Valve-in-Valve TAVR:
Challenges and Solutions

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AP Valves 2023- 10 mins

Disclosures

Grant Support/Drugs

- MyoKardia/BMS

Grant Support/Devices

- Edwards Lifesciences
- Boston Scientific
- CathWorks
- I-Rhythm

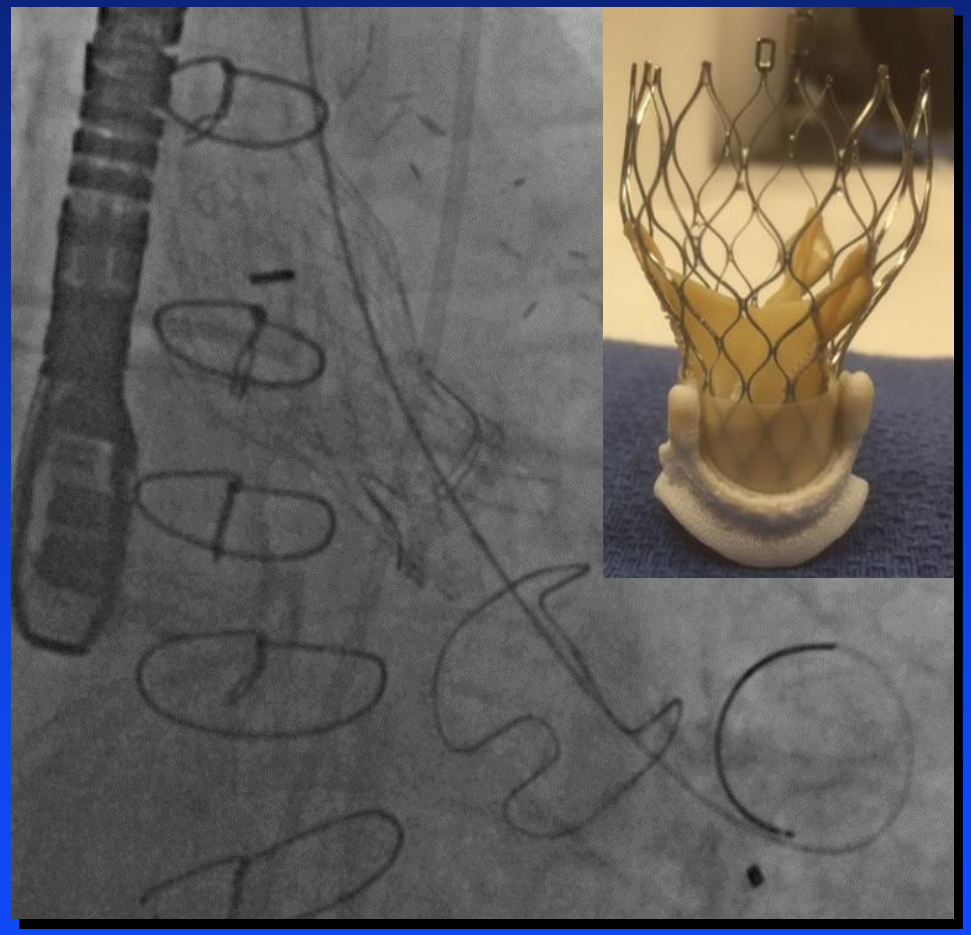
- Abbott Vascular
- Corvia
- Phillips
- Zoll/Therox

Consulting/Advisory Boards

- Medtronic
- Boston Scientific
- HeartBeam

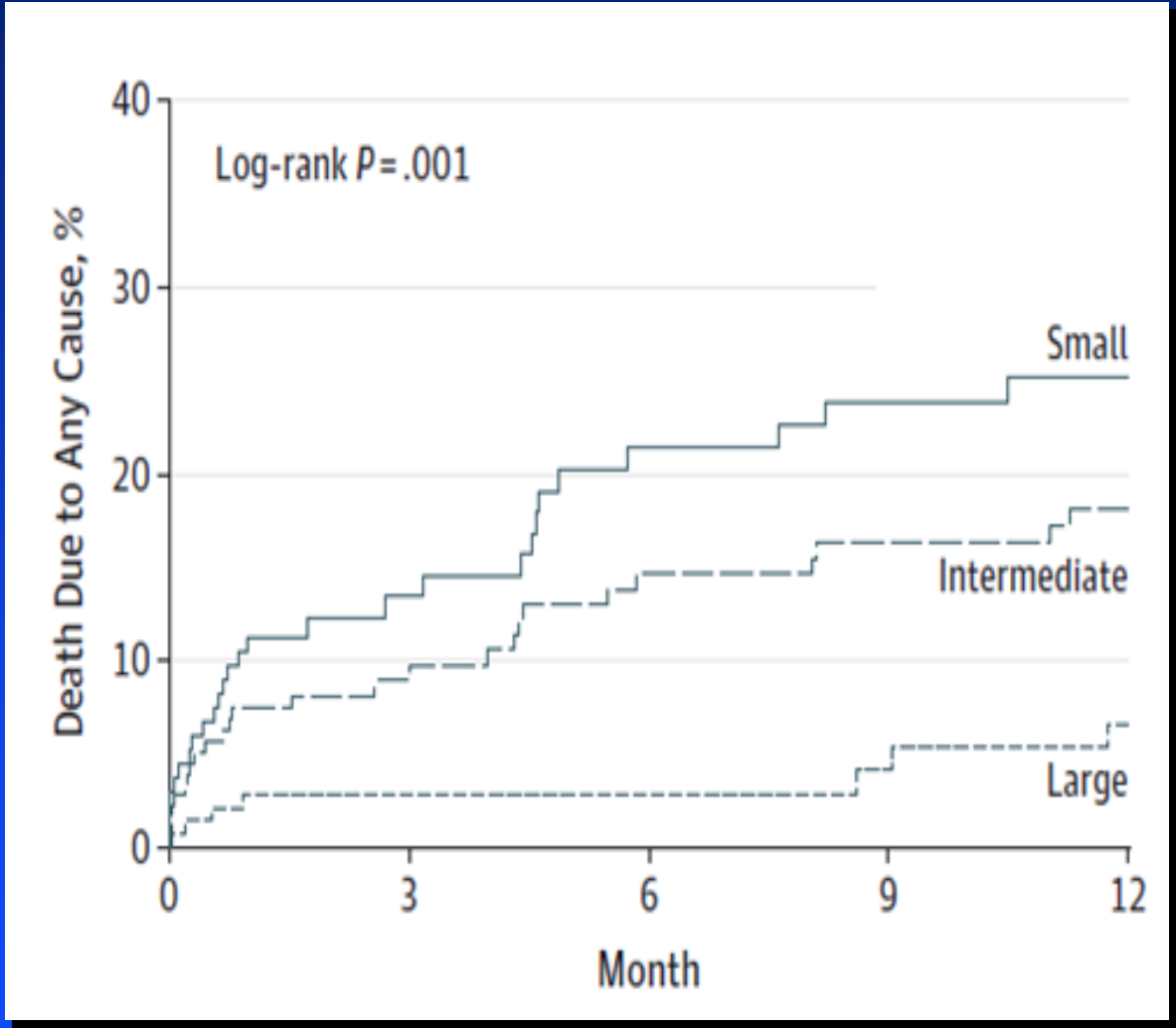
- Edwards Lifesciences
- Abbott Vascular

Valve-in-Valve TAVR



- Represents ~5% of all TAVRs in US
- At present, there are 2 major challenges in performing ViV TAVR
  - Patient-prosthesis mismatch (especially when treating small surgical valves)
  - Coronary obstruction

Impact of Surgical Valve Size on 1-Year Mortality



VIVID Registry

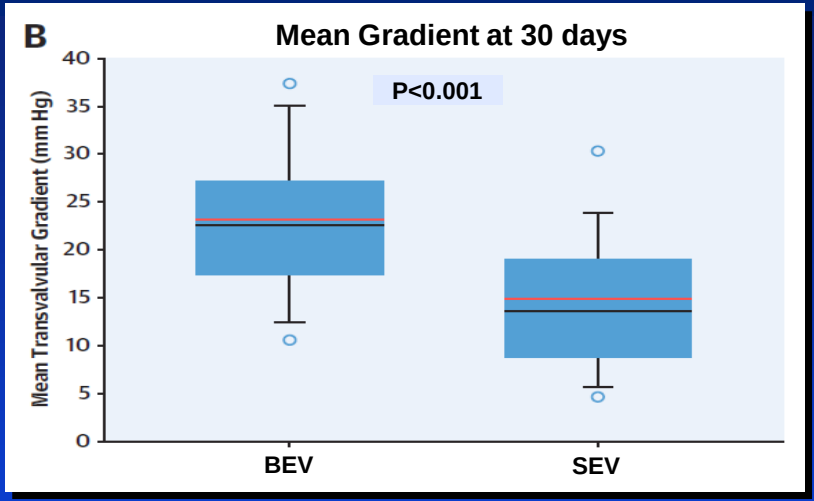
- 459 pts with failed surgical bioprostheses treated with ViV TAVR (59% balloon expandable, 41% self-expanding)
- Patients stratified based on size of original surgical valve
  - *Small ≤ 21 (n=133)*
  - *Medium 22-24 (n=176)*
  - *Large ≥ 25 (n=139)*
- Small surgical valve independently associated with 1-year mortality (HR 2.04, p=0.02) → likely due to patient-prosthesis mismatch

