Why I Chose SAPIEN as No. 1 Valve

Jung-Hee Lee, MD, PhD

Wounju Severance Christian Hospital, Yonsei University
Wonju College of Medicine, Republic of Korea

Disclosure

- Speaker’s name: Jung-Hee Lee, MD, PhD
- I’m a compensated consultant / proctor of Edwards Lifesciences SAPIEN valve.

Considerations Before Valve Selection

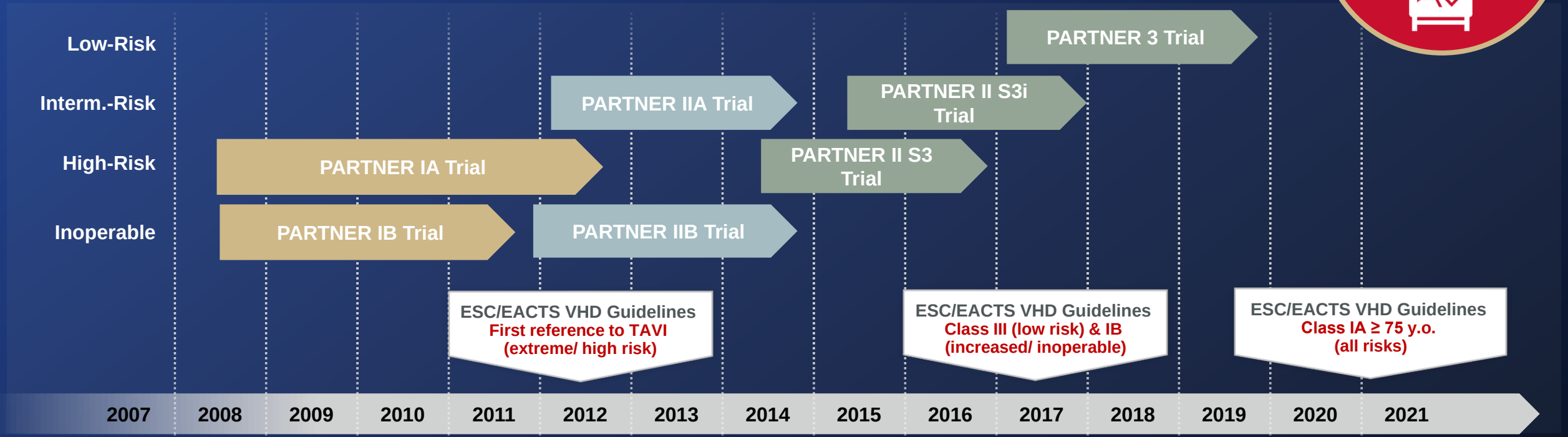
Balloon-Expandable vs. Self-Expandable

- Proven Clinical Outcomes
- Long-Term Valve Durability
- Predictable Deployment, Hemodynamic with Low PVL
- Future Coronary Access
- Future Re-intervention Options

Proven Clinical Outcomes

Five generations of valves, 6000+ patients in trials, and over 1 Million patients treated around the world

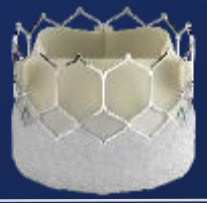
1M
patients treated*



Note: TAVI = transcatheter aortic valve implantation

* 1M patients reached in 2023

SAPIEN Platform Evolution

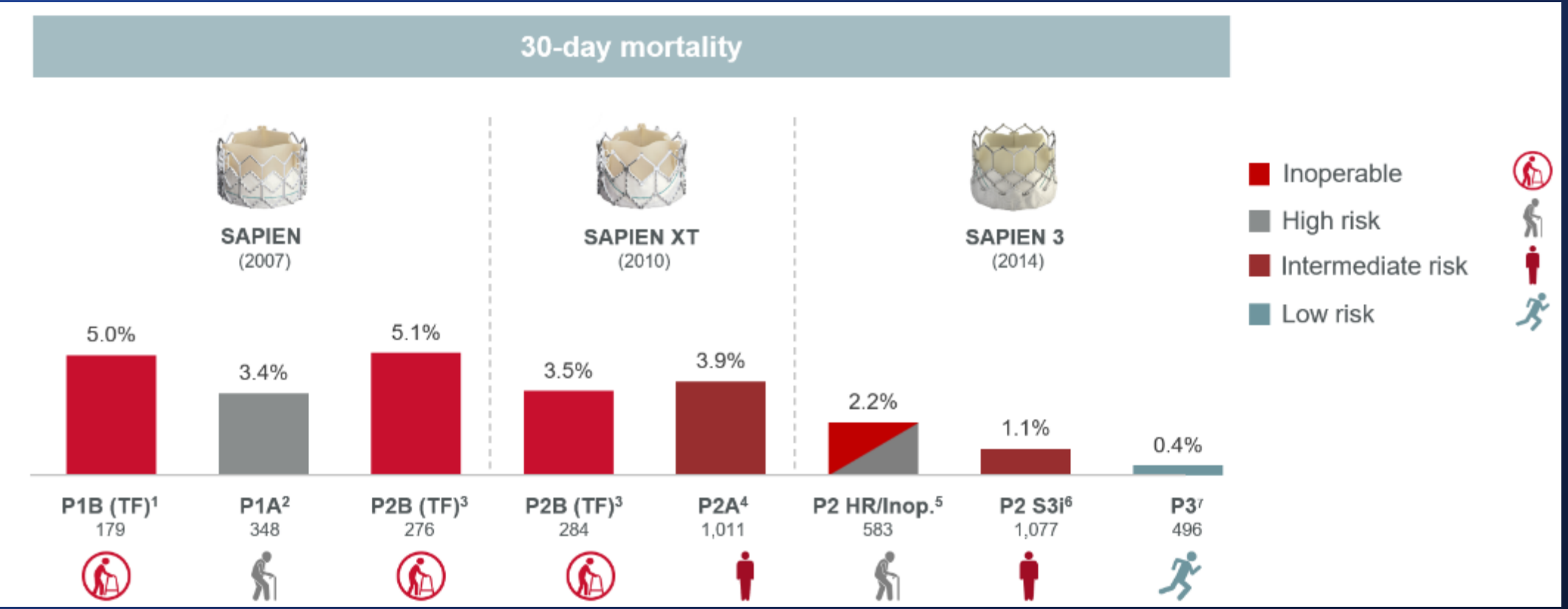
	SAPIEN valve	SAPIEN XT valve	SAPIEN 3 valve	SAPIEN 3 Ultra valve	SAPIEN 3 Ultra RESILIA valve
Valve Technology					
Sheath Compatibility					
Minimum Vessel Access Diameter	7.0 - 8.0 mm	6.0 - 6.5 mm	5.5 - 6.0 mm	5.5 - 6.0 mm	5.5 - 6.0 mm
Available Valve Sizes					
CE mark	2007	2010	2014	2018	2024

The main Edwards TAVI valve randomized studies

	PARTNER 1 trial		PARTNER 2 trial				PARTNER 3 trial
	PARTNER 1B[1]	PARTNER 1A[2]	PARTNER 2B[3]	PARTNER 2S3HR[4]	PARTNER 2A[5]	PARTNER 2S3i[6]	PARTNER 3[7]
TAVI patient profile (STS risk score and age)	Inoperable STS 11.2 Mean age 83.1	High risk STS 11.8 Mean age 83.6	Inoperable STS 11.0 Mean age 84.6	High risk/ Inoperable STS 8.4 Mean age 82.7	Intermediate risk STS 5.8 Mean age 81.6	Intermediate risk STS 5.2 Mean age 81.9	Low risk STS 1.9 Mean age 73.3
Valve used	**SAPIEN** 	**SAPIEN** 	**SAPIEN XT** 	**SAPIEN 3** 	**SAPIEN XT** 	**SAPIEN 3** 	**SAPIEN 3** 
Trial size	N=358	N=699	N=560	N=583	N=2032	N=1077	N=1000
Primary endpoint and result	All-cause mortality at 1 year: ▪ TAVI : 30,7% ▪ Therapy : 50,7% p-value<0,001 **TAVI superior to medical therapy**	All-cause mortality at 1 year: ▪ TAVI : 24,2% ▪ sAVR : 26,8% p-value = 0,44 **TAVI non-inferior to sAVR**	Mortality, disabling strokes or rehospitalization at 1 year: ▪ SAPIEN XT : 37,2% ▪ SAPIEN : 37,7% p-value = 0,9 **SAPIEN XT non inferior to SAPIEN**	All-cause mortality, all stroke and aortic insufficiency at 1 year: ▪ HR: 65% ▪ Inoperable: 43% p-value = 0,19 **Good results of TAVI for high-risk patients**	All-cause mortality or disabling strokes at 2 years: ▪ TAVI : 19,3% ▪ sAVR : 21,1% p-value = 0,001 **TAVI non-inferior to sAVR**	All-cause mortality, all strokes and mod-sev PVL at 1 year: **TAVI superior to sAVR** [−9·2%, 95% CI −13·0 to −5·4; p<0·0001)]	Mortality, disabling strokes or rehospitalization at 1 year: ▪ TAVI : 8,5% ▪ sAVR : 15,1% p-value = 0,001 **TAVI superior to sAVR**

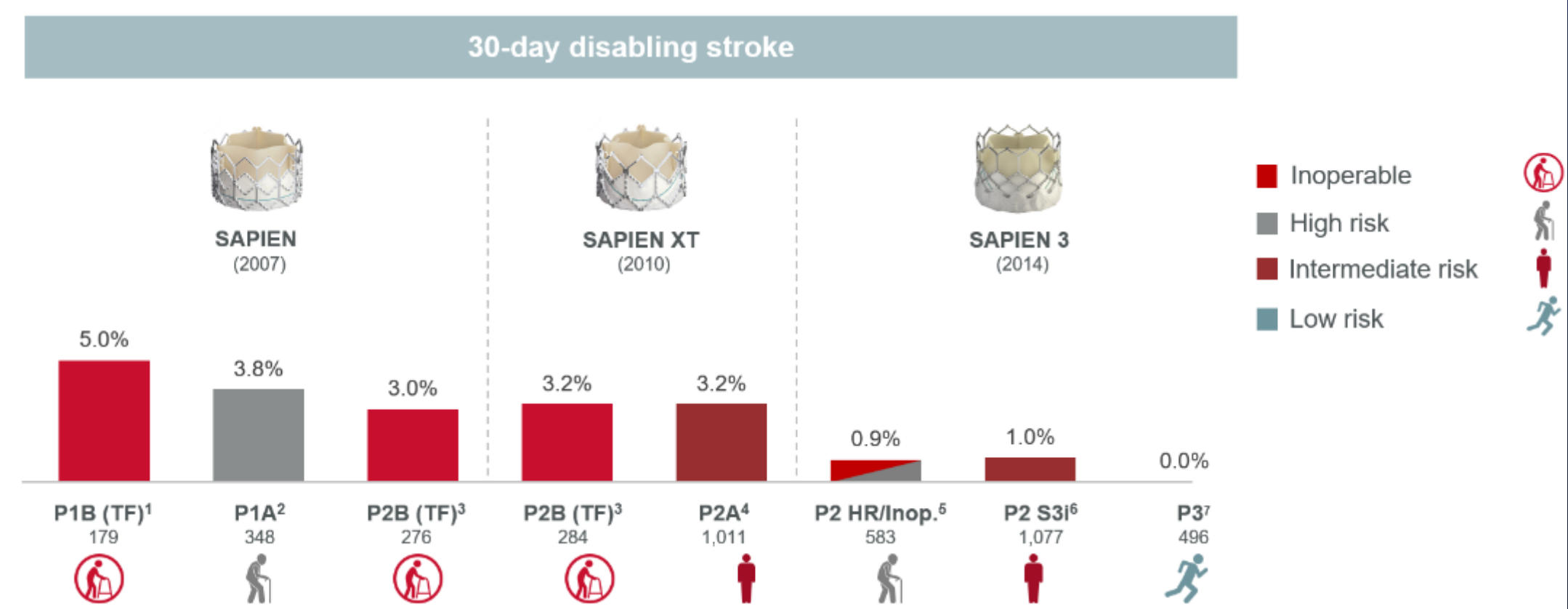
1. Leon, MB. et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N. Engl. J. Med.* 2010; 363: 1597-1607.; 2. Smith, CR. *et al*. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N. Engl. J. Med.* 2011; 364: 2187-2198.; 3. Webb, JG. *et al*. A Randomized Evaluation of the SAPIEN XT Transcatheter Valve System in Patients with Aortic Stenosis Who Are Not Candidates for Surgery: PARTNER II, Inoperable Cohort. *JACC Cardiovasc. Interv*. 2015; 8(14): 1797-1806.; 4 Herrmann, HC. *et al*. One-Year Clinical Outcomes With SAPIEN 3 Transcatheter Aortic Valve Replacement in High-Risk and Inoperable Patients With Severe Aortic Stenosis. *Circulation;* 2015; 134: 130–140. 5. Leon, MB. *et al*. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N. Engl. J. Med.* 2016; 374: 1609-1620.; 6. Thourani, VH. *et al*. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: A propensity score analysis; *The Lancet*; 2016; 387(10034): 2218-2225.; 7. Mack, MJ. *et al*. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N. Engl. J. Med.* 2019; 380(18): 1695-1705.

Clinical outcomes improve as technology and patient profiles evolve



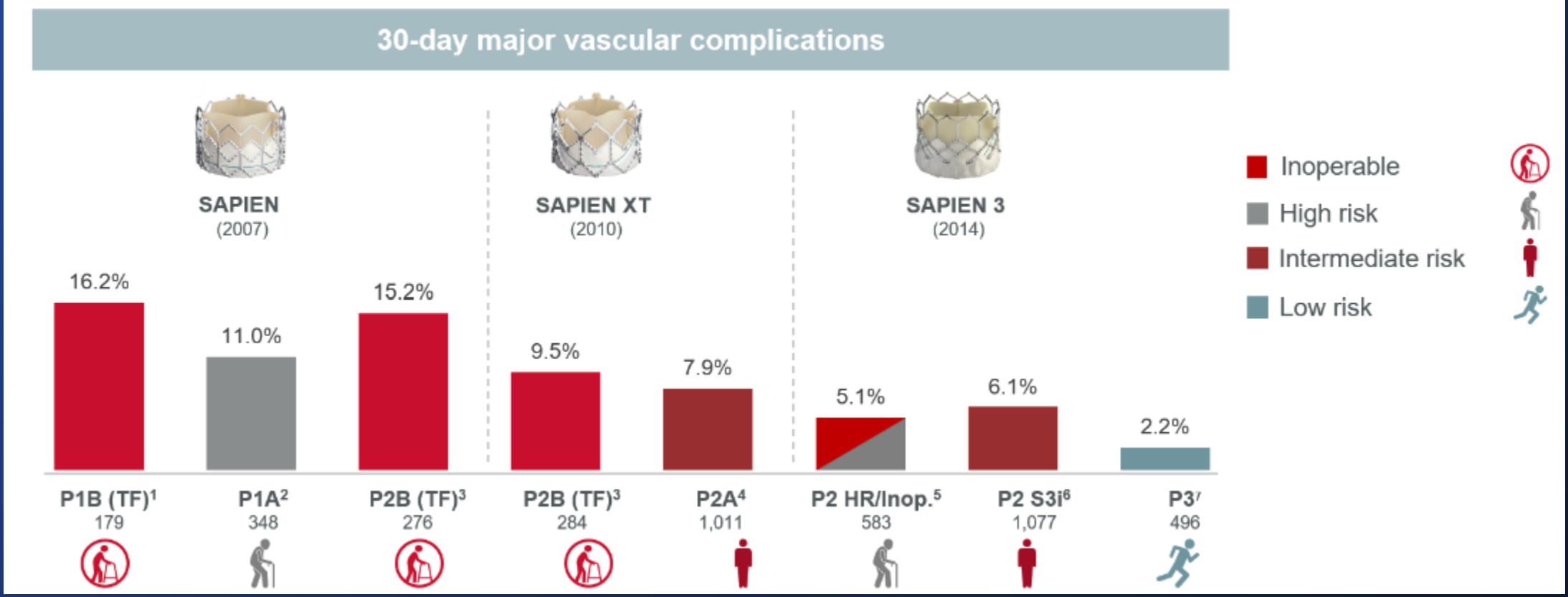
1. Leon, MB. et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N. Engl. J. Med. 2010; 363: 1597-1607.; 2. Smith, CR. et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N. Engl. J. Med. 2011; 364: 2187-2198.; 3. Webb, JG. et al. A Randomized Evaluation of the SAPIEN XT Transcatheter Valve System in Patients with Aortic Stenosis Who Are Not Candidates for Surgery: PARTNER II, Inoperable Cohort. JACC Cardiovasc. Interv. 2015; 8(14): 1797-1806.; 4. Leon, MB. et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N. Engl. J. Med. 2016; 374: 1609-1620.; 5. Herrmann, HC. *et al*. One-Year Clinical Outcomes With SAPIEN 3 Transcatheter Aortic Valve Replacement in High-Risk and Inoperable Patients With Severe Aortic Stenosis. *Circulation;* 2015; 134: 130–140. 6. Thourani, VH. *et al.* Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: A propensity score analysis; *The Lancet*; 2016; 387(10034): 2218-2225.; 7. Mack, MJ. *et al*. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N. Engl. J. Med.* 2019; 380(18): 1695-1705.

Clinical outcomes improve as technology and patient profiles evolve



1. Leon, MB. et al. Transcatheter aortic-valve implantatihigh-risk patients. N. Engl. J. Med. 2011; 364: 2187-2198.; 3. Webb, JG. et al. A Randomized Evaluation of the SAPIEN XT Transcatheter Valve System in Patients with Aortic Stenosis Who Are Not Candidates for Surgery: PARTNER II, Inoperable Cohort. JACC Cardiovasc. Interv. 2015; 8(14): 1797-1806.; 4. Leon, MB. et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N. Engl. J. Med. 2016; 374: 1609-1620.; 5. Herrmann, HC. *et al*. One-Year Clinical Outcomes With SAPIEN 3 Transcatheter Aortic Valve Replacement in High-Risk and Inoperable Patients With Severe Aortic Stenosis. *Circulation;* 2015; 134: 130–140. 6. Thourani, VH. *et al.* Transcatheter aortic valve replacement on for aortic stenosis in patients who cannot undergo surgery. N. Engl. J. Med. 2010; 363: 1597-1607.; 2. Smith, CR. et al. Transcatheter versus surgical aortic-valve replacement in versus surgical valve replacement in intermediate-risk patients: A propensity score analysis; *The Lancet*; 2016; 387(10034): 2218-2225.; 7. Mack, MJ. *et al*. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N. Engl. J. Med.* 2019; 380(18): 1695-1705.

Clinical outcomes improve as technology and patient profiles evolve



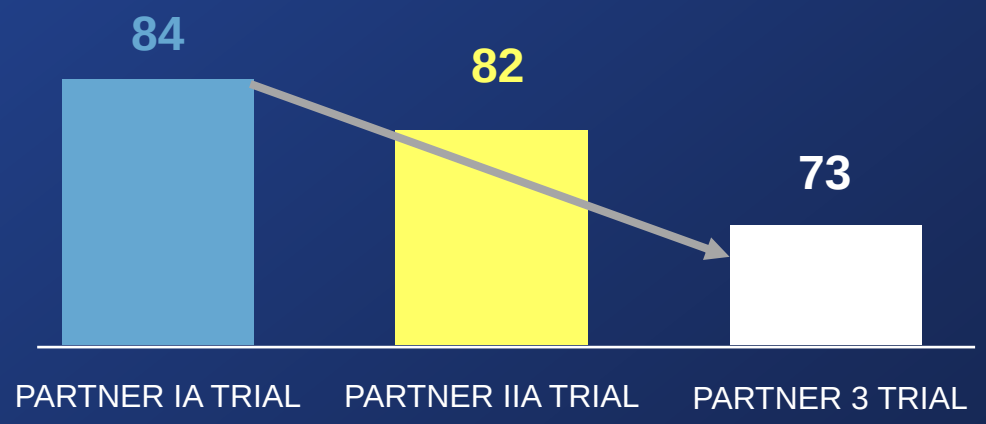
1. Leon, MB. et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N. Engl. J. Med. 2010; 363: 1597-1607.; 2. Smith, CR. et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N. Engl. J. Med. 2011; 364: 2187-2198.; 3. Webb, JG. et al. A Randomized Evaluation of the SAPIEN XT Transcatheter Valve System in Patients with Aortic Stenosis Who Are Not Candidates for Surgery: PARTNER II, Inoperable Cohort. JACC Cardiovasc. Interv. 2015; 8(14): 1797-1806.; 4. Leon, MB. et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N. Engl. J. Med. 2016; 374: 1609-1620.; 5. Kodali et al. Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis, European Heart Journal (2016) 37, 2252–2262; 6. Thourani, VH. *et al.* Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: A propensity score analysis; *The Lancet*; 2016; 387(10034): 2218-2225.; 7. Mack, MJ. *et al*. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N. Engl. J. Med.* 2019; 380(18): 1695-1705.

Long-Term Valve Durability

Today's TAVI patients have longer life expectancies

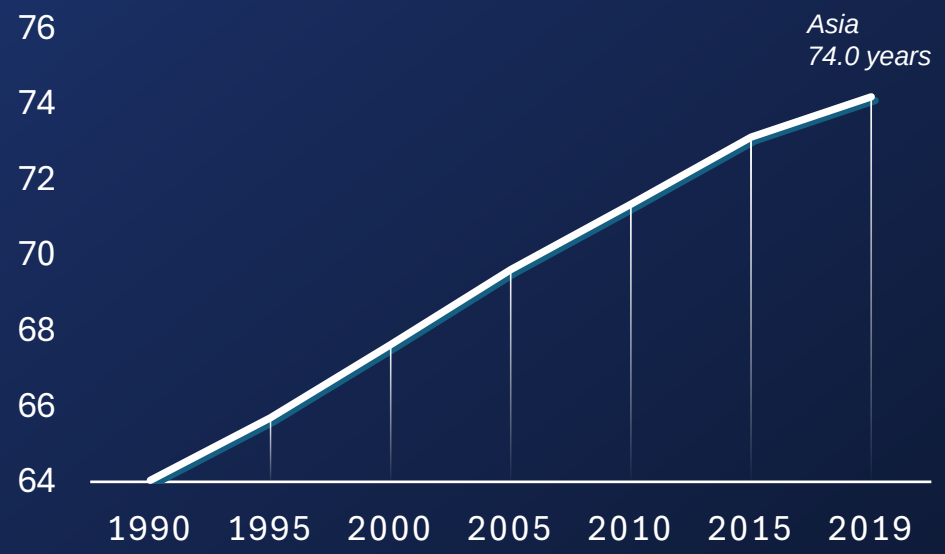
The TAVI patient population has expanded to younger patients

Low-risk patients in the PARTNER 3 trial are ~10 years younger than previous PARTNER trials



Even older patients have longer life expectancies

Life Expectancy, 1990-2019*[4]



*Shown is period of life expectancy at birth, the average number of years a newborn would live if the pattern of mortality in the given year were to stay the same throughout its life.

