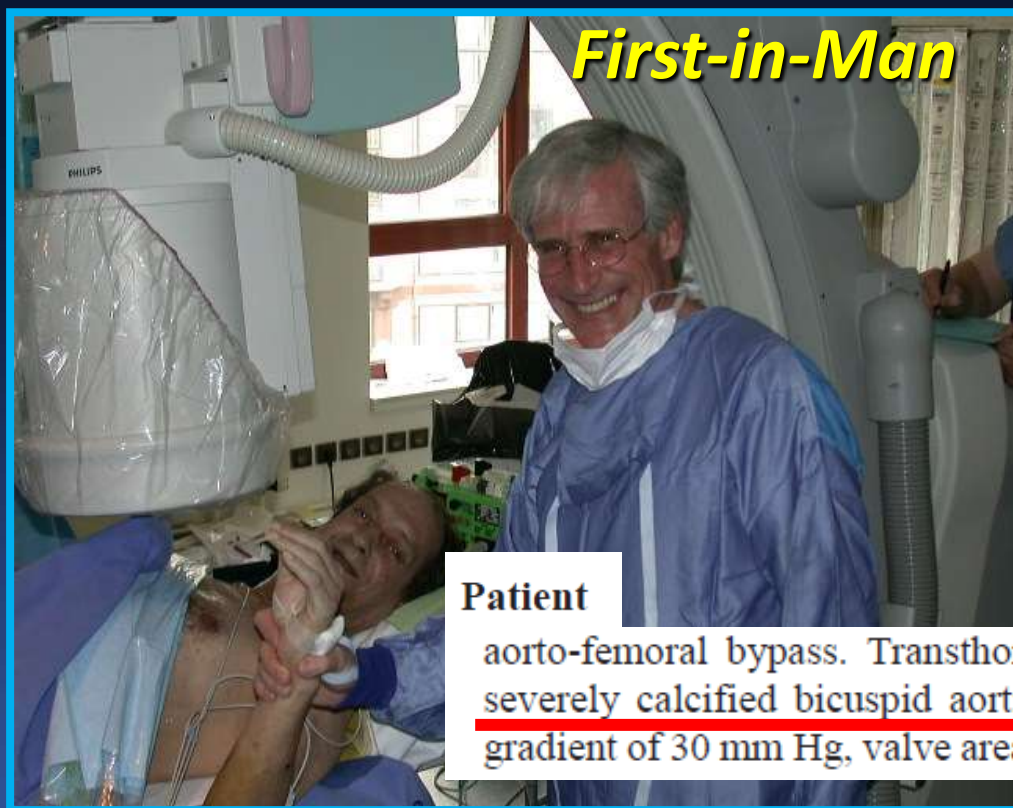


TAVR for Bicuspid AV: Tips and Tricks

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

2017 AHA/ACC Guideline

COR

LOE

TAVR was Generally Indicated in **Tricuspid AS**

IIa

B-R

IA

- Intermediate Surgical Risk
- Lower Surgical Risk
Younger Patients
- ***Bicuspid AV Stenosis***

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

TAVR for Bicuspid AV

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

Zhao ZG et al. Nat. Rev. Cardiol 2015;12:123-128

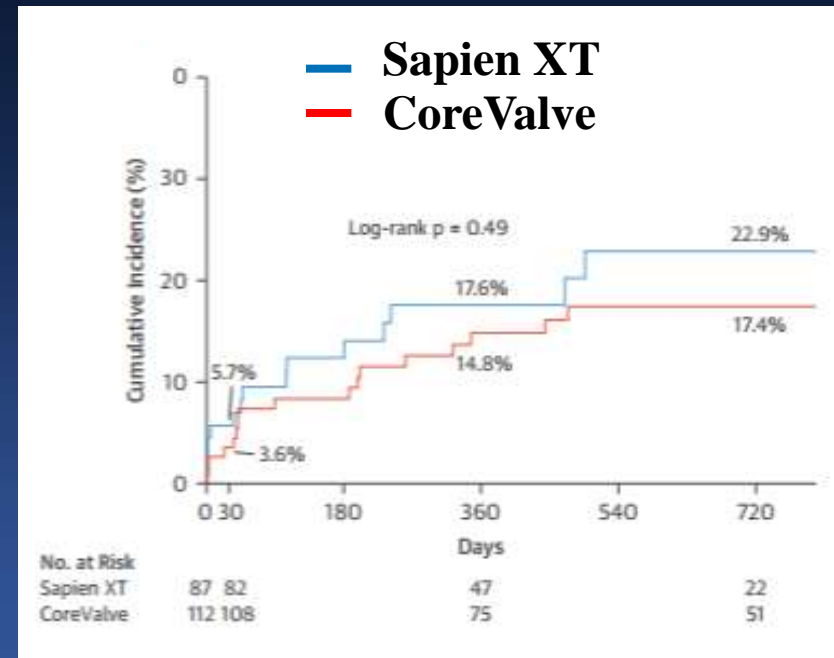
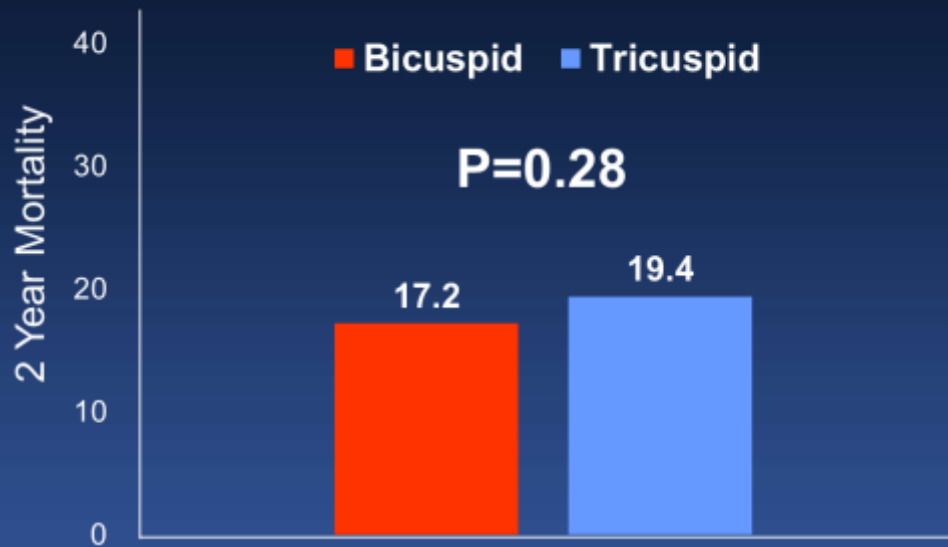
Practical Issues

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

Valve Type

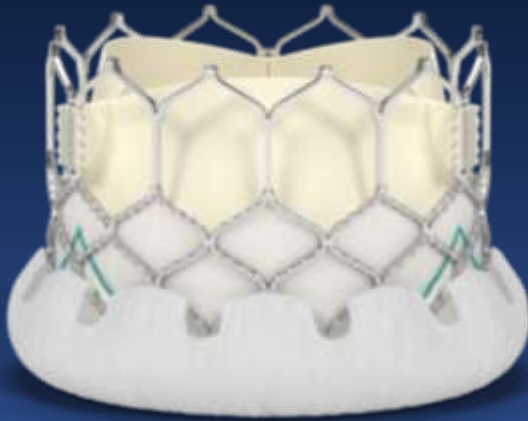
2 Year Mortality of TAVR

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

New Generation Device



S3



Evolut R



S3 for BAV

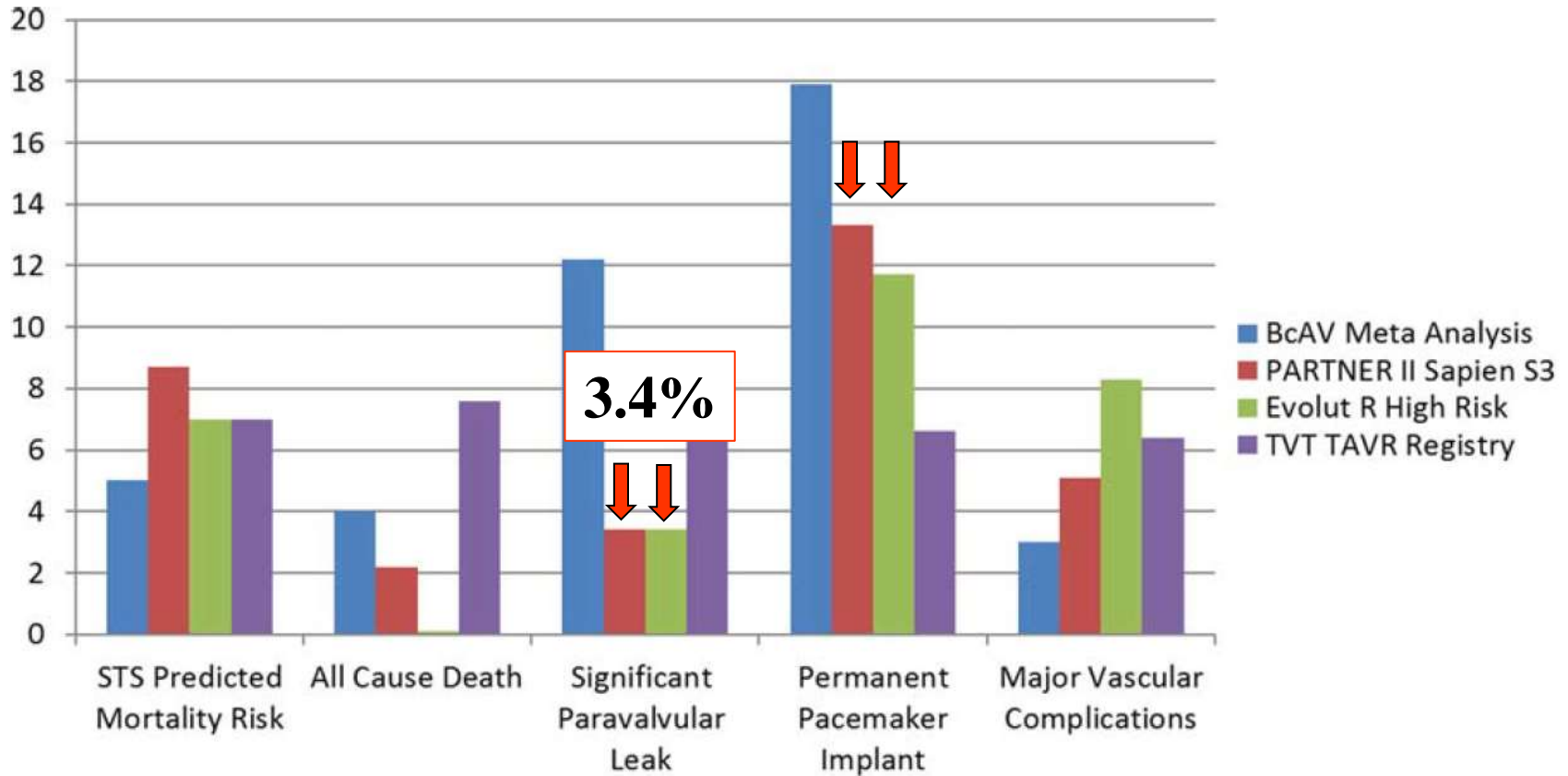
Cedars-Sinai

Outcomes	Overall (n=108)	Sapien XT (n=34)	Sapien 3 (n=74)	P value
Procedural outcomes	Age 76.7±10.4 73.3±10.6			
Procedure-related death				
Conversion to conventional surgery	1 (0.9)	0 (0.0)	1 (1.4)	>0.99
Coronary obstruction	0 (0.0)	0 (0.0)	0 (0.0)	–
Annulus rupture	1 (0.9)	0 (0.0)	1 (1.4)	>0.99
Second valve implantation	2 (1.9)	2 (5.9)	0 (0.0)	0.097
New permanent pacemaker	13 (12.0)	3 (8.8)	10 (13.5)	0.49
Postprocedural echocardiographic findings				
Mean gradient, mmHg	11.2±4.2	11.7±4.3	11.1±4.2	0.59
LVEF, %	57.2±18.4	50.0±16.4	58.0±18.6	0.28
Paravalvular leak ≥ moderate	7 (6.5)	5 (14.7)	2 (2.7)	0.03
Device success	100 (92.6)	28 (82.4)	72 (97.3)	0.006
Clinical outcomes at 30 days				
All-cause death	1 (0.9)	0 (0.0)	1 (1.4)	>0.99
Stroke	5 (4.6)	1 (2.9)	4 (5.4)	>0.99
Life-threatening bleeding	1 (0.9)	0 (0.0)	1 (1.4)	>0.99
Major vascular complication	6 (5.6)	1 (2.9)	5 (6.8)	0.66
Acute kidney injury (stage 2 or 3)	2 (1.9)	0 (0.0)	2 (2.7)	>0.99

