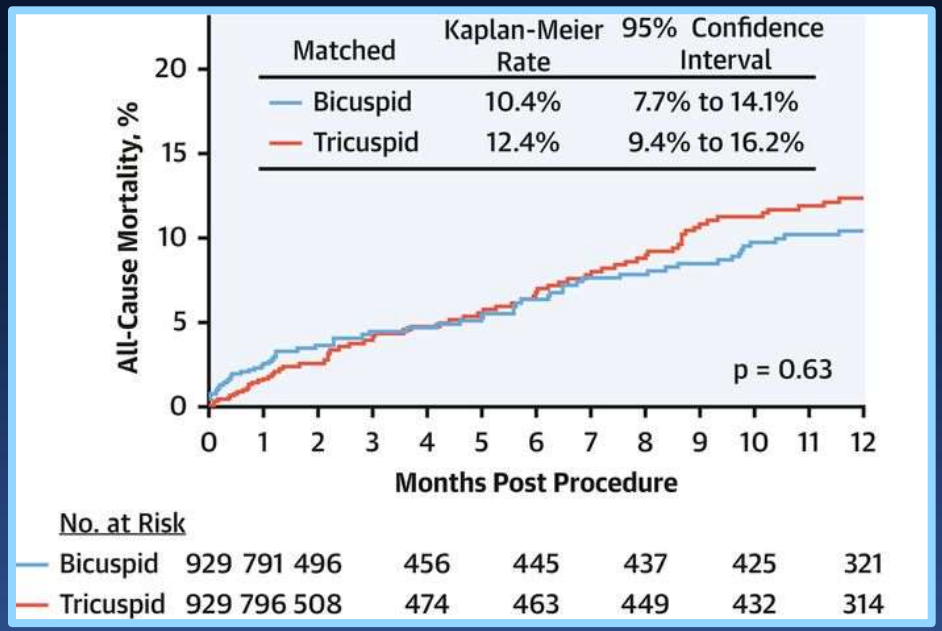
STS/ACC TVT Registry

Sapien 3



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

Evolut R



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

Which Device ?

