TAVR: Bicuspid, Severe Calcium, and Low Lying Left Main

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- **Bicuspid Aortic Valve Stenosis**
- Severe Calcification
- Low Lying Left Main

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

F/74 YO

CC: Dyspnea on exertion,

Risk Factors: Anemia, Stroke, s/p gastric cancer surgery

STS Score 1.40

Severe AS with Bicuspid Valve (Type 1, LR fusion)

Annulus Area : 497 mm^2

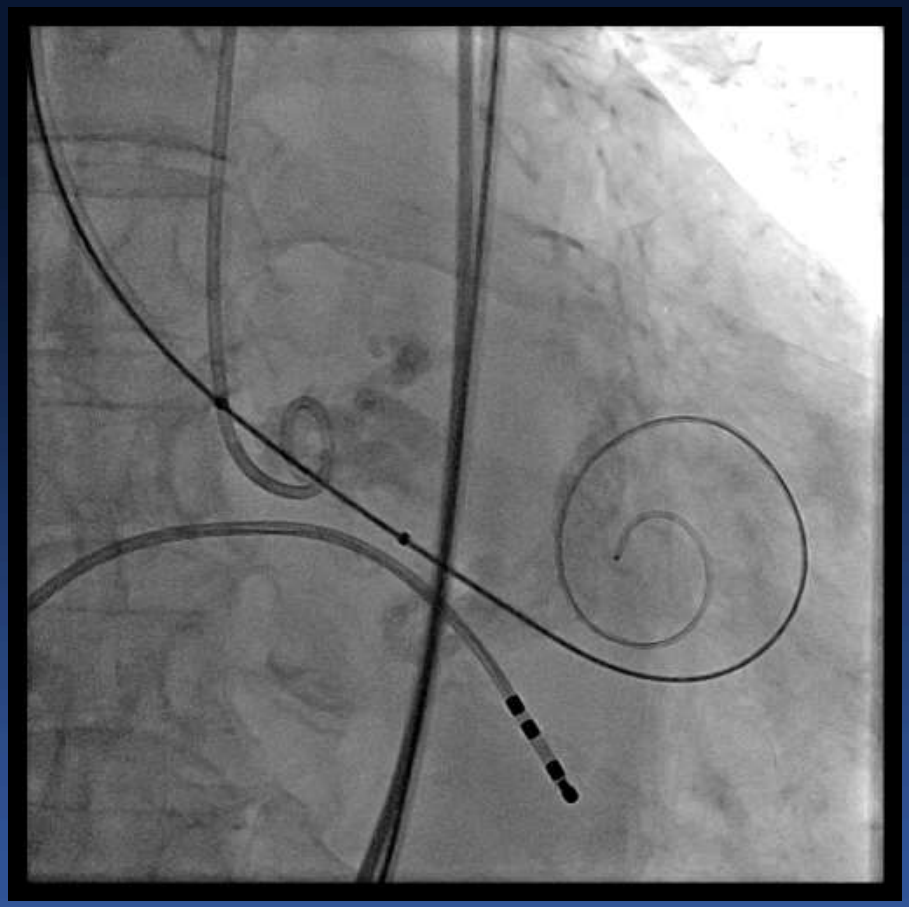
Sapien 3 26mm -> 104% oversize

Sapien 3 29mm -> 131% oversize

Annulus Perimeter : 79.9 mm

Calcium volume: 785 mm^3

(Mean calcium volume in AMC: 400 mm^3)



20mm Balloon

Sapien 3 26 mm

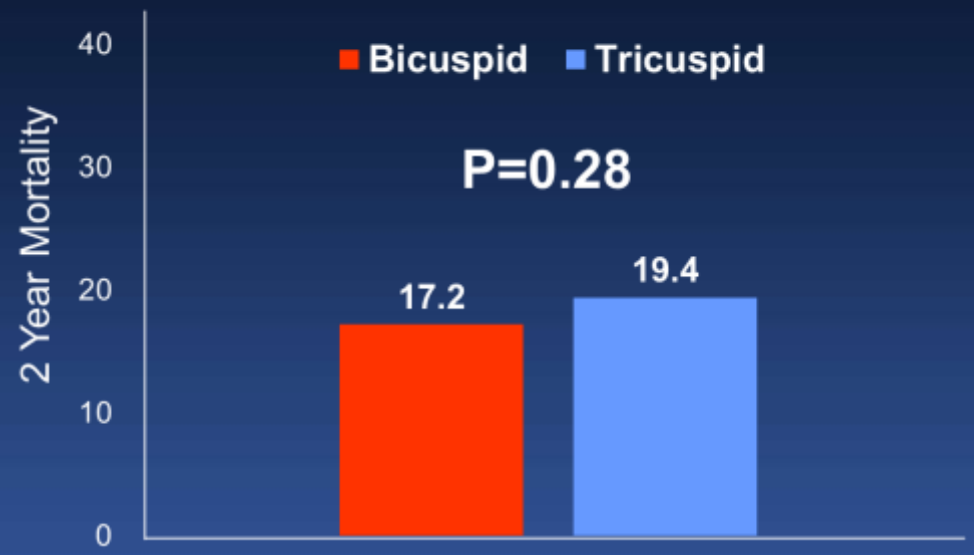
Practical Issues

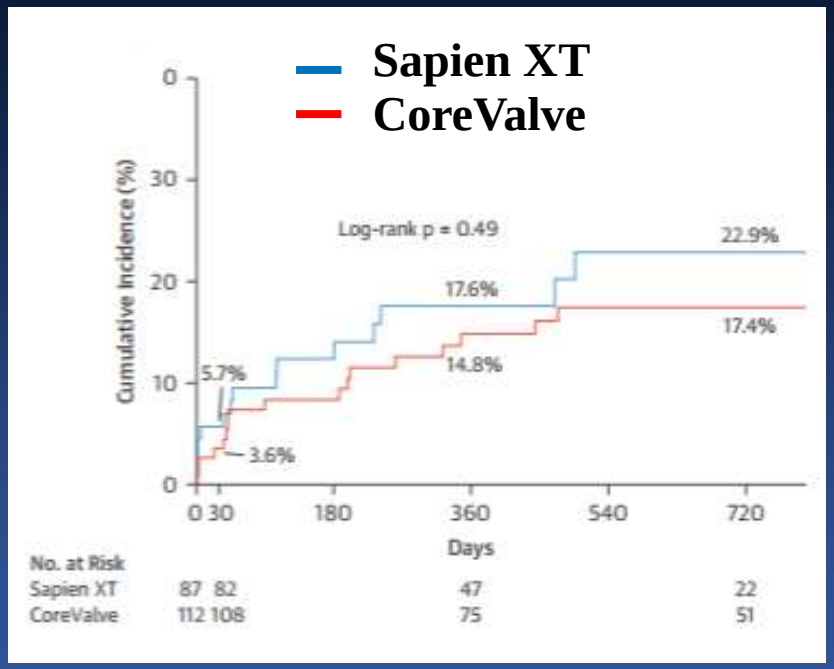
- Which Type of Valves?
- How To Select Optimal Size?
- Pre- and Post Balloon?
- Device Underexpansion
- Associated Aortopathy

Valve Type

2 Year Mortality of TAVR

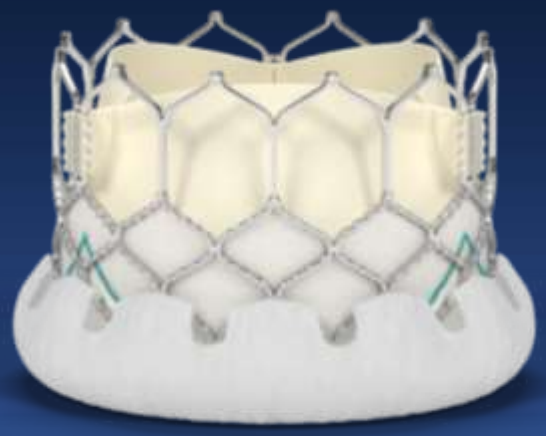
Higher Aortic Root Injury
➡ Balloon Expandable
Higher PVL
➡ Self Expandable





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

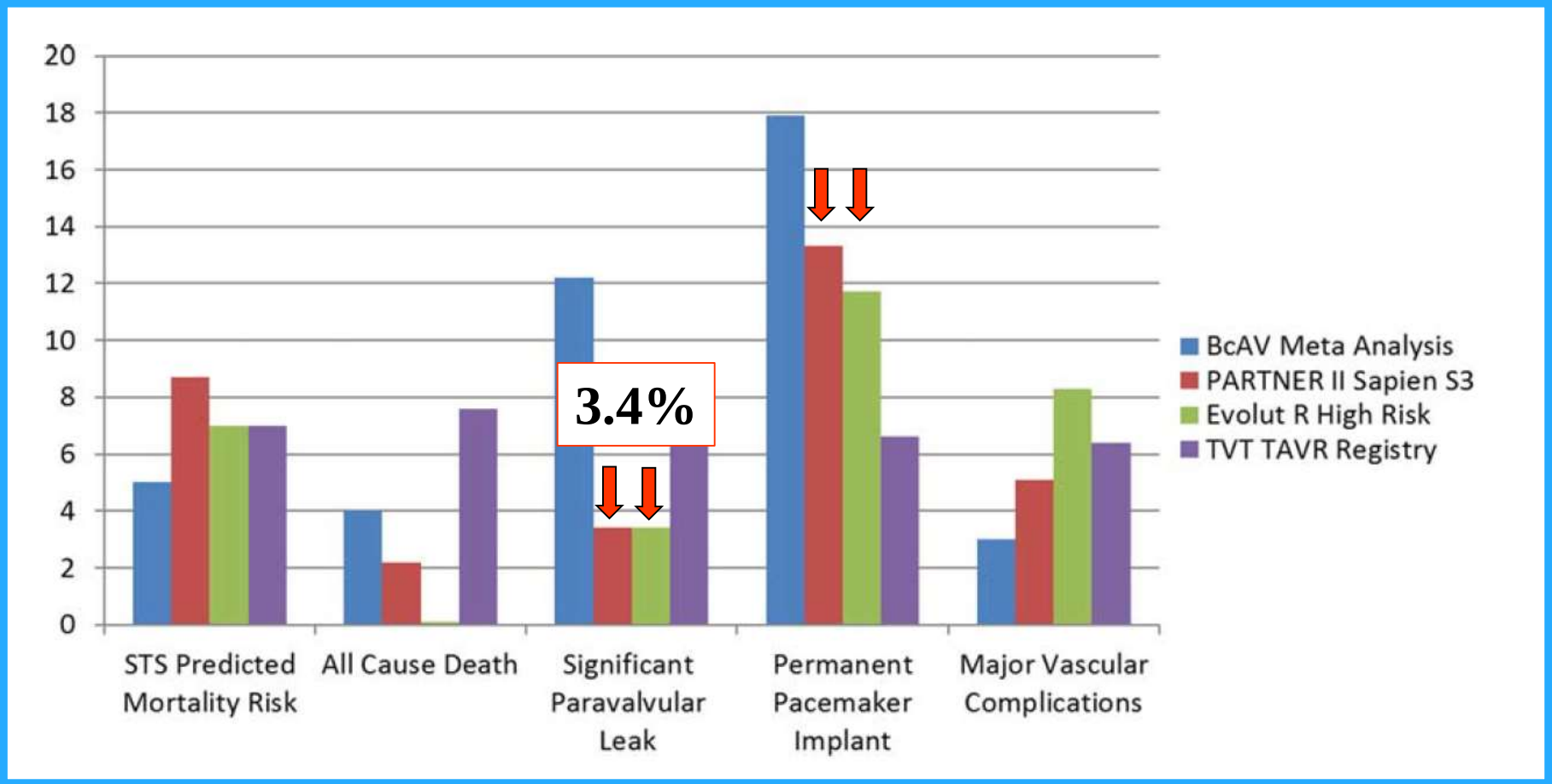
Cedars-Sinai

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

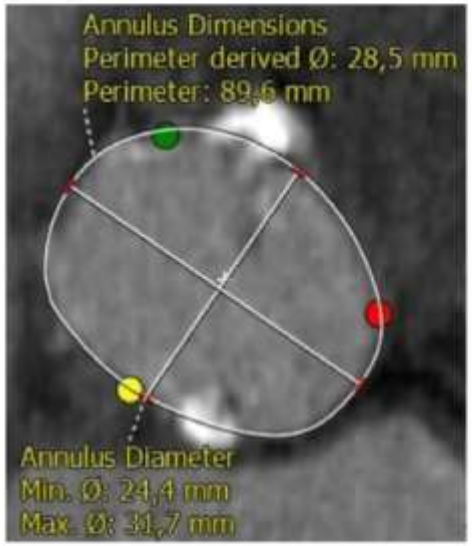
Metaanalysis from 13 observational studies

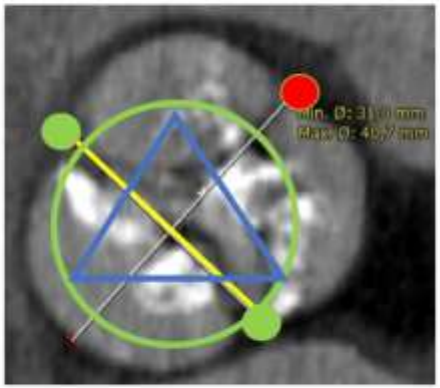


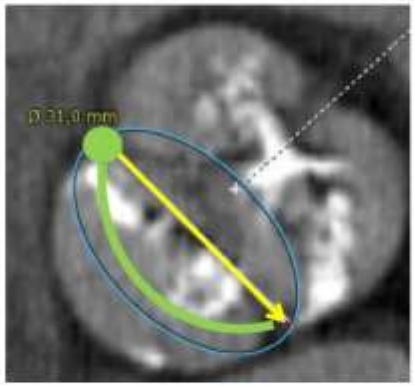
Reddy Gautam et al Catheter Cardiovasc Interv. 2018;91:975–983.

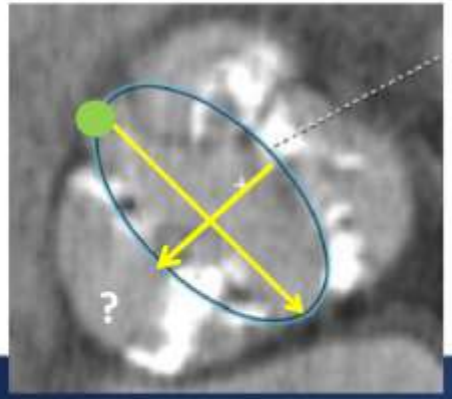
Device Sizing

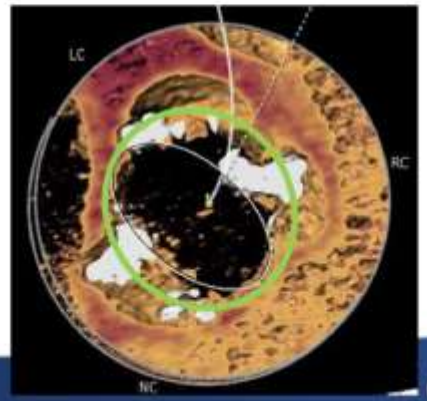
Various sizing methodologies are proposed for TAVR in BAV











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

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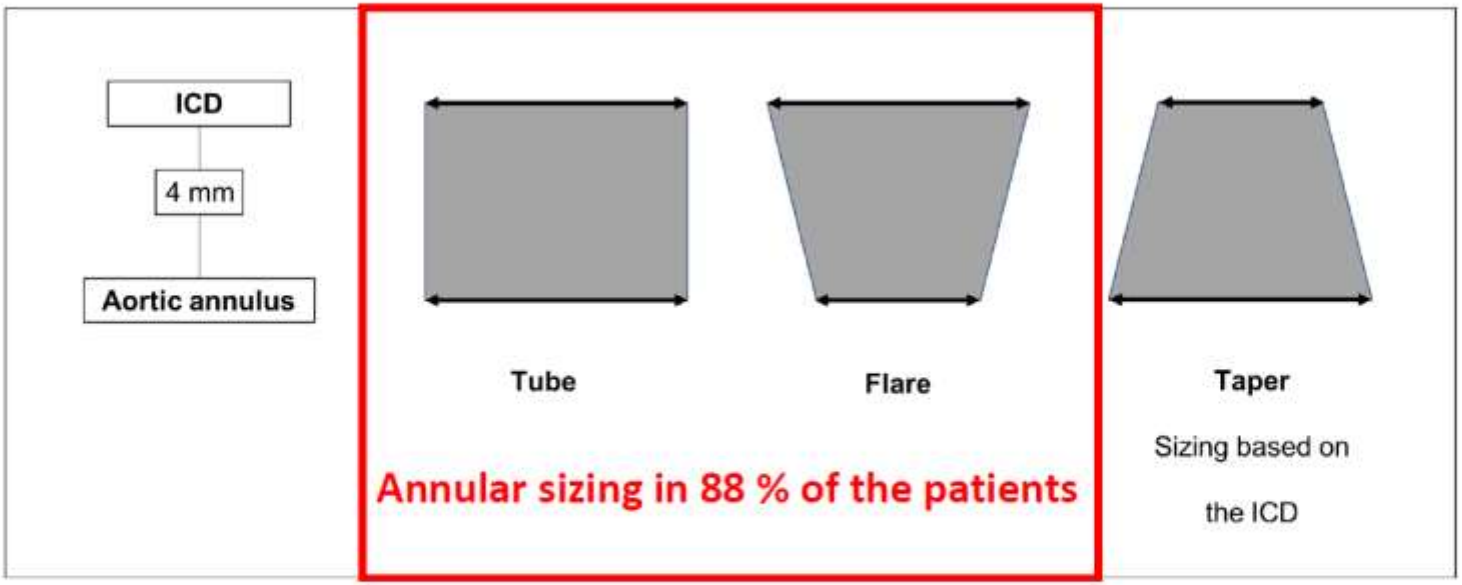
ASAN Medical Center