Yoon SH, Makkar RR et al. Annals of cardiothoracic surgery, Vol 6, No 5 September 2017

S3 and Evolut R

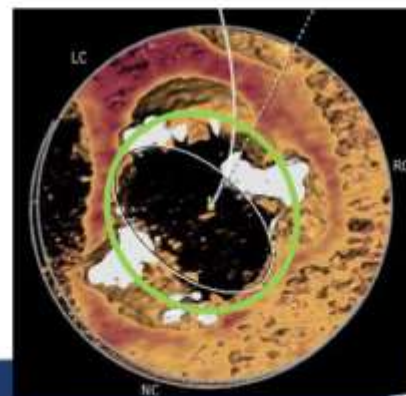
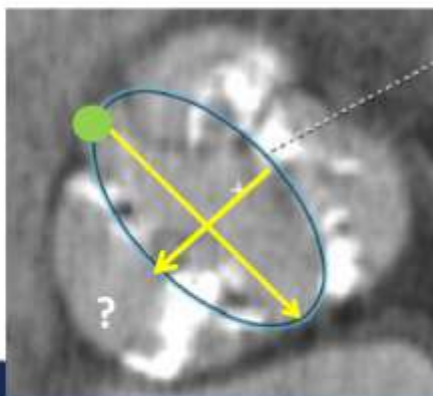
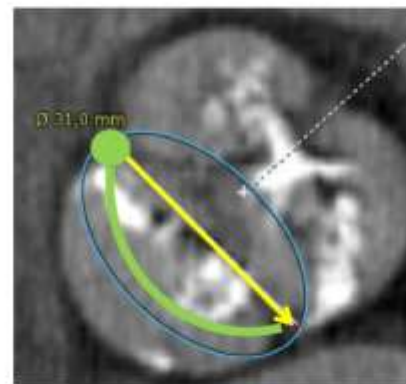
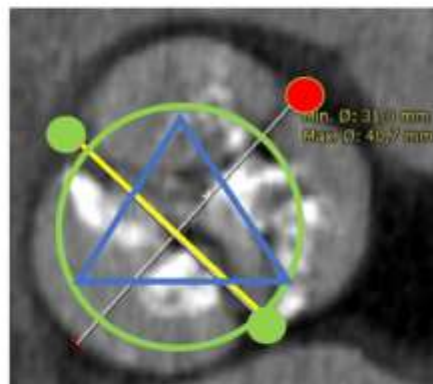
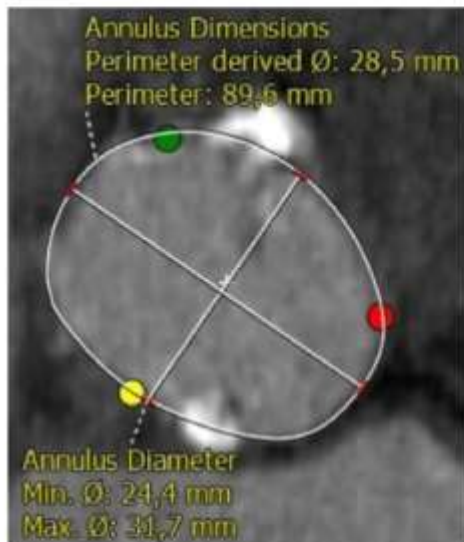
Metaanalysis from 13 observational studies



Reddy Gautam et al Catheter Cardiovasc Interv. 2018;91:975–983.

Device Sizing

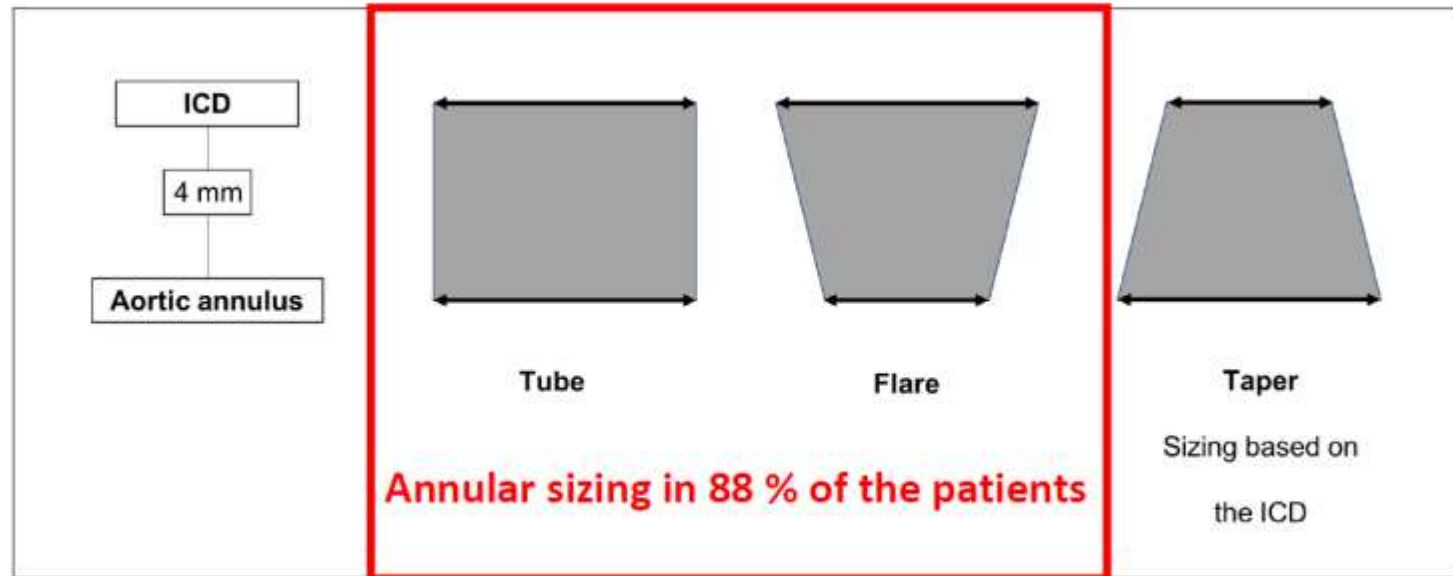
Various sizing methodologies are proposed for TAVR in BAV



Device Sizing: Don't Do Oversizing, ~5%

Sizing according to the landing zone configuration

CP
CLINIQUE
Pasteur



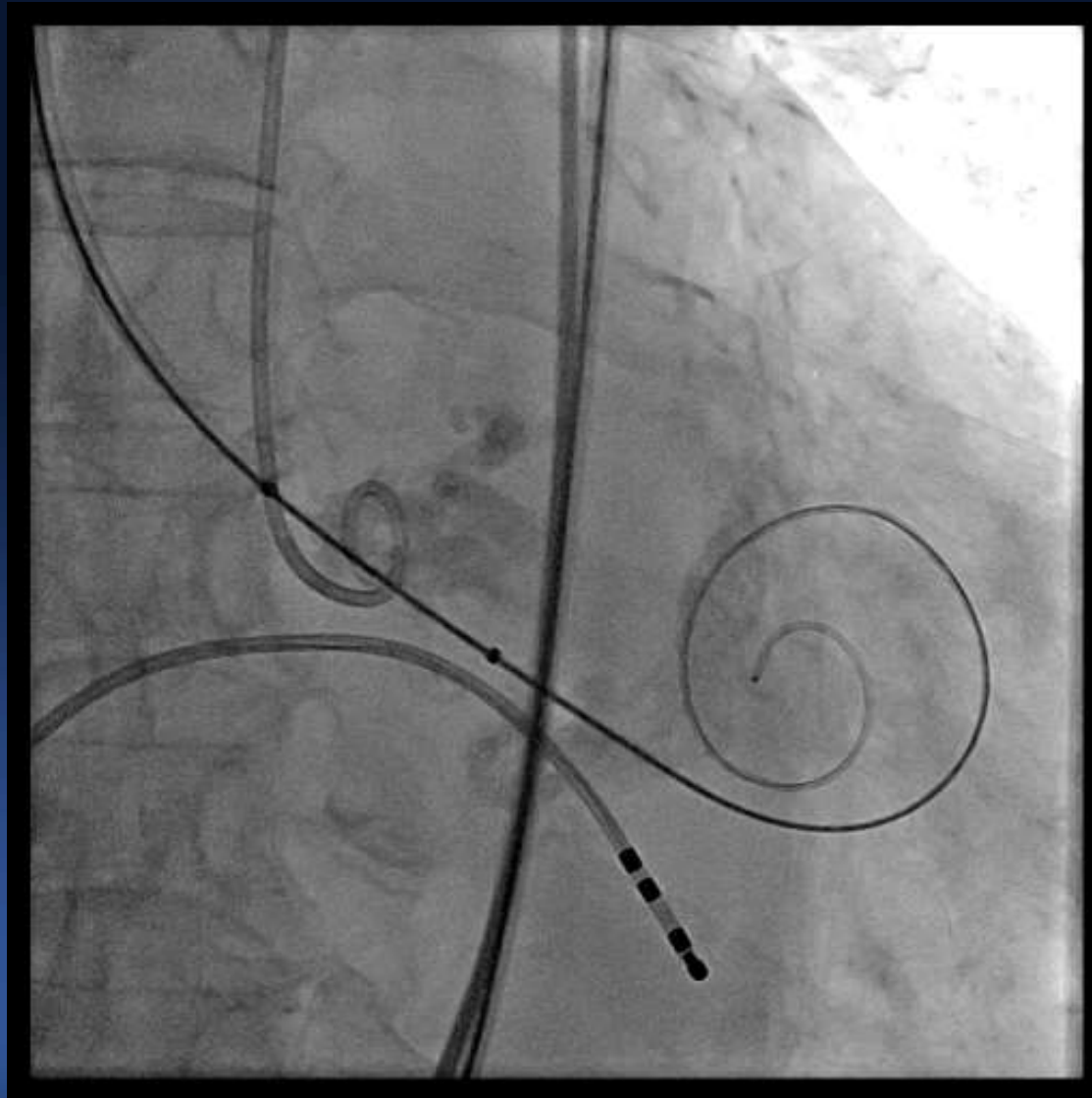
BABARD Registry (N=96, S3 65, Lotus 10, Evolut R 21)

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

Cardiovascular
Research Foundation

Courtesy of Didier Tchetché, Clinique Pasteur, Toulouse, France

BAV Is Mandatory in Bicuspid AS



M/68 YO

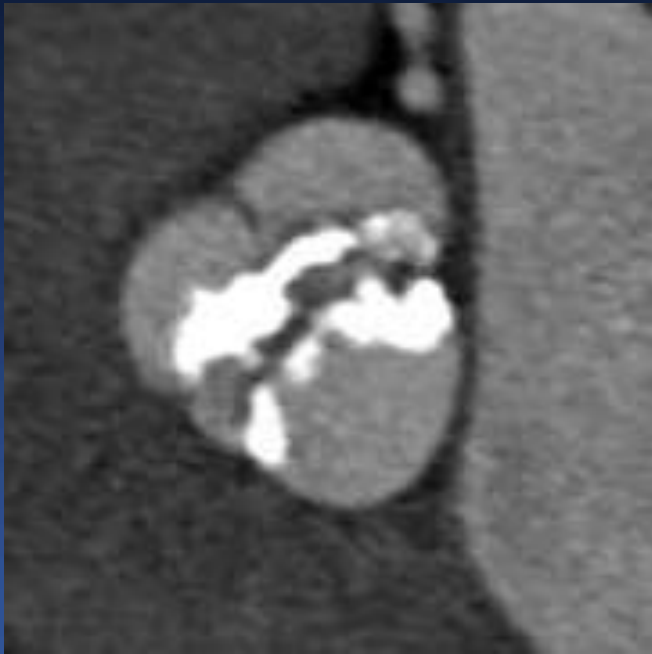
CC: Dyspnea,

Risk Factors: Liver cirrhosis with ascites, esophageal varix

Severe AS with Bicuspid Valve (Type I RL fusion)



