

TAV-in-TAV

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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
 - Unrestricted institutional grant (QHI)
 - Research role
- | Company |
|---|
| Edwards LifeSciences, Abbott Vascular |
| Edwards LifeSciences, Abbott Vascular |
| Edwards Lifesciences, Boston Scientific |

Clinical Background

Original procedure

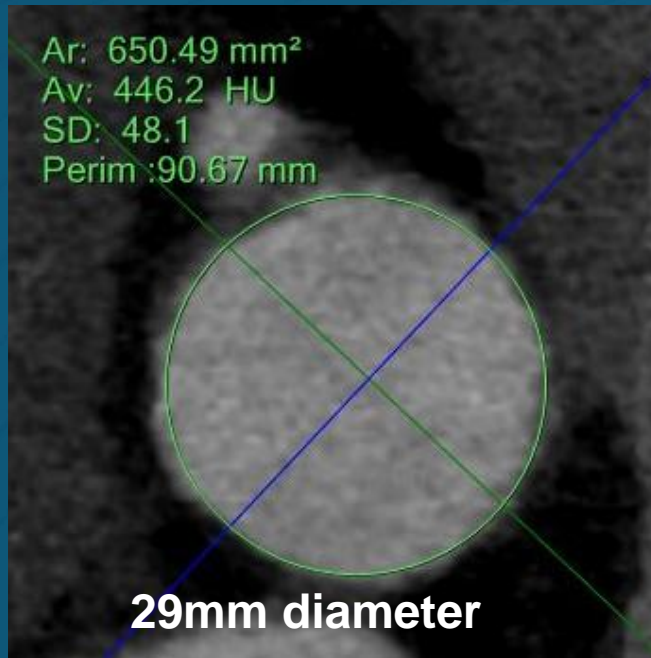
- 68 year old (2017) male, Jehovah's witness, severe aortic stenosis
- Coronary artery disease
 - CABG – 1996 – LIMA-Diagonal; RA-RCA
 - PCI to LCx 2001
 - PCI to LAD 2003; PCI to RCA 2005
- Normal LV systolic function
- Hypertension, Diabetes, OSA, GORD
- BMI 38
- Cardiac surgeon – TAVI recommended
 - Re-do; Jehovah's witness
 - **LIMA adherent to sternum** – high risk re-do

RISK SCORES	
About the STS Risk Calculator	
Procedure: AV Replacement	
Risk of Mortality:	1.998%
Morbidity or Mortality:	16.631%
Long Length of Stay:	5.316%
Short Length of Stay:	37.986%
Permanent Stroke:	1.396%
Prolonged Ventilation:	10.344%
DSW Infection:	0.343%
Renal Failure:	5.042%
Reoperation:	6.433%

