

What Should We Be Aware of Things?

: Learning from Complicated Case

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The Catholic University of Korea

Growth of TAVI

1992



Proof of TAVR Concept in Animals

2002

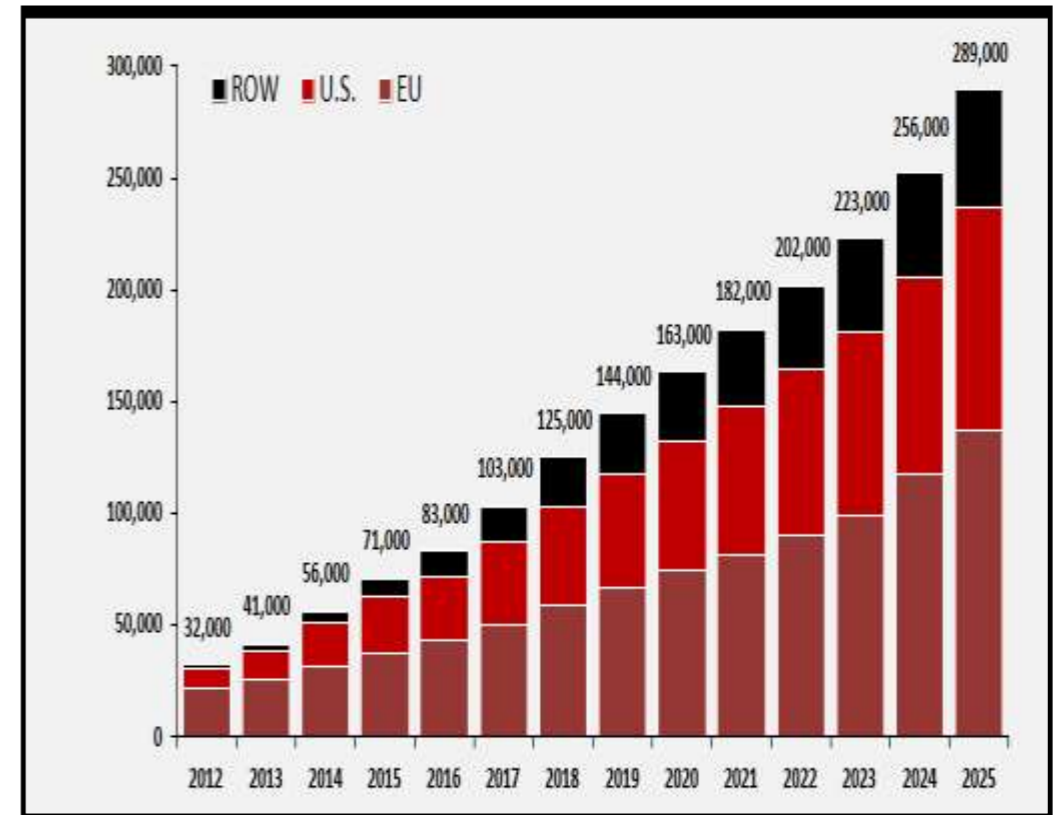
First TAVR in Humans

2010

PARTNERS Trial of TAVR published

2017

TAVR is routine clinical practice

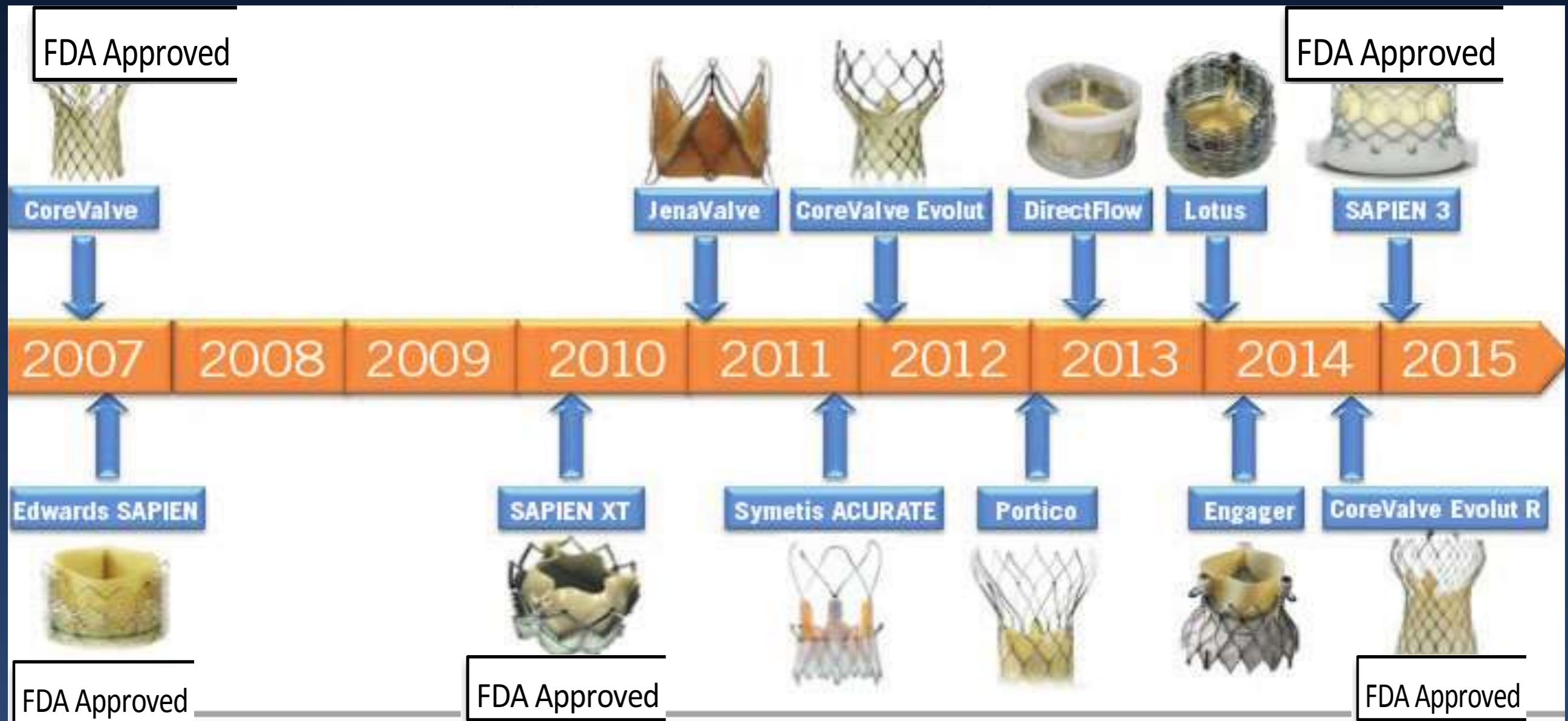


SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

In the next 10 years, TAVI will grow X4

Over the last decade, TAVR has evolved from an highly complex and hazardous procedure into a mature, safe and streamlined therapy.

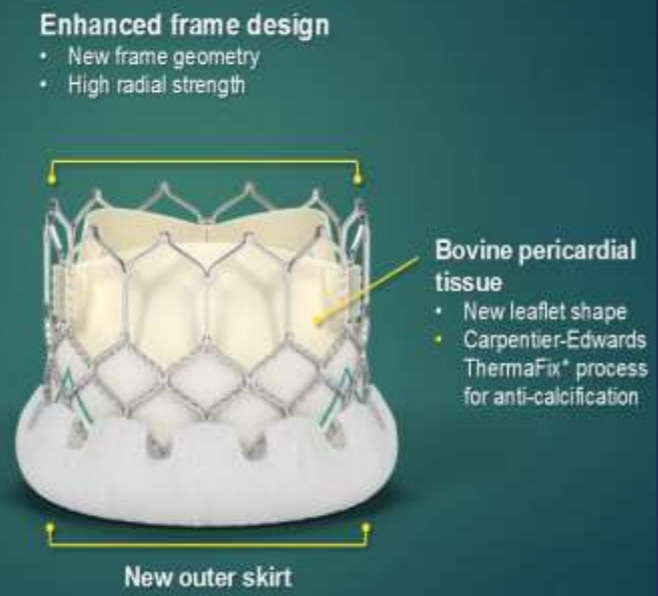
Rapid Innovations of Device



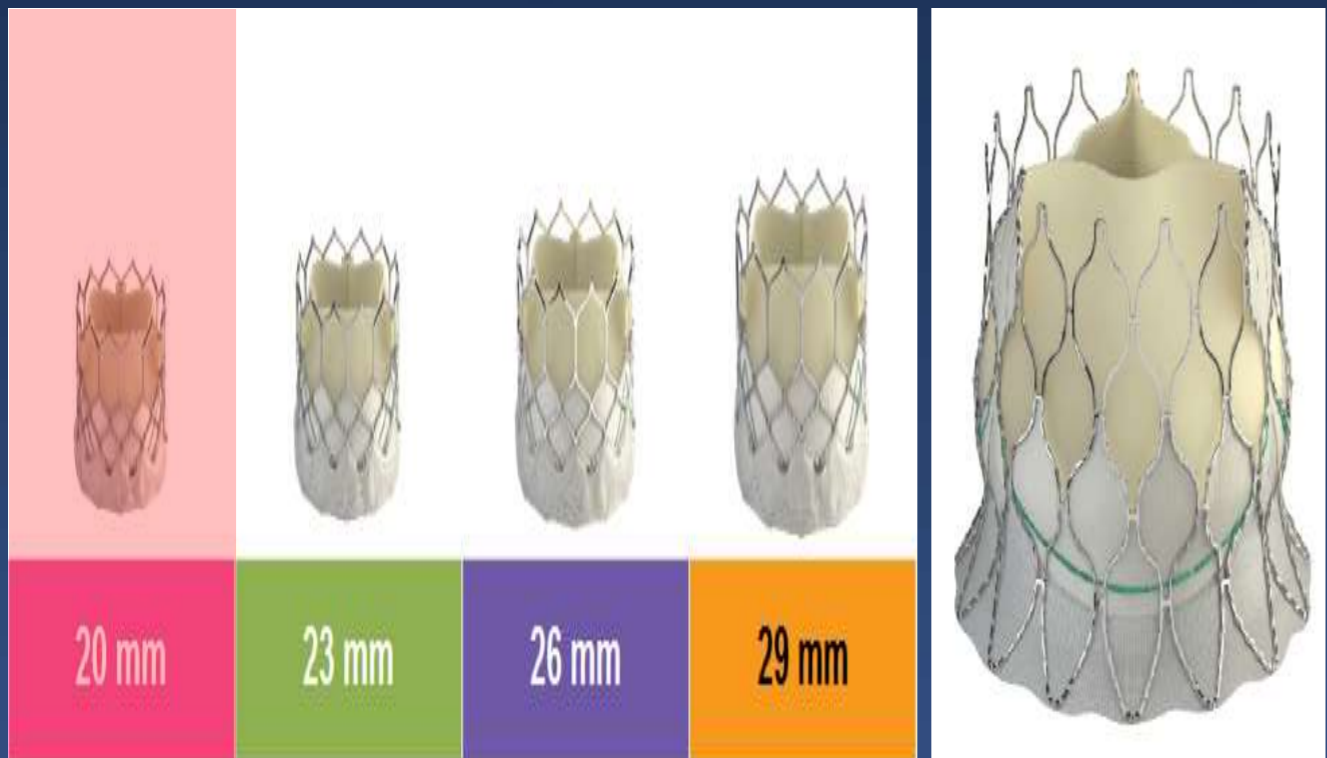
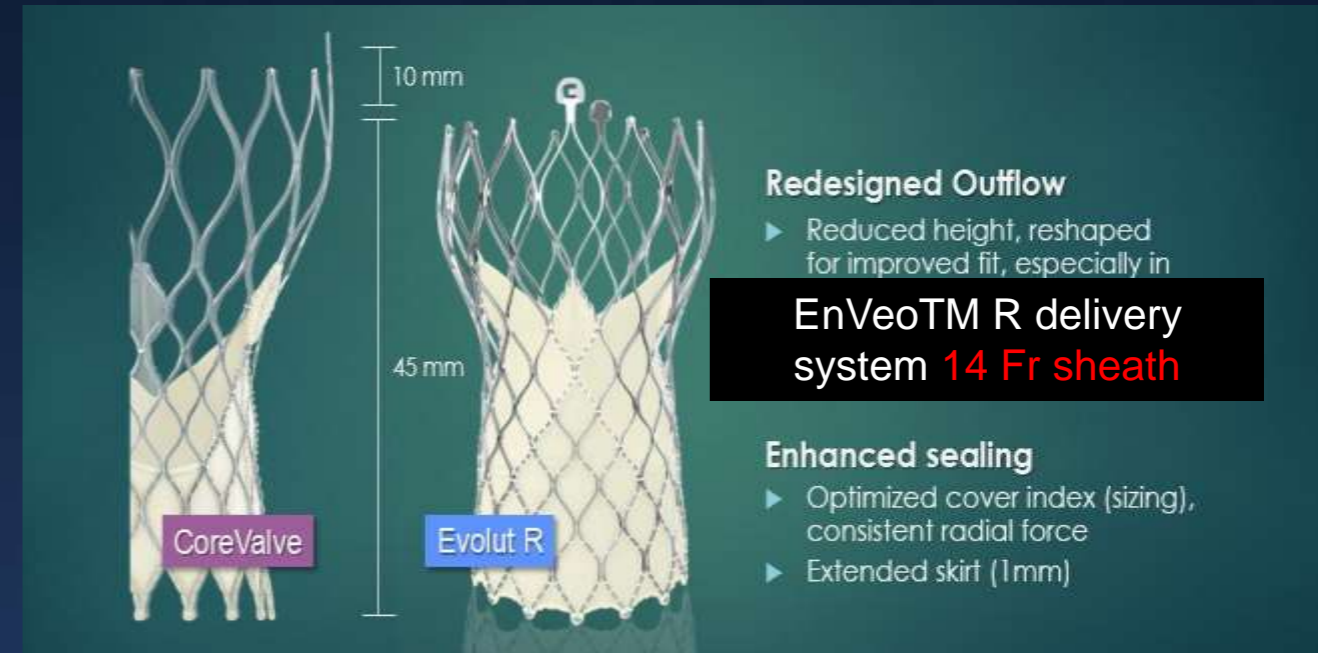
Rapid innovations and refinements have been specifically designed to overcome these limitations, that have resulted in several second-generation devices

