

TAV-in-TAV: Planning and Optimizing the Procedure

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Disclosure

- In the past 12 months, I and/or my spouse, have received the following:
 - Relevant conflict to this presentation
 - Consulting fee/Proctoring fee
- | Company |
|---------------------------------------|
| Edwards LifeSciences, Abbott, Anteris |

TAV-in-TAV vs. TAV-in-SAV: so what's so different?



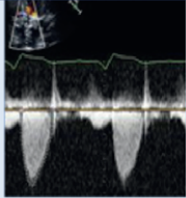
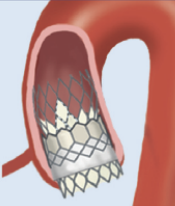

20mmS3 in 21mm Perimount
BVF with 21 mm TRUE
Gradient: 10 mmHg TTE

23mmS3 in 23mm XT
Pre BVF with 23mm TRUE
Gradient: 5 mmHg TTE

TAV-in-TAV can be straight forward

Registry data of feasibility and safety in CAREFULLY selected patients

CENTRAL ILLUSTRATION Repeated Transcatheter Aortic Valve Replacement for Transcatheter Heart Valve Dysfunction

	Incidence	Residual Gradient	Coronary Flow Obstruction	Mortality at 30 days
 Redo-TAVR For:				
Failed TAVR Valve	0.22%	13 mm Hg	0.7%	1.4%
Failed TAVR Procedure	0.11%	11.5 mm Hg	1.3%	5.4%

Landes, U. et al. J Am Coll Cardiol. 2020;75(16):1882-93.

Outcomes stratified for patients presented with probable TAVR failure and those with probable THV failure. TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve.

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Transcatheter Aortic Valve Replacement for Degenerated Transcatheter Aortic Valves

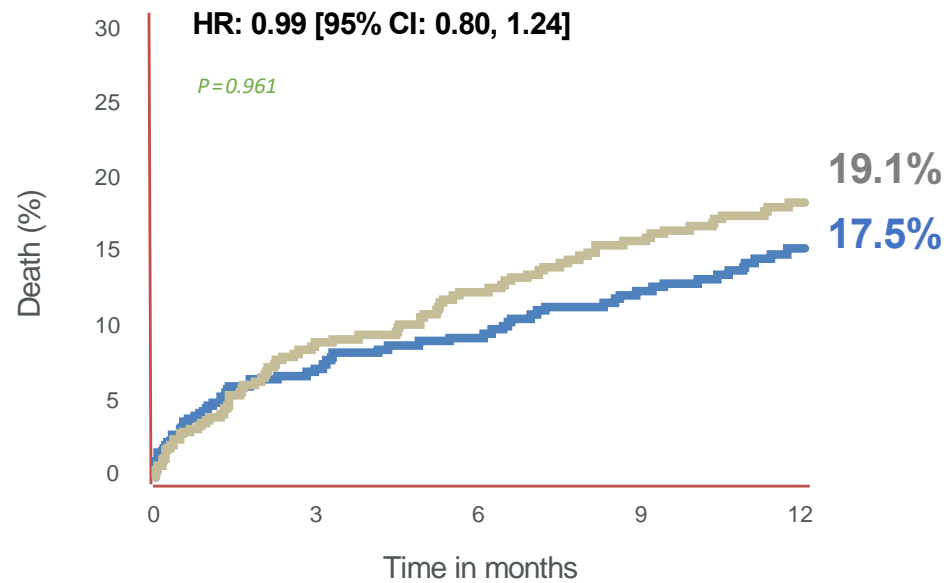
The TRANSIT International Project

Luca Testa¹, MD, PhD; Mauro Agnifili, MD; Nicolas M. Van Mieghem², MD, PhD; Didier Tchétché, MD;

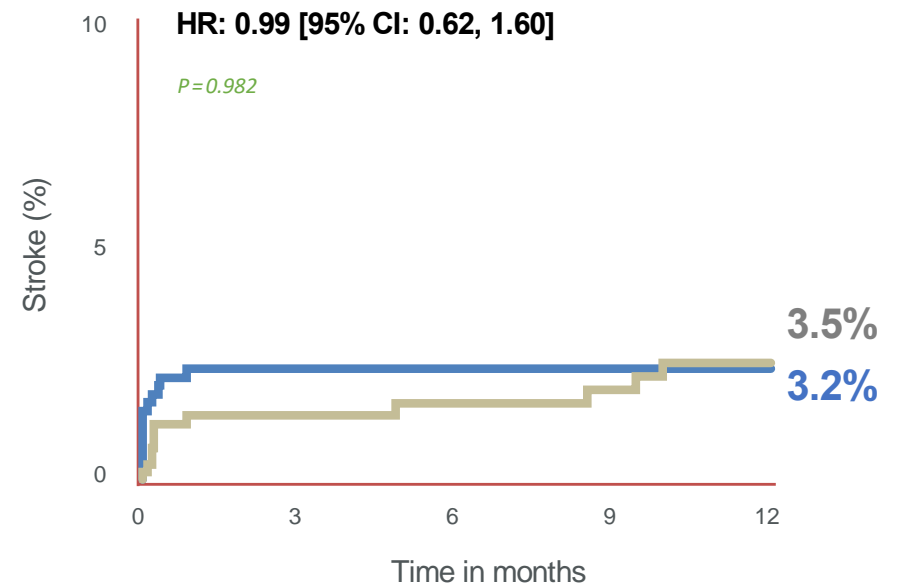
- TRANSIT
 - N=172 TAVI in TAVI
 - No coronary obstruction (!!)
- Caution:
 - Selection bias – how many cases rejected?
 - Case series only

TVT registry on TAV-in-TAV with S3U in TAVI

Primary endpoints of death and stroke for SAPIEN 3 platform¹



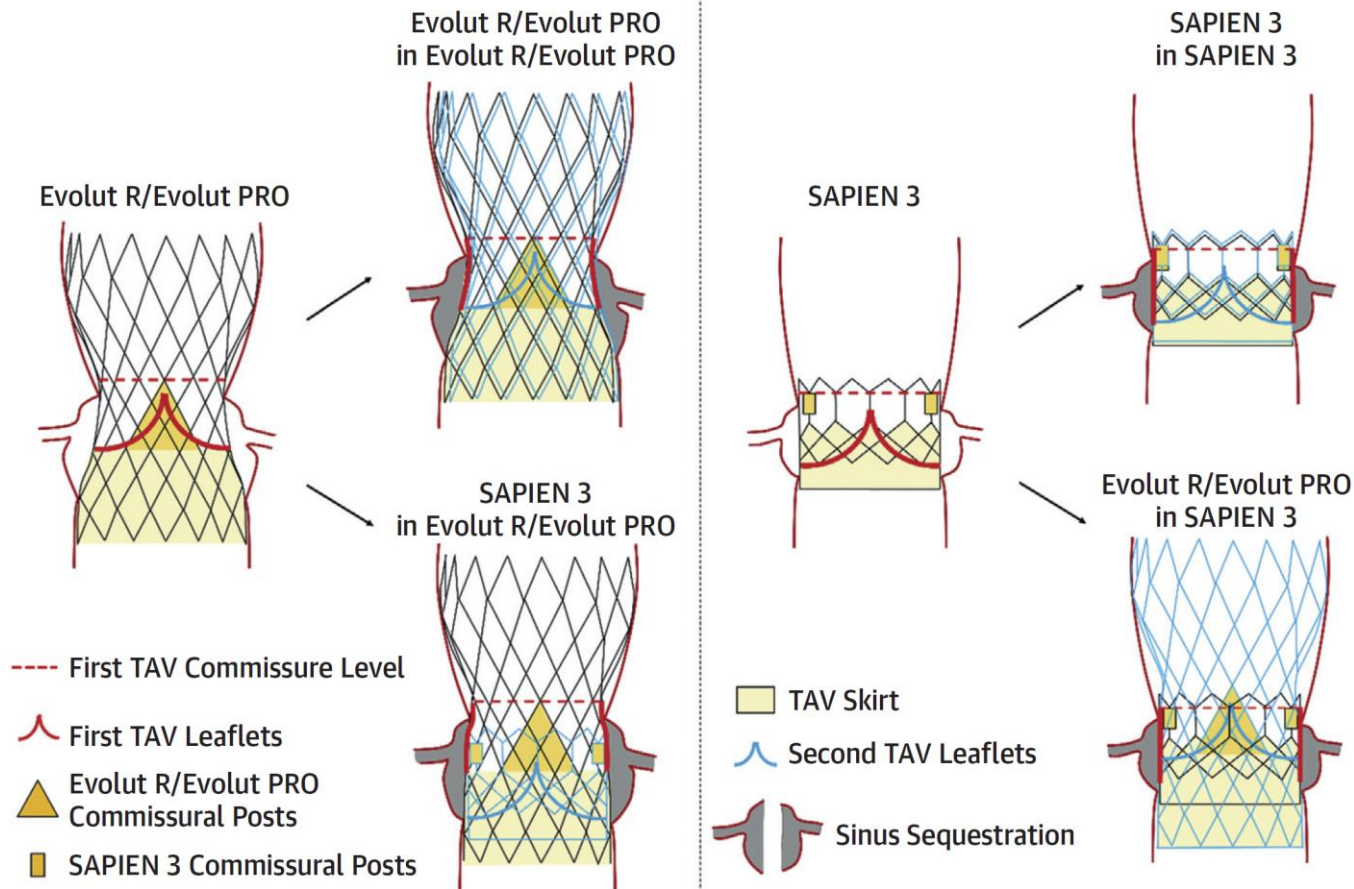
Patients	1216	724	670	626	513
at risk	1216	837	775	722	593