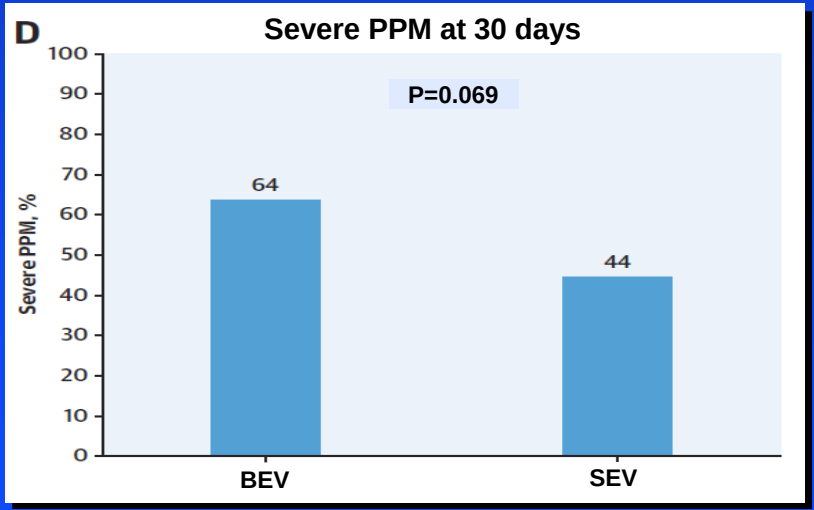
Dvir D, et al. JAMA 2014;312:162-170

Preventing Patient-Prosthesis Mismatch

- TAVR device selection
- TAVR positioning
- Bioprosthetic valve fracture

ViV TAVR: Device Selection





LYTENS Trial

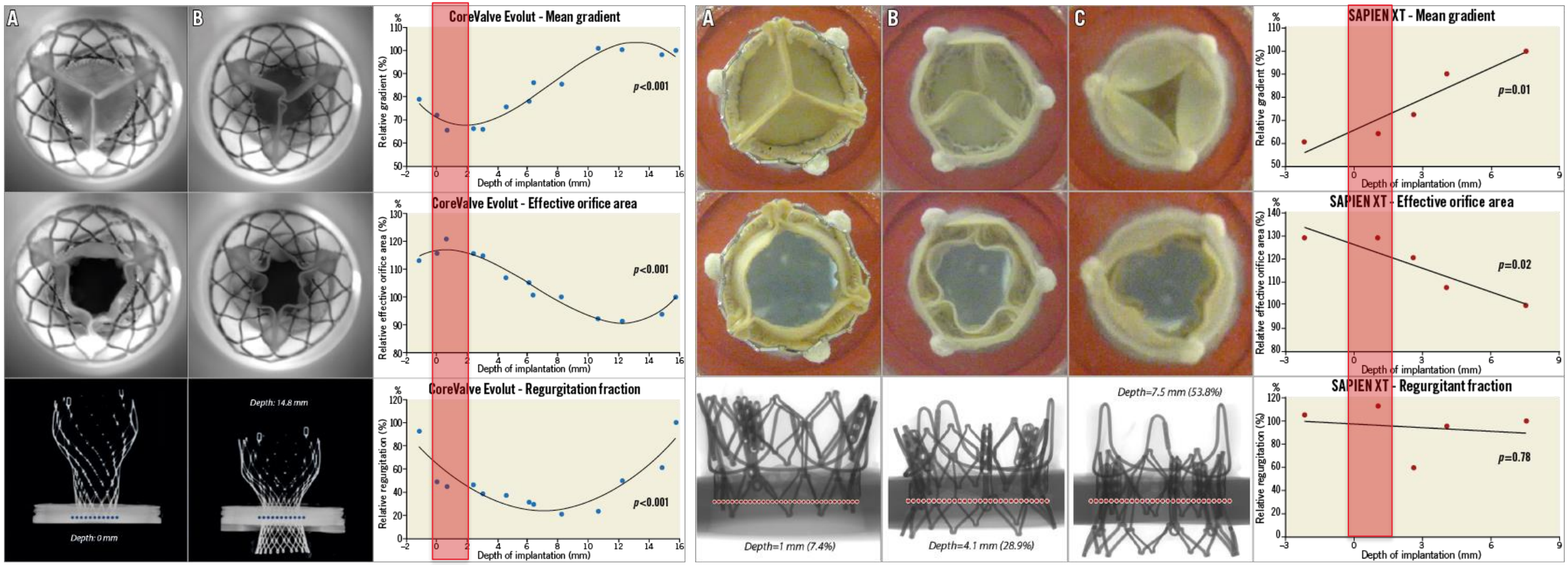
- 98 patients with failed small surgical bioprosthesis (<23 mm) randomized to BEV (S3) vs. SEV (Evolut-R, EV-PRO)
- Primary endpoint: Mean AoV gradient at 30 days by TTE
- Results
  - Immediate post-procedure invasive gradients similar
  - Mean gradient at 30-days lower with SEV (15 vs. 23 mmHg; p<0.001)
  - Severe PPM trended lower with SEV (64% vs. 44%, p=0.07)
  - Despite less BVF in SEV group (13% vs. 30%, p=0.04)

Rodes-Cabau J, et al. JACC Intv 2022; 80:681-93

Preventing Patient-Prosthesis Mismatch

- TAVR device selection
- TAVR positioning
- Bioprosthetic valve fracture

Impact of Implantation Depth on Hemodynamics



High implant (lowest depth) optimizes hemodynamics with both SEV and BEV

Simonato, et al. EuroIntervention 2016;12:909-917

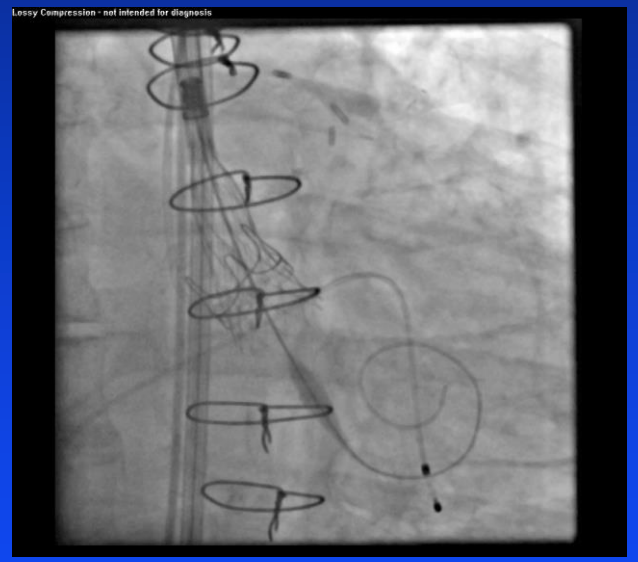
Preventing Patient-Prosthesis Mismatch

- TAVR device selection
- TAVR positioning
- Bioprosthetic valve fracture

Preventing Patient-Prosthesis Mismatch

Prior 19 mm Magna (TRUE ID 17mm); VIV TAVR performed with 23 mm Evolut R

Baseline



After 26 mm EVOLUT

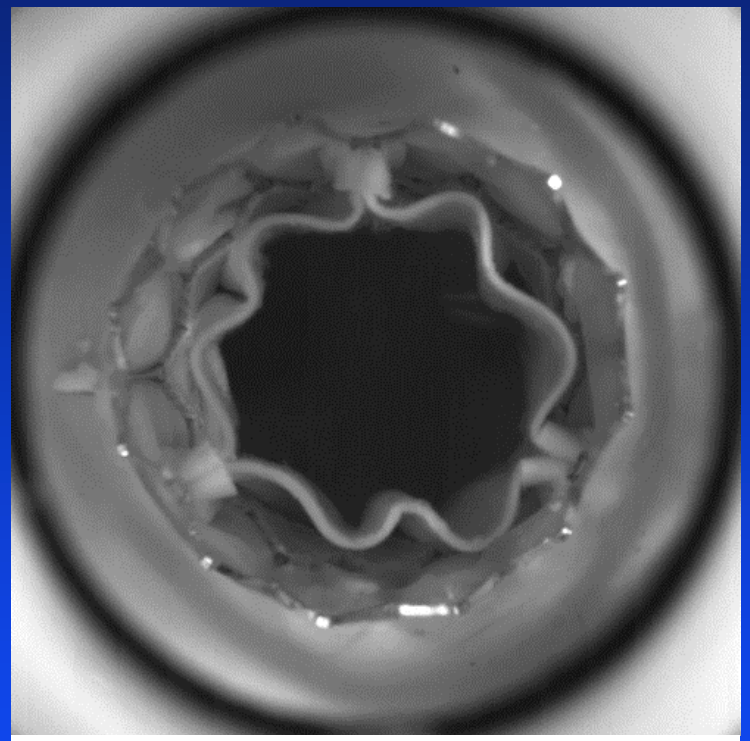
Mean gradient = 63 mmHg
AVA 0.8 cm2

Mean gradient = 44 mmHg
AVA 1.0 cm2

BVF with 20 mm True Balloon (18 atm)

