Aortic regurgitation remains off-limits for TAVI?
CON

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Disclosures

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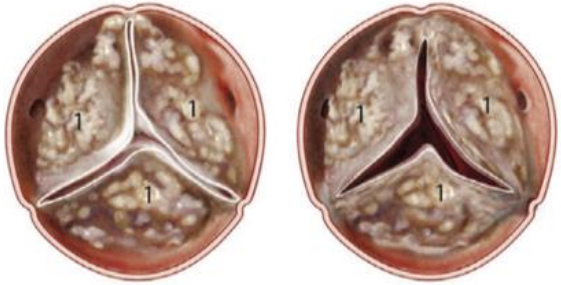
Challenges of TAVR in pure AR

Franzone, JACC 2016

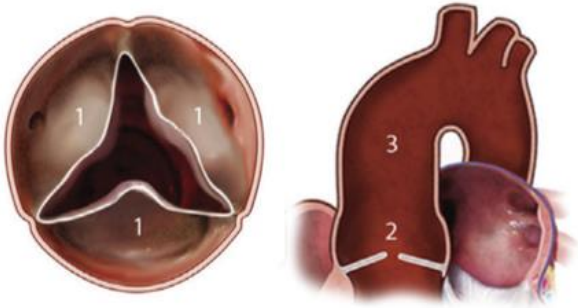
Calcific Aortic Valve Stenosis

1- Nodular calcific deposits on aortic side



Aortic Valve Regurgitation

1- Minimal or absent cusp calcification
2- Dilated aortic root
3- Frequent coexistence of dilated ascending aorta



Technical Challenges of TAVR in Aortic Valve Regurgitation

- Suboptimal Fluoroscopic Visualization of the Native Valve
- Insufficient Anchoring and Sealing of the Transcatheter Device
  - Risk of Misplacement and Migration of the Device
  - Risk of Residual Valvular Regurgitation
  - Permanent pacemaker

Transcatheter Aortic Valve Replacement in Pure Native Aortic Valve Regurgitation

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JACC 2017

TAVR in in Pure Native Aortic Valve Regurgitation

40 centres, 331 patients between 2007 and 2017

	Overall (N = 331)	Early-Generation Devices (n = 119)	New-Generation Devices (n = 212)
Device type			
Sapien XT	9 (2.7)	9 (7.6)	–
Sapien 3	41 (12.4)	–	41 (19.3)
CoreValve	110 (33.2)	110 (92.4)	–
Evolut R	50 (15.1)	–	50 (23.6)
JenaValve	64 (19.3)	–	64 (30.2)
Direct Flow	35 (10.6)	–	35 (16.5)
J-Valve	1 (0.3)	–	1 (0.5)
Engager	7 (2.1)	–	7 (3.3)
Portico	3 (0.9)	–	3 (1.4)
Acurate	5 (1.5)	–	5 (2.4)
Lotus	6 (1.8)	–	6 (2.8)

Early-Generation (n=119):
CoreValve (92%)
Sapien XT (8%)

New-Generation (n=212):
JenaValve (30%)
EvolutR (24%)
Sapien 3 (19%)
Direct Flow (17%)
Lotus, Acurate, Portico

Yoon, JACC 201

TAVR in in Pure Native Aortic Valve Regurgitation

Baseline characteristics

	Overall (N = 331)	Early-Generation Devices (n = 119)	New-Generation Devices (n = 212)	p Value
Age, yrs	74.4 ± 12.2	74.2 ± 13.1	74.5 ± 11.6	0.81
Female	159 (48.0)	51 (42.9)	108 (50.9)	0.16
NYHA functional class III or IV	293 (88.5)	107 (89.9)	186 (87.7)	0.55
STS score	6.7 ± 6.7	7.6 ± 6.7	6.2 ± 6.7	0.08
Euro SCORE II	9.8 ± 10.7	11.7 ± 12.9	8.9 ± 9.4	0.03
Creatinine, mg/dl	1.4 ± 1.0	1.5 ± 1.1	1.4 ± 1.0	0.48
Hypertension	255 (77.0)	88 (73.9)	167 (78.8)	0.32
Diabetes mellitus	43 (13.0)	22 (17.6)	22 (10.4)	0.06
Chronic pulmonary disease	98 (29.6)	28 (23.5)	70 (33.0)	0.07
Peripheral vascular disease	65 (19.6)	20 (16.8)	45 (21.2)	0.33
Prior cerebrovascular accident	33 (10.0)	8 (6.7)	25 (11.8)	0.14
Coronary artery disease	156 (47.1)	52 (43.7)	104 (49.1)	0.35
Prior myocardial infarction	72 (21.8)	23 (19.3)	49 (23.1)	0.42
Prior PCI	90 (27.2)	29 (24.4)	61 (28.8)	0.39
Prior CABG	49 (14.8)	20 (16.8)	29 (13.7)	0.44
Prior mitral valve surgery	29 (8.8)	7 (5.9)	22 (10.4)	0.17
Prior permanent pacemaker	51 (15.4)	22 (18.5)	29 (13.7)	0.25
Atrial fibrillation	115 (34.7)	36 (30.3)	79 (37.3)	0.20

Early-Generation:
CoreValve, Sapien XT

New-Generation:
JenaValve, EvolutR, Sapien 3, Direct Flow
Lotus, Acurate, Portico

Yoon, JACC 201

TAVR in in Pure Native Aortic Valve Regurgitation

Procedural characteristics

	Overall (N = 331)	Early-Generation Devices (n = 119)	New-Generation Devices (n = 212)	p Value
General anesthesia	192 (58.0)	58 (48.7)	134 (63.2)	0.01
Local anesthesia	139 (42.0)	58 (51.3)	78 (36.8)	0.01
Access site				
Transfemoral access	233 (70.4)	104 (87.4)	129 (60.8)	<0.001
Non-transfemoral access	98 (29.6)	15 (12.6)	83 (39.2)	<0.001
Transapical access	80 (24.2)	4 (3.4)	76 (35.8)	<0.001
Trans-subclavian access	10 (3.0)	4 (3.4)	6 (2.8)	0.79
Transaortic access	6 (1.8)	5 (4.2)	1 (0.5)	0.02
Transcarotid access	2 (0.6)	0 (0.0)	2 (1.7)	0.13
Procedure time, min	102.1 ± 65.6	89.8 ± 50.2	109.1 ± 72.1	0.047
Fluoroscopy time, min	22.2 ± 17.8	29.1 ± 23.2	18.4 ± 12.5	<0.001
Contrast agent, ml	162.2 ± 88.7	180.1 ± 95.2	150.9 ± 82.7	0.01
Balloon pre-dilation	26 (7.9)	7 (5.9)	19 (9.0)	0.32
Balloon post-dilation	47 (14.2)	23 (19.3)	24 (11.3)	0.045

Early-Generation:
CoreValve, Sapien XT

New-Generation:
JenaValve, EvolutR, Sapien 3, Direct Flow
Lotus, Acurate, Portico

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TAVR in in Pure Native Aortic Valve Regurgitation

Outcomes at 30 days

	Overall (N = 331)	Early-Generation Devices (n = 119)	New-Generation Devices (n = 212)	p Value
All-cause mortality	36 (10.9)	16 (13.4)	20 (9.4)	0.26
Cardiovascular mortality	32 (9.7)	14 (11.8)	16 (8.5)	0.33
Stroke	14 (4.2)	2 (1.7)	12 (5.7)	0.08
Bleeding	39 (11.8)	18 (15.1)	21 (9.9)	0.16
Major	25 (7.6)	12 (10.1)	13 (6.1)	0.19
Life-threatening	14 (4.2)	6 (5.0)	8 (3.8)	0.58
Major vascular complication	14 (4.2)	7 (5.9)	7 (3.3)	0.26
Acute kidney injury (stage 2 or 3)	27 (8.2)	14 (11.8)	13 (6.1)	0.07

Early-Generation:
CoreValve, Sapien XT

New-Generation:
JenaValve, EvolutR, Sapien 3, Direct Flow
Lotus, Acurate, Portico

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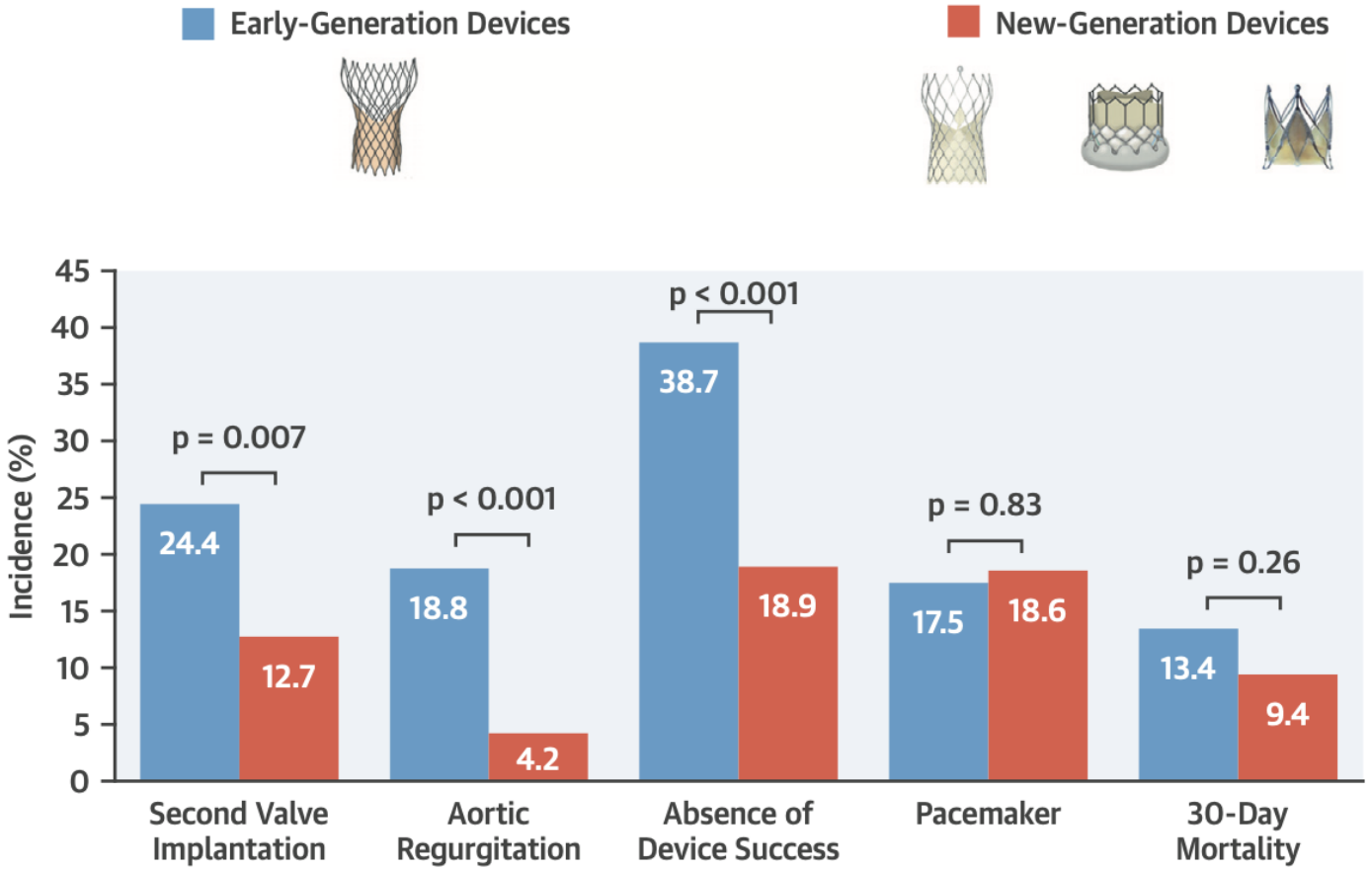
Outcomes According to Devices



