

Figure 1 Current Widely Available Transcatheter Valves

(A) The Edwards SAPIEN THV balloon-expandable valve (Edwards Lifesciences, Irvine, California) incorporates a stainless steel frame, bovine pericardial leaflets, and a fabric sealing cuff. (B) The SAPIEN XT THV (Edwards Lifesciences) utilizes a cobalt chromium alloy frame and is compatible with lower profile delivery catheters. (C) The Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) incorporates a self-expandable frame, porcine pericardial leaflets, and a pericardial seal.

Bicuspid Aortic Valves:

Has TAVI a role?

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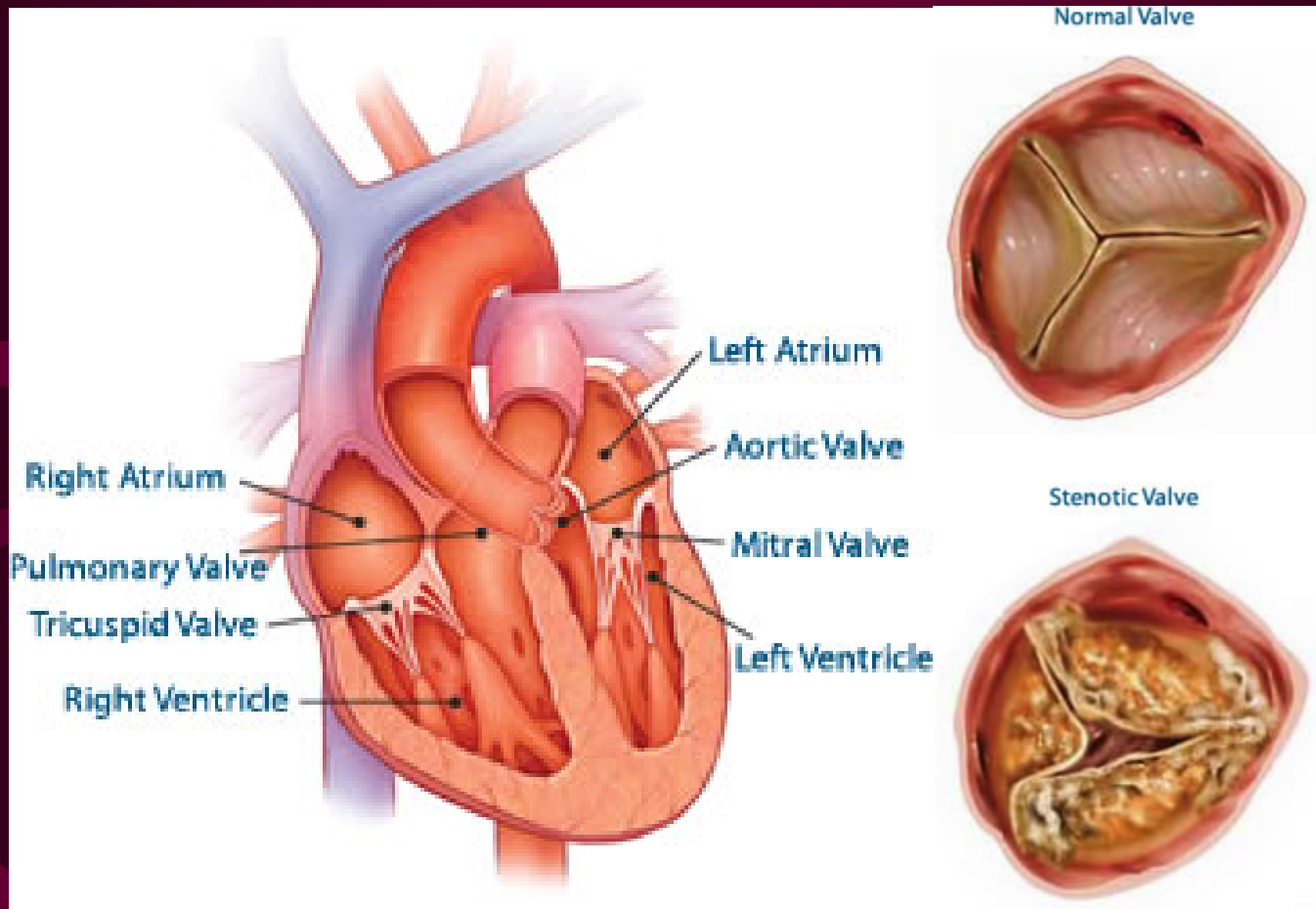
Athens Medical Center

Cardiac Catheterization Laboratory

22/11/2019

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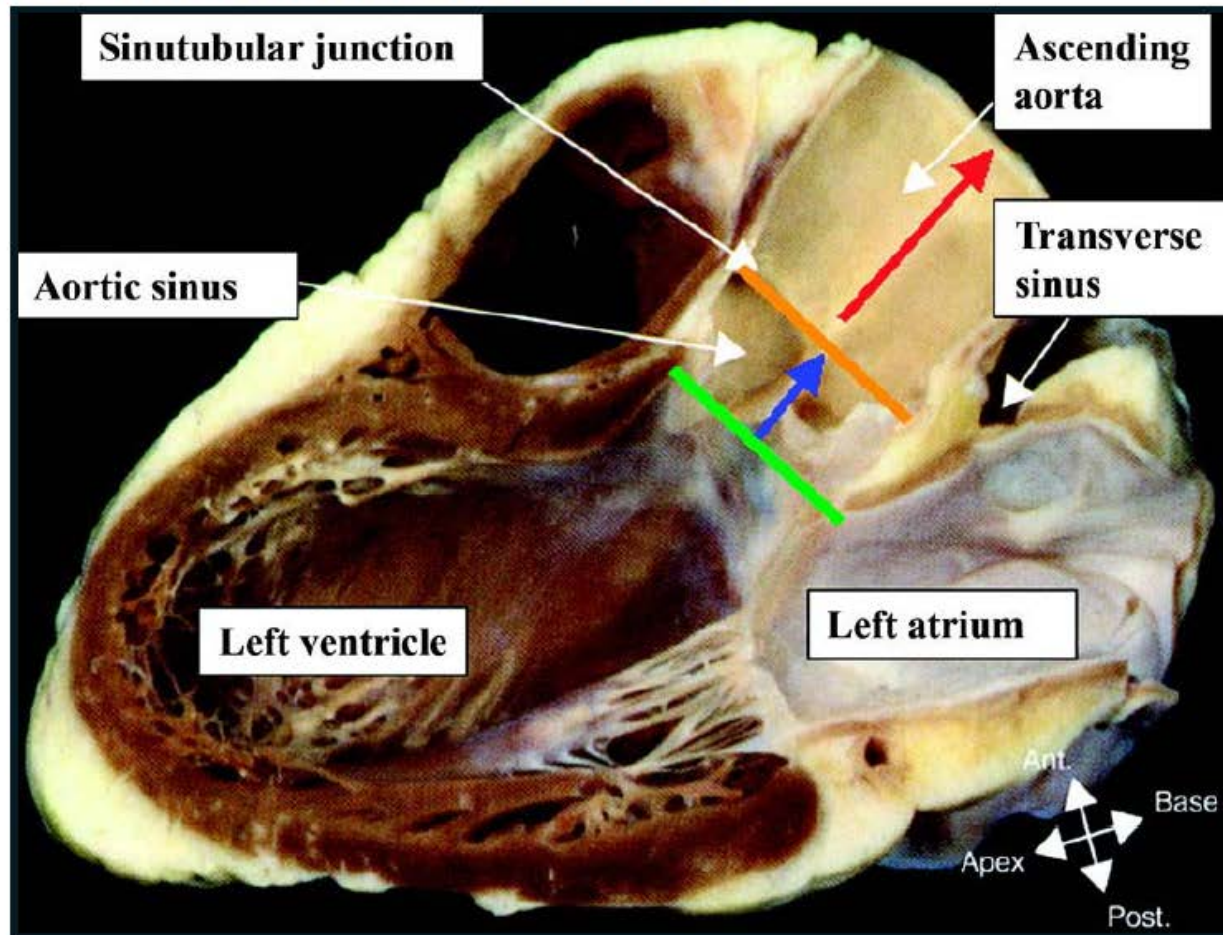
Aortic Valve Anatomy



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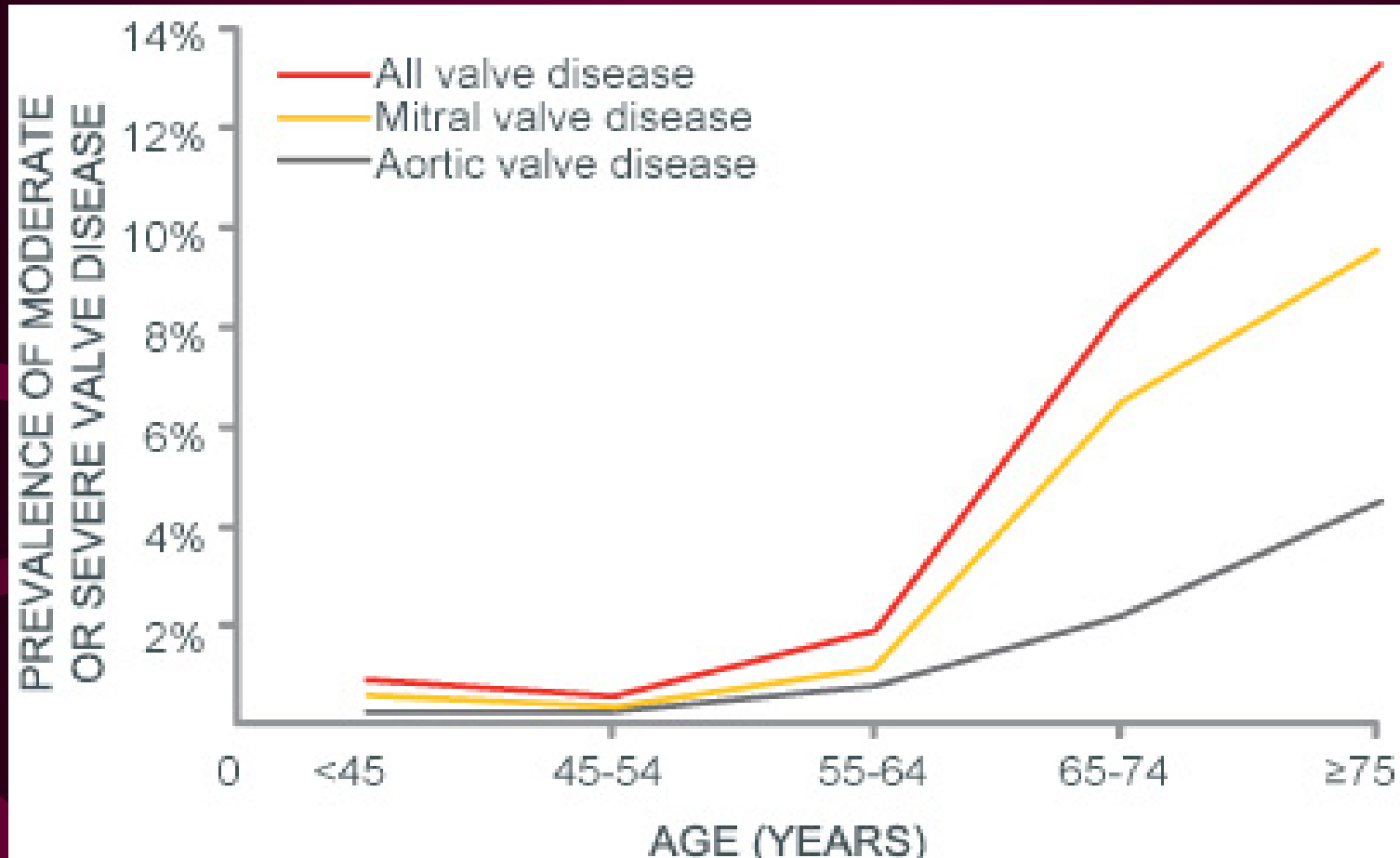
Aortic Root Anatomy

Aortic Root Anatomic Overview



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Incidence of Aortic and Mitral Valve Disease



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Causes of Aortic Stenosis

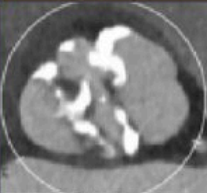
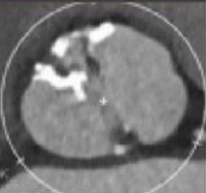


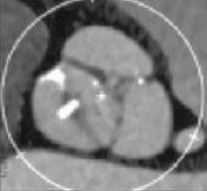



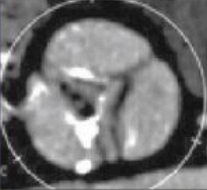
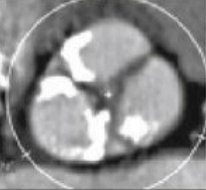


- Age related-Annular Calcification
- History of Rheumatic Fever
- Congenital Anomalies (Bicuspid)
- History of Chest Radiation
- Autoimmune Diseases
- Congenital Hypercholesterolemia
- End-stage Renal Disease

Bicuspid Aortic Valve (BAV)

Epidemiology

- Incidence is 0,4-2,25% in the general population (a very common congenital cardiac abnormality)
- 20-50% of BAV patients will undergo AVR
- 50% of SAVR patients of all ages is some form of bicuspid AS
- 27,5% of octogenarians and 41,7% of younger patients undergoing SAVR have BAV