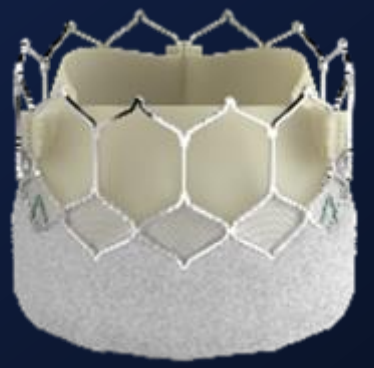
1. Leon MB, Smith CR, Mack MJ, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363(17):1597-1607.
2. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2016;374(17):1609-1620.
3. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380(18):1695-1705.
4. Life expectancy, 1990 to 2019 (ourworldindata.org)

Recent guidelines have expanded the range of patients eligible for TAVI

2020 ACC/AHA Guideline update recommends considering TAVI for patients 65 and older[1]

Age 65-80 y	Age >80y
SAVR *Class 1*	**TF TAVI** *Class 1*
TF TAVI *Class 1*	**SAVR** *Class 2A*

Now more than ever, patients need a valve that is durable[2]



1. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients with Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2020. Epublished DOI: 10.1016/j.jacc.2020.11.018.

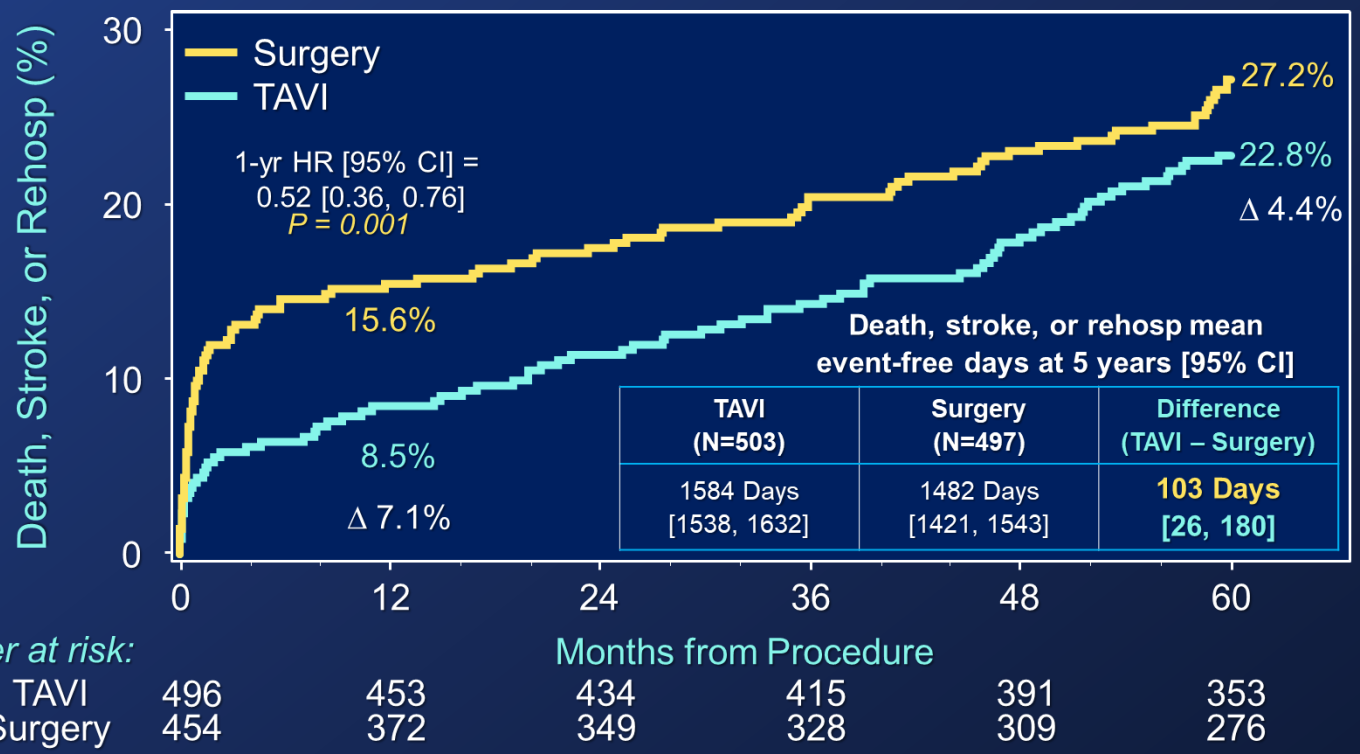
2. Pibarot, et al. Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in PARTNER-2 Trial. *J Am Coll Cardiol*. 2020.

Consistently demonstrating the results you need for the outcomes that matter

PARTNER 3 Low-Risk Trial

Primary endpoint

Death, stroke, or rehospitalization†



Only the SAPIEN 3 platform is proven superior to surgery in low-risk patients at 1 year and proven equally effective at 5 years*[1,2]

† Rehospitalization is defined as any hospitalization related to the procedure, the valve, or heart failure.

* The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and rehospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

PARTNER 3 5-Year Results - Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 TAVR to 5.1% SAVR). Low rates of all-cause mortality through five years (10.0% SAPIEN 3 TAVR vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 TAVR to 2.7% SAVR). Low rates of stroke through five years (5.85% SAPIEN 3 TAVR vs. 6.4% SAVR). Lower rates of rehospitalization with SAPIEN 3 TAVR through five years (13.7% vs. 17.4%).

1. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380:1695-1705.
2. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement in low-risk patients at 5 years. N Engl J Med. 2023;10.1056/NEJMoa2307447.

The SAPIEN 3 platform is designed to deliver the outcomes you demand

	30 days[1]		1 year[1]			5 years[3]		
	TAVR	Surgery	TAVR	Surgery	P-Value[2]	TAVR	Surgery	P-Value[4]
All-cause mortality*	**0.4%**	1.1%	**1.0%**	2.5%	**<0.09**	**10.0%**	8.2%	***0.35***
All-stroke*	**0.6%**	2.4%	**1.2%**	3.1%	**0.04**	**5.8%**	6.4%	**0.60**
Rehospitalization*†	**3.4%**	6.5%	**7.3%**	11.0%	**0.046**	**13.7%**	17.4%	**0.09**
Life-threatening/disabling, major or serious bleeding*	**3.6%**	24.5%	**7.7%**	25.9%	**<0.001**	**10.2%**	14.8%	***0.02***
New-onset AFIB*	**5.0%**	39.5%	**7.0%**	40.9%	**<0.001**	**13.7%**	42.4%	***<0.0001***
AKI*	**0.4%**	1.8%	**0.4%**	1.8%	**0.05**			

*These endpoints were not subject to multiplicity adjustment.
† Rehospitalization is defined as any hospitalization related to the procedure, the valve, or heart failure.

1. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380(18):1695-1705.
2. The PARTNER 3 Trial, low-risk patients (N=496 TAVR, N=454 SAVR). Edwards Lifesciences clinical report on file.
3. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement in low-risk patients at 5 years. *N Engl J Med*. 2023;10.1056/NEJMoa2307447.
4. Leon MB, Mack MJ, et al. Five-year clinical and echocardiographic outcomes from the PARTNER 3 low-risk randomized trial. Presented at TCT 2023.

VARC 3: The factors that significantly impact valve durability[1]

Structural valve deterioration (SVD)

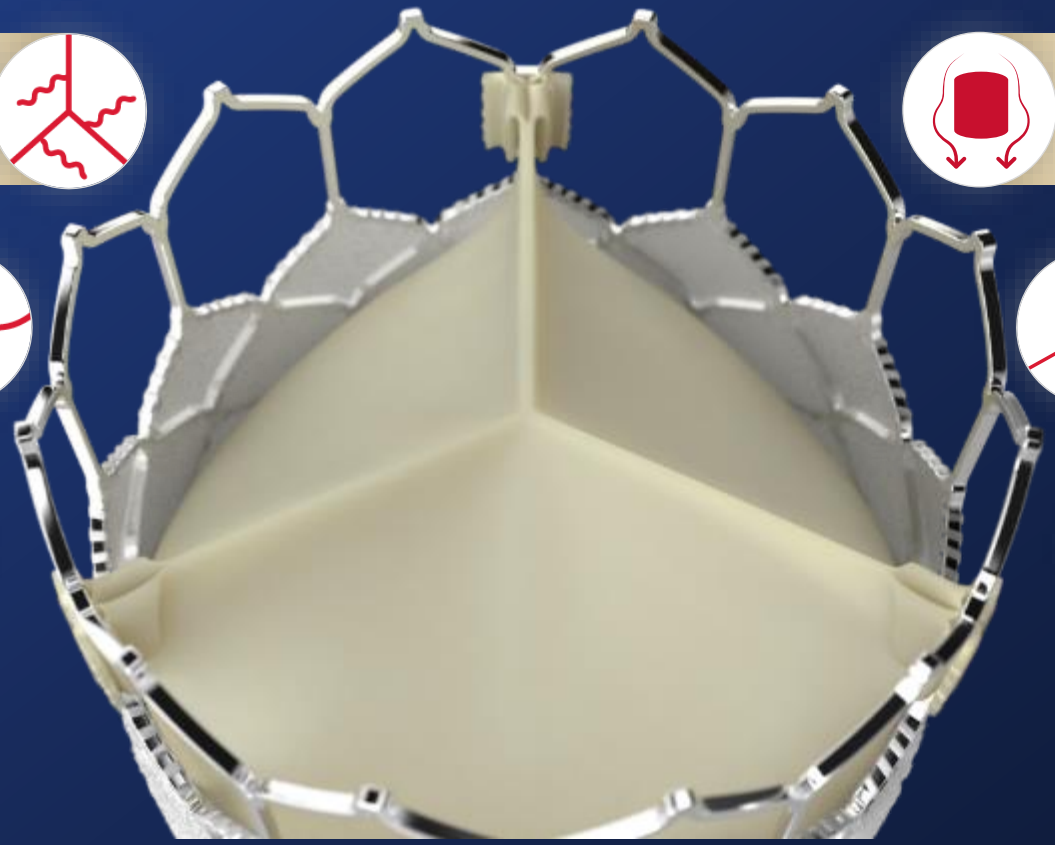
Intrinsic, permanent changes

- Wear and tear
- Leaflet disruption/ flail
- Leaflet calcification

Non-structural valve dysfunction (NSVD)

Abnormalities, not intrinsic

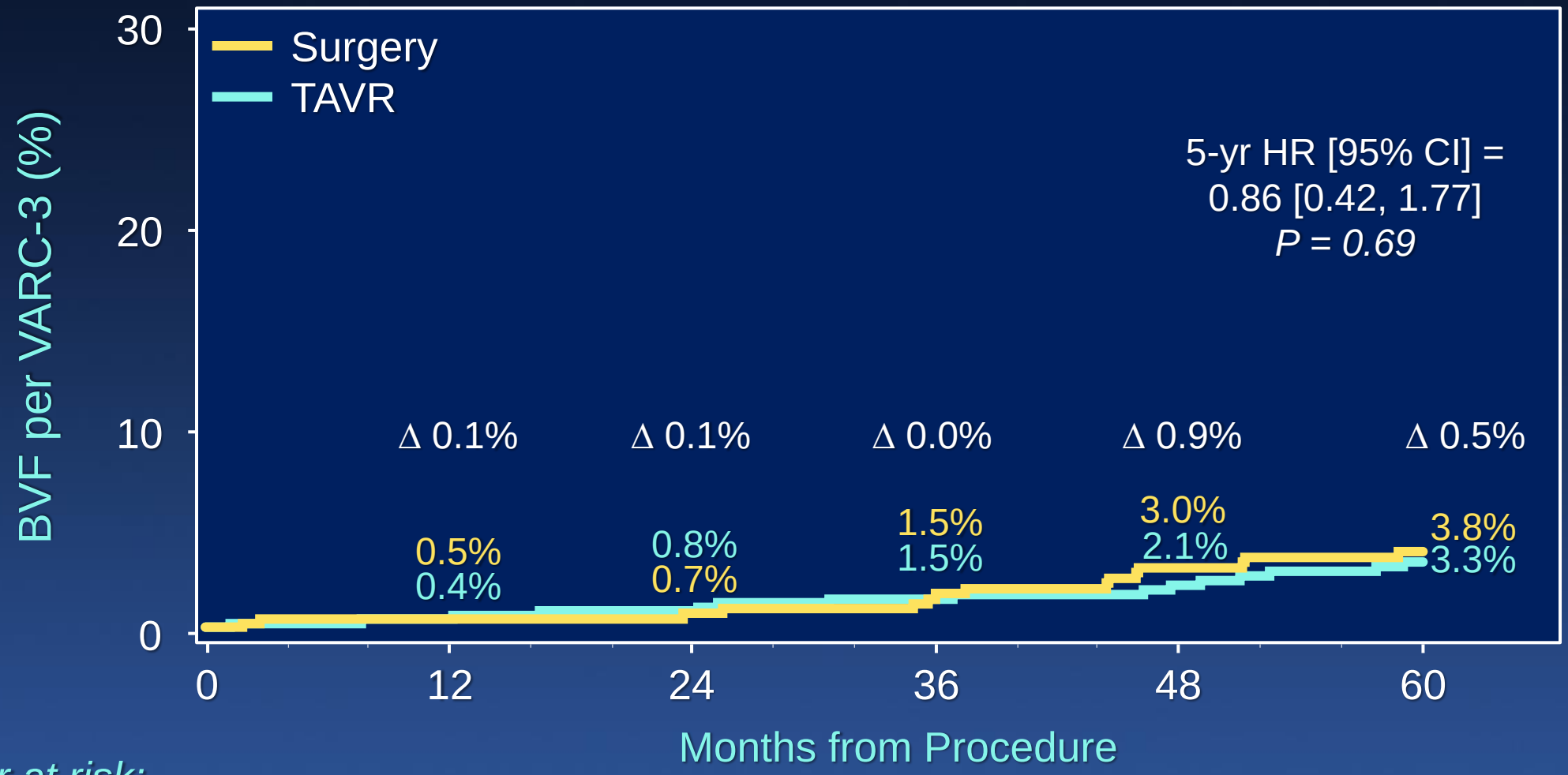
- Paravalvular leak (PVL)
- Inappropriate positioning or sizing
- Patient-prosthesis mismatch



1. Généreux P, Piazza N, Alu MC, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. *Eur Heart J.* 2021;42(19):1825-1857.

THE PARTNER 3 TRIAL

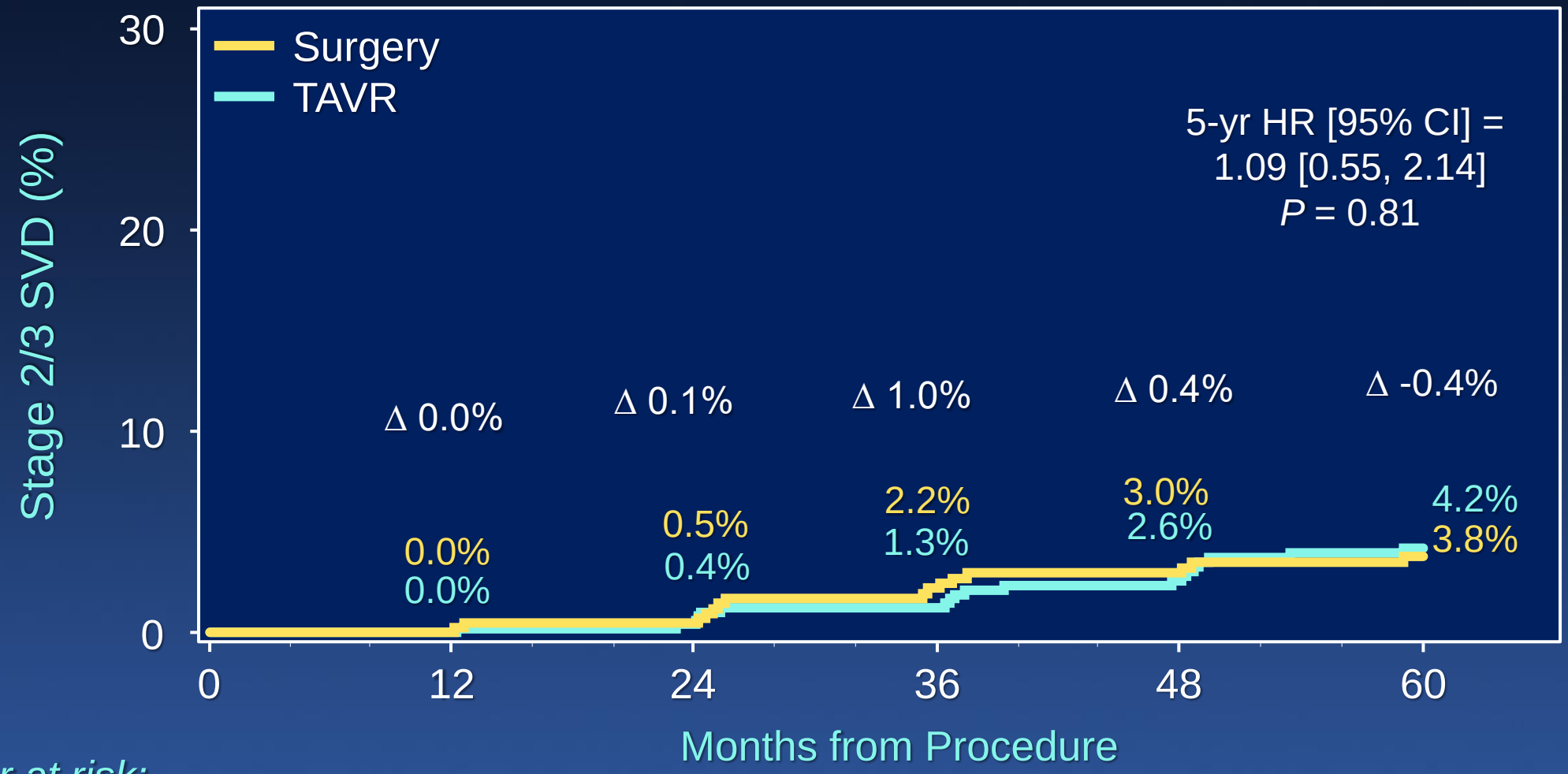
BVF to 5 Years (VARC-3)



Number at risk:

TAVR	496	489	475	454	430	392
Surgery	454	426	407	390	369	334

THE PARTNER 3 TRIAL Stage 2/3 SVD to 5 Years (VARC 3)



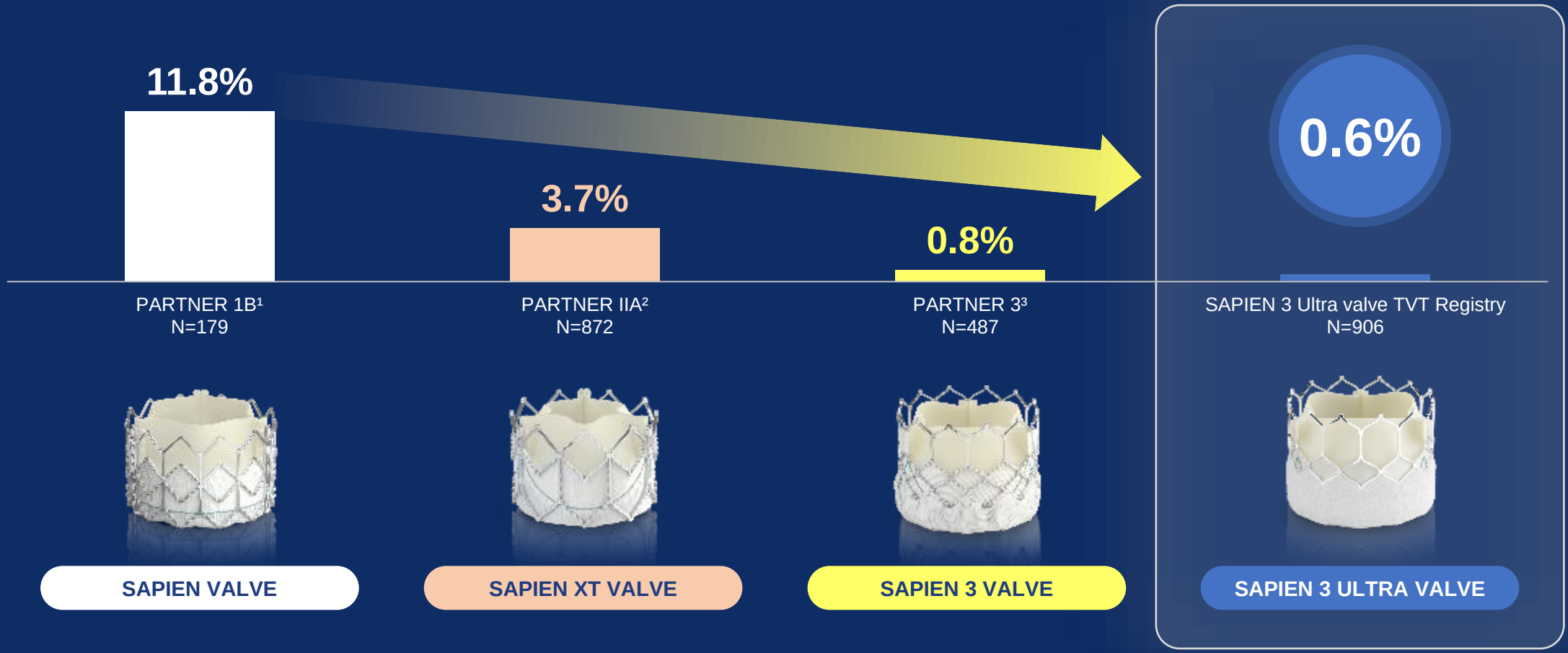
Number at risk:

TAVR	496	490	476	454	428	387
Surgery	454	426	407	385	366	332

Predictable Deployment, Hemodynamic with Low PVL

Delivering on the changing expectations of TAVR

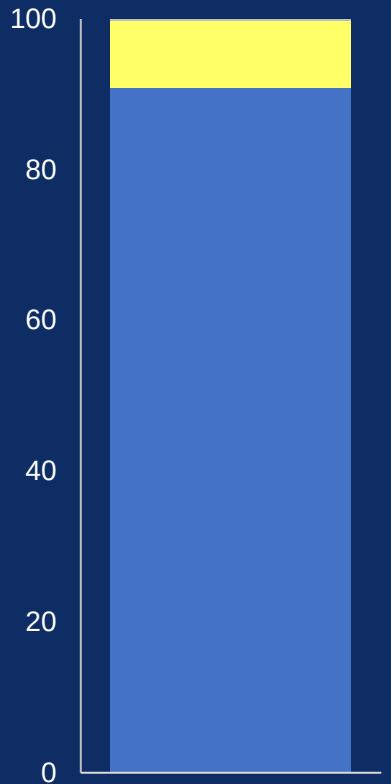
Moderate or severe PVL at 30 days



1. Leon MB, Smith CR, Mack MJ, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med.* 2010;363(17):1597-1607.
2. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2016;374(17):1609-1620.
3. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380(18):1695-1705.
4. Nazif T, Cahill T, Daniels D, et al. Real-world experience with the SAPIEN 3 Ultra Transcatheter Heart Valve: A propensity matched analysis from the United States. *Circ Cardiovasc Interv*. 2021; 14(9):948-957

Designed to meet the PVL outcomes you demand

In a study of 1,324 real-world patients, the SAPIEN 3 Ultra valve demonstrated[1]:

