Successful Self-expandable TAVI Case :

Hemodynamic Advantages for Small Annulus and Challenging Anatomy

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Small Aortic Annulus

- Small Annuli Are Common:
  SAVR prostheses ≤ 21mm [1] = 22-44%
- Use of small TAVR prostheses:

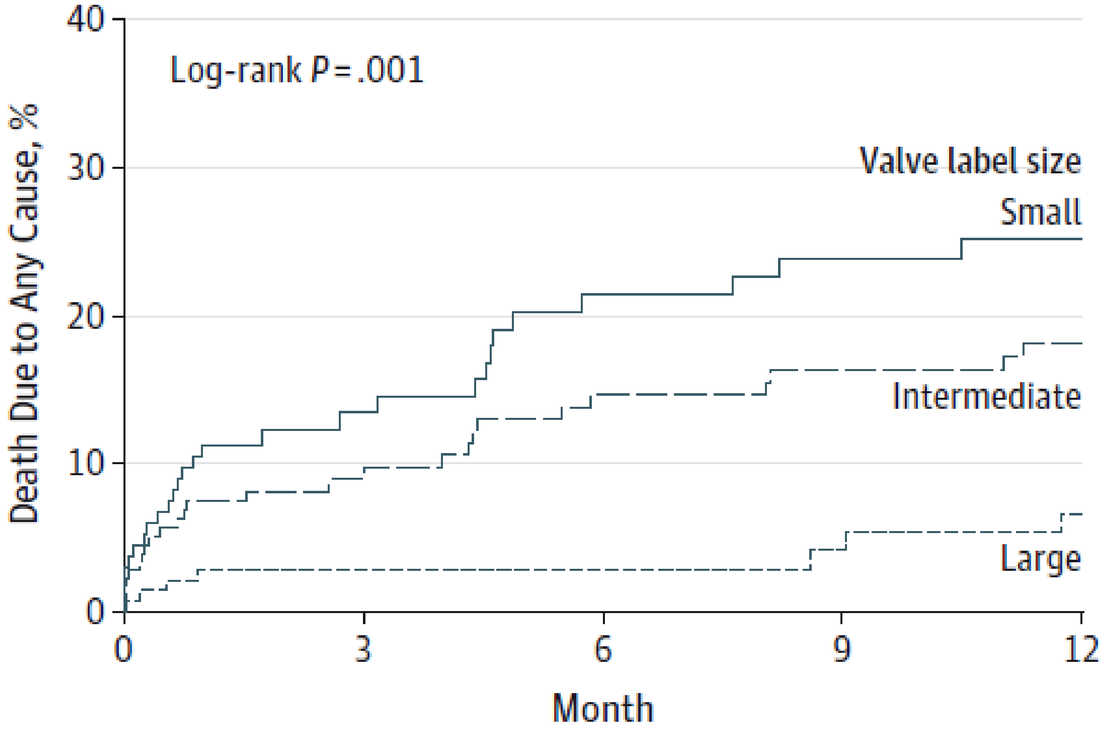
	Area ≤ 430 mm2 (IFU 20/23 mm BE) PARTNER Trials	Perimeter-derived diam ≤ 23.4 mm (IFU 23/26 SE) Corevalve/EVOLUT Trials
Intermediate Risk Trials [2,3]	**36%**	**22%**
Low Risk Trials [4,5]	**31%**	**21%**

- Higher in Southern Europe and Asia [1]
- TAV in SAV = 70-80% [6,7]
- Several fold higher in women who make up ~90% of small annulus population [1]

1 Freitas-Ferraz et al, Circ 2017;139:2685
2 Reardon et al, NEJM 2017;376:1321
3 Kodali et al, European Heart J 2016;37:2252
4 Popma et al, NEJM 2019;380:1706
5 Mack et al, NEJM 2019;380:1695
6 Dvir et al, JAMA 2014;312:162
7 Webb et al, JACC 2017;69:2253

Mortality with Surgical Valve label size

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

- **The smaller the surgical valve, the higher the mortality!**
- **Probably due to patient-prosthesis mismatch**

Dvir, et al. JAMA. 2014; 312(2):162-170

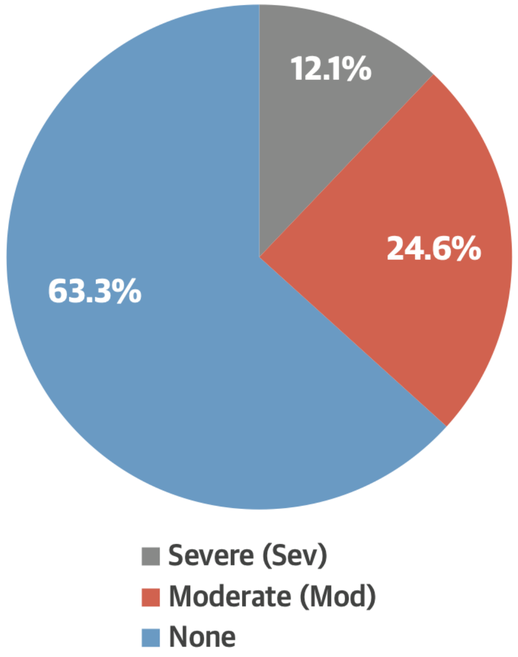
Patient-Prosthesis Mismatch (PPM)

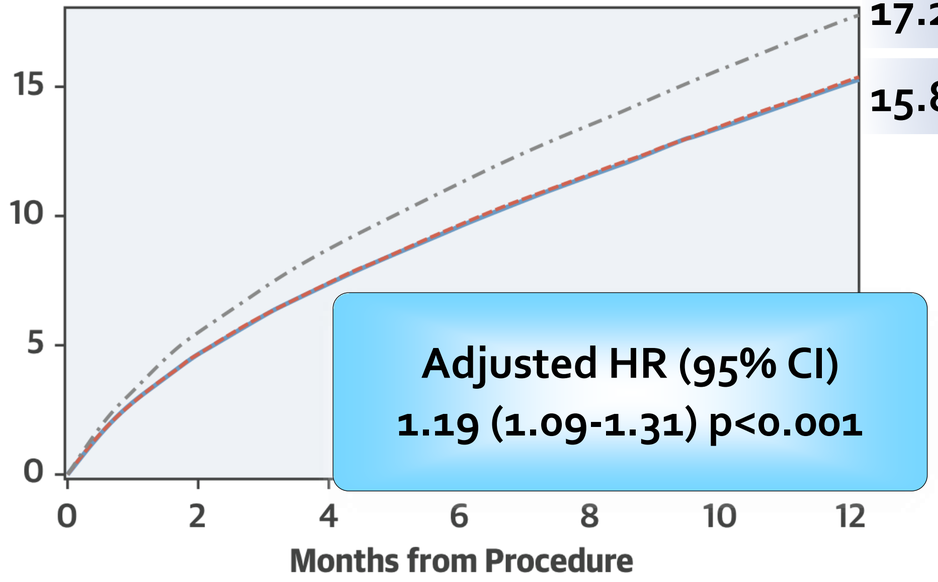
- Patient-prosthesis mismatch occurs when the effective orifice area (***EOA) of the implanted prosthetic valve is too small for the patient's body size***
- PPM is defined by indexed EOA/body surface area (BSA) ; none (>0.85 cm^2/m^2), moderate (0.85 to 0.65 cm^2/m^2), and severe (≤0.65cm^2/m^2)
  - Mod to severe : increased risk of adm of HF, redo AVR
  - Any degree : lower survival
- ***TAVR has been associated with a decreased risk of PPM compared to SAVR, especially in patients with small aortic annuli***

Lancellotti P, et al. Eur Heart J Cardiovasc Imaging. 2016;17(6):589-590.

Effect of PPM in Mortality

Prosthesis-Patient Mismatch (PPM) | **Mortality (%)**





17.2% Severe PPM

15.8% Moderate/None

Adjusted HR (95% CI)
1.19 (1.09-1.31) p<0.001

TAVR in STS/ACC TVT Registry™ All TAVR Devices (N=63,393)

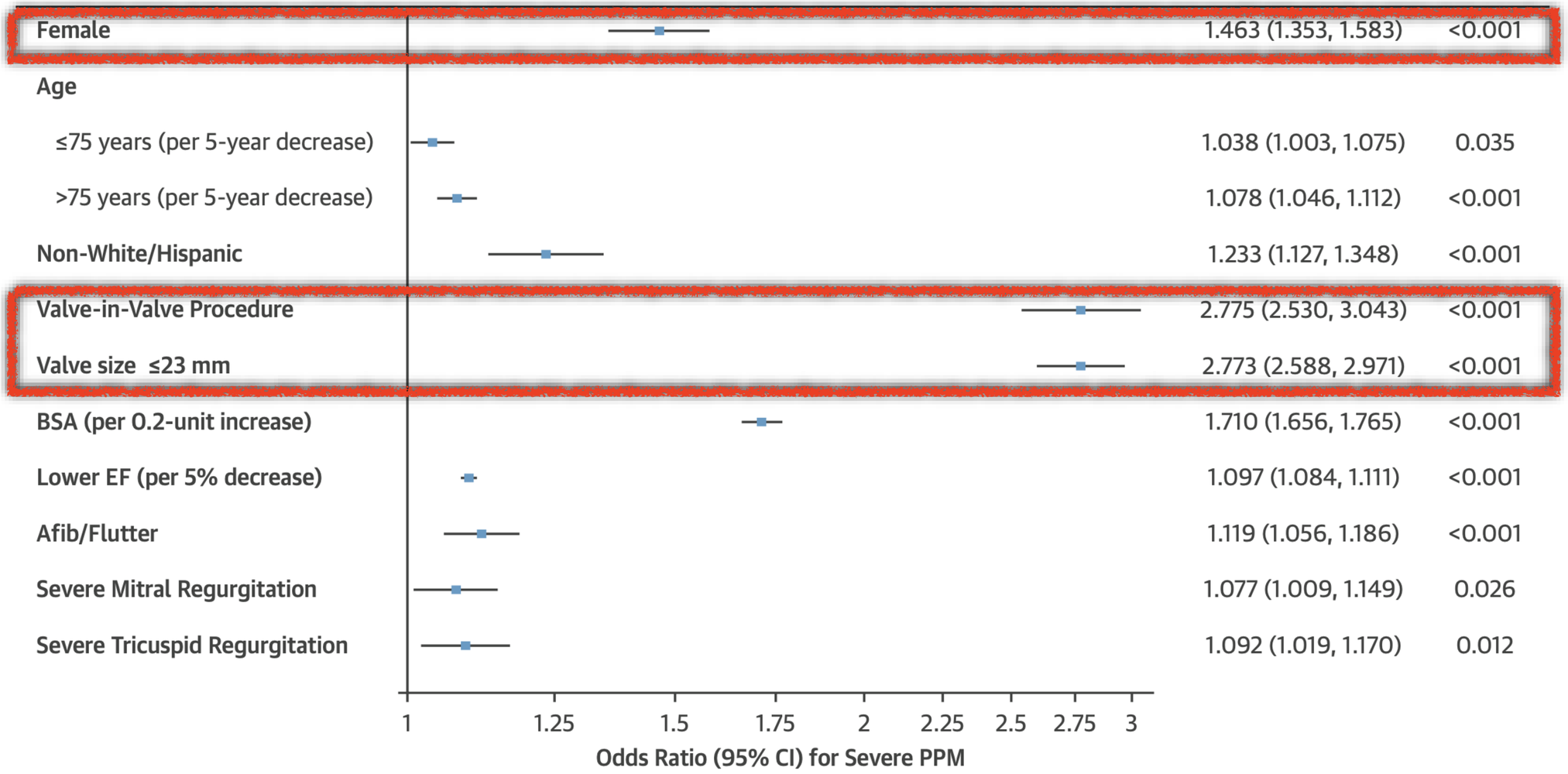
Number at Risk Adjusting for Baseline Covariates:

	Day 0	Month 4	Month 8	Month 12
No PPM	23,635	21,080	16,734	13,136
Mod PPM	8,983	7,995	6,277	4,831
Sev PPM	4,152	3,626	2,976	2,130

J Am Coll Cardiol 2018;72:2701–11

Predictors of Severe PPM

TAVR in STS/ACC TVT Registry™ All TAVR Devices (N=63,393)



J Am Coll Cardiol 2018;72:2701–11

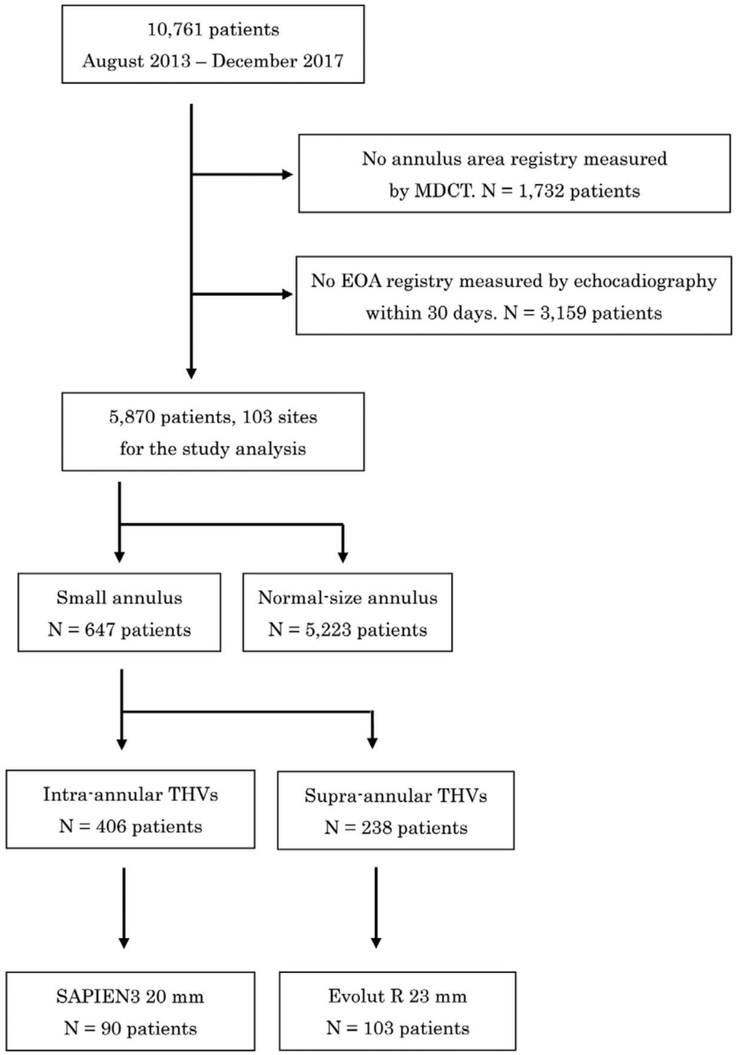
TAVR in SAA Japan Data

Transcatheter Aortic Valve Replacement in Patients With a Small Annulus

— From the Japanese Nationwide Registry (J-TVT) —

Kentaro Meguro, MD, PhD; Hiraku Kumamaru, PhD; Shun Kohsaka, MD, PhD; Takuya Hashimoto, MD, PhD; Ryota Kakizaki, MD, PhD; Tadashi Kitamura, MD, PhD; Hideyuki Shimizu, MD, PhD; Junya Ako, MD, PhD

- Japanese national TAVR registry between August 2013 and December 2017 were analyzed (n=10,761)
- Among a total of 5,870 registered patients, 647 (11.0%) had small annulus (area ≤314mm²)