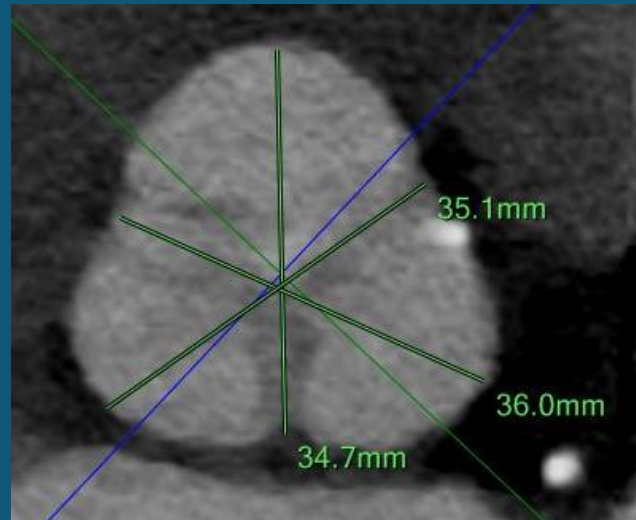
CT analysis

June 2017

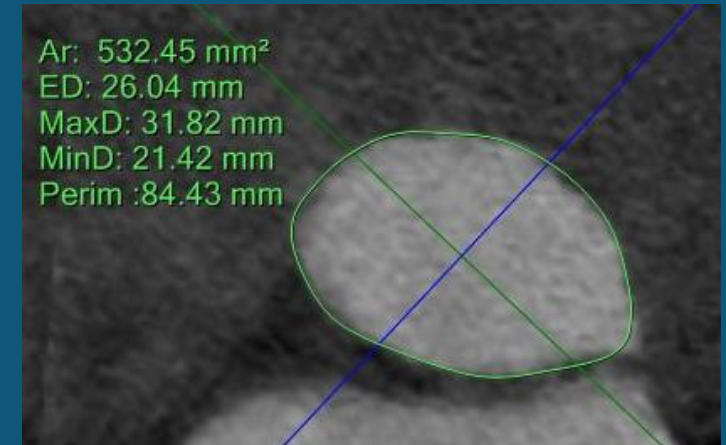
Sinotubular junction



Sinus of Valsalva



Aortic annulus



Area 535mm²

Perimeter 84mm

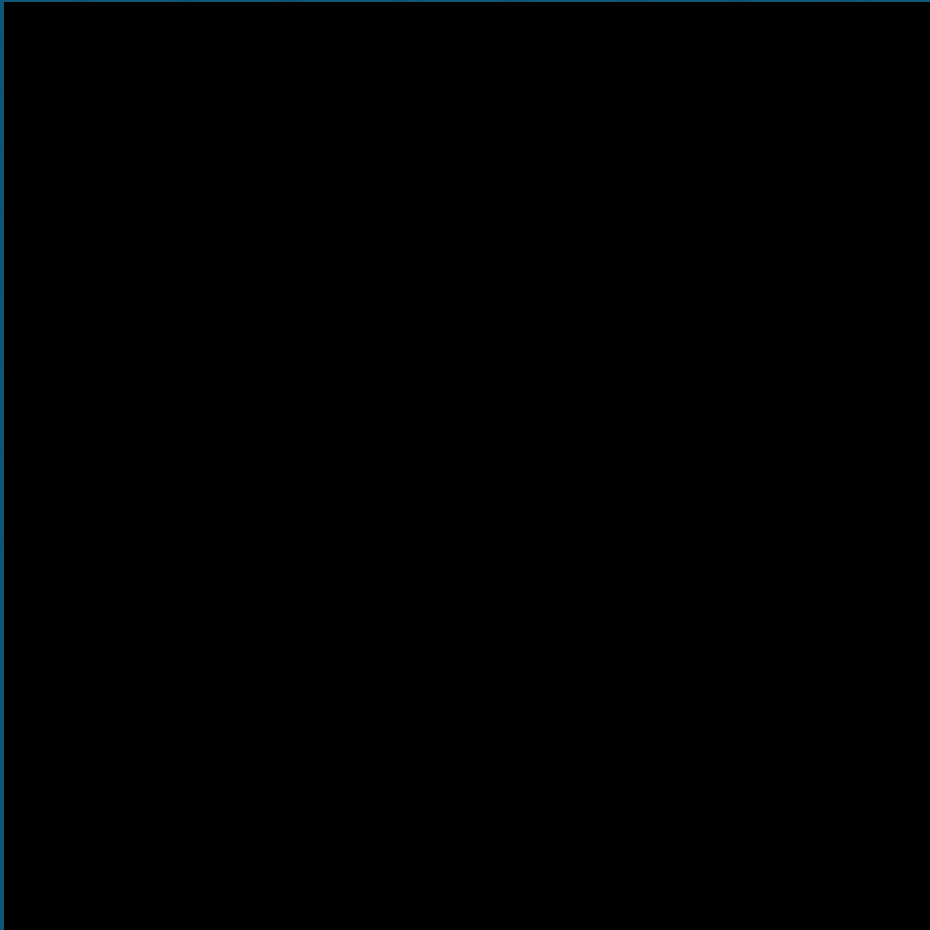
Max diameter 32mm

Min diameter 21mm

- ? Underfilled 29mm S3 (2017)

Original TAVI procedure – June 2017

Right transfemoral TAVI 29mm S3 -3cc filling



TAVI	Mean	Area	Vmax	PVL
Day 1	8mmHg	2.7 cm ²	2.1m/s	0-1

Uncomplicated discharge day 2 POD
Discharged on aspirin as single antithrombotic

TAVI	Mean	Area	Vmax	PVL
Day 180	14mmHg	2.5 cm ²	2.7m/s	0-1

Five years post TAVI

- Increasing exertional dyspnoea
- Local cardiologist:
 - Coronary angiography and graft study:
 - Unchanged
 - “Unlikely reason for dyspnoea”
- Year 5...
 - “Request for redo TAVI as soon as possible”
- Melanoma – immunotherapy – new