New approval of Device

EDWARDS

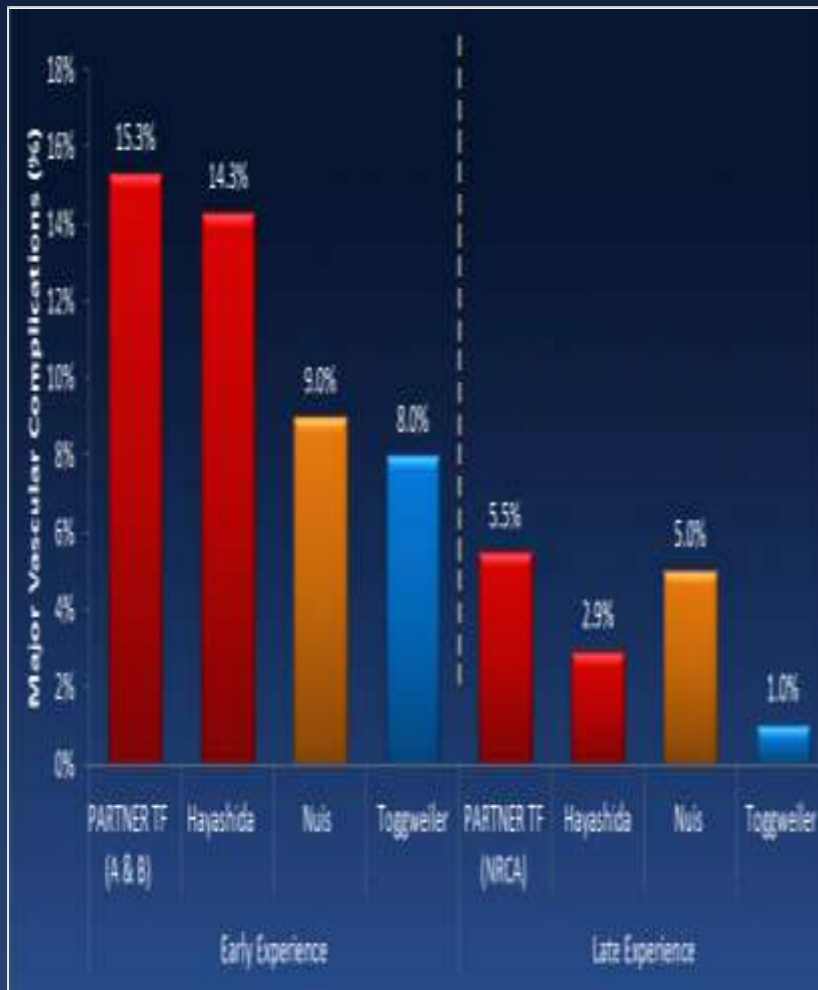


MEDTRONIC

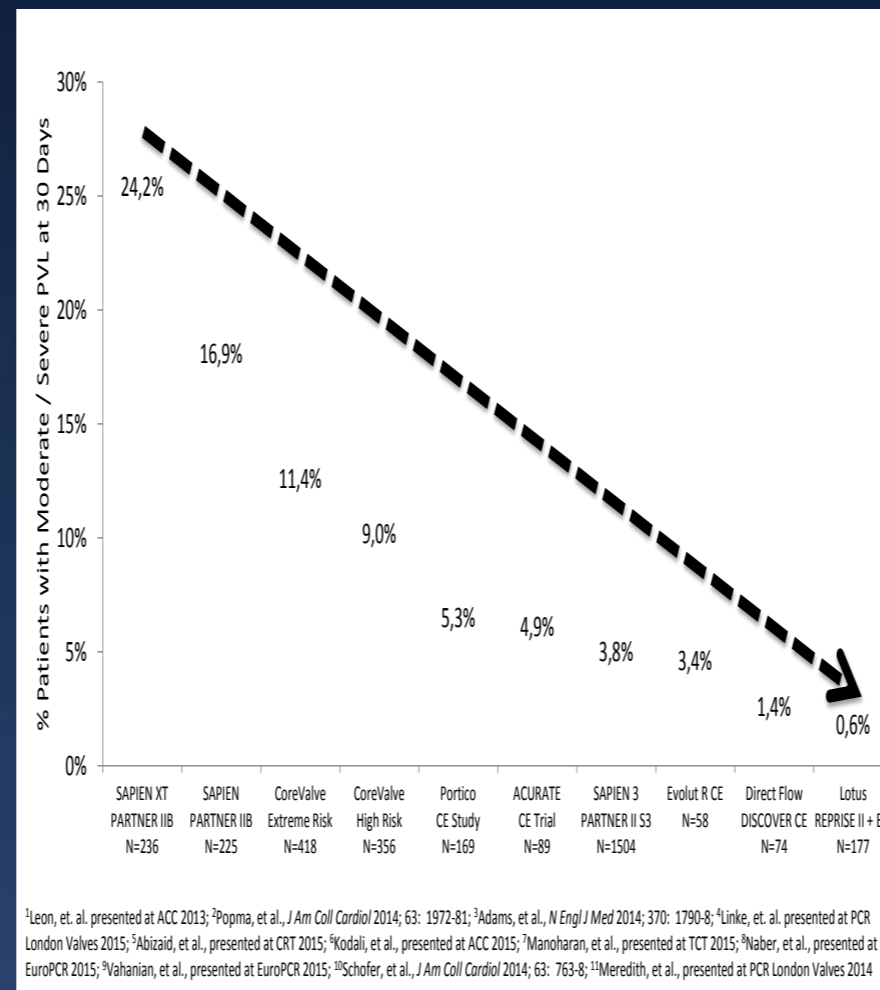


Recently TAVI outcome

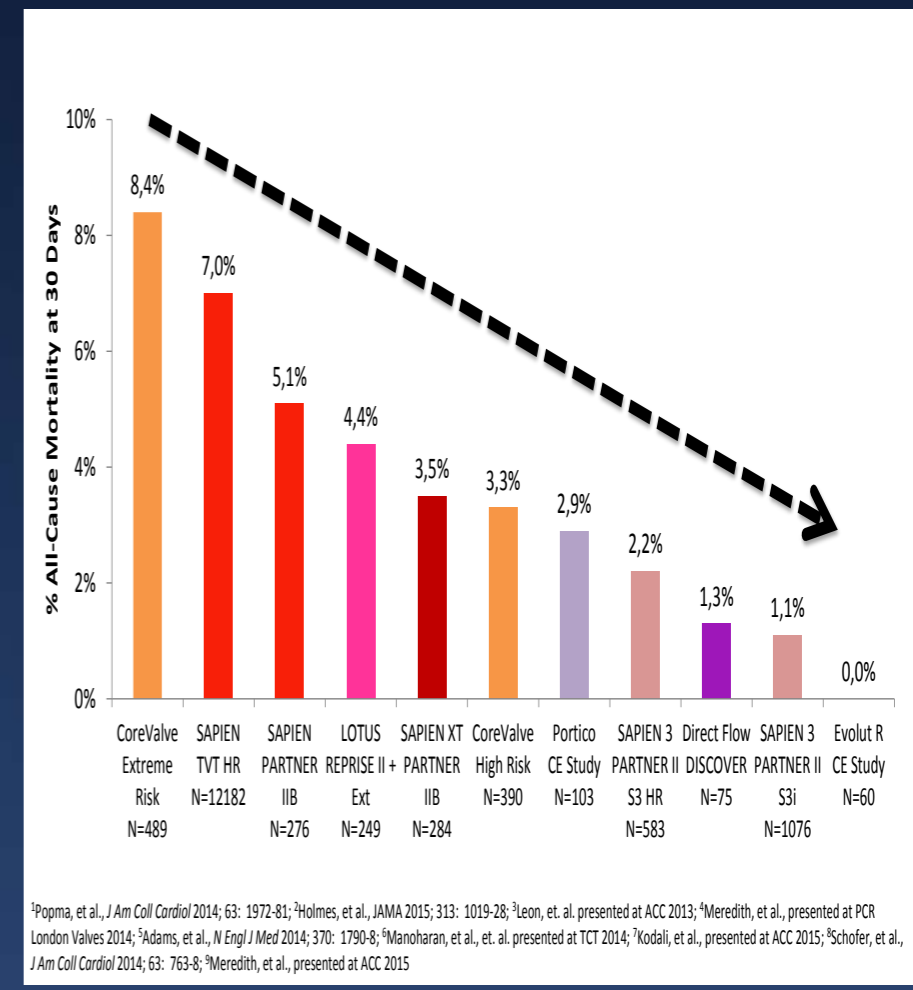
Vascular Complications



Paravalvular Leak



30-day All-cause Mortality



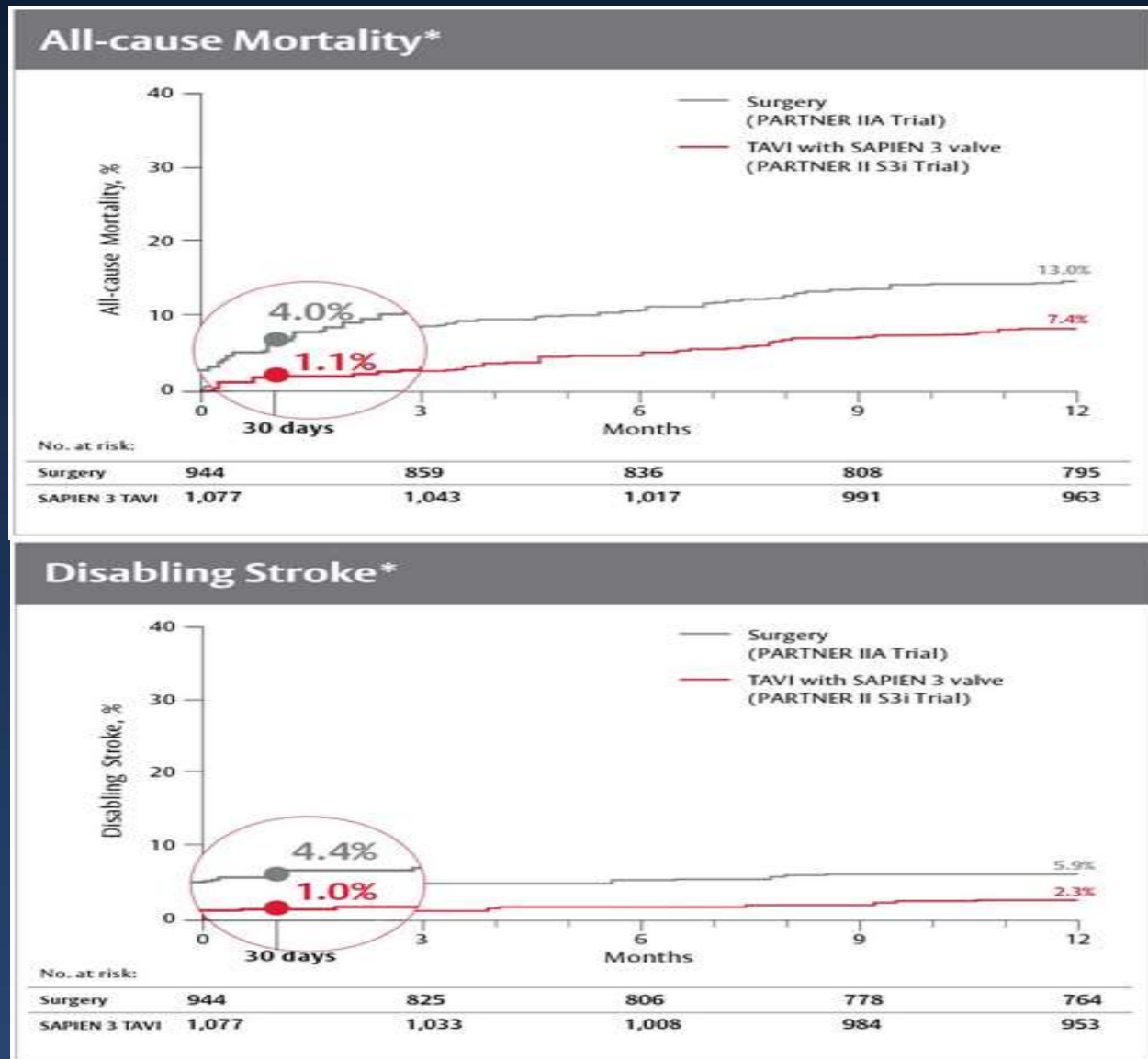
- ✓ With **impressive reduction** of vascular complications, paravalvular leaks, and other undesirable effects
- ✓ These improvements have finally led with a clear reduction of peri-procedural mortality, which is currently at **around 1%** at 30 days

