29th TCTAP2024

New TAVI trends to improve Lifetime Management

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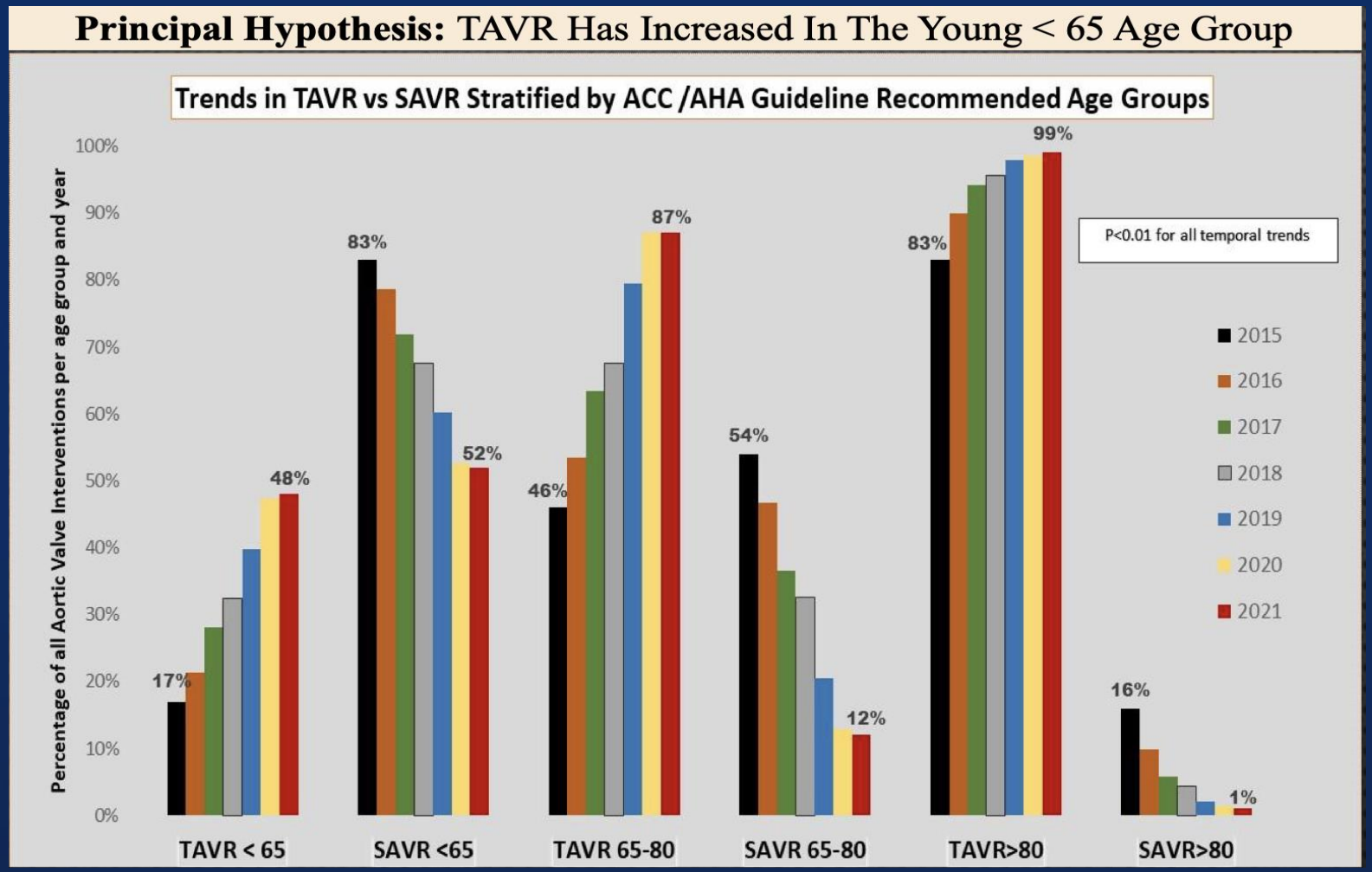
CVRF

Disclosure

- In the past 12 months, I and/or my spouse, have received the following:

• Relevant conflict to this presentation	Company
• Consulting fee/Proctoring fee	Edwards LifeSciences, Anteris Medical
• Unrestricted institutional grant (QHI)	Edwards LifeSciences, Abbott Vascular

TAVI in the real world



In a US national database of 142,953 patients (2015 – 2021):

- **Almost 50% of patients younger than 65 years old were treated with TAVI**
- **Young ≠ low risk**
- **Patients may now outlive their 1st THV**

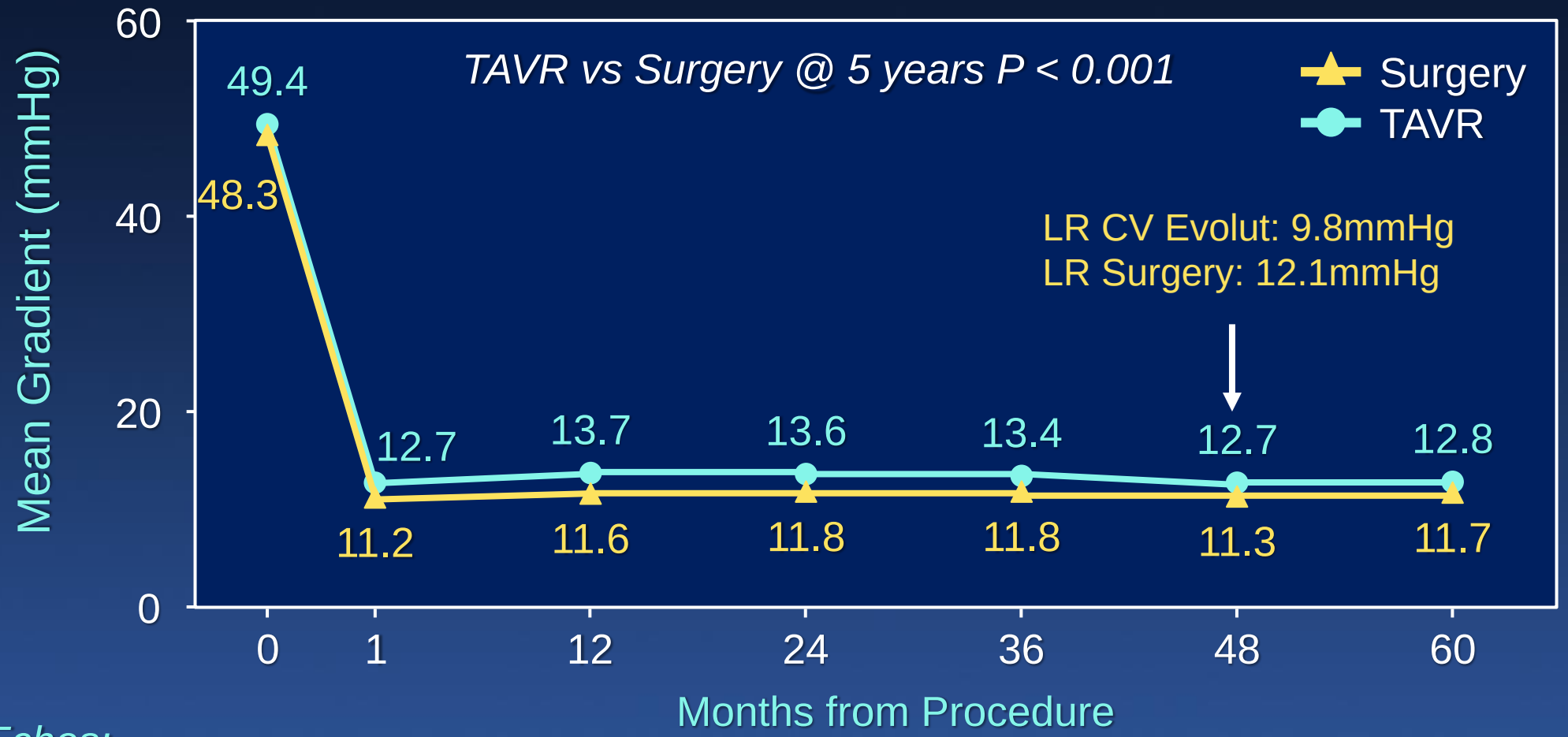
Sharma T, et al. JACC 2022

Optimal durability

THE PARTNER 3 TRIAL

Valve Hemodynamics

Mean Gradient



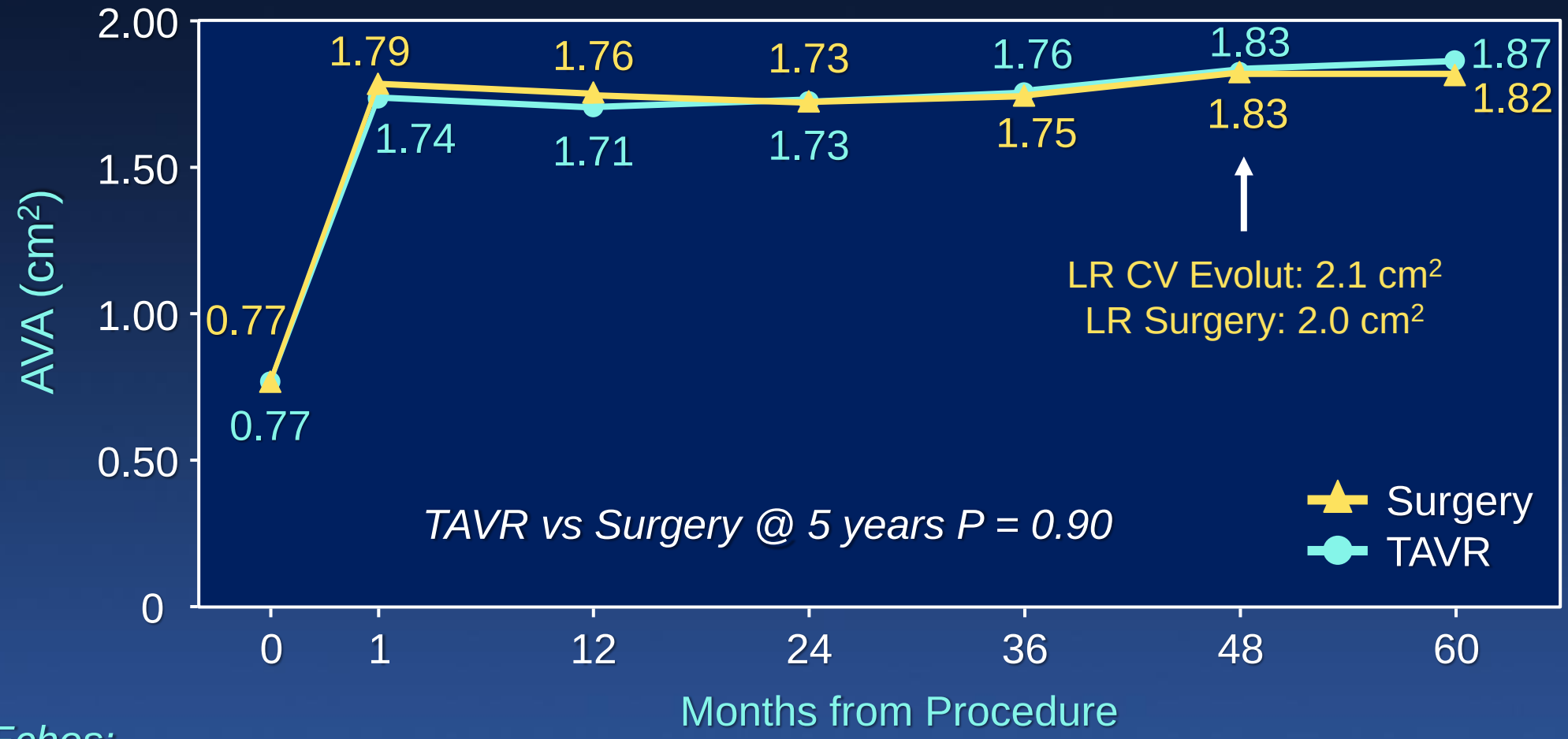
No. of Echos:

TAVR	483	492	474	437	372	348	329
Surgery	442	432	391	360	304	305	282

THE PARTNER 3 TRIAL

Valve Hemodynamics

Aortic Valve Area

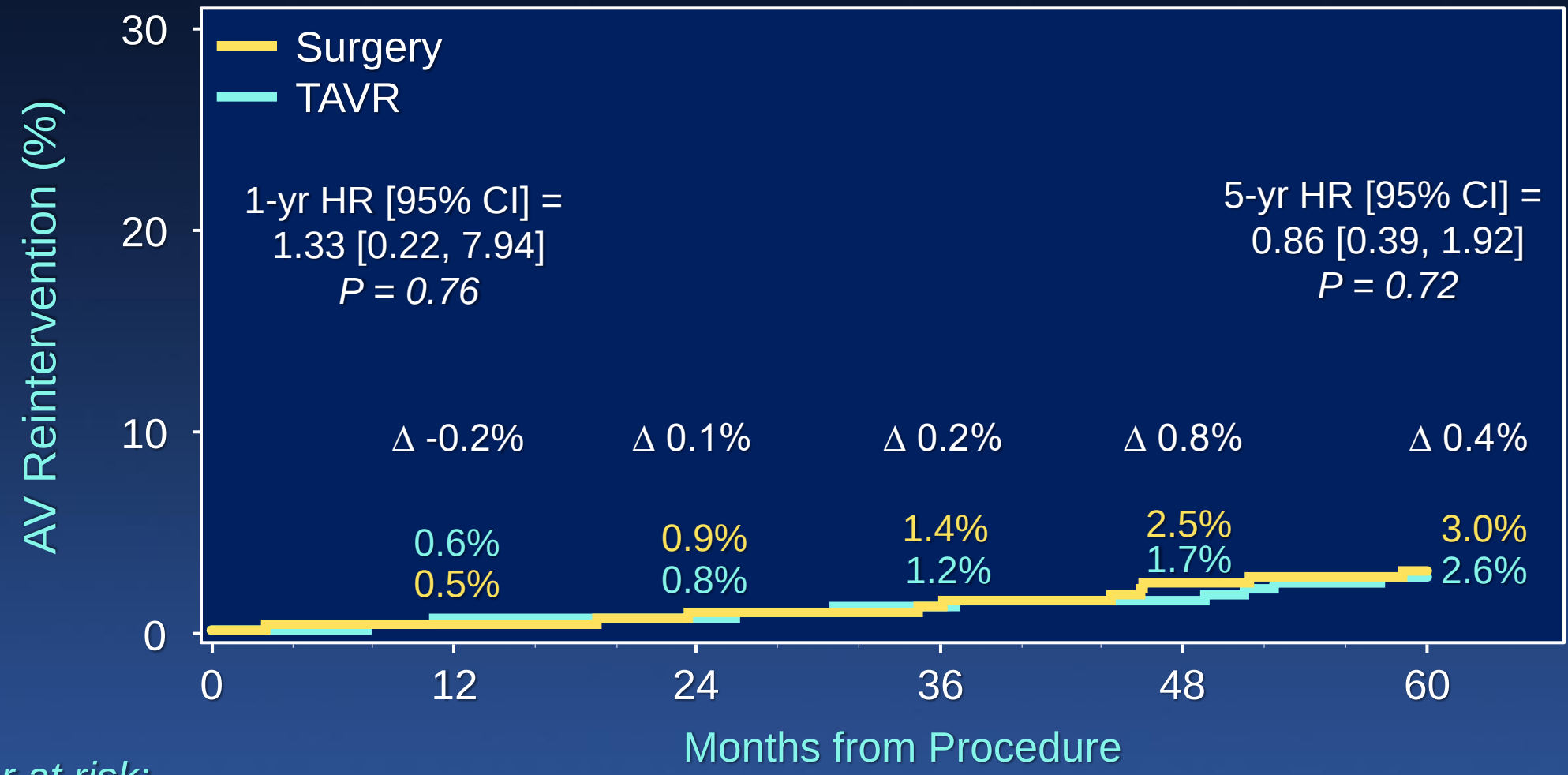


No. of Echos:

TAVR	458	482	450	416	347	334	320
Surgery	424	415	371	342	289	295	275

THE PARTNER 3 TRIAL

AV Reintervention



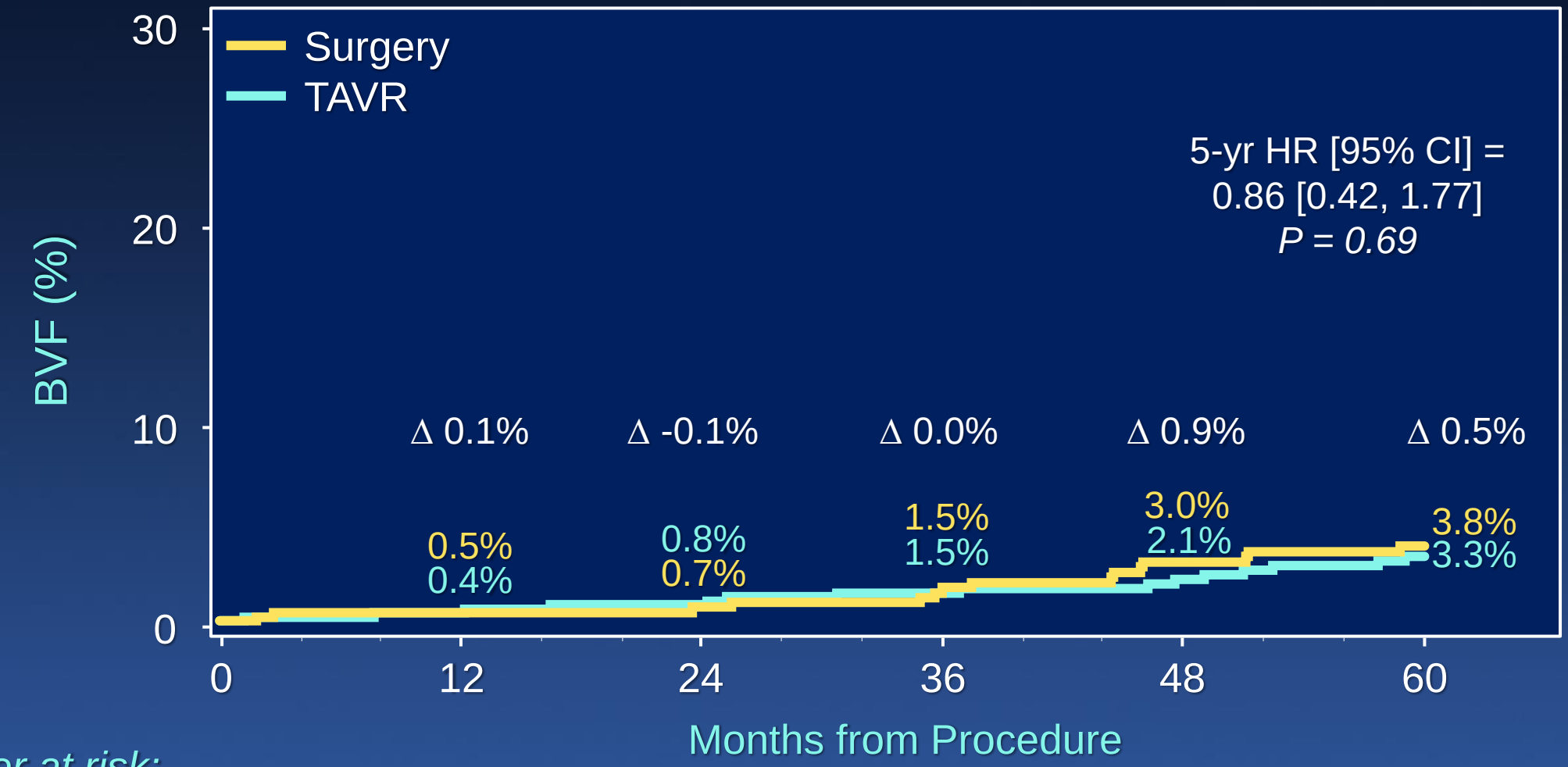
Number at risk:

TAVR	496	488	475	456	433	396
Surgery	454	426	406	390	371	337

THE PARTNER 3 TRIAL

VARC-3 BVF to 5 Years

All-cause

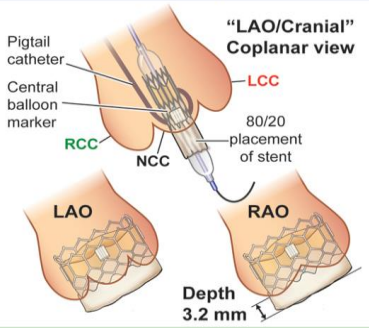
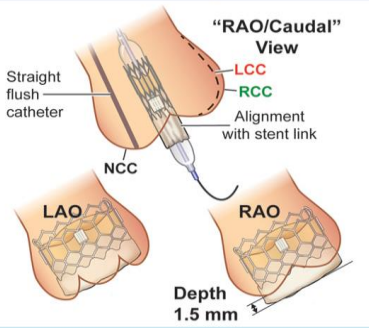


Number at risk:

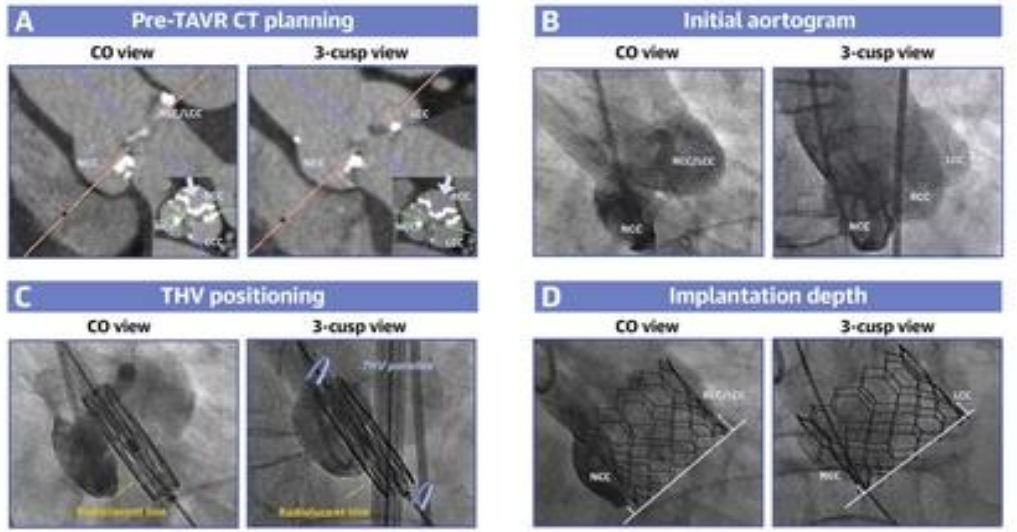
TAVR	496	489	475	454	430	392
Surgery	454	426	407	390	369	334

Optimizing index TAVI result – High implantation

Optimizing outcomes – harmonizing implant depth

	Conventional Deployment Technique		High Deployment Technique
			
Implantation Depth	3.2 ± 1.9 mm		1.5 ± 1.6 mm
30-day Permanent Pacemaker Implantation	13.1%		5.5%
New-onset Left Bundle Branch Block at Discharge	12.2%		5.3%
1-year Aortic Regurgitation	15.9% 2.7%	Mild (≥1+ – <2+) Moderate-to-severe (≥2+)	16.5% 1%
1-year Hemodynamic Performance	11.8 ± 4.9 mmHg 22.5 ± 9 mmHg 0.48 ± 0.13	Mean gradient Peak gradient Doppler velocity index	13.1 ± 6.5 mmHg 25 ± 11.9 mmHg 0.47 ± 0.15

CENTRAL ILLUSTRATION: Hybrid Approach Using the Cusp-Overlap Technique for Balloon-Expandable THV Implantation: Procedural Planning, THV Positioning, Implantation Depth, and Outcomes (N = 102)



Mean THV implantation depth: 3.0 ± 1.4mm (CO view) and 2.5 ± 1.4mm (3-cusp view)
1-month permanent pacemaker implantation: n = 7 (6.8%)

Akodad M, et al. J Am Coll Cardiol Intv. 2022;15(23):2387-2395.

Higher and higher – the elusive 90:10 placement:

1. **Radiolucent line for deployment**
2. **Cusp-overlap technique**

Y Sammour. *Circ Cardiovasc Interv*. 2021
M Akodad et al. *J Am Coll Cardiol Intv* 2022

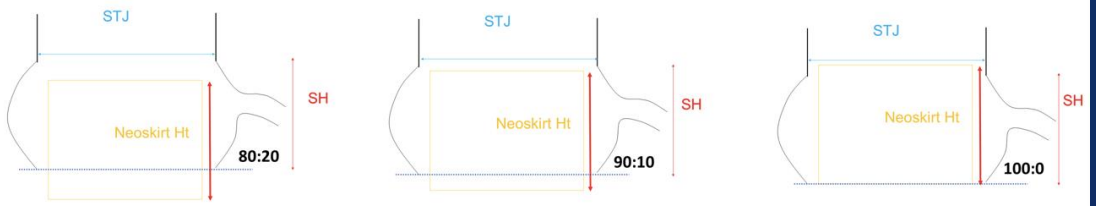
Sinus sequestration risk worsens with high implant

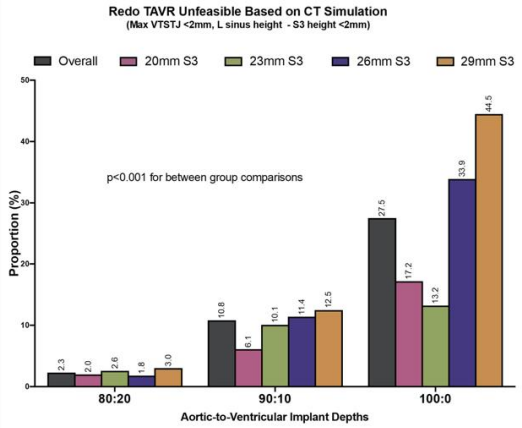
CENTRAL ILLUSTRATION: TAVR Device Implantation Depth and Outcomes

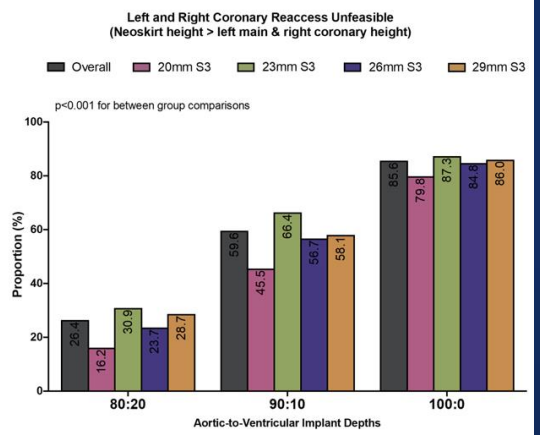
Impact of High Implantation of Transcatheter Aortic Valve on Subsequent Conduction Disturbances and Coronary Access, N = 418