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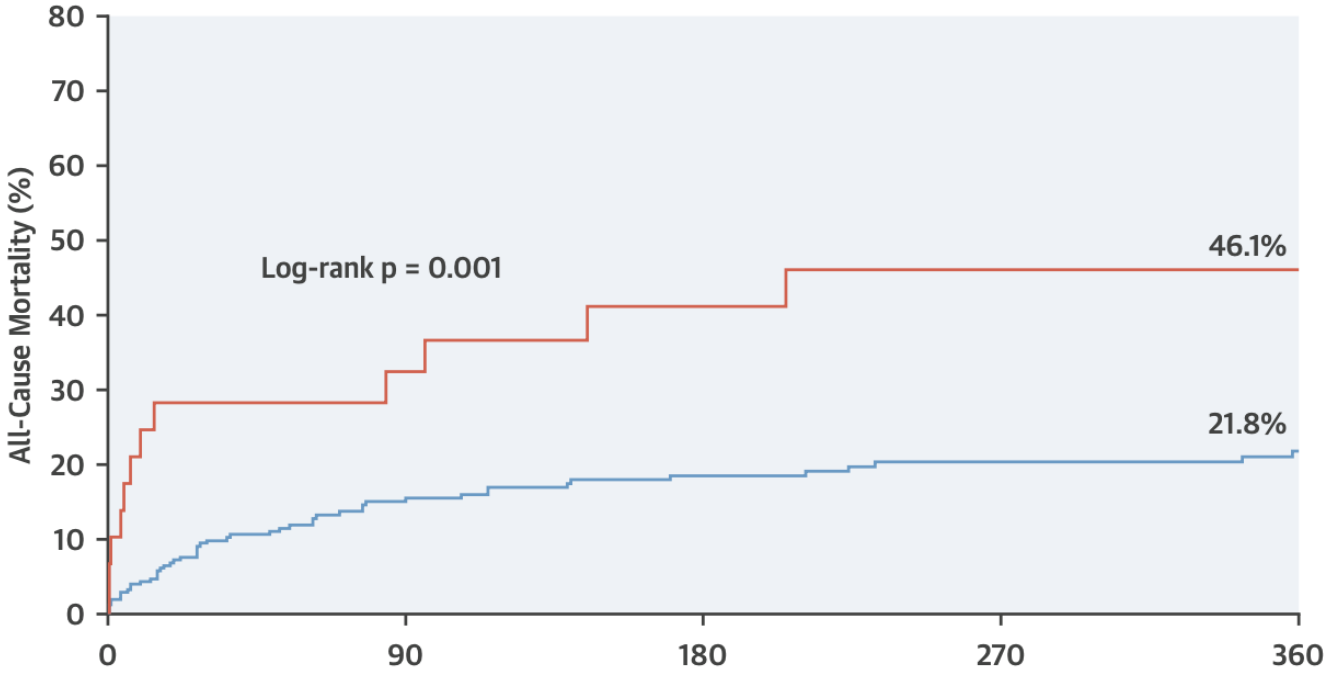
Mortality and Post-Procedural Aortic Regurgitation



No. at Risk			
AR ≤ mild	302	156	109
AR ≥ moderate	29	14	10

Post-Procedural AR ≥ Moderate

Post-Procedural AR ≤ Mild

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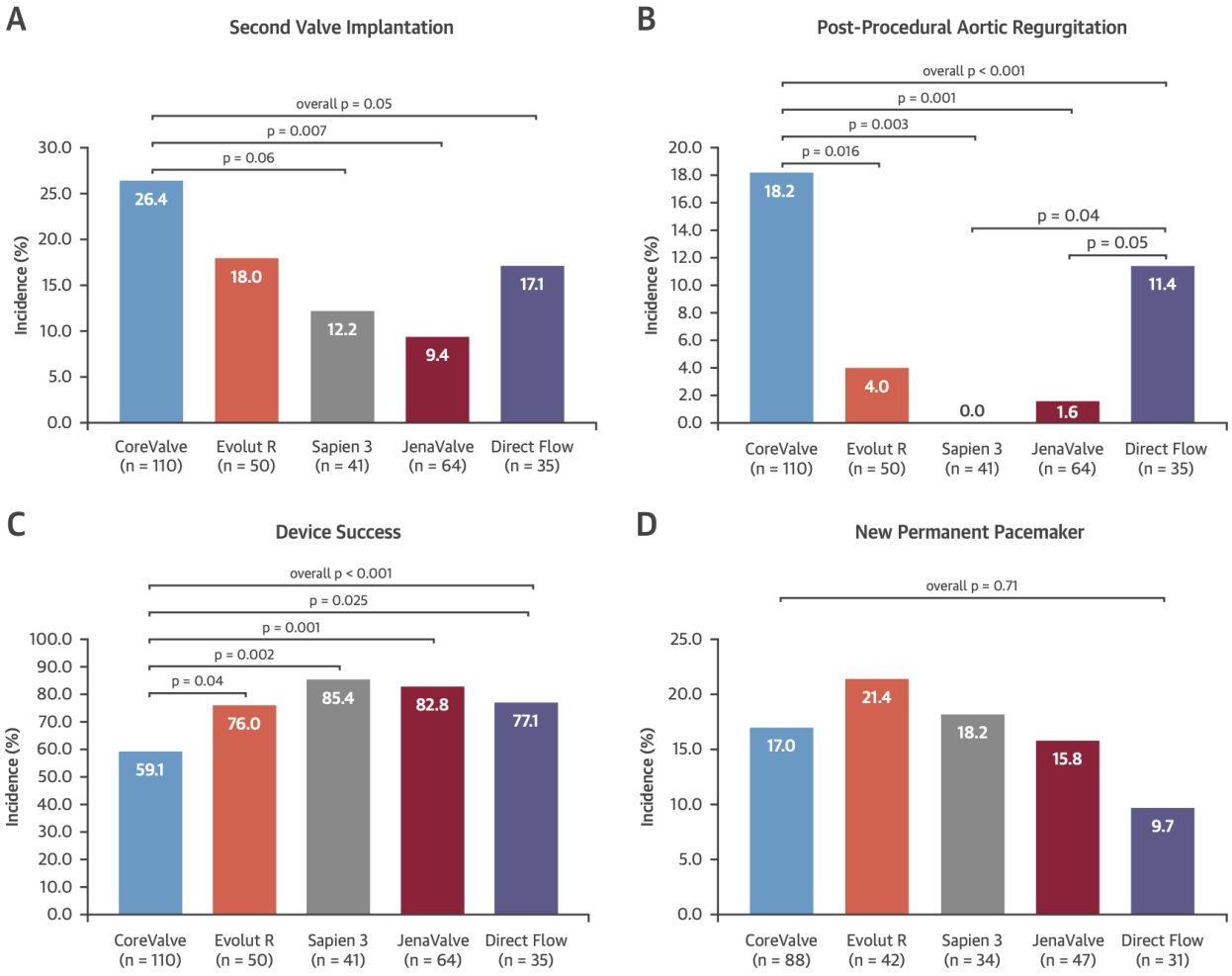
Outcomes according to device



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TAVR in in Pure Native Aortic Valve Regurgitation

Predictors of all-cause mortality

	Univariable Model		Multivariable Model	
	HR (95% CI)	p Value	HR (95% CI)	p Value
Age, yrs	1.00 (0.98–1.02)	0.98		
Female	1.05 (0.65–1.72)	0.84		
NYHA functional class IV at baseline	1.33 (0.79–2.26)	0.29		
STS score	1.03 (1.01–1.06)	0.019	1.03 (1.00–1.06)	0.037
Creatinine, mg/dl	1.00 (0.80–1.25)	0.99		
Peripheral vascular disease	1.42 (0.81–2.50)	0.23		
Chronic pulmonary disease	1.34 (0.80–2.25)	0.26		
Prior cerebrovascular accident	0.78 (0.31–1.94)	0.59		
Prior coronary artery bypass graft surgery	1.41 (0.84–2.37)	0.19		
LVEF ≤45%	1.89 (1.15–3.10)	0.012	1.78 (1.07–2.94)	0.026
Mitral regurgitation ≥ moderate at baseline	1.99 (1.22–3.25)	0.006	2.11 (1.29–3.45)	0.003
Pulmonary hypertension	1.41 (0.83–2.40)	0.20		
Transfemoral access	0.81 (0.48–1.34)	0.41		
New-generation devices	0.69 (0.42–1.12)	0.13		
Need for second valve implantation	1.69 (0.93–2.96)	0.087		
Post-procedural aortic regurgitation ≥ moderate	2.72 (1.45–5.10)	0.002	2.85 (1.52–5.35)	0.001
Late experience	0.83 (0.50–1.36)	0.46		

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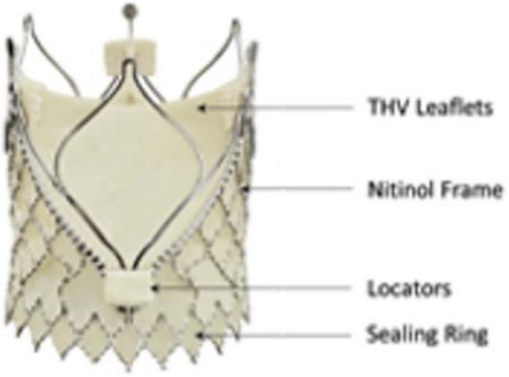
TAVR in in Pure Native Aortic Valve Regurgitation

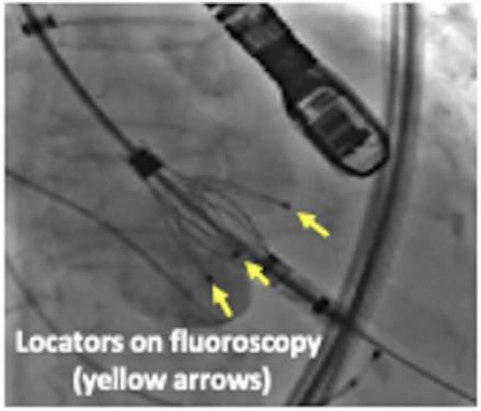
- **Developments in 2021**
- **My personal experience**

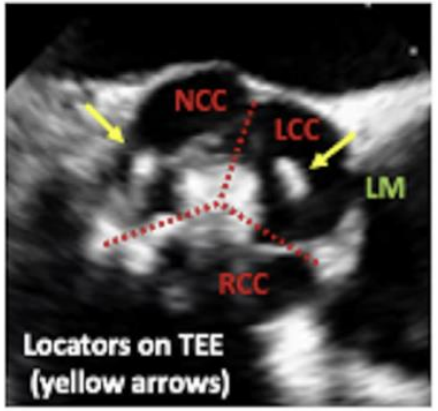
JenaValve Trilogy

Valve orientation and commissural alignment (CA)

A **JenaValve Trilogy Locator Technology**





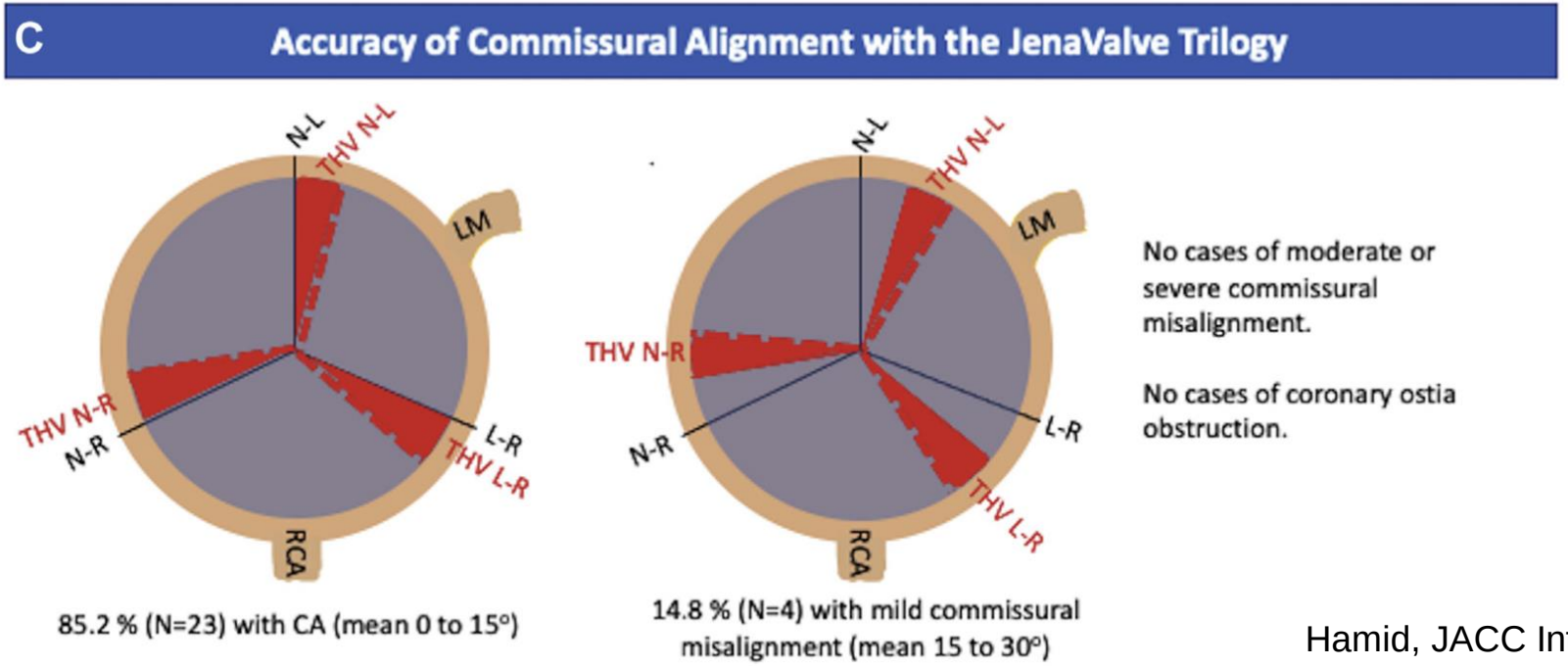


Three tissue covered locators are visible on fluoroscopy due to their radiopaque tantalum markers. The locators engage the native leaflets and assist with valve positioning, anchoring and sealing. Contrast injections confirm the correct position of the locators in each aortic cusp prior to valve deployment. TEE can be used to confirm locator is positioned mid-cusp.