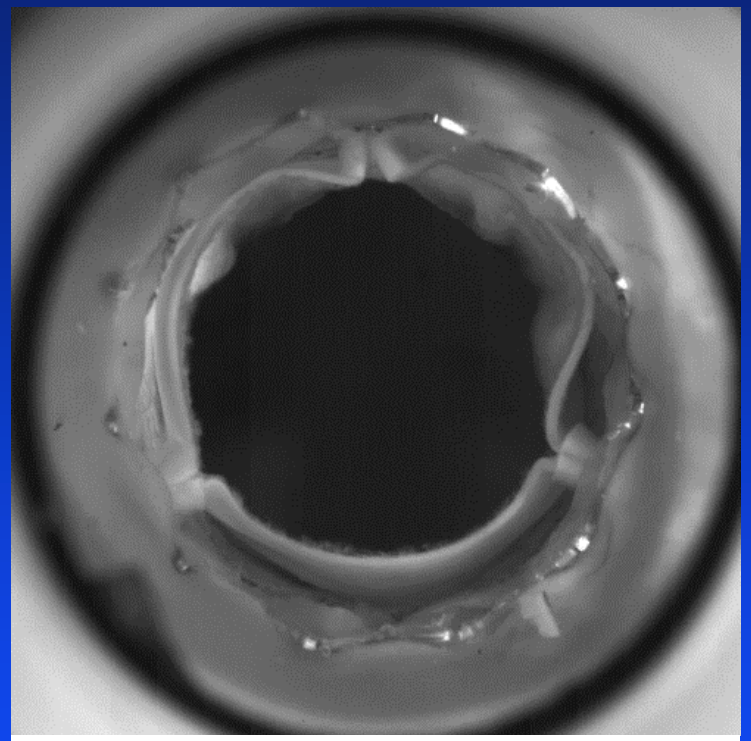
Mean gradient = 18 mmHg
AVA 1.9 cm2

Effects of THV Underexpansion



Before BVF:
"Pinwheeling"

BVF



After BVF:
No "Pinwheeling"

Courtesy of J. Sathananthan and J. Webb

Not All Valves Can Be Fractured

Valves that can be fractured
Biocor Epic
Magna/Magna Ease
Mitroflow
Mosaic
Perimount (newer generation, perforated ribbon)
Inspiris

Chhatrwialla AK, et al. Circ Cardiovasc Interv. 2018

Not All Valves Can Be Fractured

Valves that can be fractured	Valves that can be "remodeled"
Biocor Epic	C-E Standard
Magna/Magna Ease	C-E SAV
Mitroflow	Perimount (older generation)
Mosaic	Trifecta
Perimount (newer generation, perforated ribbon)	
Inspiris	

Chhatrwialla AK, et al. Circ Cardiovasc Interv. 2018

Not All Valves Can Be Fractured

Valves that can be fractured	Valves that can be "remodeled"	Neither
Biocor Epic	C-E Standard	Avalus
Magna/Magna Ease	C-E SAV	Hancock II
Mitroflow	Perimount (older generation)	
Mosaic	Trifecta	
Perimount (newer generation, perforated ribbon)		
Inspiris		

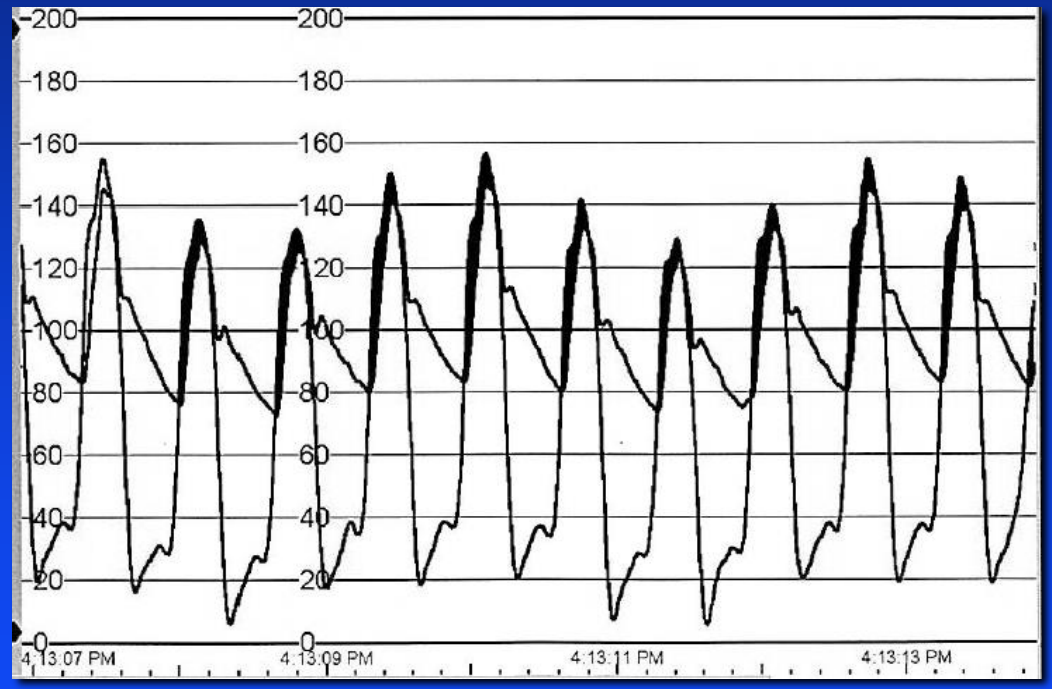
Chhatrwialla AK, et al. Circ Cardiovasc Interv. 2018

Bioprosthetic Valve Remodeling (BVR)

Prior 21 mm Trifecta (TRUE ID 19mm); VIV TAVR performed with 23 mm Evolut R

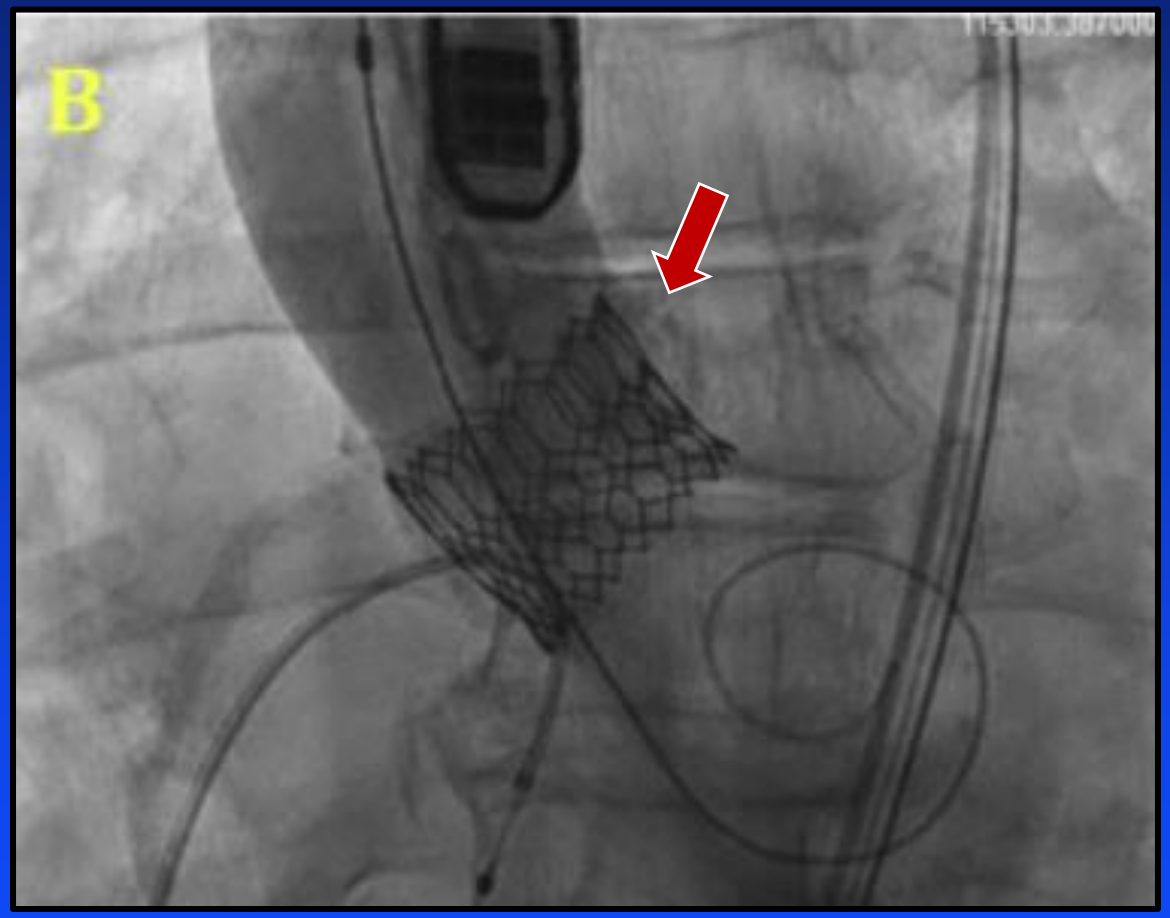
Mean gradient 29 mmHg, AVA 1.0 cm^2 after VIV TAVR → ***BVR***

22 mm True Balloon (10 atm)



Mean gradient = 13 mmHg
AVA = 1.4 cm^2

Coronary Obstruction



Spanish TAVI Registry (2009-2021)

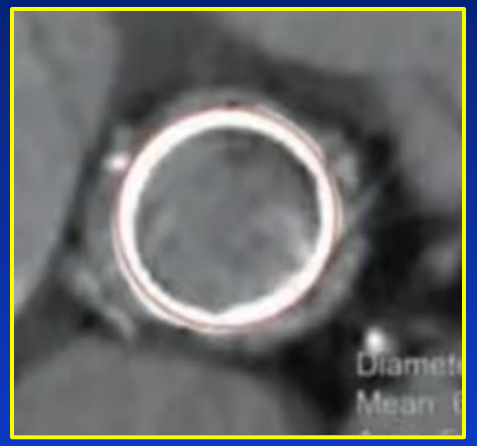
- Incidence 0.8% → constant over time
- Incidence ~5% in ViV TAVR (↑5x vs. native TAVR)
- In-hospital mortality 37%
- Most cases occur during procedure but ~15% present late (including 5% after discharge)