Patients	1216	712	656	613	503
at risk	1216	368	761	708	579

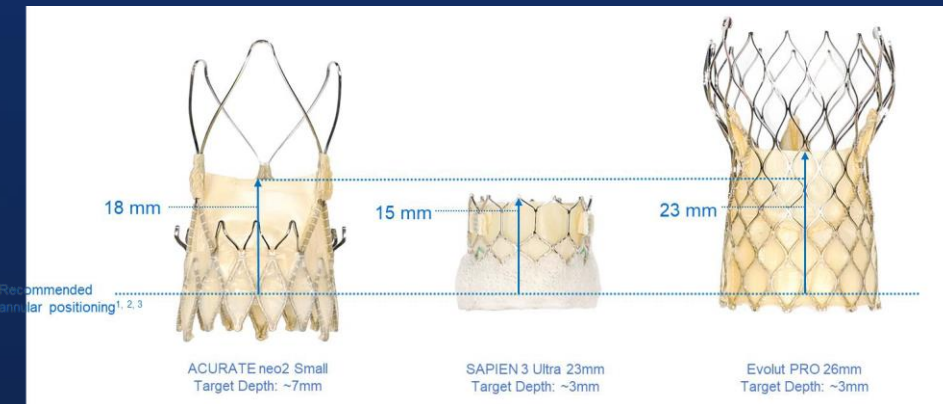
TAV-in-TAV: coronary obstruction risk!