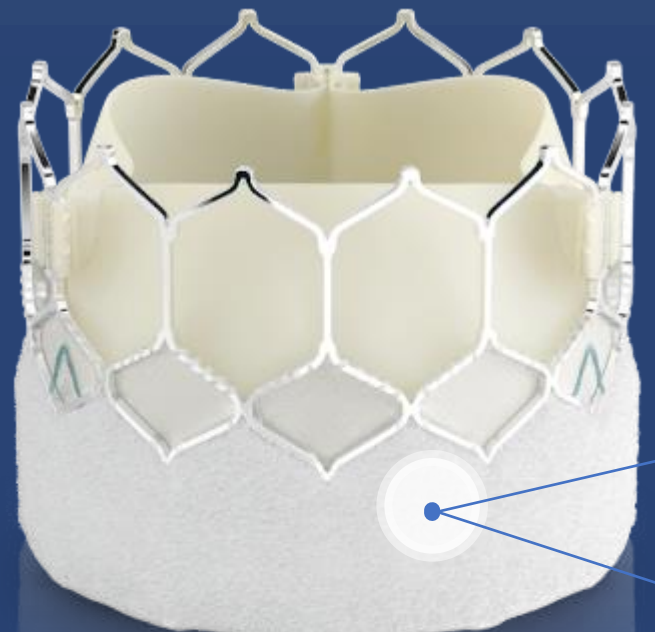


Discharge paravalvular regurgitation

0.1%
≥ moderate

9.0%
mild

90.9%
none



Textured, biocompatible PET material, similar to the SAPIEN 3 valve

SAPIEN 3 Ultra valve

SAPIEN 3 Ultra transcatheter aortic valve replacement technology features a 40% taller, textured outer skirt for PVL protection*

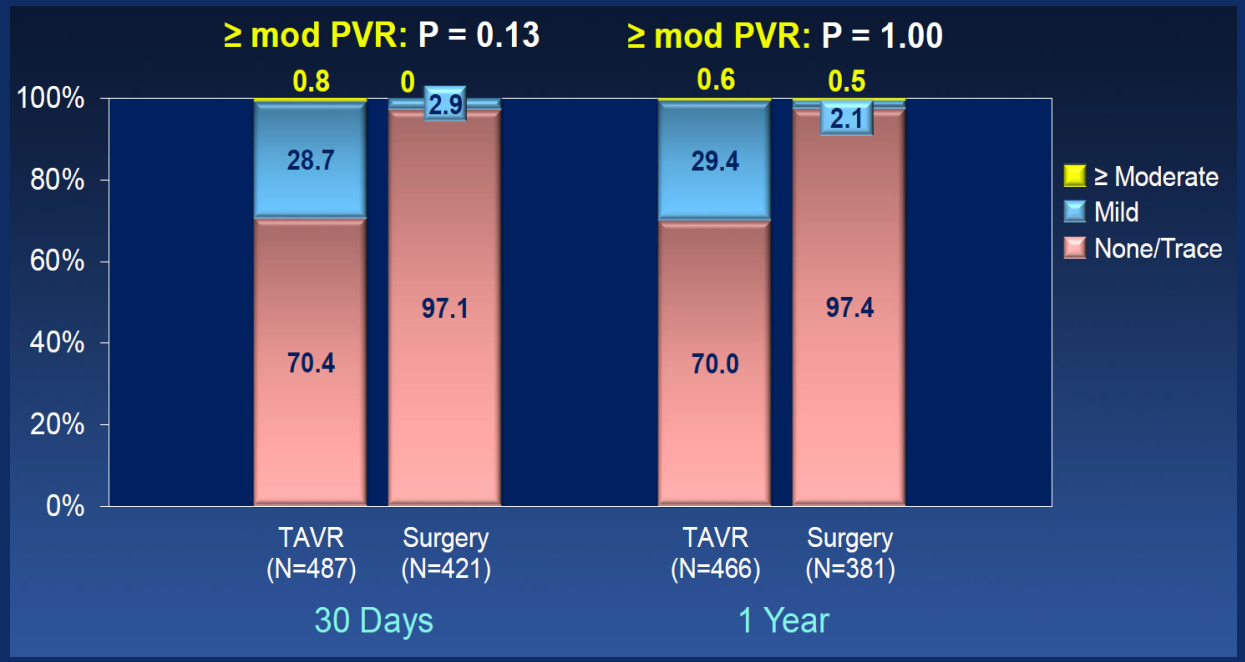
*Compared to SAPIEN 3 valve

1. Nazif T, Daniels D, McCabe J, Chehab B, et al. Real-world experience with the SAPIEN 3 Ultra TAVR: A propensity matched analysis from the United States. Presented virtually at TVT Connect 2020.

Balloon-expandable vs. Self-expandable TAVR

Data from recent big RCT

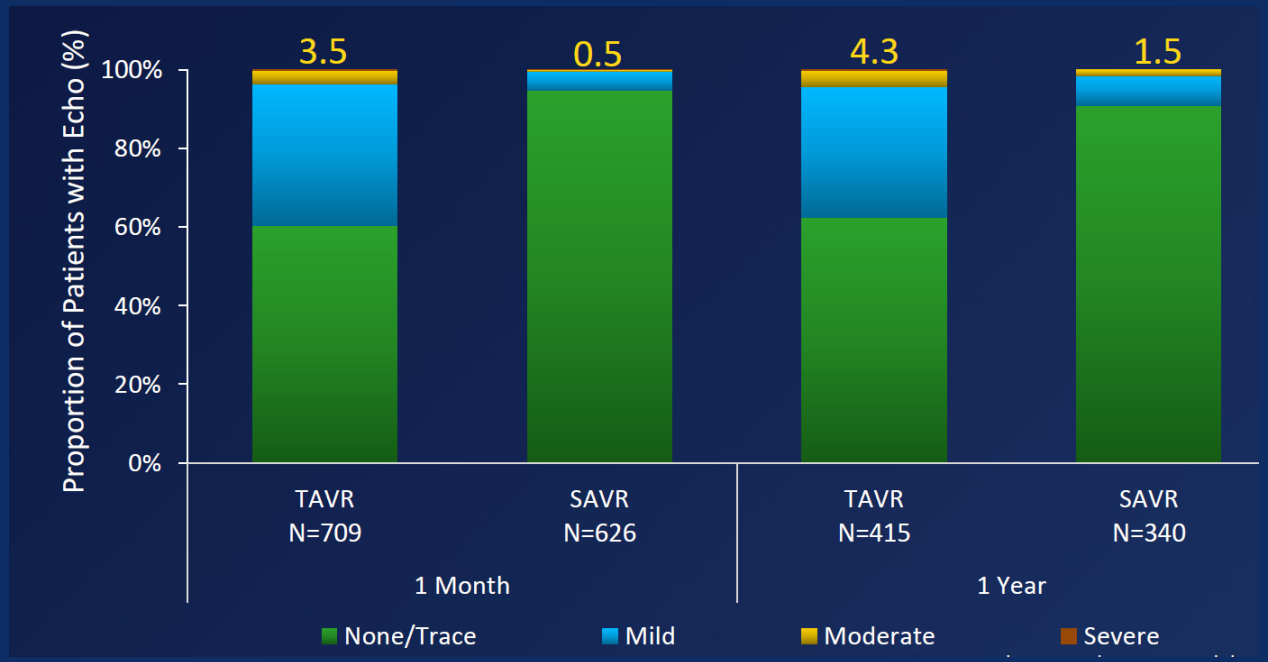
PARTNER 3 trial



≥ mod PVL : **0.8%** (1 month) → **0.6%** (1 year)

N Engl J Med 2019;380:1695-705.

EVOLUT Low Risk trial



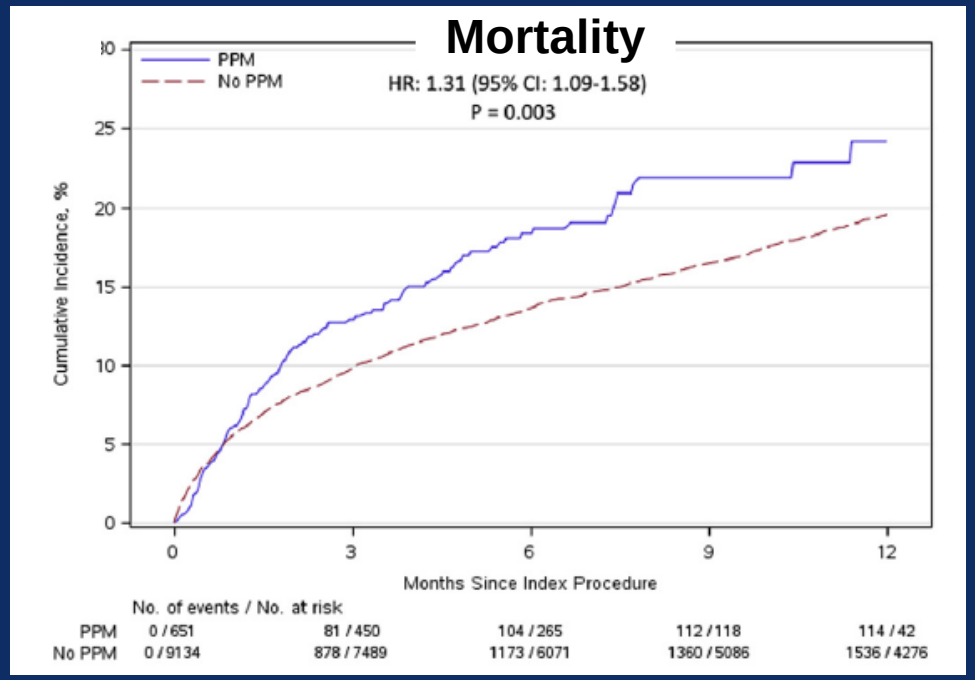
≥ mod PVL : **3.5%** (1 month) → **4.3%** (1 year)

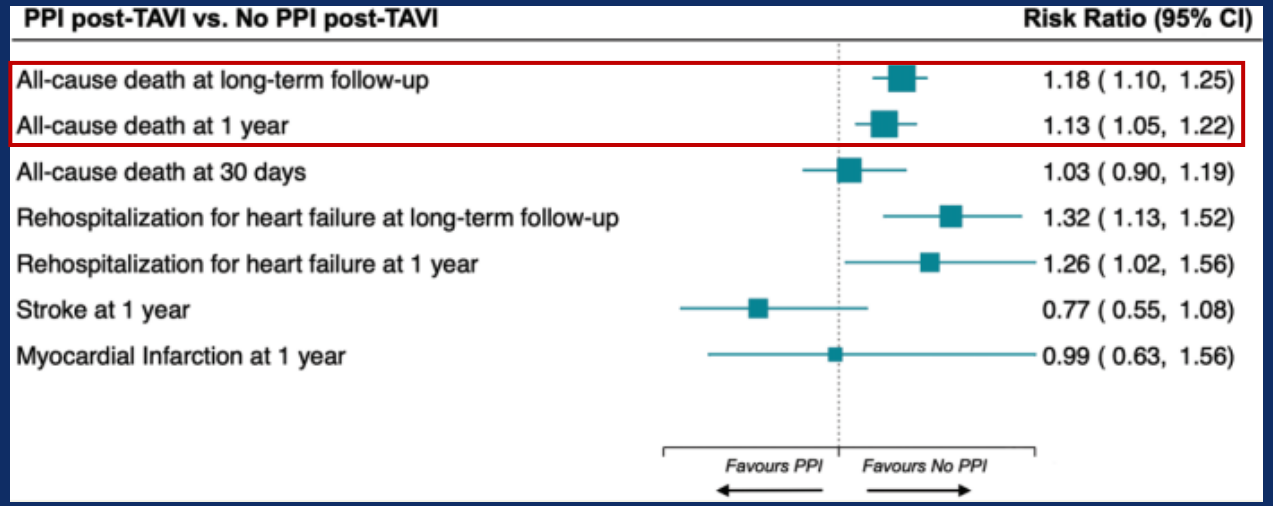
N Engl J Med 2019;380:1706-1715.

Conduction disturbance

- Incidence
  - 651 / 9785 patients : 6.7%
  - High incidence of PPM in TAVI compared to SAVR.
  - Self-expanding valves (25.1%) vs. Balloon-expanding valves (4.3%)

U.S. STS/ACC TVT JACC Cardiovasc Interv 2016;9:2189-99

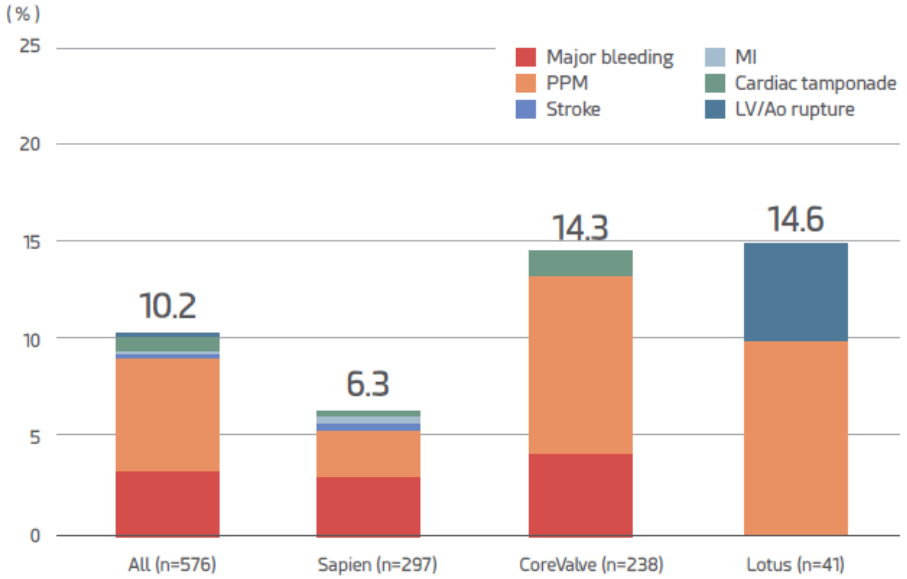




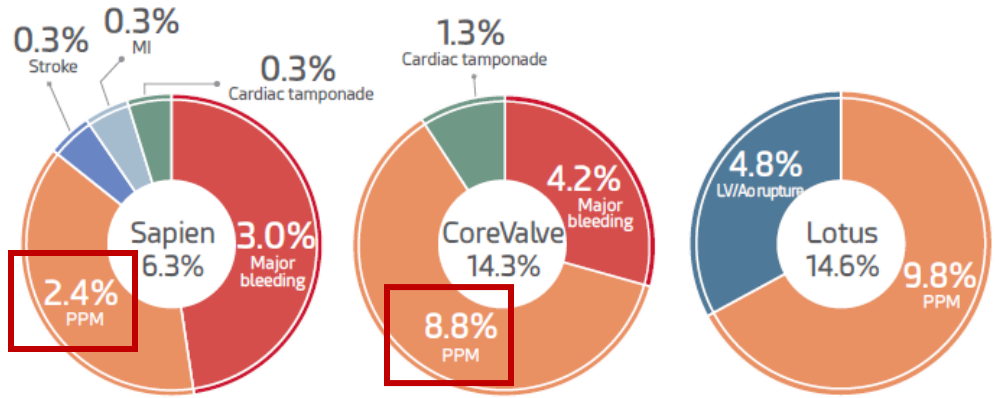
Zito A, et al. Europace. 2022;24:1127–1136.

K-TAVI Registry

Complications by device



Complications by device



SMART Trial

Prospective, randomized controlled, post-market trial conducted at 83 international sites

All-comer trial with all surgical risk categories including bicuspid patients

Key eligibility

- ☐ Symptomatic severe AS*
- ☐ Small aortic annulus (≤ 430 mm^2 by MDCT)

Randomization

1:1 stratified by site & sex

SEV (N=355)

Medtronic Evolut PRO/PRO+/FX

716 patients treated

BEV (N=361)

Edwards SAPIEN 3/SAPIEN 3 Ultra

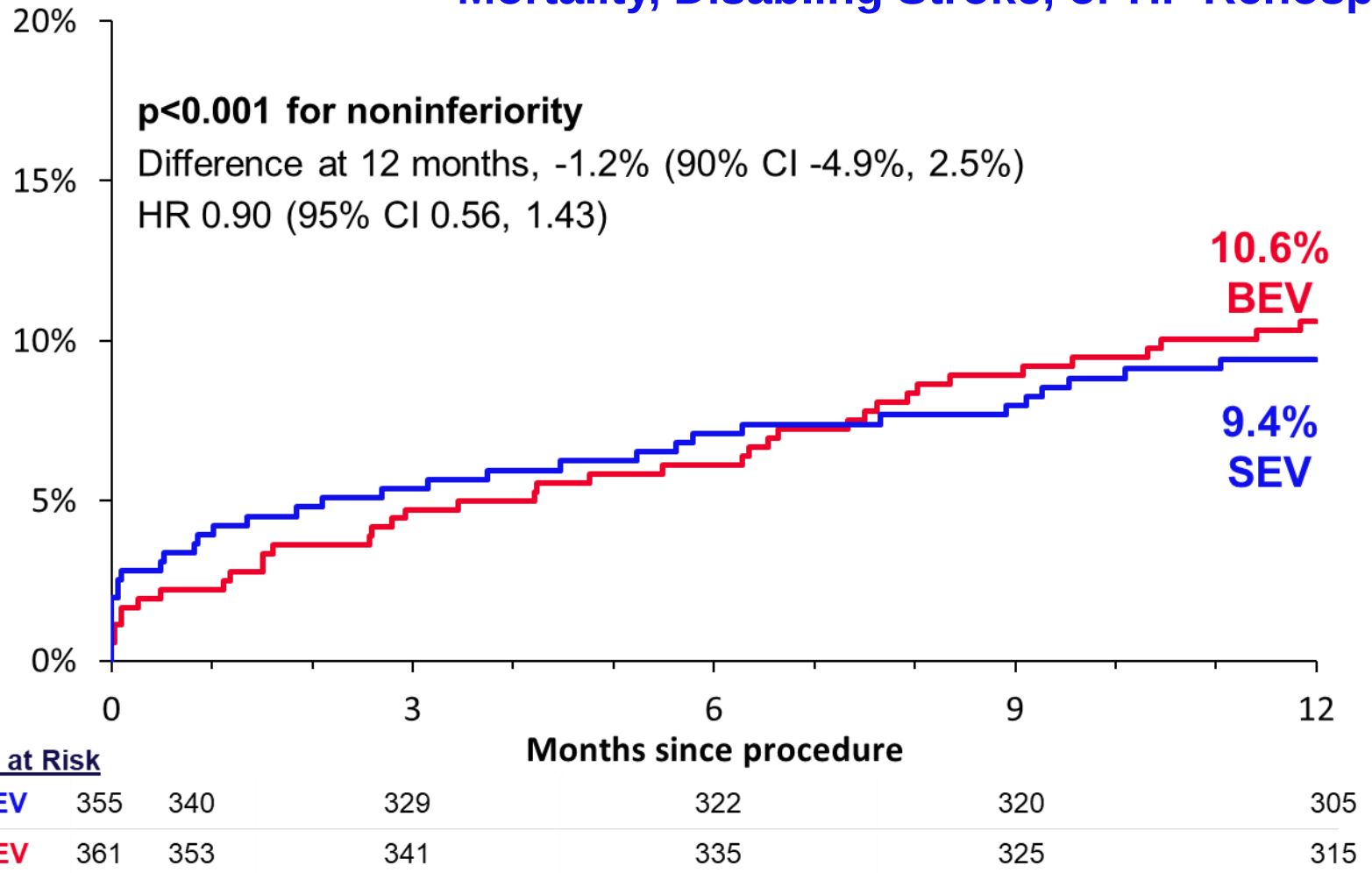
Co-Primary Endpoints at 1 year with planned 5-year follow-up

Co-Primary Endpoint 1: Composite of mortality, disabling stroke, or heart failure rehospitalization through 12 months
Co-Primary Endpoint 2: Bioprosthetic valve dysfunction through 12 months

*AVA ≤1.0 cm^2 (AVAi ≤0.6 cm^2/m^2) or mean gradient ≥40 mmHg or max velocity ≥4.0 m/s; 30-day predicted risk of surgical mortality <15% by heart team assessment.

Co-primary endpoint 1:
Clinical outcome composite through 12 months powered for noninferiority

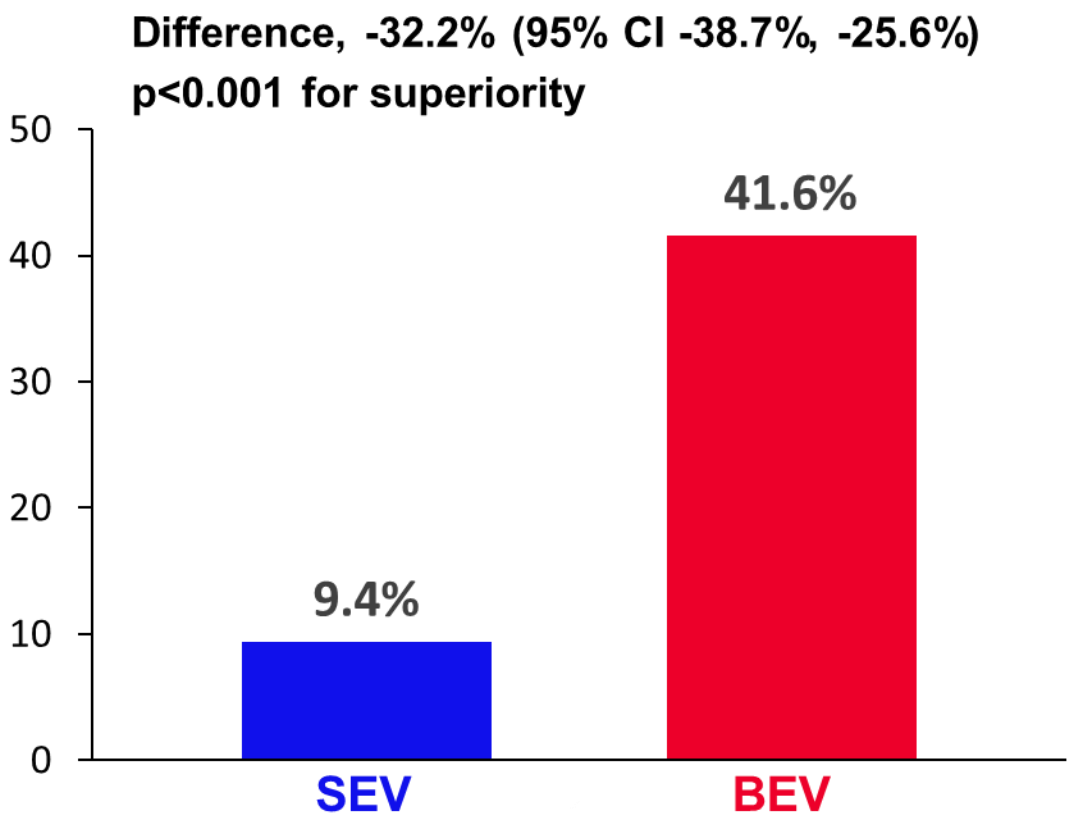
Mortality, Disabling Stroke, or HF Rehospitalization



