TAVI for Bicuspid Aortic Valve

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Bicuspid AV:

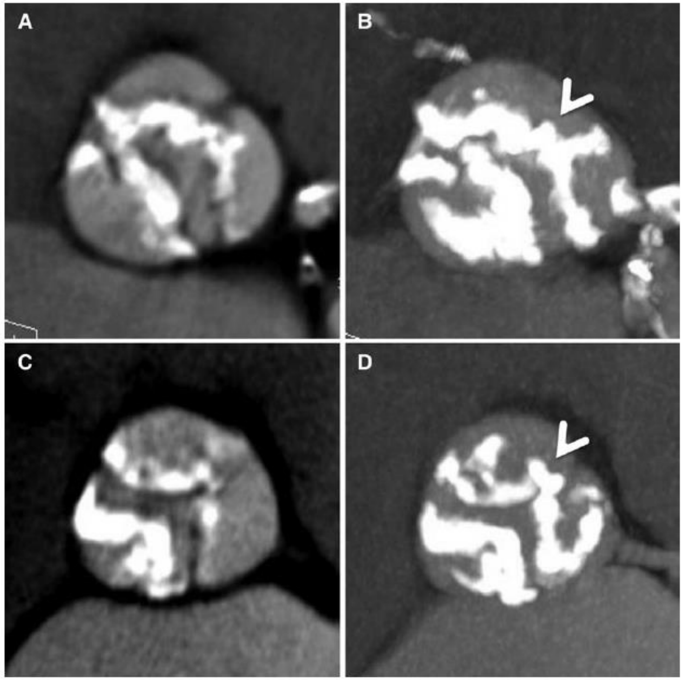
- a congenital defect affecting 0.5 to 2.0% of the global population
- Heterogeneous cusp and sinus morphology
- Often asymmetrical leaflet fusion
- Heavy and asymmetric calcifications
- Long commissural distance

- Aortic root angulation (transverse aorta)
- Aortopathy
- Coarctation of aorta

Why is TAVI in Bicuspid AV more complicated?

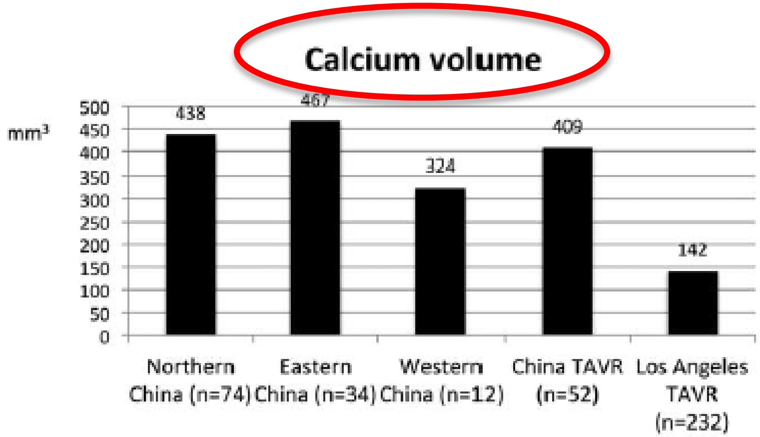
- Difficulty in sizing
- Risk of rupture due to uneven expansion
- Long commissure, underexpansion => increased risk of paravalvular leak
- Risk of coronary obstruction

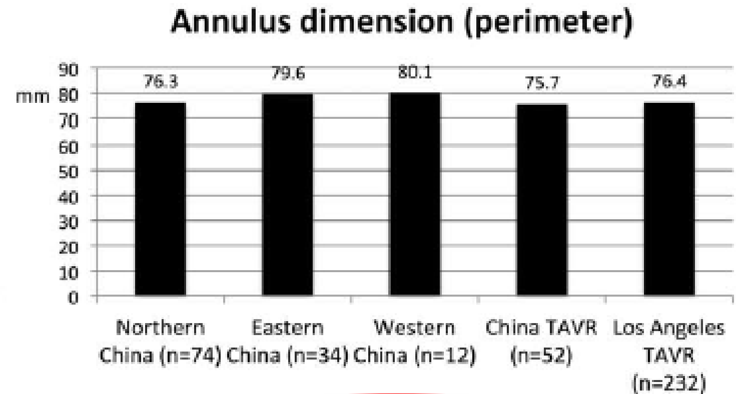
Bicuspid AV: type 1 L-R

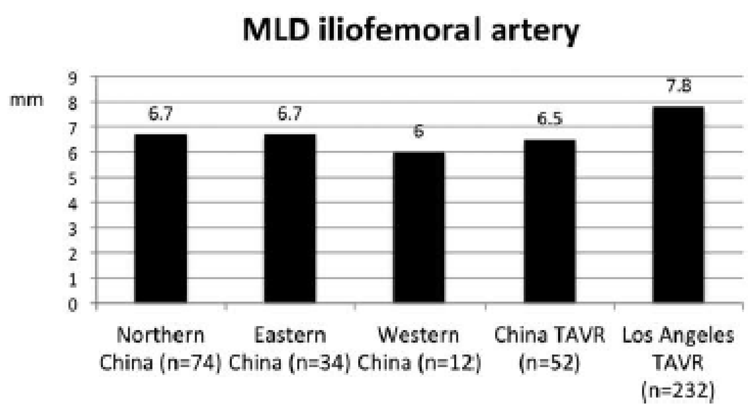


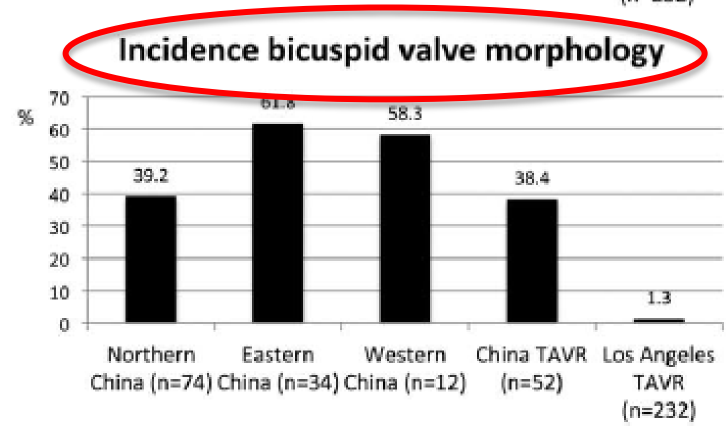
Hayashida K,
Circ Cardiovasc Interv . 2013;6:284

BAV in Chinese Patients Undergoing TAVI









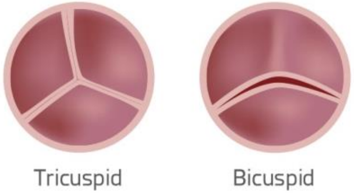
Jilaihawi H, CCI 2015;85:752

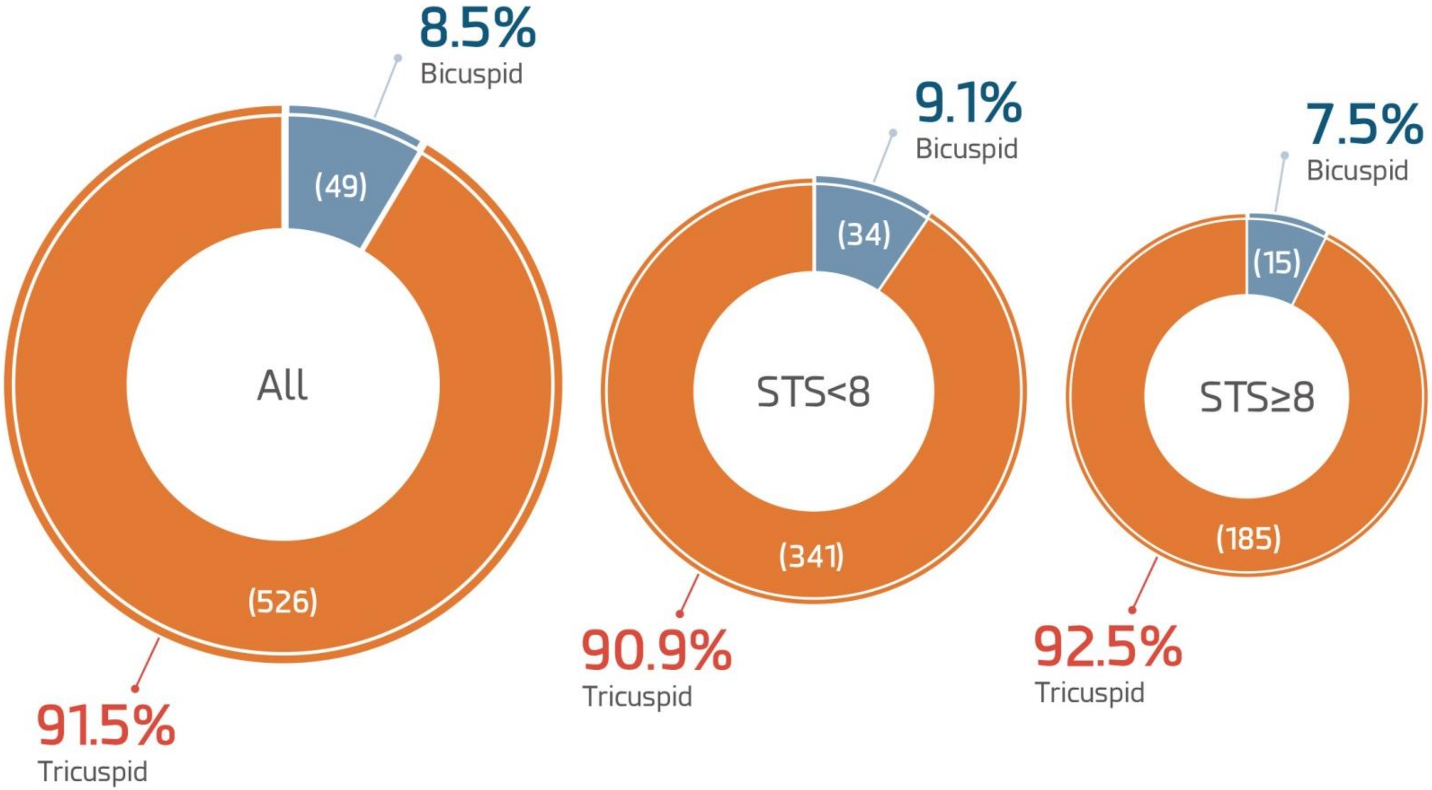
The First Cohort of K-TAVI Registry

Korean Transcatheter Aortic Valve Implantation Registry

KOREAN SOCIETY OF INTERVENTIONAL CARDIOLOGY

Distribution of valve morphology





Frequency by Decades of Bicuspid, and Tricuspid AV in Adults Undergoing SAVR for Severe AS

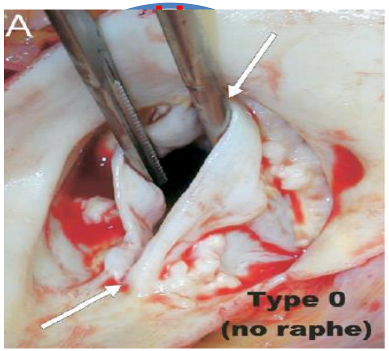
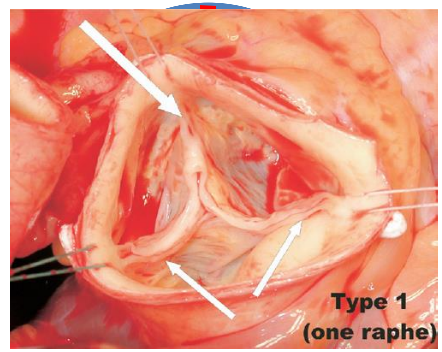
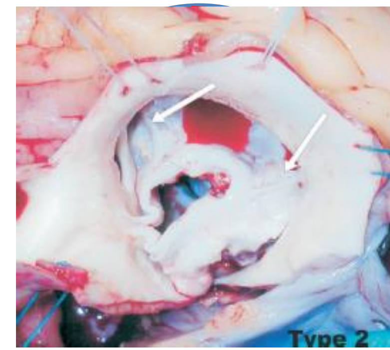
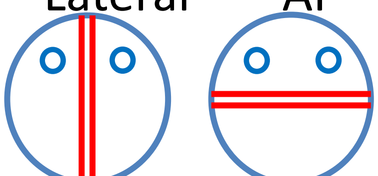
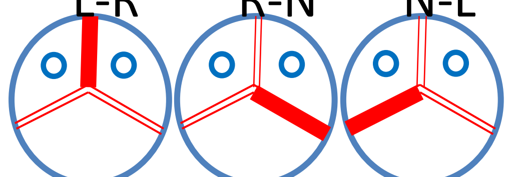
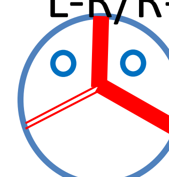
operatively excised, stenotic aortic valves from 932 patients

Aortic Valve Structure	Cases, n (%)	Ages (y) of Patients by Decades at Time of Aortic Valve Replacement							
		21–30	31–40	41–50	51–60	61–70	71–80	81–90	91–100
Men									
Unicuspid	34 (6)	3	4	11	8	4	4	0	0
Bicuspid	309 (53)	1	4	20	54	111	94	24	1
Tricuspid	234 (40)	0	0	0	14	50	119	51	0
Uncertain	7 (1)	0	0	0	0	3	2	2	0
Subtotals, n (%)	584 (100)	4 (<1)	8 (1)	31 (5)	76 (13)	168 (29)	219 (38)	77 (13)	1 (<1)
Women									
Unicuspid	12 (3)	1	2	3	1	4	1	0	0
Bicuspid	149 (43)	1	5	10	20	44	55	14	0
Tricuspid	183 (53)	0	0	2	11	43	79	47	1
Uncertain	4 (1)	0	0	1	0	0	3	0	0
Subtotals, n (%)	348 (100)	2 (<1)	7 (2)	16 (5)	32 (9)	91 (26)	138 (46)	61 (18)	1 (<1)

Values in parentheses are percentages.