Ribeiro et. al. JACC Intv 2013

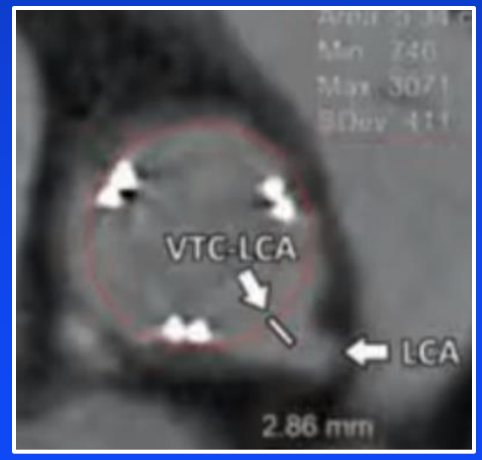
Ojeda S, et al. JACC Intv 2023

Risk Factors for Coronary Obstruction

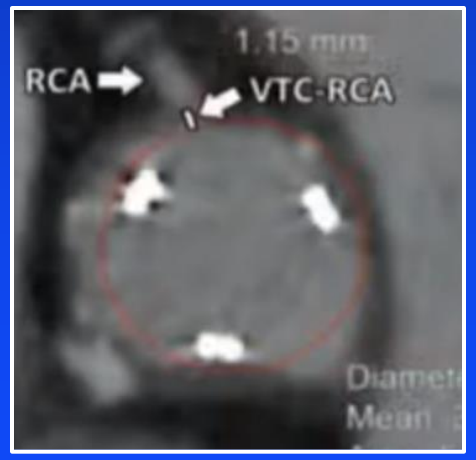
- Small/effaced sinuses of Valsalva
- Low coronary height (<10 mm)
- Valve to coronary (VTC) distance < 4 mm
- Surgical valve with leaflets mounted external to valve frame (Mitroflow, Trifecta)



- 21 mm Mitroflow
- Planned 23 mm S3 with BVF



LM VTC 2.8 mm

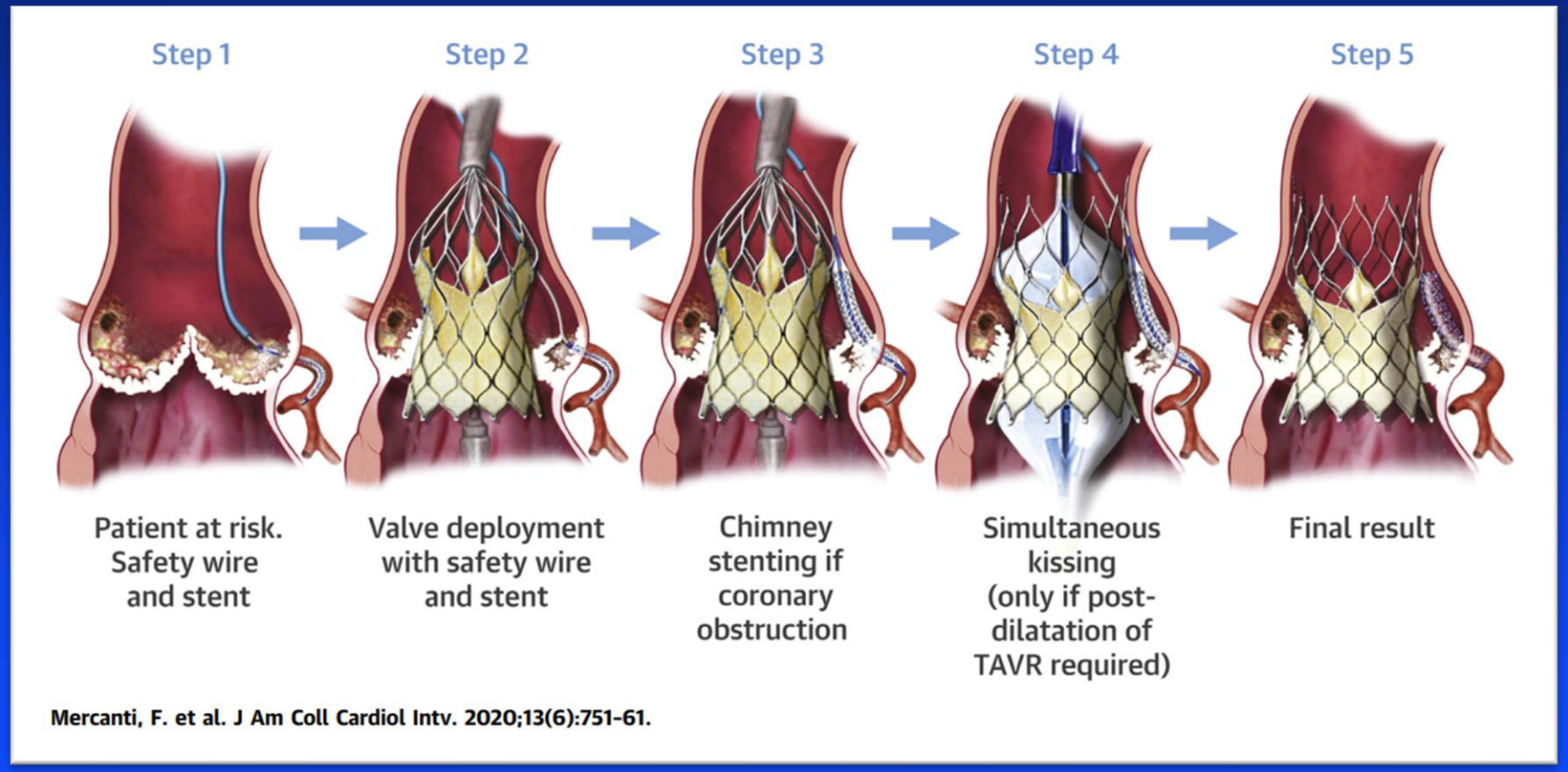


RCA VTC 1.2 mm

Preventing Coronary Obstruction with ViV TAVR

- Coronary protection/chimney stenting
- Leaflet modification

Coronary Protection/Chimney Stenting



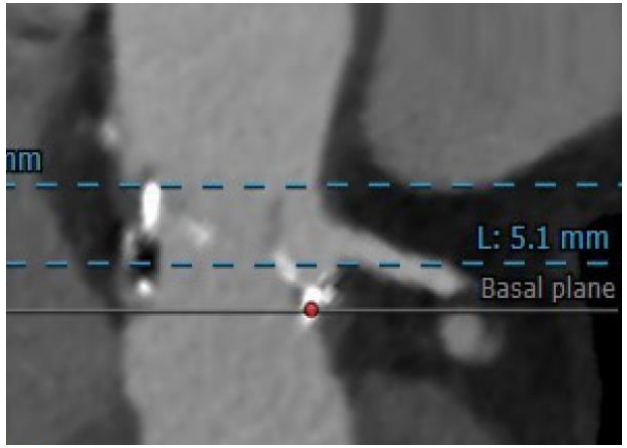
Mercanti, F. et al. J Am Coll Cardiol Intv. 2020;13(6):751-61.

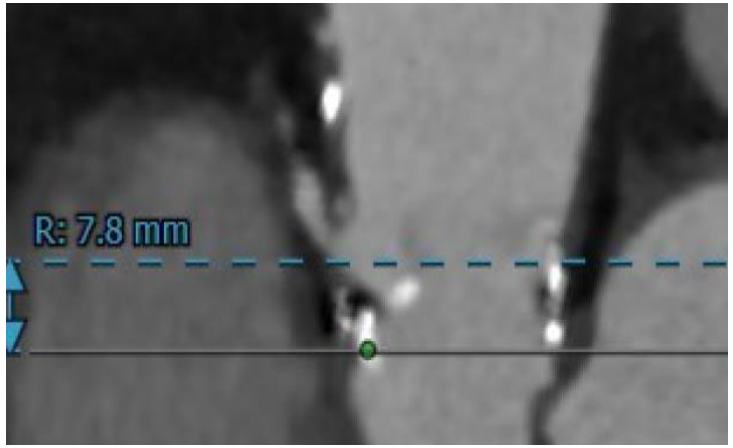
- Can consider protection with wire and guide extension catheter to avoid challenges with stent removal
- Makes future coronary reaccess very difficult or impossible

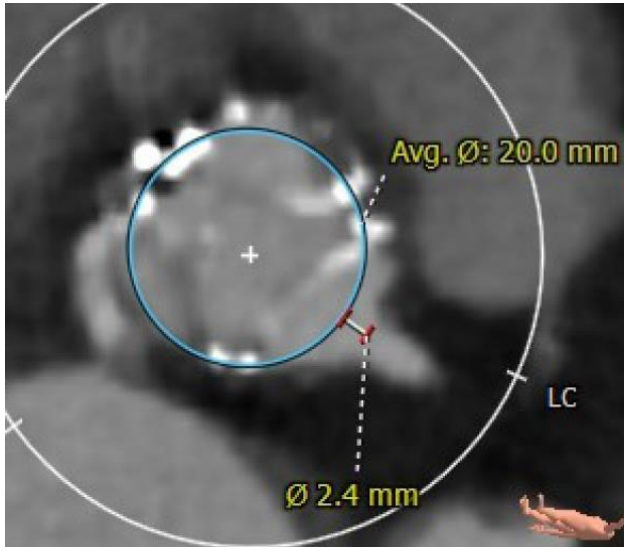
Preventing Coronary Obstruction with ViV TAVR