Hamid, JACC Intervent 2021

JenaValve Trilogy

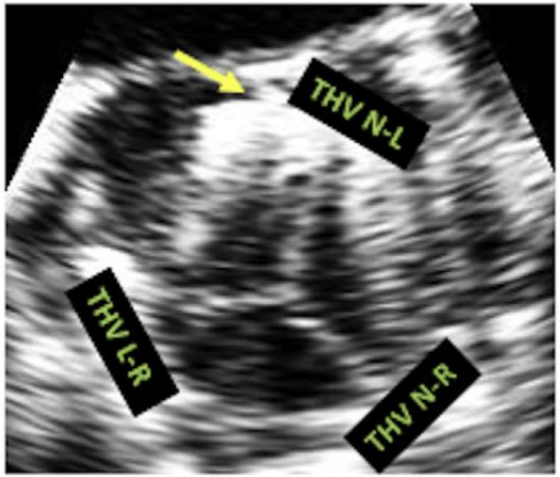
- 27 patients, 80.7±7.7 years (29.6% male), aortic regurgitation in 15 (56%) and aortic stenosis in 12 (44%)
- **CA can reliably be achieved with TEE-guided transfemoral delivery of the JenaValve THV**



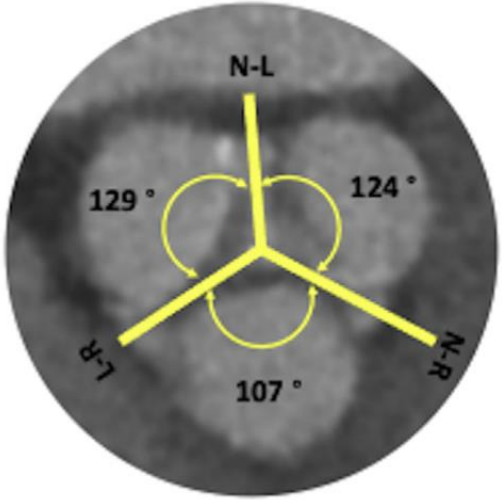
Hamid, JACC Intervent 202

JenaValve Trilogy

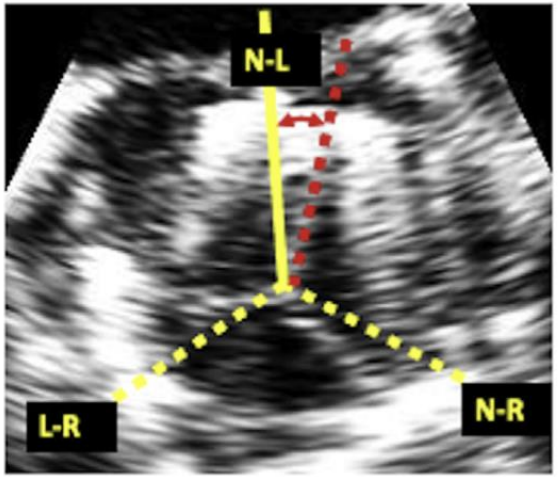
B **Assessment of Commissural Alignment**



<u>Step 1:</u> The native N-L commissure was identified on 3D echo (yellow arrow).



<u>Step 2:</u> CCTA measurements were used to determine the location of the native commissures on 3D echo relative to the native N-L commissure (yellow dotted lines).



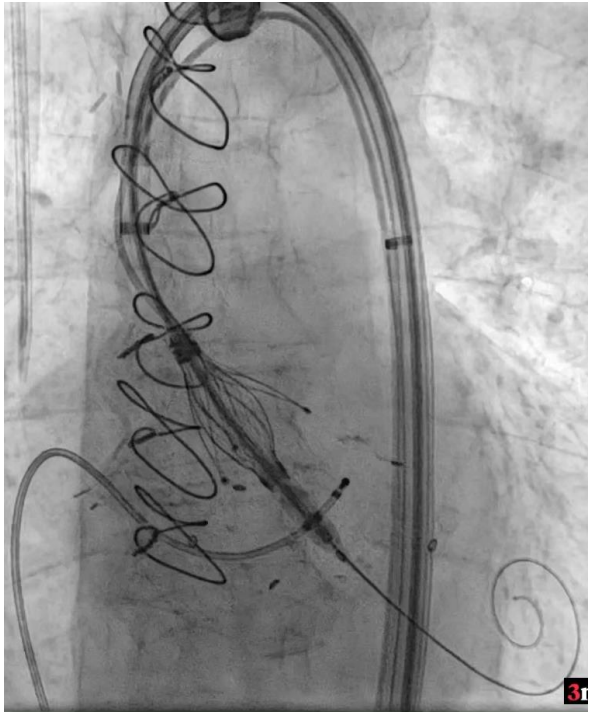
<u>Step 3:</u> The THV commissures (red dotted line) were identified on 3D echo and angles between THV commissures and native commissures were measured (red arrow).

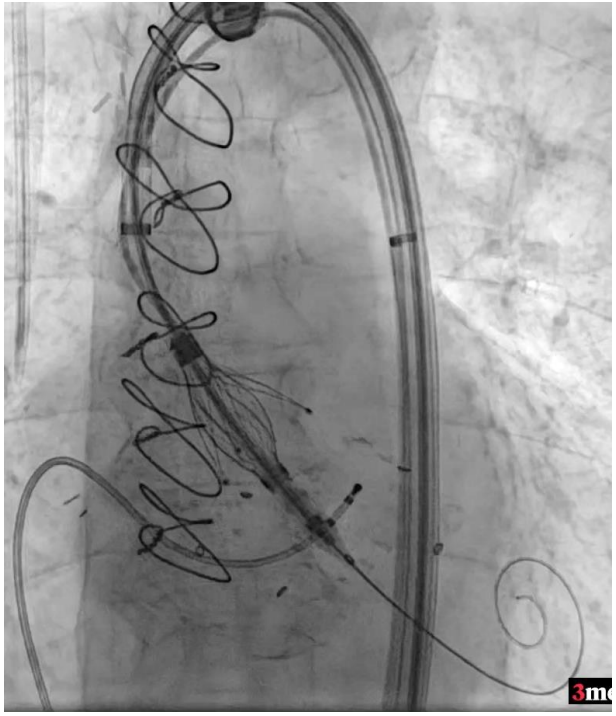
Hamid, JACC Intervent 202

JenaValve in pure AR

Vienna General

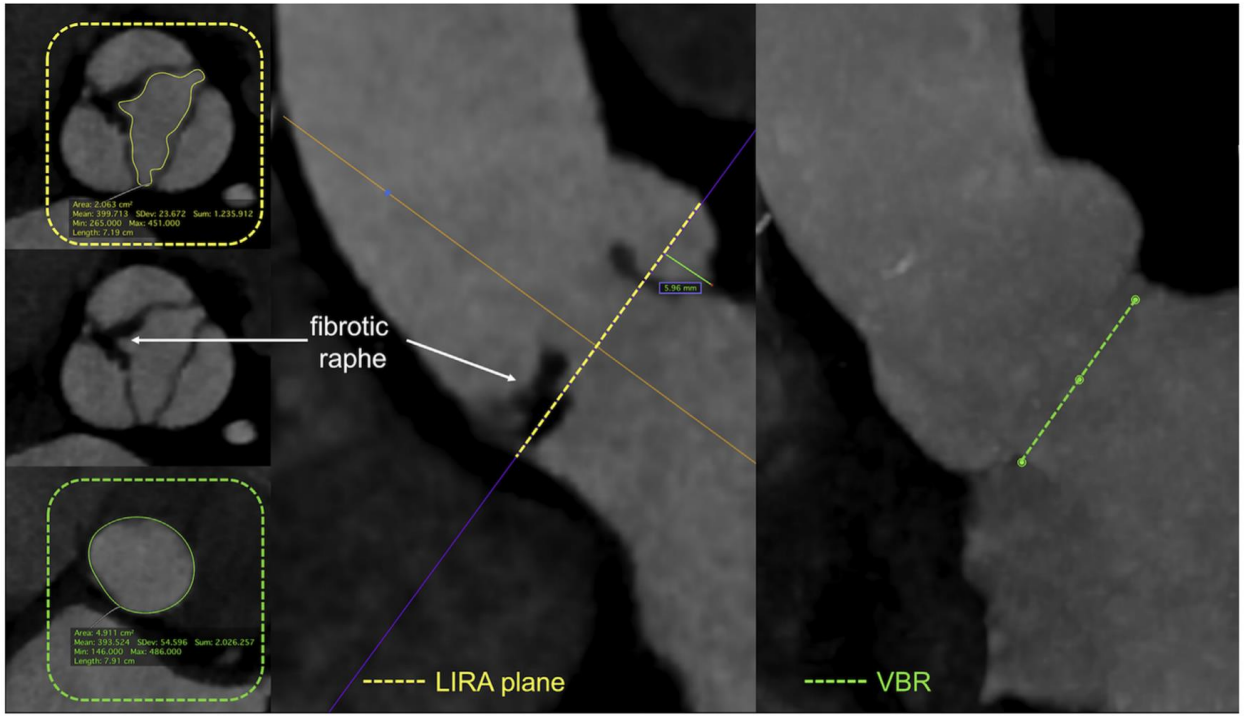
JenaValve in pure AR





Vienna General Hospital

EvolutR in Bicuspid Valve With Pure Aortic Regurgitation
Prosthesis Sizing According to the LIRA Method

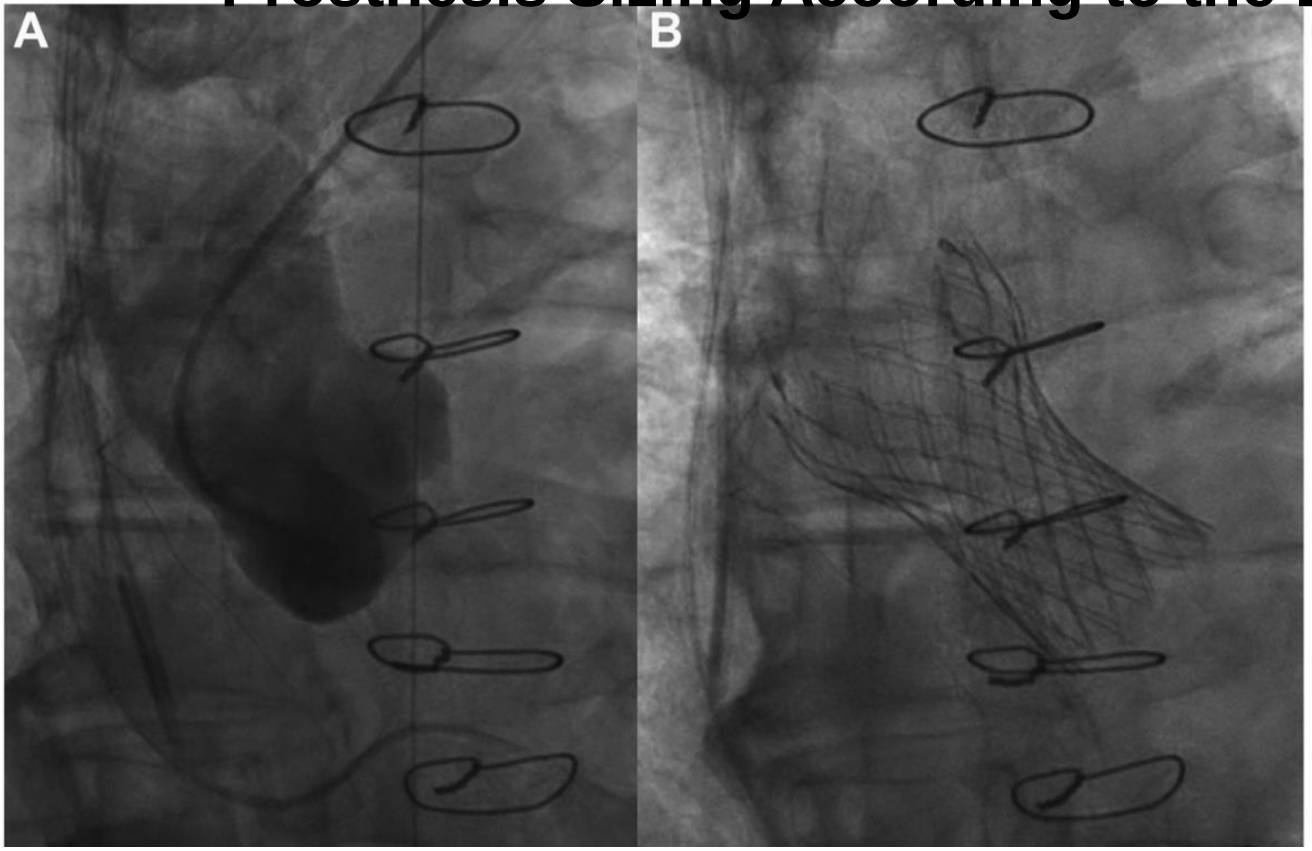


Annulus area: 491mm^2
Raphe area: 206mm^2

Level of implantation at the raphe (LIRA) plane, indicated by the yellow dashed line, with a right-noncoronary fibrotic raphe (left); virtual basal ring (VBR)