Device Sizing: Annular Sizing…

Sizing according to the landing zone configuration



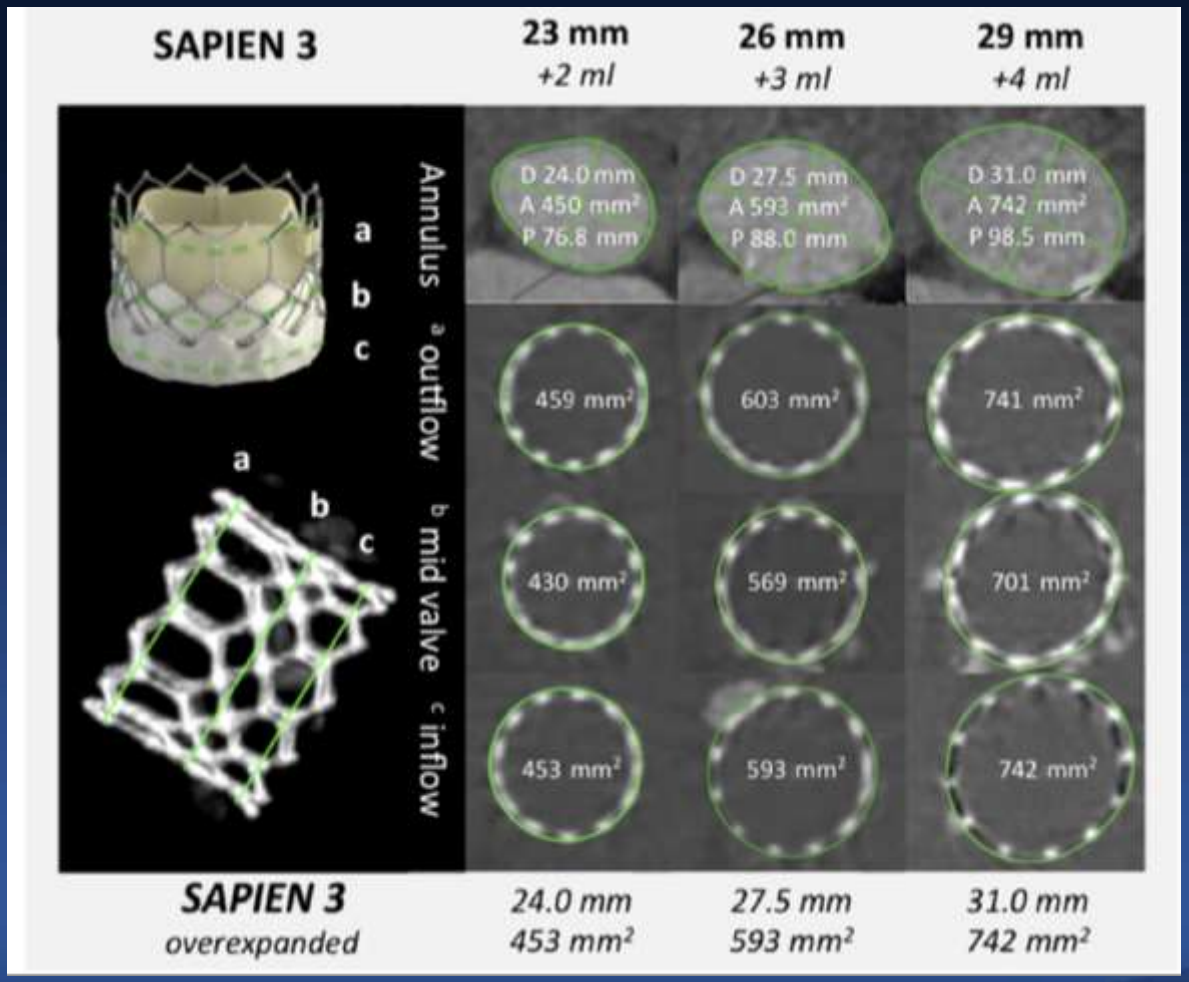
BABARD Registry (N=96, S3 65, Lotus 10, Evolut R 21)

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

Don't Do Too Much Oversizing

Courtesy of Didier Tchetche, Clinique Pasteur, Toulouse, France

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



Shivaraju A et al. JACC Cardiovasc Interv. 2015;8(15):2041-3.

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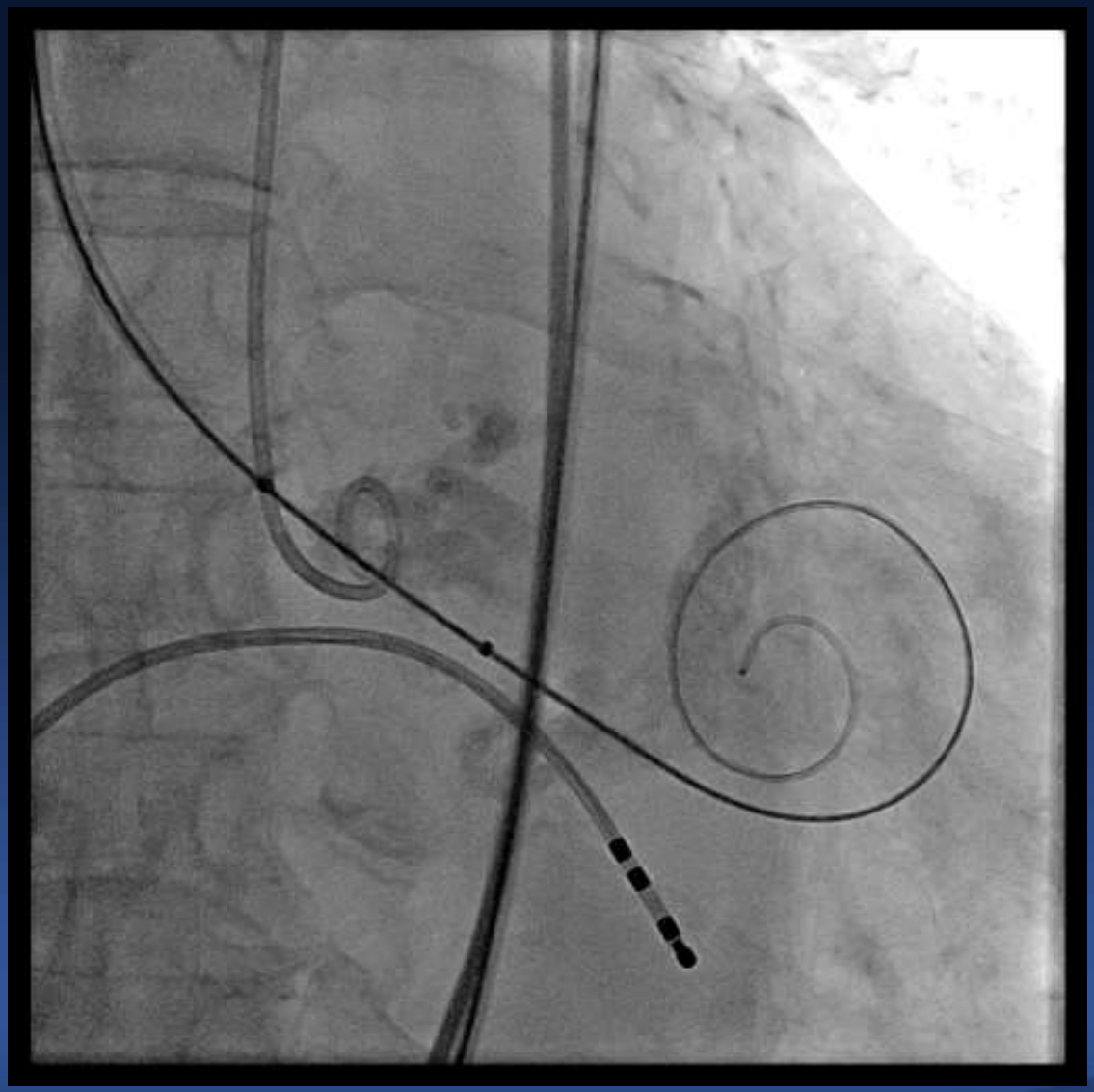
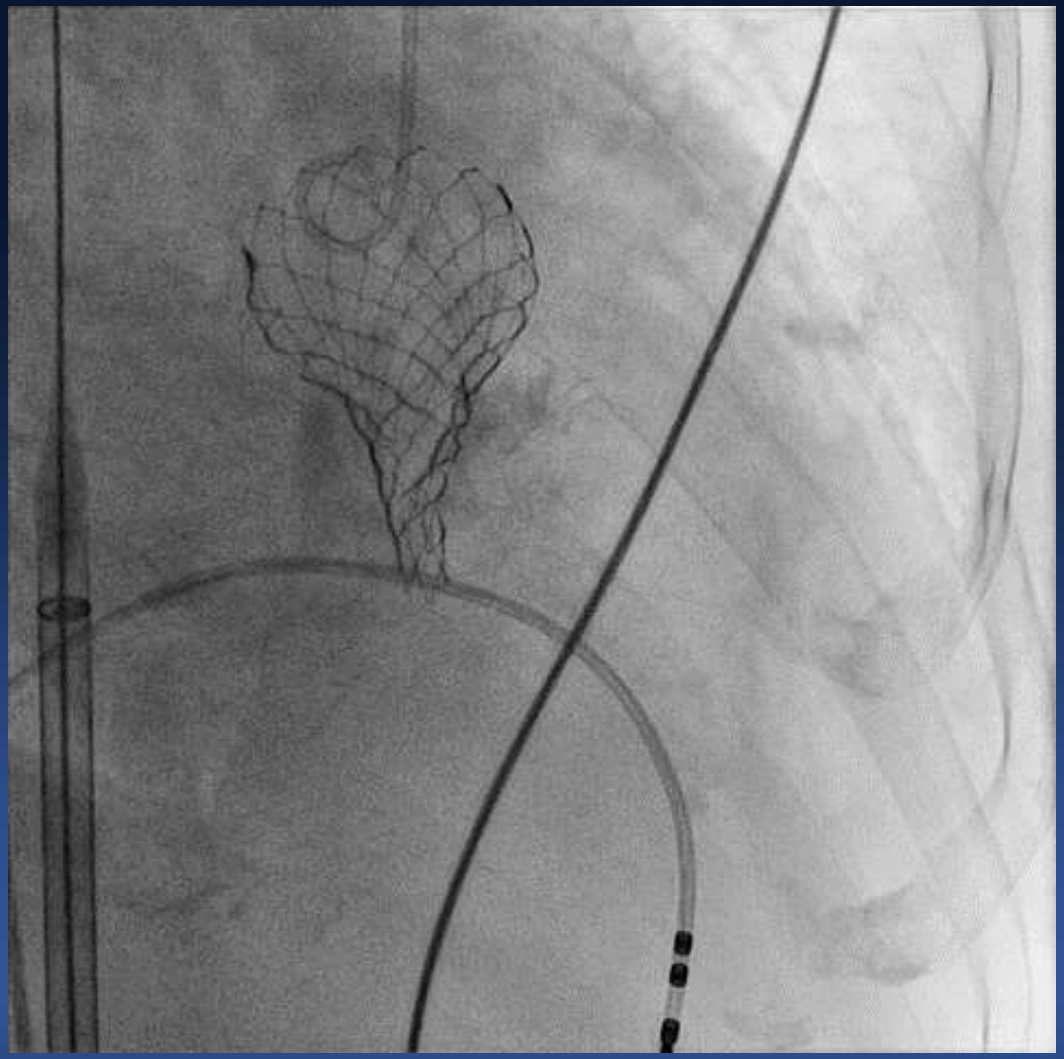
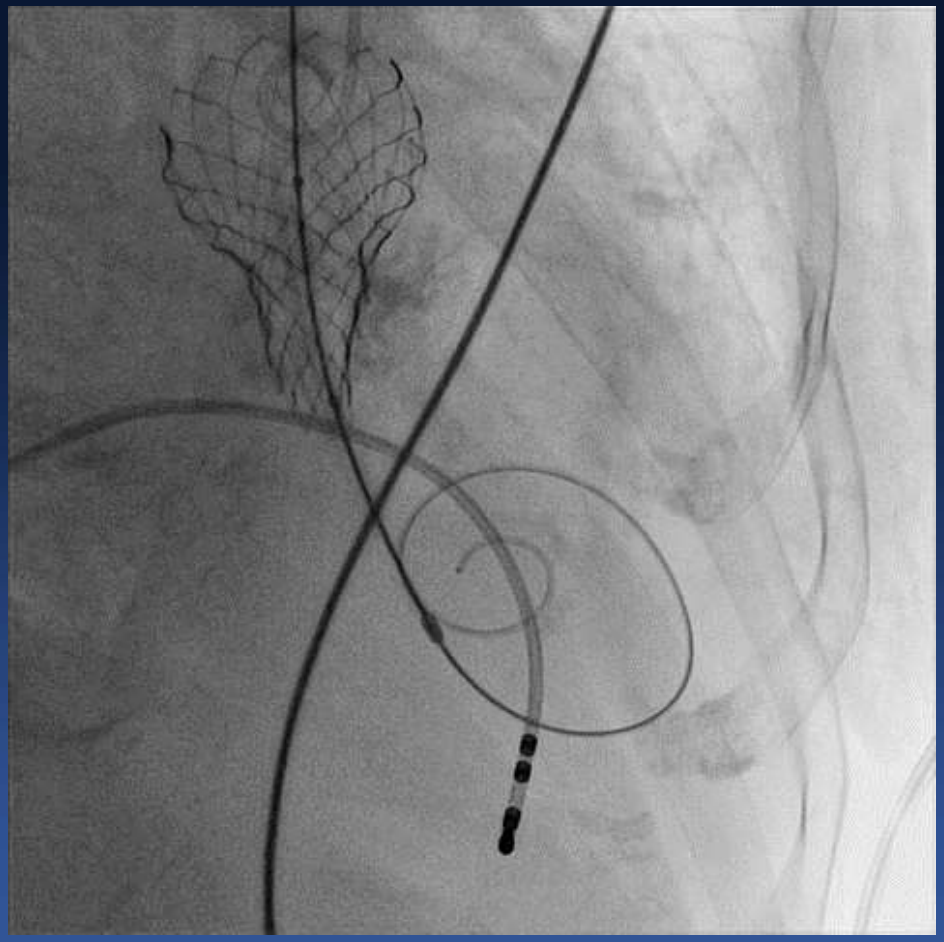
BAV Is Mandatory in Bicuspid AS