Circulation Journal 2021 doi:10.1253/circj.CJ-20-1084

TAVR in SAA Japan Data

Table 2. Clinical and Echocardiographic Outcomes Within 30 Days

	Small annulus (n=647)	Normal-sized annulus (n=5,223)	P value
Clinical outcomes			
30-day mortality	9 (1.4)	35 (0.7)	0.05
New pacemaker implantation	42 (6.5)	287 (5.5)	0.30
Stroke	14 (2.2)	75 (1.4)	0.15
Echocardiographic outcomes			
Effective orifice area (cm^2)	1.5 (1.2–1.8)	1.7 (1.4–2.0)	<0.001
Indexed effective orifice area (cm^2/m^2)	1.10 (0.92–1.35)	1.16 (0.96–1.39)	<0.001
Mean pressure gradient (mmHg)	10.0 (6.9–14.2)	8.5 (6.0–11.5)	<0.001
Paravalvular leakage ≥moderate	112 (17.3)	1,272 (24.4)	<0.001
Prosthesis-patient mismatch			0.002
Severe	17 (2.6)	107 (2.0)	
Moderate	101 (15.6)	580 (11.1)	
Insignificant	529 (81.8)	4,536 (86.8)	

Table 3. Significant Predictors of Patient-Prosthesis Mismatch Within 30 Days in Multivariate Analysis

	Odds ratio (95% CI)	P value
Male	0.51 (0.40–0.65)	<0.001
Height (per 1 cm)	1.03 (1.02–1.05)	<0.001
Weight (per 1 kg)	1.03 (1.02–1.04)	<0.001
Hyperlipidemia	1.25 (1.06–1.46)	0.01
End-stage renal disease	0.47 (0.14–1.63)	0.23
Prior CABG	1.30 (0.97–1.75)	0.08
Prior stroke	0.86 (0.64–1.15)	0.30
Pacemaker	1.26 (0.93–1.71)	0.13
Left ventricular ejection fraction (per 1%)	0.993 (0.987–0.999)	0.03
Mean aortic pressure gradient (per 1 mmHg)	1.005 (1.001–1.009)	0.03
Aortic insufficiency grade ≥3	1.33 (1.01–1.75)	0.04
Mitral insufficiency grade ≥3	1.34 (1.01–1.78)	0.04
Bicuspid valve	1.75 (1.13–2.70)	0.01
Transfemoral approach	0.822 (0.678–0.997)	0.047
Small annulus	1.84 (1.46–2.32)	<0.001

Small annulus :

- smaller indexed effective orifice area (IEOA, 1.10 cm/m[0.92-1.35] vs. 1.16 cm/m? [0.96-1.39], P<0.001)

- higher mean pressure gradient (mPG, 10.0 mmHg [6.9-14.2] vs. 8.5 mmHg [6.0-11.5], P<0.001)

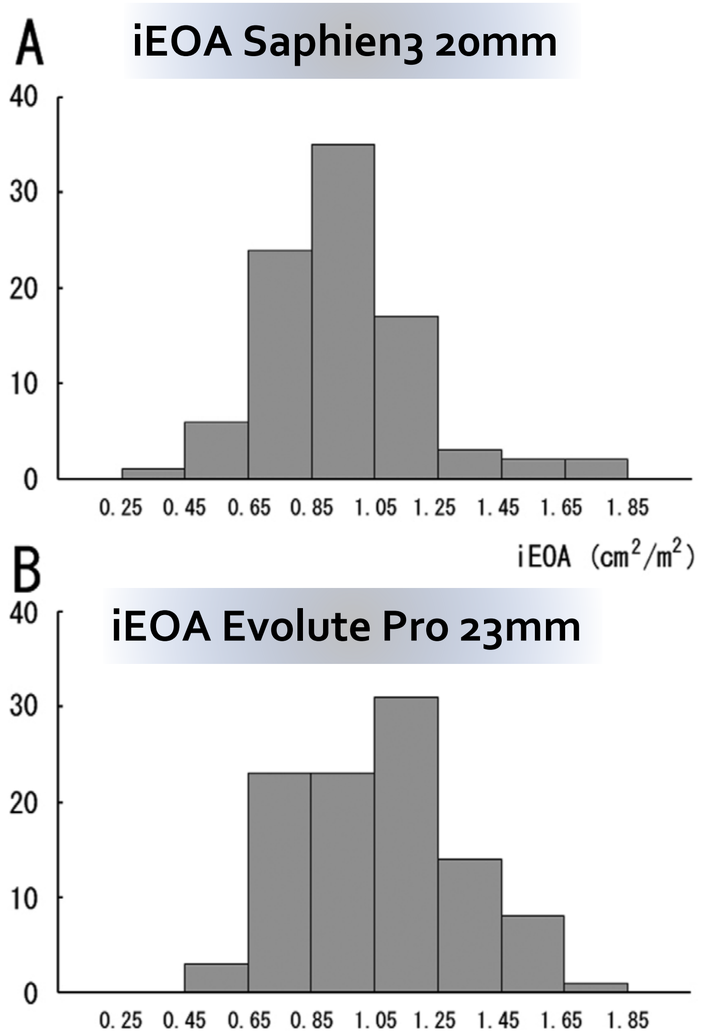
Circulation Journal ORIGINAL ARTICLE doi:10.1253/circj.CJ-20-1084

TAVR in SAA Japan Data : BEV vs SEV

Table 5. Clinical and Echocardiographic Outcomes Within 30 Days in Patients With SAPIEN3 20 mm and Evolut R 23 mm

	SAPIEN 3 20 mm (n=90)	Evolut R 23 mm (n=103)	P value
Clinical outcomes			
30-day mortality	0 (0.0)	0 (0.0)	1.00
New pacemaker implantation	4 (4.4)	10 (9.7)	0.16
Stroke	1 (1.1)	2 (1.9)	1.00
Echocardiographic outcomes			
Effective orifice area (cm^2)	1.2 (1.0–1.4)	1.4 (1.1–1.5)	0.002
Indexed effective orifice area (cm^2/m^2)	0.94 (0.78–1.06)	1.07 (0.84–1.24)	0.001
Mean pressure gradient (mmHg)	14.0 (10.0–18.5)	11.0 (7.0–14.0)	<0.001
Paravalvular leakage ≥moderate	13 (14.4)	17 (16.5)	0.69
Prosthesis-patient mismatch			0.21
Severe	7 (7.8)	3 (2.9)	
Moderate	24 (26.7)	23 (22.3)	
Insignificant	59 (65.6)	77 (74.8)	

- 20 mm Saphien3 vs 23mm Evolute Pro : smaller iEOA (0.94 cm≥/m? [0.78-1.06] vs. 1.07 cm?/m? [0.8-1.24], P=0.001) and higher mPG (14.0 mmHg [10.0-18.5] vs. 11.0 [7.0-14.0], P<0.001)
- the incidence of paravalvular leakage (≥moderate) was similar (14.4% Vs. 16.5%, P=0.69).



Circulation Journal ORIGINAL ARTICLE doi:10.1253/circj.CJ-20-1084

TAVR in SAA Korean Data

Features and Outcomes of Small Aortic Valve Annulus Transcatheter Aortic Valve Replacement: The Korean TAVR Registry

In Tae Moon, MD[1,*], Si-Hyuck Kang, MD, PhD[2,3,*], Chang-Hwan Yoon, MD, PhD[2,3], Tae-Jin Youn, MD, PhD[2,3], Kiyuk Chang [4], Cheol Woong Yu [5], and In-Ho Chae, MD, PhD[2,3]

- All patients treated with TAVR between June 2015 and June 2018 at 21 TAVR centers in Korea were retrospectively analyzed. (Median FU 517 days)
- small aortic annulus : mean diameter of less than 20 mm measured by CT
- primary outcomes : procedure-related complications and major adverse cardiac events (MACE)
- secondary outcomes : AR, PVL, iEOA, PPM, and aortic valve pressure gradient

Table 1. Baseline characteristics of small and non-small annulus valves

Variables	Small annulus (n = 70)	Non-small annulus (n = 590)	*P* value
Annular diameter	18.7 ± 1.0	23.4 ± 2.3	< 0.001
Age (yr)	78.3 ± 5.3	78.6 ± 6.8	0.631
Sex, male	14 (20.0)	314 (53.2)	< 0.001
BMI (kg/m^2)	24.1 ± 3.6	23.8 ± 3.6	0.530
Diabetes mellitus	22 (31.4)	211 (35.8)	0.820
Hypertension	53 (70.7)	439 (74.9)	0.513
Liver cirrhosis	2 (2.9)	9 (1.5)	0.742
COPD	16 (22.9)	146 (24.7)	0.841
Stroke	7 (10.0)	102 (17.3)	0.036
PCI history	19 (27.1)	153 (25.9)	0.941
Heart surgery history	8 (11.4)	27 (4.6)	0.033
AV Vmax (m/s)	4.7 ± 0.7	4.6 ± 0.8	0.474
AV mean PG (mmHg)	53.2 ± 16.4	52.3 ± 17.4	0.700
LV EF (%)	62.4 ± 8.8	55.9 ± 12.3	< 0.001
Creatinine (mg/dL)	1.2 ± 1.3	1.4 ± 1.6	0.207
STS score	7.0 ± 4.9	7.6 ± 6.9	0.313

J Cardiovasc Interv. 2023 Jul;2(3):187-198

TAVR in SAA Korean Data

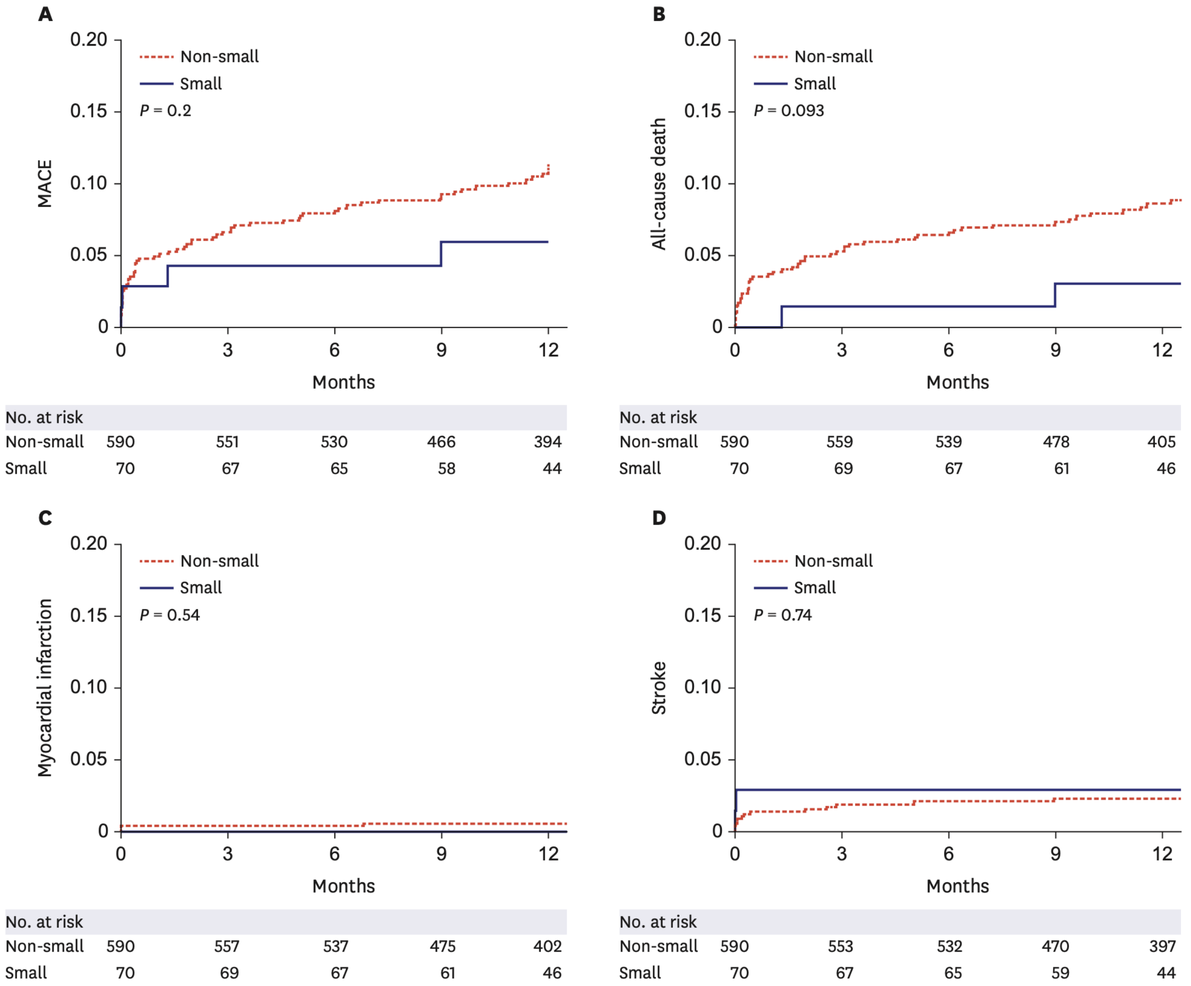


Table 3. Prosthesis parameters of small and non-small annulus valves

Parameters	Small (n = 70)	Non-small (n = 590)	*P* value
Post-procedure	(n = 69)	(n = 553)	
EOA index	1.070 ± 0.260	1.148 ± 0.324	0.025
AV maximal PG (mmHg)	25.5 ± 10.0	22.1 ± 9.3	0.005
AV mean PG (mmHg)	13.2 ± 5.8	11.6 ± 5.0	0.020
PPM			0.088
None (> 0.85 cm^2/m^2)	52 (75.4)	465 (84.1)	
Moderate (≤ 0.85 cm^2/m^2)	14 (20.3)	80 (14.5)	
Severe (< 0.65 cm^2/m^2)	3 (4.3)	8 (1.4)	
At 1 month	(n = 60)	(n = 468)	
EOA index	0.993 ± 0.246	1.113 ± 0.320	0.001
AV maximal PG (mmHg)	23.7 ± 11.4	21.8 ± 9.1	0.230
AV mean PG (mmHg)	12.1 ± 6.3	11.5 ± 4.8	0.470
PPM			0.004
None (> 0.85 cm^2/m^2)	40 (66.7)	378 (80.8)	
Moderate (≤ 0.85 cm^2/m^2)	15 (25.0)	81 (17.3)	
Severe (< 0.65 cm^2/m^2)	5 (8.2)	9 (1.9)	
At 1 year	(n = 49)	(n = 372)	
EOA index	1.041 ± 0.247	1.085 ± 0.299	0.265
AV maximal PG (mmHg)	22.5 ± 10.5	22.3 ± 9.5	0.849
AV mean PG (mmHg)	12.5 ± 5.8	11.8 ± 5.2	0.389
AV mean PG > 20 mmHg	5 (10.2)	23 (6.2)	0.449
PPM			0.718
None (> 85 cm^2/m^2)	37 (77.1)	293 (80.1)	
Moderate (≤ 0.85 cm^2/m^2)	8 (16.7)	59 (16.1)	
Severe (< 0.65 cm^2/m^2)	3 (6.2)	14 (3.8)	

