Challenges in Valve-in-Valve TAVR

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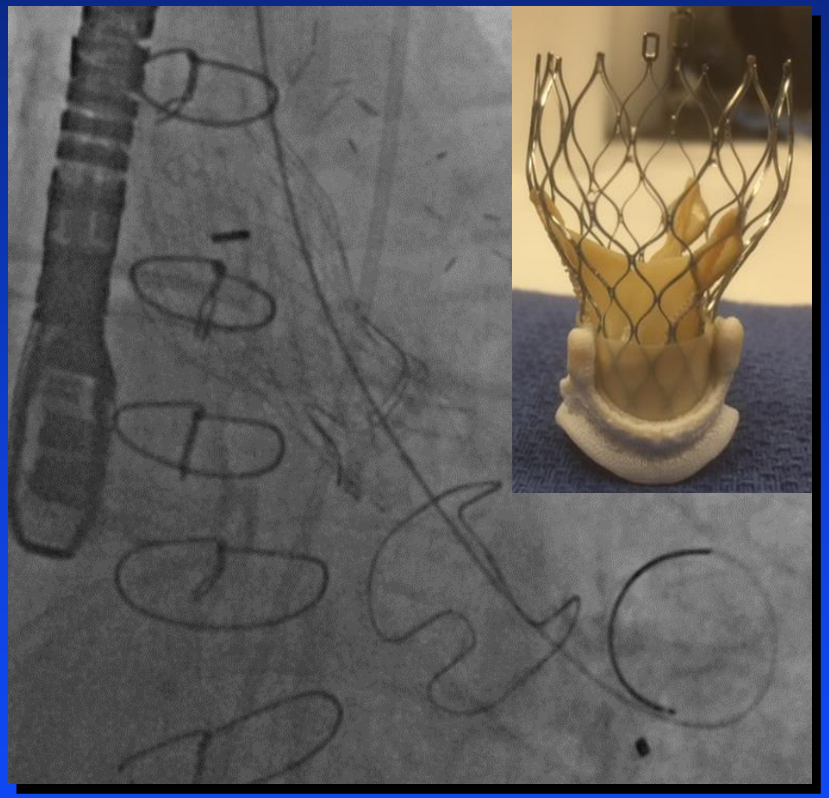
DJC: 4/19

Valve-in-Valve TAVR



- VIV TAVR is an effective alternative to redo surgery for patients with failing tissue valves.
- In the US, VIV TAVR is currently approved for high-risk patients using both balloon-expandable and self-expanding devices.
- Given the less invasive nature of VIV TAVR, it is increasingly used for patients at intermediate risk as well

Challenges with ViV TAVR

- Small surgical bioprostheses/PPM
- Coronary occlusion

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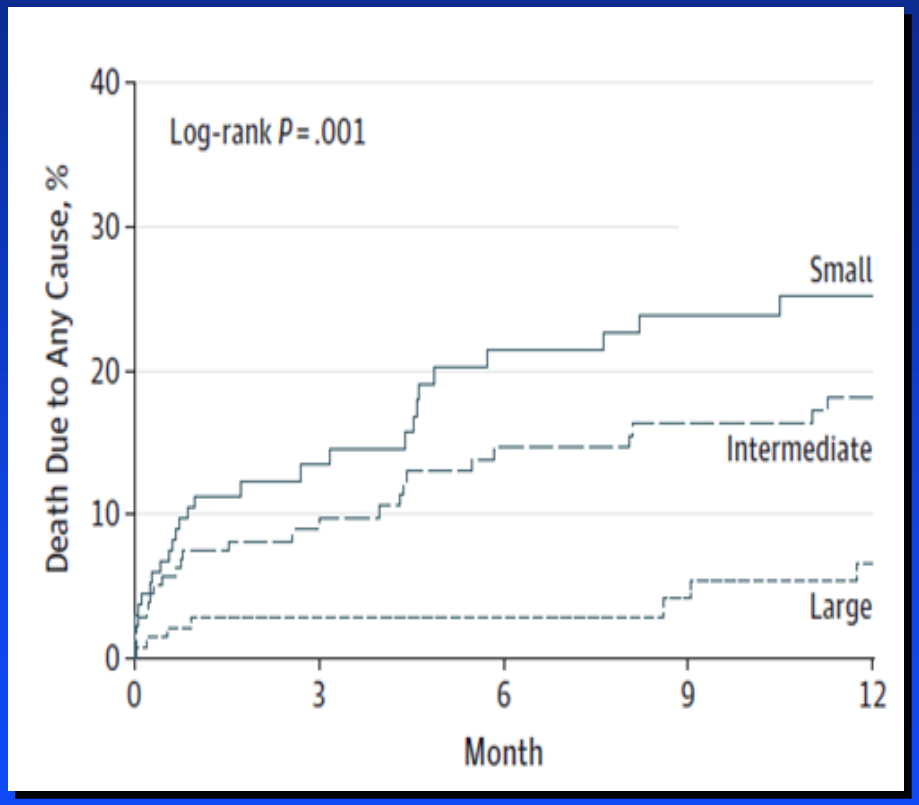
Impact of Surgical Valve Size on 1-Year Mortality



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)