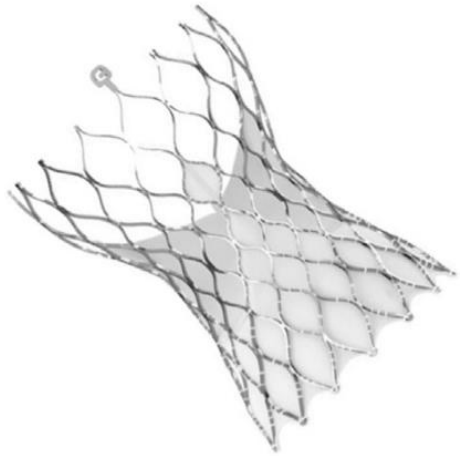
Bellini, JACC Intervent 2021

EvolutR in Bicuspid Valve With Pure Aortic Regurgitation
Prosthesis Sizing According to the LIRA Method



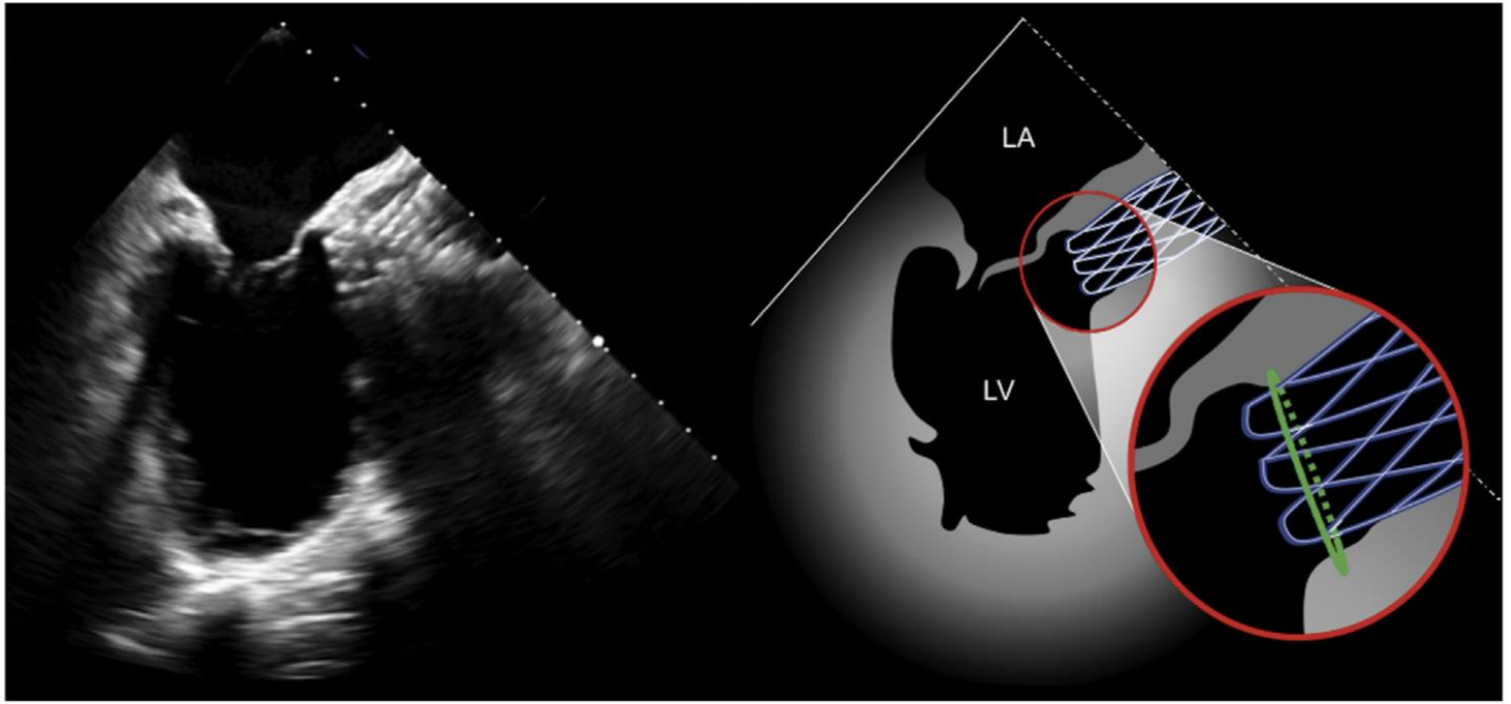
C

CoreValve Evolut R 34



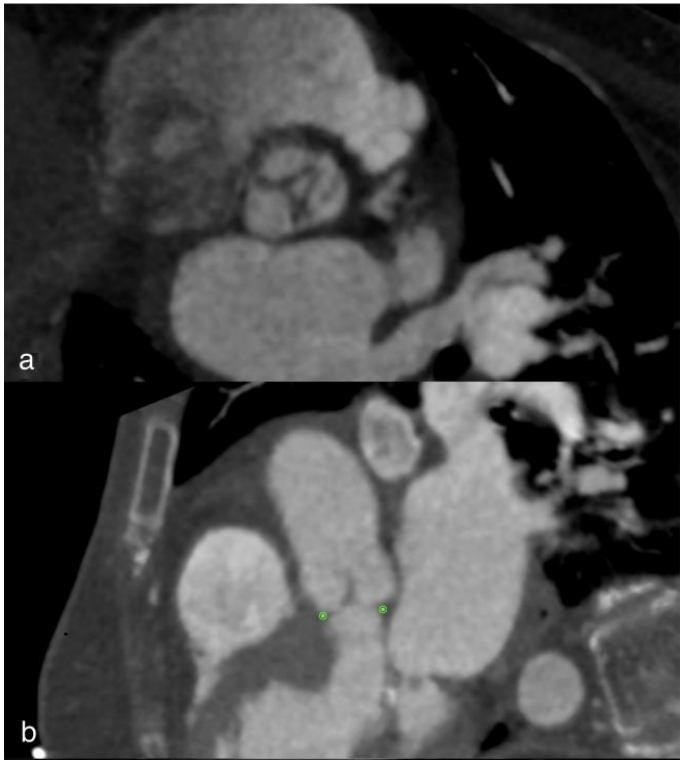
Bellini, JACC Intervent 2021

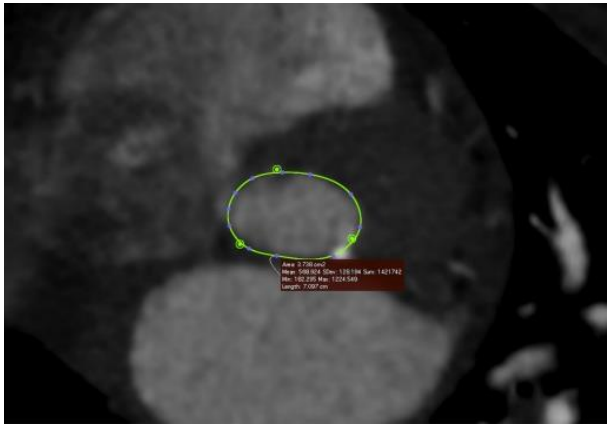
EvolutR in Bicuspid Valve With Pure Aortic Regurgitation
Prosthesis Sizing According to the LIRA Method



