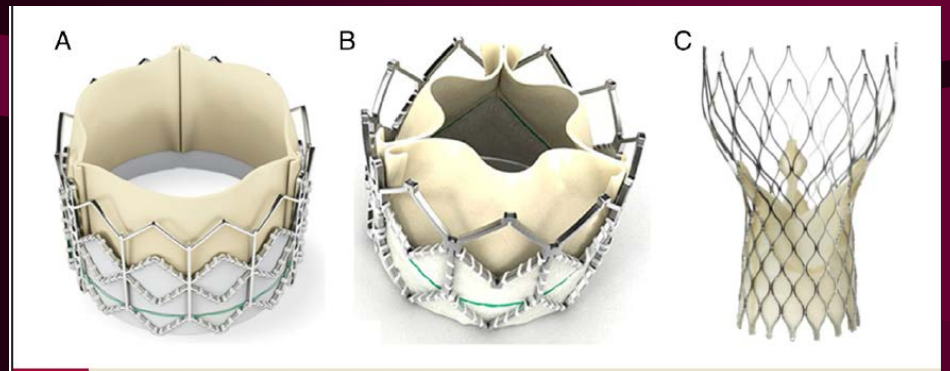

Figure 1 Current Widely Available Transcatheter Valves

(A) The Edwards SAPIEN THV balloon-expandable valve (Edwards Lifesciences, Irvine, California) incorporates a stainless steel frame, bovine pericardial leaflets,x 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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Director, Interventional Cardiologist

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Cardiac Catheterization Laboratory

23/11/2018

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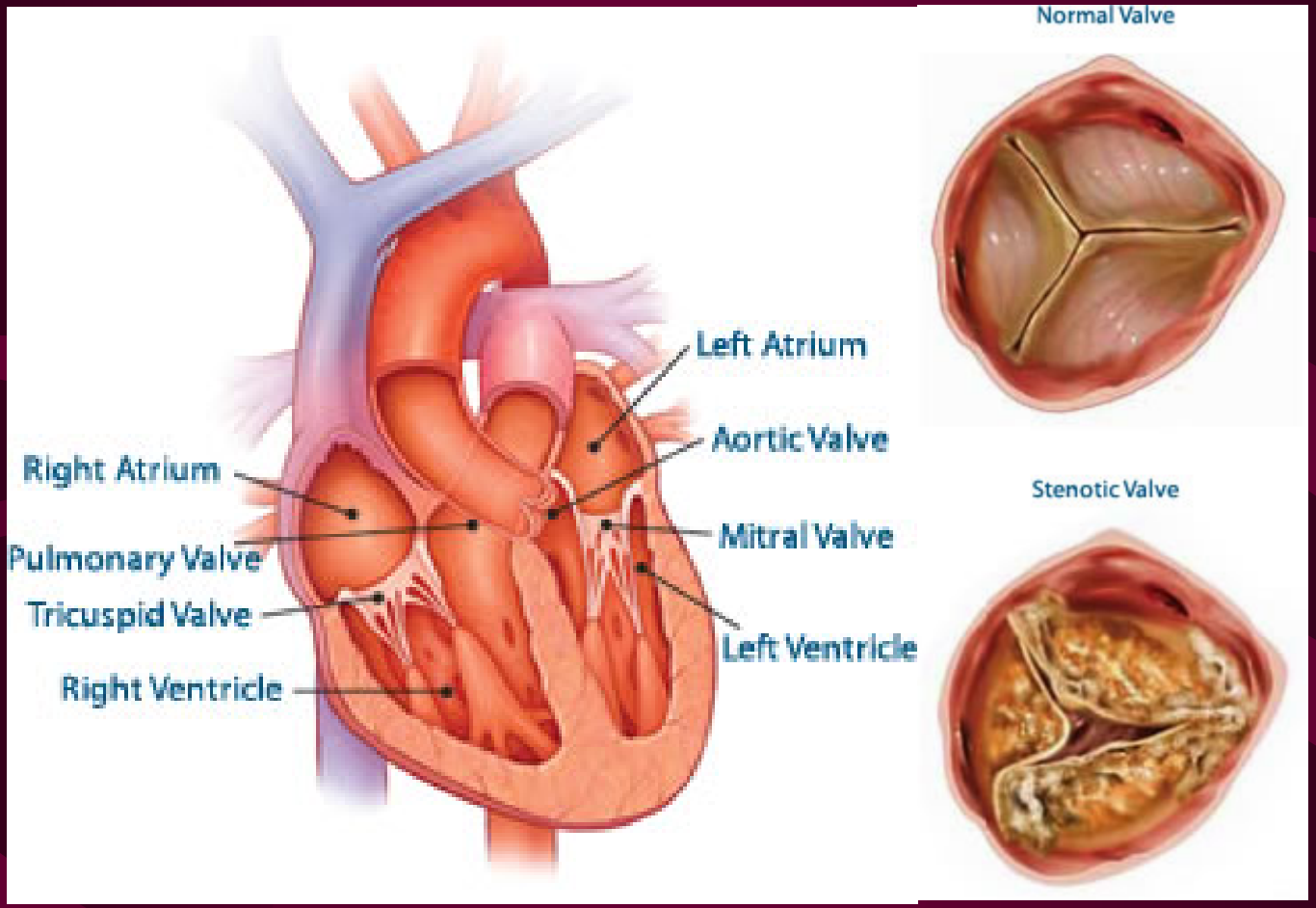
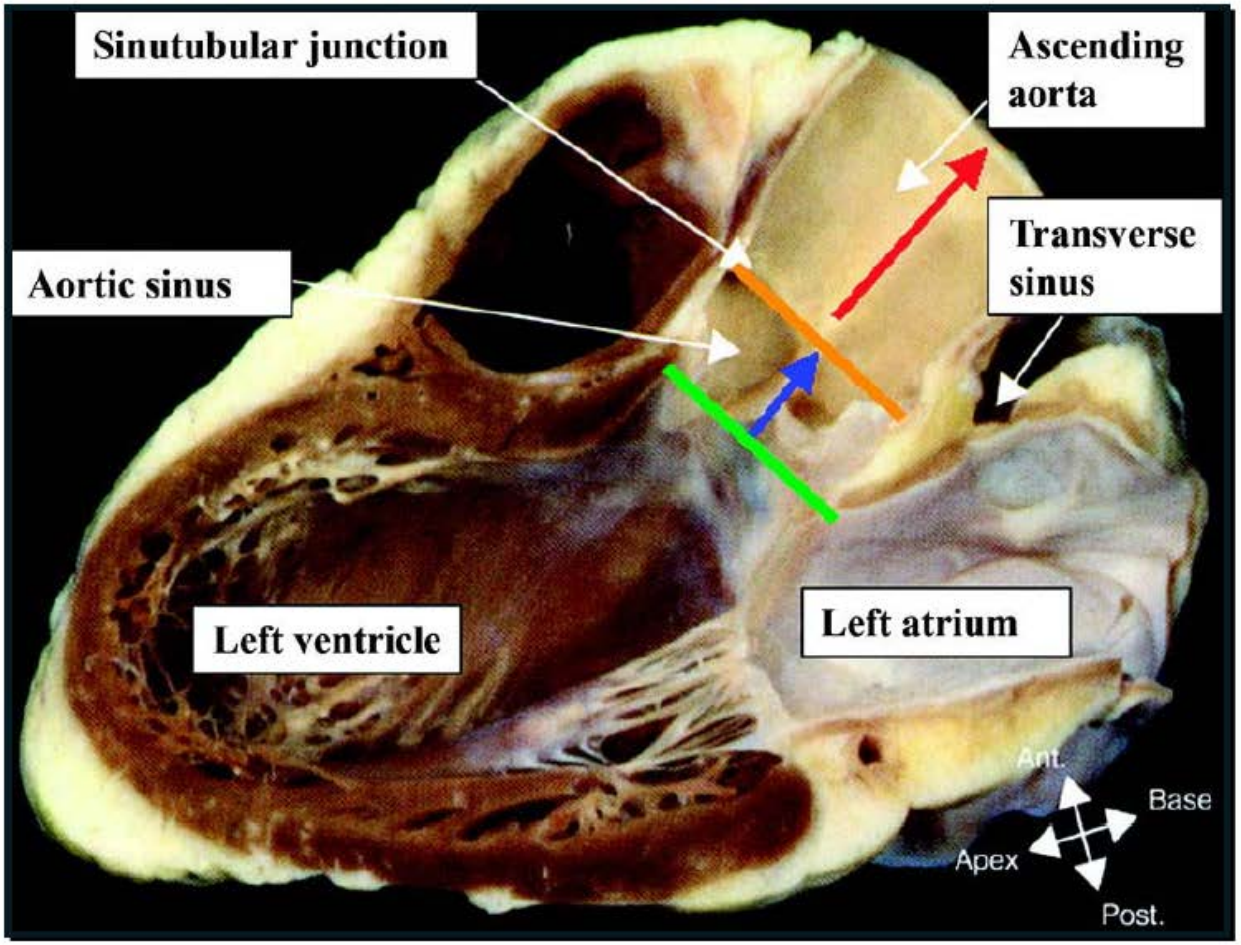
Aortic Valve Anatomy