12 Months	SEV (N=355)	BEV (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)

Co-primary endpoint 2:
BVD through 12 months powered for superiority

Bioprosthetic Valve Dysfunction through 12 months



	SEV (N=350)	BEV (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

PVL data

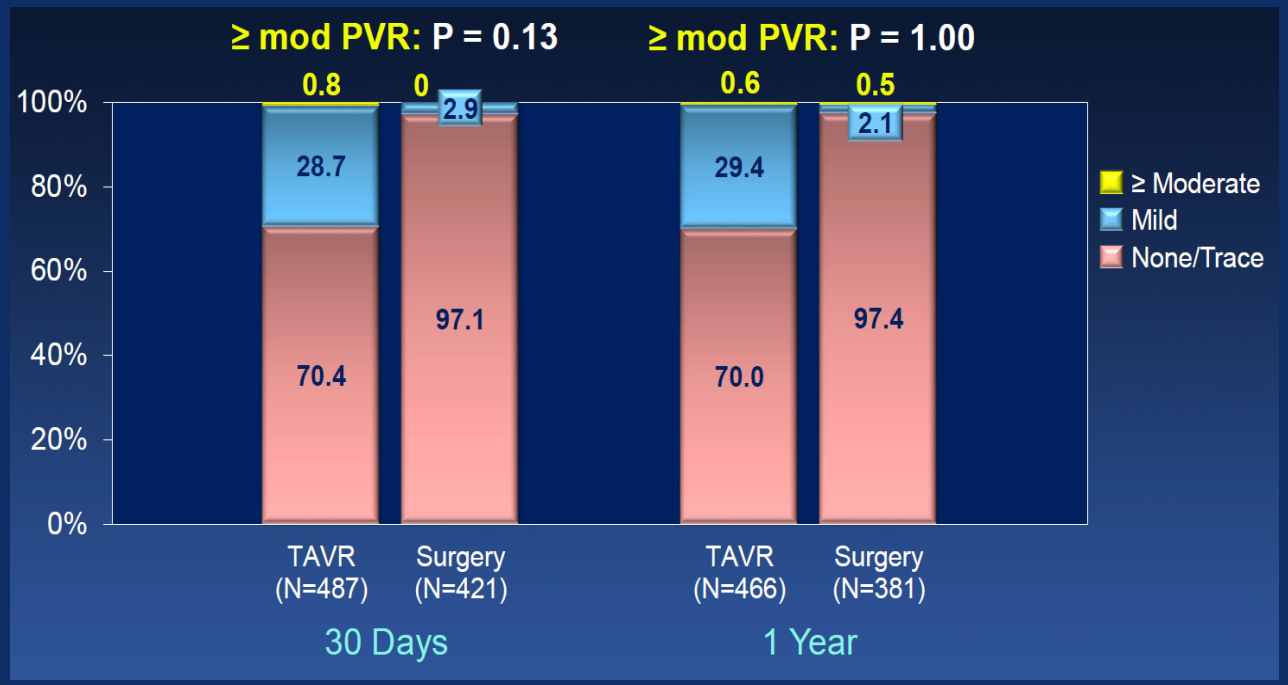
SMART Trial

Table S13. Additional Echocardiographic Outcomes in the Implanted Population

	SEV (N=350)	BEV (N=365)	Difference (95% CI)
Doppler velocity index			
12 Months	0.63±0.14 (287)	0.44±0.10 (281)	0.19 (0.17, 0.21)
Severe prosthesis-patient mismatch – no./total no. (%)			
30 Days	5/273 (1.8)	21/296 (7.1)	-5.3 (-8.6, -1.9)
12 months	8/267 (3.0)	26/266 (9.8)	-6.8 (-10.9, -2.7)
Moderate or Severe prosthesis-patient mismatch – no./total no. (%)			
30 Days	28/273 (10.3)	104/296 (35.1)	-24.9 (-31.4, -18.4)
12 Months	30/267 (11.2)	105/266 (39.5)	-28.2 (-35.2, -21.2)
Moderate or severe total aortic regurgitation – no./total no. (%)			
12 Months	0/298 (0.0)	3/300 (1.0)	-1.0 (-2.1, 0.1)
Mild or greater total aortic regurgitation – no./total no. (%)			
12 Months	42/298 (14.1)	61/300 (20.3)	-6.2 (-12.3, -0.2)
Mild or greater paravalvular regurgitation – no./total no. (%)			
12 Months	42/297 (14.1)	58/296 (19.6)	-5.5 (-11.5, 0.6)

Echocardiographic findings are based on Echocardiography Core Laboratory assessment. Outcomes are reported using echocardiographic data from the indicated study visit (30 days or 12 months). Prosthesis-patient mismatch was based on VARC-3 criteria.
BEV denotes balloon-expandable valve, SEV self-expanding valve

PARTNER 3 Trial

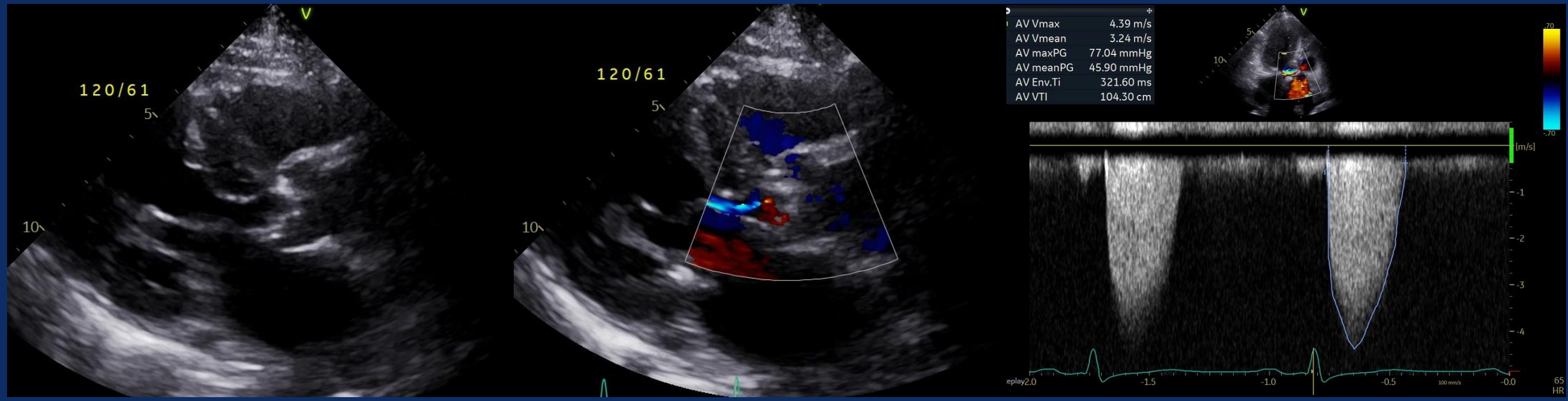


≥ mod PVL : **0.8%** (1 month) → **0.6%** (1 year)

N Engl J Med 2019;380:1695-705.

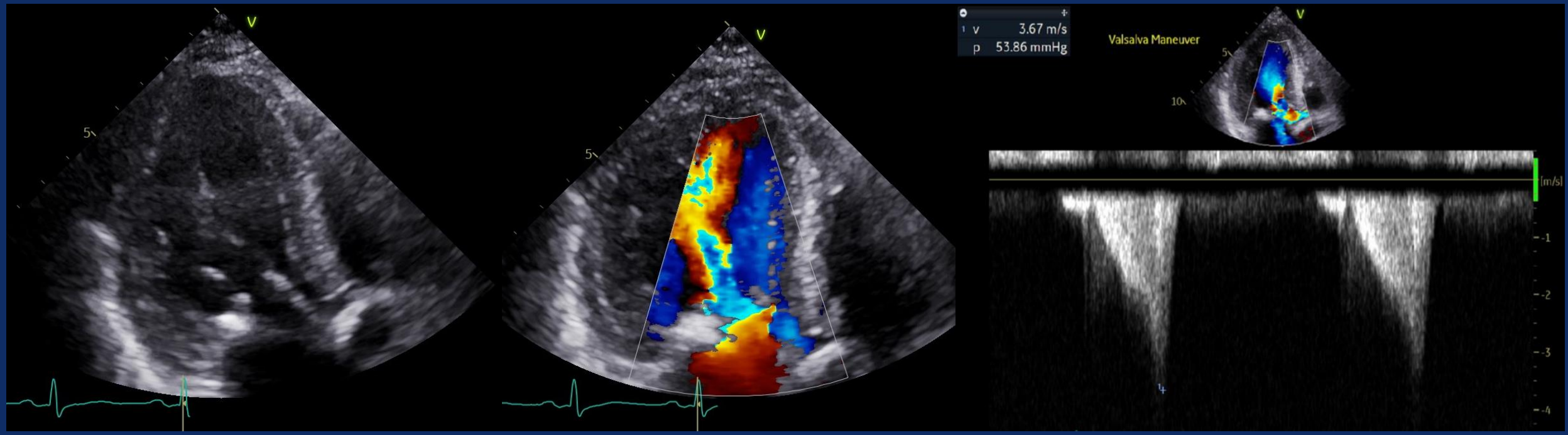
88/F, HFpEF, STS Score (13.1%)

Echocardiography findings (1)



- Severe AS d/t degenerative change (AVA 0.81cm2, V max 4.39m/sec, MSPG 45mmHg)
- Preserved LV systolic function (EF 53%)

Echocardiography findings (2)

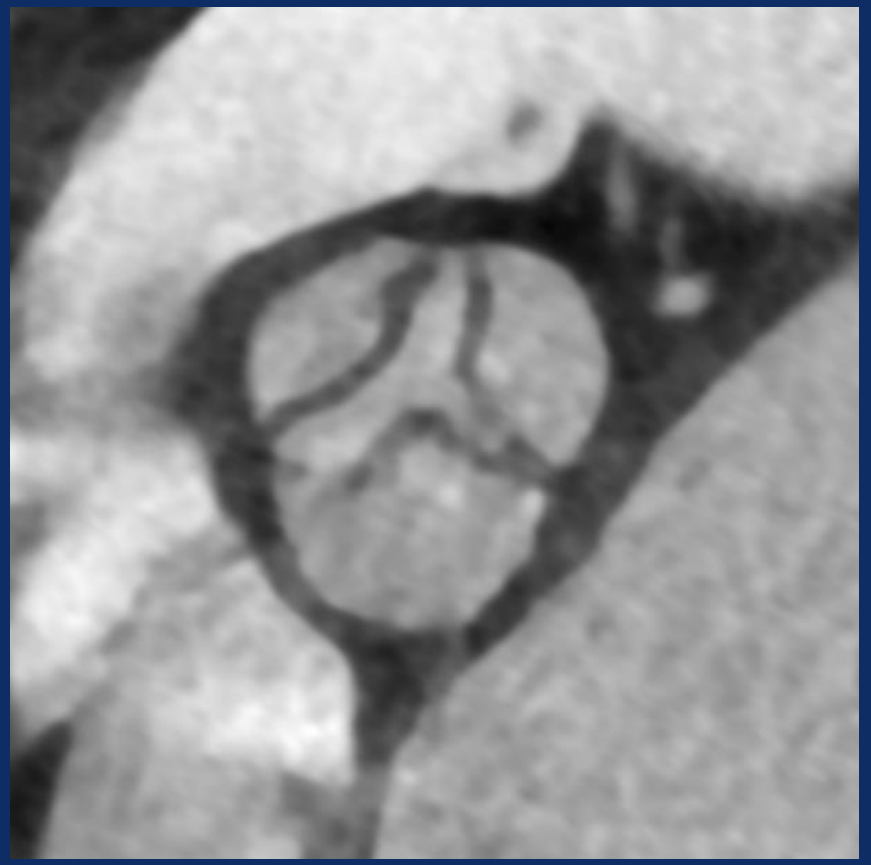


- **Flow acceleration with LVOT obstruction d/t chordae SAM.**

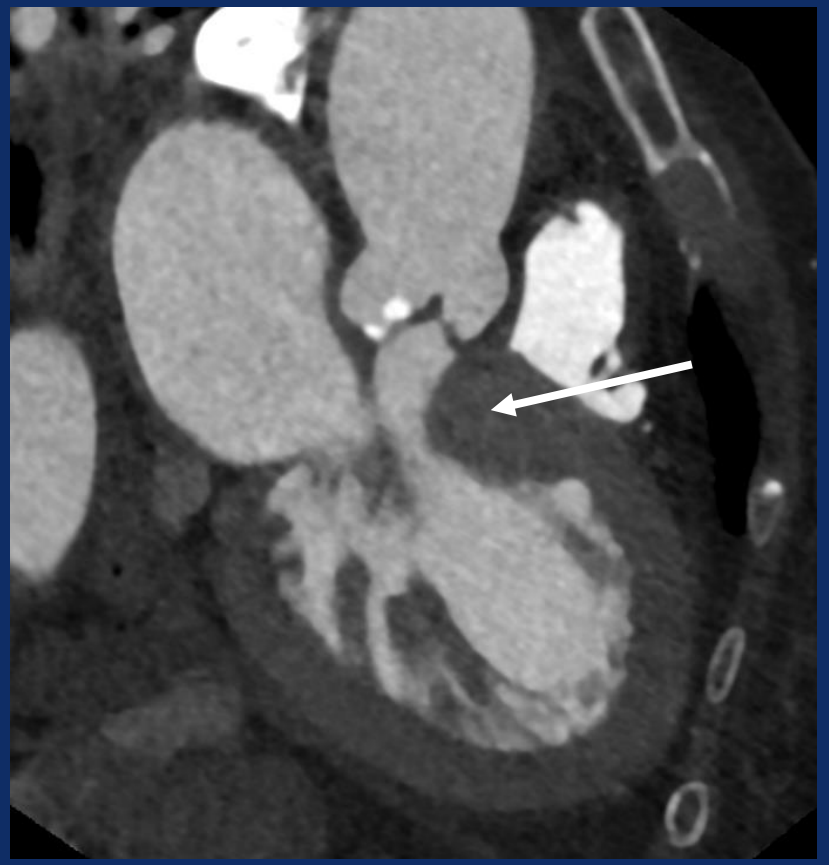
  Rest/valsalva PG:65/90mmHg.

Heart CT evaluation

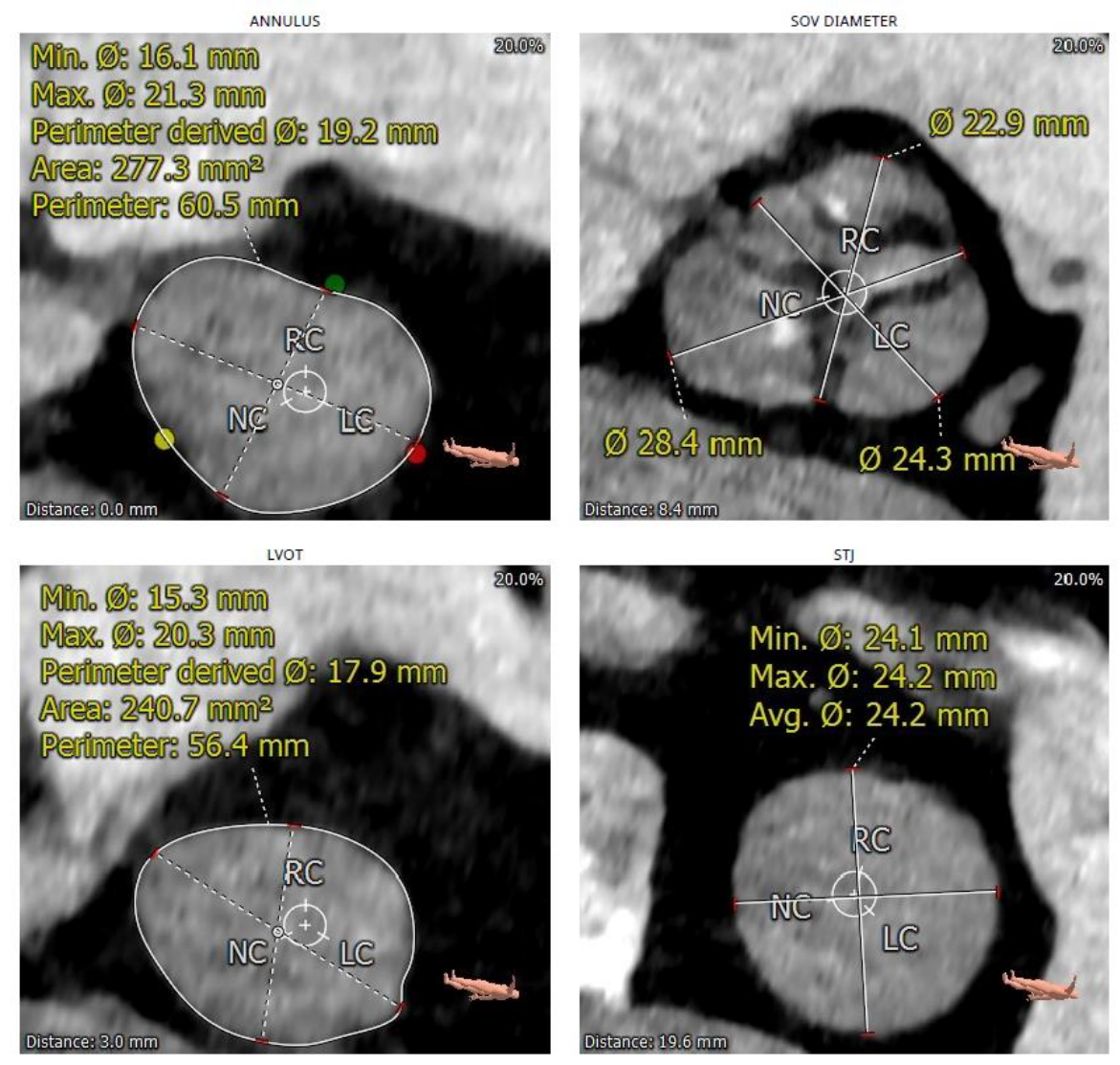
Diastole

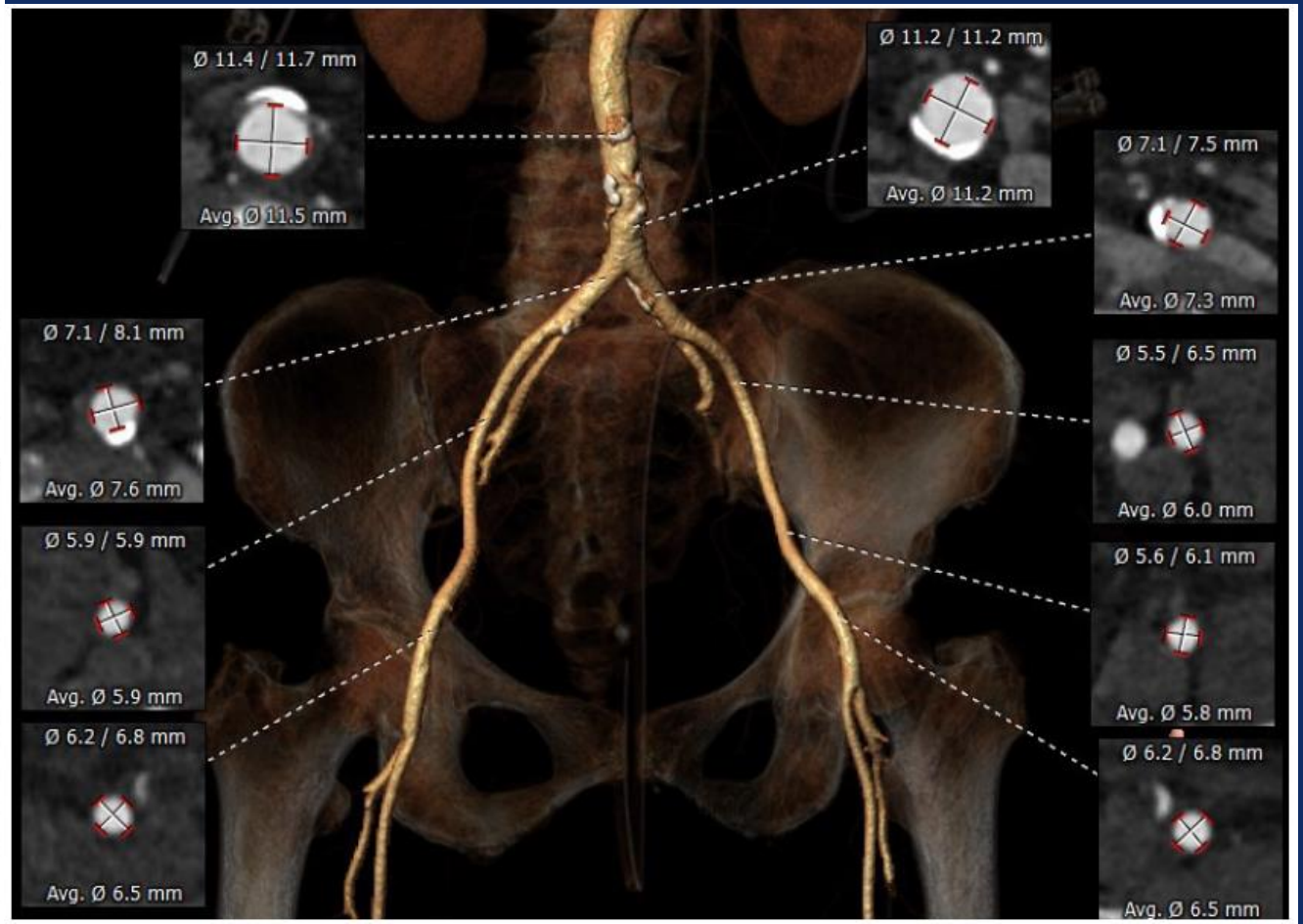


Systole



Long axis





- **Annulus area: 305.5mm²**
- **Area driven diameter: 19.7mm**
- **Perimeter driven diameter: 19.2mm**

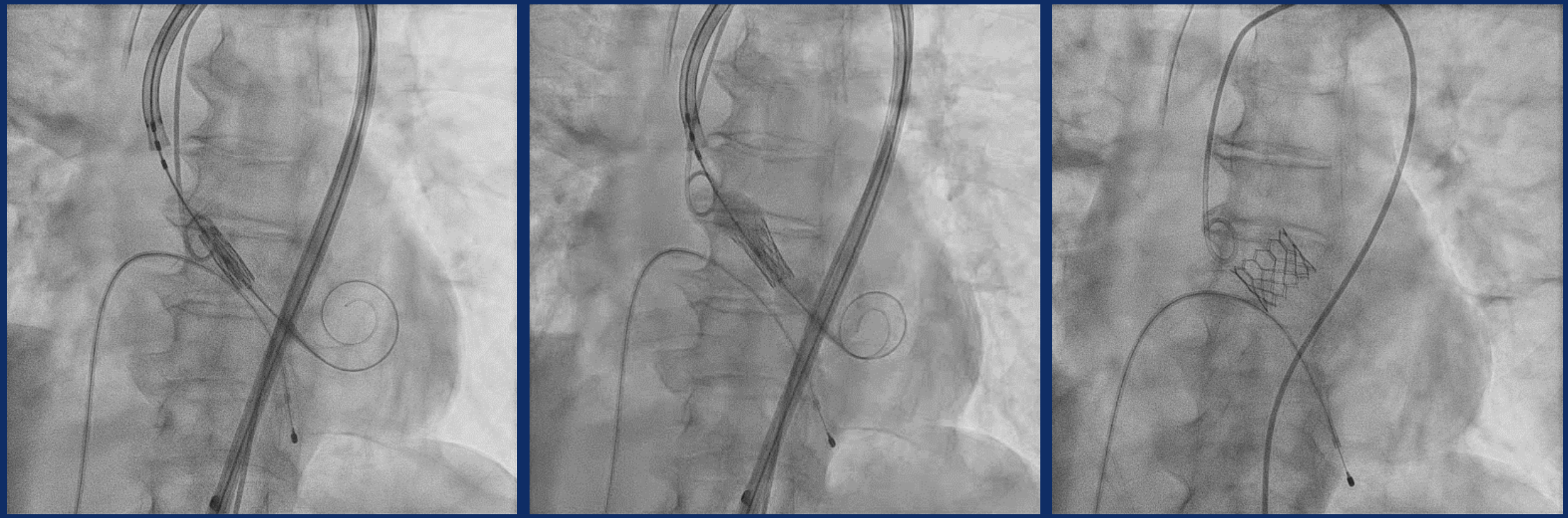
Discussion Point
- Which valve do you select?

