

Coronary access post TAVI

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Disclosures

• Consultant to Edwards Lifesciences, Medtronic, Abbott, Jena, PiCardia

Coronary access after TAVI PREVALENCE OF CAD IN TAVI PATIENTS

- Prevalence of CAD in patients with severe aortic stenosis undergoing TAVI ranges from 40% to 75%¹
- Single and multicenter studies report a range of 1.9% - 5.7% of aortic valve replacement (TAVI or SAVR) patients required PCI post TAVI^{2,3, 4}

TAVI Patients with CAD¹
40 - 75%

Post-TAVI PCI Rates^{2,3, 4}
1.9 — 5.7%

^{1.} Yudi, et. Al. JACC, 2018.

^{2.} Tanaka, et al. Cardiovascular Revasc Med, 2019 (in press).

^{3.} Kleiman, et al. CRT, 2019.

^{4.} Allali, et al. Cardiovascular Revasc Med, 2016.

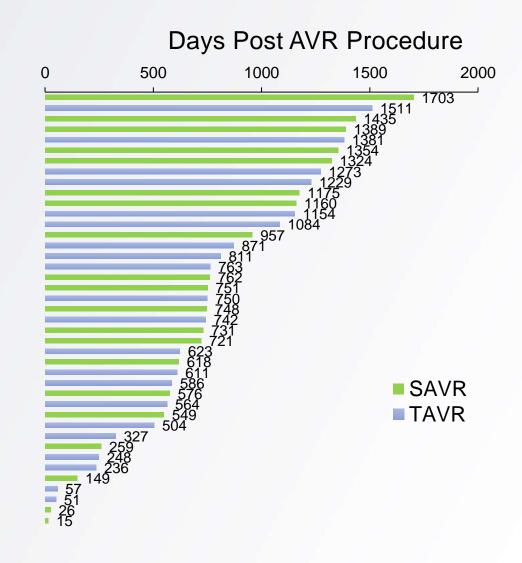
Coronary access after TAVI

TIMING OF POST-AVR PCI

In the multicenter SURTAVI trial, 2.2% (36/1660) of patients required PCI after valve replacement with a surgical or transcatheter valve.

The duration of time between the index AVR procedure and PCI varied widely for both TAVI and SAVR patients:

- Mean days from index AVR to PCI Procedure
 - TAVI: 699.8±406.9 days
 - SAVR: 822.1 ±527.1 days
- Linearized rate of PCI post AVR in patients (per year)
 - TAVI: 0.008
- Kleiman, et al. (2019) 0.009



Coronary access after TAVI PREVALENCE AND SEVERITY OF ACUTE CORONARY SYNDROME POST-TAVI

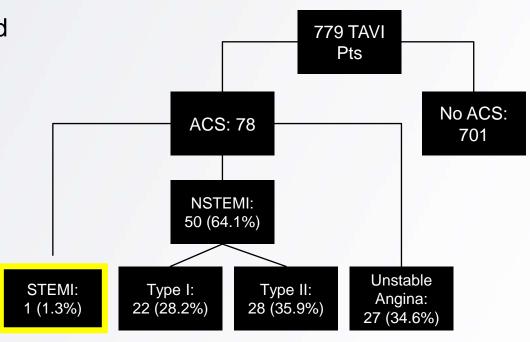
A recent study examined rates of acute coronary syndrome (ACS) in 779 consecutive TAVI patient treated from May 2007 to November 2017 and followed at 1, 6, and 12 months, and yearly thereafter:

Demographics

- Mean age 79 +/- 9 years
- Mean STS 6.8 +/- 5.1%
- · 68% had history of CAD
- Median follow up of 25 months

Results

- 10% presented at least 1 episode of ACS
 - Unstable angina = 34.6% (27 patients)
 - NSTEMI = 64.1% (50 patients)
 - STEMI = 1.3% (1 patient)



Vilalta, et al. JACC, 2018.