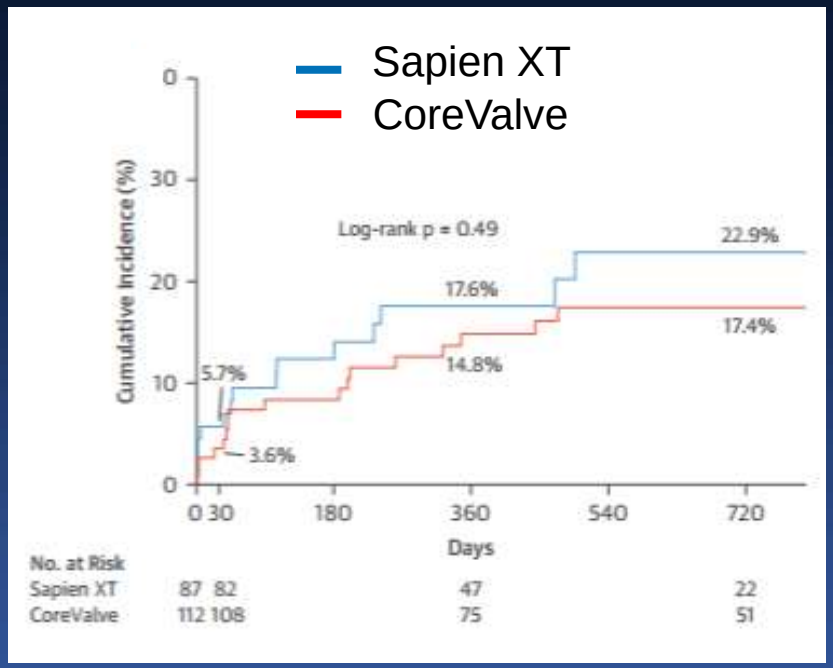
S3

Evolut R

SEV vs. BEV

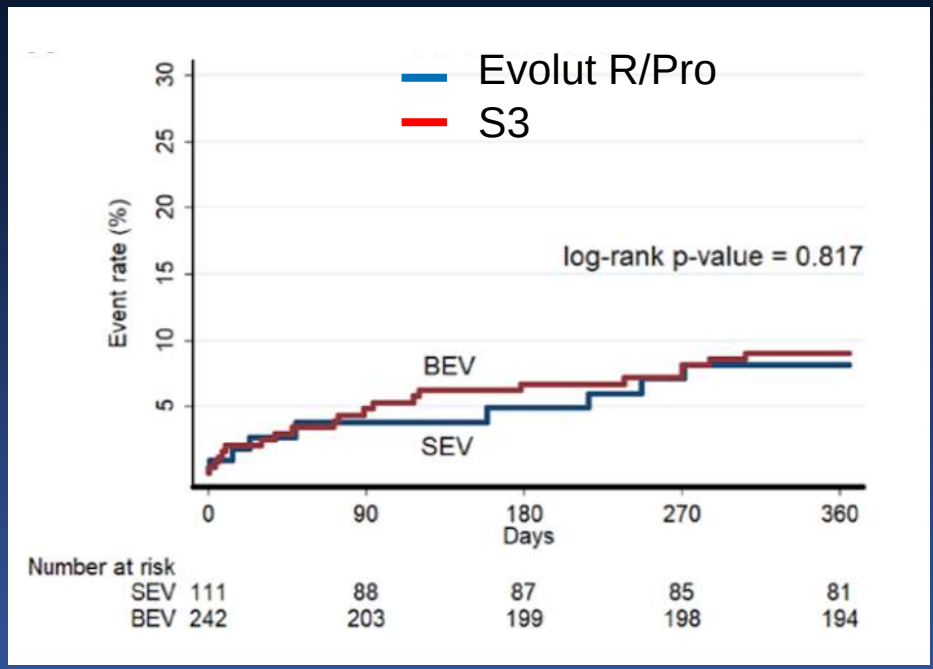
All Cause Mortality

The Bicuspid TAVR Registry



J Am Coll Cardiol 2016;68:1195–205

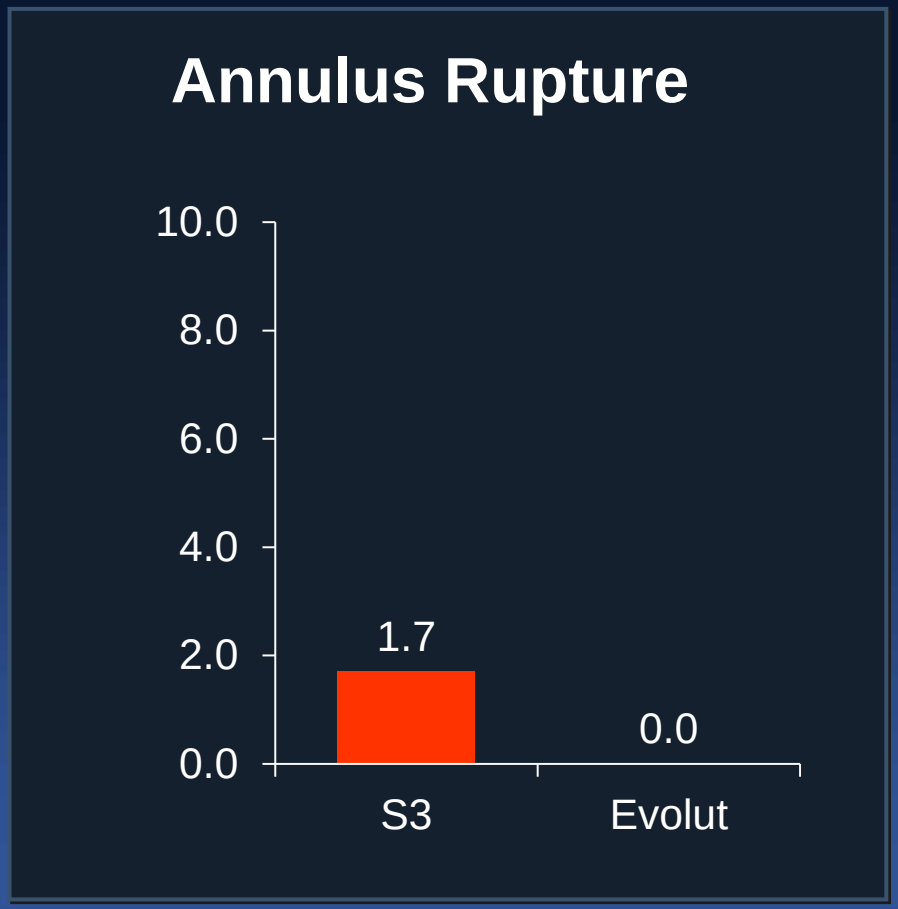
The BEAT Registry

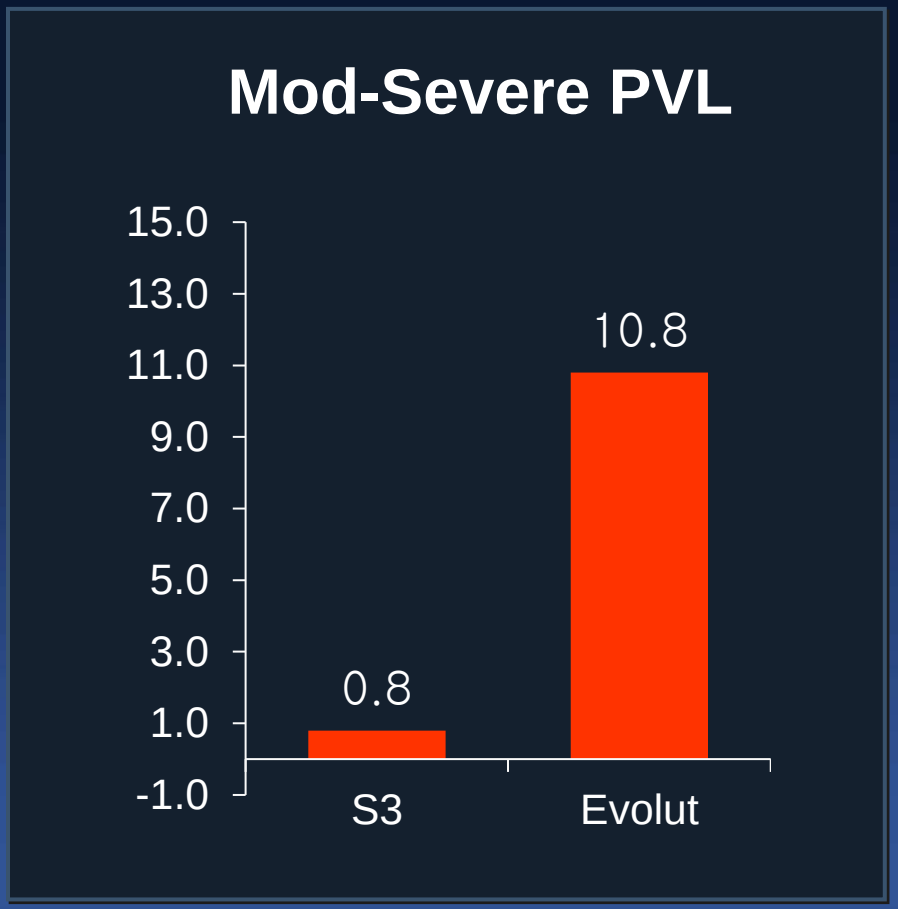


Circ Cardiovasc Interv. 2020;13:e008714

S3 vs. Evolut R/PRO

The BEAT Registry



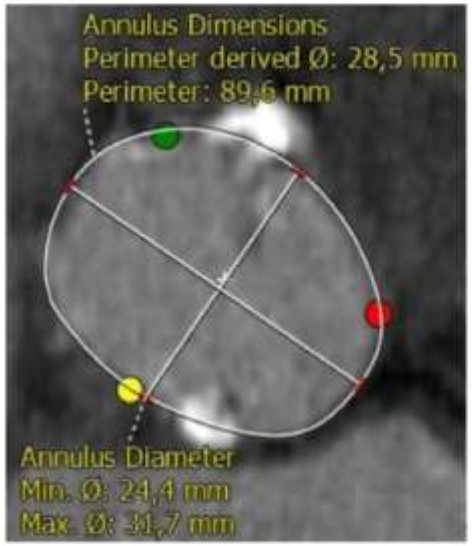


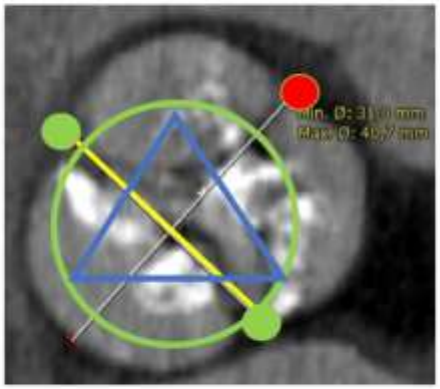
Circ Cardiovasc Interv. 2020;13:e008714

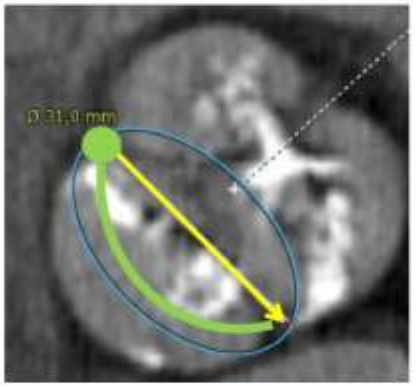
Device Sizing

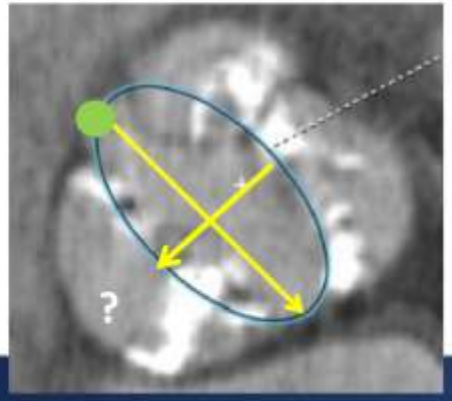
Various sizing methodologies are proposed for TAVR in BAV

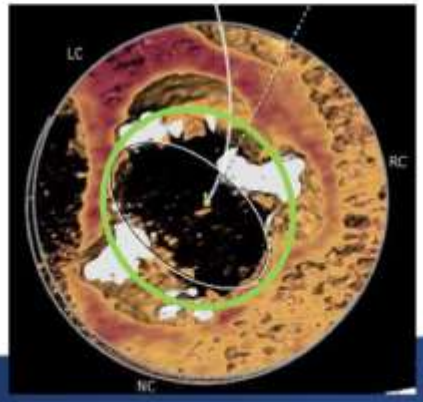
CLINIQUE Pasteur











THE STRUCTURAL HEART DISEASE SUMMIT 2018
Transcatheter Valve Therapies (TVT) and LAA/PFO Closure

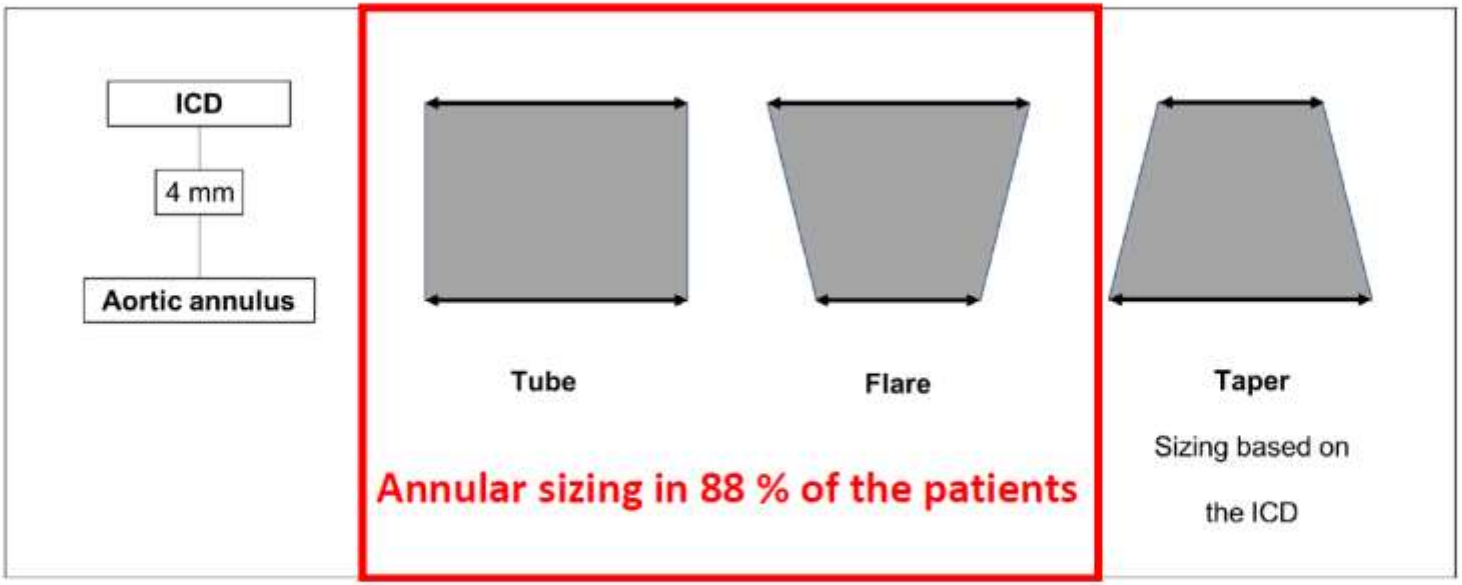
Cardiovascular Research Foundation

Courtesy of Didier Tchetche, Clinique Pasteur, Toulouse, France

Device Sizing

Sizing according to the landing zone configuration

CLINIQUE Pasteur



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

Circulation: Cardiovascular Interventions. 2019;12

Device Sizing

Annulus Sizing

S3

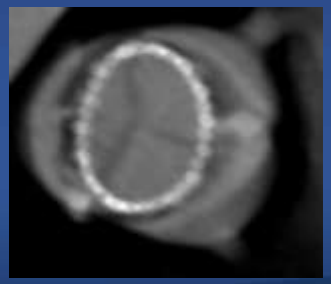
Don’t Do Oversizing Too Much, ~5%

BE “remodels” the annulus

Supra-annulus Sizing

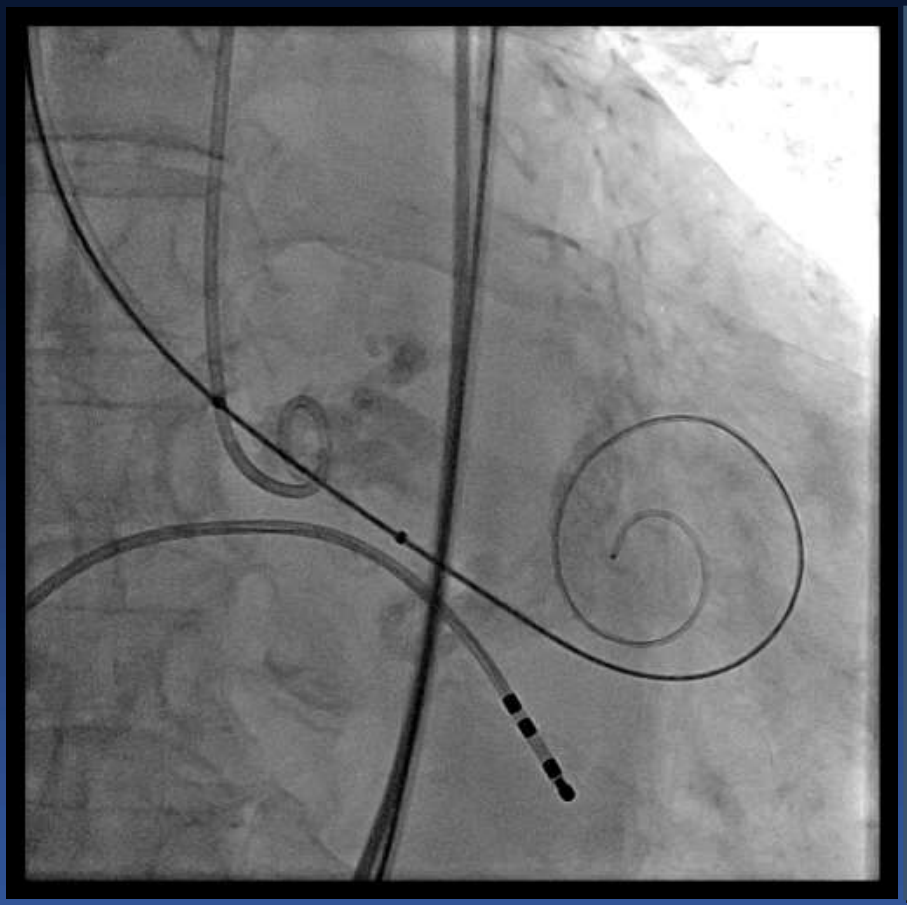
- Sequential balloon sizing
- Intercommissural distance
- LIRA method
- CASPER method