Skirt



Annulus area : 579 mm²

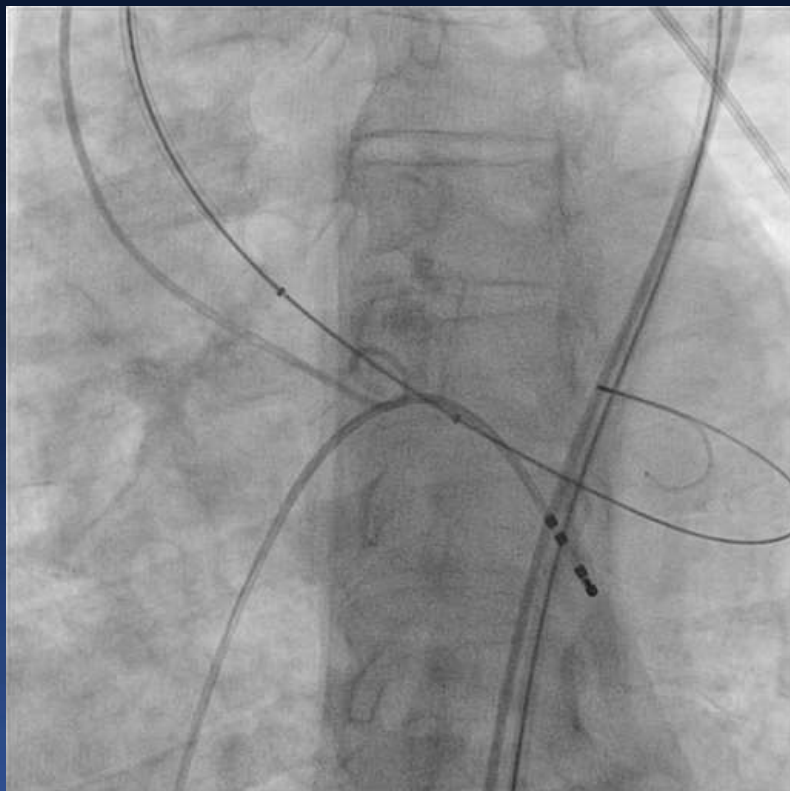
S3 26mm -> 90% oversize

S3 29mm -> 112% oversize

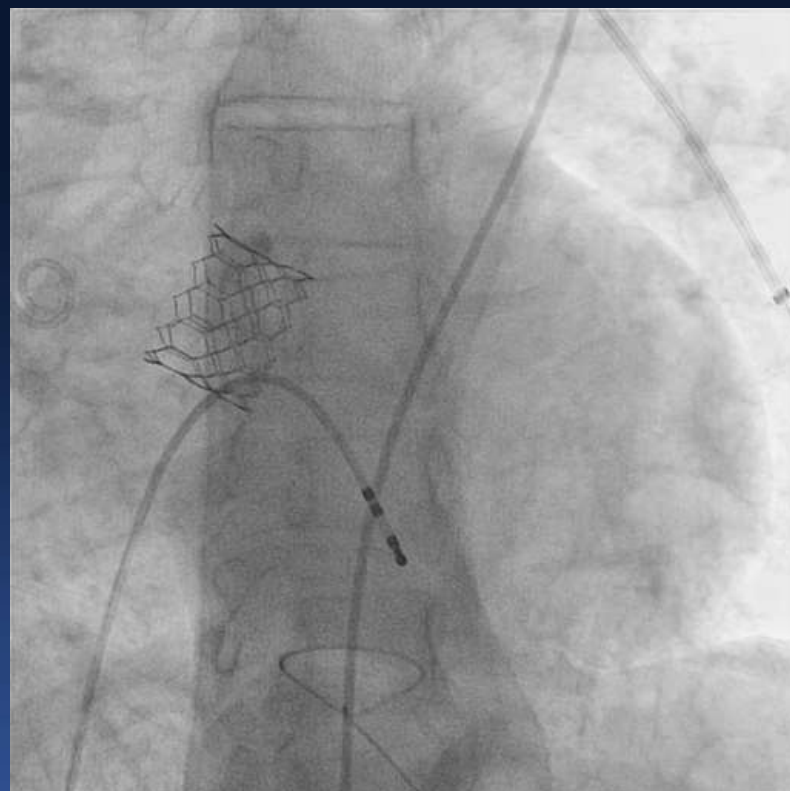
Annulus perimeter : 86 mm

Calcium volume: 1132 mm³

(Mean calcium volume in AMC: 400 mm³)

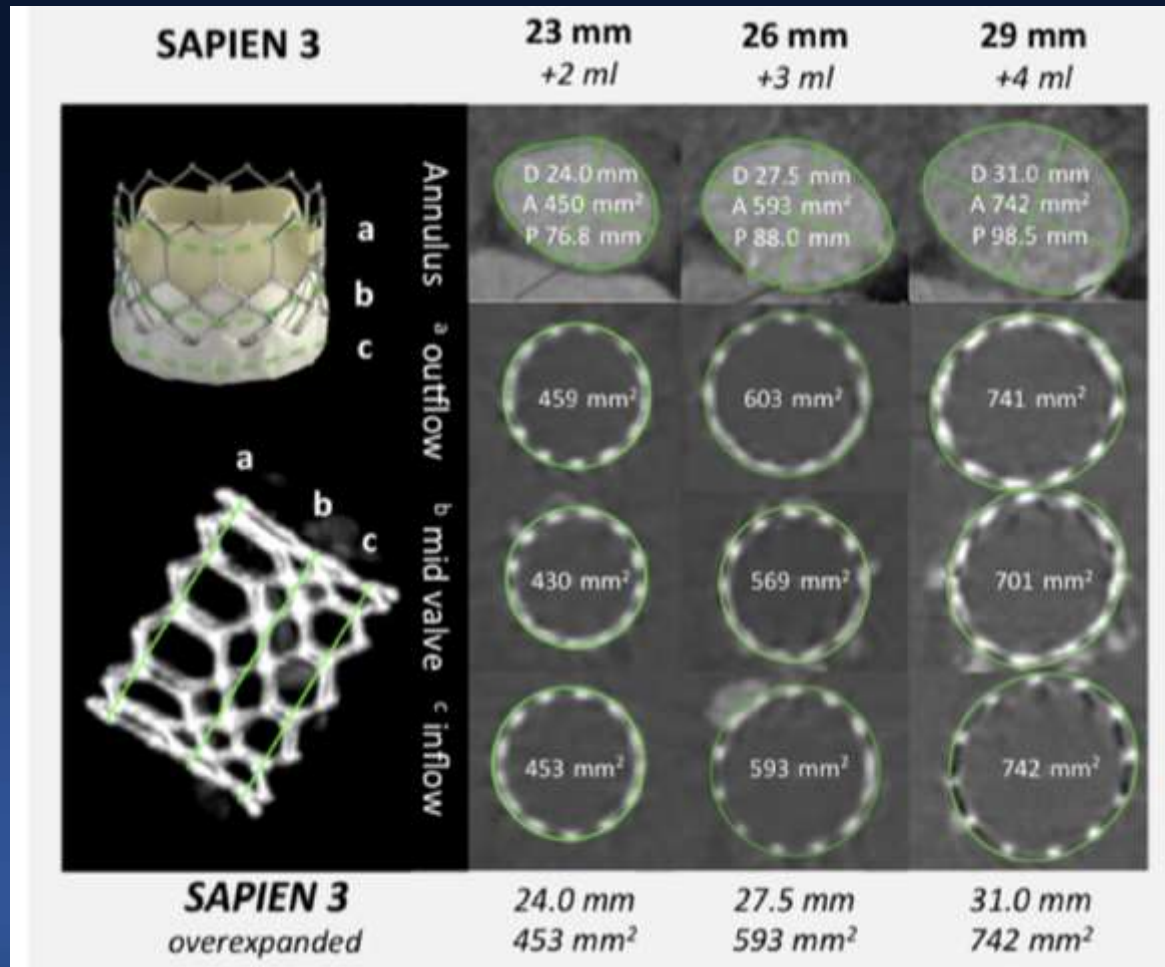


20mm Balloon



Sapien 3 26 mm + 2cc

Norminal Sizing And Overfill Strategy Would be Safer In (Severely Calcified) BAV TAVR with S3