TAVI	Mean	Area	Vmax	PVL
Day 1	8mmHg	2.7 cm ²	2.1m/s	0-1

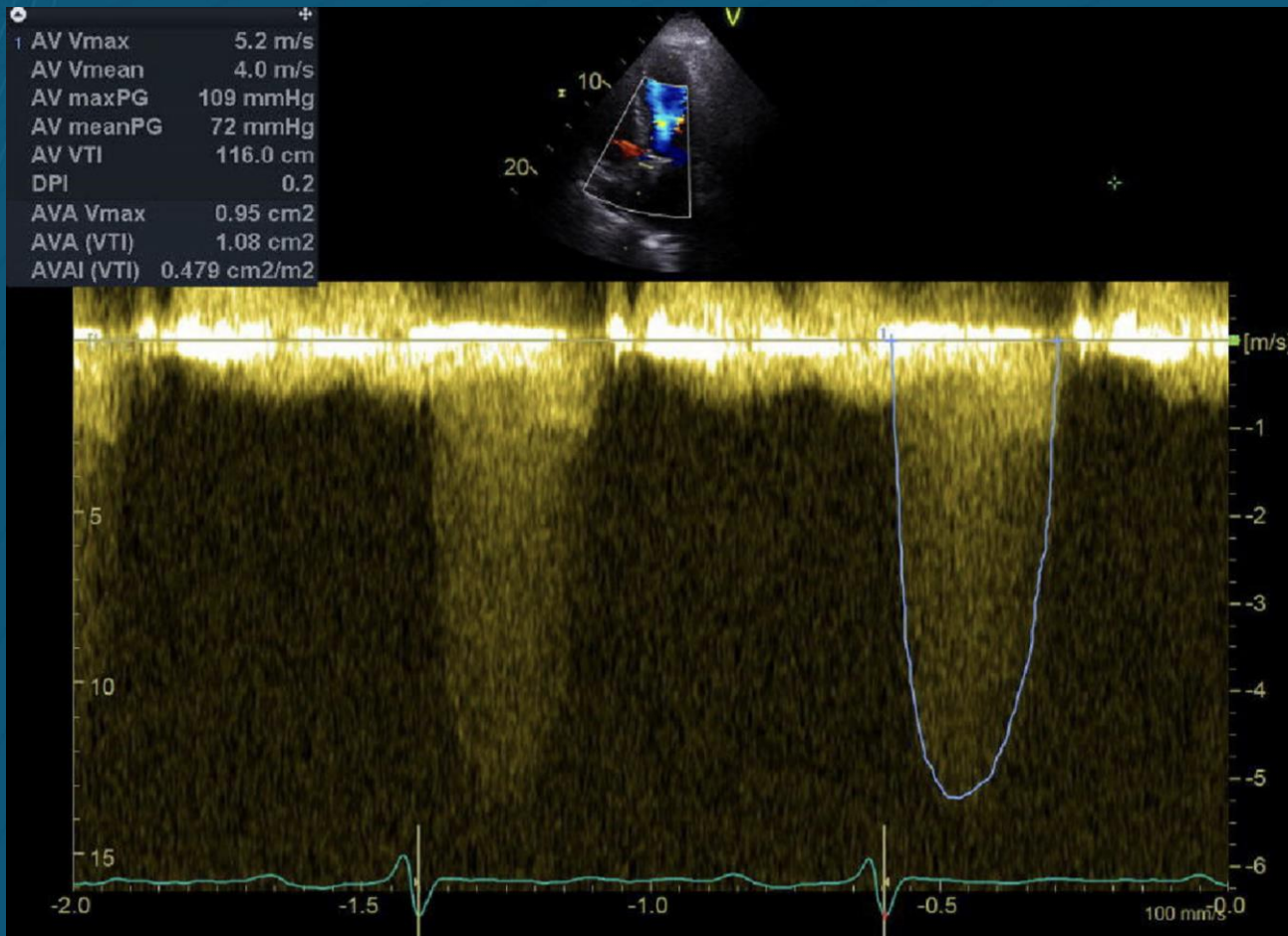
TAVI	Mean	Area	Vmax	PVL
Day 180	14mmHg	2.5 cm ²	2.7m/s	0-1

TAVI	Mean	Area	Vmax	PVL
Year 4.5	18mmHg	1.6 cm ²	3.0m/s	0-1

TAVI	Mean	Area	Vmax	PVL
Year 5	43mmHg	0.8 cm ²	4.0m/s	0-1

TAVI stenosis assessment

TTE and TEE



- TEE comments

- Heavily restricted THV leaflets
- Heavily calcified
- Possible thrombus

- Discharged on DOAC & return for likely TAV-in-TAV

TAV-in-TAV assessment

Step by step approach

- **Confirmation of diagnosis**
 - Stenosis
 - Regurgitation
- **Exclusion of other diagnoses or confounders**
 - Pseudo-stenosis vs. true stenosis
 - LVOT gradient
 - Patient prosthesis mismatch – e.g. high baseline gradient
 - Infective endocarditis
 - Thrombus