¹Leon, et al. presented at ACC 2013; ²Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; ³Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ⁴Linke, et al. presented at PCR London Valves 2015; ⁵Abizaid, et al., presented at CRT 2015; ⁶Kodali, et al., presented at ACC 2015; ⁷Manoharan, et al., presented at TCT 2015; ⁸Naber, et al., presented at EuroPCR 2015; ⁹Vahanian, et al., presented at EuroPCR 2015; ¹⁰Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; ¹¹Meredith, et al., presented at PCR London Valves 2014

¹²Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; ¹³Holmes, et al., *JAMA* 2015; 313: 1019-28; ¹⁴Leon, et al. presented at ACC 2013; ¹⁵Meredith, et al., presented at PCR London Valves 2014; ¹⁶Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ¹⁷Manoharan, et al., et al. presented at TCT 2014; ¹⁸Kodali, et al., presented at ACC 2015; ¹⁹Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; ²⁰Meredith, et al., presented at ACC 2015

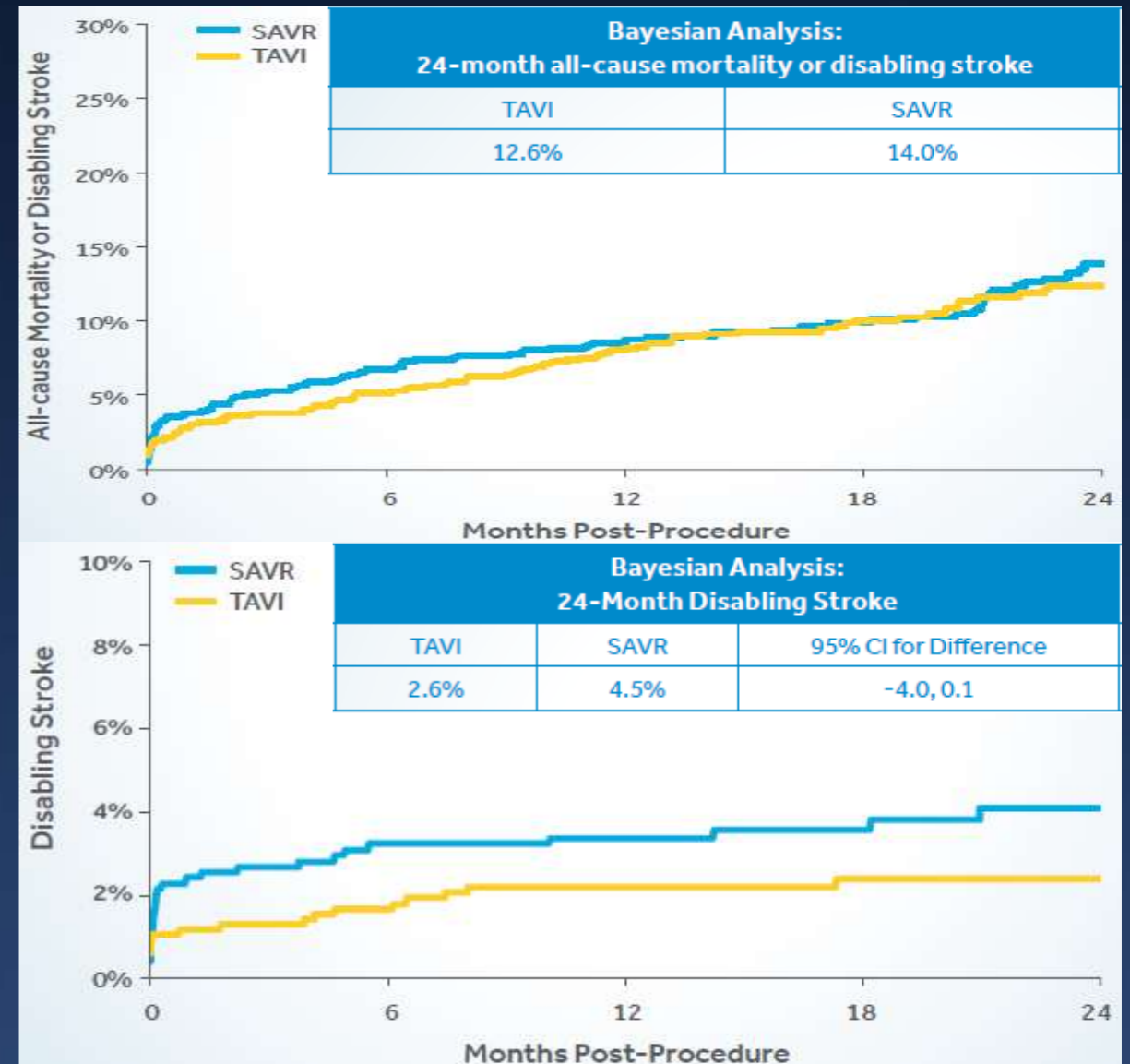
PARTNER II & SURTAVI

PARTNER II



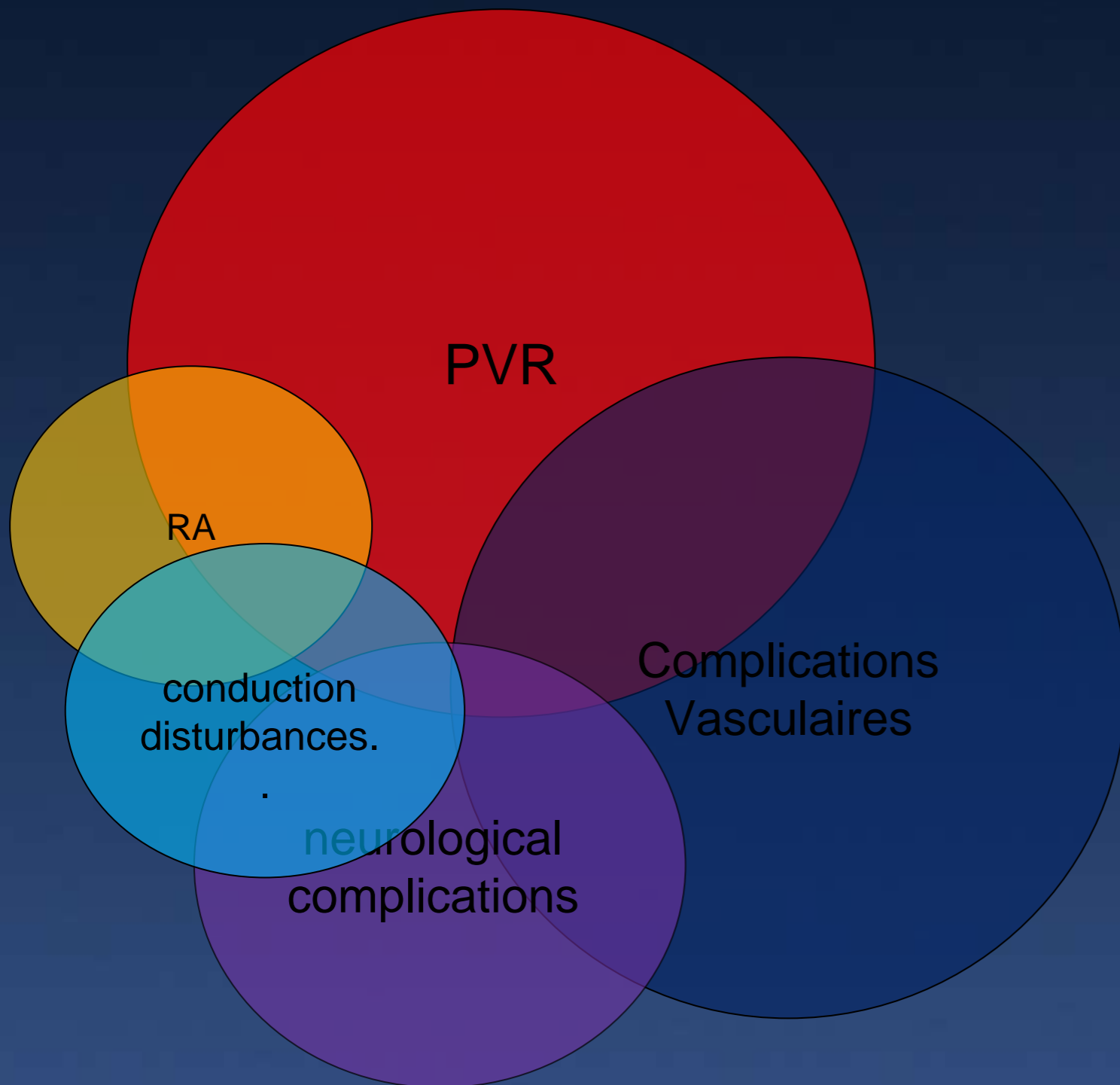
Thourani V., et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: A propensity score analysis. *Lancet*. 2016;387: 2218-25.
 The PARTNER II Trial intermediate-risk cohort unadjusted clinical event rates, AT population.

SURTAVI



NOTE: The SURTAVI study utilized a novel Bayesian statistical methodology. A subset of the cohort had complete data at 24 months. The remaining subjects have incomplete data at various intervals in the follow-up. *N Engl J Med* 2017; 376:1321-1331 [April 6, 2017](#)

Still.... TAVI Complication



<General complications>

1. Aortic dissection
2. Annular rupture
3. Peri-aortic hematoma
4. Coronary Occlusion
5. Vascular complication

Contents

✓ View point – Iliac artery rupture & Aortic

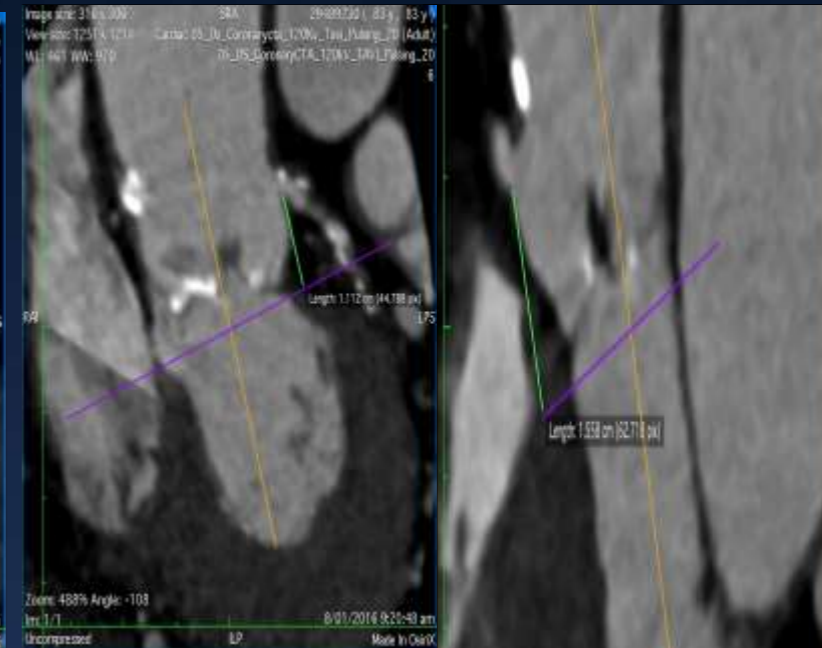
✓ View point – Guide wire-induced LV injury