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

ViV TAVR in Small Bioprosthetic Valve

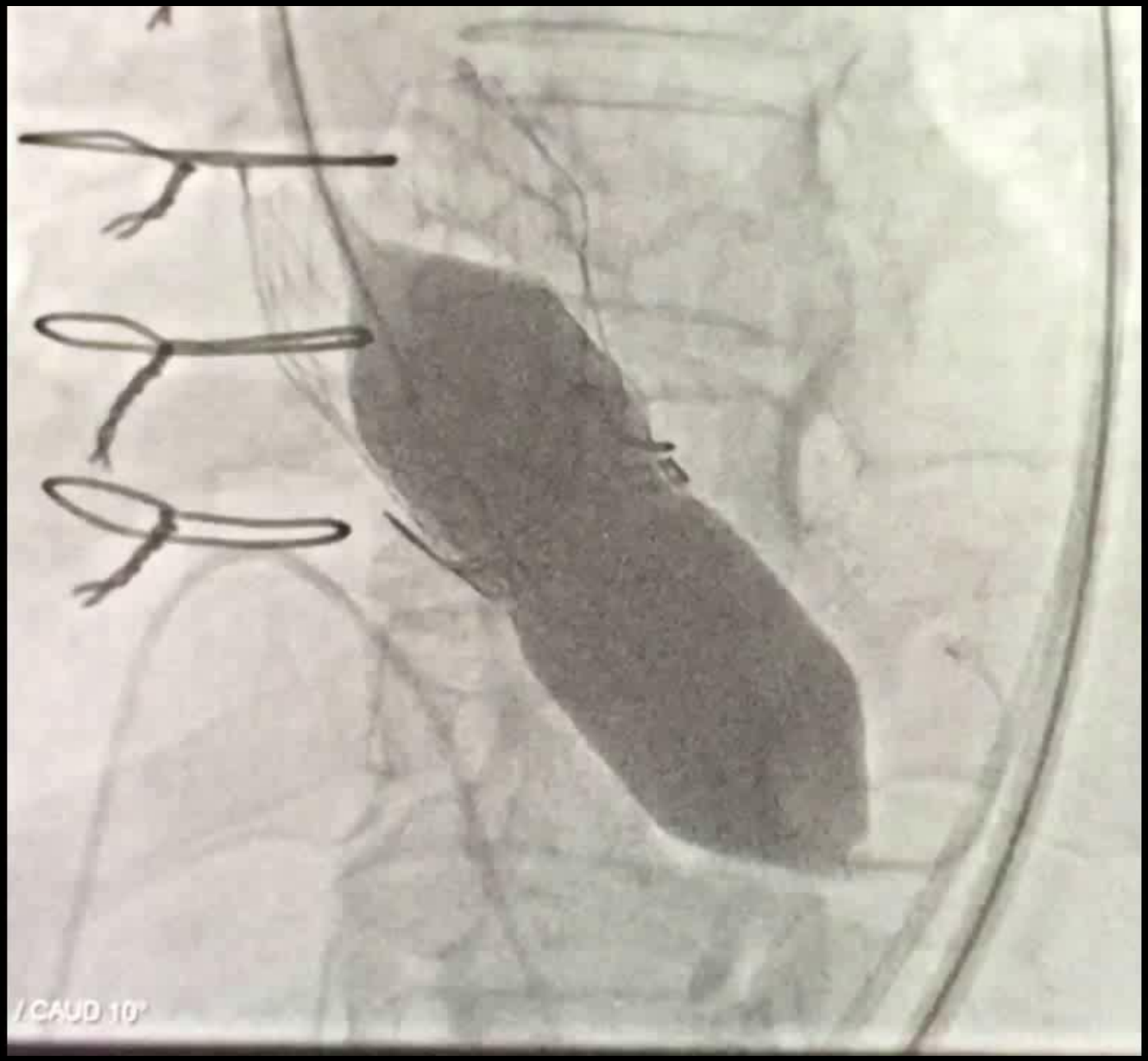
Mean gradient = 63 mmHg
AVA 0.8 cm2

- 71 y.o. man s/p AVR/CABG x 3 in 2007 (19 mm Magna)
- Did well until late 2015 when he began to notice ↑'ing DOE and fatigue
- Echo: severe bioprosthetic AS (mean gradient 60 mmHg) with trivial AI
- Referred for redo AVR vs. TAVR→ felt to be high risk due to proximity of RV to sternum

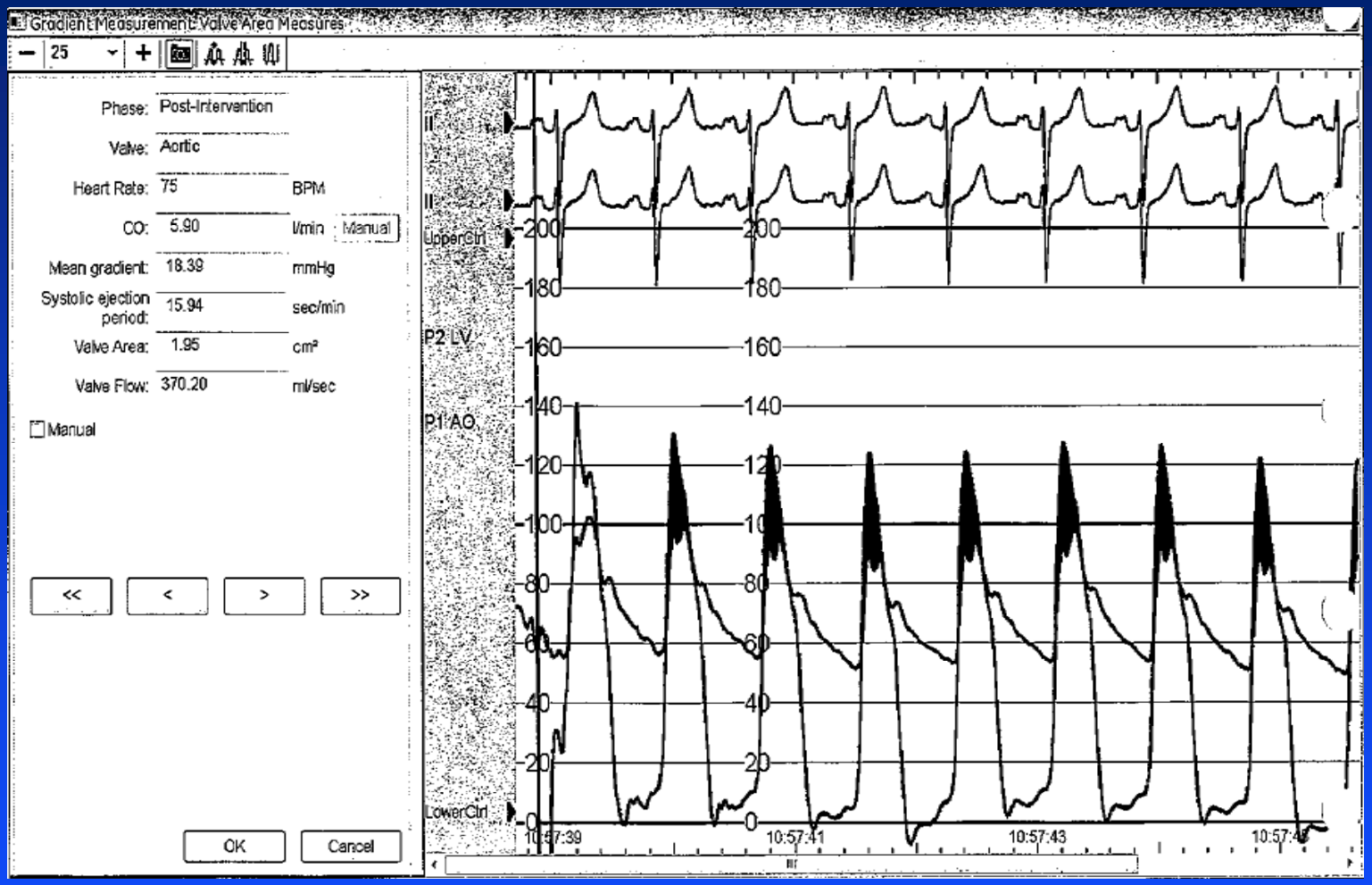
After ViV TAVR (26 mm Evolut) and Post-Dilation