	Evolut R/PRO/PRO+		SAPIEN 3	
	Conventional Implantation Technique	High Implantation Technique	Conventional Implantation Technique	High Implantation Technique
	3-Cusp Coplanar View	Cusp Overlap View / Commissural Alignment	3-Cusp Coplanar View	3-Cusp Coplanar View
	Pigtail Catheter; NCC RCC LCC	NCC RCC LCC; Flush Port at 3 o'clock	NCC RCC LCC	NCC RCC LCC
	Target Implantation Depth 3 to 5 mm at NCC	Target Implantation Depth 1 to 3 mm at NCC	Central Balloon Marker-Guided Implantation	Radiolucent Line-Guided Implantation
Conduction Disturbances After TAVR				
30-Day Permanent Pacemaker Implantation	10.8%	0.0%	2.2%	2.0%
New-Onset Persistent Left Bundle Branch Block	11.3%	4.2%	7.0%	1.1%
Coronary Access After TAVR Assessed by Post-TAVR CT				
THV Implantation Depth (Mean of the Depth at NCC, RCC, and LCC)	5.4 ± 2.2 mm	3.5 ± 1.2 mm	4.3 ± 1.4 mm	2.6 ± 0.9 mm
Interfered by THV Skirt	9.1%	22.0%	0.7%	0.9%
Interfered by THV Commissural Posts	42.7%	26.0%	15.3%	15.7%
CT-Identified Risk of Sinus Sequestration in TAVR-in-TAVR				
Risk of Sinus Sequestration in TAVR-in-TAVR	41.8%	64.0%	5.3%	17.6%

CT analysis of 1,900 consecutive patients simulating SAPIEN 3 TAVR across 3 targeted implant depths





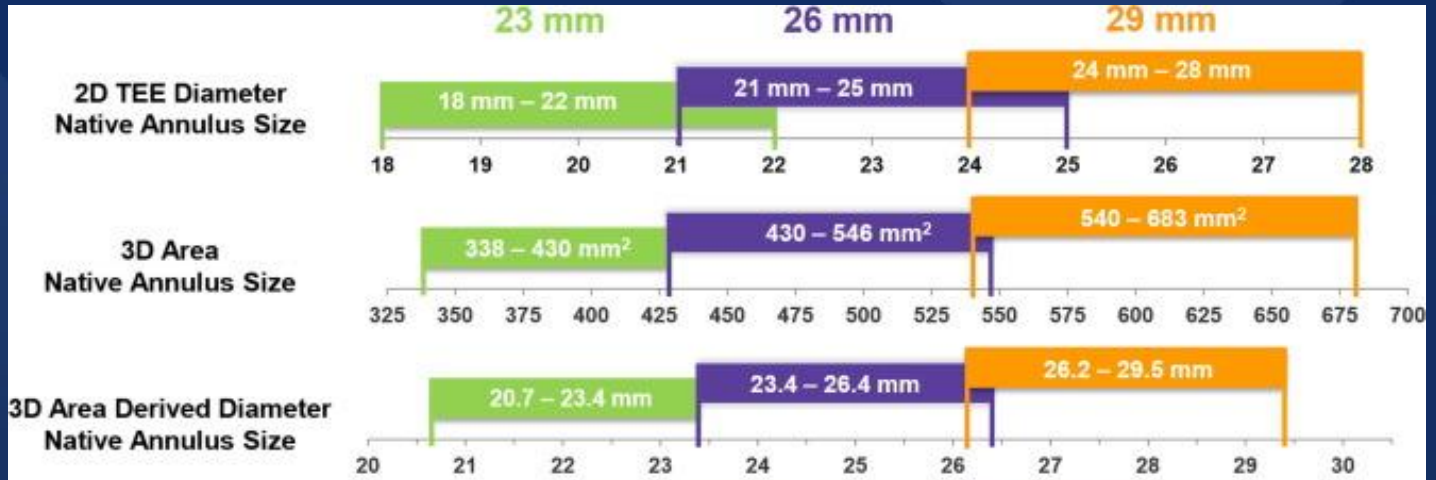


Key Findings:

1. **Stepwise reduction in redo-TAVR feasibility with:**
   - Shallow implant depth (p<0.001)
   - Increasing THV size, but only at 100:0 implant (p<0.001)
2. **Challenging coronary access with:**
   - Shallow implant depth
   - Increasing THV size (across all implant depths)
3. If Commissural Alignment is attained (assuming utilization of leaflet modification techniques) → **Redo-TAVR 100% feasible**

Koshy AN, GHL Tang, Circ Intv 2024
Ochiai T JACC Intv 2023

Optimizing index TAVI result – Individualizing THV sizing algorithm



SAPIEN 3 Valve	23 mm	26 mm	29 mm
Sheath ID (unexpanded)	14F	14F	16F
Minimum Access Vessel Diameter *	5.5 mm	5.5 mm	6.0 mm

Underfilling and overfilling BEV

2019 PCR london valves

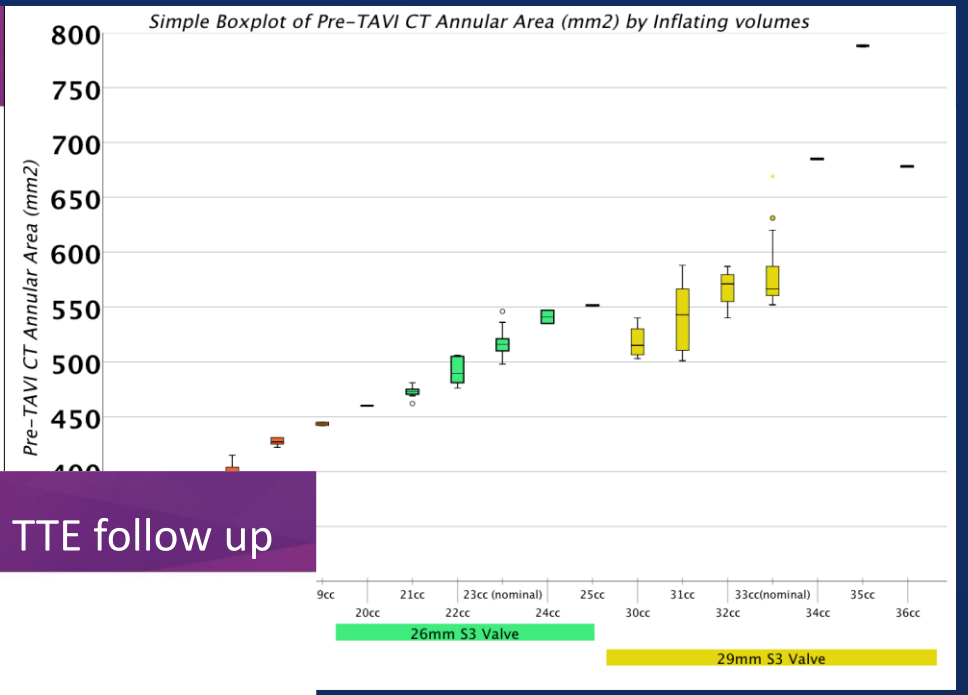
Clinical and echocardiographic impact of *under* and *over* expansion of SAPIEN 3 transcatheter heart valves to tailor to aortic annular sizes

Srikantha Adusumalli MBBS[1,2] ,Dale J Murdoch MBBS[1,2], Karthik Gopal MBBS[1,2], David Platts MBBS[1,2], Karl K Poon MBBS[1,2]
[1] Heart and Lung Institute, Dept c
[2] School of

PCR By and For you PCRonline.c

2019 PCR london valves

Figure demonstrates the balloon inflation volumes of 23mm, 26mm & 29mm S3 THV depending on the CT



2019 PCR london valves

Summary of clinical and TTE follow up

- No valve reintervention or heart failure rehospitalization.
- No stroke or TIA reported.
- *One case of subclinical valve thrombosis.*

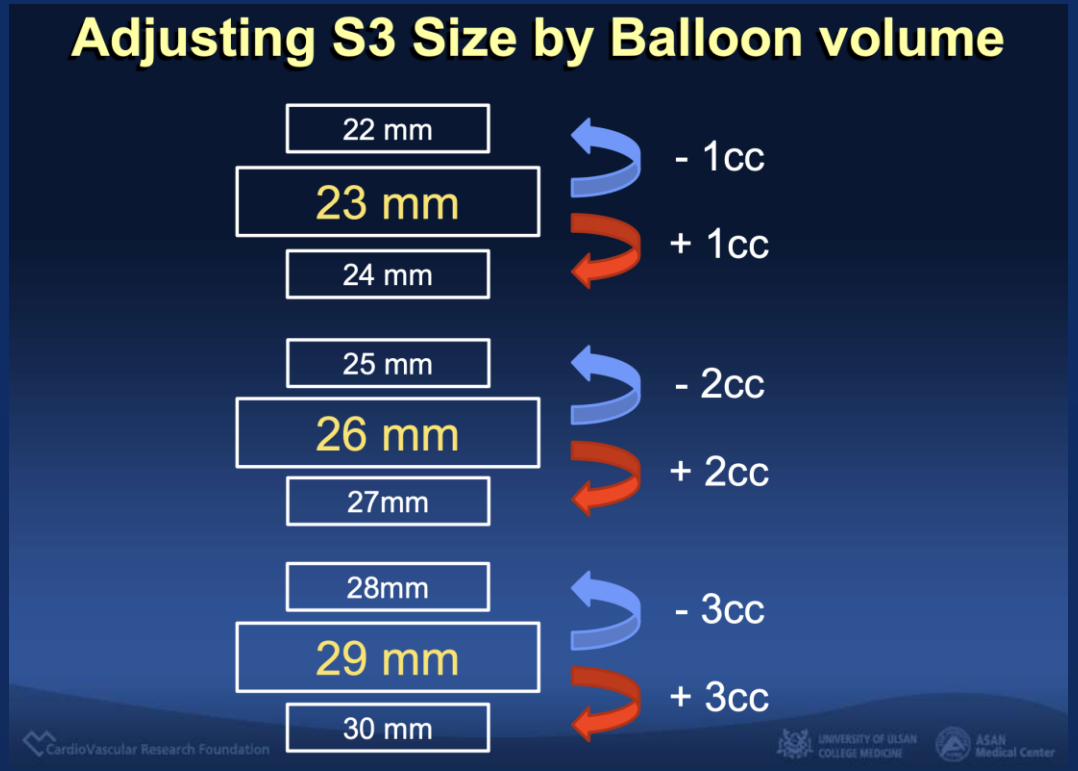
- All patients on follow-up 30D TTE with ≦ mild PVL (66% trivial/none; 34% mild).
- 58.5% of S3s were deployed nominally
- 16% of S3s were overfilled (mostly <10% volume)
- 23% of S3s were underfilled (<10% volume)

AMC – sizing technique

Optimal Sizing of Sapien 3 THV by MDCT

: AMC Sizing Algorithm

Do-Yoon Kang, MD
Heart Institute, University of Ulsan College of Medicine
Asan Medical Center, Seoul, Korea



Is it better to overfill a smaller THV?