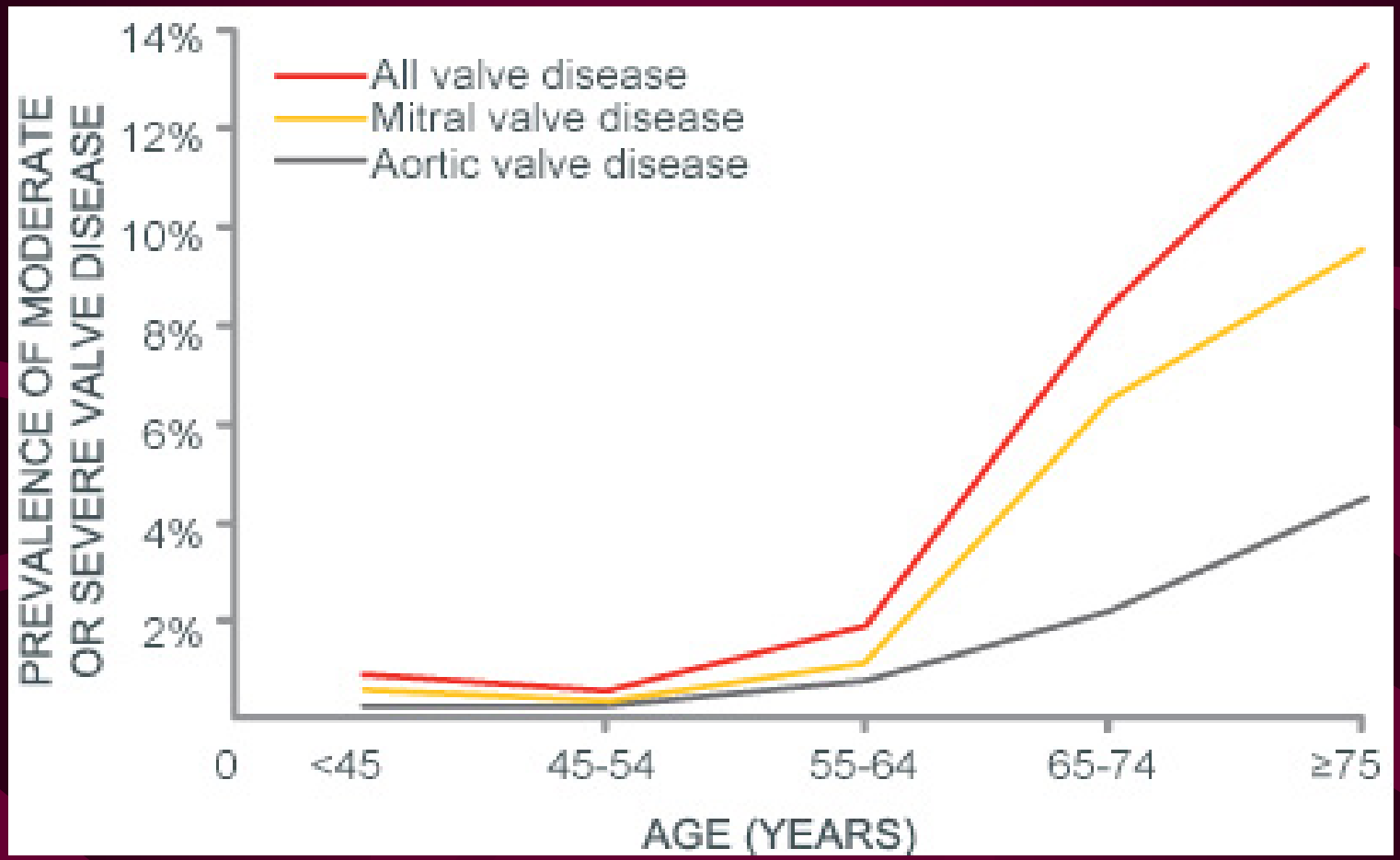


Aortic Root Anatomy

Aortic Root Anatomic Overview



Incidence of Aortic and Mitral Valve Disease



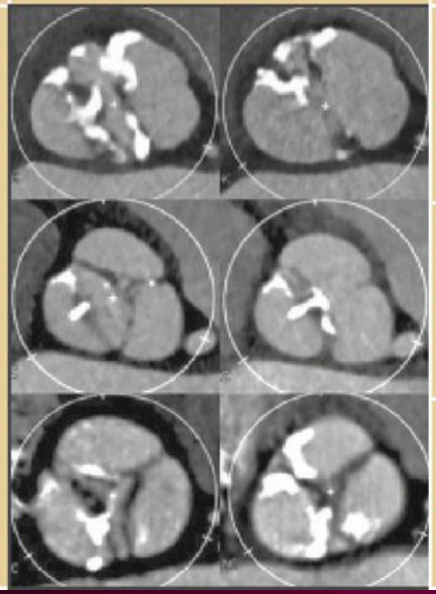
Causes of Aortic Stenosis

- 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) Epidemiolology

- 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 octogenerians and 41,7% of younger patients undergoing SAVR have BAV

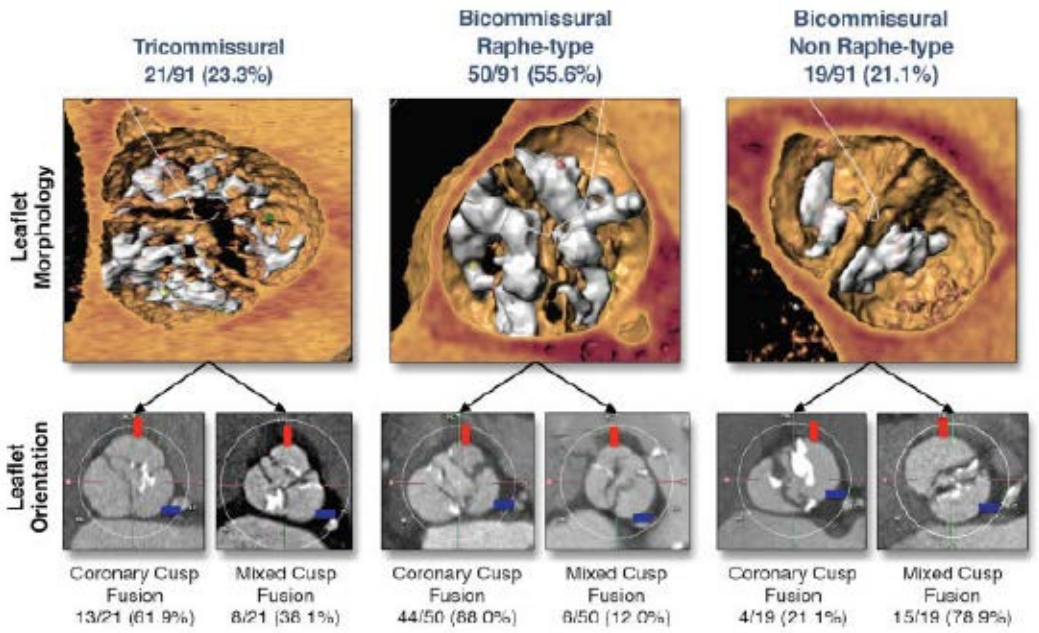
BAV Sievers & Jilaihawi Classification

	MDCT systole / diastole	Schematic systole / diastole	Sievers et al.*	Jilaihawi et al.	Fusion Site
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

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.

Interventional Cardiology Review 2018;13(2):62–5.

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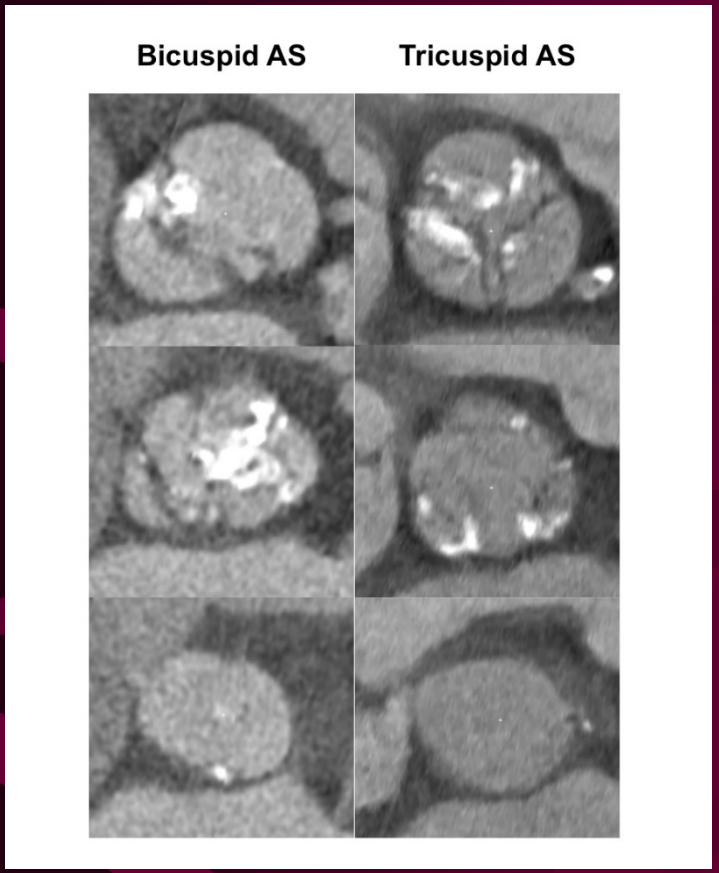
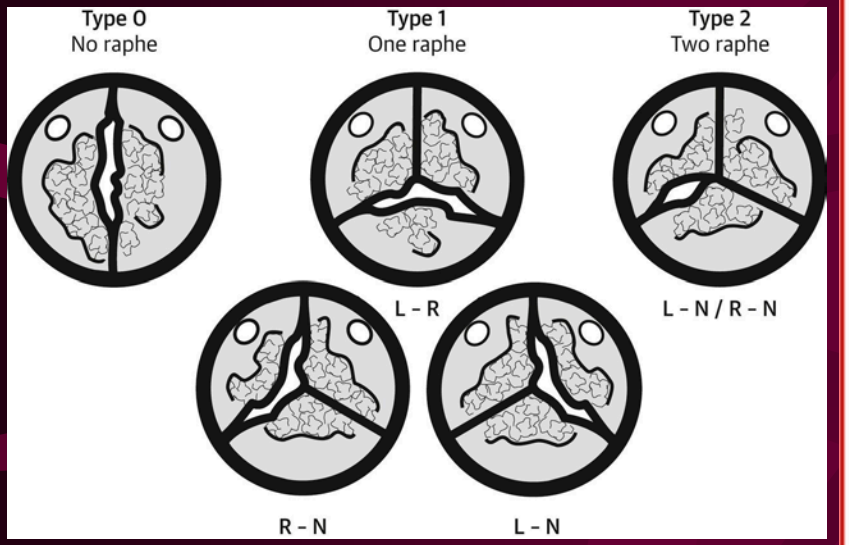
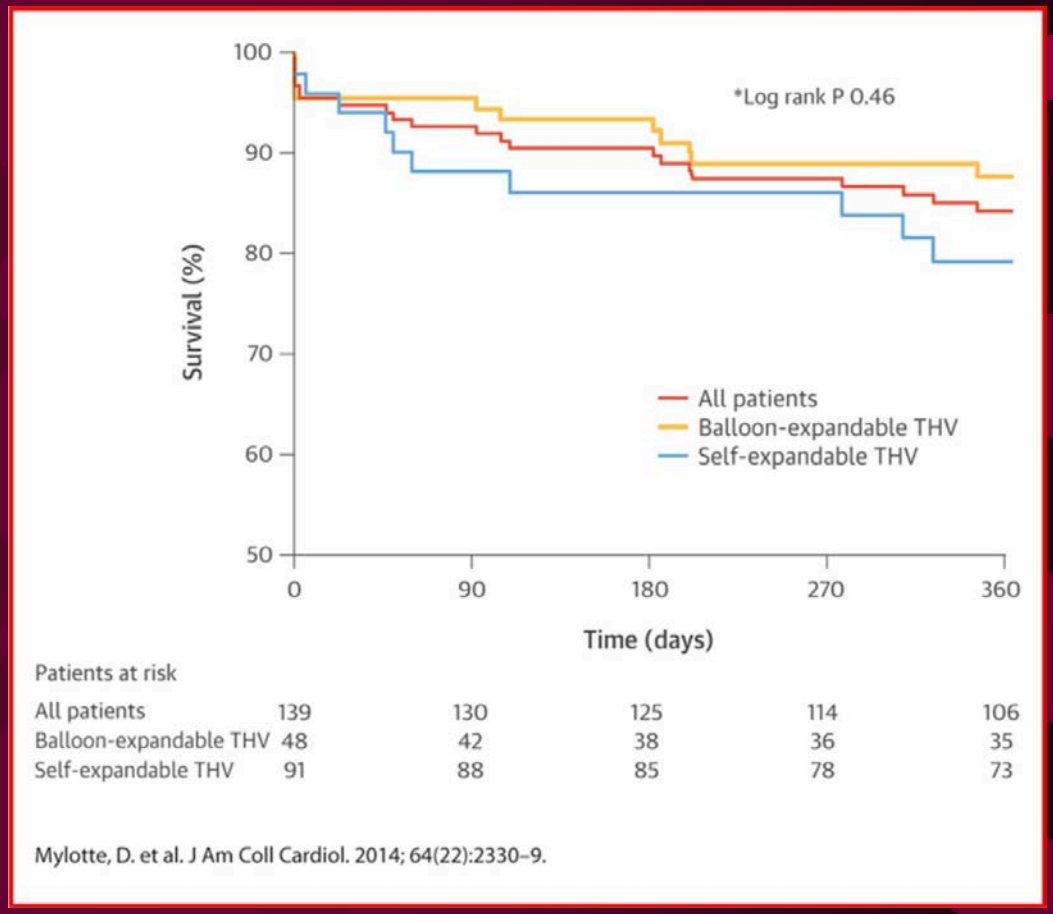
Concerns regarding Bicuspid vs Tricuspid Aortic Valve