Coronary access after TAVI POST-TAVI ANGIOGRAPHY AND PCI SUCCESS RATES

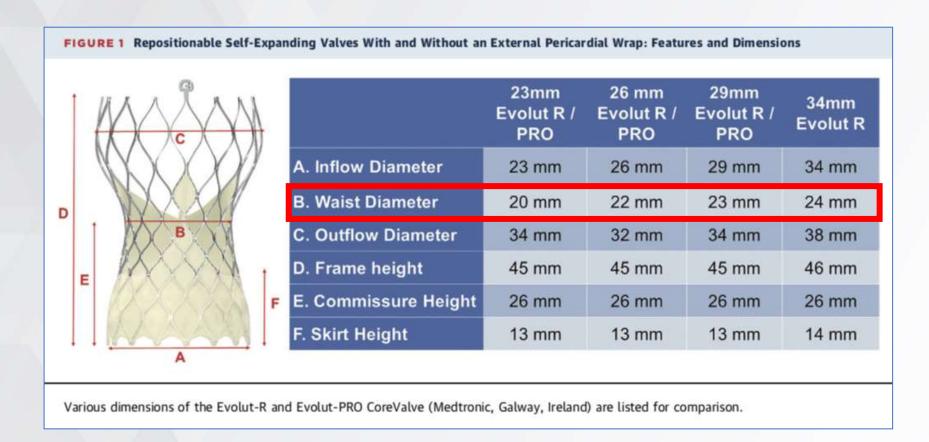
Clinical data show that coronary access post-TAVI is technically feasible and generally reported positive outcomes for all TAV types:

	Source	TAVs	PCI Success Rate**
	Tanaka, et al. Cardiovascular Revasc Med, 2019 ¹	37 CoreValve™ 4 Evolut R™	28/30 (93.3%)
	Kleiman, et al. Presentation at CRT, 2019 ²	20 CoreValve	30/33 (90.9%)
	Htun et al., Catheter Cardiovasc Inter, 2018 ³	28 CoreValve	29/29 (100%)
	Zivelonghi et al., Am J Cardiol, 2017 ⁴	41 SAPIEN 3™* 25 Evolut R	17/17 (100%)
	Chetcuti et al., TCT, 2016 ⁵	169 CoreValve	103/113 (91.2%)
	Allali et al. Cardiovasc Revasc Med, 2016 ⁶	24 CoreValve	23/24 (95.8%)
ef	Blumenstein et al., Clin Res Cardiol, 2015 ⁷ er to individual study for definition of PCI success rates.	19 SAPIEN™* 10 CoreValve 4 Symetis™* 1 Portico™* 1 Jena Valve™*	10/10 (100%)

Average PCI Success Rate**1-7 93.8%

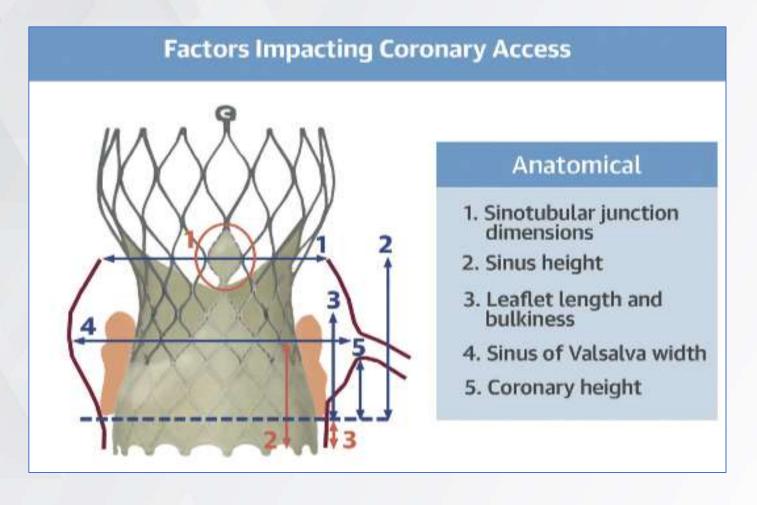
^{**} PCI success rates calculated for those patients in which PCI was attempted.

Re-access to Coronaries: Understand the Device



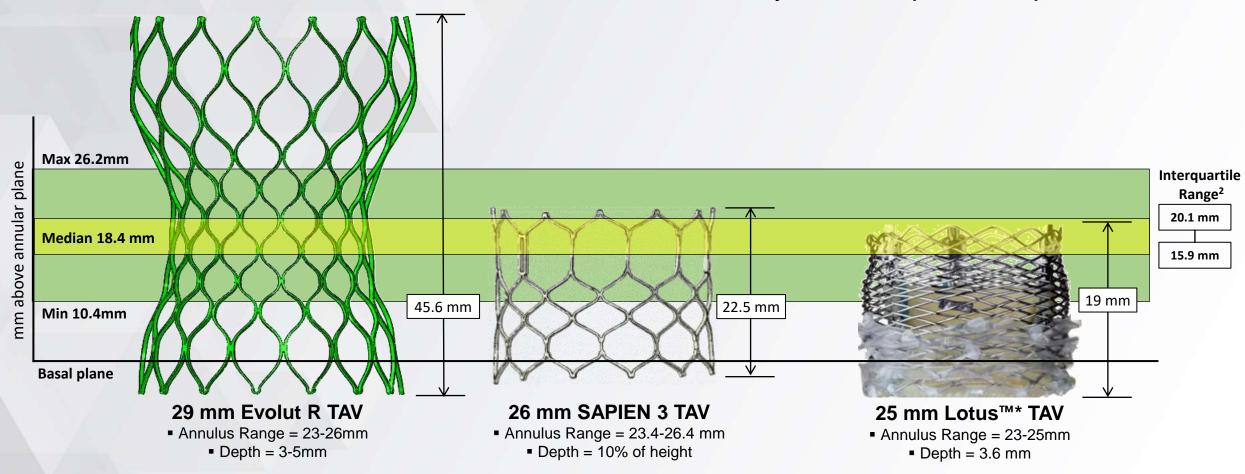
¹Yudi, et al., *J Am Coll Cardiol* 2018; 71(12):1360–78