Bellini, JACC Intervent 2021

Symetis ACURATE neo for the treatment of pure AR

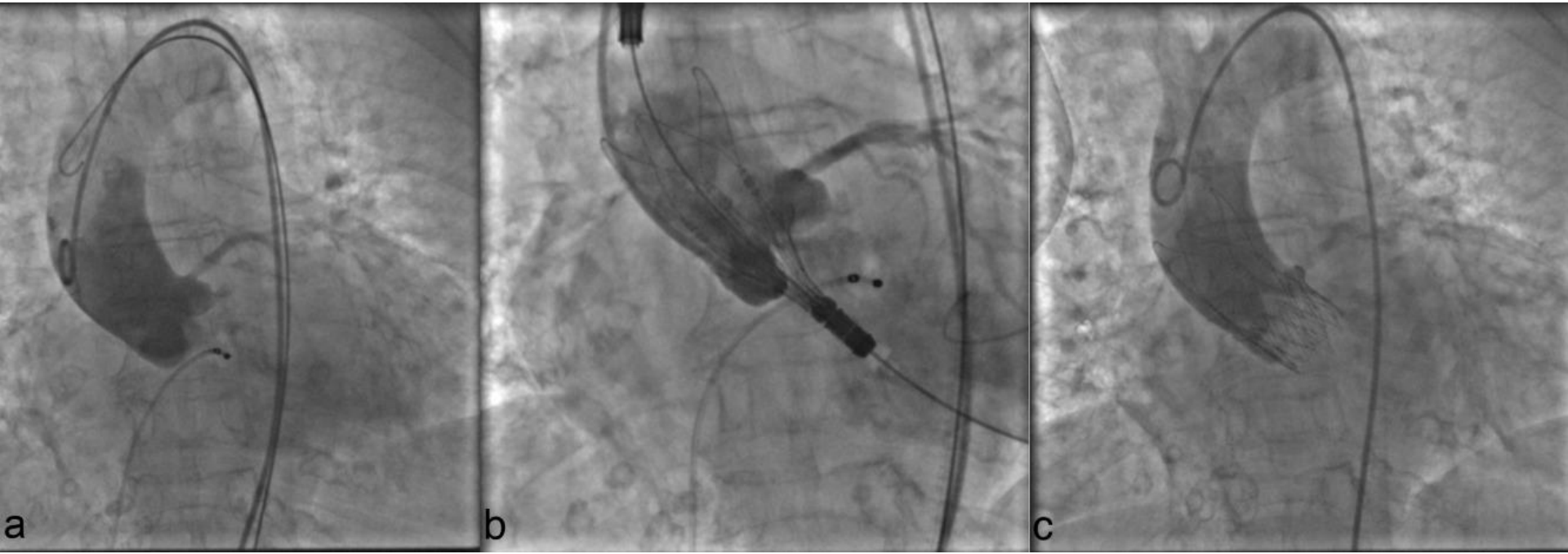




Annulus area: 370mm^2
Perimeter: 71mm
Symetis Acurate S

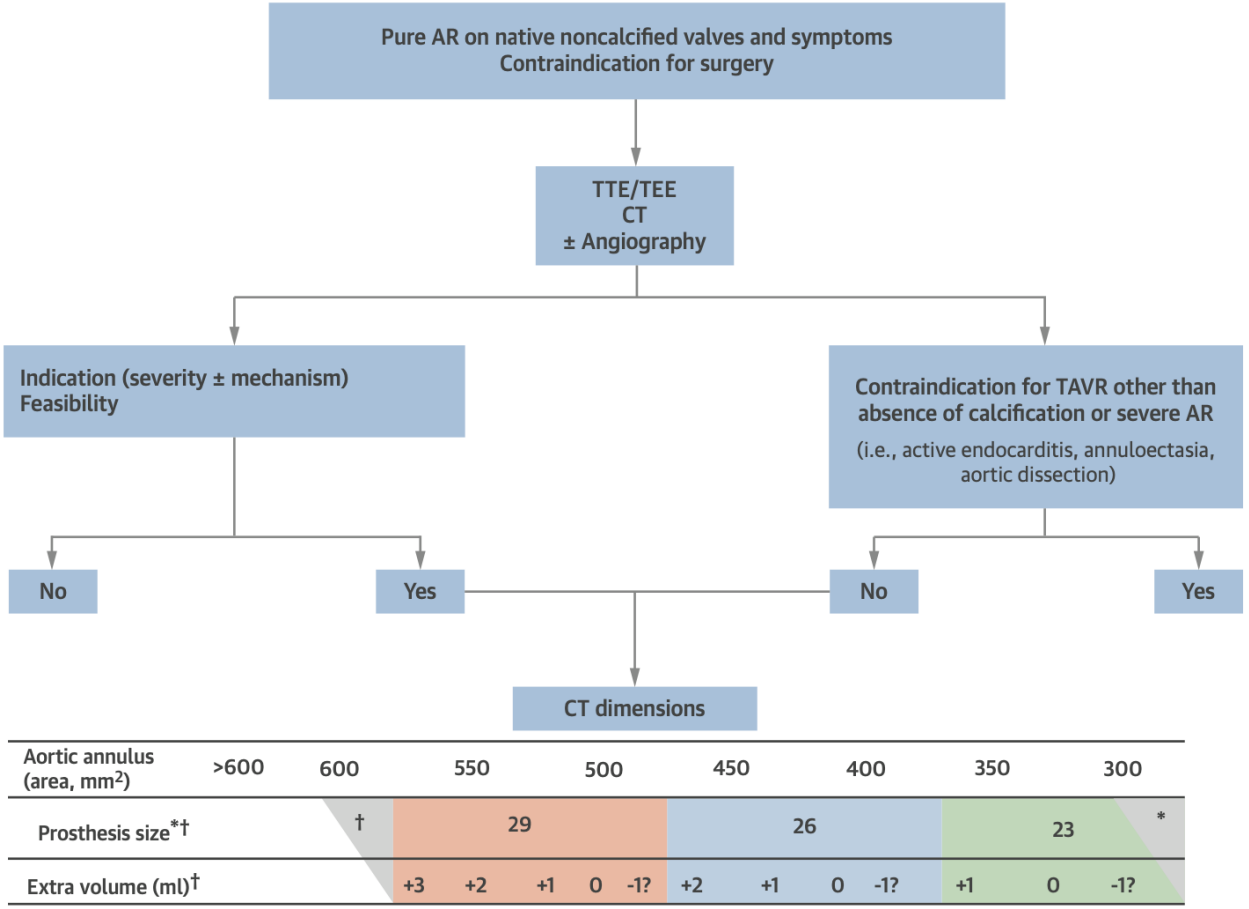
Cerillo, Catheterization and Cardiovascular Interventions, 2016