Roberts WC, Circulation. 2005;111:920

Sievers Classification

Type 0	Type 1	Type 2
0 raphe	1 raphe	2 raphes
		
Lateral AP 	L-R R-N N-L 	L-R/R-N 

BAV vs. TAV for TAVI

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

Sung-Han Yoon, MD,[a] Sabine Bleiziffer, MD,[b] Ole De Backer, MD,[c] Victoria Delgado, MD,[d] Takahide Arai, MD,[e] Johannes Ziegelmueller, MD,[b] Marco Barbanti, MD,[f] Rahul Sharma, MD,[a] Gidon Y. Perlman, MD,[g] Omar K. Khalique, MD,[h] Erik W. Holy, MD,[i] Smriti Saraf, MD,[j] Florian Deuschl, MD,[k] Buntaro Fujita, MD,[l] Philipp Ruile, MD,[m] Franz-Josef Neumann, MD,[n] Gregor Pache, MD,[n] Masao Takahashi, MD,[o] Hidehiro Kaneko, MD,[p] Tobias Schmidt, MD,[q] Yohei Ohno, MD,[g] Niklas Schofer, MD,[k] William K.F. Kong, MD,[d,r] Edgar Tay, MD,[r] Daisuke Sugiyama, MD,[a] Hiroyuki Kawamori, MD,[a] Yoshio Maeno, MD,[a] Yigal Abramowitz, MD,[a] Tarun Chakravarty, MD,[a] Mamoo Nakamura, MD,[a] Shingo Kuwata, MD,[t] Gerald Yong, MD,[u] Hsien-Li Kao, MD,[v] Michael Lee, MD,[w] Hyo-Soo Kim, MD,[x] Thomas Modine, MD,[y] S. Chiu Wong, MD,[z] Francesco Bedgoni, MD,[aa] Luca Testa, MD,[aa] Emmanuel Teiger, MD,[o] Christian Butter, MD,[p] Stephan M. Ensminger, MD,[l] Ulrich Schaefer, MD,[k] Danny Dvir, MD,[g] Philipp Blanke, MD,[g] Jonathon Leipsic, MD,[g] Fabian Nietlispach, MD,[t] Mohamed Abdel-Wahab, MD,[i] Bernard Chevalier, MD,[e] Corrado Tamburino, MD,[f] David Hildick-Smith, MD,[j] Brian K. Whisenant, MD,[bb] Seung-Jung Park, MD,[cc] Antonio Colombo, MD,[dd] Azeem Latib, MD,[dd] Susheel K. Kodali, MD,[h] Jeroen J. Bax, MD,[d] Lars Søndergaard, MD,[c] John G. Webb, MD,[e] Thierry Lefèvre, MD,[e] Martin B. Leon, MD,[h] Raj Makkar, MD[a]

ABSTRACT

BACKGROUND Transcatheter aortic valve replacement (TAVR) is being increasingly performed in patients with bicuspid aortic valve stenosis (AS).

OBJECTIVES This study sought to compare the procedural and clinical outcomes in patients with bicuspid versus tricuspid AS from the Bicuspid AS TAVR multicenter registry.

METHODS Outcomes of 561 patients with bicuspid AS and 4,546 patients with tricuspid AS were compared after propensity score matching, assembling 546 pairs of patients with similar baseline characteristics. Procedural and clinical outcomes were recorded according to Valve Academic Research Consortium-2 criteria.

RESULTS Compared with patients with tricuspid AS, patients with bicuspid AS had more frequent conversion to surgery (2.0% vs. 0.2%; $p = 0.006$) and a significantly lower device success rate (85.3% vs. 91.4%; $p = 0.002$). Early-generation devices were implanted in 320 patients with bicuspid and 321 patients with tricuspid AS, whereas new-generation devices were implanted in 226 and 225 patients with bicuspid and tricuspid AS, respectively. Within the group receiving early-generation devices, bicuspid AS had more frequent aortic root injury (4.5% vs. 0.0%; $p = 0.015$) when receiving the balloon-expanding device, and moderate-to-severe paravalvular leak (19.4% vs. 10.5%; $p = 0.02$) when receiving the self-expanding device. Among patients with new-generation devices, however, procedural results were comparable across different prostheses. The cumulative all-cause mortality rates at 2 years were comparable between bicuspid and tricuspid AS (17.2% vs. 19.4%; $p = 0.28$).

CONCLUSIONS Compared with tricuspid AS, TAVR in bicuspid AS was associated with a similar prognosis, but lower device success rate. Procedural differences were observed in patients treated with the early-generation devices, whereas no differences were observed with the new-generation devices. (J Am Coll Cardiol 2017;69:2579–89) © 2017 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Multi-center retrospective data:

- 561 patients with bicuspid AS
- 4,546 patients with tricuspid AS

=> 546 pairs of patients after propensity score matching

Yoon SH, JACC 2017;69:2579

BAV vs. TAV for TAVI

Baseline data

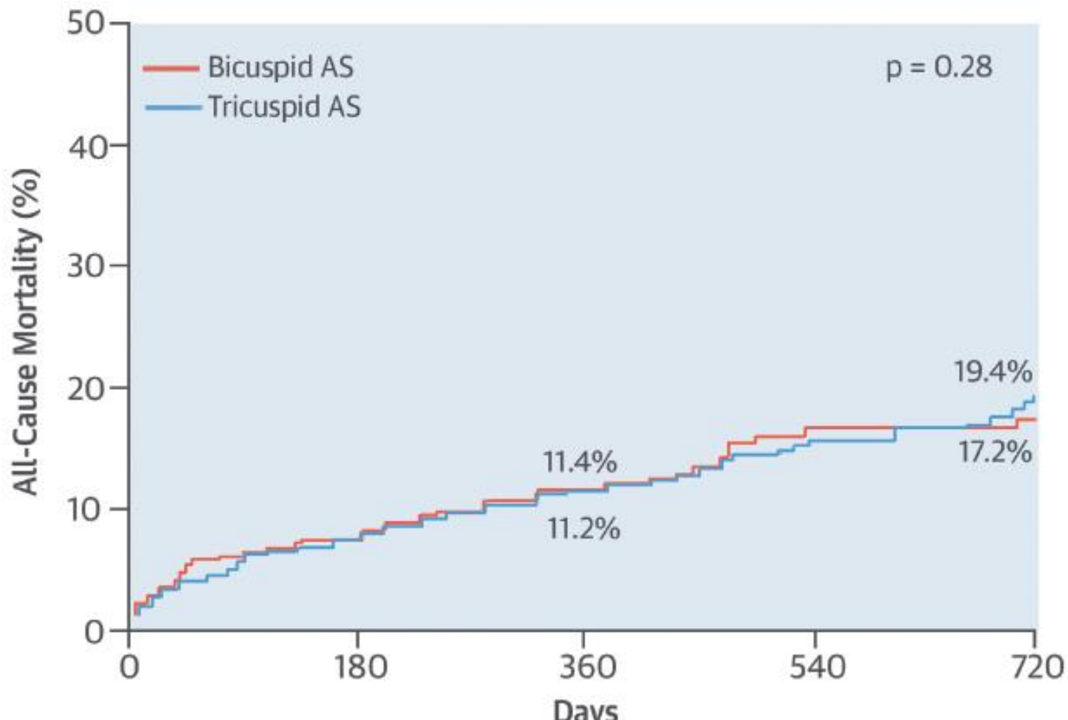
	Propensity Score Matched Cohort		
	Bicuspid AS (n = 546)	Tricuspid AS (n = 546)	p Value
Age, yrs	77.2 ± 8.2	77.2 ± 8.8	0.91
Male	343 (62.8)	331 (60.6)	0.48
NYHA functional class III or IV	439 (80.4)	428 (82.1)	0.48
Logistic EuroSCORE, %	16.1 ± 12.0	16.9 ± 13.9	0.58
STS score, %	4.6 ± 4.6	4.3 ± 3.0	0.29
Hypertension	382 (70.0)	385 (70.5)	0.89
Diabetes mellitus	128 (23.4)	127 (23.3)	>0.99
Creatinine, mg/dl	1.2 ± 0.9	1.2 ± 0.7	0.81
Peripheral vascular disease	83 (15.2)	85 (15.6)	0.93
Prior cerebrovascular accident	77 (14.1)	69 (12.6)	0.53
Chronic lung disease	98 (17.9)	82 (15.0)	0.23
Prior PCI	121 (22.2)	128 (23.4)	0.66
Prior CABG	62 (11.4)	67 (12.3)	0.70
Echocardiographic findings			
Mean gradient, mm Hg	49.7 ± 17.7	48.5 ± 17.1	0.25
Aortic valve area, cm^2	0.7 ± 0.2	0.7 ± 0.2	0.86
LVEF, %	51.6 ± 15.0	51.6 ± 15.2	0.99

Early 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)