Re-access to Coronaries: Understand Patient Anatomy



Coronary access after TAVI CORONARY OSTIA HEIGHT RELATIVE TO TAV FRAME

All commercial TAV frames extend above left coronary ostia in up to 25% patients.¹



^{1.} Coronary ostia height measurements are from CoreValve US IDE Trial; Measurements represent the height from the basal plane to the center of the left coronary ostium. 2.2. Interquartile range includes the range of heights spanning from the 25th percentile to the 75th percentile.

Coronary Access Preservation

PORTICO™ VALVE HAS LARGE CELLS

- One Portico[™] valve cell has approximately 573%[†] more area than one Evolut[‡] R/PRO valve cell¹
- One Portico™ valve cell has approximately 56%†† more area than the Evolut[‡] R/PRO valve grouping of cells surrounding the coronary¹
- Portico frame cell size is 20.8F vs. 11.9F for Evolut R/PRO (size 29mm valves)²

29 mm Portico™ Valve¹	29 mm Evolut [‡] R/PRO ¹	
4	9 8 7 6 4 3 2	

	29mm Portico™ Valve²	29mm Evolut [‡] R/PRO ²	
	20.8F	11.9F	
	36 cells total 9 cells in the annulus section of the stent	135 cells total 15 cells in the annulus section of the stent	
23mm	13.5 F/4.5mm	12.1 F/4.0mm*	
25mm & 27mm/26 mm	15.8 F/5.3mm	11.8 F/3.9mm	
29mm	20.8 F/6.9mm	11.9 F/4.0mm	

⁺ Portico cell #3 = 102.20 mm² vs. Evolut PRO cell #6 = 15.19 mm² ⁺⁺ Portico cell #3 = 102.20 mm² vs. Evolut PRO cell #5 + 2x #6 + 7 = 65.44 mm²

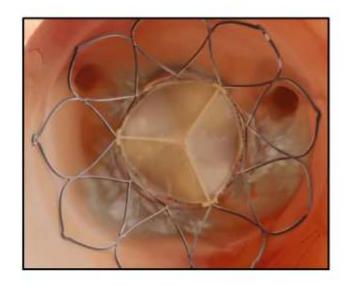
Always sheek the regulatory status for the device in your region

Abbott Data on File. 90661799 2. Abbott Data on File. 90664679. ‡Indicates a third-party trademark, which is property of its respective owner. *23mm CoreValve measured.
 Information contained herein for DISTRIBUTION outside of the U.S. ONLY.

Coronary Access Preservation

LARGE OPEN-CELL GEOMETRY AND INTRA-ANNULAR VALVE POSITION MINIMIZES OBSTRUCTION TO CORONARY BLOOD FLOW, PRESERVING CORONARY ACCESS FOR FUTURE INTERVENTIONS^{1,2}

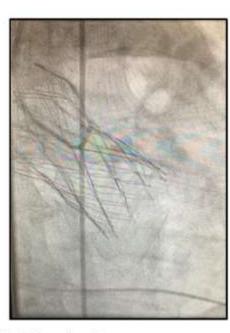
LARGE STENT CELL DIAMETERS (13.5-20.8 FRENCH) PRESERVE CORONARY ACCESS³



RIGHT CORONARY ACCESS



ACCESS



1. Portico IFU.2. Linke A, Holzhey D, Möllmann H, et al. Treatment of Aortic Stenosis With a Self-Expanding, Resheathable Transcatheter Valve: One-Year Results of the International Multicenter Portico Transcatheter Aortic Valve Implantation System Study. Circ Cardiovasc Interv. 2018;11(2):e005206. doi:10.1161/CIRCINTERVENTIONS.117.005206. 3. Abbott. Data on File. 90103707. 20.8 F access diameter for the 29 mm Portico valve. 15.8 F for 25 and 27 mm valves; 13.5 F for 23 mm valve.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY.