Symetis ACURATE neo for the treatment of pure AR



Cerillo, Catheterization and Cardiovascular Interventions, 2016

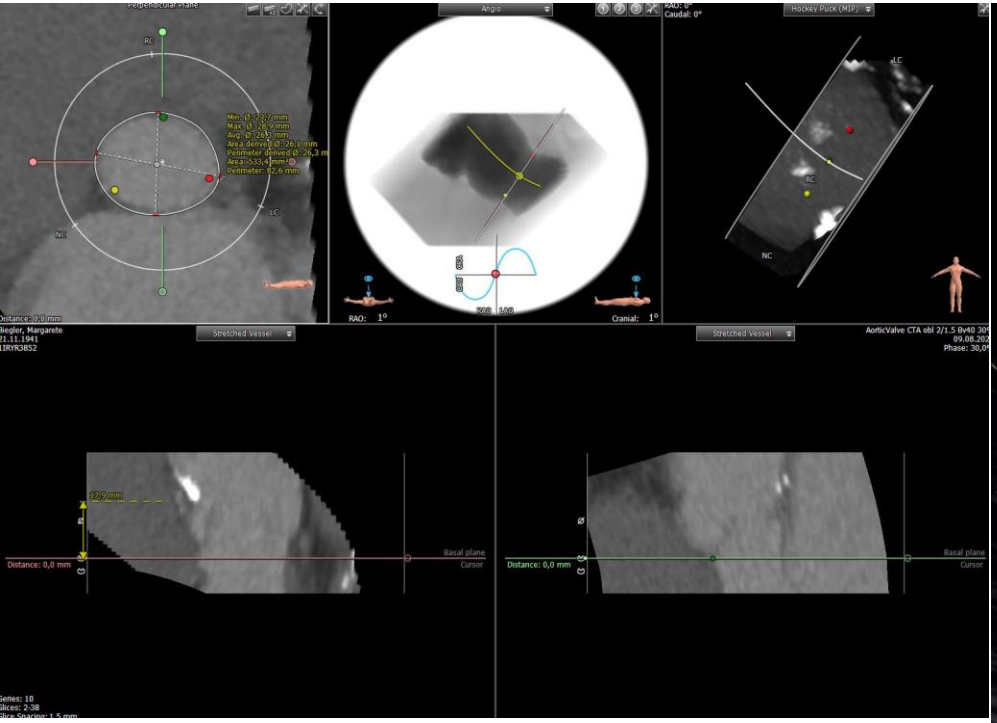
Sapien 3 in pure AR

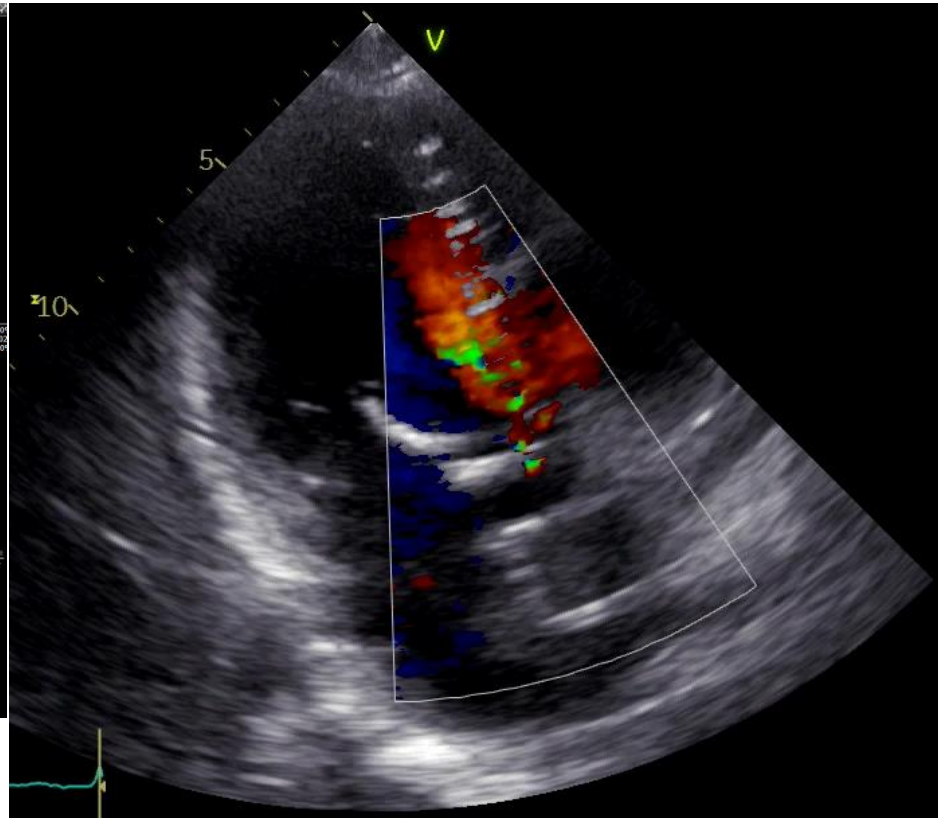


Oversizing >15% recommended

Urena, JACC 2016

Sapien 3 in pure AR

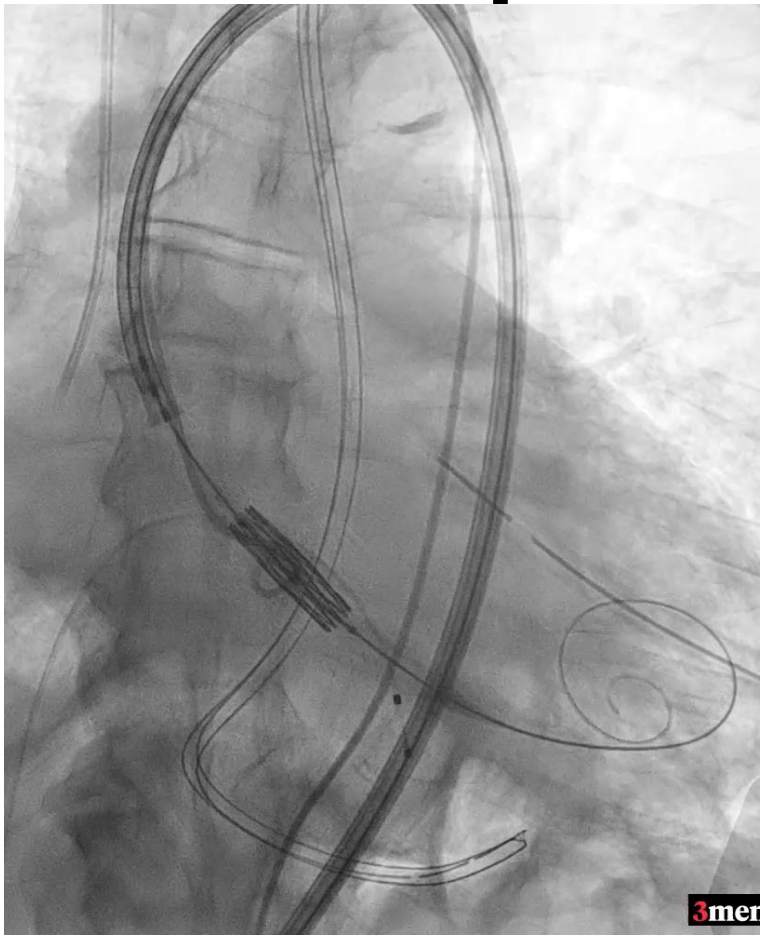


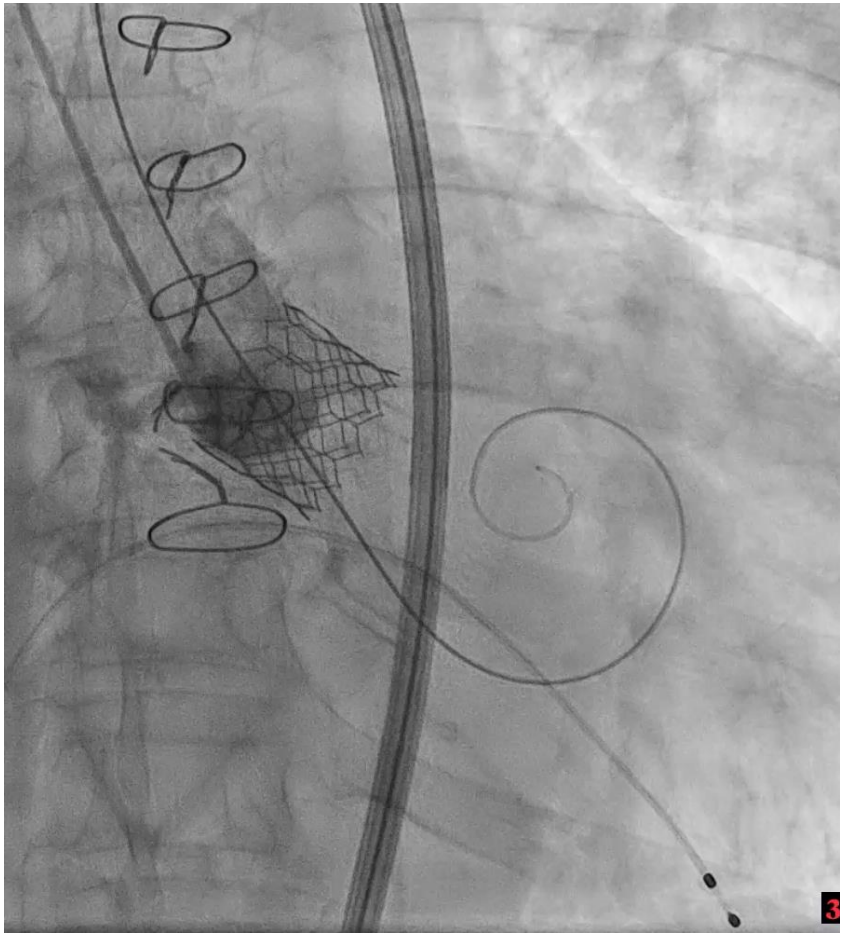


Annulus area: 533mm^2
Perimeter: 82.6mm

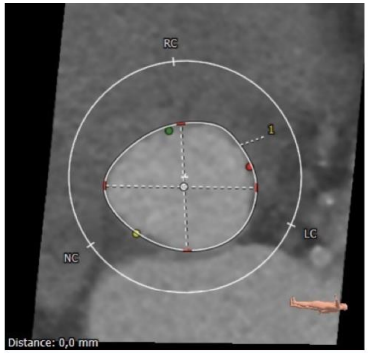
29mm Sapien 3

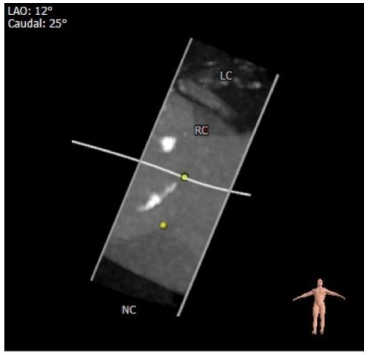
Sapien 3 in pure AR





Sapien 3 in pure AR

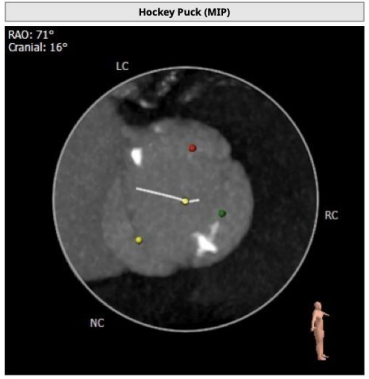


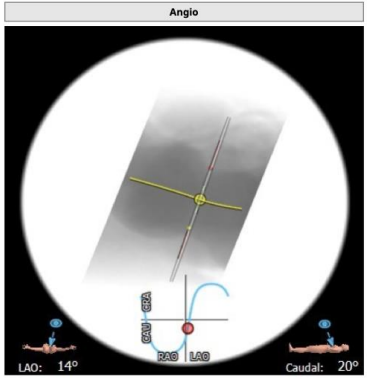


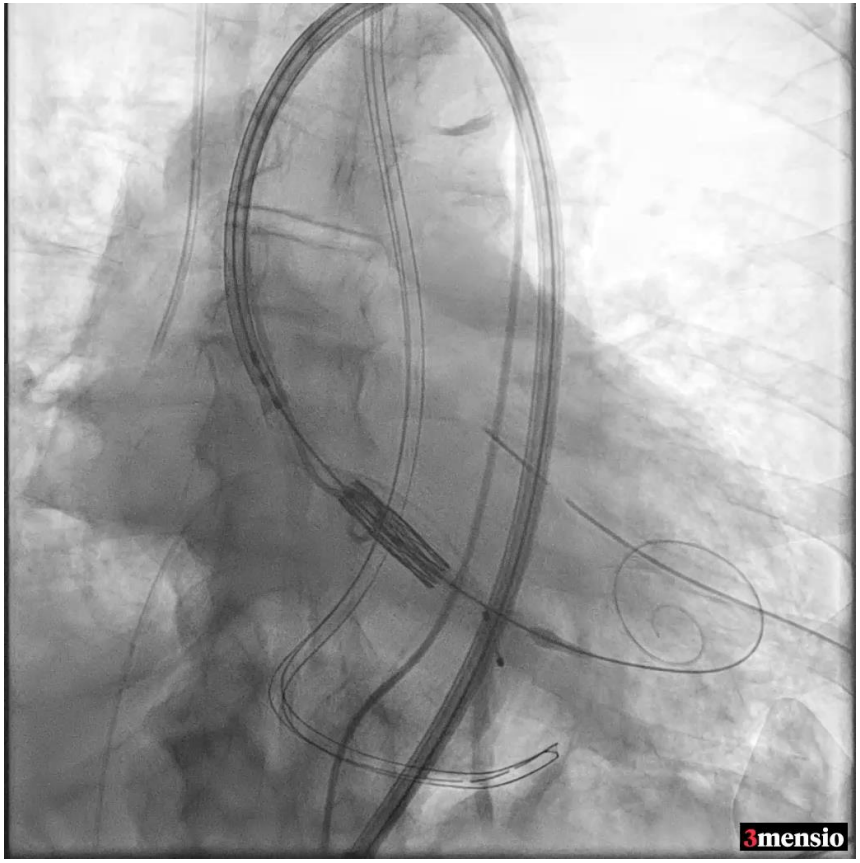
ID	Type	Label	Value
1	Polygon	Min. Ø	27,3 mm
		Max. Ø	32,6 mm
		Avg. Ø	30,0 mm
		Area derived Ø	29,6 mm
		Perimeter derived Ø	29,9 mm
		Area	685,9 mm²
		Perimeter	93,8 mm

Annulus area: 686mm^2
Perimeter: 93.8mm

Sapien 3 29mm+3ml







How to prepare for TAVR in pure AR

- Second valve ready
- Contrast during implantation
- Oversize by one size / at least 15%
- Evolut: Slower and deeper implant with rapid pacing
- After deployment.... wait 5-10 min (migration!)
- Ventricular migration: consider snaring or 2nd valve
- Pop-out: second valve with normal implant depth
- Consider cerebral protection

Proper preparation prevents poor performance

Thank you for your attention

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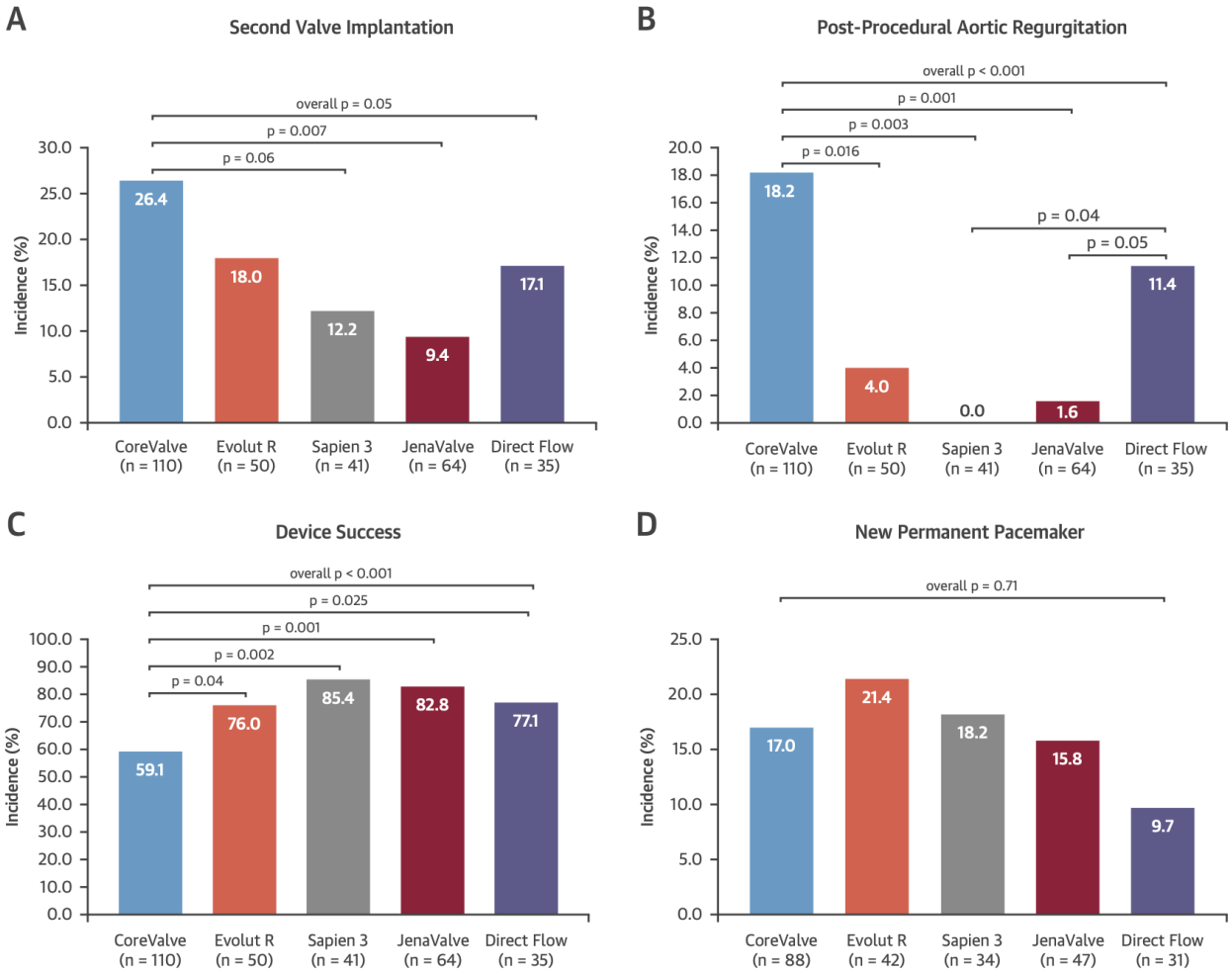
Outcomes according to device



Yoon, JACC 201

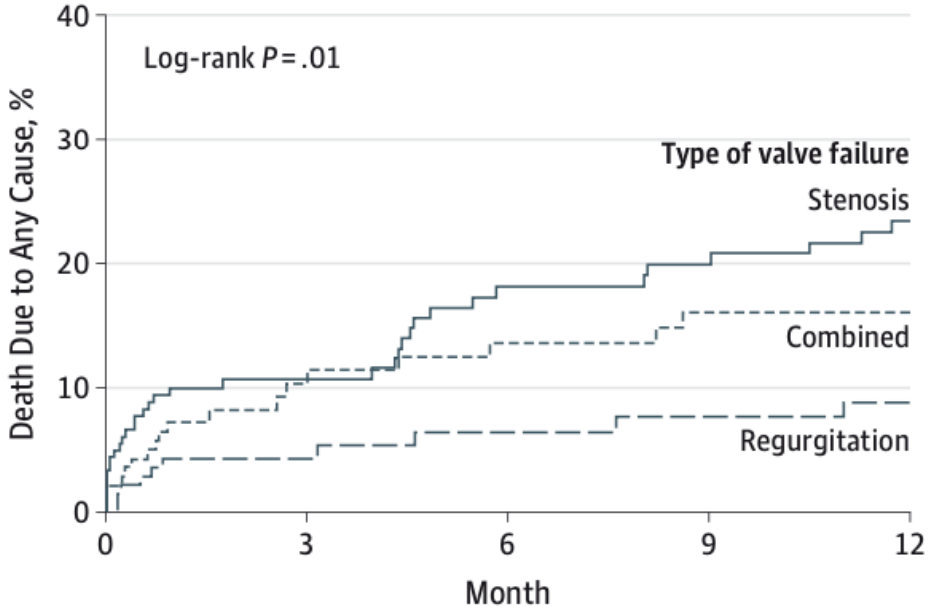
TAVR in Failed Bioprosthetic Surgical Valves

- Multinational valve-in-valve registry 2007-2013, 55 centres
- 459 patients with degenerated bioprosthetic valves undergoing valve-in-valve implantation
- Mean age 77.6 years; 56% men; median STS score 9.8%
- Surgical valves classified as small (<=21mm; 29.7%), intermediate (>21 and <25 mm; 39.3%), and large (>=25 mm; 31%)
- Modes of bioprosthesis failure were stenosis (40%),regurgitation(30%), and combined (30%)
- The stenosis group had a higher percentage of small valves (37% vs 20.9% and 26.6% in the regurgitation and combined groups

Dvir, JAMA 2014

TAVR in Failed Bioprosthetic Surgical Valves

A Mechanism of surgical valve failure



No. at risk by type of valve failure

Stenosis	181	112	98	91	86
Regurgitation	139	92	84	78	76
Combined	139	85	76	68	66

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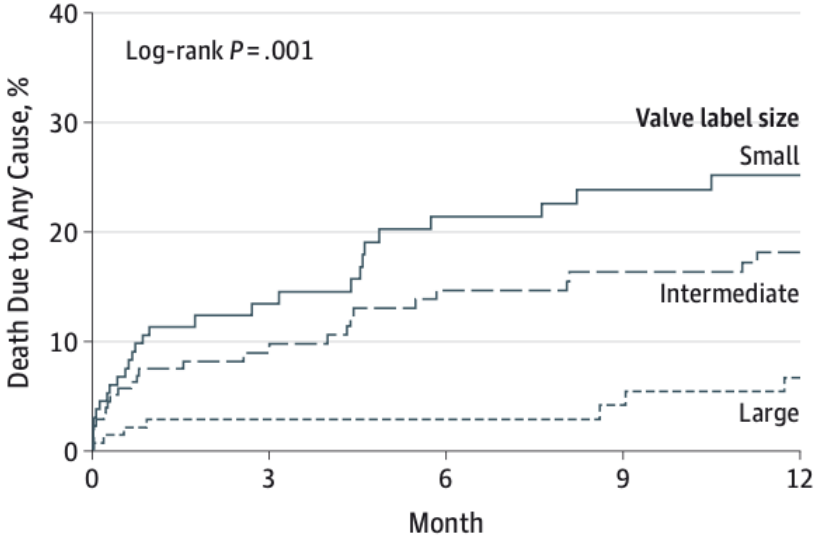
TAVR in Failed Bioprosthetic Surgical Valves

B Surgical valve label size[a]



No. at risk by valve label size					
Small	133	81	68	61	57
Intermediate	176	116	103	95	92
Large	139	89	82	76	73

[a] Surgical valve sizes were as follows: small, label size ≤21 mm; intermediate, >21 mm and <25 mm; and large, ≥25 mm. In 11 patients (2.4%), label size was unknown.