BAV Sievers & Jilaihawi Classification

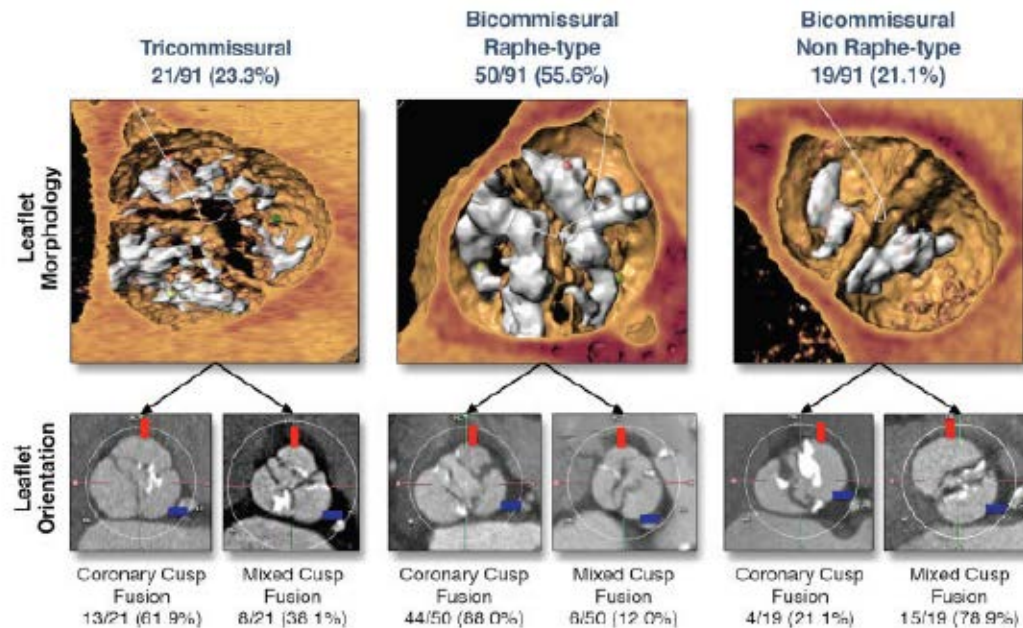
	MDCT		Schematic		Sievers et al.*	Jilaihawi et al.	Fusion Site
	systole	diastole	systole	diastole			
Bicuspid (n = 144)					Type 0 (n = 6)	Bicommissural, no raphe (n = 6/4.2%)	NA
					Type 1 (n = 138)	Bicommissural, complete raphe (n = 60/41.7%)	N-R 18.3% N-L 1.7% L-R 80.0%
						Tricommissural, incomplete raphe (n = 78/54.1%)	N-R 9.0% N-L 1.3% L-R 89.7%

Won-Keun Kim et al. JIMG 2018;11:1539-1540

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Jilaihawi Classification and MSCT Images

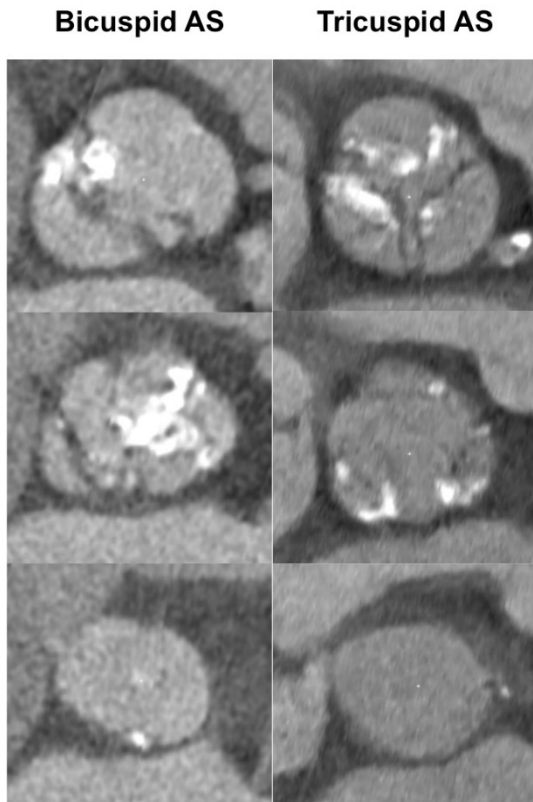
Figure 3: Classification of Bicuspid Aortic Valve



Top: Leaflet morphology is classified on the basis of number of commissures (2 or 3) and, in the presence of 2 commissures, the presence or absence of a raphe. This classification yields tricommissural, bicommissural raphe type, and bicommissural non-raphe types. Bottom: Leaflet orientation is classified on the basis of cusp fusion, which is either coronary cusp fusion or mixed non-coronary–coronary cusp fusion. Take off of the right coronary artery is indicated by the red line; take off of the left coronary artery is indicated by the blue line. Values are overall frequency of bicuspid aortic valve treated with TAVI relative to overall TAVI cases. Source: Jilaihawi et al., 2016,¹⁵ reprinted with permission from Elsevier.

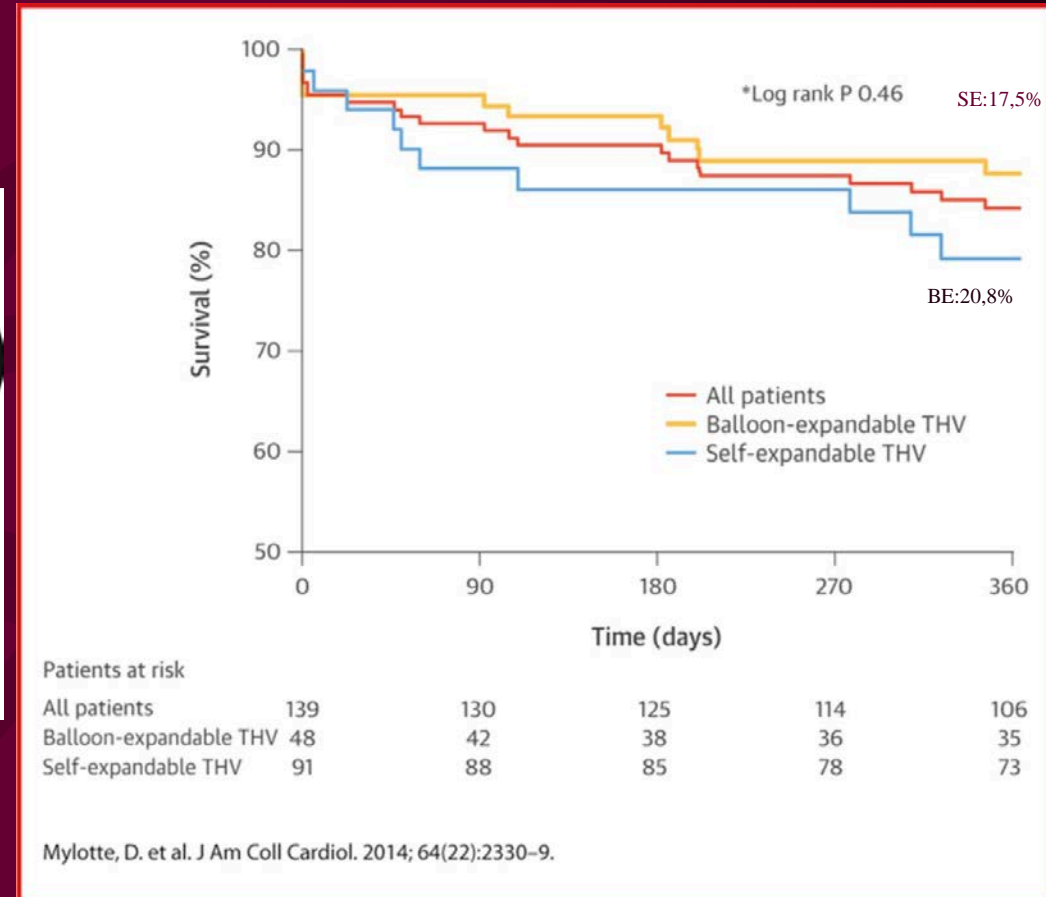
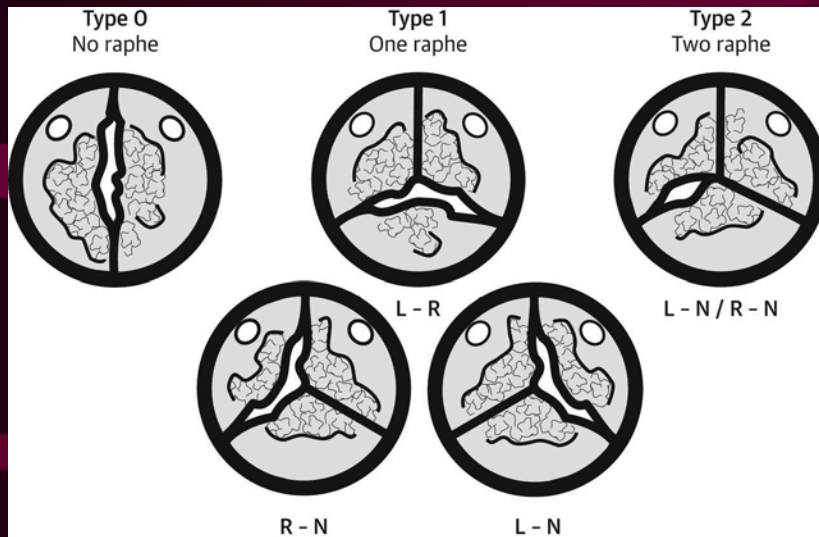
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Concerns regarding Bicuspid vs Tricuspid Aortic Valve



- Larger annulus
- Severe and asymmetric leaflet calcification
- Presence of calcified raphe
- Risk of coronary obstruction, annulus rupture, valve non expansion, paravalvular regurgitation
- Concomitant aortopathy
- Risk of aortic dissection and/or rupture
- Younger patients
- Long-term durability of transcatheter heart valves

Multicenter study in BAV (1st generation valves)



Mylotte D et al JACC 2014; 64:2330

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Multicenter study in BAV (PVL)

TABLE 3 Procedural Information and Outcomes

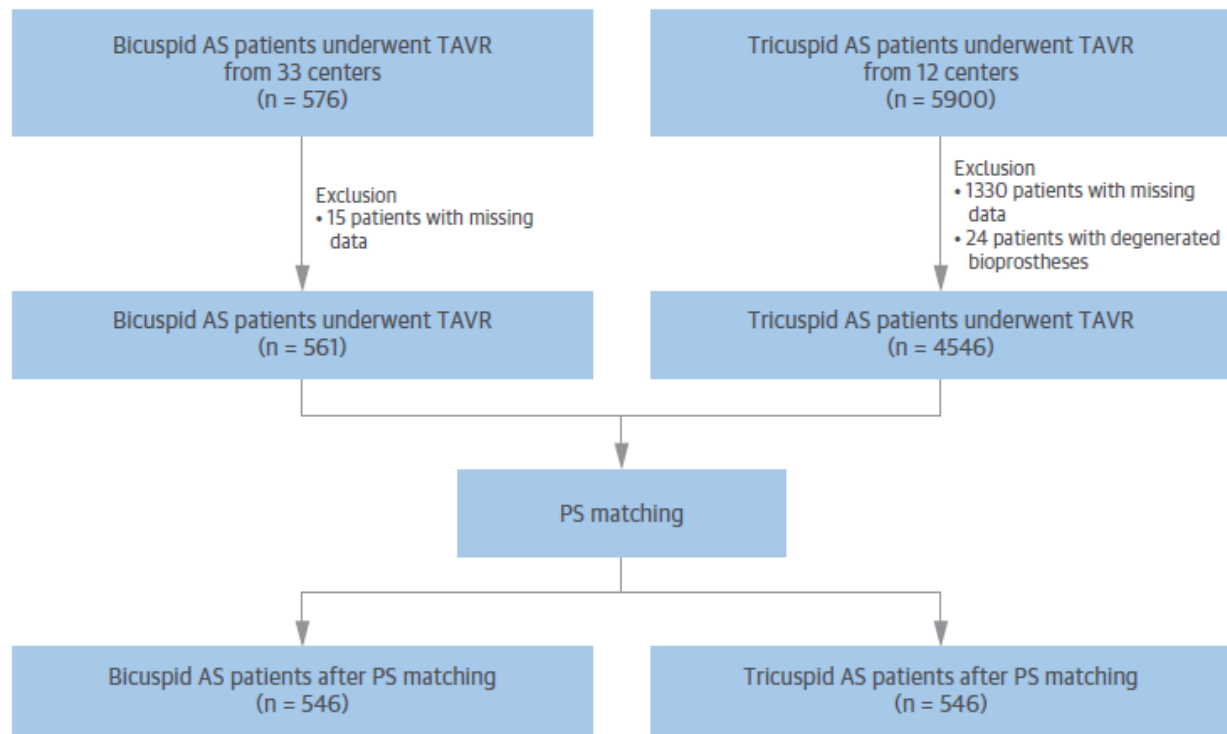
Characteristic	All Patients (n = 139)	Sapien (n = 48)	CoreValve (n = 91)	p Value
TAV size, mm	27.8 ± 2.2	26.3 ± 2.2	28.5 ± 1.8	0.0002
23 mm	10 (7.2)	10 (20.8)	-	-
26 mm	50 (36.0)	23 (47.9)	27 (29.7)	0.04
29 mm	59 (42.4)	15 (31.3)	44 (48.4)	0.07
31 mm	20 (14.4)	-	20 (22.0)	-
MSCT cover index, %	13.2 ± 9.1	8.9 ± 5.7	16.3 ± 9.8	<0.0001
MSCT-based TAV sizing	88 (63.3)	37 (77.1)	51 (56.0)	0.02
Vascular access				
Femoral	109 (78.5)	30 (62.5)	79 (86.8)	0.002
Subclavian	5 (3.6)	-	5 (5.5)	-
Apical	12 (8.6)	12 (25.0)	-	-
Aortic	12 (8.6)	6 (12.5)	6 (6.6)	-
Carotid	1 (0.7)	-	1 (1.1)	-
General anesthesia	85 (61.1)	33 (68.8)	52 (57.1)	0.20
Balloon predilation	137 (98.6)	51 (100.0)	89 (97.8)	0.54
Predilation balloon size, mm	22.5 ± 2.1	21.9 ± 2.2	22.9 ± 2.0	0.008
Balloon postdilation*	25 (18.1)	5 (10.6)	20 (22.2)	0.11
Postdilation balloon size, mm*	26.5 ± 2.3	24.7 ± 2.5	26.8 ± 2.1	0.07
TAV malposition*	9 (6.5)	2 (4.3)	7 (7.8)	0.72
TAV embolization*	3 (2.2)	2 (4.3)	1 (1.1)	0.27
Need for 2nd TAV*	5 (3.6)	1 (2.1)	4 (4.4)	0.66
Tamponade	5 (3.6)	0	5 (5.7)	0.16
Aortic root rupture	1 (0.7)	1 (2.1)	0	-
Conversion to SAVR	3 (2.2)	2 (4.2)	1 (1.1)	0.30
Postimplantation echocardiography				
Aortic regurgitation, grade (1-4)*	1.1 ± 0.9	1.0 ± 0.9	1.1 ± 0.9	0.53
≥Grade 2	38 (28.4)	9 (19.6)	29 (32.2)	0.11
≥Grade 3	8 (6.0)	3 (6.5)	5 (5.5)	0.99
Aortic valve gradient, mm Hg*	11.4 ± 9.9	11.7 ± 8.7	11.3 ± 10.4	0.82
Aortic valve area, cm ² *	1.7 ± 0.5	1.6 ± 0.4	1.7 ± 0.5	0.23
Contrast media, ml	174 ± 88	176 ± 118	172 ± 81.5	0.17
Fluoroscopy duration, min	20 (14-28)	14 (9-25)	20 (15-29)	0.004

Values are mean ± SD, n (%), or median (interquartile range). p values represent comparisons between the Edwards Sapien and Medtronic CoreValve prostheses. *Refers to 137 patients who received a TAV.
MSCT – multislice computed tomography; SAVR – surgical aortic valve replacement; TAV – transcatheter aortic valve.