- 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)

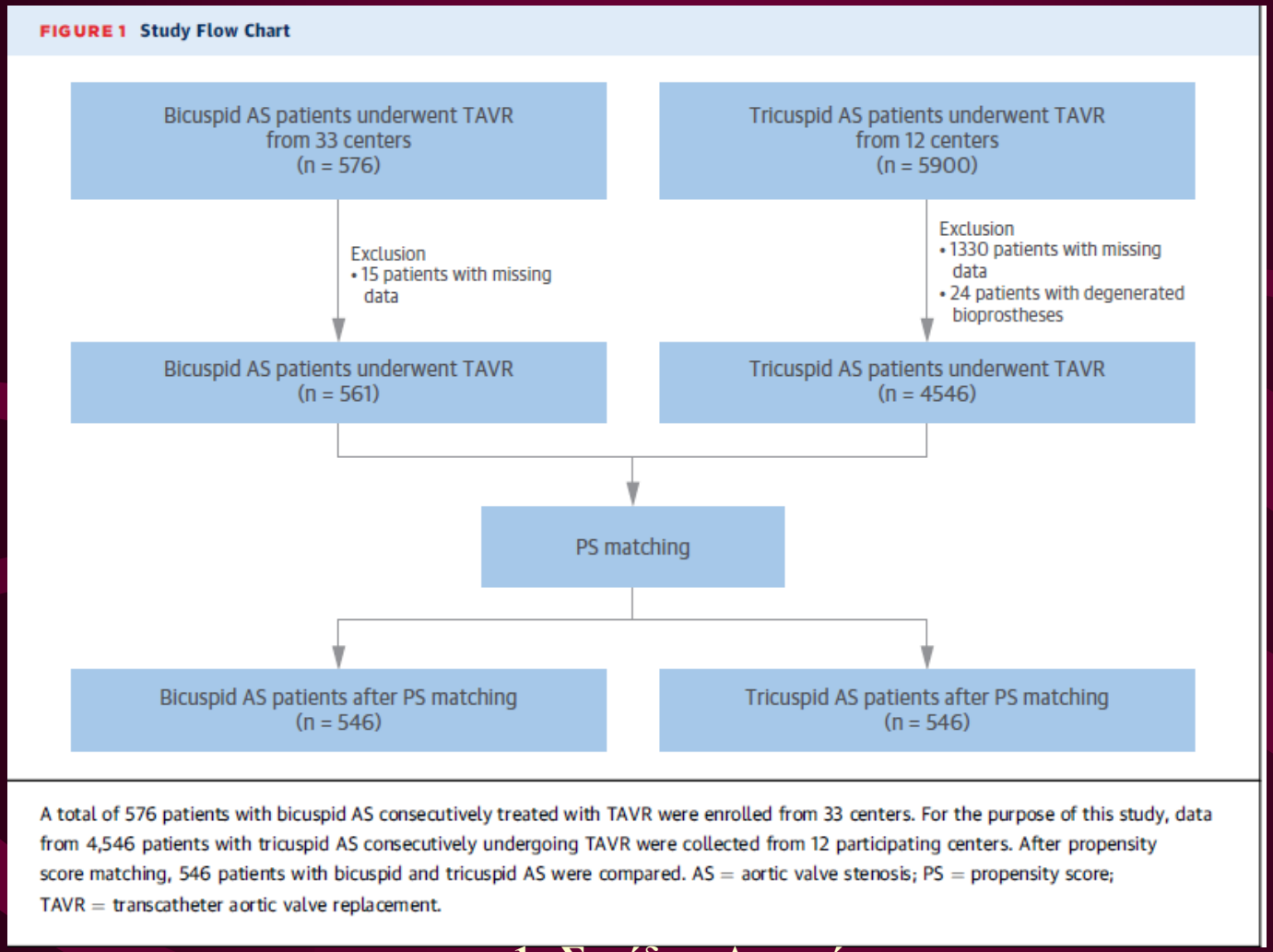
TABLE 3 Procedural Information and Outcomes

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.

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



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.

Yoon et al JACC 2017;2579

Procedure and Clinical Outcomes

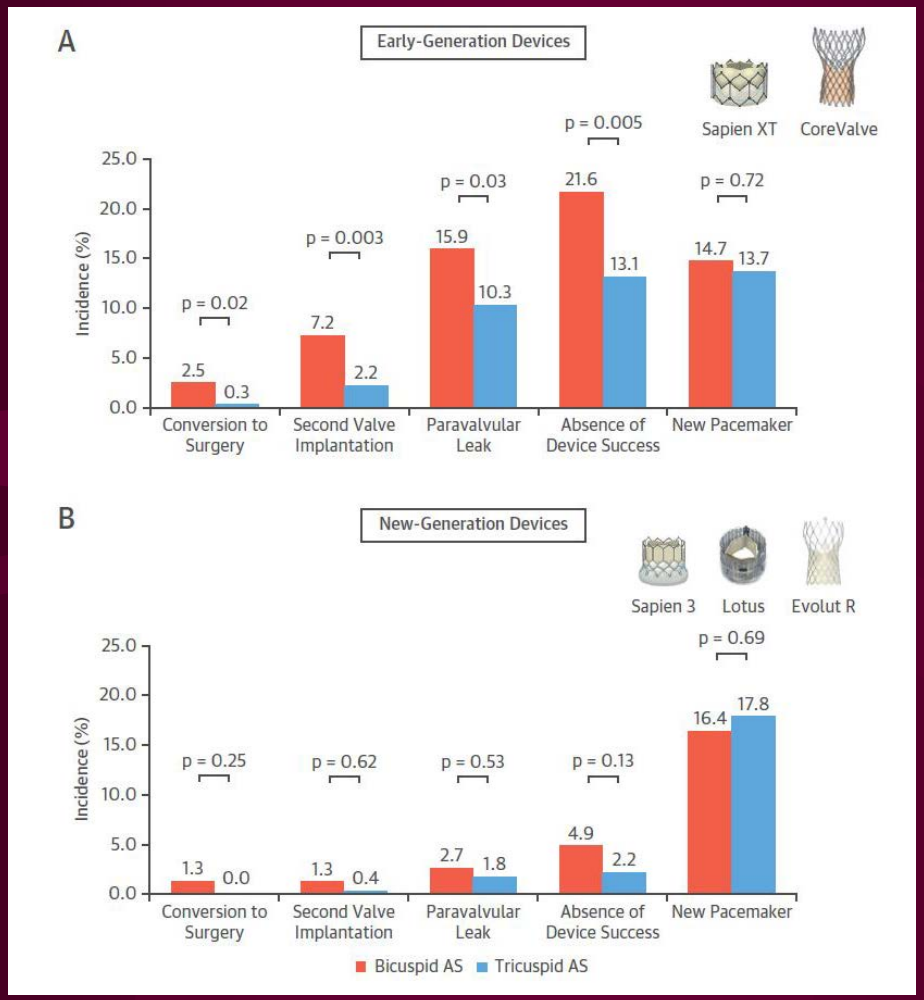
TABLE 2 Procedural and Clinical Outcomes

	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.

Yoon et al JACC 2017;2579

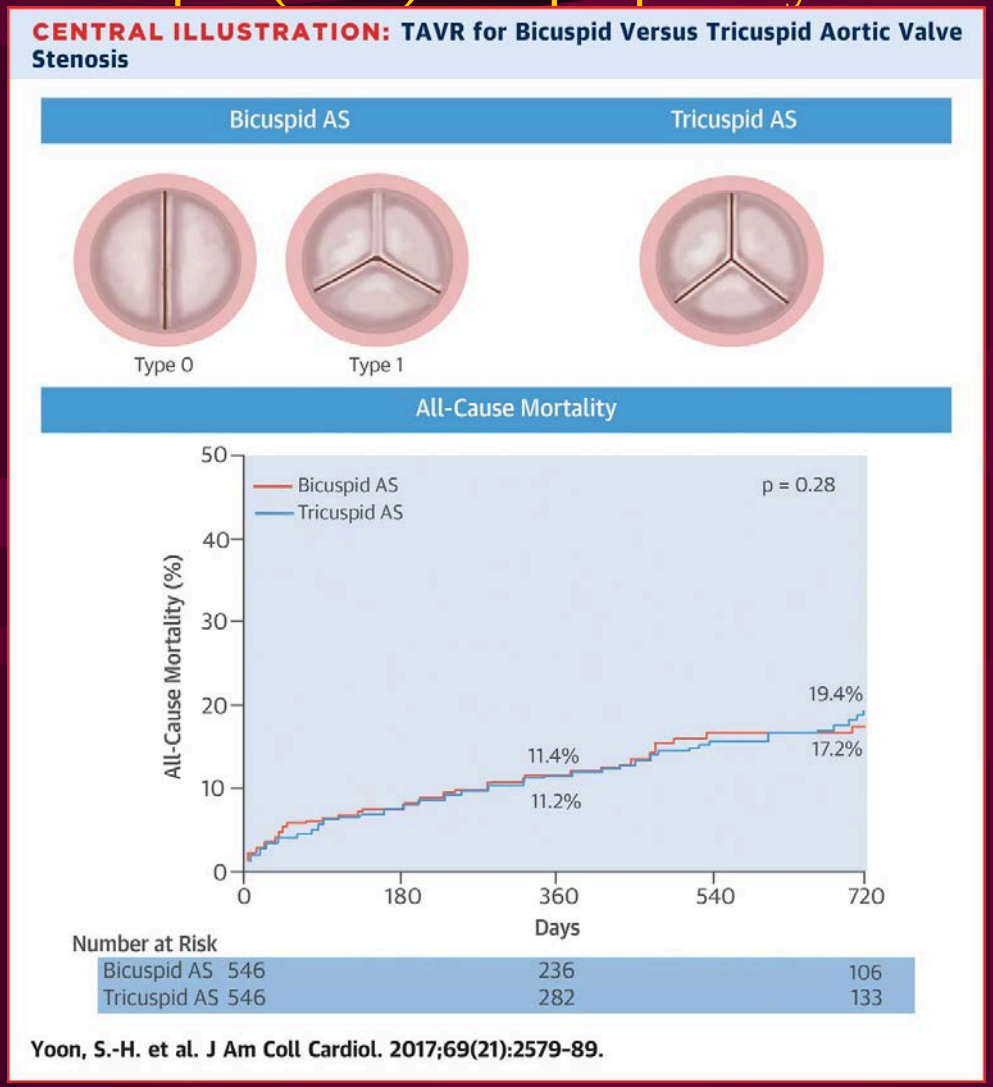
Outcomes in bicuspid vs tricuspid AS with early vs new-generation devices