Evolut R/PRO



The annulus “remodels” SE

Balloon Aortic Valvuloplasty
More Often in Bicuspid AS



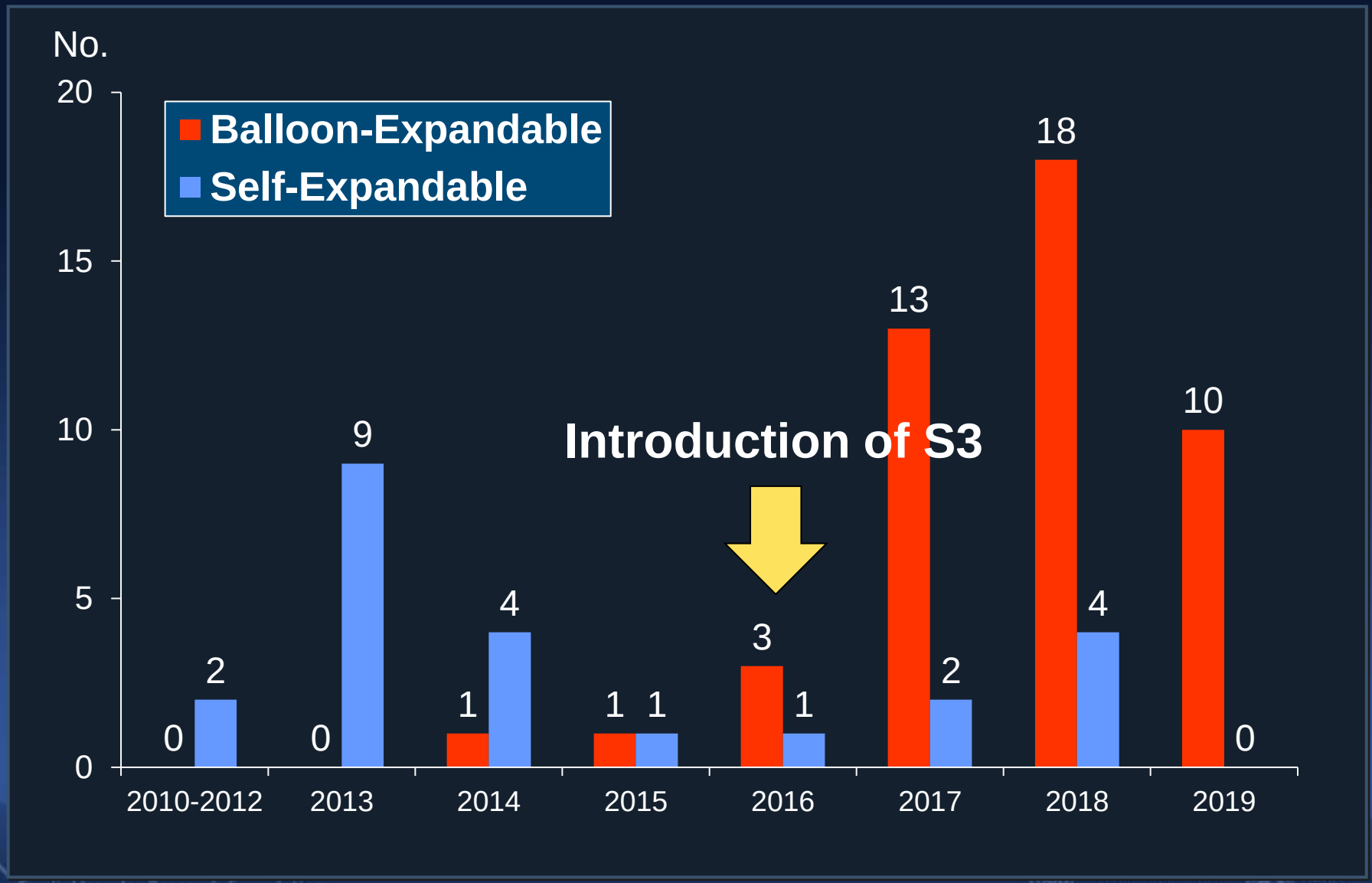
Goal

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

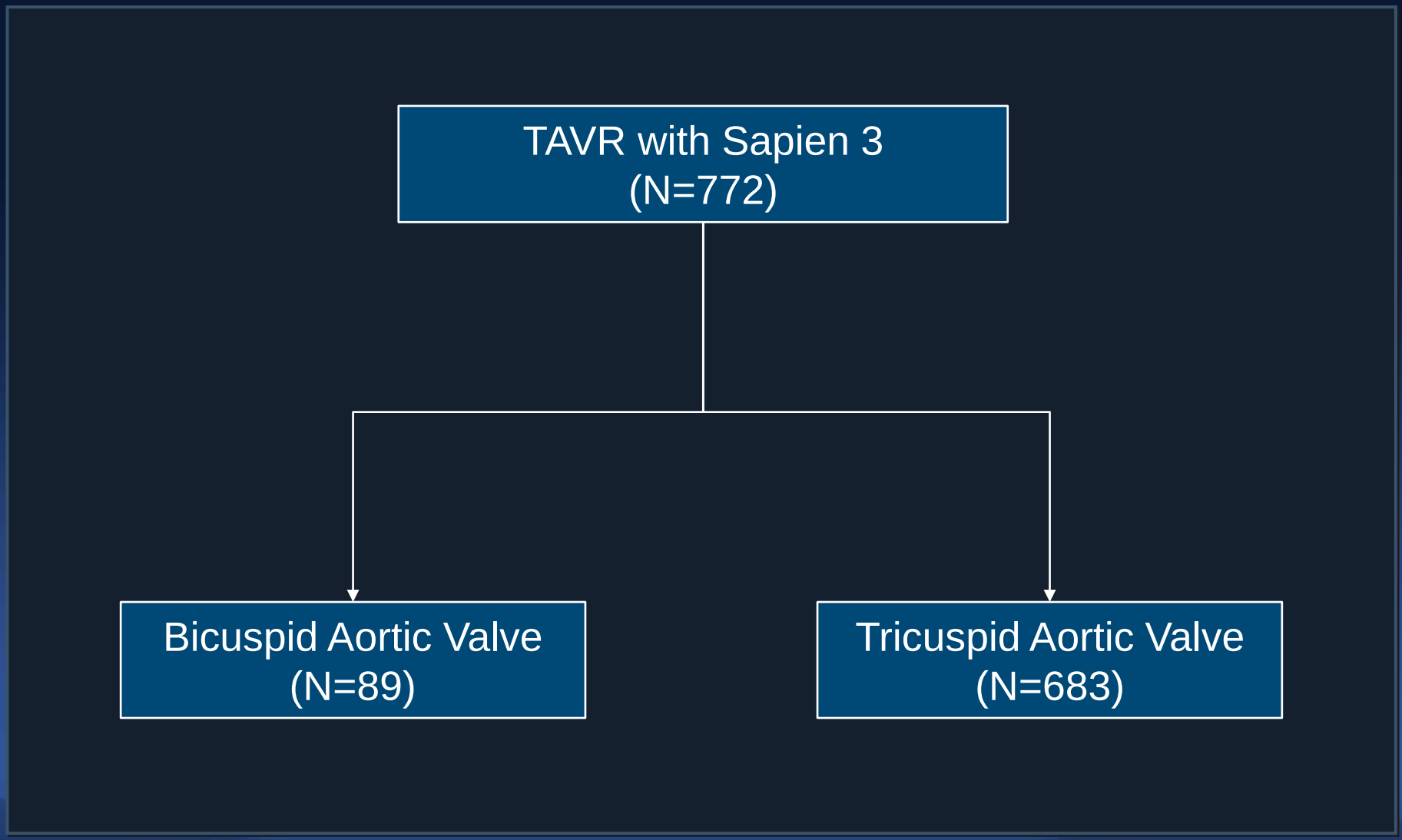
To avoid the risk of aortic complex injury, relatively small balloon should be selected based on the CT measurement of aortic valve complex.