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Outcomes in Transcatheter Aortic Valve Replacement for Bicuspid Versus Tricuspid Aortic Valve Stenosis

FIGURE 1 Study Flow Chart



A total of 576 patients with bicuspid AS consecutively treated with TAVR were enrolled from 33 centers. For the purpose of this study, data from 4,546 patients with tricuspid AS consecutively undergoing TAVR were collected from 12 participating centers. After propensity score matching, 546 patients with bicuspid and tricuspid AS were compared. AS = aortic valve stenosis; PS = propensity score; TAVR = transcatheter aortic valve replacement.

Procedure and Clinical Outcomes

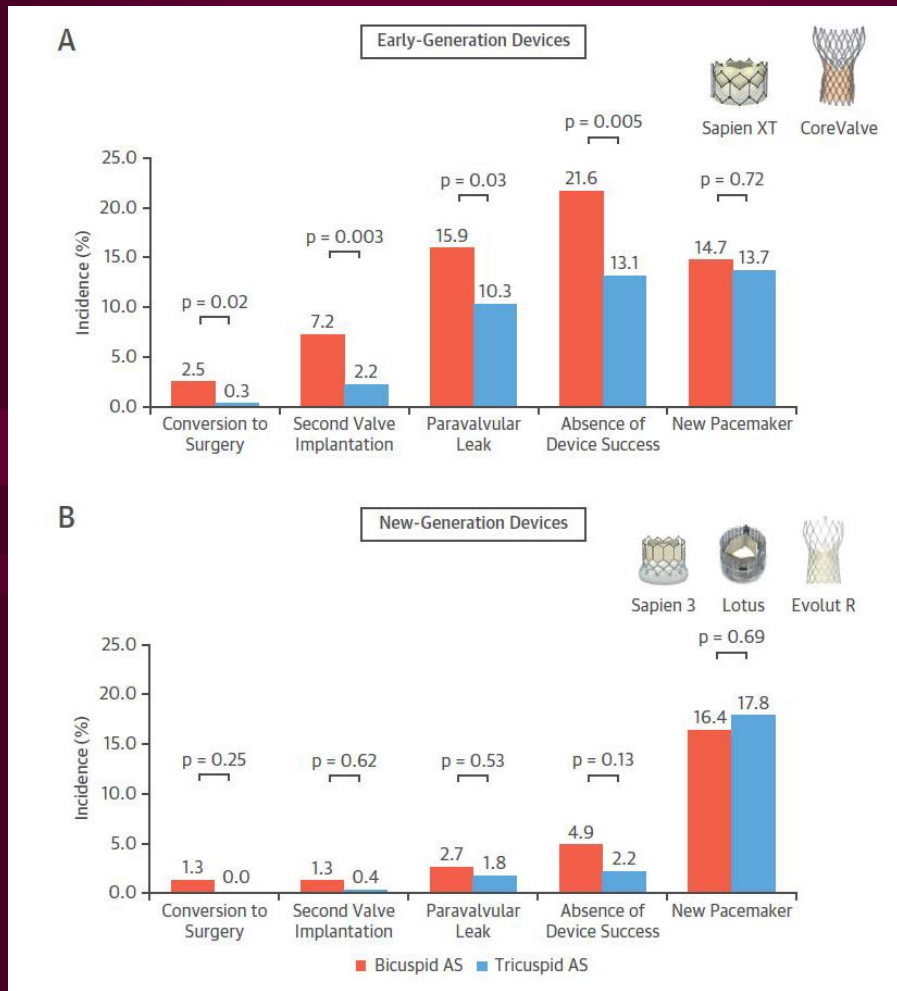
TABLE 2 Procedural and Clinical Outcomes

	Propensity Score Matched Cohort			
	Bicuspid AS (n = 546)	Tricuspid AS (n = 546)	p Value	OR (95% CI)
Procedural outcomes				
Procedure-related death	7 (1.3)	6 (1.1)	>0.99	1.17 (0.39-3.47)
Conversion to surgery	11 (2.0)	1 (0.2)	0.006	11.00 (1.42-85.20)
Coronary obstruction	5 (0.9)	3 (0.5)	0.73	1.67 (0.40-6.97)
Aortic root injury	9 (1.6)	0 (0.0)	0.004	—
Implantation of 2 valves	26 (4.8)	8 (1.5)	0.002	3.71 (1.61-8.56)
New permanent pacemaker	84 (15.4)	84 (15.4)	>0.99	1.00 (0.72-1.39)
Echocardiographic findings				
Mean gradient, mm Hg	10.8 ± 6.7	10.2 ± 4.4	0.18	
LVEF, %	54.2 ± 13.6	54.7 ± 13.9	0.79	
Moderate or severe paravalvular leak	57 (10.4)	37 (6.8)	0.04	1.61 (1.04-2.48)
Device success	466 (85.3)	499 (91.4)	0.002	0.54 (0.37-0.80)
30-day outcomes				
All-cause mortality	20 (3.7)	18 (3.3)	0.87	1.11 (0.59-2.10)
Stroke	16 (2.9)	10 (1.8)	0.33	1.60 (0.73-3.53)
Nondisabling	7 (1.3)	6 (1.1)	>0.99	1.17 (0.39-3.47)
Disabling	9 (1.6)	4 (0.7)	0.27	2.25 (0.69-7.31)
Bleeding				
Major	20 (3.7)	22 (4.0)	0.88	0.91 (0.50-1.67)
Life-threatening	11 (2.0)	19 (3.5)	0.20	0.58 (0.28-1.22)
Major vascular complication	16 (2.9)	16 (2.9)	>0.99	1.00 (0.50-2.00)
Acute kidney injury (stage 2 or 3)	11 (2.0)	5 (0.9)	0.21	2.20 (0.77-6.33)

Values are n (%) or mean ± SD, unless otherwise indicated.
CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

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Outcomes in bicuspid vs tricuspid AS with early vs new-generation devices



2 year cumulative all-cause mortality rates in patients with bicuspid (orange) vs tricuspid (blue) in a propensity score matched cohort

CENTRAL ILLUSTRATION: TAVR for Bicuspid Versus Tricuspid Aortic Valve Stenosis

Bicuspid AS Tricuspid AS



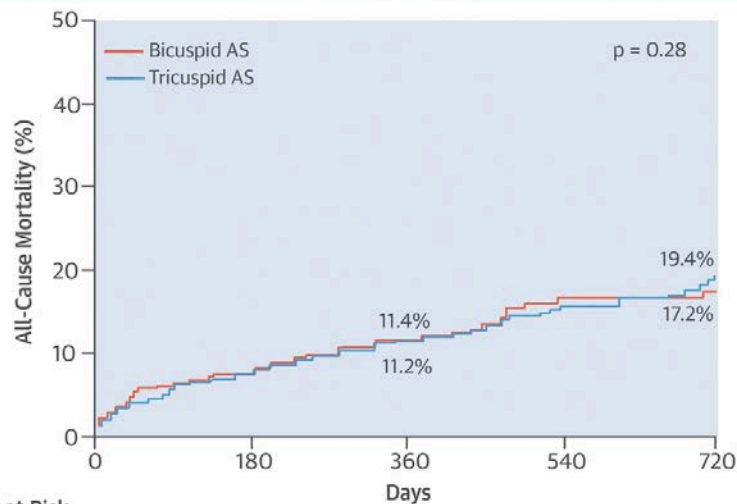
Type 0



Type 1



All-Cause Mortality



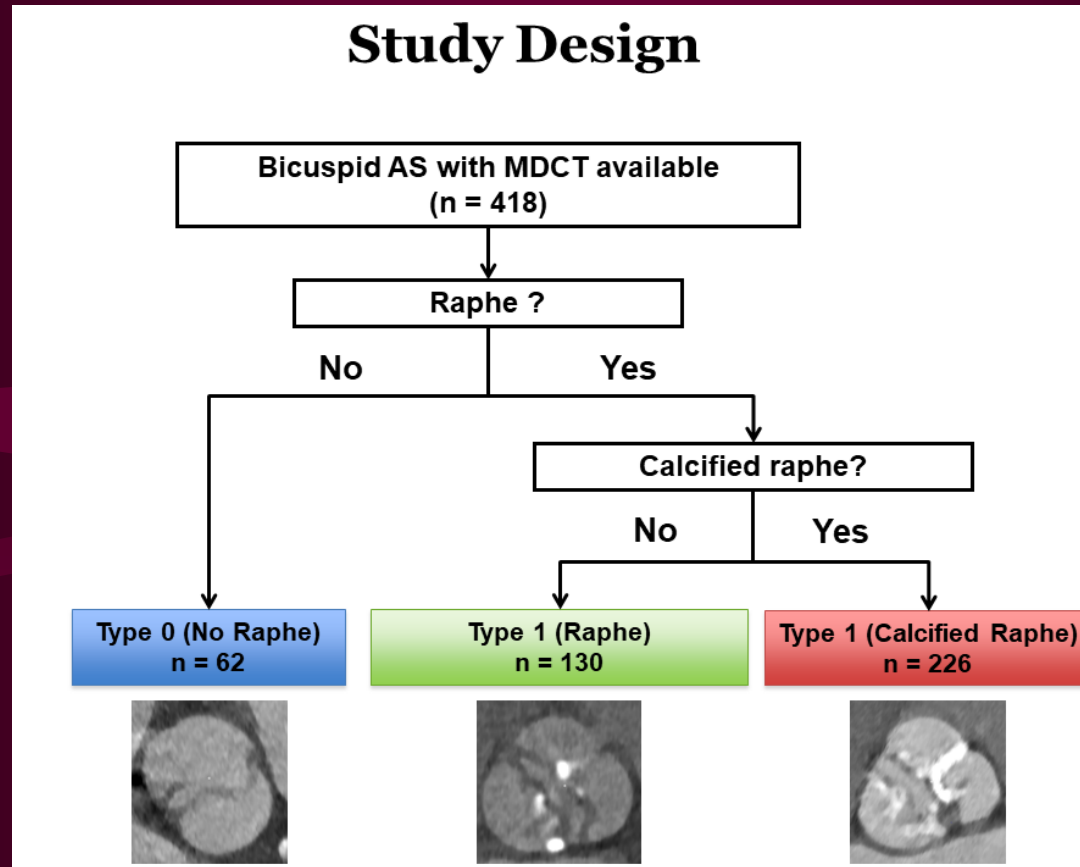
Number at Risk

Bicuspid AS	546	236	106
Tricuspid AS	546	282	133

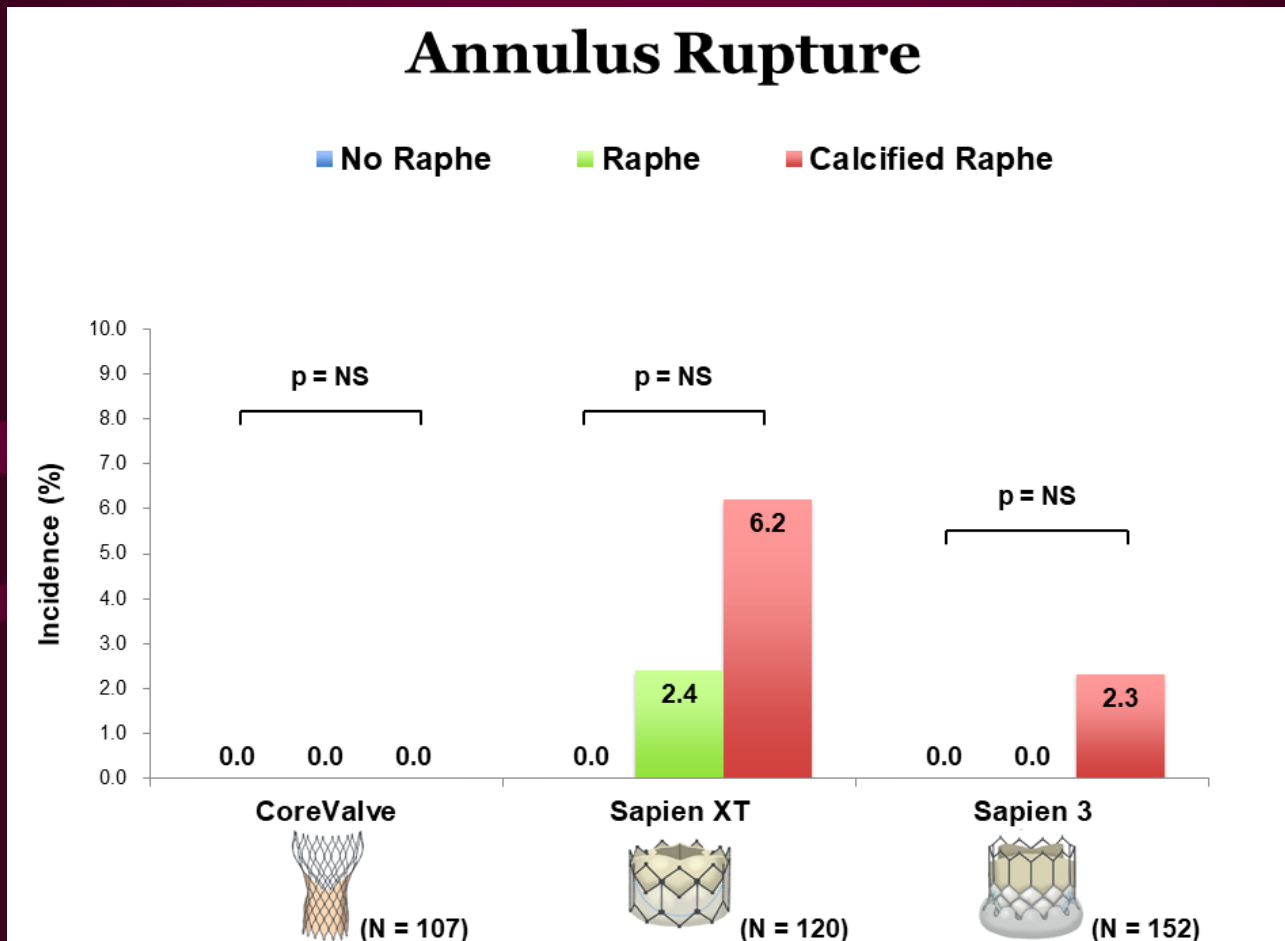
Yoon, S.-H. et al. J Am Coll Cardiol. 2017;69(21):2579-89.