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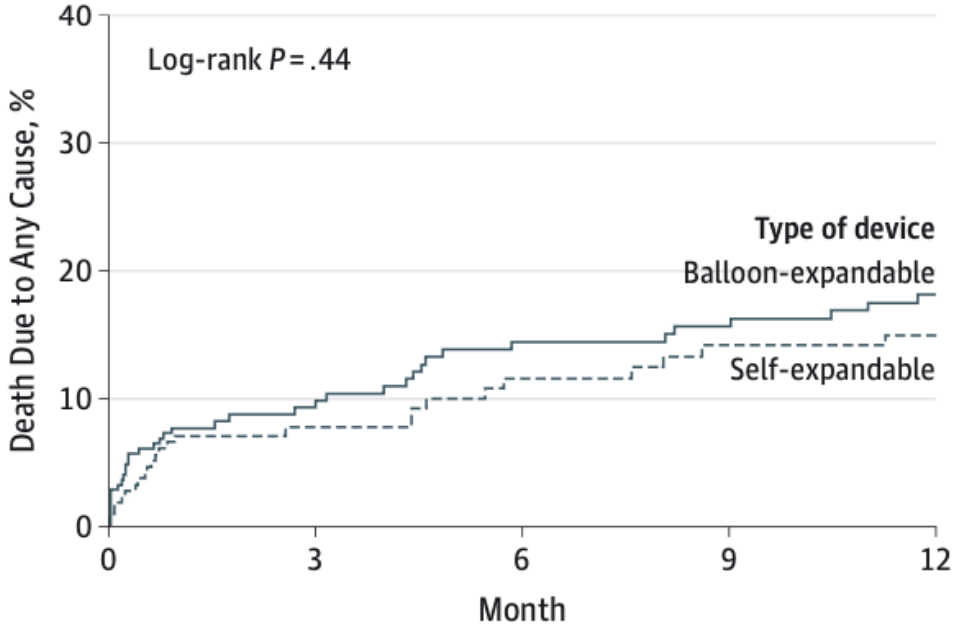
TAVR in Failed Bioprosthetic Surgical Valves

C Device used during valve-in-valve implantation



No. at risk by type of device					
Balloon-expandable	246	163	146	136	130
Self-expandable	213	126	112	101	98

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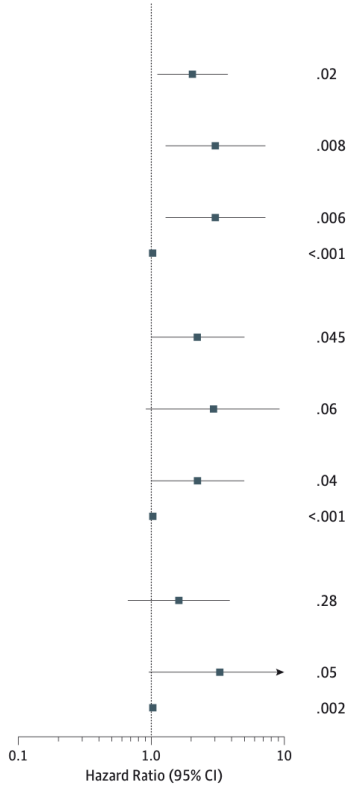
TAVR in Failed Bioprosthetic Surgical Valves

Figure 2. Results of Multivariable Analyses for Correlates for 1-Year Mortality After Valve-in-Valve Implantation

	No. of Events	Total	Hazard Ratio (95% CI)	*P* Value
Overall mortality				
Surgical valve label size				
≤21 mm	28	133	2.04 (1.14-3.67)	.02
>21 mm	34	315		
Type of valve failure				
Stenosis	34	181	3.07 (1.33-7.08)	.008
Regurgitation	12	139		
Transapical access				
Yes	34	171	2.25 (1.26-4.02)	.006
No	30	288		
STS score (per 1% increment)[a]			1.01 (1.00-1.01)	<.001
Early mortality, ≤30 d				
Surgical valve label size				
≤21 mm	15	133	2.25 (1.02-4.98)	.045
>21 mm	17	315		
Type of valve failure				
Stenosis	18	181	2.97 (0.94-9.37)	.06
Regurgitation	6	139		
Transapical access				
Yes	19	171	2.25 (1.03-4.93)	.04
No	15	288		
STS score (per 1% increment)[a]			1.01 (1.00-1.01)	<.001
Late mortality, >30 d				
Surgical valve label size				
≤21 mm	13	133	1.61 (0.68-3.80)	.28
>21 mm	17	315		
Type of valve failure				
Stenosis	16	181	3.33 (1.00-11.31)	.05
Regurgitation	6	139		
STS score (per 1% increment)[a]			1.01 (1.00-1.04)	.002



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THV Cusp

- Porcine Pericardial Tissue Leaflets

Nitinol Support Frame

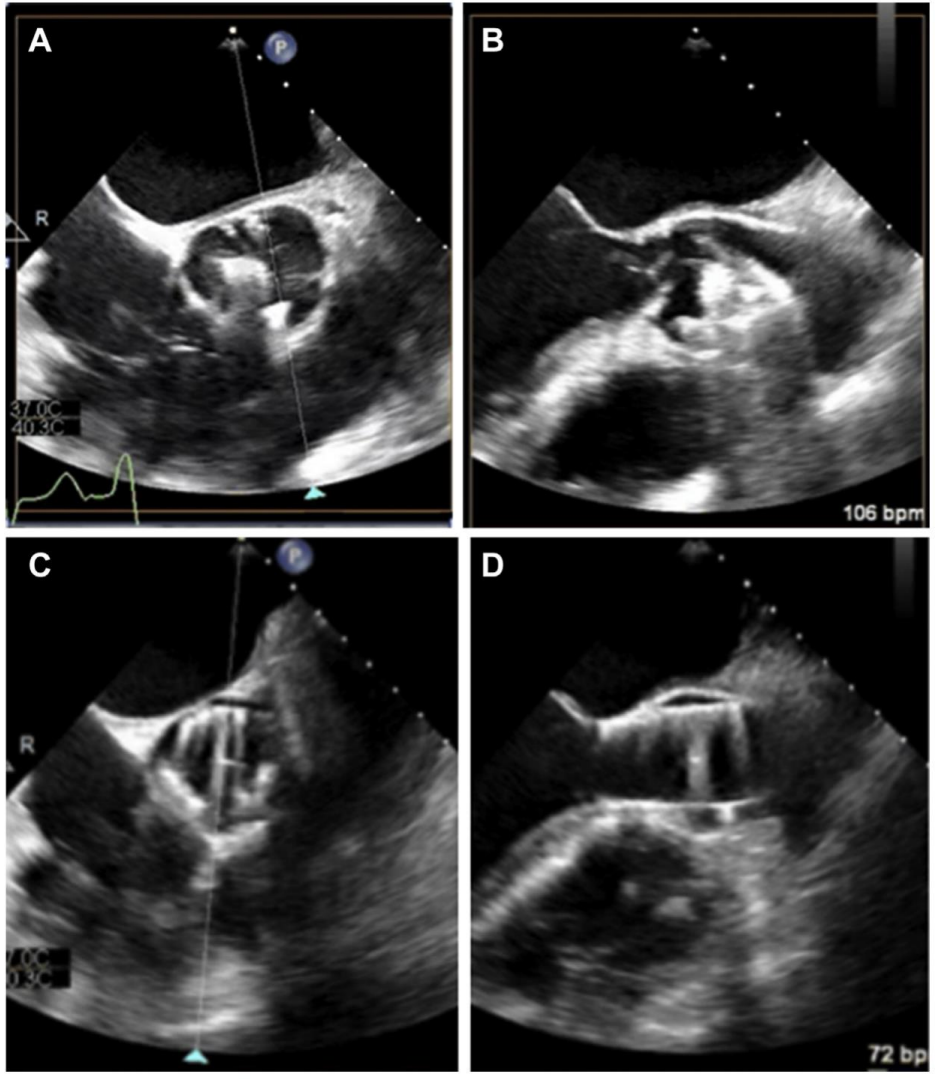
- Self expanding

Locators

- Tissue covered
- Radiopaque Tantalum marker

Sealing Ring

- (24) rhombi elements


A
R
B
106 bpm
C
R
D
72 bp

TAVR in Failed Bioprosthetic Surgical Valves

Table 1. Baseline Characteristics at the Time of Valve-in-Valve Procedure

Characteristics	All (n = 459)	Mechanism of Surgical Valve Failure				Device Used		
		Stenosis (n = 181)	Regurgitation (n = 139)	Combined (n = 139)	*P* Value	Self-Expandable (n = 213)	Balloon-Expandable (n = 246)	*P* Value
Age, mean (SD), y	77.6 (9.8)	78.8 (7.8)	77.1 (10.6)	76.6 (11.1)	.10	77.6 (10)	77.6 (9.7)	.95
Men, No. (%)	257 (56)	87 (48)	93 (66.9)	77 (55.4)	.002	113 (53.1)	144 (58.5)	.25
Height, mean (SD), cm	167.2 (9.8)	167.1 (9.9)	168.1 (9.7)	166.5 (9.8)	.20	166.9 (10)	167.4 (9.7)	.59
Weight, mean (SD), kg	73.9 (15.2)	77.6 (16.5)	72 (13.3)	70.8 (14.1)	<.001	73.7 (15)	74 (15.4)	.84
BMI, mean (SD)[a]	26.4 (4.8)	27.7 (4.8)	25.4 (3.9)	25.5 (4.2)	<.001	26.4 (4.6)	26.3 (4.4)	.78
BSA, mean (SD), m^2	1.85 (0.22)	1.89 (0.24)	1.83 (0.2)	1.8 (0.21)	.002	1.84 (0.22)	1.85 (0.23)	.76
LogEuroSCORE, median (IQR), %[b]	29 (19.1-42.3)	29.8 (20-39.9)	25.7 (16-41.9)	30.3 (22.3-44.7)	.18	29 (18.6-38.7)	29 (19.3-44.2)	.48
STS score, median (IQR), %[b]	10 (6.2-16.1)	9.9 (6.1-13.9)	9.9 (5.8-15.6)	10.8 (7.1-18.4)	.33	11 (6.2-17.3)	9.3 (6.1-14.1)	.13
Diabetes mellitus, No. (%)	125 (28.7)	69 (40.1)	28 (21.2)	28 (21.4)	.001	62 (31.1)	63 (26.5)	.29
Peripheral vascular disease, No. (%)	114 (26.1)	53 (30.6)	31 (23.5)	30 (22.9)	.22	37 (17.4)	77 (31.3)	<.001
Chronic renal failure, No. (%)[c]	224 (48.8)	80 (44.2)	71 (51.1)	72 (51.8)	.37	81 (38)	140 (56.9)	<.001
Previous stroke/TIA, No. (%)	51 (11.7)	23 (13.3)	17 (12.8)	12 (9.2)	.52	24 (12.2)	27 (11.3)	.76
>1 Previous SAVR, No. (%)	62 (13.5)	16 (8.8)	23 (16.5)	23 (16.5)	.06	27 (12.7)	35 (14.2)	.63
NYHA functional class, No. (%)								
II	35 (7.8)	14 (7.7)	10 (7.2)	11 (7.9)	.97	15 (7)	20 (8.1)	.66
III	283 (61.9)	130 (71.8)	78 (56.1)	75 (54)	.001	124 (58.2)	159 (64.6)	.16
IV	141 (30.3)	37 (26.2)	51 (36.7)	53 (38.1)	.001	74 (34.7)	67 (27.2)	.08
Left ventricular ejection fraction, mean (SD), %	50.3 (13.1)	51.7 (12.9)	49.0 (13.1)	49.7 (13.3)	.16	49.1 (13.4)	51.2 (12.8)	.08