Mechanism of Coronary Obstruction Due to Sinus Sequestration in Redo TAVR



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

- **Neoskirt concept**

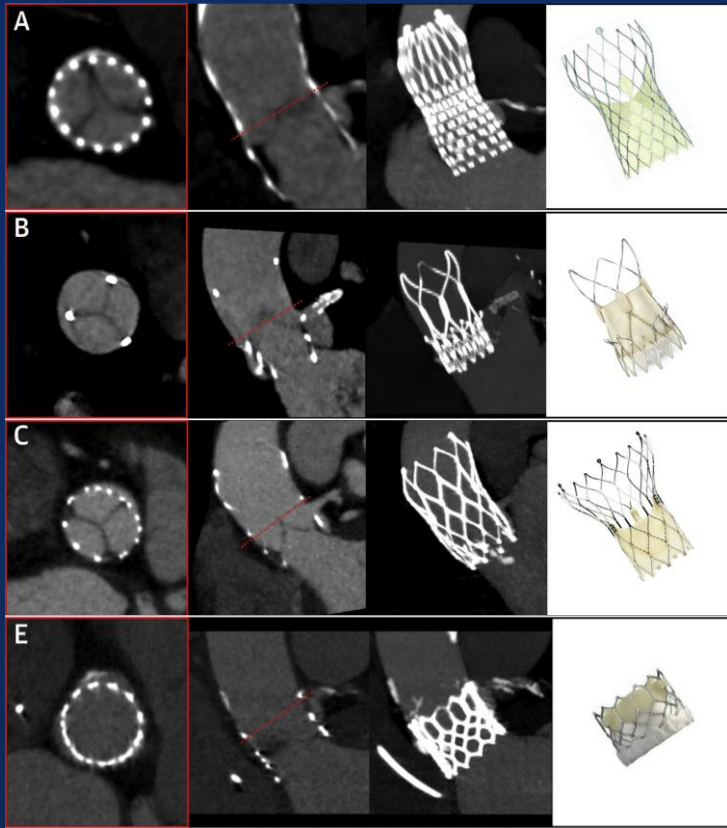


TAV-in-TAV: unique challenge – heterogeneity

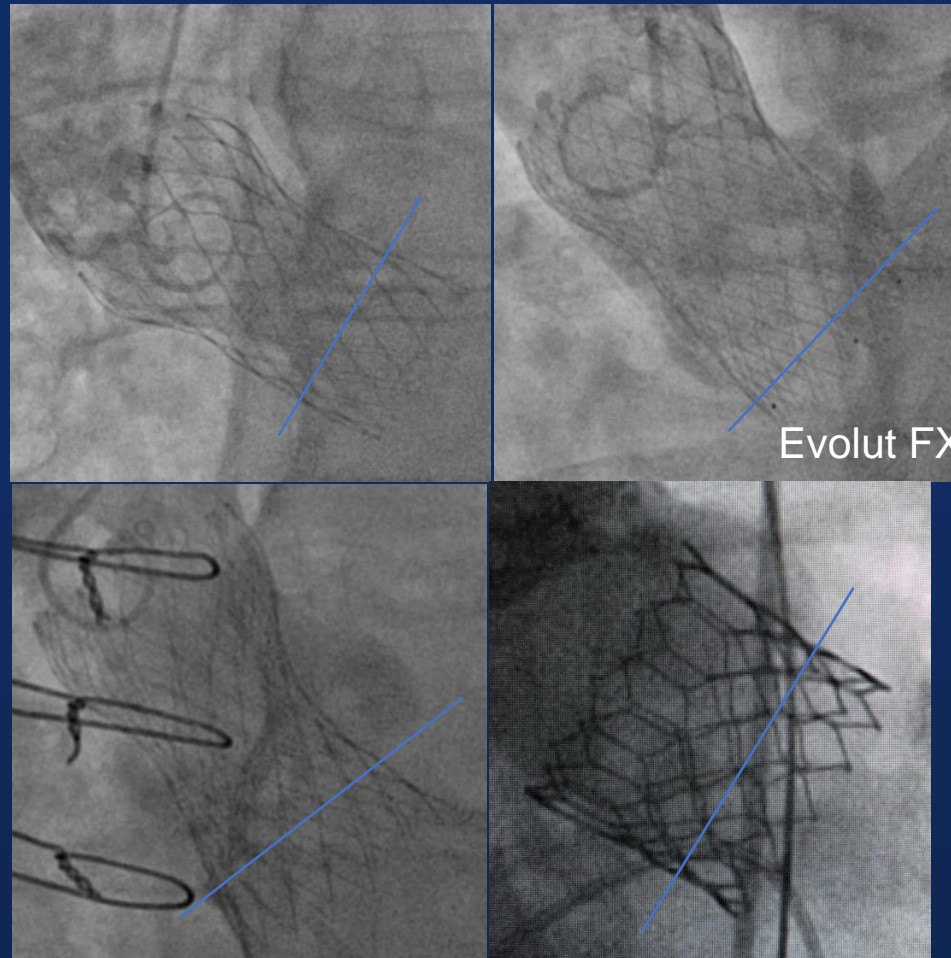
Heterogeneity in design

Variable implant depth

Variable expansion



Leaflet height
Commissural alignment



Evolut FX

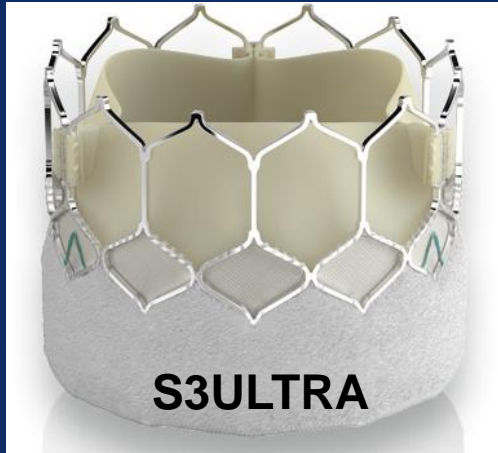


True ID 18.5 to 22mm

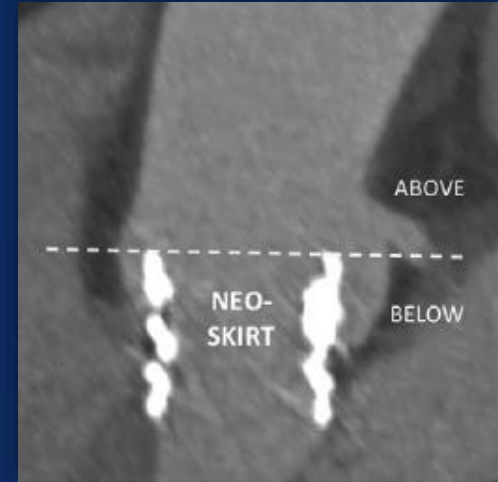


True ID 21 to 25mm

Index TAVI – Edwards Sapien platform



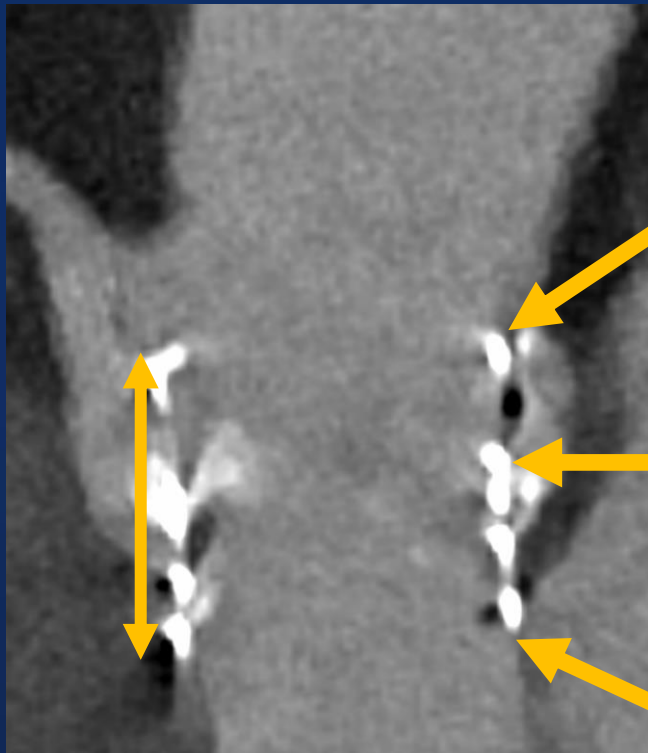
- Short frame, intra-annular
- Leaflets/neoskirt at the commissure tabs
- Due to its design, leaflets or neoskirt plane MAY not extend above STJ/coronary ostia



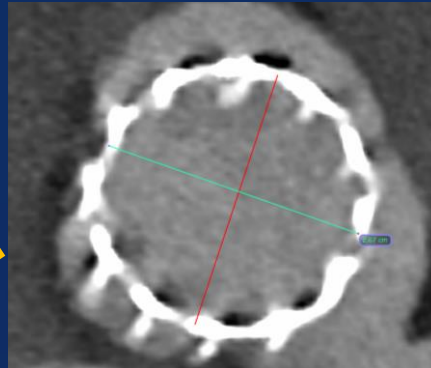
- Fundamentally lower risk of coronary obstruction "by design"

A case example – 5 year old underfilled 29mmS3

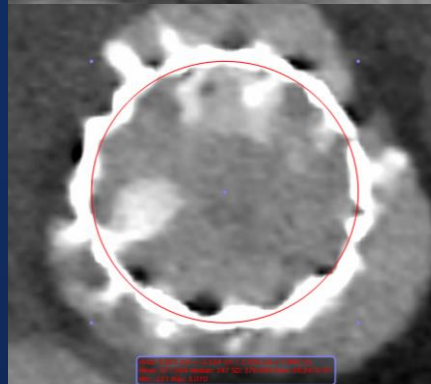
An under-expanded THV



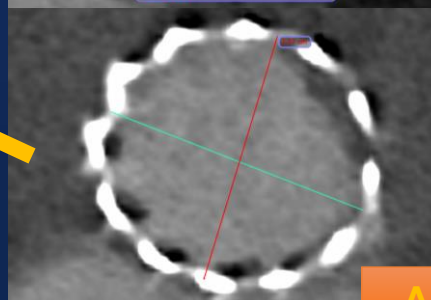
Height
23.9mm



Diameter
26.5mm



Diameter
25.5mm



Diameter
26mm



Height
23.5mm

An underexpanded 29mm S3 with a taller frame and smaller EOA

TAV-in-TAV procedure plan

Plan and Rationale

- **Right** transfemoral TAV-in-TAVI with **left** transfemoral “BVF”
 - Sentinel cerebral embolic protection
 - TRUE balloon 26mm **PRE** dilatation
 - **26mm S3U** + 2cc
 - TRUE Balloon **post** dilatation
- **Contralateral access to BVF so ipsilateral THV ready to deploy if AR**
 - **Concern re embolic risk due to multiple inflation planned**
 - **Address under-expansion prior to new THV**
 - **Achieve high pressure expansion**
 - **Prevent underexpansion of TWO stent frames**

TAV-in-TAV

Procedural outcome

Procedure outcome

- Large (6mm) debris in CEP basket
- No CVA/PPM/vascular complications
- Discharged day 2
- Discharged on **warfarin**