Mean gradient = 44 mmHg AVA 1.0 cm2

BVF with 20 mm True Balloon

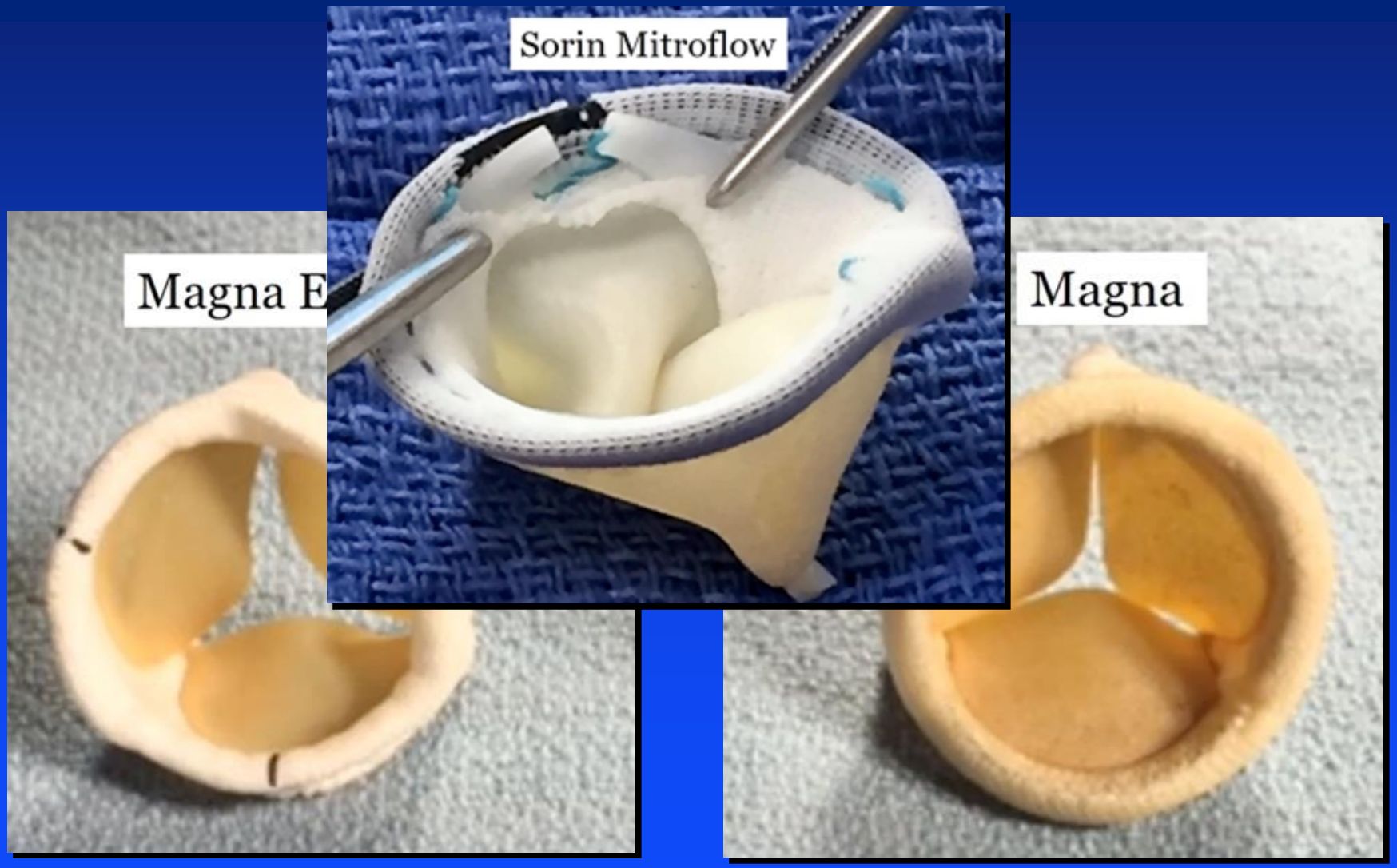


Post- 20 mm True Balloon (16 atm)