Yoon SH, JACC 2017;69:2579

All-cause Mortality after TAVI: BAV vs. TAV

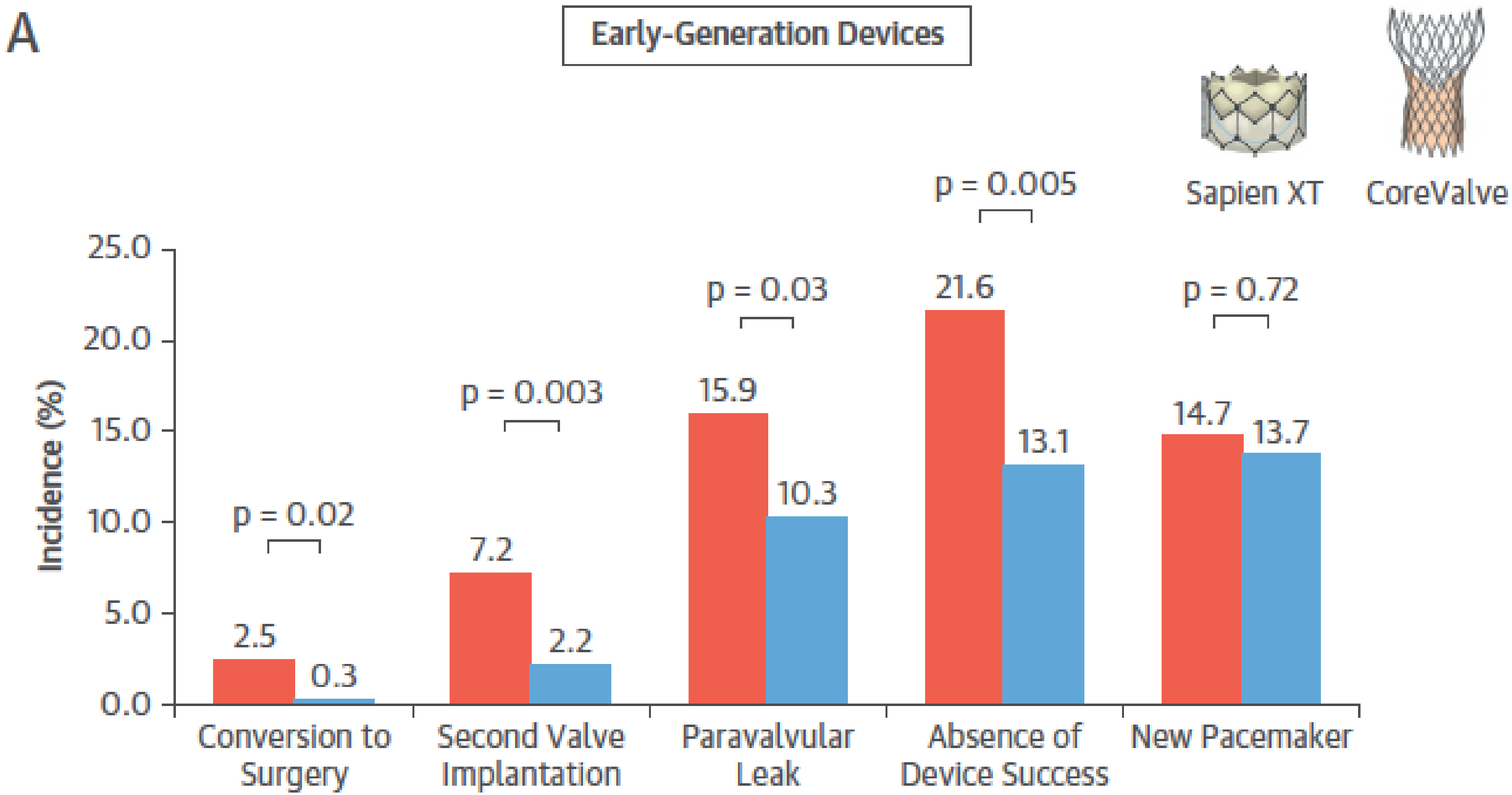


Number at Risk

Bicuspid AS	546	236	106
Tricuspid AS	546	282	133

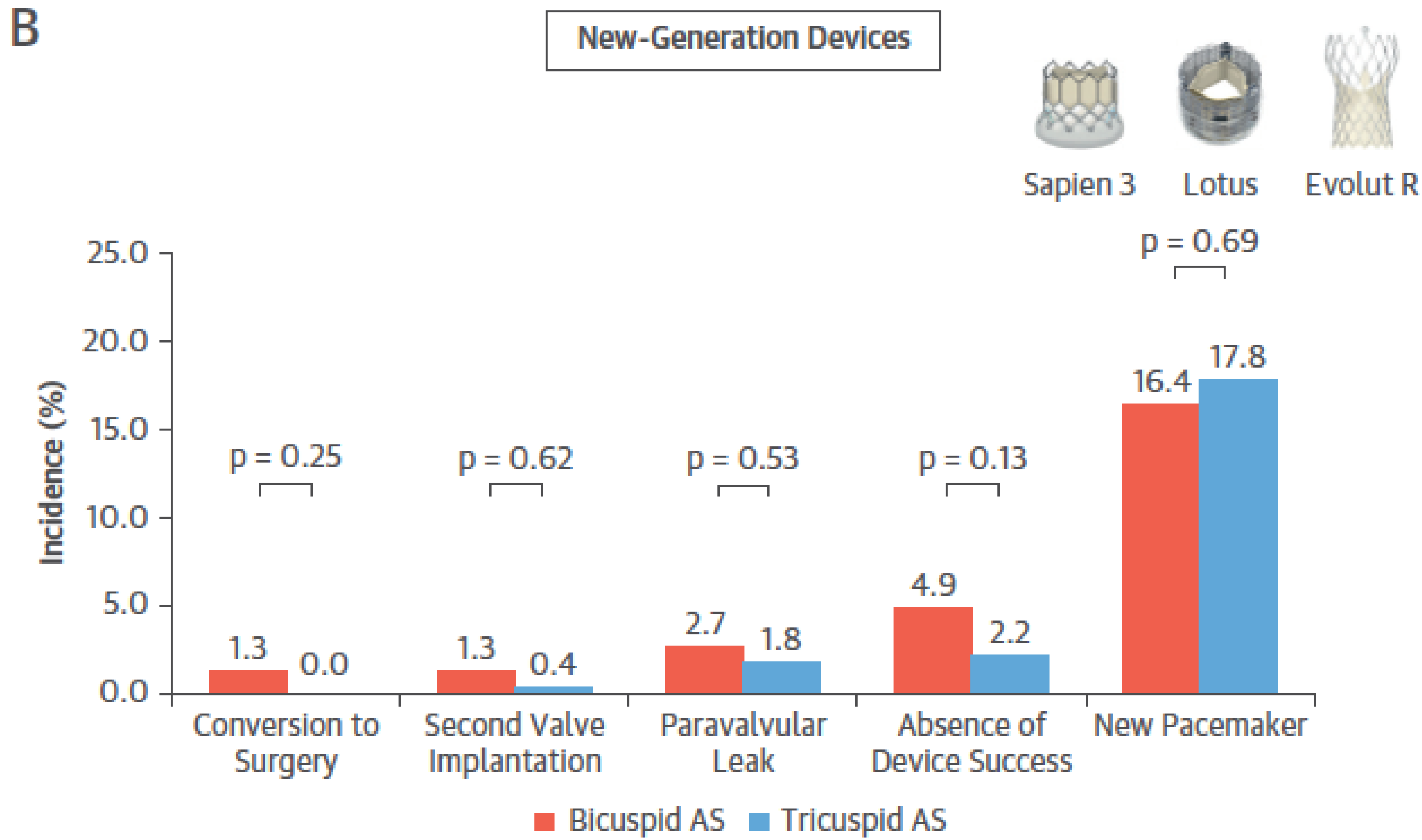
Jilaihawi H, JACC Cardiovasc Imaging 2016;9:1145

Complications: Early Generation Device



Yoon SH, JACC 2017;69:2579

Complications: New-generation Device



Early- vs. New-generation Valves for TAVI in BAV

Transcatheter Aortic Valve Replacement With Early- and New-Generation Devices in Bicuspid Aortic Valve Stenosis

Sung-Han Yoon, MD,[a] Thierry Lefèvre, MD,[b] Jung-Ming Ahn, MD,[a] Gidon Y. Perlman, MD,[c] Danny Dvir, MD,[c] Azeem Latib, MD,[d] Marco Barbanti, MD,[e] Florian Deuschl, MD,[f] Ole De Backer, MD,[g] Philipp Blanke, MD,[c] Thomas Modine, MD,[h] Gregor Pache, MD,[i] Franz-Josef Neumann, MD,[j] Philipp Ruile, MD,[j] Takahide Arai, MD,[b] Yohei Ohno, MD,[e] Hidehiro Kaneko, MD,[k] Edgar Tay, MD,[l] Niklas Schofer, MD,[f] Erik W. Holy, MD,[m] Ngai H.V. Luk, MD,[g] Gerald Yong, MD,[n] Qingsheng Lu, MD,[o] William K.F. Kong, MD,[l,p] Jimmy Hon, MD,[l] Hsien-Li Kao, MD,[q] Michael Lee, MD,[r] Wei-Hsian Yin, MD,[s] Duk-Woo Park, MD,[a] Soo-Jin Kang, MD,[a] Seung-Whan Lee, MD,[a] Young-Hak Kim, MD,[a] Cheol Whan Lee, MD,[a] Seong-Wook Park, MD,[a] Hyo-Soo Kim, MD,[t] Christian Butter, MD,[k] Omar K. Khalique, MD,[u] Ulrich Schaefer, MD,[f] Fabian Nietlispach, MD,[m] Susheel K. Kodali, MD,[u] Martin B. Leon, MD,[u] Jian Ye, MD,[c] Bernard Chevalier, MD,[b] Jonathon Leipsic, MD,[c] Victoria Delgado, MD,[q] Jeroen J. Bax, MD,[q] Corrado Tamburino, MD,[e] Antonio Colombo, MD,[d] Lars Søndergaard, MD,[g] John G. Webb, MD,[c] Seung-Jung Park, MD[a]

ABSTRACT

BACKGROUND Few studies have evaluated the clinical outcomes of transcatheter aortic valve replacement (TAVR) in patients with bicuspid aortic valve stenosis (AS). Particularly, limited data exist comparing the results of TAVR with new-generation devices versus early-generation devices.

OBJECTIVES This study sought to evaluate the clinical outcomes of TAVR for bicuspid AS with early- and new-generation devices.

METHODS The Bicuspid TAVR Registry is an international multicenter study enrolling consecutive patients with bicuspid AS undergoing TAVR between April 2005 and May 2015.

RESULTS Of 301 patients, 199 patients (71.1%) were treated with early-generation devices (Sapien XT [Edwards Lifesciences Corporation, Irvine, California]: n = 87; CoreValve [Medtronic, Minneapolis, Minnesota]: n = 112) and 102 with new-generation devices (Sapien 3 [Edwards Lifesciences Corporation]: n = 91; Lotus [Boston Scientific Corporation, Marlborough, Massachusetts]: n = 11). The mean Society of Thoracic Surgeons score was 4.7 ± 5.2 without significant differences between groups (4.6 ± 5.1 vs. 4.9 ± 5.4; p = 0.57). Overall, all-cause mortality rates were 4.3% at 30 days and 14.4% at 1 year. Moderate or severe paravalvular leak was absent and significantly less frequent with new-generation compared to early-generation devices (0.0% vs. 8.5%; p = 0.002), which resulted in a higher device success rate (92.2% vs. 80.9%; p = 0.01). There were no differences between early- and new-generation devices in stroke (2.5% vs. 2.0%; p > 0.99), life-threatening bleeding (3.5% vs. 2.9%; p > 0.99), major vascular complication (4.5% vs. 2.9%; p = 0.76), stage 2 to 3 acute kidney injury (2.5% vs. 2.9%; p > 0.99), early safety endpoints (15.1% vs. 10.8%; p = 0.30), and 30-day all-cause mortality (4.5% vs. 3.9%; p > 0.99).

CONCLUSIONS The clinical outcomes of TAVR in patients with bicuspid AS were favorable. New-generation devices were associated with less paravalvular leak and, hence, a higher device success rate than early-generation devices. (The Bicuspid Aortic Stenosis Following Transcatheter Aortic Valve Replacement Registry [Bicuspid TAVR]; NCT02394184)
(J Am Coll Cardiol 2016;68:1195–205) © 2016 by the American College of Cardiology Foundation.