Volume Underfilling May Not Avoid Complication

Calcium volume: 1100 mm³ with LVOT Calcification

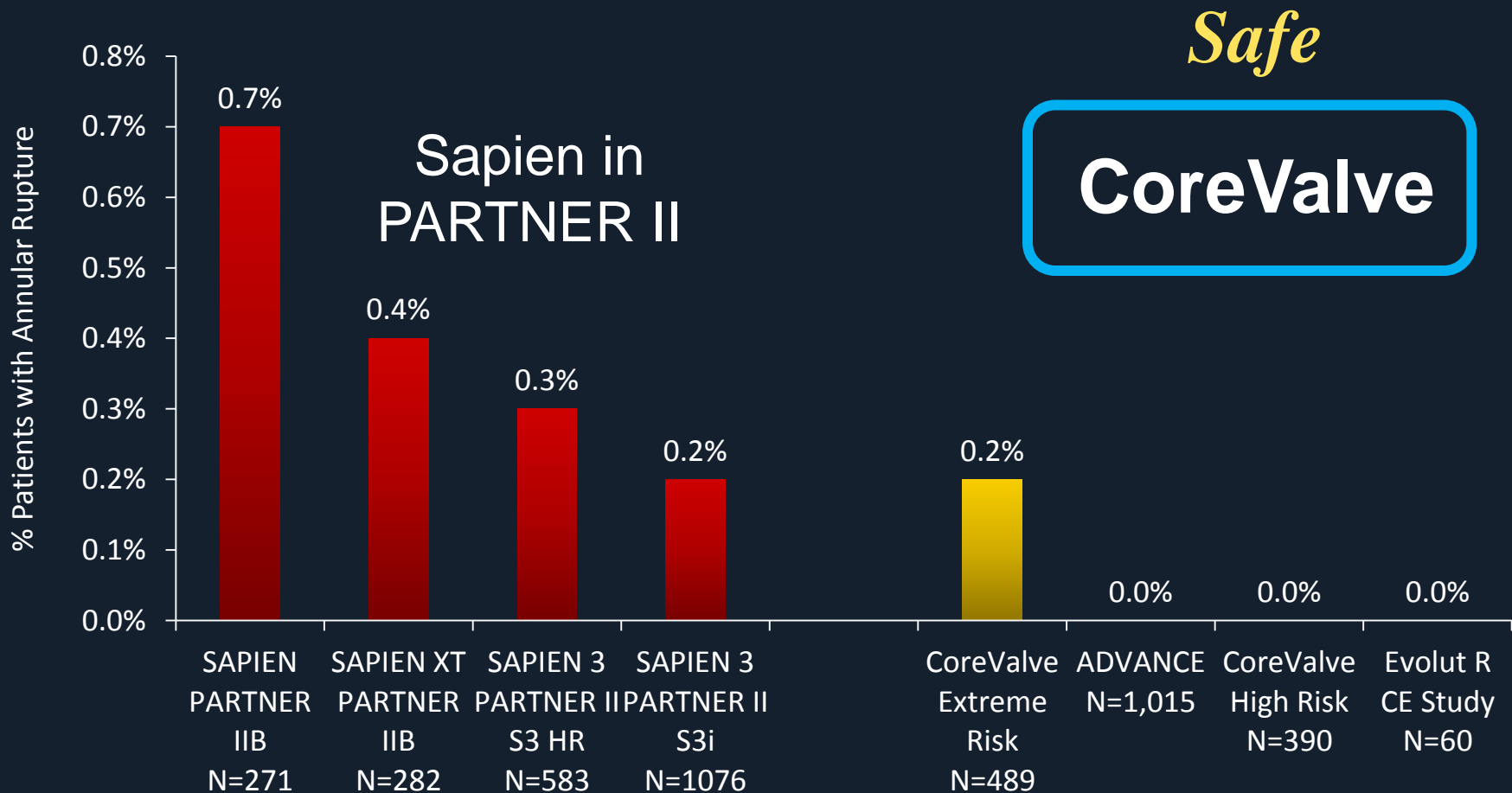
Sapien XT 29mm

18% Oversize -> 5cc Under-filling -> No oversize

Annulus Rupture

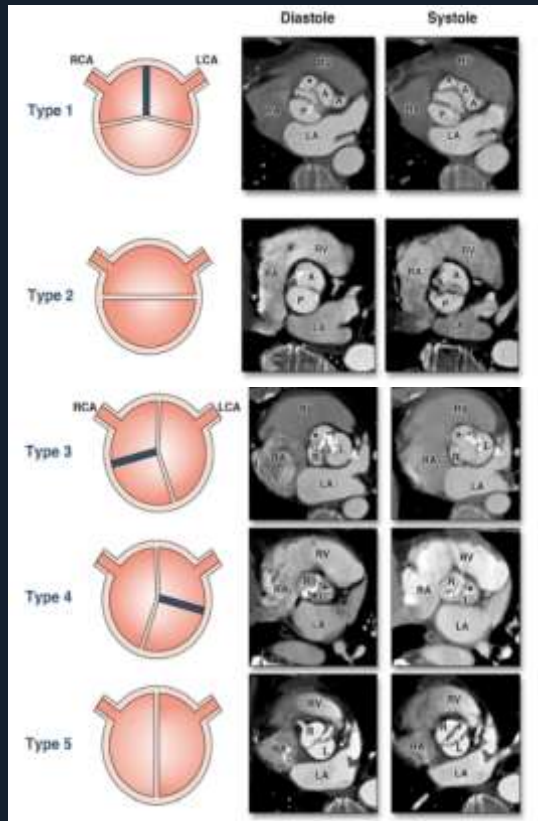


Risk of Annular Rupture

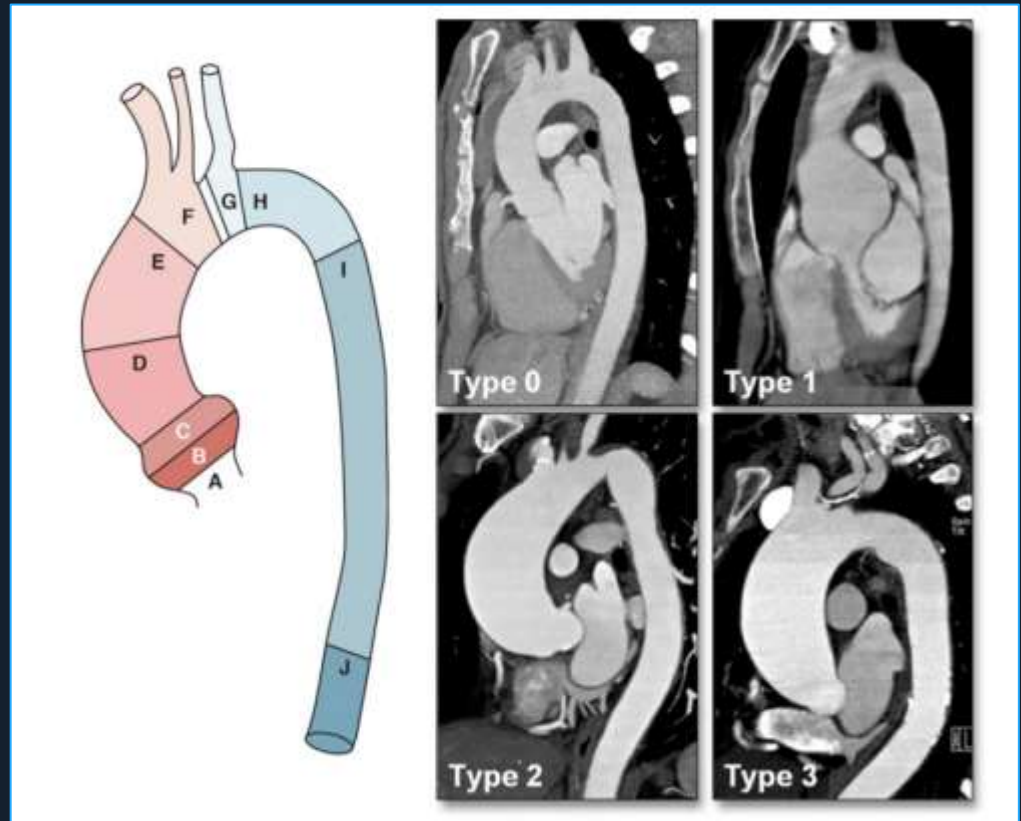


Spectrum of BAV Disease

Aortic Valve Morphology

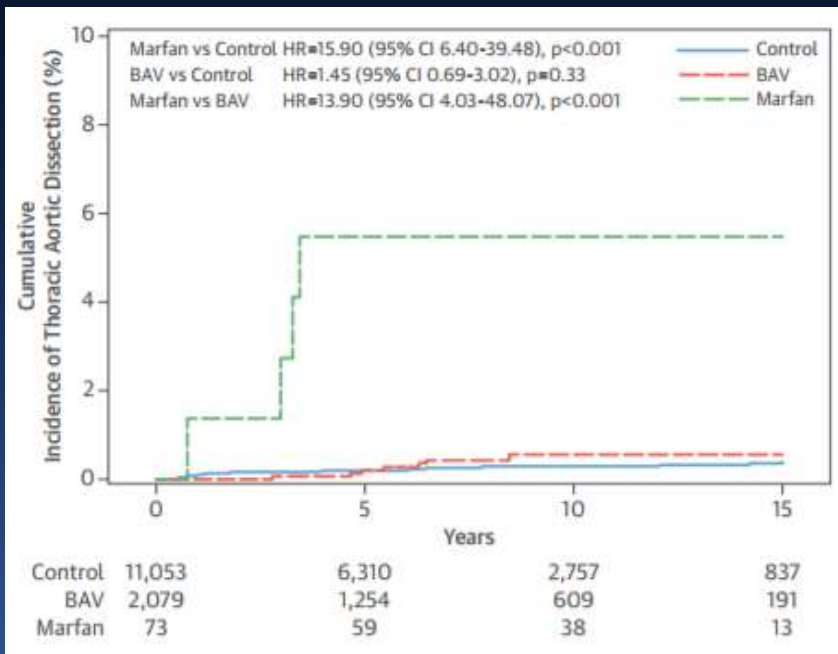


Combined Aortopathy



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