TAVR in Failed Bioprosthetic Surgical Valves

Table 2. Surgical Valve Characteristics at the Time of Valve-in-Valve Procedure

Characteristics	All (n = 459)	Mechanism of Surgical Valve Failure				Device Used		
		Stenosis (n = 181)	Regurgitation (n = 139)	Combined (n = 139)	*P* Value	Self-Expandable (n = 213)	Balloon-Expandable (n = 246)	*P* Value
Time since last SAVR, median (IQR), y[a]	9 (6-12)	8 (5-11)	10(7-14)	10 (7-14)	.04	9 (7-13)	9 (6-12)	.08
Type, No. (%)					<.001			<.001
Stented	366 (79.7)	173 (95.6)	84 (60.4)	109 (78.4)		152 (71.4)	214 (87)	
Stentless	93 (20.3)	8 (4.4)	55 (29.6)	30 (21.6)		61 (28.6)	32 (13)	
Label size, No. (%)								
≤21 mm	133 (29)	67 (37)	29 (20.9)	37 (26.6)	.005	68 (31.9)	65 (26.4)	.19
>21 mm and <25 mm	176 (38.3)	74 (40.9)	43 (30.9)	59 (42.4)	.09	83 (39)	93 (37.8)	.80
≥25 mm	139 (30.3)	34 (18.8)	65 (46.8)	40 (28.8)	<.001	53 (24.9)	86 (35)	.02
Unknown	11 (2.4)	6 (3.3)	2 (1.4)	3 (2.2)	.54	9 (4.2)	2 (0.8)	.02
Internal diameter, No. (%)								
<20 mm	126 (27.5)	53 (29.3)	32 (23)	41 (41.7)	.37	66 (31)	60 (24.4)	.11
≥20 mm and <23 mm	230 (50.1)	102 (56.4)	64 (34.5)	64 (46)	.10	100 (46.5)	130 (52.8)	.21
≥23 mm	103 (22.4)	26 (14.4)	43 (30.9)	34 (24.5)	.002	46 (21.6)	57 (23.2)	.69
AV area, mean (SD), cm^2	0.95 (0.48)	0.69 (0.21)	1.48 (0.6)	0.91 (0.31)	<.001	0.99 (0.49)	0.91 (0.46)	.04
AV index, mean (SD), cm^2/m^2[b]	0.51 (0.28)	0.38(0.13)	0.83 (0.37)	0.51(0.19)	<.001	0.55 (0.31)	0.49 (0.25)	.05
AV maximum gradient, mean (SD), mm Hg	60.8 (27.4)	75.2 (23.1)	34.3 (17.7)	64.6 (22.8)	<.001	59.7 (27.2)	61.8 (27.6)	.44
AV gradient, mean (SD), mm Hg	36.2 (18.4)	46.4 (16.1)	18.0 (10.1)	37.6 (14.9)	<.001	35 (18.5)	37.3 (18.3)	.21
AV regurgitation of at least moderate degree, No. (%)[c]	296 (64.5)	22 (12.2)	139 (100)	135 (97.1)	<.001	143 (67.1)	153 (63)	.27

TAVR in Failed Bioprosthetic Surgical Valves

Table 3. Clinical Outcomes

Outcomes	All (n = 459)	Mechanism of Surgical Valve Failure, No. (%)				Device Used, No. (%)		
		Stenosis (n = 181)	Regurgitation (n = 139)	Combined (n = 139)	*P* Value	Self-Expandable (n = 213)	Balloon-Expandable (n = 246)	*P* Value
Duration of hospital stay, median (IQR), d	8 (5-12)	7 (5-11)	7 (5-12)	8 (6-13)	.21	7 (5-12)	8 (6-13)	.07
Thirty-day outcomes								
Death, No. (%)	35 (7.6)	19 (10.5)	6 (4.3)	10 (7.2)	.04	15 (7)	20 (8.1)	.66
Cardiovascular death, No. (%)	30 (6.5)	16 (8.8)	5 (3.6)	9 (6.5)	.06	12 (5.6)	18 (7.3)	.47
NYHA functional class, No. (%)								
I/II	313 (92.6)	126 (91.3)	100 (94.3)	87 (92.6)	.83	160 (93)	153 (93.3)	.94
III/IV	25 (7.4)	12 (8.7)	6 (5.7)	7 (7.4)	.83	12 (7)	13 (7.8)	.94
Major stroke, No. (%)[a]	8 (1.7)	1 (0.6)	3 (2.2)	4 (2.9)	.26	2 (0.9)	6 (2.4)	.22
Death or major stroke, No. (%)	42 (9.2)	19 (10.5)	9 (6.5)	14 (10.1)	.42	17 (8)	25 (10.2)	.22
Major vascular complication, No. (%)[a]	42 (9.2)	14 (7.7)	10 (7.2)	18 (12.9)	.11	16 (7.5)	26(10.6)	.26
Major/life-threatening bleeding, No. (%)[a]	37 (8.1)	20 (11)	5 (3.6)	12 (8.6)	.01	10 (4.7)	27 (11)	.01
Acute kidney injury type II/III, No. (%)[a]	34 (7.4)	16 (8.8)	10 (7.2)	8 (5.8)	.58	9 (4.2)	25 (10.2)	.02
Permanent pacemaker implantation, No. (%)	38 (8.3)	17 (9.4)	12 (8.6)	9 (6.5)	.63	26 (12.2)	12 (4.9)	.005
AV area, mean (SD), cm^2	1.47 (0.5)	1.37 (0.33)	1.56 (0.51)	1.56 (0.65)	.01	1.58 (0.41)	1.38 (0.54)	.001
AV index, mean (SD), cm^2/m^{2b}	0.77 (0.25)	0.71 (0.15)	0.82 (0.23)	0.84 (0.35)	.004	0.83 (0.19)	0.74 (0.28)	.004
AV maximal gradient, mean (SD), mm Hg	28.3 (14.1)	32.2 (14.7)	22.4 (11.6)	29.1 (13.6)	<.001	26.2 (12.1)	30.3 (15.4)	.002
AV mean gradient, mean (SD), mm Hg	15.8 (8.9)	18.5 (9.8)	12 (6.7)	16.1 (8.3)	<.001	14.1 (7.3)	17.2 (9.7)	<.001
AV regurgitation of at least moderate degree, No. (%)[c]	25 (5.4)	5 (2.8)	13 (9.4)	7 (5)	.04	19 (8.9)	6 (2.4)	.002
Left ventricular ejection fraction, mean (SD), %	51.6 (11.5)	53.7 (9.9)	48.9 (11.6)	51.2 (12.9)	.002	51.2 (12.2)	51.7 (10.8)	.66
One-year outcomes								
Death, No. (%)	62 (16.8)	34 (23.4)	10 (8.8)	18 (16.1)	.01	25 (15)	37 (18.7)	.44
NYHA functional class, No. (%)								
I/II	163 (86.2)	62 (84.9)	46 (85.2)	55 (88.7)	.34	88 (81.6)	75 (82.4)	.89
III/IV	26 (13.8)	11 (15.1)	8 (14.8)	7 (11.3)	.34	10 (18.4)	16 (17.6)	.89
AV area, mean (SD), cm^2	1.38 (0.42)	1.28 (0.29)	1.51 (0.48)	1.36 (0.45)	.01	1.55 (0.41)	1.29 (0.39)	.006
AV maximal gradient, mean (SD), mm Hg	30 (14.7)	32.3 (14.9)	25.2 (15.4)	32.1 (12.5)	.005	25.3 (11.9)	33.3 (16)	<.001
AV mean gradient, mean (SD), mm Hg	16.9 (9.1)	18.3 (9.5)	13.8 (8.9)	18.4 (8)	.001	13.5 (7)	19.4 (9.6)	<.001

TAVR in in Pure Native Aortic Valve Regurgitation

	Overall (N = 331)	Early-Generation Devices (n = 119)	New-Generation Devices (n = 212)	p Value
Procedural outcomes				
Procedure-related death	10 (3.0)	5 (4.2)	5 (2.4)	0.35
Conversion to conventional surgery	12 (3.6)	4 (3.4)	8 (3.8)	0.85
Coronary obstruction	4 (1.2)	0 (0.0)	4 (1.9)	0.30
Aortic root injury	5 (1.5)	2 (1.7)	3 (1.4)	>0.99
Need for second valve implantation	55 (16.6)	29 (24.4)	27 (12.7)	0.007
New permanent pacemaker*	51 (18.2)	17 (17.5)	34 (18.6)	0.83
Re-intervention	14 (4.2)	6 (5.0)	8 (3.8)	0.58
Echocardiographic findings at discharge				
Mean gradient, mm Hg	9.3 ± 4.8	7.7 ± 4.9	10.2 ± 4.5	<0.001
LVEF, %	44.0 ± 14.3	43.5 ± 14.2	44.3 ± 14.5	0.68
Aortic regurgitation ≥ moderate	29 (9.6)	21 (18.8)	8 (4.2)	<0.001
Device success	246 (74.3)	73 (61.3)	172 (81.1)	<0.001

Early-Generation:
CoreValve, Sapien XT

New-Generation:
JenaValve, EvolutR, Sapien 3, Direct Flow
Lotus, Acurate, Portico

Yoon, JACC 201

Challenges of TAVR in pure AR

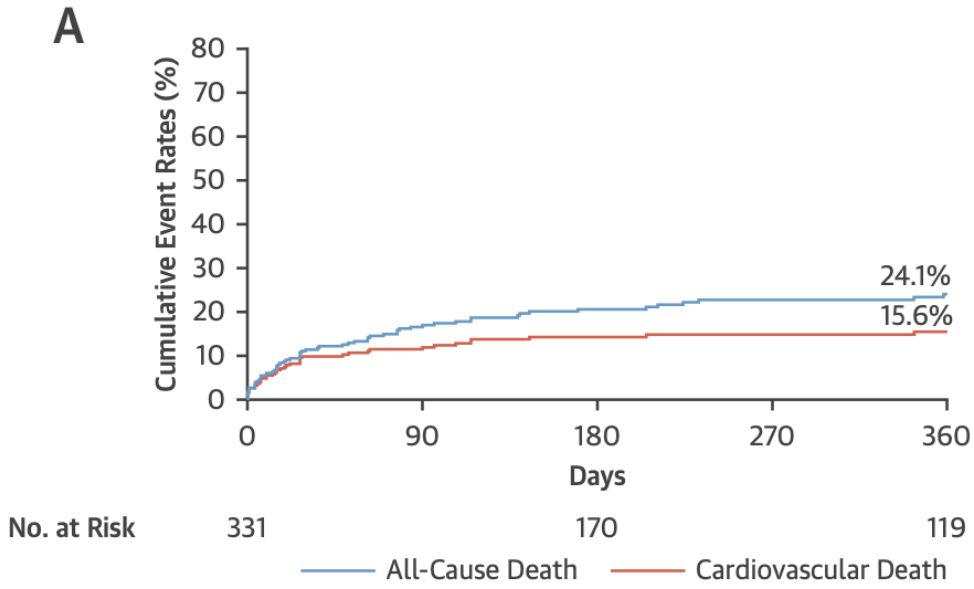
Anatomic

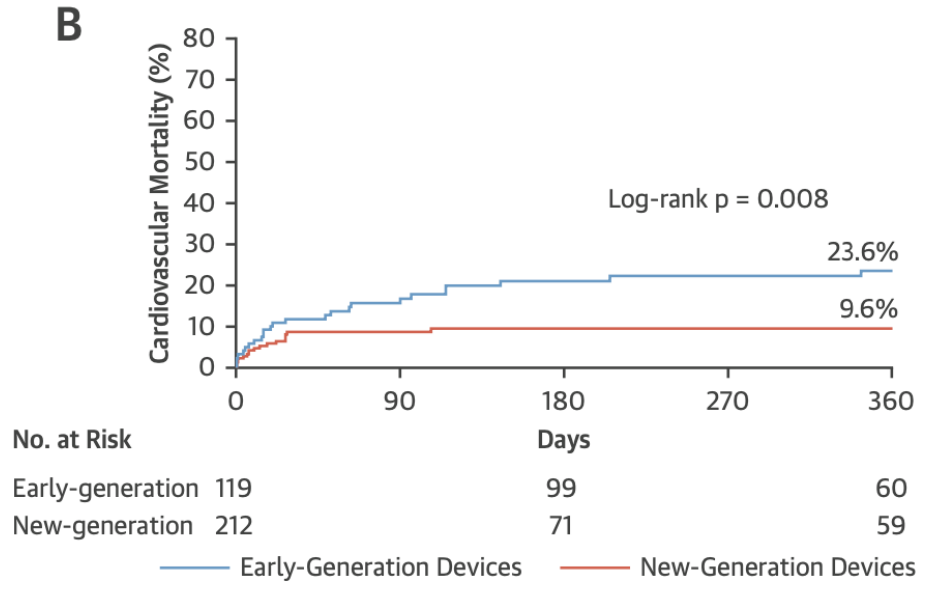
- Large aortic sinuses and annuli
- Concomitant aortic dilatation
- Insufficient anchoring due to lack of calcium

Procedural

- Lack of fluroscopic visualization of the valve
- Risk of THV migration / embolization
- Residual aortic regurgitation
- Permanent pacemaker rates
- Stroke rates

TAVR in in Pure Native Aortic Valve Regurgitation





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