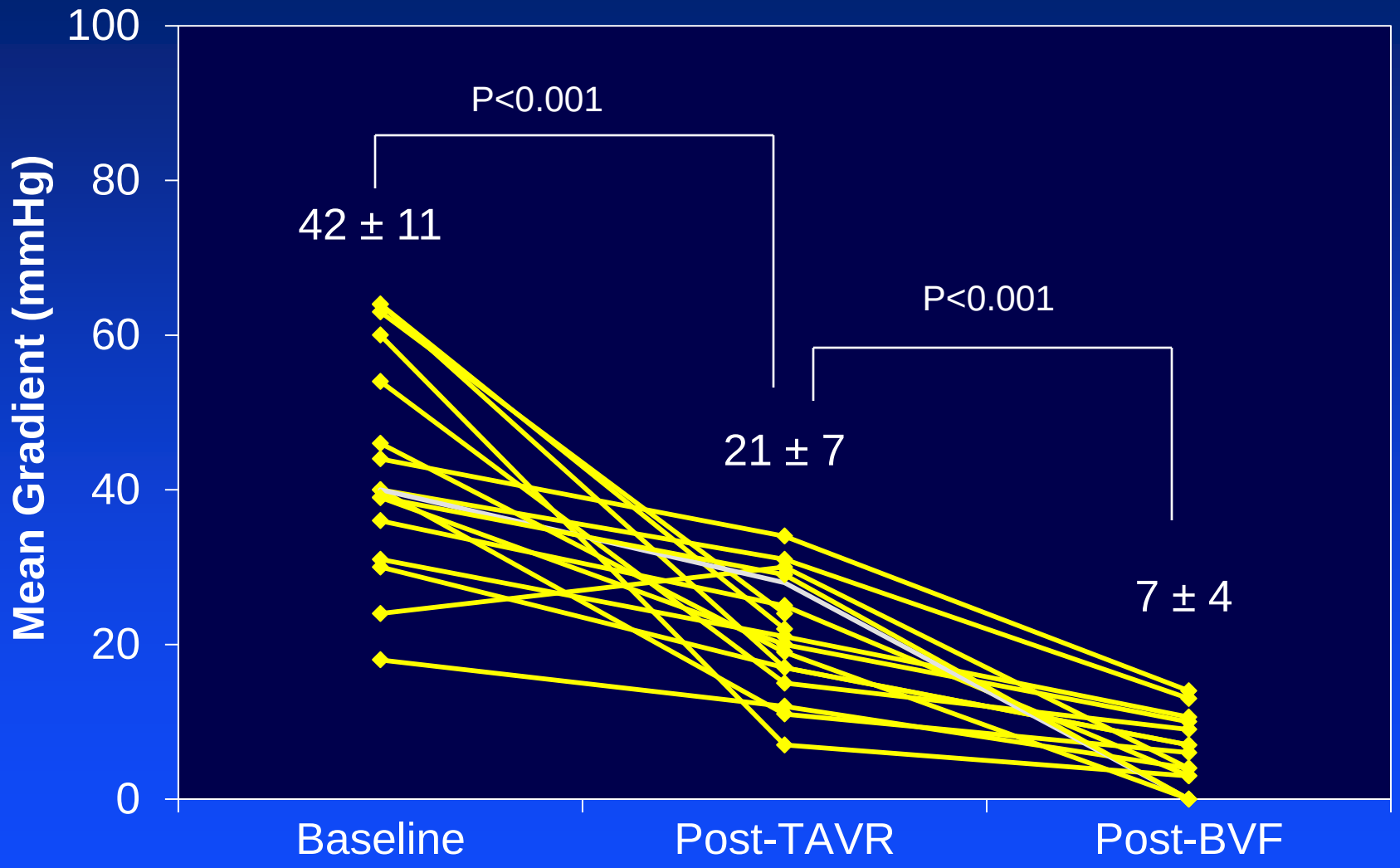


Mean gradient = 18 mmHg AVA 1.9 cm2

How Valves Fracture

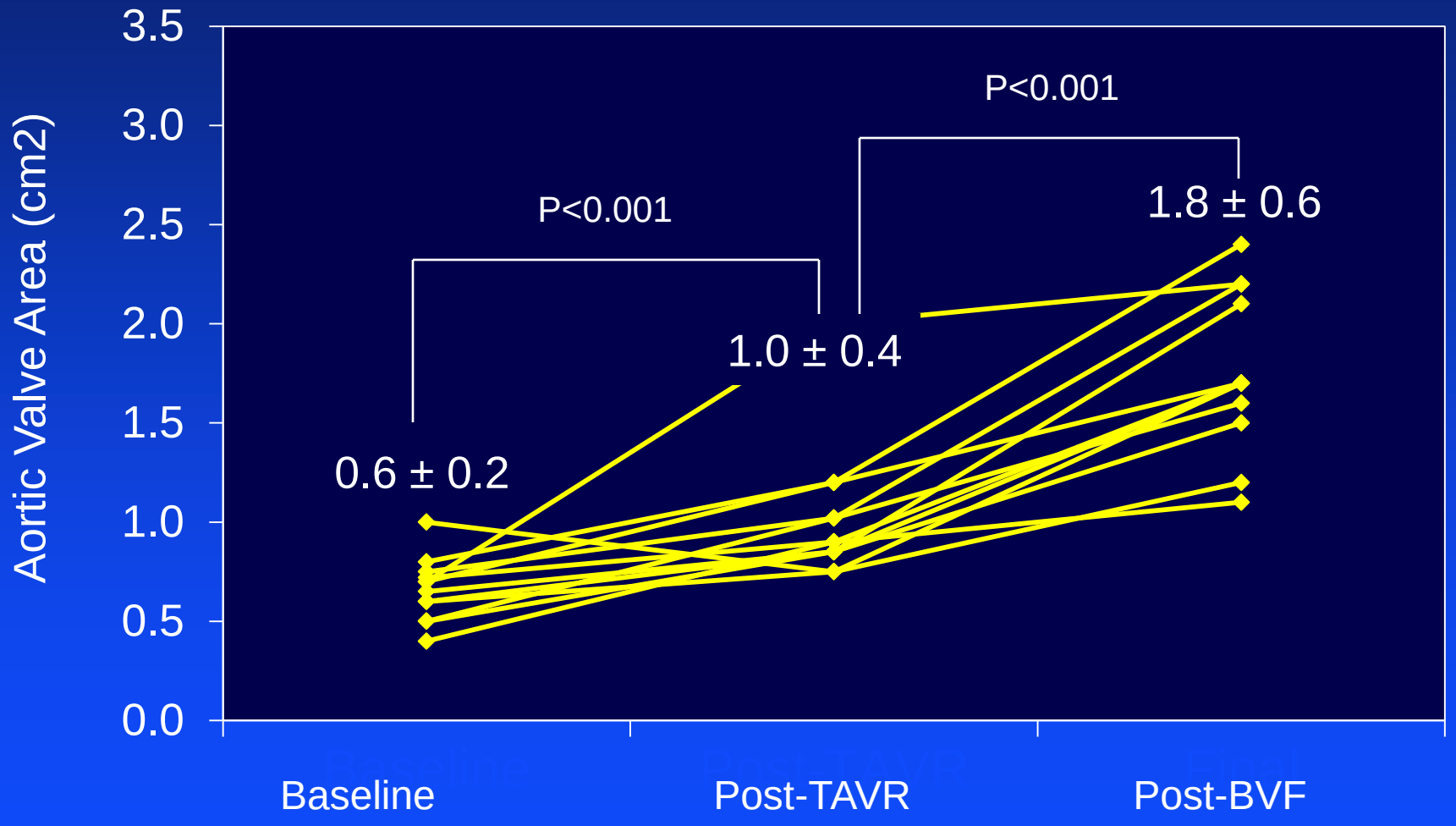


Mean Gradient



Chhatriwalla AK, et al. Circ Intv 2017

Effective Orifice Area



Chhatriwalla AK, et al. Circ Intv 2017

BVF Complications (n= 75 pts/21 centers)

- 2 minor strokes
- 1 chordal tear → moderate-severe MR (Mitraclip)
- 1 severe AI from disruption of TAVR valve → treated with second valve-in-valve
- No in-hospital death
- No coronary occlusion
- No annular rupture (clinical or subclinical)
- No PPM

* 75 cases in full series as of 6/1/18

Challenges with ViV TAVR

- Small surgical bioprostheses/PPM
- Coronary occlusion

Coronary Occlusion during ViV TAVR

- Based on VIVID registry, overall risk is 2% (5x higher than native TAVR) → increases to 3.9% in patients for whom bioprosthetic valve failure mode is stenosis (VIVID registry)
- Despite PCI success in 82%, 30-day mortality is 36% (22% with PCI success/100% without)
- Prediction challenging although some risk factors have been suggested

Risk Factors for Coronary Occlusion

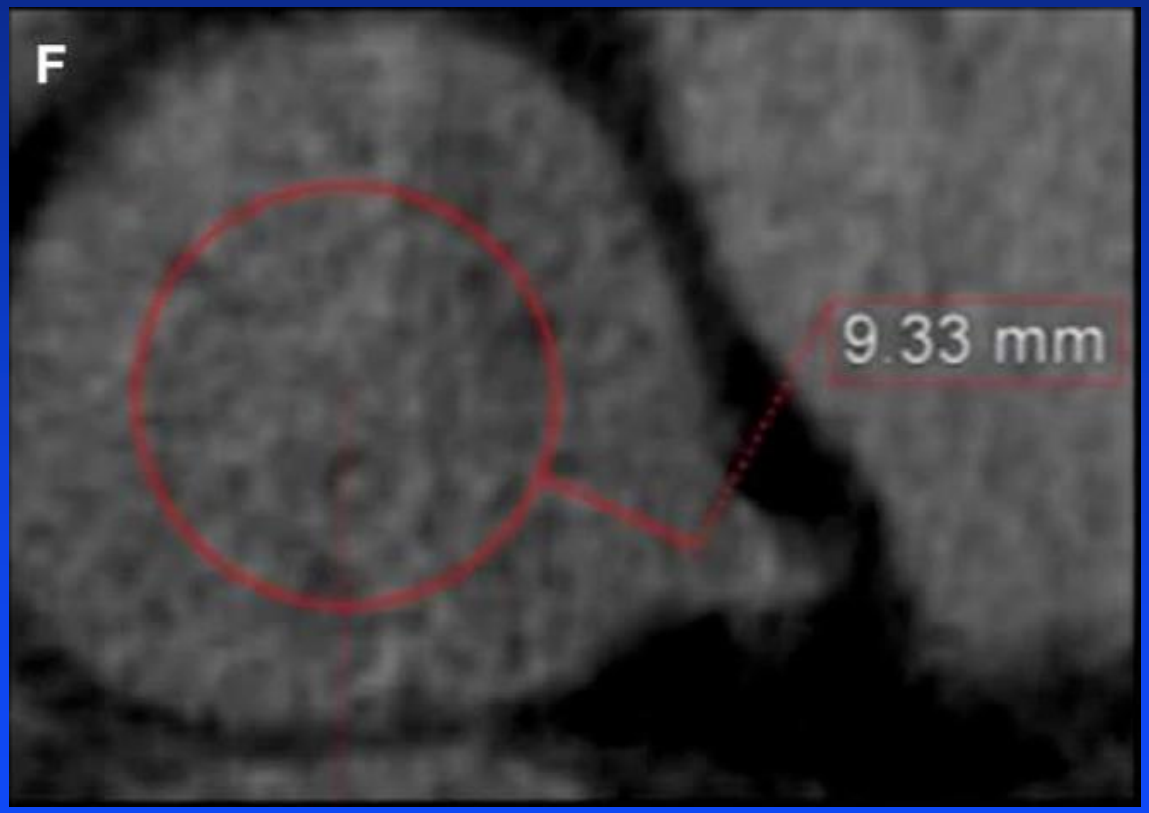
Native Anatomic Factors

- “Low” coronary ostia
- Narrow/effaced coronary sinuses
- Narrow STJ

Bioprosthetic Valve Factors

- High leaflet profile (may cover coronary)
- Supra-annular position
- Stentless valve
- Leaflets external to valve frame (Mitroflow, Trifecta)

Virtual THV to Coronary Distance (VTC)