Device Underexpansion



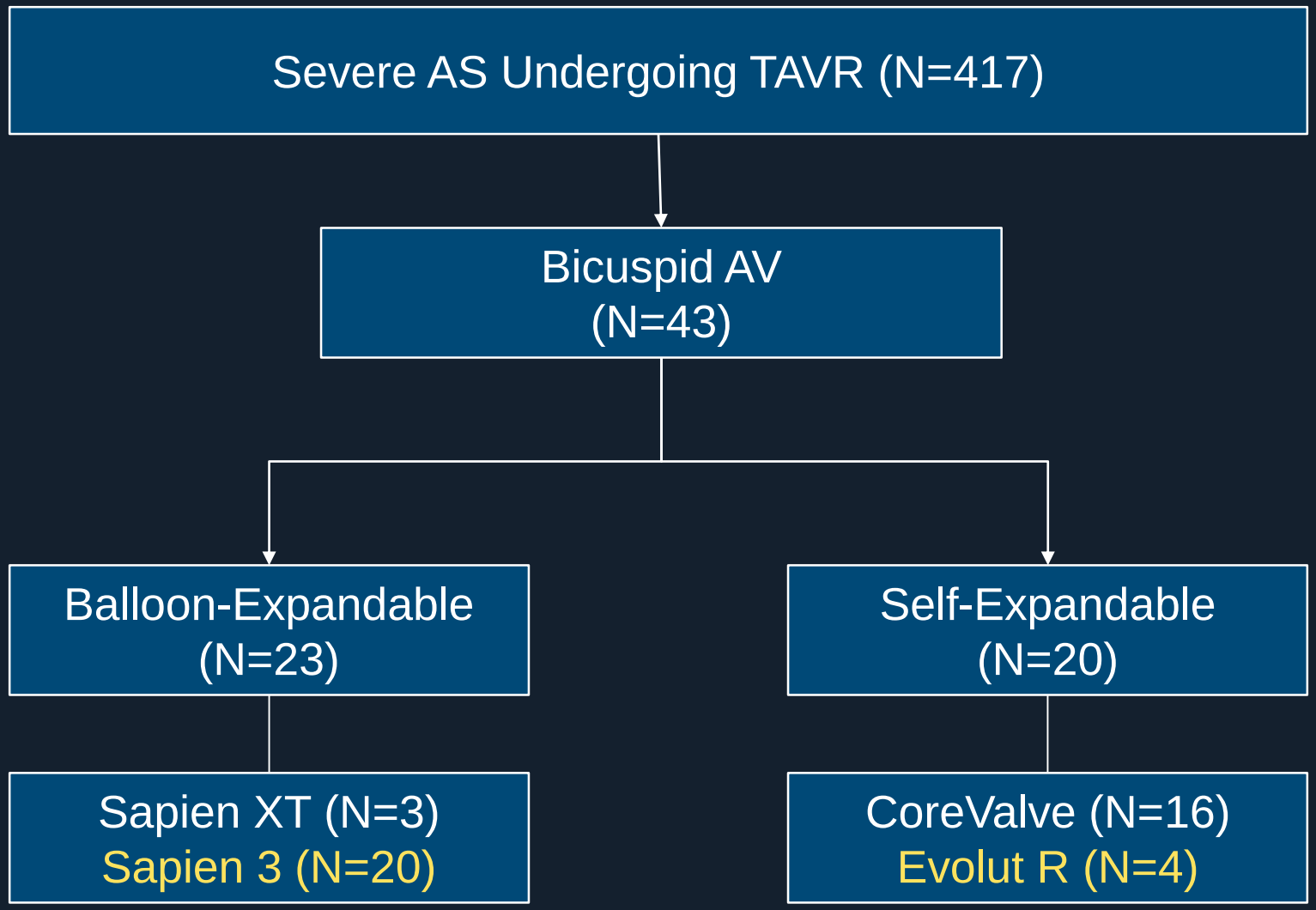
Post-Ballooning



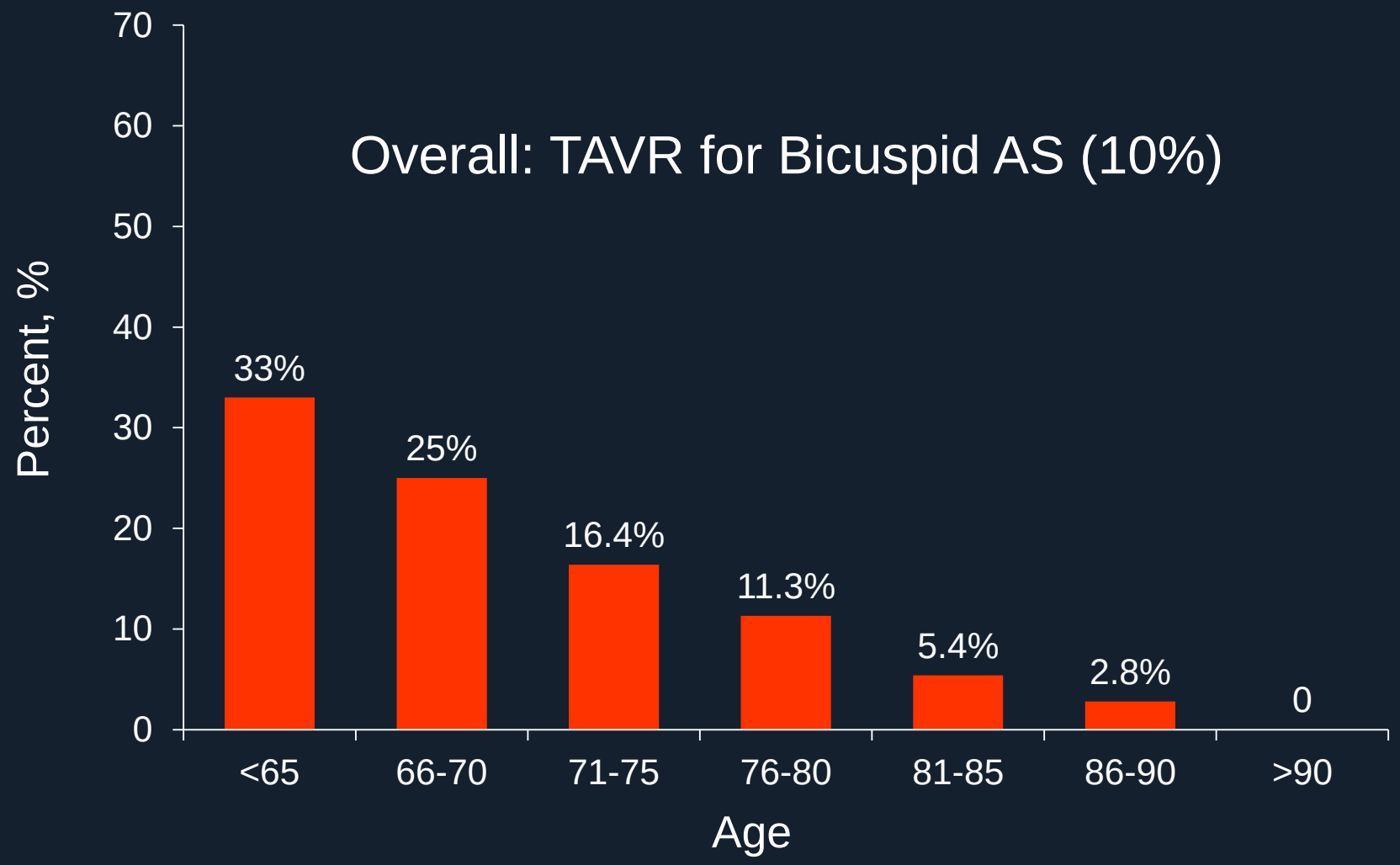
ATLAS® PTA Dilatation Catheter (20 mm x 4 cm)

Final Pressure Tracing

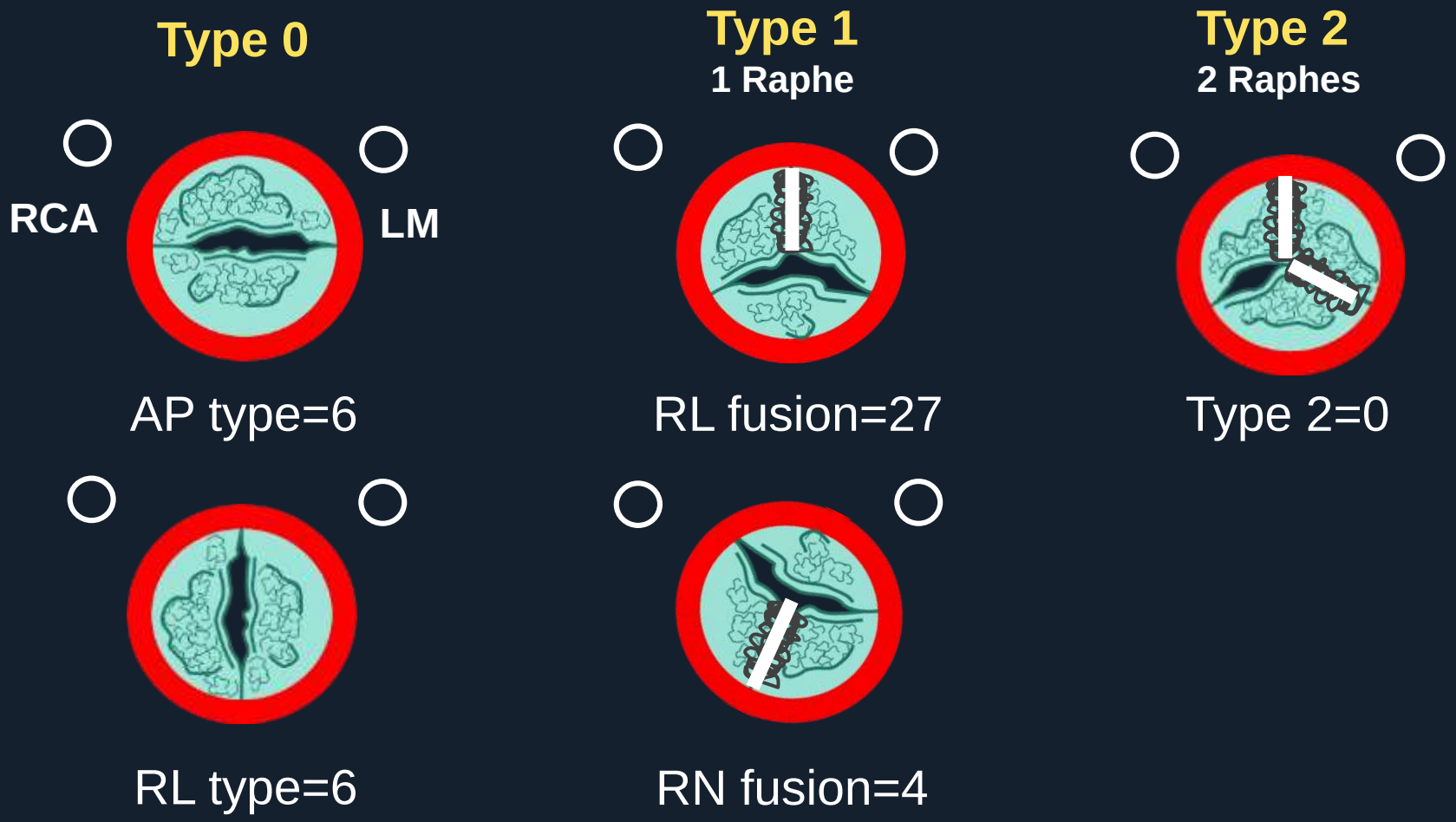
ASAN TAVR Registry



Proportion of TAVR for Bicuspid AS



Type of Bicuspid AV*



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

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ASAN Medical Center

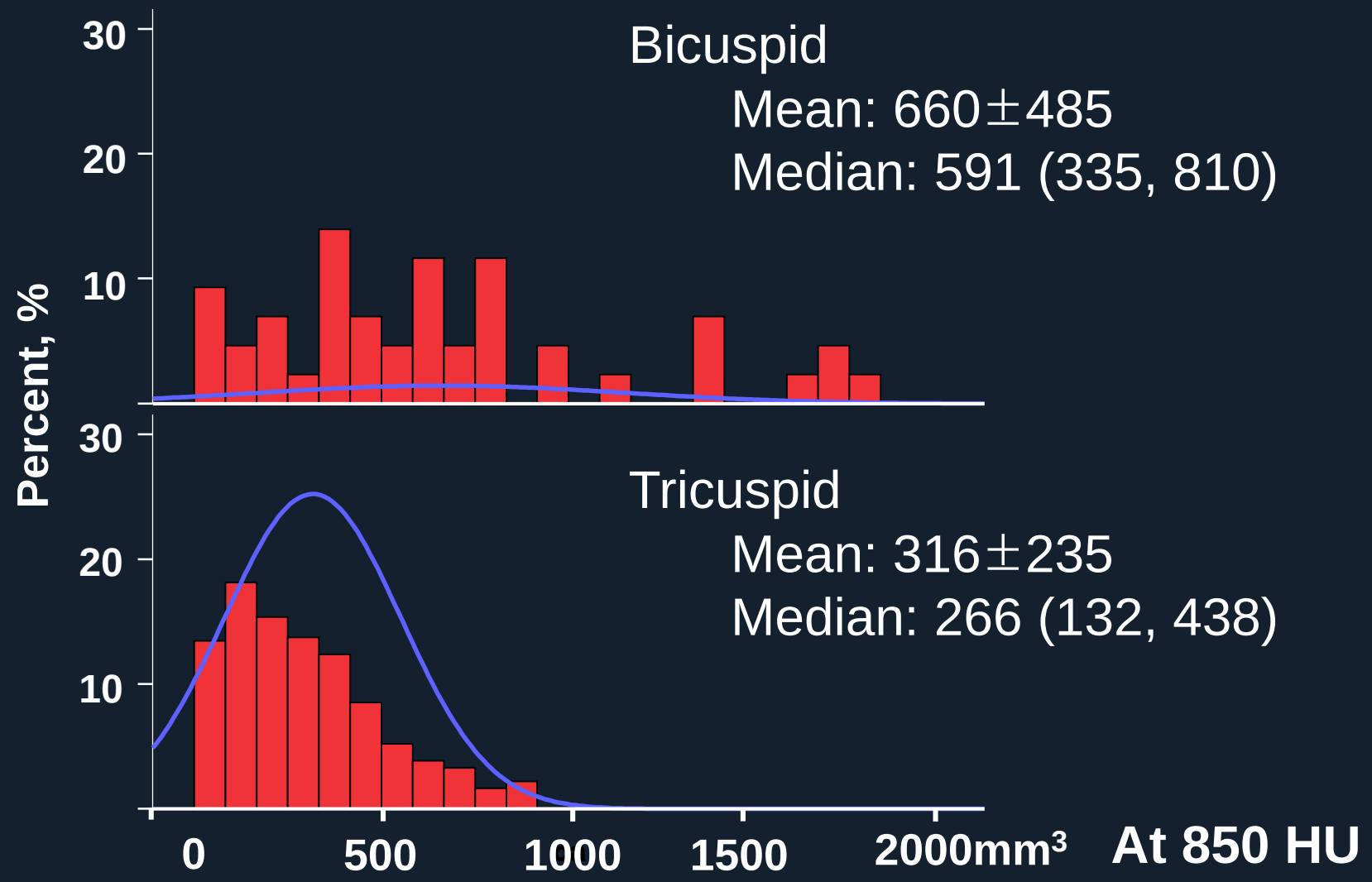
Baseline Characteristics: Young and Less Comorbid

	Bicuspid AS (N = 43)	Tricuspid AS (N = 364)	P value
Age	76.1±5.6	79.0±5.0	<0.001
Gender (Male)	72.1%	45.6%	0.001
NYHA Class III/IV	37.2%	50.0%	0.11
Logistic EuroSCORE	11.4±8.8	15.9±12.2	0.018
STS score	2.9±1.7	4.4±4.6	0.024
Diabetes Mellitus	16.3%	33.5%	0.02
Hypertension	72.1%	87.1%	0.008
Previous Stroke	14.0%	9.9%	0.41
Peripheral Vascular Disease	2.3%	6.3%	0.29
Previous PCI	11.6%	30.8%	0.009
Previous CABG	0%	6.6%	0.09
LVEF, %	59±11	59±11	0.89

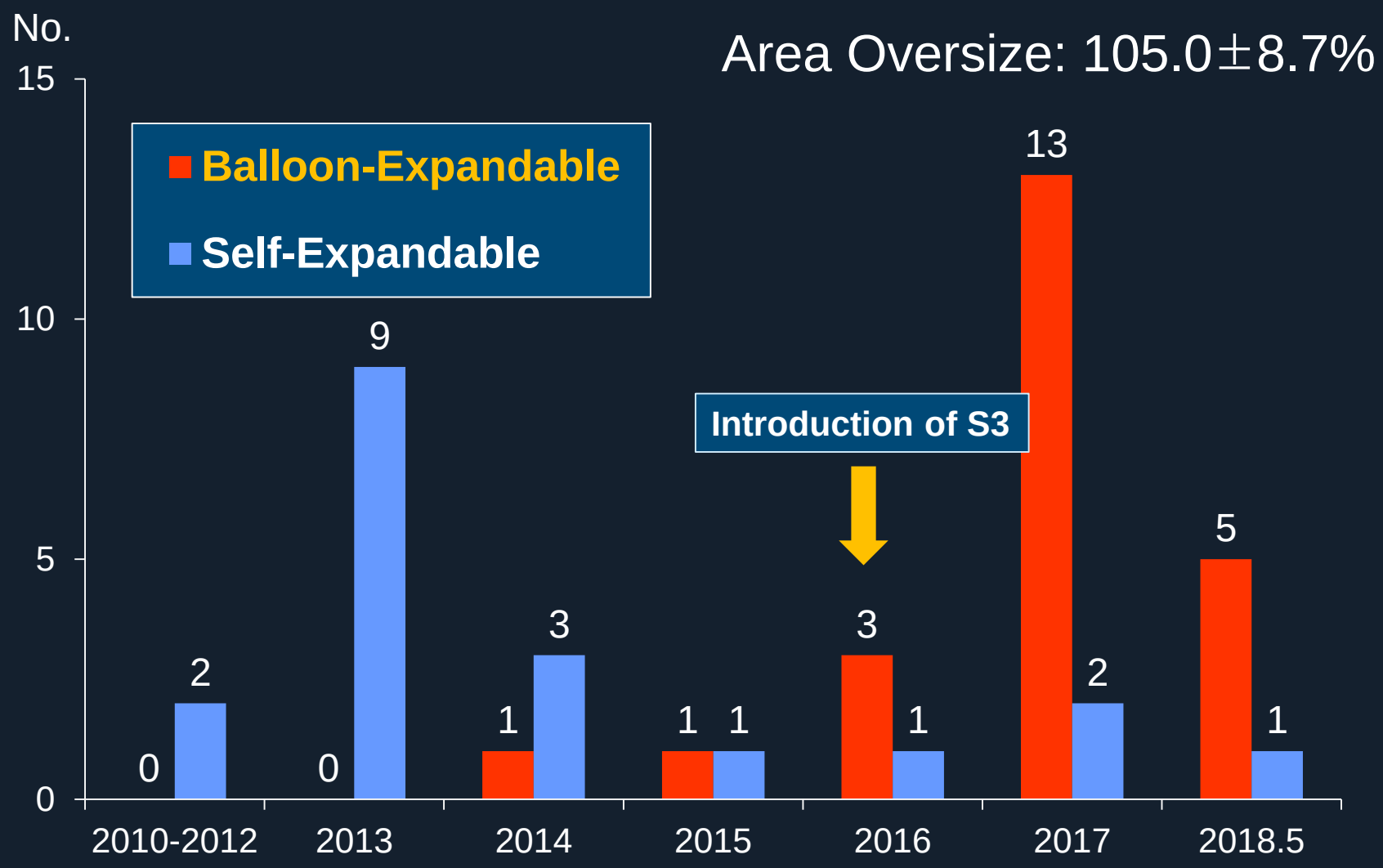
CT Measurement
Large AV Complex

	Bicuspid AS (N = 43)	Tricuspid AS (N = 364)	P value
Annulus Dimensions			
Area, mm^2	502 ± 116	425 ± 88	<0.001
Perimeter, mm	81.2 ± 8.8	74.1 ± 10.2	<0.001
Mean diameter, mm	25.6 ± 2.9	23.4 ± 3.2	<0.001
Eccentric index	0.78 ± 0.10	0.79 ± 0.11	0.86
Sinus of Valsalva area, mm^2	1013 ± 229	782 ± 189	<0.001
LVOT Area, mm^2	871 ± 243	624 ± 161	<0.001
LM Height, mm	14.8 ± 3.0	12.4 ± 2.9	<0.001
RCA Height, mm	18.5 ± 6.8	16.2 ± 3.6	0.04