JACC 2017;69(21):2579-89

1ο Συνέδριο Δομικών Παθήσεων Καρδιάς & Βαλβιδοπαθειών

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



Yoon et al JACC 2017;2579

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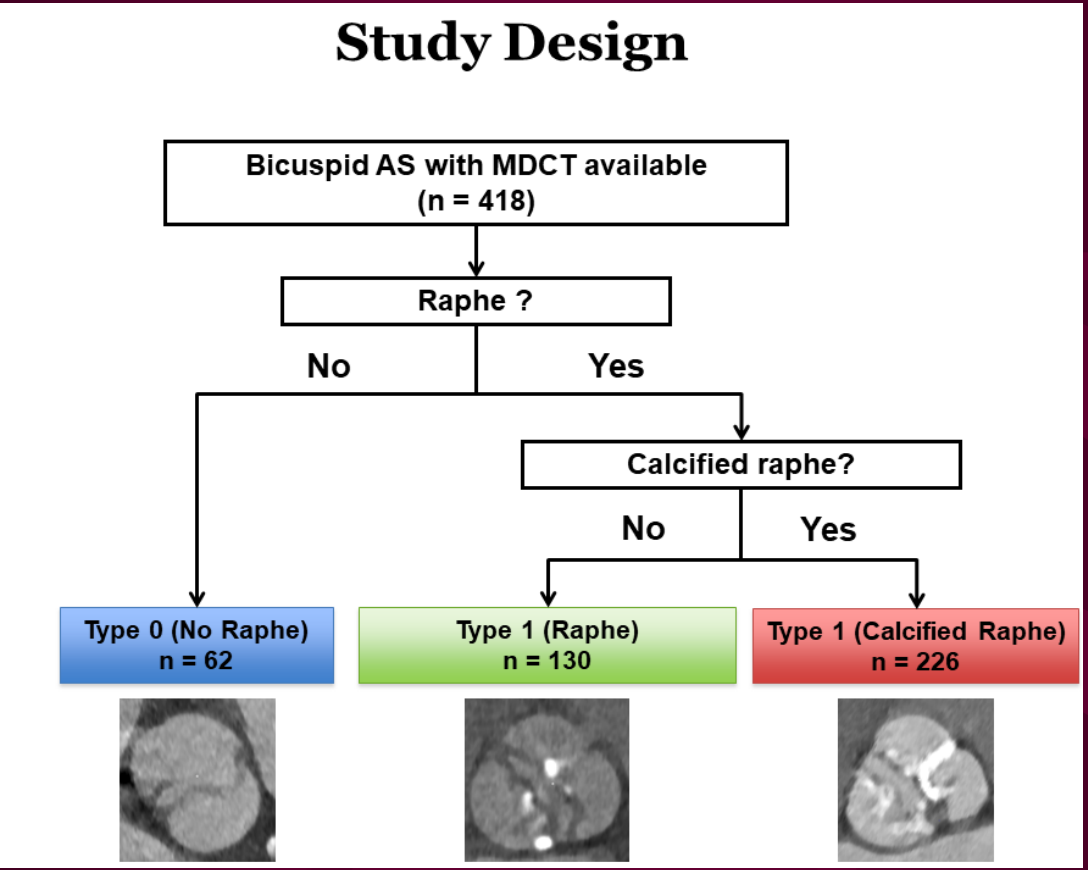
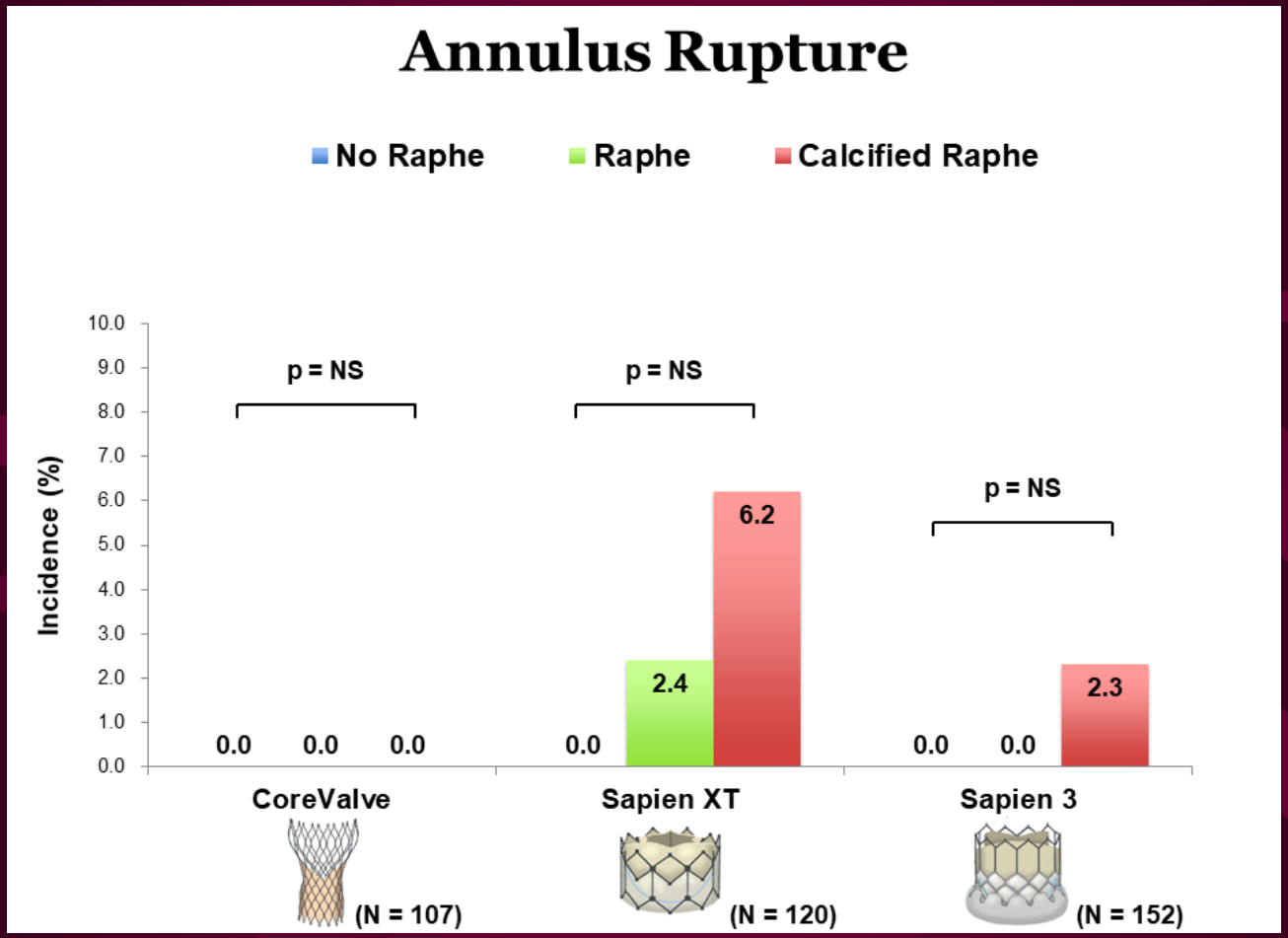
TAVI in BAV according to Device