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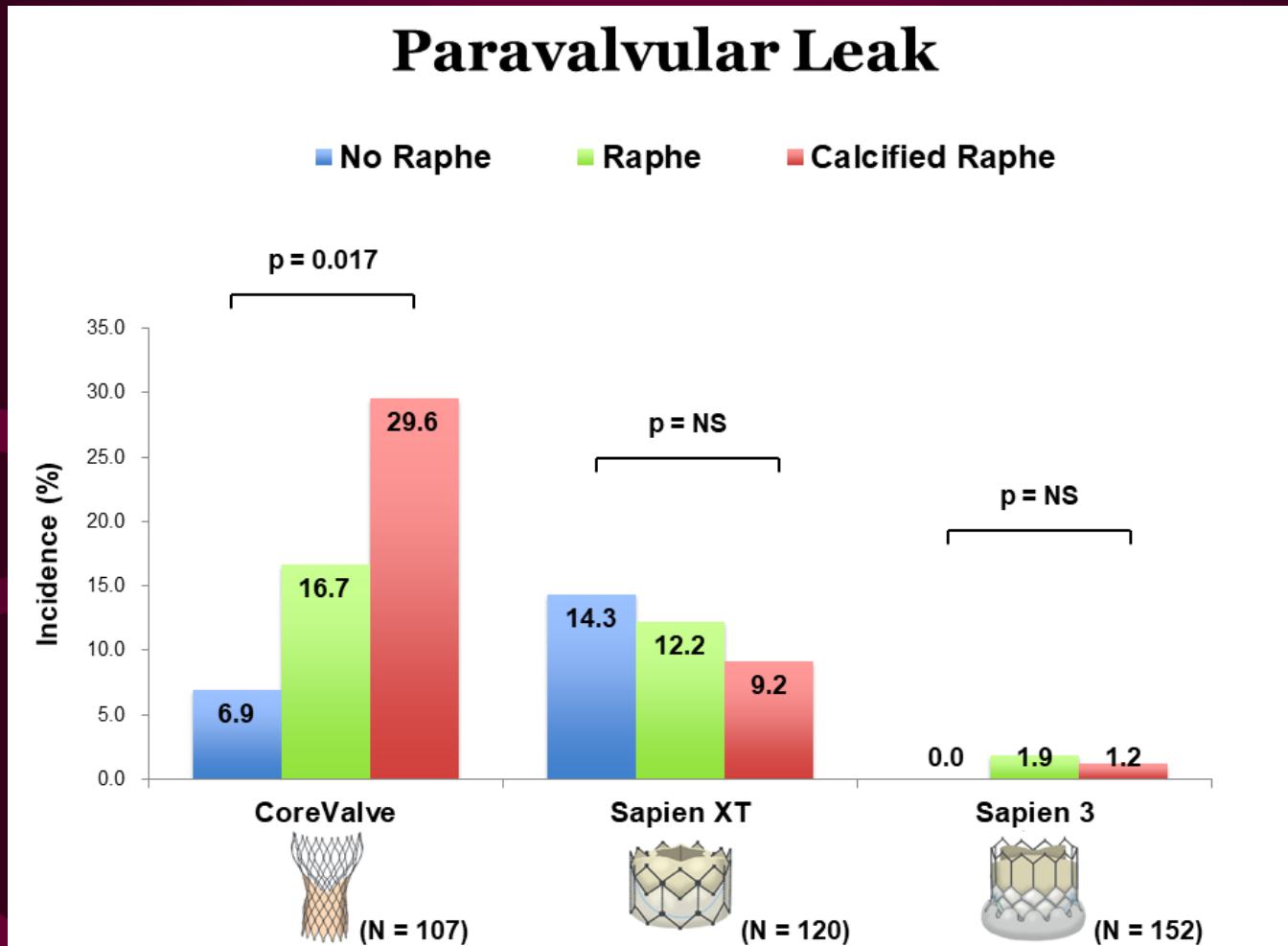
TAVI in BAV according to Device



Risk of annulus rupture



Incidence of >grade 2 PVL



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Bicuspid Aortic Valve European Registry

- 7 Centers in Europe & 1 in Canada
- 51 Patients with BAV underwent TAVR with Sapien 3 Valve
- STS PROM: 5,2% +/-3,7%
- BAV Type 0: 11,8%, Type 1: 84,2%

Bicuspid Aortic Valve European Registry – 30 day outcomes

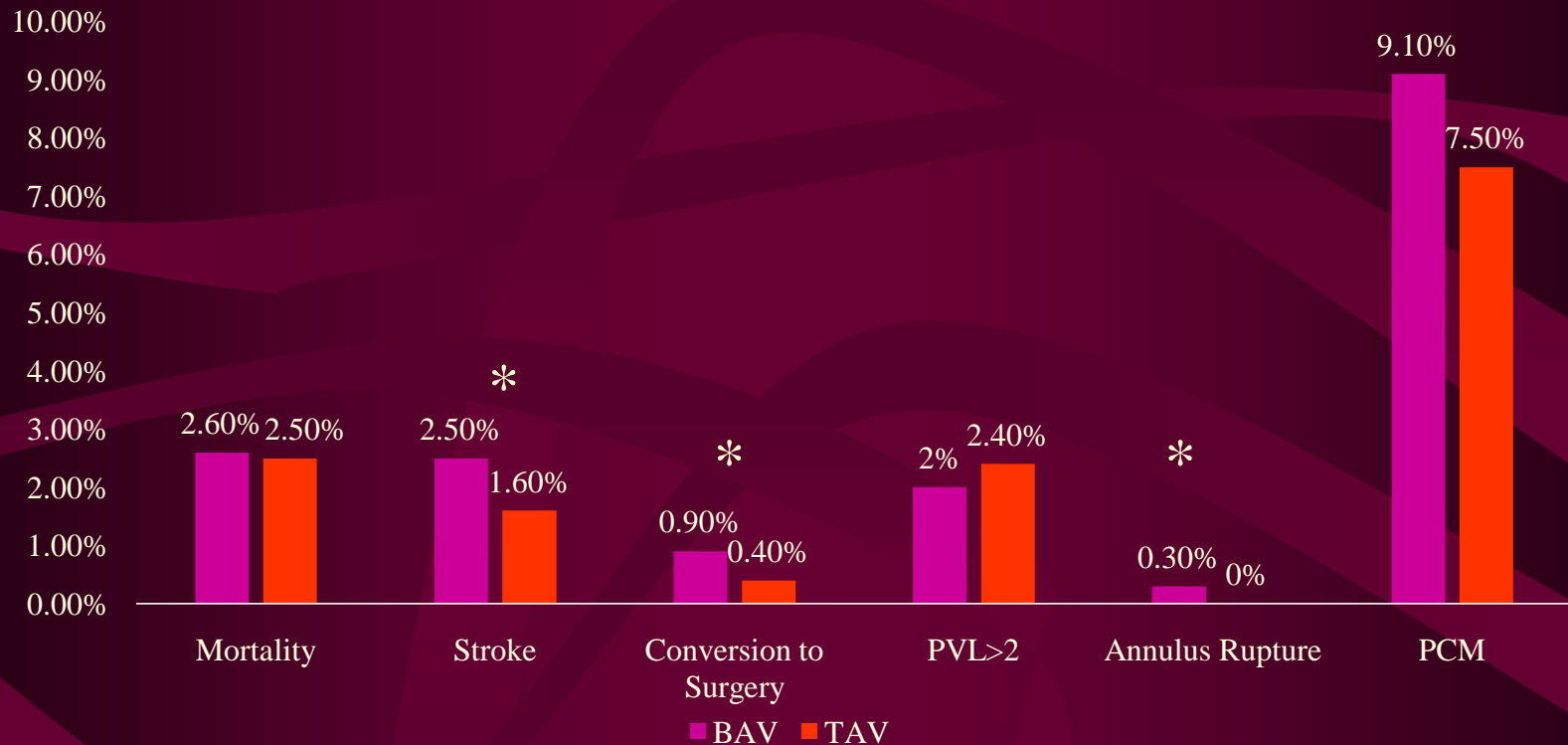
Death	3,9%
PVL (mild)	37%
PVL (severe)	0%
Vascular Complications	3,9%
Pacemaker	23,5%

Transcatheter Valve Therapies (TVT) Registry

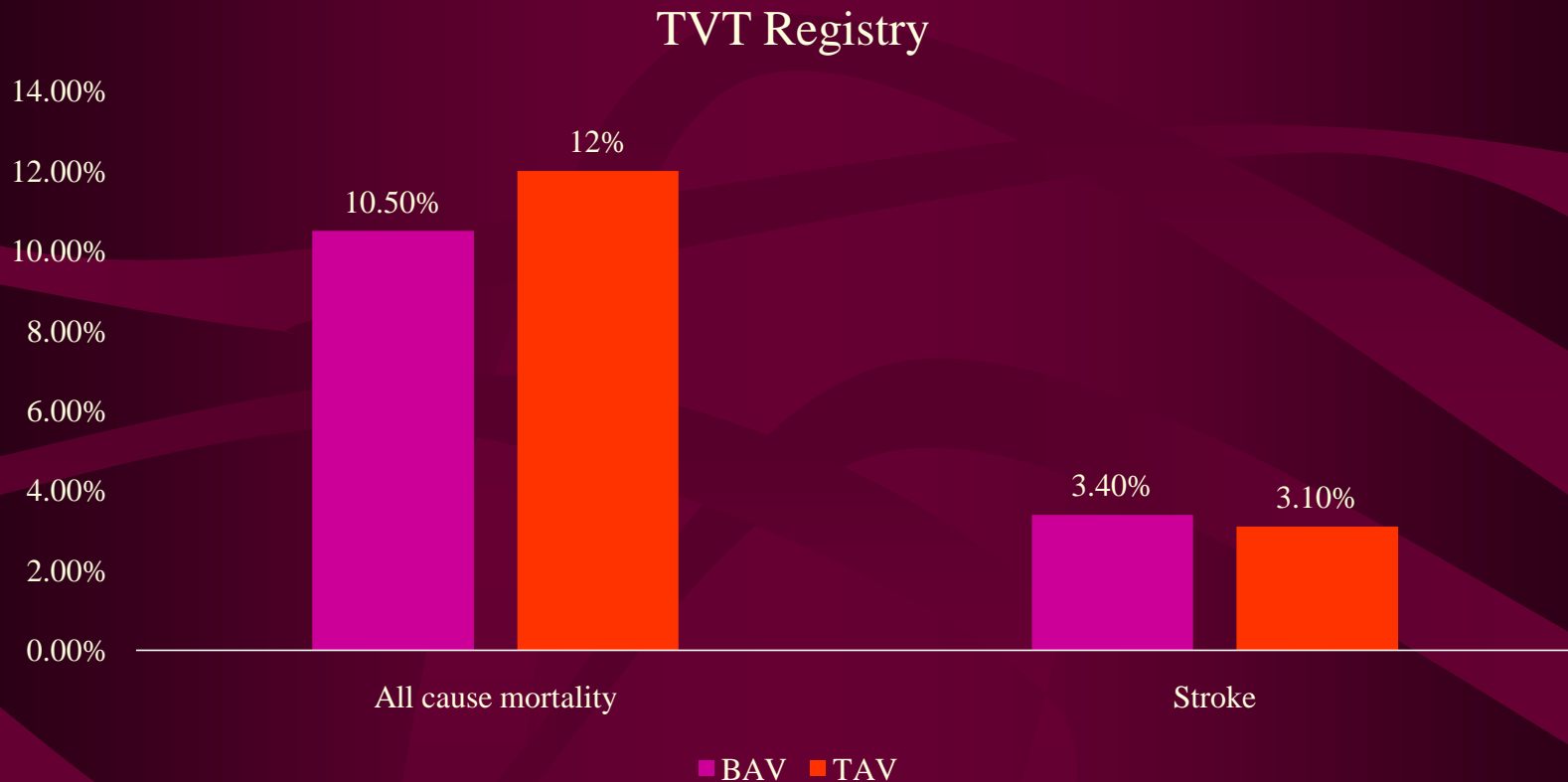
- 92236 Patients underwent TAVR with Sapien 3 Valve between 6/2015 and 11/2018
- 2726 (3%) had BAV c/w 79096 with trileaflet AV
- 1:1 PM score (2691 pts – excluded those who underwent TAVR w older devices)