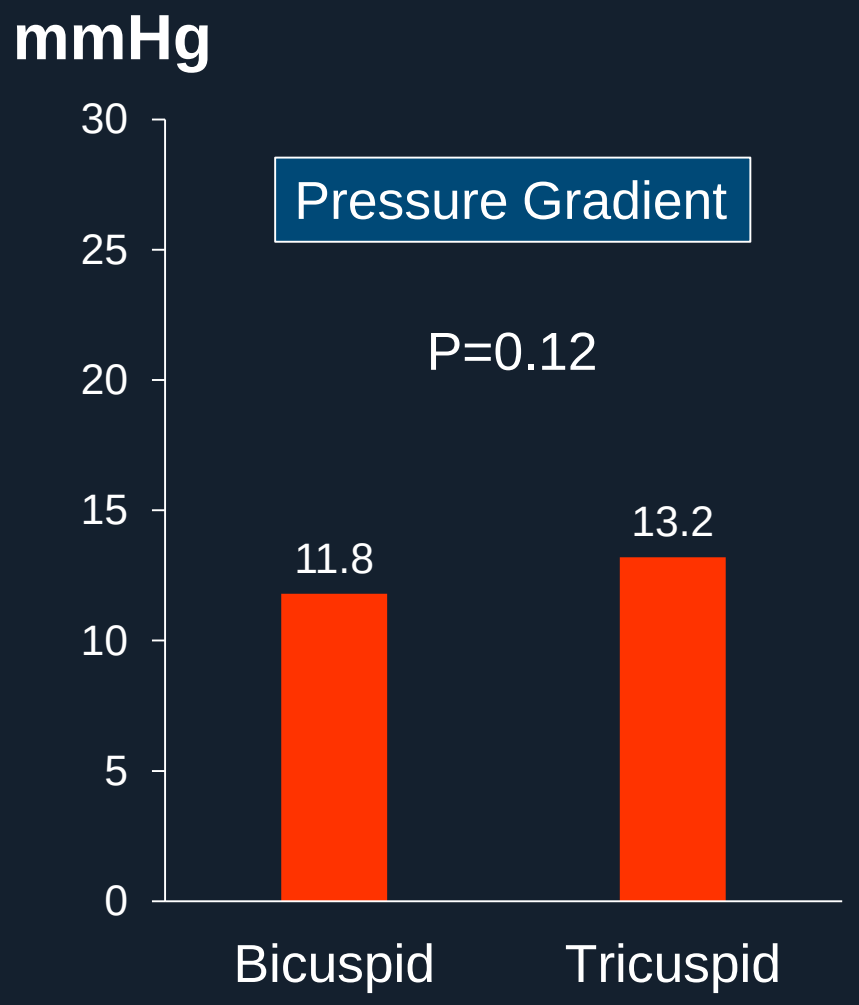
Valve Calcification Volume

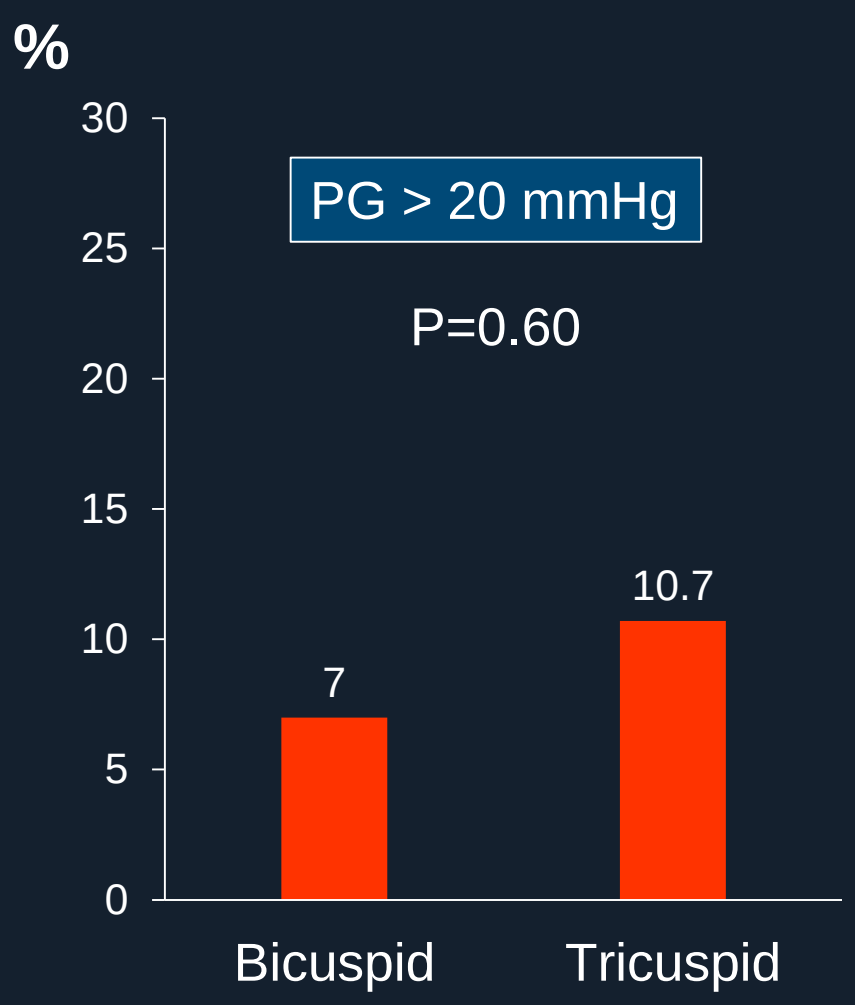


Heart Valve for Bicuspid AS

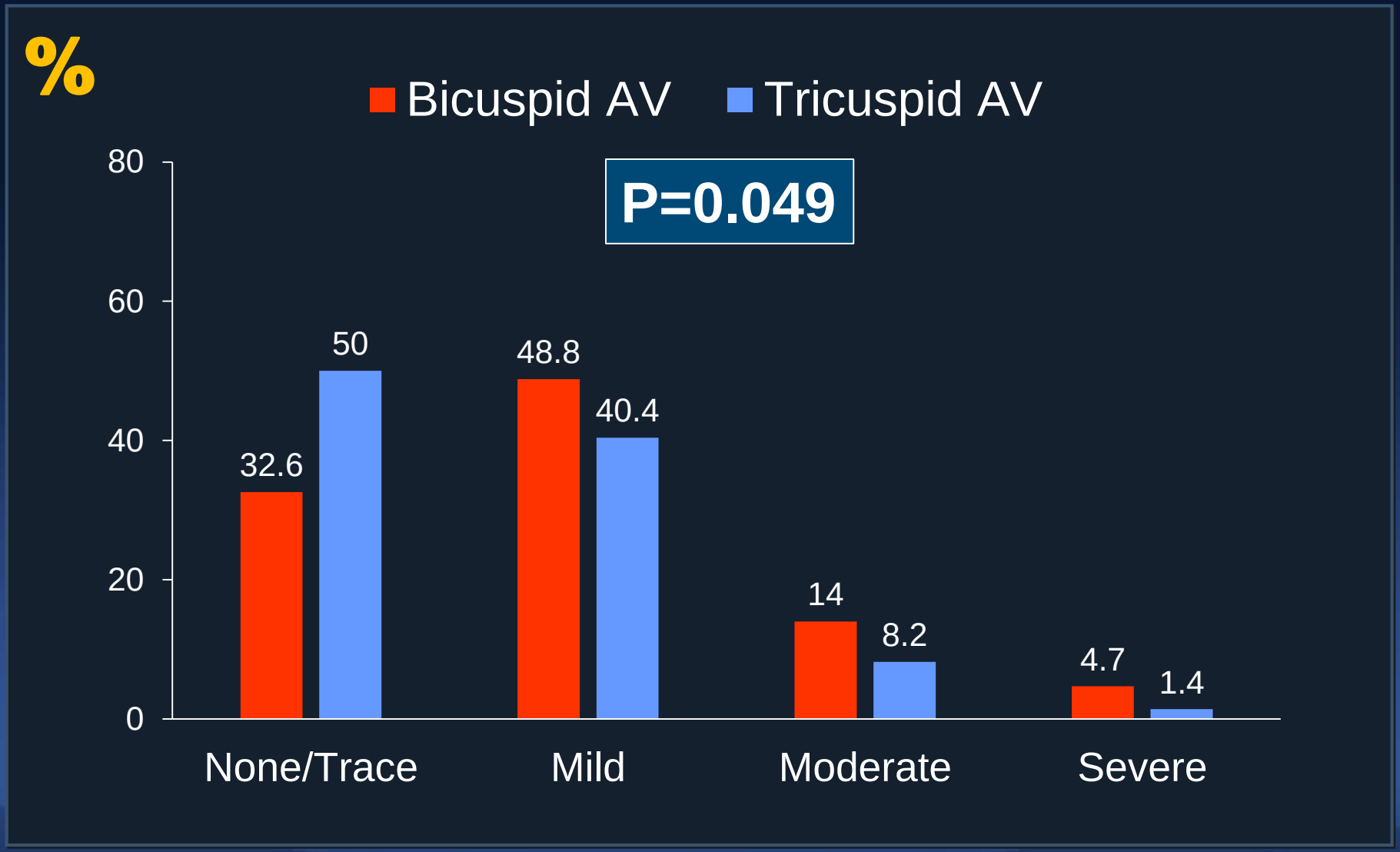


Hemodynamic Outcomes

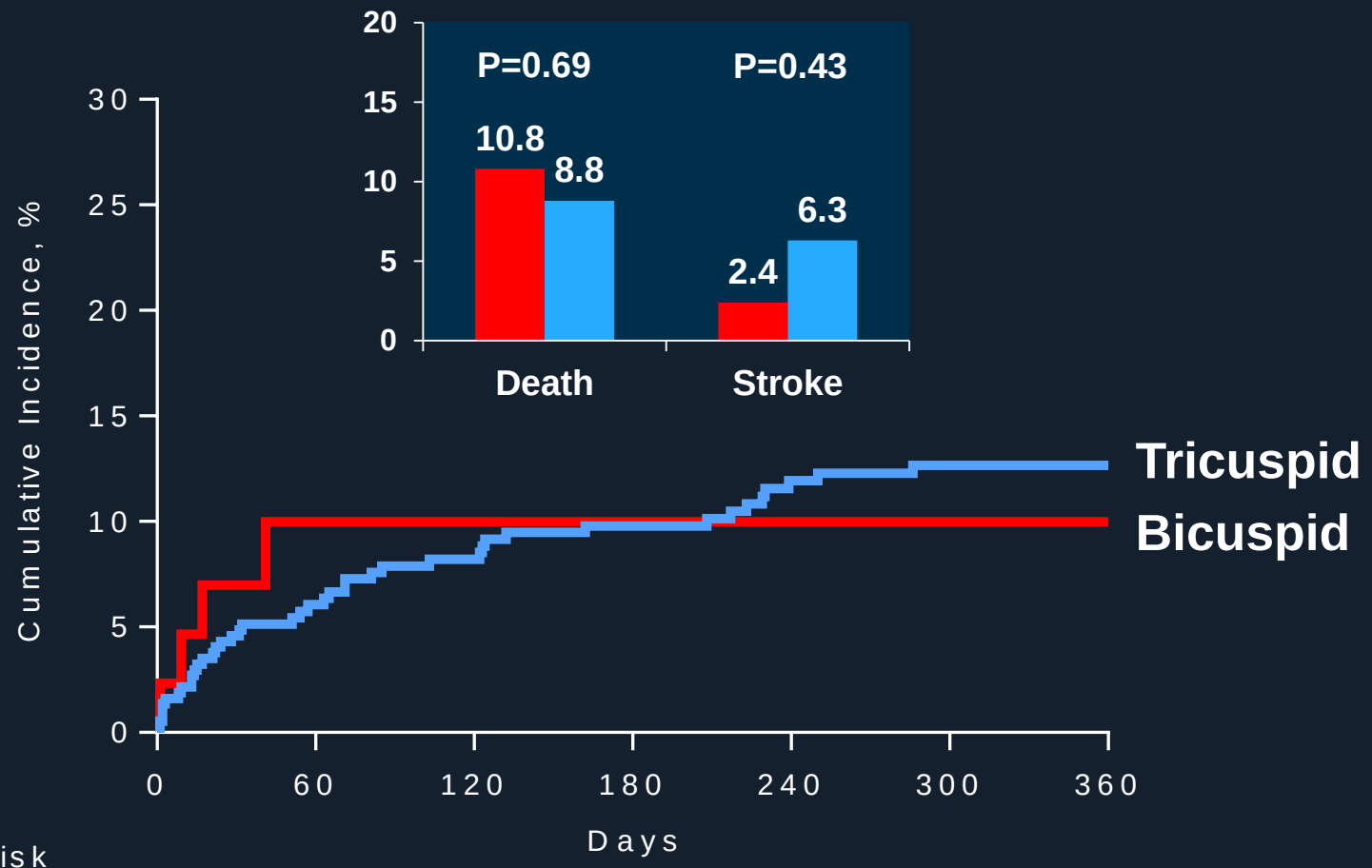




Para-Valvular Leakage



Death and Stroke*

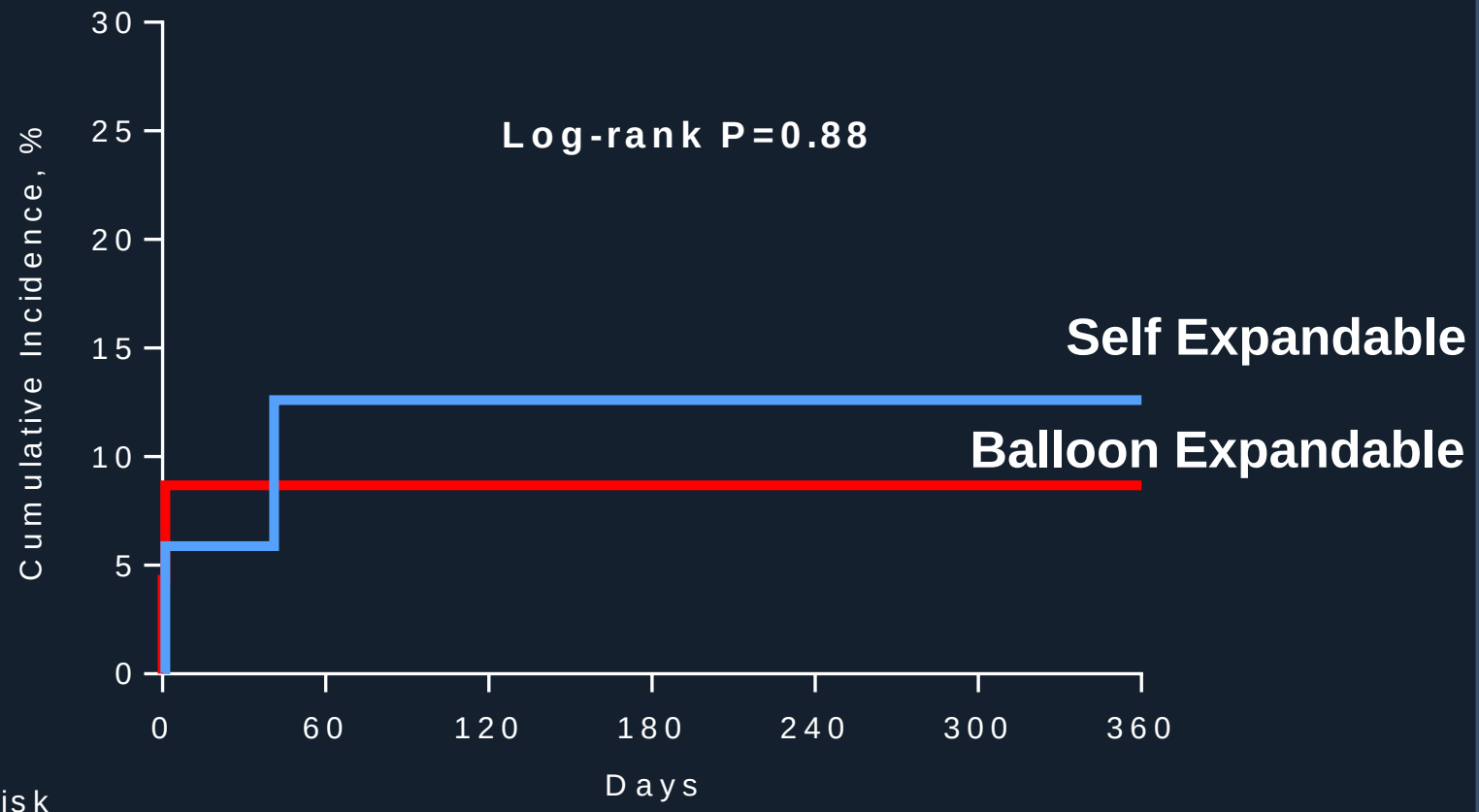


No. at Risk			
Bicuspid	43	27	19
Tricuspid	370	278	225

CardioVascular Research Foundation

*any stroke

Death and Stroke*



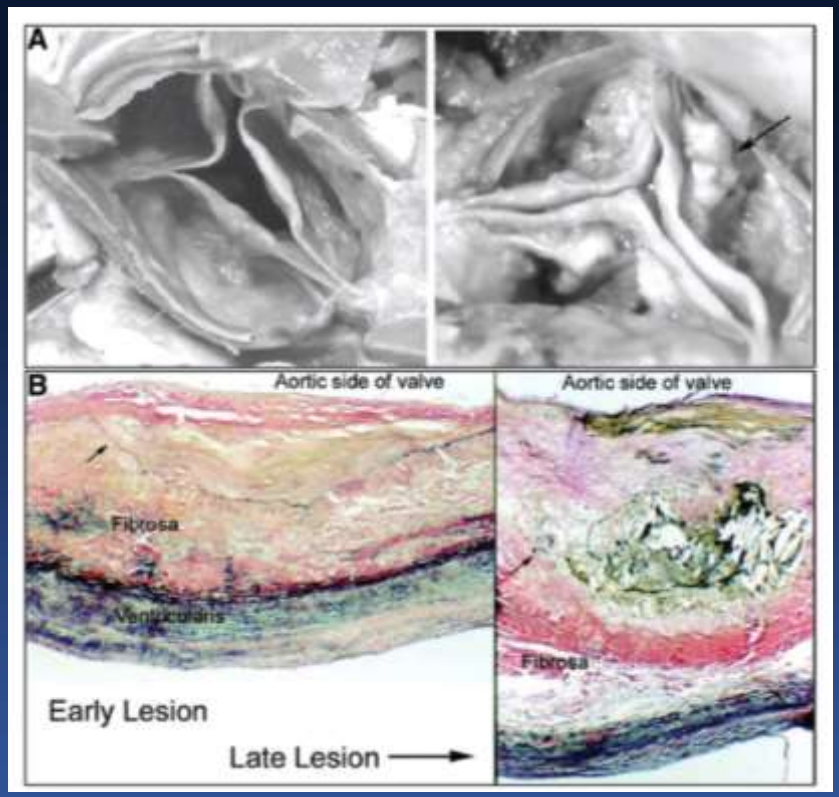
No. at Risk			
Bicuspid	23	11	4
Tricuspid	20	14	12