Echocardiographic outcome Day 1

- Mean gradient: 12mmHg
- Peak: 21mmHg
- EOA: 2.6cm²

Echocardiographic outcome Day 60

- Mean gradient: 12mmHg
- Peak: 27mmHg
- EOA: 2.6cm²



S3U 26mm +2cc inflation @ 9ATM

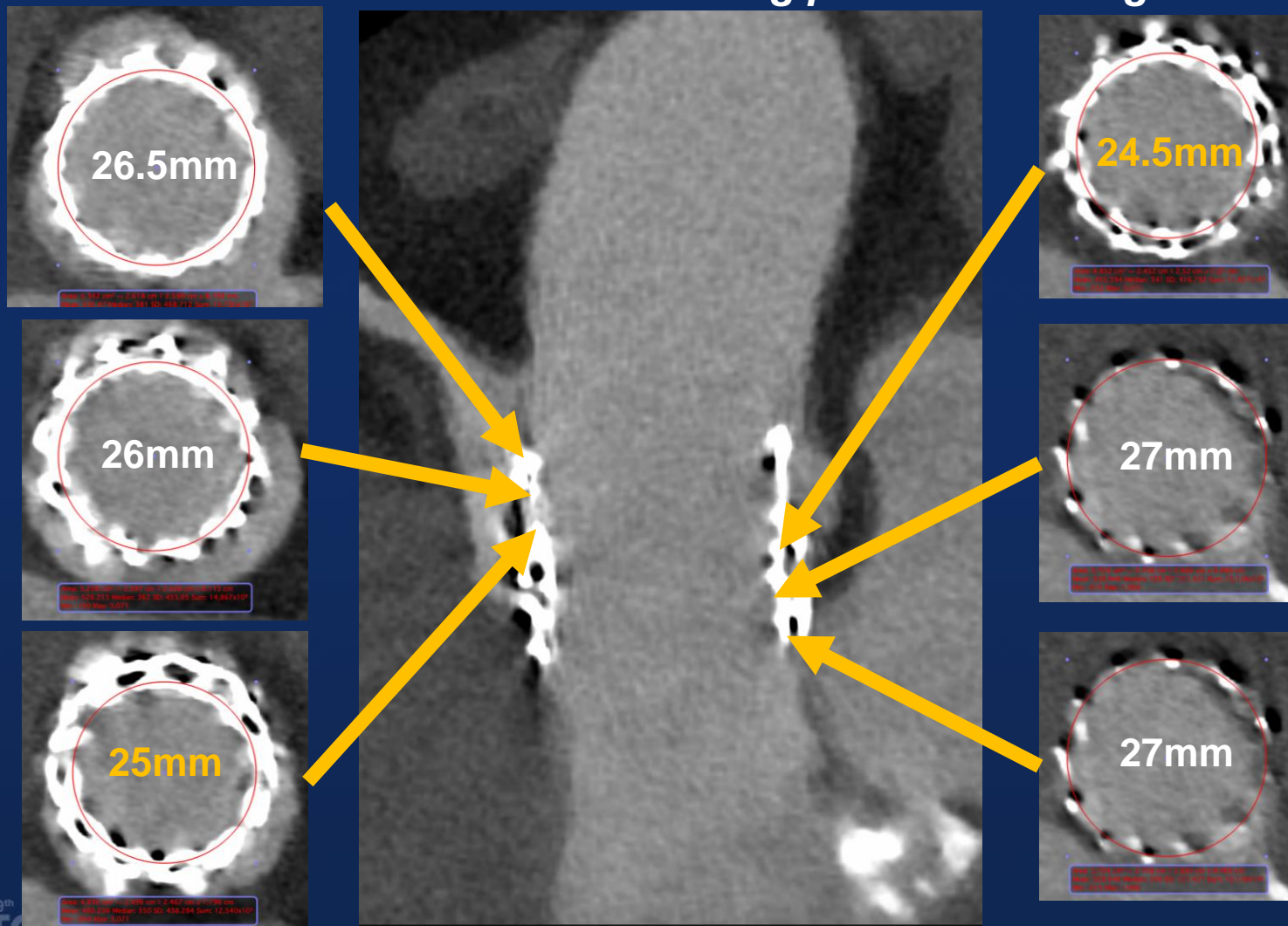
Top of new THV as per previous

TRUE 26mm balloon inflation

Coaptation length on TEE from 9mm to 4mm

TAV-in-TAVI postscript – CT TAVI

Learning points – challenges for TAV-in-TAV

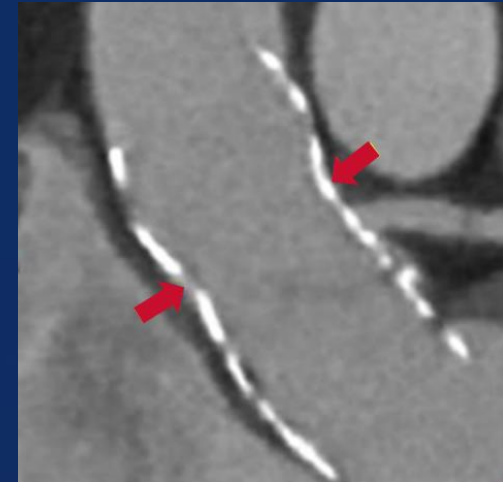


- Overall improved expansion of THV particularly the first THV, particularly inflow/outflow
- Despite predilatation significant “sandwiched” tissue from 1st THV
- Despite postdilatation mid body remains waisted

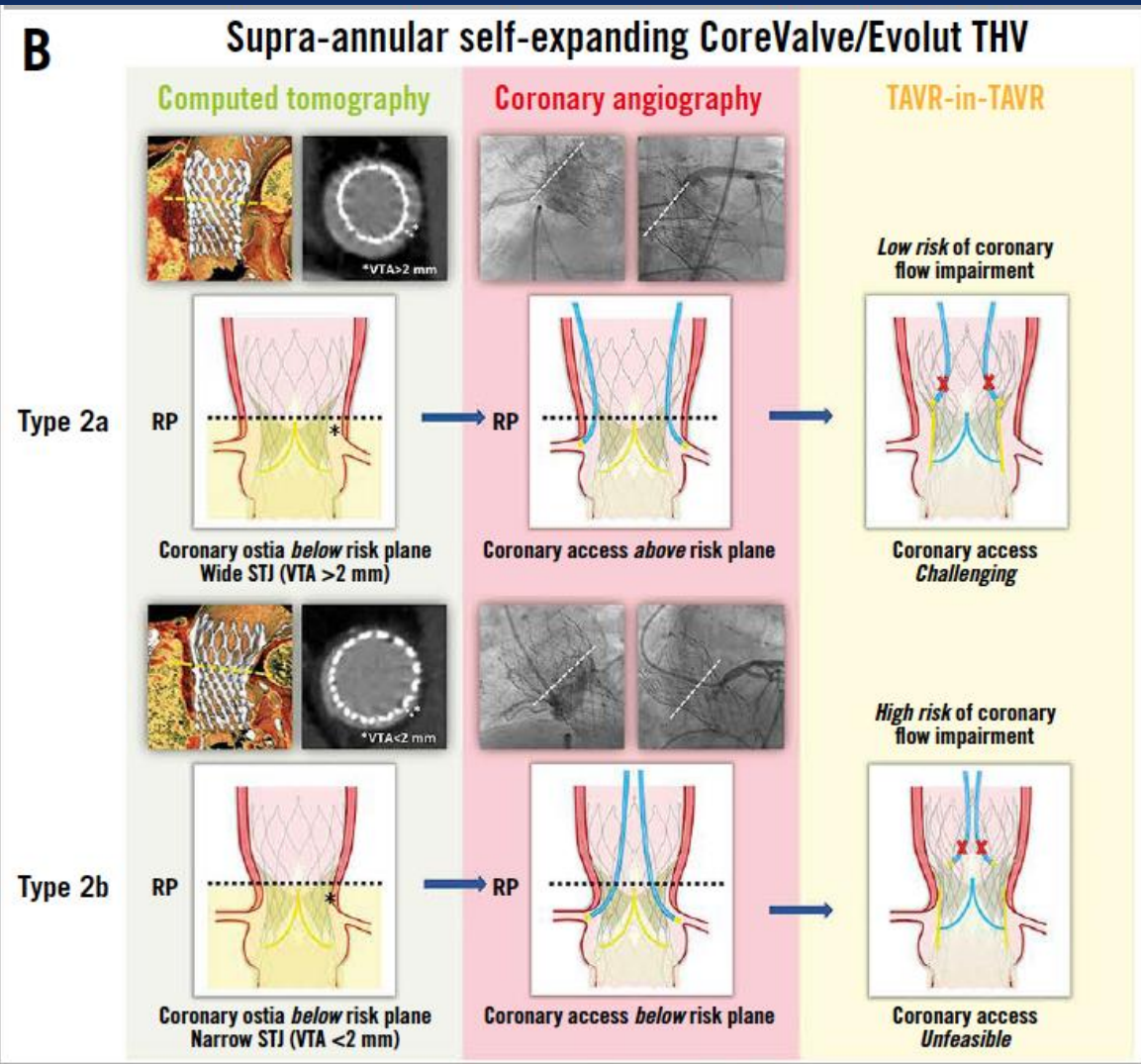
Index TAVI – Medtronic CV/Evolut R/FX



- Tall frame, supra-annular
- Leaflets/neoskirt **variable** – particularly **S3U**
- Due to its design, leaflets or neoskirt plane almost always extend above STJ/coronary ostia
- Fundamentally **very high risk** of coronary obstruction "by design"