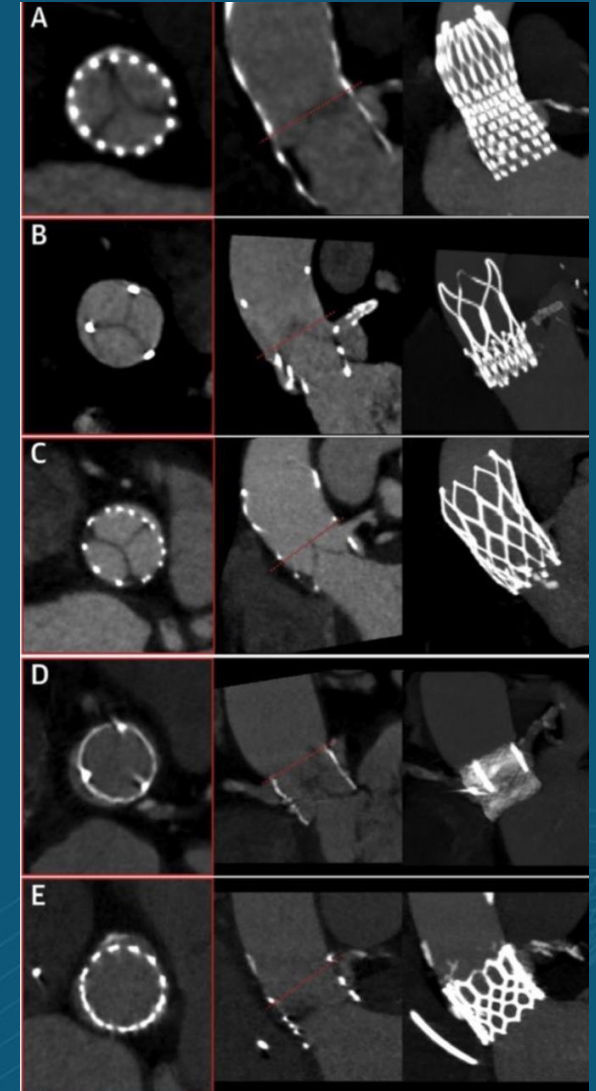
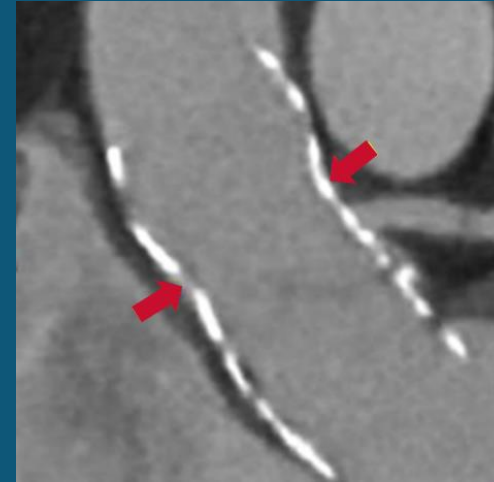
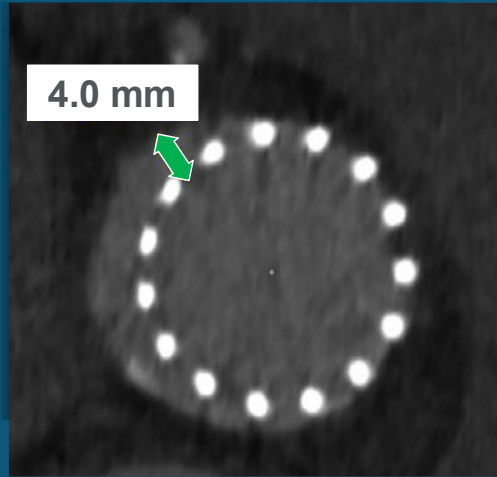
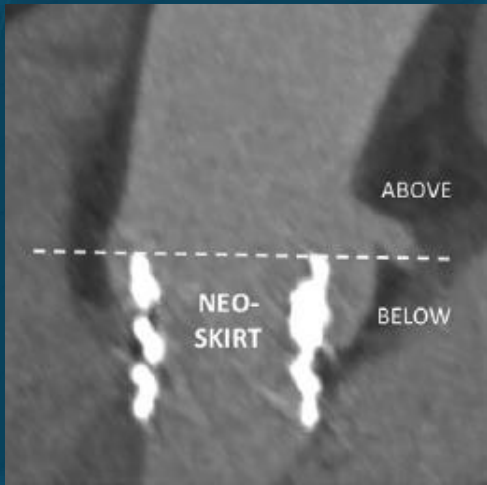
TAV-in-TAV assessment

Step by step approach

- **ALWAYS OBTAIN ORIGINAL CT IF POSSIBLE**
 - Sizing decision/THV decision
 - Calcium? Hostile anatomy? Hostile root?
- **OBTAIN ORIGINAL IMPLANT FLUOROSCOPY IF POSSIBLE**
 - Although possible to reimage particular in reference to coronary location and root anatomy
- **ANALYSE CT TAVI**
 - Risk plane; STJ and sinus sequestration risk
 - Neo-skirt
 - Original THV expansion profile

TAV-inTAVI: neoskirt and risk plane

Coronary occlusion risk assessment



Risk Plane

Level under which the stent frame of the index THV would be covered by its leaflets when they are displaced vertically with the implantation of the second THV.

VTA (Valve-to-Aorta) Distance

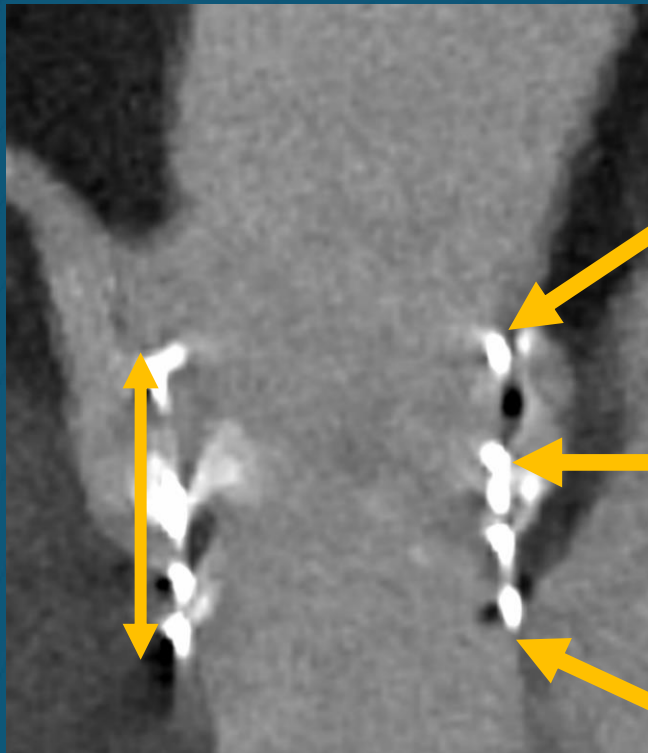
The level at which the prosthesis frame is in closest proximity to the aortic wall and represents the bottleneck where the catheter is not able to further navigate toward the coronary ostium.