J Cardiovasc Interv. 2023 Jul;2(3):187-198

BEV vs SEV in SAA Korea Data

Table 4. Baseline characteristics of BEV and SEV in small annulus

Variables	BEV (n = 27)	SEV (n = 41)	*P* value
Annulus diameter	19.0 ± 0.8	18.5 ± 1.1	0.041
Age (yr)	78.3 ± 5.5	78.5 ± 5.3	0.923
Sex, male	4 (14.8)	10 (24.4)	0.516
BMI (kg/m^2)	23.5 ± 3.2	24.7 ± 3.7	0.180
Diabetes mellitus	9 (33.3)	13 (31.7)	0.345
Hypertension	18 (66.7)	30 (73.2)	0.761
Liver cirrhosis	0 (0.0)	2 (4.9)	0.666
COPD	6 (22.2)	10 (24.4)	1.000
Stroke	4 (14.8)	3 (7.3)	0.402
PCI history	7 (25.9)	12 (29.3)	0.981
Heart surgery history	4 (14.8)	4 (9.8)	0.803
AV Vmax (m/s)	4.6 ± 0.8	4.8 ± 0.6	0.239
AV mean PG (mmHg)	52.1 ± 17.1	54.3 ± 16.3	0.589
LV EF (%)	62.1 ± 5.5	62.9 ± 10.2	0.659
Creatinine (mg/dL)	1.0 ± 0.6	1.3 ± 1.5	0.239
STS score	6.5 ± 4.4	7.4 ± 5.3	0.510

Table 5. Clinical outcomes of BEV and SEV in small annulus

Clinical outcomes	BEV (n = 27)	SEV (n = 41)	*P* value
Procedure related complications	2 (7.4)	4 (9.8)	1.000
Pacemaker insertion	2 (7.4)	4 (9.8)	1.000
Annular rupture	0 (0.0)	0 (0.0)	-
Coronary obstruction	0 (0.0)	0 (0.0)	-
Cardiac tamponade	0 (0.0)	1 (2.4)	1.000
1 month MACE	5 (18.5)	2 (4.9)	0.161
All-cause mortality	1 (3.7)	0 (0.0)	0.832
Myocardial infarction	0 (0.0)	0 (0.0)	-
Stroke	4 (14.8)	2 (4.9)	0.329
1 year MACE	5 (18.5)	2 (4.9)	0.161
All-cause mortality	2 (7.4)	0 (0.0)	0.300
Myocardial infarction	0 (0.0)	0 (0.0)	-
Stroke	4 (14.8)	2 (4.9)	0.329

Table 6. EOA, PPM, AR and paravalvular AR of BEV and SEV in small annulus

Parameters	BEV (n = 27)	SEV (n = 41)	*P* value
Post-procedure	(n = 27)	(n = 40)	
EOA index	1.006 ± 0.260	1.113 ± 0.261	0.104
AV maximal PG (mmHg)	27.5 ± 9.0	24.1 ± 10.7	0.180
AV mean PG (mmHg)	14.3 ± 5.1	12.4 ± 6.4	0.187
PPM			0.407
None (> 85 cm^2/m^2)	18 (66.7)	32 (80.0)	
Moderate (≤ 0.85 cm^2/m^2)	7 (25.9)	7 (17.5)	
Severe (< 0.65 cm^2/m^2)	2 (7.4)	1 (2.5)	
AR			0.705
None	24 (88.9)	35 (85.4)	
Mild	3 (11.1)	5 (12.2)	
Moderate	0 (0.0)	1 (2.4)	
Paravalvular AR			0.057
None	19 (70.4)	17 (41.5)	
Mild	8 (29.6)	23 (56.1)	
Moderate	0 (0.0)	1 (2.4)	
At 1 month	(n = 23)	(n = 34)	
EOA index	0.903 ± 0.222	1.043 ± 0.245	0.029
AV maximal PG (mmHg)	28.3 ± 10.3	20.9 ± 11.5	0.018
AV mean PG (mmHg)	15.5 ± 5.1	9.9 ± 6.2	0.001
PPM			0.163
None (> 85 cm^2/m^2)	12 (52.2)	26 (74.3)	
Moderate (≤ 0.85 cm^2/m^2)	9 (39.1)	6 (17.1)	
Severe (< 0.65 cm^2/m^2)	2 (8.3)	3 (8.6)	
AR			0.235
None	21 (91.3)	30 (85.7)	
Mild	1 (4.3)	5 (14.3)	
Moderate	1 (4.3)	0 (0.0)	
Paravalvular AR			0.308
None	14 (60.9)	18 (51.4)	
Mild	8 (34.8)	17 (48.6)	
Moderate	1 (4.3)	0 (0.0)	
At 1 year	(n = 16)	(n = 31)	
EOA index	0.971 ± 0.249	1.060 ± 0.226	0.240
AV maximal PG (mmHg)	29.5 ± 10.6	19.0 ± 8.9	0.001
AV mean PG (mmHg)	15.7 ± 5.3	10.9 ± 5.6	0.007
AV mean PG > 20 mmHg	3 (18.8)	2 (6.5)	0.426
PPM			0.462
None (> 85 cm^2/m^2)	11 (66.8)	24 (80.0)	
Moderate (≤ 0.85 cm^2/m^2)	3 (18.8)	5 (16.7)	
Severe (< 0.65 cm^2/m^2)	2 (12.5)	1 (3.3)	
AR			0.413
None	14 (87.5)	22 (71.0)	
Mild	2 (12.5)	8 (25.8)	
Moderate	0 (0.0)	1 (3.2)	
Paravalvular AR			0.652
None	10 (62.5)	15 (48.4)	
Mild	5 (31.2)	13 (41.9)	
Moderate	1 (6.2)	3 (9.7)	

J Cardiovasc Interv. 2023 Jul;2(3):187-198

Which Valve is better in SAA? FRANCE-TAVI Registry

Transcatheter aortic valve replacement in small aortic annuli: Results from the FRANCE-TAVI registry. The Xs-TAVI Trial

Walid Ben-Ali MD PhD FRCSC
Thomas Modine MD PhD MBA
On behalf of the France TAVI group

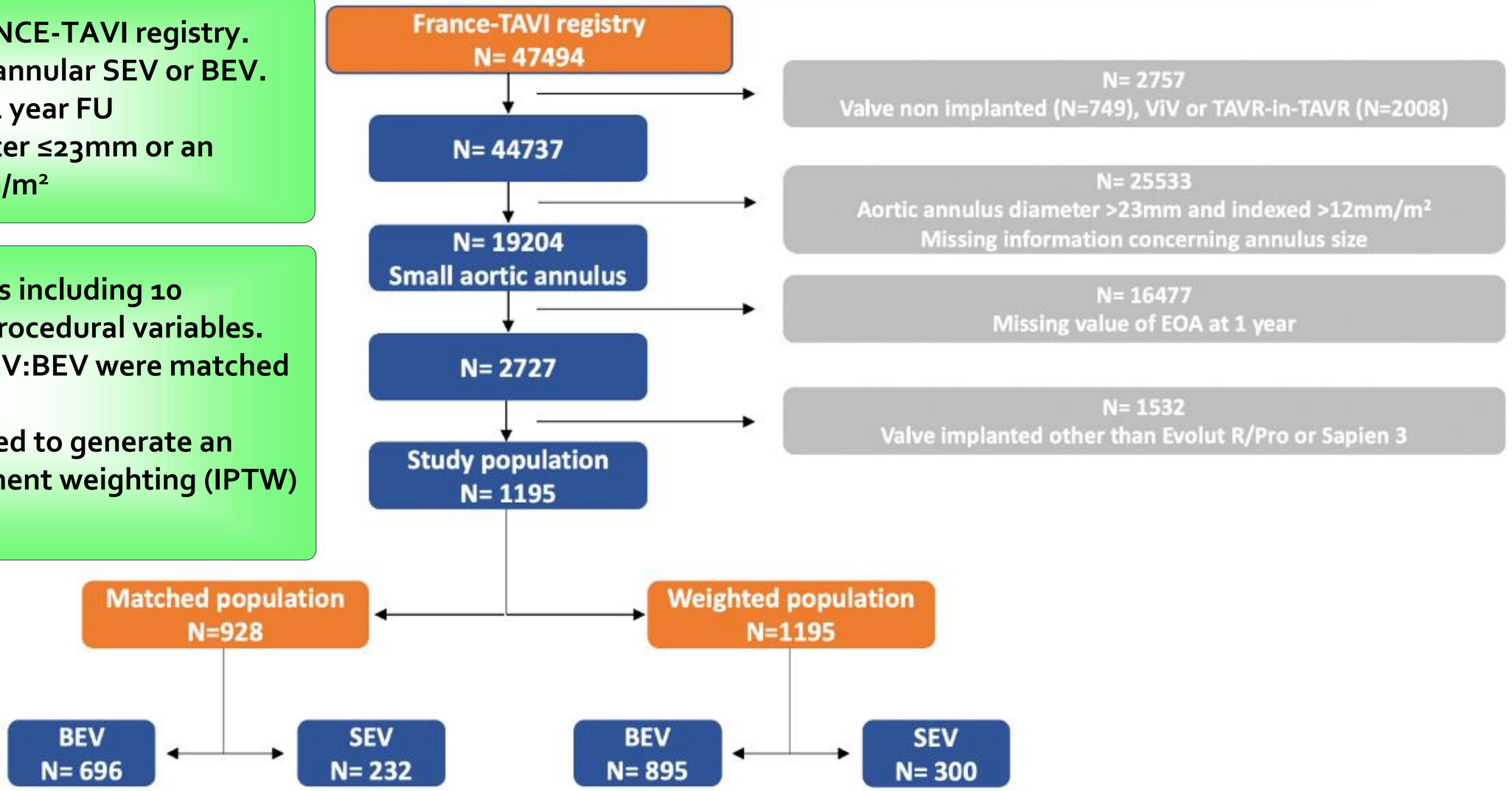
Xs-TAVI Trial

1st large all-comer real-world study comparing the SEV and BEV in small aortic annuli

in terms of hemodynamic performances and impact on clinical outcomes.

- pt. with SAA in the FRANCE-TAVI registry.
- Third generation supra-annular SEV or BEV.
- Complete Echo data at 1 year FU
- SAA defined as a diameter ≤23mm or an indexed diameter ≤12mm/m²

- Propensity score analysis including 10 anatomical, clinical and procedural variables.
- Patients treated with SEV:BEV were matched 1:3
- Propensity score was used to generate an inverse probability treatment weighting (IPTW) as sensitivity analysis



Baseline Characteristics

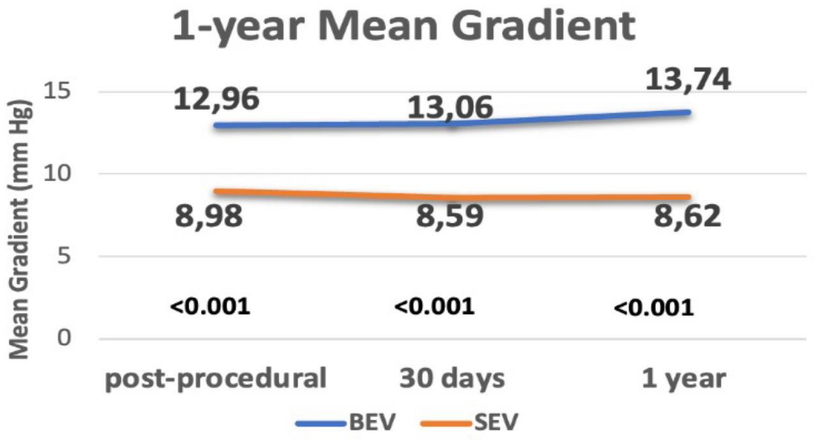
Variables	Before matching			After matching		
	BEV (N=895)	SEV (N=300)	p-value	BEV (N=696)	SEV (N=232)	p-value
Demographic characteristics						
Age (years)	82.2 ± 7	83.03 ± 6.48	0.28	82.64 ± 6.59	82.31 ± 6.67	0.8
Women (%)	33.3	20	<0.001	75.6	75.4	0.9
BMI (%)	27.36 ± 5.7	27.36 ± 6.32	0.59	27.17 ± 5.61	27.46 ± 6.49	0.8
Body surface area (m^2)	1.78 ± 0.25	1.74 ± 0.26	0.01	1.75 ± 0.24	1.75 ± 0.27	0.3
NYHA III/IV (%)	51.8	50.5	0.76	52.1	50.5	0.3
EuroSCORE 2 (%)	4.34 ± 4.06	4.63 ± 3.91	0.1	4.55 ± 4.27	4.54 ± 3.86	0.47
Comorbidities and past medical history						
Hypertension (%)	74.1	73.3	0.86	72.8	74.6	0.7
Diabetes (%)	25.4	21	0.15	24.4	23.7	0.23
Myocardial infarction < 90 days (%)	1.2	3.6	0.85	1.6	4.8	0.85
PCI (%)	27.7	28.5	0.8	25.8	29.1	0.09
Cerebrovascular event (%)	9.7	12.4	0.23	9.6	12.2	0.9
Peripheral vascular disease (%)	16.9	16.9	0.93	18.6	16.2	0.3
Stage 3 or 4 chronic renal failure (%)	5.3	9.7	0.81	6.2	6.5	0.7
Dialysis (%)	1.7	3.7	0.64	1.6	4.7	0.81
Previous permanent pacemaker (%)	8.4	7.4	0.67	8.0	5.2	0.5
Atrial fibrillation (%)	24.5	27.6	0.33	23.6	27.6	0.7
Echocardiographic characteristics						
LVEF (%)	59.15 ± 11.73	61.4 ± 11.39	<0.001	60.2 ± 11.3	60.23 ± 11.69	0.2
EOA (cm^2)	0.71 ± 0.27	0.72 ± 0.25	0.61	0.7 ± 0.24	0.72 ± 0.26	0.4
Mean gradient (mm Hg)	50.62 ± 15.7	50.84 ± 16.83	0.71	51.2 ± 15.66	51.27 ± 16.85	0.5
Aortic regurgitation ≥2 (%)	17.5	18	0.93	17.7	18.9	0.7
MSCT characteristics						
Aortic annulus diameter (mm)	22.22 ± 1.68	21.8 ± 1.55	<0.001	22.01 ± 1.47	22 ± 1.51	0.9
Indexed aortic annulus diameter (mm)	12.65 ± 1.56	12.72 ± 1.62	0.49	12.73 ± 1.55	12.8 ± 1.69	0.38