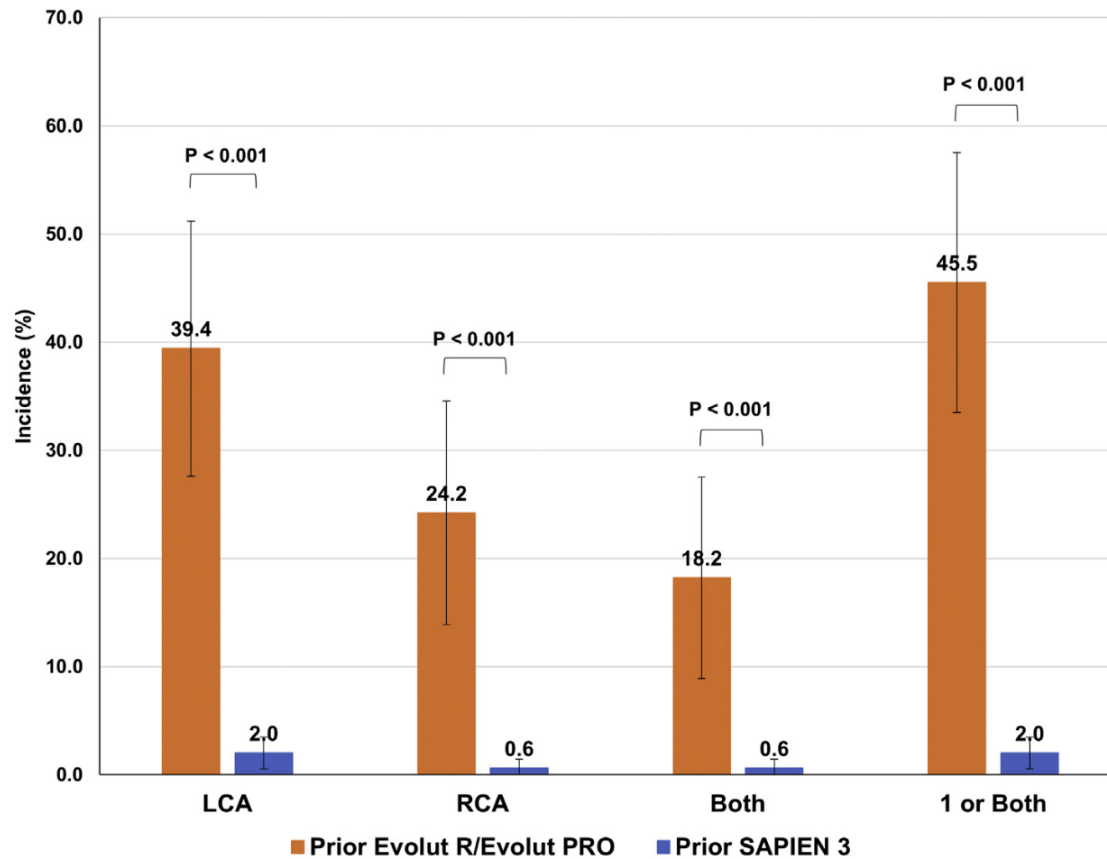
Medtronic SEV – coronary obstruction risk



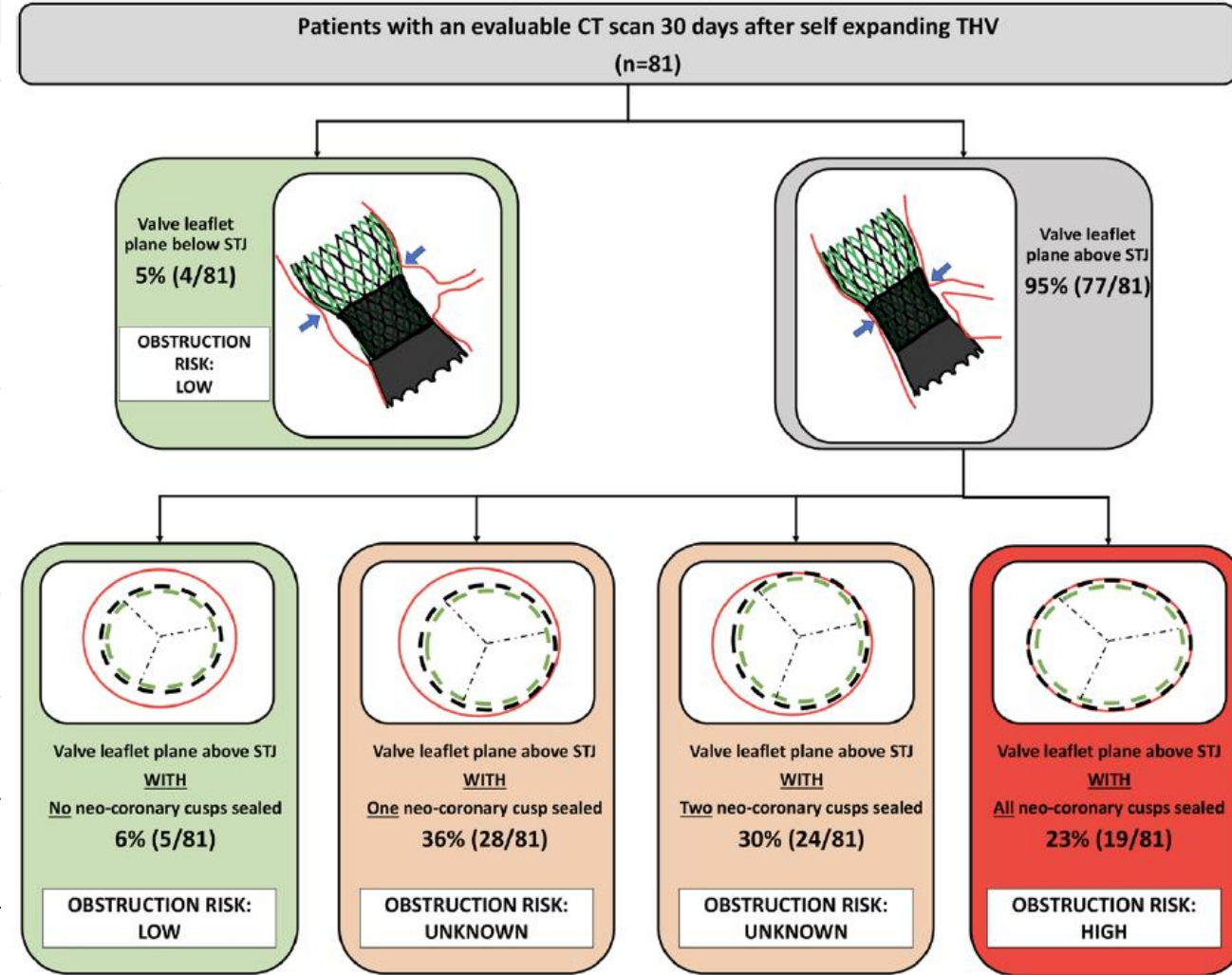
	SAPIEN 3/ULTRA N=72	EVOLUT R/PRO N=26	ACURATE NEO N=39
TAVR-in-TAVR feasible (40.9%)	CA above RP 68.1%	CA above RP 19.2%	CA above RP 5.1%
TAVR-in-TAVR theoretically feasible (27.7%)	CA under RP - VTA > 2mm 8.3%	CA under RP - VTA > 2mm 42.3%	CA under RP - VTA > 2mm 53.8%
TAVR-in-TAVR unfeasible (31.4%)	CA under RP - VTA ≤ 2mm 23.6%	CA under RP - VTA ≤ 2mm 38.5%	CA under RP - VTA ≤ 2mm 41.1%