BAV Aortopathy

Higher Surgical Risk
Very Old Age



TAVR

Lower Surgical Risk

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

Yes



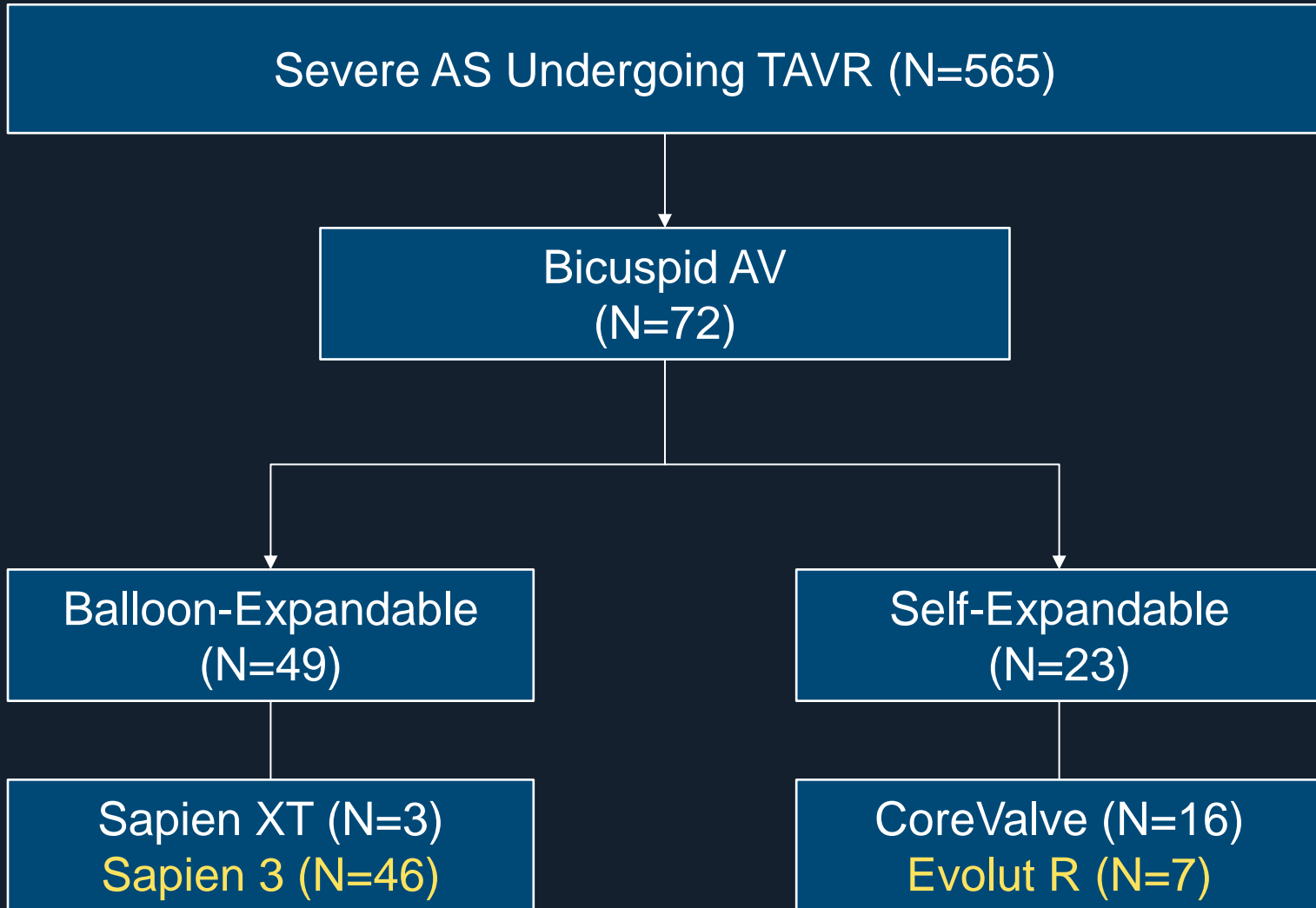
SAVR +
Aorta Surgery

No

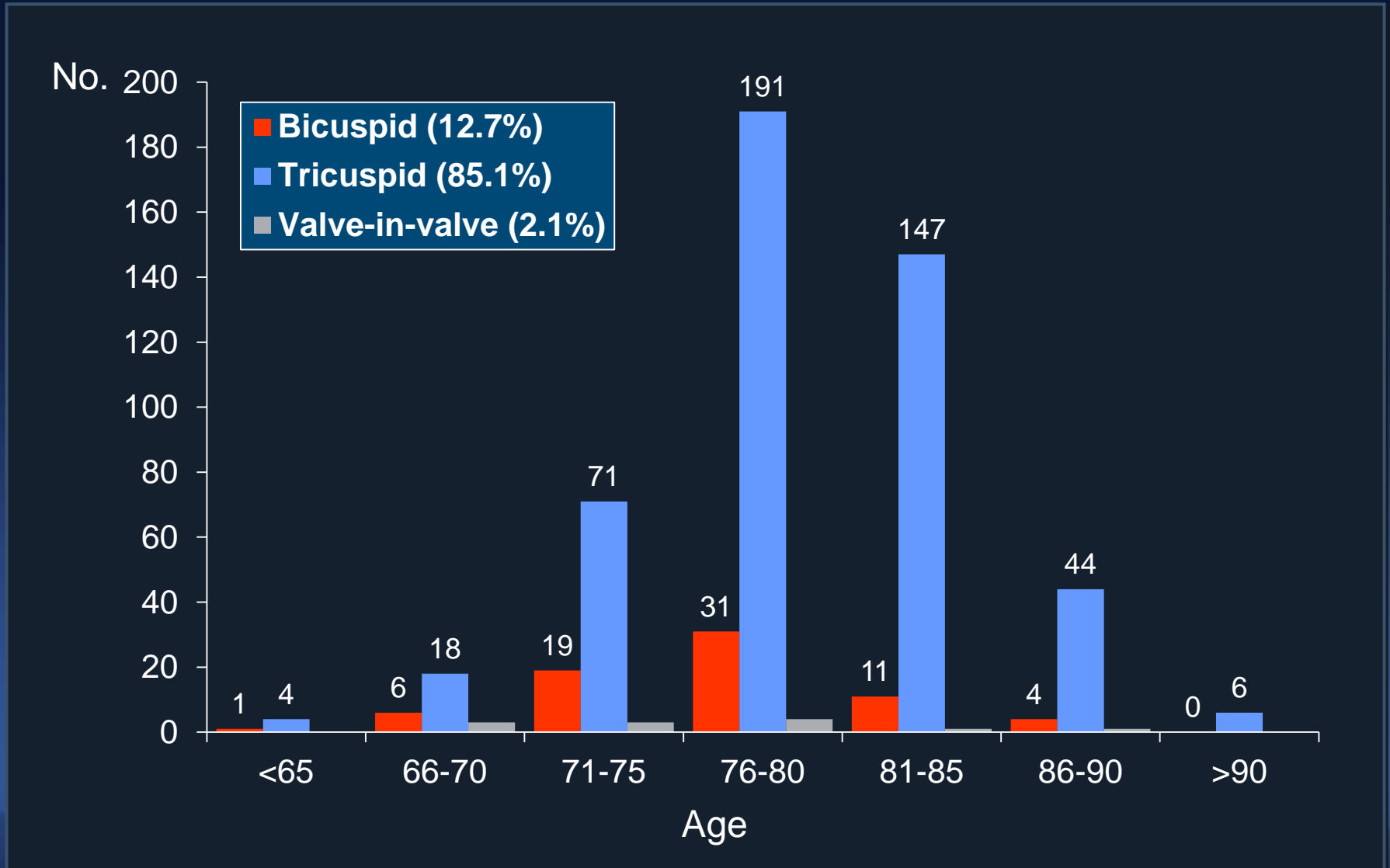


Consider TAVR
If Indicated

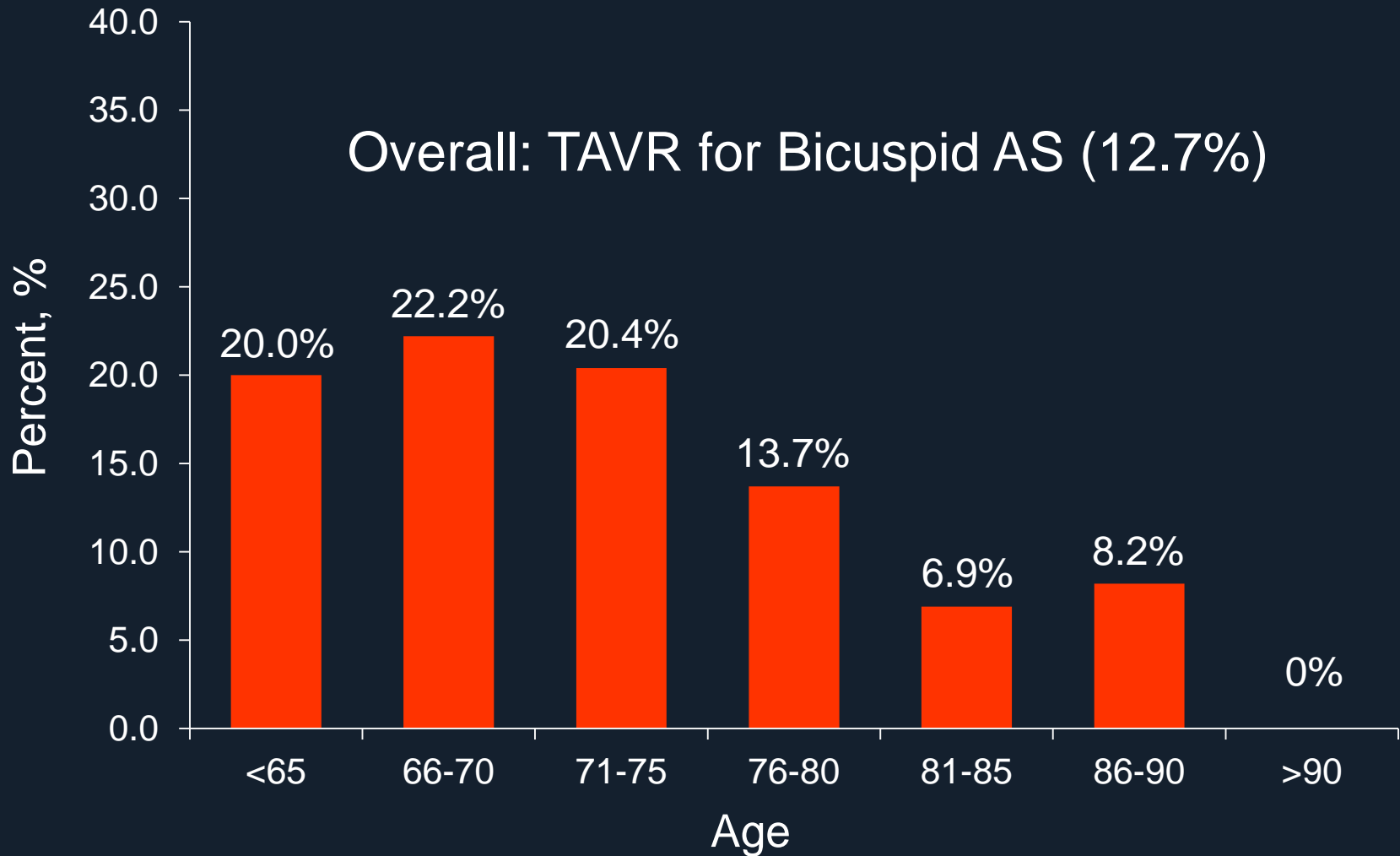
ASAN TAVR Registry



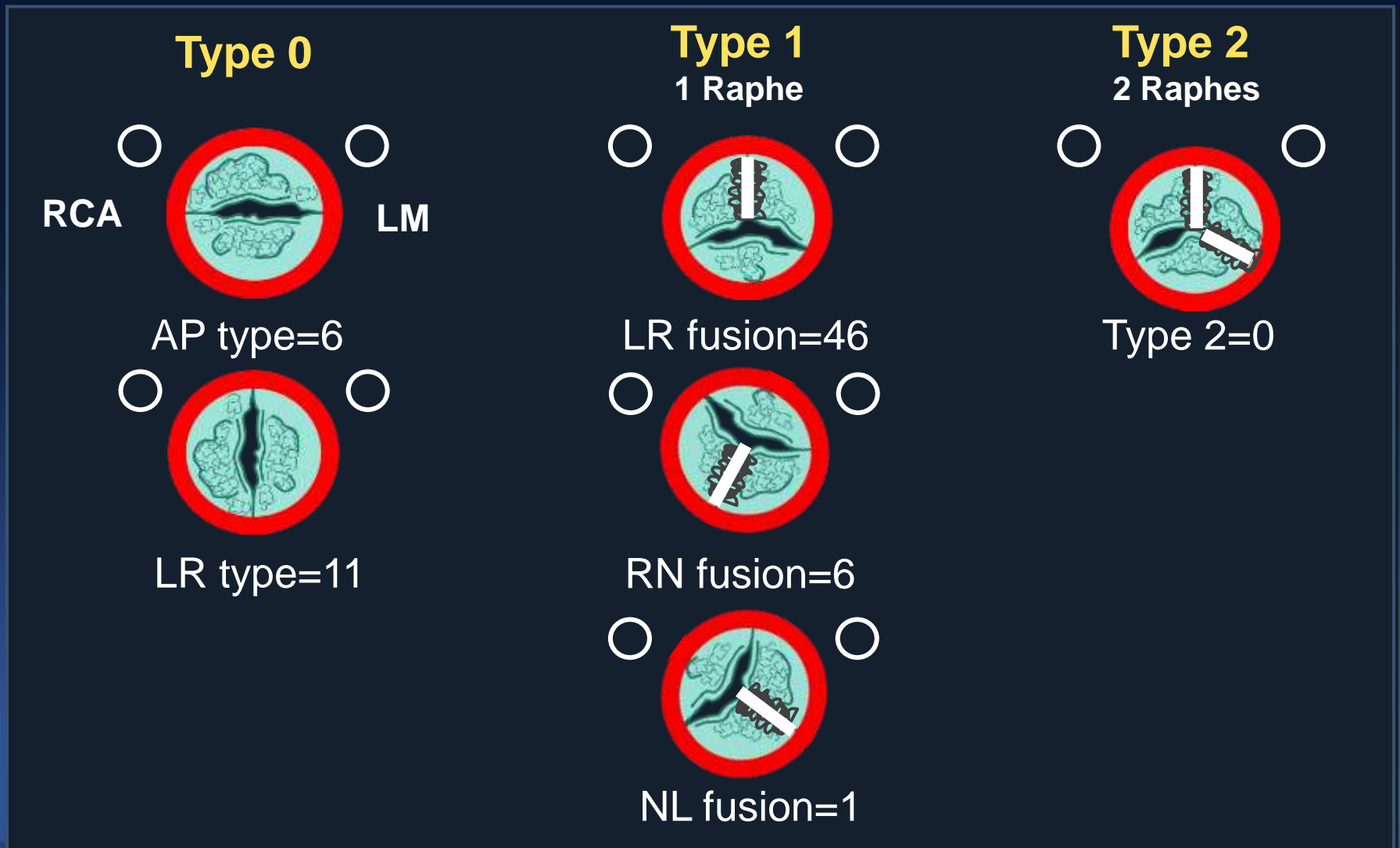
Age Proportion of TAVR for Bicuspid AS



Proportion of TAVR for Bicuspid AS



Type of Bicuspid AV*