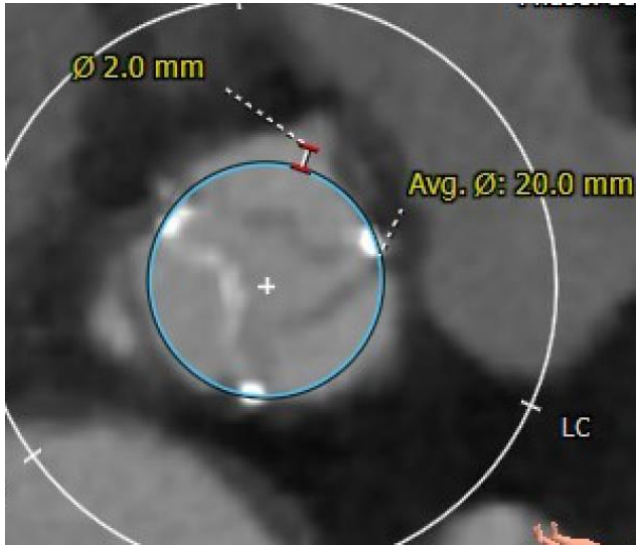
- Coronary protection/chimney stenting
- Leaflet modification

ViV Trifecta: Double BASILICA



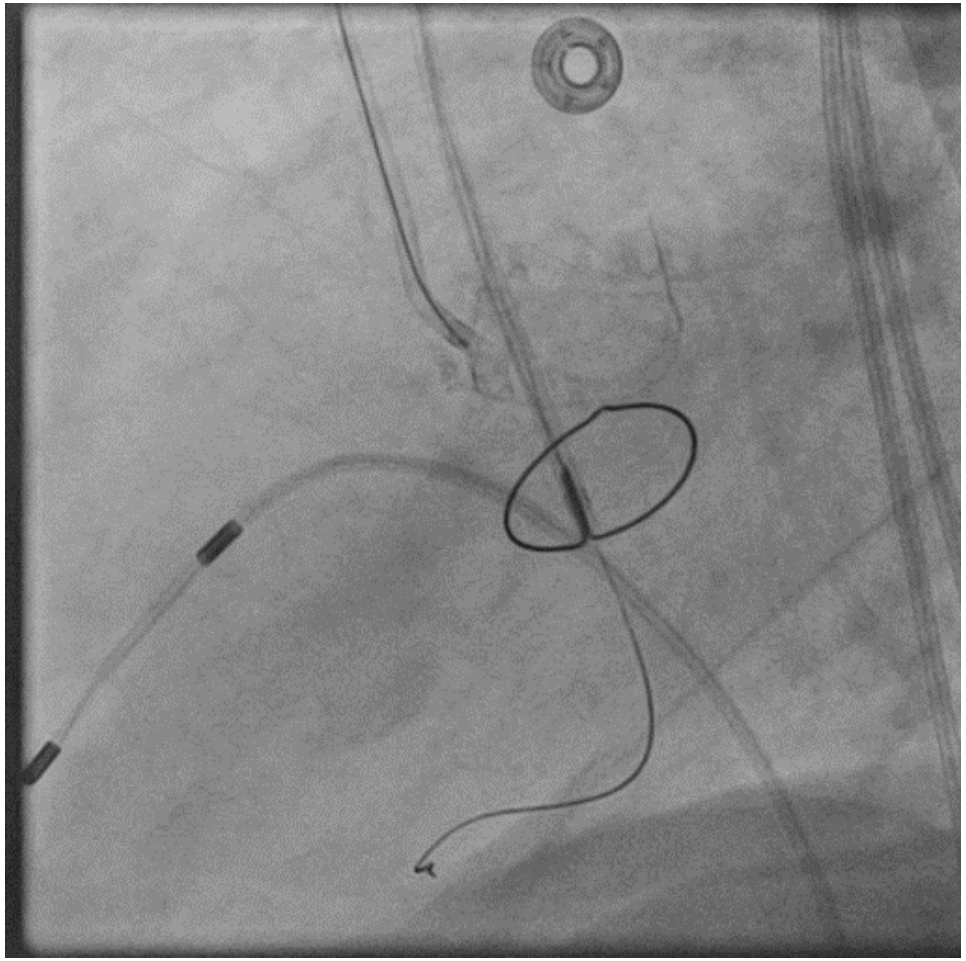


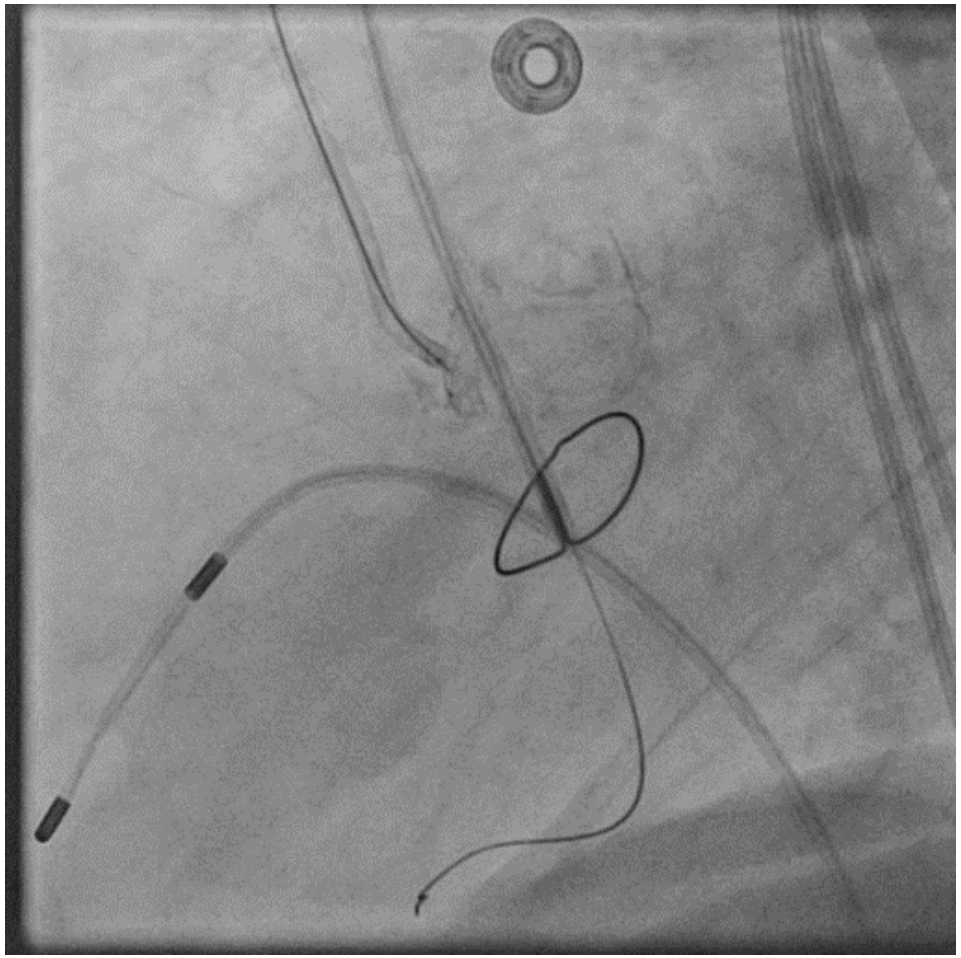




- 84 y.o. man with severe bioprosthetic AS (21 mm Trifecta)
- Pre-TAVR CT demonstrates effaced sinuses with LCA VTC 2.4 mm and RCA VTC 2.0 mm
- Coronary heights 5.1 mm and 7.8 mm
- Planned for ViV TAVR with 20 mm S3 valve (to preserve future coronary access)