Sinus Sequestration

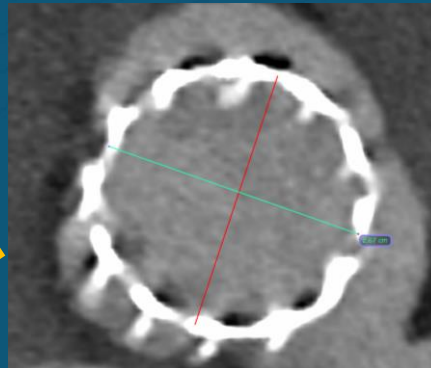
The distance is measured from a virtual valve equal to the size of the THV, to the coronary ostia.

TAV-in-TAV: current case CT analysis

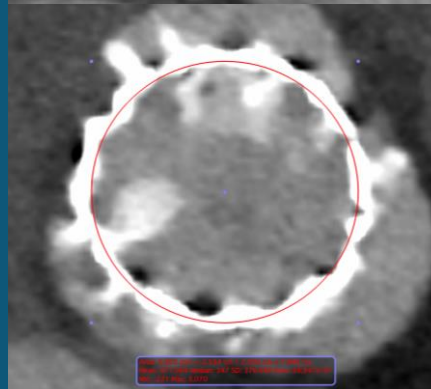
An under-expanded THV



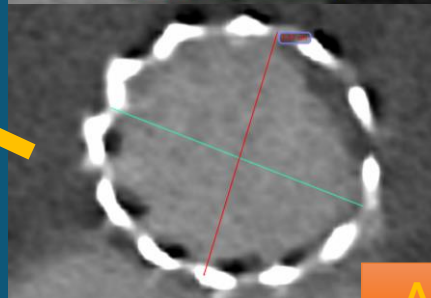
Height
23.9mm



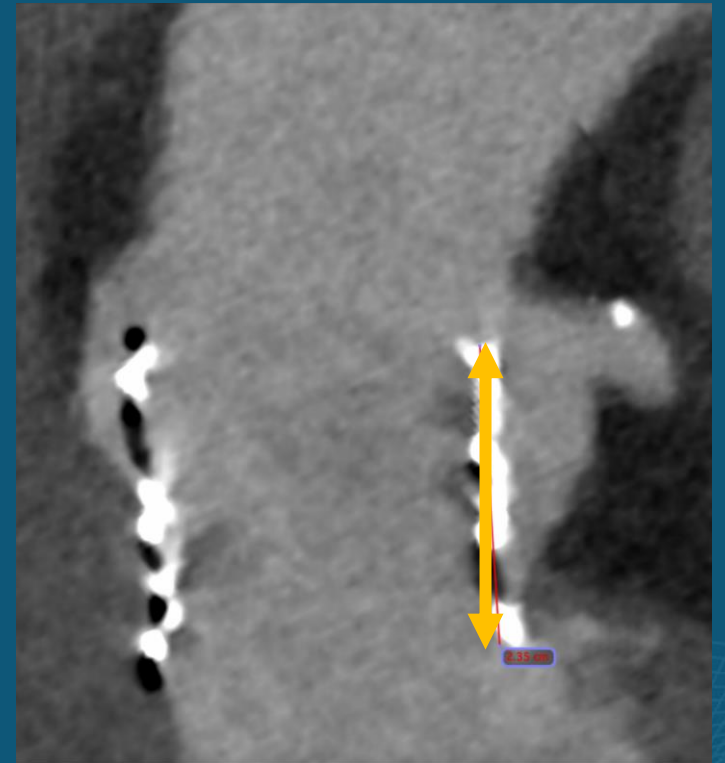
Diameter
26.5mm



Diameter
25.5mm



Diameter
26mm



Height
23.5mm

TAV-in-TAV procedure

Summary of analysis

Diagnosis

- severe/critical stenosis, possible thrombus, no regurgitation, no obvious vegetation

THV characteristics

- An underexpanded (intentionally) 29mm S3 with final expansion profile 26mm or less
- Taller stent frame

Coronary occlusion risk

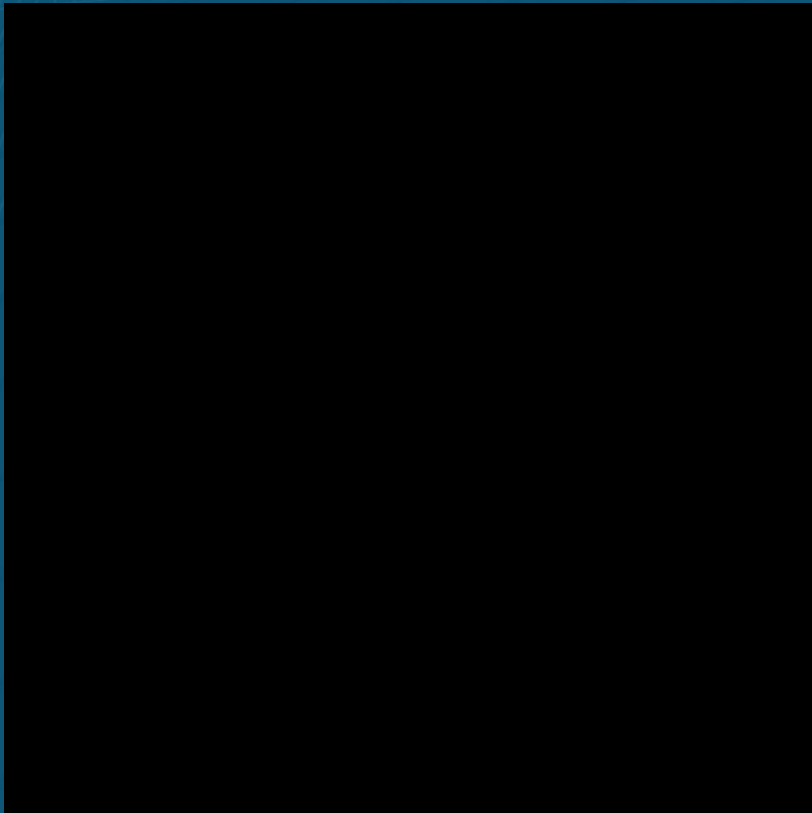
- Nil (also protected/partially grafted vasculature)