✓ View point – Valve embolization

✓ View point – Coronary Artery Occlusion

1st Iliac artery rupture

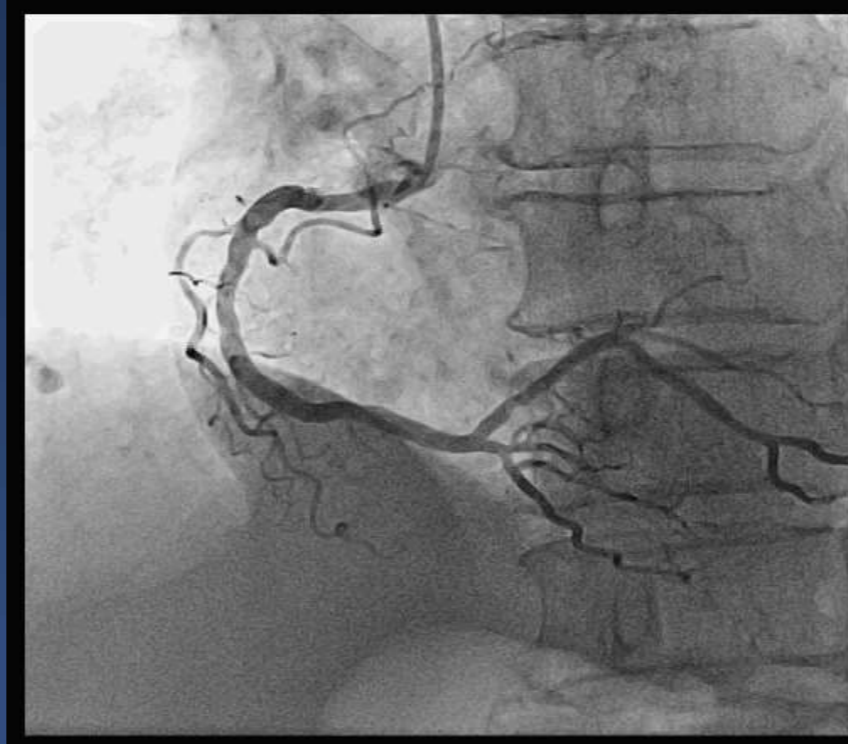
1st Iliac artery rupture during TAVR



Annulus area 370

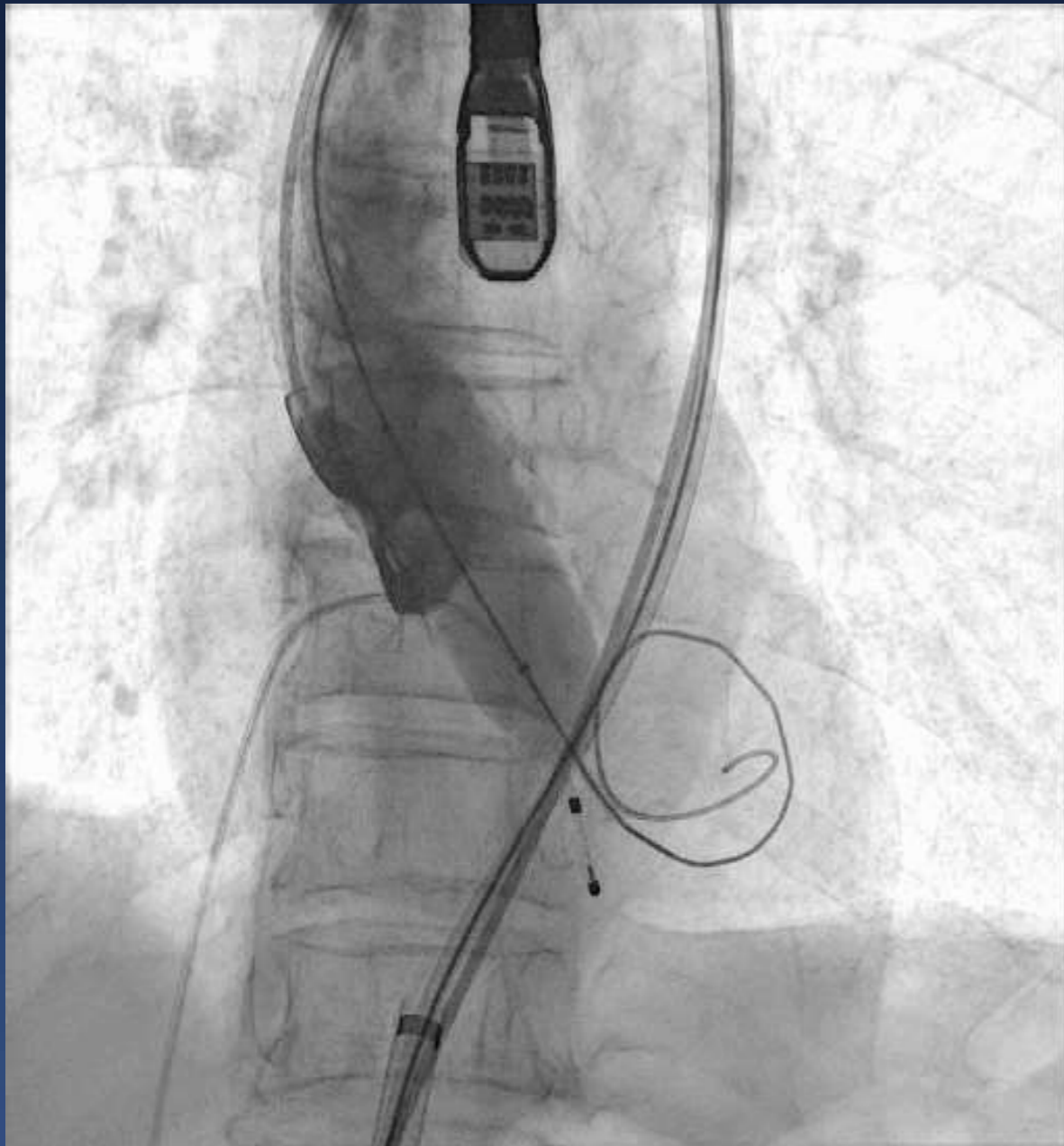


Sapien XT 23mm

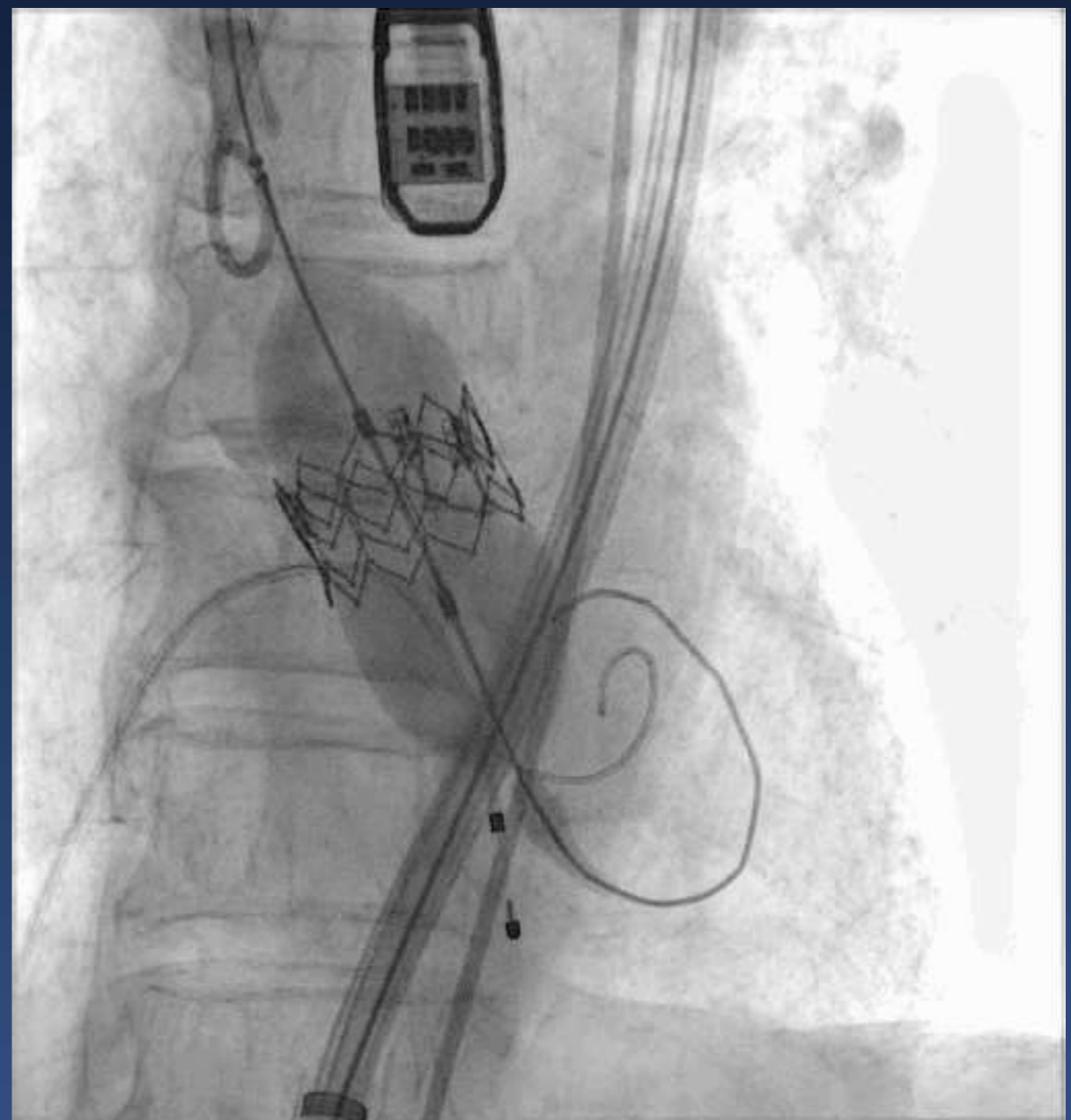


1st Iliac artery rupture during TAVR

Balloon (20mm)



Valve implantation (23mm)



1st Iliac artery rupture during TAVR

Initial PTA Balloon



Post Graft (viabahn 8*10 / 9*10)

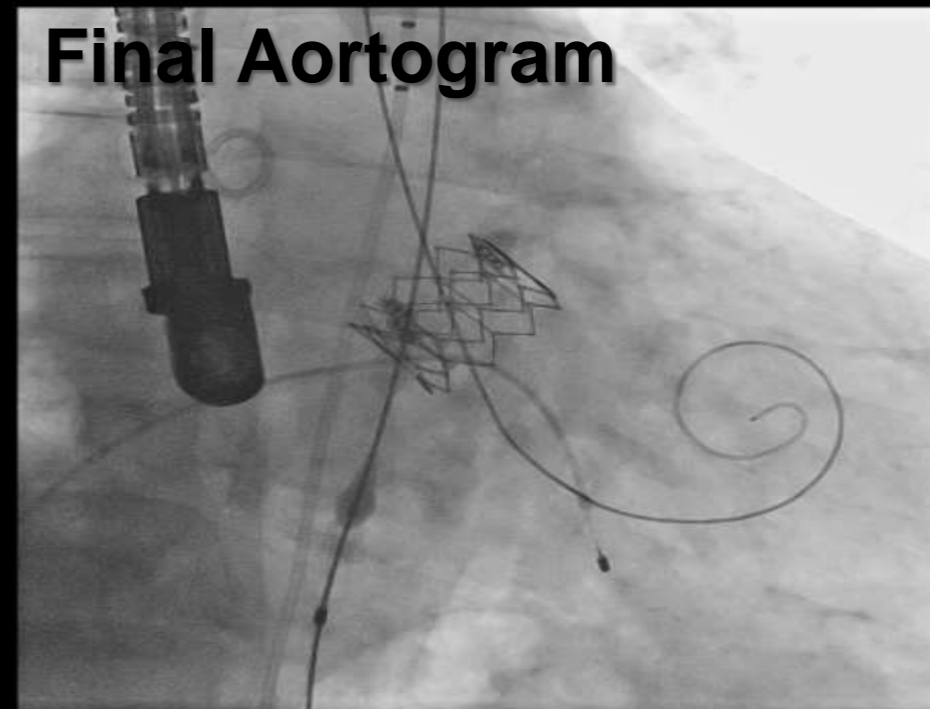


1st - 2 Iliac artery rupture during TAVR

Puncture



Final Aortogram



Remove Sheath



After Viabahn



Viabahn 8-5
Long-duration
Balloon

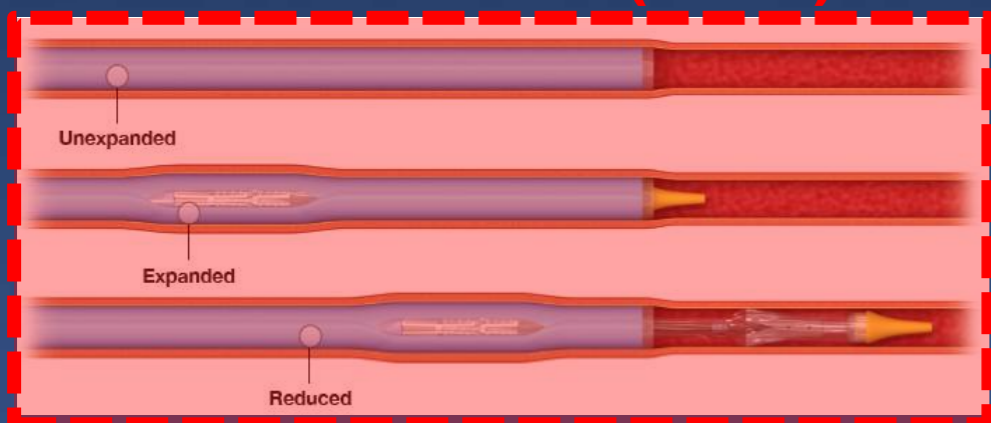
Review of 1st case – Lessons for Nurse & Tech