Check the regulatory status of the device in areas where CE marking is not the regulation in force.

EQUIPMENT LIST

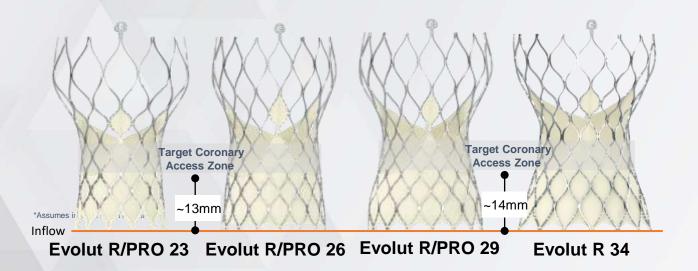
Accessing coronary ostia through a TAVI frame does not require any specialized instrumentation; the following standard equipment is typically used:

- PCI wire
- Selection of passive guide catheters (undersized by 0.5 cm may help)
- Coronary balloon
- Guide extensions



STEP 1: IDENTIFY CORONARY TAKEOFFS

- Identify the coronary take-off points using aortography and a diagnostic pigtail catheter in the outflow portion of frame.
- Identify the frame cells adjacent to the coronary ostia to target when attempting to cannulate the coronaries
 - Target access zone is typically located from the waist to node three*





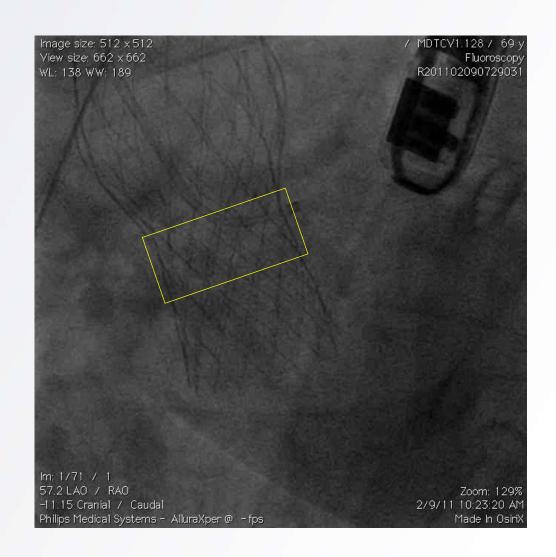
STEP 2: CANNULATE CORONARY OSTIUM

Cannulate coronary ostium through the middle of valve frame cell at the level of the coronary take-off.

- Start with passive guide catheter downsized 0.5 cm to accommodate the valve frame.
- Target the middle of the frame cell co-axial to the take off.
 - Typically between the frame waist and the third node.
- Avoid cannulation of the ostia from below the coronary takeoff.

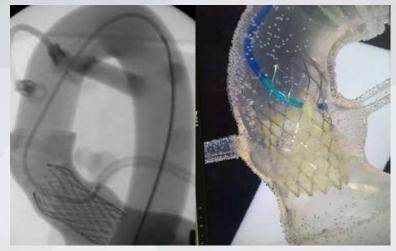
If coronary engagement is unsuccessful, consider:

- Changing guide catheter size.
- Targeting an adjacent cell.
- Attempting a partial selection, then engaging with the wire.
- Using an extension when extra support is needed or when the distance between the frame and the coronary ostia is large – common with right coronary artery.



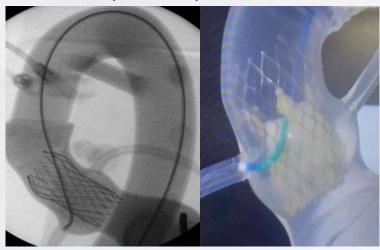
GUIDE CATHETER SELECTION EXAMPLES

Evolut R 26mm Valve Implant Depth ~4-5mm



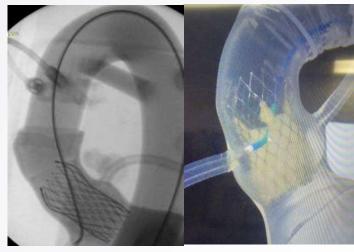
- 6Fr JL3.5 to LCA
- Access LCA from above or lateral position, back tip out with the PCI wire prior to removing guide
- Leverage angiography wire to push tip off frame and reposition, if necessary