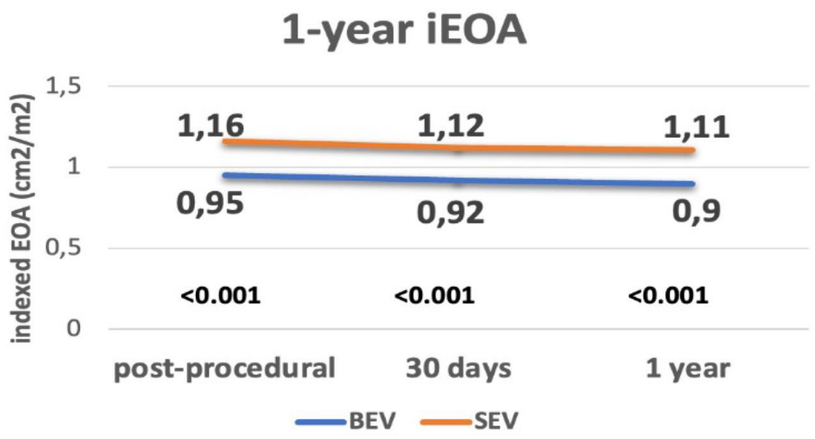
CRF TCT

Well Matched Groups

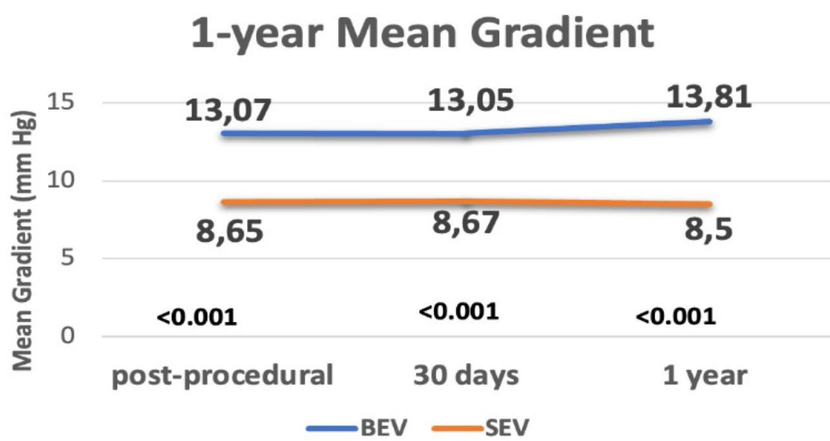
1-year Hemodynamic Valve Performance

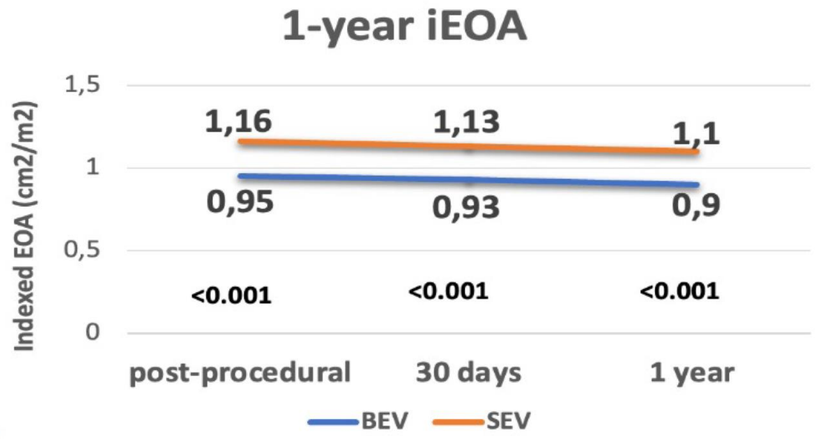
Global population (before matching) N=1 195





Matched population N=928



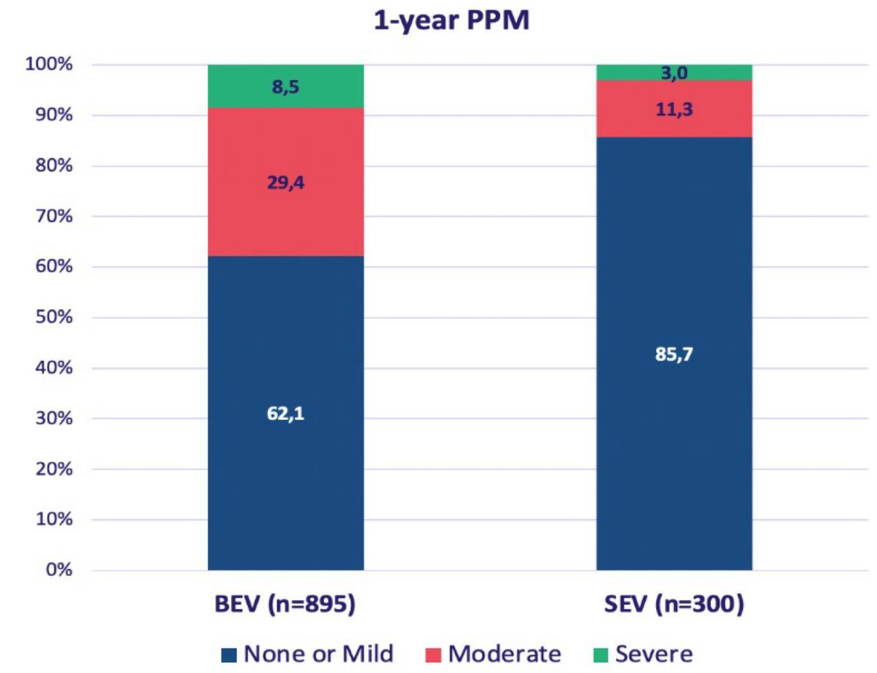


Supra-annular SEV showed superior 1-year hemodynamic valve performance.

PVL ≥ 2 at 1-year: 15.3 vs 15.9%; p=0.3

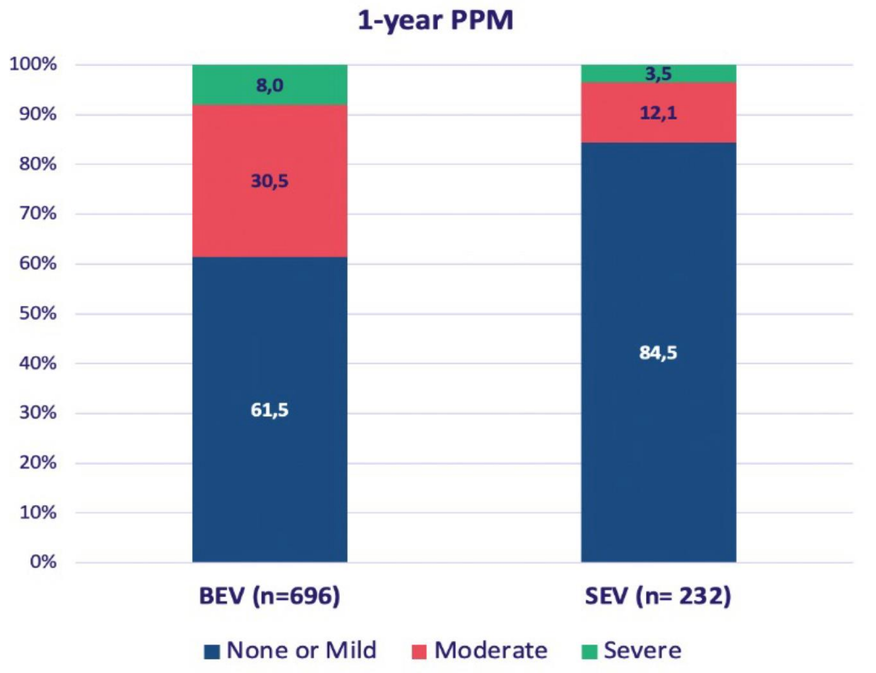
1-year Hemodynamic Valve Performance

Global population (before matching) N=1 195



	P-value (χ2 test)
Severe PPM vs no severe PPM	<0.001
Moderate or severe PPM vs no PPM	<0.001

Matched population N= 928



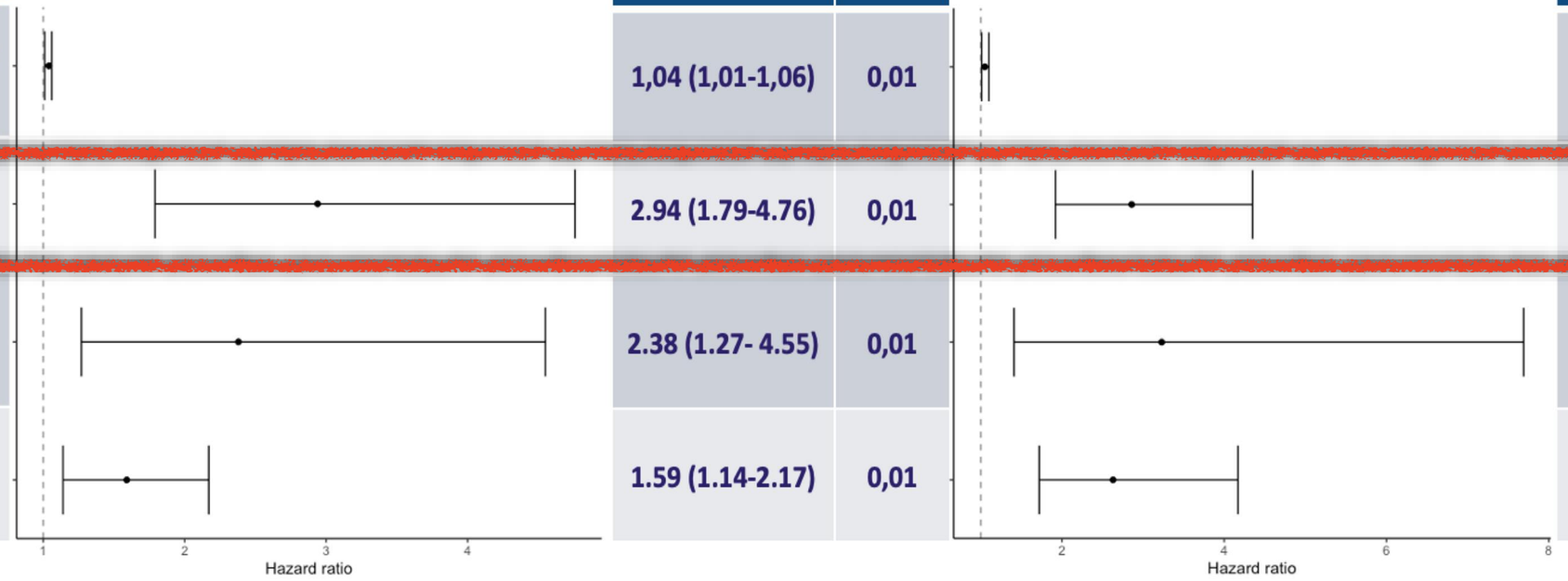
	P-value (McNemar test)
Severe PPM vs no severe PPM	<0.001
Moderate or severe PPM vs no PPM	<0.001

Supra-annular SEV showed superior 1-year hemodynamic valve performance.

What are the essential Results?

Forest plot of Independent Predictors of 1-year Moderate to Severe PPM

Variables	MATCHED HR	MATCHED p	IPTW HR	IPTW p
Post proc mean gradient (1 mm Hg increase)	1,04 (1,01-1,06)	0,01	1,05 (1,01-1,1)	0,03
Valve type (SEV ref)	2.94 (1.79-4.76)	0,01	2.86 (1.92-4.35)	0,01
Annulus size (1 mm decrease)	2.38 (1.27- 4.55)	0,01	3.23 (1.41-7.69)	0,005
Female gender	1.59 (1.14-2.17)	0,01	2,63 (1.72-4.17)	<0.001

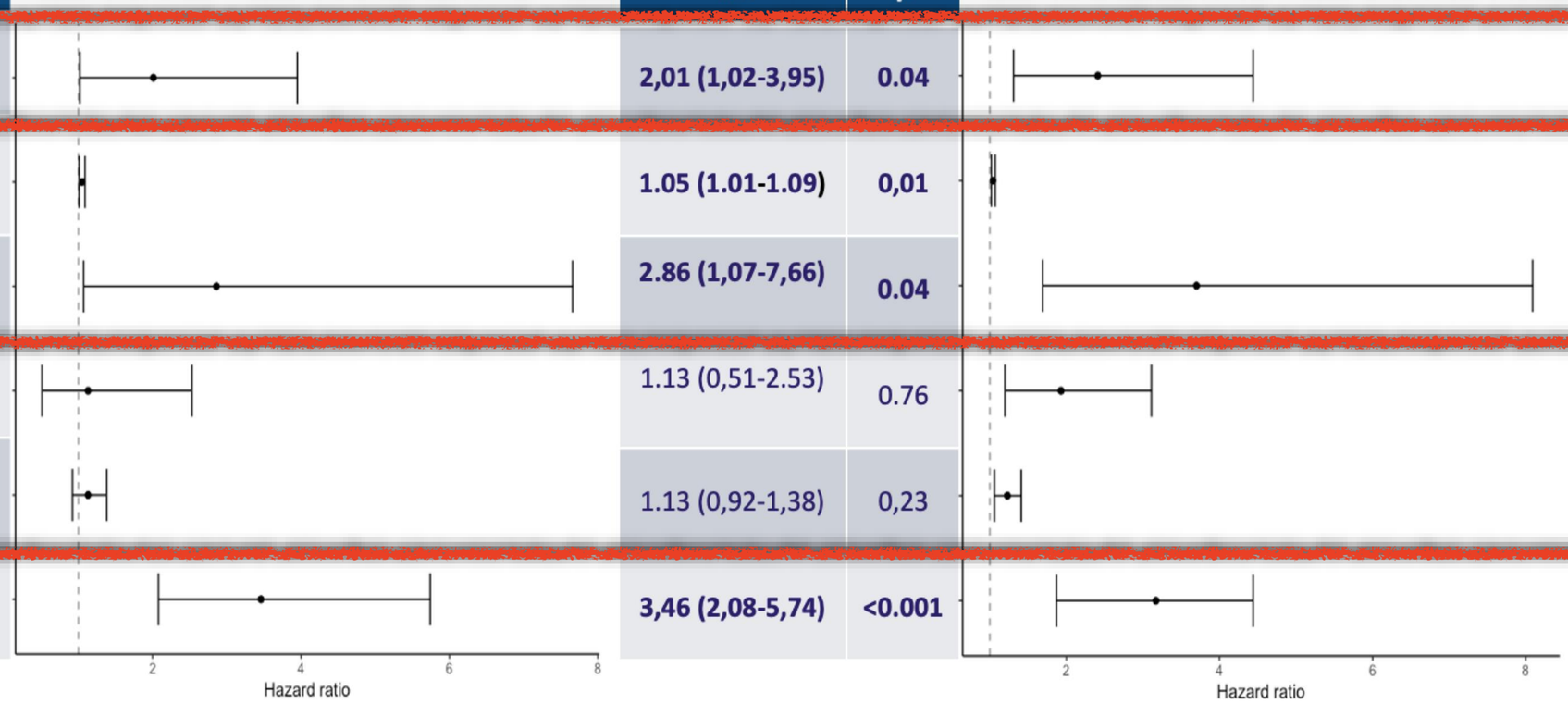


BEV was an independent predictor of 1-year moderate or severe PPM

What are the essential Results?