- The patient had **small aortic annulus** (**305.5mm^2 by MDCT**)
- **No aortic valve calcification** was noted.
- In TTE, **sigmoid septum** & LVH was noted.

- **(1) BEV: SAPIEN 3 Ultra 20mm (7.4% oversize)**

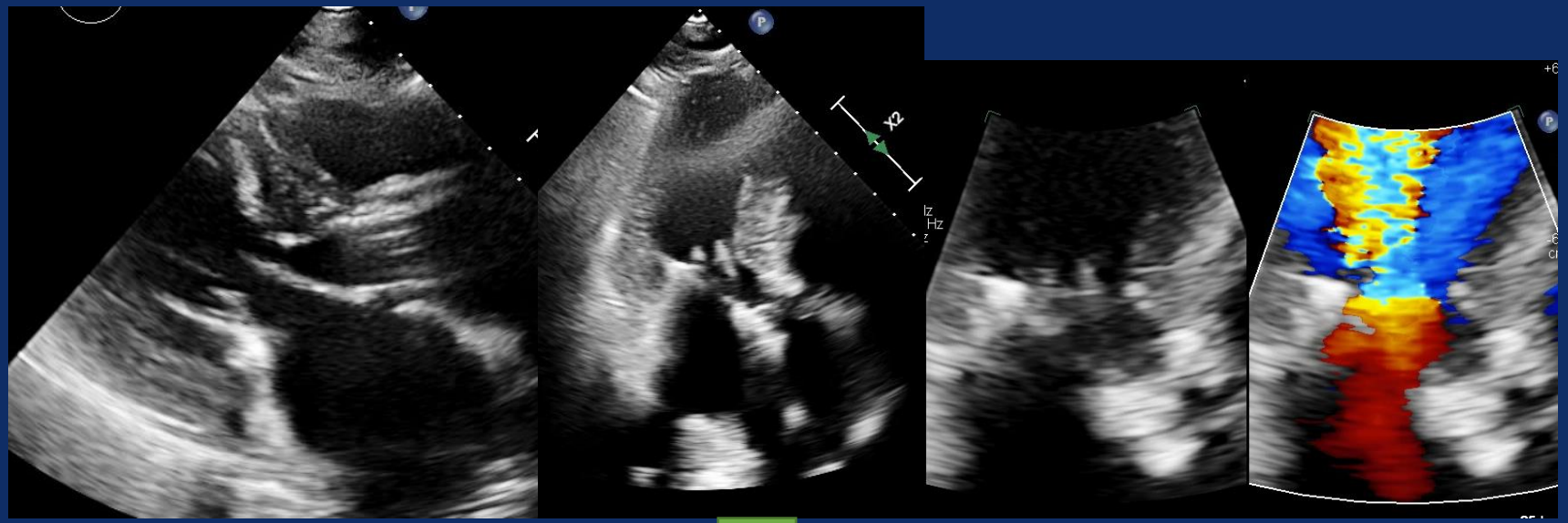
- **(2) SEV: Evolut PRO 23mm (20% oversize)**

TAVI



SAPIEN3 ultra 20mm – nominal volume (7.4% oversize)

Echocardiography after TAVI



[3months after TAVI]

- LVOT obstruction

: Rest PG = 103mmHg

- **MSPG 22.2mmHg**

[12 months after TAVI]

- Disappeared LVOT obstruction
- **MSPG: 22.2→ 11.4mmHg**

Analysis Populations
Small vs Large Annulus

Symptomatic Severe Aortic Stenosis Patients in the PARTNER 2 S3i registry (n=870) or PARTNER 3 RCT (n=485)

1355 patients who received SAPIEN 3 TF-TAVI

476 (35%) pts with CT systolic aortic annular area ≤430 mm^2

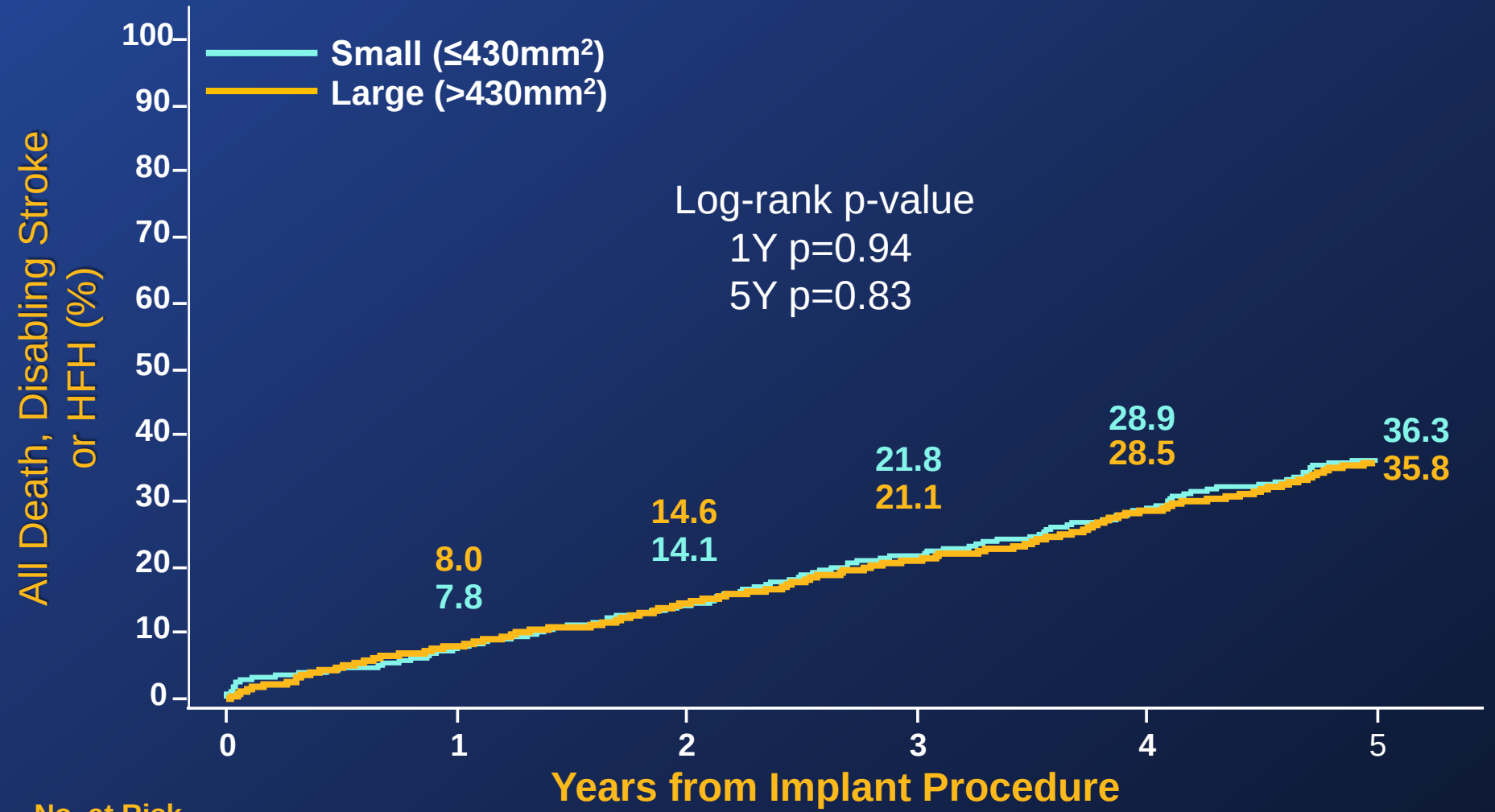
879 (65%) pts with CT systolic aortic annular area >430 mm^2

PRIMARY ENDPOINT AT 5 YEARS:
Non-hierarchical composite of all-cause death, disabling stroke, or HF hospitalization

NY Valves 2024, Hahn R. et al
Hahn R. et al., JACC Cardiovasc Interv. 2025 Feb 24;18(4):506-517.

THE PARTNER TRIALS

Excellent clinical outcomes irrespective of annulus size

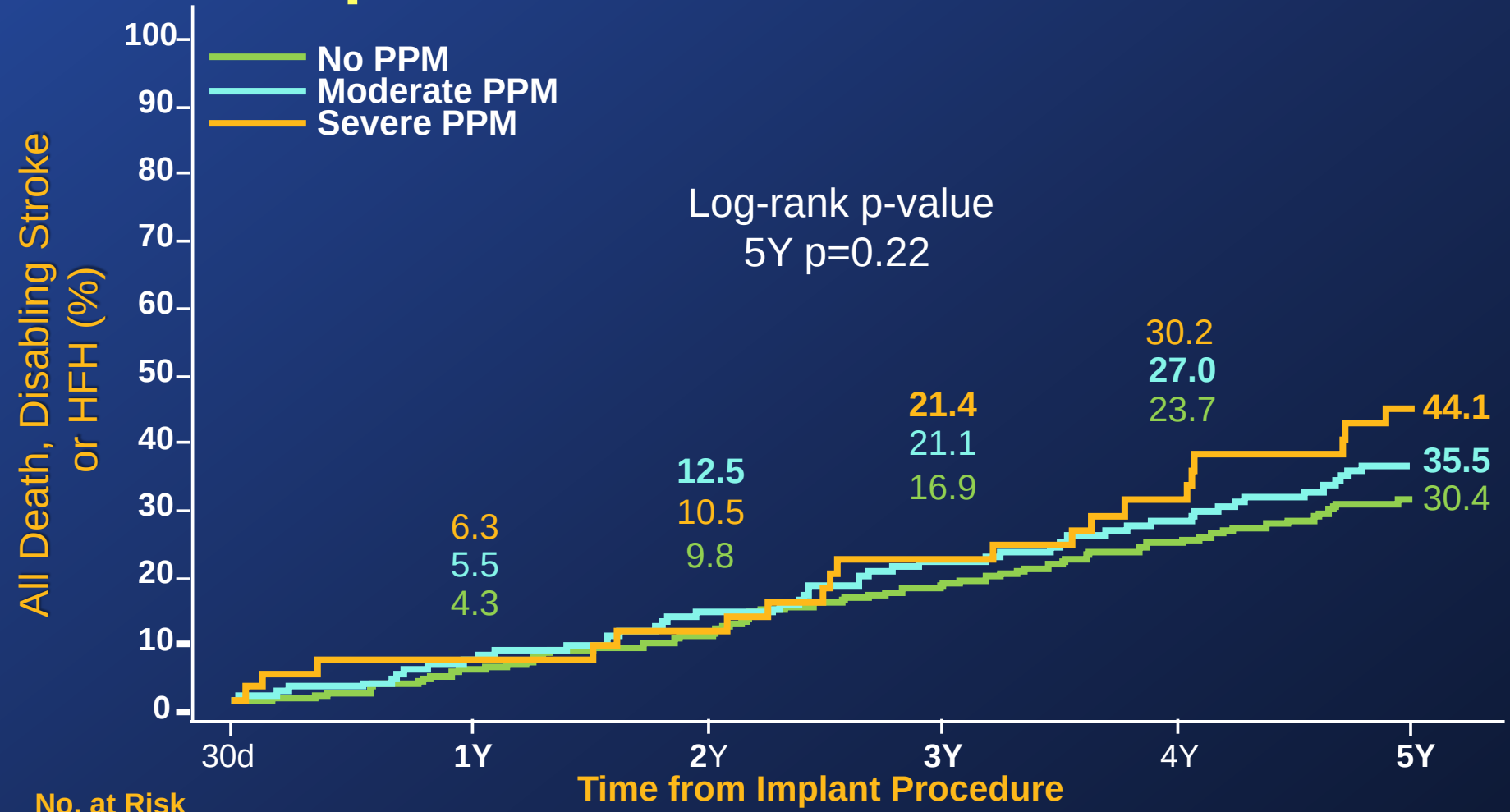


NY Valves 2024, Hahn R. et al

Hahn R. et al., JACC Cardiovasc Interv. 2025 Feb 24;18(4):506-517

THE PARTNER TRIALS

30-day PPM was not associated with clinical outcomes in small annulus patients



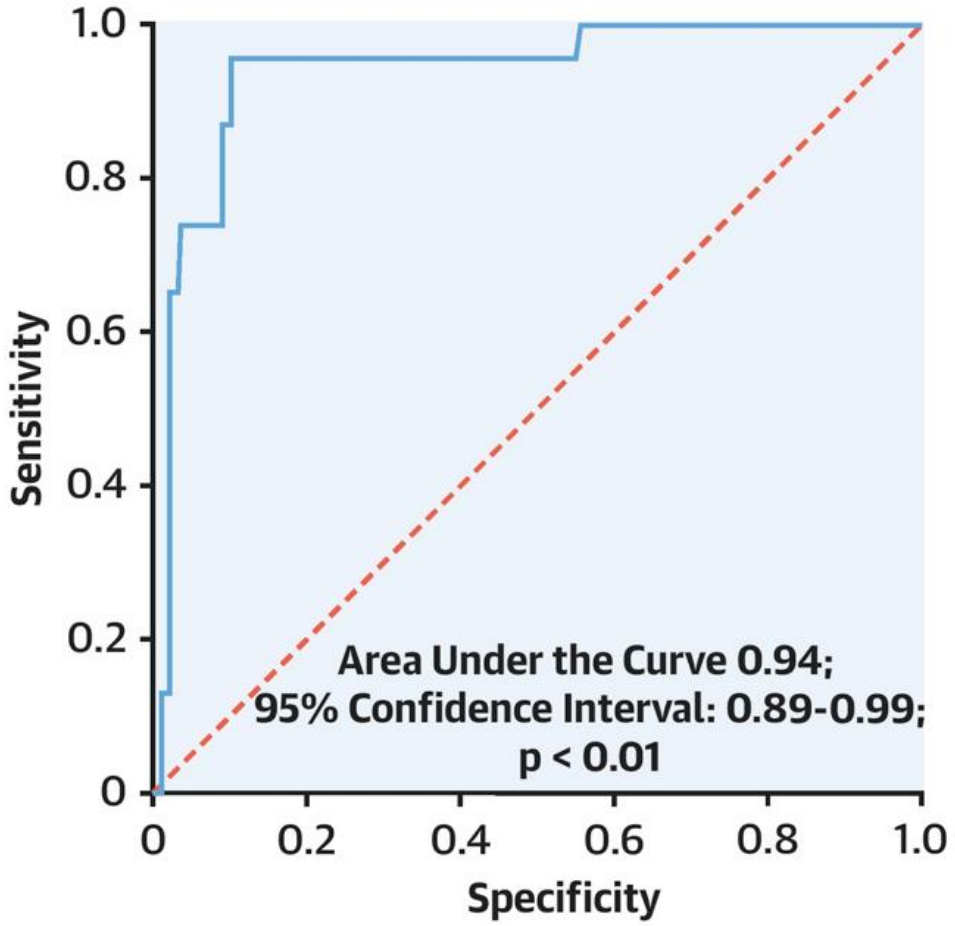
NY Valves 2024, Hahn R. et al

Hahn R. et al., JACC Cardiovasc Interv. 2025 Feb 24;18(4):506-517

THE PARTNER TRIALS

Future Coronary Access

Predictors of Unsuccessful Coronary Cannulation after TAVR



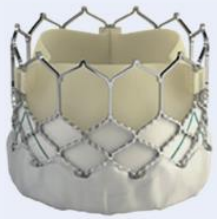
Transcatheter Aortic Valve/ Sinuses of Valsalva Relation
Odds Ratio 1.1;
95% CI: 1.0-1.2; p < 0.01

Transcatheter Aortic Valve Implant Depth
Odds Ratio 1.7;
95% CI: 1.3-2.3; p < 0.01

Evolut Transcatheter Aortic Valve
Odds Ratio 29.6;
95% CI: 2.6-335.0; p < 0.01

Marco Barbanti et al. *J Am Coll Cardiol Intv* 2020; 13:2542-2555.

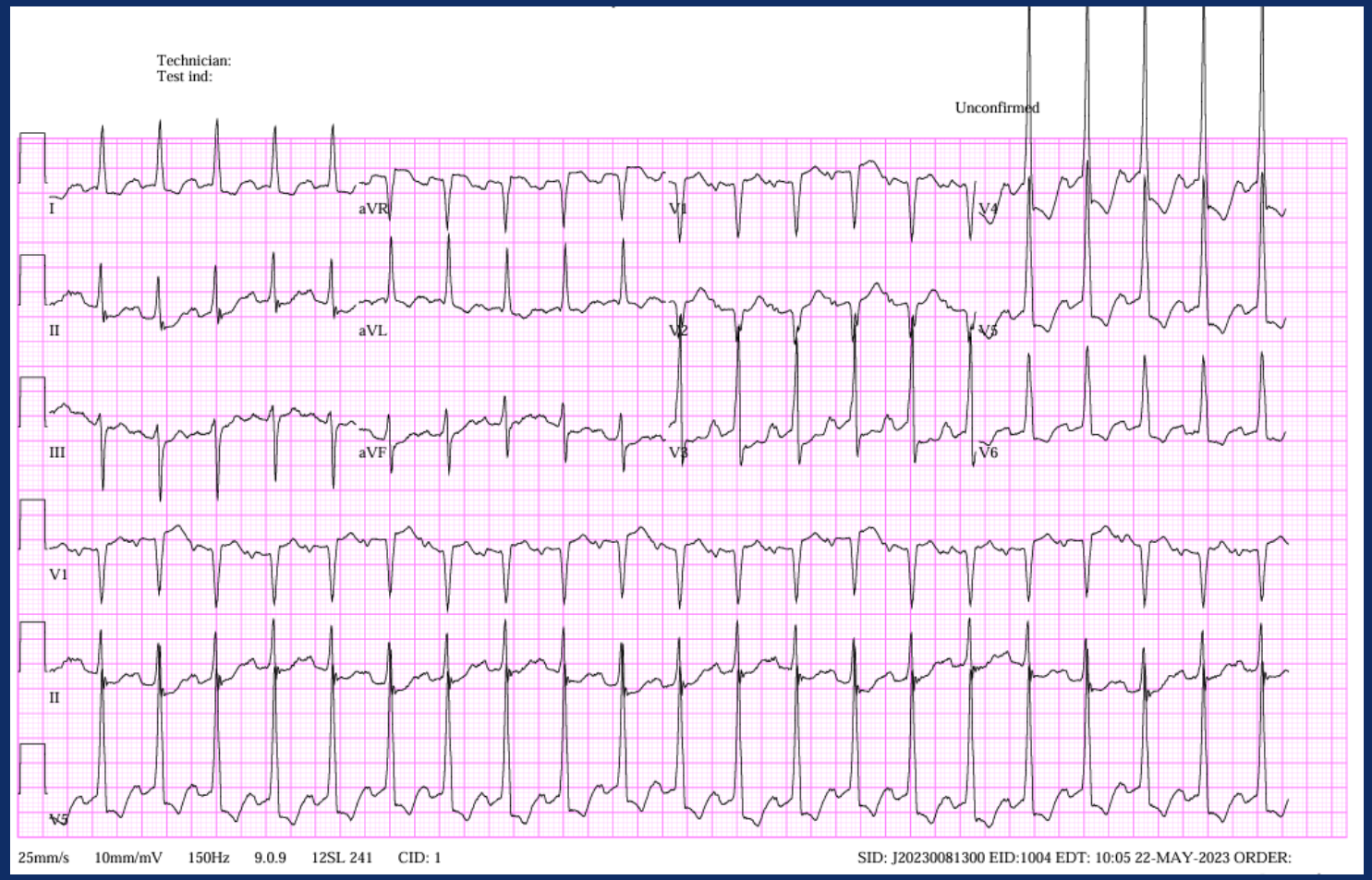
Impact on Final Valve Orientation and Coronary Artery Overlap

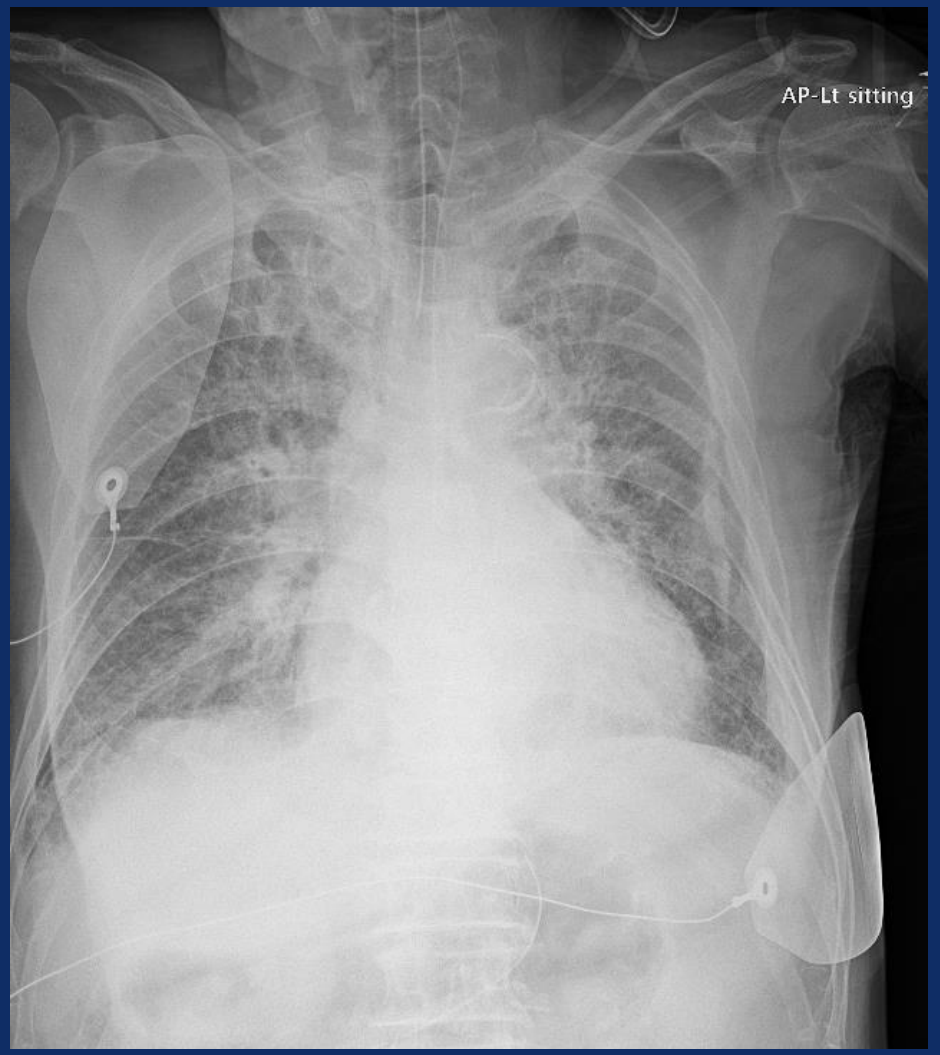
	Sapien 3	Evolut	ACURATE-neo
			
Method of Transcatheter Valve Orientation	1 commissure crimped at 3, 6, 9 and 12 o'clock	"Hat" marker position at initial deployment	Commissure position at initial deployment
Impact of Initial Deployment Orientation on Commissural Alignment	None	• Insert catheter with flush port facing 3 o'clock • Alignment improves when "Hat" at outer curve (OC)/ center front (CF)	• Insert catheter with flush port facing 12 o'clock • Alignment improves when commissure at center back (CB)/ inner curve (IC)
Severe Overlap With Left Main	32.7%-39.7%	15.7% (OC/CF) vs. 66.0%	0-7.1% (CB/IC) vs. 14.8%-75.9%
Severe Overlap With Right Coronary Artery	28.8%-51.6%	7.1% (OC/CF) vs. 51.1%	7.1%-12.5% (CB/IC) vs. 62.1%-74.1%

- Initial SAPIEN 3 orientation had no impact on alignment, but specific initial orientations of Evolut and ACURATE improved alignment.