CardioVascular Research Foundation

*any stroke

- Bicuspid Aortic Valve Stenosis
- **Severe Calcification**
- Low Lying Left Main

Friends and Foes



Calcification

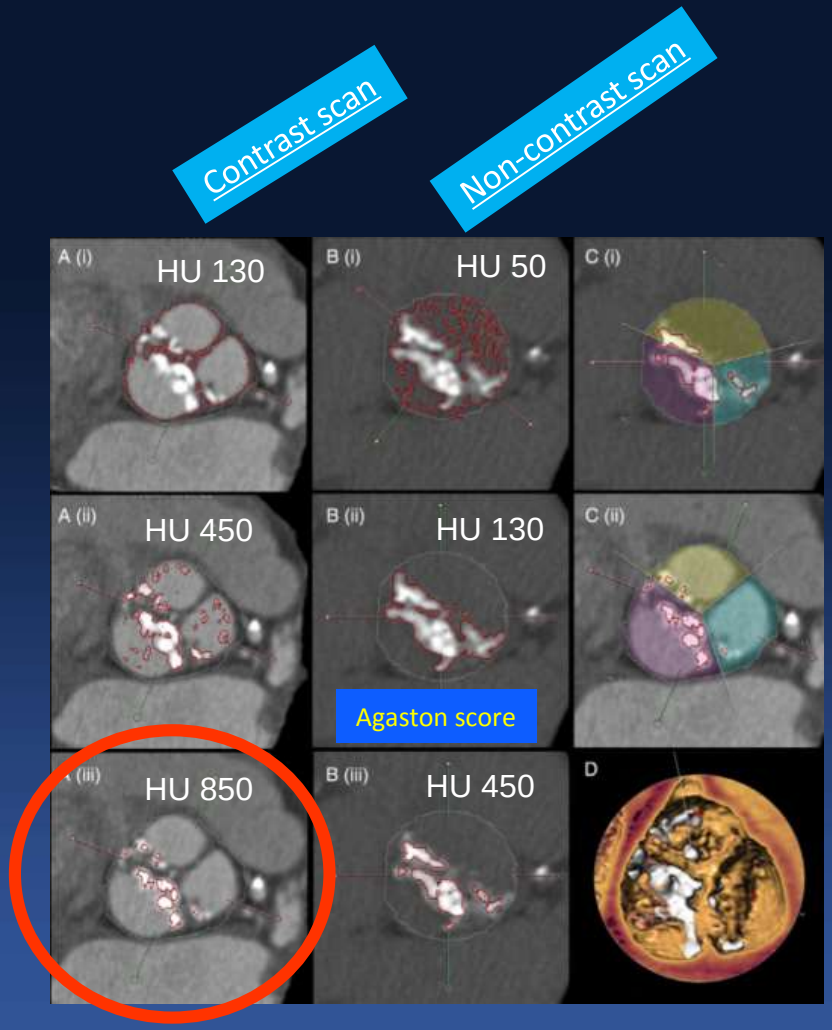
- Anchoring
- Complication
  - Paravalvular leakage
  - Aortic injury
  - Coronary obstruction
  - Pacemaker implantation

Calcium Quantification

- Contrast vs. Non-contrast

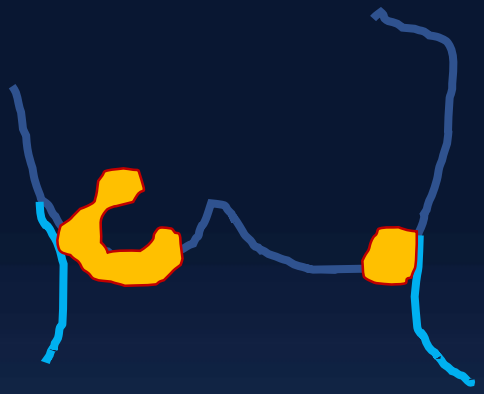
- HU threshold

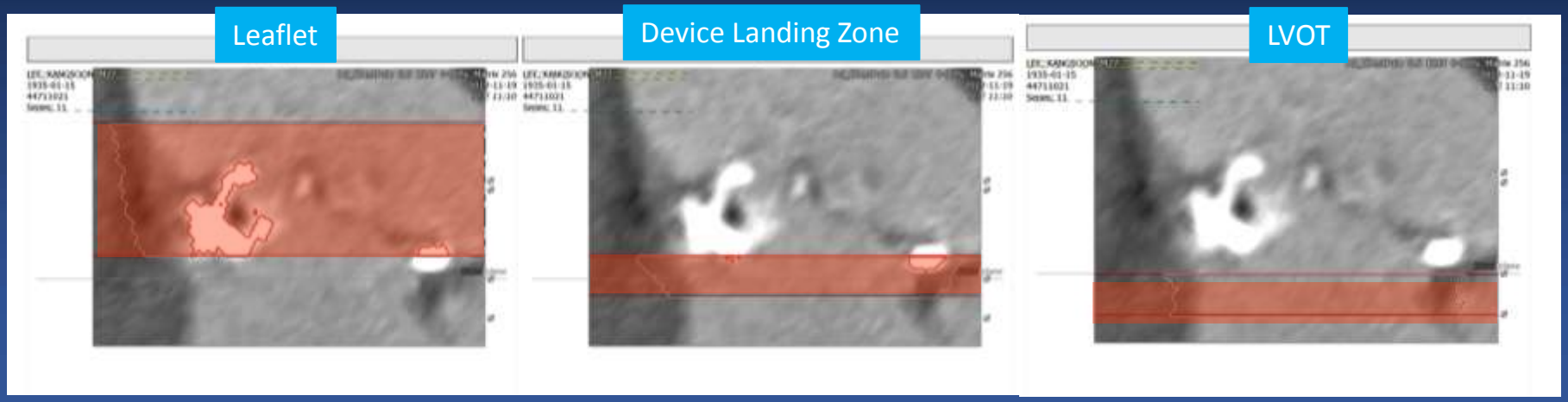
- Location: Leaflet, Annulus, LVOT



European Heart Journal – Cardiovascular Imaging (2014) 15, 1324–1332

3-mensio, Contrast scan, 850 HU





Leaflet Calcification Is Associated With PVL

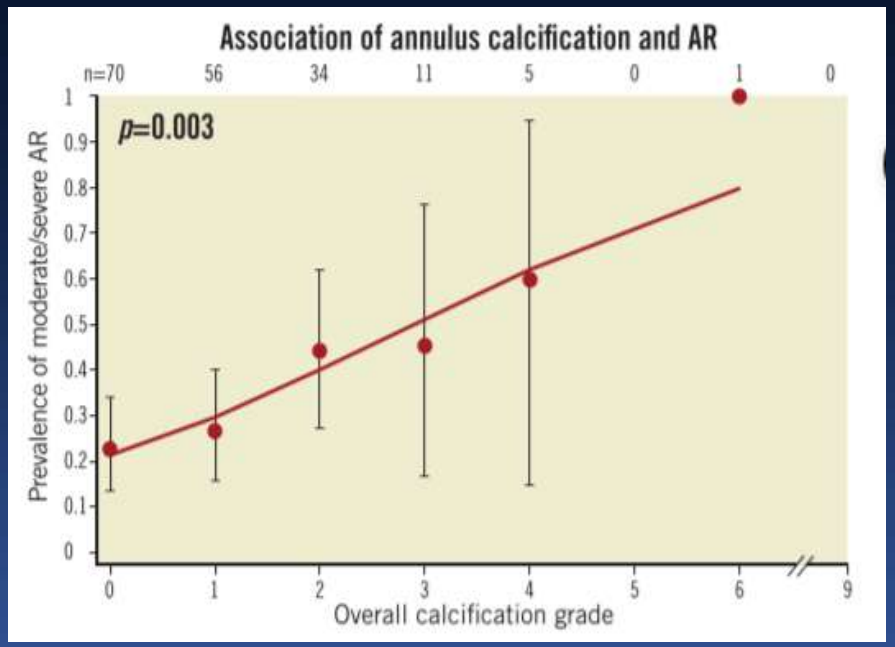


Table 2 Calcium leaflet quantification cut-offs for PVL ≥ moderate depending on methodology and threshold for calcium detection

Methodology	Cut-off
Volume: 3-mensio contrast (850-HU)	≥235 mm^3
Volume: 3-mensio non-contrast (130-HU)	≥2506 mm^3
Volume: 3-mensio non-contrast (450-HU)	≥626 mm^3
Agatston score (non-contrast 130-HU)	≥4528 AU

Independent Predictor

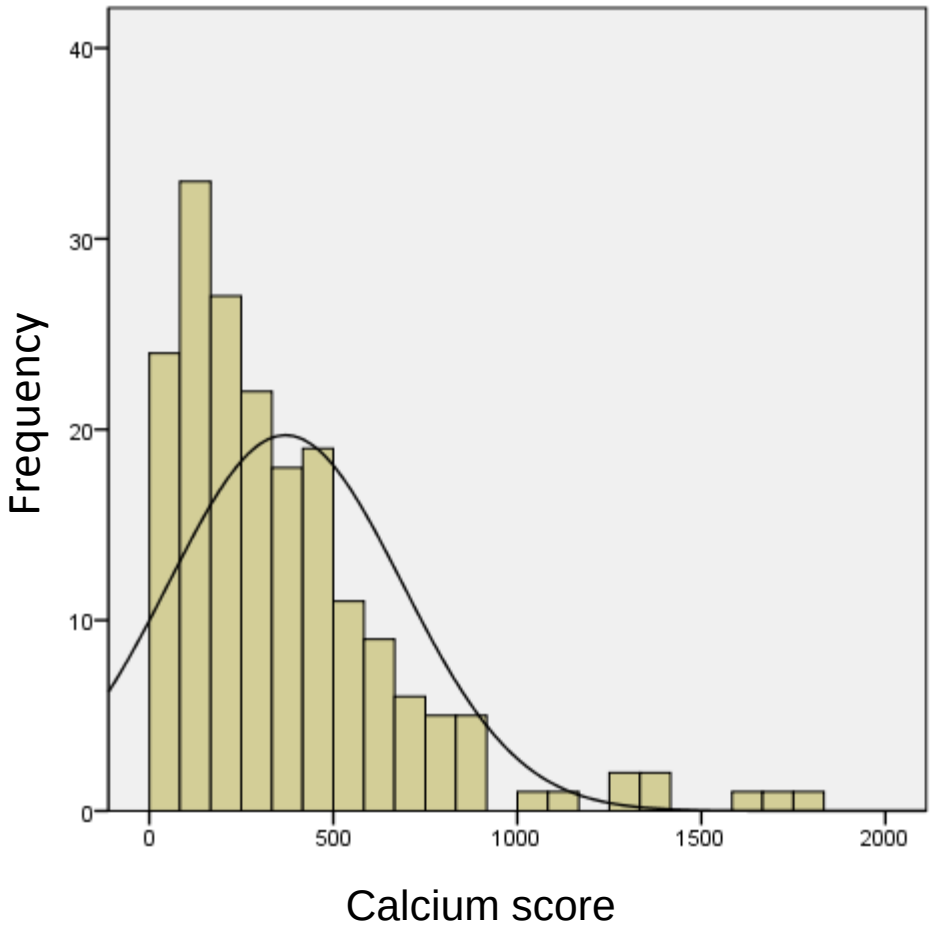
Leaflet Calcium volume >235mm^3
Any LVOT calcification

EuroIntervention 2014;10:732-738

European Heart Journal – Cardiovascular Imaging (2014) 15, 1324–1332

Distribution of Calcium Score

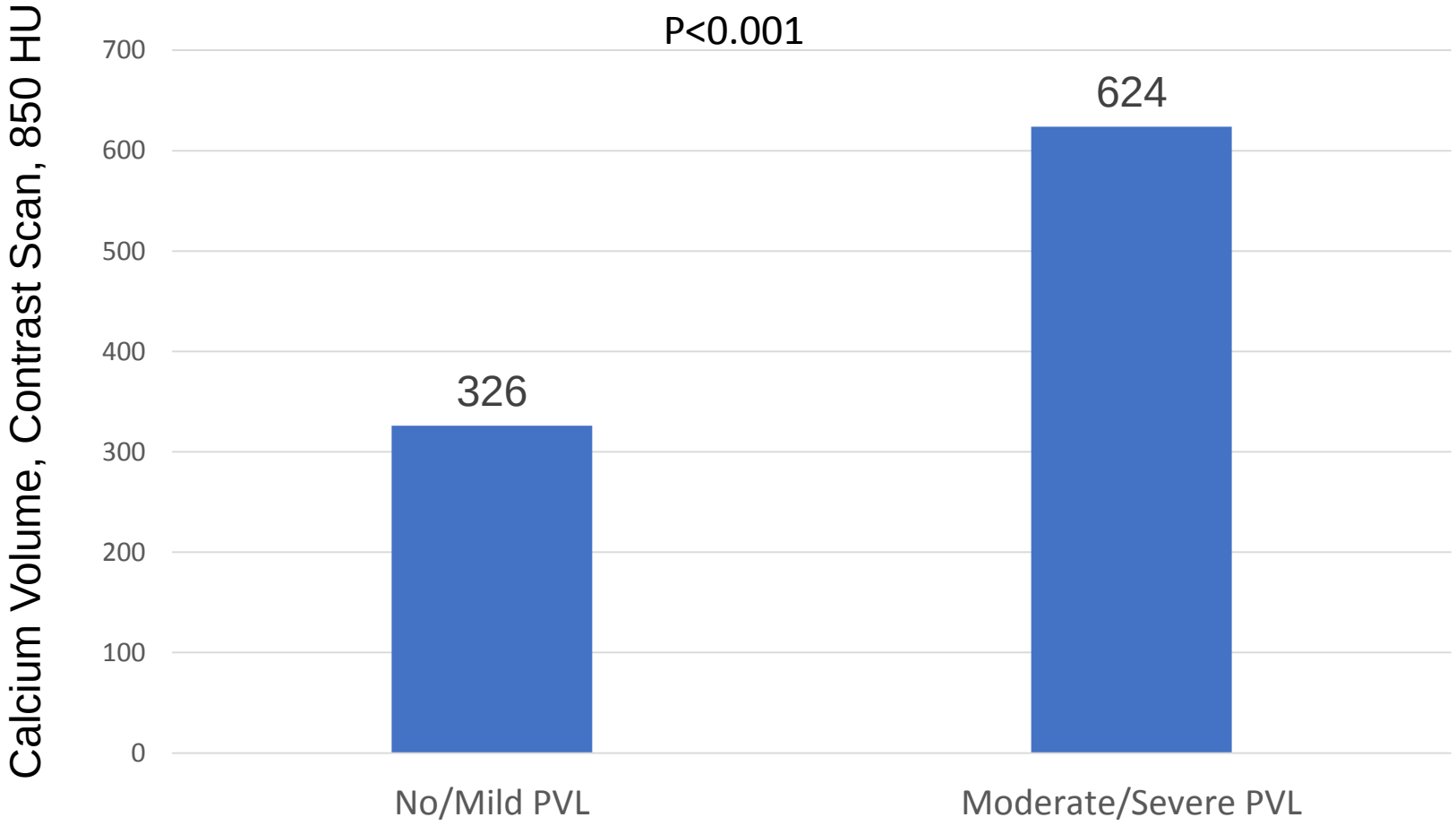
ASAN TAVR Registry



3-mensio, Contrast scan, 850 HU

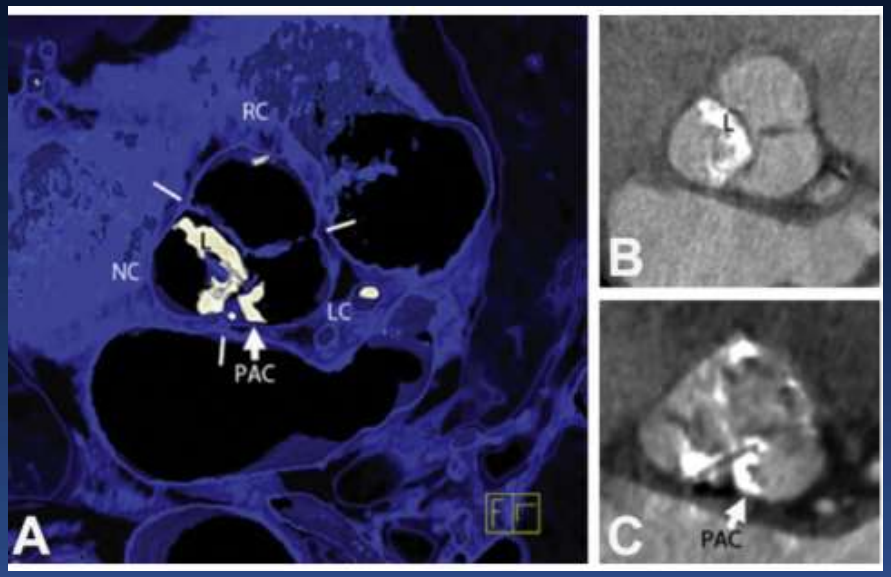
Mean 369±317
Median 286 (IQR, 149-487)