Balloon Size: Smaller Than Minimal Diameter

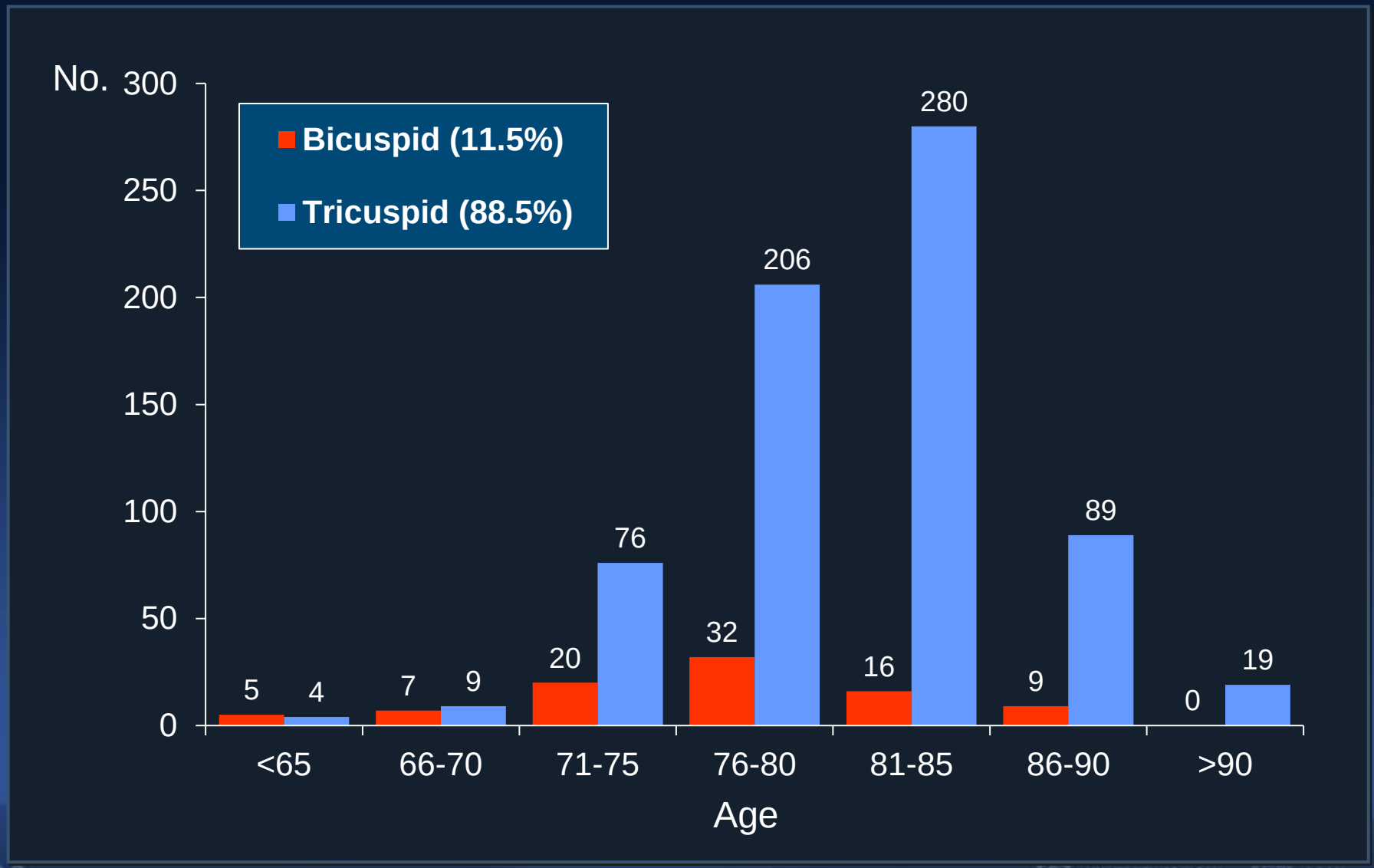
Heart Valve for Bicuspid AS



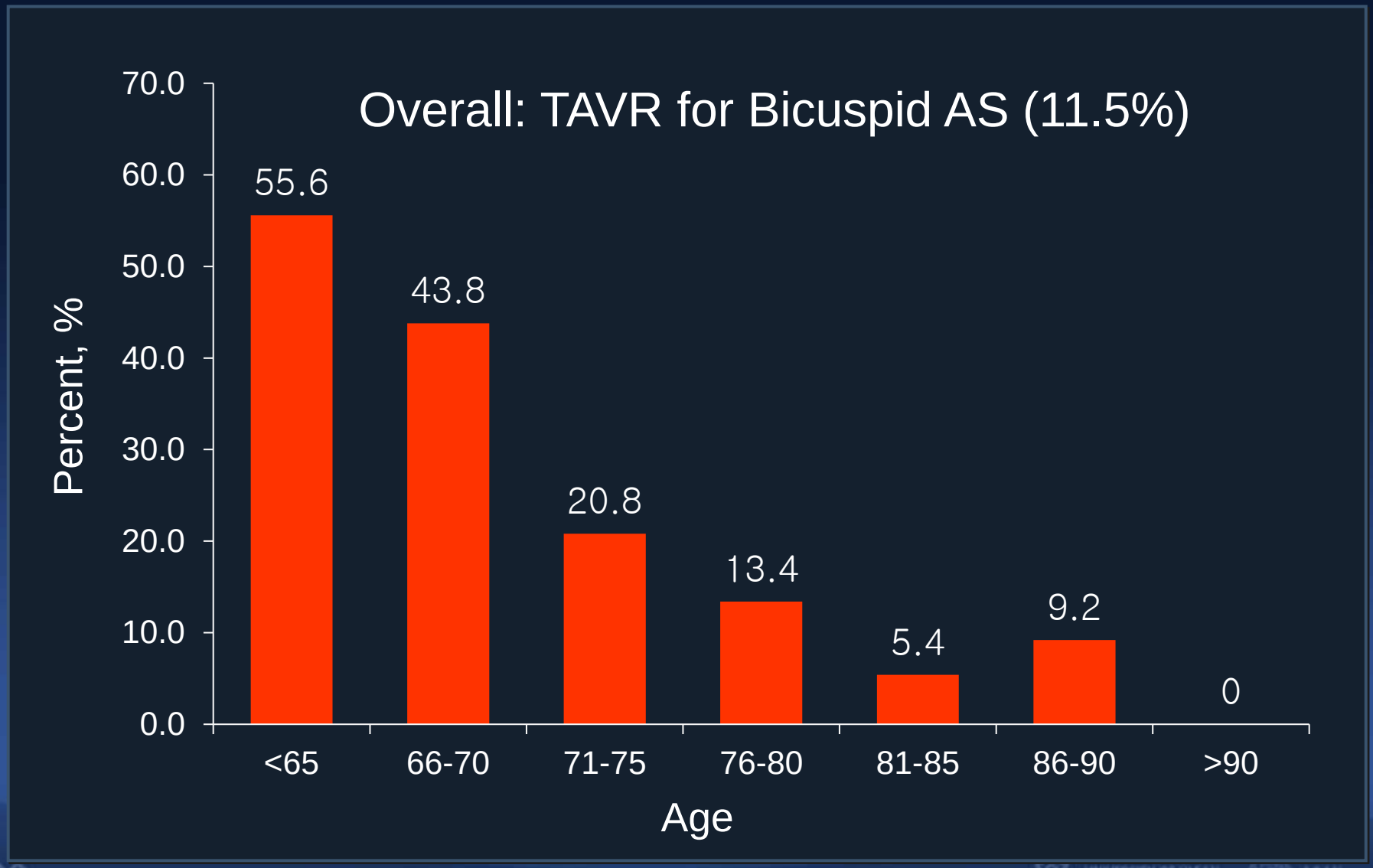
ASAN TAVR S3 Registry (2016-2021)



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

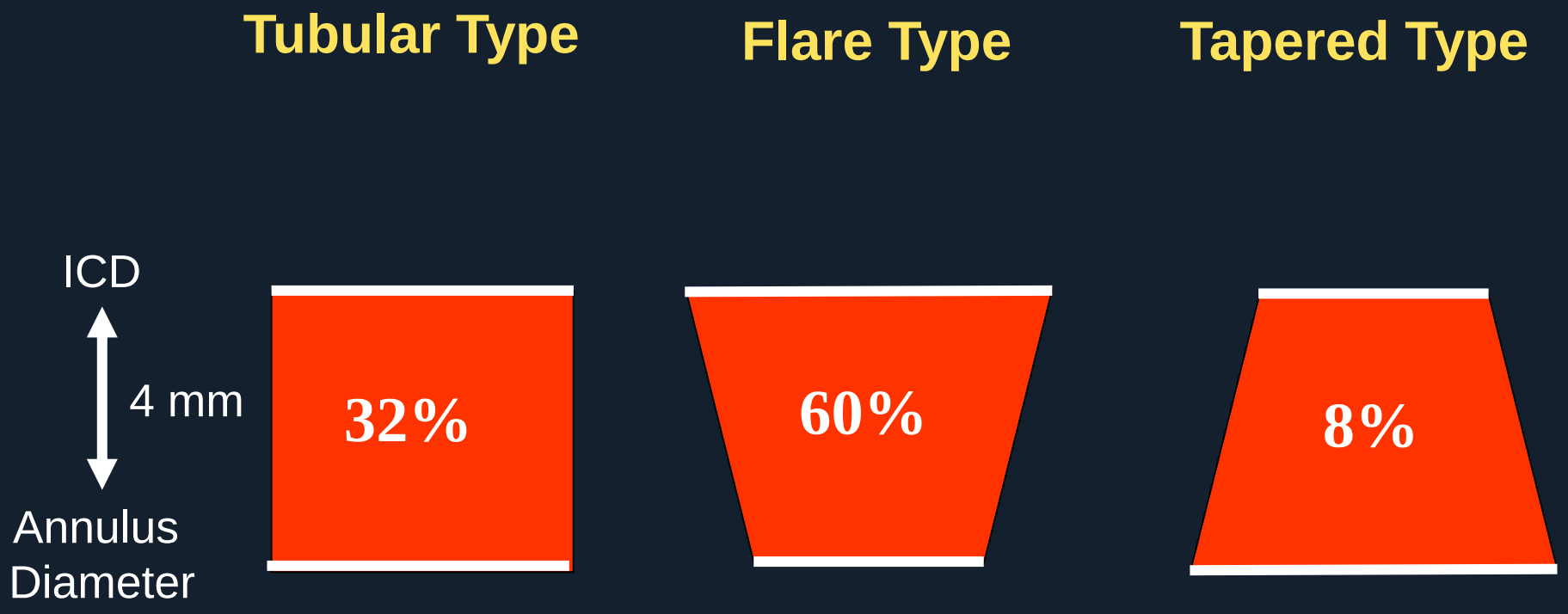
NL fusion=1

Type 2
2 Raphes

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

Circulation: Cardiovascular Interventions. 2019;12

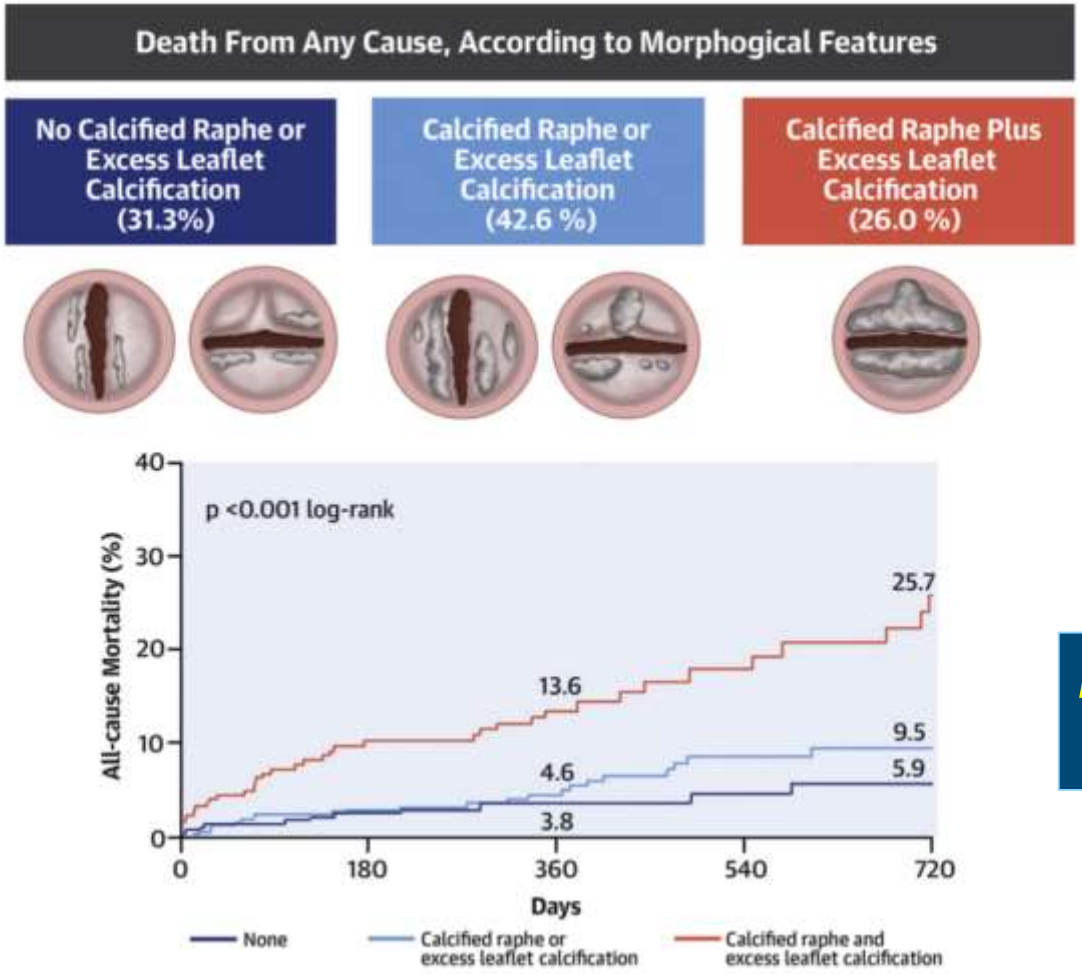
Baseline Characteristics

	Bicuspid AS (N = 89)	Tricuspid AS (N = 683)	P value
Age	76.9±6.6	80.9±5.0	0.001
Gender (Male)	69.7%	44.9%	<0.001
NYHA Class III/IV	20.3%	30.2%	0.24
BMI	23.7±3.2	24.1±3.8	<0.001
STS score	2.88±1.6	4.1±2.6	<0.001
Diabetes Mellitus	23.6%	35.9%	0.022
Hypertension	57.3%	79.9%	<0.001
Previous Stroke	14.6%	12.0%	0.48
Peripheral Vascular Disease	2.2%	4.2%	0.37
Previous PCI	10.1%	24.9%	0.002
Previous CABG	0%	3.5%	0.10
LVEF, %	58.3±9.4	59.3±10.3	0.38

CT Measurement

	Bicuspid AS (N = 89)	Tricuspid AS (N = 683)	P value
Annulus Dimensions			
Area, mm^2	518±100	428±76	<0.001
Perimeter, mm	81.7±8.1	74.3±7.2	<0.001
Mean diameter, mm			
Maximum	28.7±3.3	26.6±2.6	<0.001
Minimum	22.8±2.5	20.6±2.1	<0.001
STJ area, mm^2	856±235	640±140	<0.001
LVOT Area, mm^2	505±121	403±99	<0.001
LM Height, mm	16.2±3.9	13.2±2.6	<0.001
RCA Height, mm	18.5±3.4	17.2±2.8	0.001