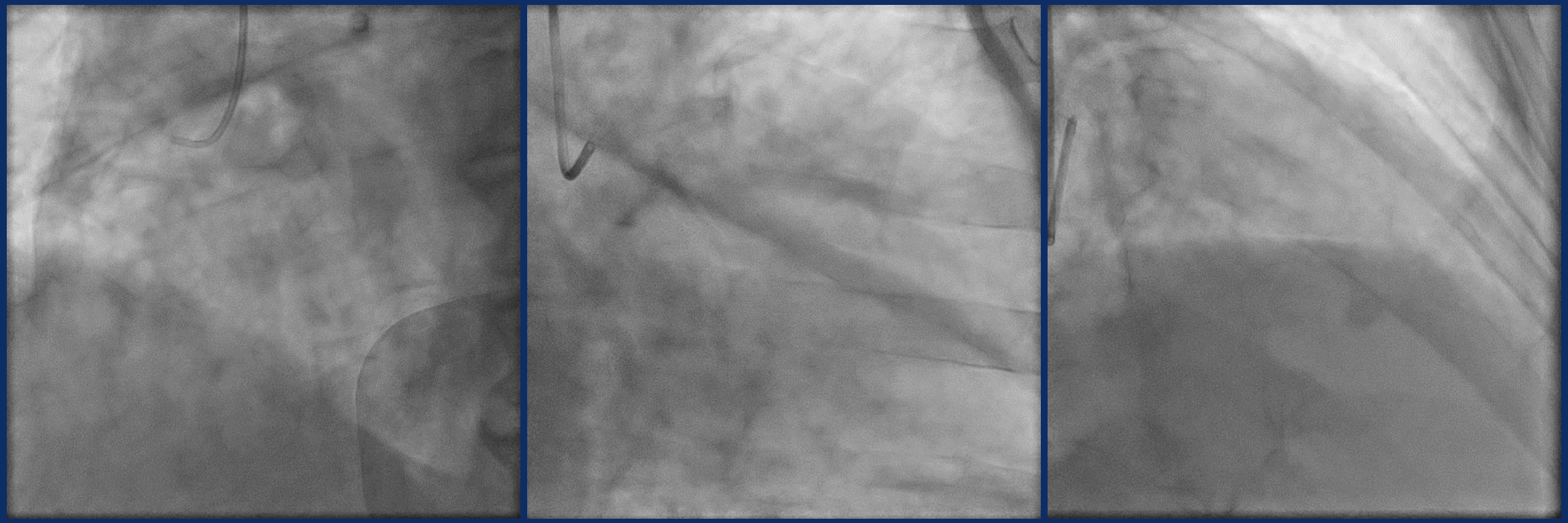
Tang, G.H.L. et al. J Am Coll Cardiol Intv. 2020;13(9):1030–42.

M/85, severe chest pain, cardiogenic shock

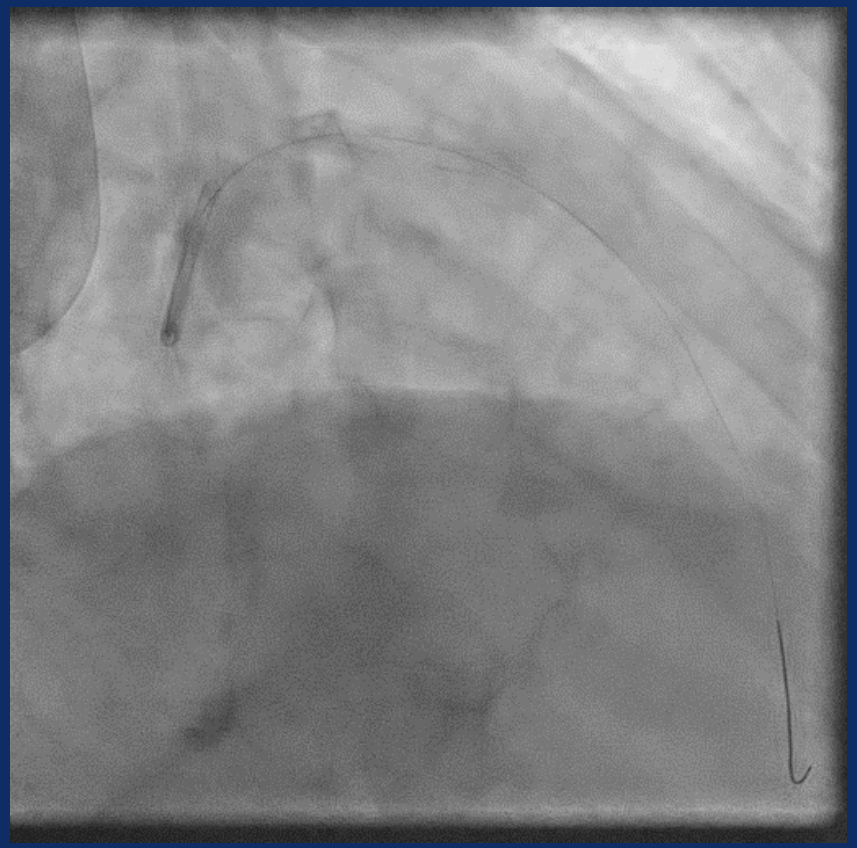


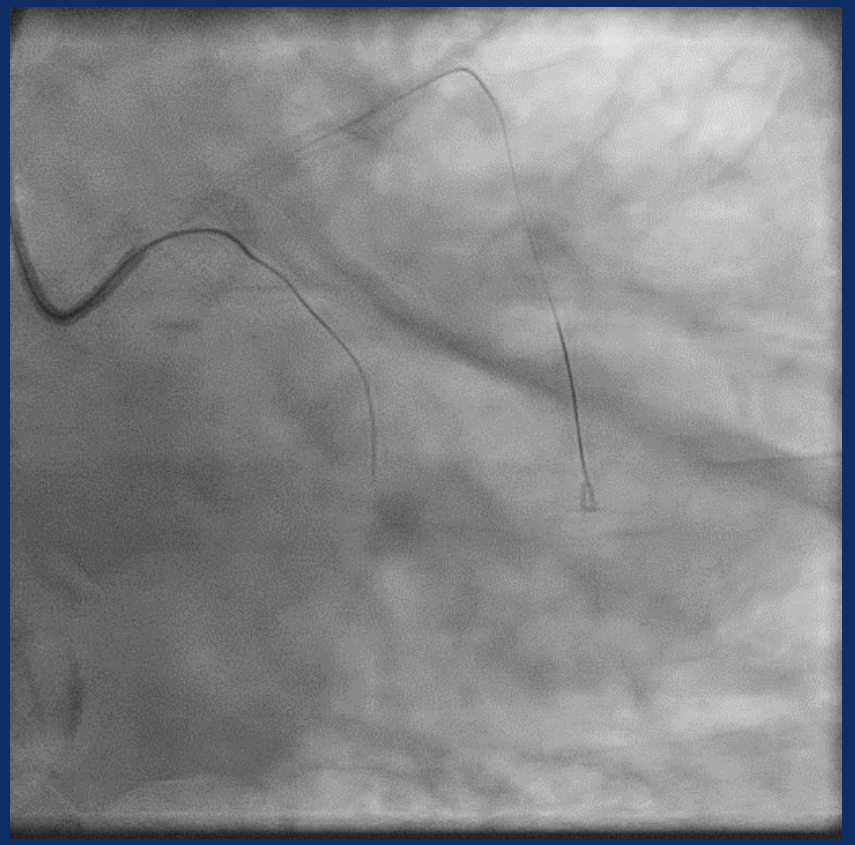


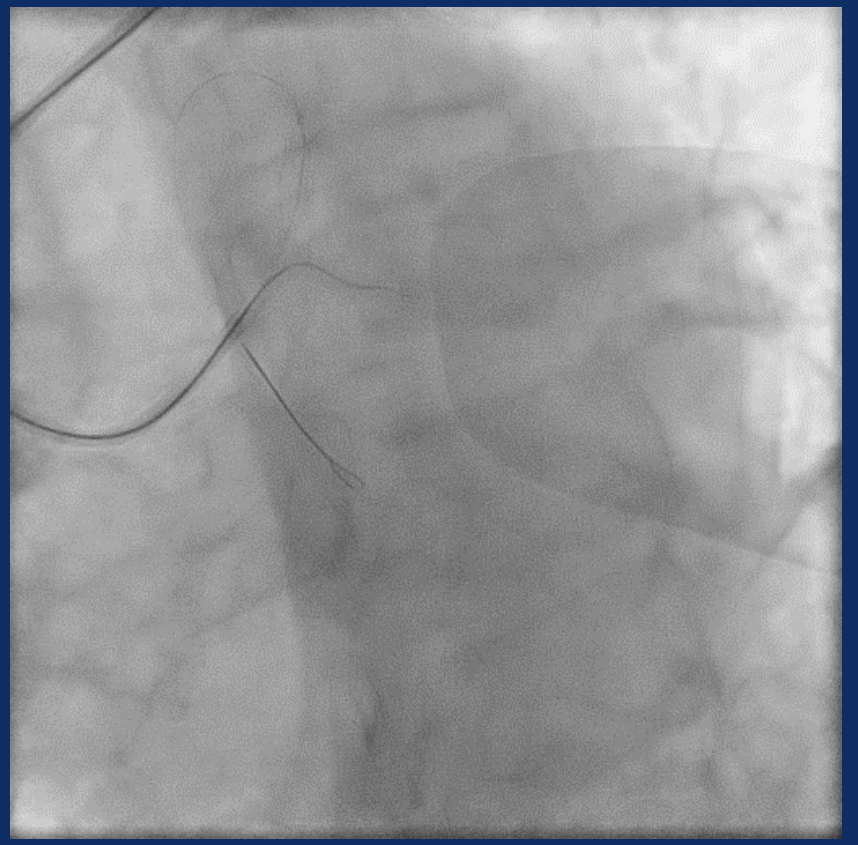
CAG



LAD PCI / LCX CTO PCI

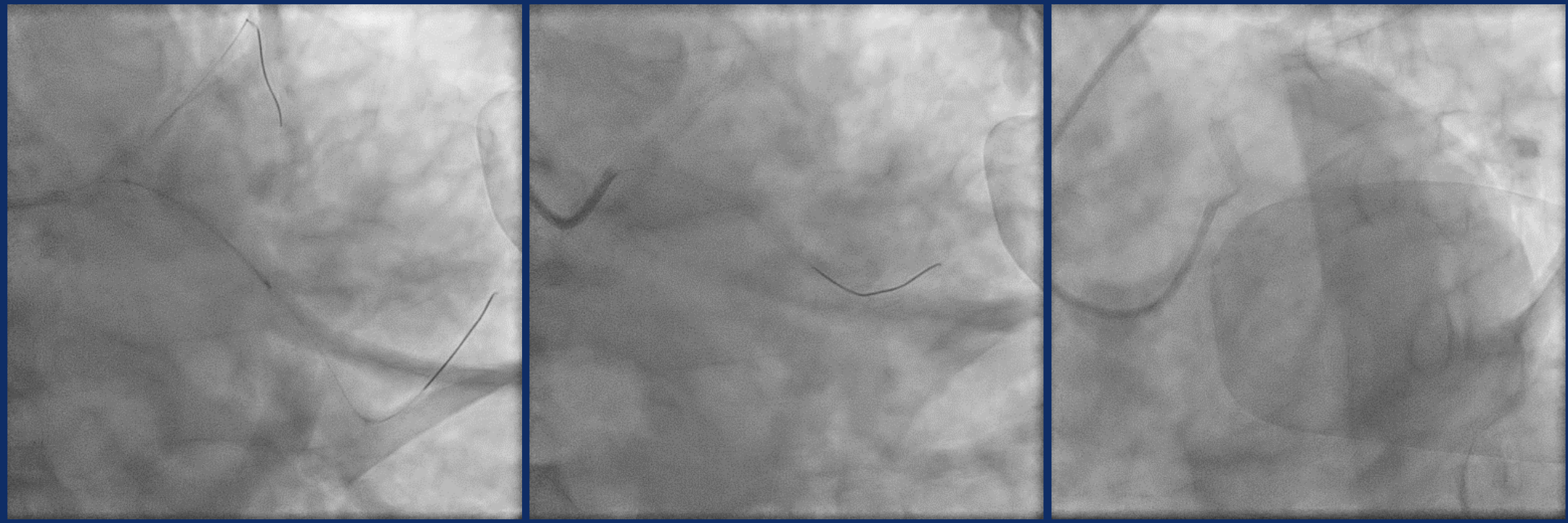






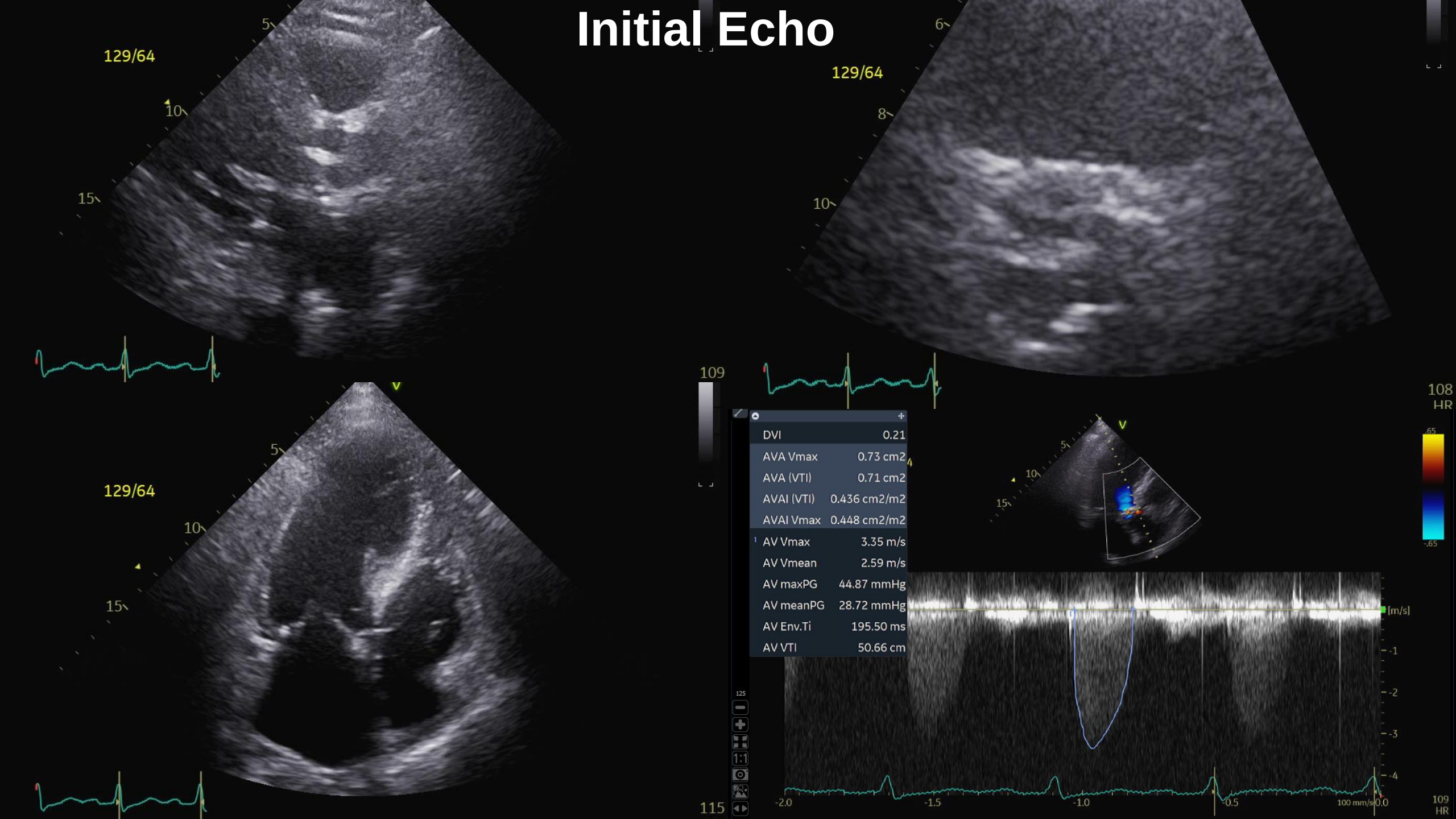
pLAD with Xience skypoint 3.5/33

Two stent technique (T-stenting)