The need to optimize the first procedure

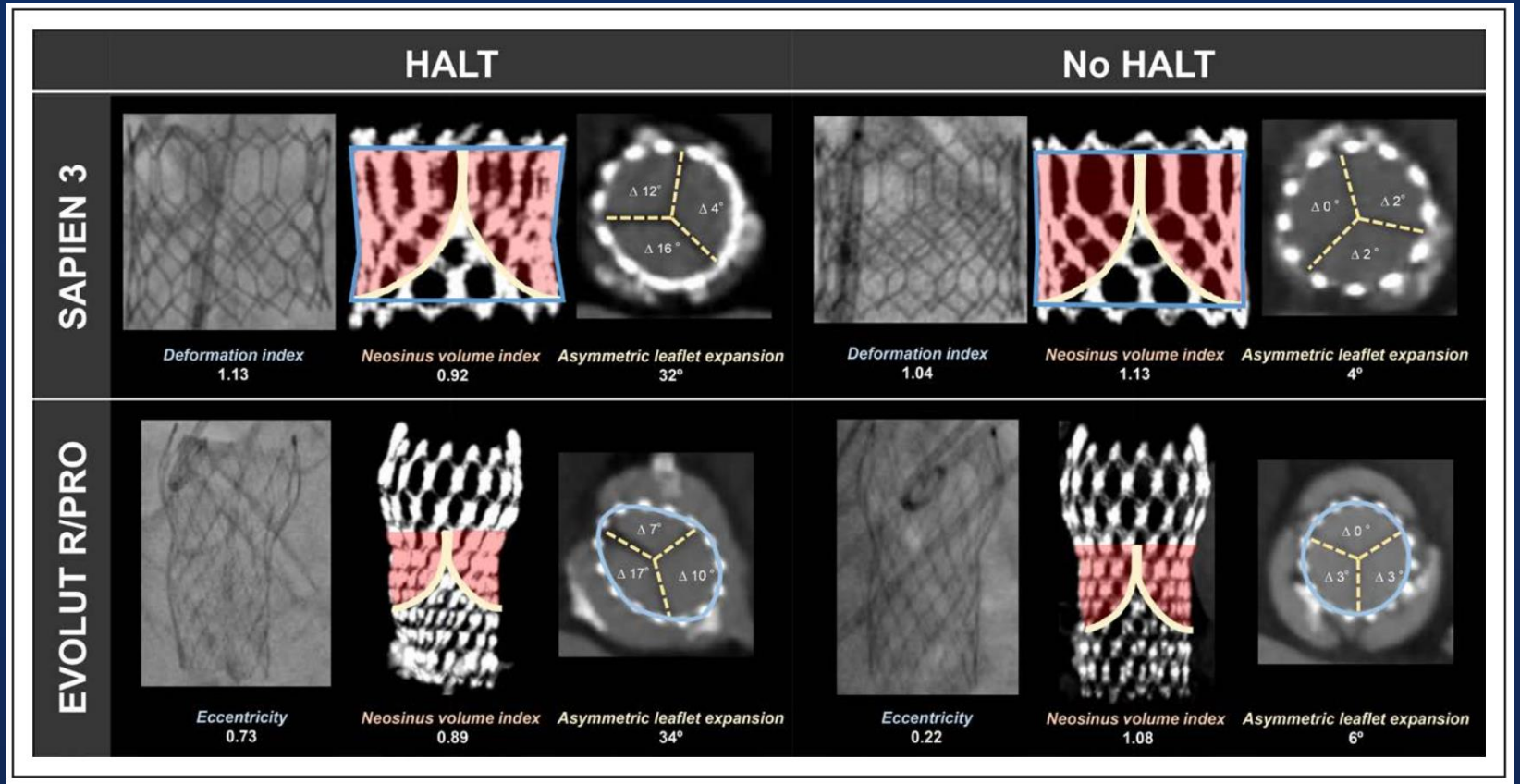


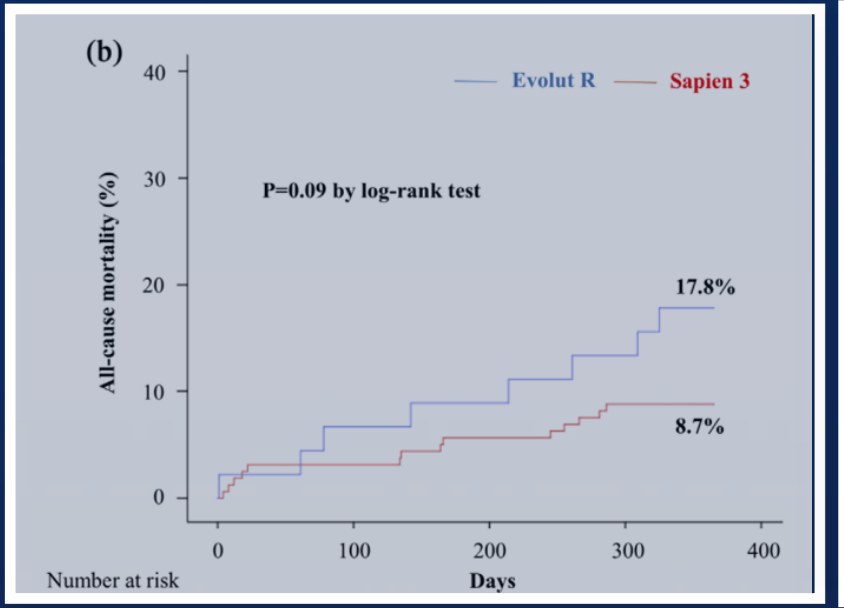
Figure 4. Transcatheter aortic valve replacement prosthesis deformation on fluoroscopy and computed tomography.
The transcatheter aortic valve replacement frame deformation seen in the fluoroscopy immediately after the procedure is also confirmed in the postprocedure CT at 30 days in both SAPIEN 3 and EVOLUT R/PRO. HALT, hypoattenuated leaflet thickening.

Fukui, M, et al. Deformation of Transcatheter Aortic Valve Prostheses: Implications for Hypoattenuating Leaflet Thickening and Clinical Outcomes. Circulation 2022

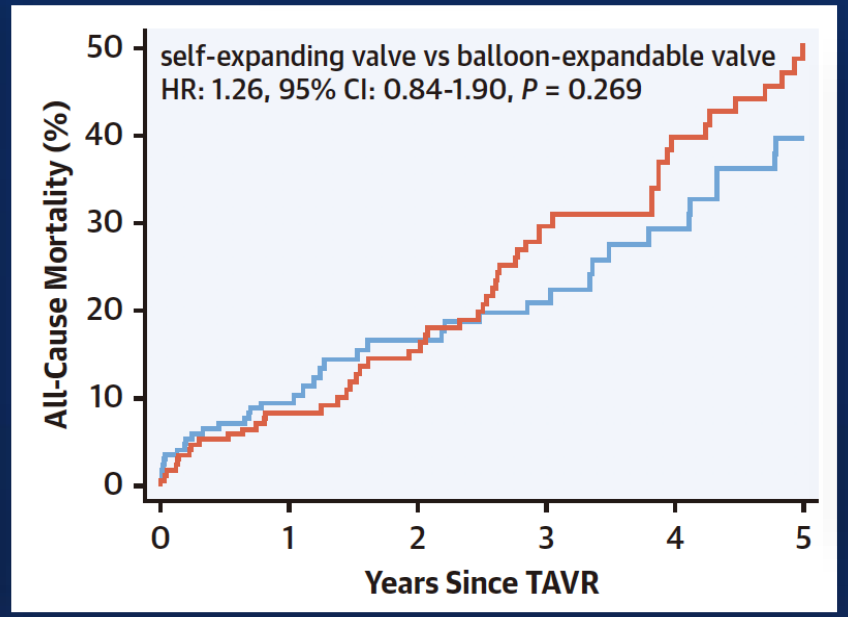
Optimizing index TAVI result – small annuli patients

Real world registry data on S3U in small annuli

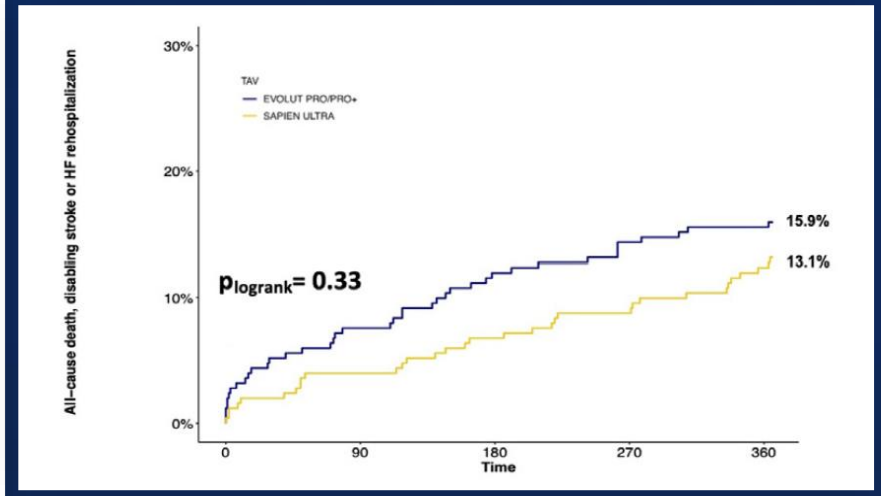
OCEAN
N=205
Female 87%



BERN
N=332
Female 81%



OPERA
N=502
Female 72%



Excellent clinical outcomes despite all 3 studies demonstrating higher echo-derived gradients and higher rates of severe PPM for SAPIEN platform

Hase H, Yoshijima N, Yanagisawa R, et al. TAVR with Evolut R versus Sapien 3 in Japanese patients with a small aortic annulus: The OCEAN-TAVI registry. *Catheter Cardiovasc Interv*. 2021;97(6):E875-E886.
Okuno T, Tomii D, Lanz J, et al. 5-Year Outcomes With Self-Expanding vs Balloon-Expandable Transcatheter Aortic Valve Replacement in Patients With Small Annuli. *JACC Cardiovasc Interv*. 2023;16(4):429-440.
Scotti, A, Sturla, M, Costa, G. et al. Evolut PRO and SAPIEN ULTRA Performance in Small Aortic Annuli: The OPERA-TAVI Registry. J Am Coll Cardiol Intv. 2024 Mar, 17 (5) 681–692.

OPERA-TAVI registry – small annuli

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 17, NO. 5, 2024

PUBLISHED BY ELSEVIER

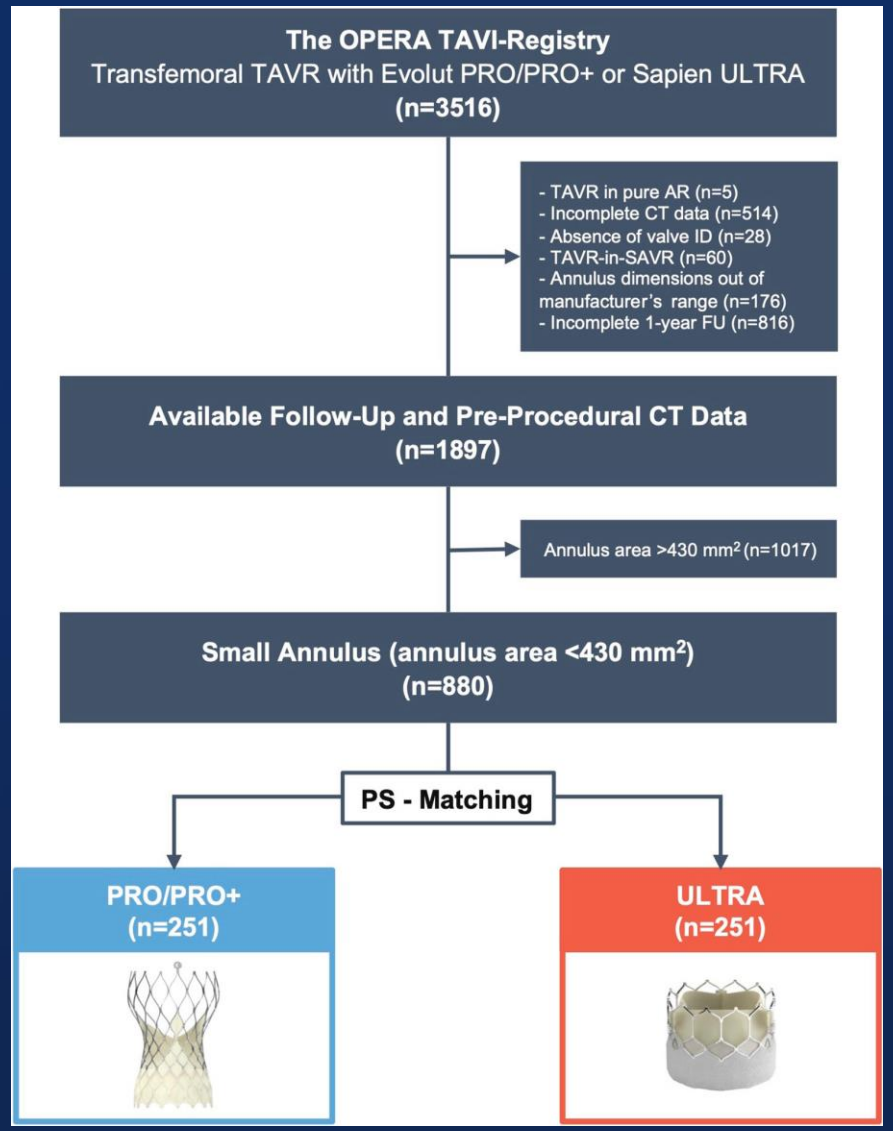
ORIGINAL RESEARCH

STRUCTURAL

Evolut PRO and SAPIEN ULTRA Performance in Small Aortic Annuli

The OPERA-TAVI Registry

Andrea Scotti, MD,[a,*] Matteo Sturla, MD,[a,*] Giuliano Costa, MD,[b] Francesco Saia, MD,[c] Thomas Pilgrim, MD,[d] Mohamed Abdel-Wahab, MD,[e] Philippe Garot, MD,[f] Caterina Gandolfo, MD,[g] Luca Branca, MD,[h] Ignacio Amat Santos, MD,[i] Darren Mylotte, MD,[j] Francesco Bedogni, MD,[k] Ole De Backer, MD,[l] Luis Nombela Franco, MD,[m] John Webb, MD,[n] Flavio Luciano Ribichini, MD,[o] Andrea Mainardi, MD,[o] Stefano Andreaggi, MD,[o] Alessandro Mazzapicchi, MD,[c] Daijiro Tomii, MD,[d] Pietro Laforgia, MD,[f] Stefano Cannata, MD,[g] Claudia Fiorina, MD,[h] Simone Fezzi, MD,[j] Enrico Criscione, MD,[k] Mattia Lunardi, MD,[o] Enrico Poletti, MD,[k] Mattia Mazzucca, MD,[k] Angelo Quagliana, MD,[l] Nicholas Montarello, MD,[l] Breda Hennessey, MD,[m] Matias Mon-Noboa, MD,[m] Myriam Akodad, MD,[f,n] David Meier, MD,[n,p] Federico De Marco, MD,[q] Marianna Adamo, MD,[h] Carmelo Sgroi, MD,[b] Claudia Maria Reddavid, MD,[b] Roberto Valvo, MD,[k] Orazio Strazzieri, MD,[b] Silvia Crescenzia Motta, MD,[b] Valentina Frittitta, MD,[b] Elena Dipietro, MD,[b] Alessandro Comis, MD,[b] Chiara Melfa, MD,[b] Mariachiara Calì, MD,[b] Sofia Sammartino, MD,[b] Giulia Laterra, MD,[p,r] Holger Thiele, MD,[e] Lars Sondergaard, MD,[l] Corrado Tamburino, MD,[b] Marco Barbanti, MD,[s,†] Azeem Latib, MD[a,†]



SMART vs. OPERA TAVI – small annuli

	SMART		OPERA TAVI	
	SEV	**BEV**	**SEV**	**BEV**
PVL ≥ Mild	14.1%	20.3%	48.5%	18.6%
Echo MG	7.7mmHg	15.7mmHg	7mmHg	13mmHg
Echo EOA	1.98cm^2	1.5cm^2	1.8cm^2	1.42cm^2
Severe PPM	3%	9.8%	1.3%	5.7%
Pacemaker Implantation	14%	9.3%	19.9%	6.4%
Mortality/disabling stroke/HFH	9.4%	10.6%	15.9%	13.1%
Valve Size 29 SEV	28.9%		14.7%	