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

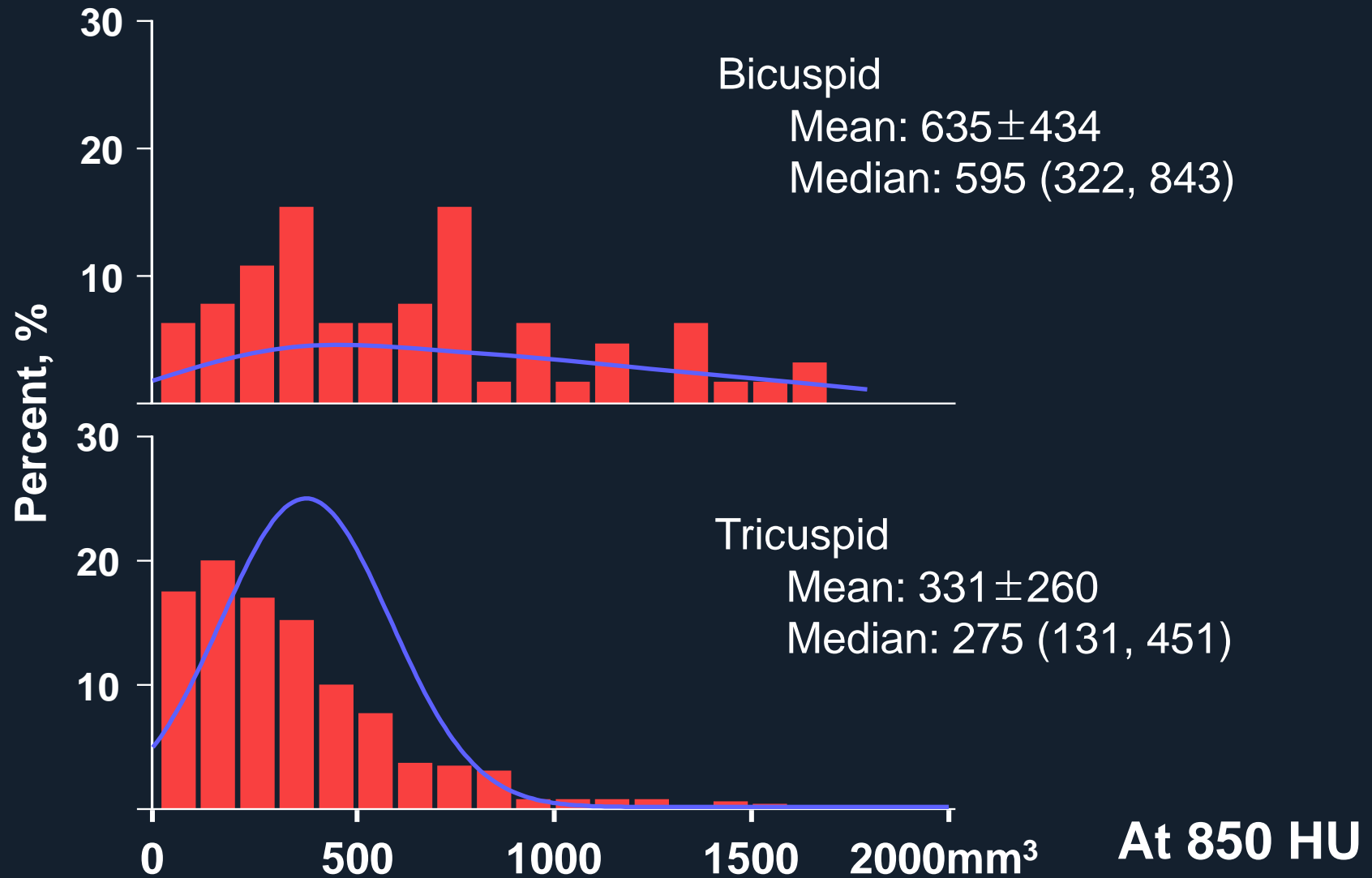
Baseline Characteristics

	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

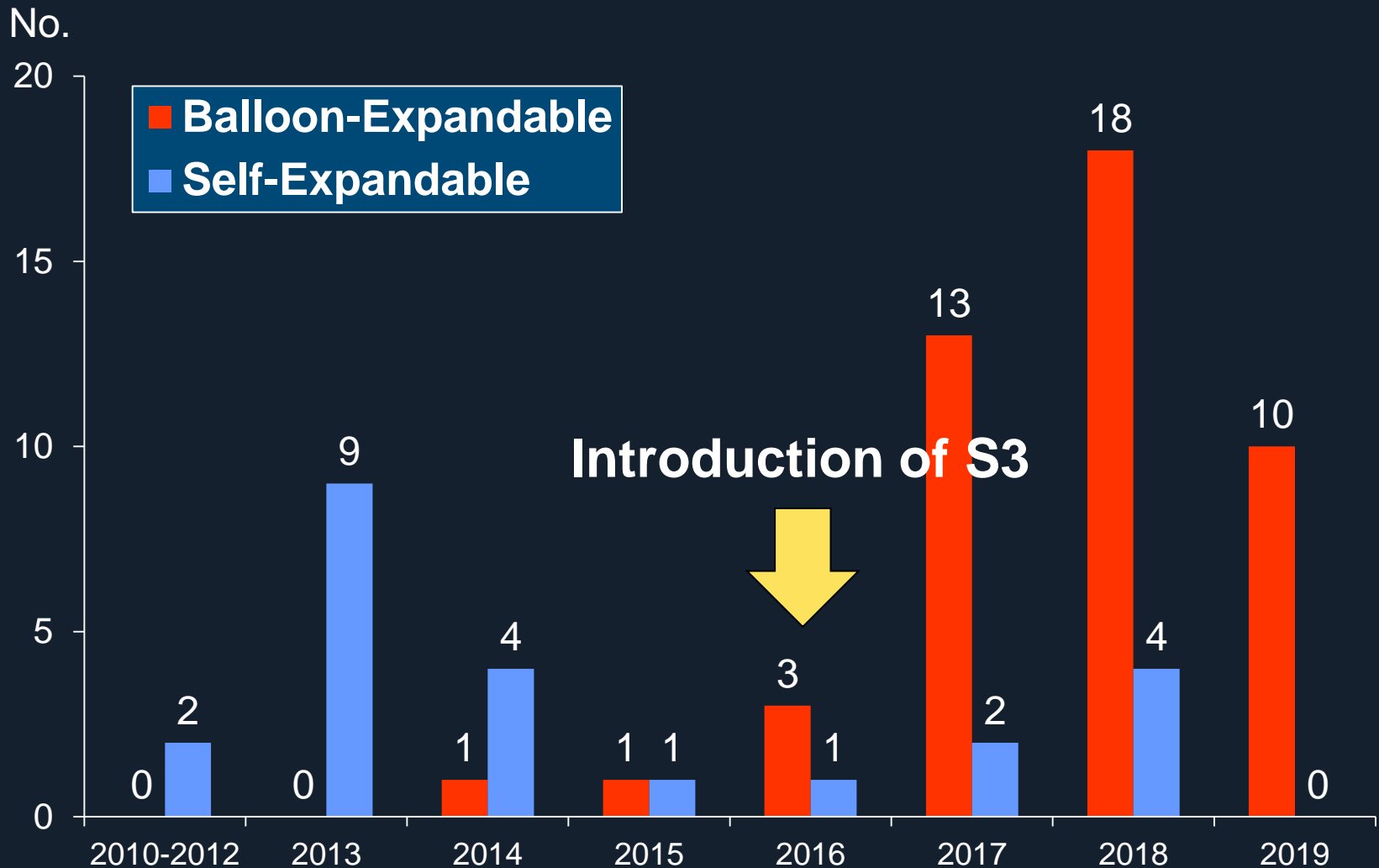
CT Measurement

	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



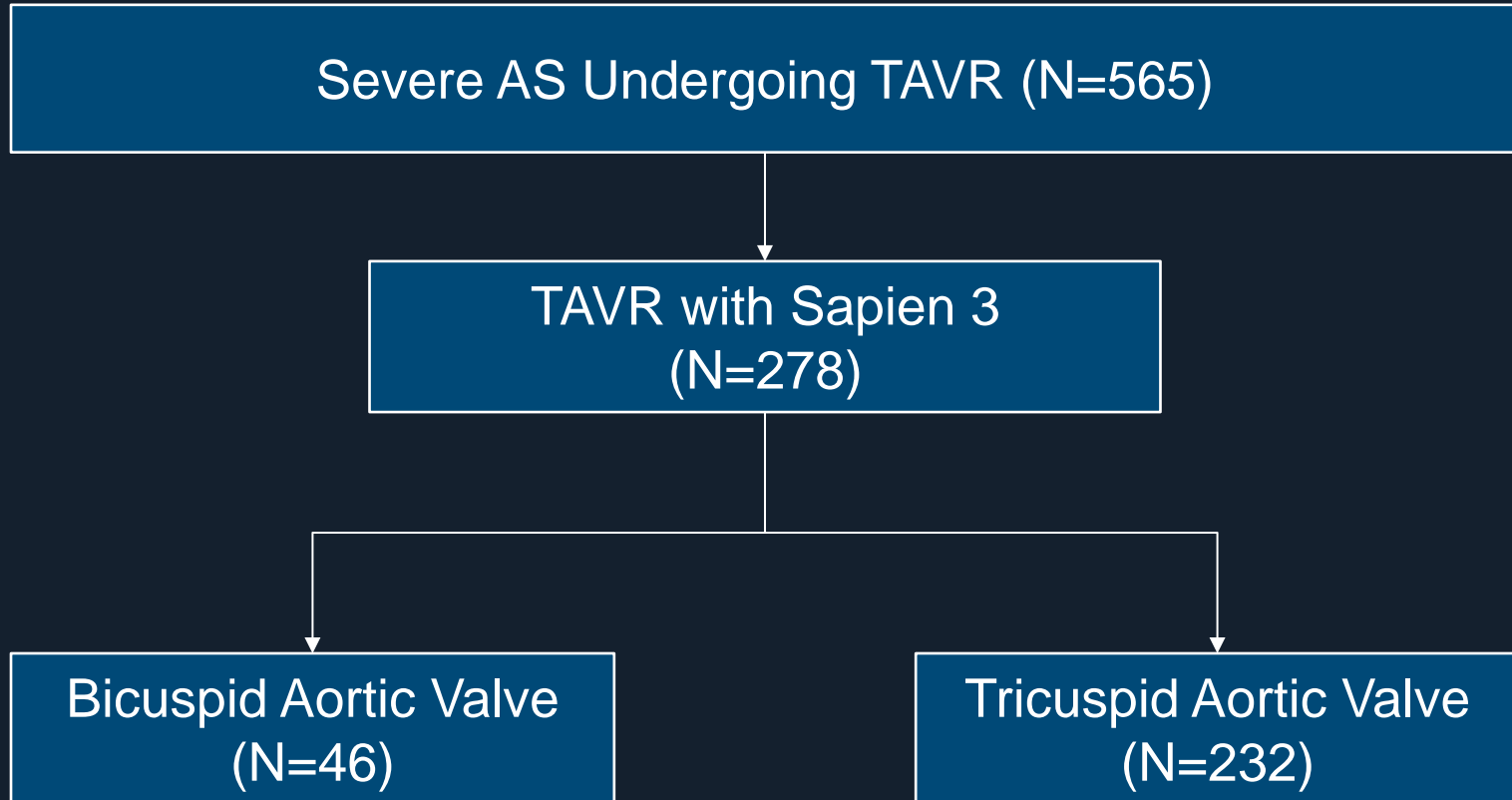
Heart Valve for Bicuspid AS



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

ASAN TAVR Registry

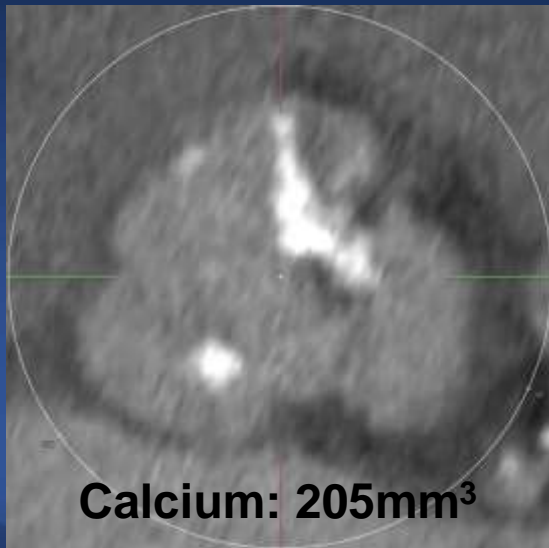
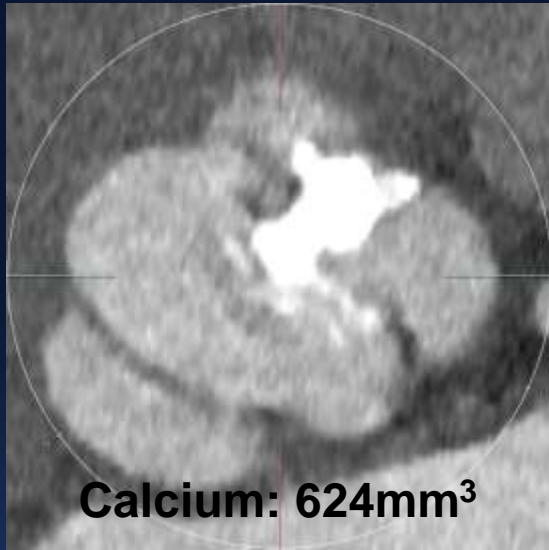