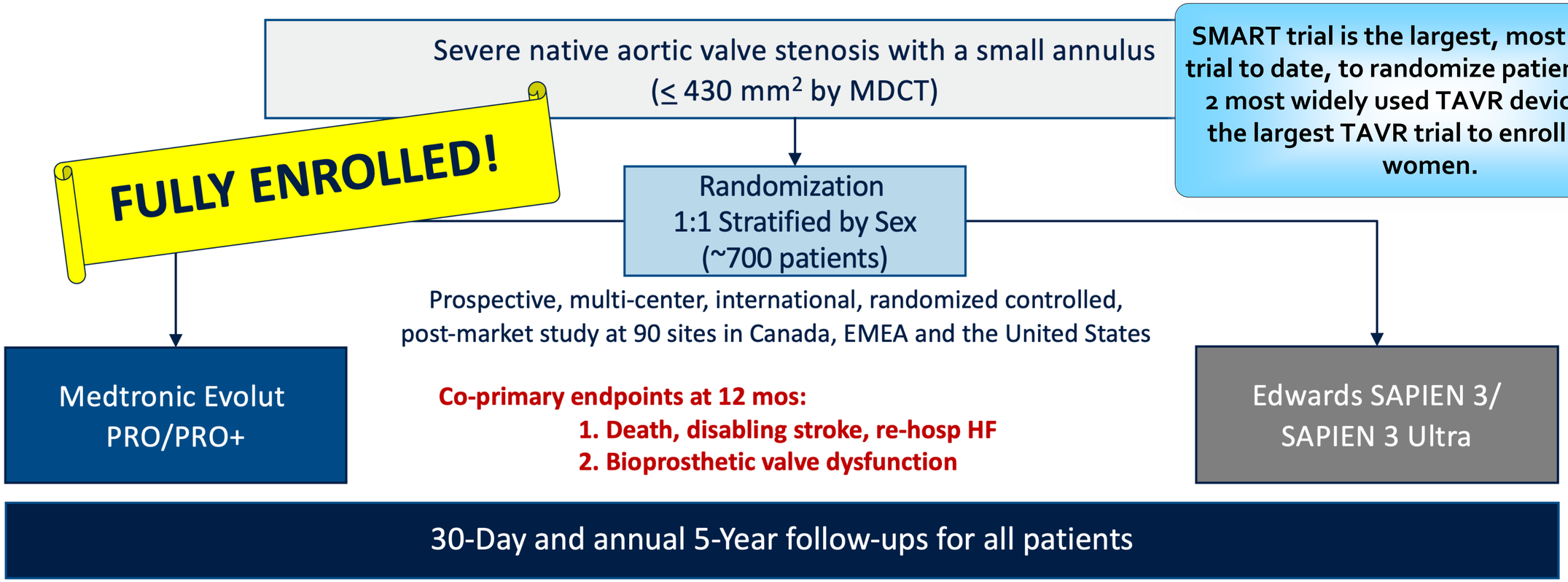
Forest plot of Independent Predictors of 3-year All-Cause Mortality

Variables	MATCHED HR	MATCHED p	IPTW HR	IPTW p
Severe PPM at 1 year	2,01 (1,02-3,95)	0.04	2.41 (1.31-4.44)	0,004
Index hospitalization (1 day increase)	1.05 (1.01-1.09)	0,01	1.04 (1.02-1.07)	0.002
Major bleeding	2.86 (1,07-7,66)	0.04	3.70 (1.69-8.09)	0.001
Valve type (SEV ref)	1.13 (0,51-2.53)	0.76	1,93 (1,2-3,11)	0.03
Annulus size (1 mm decrease)	1.13 (0,92-1,38)	0,23	1.23 (1.06-1.41)	0.005
Atrial fibrillation	3,46 (2,08-5,74)	<0.001	3.17 (1.87-4.44)	<0,001



Severe PPM at 1y independent predictor of 3yr all-cause death

Which Valve is better in SAA? : SMART (SMall Annuli Randomized To Evolut or SAPIEN) Trial



Study Organization	Chair/PI: Howard C. Herrmann, MD Co-PIs: Roxana Mehran, MD and Didier Tchetche MD
Major inclusion/exclusion criteria	• Small annulus with all risk groups (low to high) • An "all-comers" trial (including bicuspid valves) • Patient's anatomy must be suitable for TF TAVR treatment with both devices
External Support (Medtronic)	Echocardiographic Core Laboratory, Clinical Events Committee (CEC), Data Safety Monitoring Board (DSMB), Subject Confirmation of Qualification/Case Planning Committee (screening phase)

Am Heart J 2022;243:92–102

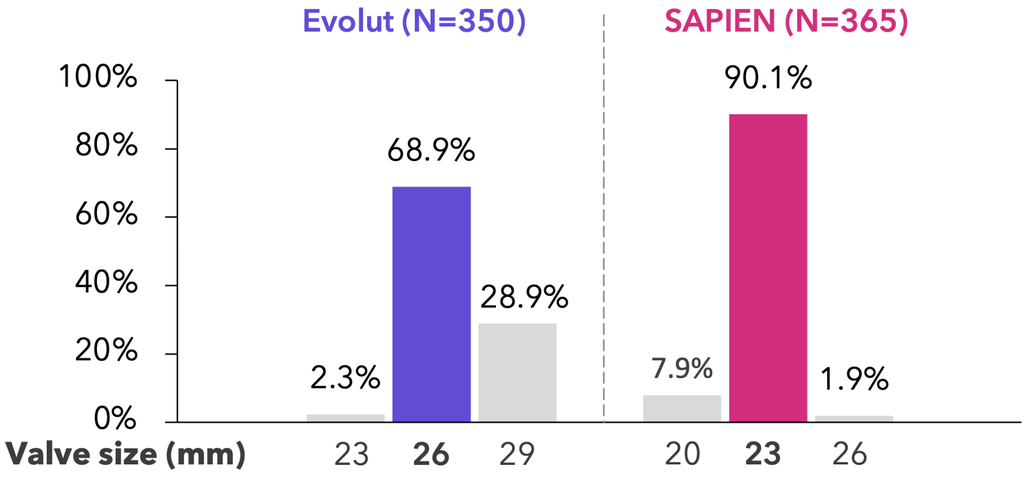
SMART (SMall Annuli Randomized To Evolut or SAPIEN) Trial

Valve and procedural data

SMART Trial

Valve size

Aortic annulus size	Evolut (N=355)	SAPIEN (N=361)
Mean area (mm²)	380.9 ± 34.2	382.8 ± 33.9
Mean perimeter (mm)	70.3 ± 3.2	70.4 ± 3.2



Procedural characteristics and outcomes

Characteristic	Evolut (N=355)	SAPIEN (N=361)	P Value[a]
Total time in the procedure room[b] (min)	116 ± 44	106 ± 43	0.002
Catheter (device) time in the body (min)	18 ± 15	14 ± 12	<0.001
Contrast volume[c] (ml)	121 ± 59	95 ± 43	<0.001
Valve embolization	1.1	0.0	0.06
Device success at 30 days (VARC-2)[d]	85.2%	59.2%	<0.001
Device success at 30 days (VARC-3)[e]	94.5%	86.6%	<0.001

[a]Continuous variables compared using t-tests; categorical variables compared using chi-squared tests.
[b]Data available for 354 Evolut and 361 SAPIEN patients.
[c]Data available for 347 Evolut and 357 SAPIEN patients.
[d]Evaluated according to VARC-2 criteria in 291 Evolut and 319 SAPIEN patients.
[e]Evaluated according to VARC-3 criteria in 327 Evolut and 328 SAPIEN patients.

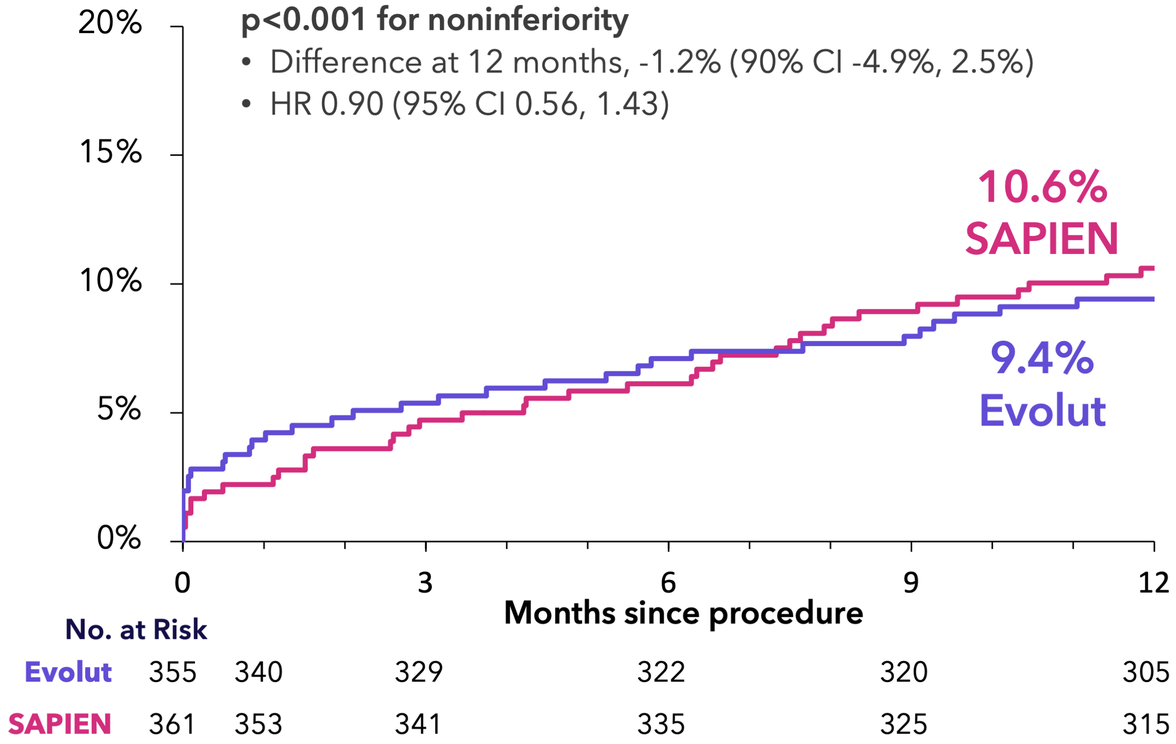
SMART (SMall Annuli Randomized To Evolut or SAPIEN) Trial

Co-primary endpoint 1:

Clinical outcome composite through 12 months powered for noninferiority

SMART Trial

Mortality, Disabling Stroke, or HF Rehospitalization



12 Months	Evolut (N=355)	SAPIEN (N=361)	HR (95% CI)
All-cause mortality	5.1%	5.9%	0.88 (0.47, 1.65)
Disabling stroke	3.1%	2.6%	1.26 (0.52, 3.03)
HF rehosp	3.8%	3.5%	1.11 (0.51, 2.44)

SMART (SMall Annuli Randomized To Evolut or SAPIEN) Trial

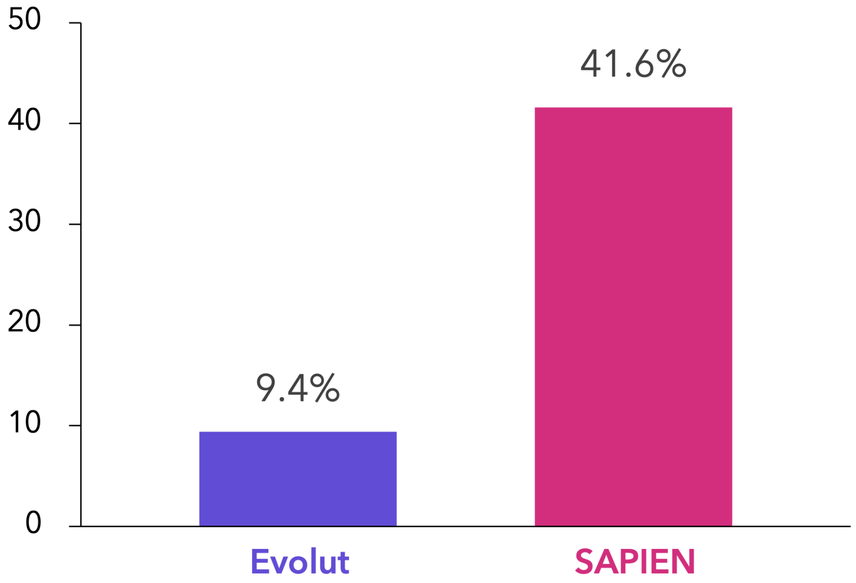
Co-primary endpoint 2:

BVD through 12 months powered for superiority

SMART Trial

Bioprosthetic Valve Dysfunction through 12 months

Difference, -32.2% (95% CI -38.7%, -25.6%)
p<0.001 for superiority



	Evolut (N=350)	SAPIEN (N=365)	P Value
BVD composite	**9.4%**	**41.6%**	**<0.001**
HSVD	3.2%	32.2%	
NSVD	5.9%	18.2%	
Thrombosis (clinical)	0.3%	0.3%	
Endocarditis	0.6%	2.3%	
AV Reintervention	0.9%	0.6%	

HSVD = Mean gradient ≥ 20 mmHg
NSVD = Severe PPM per VARC-3 or ≥moderate total AR

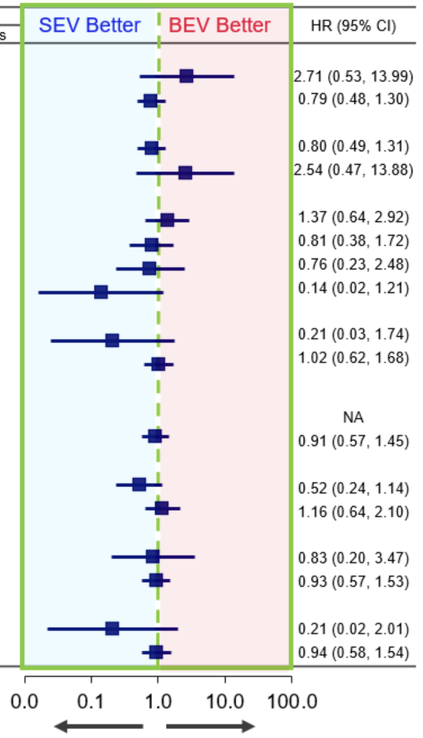
SMART (SMall Annuli Randomized To Evolut or SAPIEN) Trial

Prespecified subgroup analyses for the co-primary endpoints

SMART Trial

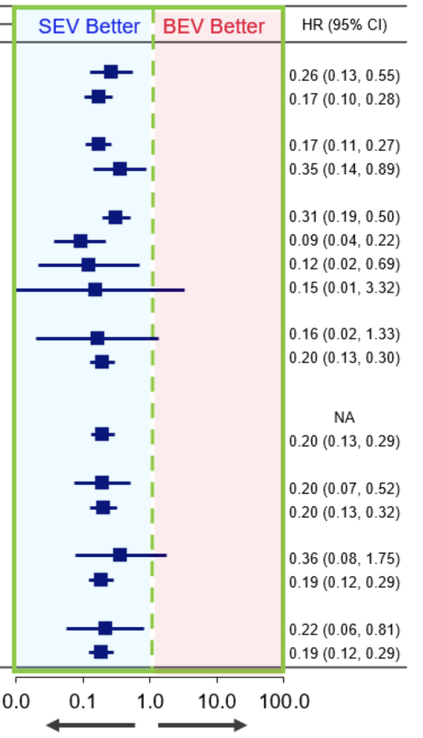
Clinical Outcome Composite Through 12 Months

Variable	SEV KM rate through 12 months	BEV KM rate through 12 months	HR (95% CI)
Age, years			
<75	8.1%	3.1%	2.71 (0.53, 13.99)
≥75	9.7%	12.2%	0.79 (0.48, 1.30)
Sex			
Female	9.4%	11.8%	0.80 (0.49, 1.31)
Male	9.3%	3.8%	2.54 (0.47, 13.88)
STS-PROM, %			
<3	8.3%	6.3%	1.37 (0.64, 2.92)
≥3 - <5	9.9%	12.2%	0.81 (0.38, 1.72)
≥5 - <8	13.7%	17.8%	0.76 (0.23, 2.48)
≥8	7.7%	41.7%	0.14 (0.02, 1.21)
LVEF, %			
<50	6.7%	27.3%	0.21 (0.03, 1.74)
≥50	9.3%	9.3%	1.02 (0.62, 1.68)
Renal dysfunction (on dialysis)			
Yes	0.0%	0.0%	NA
No	9.6%	10.7%	0.91 (0.57, 1.45)
Atrial fibrillation/flutter			
Yes	14.7%	26.2%	0.52 (0.24, 1.14)
No	8.3%	7.4%	1.16 (0.64, 2.10)
Prior cerebrovascular accident			
Yes	13.3%	16.7%	0.83 (0.20, 3.47)
No	9.3%	10.1%	0.93 (0.57, 1.53)
Pre-existing LBBB/CHB			
Yes	3.7%	16.1%	0.21 (0.02, 2.01)
No	9.6%	10.2%	0.94 (0.58, 1.54)



BVD Through 12 Months

Variable	SEV KM rate through 12 months	BEV KM rate through 12 months	HR (95% CI)
Age, years			
<75	19.2%	52.8%	0.26 (0.13, 0.55)
≥75	7.5%	39.0%	0.17 (0.10, 0.28)
Sex			
Female	8.4%	41.8%	0.17 (0.11, 0.27)
Male	16.5%	40.3%	0.35 (0.14, 0.89)
STS-PROM, %			
<3	14.1%	39.8%	0.31 (0.19, 0.50)
≥3 - <5	5.0%	47.4%	0.09 (0.04, 0.22)
≥5 - <8	3.4%	34.5%	0.12 (0.02, 0.69)
≥8	0.0%	33.3%	0.15 (0.01, 3.32)
LVEF, %			
<50	10.0%	46.3%	0.16 (0.02, 1.33)
≥50	9.4%	41.2%	0.20 (0.13, 0.30)
Renal dysfunction (on dialysis)			
Yes	0.0%	0.0%	NA
No	9.6%	42.0%	0.20 (0.13, 0.29)
Atrial fibrillation/flutter			
Yes	8.5%	41.9%	0.20 (0.07, 0.52)
No	9.8%	40.6%	0.20 (0.13, 0.32)
Prior cerebrovascular accident			
Yes	10.5%	33.7%	0.36 (0.08, 1.75)
No	9.5%	42.2%	0.19 (0.12, 0.29)
Pre-existing LBBB/CHB			
Yes	13.1%	49.0%	0.22 (0.06, 0.81)
No	9.3%	42.0%	0.19 (0.12, 0.29)



No significant interactions were observed between treatment and any of the prespecified baseline subgroups with respect to either of the co-primary endpoints.