International Bicuspid TAVR registry

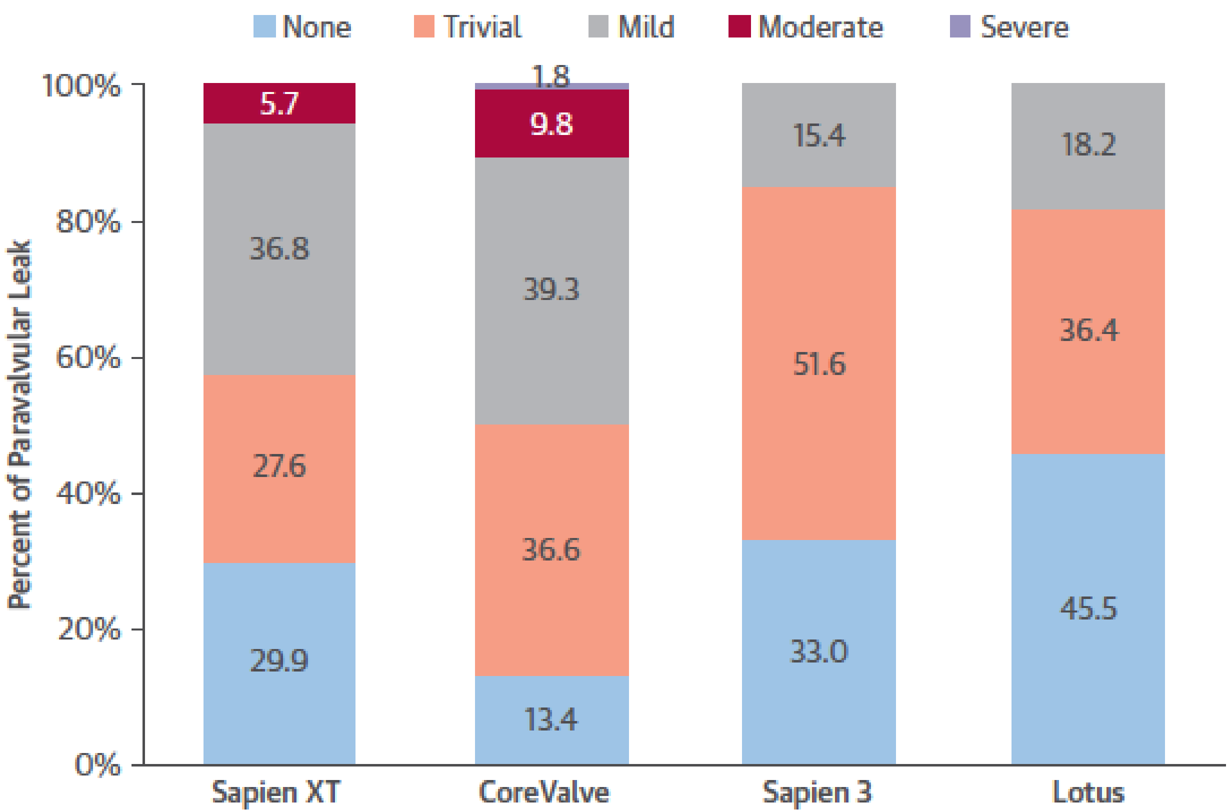
between April 2005 and May 2015

N=301,

- Early generation, n=199
- New-generation, n=102

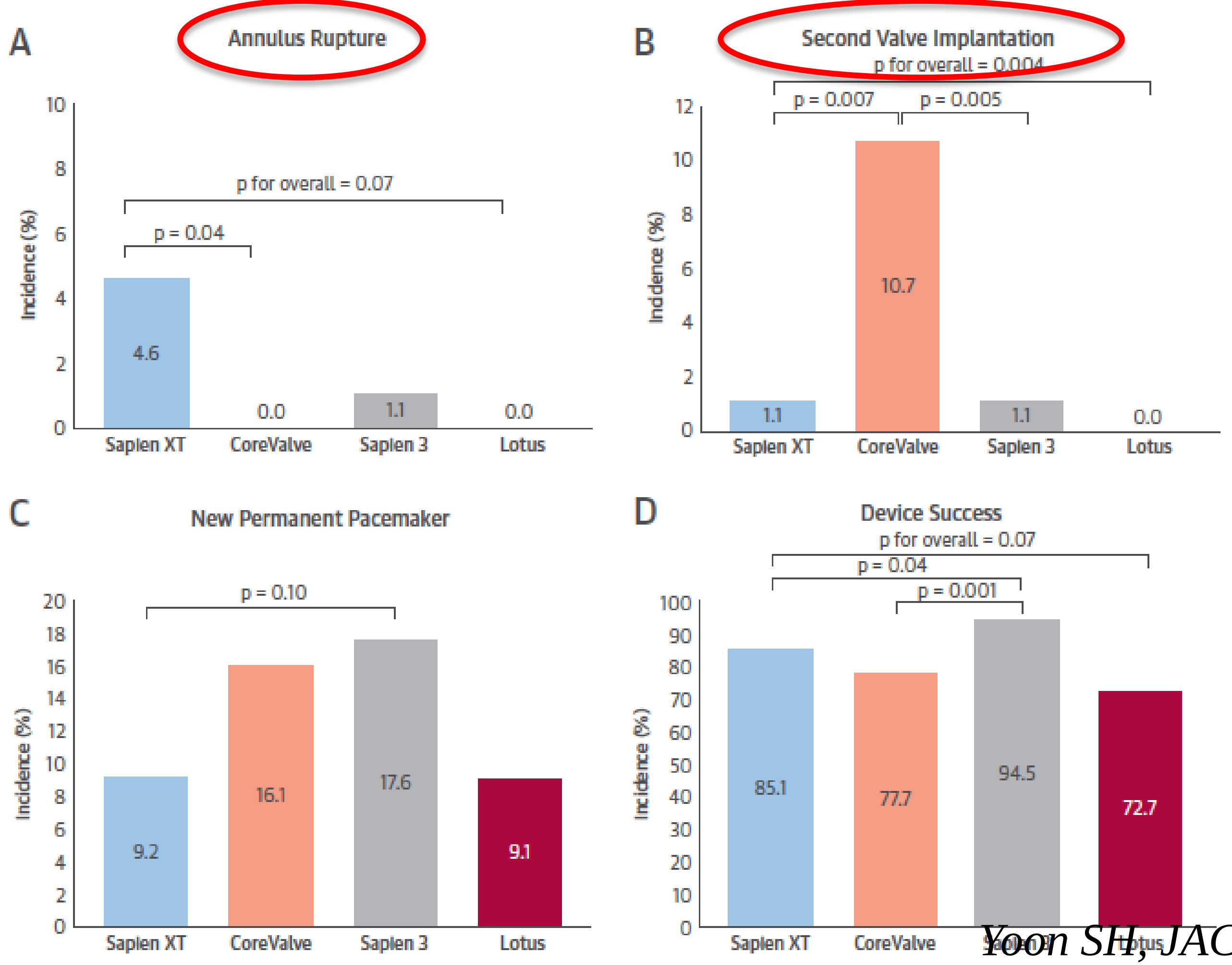
Yoon SH, JACC 2016;68:1195

Paravalvular Leak



Yoon SH, JACC 2016;68:1195

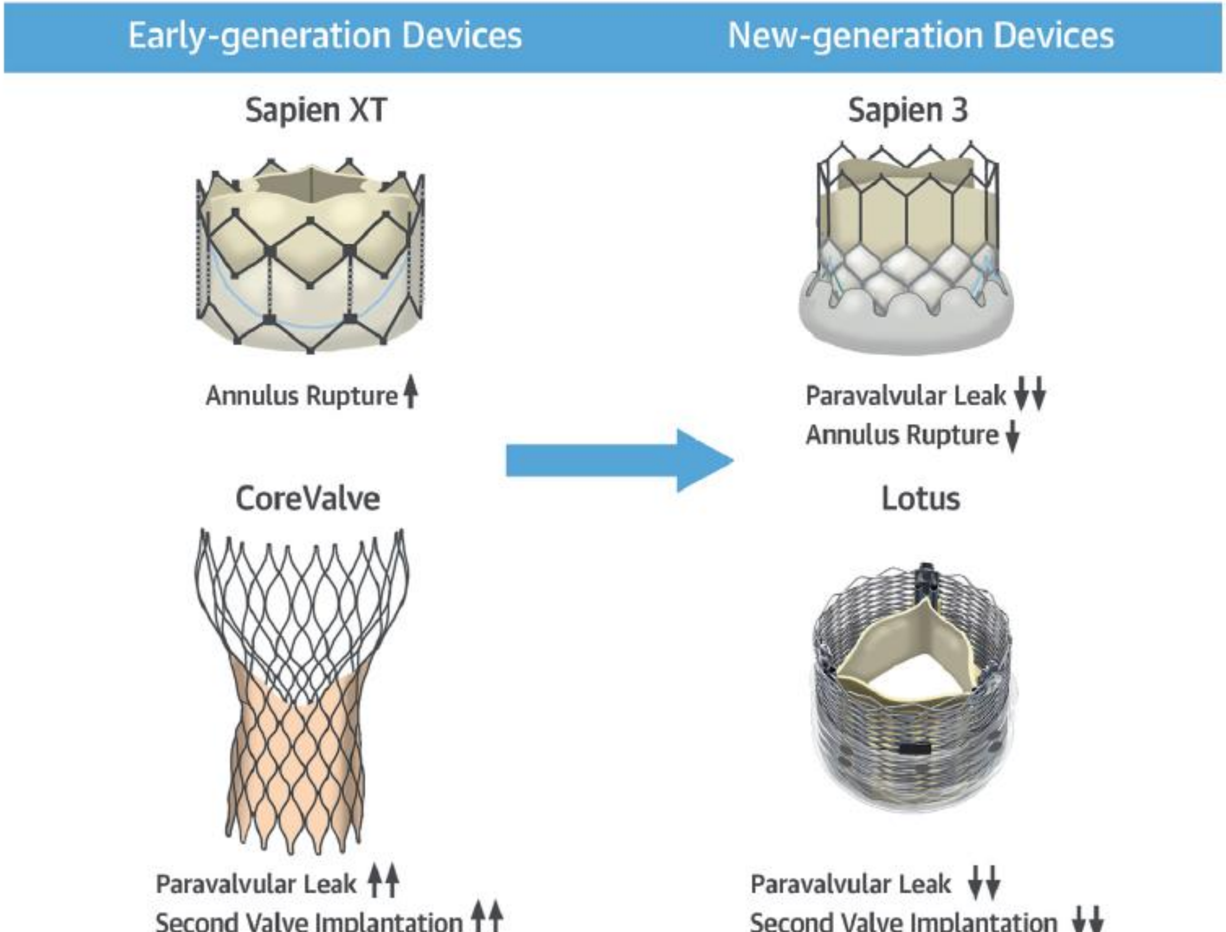
Complications according to Devices



Yoon SH, JACC 2016;68:1195

Severanc

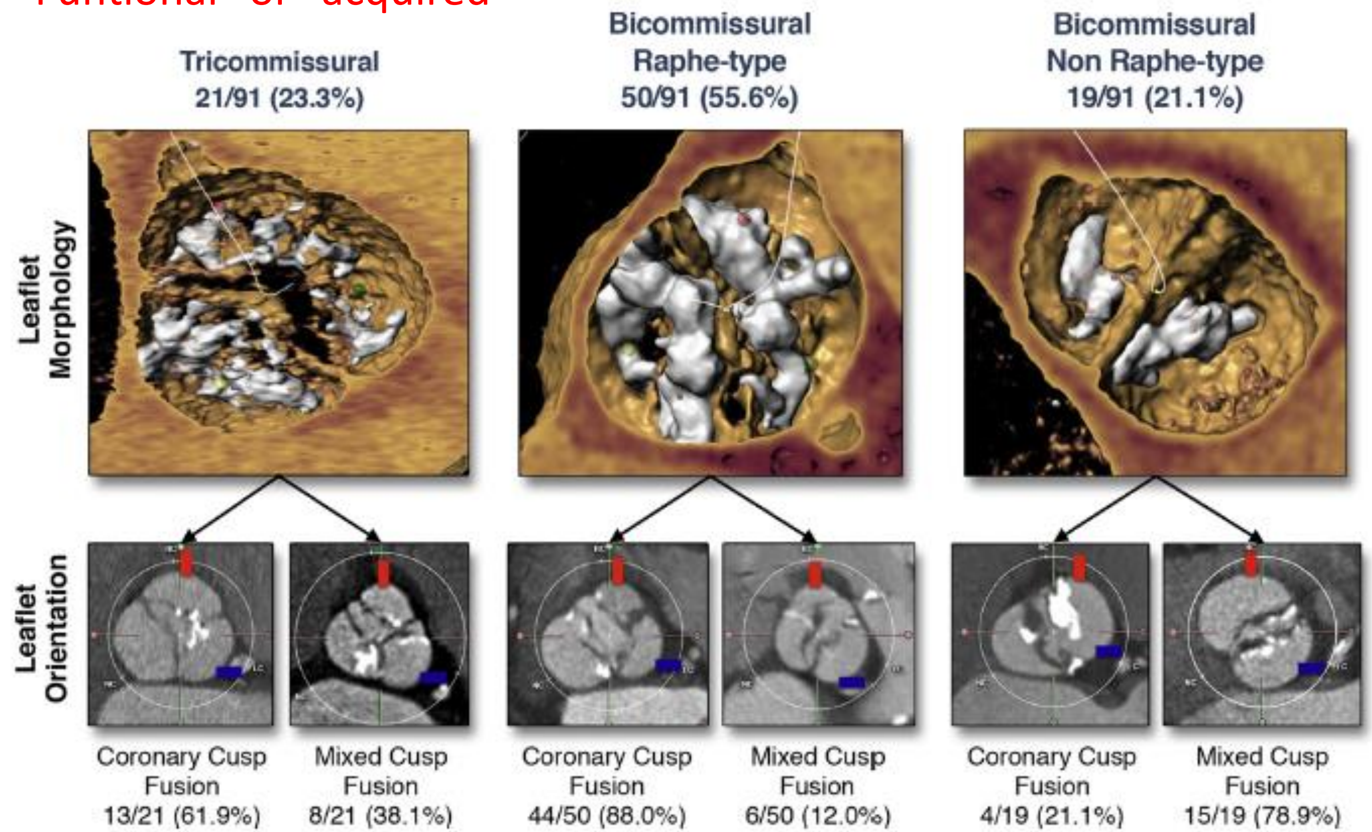
Improvement of Devices



Yoon SH, JACC 2016;68:1195

New Classification in TAVI Era

“Funtional” or “acquired”



Jilaihawi, H, JACC Img 2016;9:1145

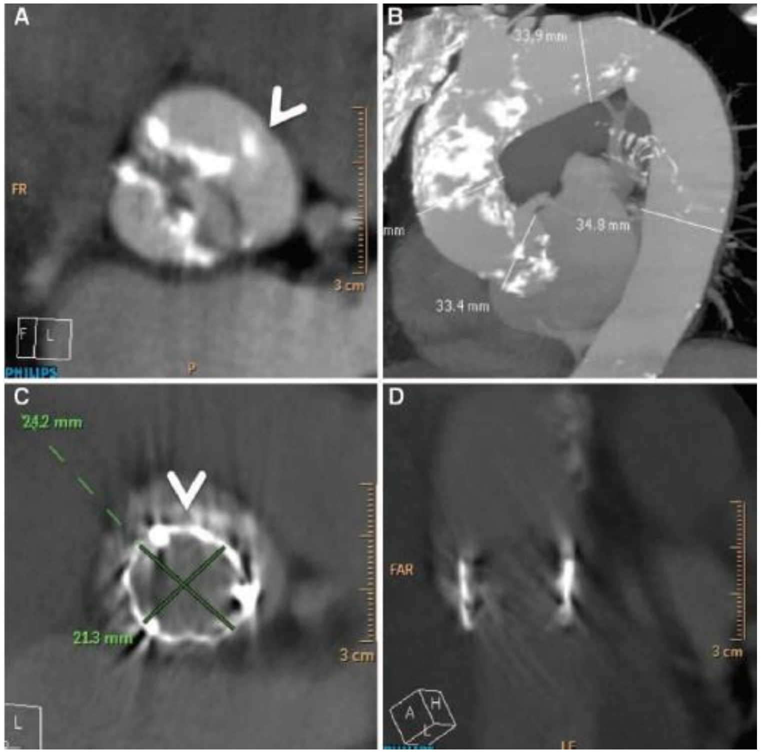
TAVI Outcomes according to BAV Types

	Tricommissural* BAV (n = 24)	Bicommissural* BAV (n = 99)	p Value	Bicommissural Non-Raphe Subtype (n = 21)	Bicommissural Raphe Subtype (n = 74)	p Value
Procedural outcomes						
Procedural death	0/24 (0)	2/99 (2.0)	>0.99	2/21 (9.5)	0/74 (0)	**0.047**
Prosthesis embolization	0/24 (0)	2/99 (2.0)	>0.99	0/21 (0)	2/74 (2.7)	>0.99
Transcatheter-valve-in-transcatheter-valve	0/24 (0)	4/99 (4.0)	>0.99	2/21 (9.5)	2/74 (2.7)	0.21
Tamponade	1/24 (4.2)	2/98 (2.0)	0.49	1/21 (4.8)	1/73 (1.4)	0.40
Aortic root injury	0/24 (0)	2/98 (2.0)	>0.99	1/21 (4.8)	1/73 (1.4)	0.40
Coronary compromise	0 (0)	0 (0)	>0.99	0/21 (0)	0/73 (0)	>0.99
Conversion to surgery	1/24 (4.2)	2/98 (2.0)	0.49	1/21 (4.8)	1/73 (1.4)	0.40
Balloon post-dilation	3/24 (12.5)	21/97 (21.6)	0.40	4/21 (19.0)	16/72 (22.2)	>0.99
Pre-discharge TTE			0.48			0.57
Paravalvular AR grade						
None/Trace	9/21 (42.9)	31/96 (32.3)		8/20 (40.0)	23/72 (31.9)	
Mild	8/21 (38.1)	48/96 (50.0)		9/20 (45.0)	35/72 (48.6)	
Moderate	4/21 (19.0)	13/96 (13.5)		2/20 (10.0)	11/72 (15.3)	
Severe	0/21 (0)	4/96 (4.2)		1/20 (5.0)	3/72 (4.2)	
Mean AV gradient	8 (7-13)	10 (7.4-13)		10 (7-14)	9.5 (7.8-13)	>0.99
30-day outcomes						
Death	1/24 (4.2)	4/99 (4.0)	>0.99	2/21 (9.5)	2/74 (2.7)	0.21
Cerebrovascular event	1/24 (4.2)	3/96 (3.1)	>0.99	0/20 (0)	3/72 (4.2)	0.39
Acute kidney injury ≥ stage 3	0/24 (0)	1/83 (1.2)	>0.99	0/19 (0)	1/63 (1.6)	>0.99
New permanent pacemaker	5/19 (26.3)	21/81 (25.9)	>0.99	4/18 (22.2)	16/60 (26.7)	>0.99