Calcification Morphology and Outcomes

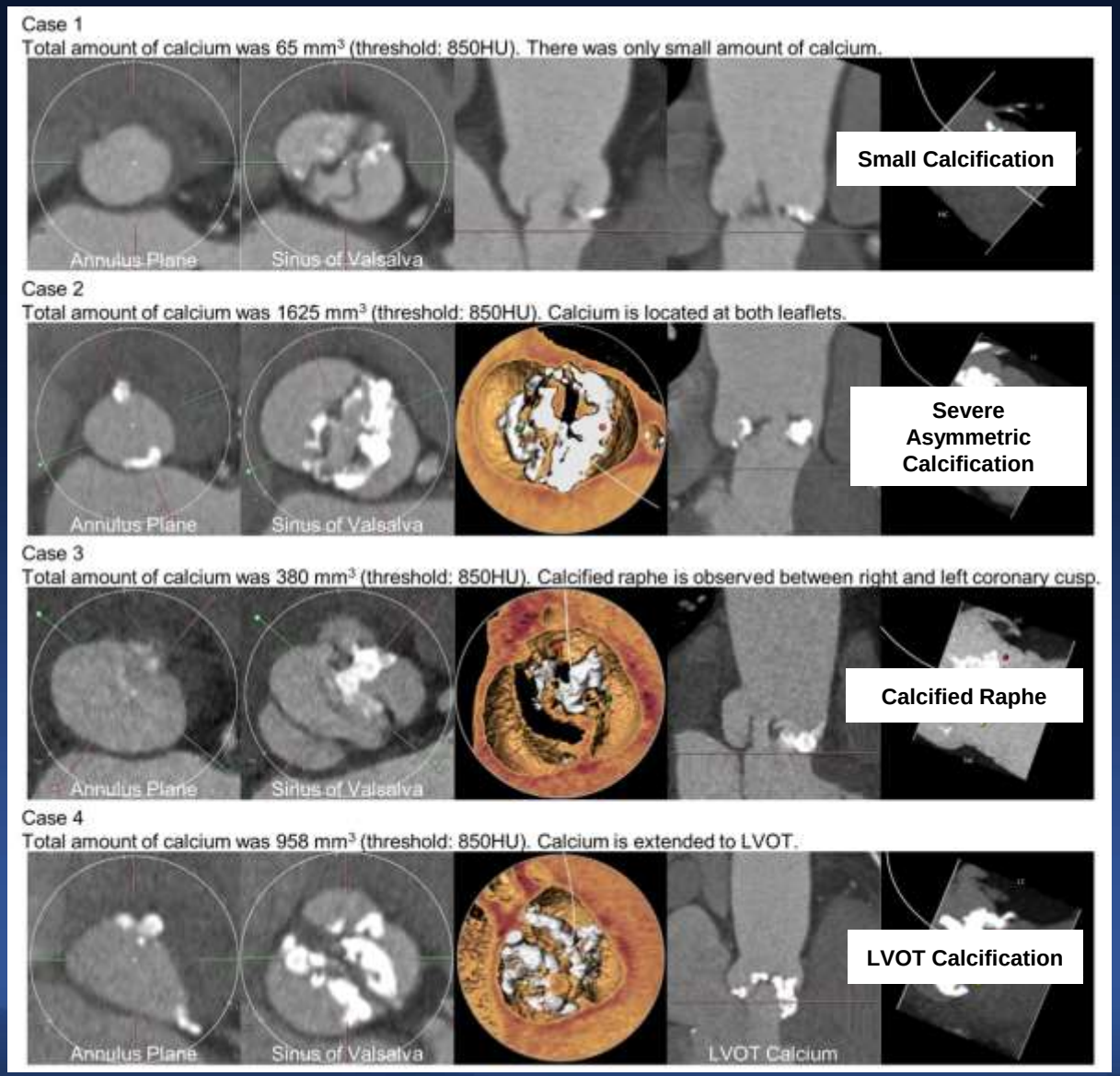


Severe AV calcification

Higher Aortic Root Injury
Higher PVL

J Am Coll Cardiol. 2020;76(9):1018–30

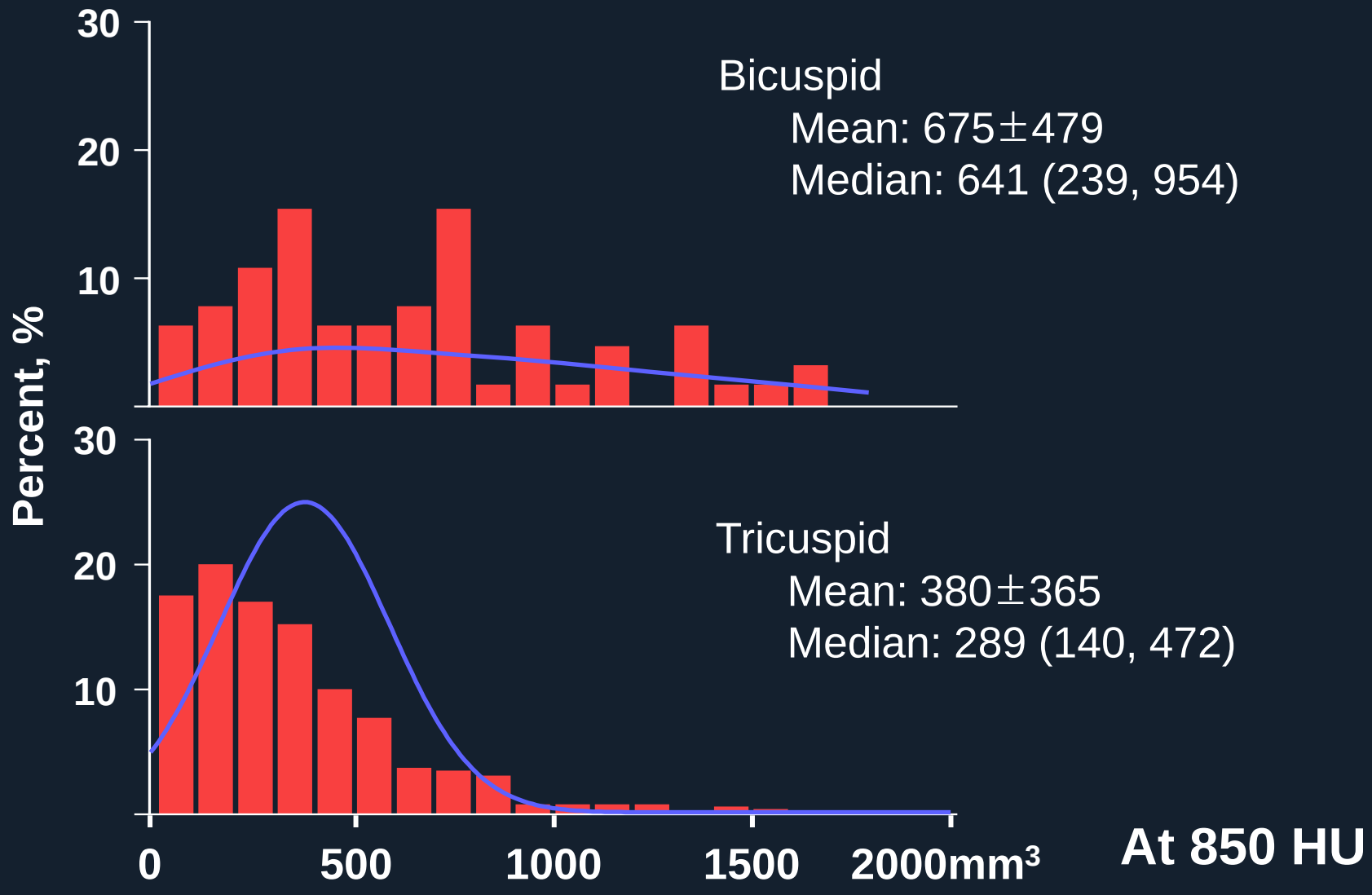
Mount and Morphology of Calcification



Lower Risk

Higher Risk

Valve Calcification Volume



S3 Area Oversizing Based on the CT

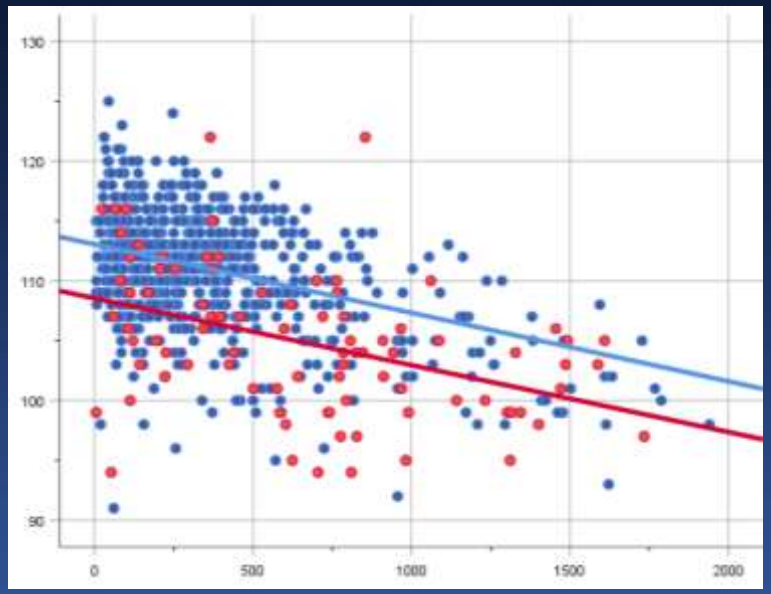
10-15%, Cutoff

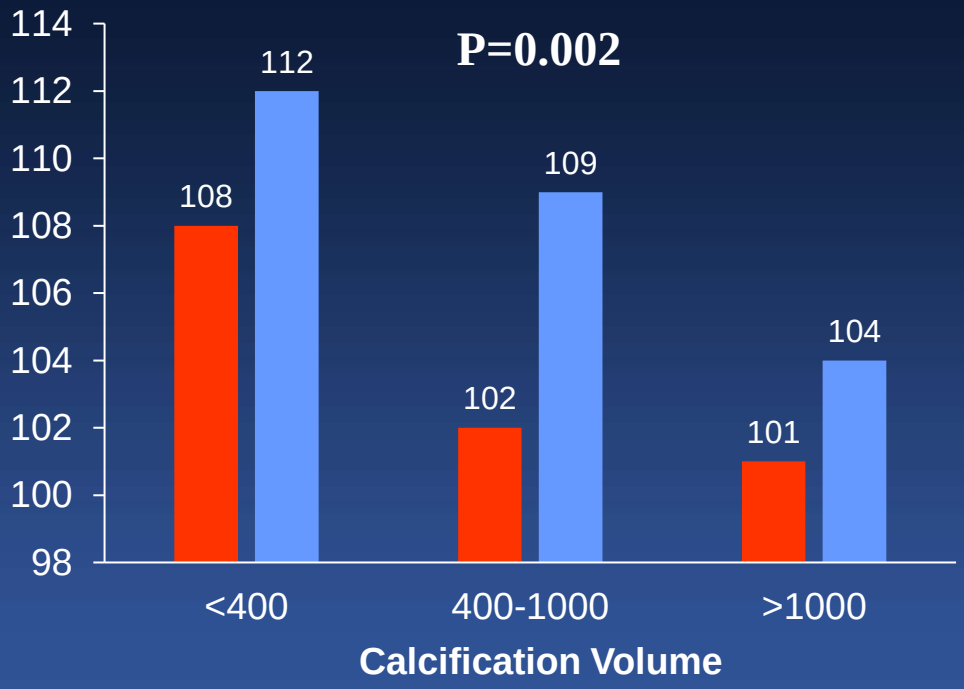
Mild Calcification (Ca volume < 400 mm^3)	*10~15%*
Moderate Calcification (Ca volume 400-1000 mm^3)	*5~10%*
Severe Calcification (Ca volume > 1000 mm^3)	*0~5%*
Bicuspid AS and Heavy Calcification	*0%*