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 Procedure



TRUE 26mm balloon inflation
S3 26mm in waiting

S3 26mm +2cc inflation @ 9ATM
Top of new THV as per previous

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

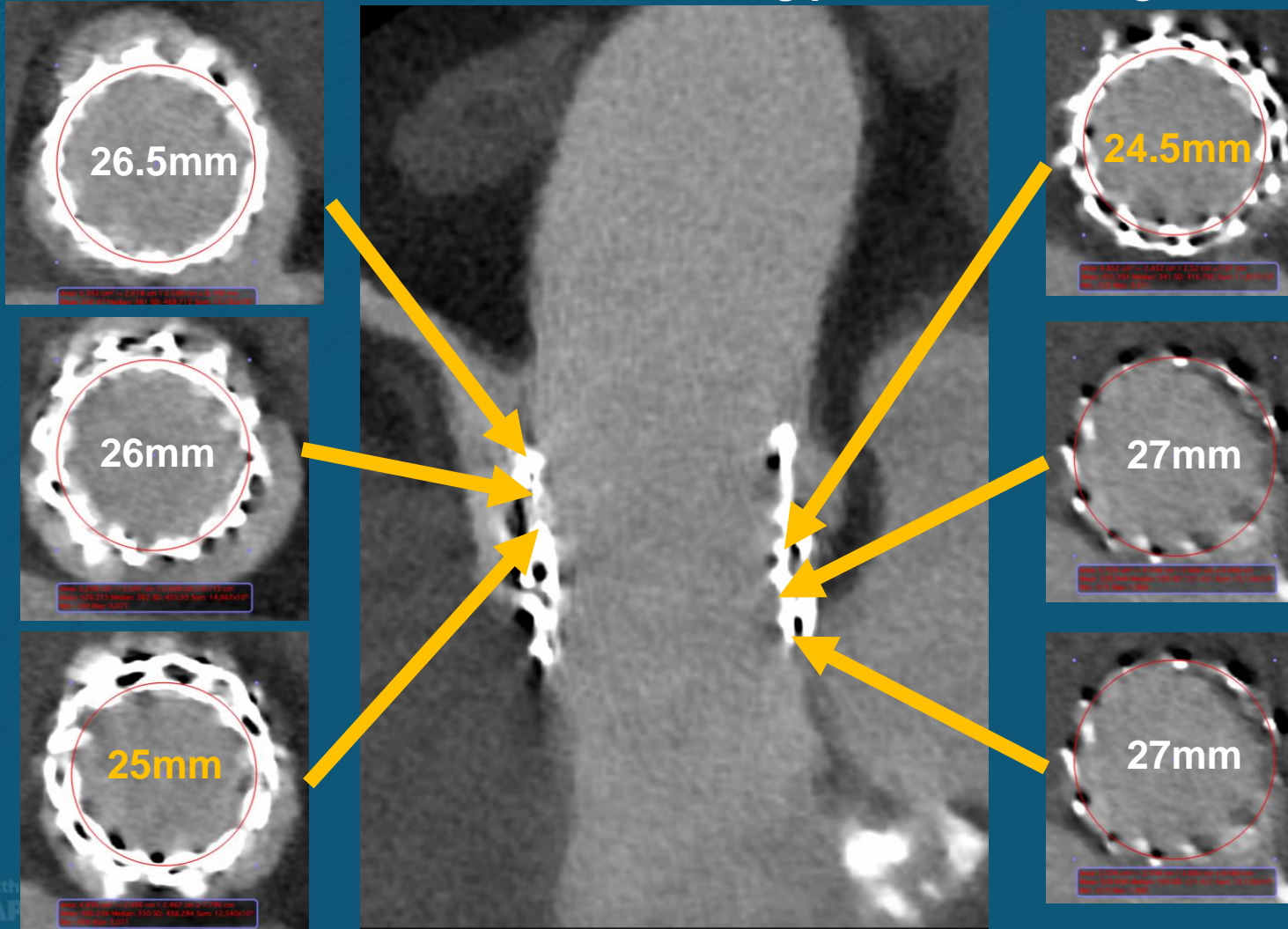
- Mean gradient: 12mmHg
- Peak: 27mmHg
- EOA: 2.6cm²