Yoon et al JACC 2017;2579

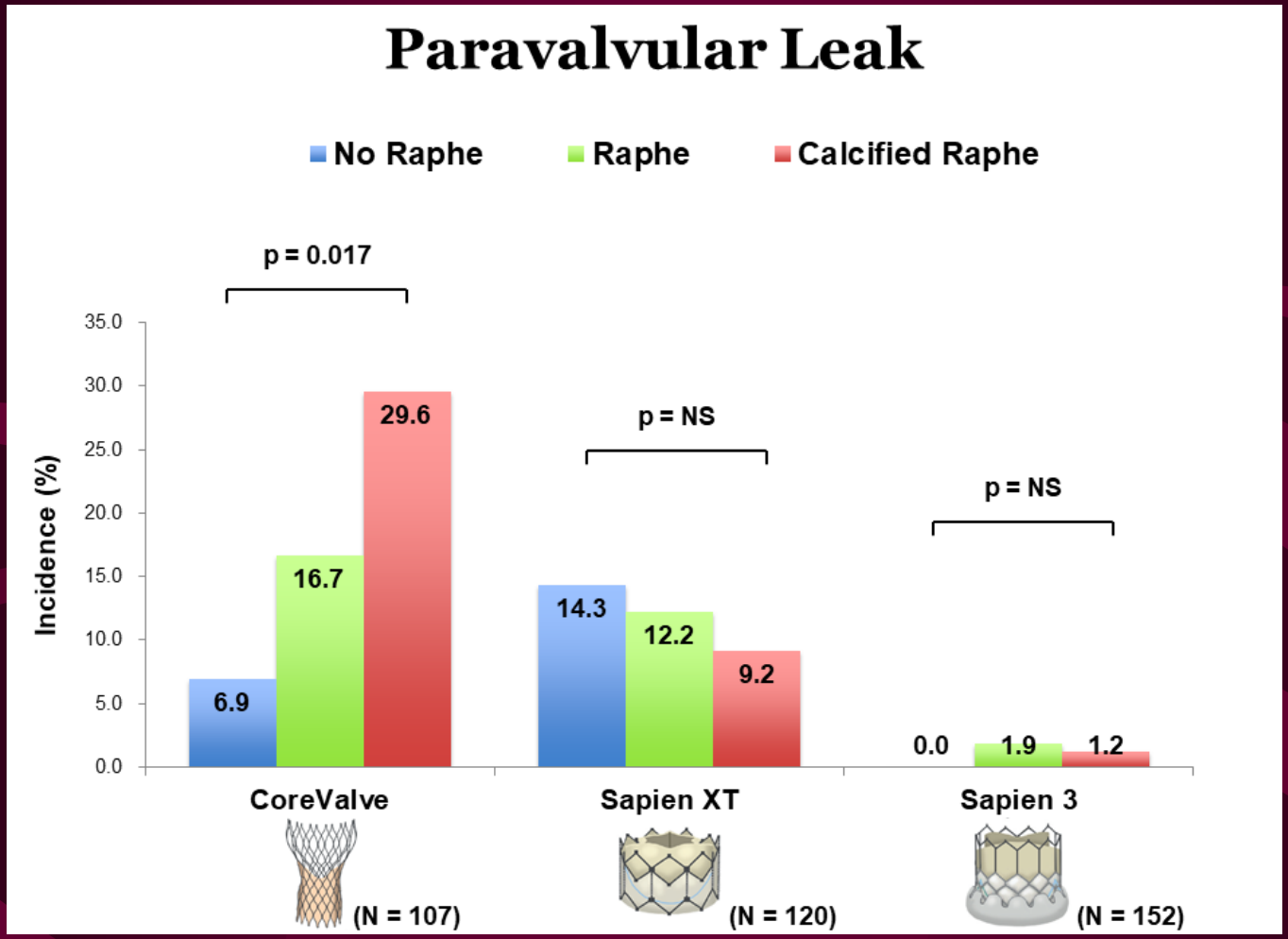
1ο Συνέδριο Δομικών Παθήσεων Καρδιάς & Βαλβιδοπαθειών

Risk of annulus rupture



Yoon et al JACC 2017;2579

Incidence of >grade 2 PVL



Yoon et al JACC 2017;2579

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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

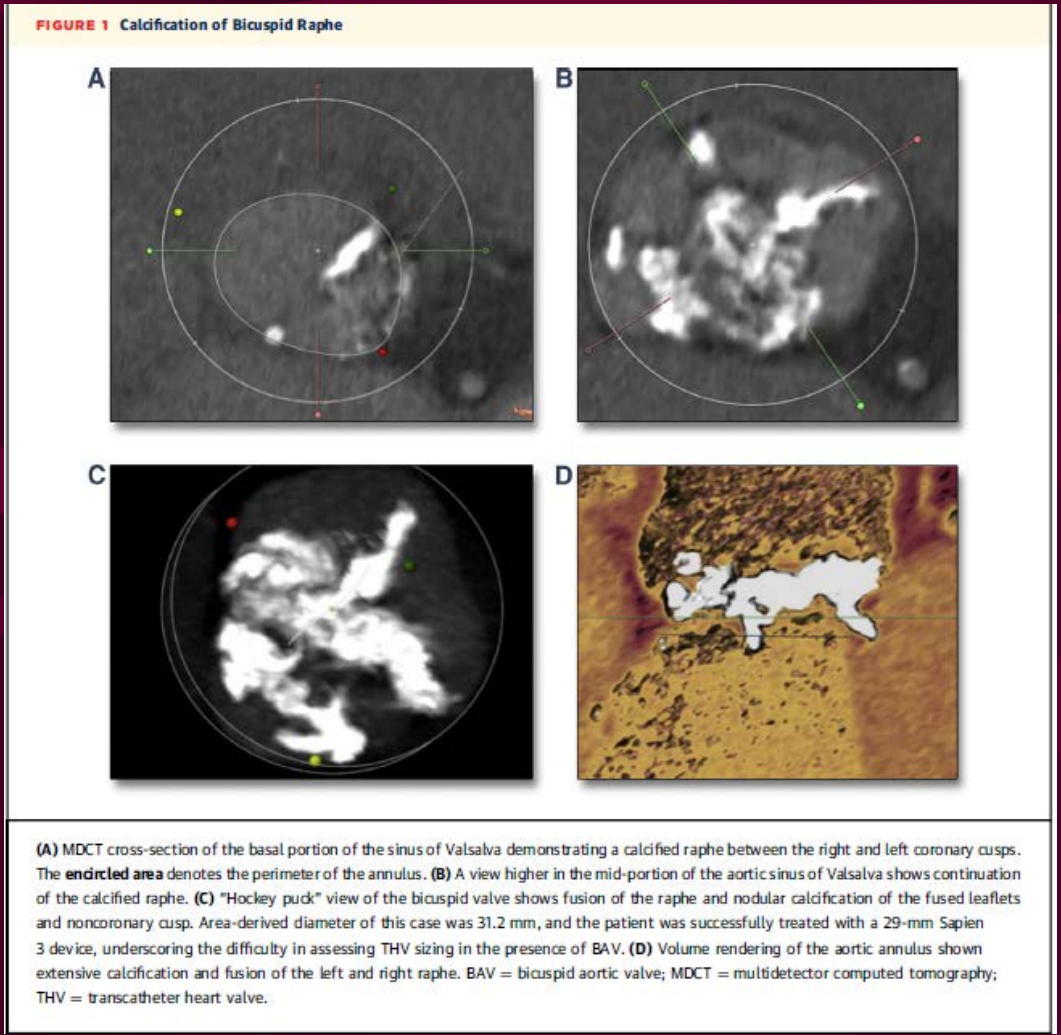
Advantages of MSCT

- 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

Calcified raphe between L & R

Mid aortic sinus – calcified raphe



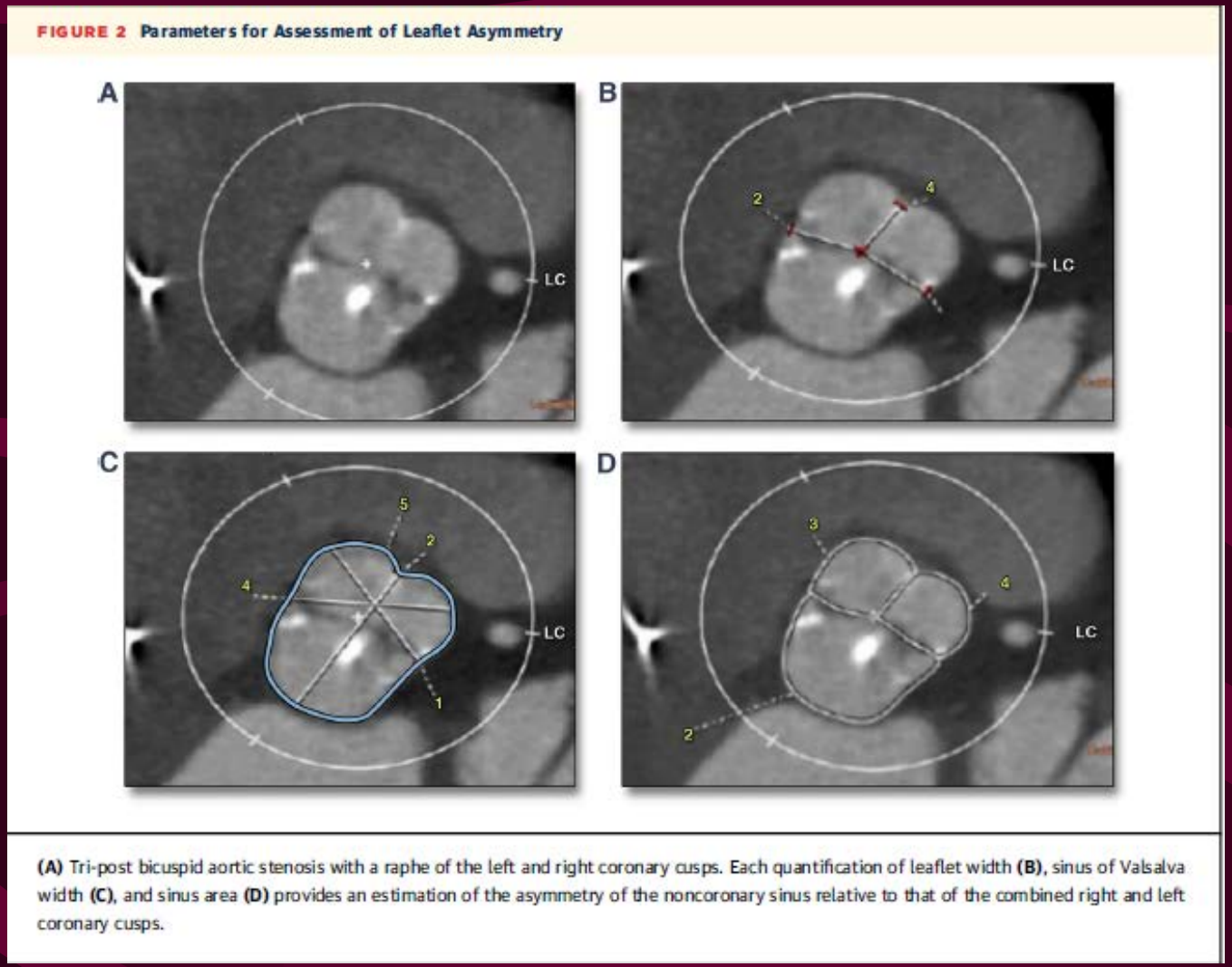
Hockey puck view- fusion of raphe and nodular calcification of leaflets