30 day TVT Registry Outcomes

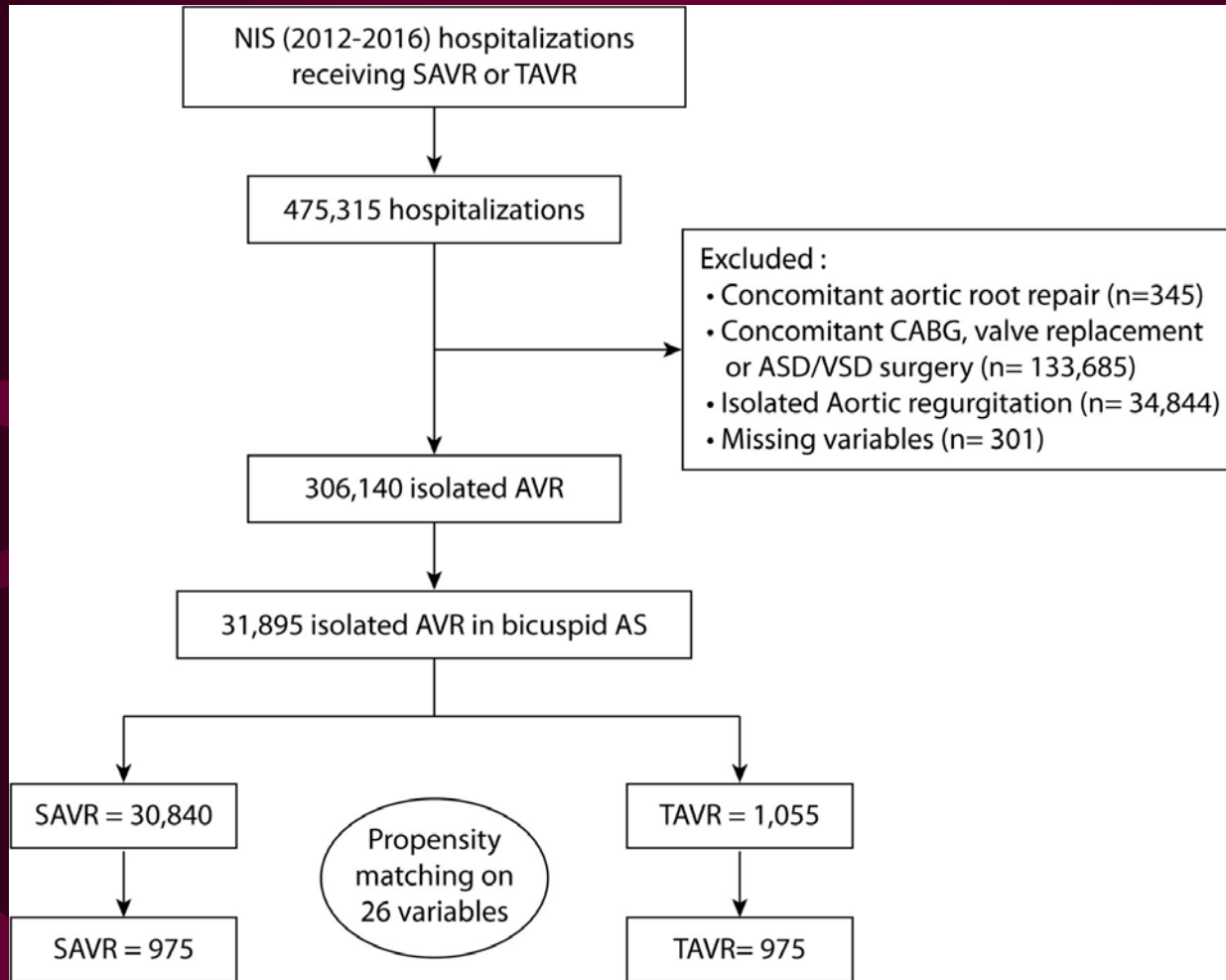
TVT Registry



1 year TVT Registry Outcomes



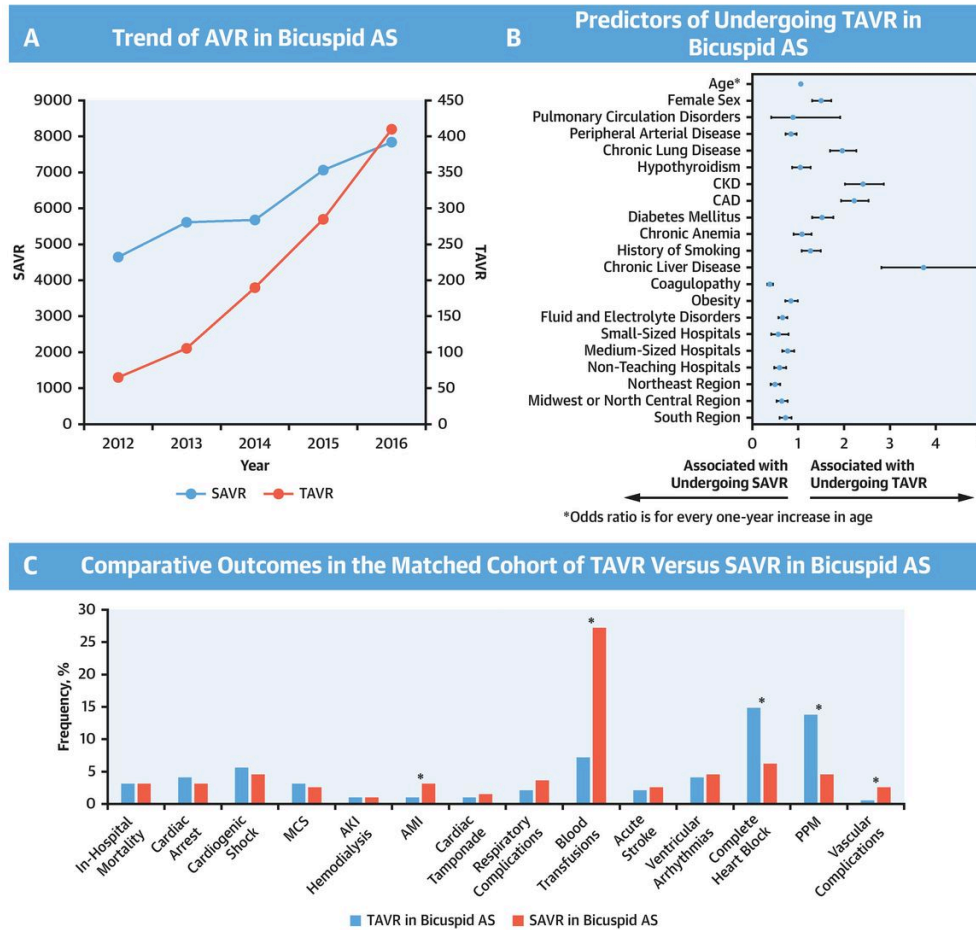
National Inpatient Sample (NIS) Database: TAVR vs SAVR for BAV



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NIS Database 2012-2016

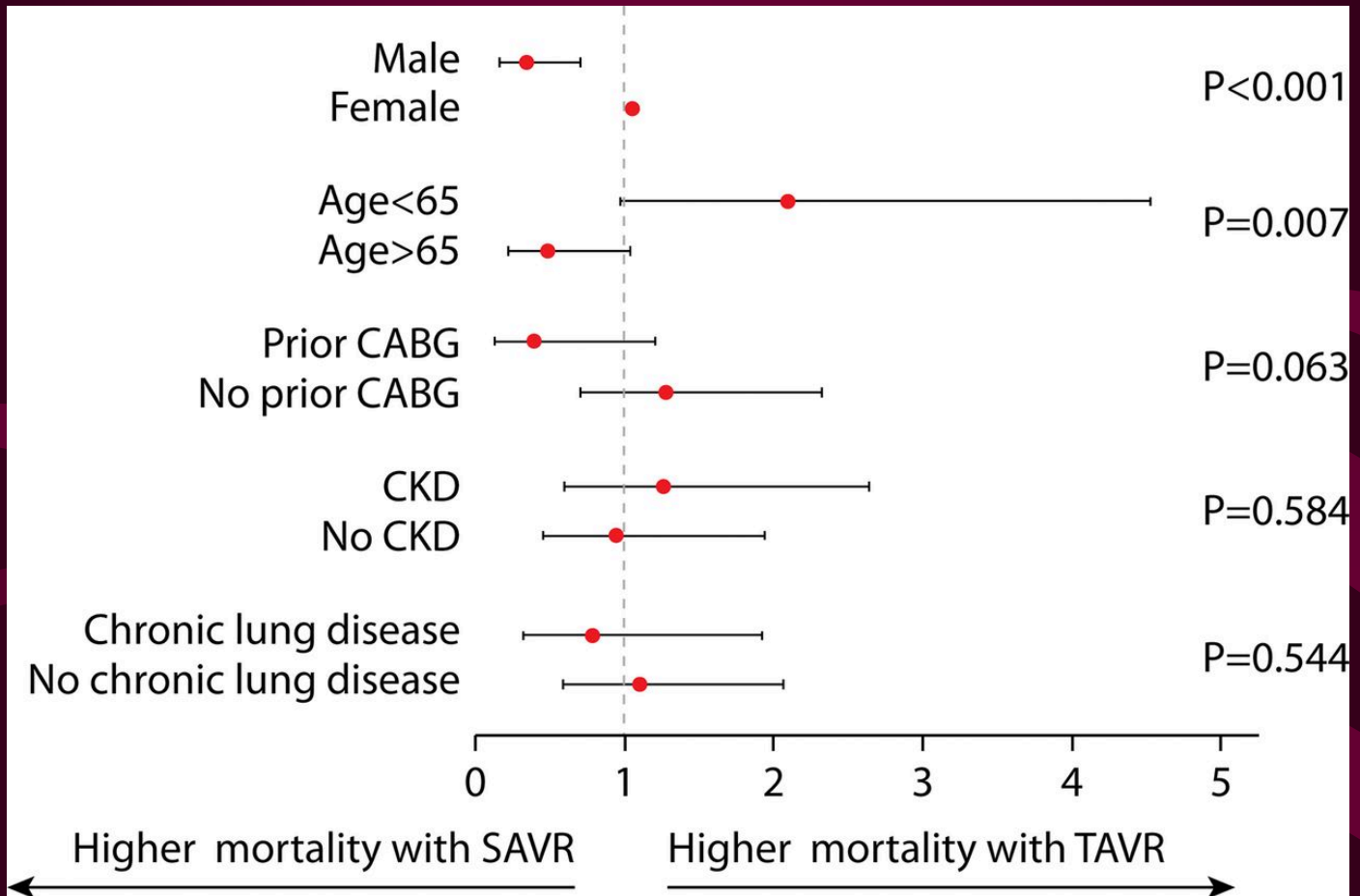
CENTRAL ILLUSTRATION: Trends, Predictors, and Outcomes of TAVR for Bicuspid Severe Aortic Stenosis



Elbadawi, A. et al. J Am Coll Cardiol Intv. 2019;12(18):1811-22.

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NIS database-Subgroup Analysis



Current status and planning of performing TAVI in BAV patients

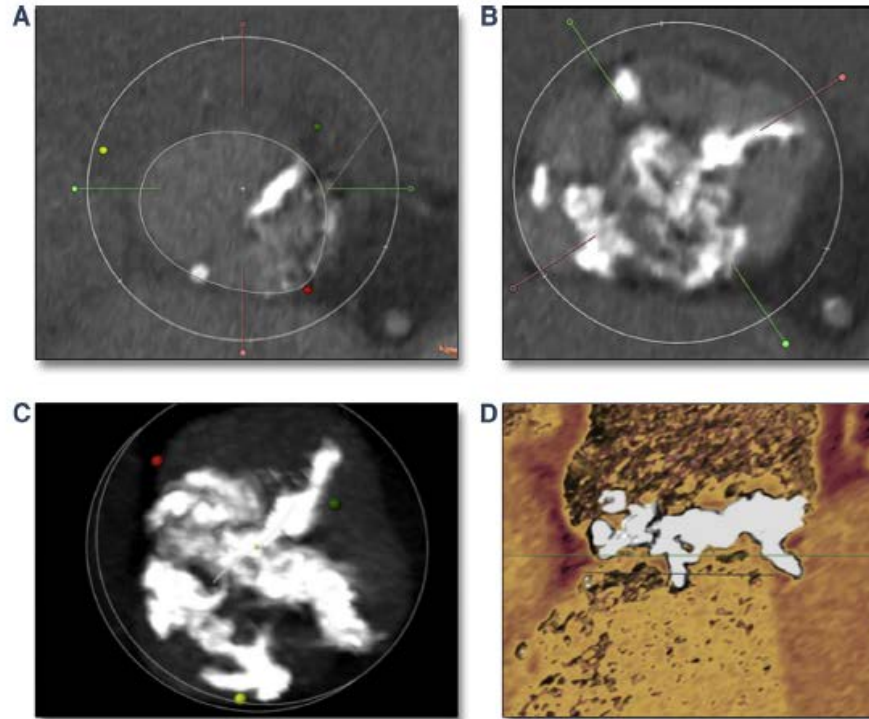
- Role of MSCT and careful selection of eligible patients
- Appropriate sizing and using of the correct device
- Technical procedural considerations

Advantages of MSCT

- 3D assessment of annular morphology and dimensions
- LVOT, SV and aortic root assessment
- Determination of coronary height
- Presence of concomitant aortopathy

Calcification of bicuspid raphe

FIGURE 1 Calcification of Bicuspid Raphe



(A) MDCT cross-section of the basal portion of the sinus of Valsalva demonstrating a calcified raphe between the right and left coronary cusps. The **encircled area** denotes the perimeter of the annulus. (B) A view higher in the mid-portion of the aortic sinus of Valsalva shows continuation of the calcified raphe. (C) "Hockey puck" view of the bicuspid valve shows fusion of the raphe and nodular calcification of the fused leaflets and noncoronary cusp. Area-derived diameter of this case was 31.2 mm, and the patient was successfully treated with a 29-mm Sapien 3 device, underscoring the difficulty in assessing THV sizing in the presence of BAV. (D) Volume rendering of the aortic annulus shown extensive calcification and fusion of the left and right raphe. BAV = bicuspid aortic valve; MDCT = multidetector computed tomography; THV = transcatheter heart valve.