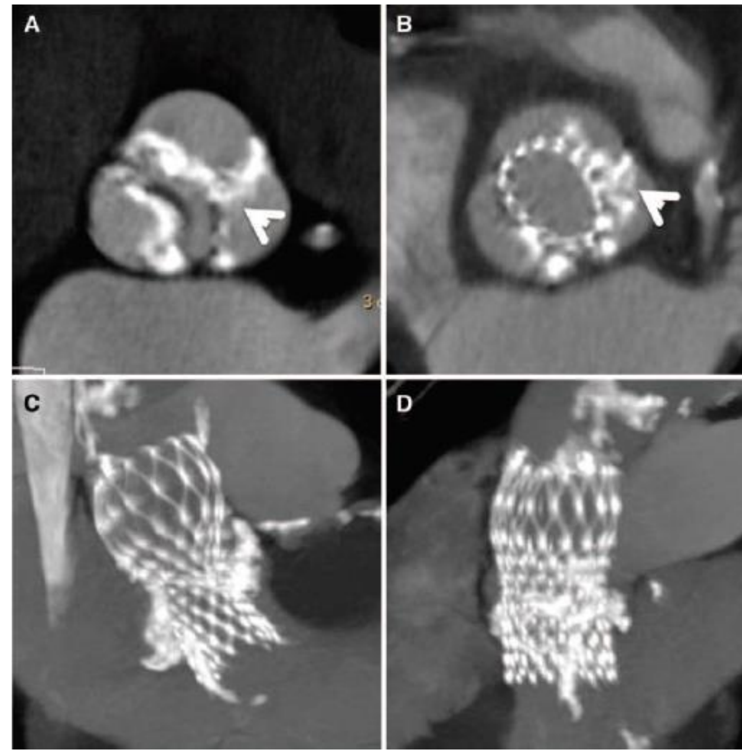
Jilaihawi, H, JACC Img 2016;9:1145

BEV vs SEV for TAVI in BAV

Balloon-expanding valve



Self-expanding valve



Hayashida K, Circ Cardiovasc Interv. 2013;6:284

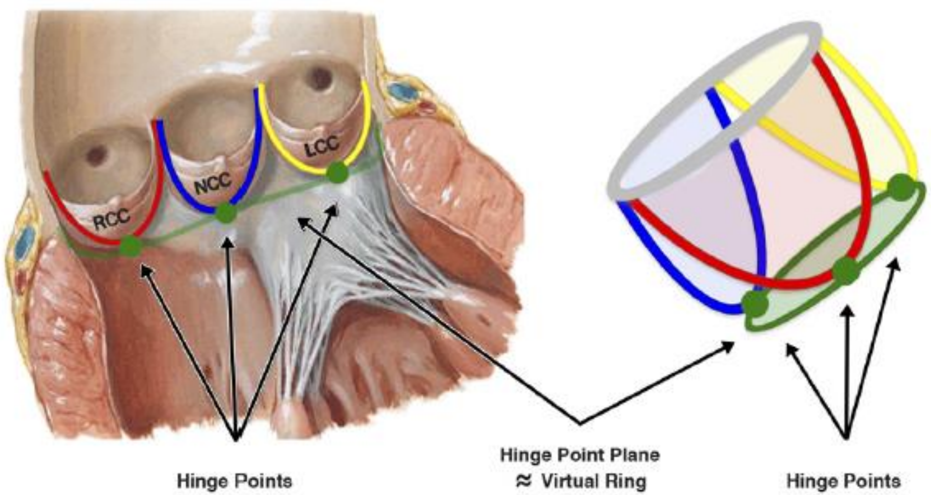
TAVI Outcomes according to Valve Types and Pre-procedural CT

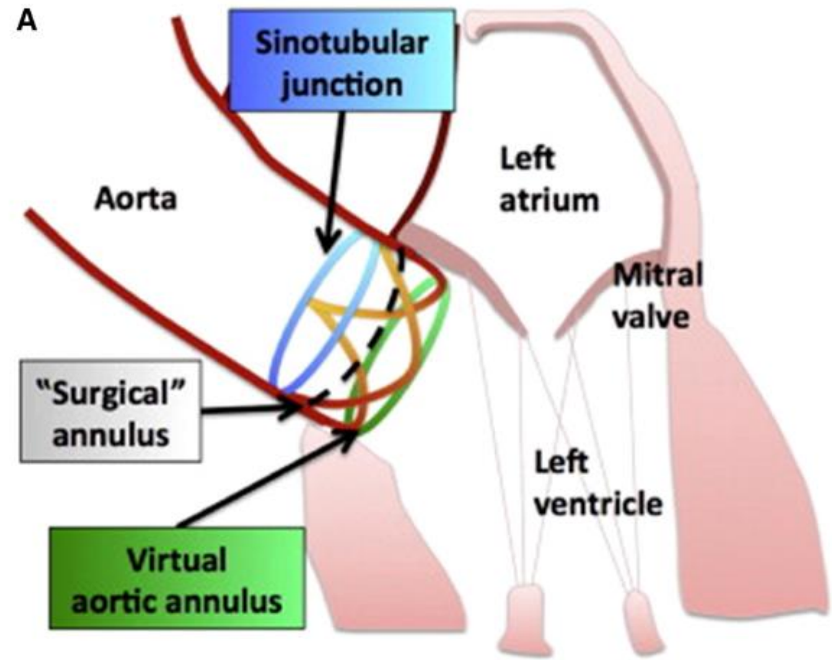
	BAV TAVR (n = 130)	BE TAVR (n = 70)	SE TAVR (n = 60)	p Value	No Pre-Procedural CT* (n = 50)	Pre-Procedural CT* (n = 80)	p Value
Procedural Outcomes							
Procedural death	2/130 (1.5)	1/70 (1.4)	1/60 (1.7)	>0.99	2/50 (4.0)	2/80 (2.5)	0.64
Prosthesis embolization	2/130 (1.5)	2/70 (2.9)	0/60 (0)	0.5	1/50 (2.0)	1/80 (1.3)	>0.99
Transcatheter-valve-in-transcatheter-valve	4/130 (3.1)	1/70 (1.4)	3/60 (5.4)	0.34	2/50 (4.0)	2/80 (2.5)	0.64
Tamponade	3/129 (2.3)	2/69 (2.9)	1/60 (1.7)	>0.99	0/50 (0)	3/80 (3.8)	0.29
Aortic root injury	3/129 (2.3)	3/69 (4.3)	0/60 (0)	0.25	2/49 (4.1)	1/80 (1.3)	0.56
Coronary compromise	0/129 (0)	0/69 (0)	0/60	NA	0/49 (0)	0/80 (0)	NA
Conversion to surgery	4/129 (3.1)	2/69 (2.9)	2/60 (3.3)	>0.99	3/49 (6.1)	1/80 (1.3)	0.15
Balloon post-dilation	24/128 (18.8)	7/69 (10.1)	17/59 (28.8)	0.011	10/49 (20.4)	14/79 (17.7)	0.82
Pre-discharge TTE							
Paravalvular AR				0.27			0.003
None/Trace	43/127 (33.9)	24/68 (35.3)	19/59 (32.2)		9/49 (18.4)	34/78 (43.6)	
Mild	61/127 (48.0)	28/68 (41.2)	33/59 (55.9)		26/49 (53.1)	35/78 (44.9)	
Moderate	19/127 (15.0)	13/68 (19.1)	6/59 (10.2)		10/49 (20.4)	9/78 (11.5)	
Severe	4/127 (3.1)	3/68 (4.4)	1/59 (1.7)		4/49 (8.2)	0/78 (0)	
Mean AV gradient	9.3 (7.0-13.0)	10.0 (7.0-13.3)	9.0 (7.0-13.0)	0.58	10.7 (7.0-13.0)	9.0 (7.0-13.0)	0.43
30-day outcomes							
Death	5/130 (3.8)	2/70 (2.9)	3/60 (5.0)	0.66	2/50 (4.0)	3/80 (3.8)	>0.99
Cerebrovascular event	4/127 (3.2)	3/67 (4.5)	1/60 (1.7)	0.3	0/49 (0)	4/78 (5.1)	0.27
Acute kidney injury ≥ stage 3	1/114 (0.9)	1/68 (1.5)	0/46 (0)	>0.99	0/35 (0)	1/79 (1.3)	>0.99
New permanent pacemaker	28/107 (26.2)	14/55 (25.5)	14/52 (26.9)	0.83	10/43 (23.3)	18/64 (28.1)	0.66

Jilaihawi, H, JACC Img 2016;9:1145

Virtual Annulus

virtual ring formed by the basal attachments of the aortic valve cusps located at the base of the crown.



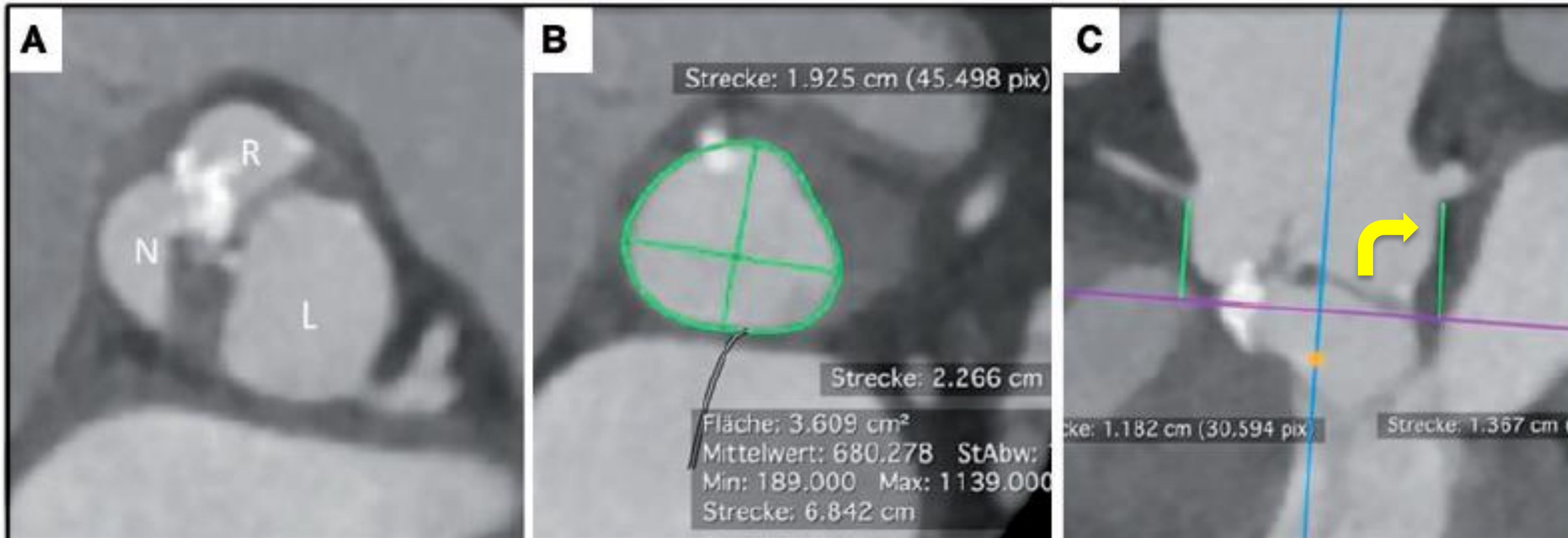


CT Images of Biscupid AV

Type 1 BAV

Difficult 3D alignment in cases of Type 0

Cusps are longer in BAV



EHJ 2017;38:1177

How to determine the valve size?