- High Risk: < 3mm
- Intermediate Risk: 3-6 mm
- Low Risk: > 6 mm

Dvir D, et al. *Circ Cardiovasc Interv* 2015

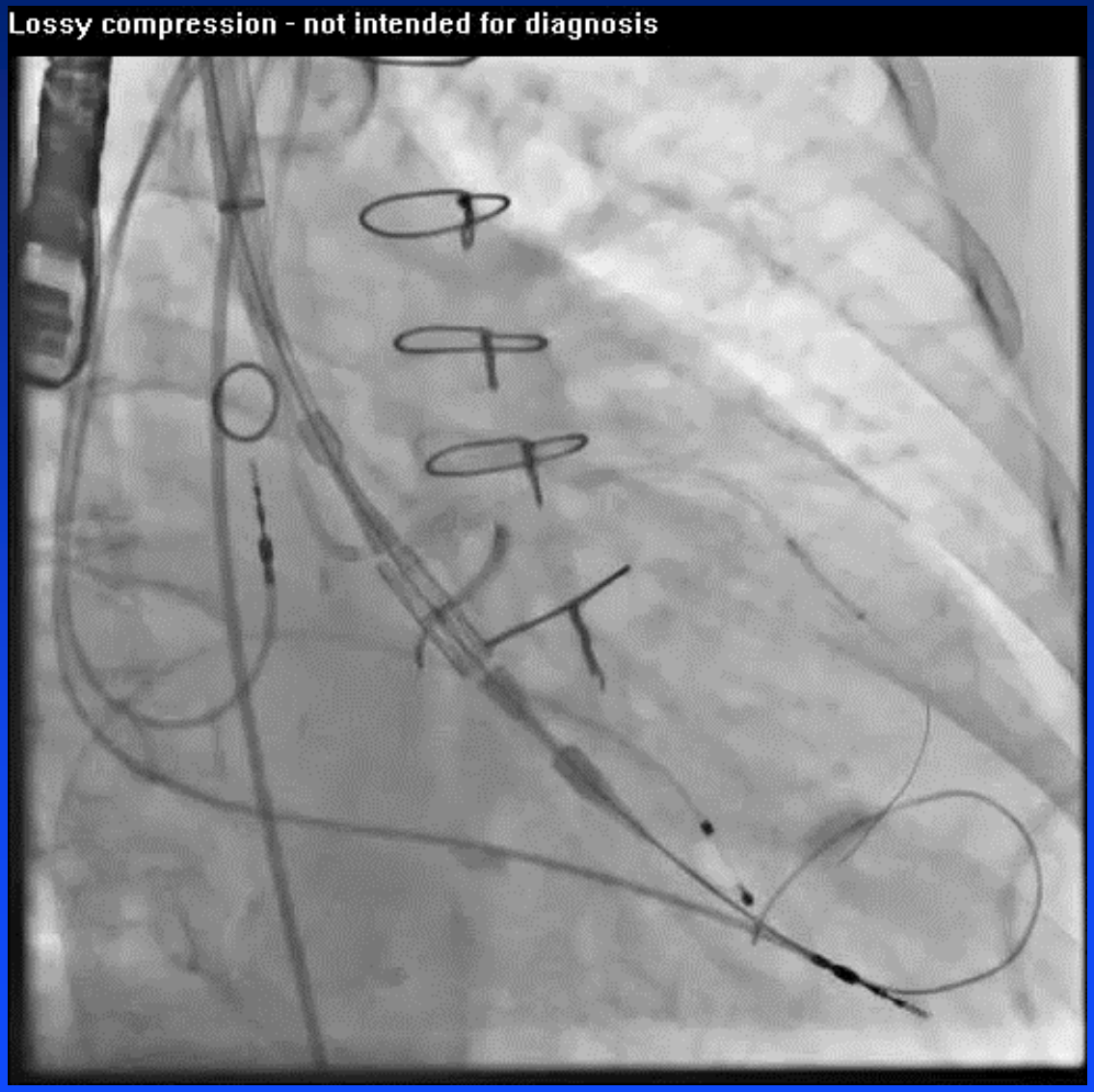
High Risk Case

- 68 y/o female with bioprosthetic AS (21 mm Trifecta, mean gradient 65 mmHg)
- Prolonged hospitalization following SAVR
- Obese, Multiple TIA's→ extreme risk for redo SAVR
- Low takeoff of left main and narrow sinuses

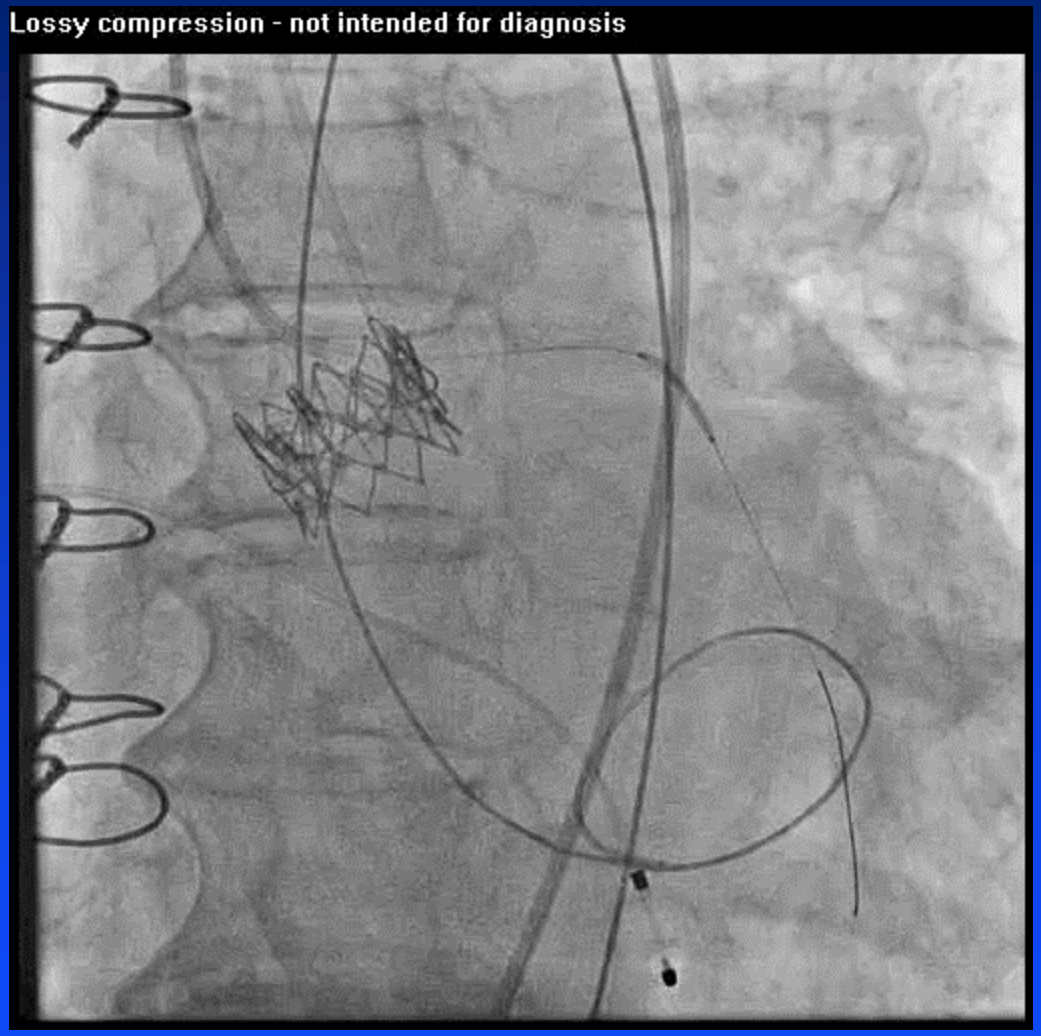
Plan

- ViV TAVR with 23 mm Sapien XT
- Coronary protection with wire and pre-positioned stent
- Possible BVF depending on initial results