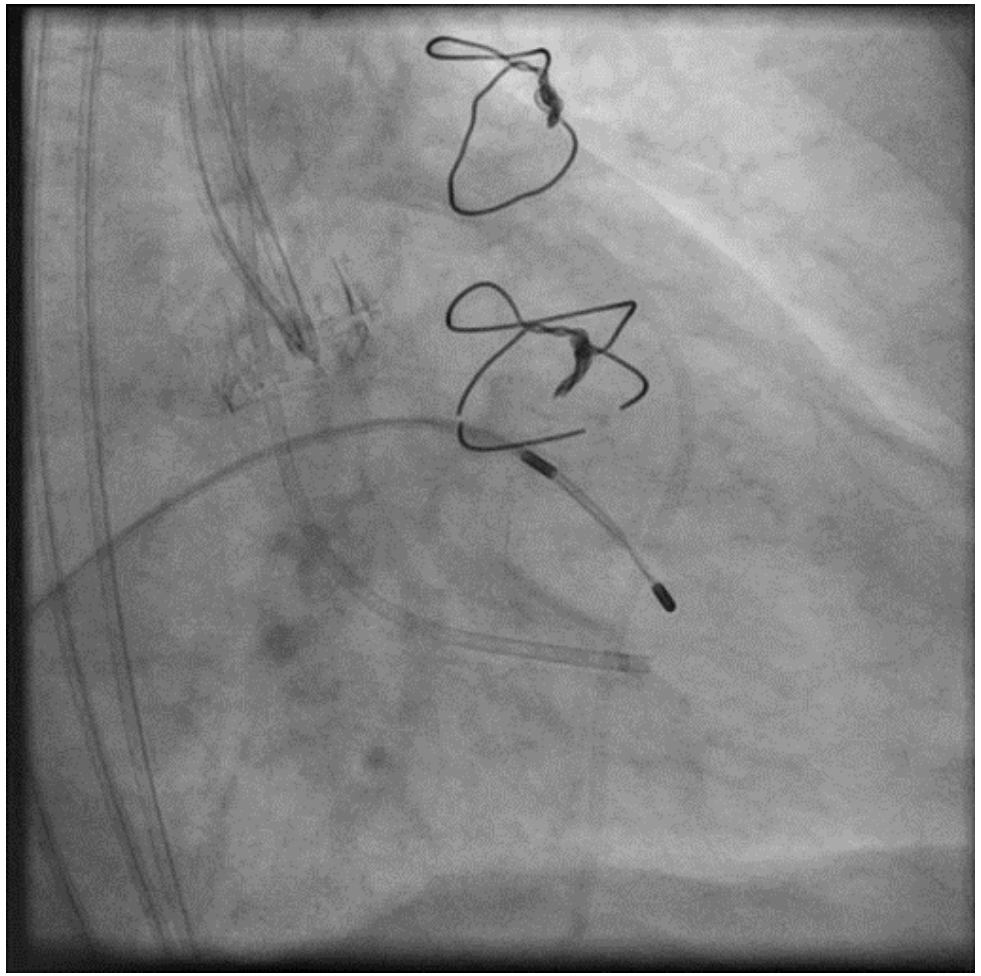
ViV Trifecta: Double BASILICA



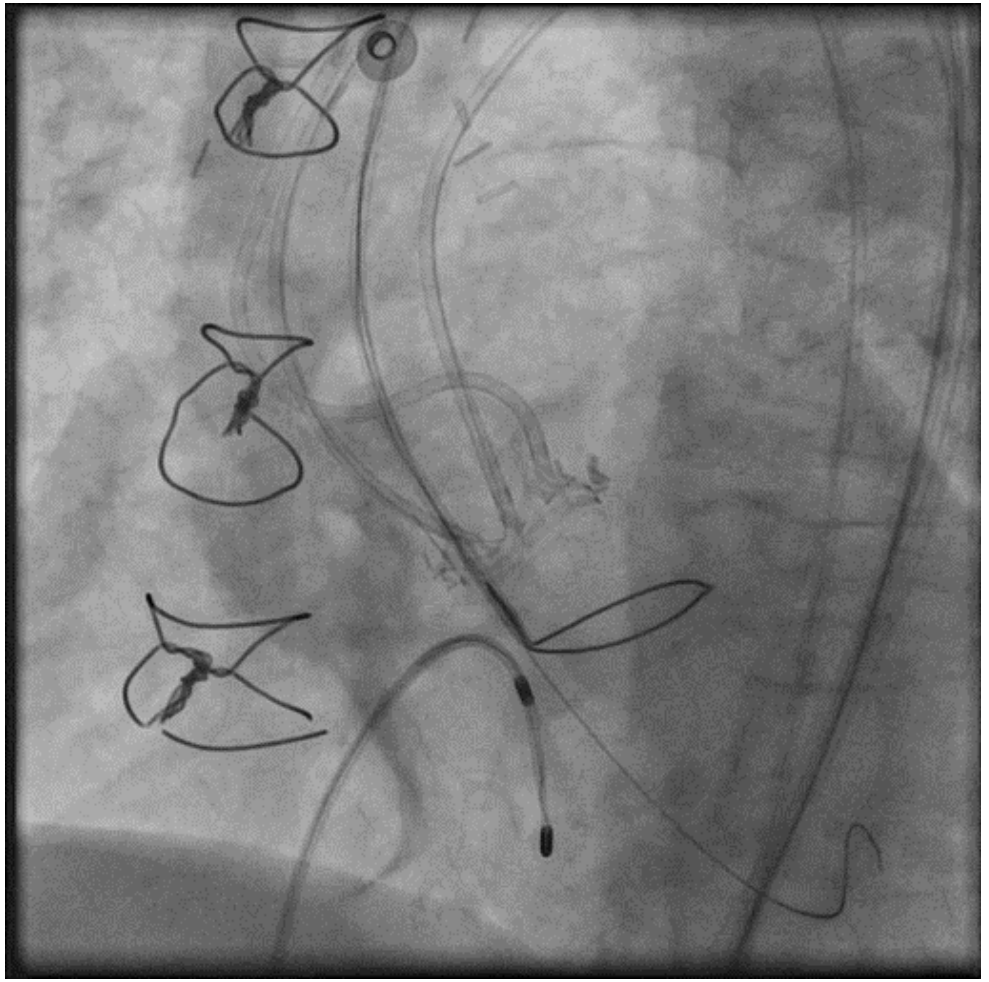


Right Coronary Cusp Positioning and Crossing

ViV Trifecta: Double BASILICA

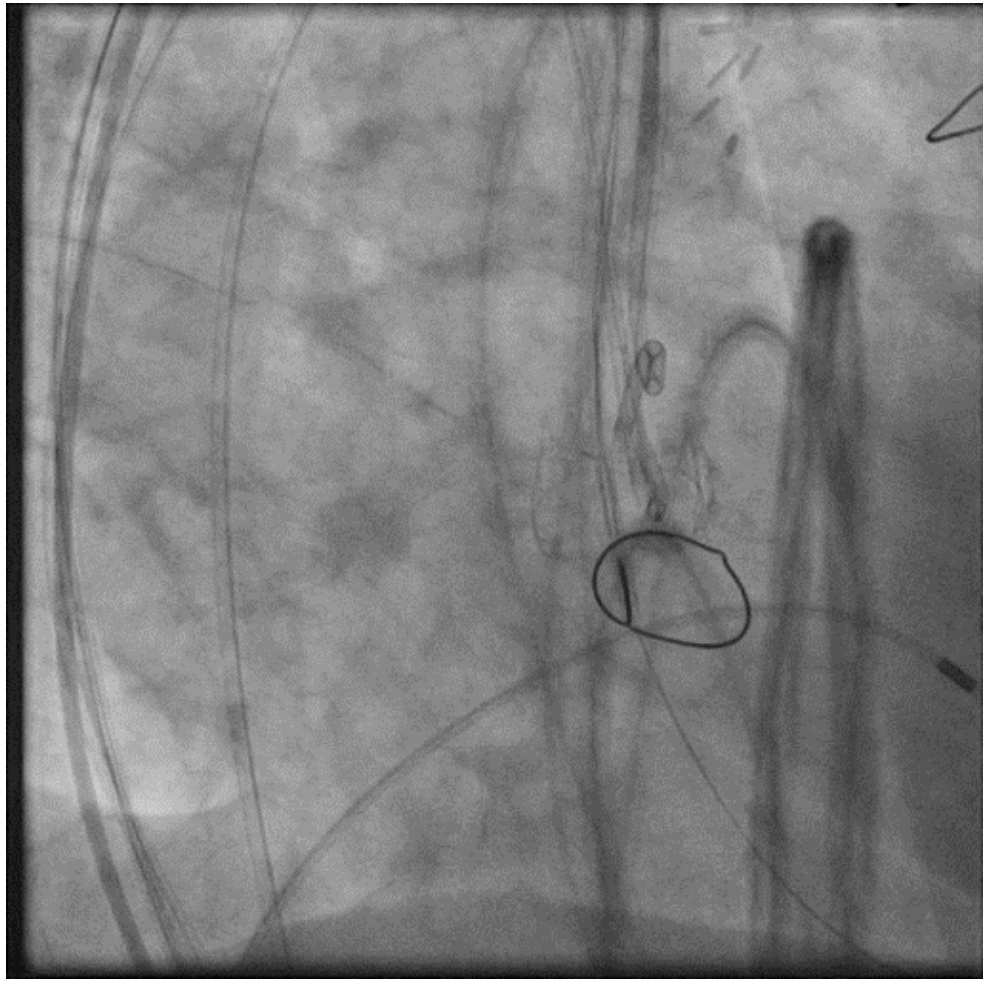


Right Cusp “Flying V”