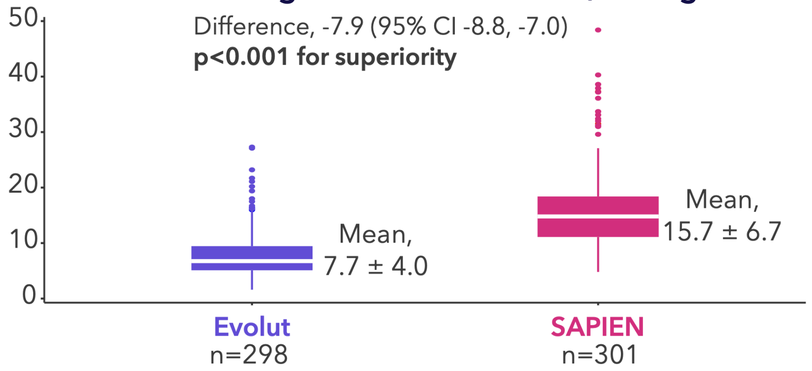
SMART (SMall Annuli Randomized To Evolut or SAPIEN) Trial

Hypothesis-tested secondary endpoints

SMART Trial

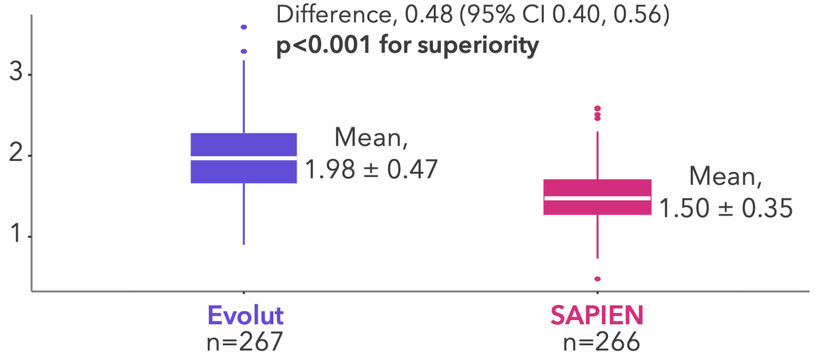
Mean gradient at 12 months, mmHg

Difference, -7.9 (95% CI -8.8, -7.0)
p<0.001 for superiority



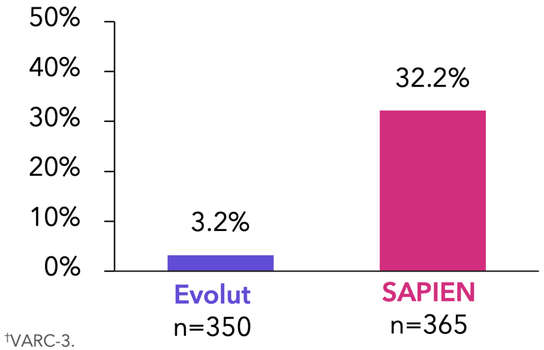
EOA at 12 months, cm^2

Difference, 0.48 (95% CI 0.40, 0.56)
p<0.001 for superiority



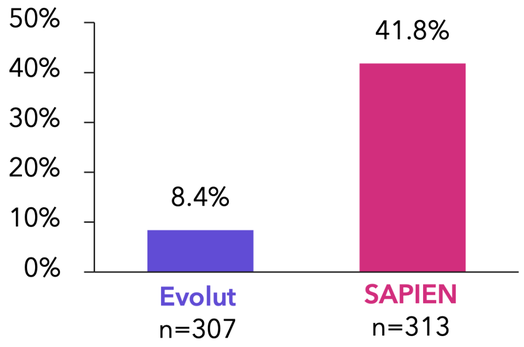
HSVD through 12 months, %

Difference, -29.1% (95% CI -34.6%, -23.5%)
p<0.001 for superiority



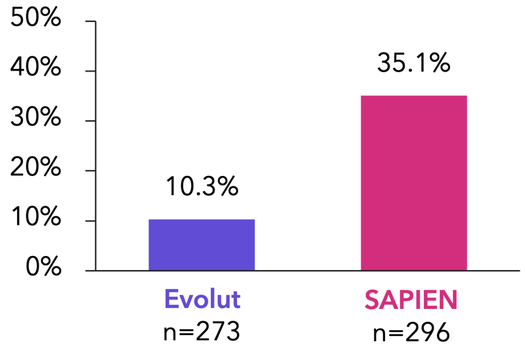
BVD in women through 12 months, %

Difference, -33.4% (95% CI -40.4%, -26.4%)
p<0.001 for superiority



Moderate/severe PPM† at 30 days, %

Difference, -24.9% (95% CI -31.4%, -18.4%)
p<0.001 for superiority



†VARC-3.

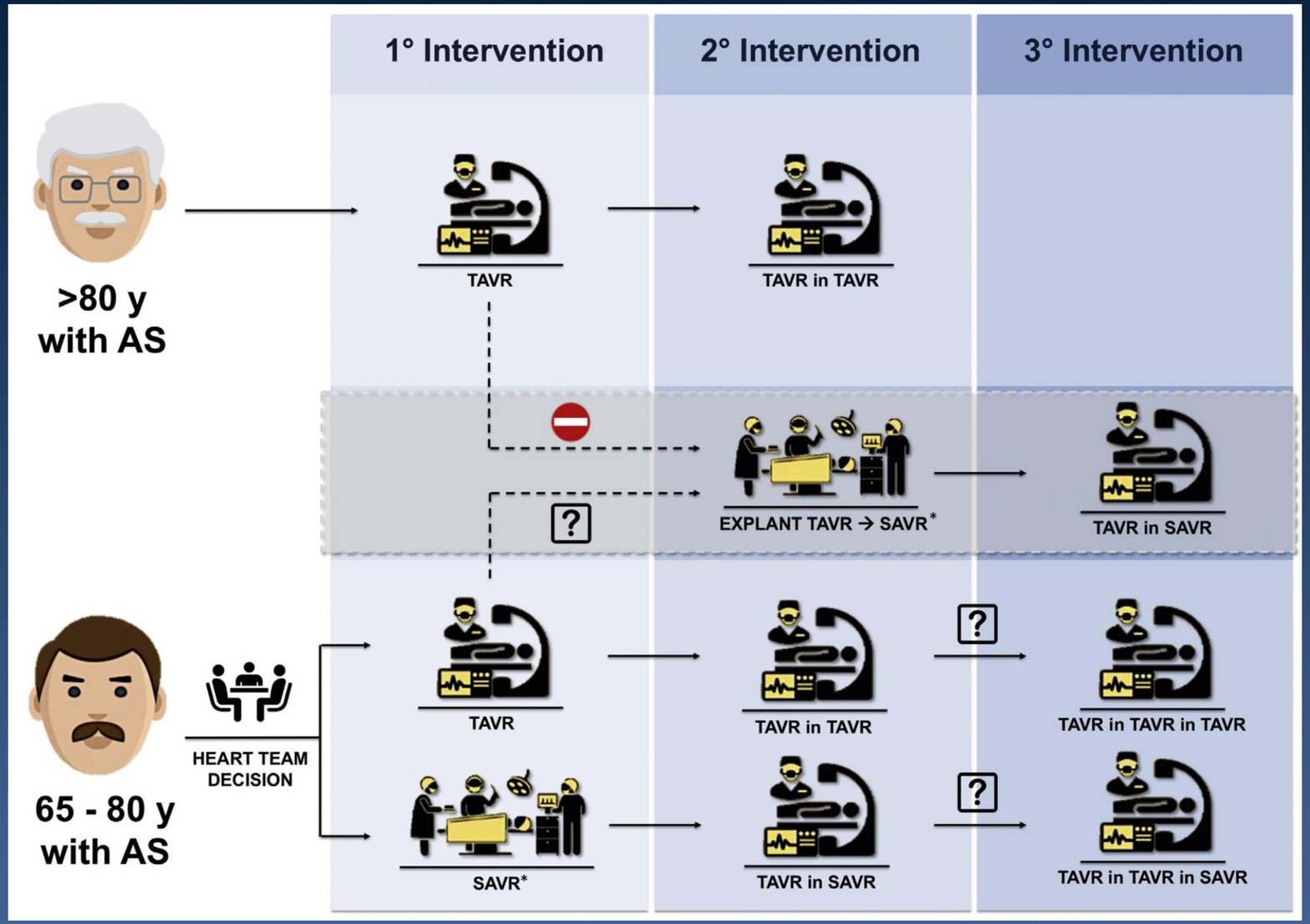
So… How to select THV in small annulus ?

- From these studies… ***SEV better in small annulus*** ; hemodynamic better in SEV, with more PVL in 2nd gen., but no difference in 3rd gen. SEV, but with disadvantages of more PM insertion in SEV

- Small annulus with SOV / coronary height ok ; SEV
- Small annulus with SOV narrow / low coronary height
  - Low op risk ; surgery
  - High op risk ; 1) SEV + Coronary Protection or BASILICA, 2) BEV(other CIx. Of SEV), 3) abort
- Small annulus with severe LVOT calcium ; case-by-case and decide by calcium anatomy & distribution

Let's Not Forget about lifelong management of AS

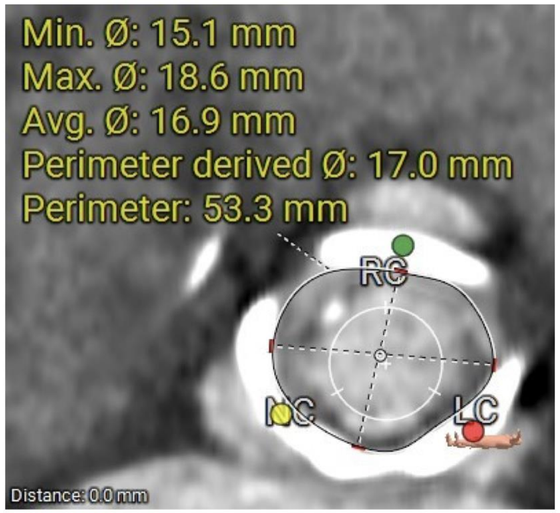
- More and more TAVRs in bioprosthetic failed valves…
  - TAVR in surgical valve (ViV)
  - TAVR in TAVR valve (TiV)



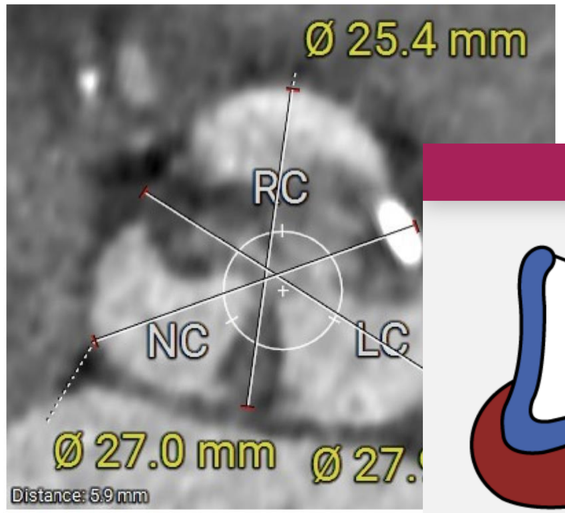
Giuseppe Tarantini Et al, JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 15, 2021

82/F, failed previous AVR, stroke Hx.