1. Careful & meticulous assessment of access arterial tress using CT
2. Consider alternative access sites including subclavian, carotid, conduit (direct aortic), open iliac, transcava
3. Iliofemoral angiography after vascular closure from the contralateral femoral artery
4. Sudden unexplained hypotension just after TAVR → consider iliac artery rupture first
5. Covered stents should be always in the cath lab
→ We need to find the replacement viabahan (Gore)

Review of 1st case - Main Sheath

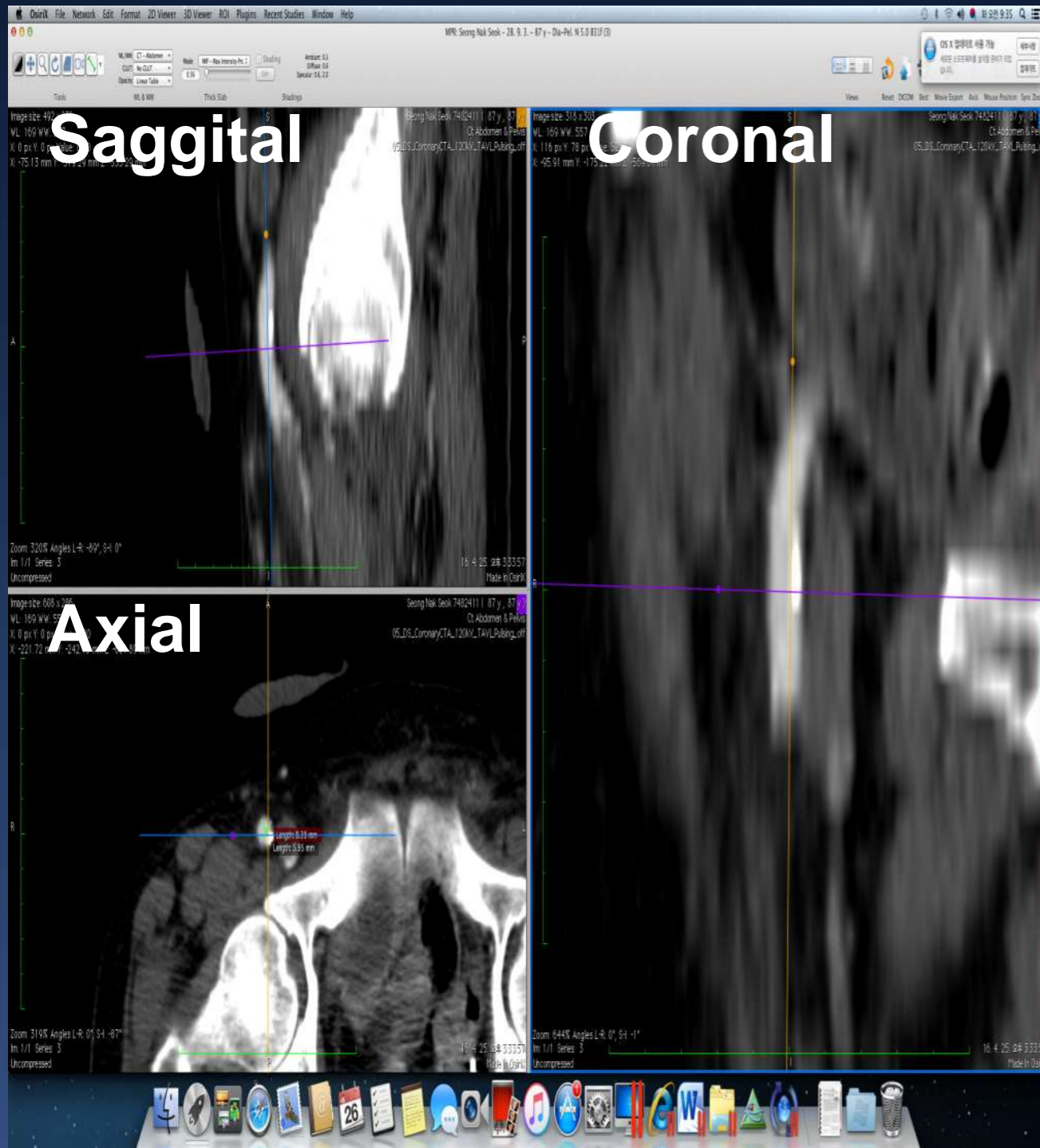
Company	THV	Delivary	Sheath	Sheath ID (unexpanded)	Sheath OD (unexpanded)	Minimum Vessel Diameter*
Edwards	SAPIEN 3 valve 23, 26 mm	Max 22Fr	E-sheath 14Fr	14F (4.6 mm)	18Fr (6.0 mm)	5.5 mm
	SAPIEN 3 valve 29 mm	Max 24Fr	E-sheath 16Fr	16F (5.3 mm)	20Fr (6.7 mm)	6.0 mm
Medtronic STJ	Evolute R 23, 26, 29 mm	Max 18Fr	STJ	16F (5.3 mm)	18Fr (5.9 mm)	5.0 mm
Boston	Lotus 23mm		LIS-S	20F (6.7 mm)	22Fr (7.4 mm)	6.0 mm
	Lotus 25, 27mm		LIS-L	21F (7.1 mm)	24Fr (7.9 mm)	6.5 mm

Dynamic Expansion Mechanism (DEM)