Coronary Protection for 23 mm Sapien XT

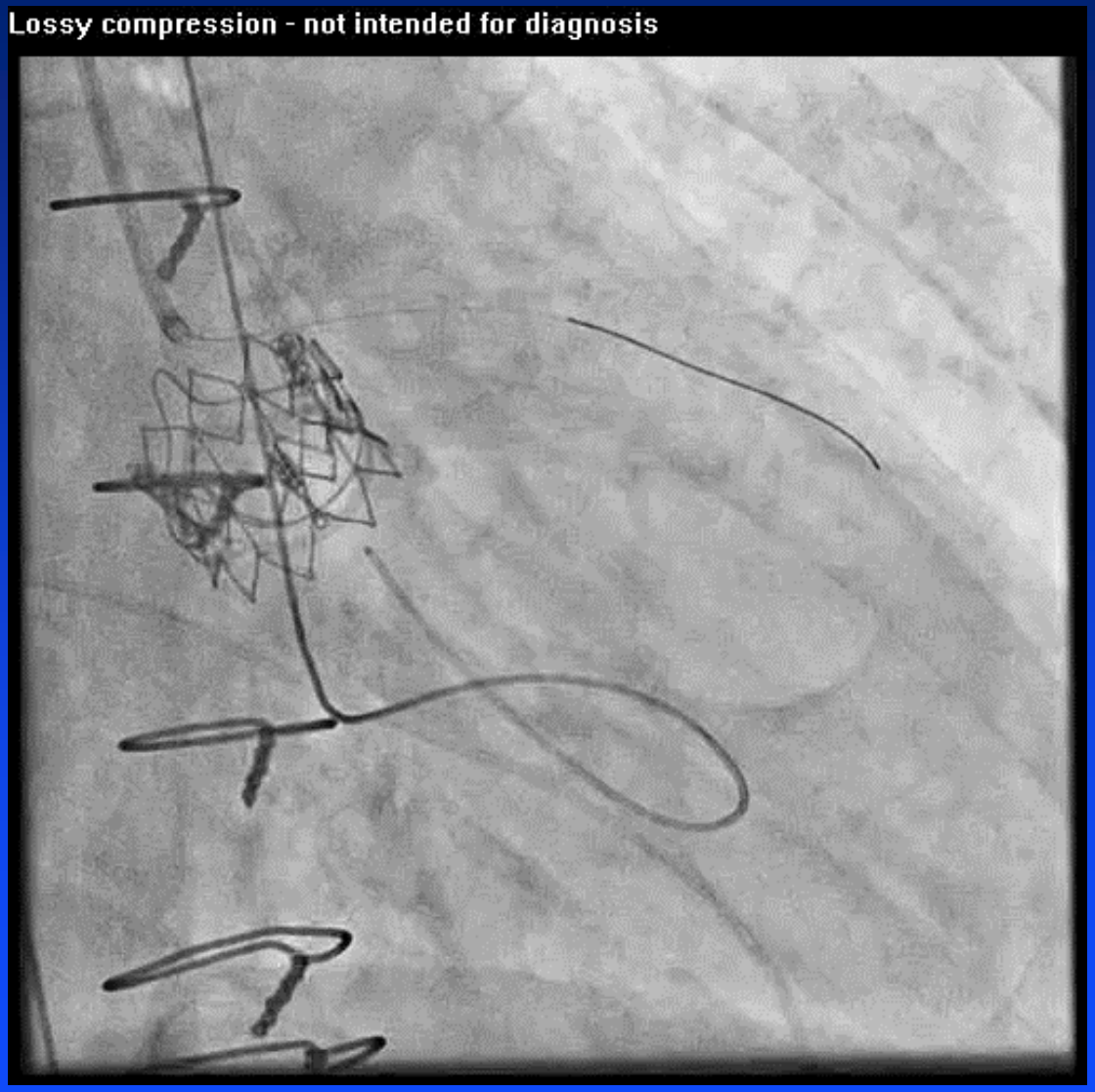


Post-TAVR



- Diffuse severe ST depression
- Persistent hypotension
- TEE→ severe anterior hypokinesis
- LVEDP = 55 mmHg

Stent retracted and deployed in LM

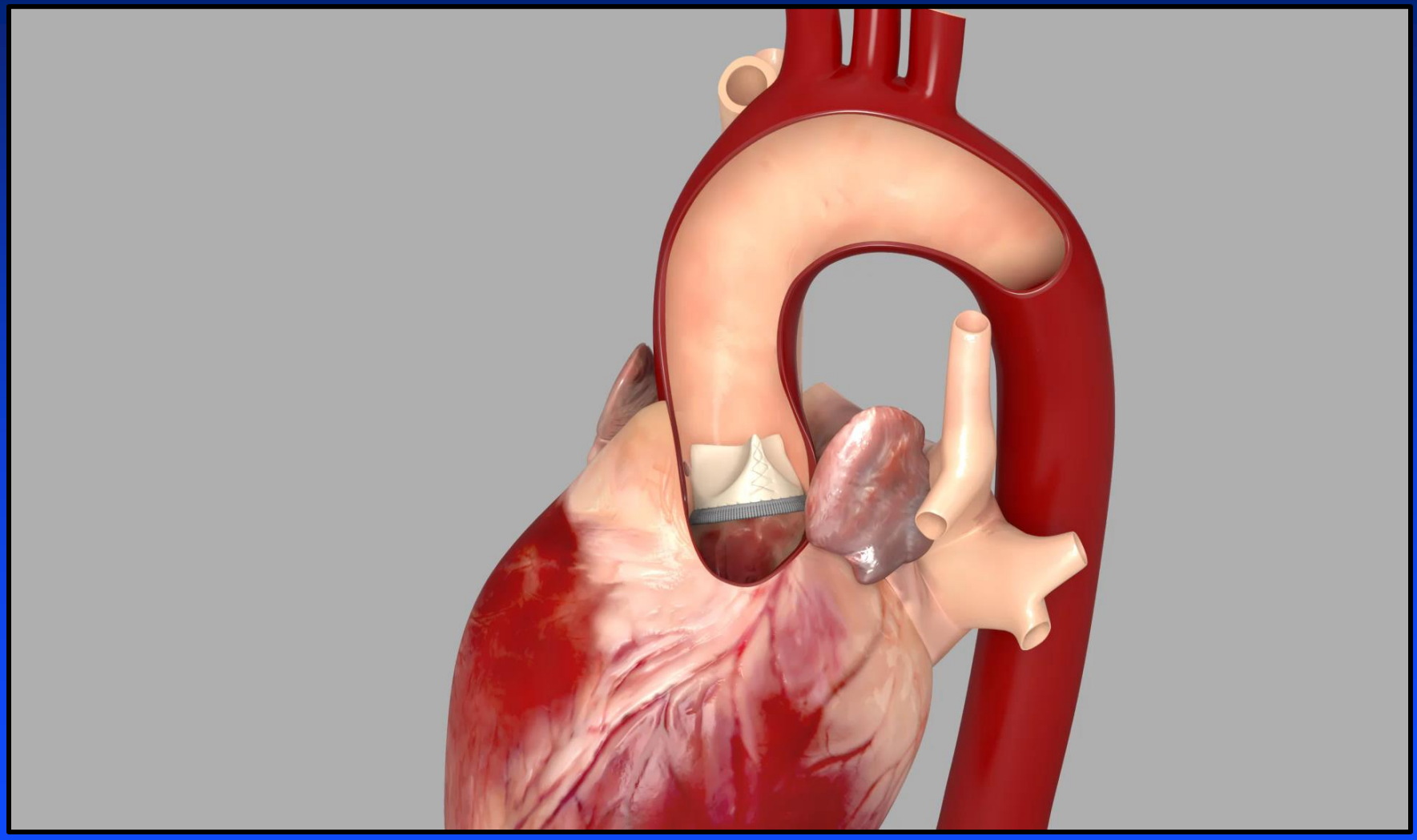


- EKG changes, LV dysfunction, and ↓'d BP improved immediately
- Mean gradient 20 mmHg
- No BVF!
- Discharged next day