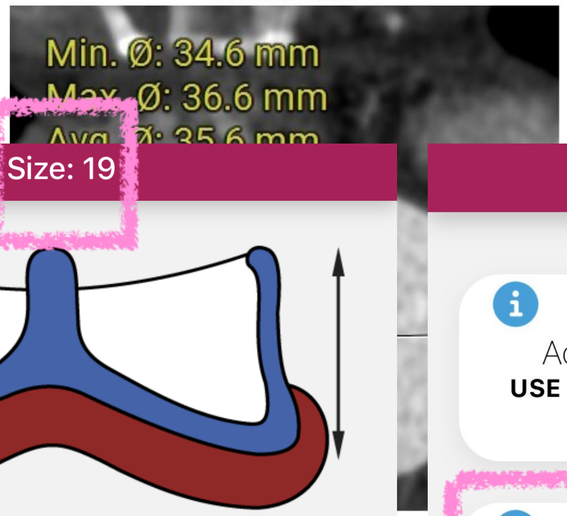
ANNULUS



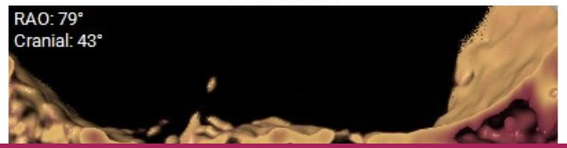
SOV DIAMETER



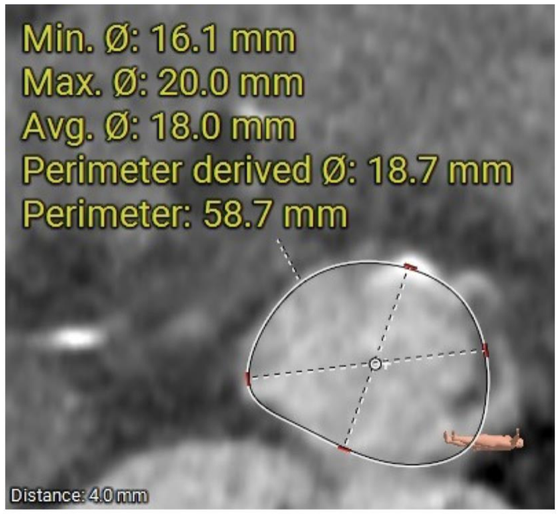
ASCENDING AORTA



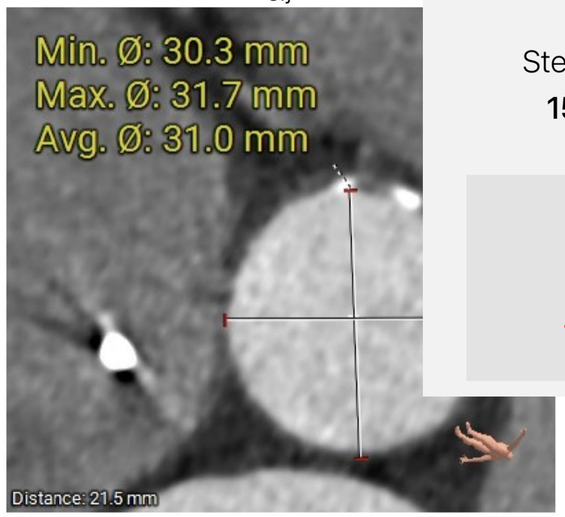
AORTIC VALVE CALCIFICATION



LVOT



STJ



Size: 19

Stent ID	Height	True ID
15.4	11	15.4

Fracturable

True Balloon Size: 18/20mm

After fracture
THV size needed may be larger

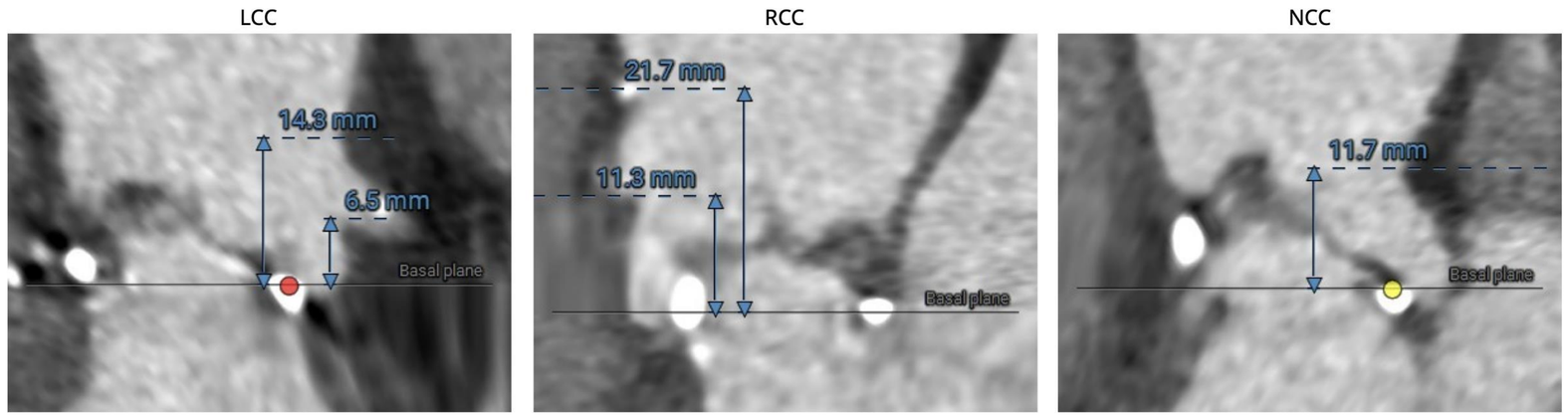
Area (mm²) 263.2 , Derived Ø (mm) 18.3

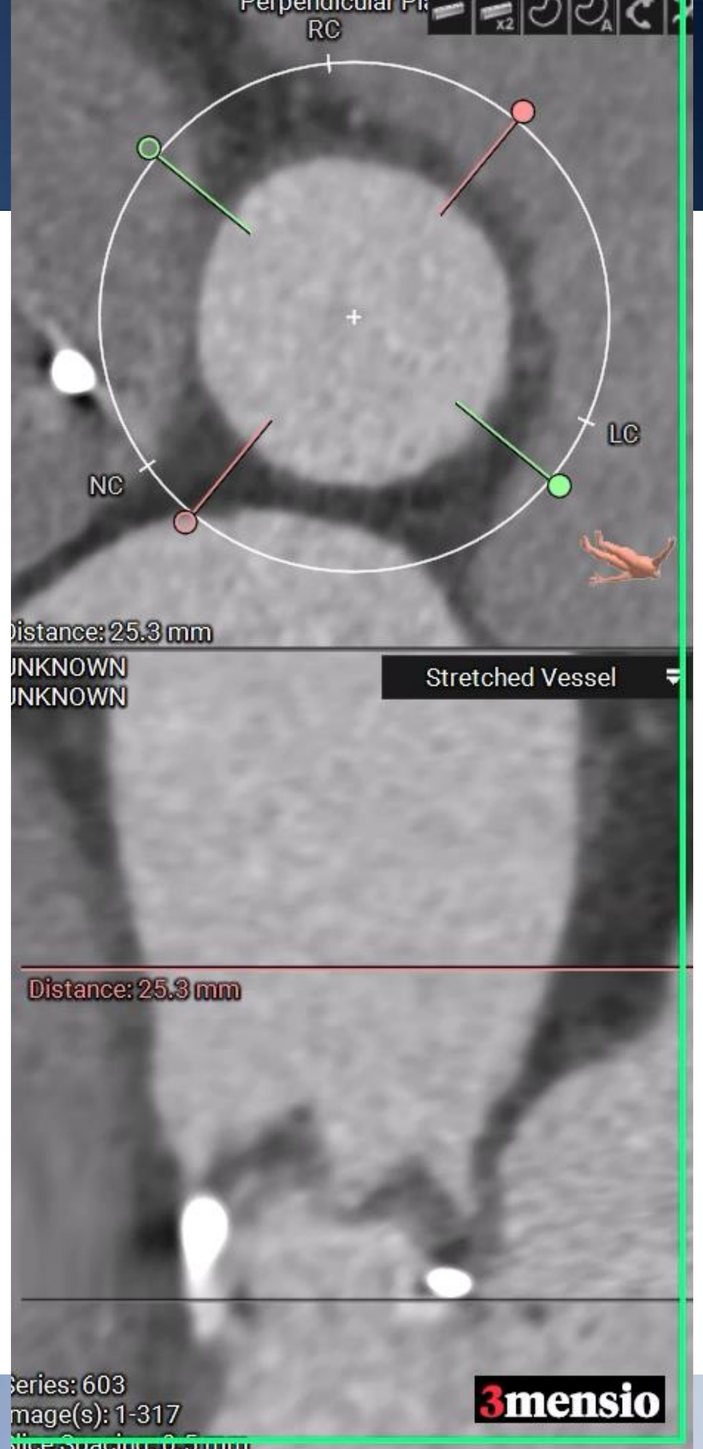
THV Selector: Current

- Acurate NEO — **USE WITH CAUTION**
- Allegra — **USE WITH CAUTION**
- Evolut — **USE WITH CAUTION**
- Portico — **USE WITH CAUTION**
- S3 — **USE WITH CAUTION**

Pre-TAVI CT Measurements

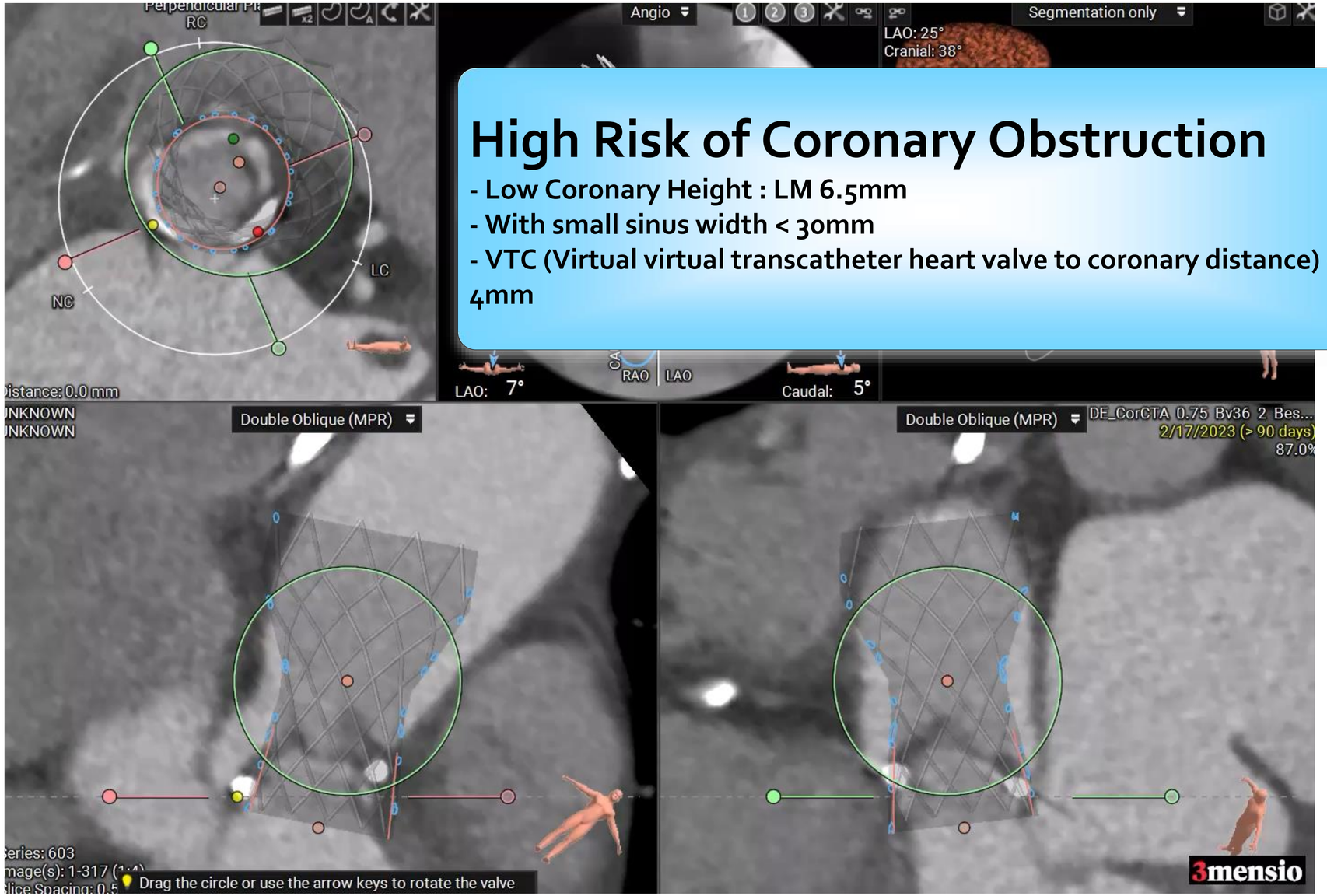
SINUS HEIGHT





Low Coronary Height : LM 6.5mm

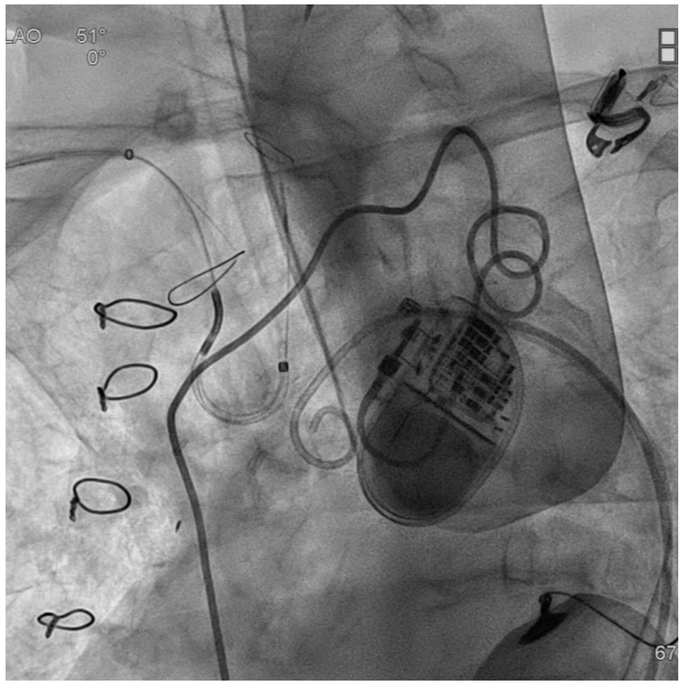
3D simulation by pre-TAVI CT



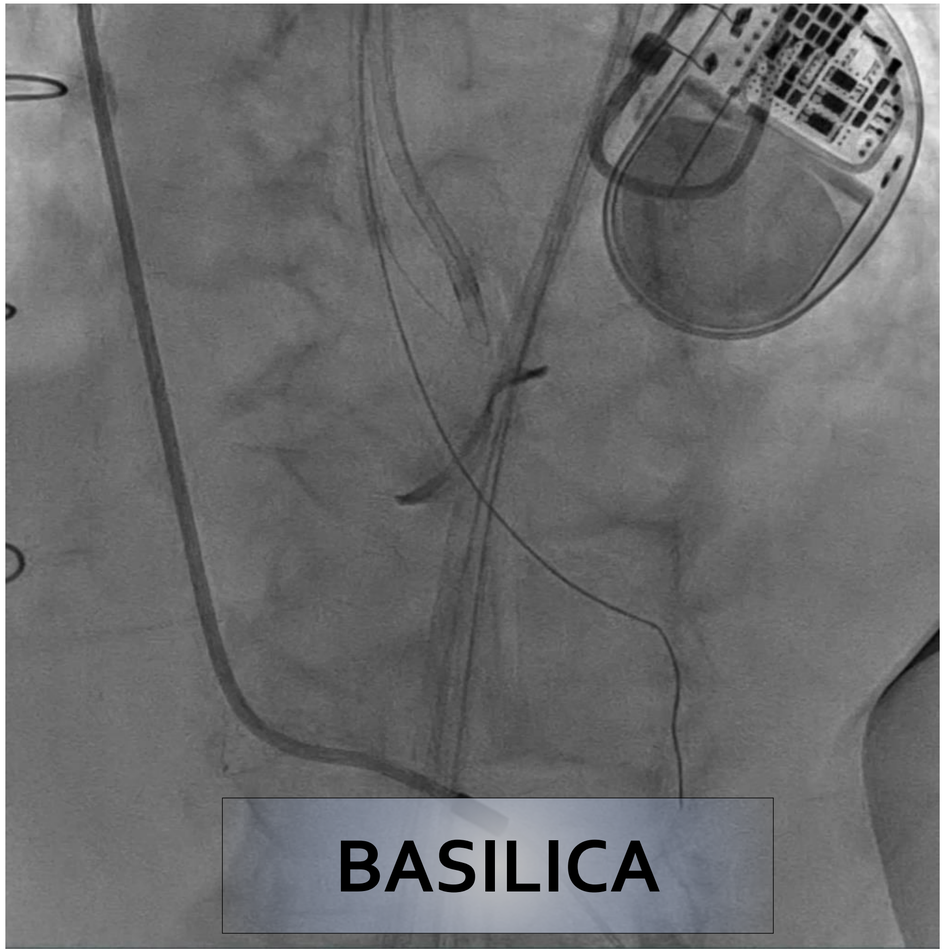
High Risk of Coronary Obstruction

- Low Coronary Height : LM 6.5mm
- With small sinus width < 30mm
- VTC (Virtual virtual transcatheter heart valve to coronary distance) < 4mm