Asan TAVR Registry



Protruding vs. Adherent Calcium

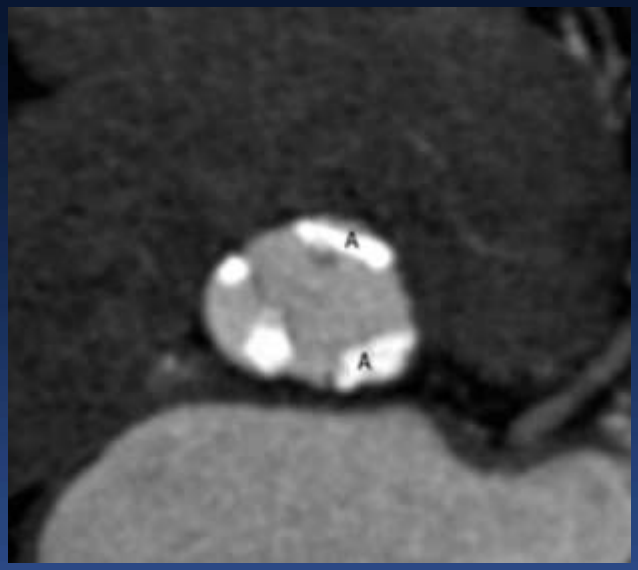
Protruding annular calcification



Depth>Width

More PVL

Adherent annular calcification



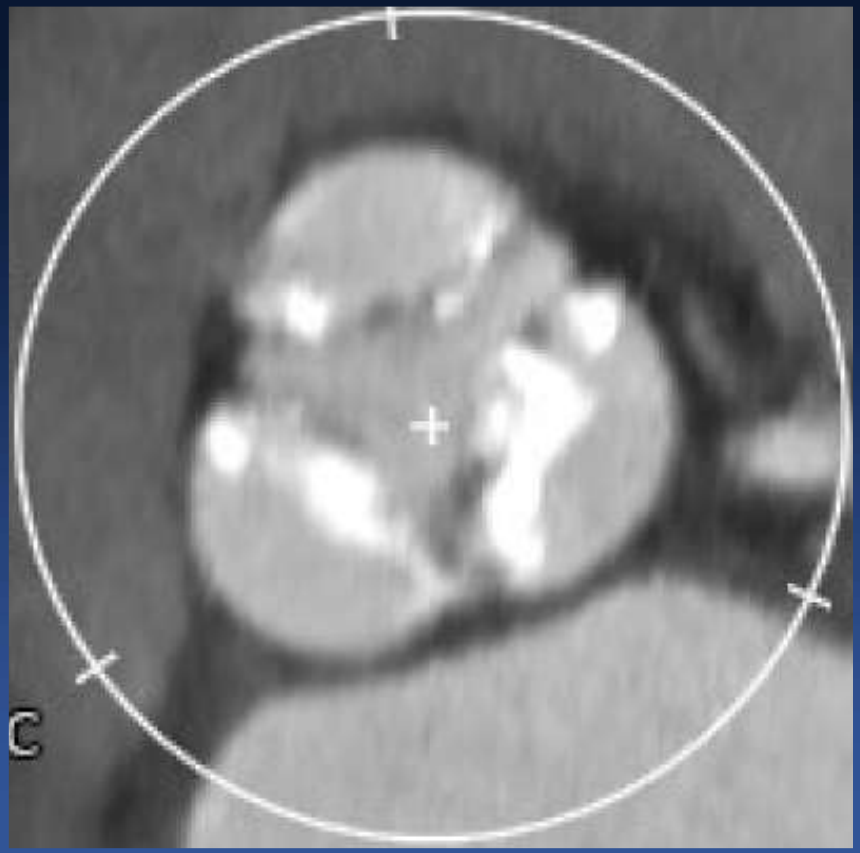
Depth<Width

"Sealing" effect

Ann Thorac Surg 2013;96:1574–80

Calcium Location and PVL Location

Case 1: Leaflet Calcification



Total Amount of Calcium	**696 mm³**

Case 2: Commissure Calcification

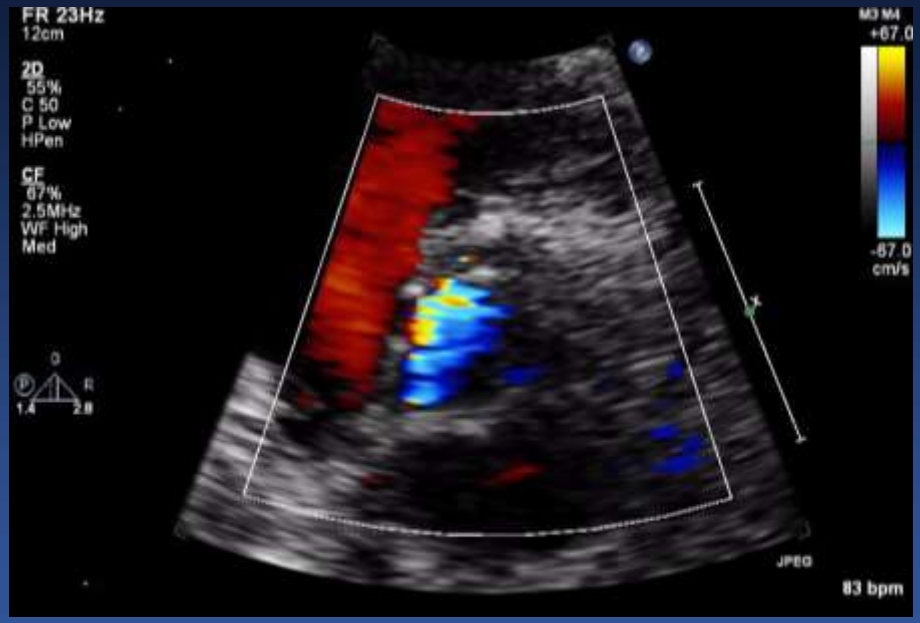
Total Amount of Calcium	**375 mm³**

Post TAVR Echo

Case 1: Leaflet Calcification

Total Amount of Calcium	**696 mm³**

Case 2: Commissure Calcification



Total Amount of Calcium	**375 mm³**

Oversizing is Important But…

Predictors for Annulus Rupture

	OR (95% CI)	P value
Device Area / CT Area ≥ 20%	8.38 (2.67-26.33)	< 0.001
Moderate/ Severe LVOT calcification	10.92 (3.23-36.91)	< 0.001

31 patients experienced annulus rupture during TAVI were matched control patients. Logistic regression analysis identified device area oversizing ≥20% and moderate/severe LVOT calcification as predictor for annulus rupture.

Barbanti M et al. Circulation 2013;128(3):244-53

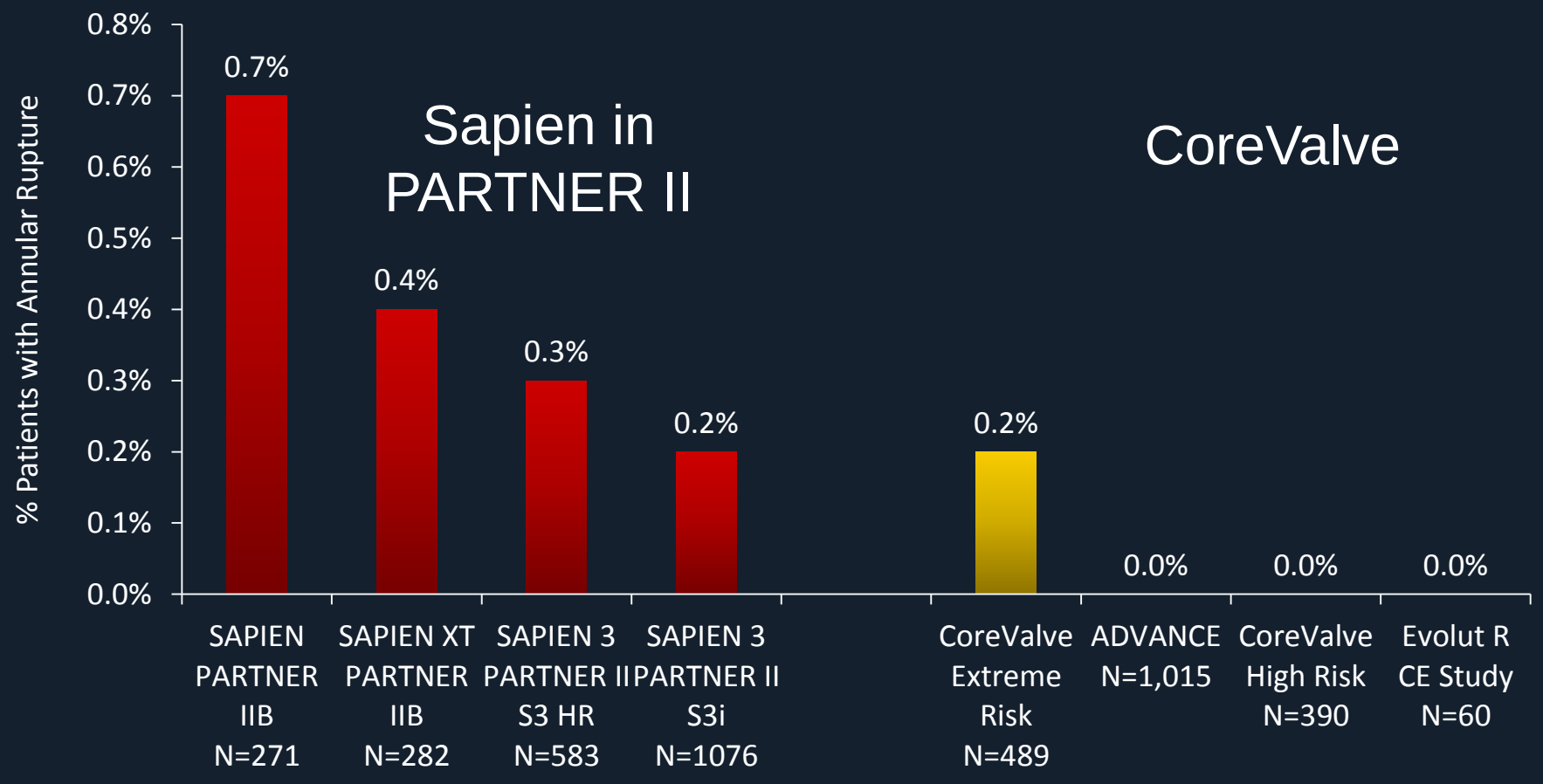
LVOT Calcification

"Vulnerable area"

Epicardial fat segment is not covered by cardiac structures and leads directly to the epicardial fat and the pericardium

Hayashida et al. CCI 82:E742–E746 (2013)

Risk of Annular Rupture



[1]Leon, et. al. presented at ACC 2013; [2]Kodali, et al., presented at ACC 2015; [3]Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; [4]Linke, et al. , *Eur Heart J* 2014; 35: 2672-84; [5]Adams, et al., *N Engl J Med* 2014; 370: 1790-8; [6]Meredith, et. al. presented at EuroPCR 2015

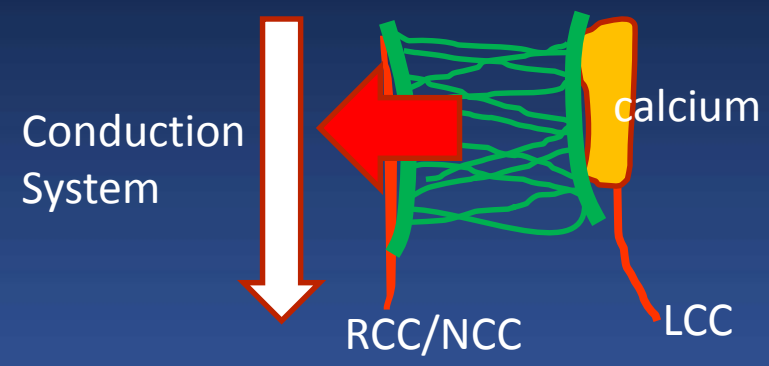
Pacemaker Implantation

TABLE 6 Univariate and Multivariate Regression Analysis to Identify Predictors of Permanent Pacemaker Implantation

	Univariate Analysis			Multivariate Analysis		
	OR	95% CI	p Value	OR	95% CI	p Value
Age (yrs)	1.1	0.99-1.13	0.094			
Female	1.9	0.89-3.98	0.096			
LVEF	1.0	0.98-1.04	0.618			
Logistic EuroSCORE I	1.0	0.96-1.03	0.619			
Atrial fibrillation	0.9	0.40-1.92	0.749			
AVB grade I	0.8	0.18-3.74	0.787			
LBBB	1.8	0.22-14.42	0.588			
RBBB	8.3	2.11-32.98	0.003	16.9	3.0-95.5	0.001
Incomplete RBBB	2.0	0.38-10.26	0.417			
NCC calcification >790.8 mm^3	3.0	0.97-9.29	0.056			
RCC calcification >203.8 mm^3	0.6	0.29-1.30	0.200			
LCC calcification >131.4 mm^3	2.2	0.93-5.02	0.075			
$LVOT_{NC}$ calcification >3.2 mm^3	2.9	1.20-7.01	0.018	0.8	0.2-2.9	0.736
$LVOT_{RC}$ calcification >4.8 mm^3	4.0	1.83-8.58	<0.001	4.7	1.6-14.1	0.005
$LVOT_{LC}$ calcification >13.7 mm^3	4.4	2.02-9.70	<0.001	3.7	1.3-10.6	0.016
Pre-dilation	1.9	0.90-4.12	0.094			
Post-dilation	2.7	0.66-10.96	0.169			
Out-of-range oversizing	0.4	0.09-1.71	0.210			
Oversizing >20%	0.6	0.17-2.10	0.424			
Implantation depth >25.5% ventricular part of the stent frame	9.7	4.32-21.90	<0.001	15.7	5.7-43.5	<0.001

CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

It may be speculated that the described asymmetry of calcium distribution may lead to a shift of the expanded prosthesis away from the central line in the direction of the area under the right and noncoronary aortic cusps. Thereby, the mechanical stress on the AV conduction system might be increased locally by the uneven distribution of radial forces.



RBBB
LVOT-Right Coronary Cusp Calcification
LVOT-Left Coronary Cusp Calcification

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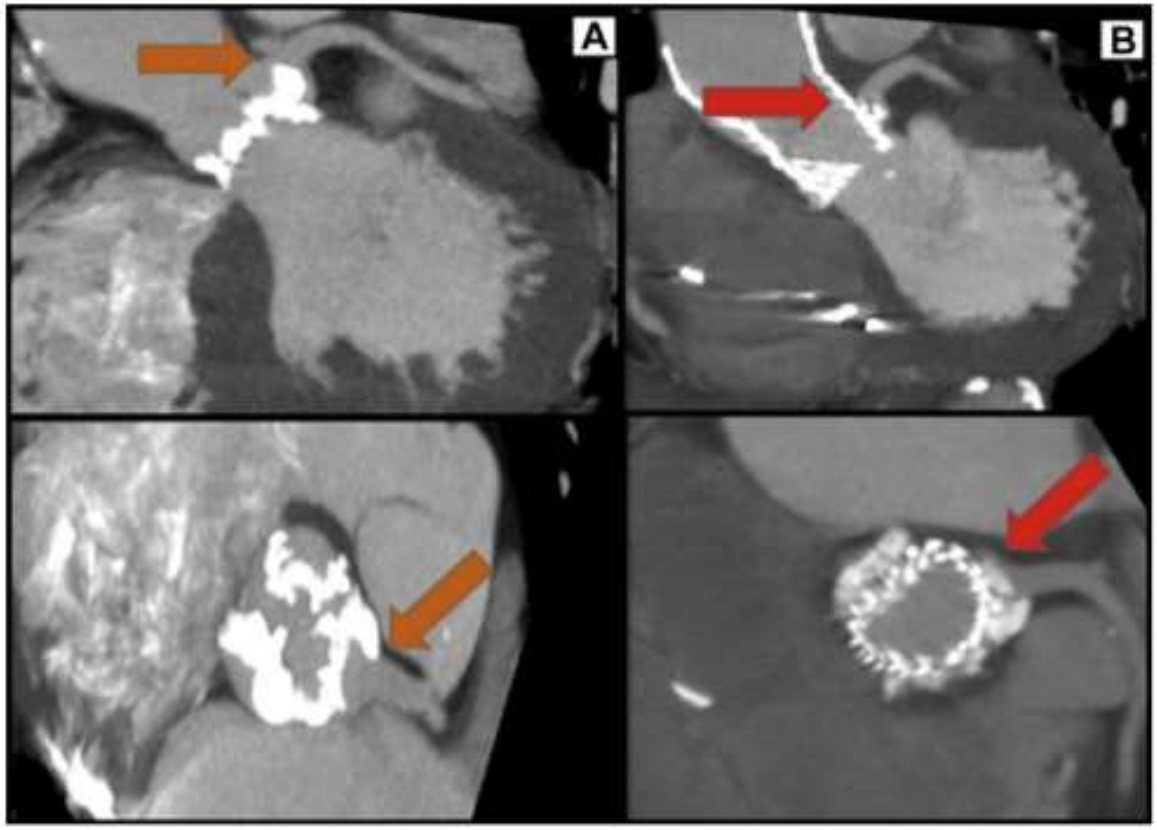
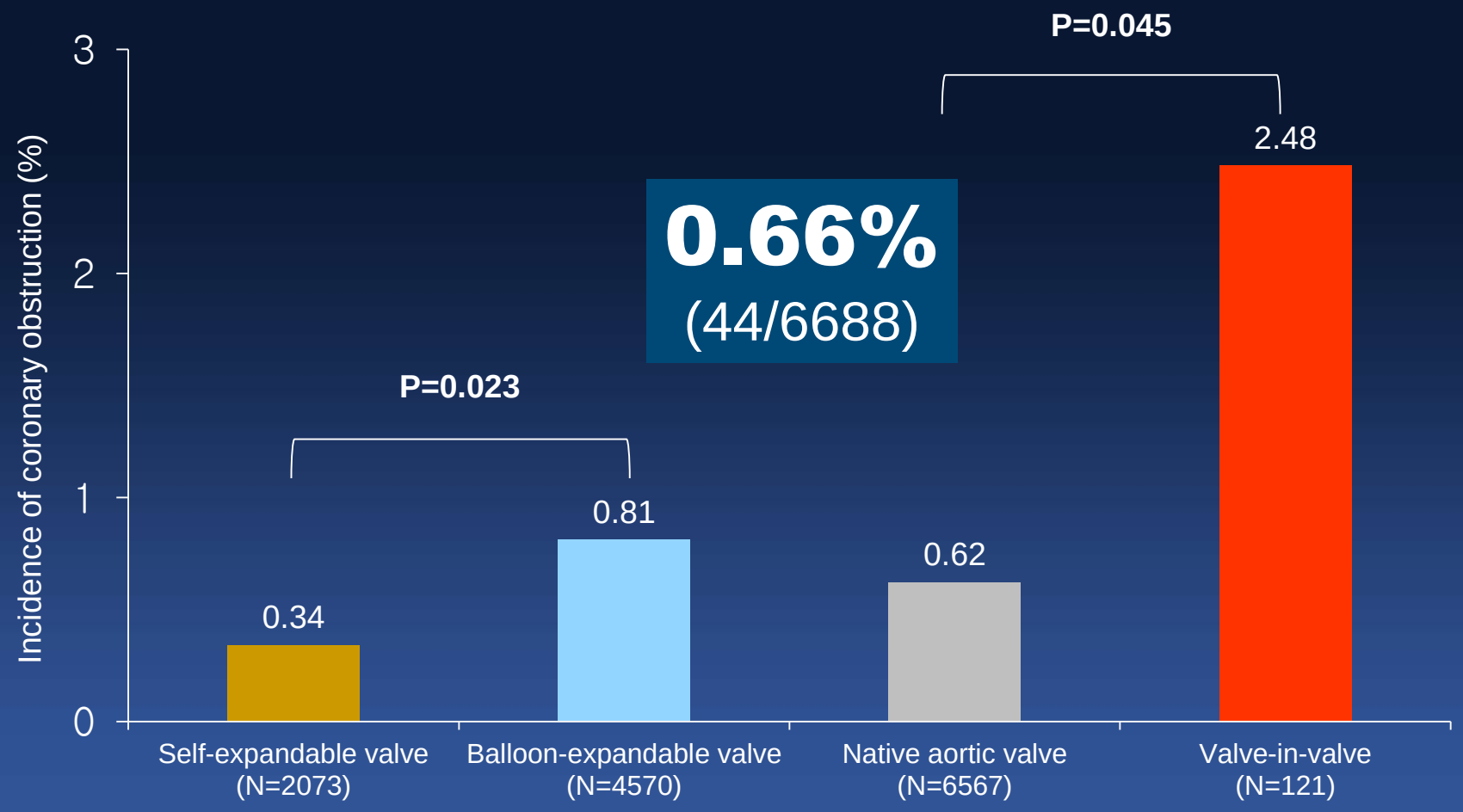
- Bicuspid Aortic Valve Stenosis
- Severe Calcification
- **Low Lying Left Main**