TRUE 26mm balloon inflation

Coaptation length on TEE from 9mm to
4mm

TAV-in-TAVI postscript – CT TAVI

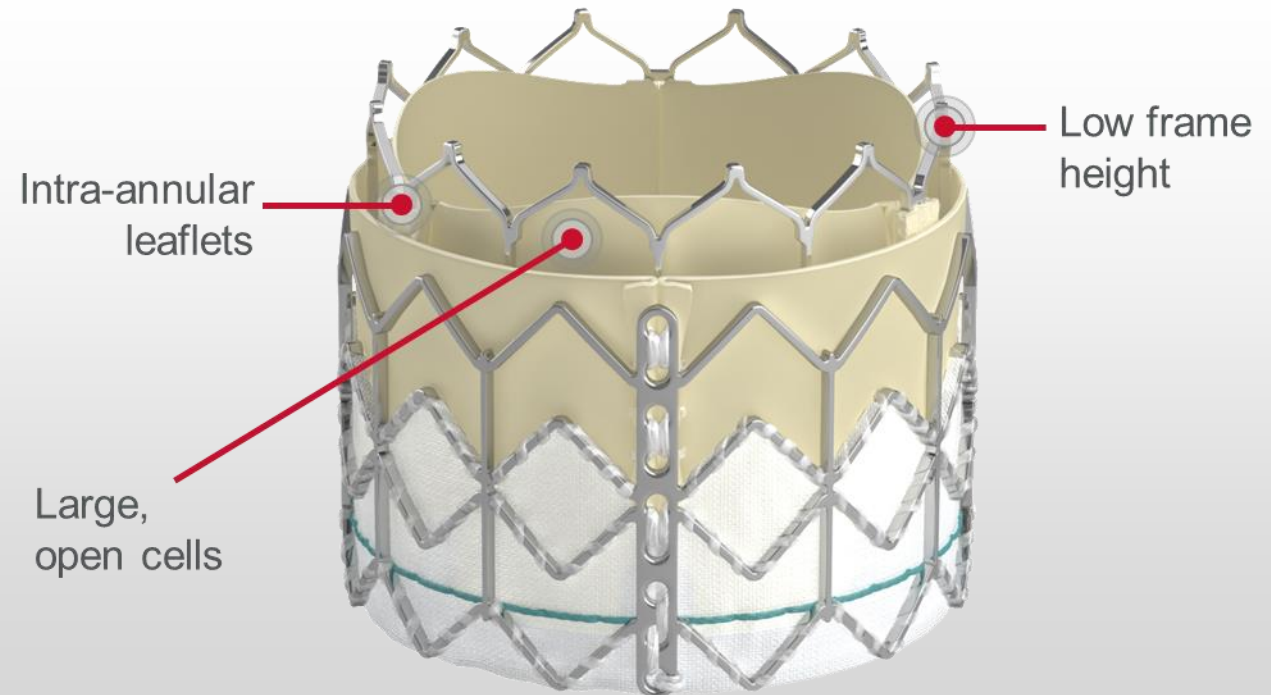
Learning points – challenges for TAV-in-TAV



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

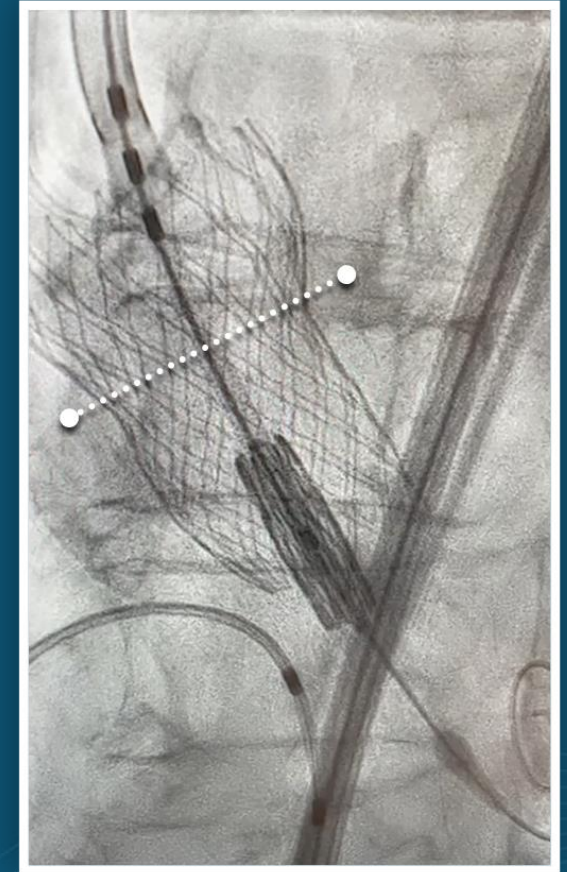
Supporting Future Interventions: THV-in-THV Applications

- Only the Edwards SAPIEN 3 THV and the Edwards SAPIEN 3 Ultra THV platforms are currently indicated for THV-in-THV implantation in the United States



Supporting Future Interventions: THV-in-THV Applications

- **Leaflet overhang** results when the index THV leaflets “*overhang*” the top of the second THV
 - Includes instances of placing a shorter intra-annular valve inside an index supra-annular valve
 - High index valve implantation height may increase risk of future leaflet overhang
- **Consequences may include:**
 - Suboptimal blood flow
 - Inadequate closing of the leaflets, which may lead to regurgitation
 - Impact to longevity of the second valve



Lifetime management – TAV-in-TAV – don't bank on it

Repeat Transcatheter Aortic Valve Replacement for Transcatheter Prosthesis Dysfunction



Uri Landes, MD,^{a,b} John G. Webb, MD,^a Ole De Backer, MD,^c Lars Sondergaard, MD, MSc,^c

	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;