Calcification and fusion of L&R raphe

Popma J, Ramadan R JACC Imaging 2016;1159

1ο Συνέδριο Δομικών Παθήσεων Καρδιάς & Βαλβιδοπαθειών

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



Popma J, Radaman R, JACC Imaging 2016;1159

Low coronary ostia

Type I-R&L 16,9 mm fused cusp – Asymmetric annulus Coronary ostia at 11 mm

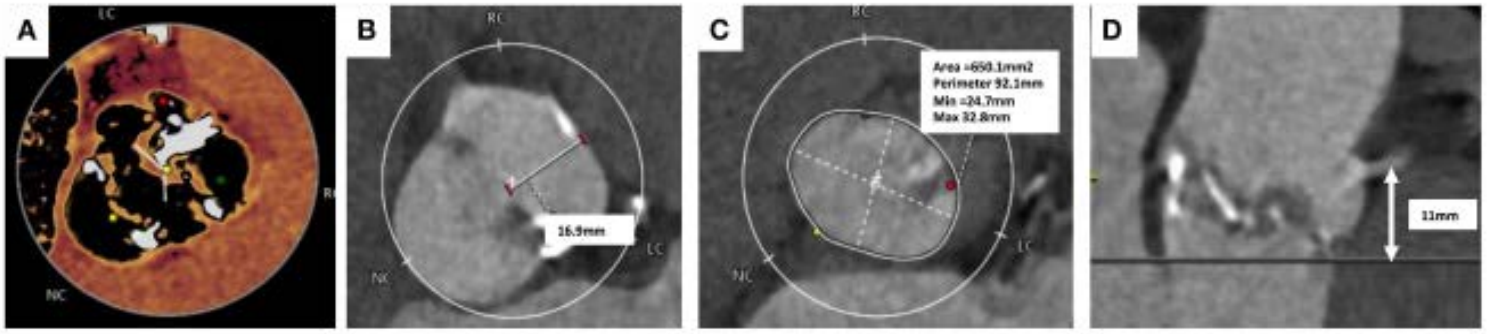


FIGURE 3 | Computer Tomography Imaging of bicuspid aortic valve. **(A)** Sievers Type 1 Raphe-type bicuspid aortic valve (BAV) with mixed cusp fusion (left-right). **(B)** Large bulky cusps measuring 16.9 mm maximum diameter. **(C)** Asymmetric large annulus. **(D)** Low lying coronary ostia at 11 mm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

Das R, Puri R, Frontiers in Cardiovasular Medicine 2018;Vol 5, Article 91

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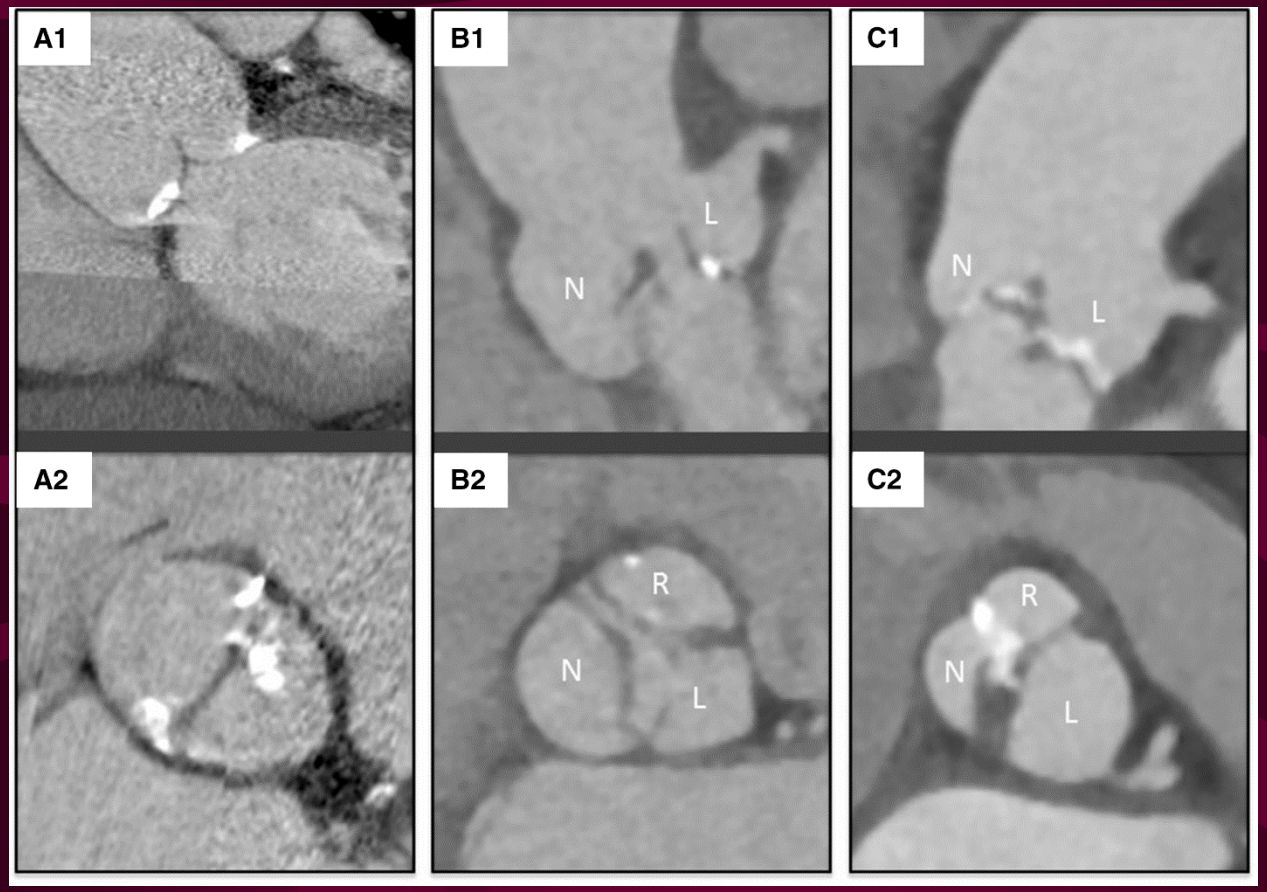
Procedure and Technical considerations-MSCT Images

Type 0 (A1-A2)

Type I (B1-B2) Coronary cusp fusion

Type I (C1-C2) Mixed coronary cusp fusion



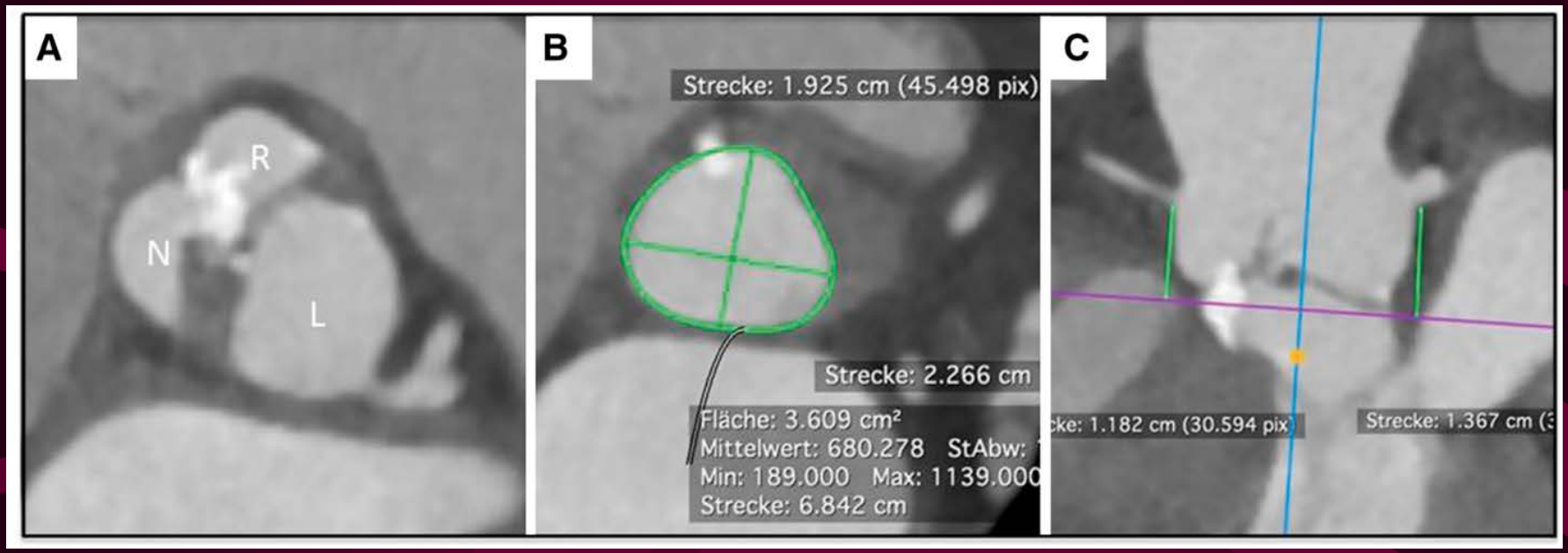
Eur Heart J. 2017;38(16):1177-1181.
doi:10.1093/eurheartj/ehx167