Procedural Outcomes

Sapien 3 Cohort

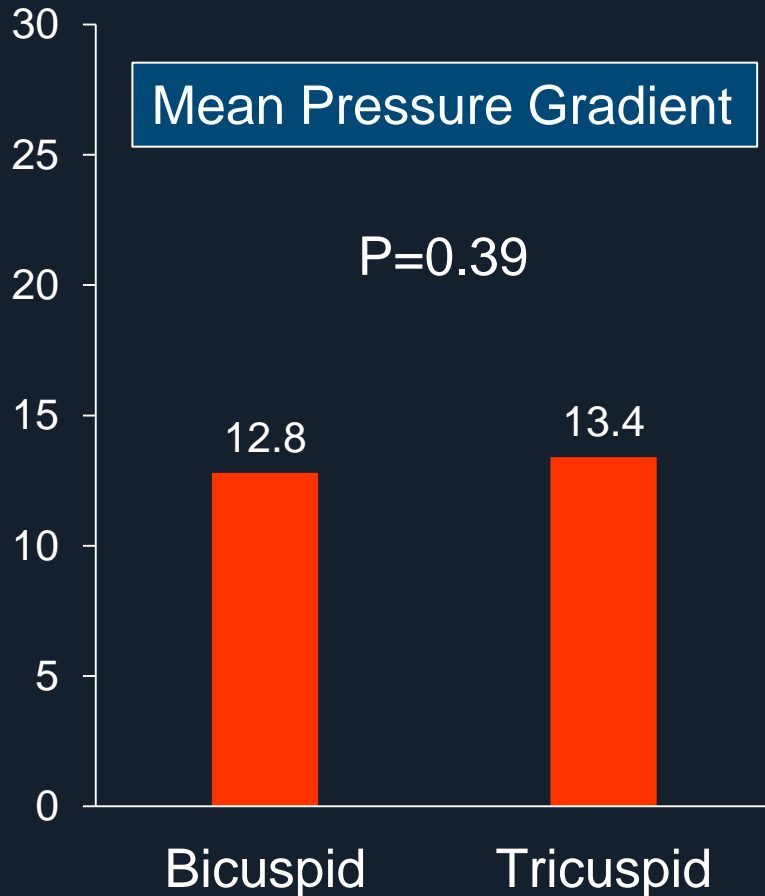
	Bicuspid AS (N = 46)	Tricuspid AS (N = 232)	P
Valve Oversizing to annulus, %	106.4±7.2	113.4±6.1	<0.001
Pre-Balloon Valvuloplasty	38 (82.6%)	119 (51.3%)	<0.001
Conversion To Surgery	1 (2.2%)	0%	0.17
	Valve migration: 1		
Coronary Obstruction	0%	3 (1.3%)	0.58
Annular Rupture	0%	1 (0.4%)	0.84
Second Valve 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