Calcified raphe
between L & R

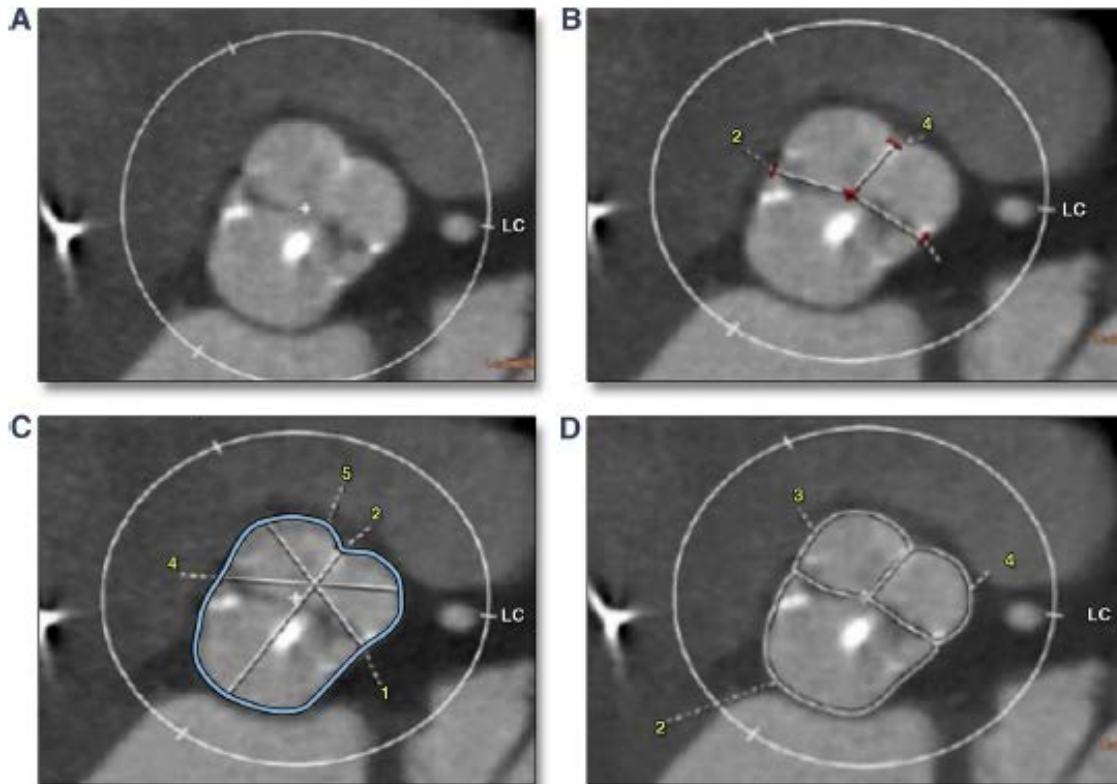
Mid aortic sinus –
calcified raphe

Hockey puck view-
fusion of raphe and
nodular calcification
of leaflets

Calcification and
fusion of L&R raphe

Leaflet Asymmetry (raphe between R&L – asymmetry of non coronary sinus)

FIGURE 2 Parameters for Assessment of Leaflet Asymmetry



(A) Tri-post bicuspid aortic stenosis with a raphe of the left and right coronary cusps. Each quantification of leaflet width (B), sinus of Valsalva width (C), and sinus area (D) provides an estimation of the asymmetry of the noncoronary sinus relative to that of the combined right and left coronary cusps.

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Low coronary ostia

Type I-R&L

16,9 mm fused cusp – Asymmetric annulus

Coronary ostia at 11 mm

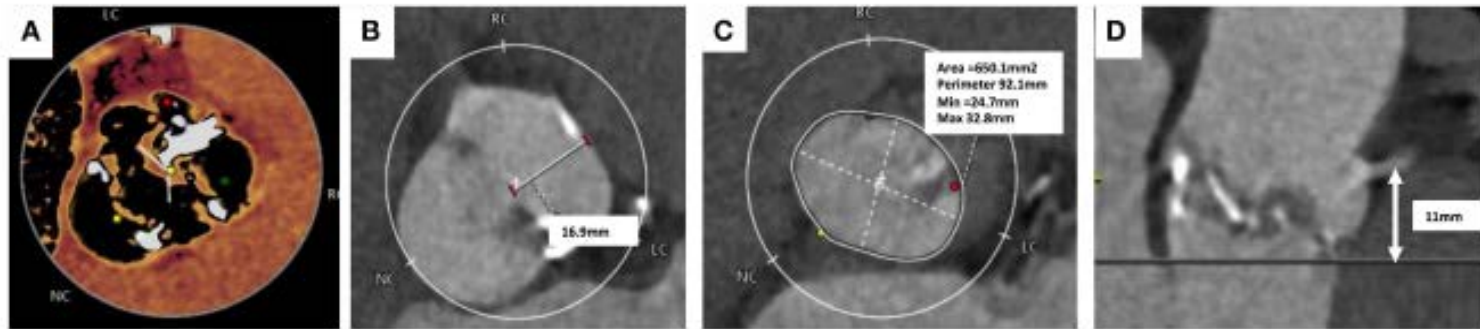
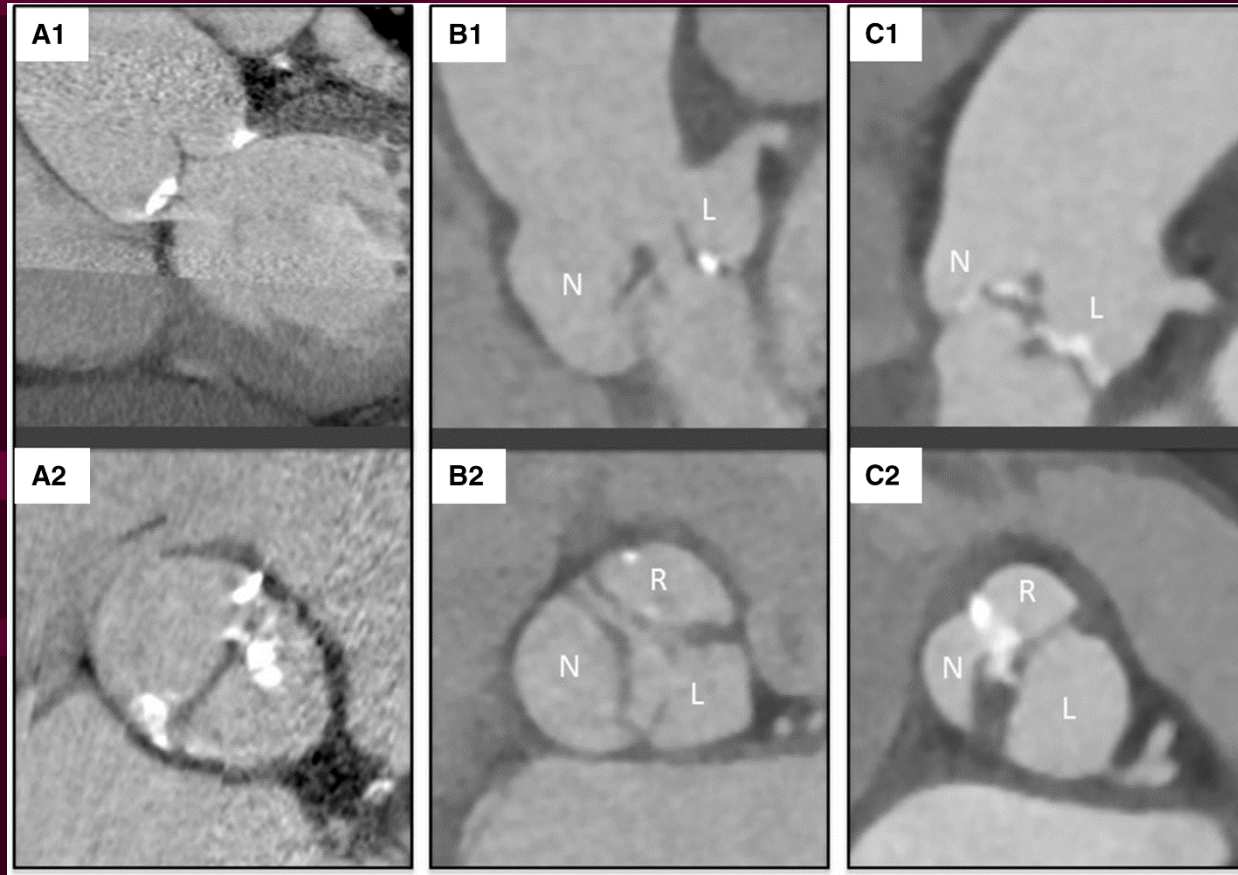


FIGURE 3 | Computer Tomography Imaging of bicuspid aortic valve. **(A)** Sievers Type 1 Raphe-type bicuspid aortic valve (BAV) with mixed cusp fusion (left-right). **(B)** Large bulky cusps measuring 16.9 mm maximum diameter. **(C)** Asymmetric large annulus. **(D)** Low lying coronary ostia at 11 mm combined with large bulky leaflets indicate a risk of coronary occlusion during TAVI.

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Procedure and Technical considerations-MSCT Images



Type 0 (A1-A2)

Type I (B1-B2)
Coronary cusp
fusion

Type I (C1-C2)
Mixed
coronary cusp
fusion

Eur Heart J. 2017;38(16):1177-1181.
doi:10.1093/eurheartj/ehx167

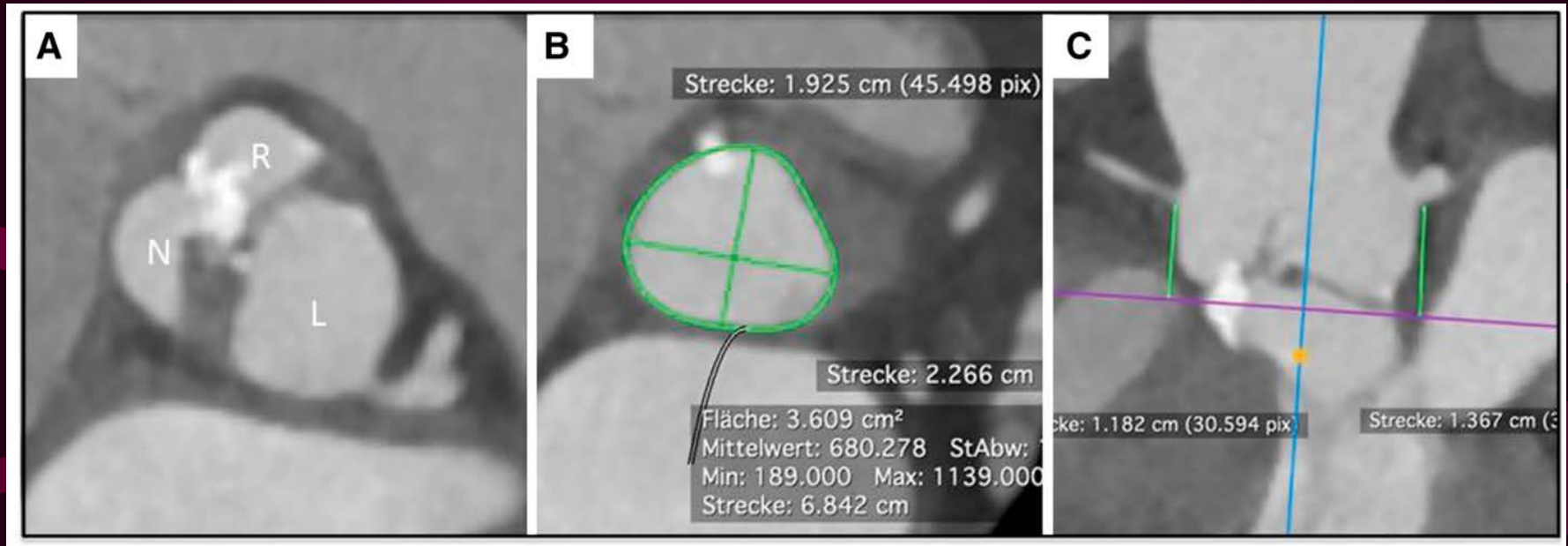
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Procedure and Technical considerations-MSCT

Type I mixed cusp fusion

Difficult annulus 3D allignement

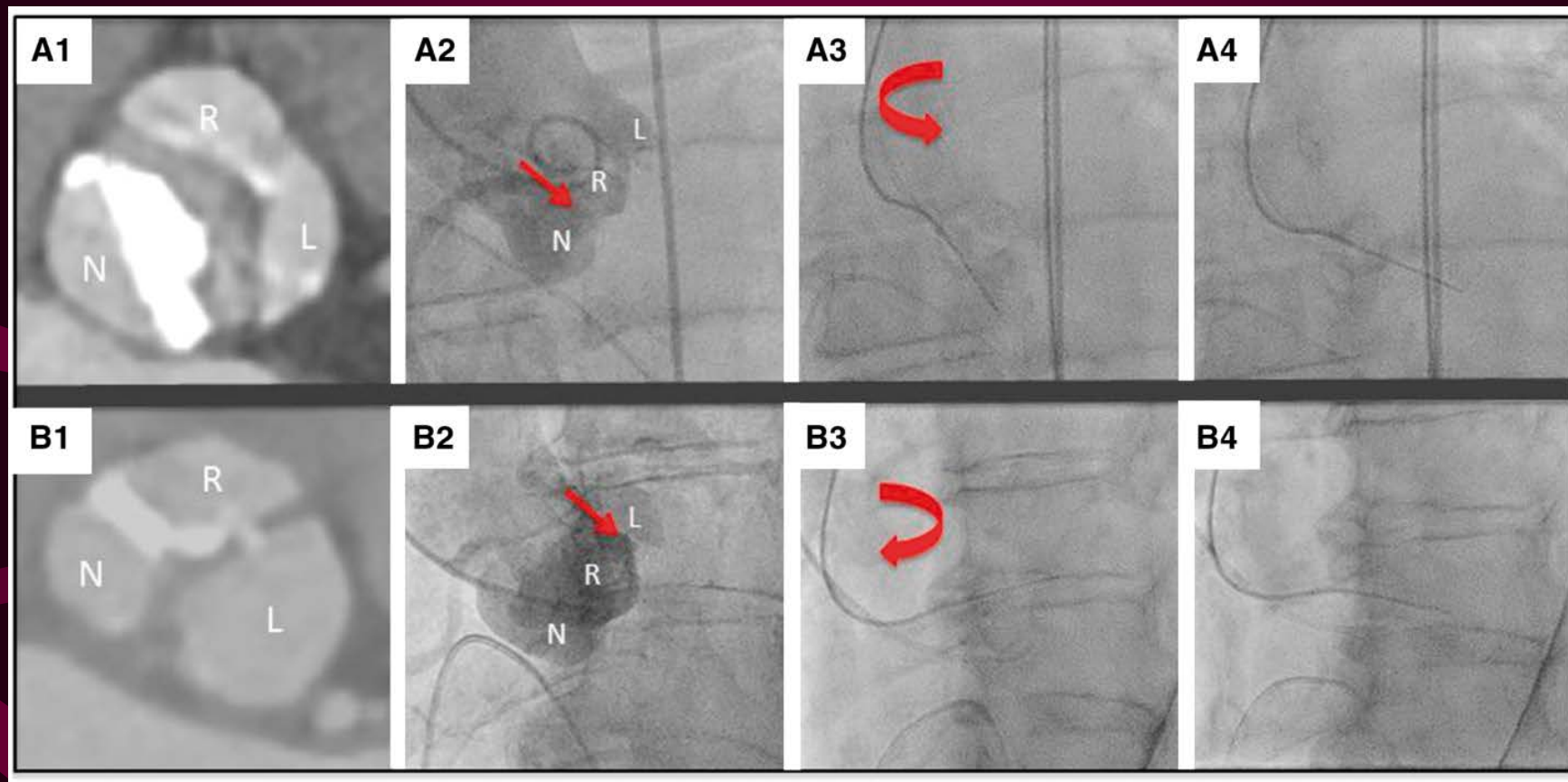
Coronary ostia > 10 mm



Eur Heart J. 2017;38(16):1177-1181.
doi:10.1093/eurheartj/ehx167

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Procedure and Technical considerations-Wiring