With permission from Amr Abbas, OU/William Beaumont, MI, USA

29th TCTAP2024

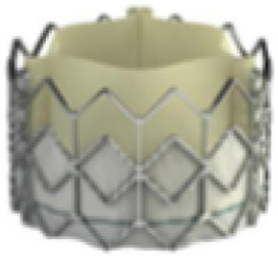
S3Ultra RESILIA – the next/current generation of BEV

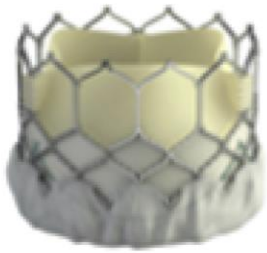
Japan and USA experience

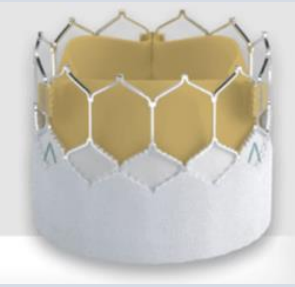
CVRF

The Fifth Generation Balloon Expandable THV: Sapien 3 Ultra Resilia Valve (S3UR)

Gen 1	Gen 2	Gen 3	Gen 4	Gen 5
Sapien	Sapien XT	Sapien 3	Sapien Ultra	Sapien 3 Ultra Resilia

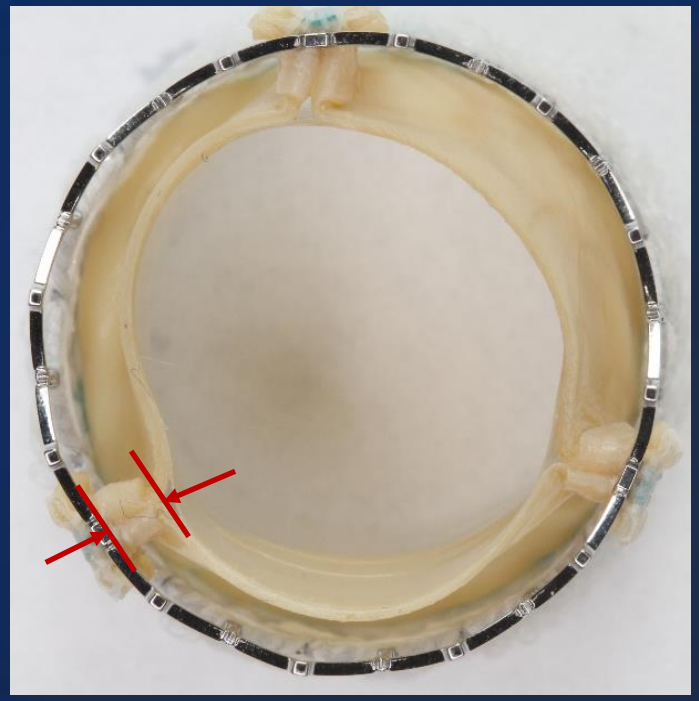






S3UR vs Predecessor THV Design Features

SAPIEN 3 Ultra
(20mm – 29mm)

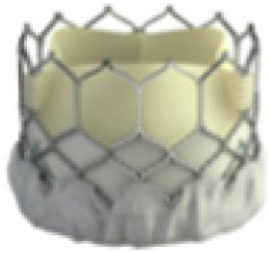


Sapien 3 and Sapien 3 Ultra leaflet attachment geometry

SAPIEN 3 Ultra Resilia
(20mm and 23mm)

S3UR 20mm and 23mm valve sizes have a redesigned leaflet attachment hinge length to optimize hemodynamic performance

Sapien 3



20mm

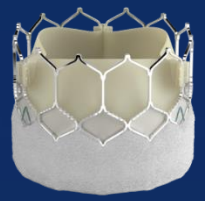
23mm

26mm

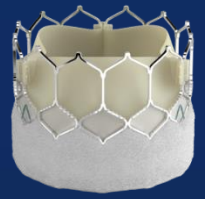
29mm

Sapien Ultra

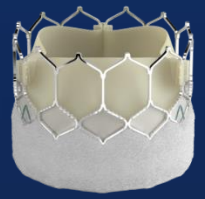
20mm



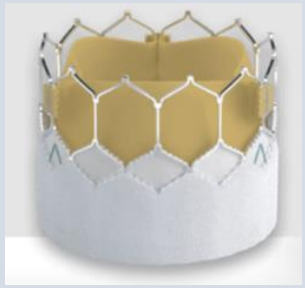
23mm



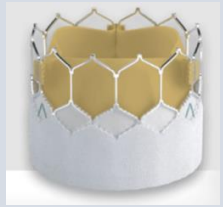
26mm



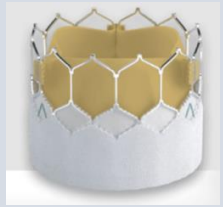
Sapien Ultra Resilia



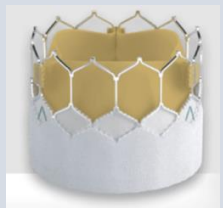
20mm



23mm



26mm



29mm

S3UR includes a 29mm valve size

OCEAN-TAVI S3U vs S3UR propensity matched 618 patients

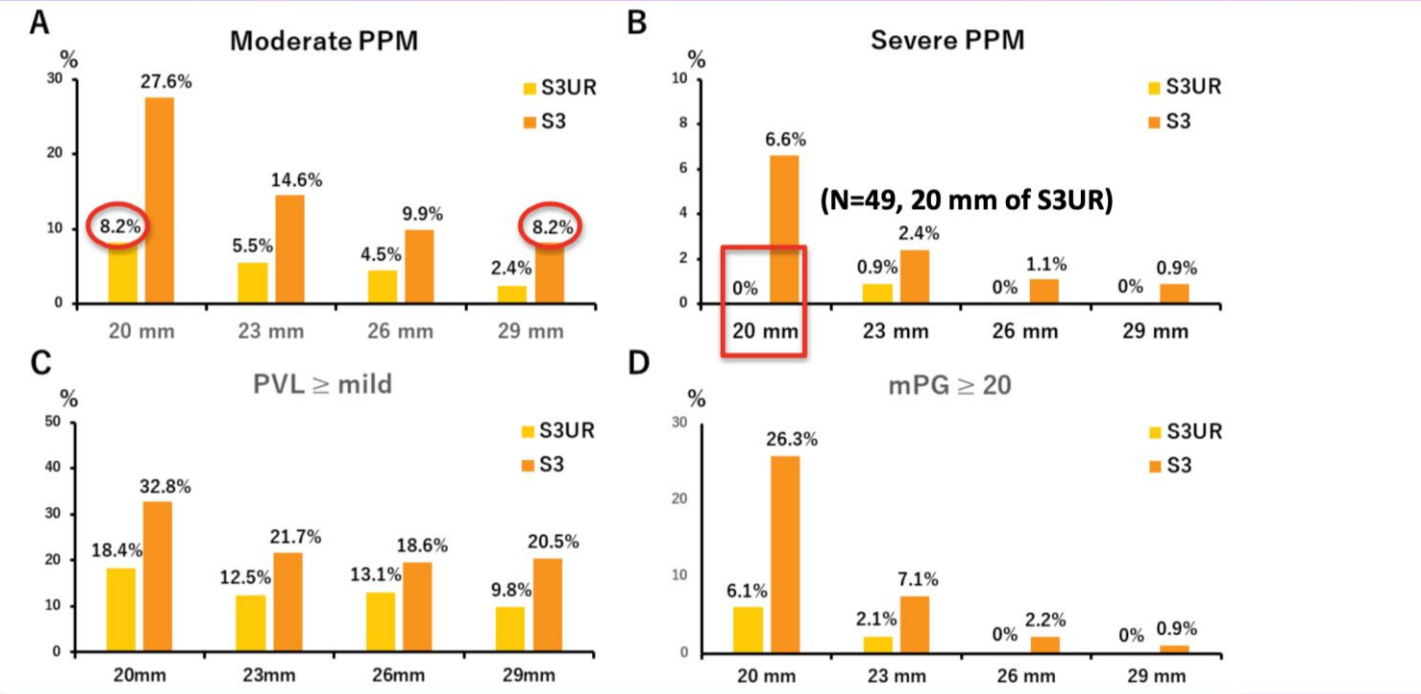
2023 PCR london valves

Improved valve performance of latest-generation balloon-expandable Sapien-3 Ultra RESILIA: Insights from the OCEAN-TAVI registry

Masanori Yamamoto, MD, PhD
on the behalf of OCEAN-TAVI investigators
Toyohashi/Nagoya/Gifu Heart Centre

PCR EAPCI

Subgroup analysis for the each valve size



2023 PCR london valves PCRLondonValves.com PCR EAPCI

Improved gradient and reduced PPM across all sizes

Most pronounced for 20mm and 23mm S3U vs. S3UR

TVT registry S3U vs S3UR propensity matched 10312 patients

Real-World Outcomes for the Fifth-Generation Balloon Expandable Transcatheter Heart Valve in the United States

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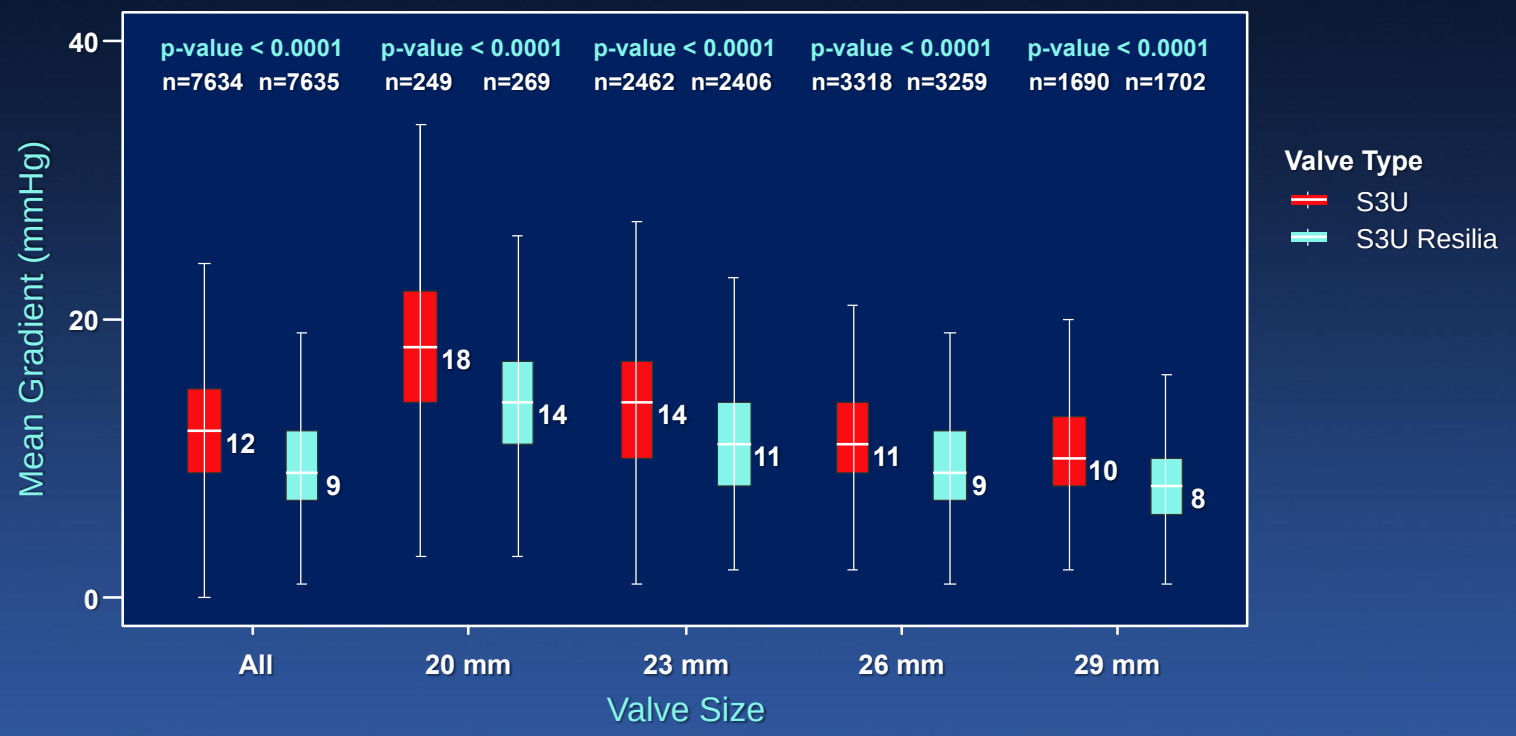
ABSTRACT

BACKGROUND The fifth-generation SAPIEN 3 Ultra Resilia valve (S3UR) incorporates several design c compared with its predecessors, the SAPIEN 3 (S3) and SAPIEN 3 Ultra (S3U) valves, including bovine leafl a novel process intended to reduce structural valve deterioration via calcification, as well as a taller exter 29-mm valve size to reduce paravalvular leak (PVL). The clinical performance of S3UR compared with S large patient population has not been previously reported.

OBJECTIVES The aim of this study was to compare S3UR to S3/S3U for procedural, in-hospital, and 30- echocardiographic outcomes after transcatheter aortic valve replacement (TAVR).