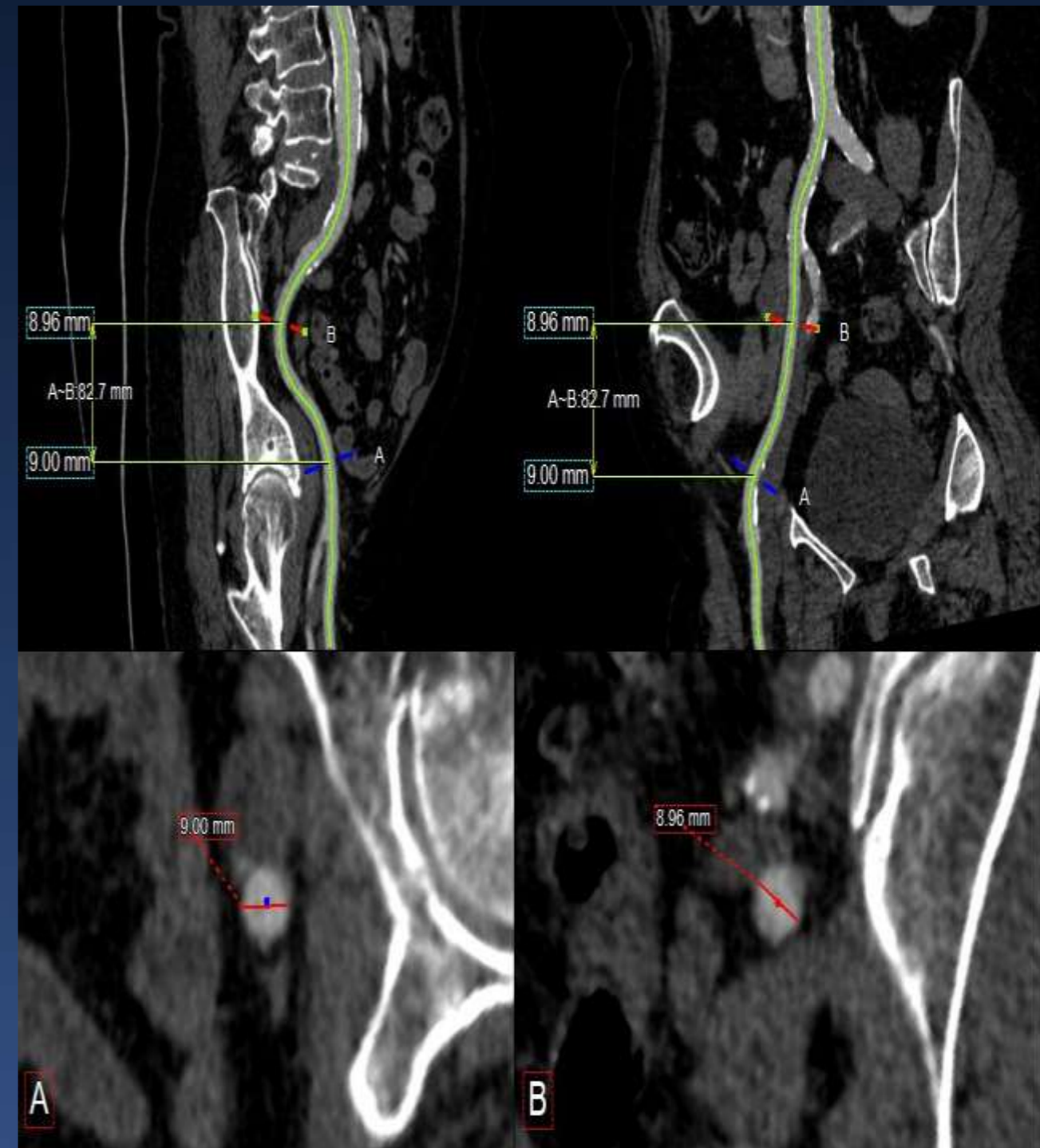


Review of 1st case CFA~CIA → Fr available

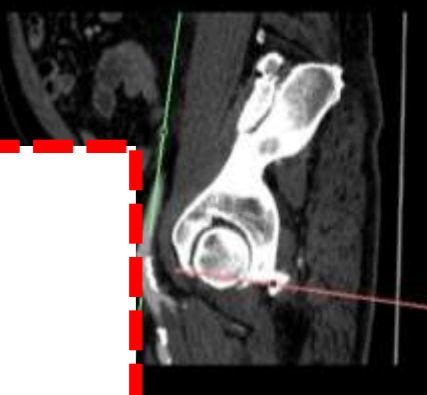
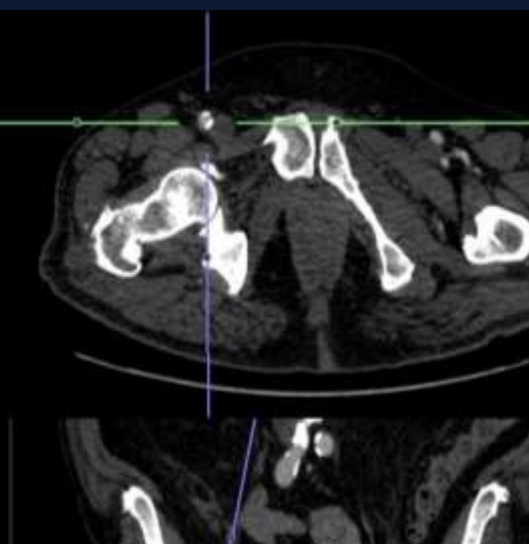
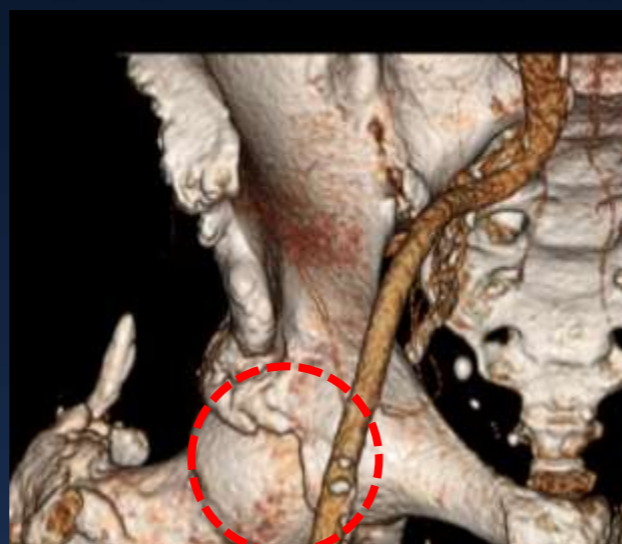
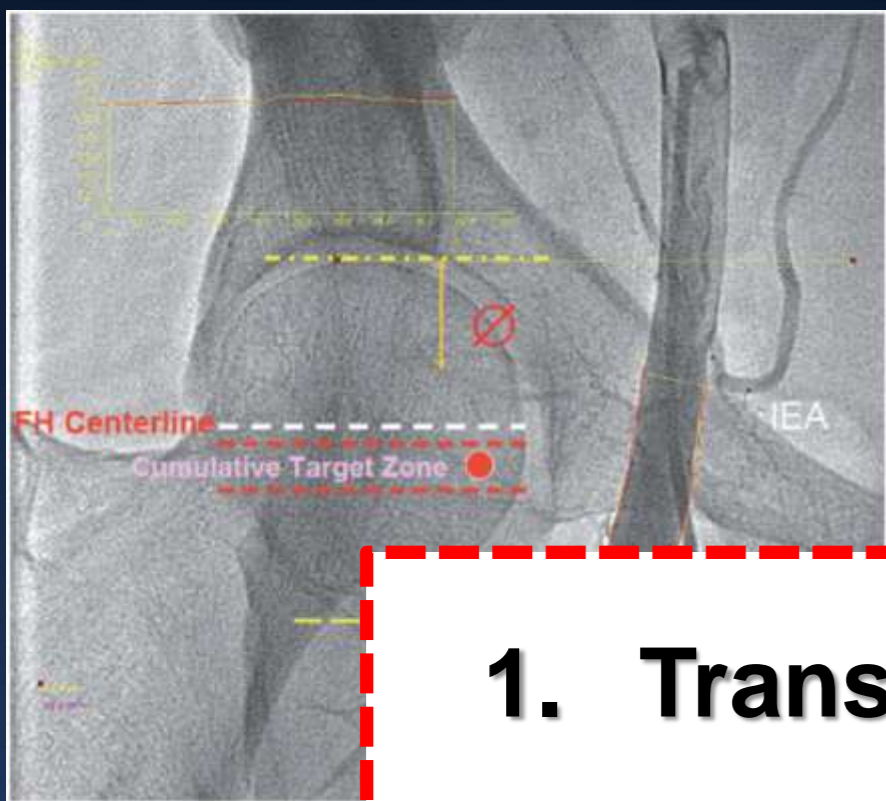
MPR



Curved MPR

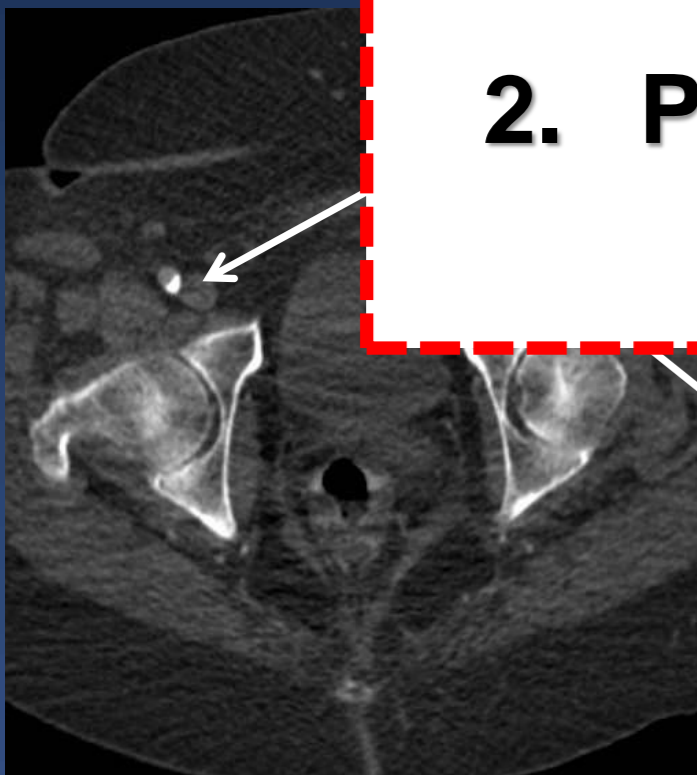


Review of 1st case - **Puncture site**



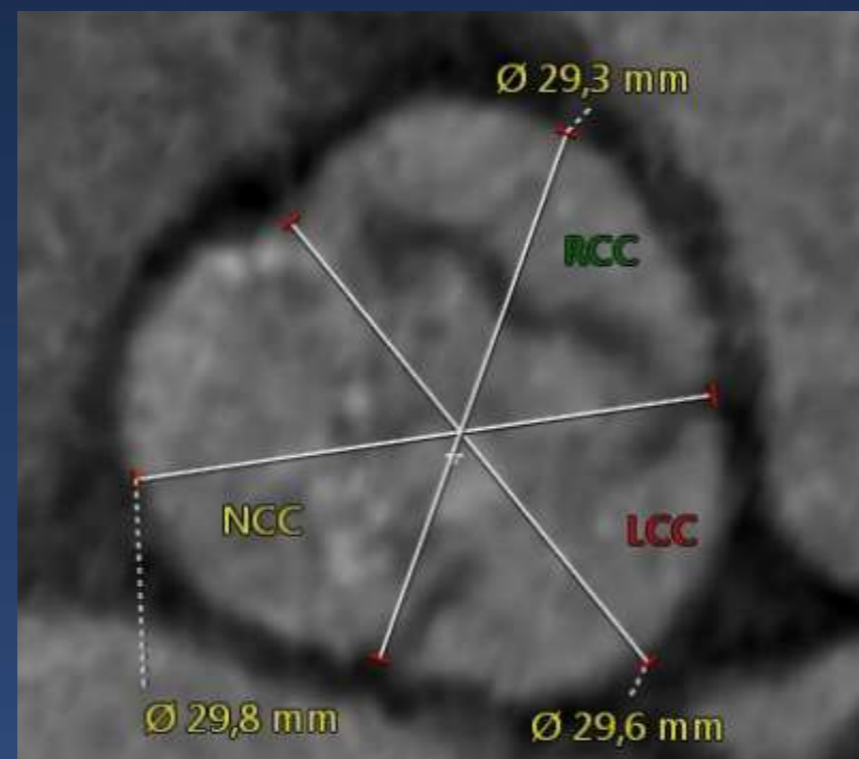
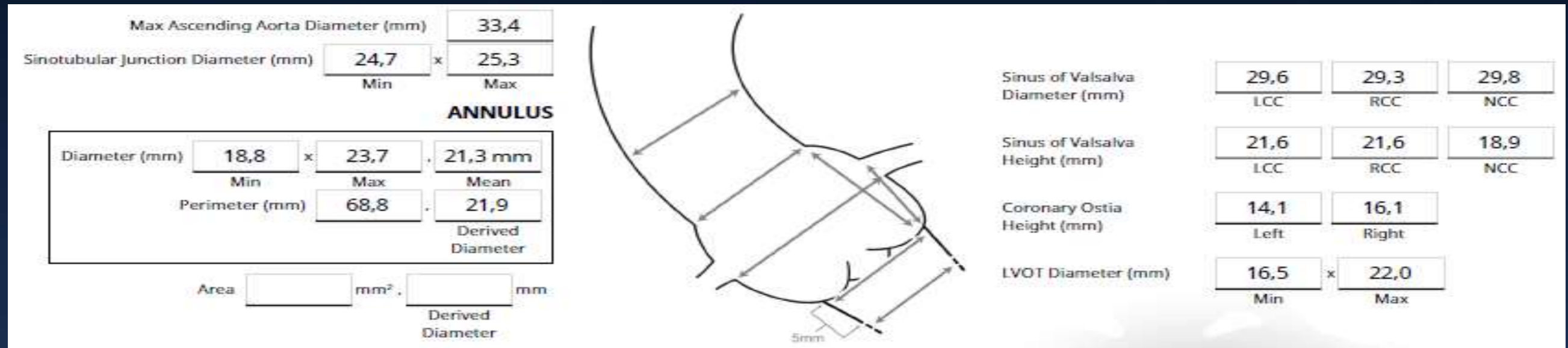
1. Trans femoral or others

**2. Puncture site → Rt or Lt
Upper or Lower**



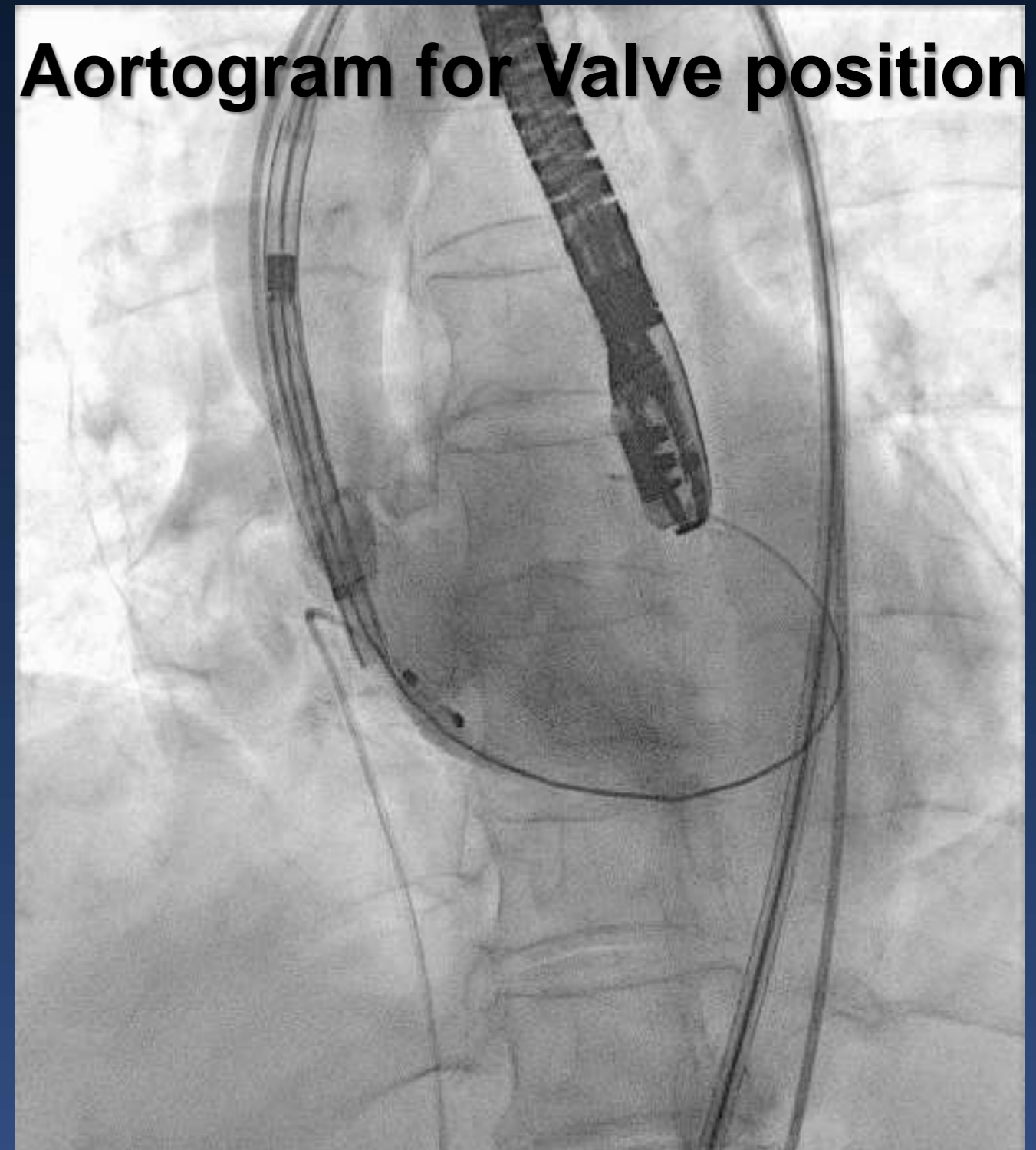
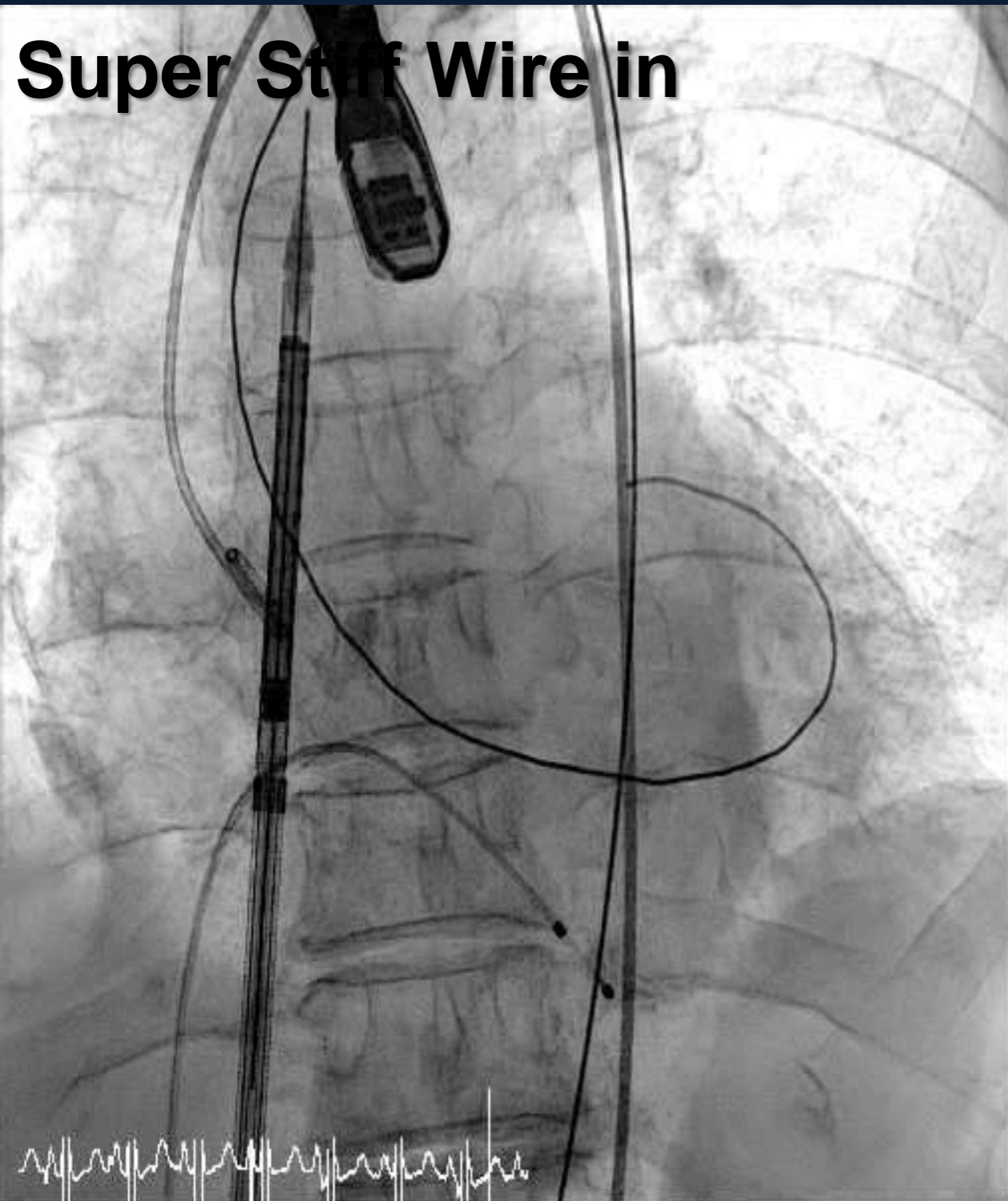
2nd Guide wire-induced LV injury