Medtronic SEV – challenging TAV-in-TAV

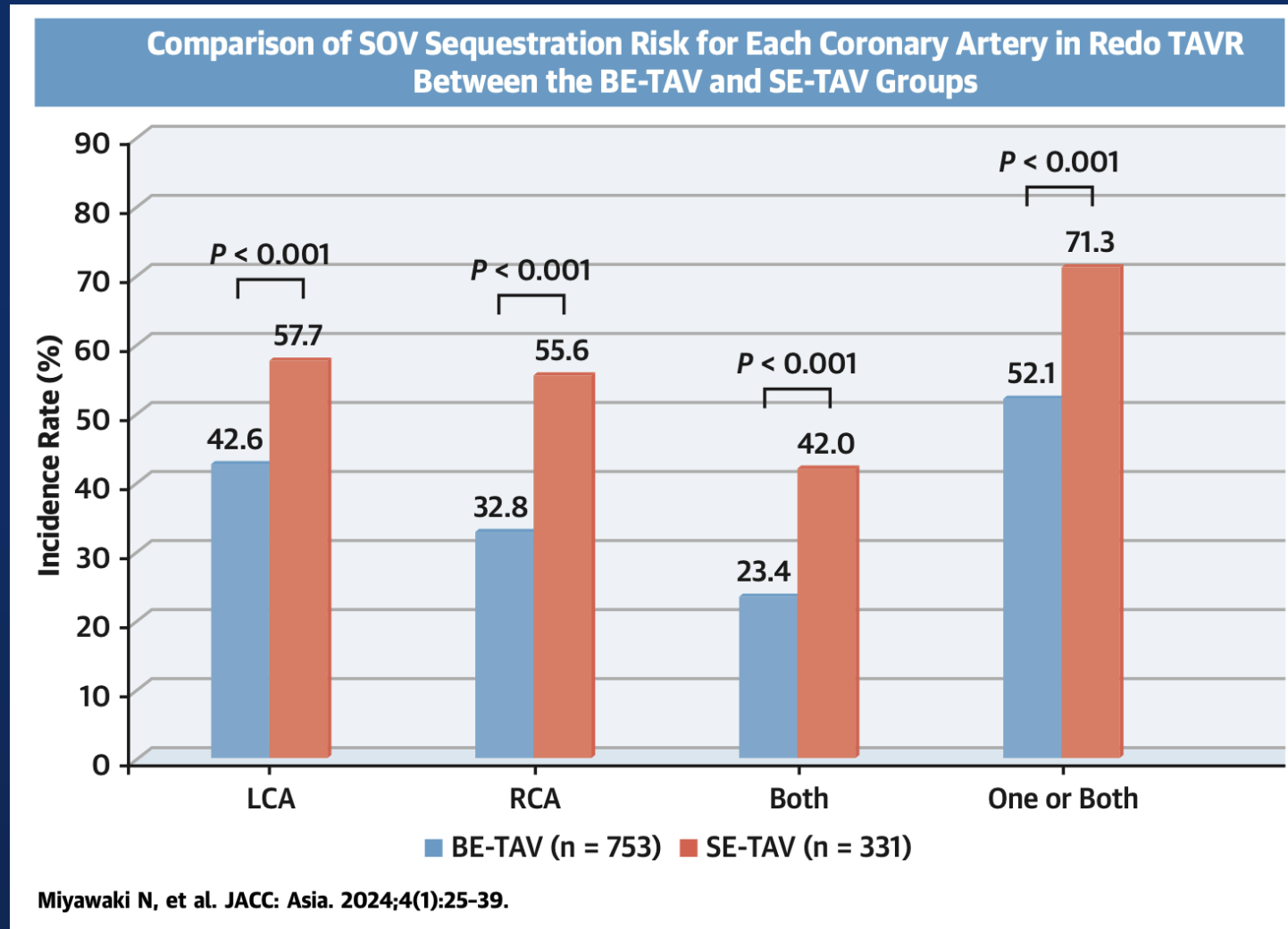
FIGURE 3 CT-Identified Risk of Sinus Sequestration in Redo TAVR in Evolut R/Evolut PRO and SAPIEN 3



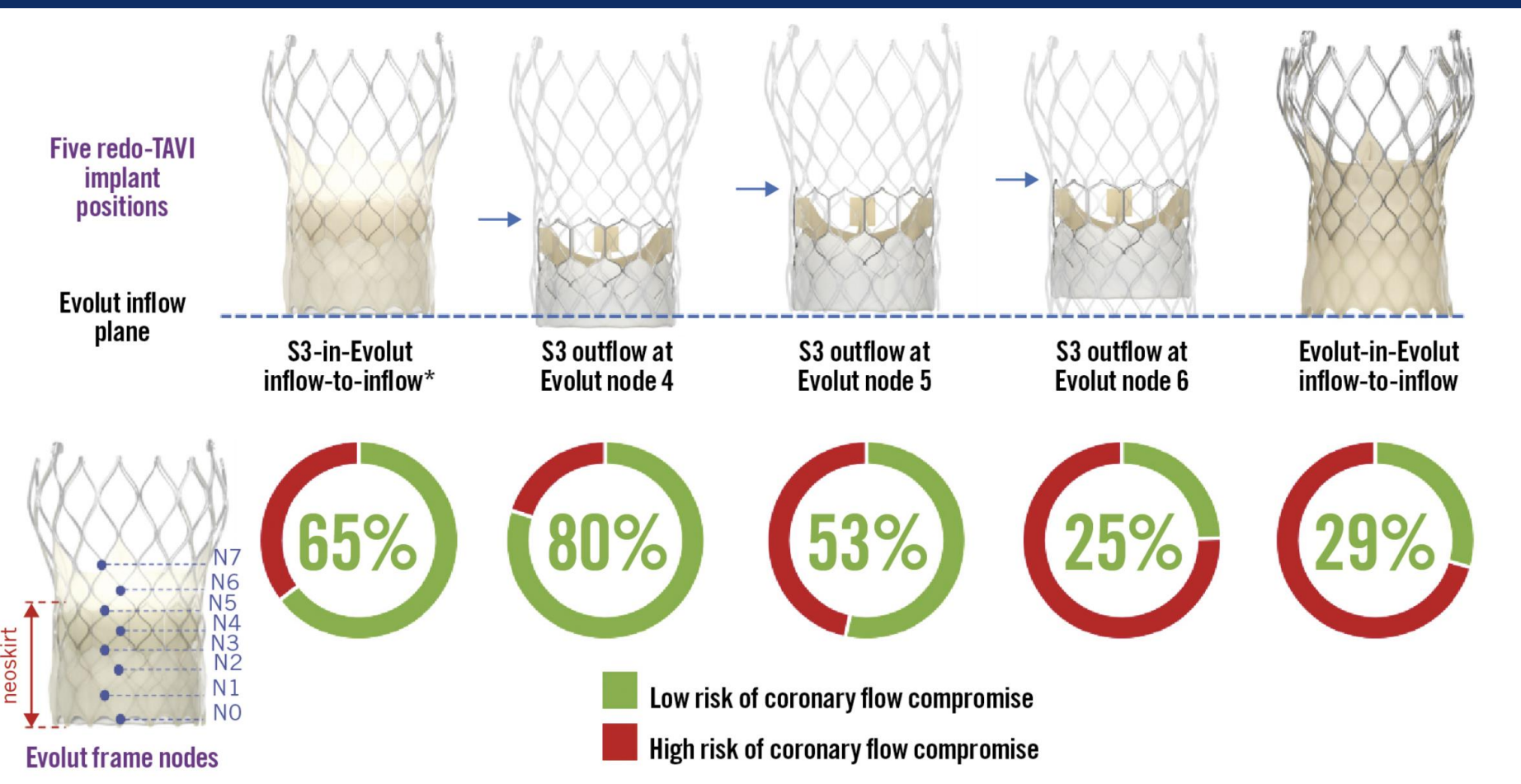
CT-identified risk of sinus sequestration in redo TAVR in prior Evolut R/Evolut PRO and prior SAPIEN 3 are shown. Abbreviations as in