Volume Adjusted Device Under-Over Sizing

Bicuspid: 104.8%

Tricuspid: 110.9%





M/79 with Bicuspid AS

Annulus plane

Aortic Annulus parameters	
Annulus short diameter	26.0 mm
Annulus long diameter	28.6 mm
Annululs mean diameter	27.3 mm
Annulus area	589 mm^2
Annulus area-driven diameter	27.4 mm
Annulus perimeter	86.5 mm
Annulus perimeter-driven diameter	27.5 mm

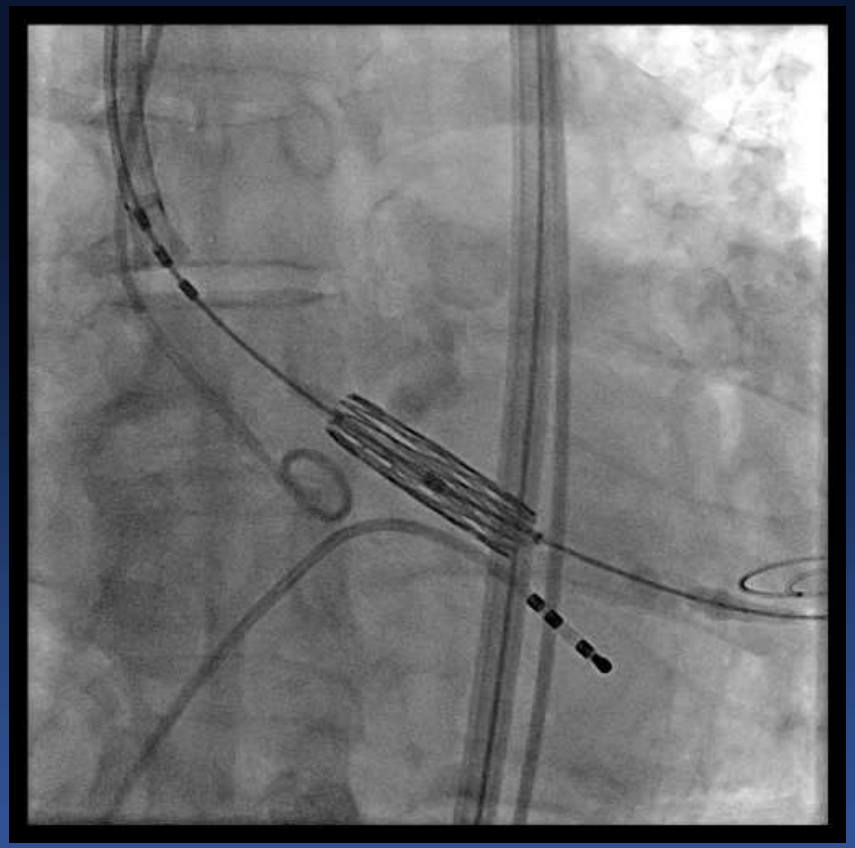
Calcium Amount

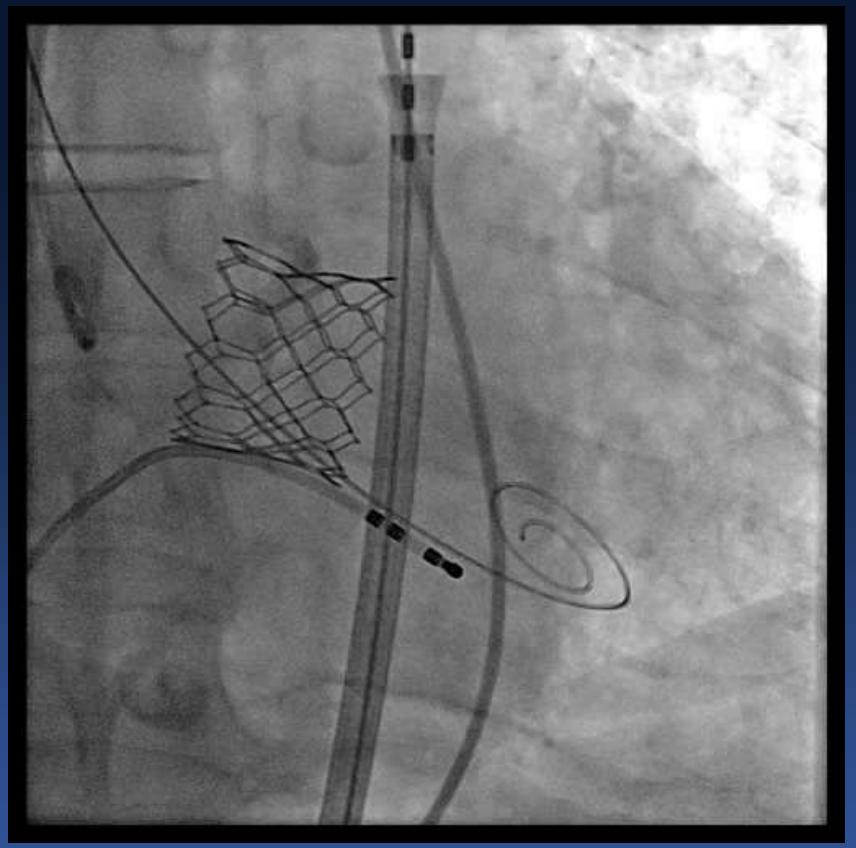
Calcium volume	
RCC	616 mm^3
LCC	48 mm^3
Total	664 mm^3

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

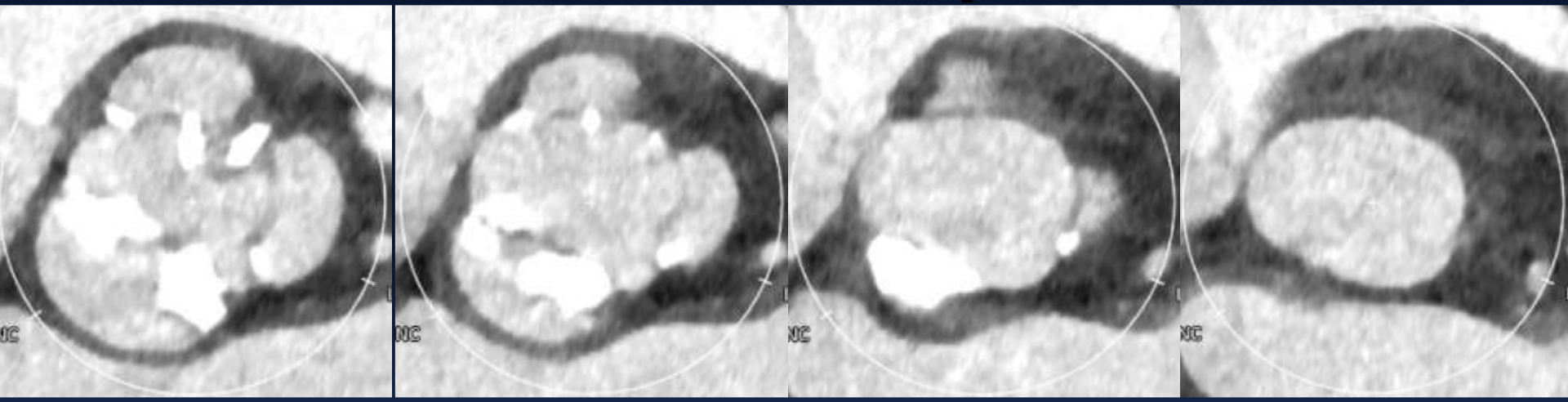
Size	Area_oversize (%)	Perimeter_oversize (%)
24	75.6	86.2
25	82.0	89.8
26	88.1	93.3
27	95.0	96.9
28	102.2	100.5
29	110.2	104.4
30	117.9	108.0

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





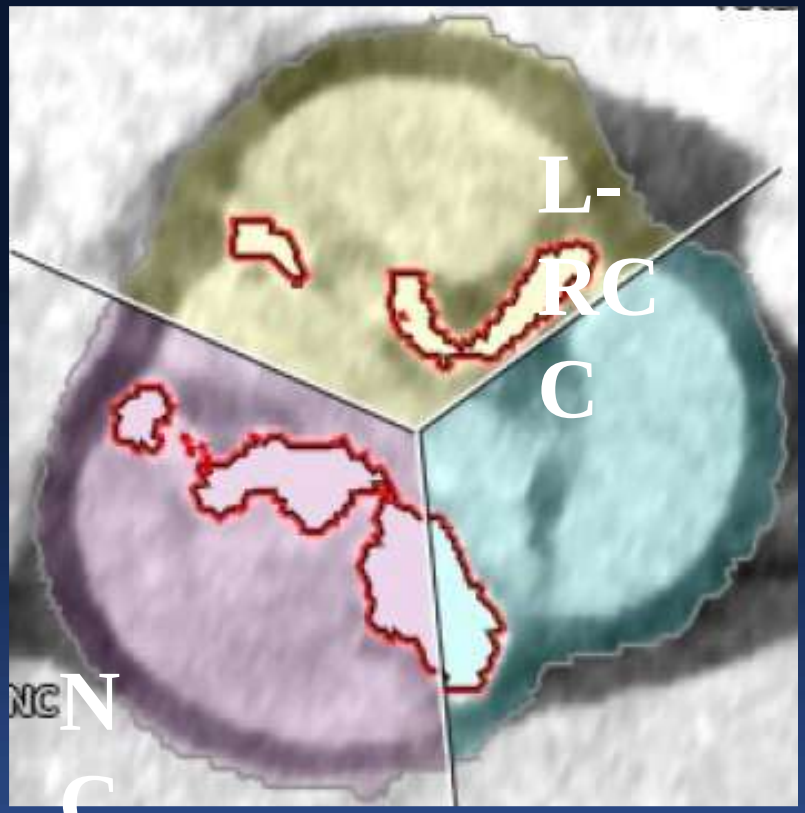
M/79 with Bicuspid AS



Annulus plane_20%

Aortic Annulus parameters	
Annulus short diameter	21.0 mm
Annulus long diameter	28.8 mm
Annulus mean diameter	24.9 mm
Annulus area	500 mm^2
Annulus area-driven diameter	25.2 mm
Annulus perimeter	81.1 mm
Annulus perimeter-driven diameter	25.8 mm