Moderate PVR

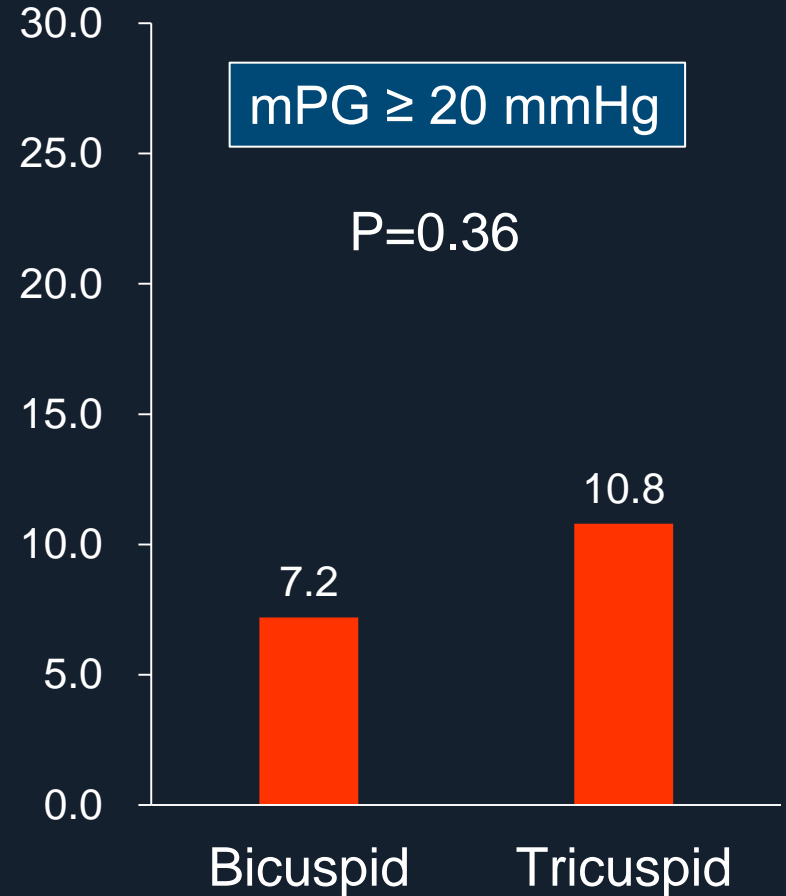


Hemodynamic Outcomes

mmHg

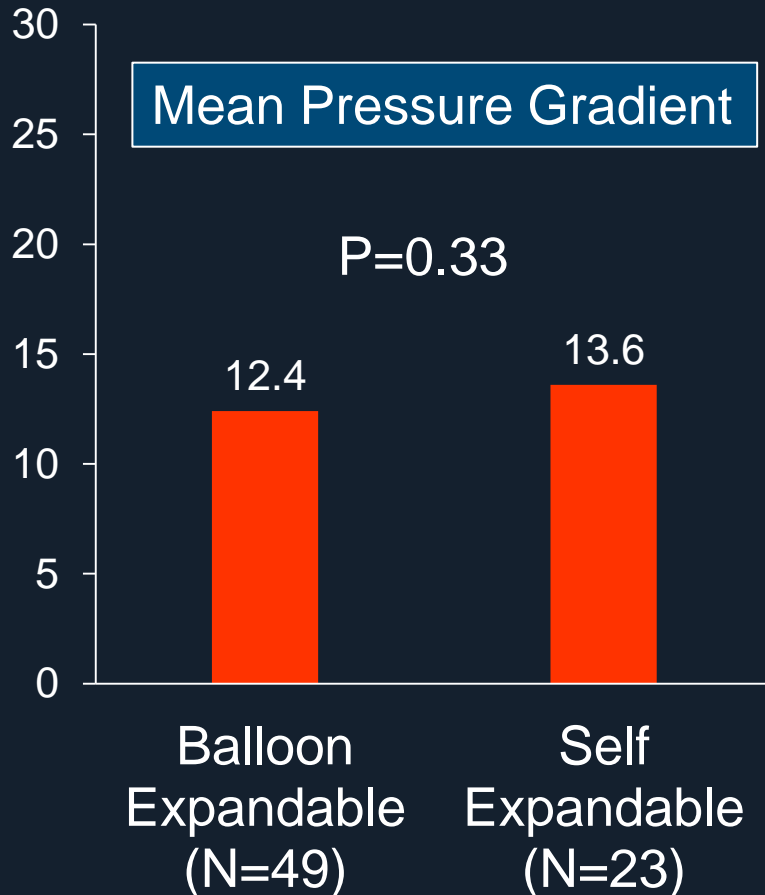


%

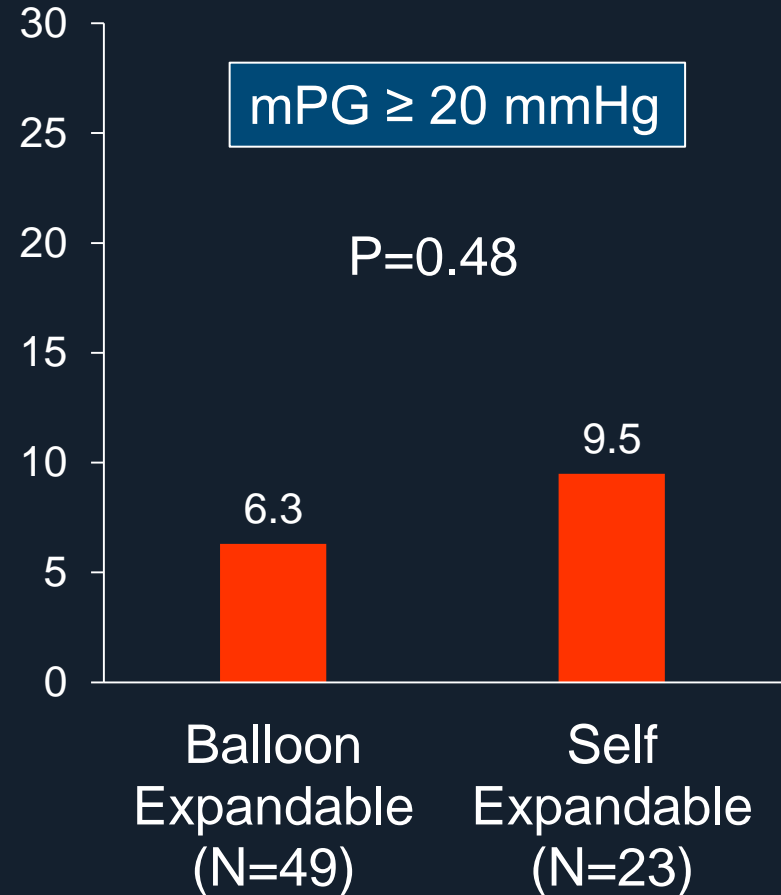


Hemodynamic Outcomes

mmHg



%

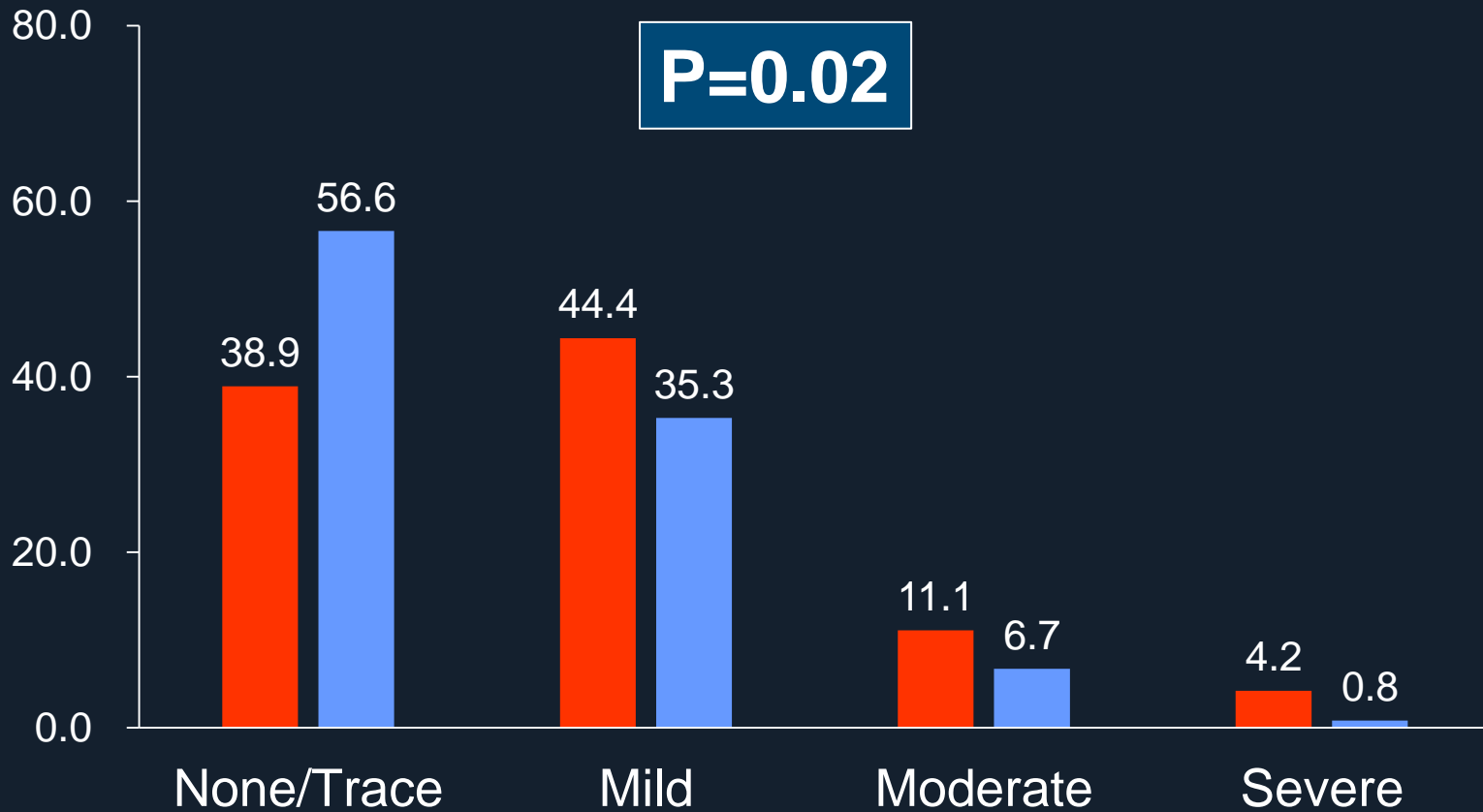


Para-Valvular Leakage

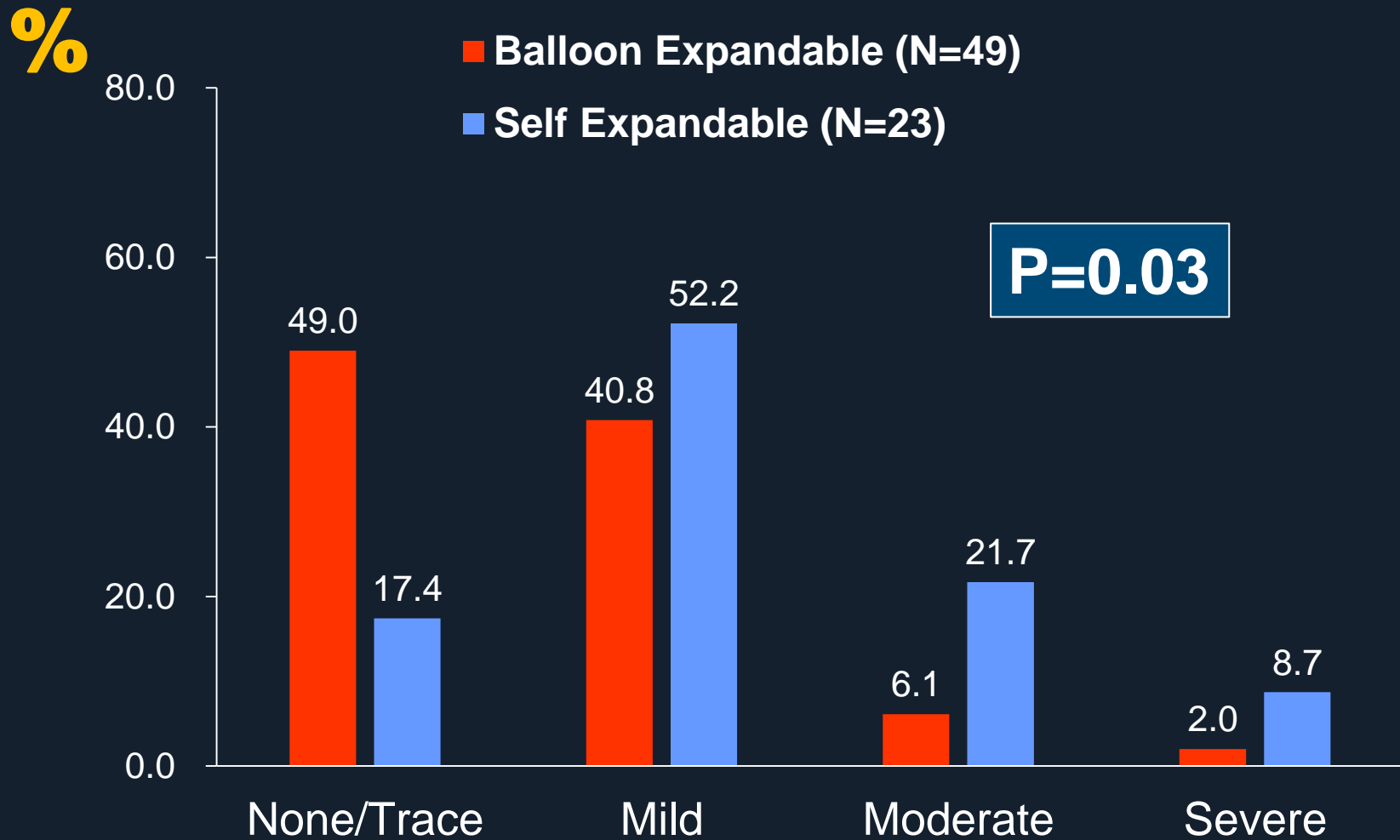
%

■ Bicuspid AV ■ Tricuspid AV

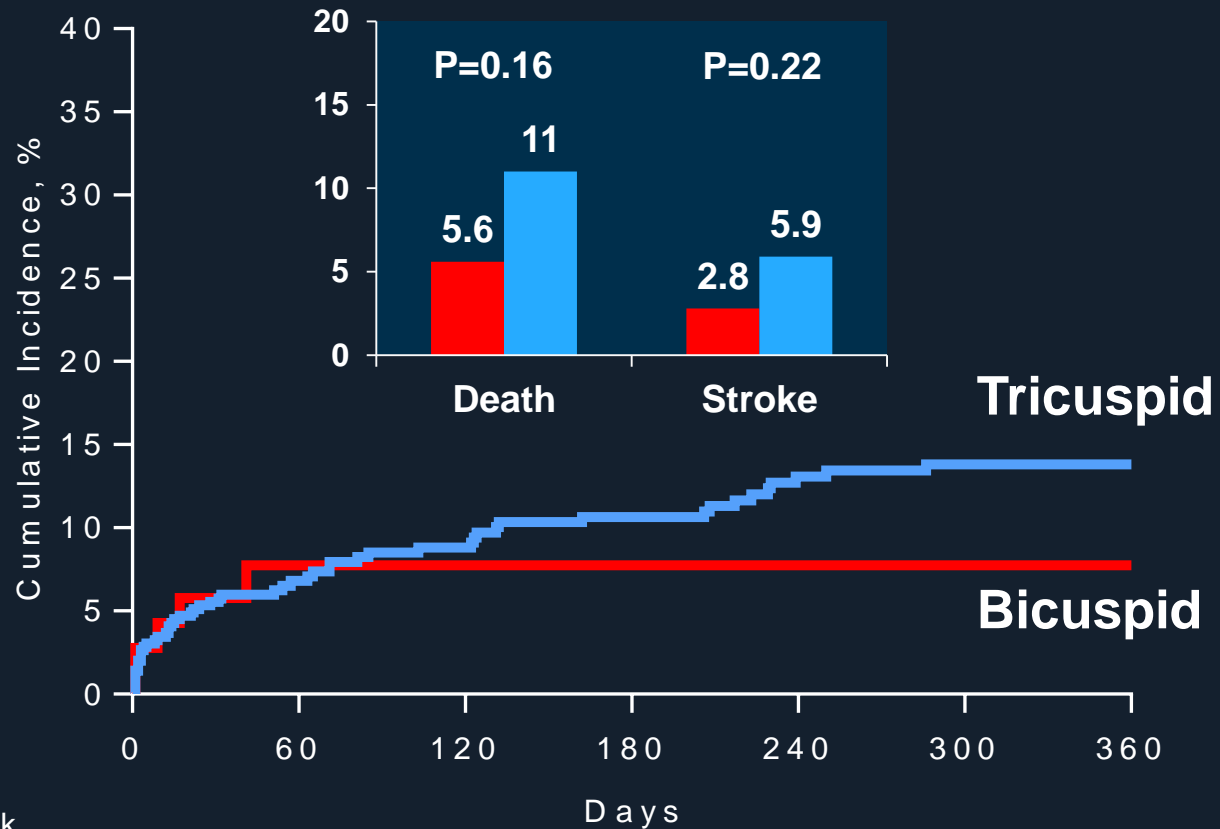
P=0.02



Para-Valvular Leakage



Death and Stroke*



No. at Risk

Bicuspid

72

Days

28

19

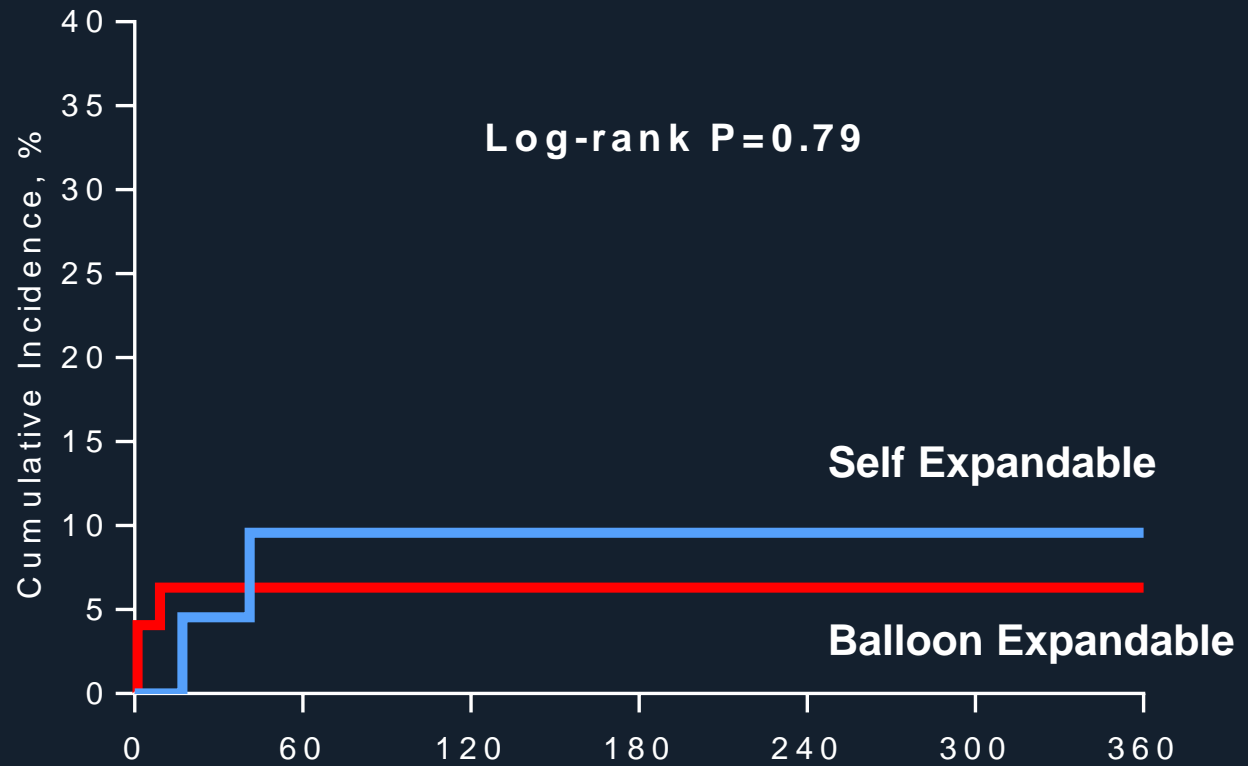
Tricuspid

493

279

223

Death and Stroke*



No. at Risk

Balloon expandable 49

Self expandable 23

Days

12

17

4

16

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.