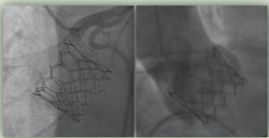
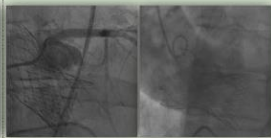
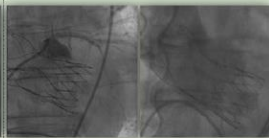
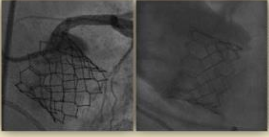
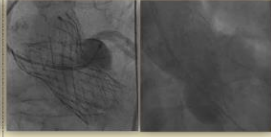
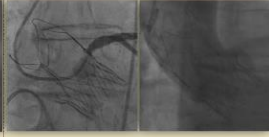
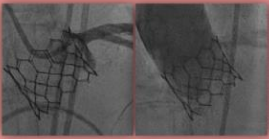
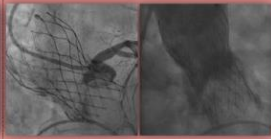
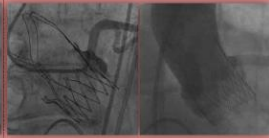
- TRANSIT
 - N=172 TAVI in TAVI
 - No coronary obstruction (!!)
- Caution:
 - Selection bias – how many cases rejected?
 - Case series only

Lifetime management – TAV-in-TAV – don't bank on it

Journal of the American Heart Association

ORIGINAL RESEARCH

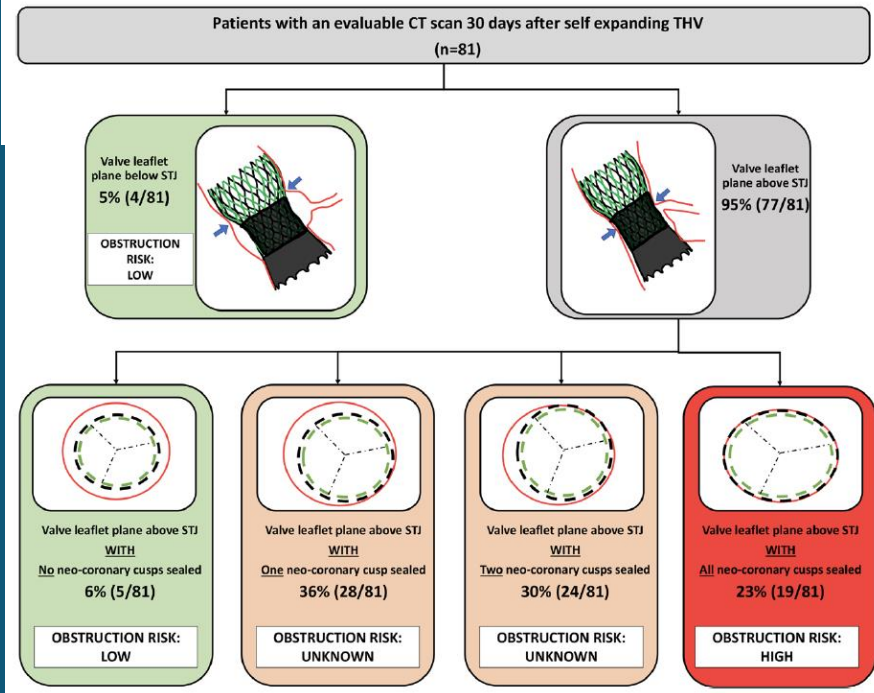
Coronary Angiography After Transcatheter Aortic Valve Replacement (TAVR) to Evaluate the Risk of Coronary Access Impairment After TAVR-in-TAVR

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

Circulation: Cardiovascular Interventions

A specially challenging combination of supra-annular THV with narrow sinotubular junction

Risk of Coronary Obstruction and Feasibility of Coronary Access After Repeat Transcatheter Aortic Valve Replacement With the Self-Expanding Evolut Valve



Controversies in TAVI-in-TAVI

- Optimal 1st THV?
- Re-do THV device?
- Predilate? Predilate with TRUE balloon?
- SEV in BEV; SEV in SEV; BEV in BEV; SEV in BEV???
- Trapped tissue between THV? Nidus for thrombosis?
- Placement of re-do THV?

TAV-in-TAV: a new disease

- There are some case series on TAV-in-TAV focusing on **feasibility** and **survival** in TAV-in-TAV.
- No literature of failed TAVI not suitable for TAV-in-TAV – EXPLANT vs. TAV-in-TAVI. Poor results from some EXPLANT studies.
- Even if TAV-in-TAV may be feasible, **significant knowledge gap**:
 - Technical considerations
 - Durability?
 - Hemodynamics?
- With this knowledge gap, more important than ever to plan the first TAVI (or consider surgery) in **younger patients** for the future.

TAV-in-TAV: key concepts

- 1. Index procedure –obtain original CT data & implant images if possible**
 - Understand sizing strategy and original anatomy
 - Understand the implication of THV placement and suprannular vs. intrannular
- 2. Pre procedural planning – CT TAVI**
 - Comprehensive understanding of THV placement, leaflet, STJ, coronary etc
- 3. Procedural plan**
 - Anticipate the need to predilate – perhaps more for BEV?
 - Sentinel? BASILICA? Short-cut?
- 4. Post procedural plan**
 - ? Anticoagulate?