Evolut R 29mm Valve Implant Depth ~2-3mm



- 7Fr JR4.0 to RCA
- Access RCA but need help with angio wire for tip placement into appropriate cell for cannulation into RCA
- Leverage angiography wire to push tip off frame and reposition, if necessary

Evolut R 23mm Valve Implant Depth ~2-3mm

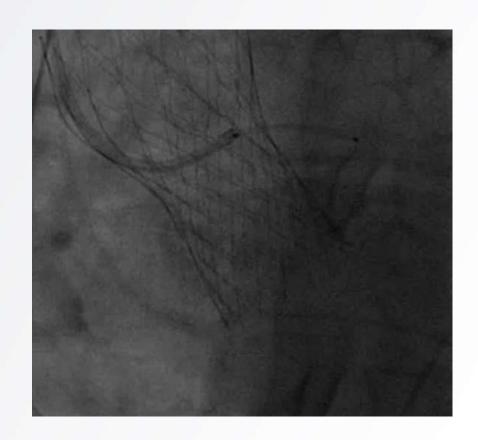


- 6F JR3.5 to RCA
- Access RCA but need help with angio wire for tip placement into appropriate cell for cannulation into the RCA
- Leverage angiography wire to push tip off frame and reposition if necessary

STEP 3: PERFORM INTERVENTION

Advance a coronary balloon or stent through the guide catheter to perform intervention.

- A support catheter can be used if additional support is needed to reach the lesion or obstruction.
- If obstruction is caused by native leaflets, a 'snorkeling technique' where the stent is deployed partially extending from the ostium can be employed to treat the obstruction.



Post-TAVI Coronary Access STEP 4: CONFIRM PATENCY AND REMOVE CATHETER AND GUIDEWIRE

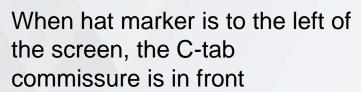
After performing intervention, confirm patency and disengage guide catheter from ostium and withdraw through frame cell.

- Always remove guide catheter over a wire and slightly rotate the catheter as retracting to minimize interaction with the top of the frame cell.
- If there is difficulty removing the guide catheter, a coronary balloon can be used to disengage from the frame cell when pulling.



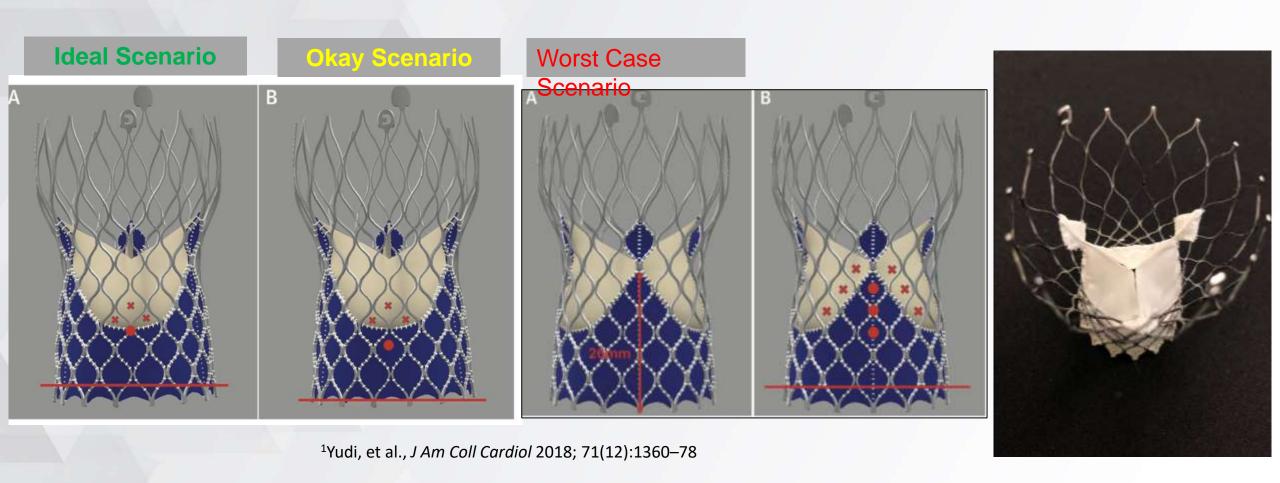
Commissural alignment during TAVR deployment Will facilitate coronary access afterwards







Can pre-procedural planning help alleviate some of the challenges with post-TAVR PCI