2nd Guide wire-induced LV injury



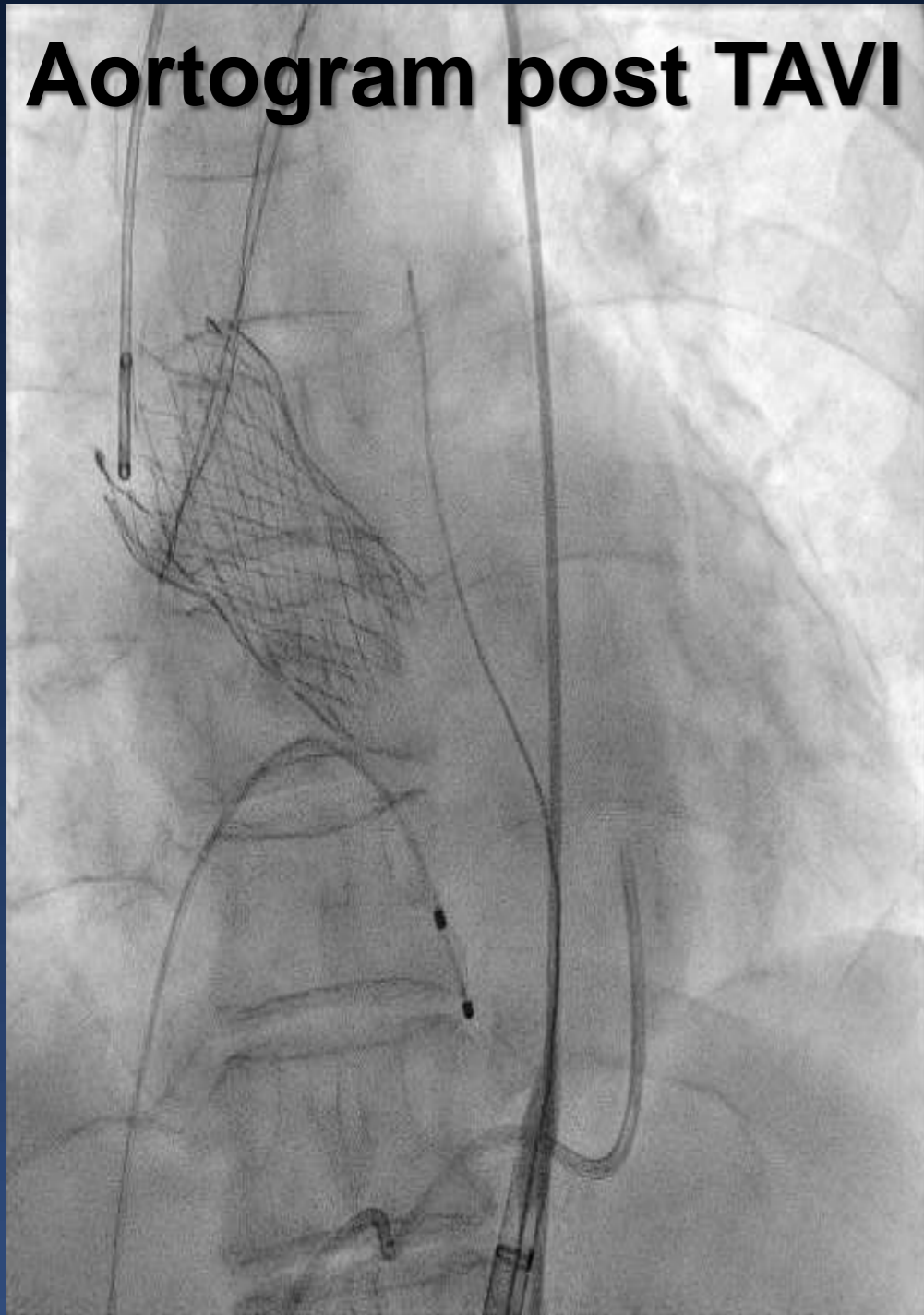
68.8mm (Annulus Diameter : 21.9mm) → CoreValve Evolut R 26mm