Tricuspid valve | **Bicuspid valve**

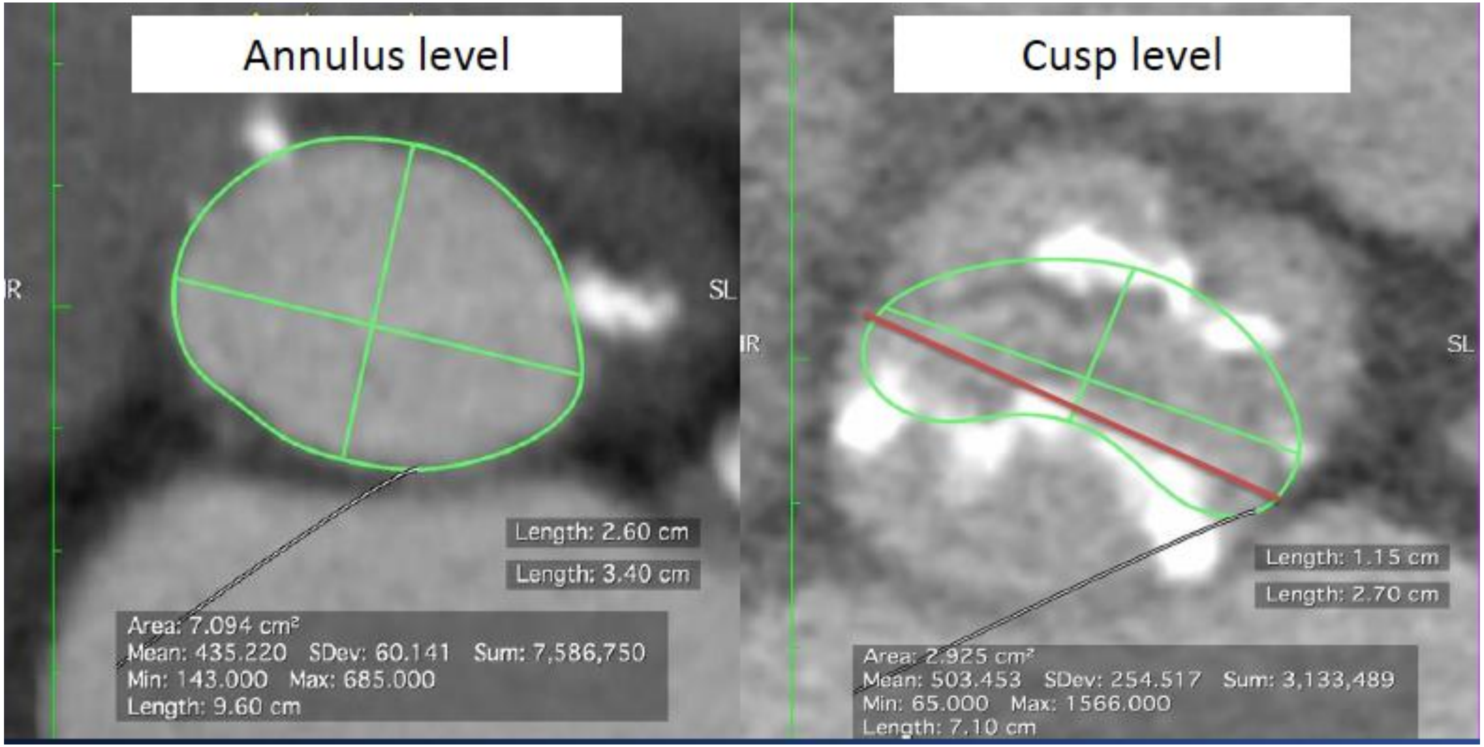


Image from TCT 2016 presentation, Lars Sondergaard

Post-procedural CT

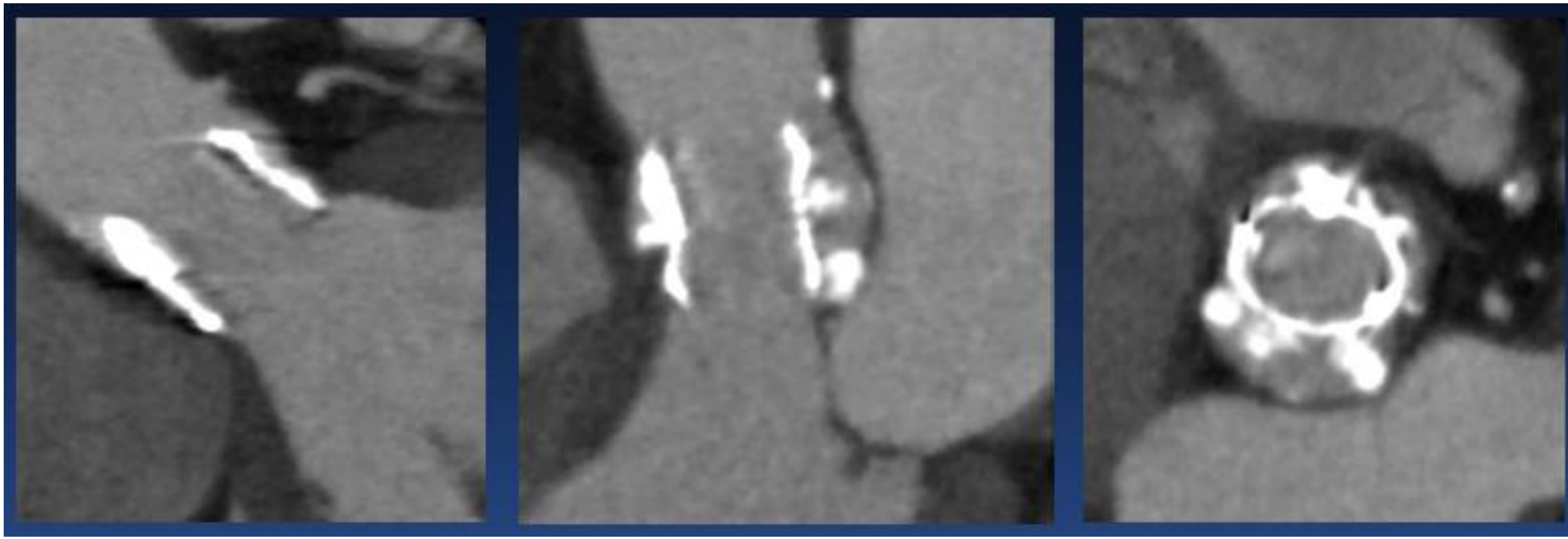
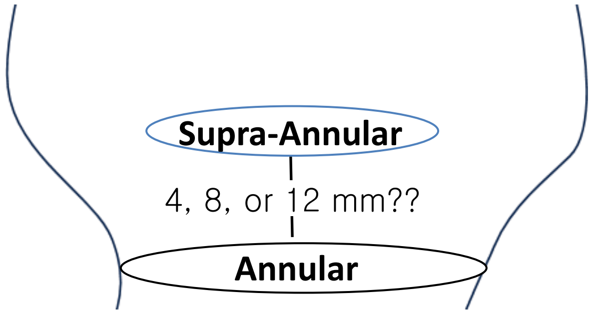


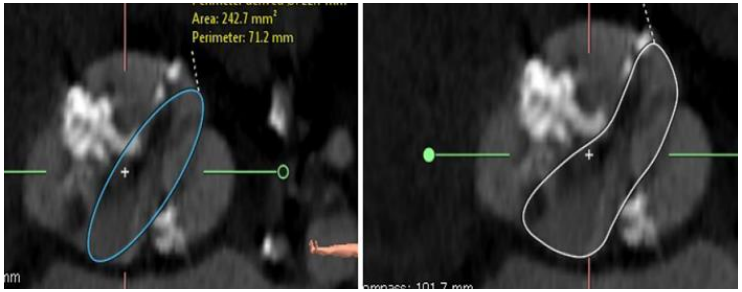
Image from TCT 2016 presentation, Lars Sondergaard

Bicuspid AV: TAV Sizing

Which height to measure??



Which tool to define the perimeter??



Mount Everest

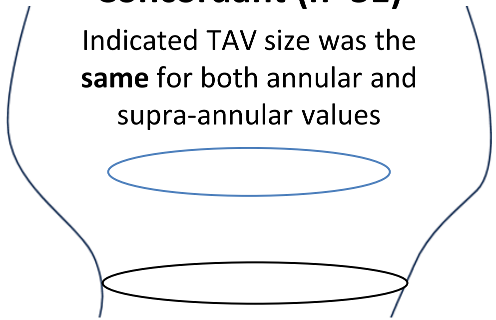
Presentaton by Nicolo Piazza

Bicuspid TAV sizing

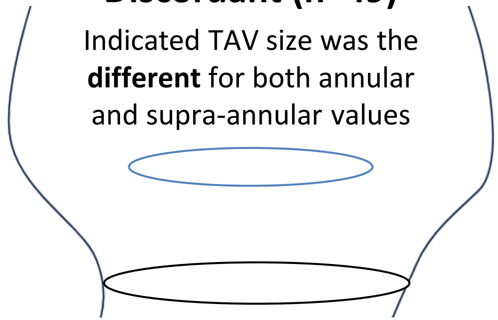
MEDTRONIC CLINICAL DATA ANALYSIS

- BIDMC core lab measured each patient at the annular and supra-annular levels
  - The annular measurement was based on basal plane perimeter
  - The supra-annular measurement was taken four mm above the annulus using the intercommissural long axis and standard ellipse tool with a fixed relationship
- The indicated TAV size for both measurements was compared and patients were categorized into two groups:

Concordant (n=31)



Discordant (n=49)

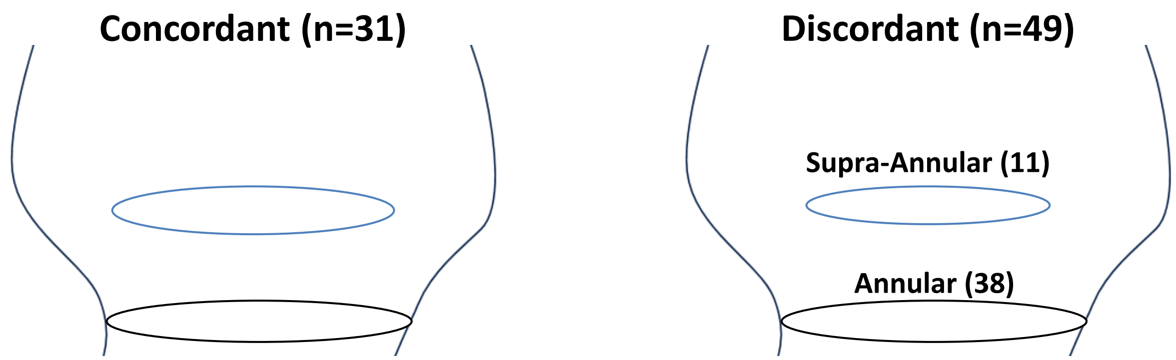


Bicuspid TAV sizing

MEDTRONIC CLINICAL DATA ANALYSIS

Discordant measures were then compared to the TAV size selected for implantation and divided into two groups:

- Annular: the implanted TAV size corresponded to the annular indicated TAV
- Supra-annular: the implanted TAV size corresponded to the supra-annular indicated TAV



Medtronic Clinical Data Analysis

30-DAY RESULTS – ALL TAVS (N=80)

Clinical results indicate that bicuspid sizing methodology appears to be a balance between a risk of PVL and need for multiple valves:

PVL > Mild	Sizing Method (80)	> 1 Valve
3 (27.3%)	← Supra-Annular (11) →	1 (9.1%)
2 (3.3%)	Concordant (31)	2 (6.5%)
3 (7.9%)	← Annular (38) →	9 (23.7%)

- TAVs corresponding to supra-annular sizing had higher rates of PVL > mild (27.3%) versus lower multiple valve use (9.1%)
- TAVs corresponding to annular sizing showed a greater risk for multiple valve use (23.7%) but lower rates of PVL > mild (7.9%)
- Best PVL and multiple valve performance occurred when both annular and supra-annular measurements indicated the same valve size (measurements were concordant)

Medtronic Clinical Data Analysis

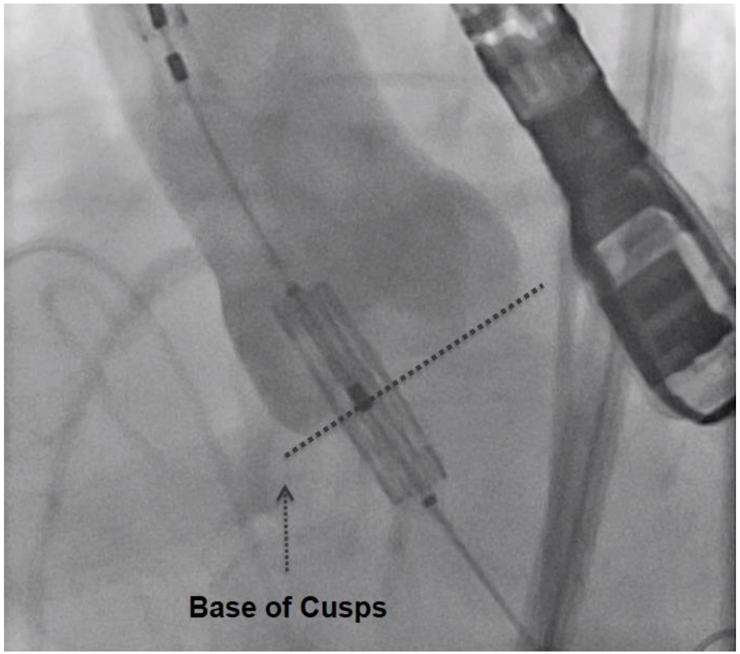
COREVALVE VS. EVOLUT R TAVS

- CoreValve TAVs demonstrate a high risk of PVL > mild and use of multiple valves across all corresponding measurements
- Evolut R TAVs show a high risk of PVL > mild only with supra-annular sizing and reduced risk of multiple valve use compared to CoreValve across all measurement categories

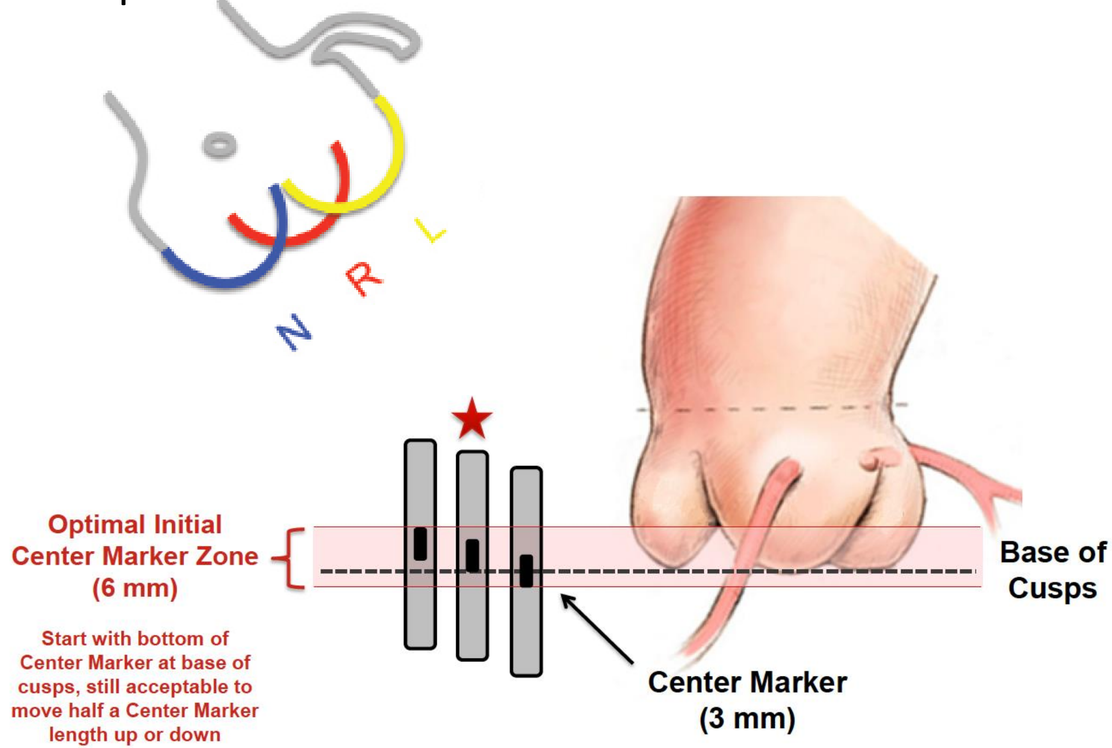
PVL > Mild			> 1 Valve	
Evolut R (15)	CoreValve(65)	**Sizing Method (80)**	CoreValve (65)	Evolut R (15)
1/3 (33.3%)	2/8 (25%)	**← Supra-Annular (11)→**	1/8 (12.5%)	0/3
0/6	2/25 (8%)	**Concordant (31)**	3/25 (12%)	0/6
0/6	3/32 (9.4%)	**← Annular (38) →**	8/32 (25%)	1/6 (16.7%)

Given the reduction in multiple valve use and effective PVL performance with the Evolut R System when sizing the TAV to the annulus, annular sizing may be preferential to supra-annular sizing in ***most*** bicuspid cases.