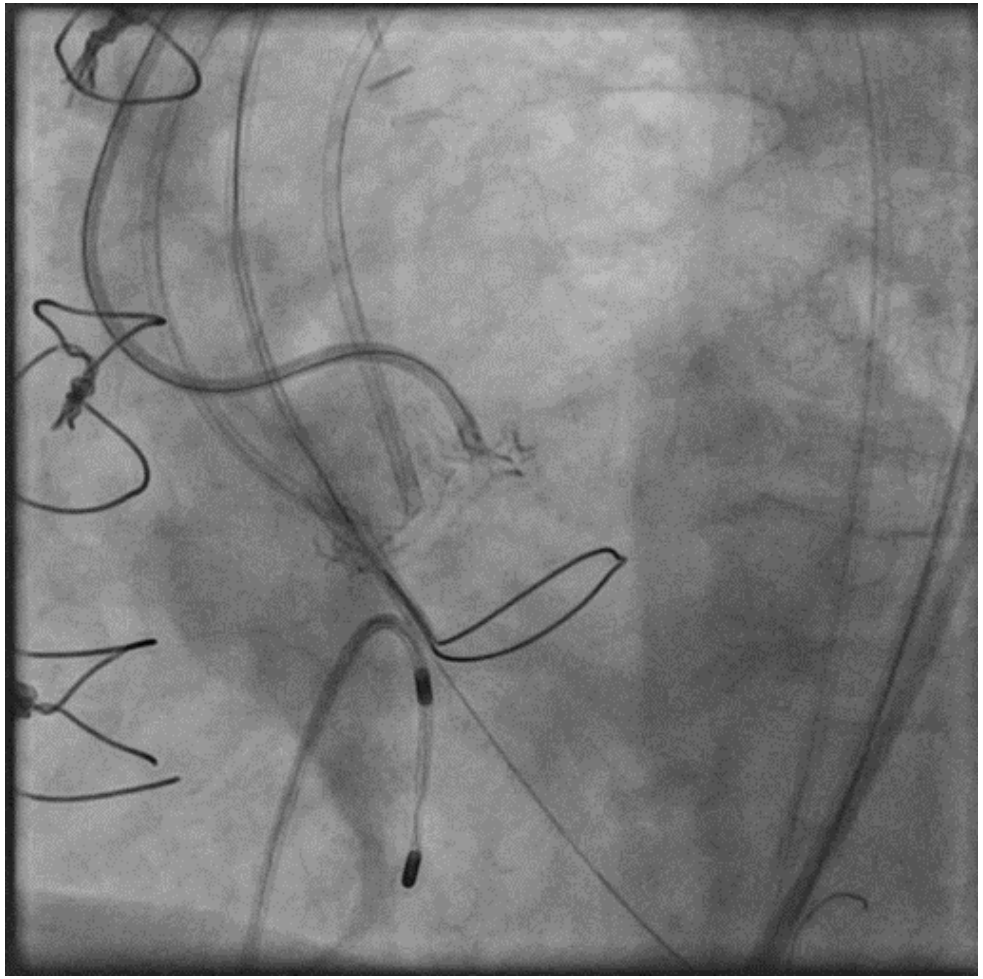


Left Cusp Positioning

ViV Trifecta: Double BASILICA

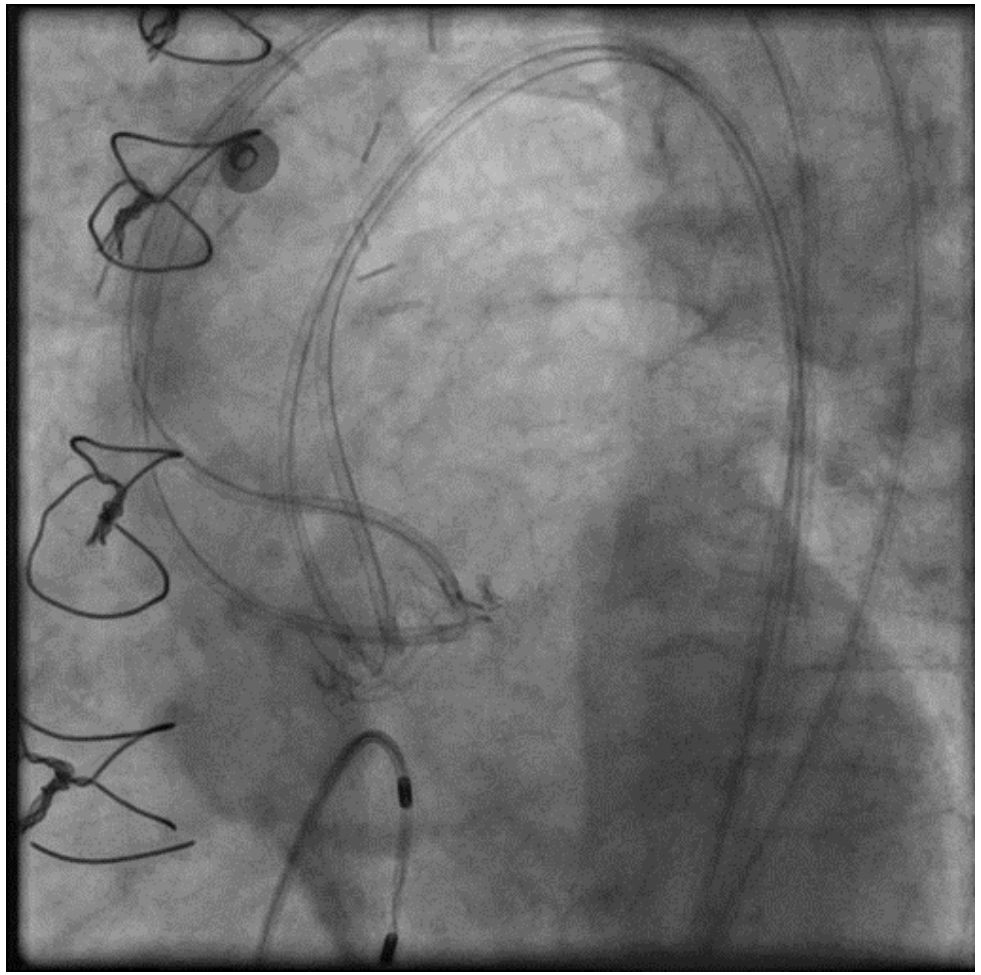


Left Cusp Positioning (en face)