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

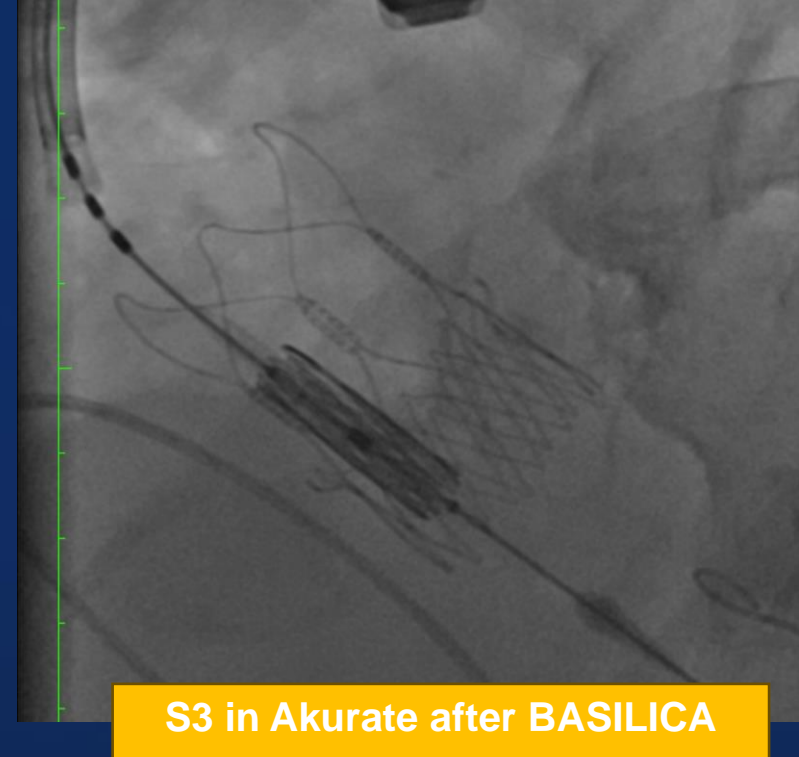
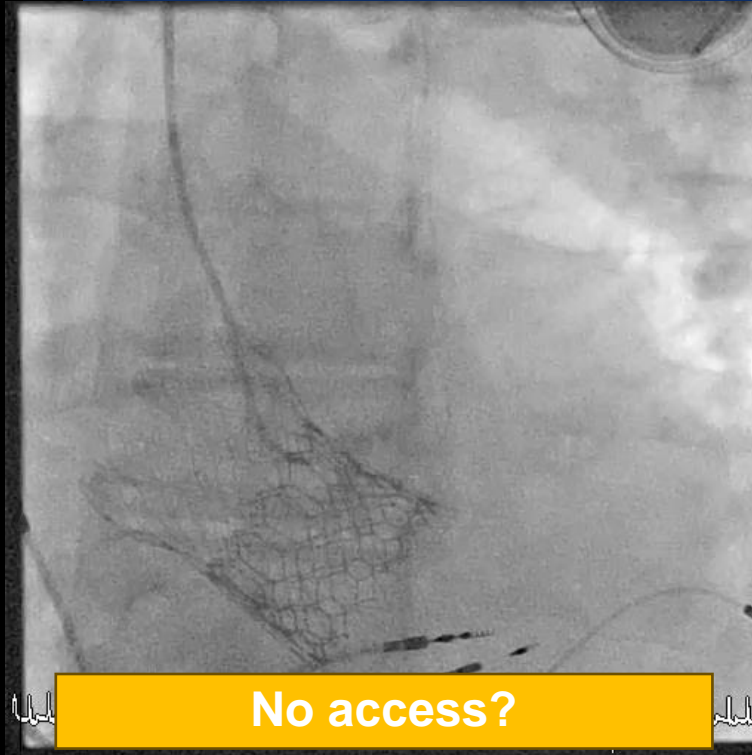
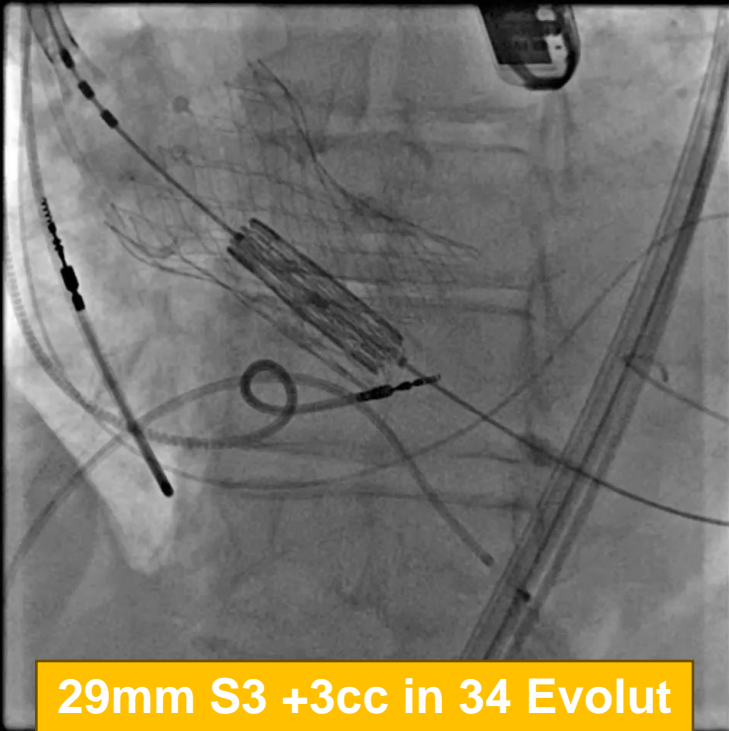


S3U in Evolut – implant lower to avoid coronary obstruction – in exchange for leaflet overhang



TAV-in-TAV – no coronary obstruction does not mean coronary access

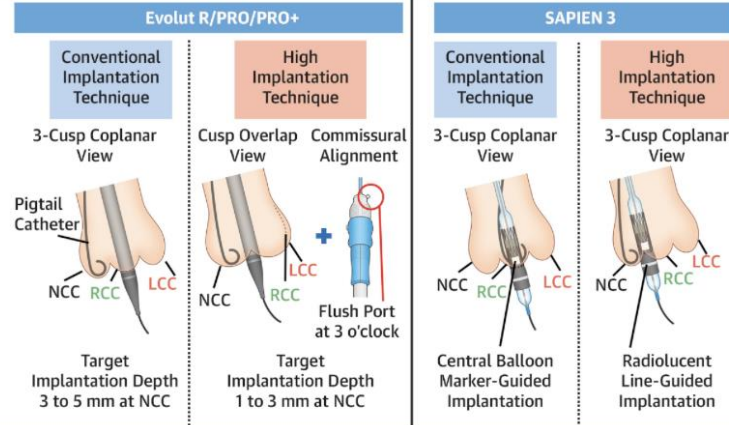
Lossy Compression - not intended for diagnosis



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

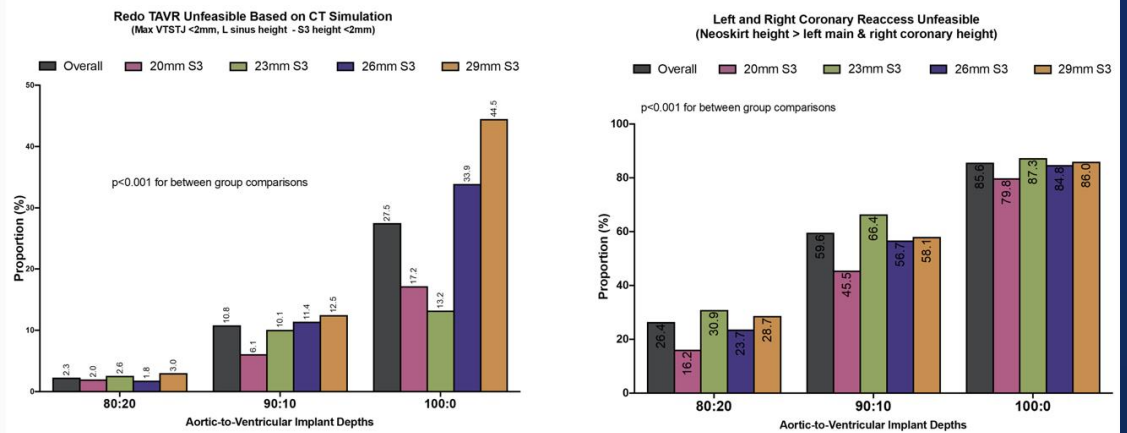
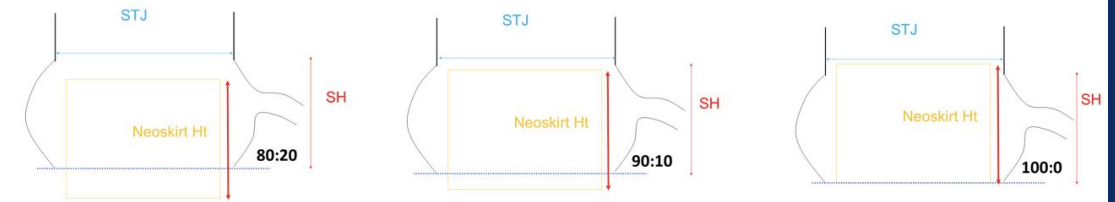


Conduction Disturbances After TAVR				
30-Day Permanent Pacemaker Implantation	10.8%	0.0%	2.2%	2.0%
New-Onset Persistent Left Bundle Branch Block	11.3%	4.2%	7.0%	1.1%

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:**
- 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)
 - Challenging coronary access with:
 - Shallow implant depth
 - Increasing THV size (across all implant depths)
 - If Commissural Alignment is attained (assuming utilization of leaflet modification techniques) → Redo-TAVR 100% feasible

Redo TAVI App – Thanks Dr Fukui & Bapat!