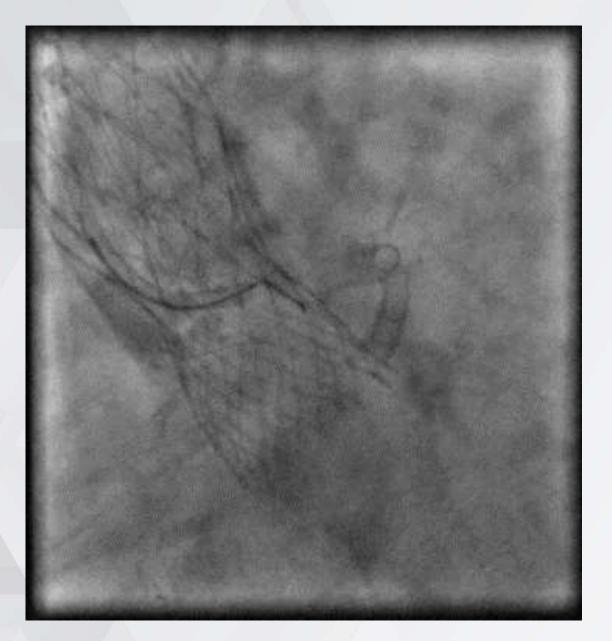


Tips for diagnostic Cath /PCI

- PREVENTION- Select a THV that will enable reasonable coronary access later on.
- PREVENTION- TAVI commissural alignment is important during deployment.
- If it is an elective procedure consider getting coronary CTA
- Understand well the characteristics of the THV device.
- Understand well the patient anatomy.
- Start with aortogram (or review the post TAVR aortigram)

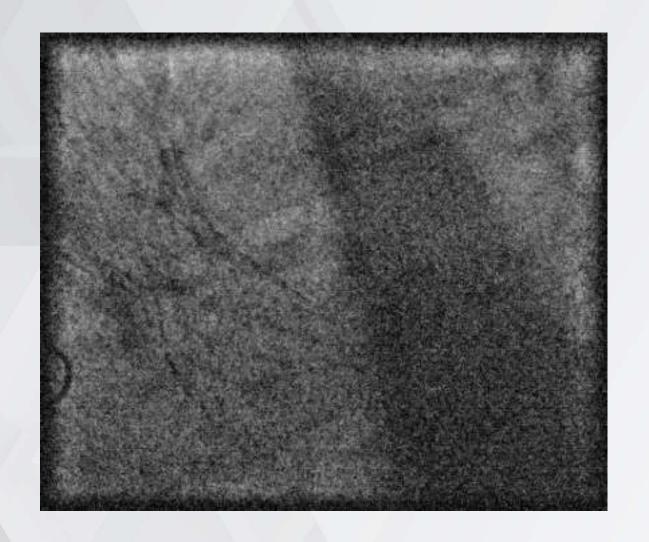
Tips for diagnostic Cath /PCI

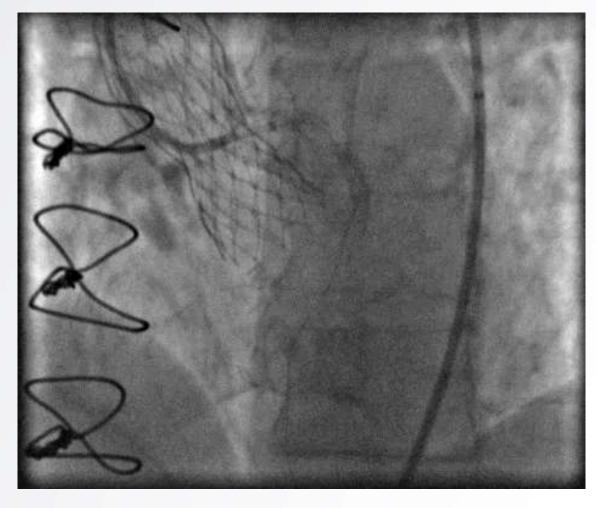
- Use smaller passive cannulation catheters (i.e. JL 3.0 or 3.5)
- Consider MP / IM for the RCA
- Use the j-wire to help you get to the desired frame diamond with the catheter
- Consider using a guideliner for PCI. You need better support!
- Consider free coronary wiring (without guide engagement).
- Changing guide catheters or targeting different cells may help if having difficulty.
- Do not fear PVL seen in guide injection (you are behind the frame)
- Be careful not to damage the THV device.
- Remove the catheter over a wire carefully!