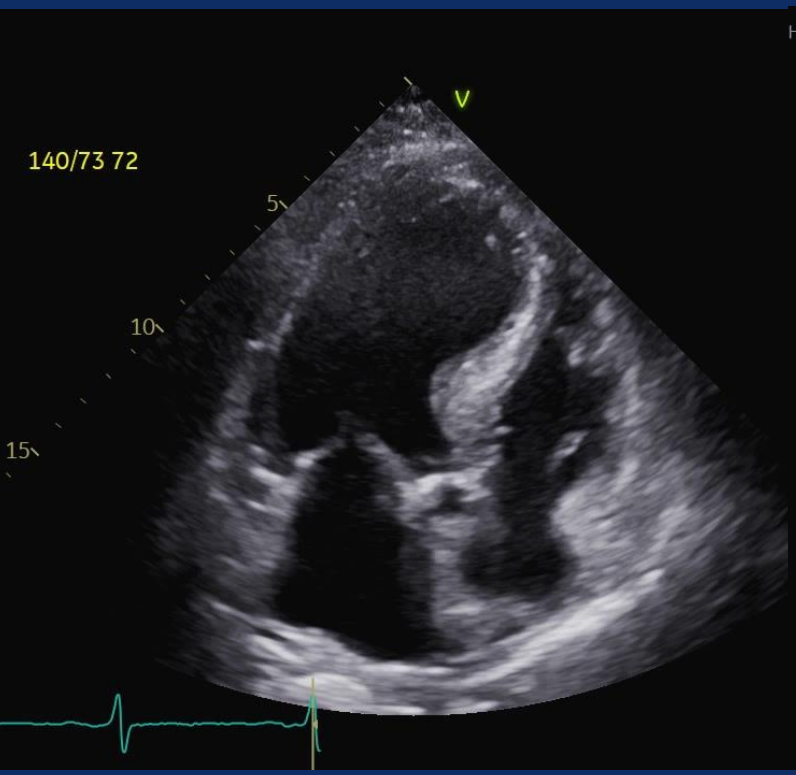


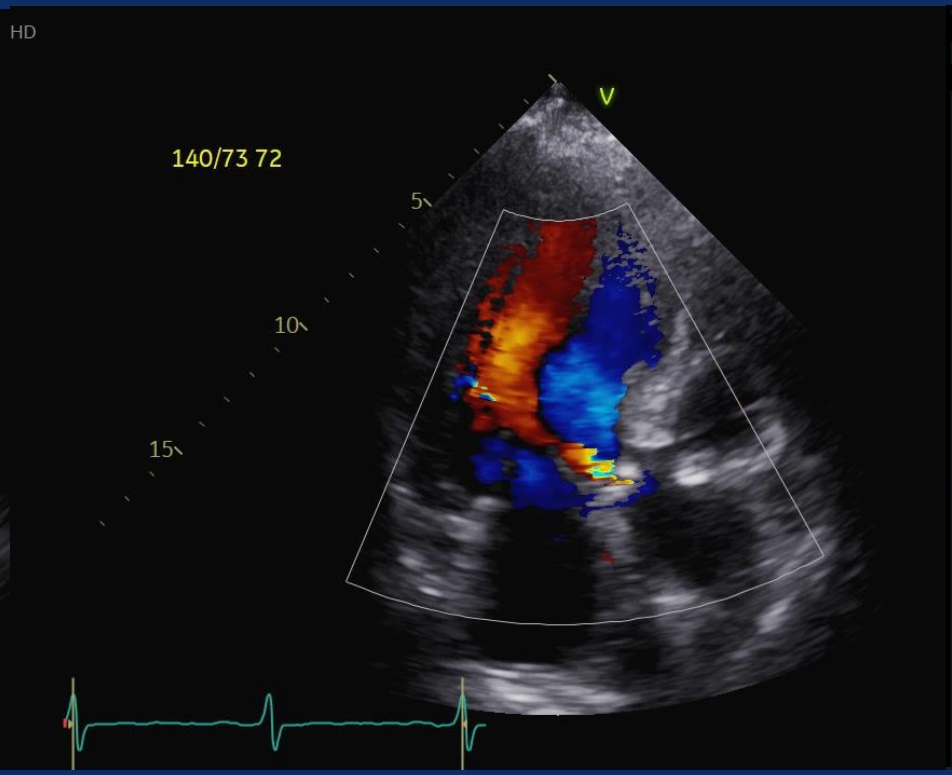
pLCX with Xience skypoint 2.5/33

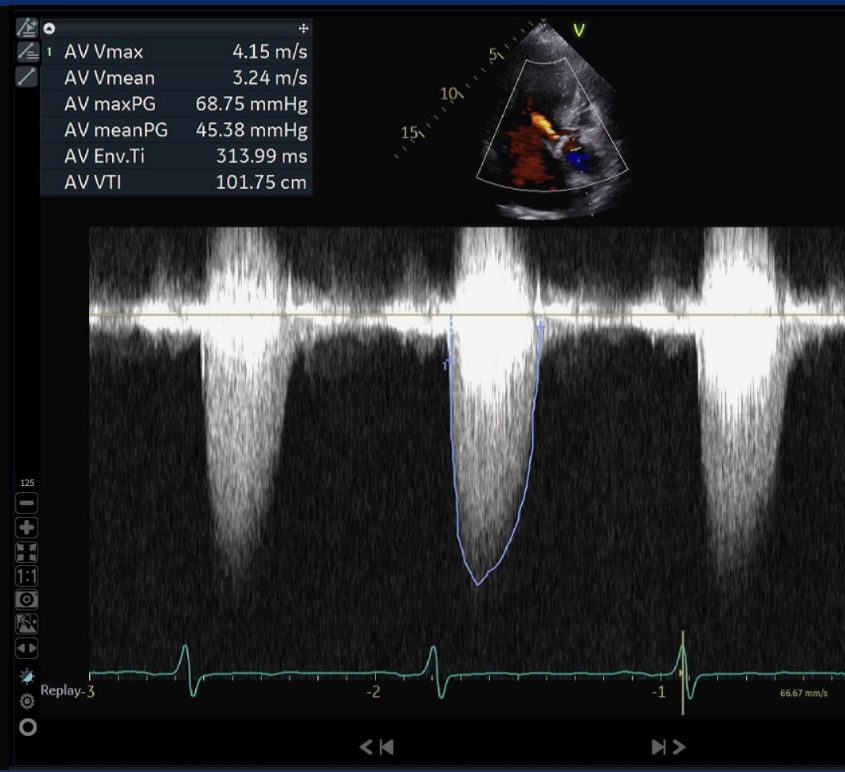
Initial Echo



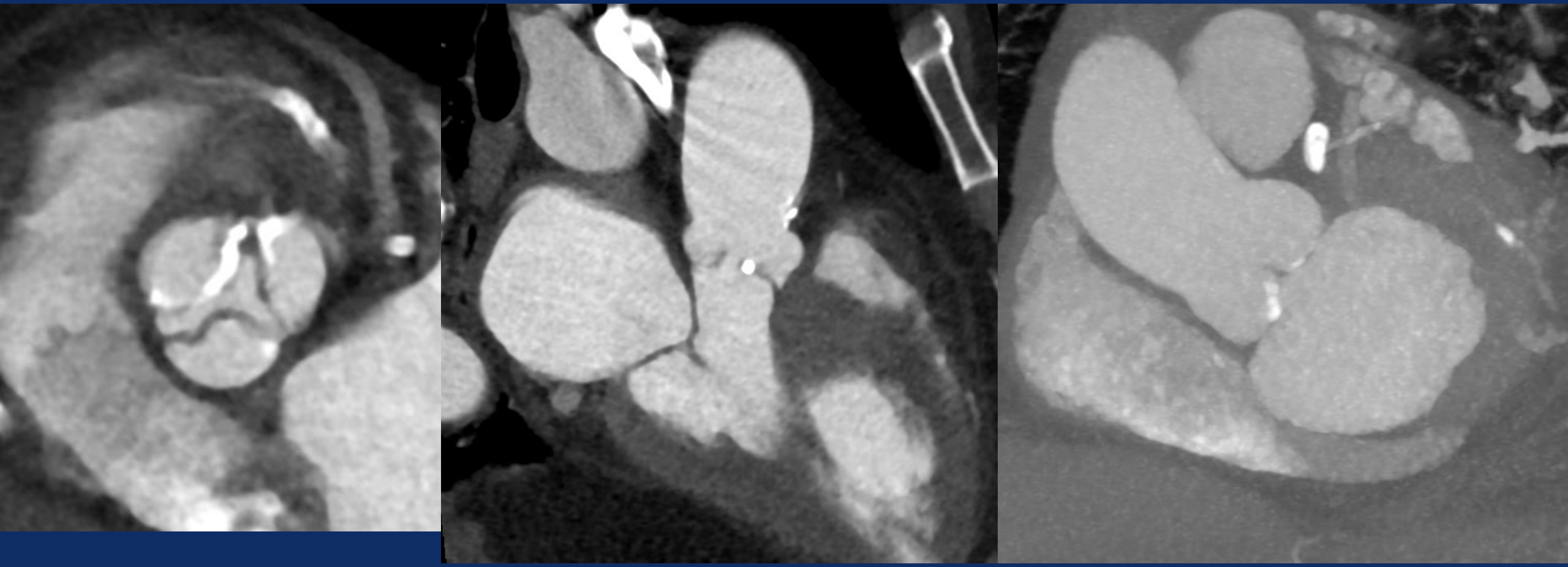
FU Echo after ICU care



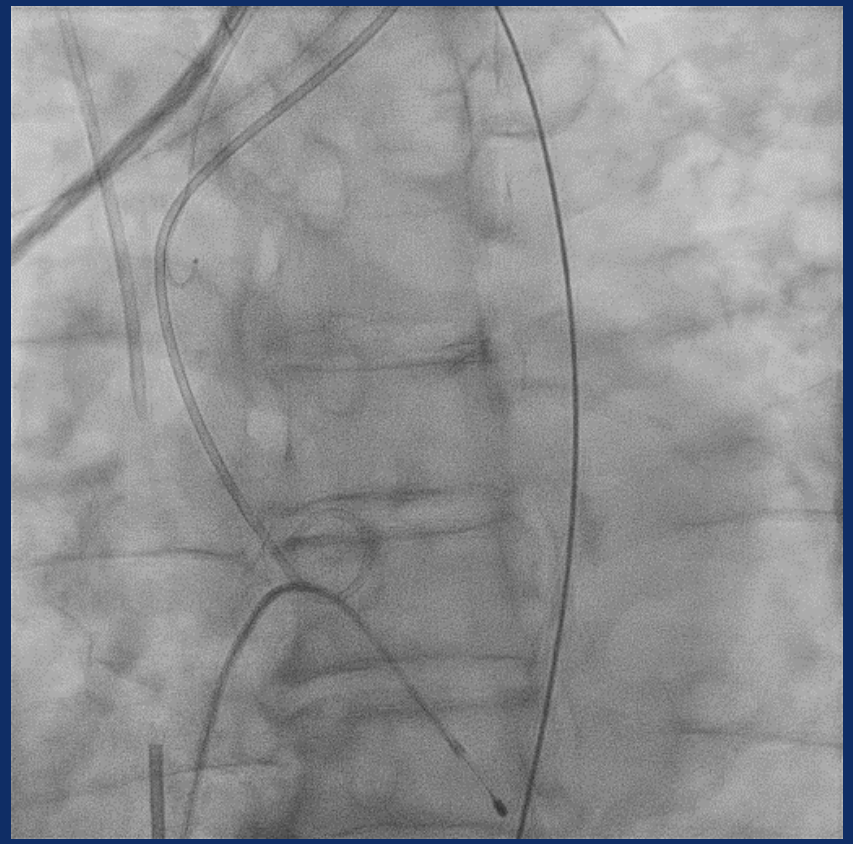


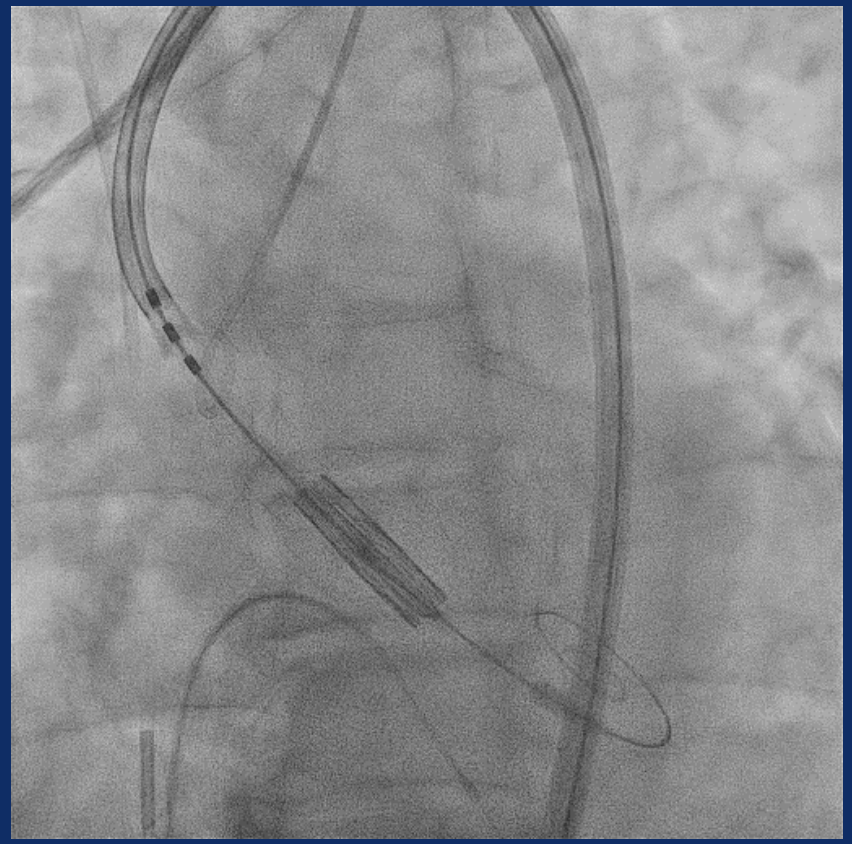


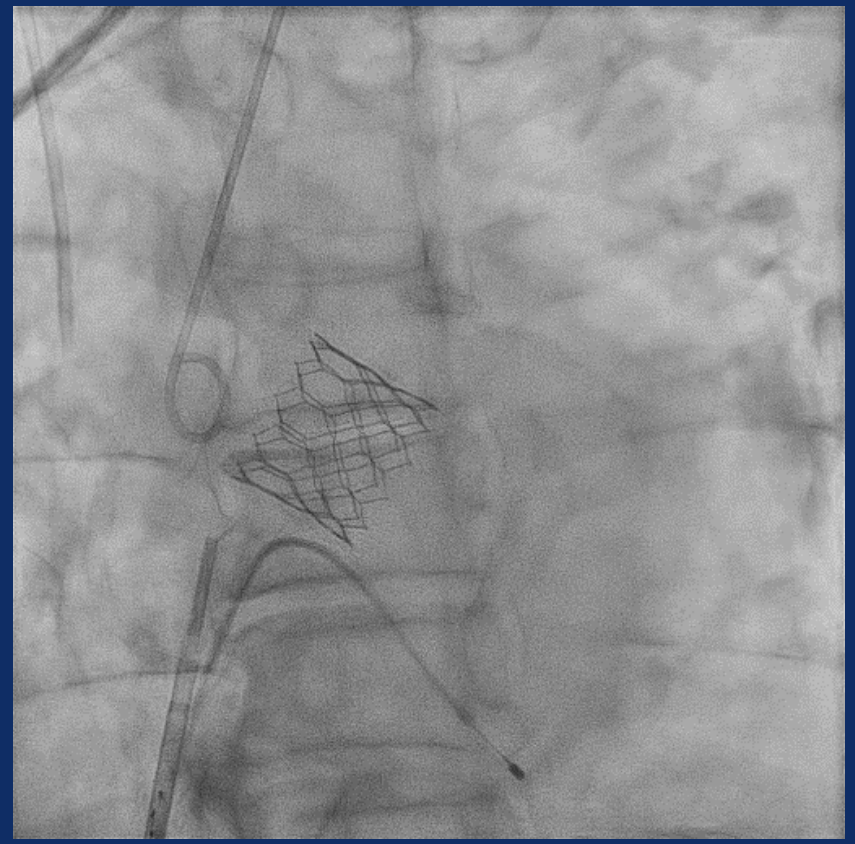
Heart CT



TAVI with SAPIEN3 ultra 26mm







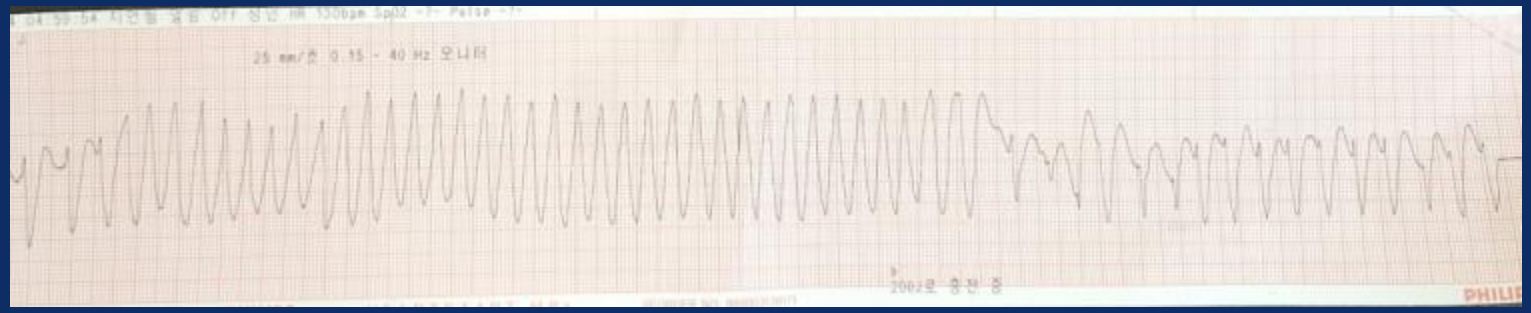
1-year after discharge

- Chest pain & sudden collapse

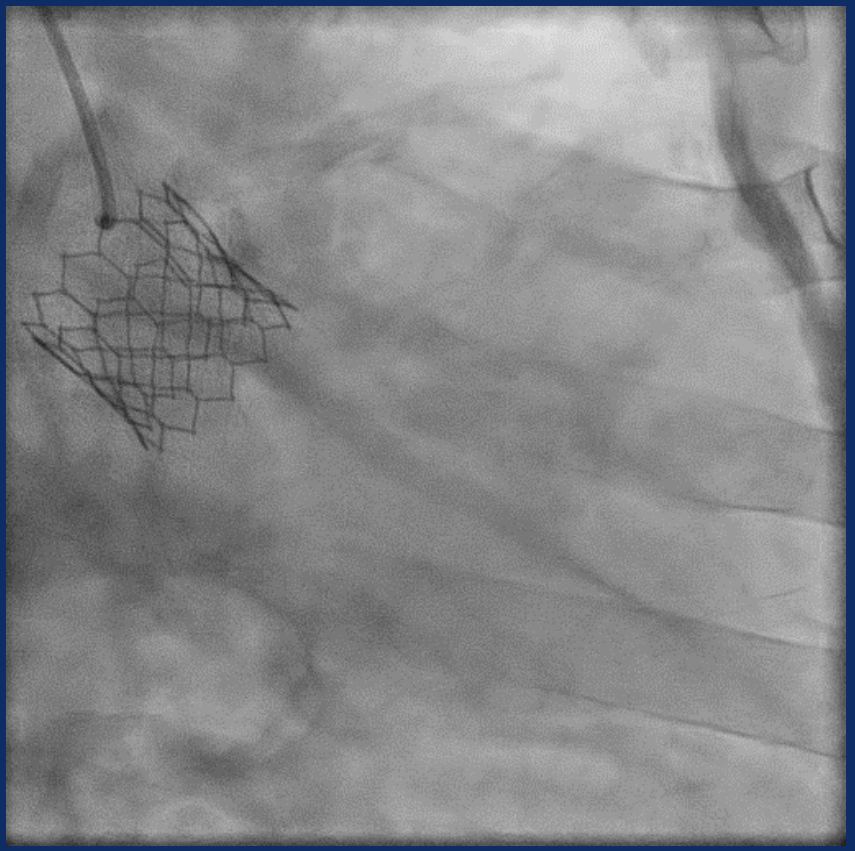
- Cardiac marker

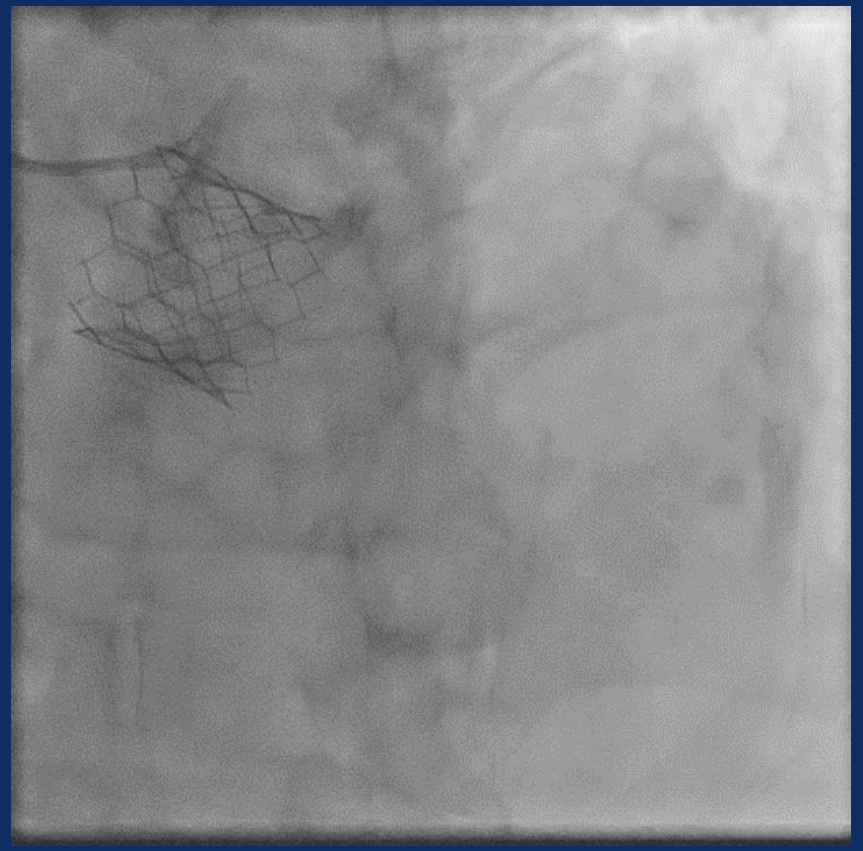
CK-MB	:	62.22	ng/mL ▲	(<5.0)
Troponin I	:	> 25000.00	pg/mL ▲	(0.00~45.43)

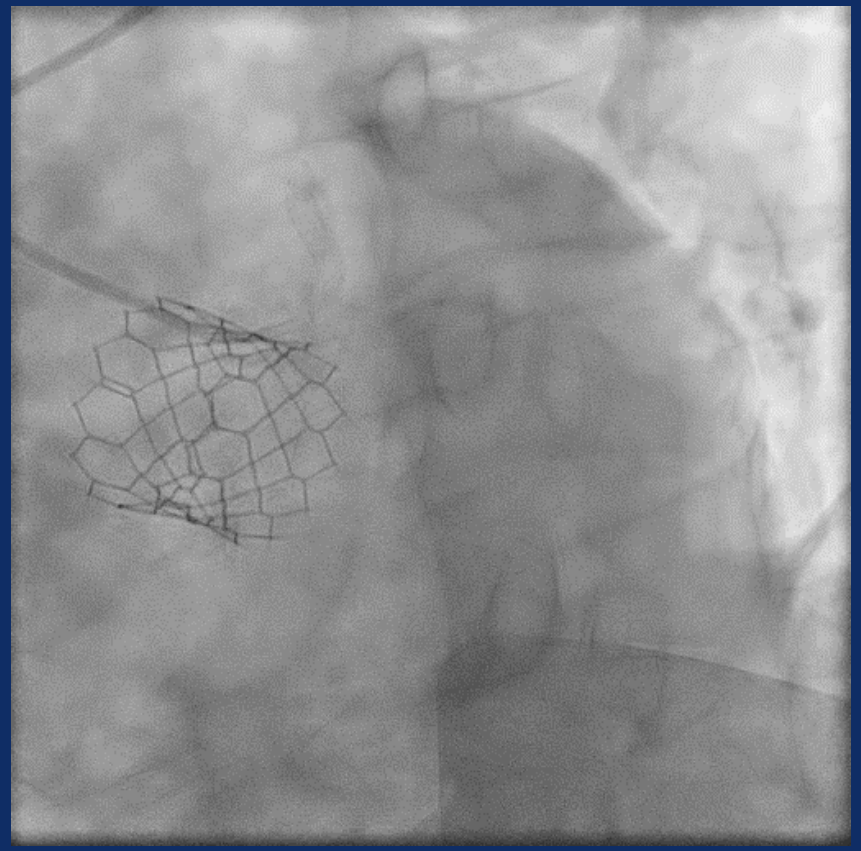
- 119 Defibrillator



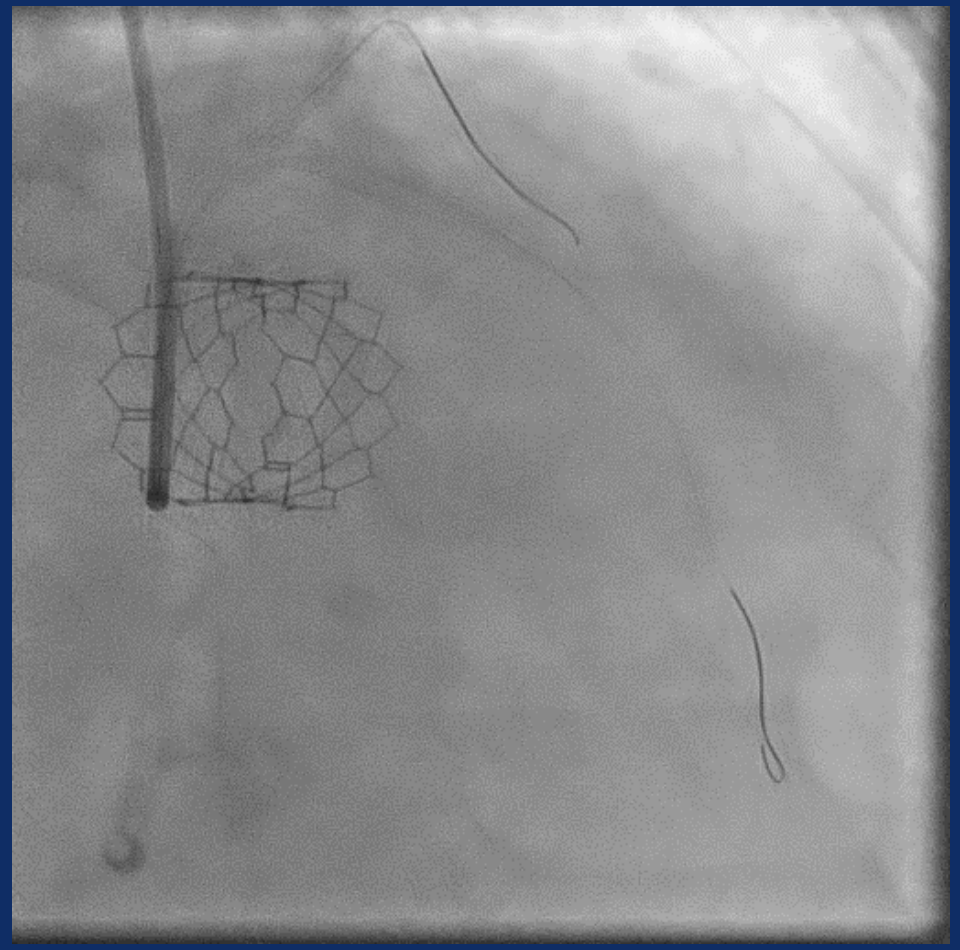
CAG

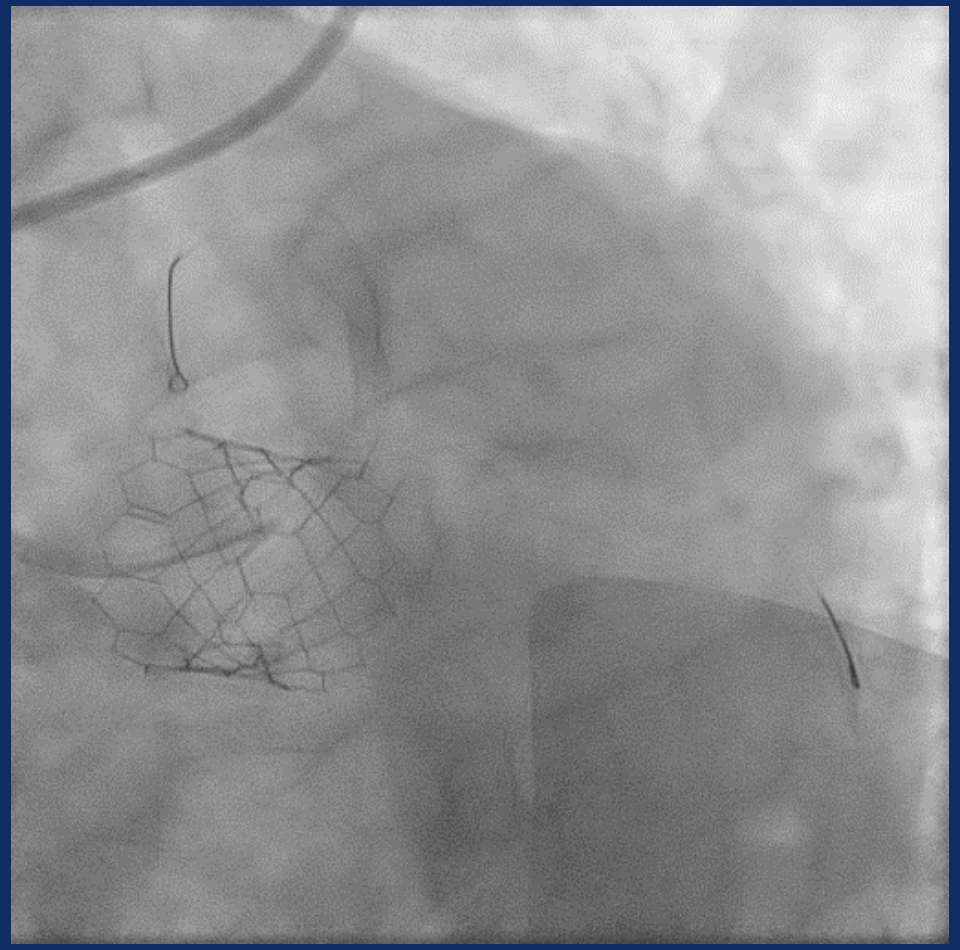






PCI





s/p PCI at LM-pLAD with stent (Genoss 4.0/28) & LCXos-pLCX with DEB (Prevail 3.0/15)

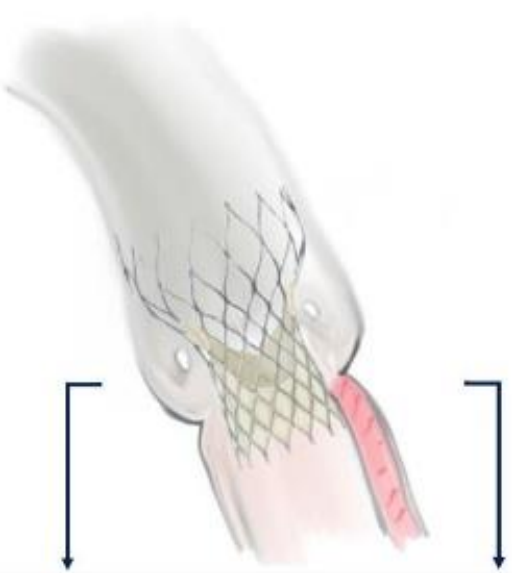
Future Re-intervention Options

Lifetime Strategy on Aortic Valve Reintervention

- The choice of first intervention represents the most important as it not only has to provide the longest durability, but also to allow second and, possibly, third intervention.