Eur Heart J. 2017;38(16):1177-1181.
doi:10.1093/eurheartj/ehx167

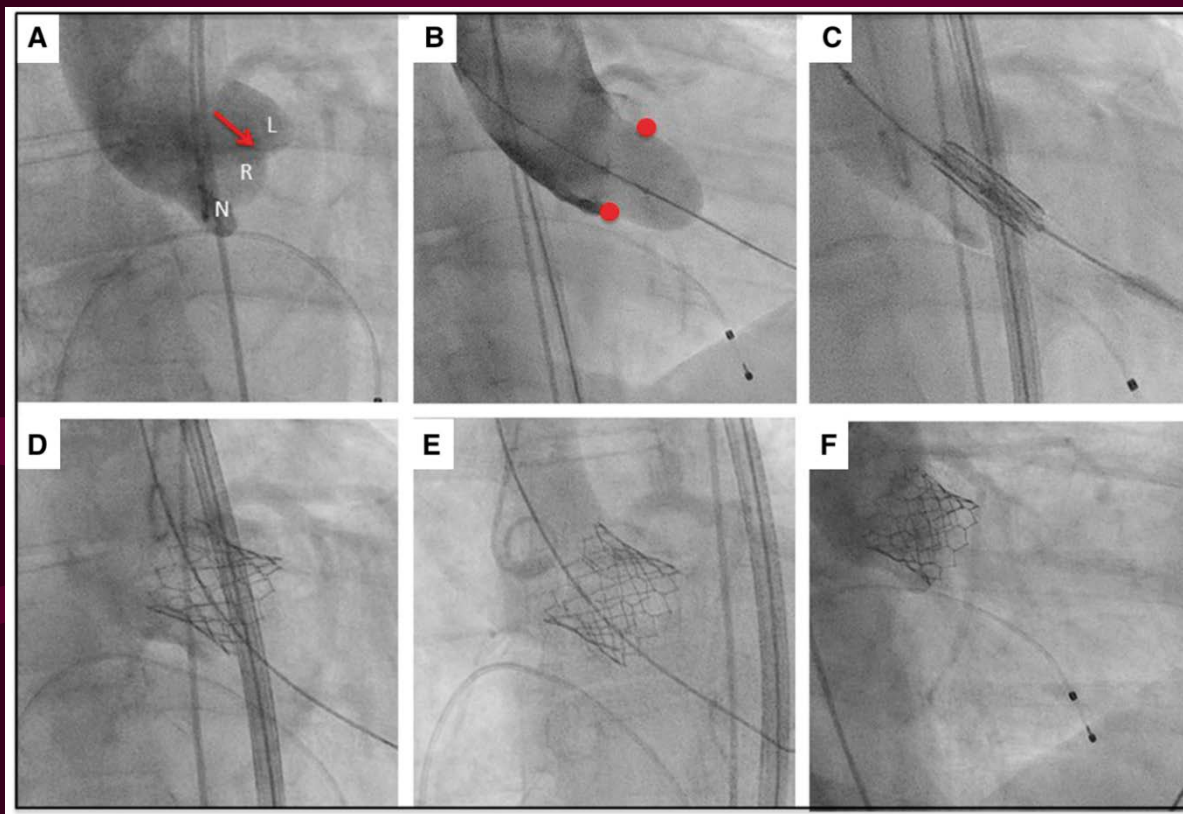
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Procedure and Technical considerations

Type I-N&R fusion)

20 mm Balloon

Sapien 3 23 mm



Sapien 3 under-deployment

Post dilatation with normal volume and final result

Eur Heart J. 2017;38(16):1177-1181.
doi:10.1093/eurheartj/ehx167

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Bicuspid Valve TAVI Case

- 84 yo male with worsening dyspnea (NYHA III)
- Cardiac Echo with severe AS (0,6 cm², mean gradient 60 mm Hg, EF=45%, PA pressure 56 mm Hg)
- Ostial LM (40%) and mild rest epicardial atherosclerosis
- Afib undes anticoagulation, PVD, Pacer, mild COPD

MSCT Analysis

Max Ascending Aorta Diameter (mm)

Sinotubular Junction Diameter (mm) x

Min Max

ANNULUS

Diameter (mm) x ,

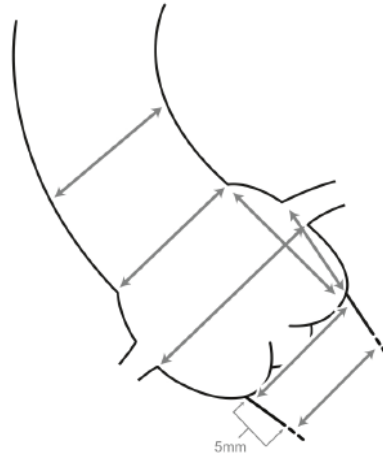
Min Max Mean

Perimeter (mm) ,

Derived Diameter

Area mm² , mm

Derived Diameter



Sinus of Valsalva Diameter (mm)

LCC RCC NCC

Sinus of Valsalva Height (mm)

LCC RCC NCC

Coronary Ostia Height (mm)

Left Right

LVOT Diameter (mm) x ,

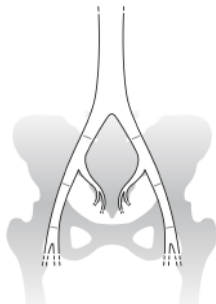
Min Max Mean

RIGHT

CIA Min Diameter (mm) x

EIA Min Diameter (mm) x

Femoral Min Diameter (mm) x



LEFT

CIA Min Diameter (mm) x

EIA Min Diameter (mm) x

Femoral Min Diameter (mm) x

RIGHT

Subclavian Min Diameter (mm)

Annular Angulation

LEFT

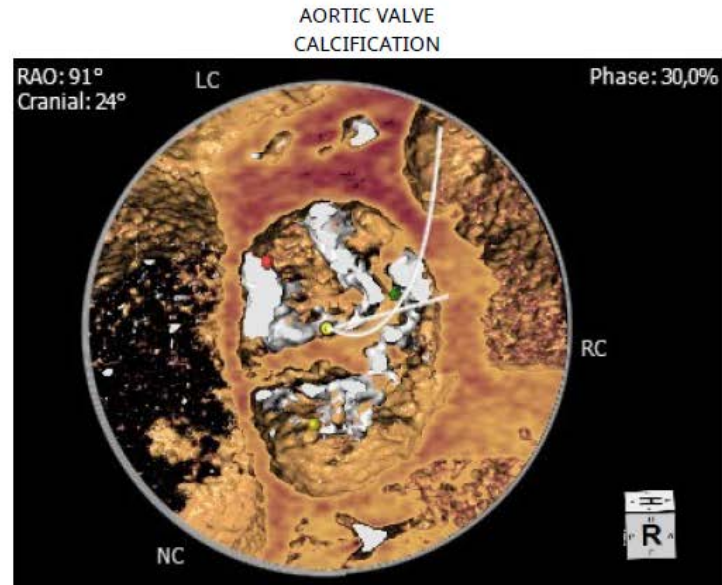
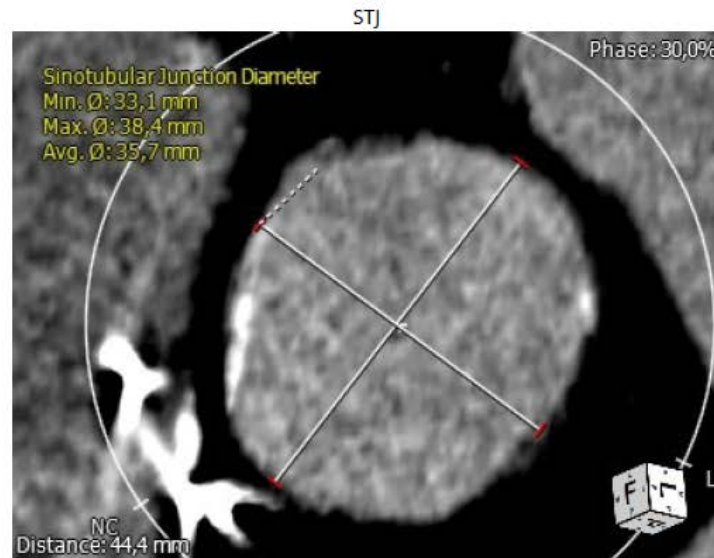
Subclavian Min Diameter (mm) x

Please review images for direct aortic evaluation.

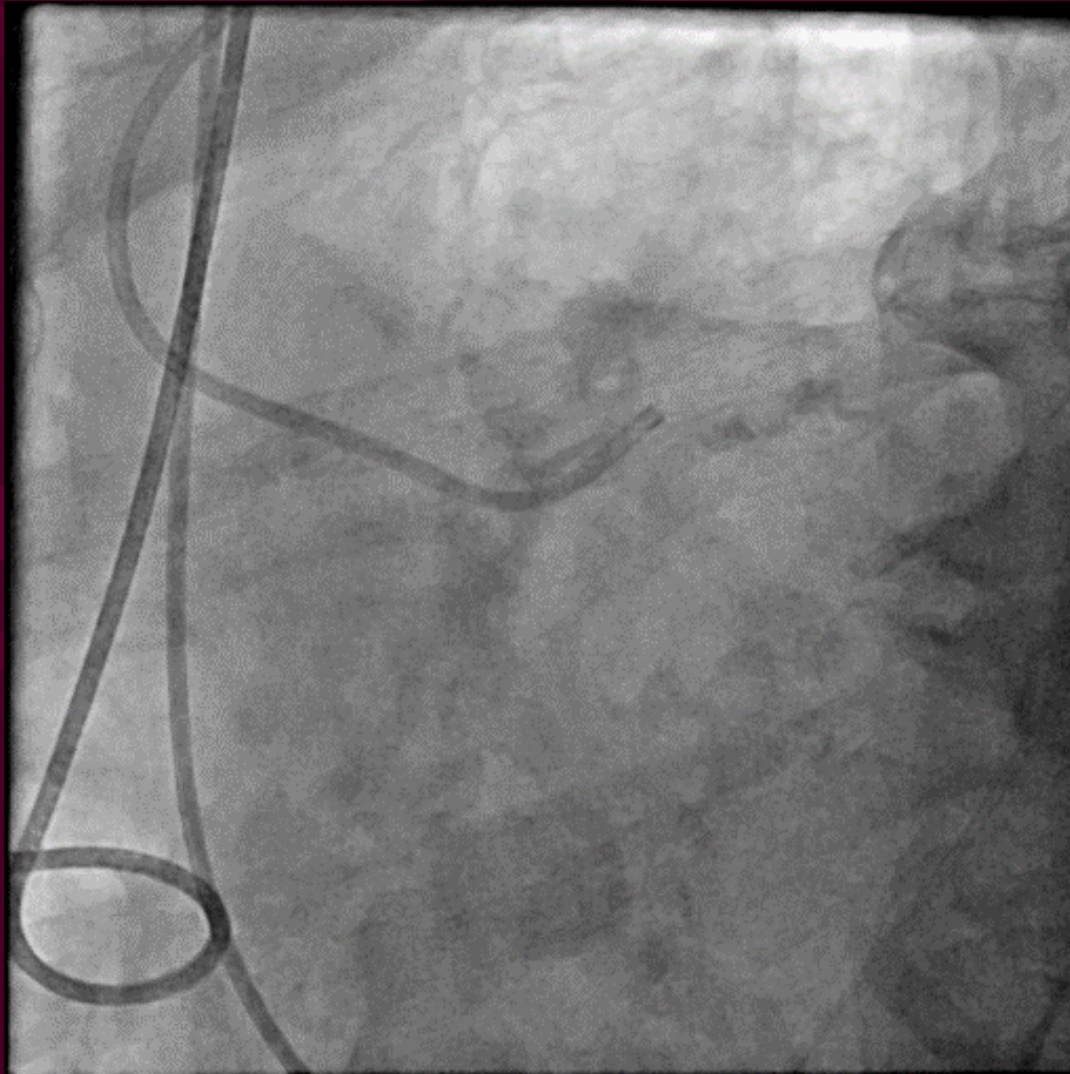
Calcium: Mild Moderate Severe

MSCT Images (Type I N-R)