CT findings – Aortic Valve Complex



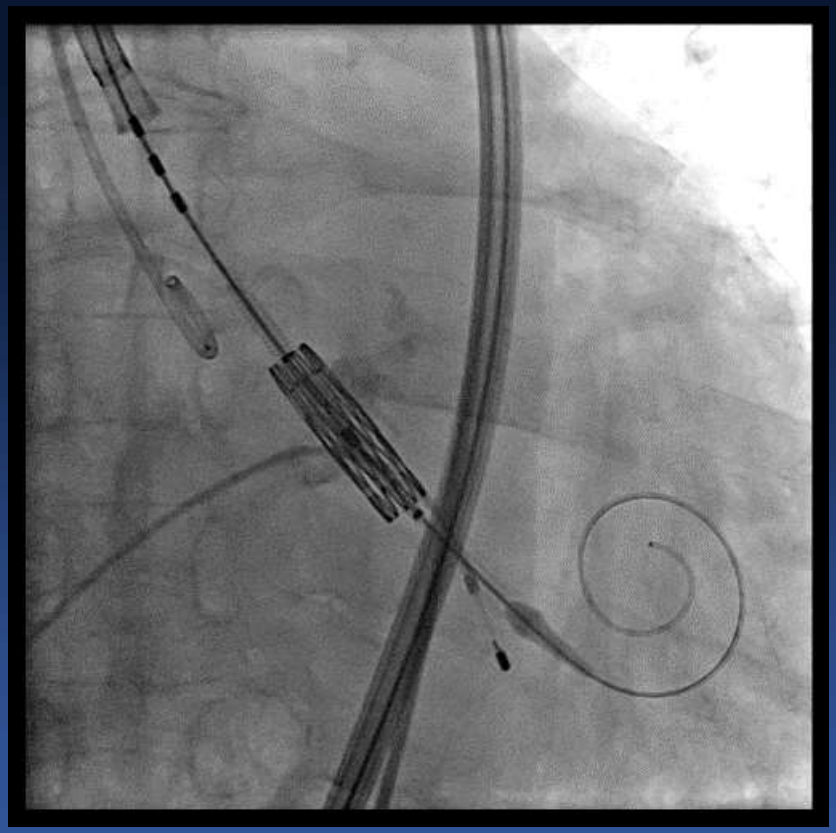
Calcium volume	
NCC	875 mm³
L-RCC	436 mm³
Total	1316 mm³

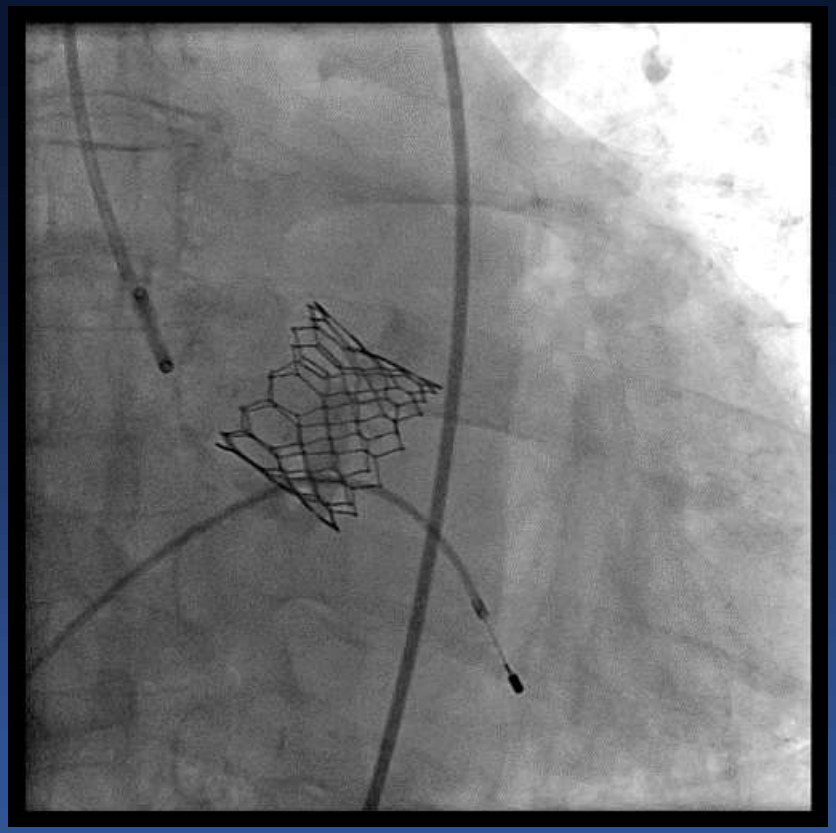
Mean Amount of total Calcium: 618.5 ± 446.9

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

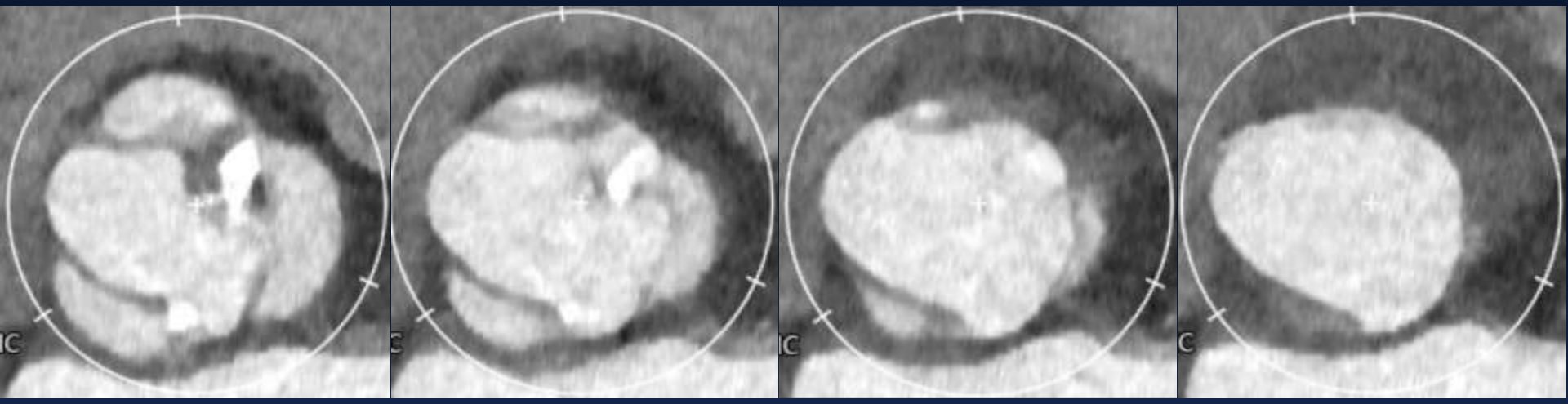
Size	Area Oversize (%)	Perimeter Oversize (%)
23	81.8	88.1
24	89.1	91.9
25	96.6	95.8
26	103.8	99.5
27	111.9	103.3
28	120.4	107.2
29	129.8	111.3

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





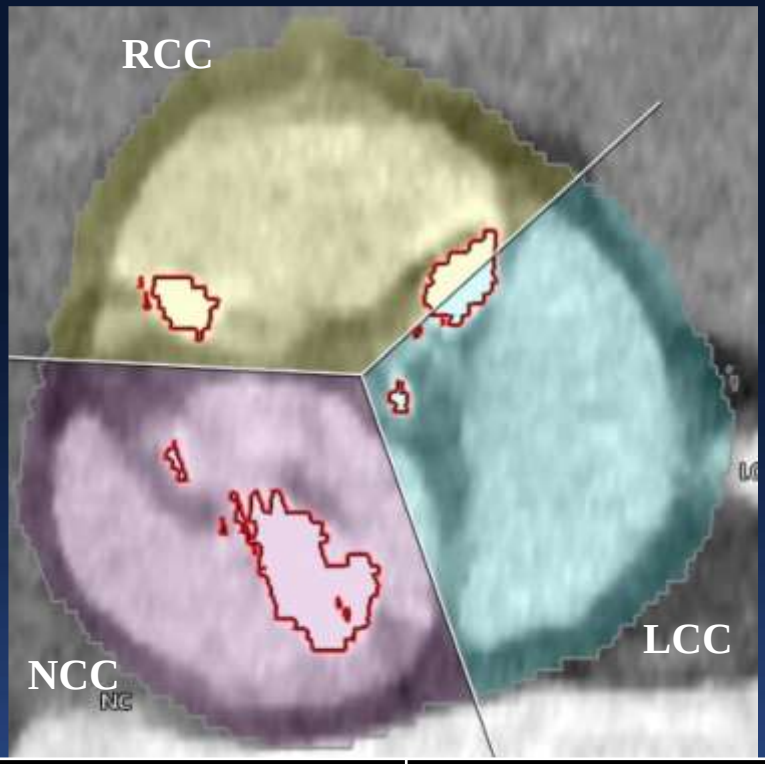
M/83 with Bicuspid AS



Annulus plane

Aortic Annulus parameters	
Annulus short diameter	25.3 mm
Annulus long diameter	34.1 mm
Annulus mean diameter	29.7 mm
Annulus area	710 mm^2
Annulus area-driven diameter	30.1 mm
Annulus perimeter	97.0 mm
Annulus perimeter-driven diameter	30.9 mm

CT findings – Aortic Valve Complex



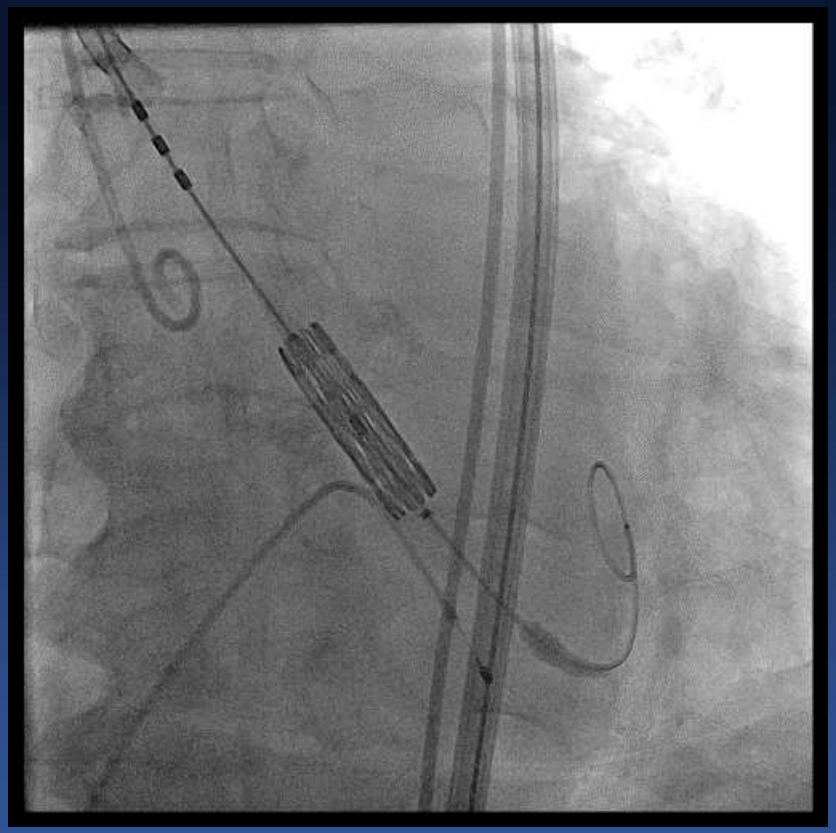
Calcium volume	
NCC	366 mm^3
RCC	295 mm^3
LCC	166 mm^3
Total	828 mm^3