Issues with Coronary Protection

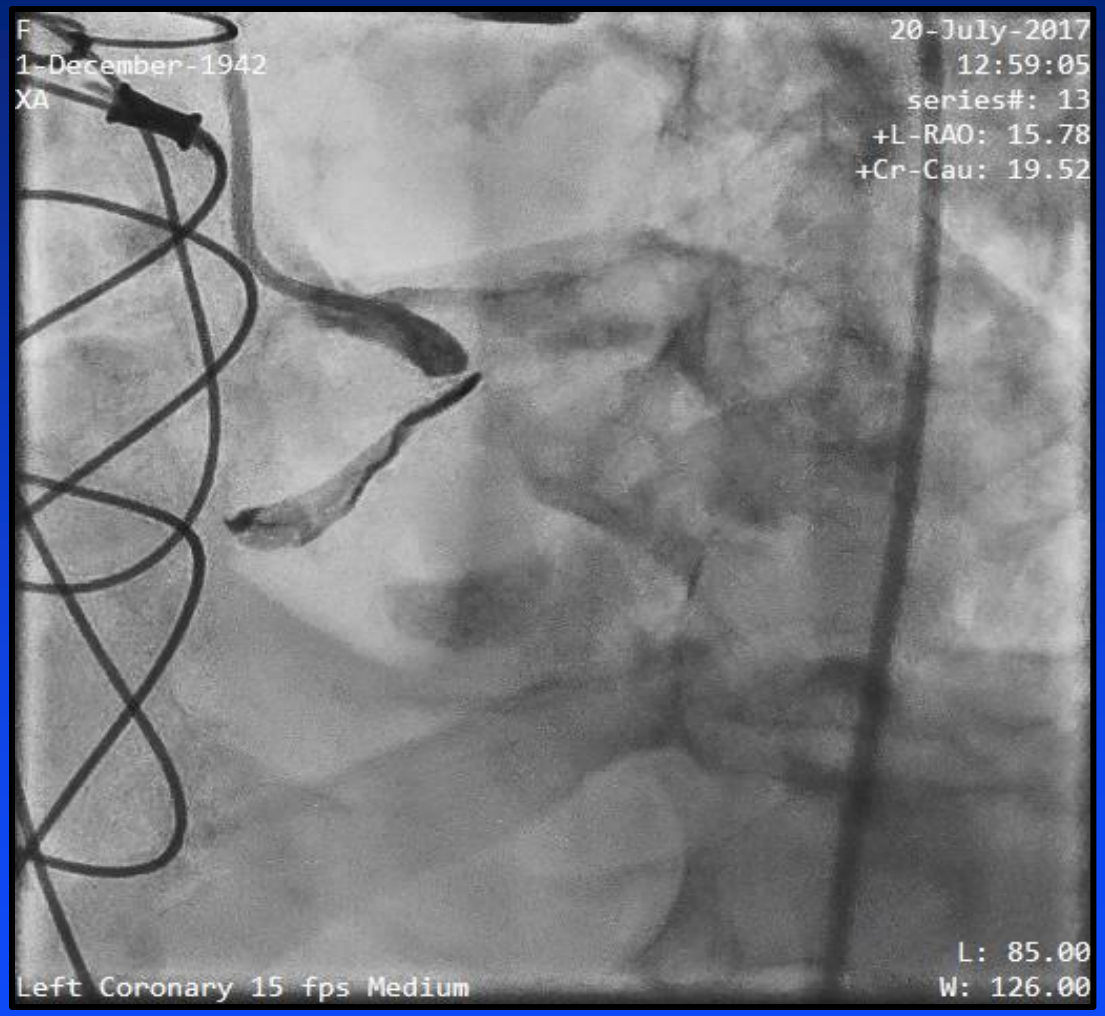
- Stent deployment may be challenging→ how far back to stent/snorkel?
- When stent deployment is unnecessary, stent retraction/removal may be difficult
- Need for long-term DAPT, especially with snorkel stent technique
- Up to 1/3 of clinically significant coronary occlusions occur late

BASILICA Procedure



Courtesy of A. Greenbaum

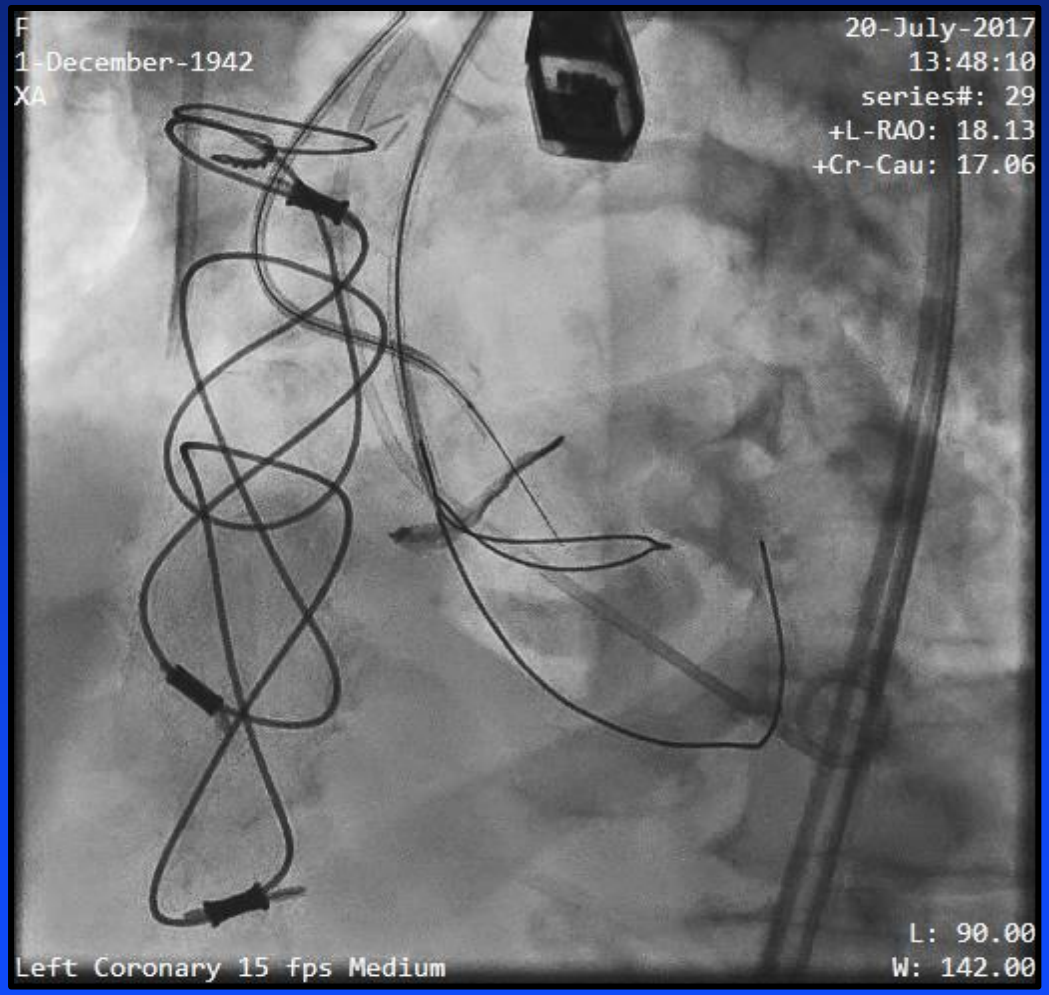
BASILICA: Case Example



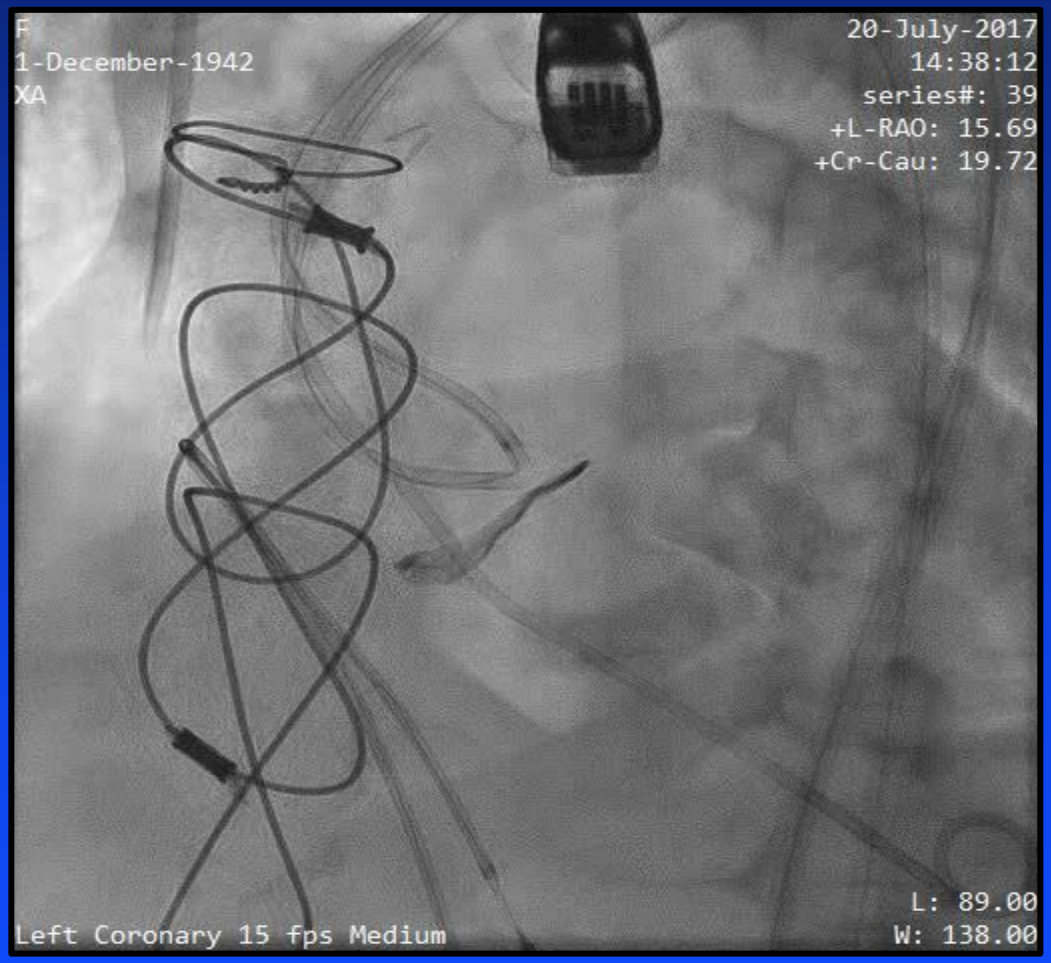
- 21 Mitroflow valve (external leaflets)
- High risk of left coronary artery obstruction on CT and angiography→ leaflet seen here as potential trap door shutting the coronary artery after valve-in-valve TAVR