30-Day Echo-based Mean Gradient by Valve Size



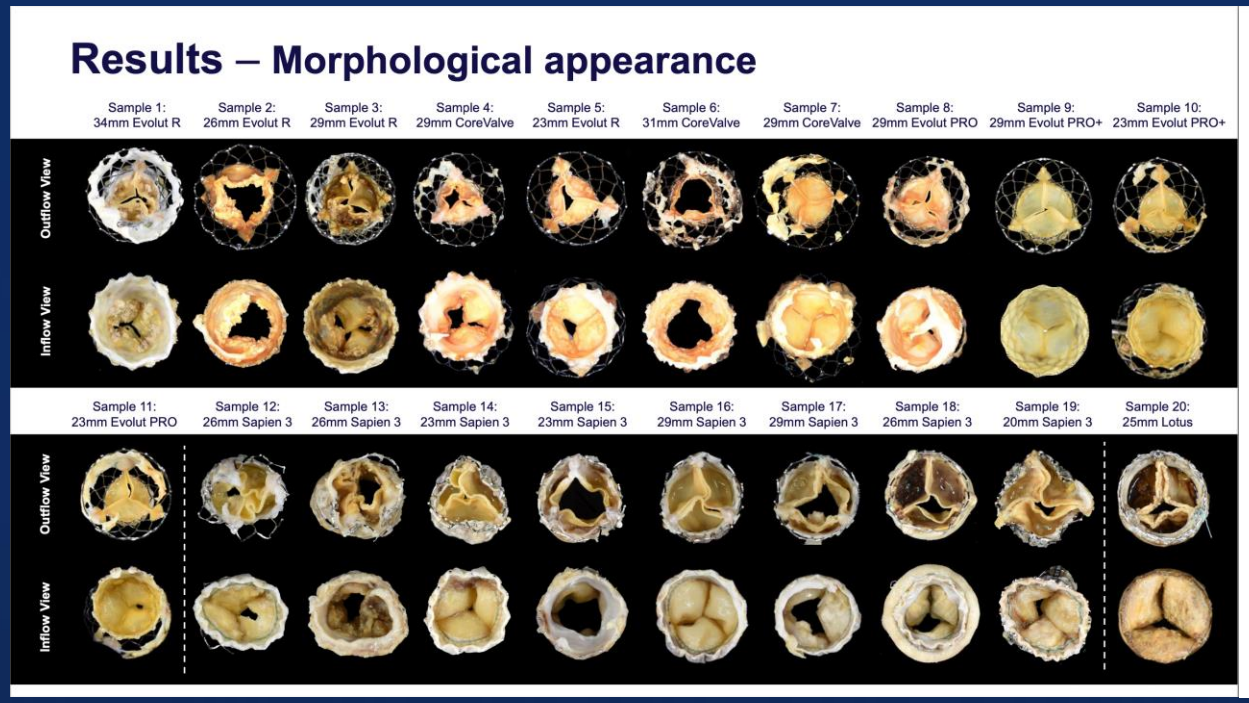
Statistically significant improvement in gradient across all THV sizes

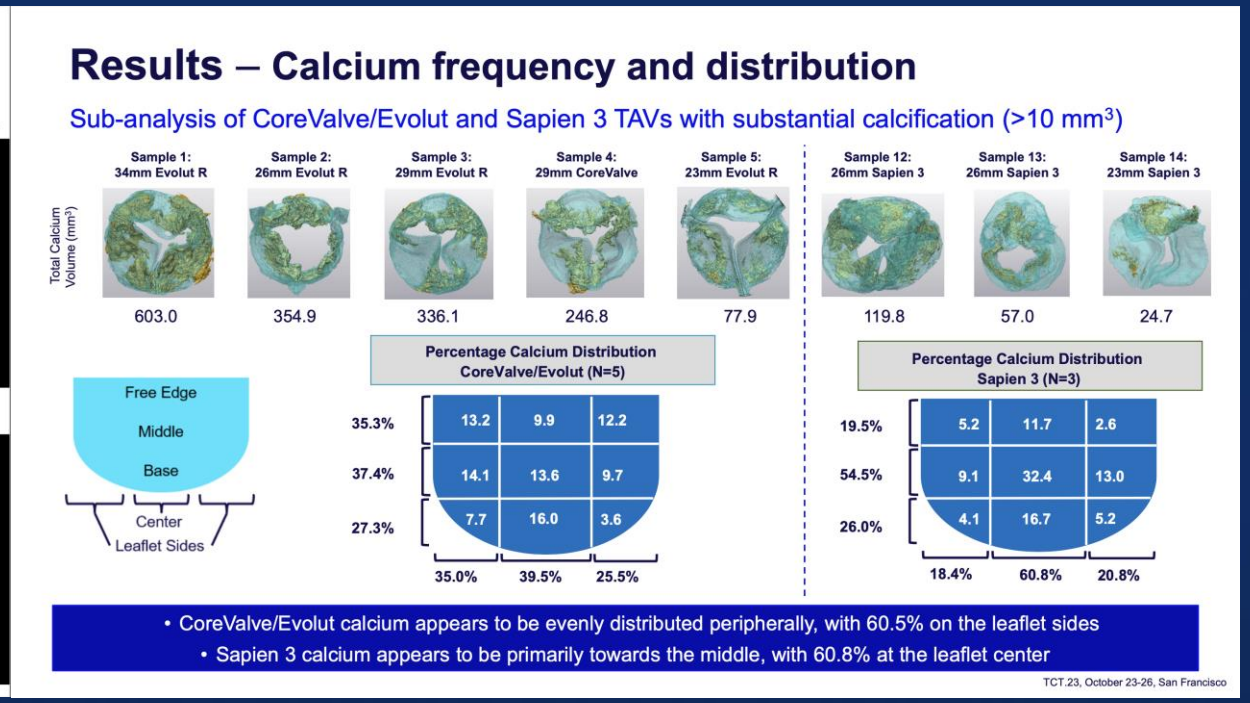
TAV-in-TAV

The importance of the FIRST TAVI – an Asia-Pacific perspective

ALL bioprostheses fail eventually

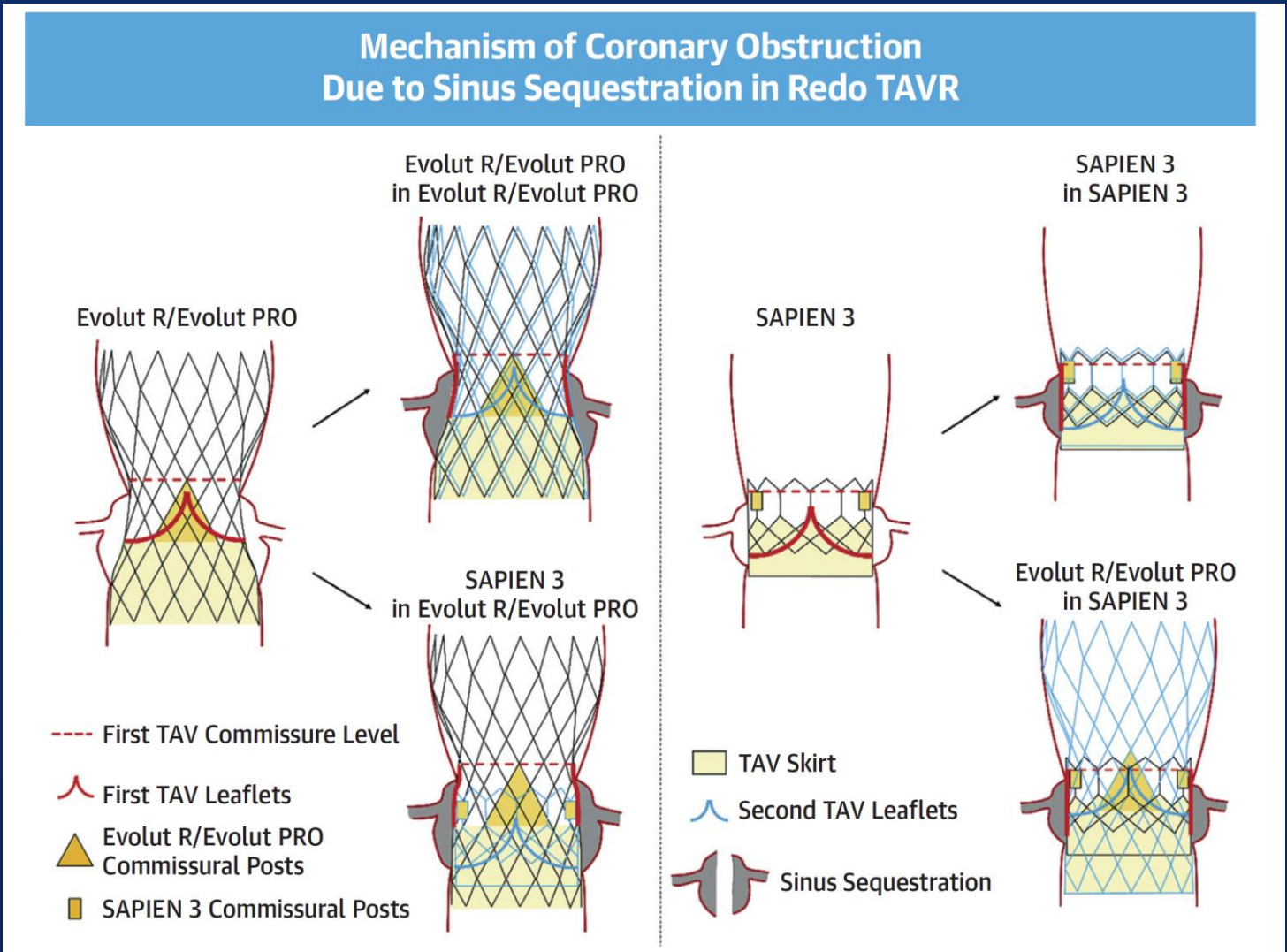
Calcification Patterns in TAVR EXPLANTS: informing durability & implications for reintervention





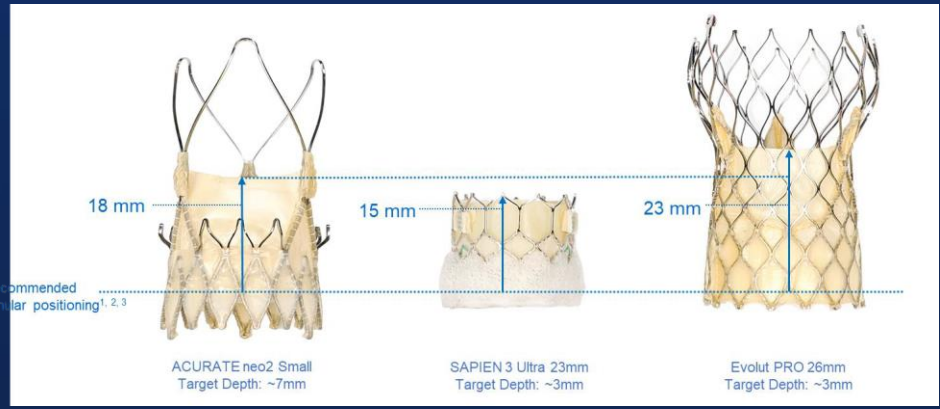
With permission from Stephanie Sellers, Uni British Columbia, St Paul's Vancouver
TCT San Francisco 2023

TAV-in-TAV: coronary obstruction risk!



- Placement of a THV within a THV will render the 1st THV a **stent graft**, pinning down the original leaflets