Procedure and Technical considerations-MSCT

Type I mixed cusp fusion

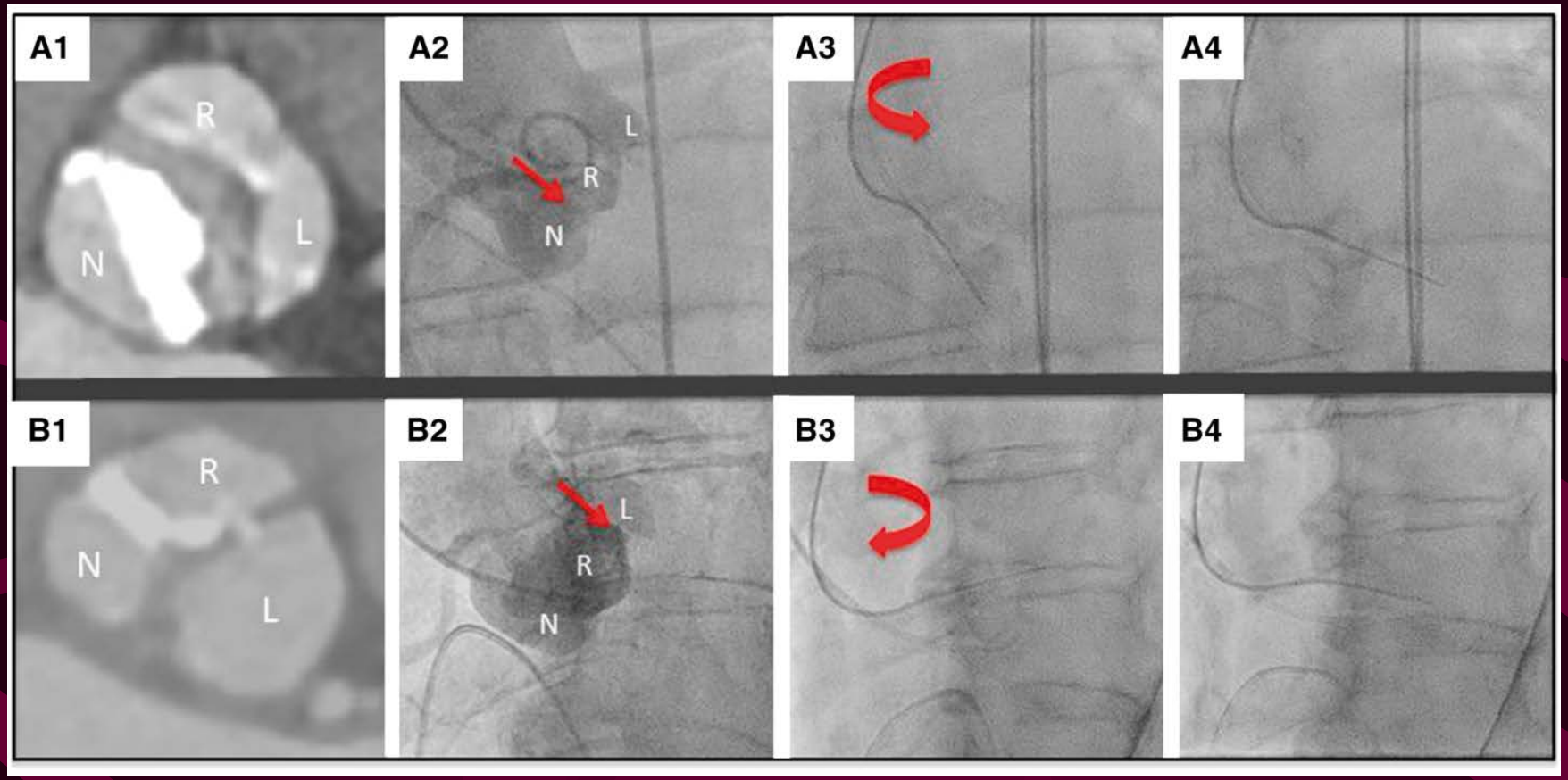
Difficult annulus 3D allignement

Coronary ostia>10 mm



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

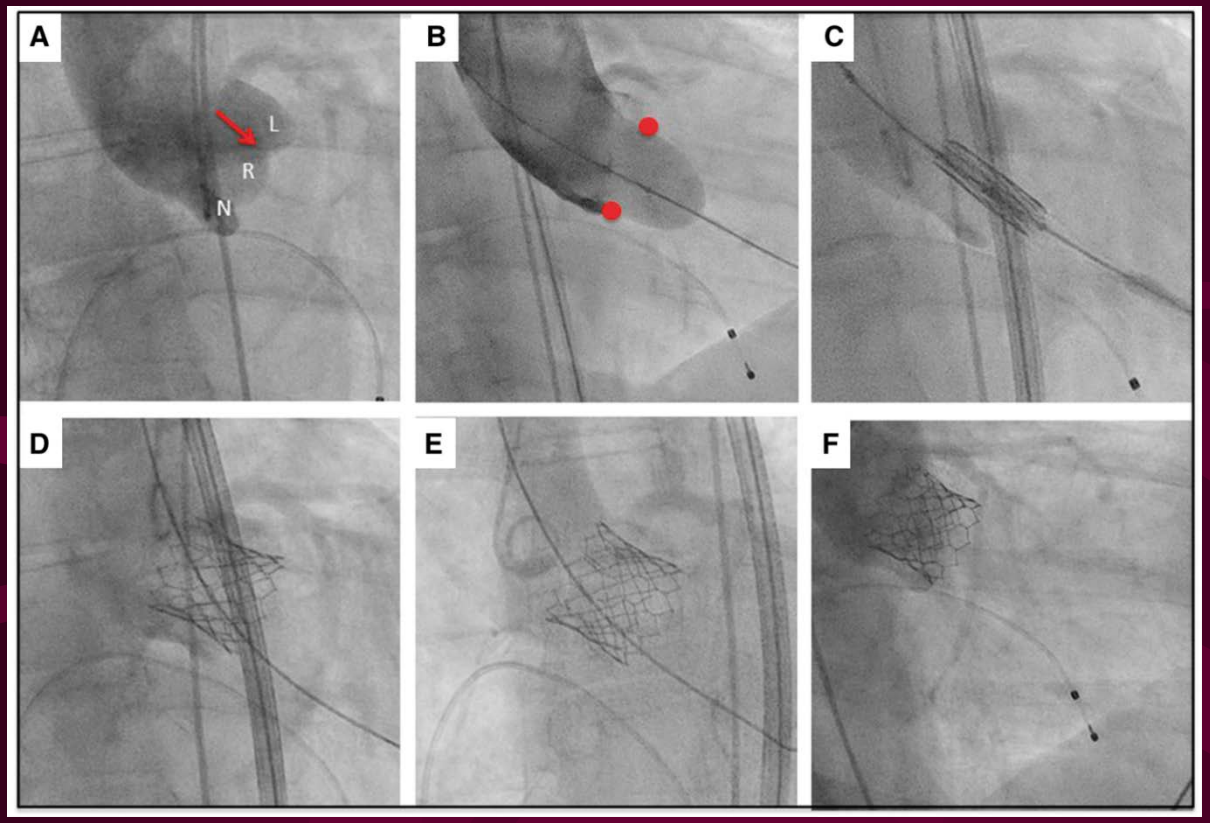
Procedure and Technical considerations-Wiring



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

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

Bicuspid Valve TAVI Case

- 84 yo male with worsening dyspnea (NYHA III)
- Cardiac Echo with severe AS (0,6 cm^2, mean gradient 60 mm Hg, EF=45%, PA pressure 56 mm Hg)
- Ostial LM (40%) and mild rest epicardial atherosclerosis
- Afib undes anticoagulation, PD, Pacer, mild COPD

MSCT Analysis

Max Ascending Aorta Diameter (mm): 41,2

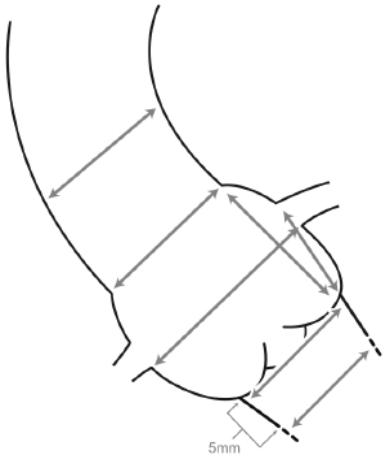
Sinotubular Junction Diameter (mm): 33,1 (Min) x 38,4 (Max)

ANNULUS

Diameter (mm): 26,0 (Min) x 32,3 (Max), 29,1 (Mean)

Perimeter (mm): 94,1, 30,0 (Derived Diameter)

Area: 688,7 mm², 29,6 (Derived Diameter) mm



Sinus of Valsalva Diameter (mm)	42,1 (LCC)	31,1 (RCC)	(NCC)
Sinus of Valsalva Height (mm)	38,9 (LCC)	39,9 (RCC)	(NCC)
Coronary Ostia Height (mm)	27,0 (Left)	33,0 (Right)	

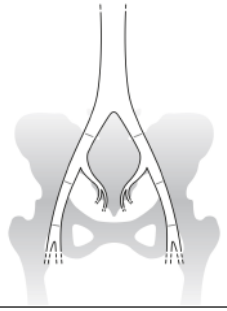
LVOT Diameter (mm): 28,6 (Min) x 40,6 (Max), 34,6 (Mean)

RIGHT

CIA Min Diameter (mm): 12,0 x 12,3

EIA Min Diameter (mm): 10,1 x 10,2

Femoral Min Diameter (mm): 9,5 x 10,7



LEFT

CIA Min Diameter (mm): 12,0 x 12,1

EIA Min Diameter (mm): 11,1 x 12,4

Femoral Min Diameter (mm): 10,8 x 11,2

RIGHT

Subclavian Min Diameter (mm): x

Annular Angulation: 63,7

LEFT

Subclavian Min Diameter (mm): x

Please review images for direct aortic evaluation.

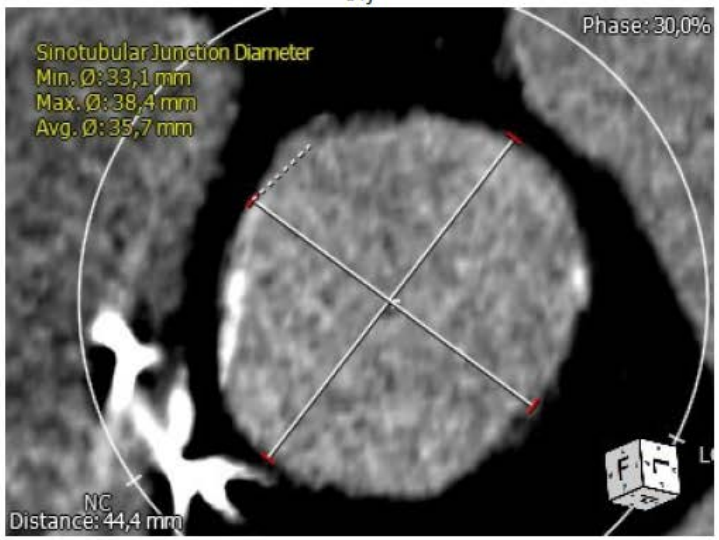
Calcium: Mild ☐ Moderate ☑ Severe ☐

1ο Συνέδριο Δομικών Παθήσεων Καρδιάς & Βαλβιδοπαθειών

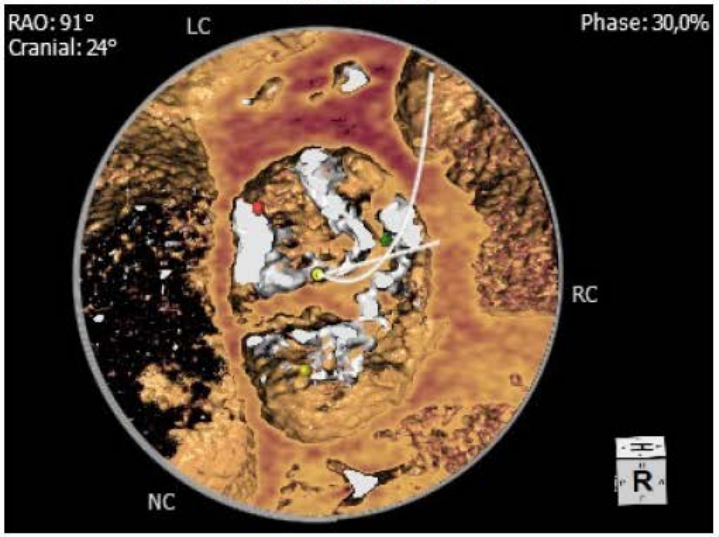
MSCT Images (Type I N-R)