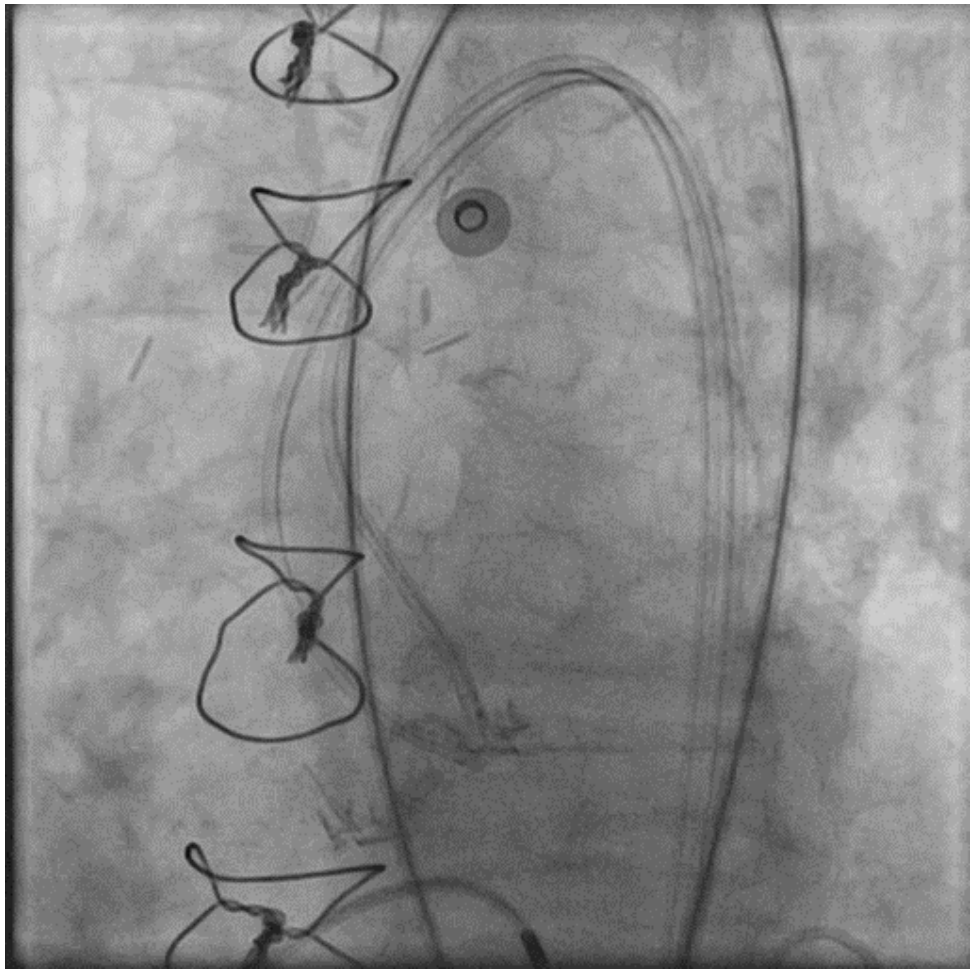


Left Cusp Crossing

ViV Trifecta: Double BASILICA

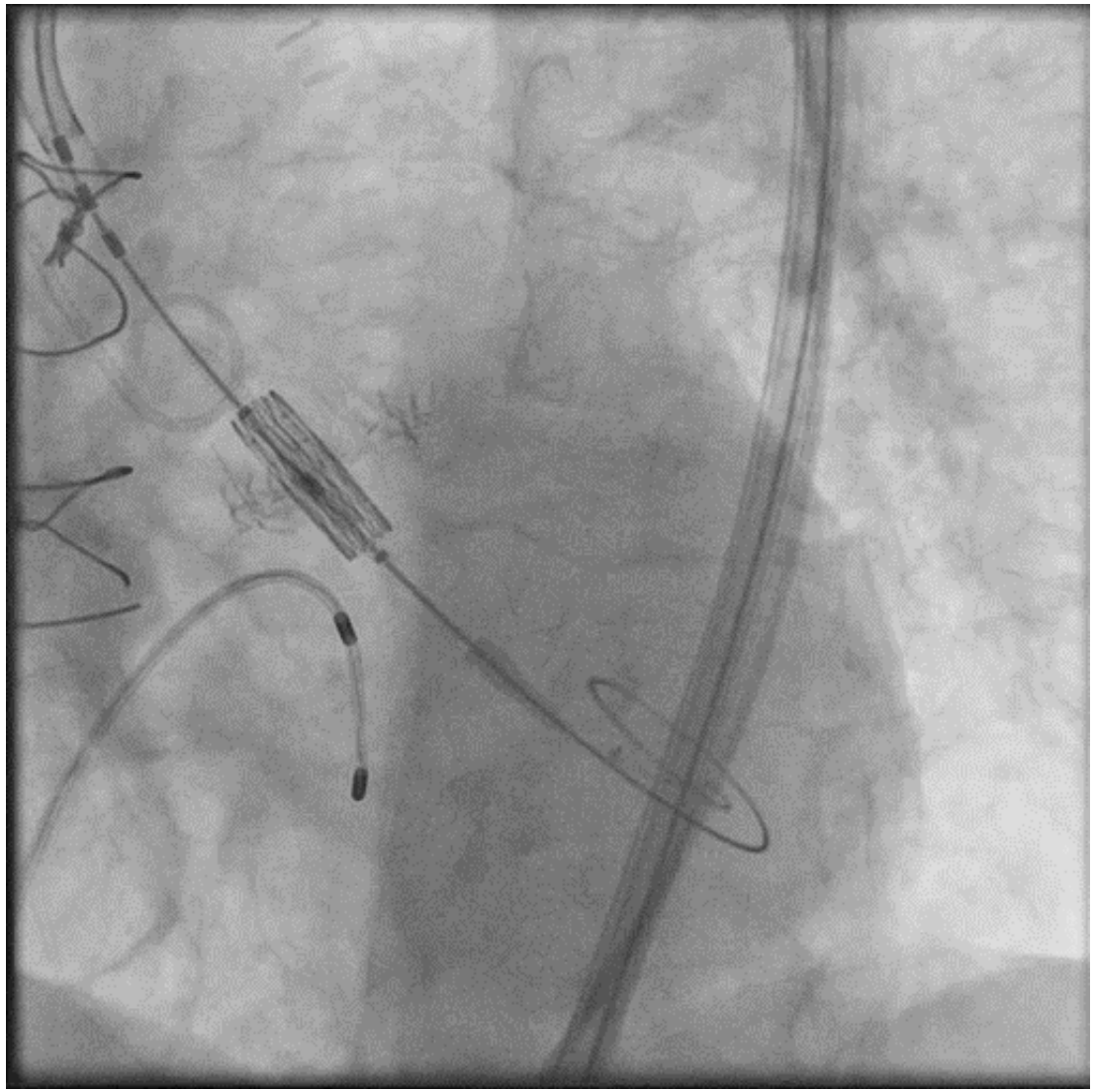


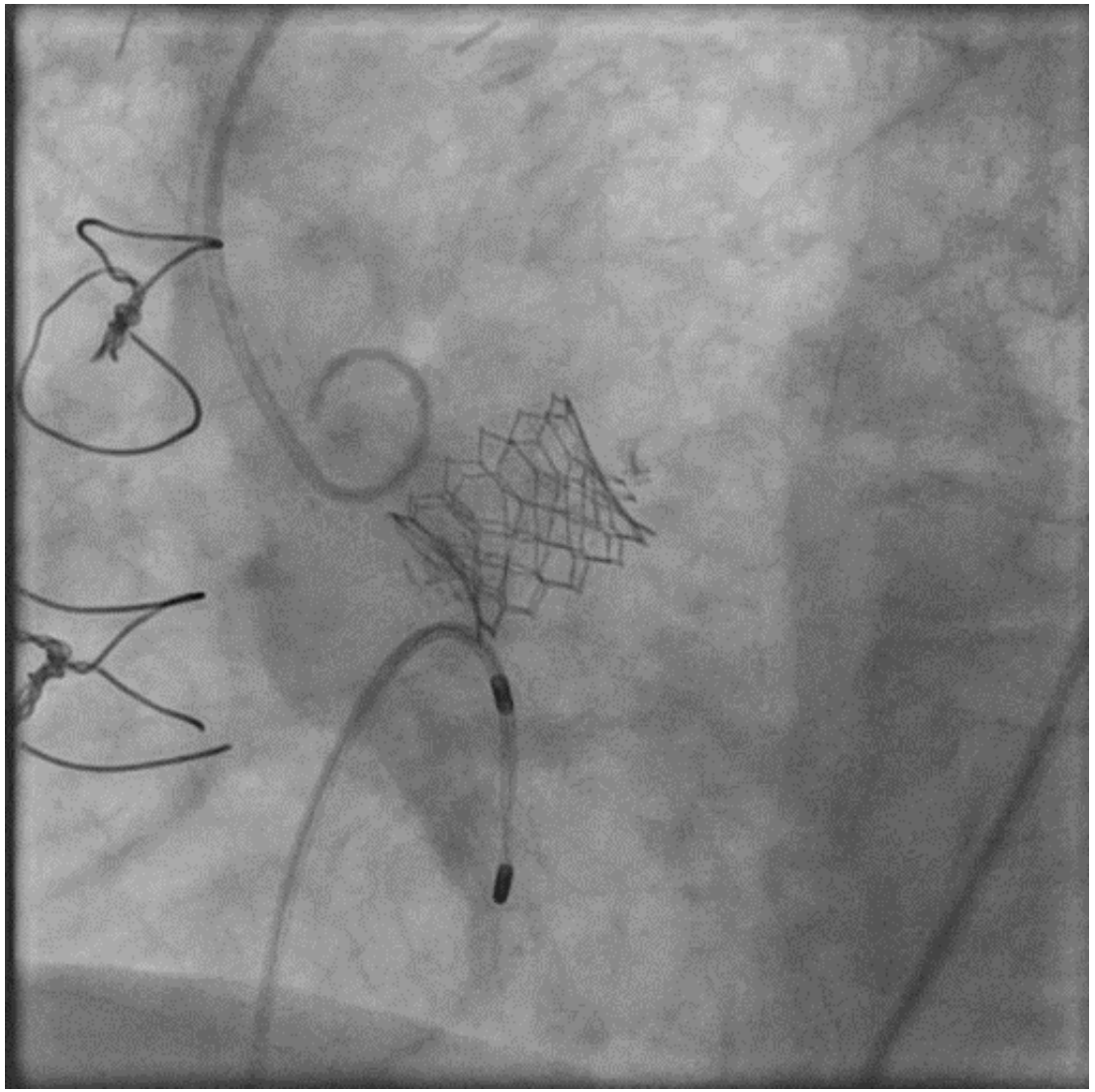
Right Cusp Laceration



Left Cusp Laceration

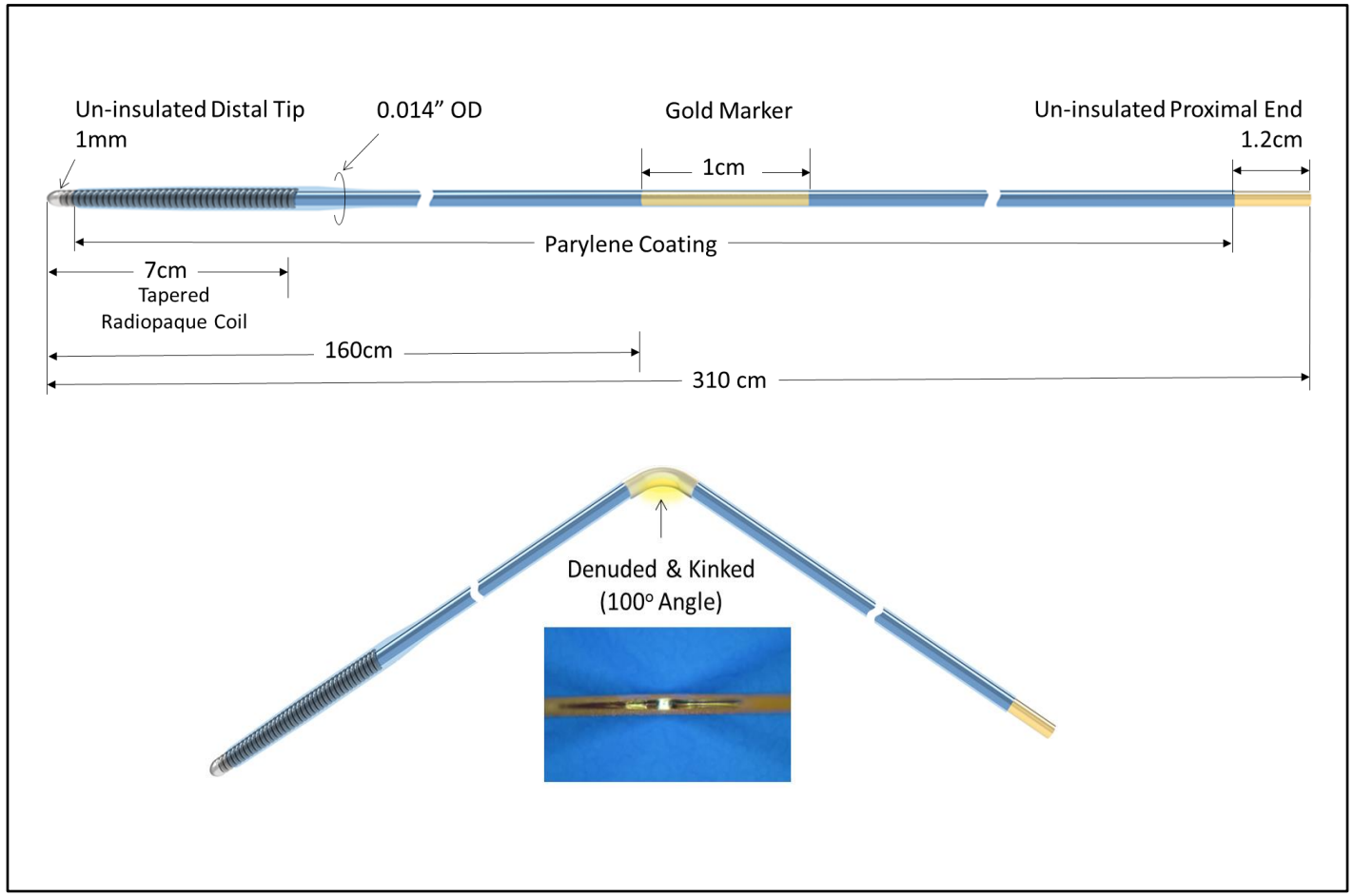
ViV Trifecta: Double BASILICA





Can we make leaflet modification easier?

Telltale System



Summary: ViV TAVR Challenges

- ViV TAVR is an important TAVR subset that presents several unique challenges:

Patient-Prosthesis Mismatch

- In many cases, PPM can be minimized by thoughtful selection and placement of the TAVR valve
- BVF can improve short-term hemodynamics, particularly when treating small surgical valves → Long-term outcome data needed

Coronary Obstruction

- Detailed CT analysis and preparation are critical for avoidance of coronary obstruction
- In addition to coronary protection ± chimney stenting, BASILICA is a promising approach to prevention of coronary obstruction → Newer devices should facilitate uptake of these techniques