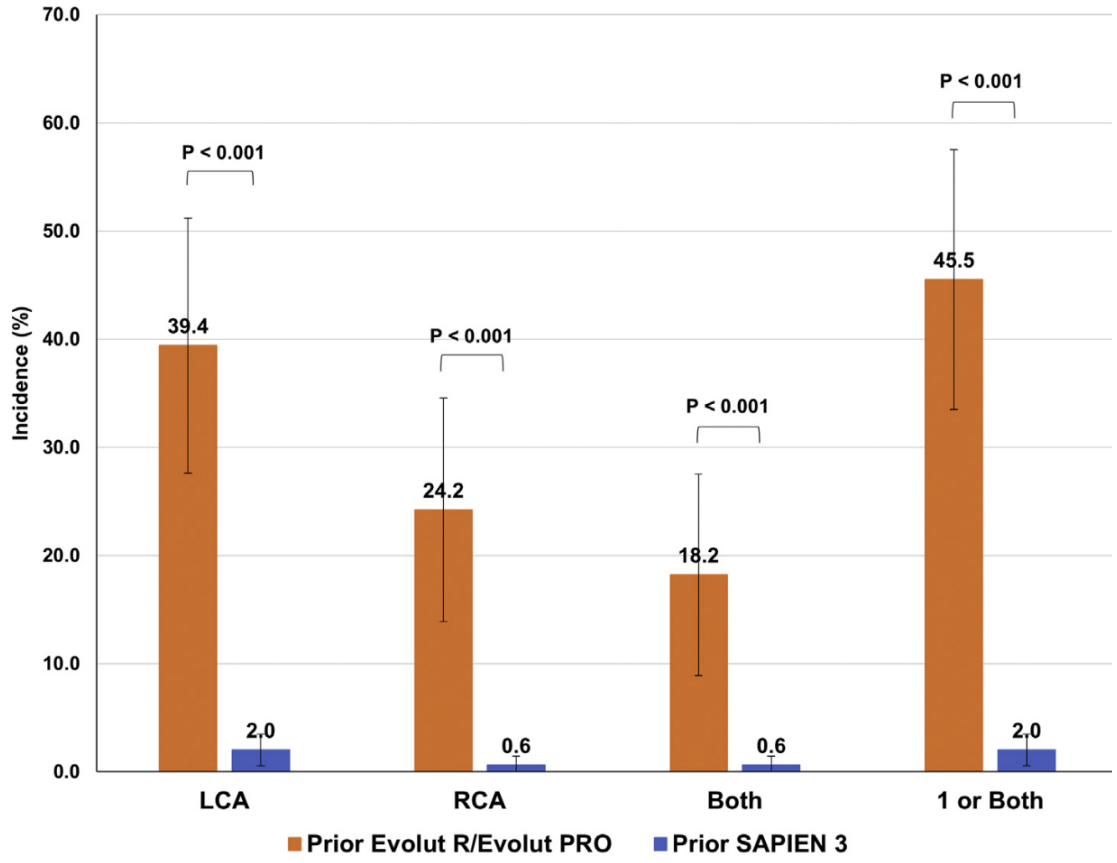
- **Neoskirt concept**



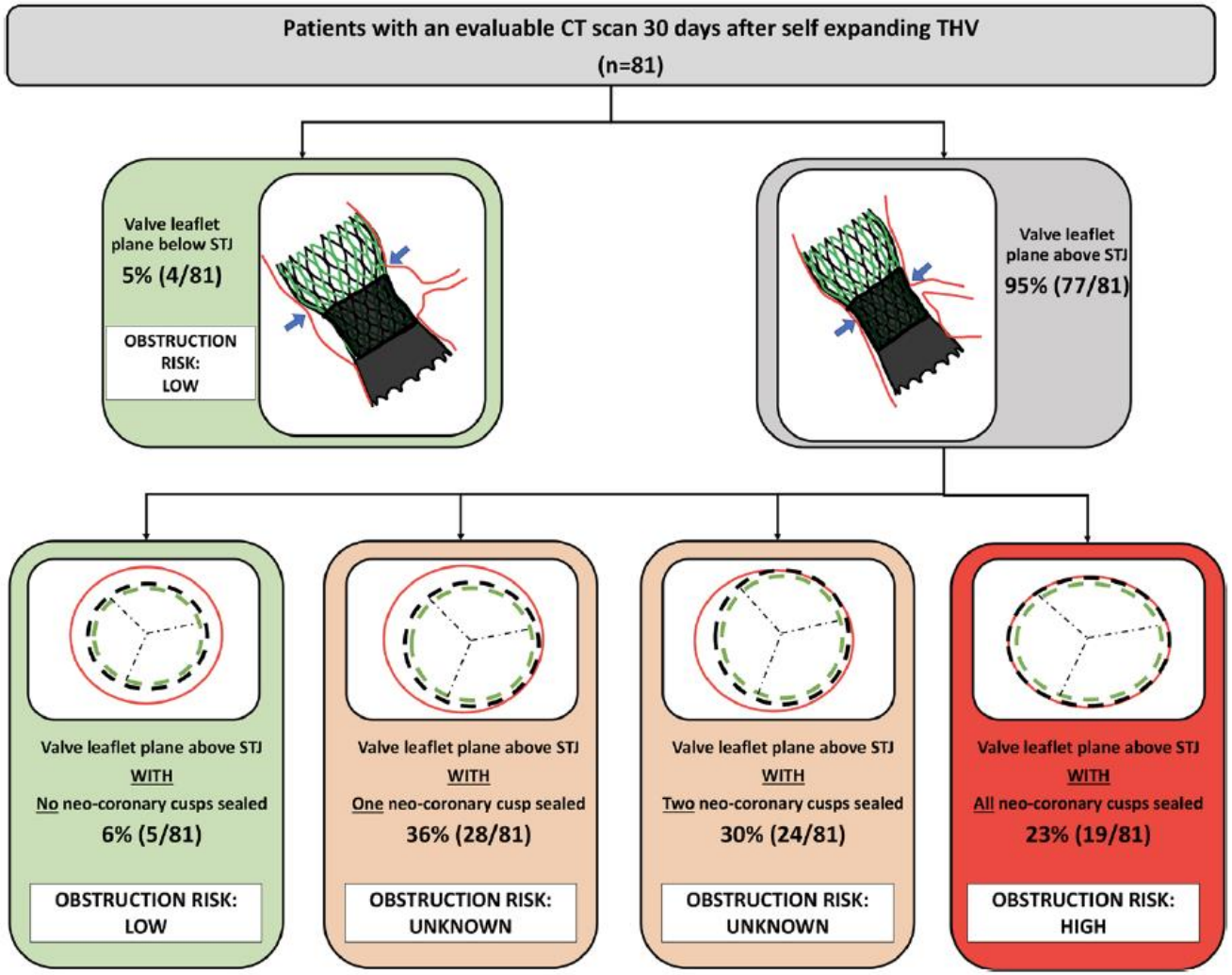
Ochiai T et al. Risk of Coronary Obstruction Due to Sinus Sequestration in Redo Transcatheter Aortic Valve Replacement JACC Intv 2020;13:2617-27

Medtronic SEV – challenging TAV-in-TAV

FIGURE 3 CT-Identified Risk of Sinus Sequestration in Redo TAVR in Evolut R/Evolut PRO and SAPIEN 3

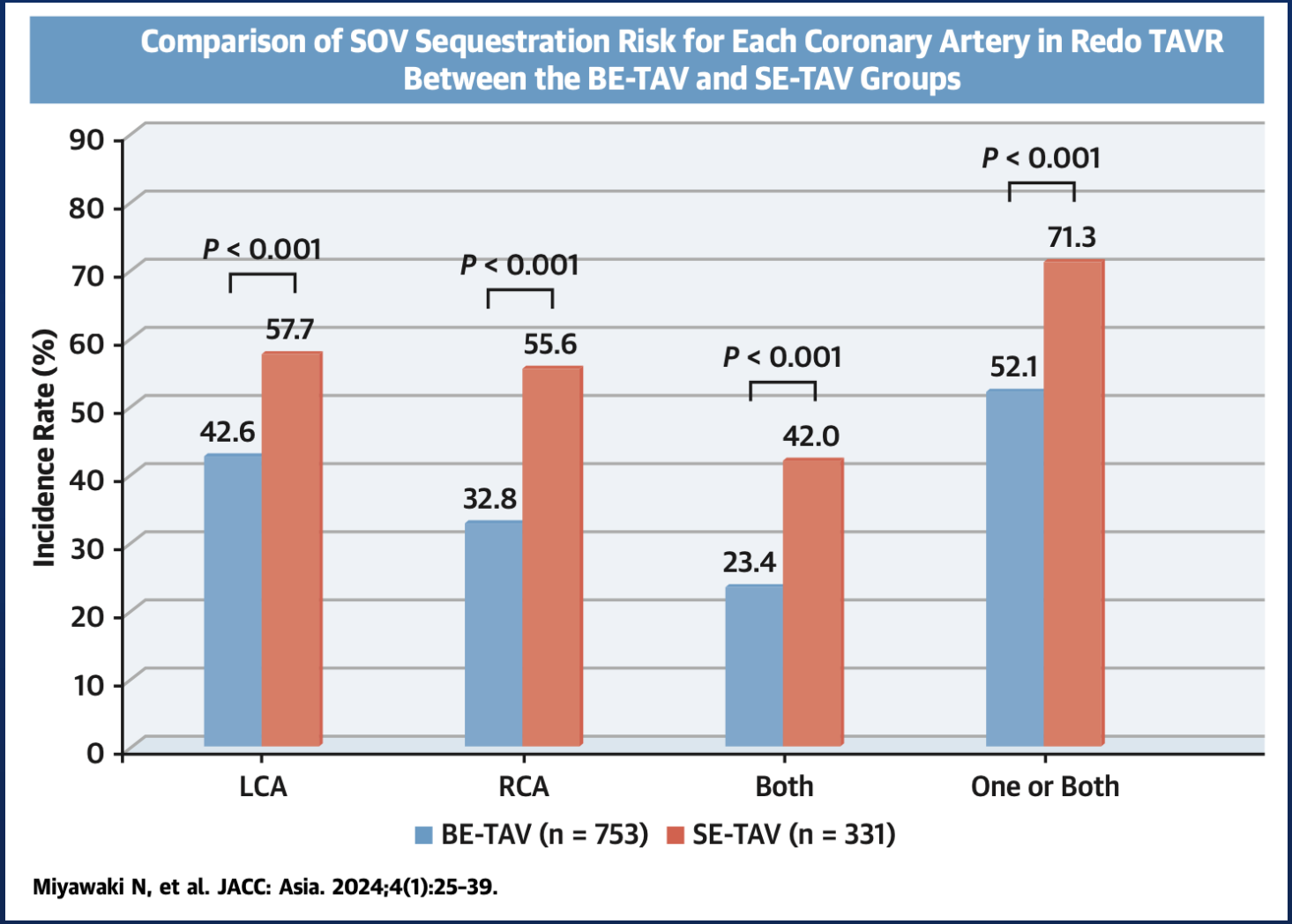


CT-identified risk of sinus sequestration in redo TAVR in prior Evolut R/Evolut PRO and prior SAPIEN 3 are shown. Abbreviations as in



Ochiai T et al. Risk of Coronary Obstruction Due to Sinus Sequestration in Redo Transcatheter Aortic Valve Replacement JACC Intv 2020;13:2617-27
Forrestal BJ, Risk of Coronary Obstruction and Feasibility of Coronary Access After Repeat Transcatheter Aortic Valve Replacement With the Self-Expanding Evolut Valve: A Computed Tomography Simulation Study, Circ Intv 2021

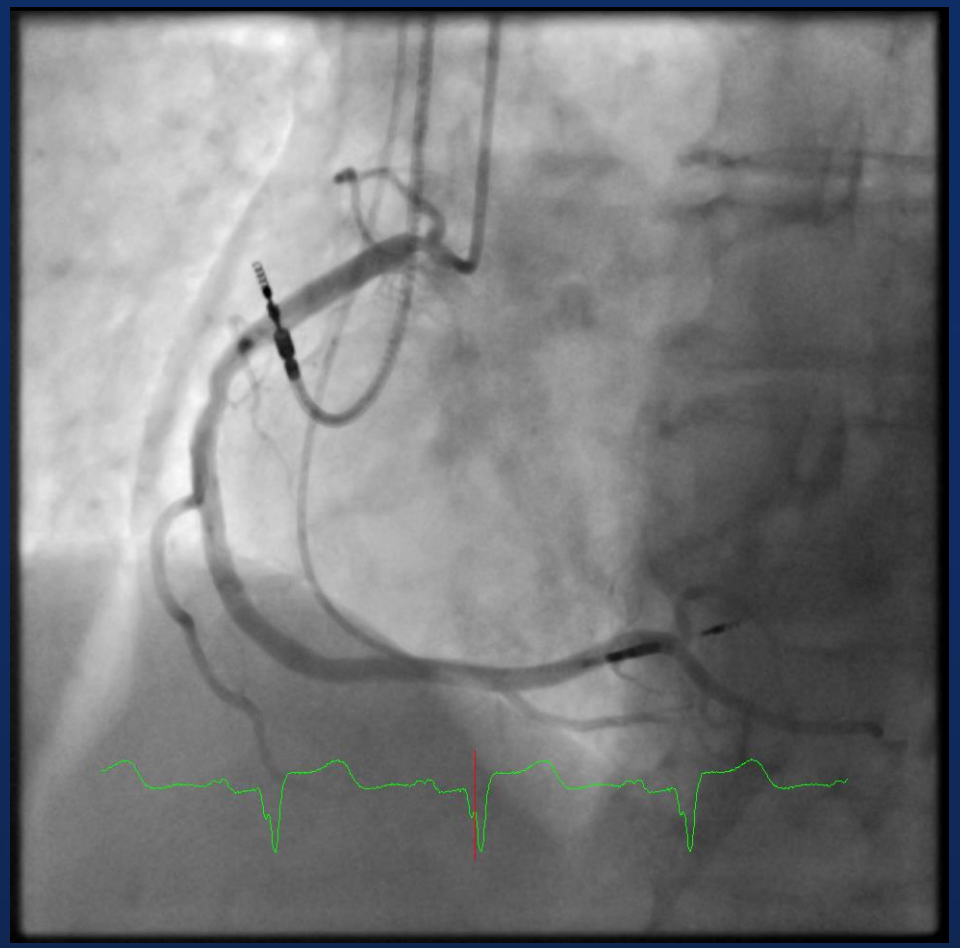
TAV-in-TAV in Asian population – more difficult?