Aorta

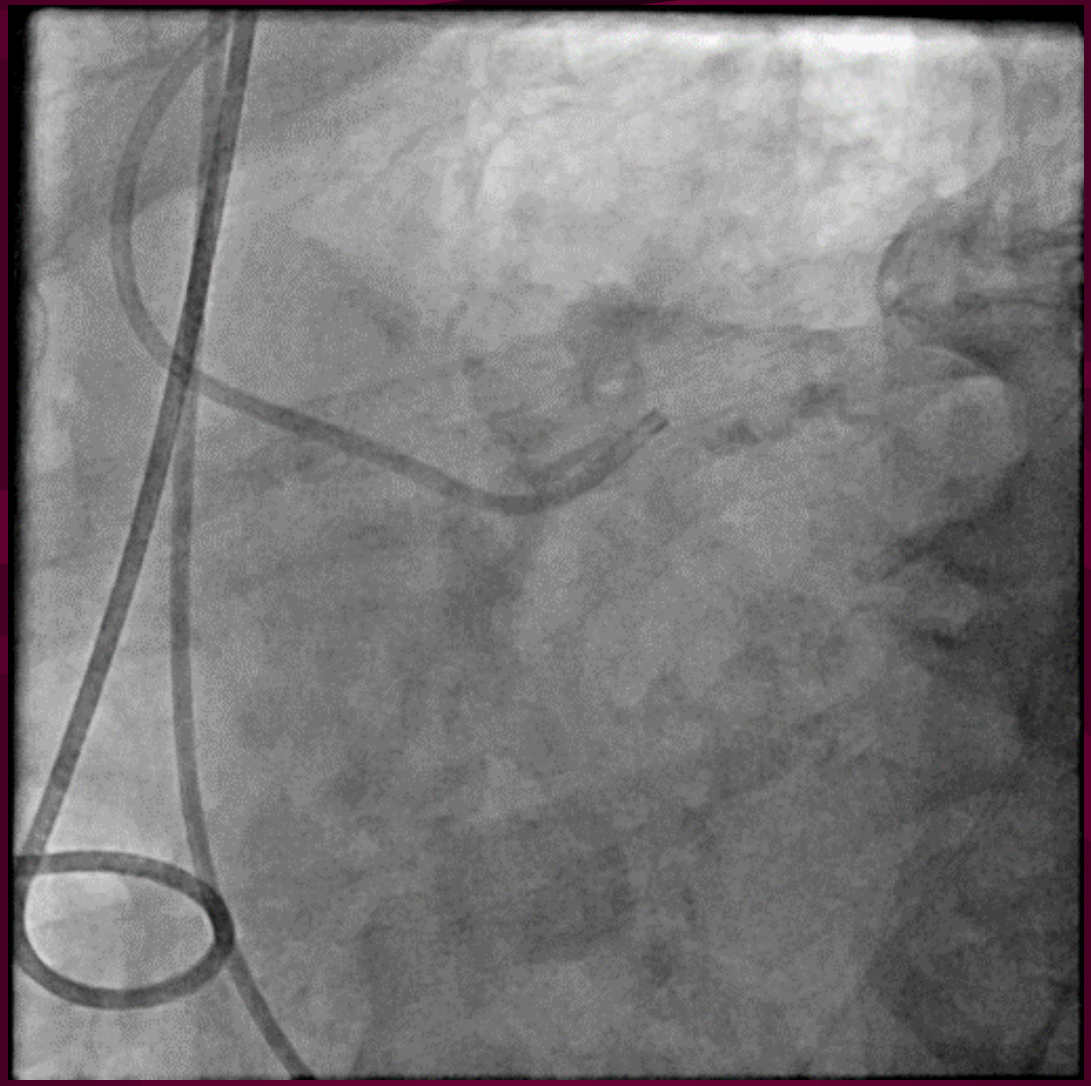
STJ



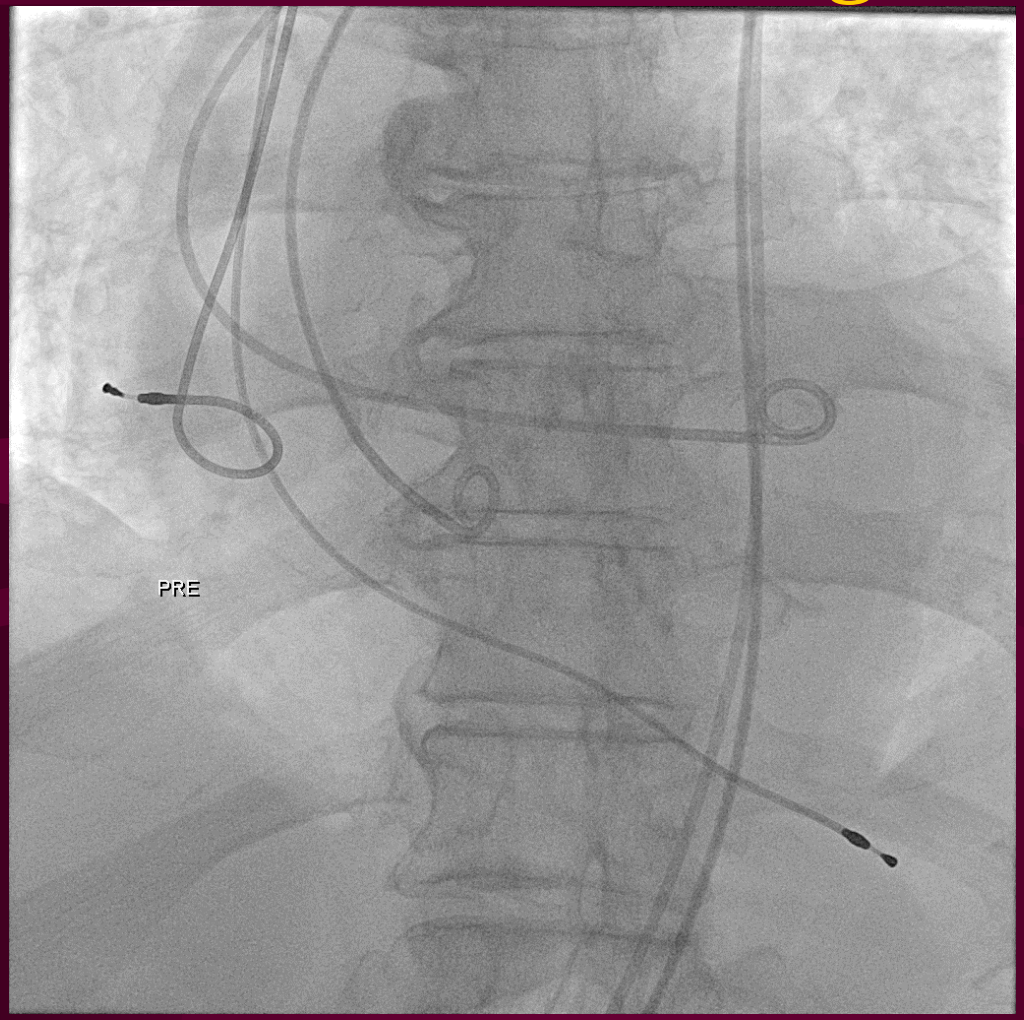
AORTIC VALVE CALCIFICATION



LM Angiography



Pre TAVI Aortogram

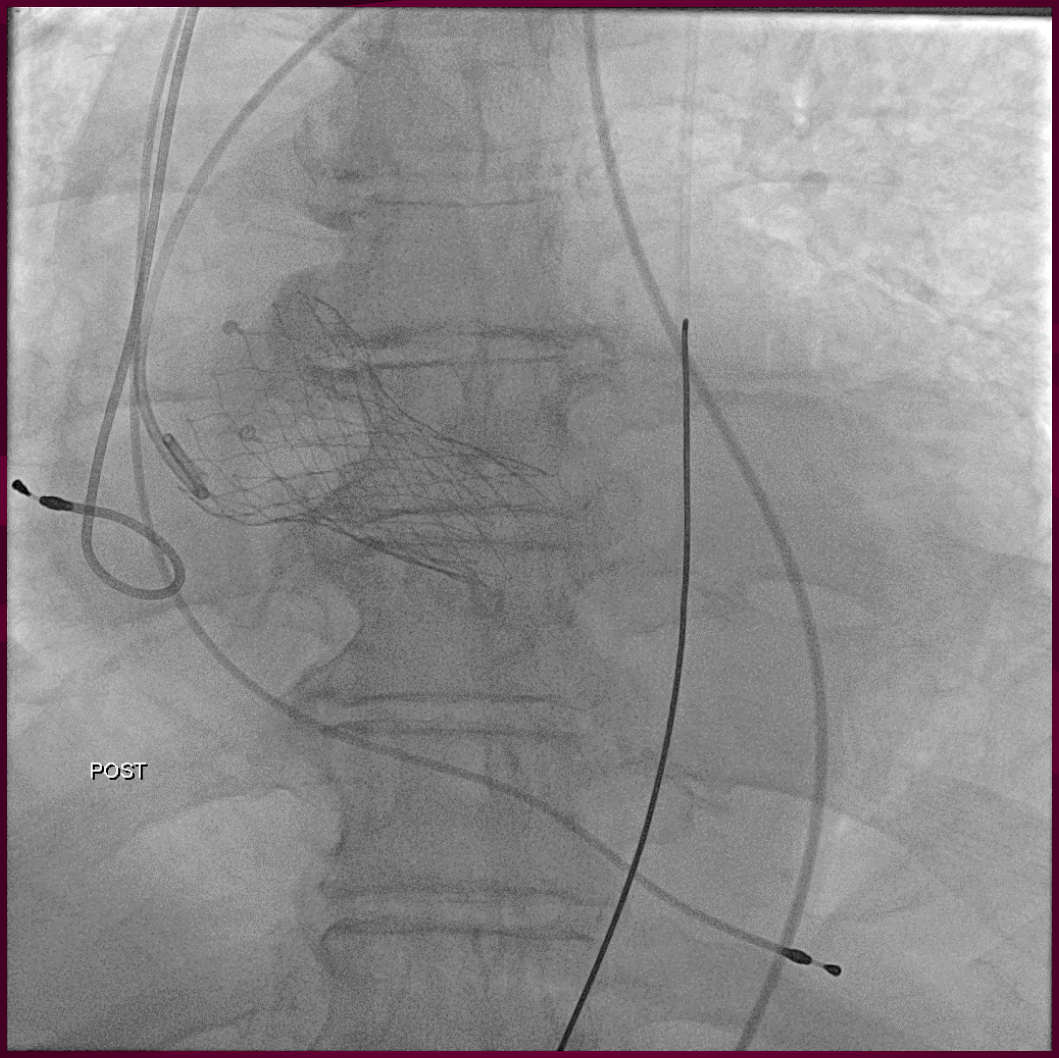


TAVI pre sizing (22 mm Balloon)

Post Initial Deployment

Post TAVI Balloon (28 mm)

Final Result (PVL 1-2)



Conclusions

- TAVI in patients with bicuspid aortic valve is feasible but has some 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
- Outcomes with second generation devices are comparable (short-term) with tricuspid valve patients undergoing TAVI