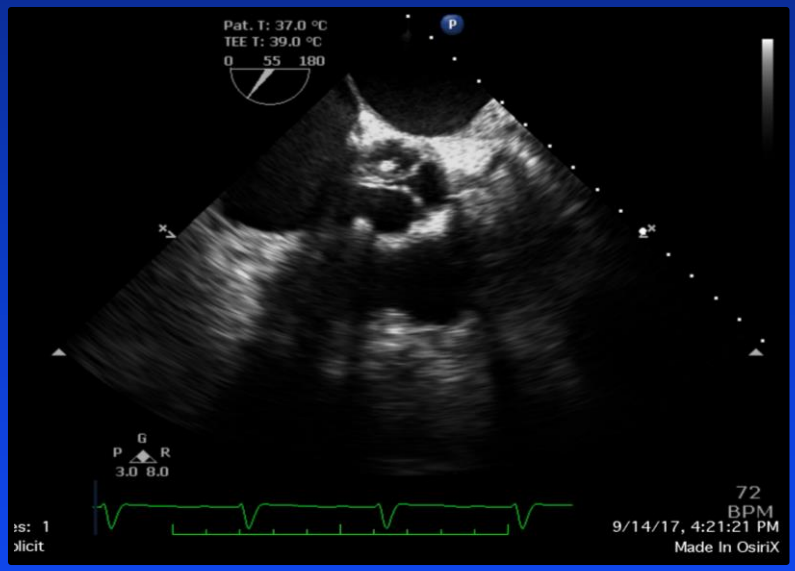
Case courtesy of Adam Greenbaum

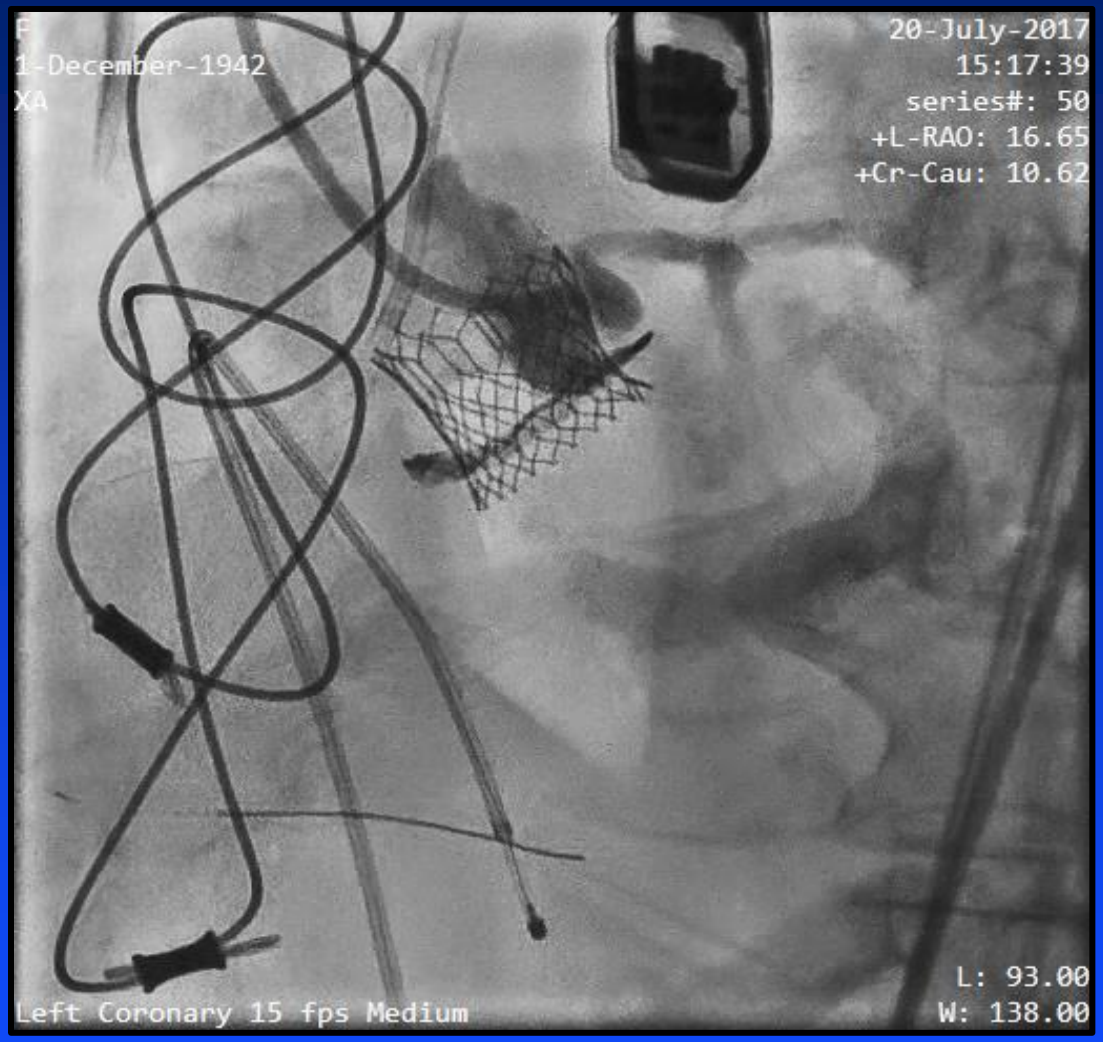
Leaflet traversal with Astato guidewire into Gooseneck snare



Leaflet laceration with modified Astato guidewire







Good flow to the left coronary artery after BASILICA and TAVR

US IDE Trial

- 30 patients at high risk of coronary occlusion (4 sites)
- Mean age 74; prior SAVR in 17 (57%)
- Valve cusp: 18 left / 5 right / 7 both

Preliminary Results

- Successful leaflet traversal 35/37 (95%)
- Successful laceration 35/35 (100%)
- Coronary obstruction 0%
- In-hospital mortality 3%; stroke 7%

Khan JM, et al. TCT 2018

Summary

- While TAVR for pts with failed surgical bioprostheses is generally safe and provides acceptable 1-yr outcomes, ViV TAVR poses several unique challenges including PPM and an increased risk of coronary occlusion
- Several novel techniques have been developed for mitigating these risks including BVF, coronary protection, and the BASILCA procedure
- Additional research is necessary (and ongoing) in order to better understand the long term risks and benefits of each of these techniques