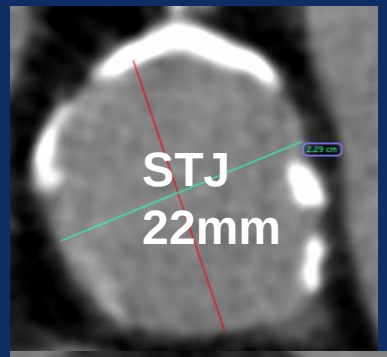
Miyawaki, N, et al Assessing Potential Risks of Future Redo Transcatheter Aortic Valve Replacement in Asian Patients, JACC Asia 2024

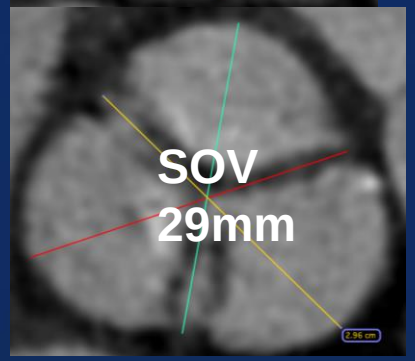
Case example of S3U in 2024

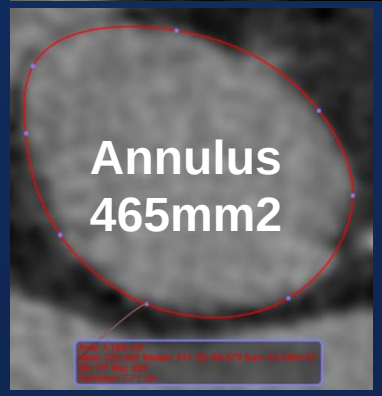
- 76-year-old female (158cm; 50kg; BSA 1.48)
- Severe aortic stenosis with normal LVEF
- Severe proximal RCA calcified stenosis – for TAVI
- For future rota PCI if chest pain



CT analysis and MDT







Miscellaneous:

MDT Date: 29/ 2/2024

Outcome:

F/U Post MDT:

(Not Sapien)

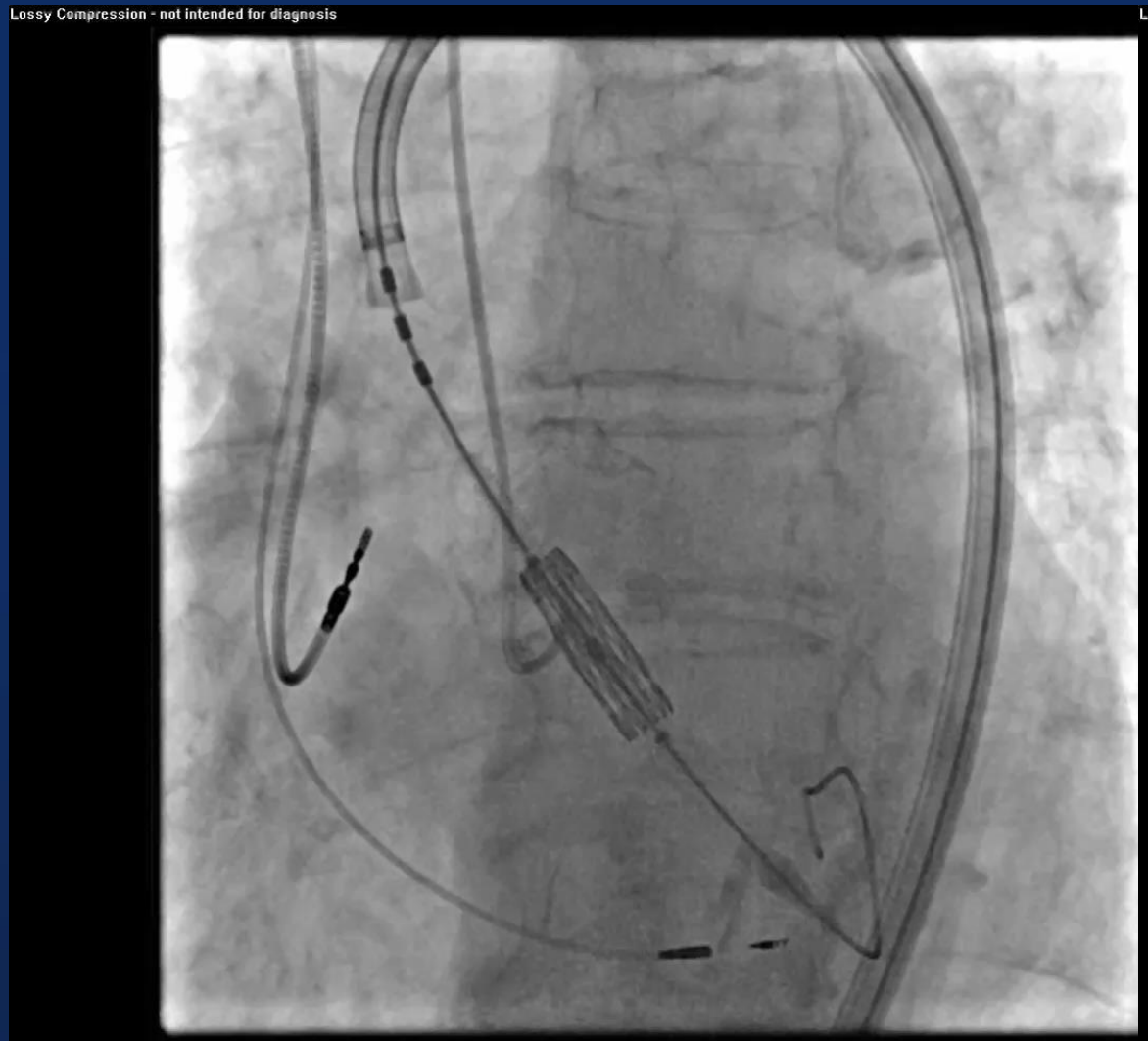
* large calcium * *
STJ - rock.
Coronary access -
needs - Self expanding. ? fx.

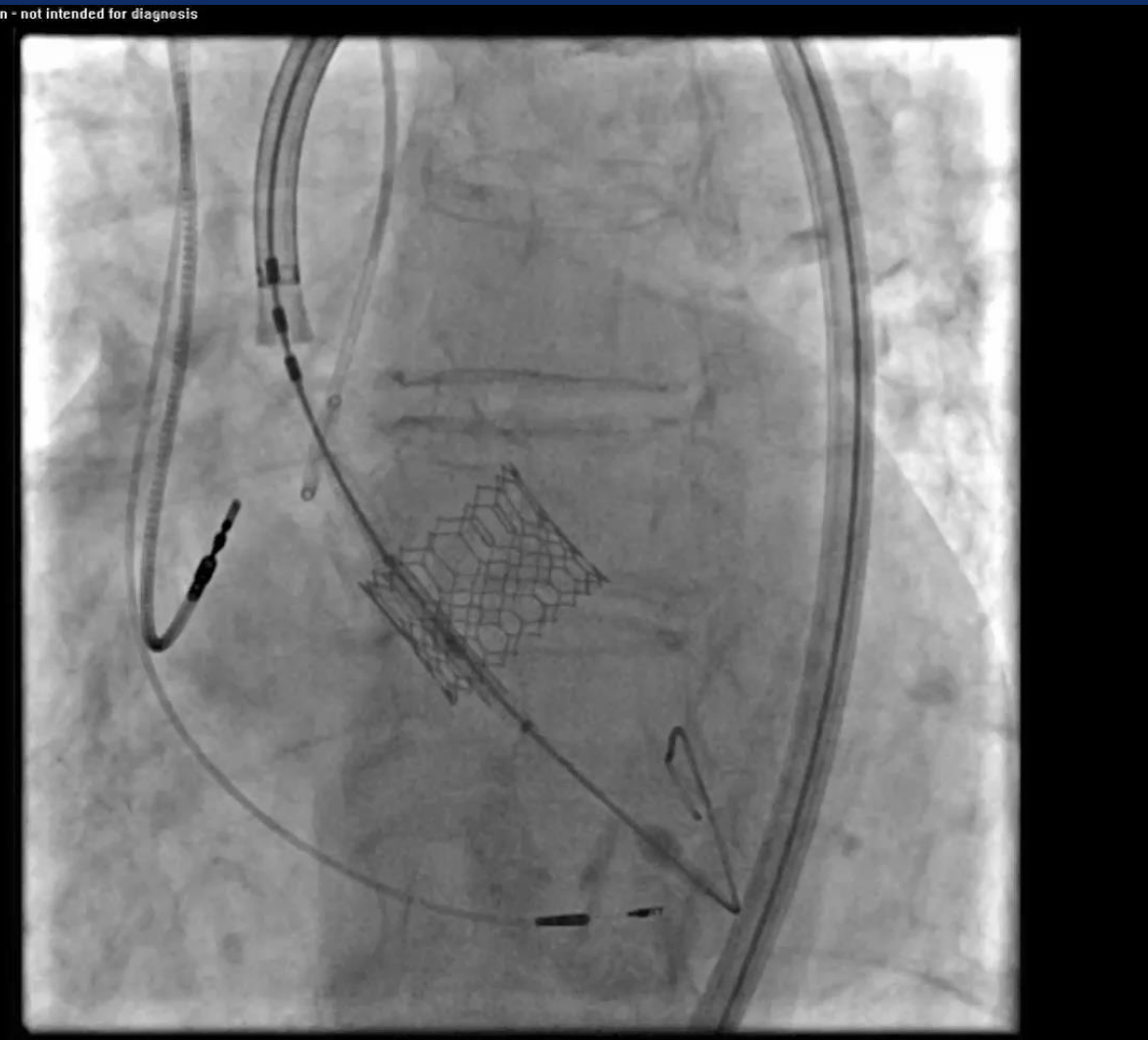
It was noted she had a very calcified aortic root anatomy with a significantly calcified ST junction. She also has at least moderate ostial calcified RCA disease on CT. Angiographically Karl, this is certainly not critical/severe.

We thought transfemoral access was satisfactory.

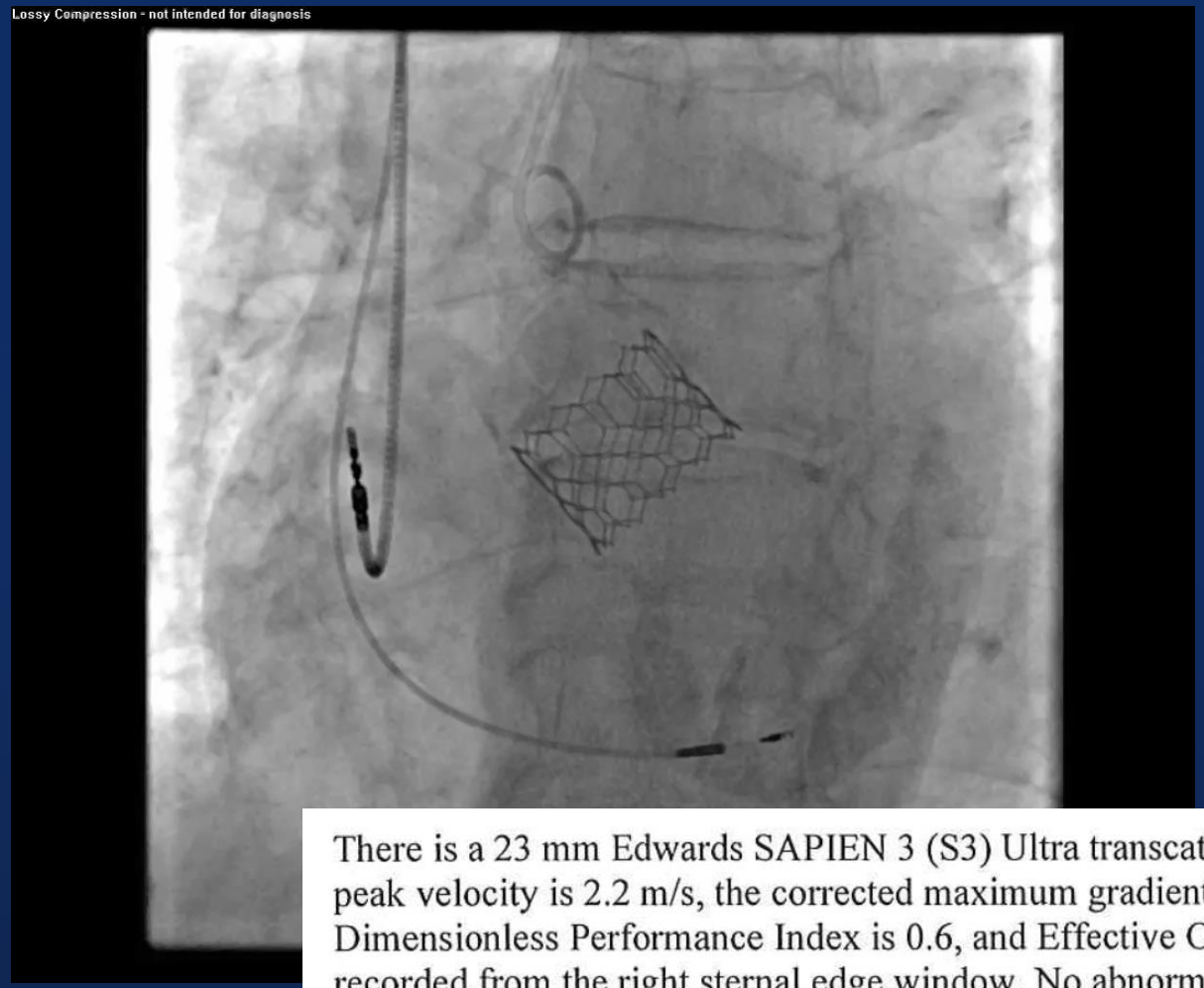
Based on her aortic root anatomy we thought a balloon expandable valve was not ideal for her situation and she could be considered for an Evolut FX.

TAVI 23mm +2cc “double tap”





TAVI 23mm+2cc double tap result



- Use a smaller THV over expand it (S3U/R)
- ”Lowish” initial implant depth
- Compensated by overfilling THV
- Further confirmed with “double tapping”

Results:

- Guaranteed coronary access and future TAV in-TAV

There is a 23 mm Edwards SAPIEN 3 (S3) Ultra transcatheter aortic valve replacement, which appears well seated. The peak velocity is 2.2 m/s, the corrected maximum gradient is 12 mmHg and the corrected mean gradient is 5.5 mmHg. Dimensionless Performance Index is 0.6, and Effective Orifice Area (EOA) is 2.1 cm². The highest velocity was recorded from the right sternal edge window. No abnormal regurgitation detected.

Conclusion

- S3U platform has proven durability.
- Adaptable to a wide variety of annuli including small annuli.
- Multiple multicenter real-world registries on excellent outcomes in small annuli patients.
- New tissue technology may provide better EOA and hemodynamics and possibility improved durability.
- S3UResilia.
- Short valve frame is very beneficial for future TAV-in-TAV feasibility and should be a consideration in patients who will likely require TAV-in-TAV in their lifetime management.