"Air Mailing"

- JR4, guideliner and Microcatheter.
- Able to wire by "air-mailing" coronary wire from middle of frame into LM
- Wire supported by Microcatheter and Guideliner

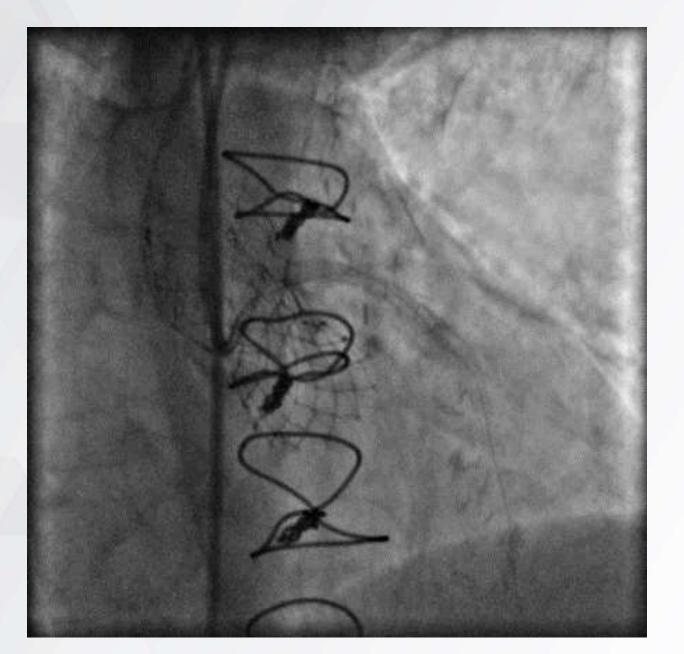


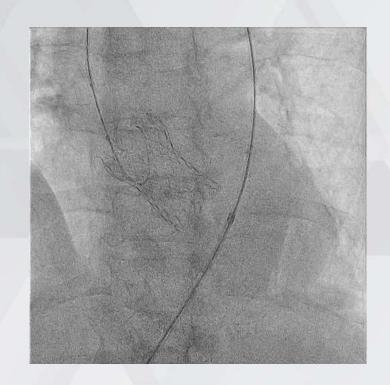


Tip: An Additional LAD wire for support

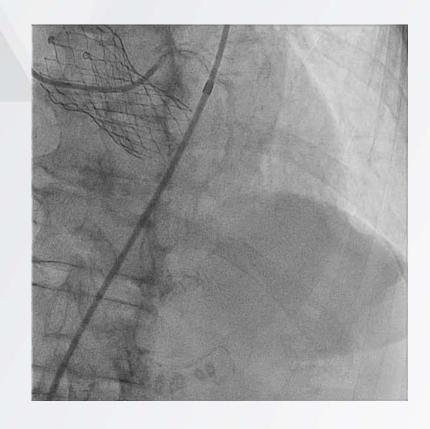
Tip: Now Guide liner through valve frame to engage the LM