21:09

REDO TAV

Supported by



Joseph F. and Mary M. Fleischhacker Family Foundation



Developed by
Dr. Miho Fukui
Dr. Vinayak (Vinnie) Bapat

Contributions by
Dr. Atsushi Okada



mplsheart.org/apps

21:16

CT Planning

Use this app workflow along with CT software

Index TAV and 2nd TAV combination specific

Steps

- 1 Index TAV & Measurements
- 2 Identify Coronary Risk Plane (CRP)
- 3 Select Second TAV
- 4 Choose NSP & Assess NSP/CRP
- 5 Second TAV Sizing
- 6 Coronary Risk Assessment
- 7 Summary Report
- 8 Pre-Index TAV CT Data (Optional)

CT Cardiac Phase to Use

Ideal: Mid-Diastolic (70-85%)

Alternative: End-Systolic (35-45%) or whenever least artifact

Step 1 →

S3-in-S3, MyVal-in-MyVal

Step 1. Confirm Index TAV

Step 2. Identify CRP in relation to index TAV

Step 3. Select second TAV

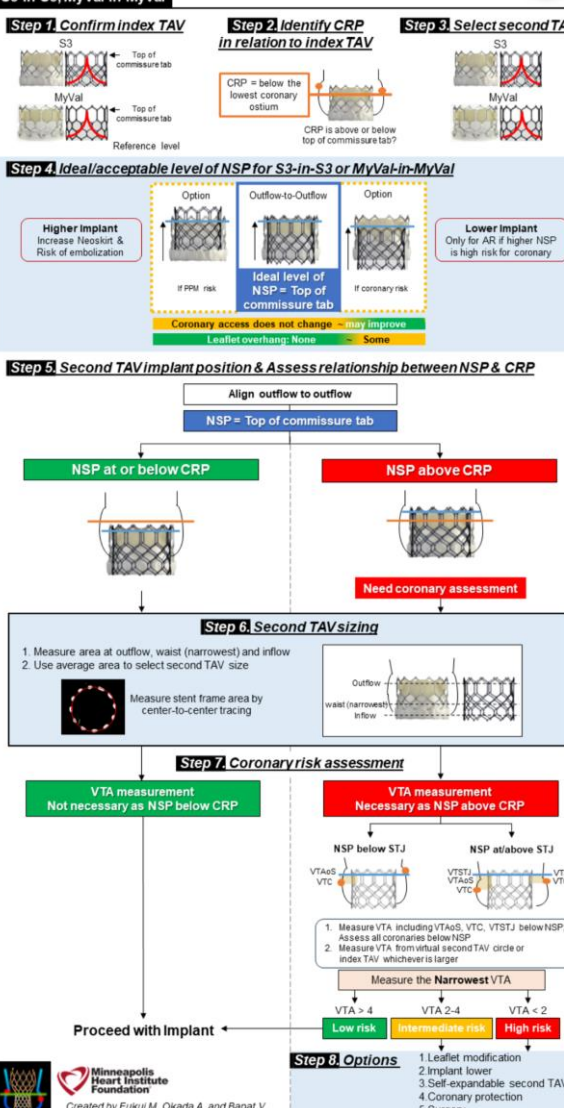
Step 4. Ideal/acceptable level of NSP for S3-in-S3 or MyVal-in-MyVal

Step 5. Second TAV implant position & Assess relationship between NSP & CRP

Step 6. Second TAV sizing

Step 7. Coronary risk assessment

Step 8. Options



Created by Fukui M, Okada A, and Bapat V

S3 in Evolut/Corevalve, MyVal in Evolut/Corevalve

Step 1. Confirm Index TAV

Step 2. Identify CRP in relation to index TAV

Step 3. Select second TAV

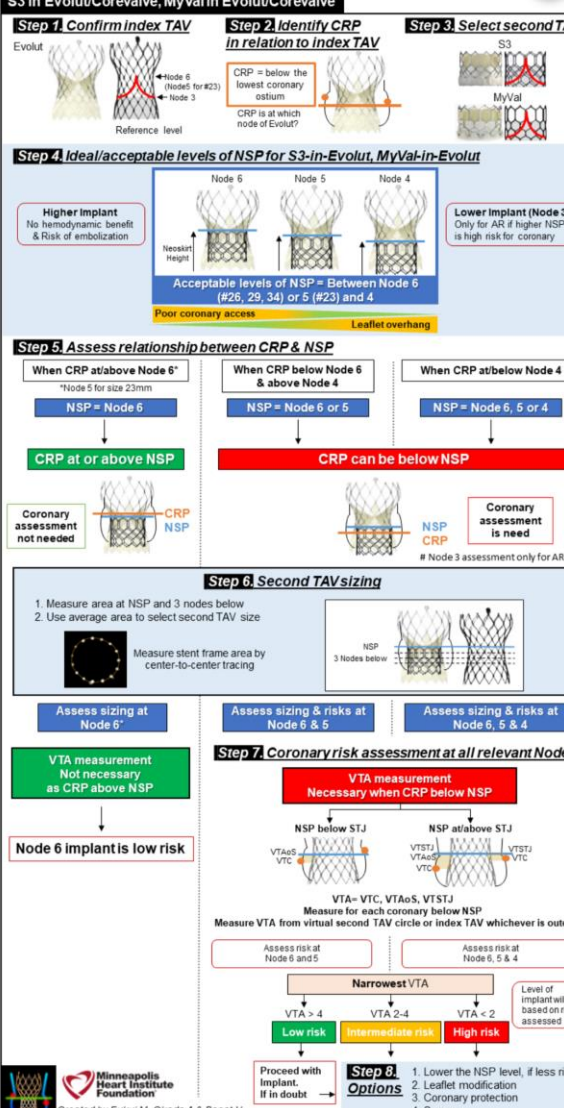
Step 4. Ideal/acceptable levels of NSP for S3-in-Evolut, MyVal-in-Evolut

Step 5. Assess relationship between CRP & NSP

Step 6. Second TAV sizing

Step 7. Coronary risk assessment at all relevant Nodes

Step 8. Options



Created by Fukui M, Okada A, and Bapat V

Several key take home practical tips

- TAV-in-TAV perhaps with GA?
 - Millimeter precision – aim for that Node 4
- Predilate/TRUE balloon 1st THV particularly BEV
 - Recognize and correct underexpansion of 1st THV
- Beware of further expansion of 1st THV particularly Evolut/CoreValve
 - VTA distance could be even less
- Cerebral embolic protection?

Conclusion

- TAV-in-TAV requires meticulous pre-procedural planning to avoid coronary obstruction.
- TAV-in-TAV requires optimized procedural set-up.
- There are **significant knowledge gaps** in TAV-in-TAV and whilst feasible in most cases with good outcomes ongoing collaboration particularly **post**procedural CTs will add to our understanding on this impending problem.
- Current data would support the use of a short-frame THV if future TAV-in-TAV is to be considered.
- Further, the index procedure should be optimized.