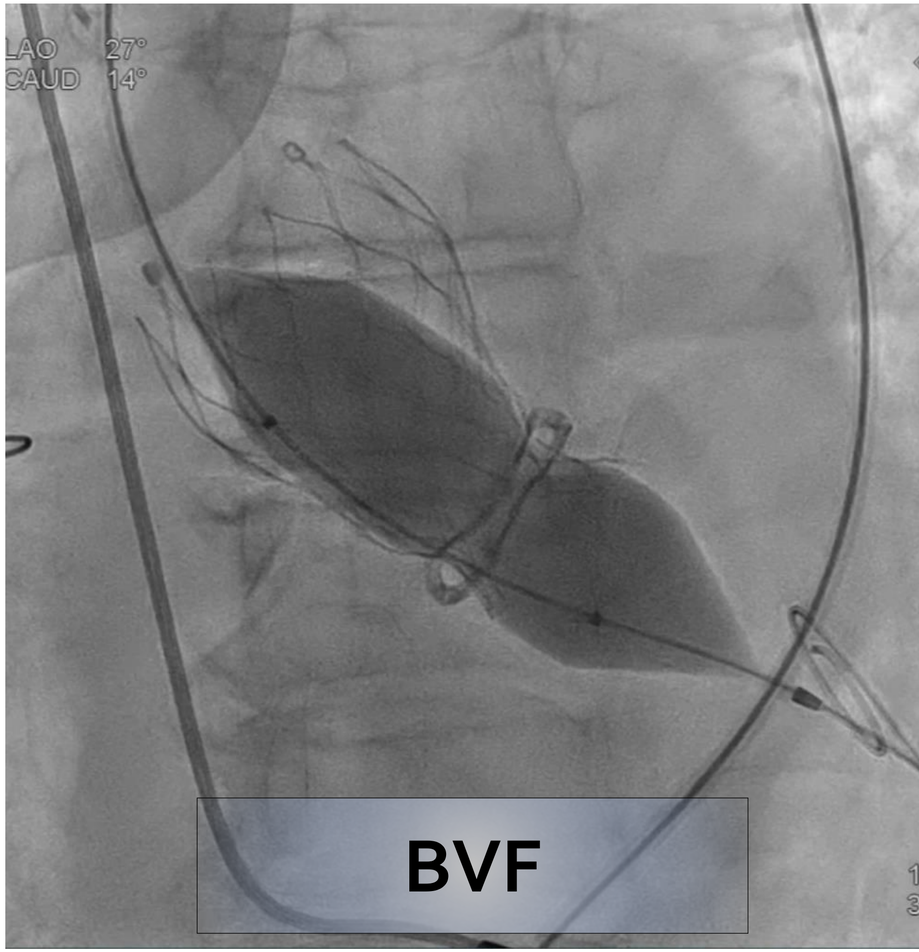
High Risk TAVR d/t small annulus & previous small AV



Sentinel Device

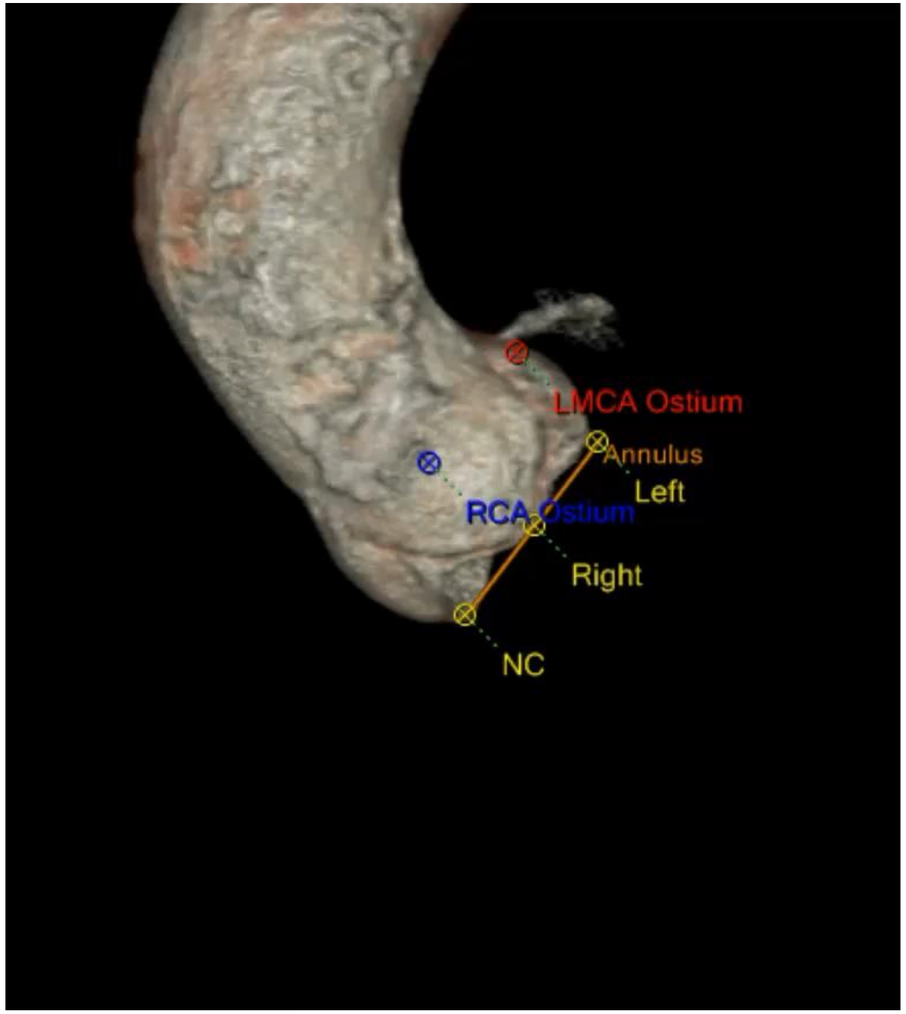


BASILICA



BVF

Pacemaker Issues…



Cusp overlap view isolates the NCC by overlapping the RCC and LCC and is generally in the RAO imaging plane

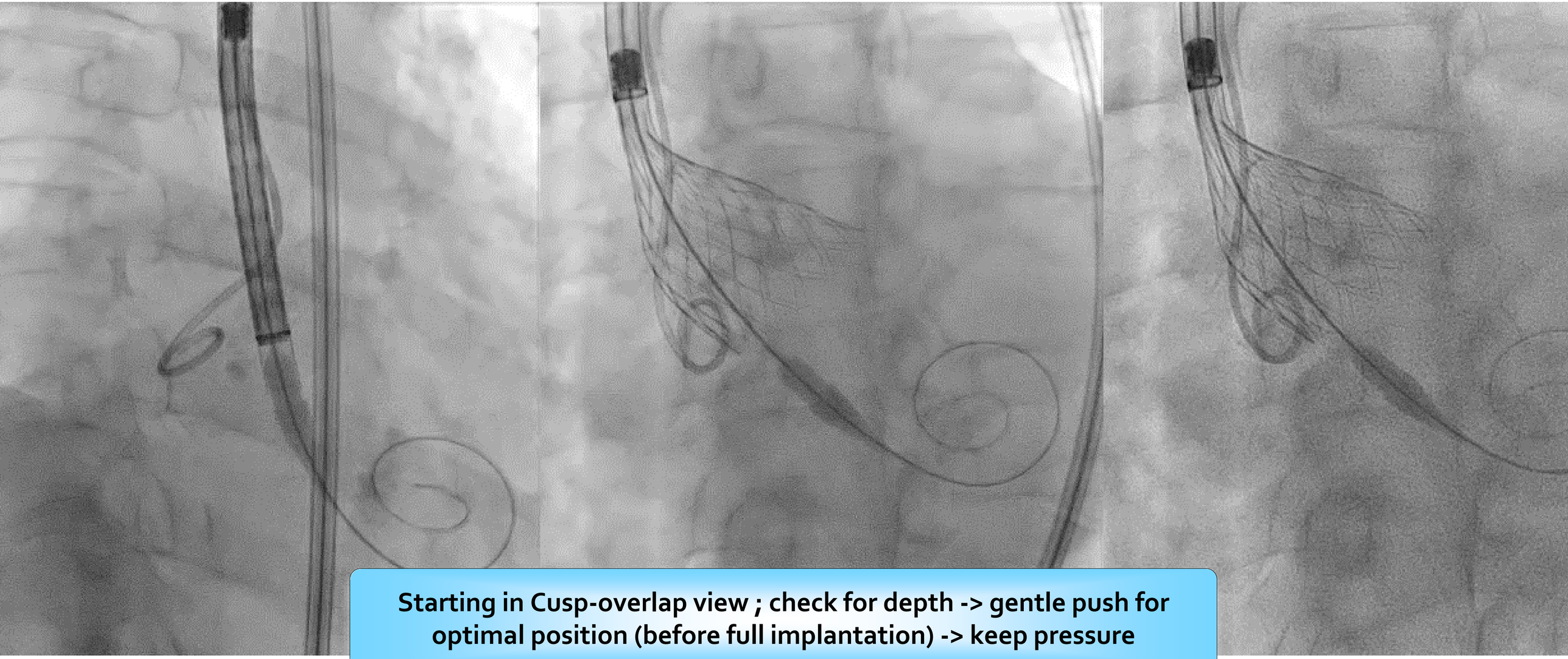
This view provides a good anatomical reference for deployment depth at the point of contact (NCC) as it:

- Maintains basal plane alignment of coronary cusps
- Elongates the outflow tract in a long axis view
- Reduces or removes parallax in the marker band
- Assists with depth visualization near the non-right commissure and membranous septum during deployment
- Provides a favorable root viewing angle inclusive of anatomies with root angulation approaching 70˚

To have an efficient, scripted procedure, you require a high quality gated CT with contrast; free from motion artifact and slice misregistration.

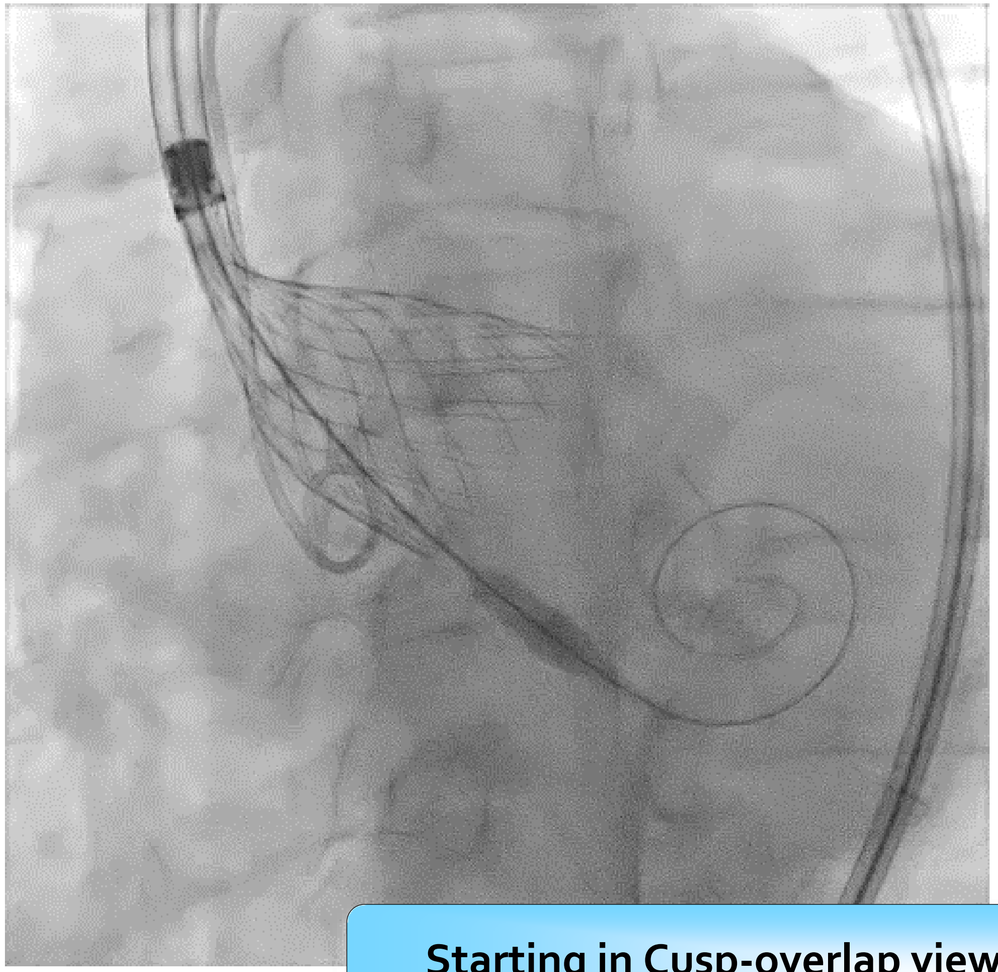
Cusp Overlap Technique (COT) surprisingly reduced Pacemaker rate of SEV

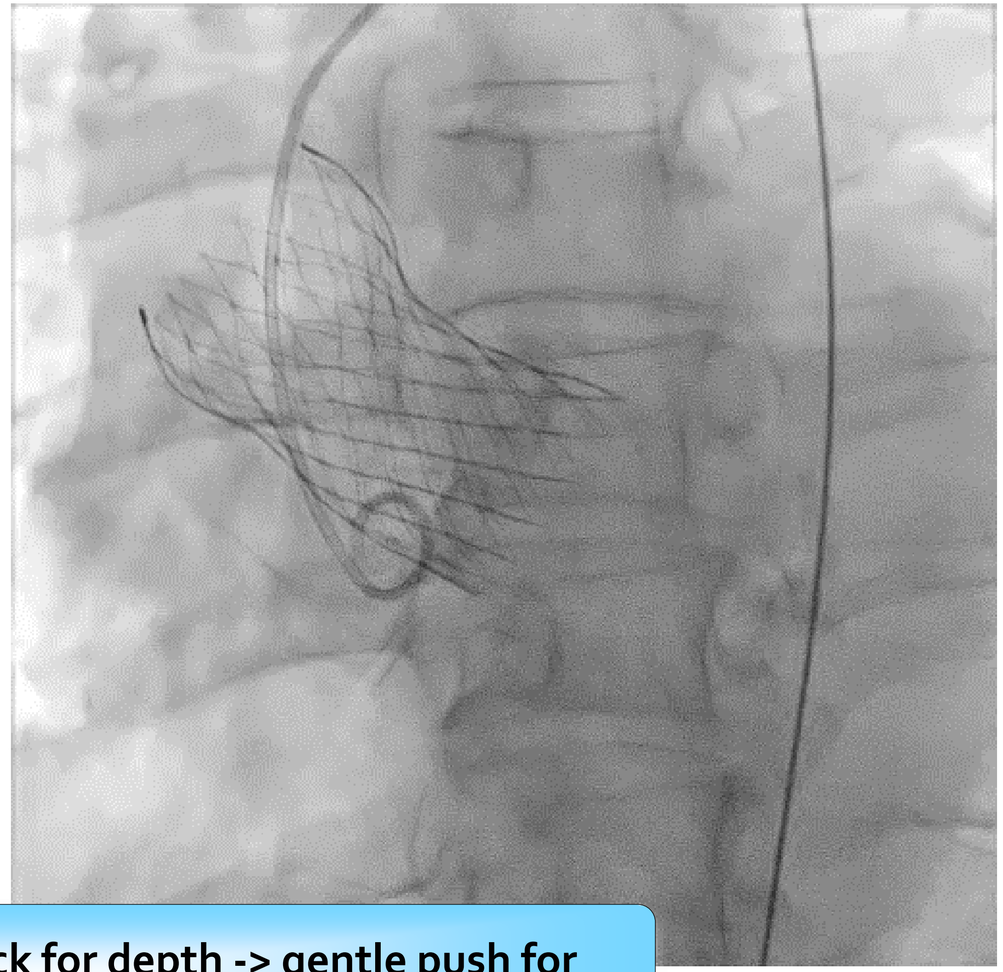
COT + Gentle Push-Deliver Method



Starting in Cusp-overlap view ; check for depth -> gentle push for optimal position (before full implantation) -> keep pressure

COT + Gentle Push-Deliver Method





Starting in Cusp-overlap view ; check for depth -> gentle push for optimal position (before full implantation) -> keep pressure

Take Home Messages

- ***Small annulus with SOV / coronary height ok ; SEV***
- Small annulus with SOV narrow / low coronary height
  - Low op risk ; surgery
  - High op risk ; 1) SEV + Coronary Protection or BASILICA, 2) BEV(other CIx. Of SEV), 3) abort
- Small annulus with severe LVOT calcium ; case-by-case and decide by calcium anatomy & distribution
- Considering age…
  - >80 ; above selection
  - <75 ; surgery with aortic root enlargement