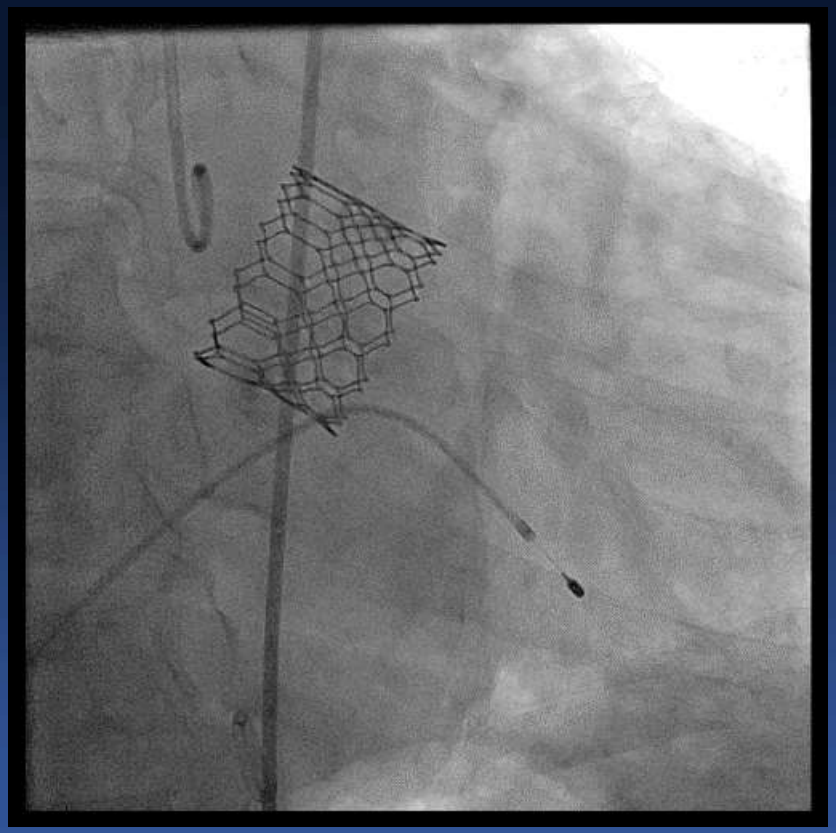
Mean Amount of total Calcium: 356.7 ± 303.8

S3 29mm
(-9% Undersizing)

Size	Area Oversize (%)	Perimeter Oversize (%)
26	73.1	83.2
27	78.8	86.4
28	84.8	89.6
29	91.4	93.1
30	97.8	96.3
31	104.4	99.5

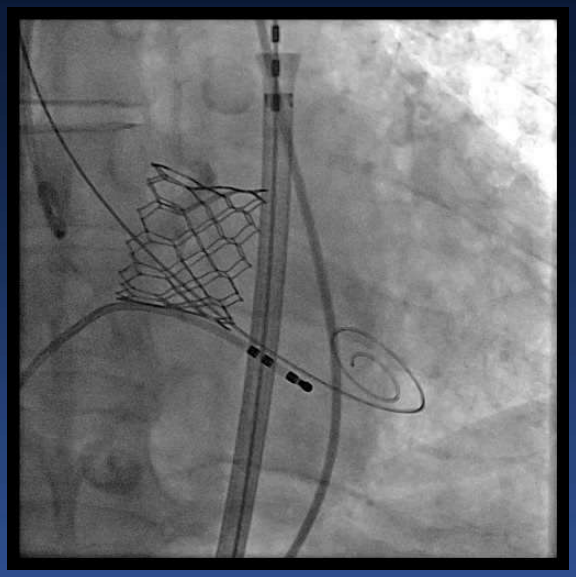
S3 29mm
(9% Undersizing)



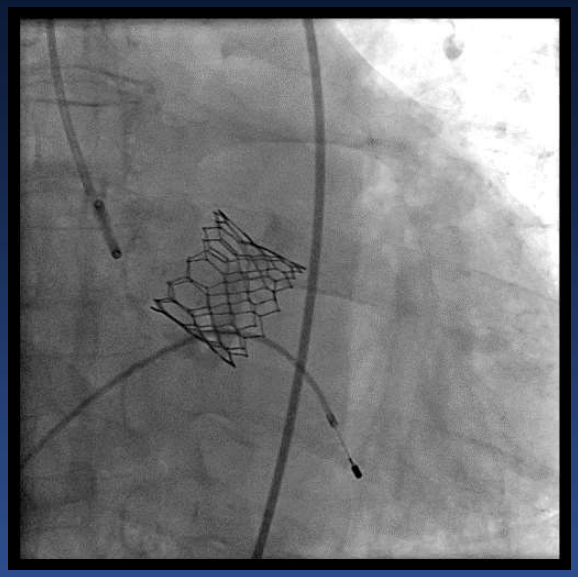


Undersizing is Effective and Safe

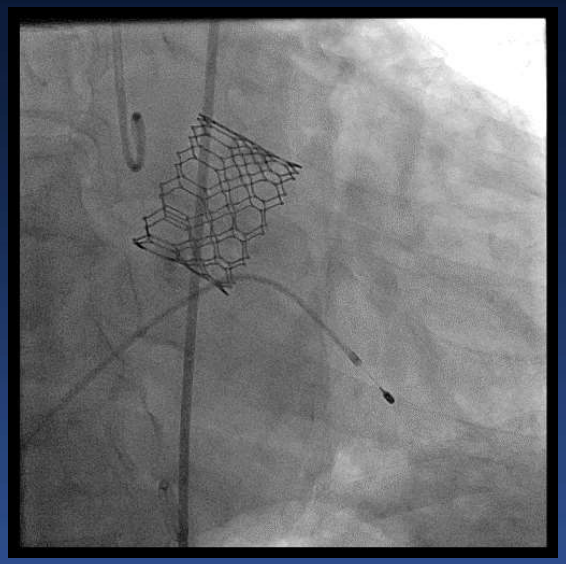
S3 29mm
with -3cc Underfill
(2% Oversizing)



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



S3 29mm
(9% Undersizing)

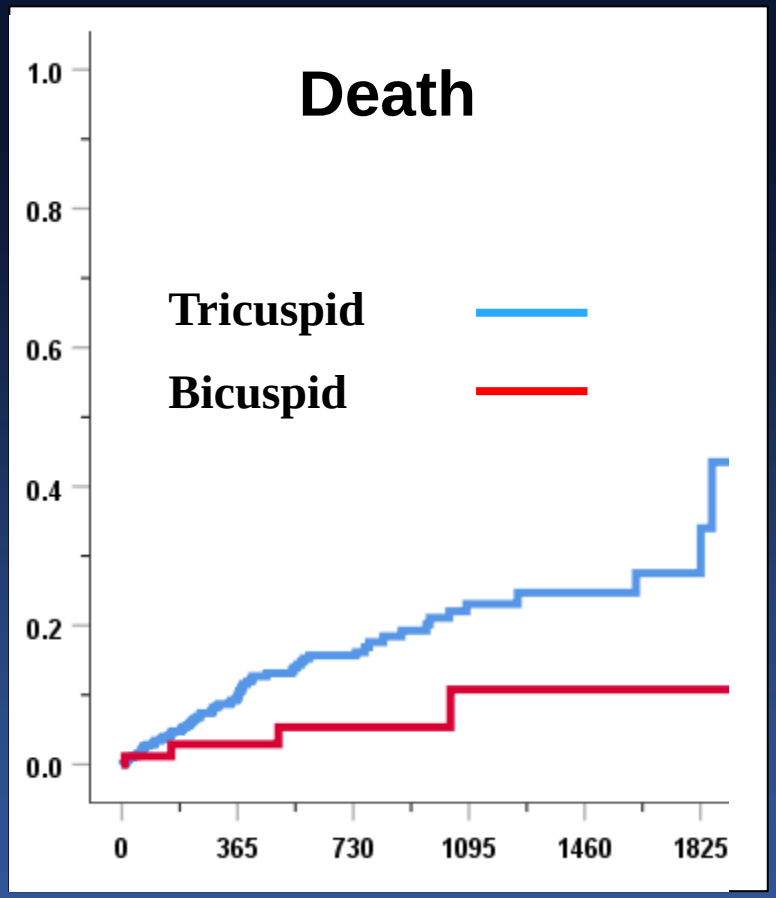


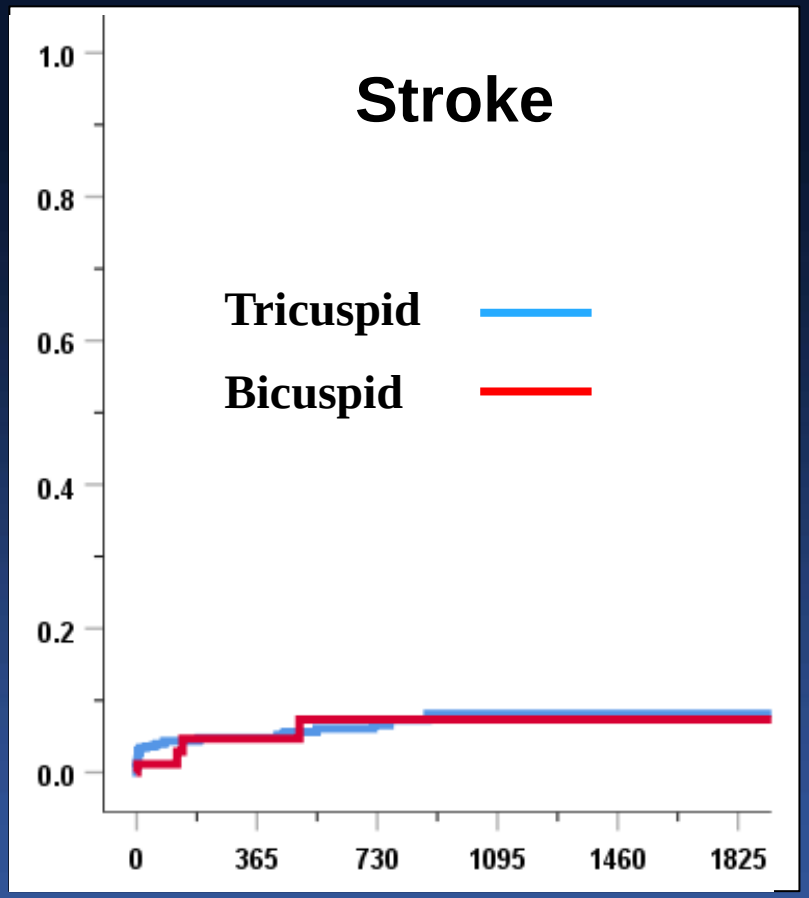
Don’t Do Oversizing in S3, ~5%

Procedural Outcomes

	Bicuspid AS (N = 89)	Tricuspid AS (N = 493)	P value
Pre-Balloon Valvuloplasty	66 (74.2%)	288 (42.2%)	<0.001
Post-Balloon Valvuloplasty	14 (15.7%)	89 (13.0%)	0.48
Annular Root Injury	0	1 (0.1%)	0.24
New Permanent Pacemaker	4 (4.5%)	50 (7.3%)	0.33
PVL ≥ Moderate	4 (4.5%)	8 (1.2%)	0.017

Death and Stroke





Optimal TAVR by BEV 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.
- Aortic injury should be cautious.
- TAVR for bicuspid AS is not associated with excess risk of mortality and stroke.
- S3 implantation on bicuspid AV is not generally different from S3 implantation on tricuspid AV but,
- **Don’t Do Oversizing, ~5%, depending on the severity of calcification**