And then just LAD PCI

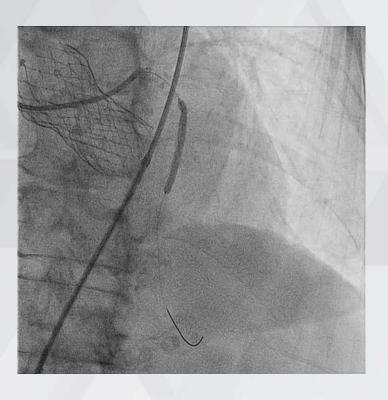




Multivessel PCI post TAVR







Multivessel PCI post TAVR







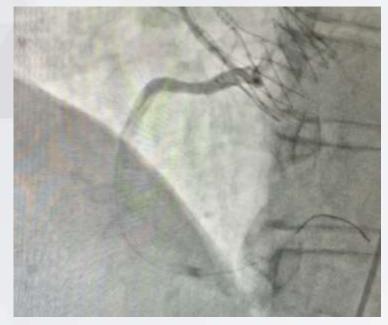




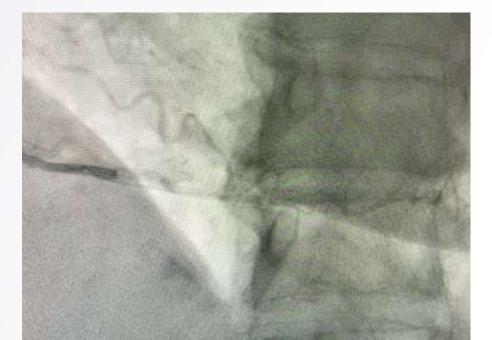


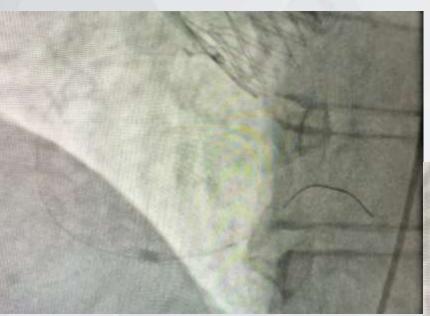


Inferior STEMI post Acurate TAVR



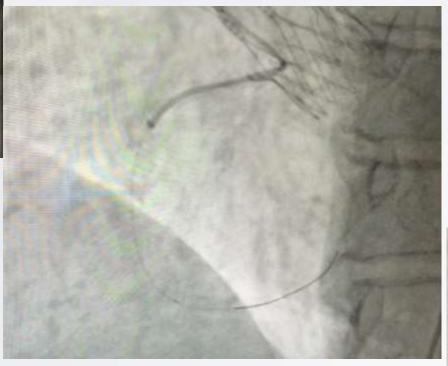
The operator was unable to deliver equipent





Inferior STEMI post Acurate TAVR

Came for another procedure... IM guide, free coronary wiring, guideliner

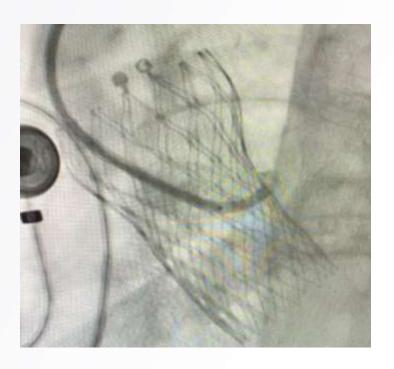






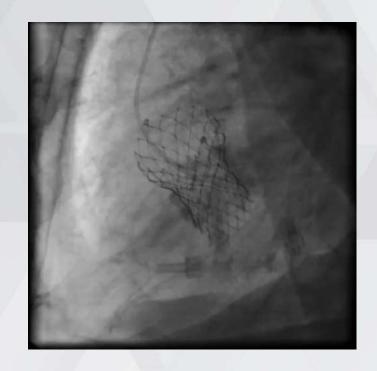
Left main PCI post TAVR





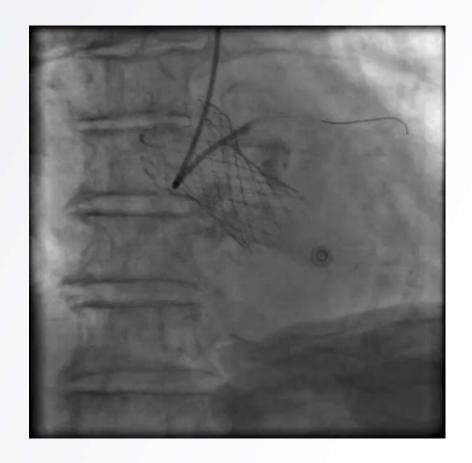


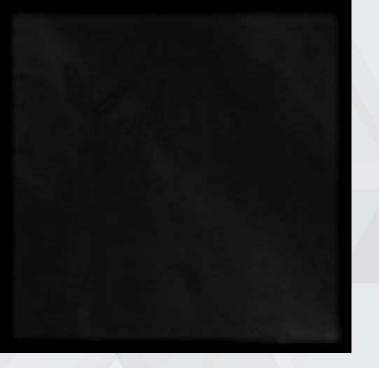




Anterior STEMI post TAVR

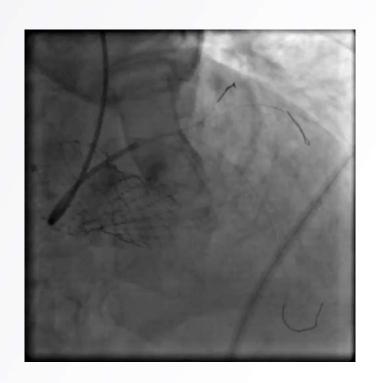






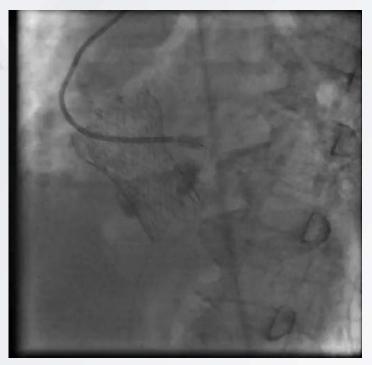
Anterior STEMI post TAVR







Anterior STEMI post TAVR





SUMMARY

- Clinical studies show that coronary access post-TAVI is technically feasible and have reported positive outcomes for all TAV types
- Access can be achieved using standard tools and approaches with minor modifications
- There are numerous tips and tricks on how to perform well post TAVI coronary access.
- Ask for help from a TAVI operator

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