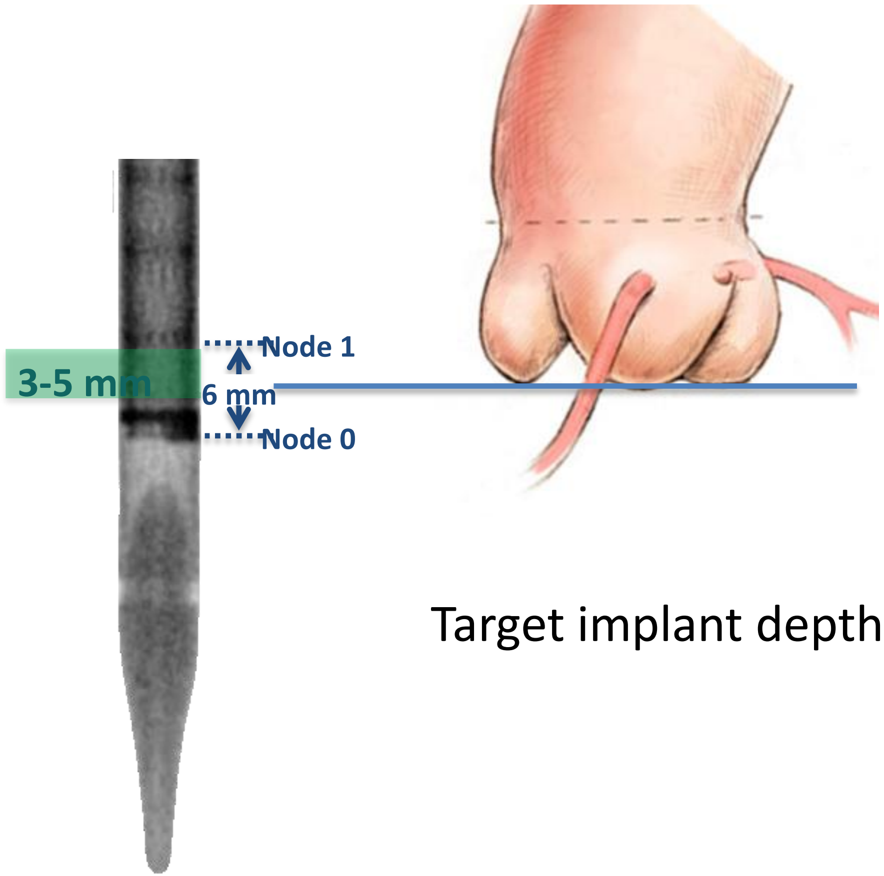
Sapien Valve Positioning for TAV



Coplanar view



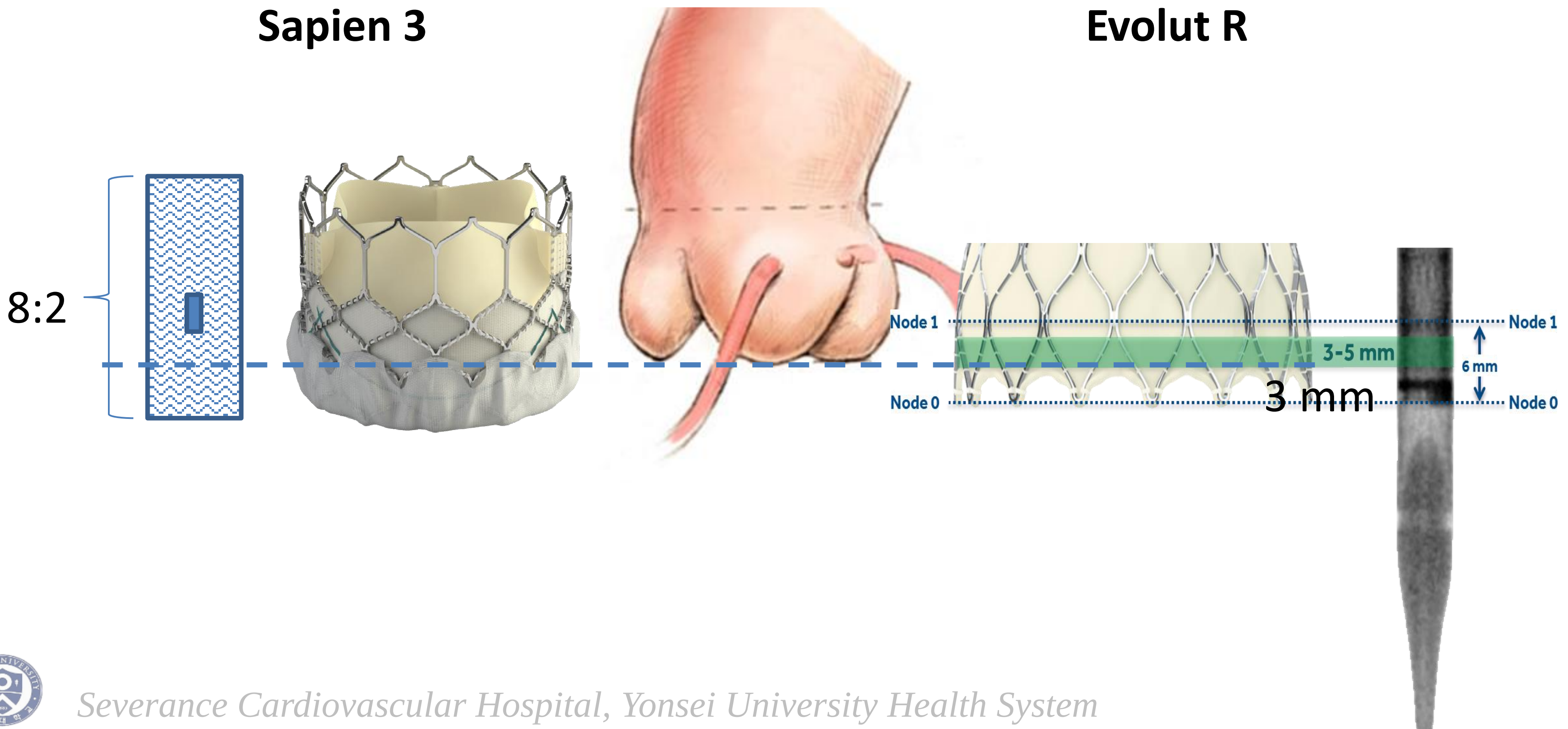
Evolut R: Implantation Depth for TAV



Target implant depth is **3 - 5 mm**

Target Implantation Depth for BAV

Slightly higher than in cases of TAV



Balloon Sizing Method

BAV with Aortopathy

Class IIa

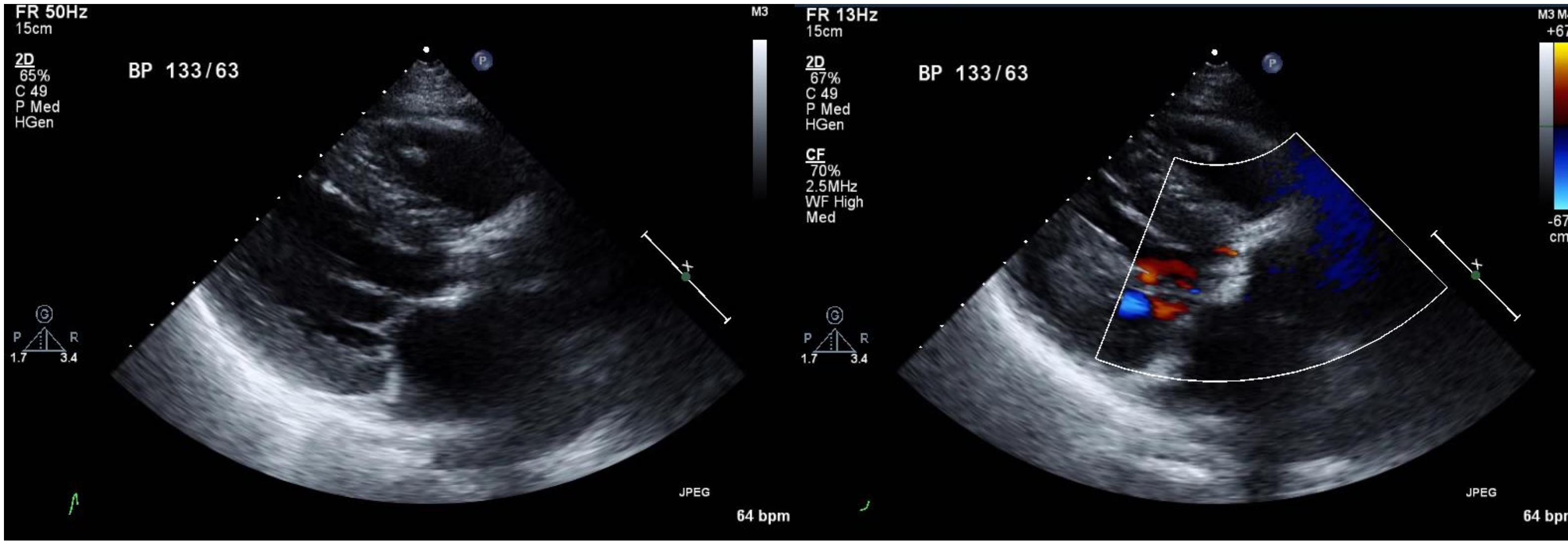
- Replacement of the ascending aorta is reasonable in patients with a bicuspid aortic valve who are undergoing aortic valve surgery because of severe AS or AR if the diameter of the ascending aorta is greater than 4.5 cm. (Level of Evidence: C)

2014, 2017 ACC/AHA Guidelines

F/86 (WGN,#2571096)

- CC : DOE (NYHA II)
- 150 cm / 39 Kg / BSA 1.27 m^2
- Comorbidities: None
- Euroscore II: 3.98 %
- STS score: 3.991 %

TTE



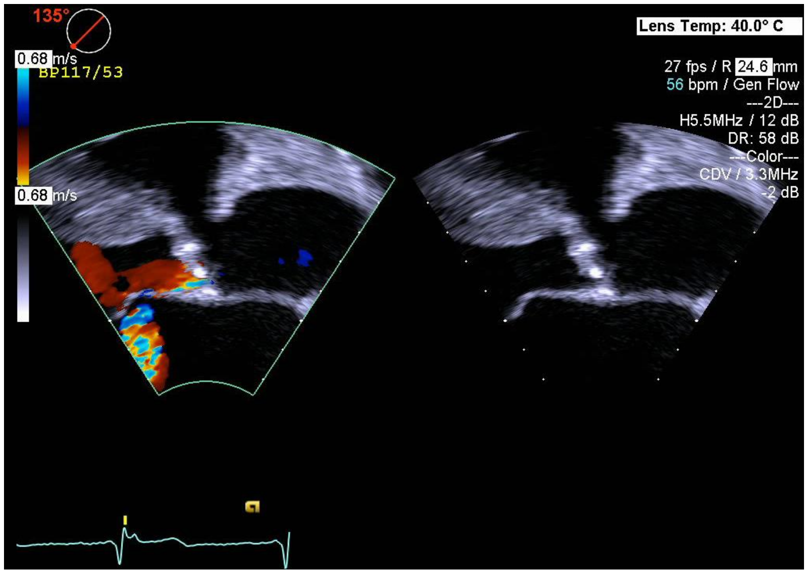
Severe AS (AVA: 0.36 cm^2 by C.E.) d/t heavy calcification

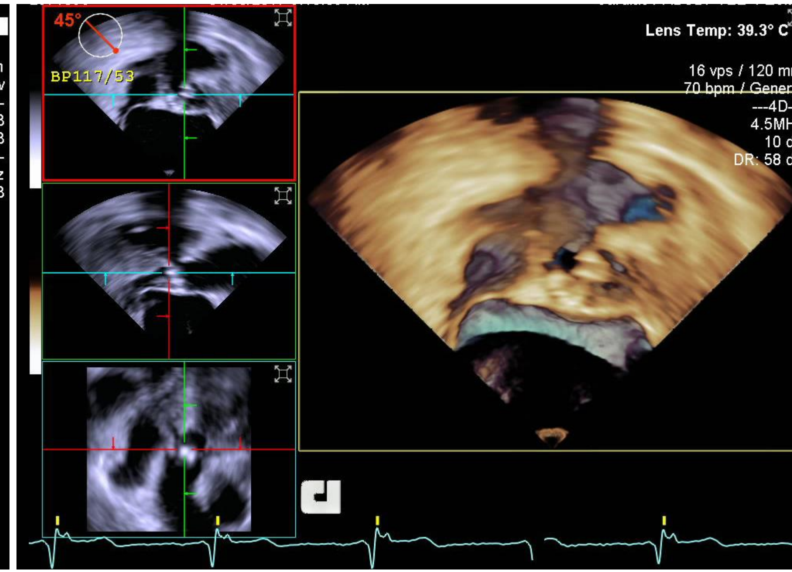
Eccentric AR (GI) with dilated ascending aorta (41mm)

LVEF: 66%, LVEDD/ESD: 41/27 mm

Concentric LVH (LVMI : 168g/m2)

TEE

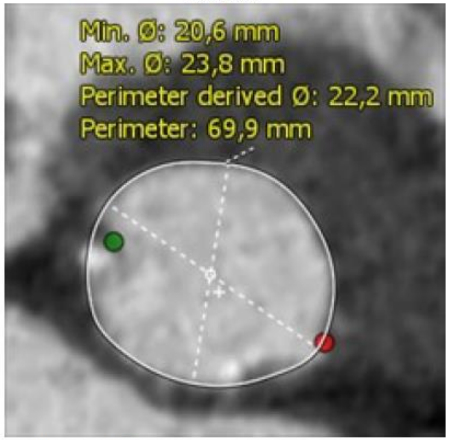




Severe AS (AVA : 0.43 cm2 by 2D) & Mild AR (GI)
due to heavy calcified aortic valves