Coronary Obstruction With Bulky Calcium



JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 8, 2014:e105 – 7

Coronary Obstruction



Riberiro HB, et al. J Am Coll Cardiol. 2013 Oct 22;62(17):1552-62

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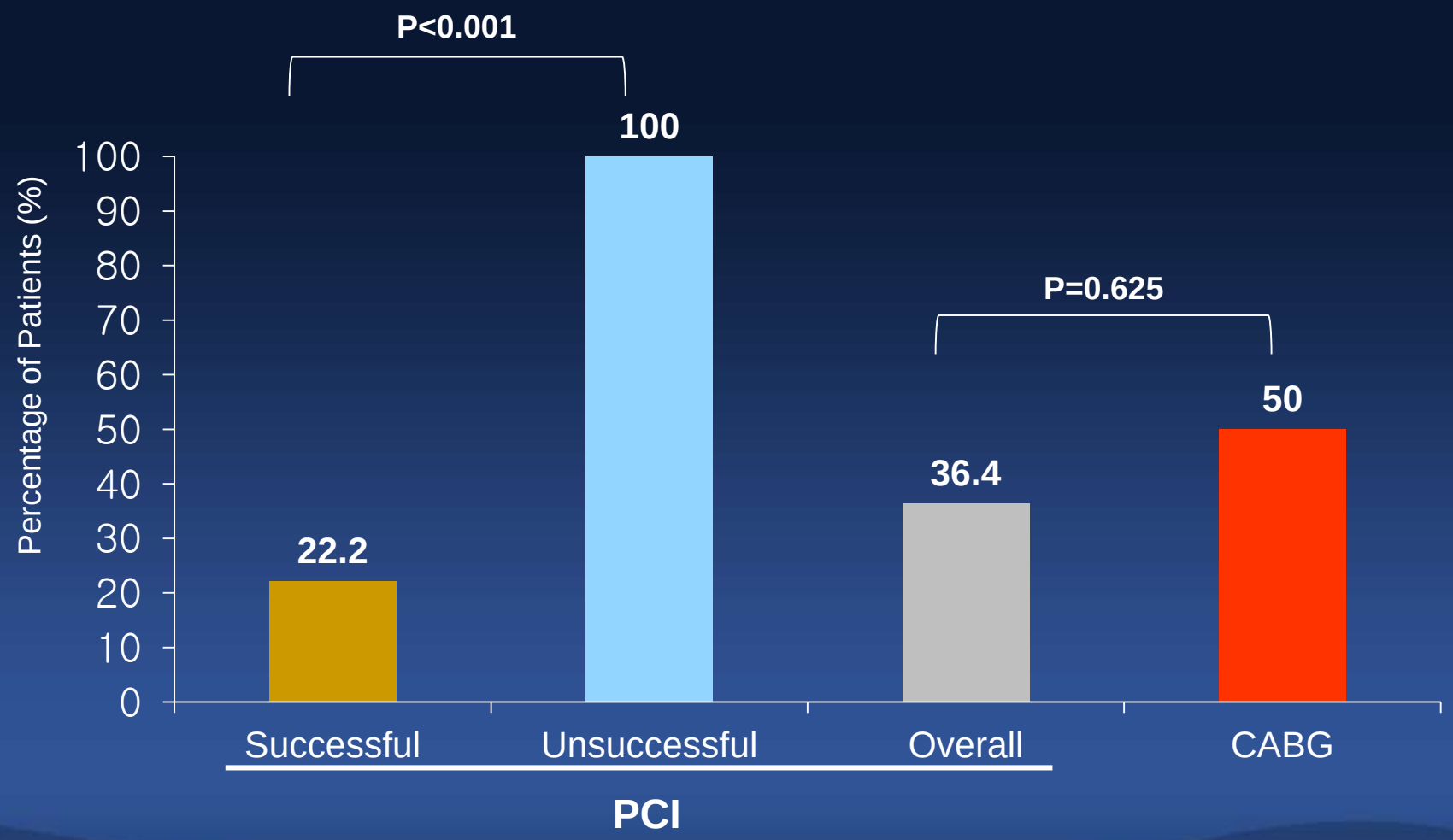
Coronary Obstruction

30 Day Mortality



Riberiro HB, et al. J Am Coll Cardiol. 2013 Oct 22;62(17):1552-62

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Causes of Coronary Obstruction

- The displacement of a **Bulky Calcified Native Valve** over a coronary ostium: The most cases
- An obstruction by a portion of the THV frame or the sealing cuff placed directly over a coronary ostium (hypothetically)

Interventional Cardiology Review, 2015;10(2):94–7

Risk of Coronary Obstruction

Multifactorial

- Women
- Low Coronary Height (<10mm to <12mm)
- Shallow Sinus of Valsalva (<30mm)
- Long Leaflet
- Left Coronary Artery
- Bulky Calcification
- Valve Implantation Height
- Device (Balloon Expandable)

Yamamoto M, et al. Int J Cardiol. 2016 May 4;217:58-63

Riberiro HB, et al. J Am Coll Cardiol. 2013 Oct 22;62(17):1552-62

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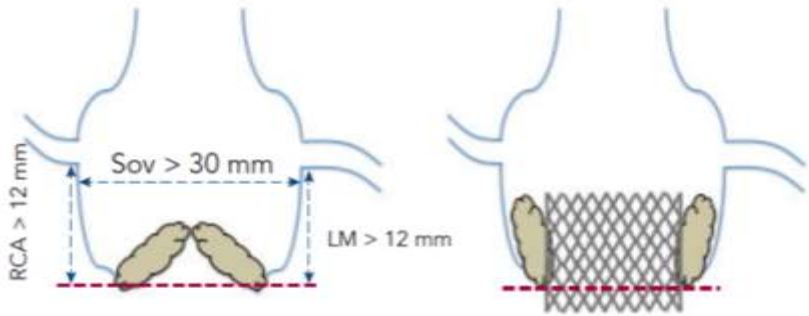
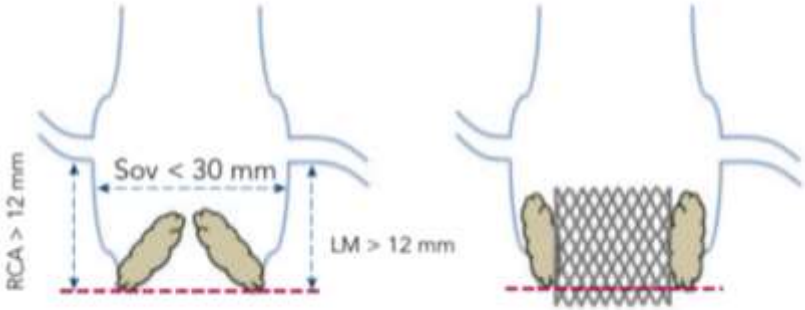
Aortic Root Scenarios

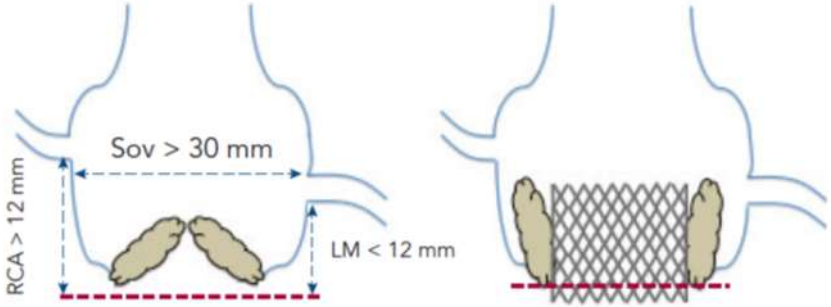
Wide and High



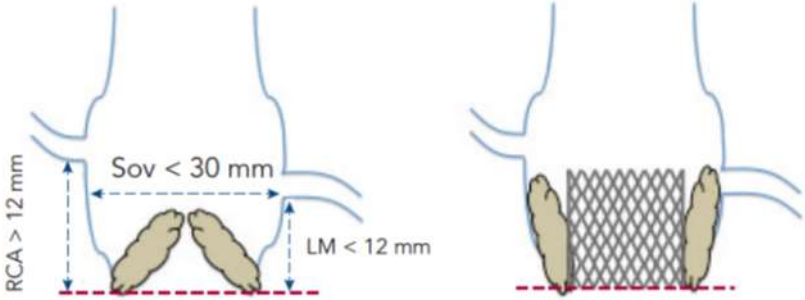
Shallow and High



Wide and Low



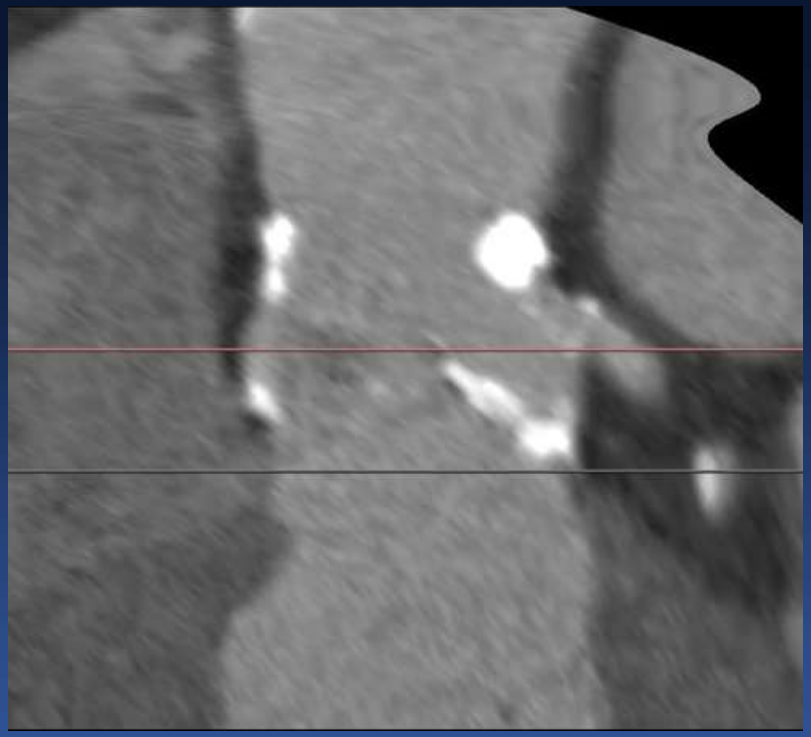
Shallow and Low



Interventional Cardiology Review, 2015;10(2):94–7

Low Coronary Height

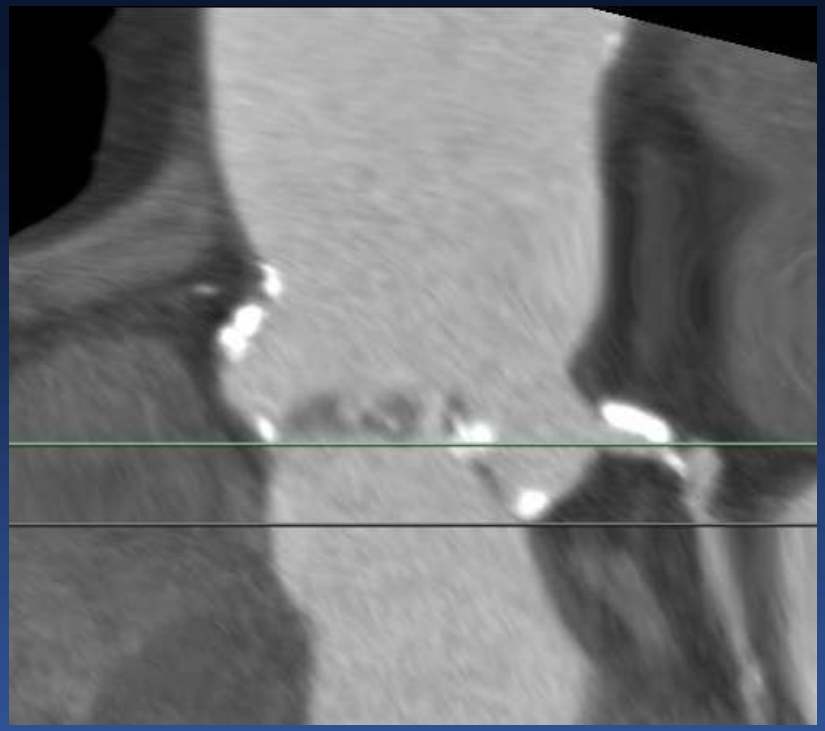
Patient 1



LCA Height 10mm

SOV 26 mm

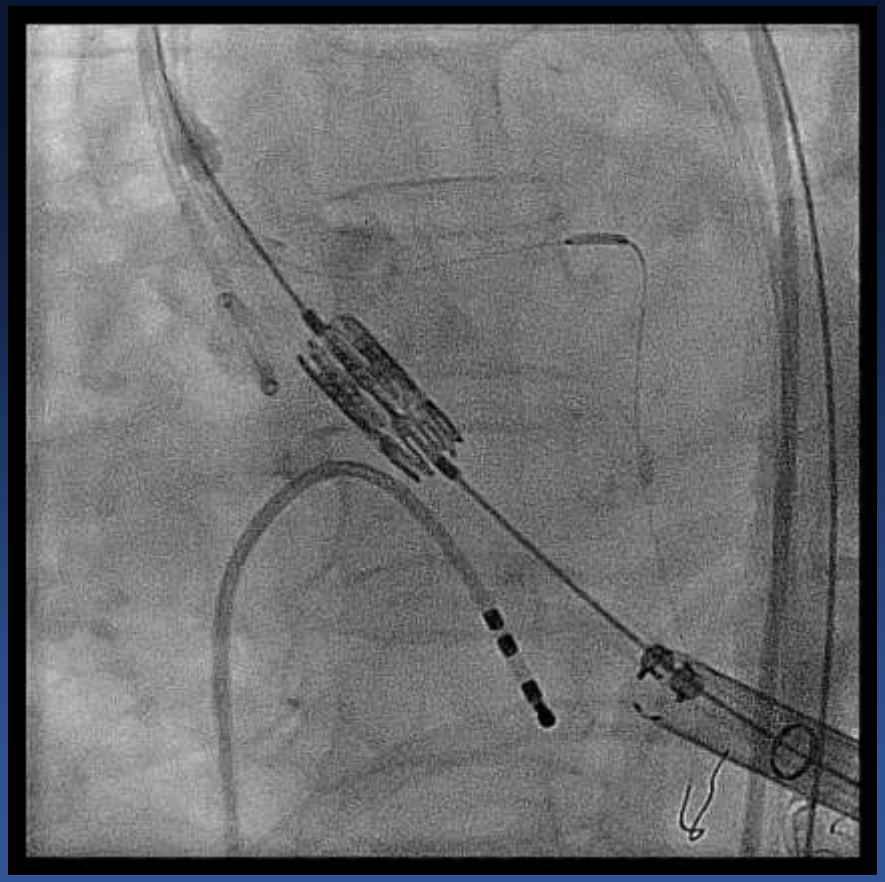
Patient 2

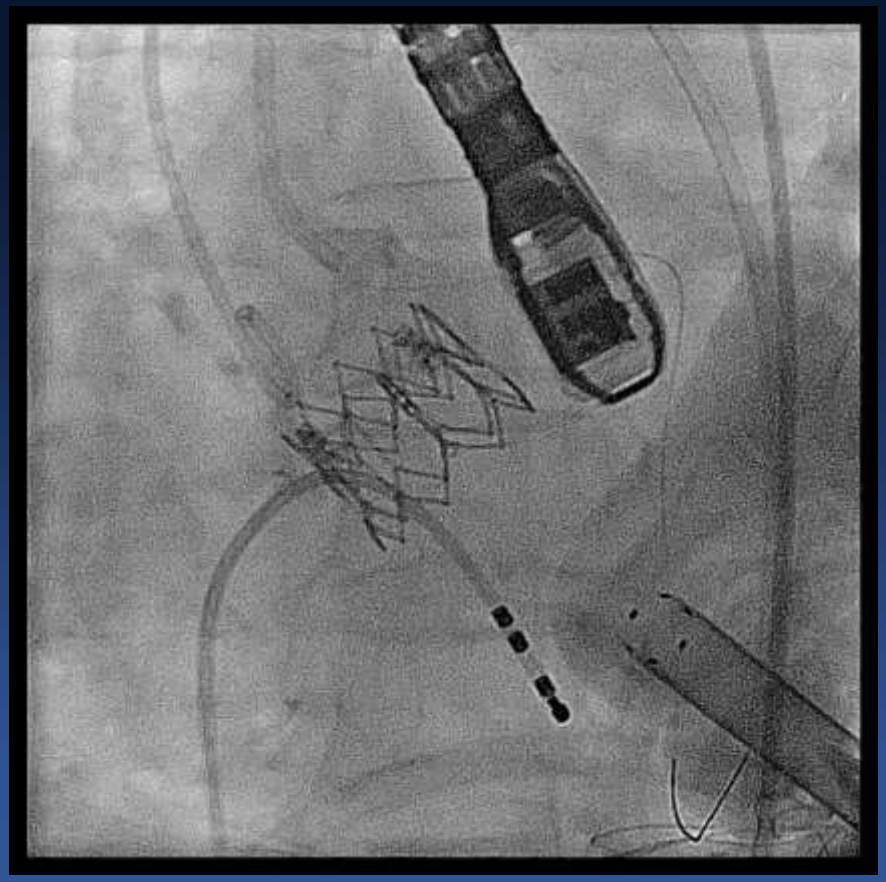


LCA Height 7.8mm

SOV 33 mm

Patient 1: Shallow and Low
(Coronary Height 10mm, SOV 26mm)