Aorta

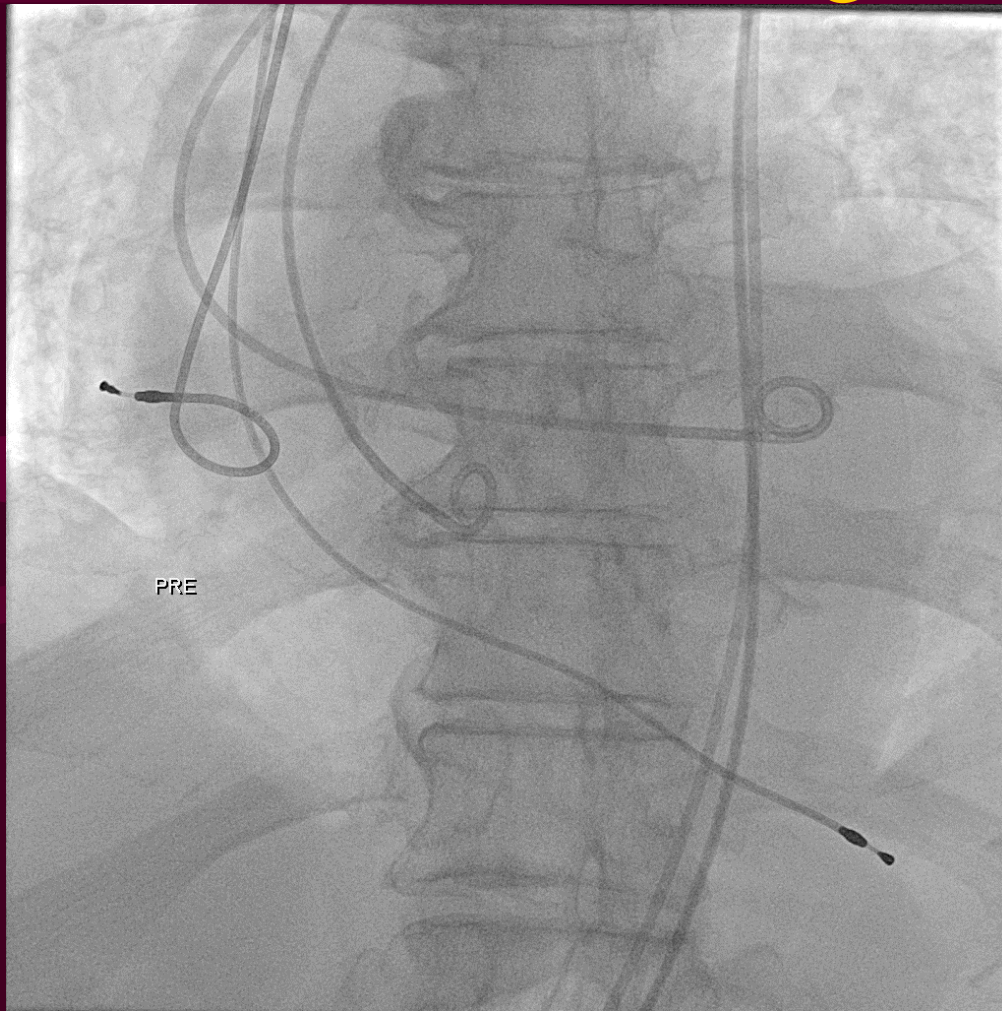


LM Angiography



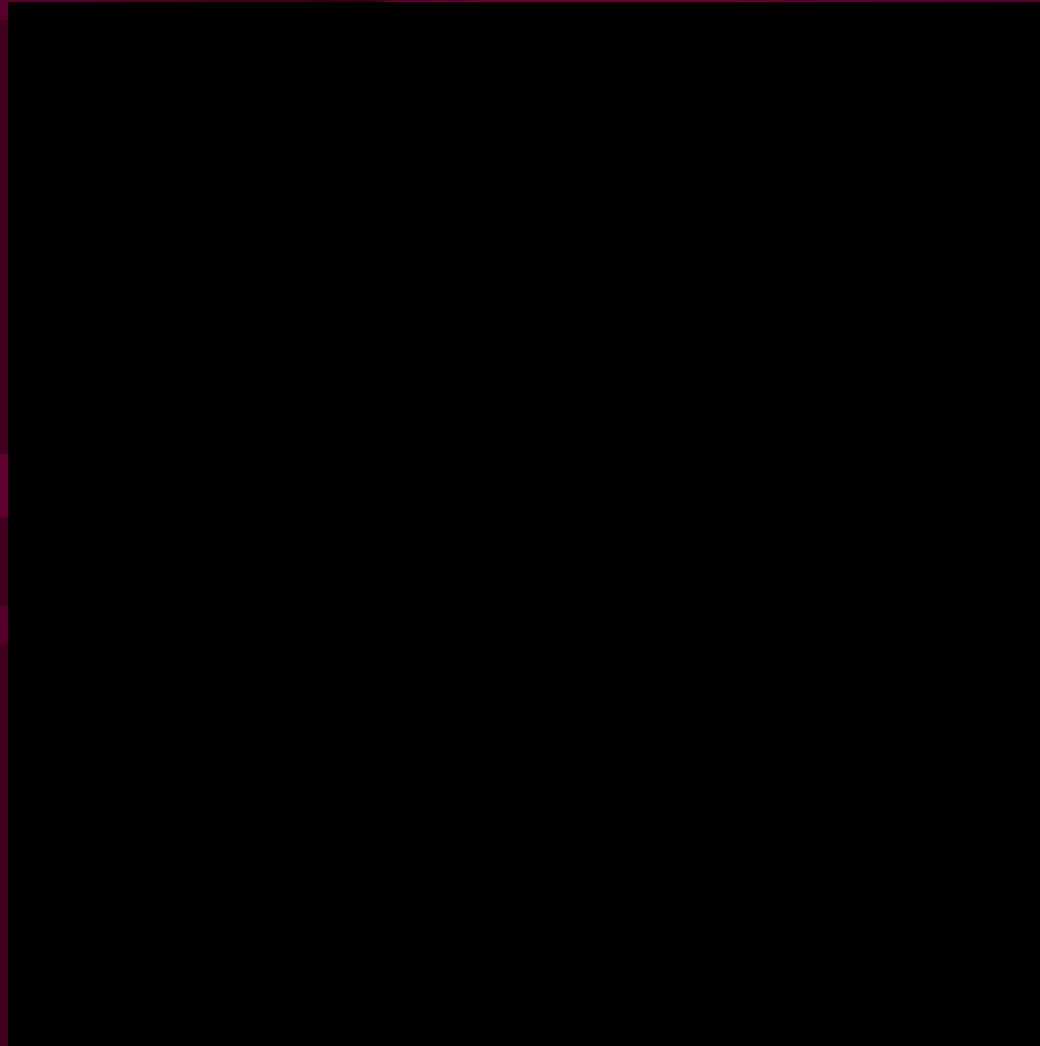
2ο Συνέδριο Δομικών
Παθήσεων Καρδιάς &
Βαλβιδοπαθειών

Pre TAVI Aortogram



2ο Συνέδριο Δομικών
Παθήσεων Καρδιάς &
Βαλβιδοπαθειών

TAVI pre sizing (22 mm Balloon)



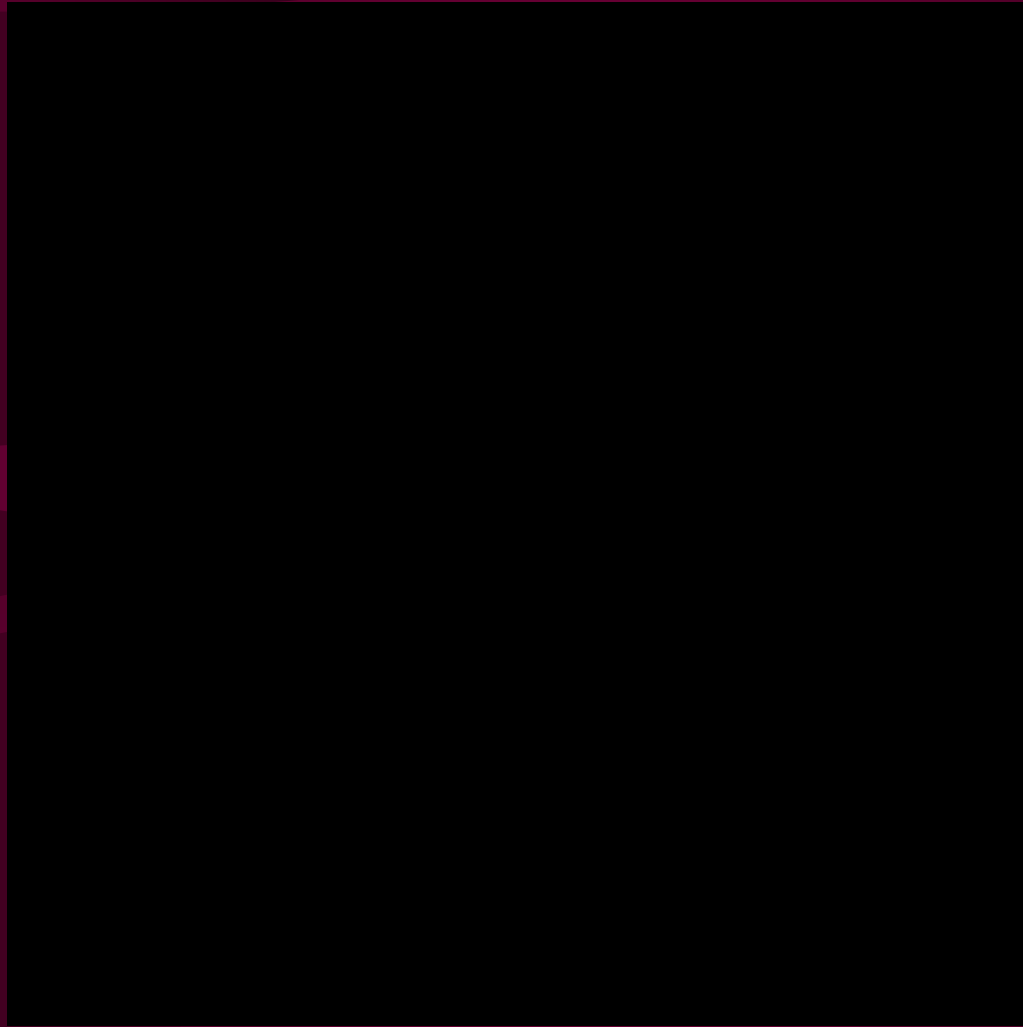
2ο Συνέδριο Δομικών
Παθήσεων Καρδιάς &
Βαλβιδοπαθειών

Post Initial Deployment



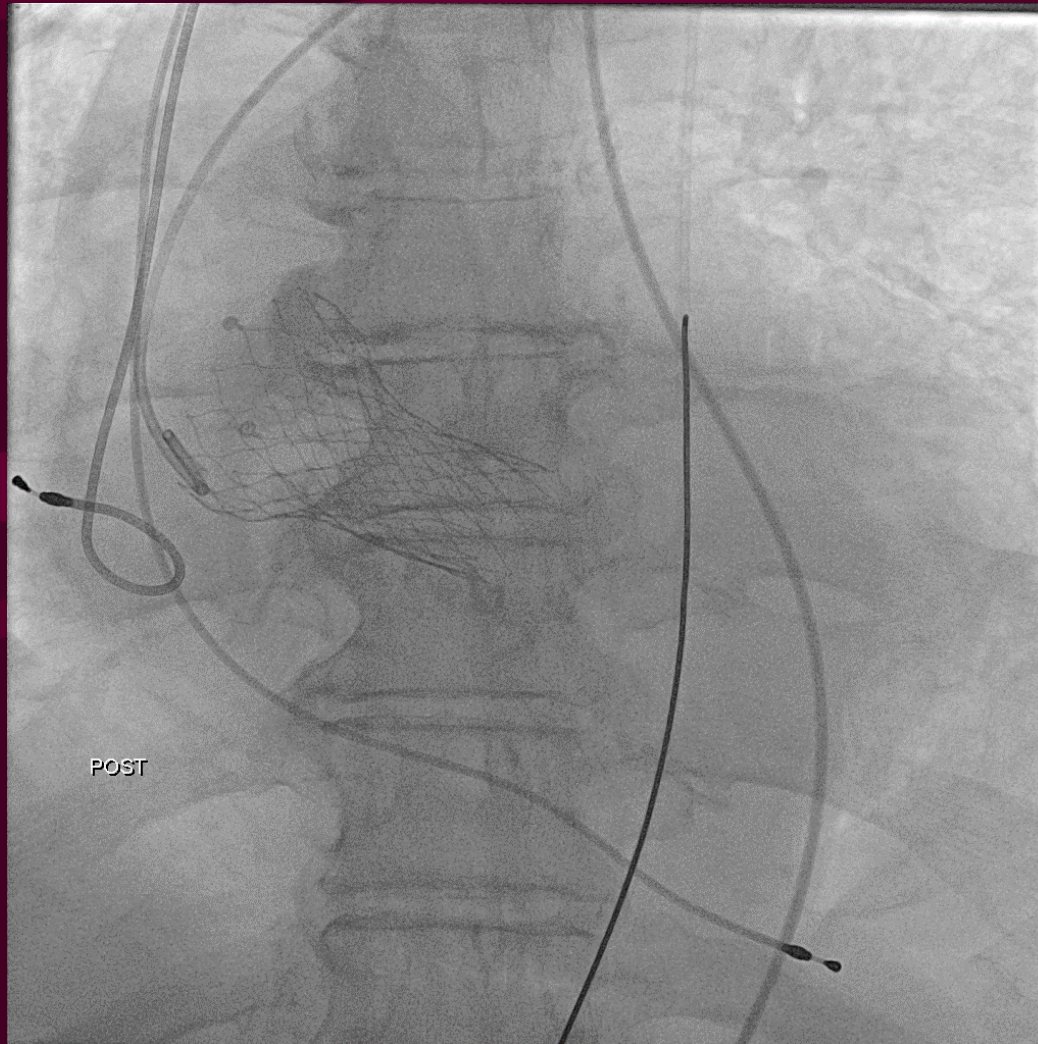
2ο Συνέδριο Δομικών
Παθήσεων Καρδιάς &
Βαλβιδοπαθειών

Post TAVI Balloon (28 mm)



2ο Συνέδριο Δομικών
Παθήσεων Καρδιάς &
Βαλβιδοπαθειών

Final Result (PVL 1-2)



2ο Συνέδριο Δομικών
Παθήσεων Καρδιάς &
Βαλβιδοπαθειών

Conclusions

- TAVI in patients with bicuspid aortic valve is feasible but has challenges
- Requires careful selection of eligible patients based on Imaging criteria (MSCT) & type of bioprosthetic valve
 - Annulus size
 - Coronary Ostia
 - Asymmetry of leaflets and calcification
 - Calcification of raphe
 - Concomitant aortopathy
- Procedural considerations
 - Wiring of the valve
 - Balloon pre sizing and post deployment
 - Stroke prevention?
- Outcomes with second generation devices are comparable (short-term) with tricuspid valve patients undergoing TAVI and with those with BAV undergoing SAVR