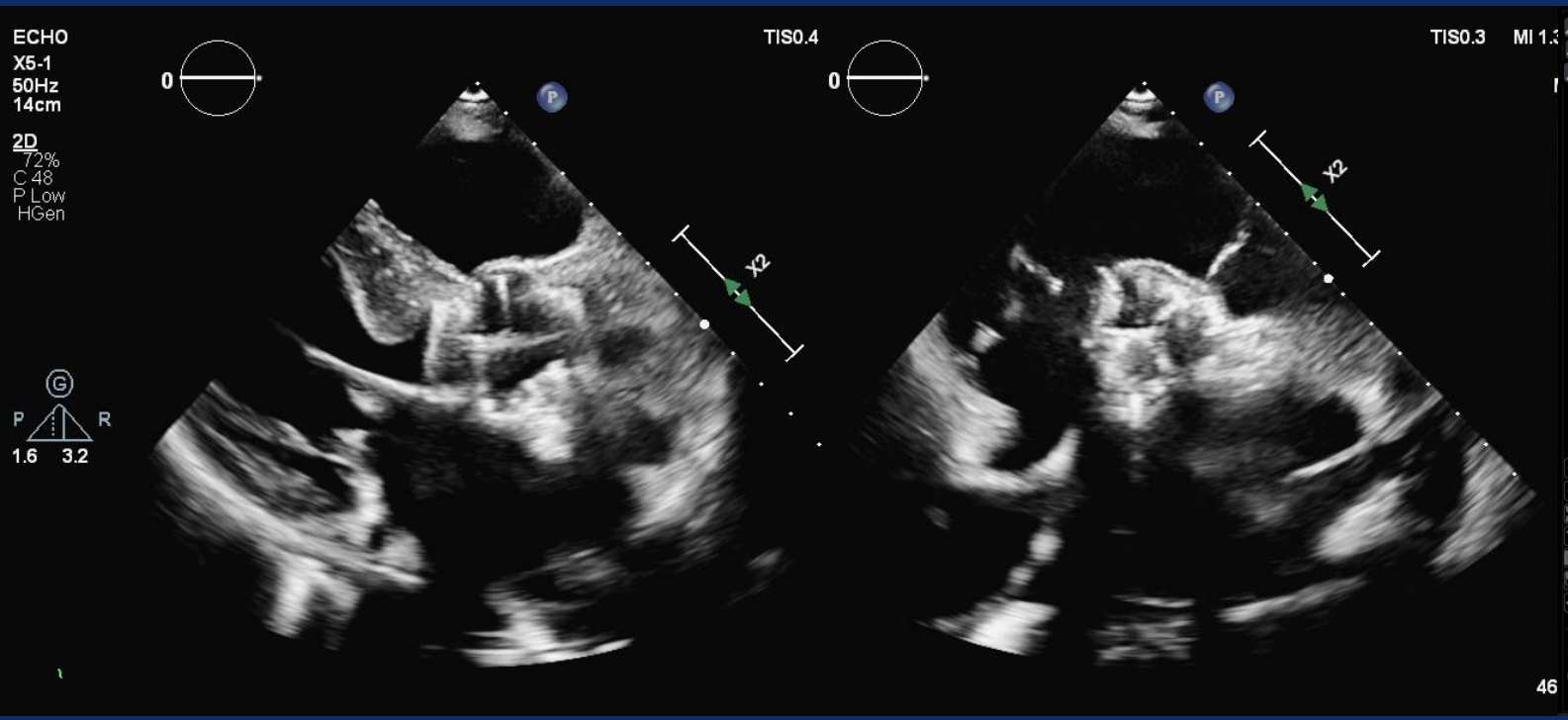
- Center and operator experience should play an important role as well as patient’s preference.

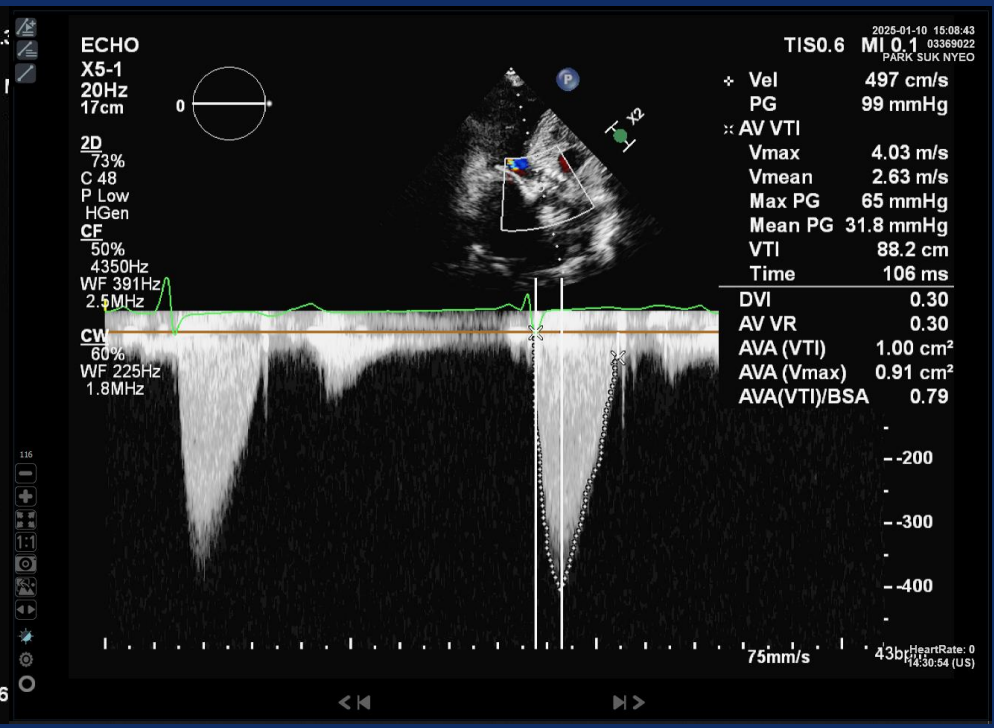
Possible Scenario

1st procedure	TAVR		SAVR	
				
2nd procedure	TAVR	TAVR explant + SAVR	TAVR	Redo SAVR
	Minimally invasive procedure	Possible 3rd procedure	Wide experience with TAVR-in-SAVR Easy Coronary reaccess after SAVR Surgery at young age	Possible 3rd procedure
	Risk of coronary obstruction Difficult coronary reaccess Few options for 3rd procedure	Poor experience with TAVR explant Possible concomitant aortic repair	Few options for 3rd procedure	Higher operative risk

Giulio R. et al. Circ Cardiovasc Interv. 2022;15:e012388.

F/83, Dyspnea, s/p Sutureless AVR (Perceval L-size) (7yrs ago)

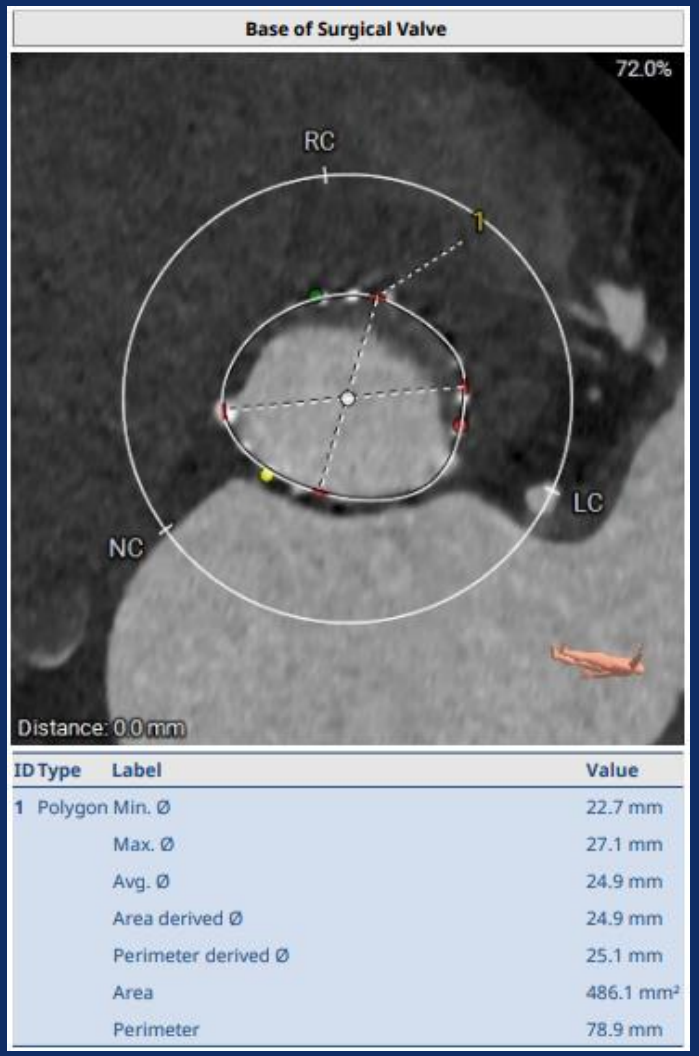




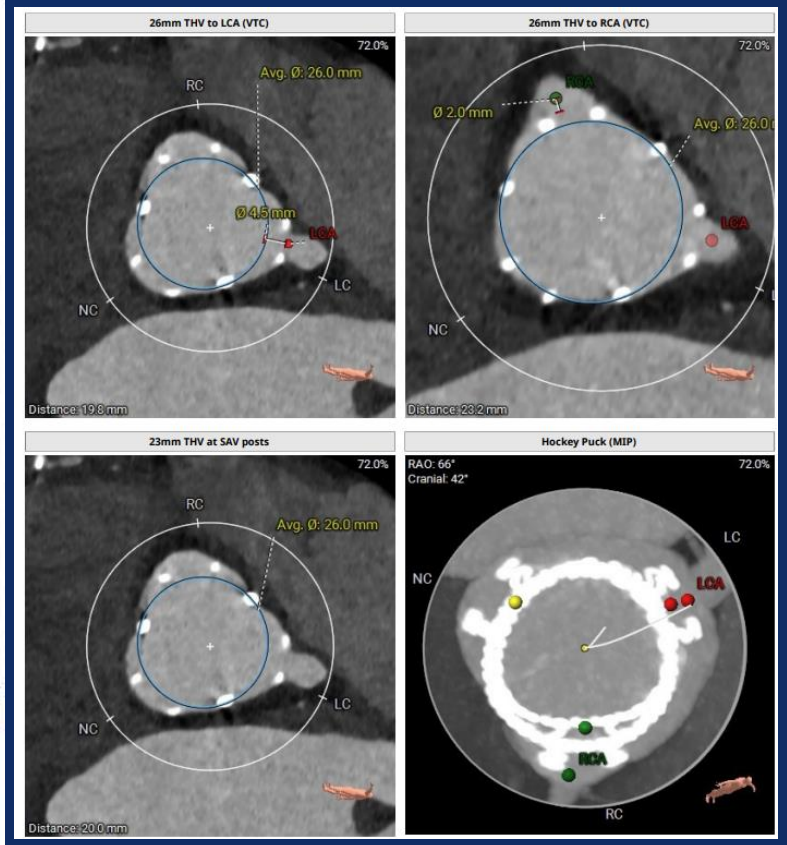
s/p AVR status with elevated AV peak velocity d/t LOM of NCC & RCC.

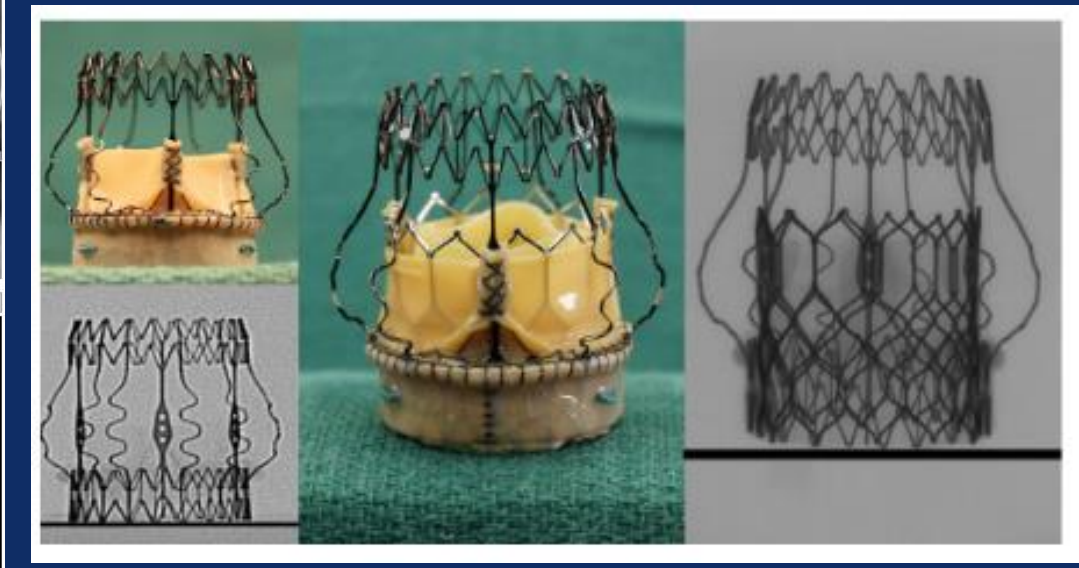
- AVA:1.39→**1.0cm²** by CE, indexed AVA:1.12→ **0.79cm²/m².**
- Vmax:3.04→ **4.03m/s**, MSPG:19.5→ **31.8mmHg**, SVi:70ml/m2

Heart CT

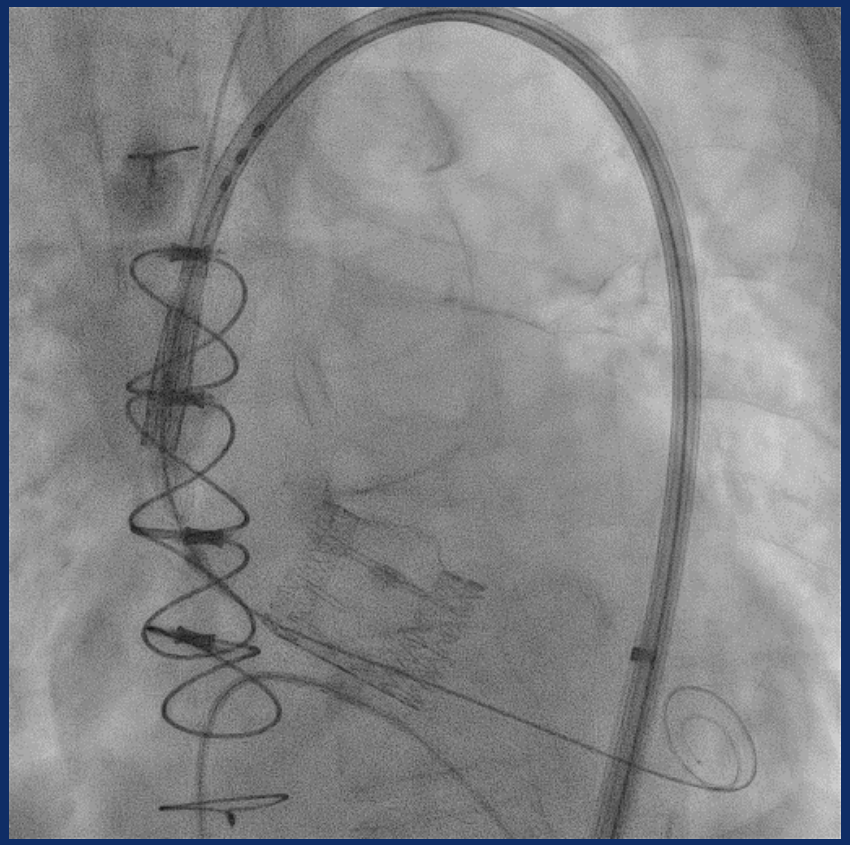


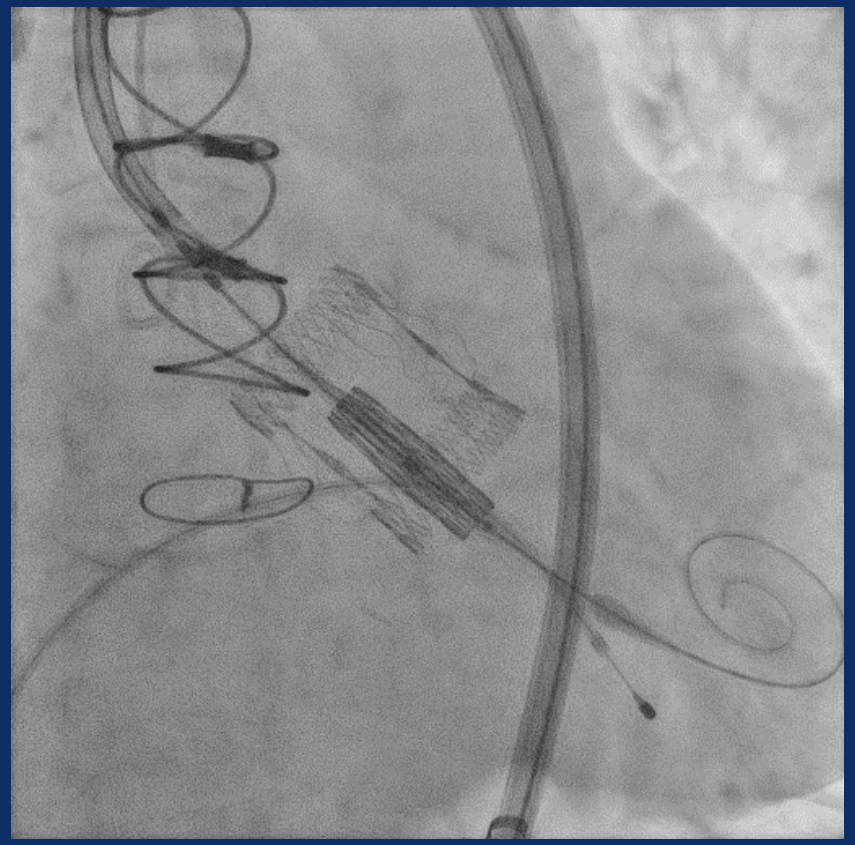
ID	Type	Label	Value
1	Polygon	Min. Ø	22.7 mm
		Max. Ø	27.1 mm
		Avg. Ø	24.9 mm
		Area derived Ø	24.9 mm
		Perimeter derived Ø	25.1 mm
		Area	486.1 mm²
		Perimeter	78.9 mm

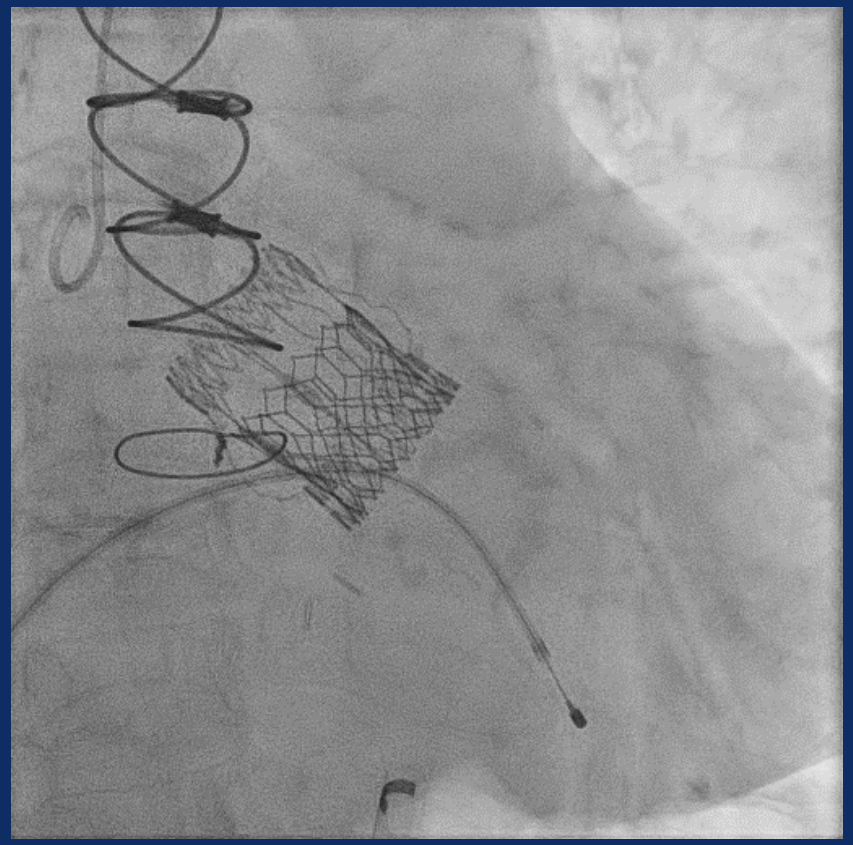




TAVI - SAPIEN 3 Ultra 26mm, norminal







Conclusion

- SAPIEN valve offers a robust clinical evidence base across all surgical risk profiles, supported by more than 1 million implantations worldwide.
- Balloon-expandable design ensures precise deployment, excellent hemodynamics, and low PVL.
- Demonstrates low pacemaker rates and favorable coronary access, critical for younger patients with longer life expectancy.
- Proven durability and valve-in-valve compatibility support lifetime management strategies.