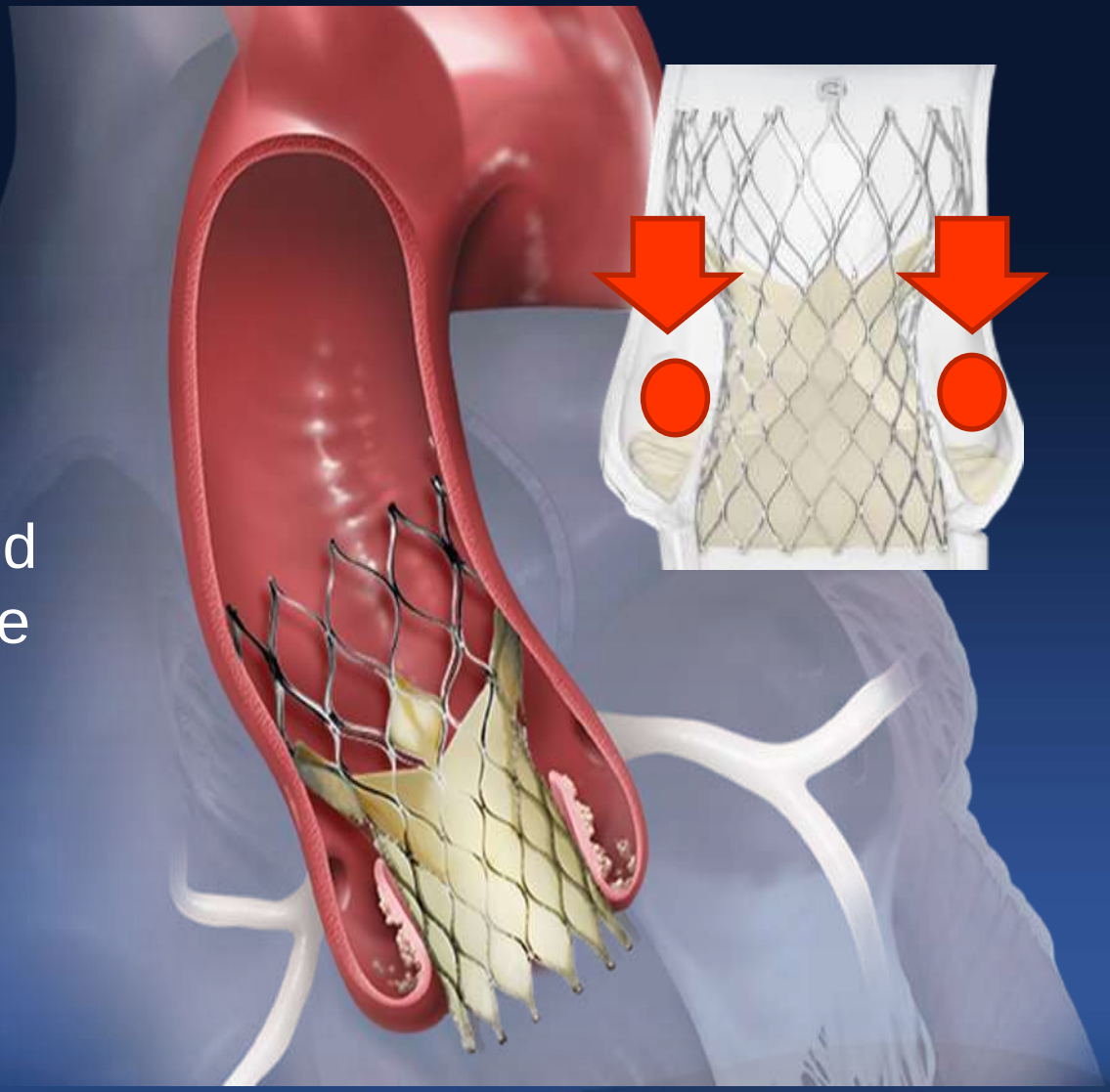




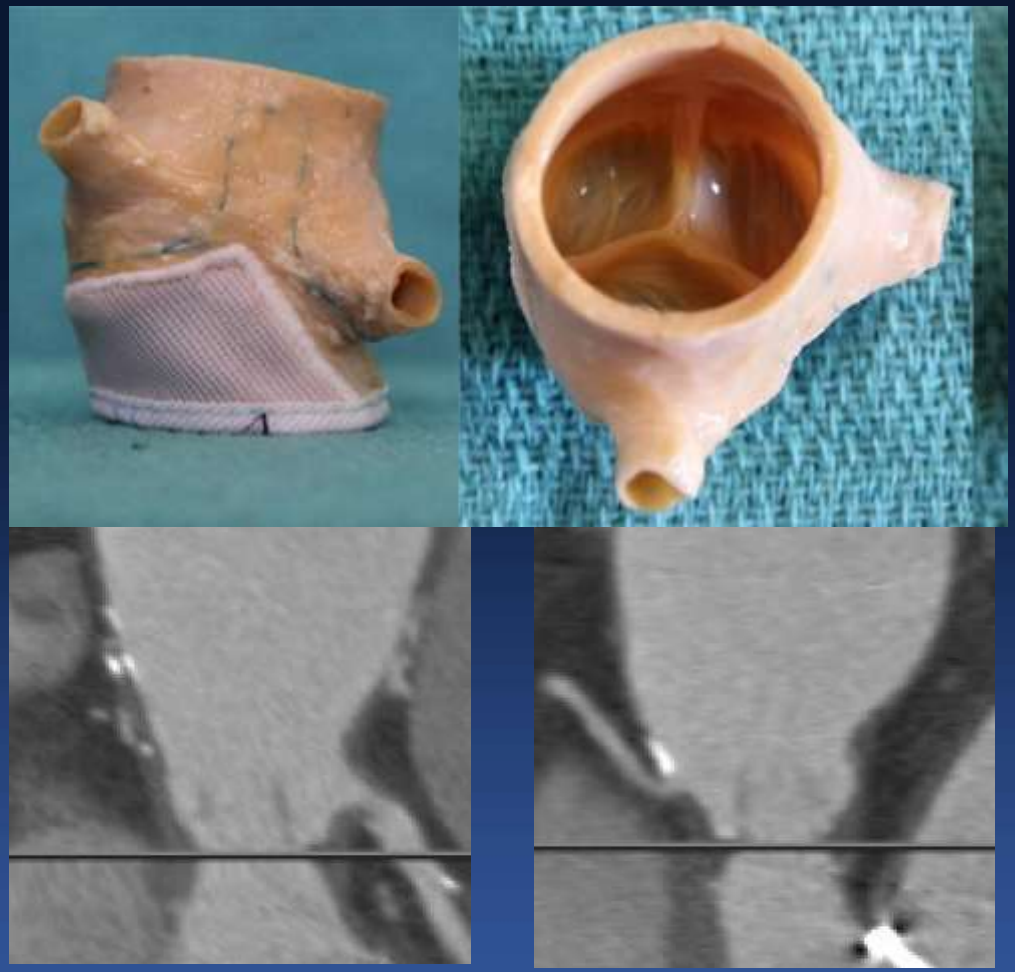
If Coronary Obstruction Occur,

Evolut R

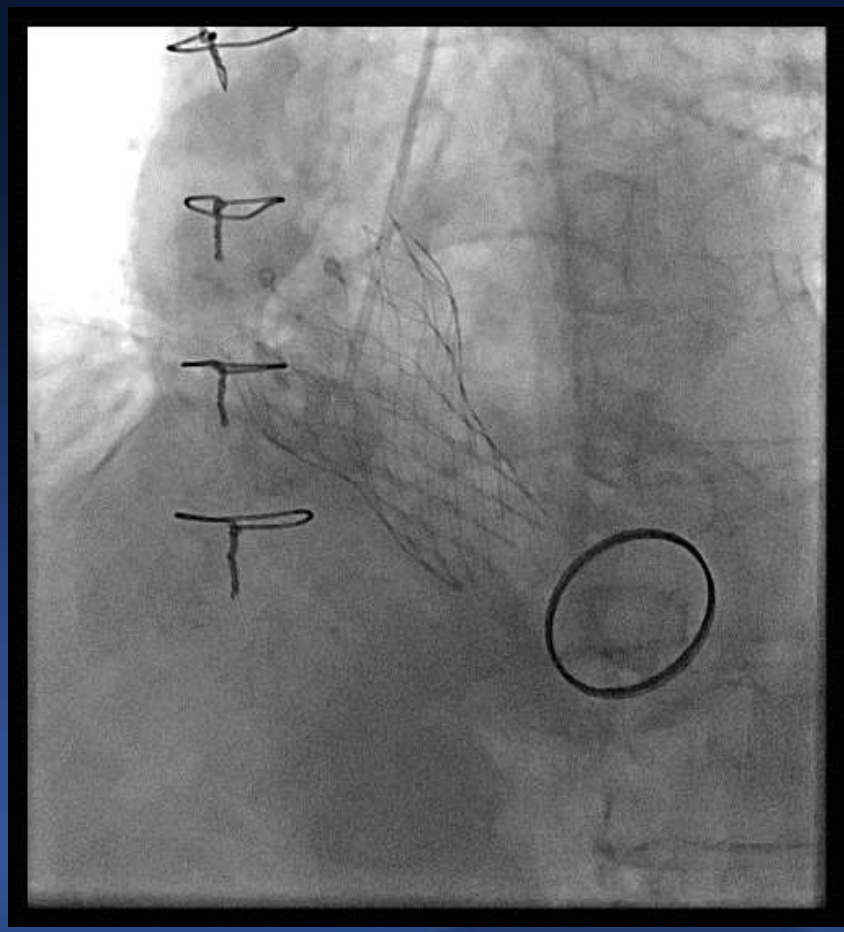
- Tapered shape of the frame
- If needed, coronary access can be achieved through the struts of the frame
- Can be completely recaptured in an emergency situation



Low Coronary Height



Prima Root 21 mm



Coronary Height	
LCA	6.8 mm
RCA	7.5 mm

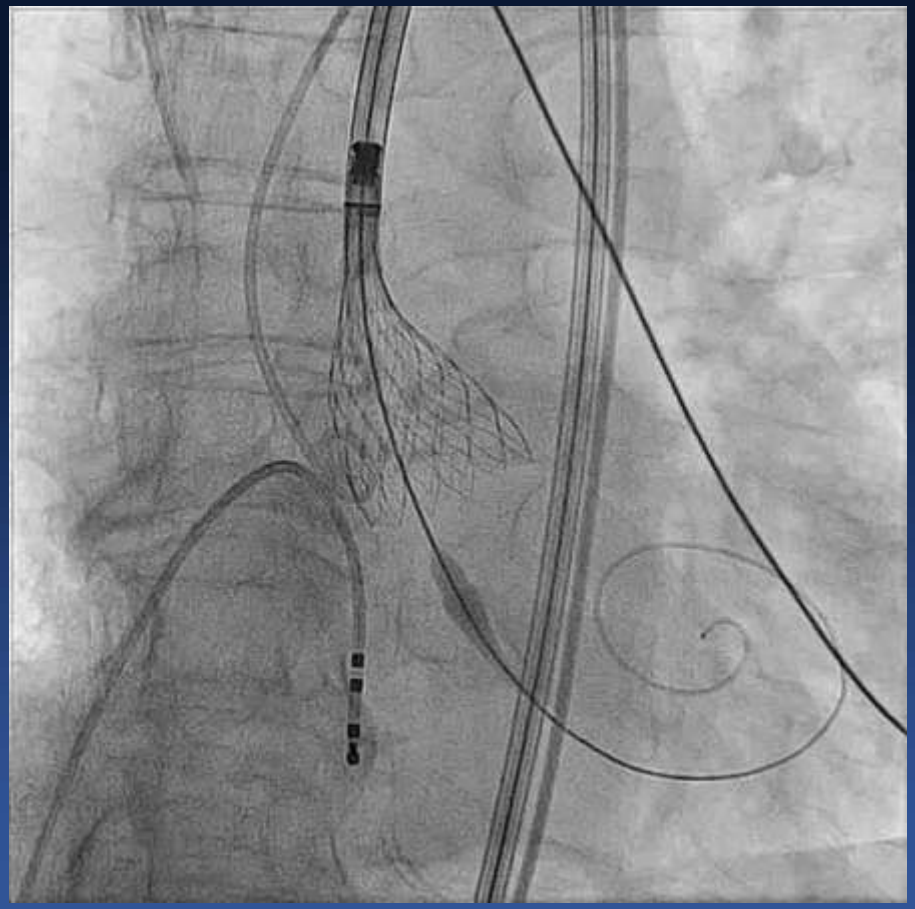
BAV is helpful

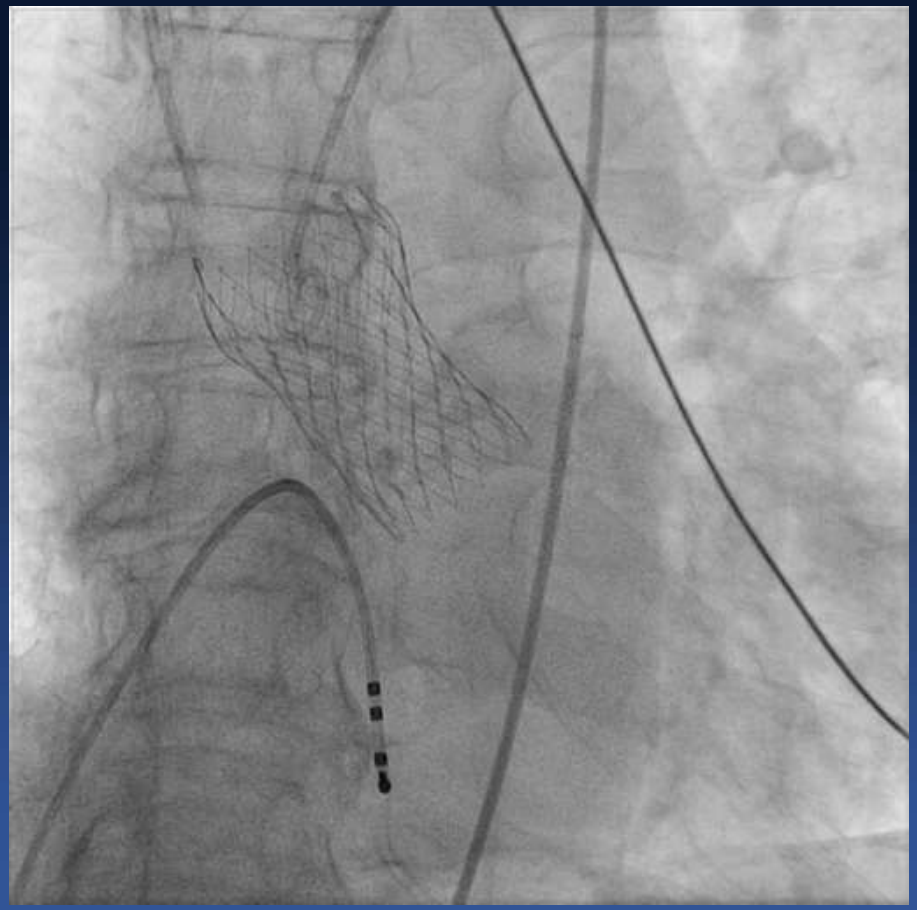
LCA

RCA

Coronary Height	
LCA	9.7 mm
RCA	13.6 mm

Patient 2
(Coronary Height 7.8mm, SOV 33mm)





Thank you.