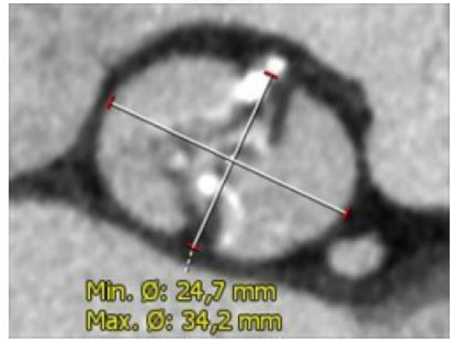
CT analysis

ANNULUS



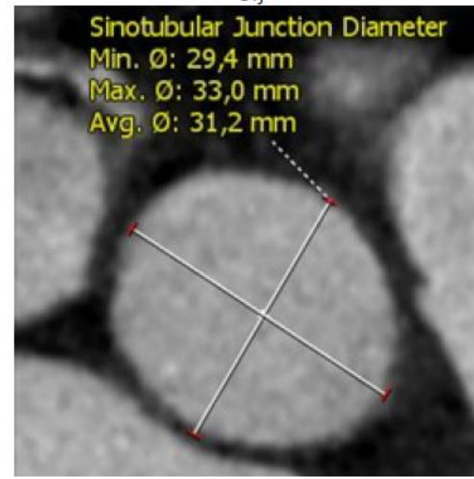
Cardiac phase 30%

SOV DIAMETER

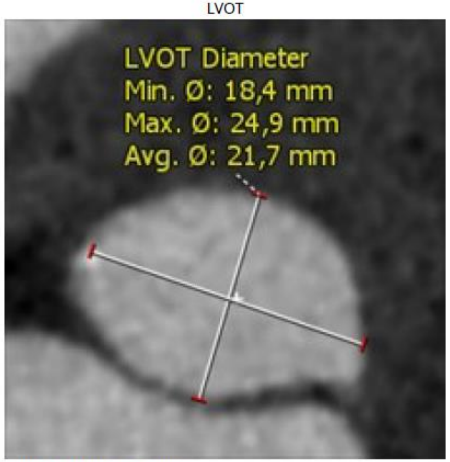


In Systole (Cardiac phase 30%)

STJ

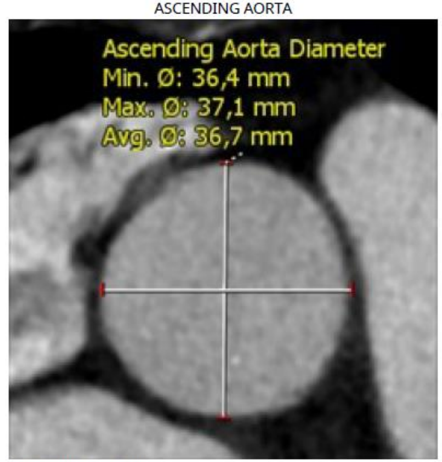


LVOT



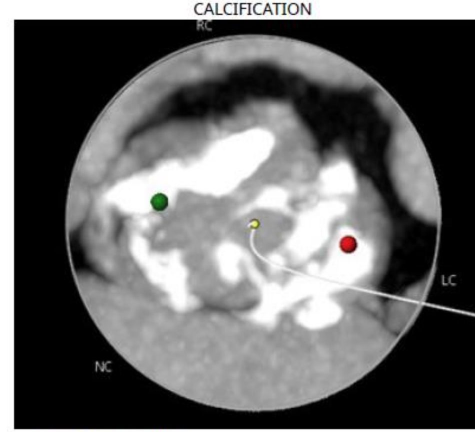
5mm below basal plane

ASCENDING AORTA



40mm above basal plane

AORTIC VALVE CALCIFICATION



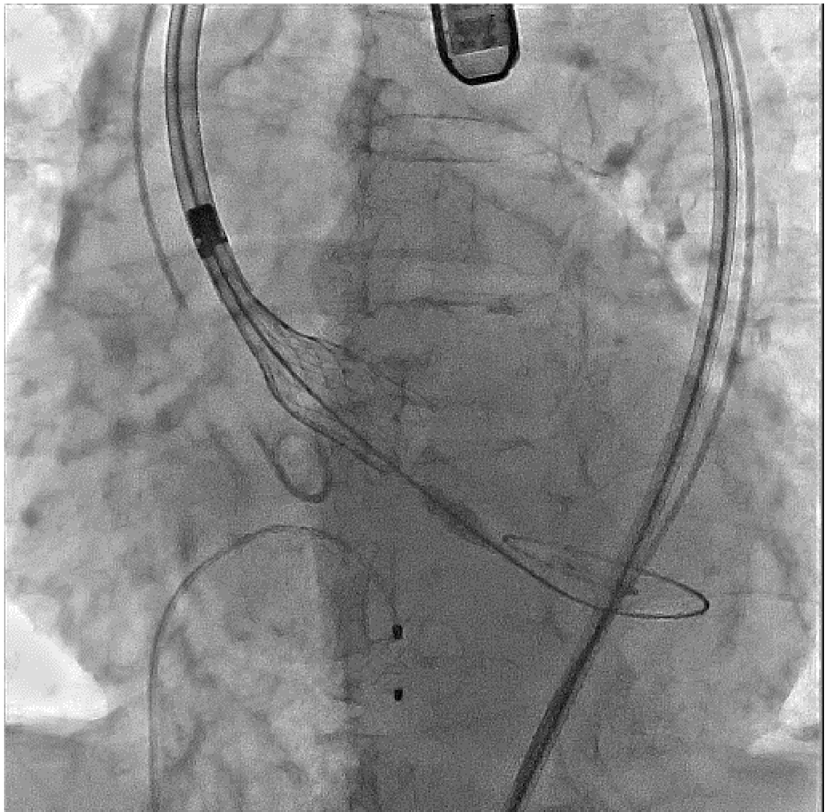
Severe calcified leaflets

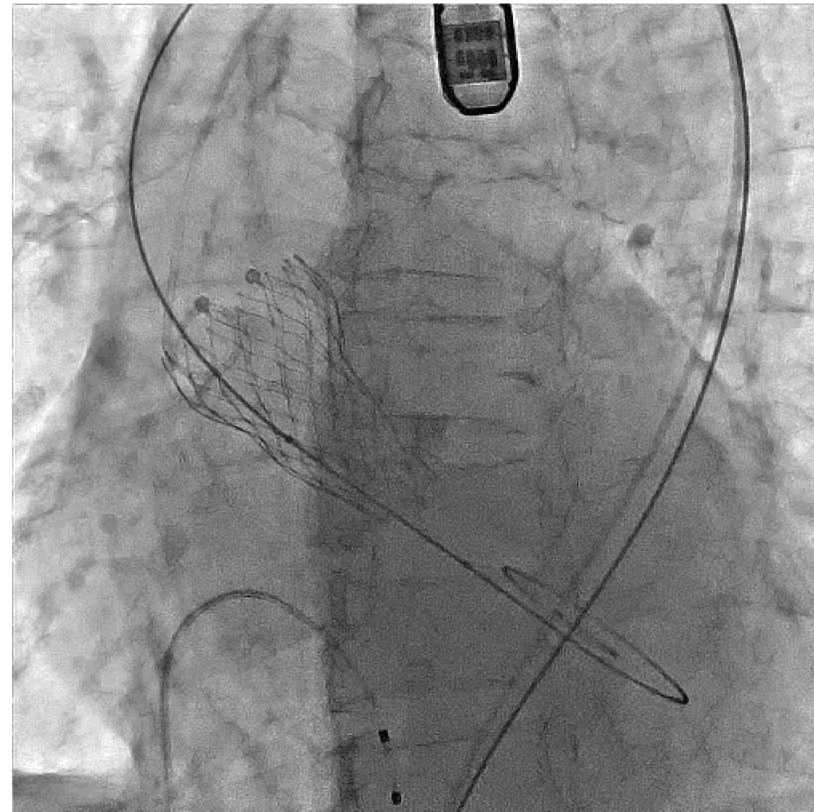
Evolut R

Annular Perimeter 69.9 mm

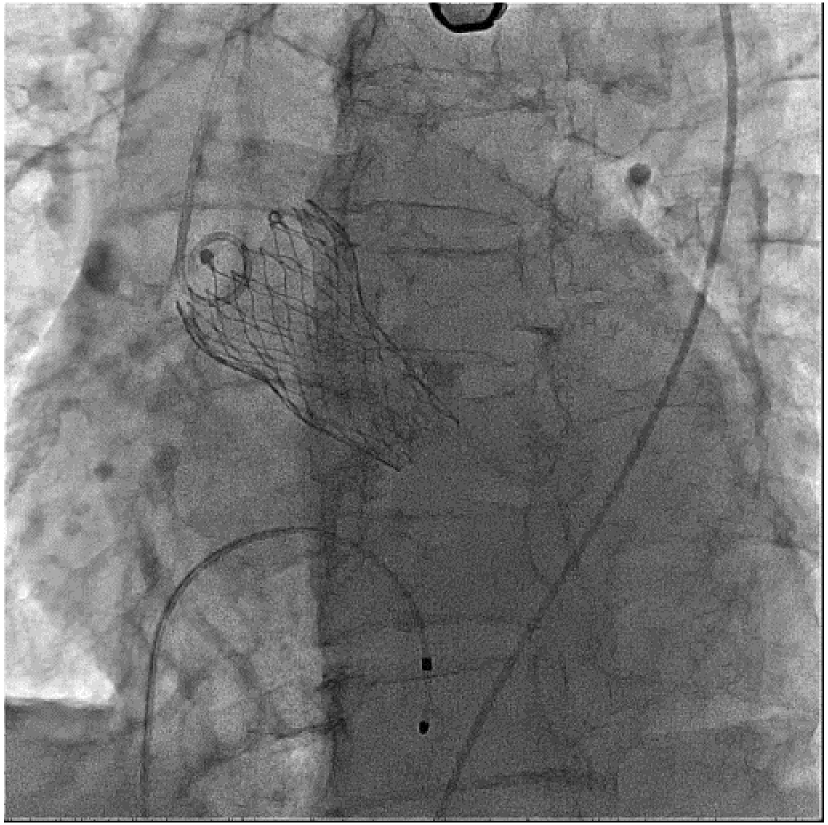
Valve Size Selection	CoreValve® Evolut® R			
				
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter	18-20 mm	20-23 mm	23-26 mm	26-30 mm
Annulus Perimeter†	56.5-62.8 mm	62.8-72.3 mm	72.3-81.7 mm	81.7-94.2 mm
Sinus of Valsalva Diameter (Mean)	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva Height (Mean)	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm

TAVI

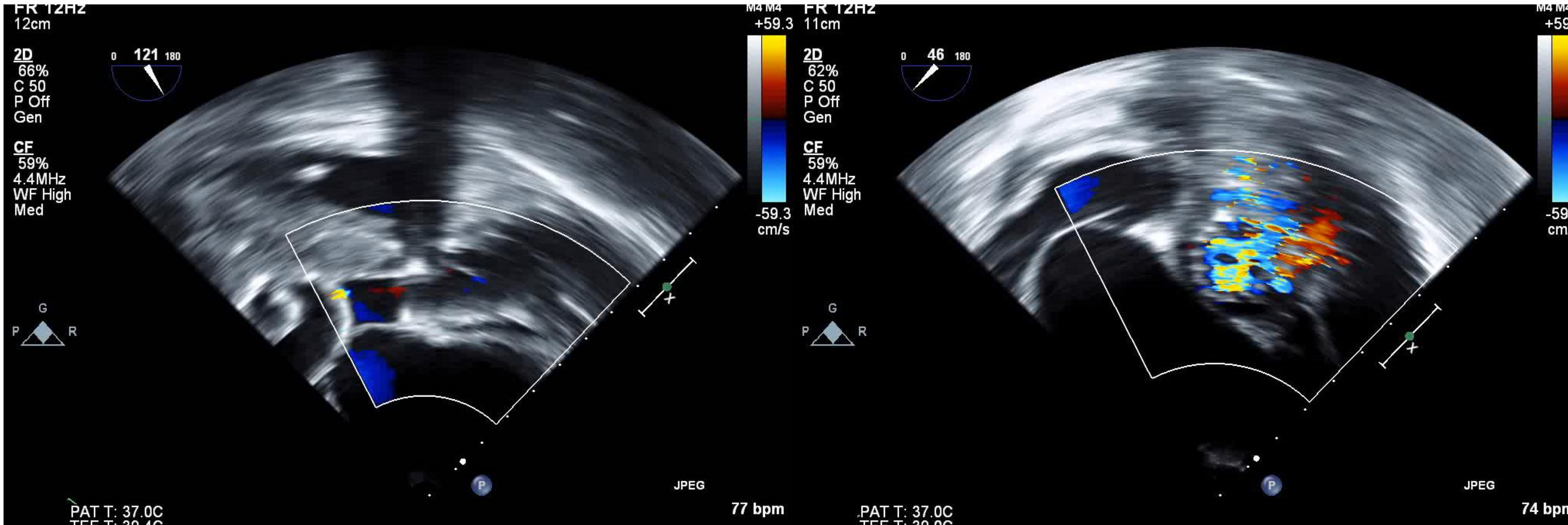




Final



Post-TAVI TEE



Take Home Messages

- TAVI for Bicuspid AV is challenging because of asymmetric annulus morphology, combined severe calcifications, and difficulties with CT measurement and implantation imaging guidance.
- However, with technically improved valve devices, device success rate is increased and complications are reduced.
- With new generation devices, there are no significant differences in TAVI outcomes between TAV and BAV
- For safe and successful TAVI in bicuspid AV, detailed review of preprocedural imaging studies and planning is essential.

Thank you
for your attention!