2nd Guide wire-induced LV injury

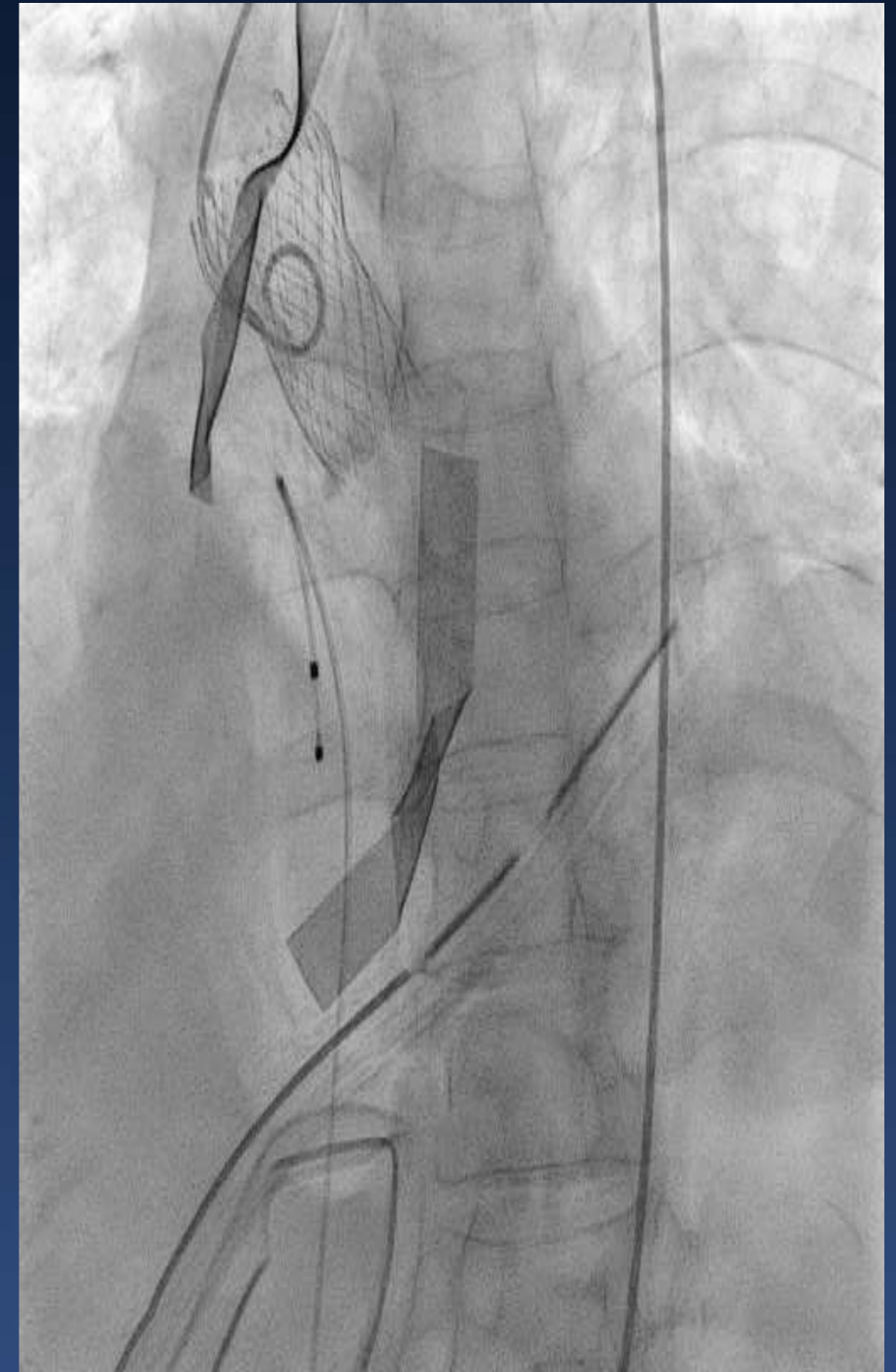


2nd Guide wire-induced LV injury

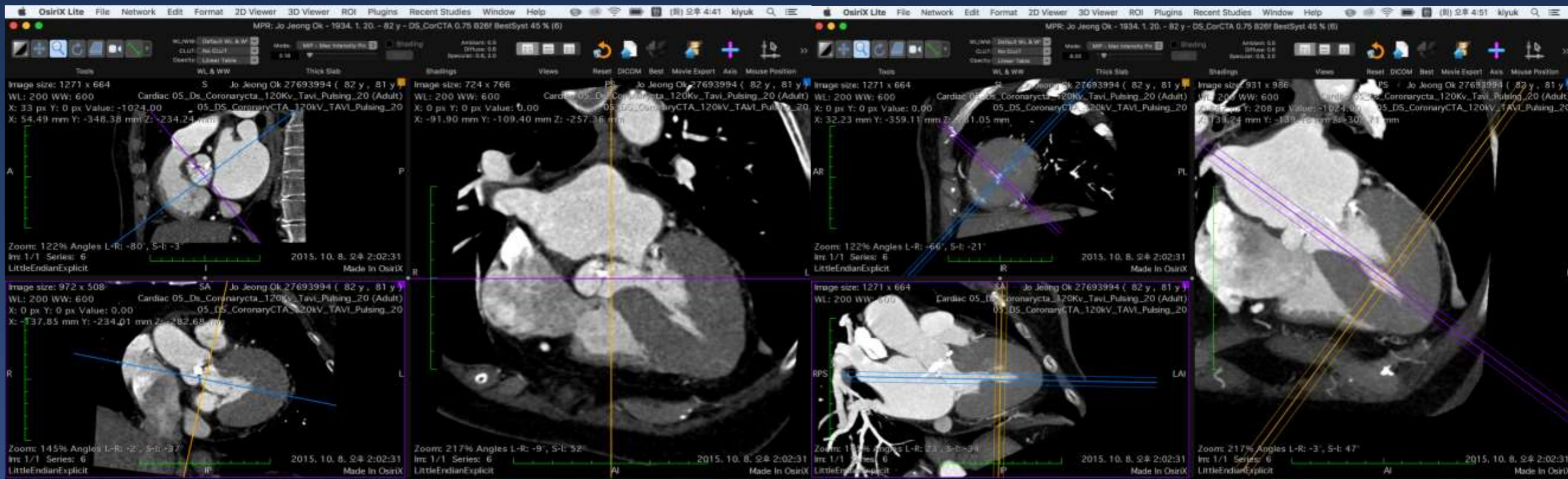
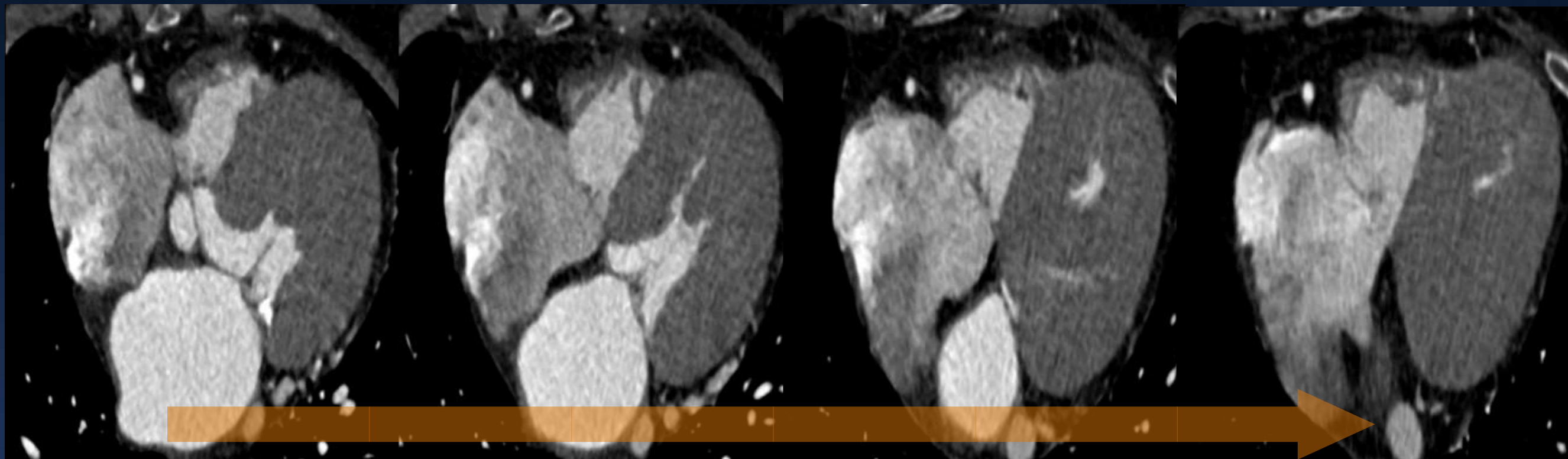
Aortogram post TAVI



**Emergency OP
In Hybrid room**

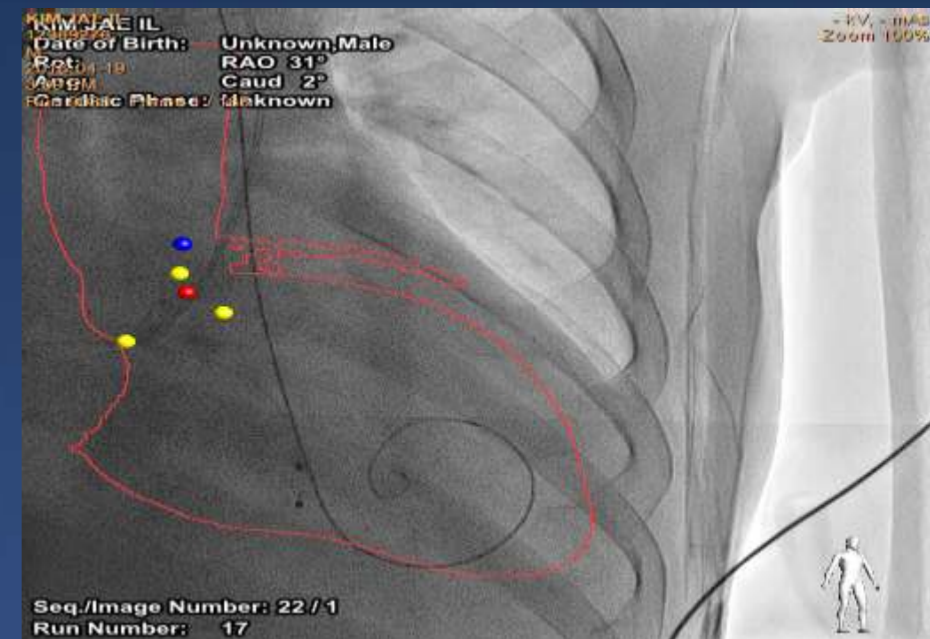
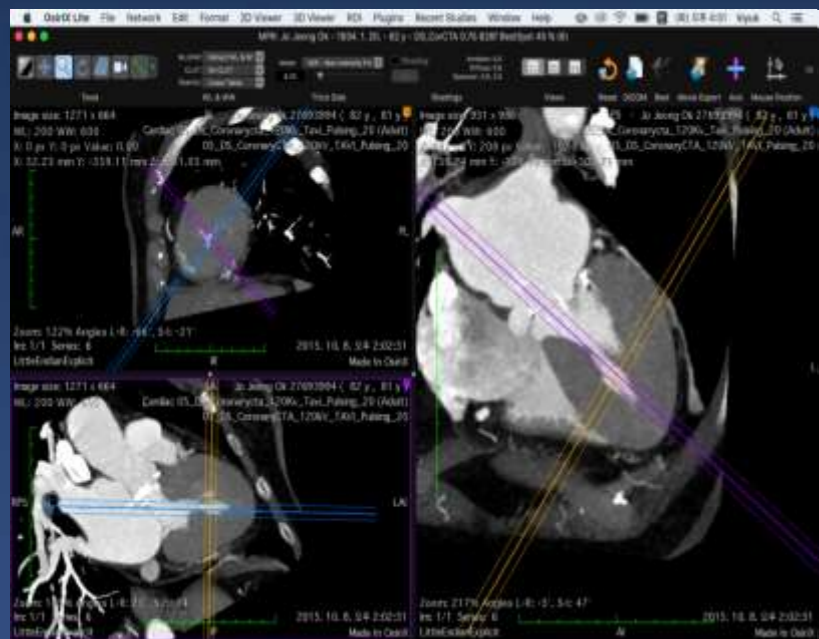


2nd Guide wire-induced LV injury



2nd CASE Review – Lessons for Nurse & Tech

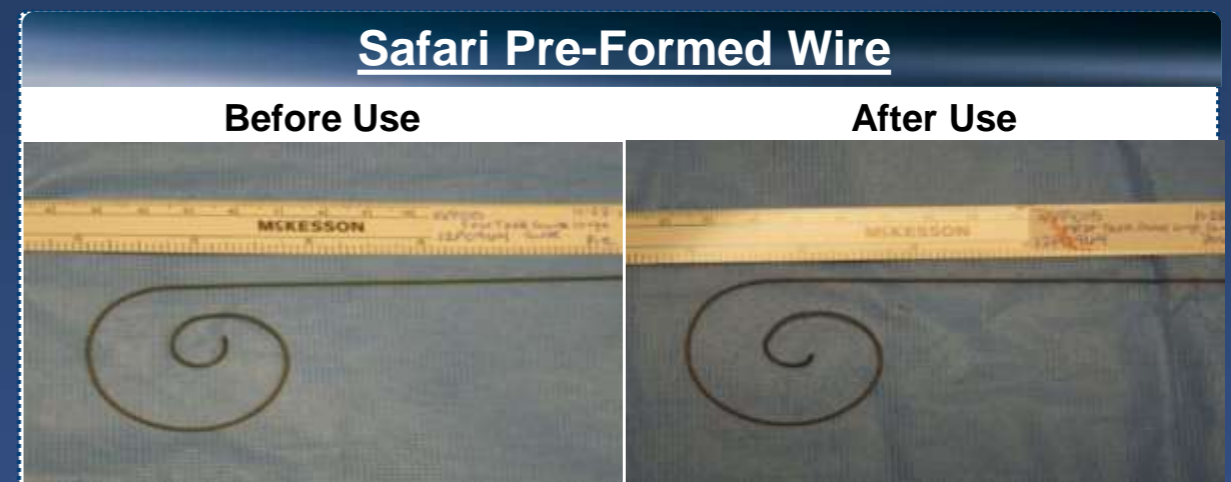
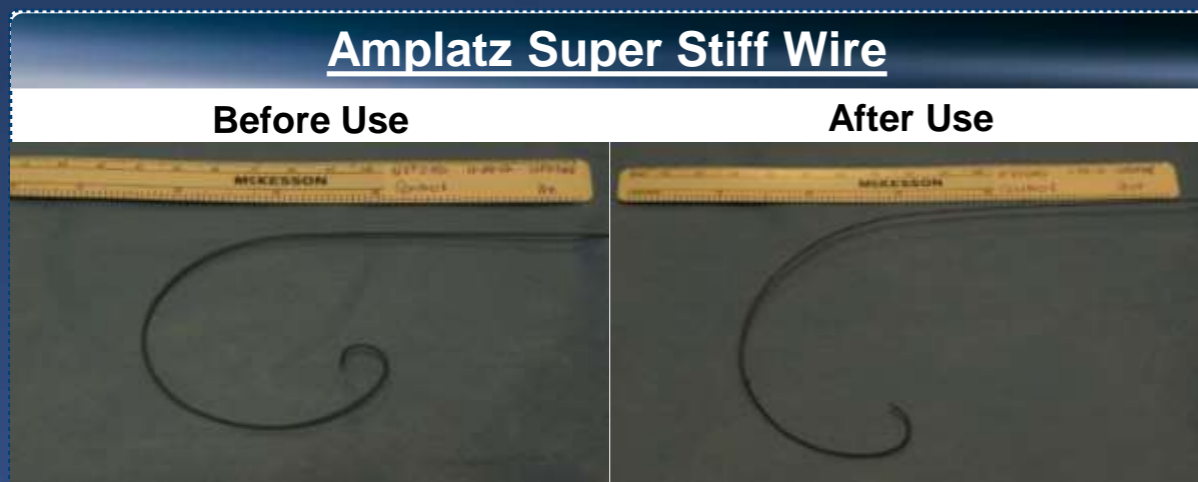
- ✓ Check to **LV volume & hypertrophy** from Work up
- ✓ Initial LV gram & Exchange the wire through a pigtail in RAO view
- ✓ Always check the position of wire or catheter and heart motion
- ✓ Use Navigator system
- ✓ Prepare of pericardial centesis for cardiac tamponade
- ✓ Transfer position of Emergency OP



2nd CASE Review – Wire & Catheter

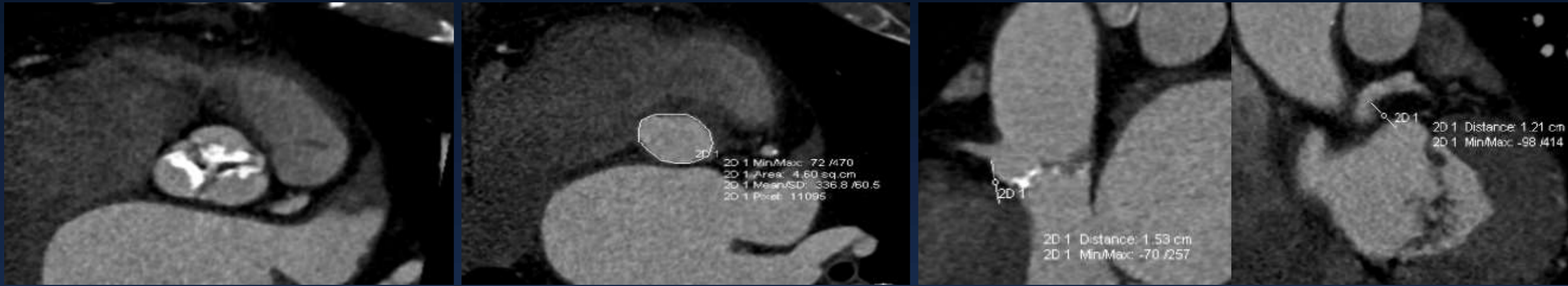
Usage	Order	Length	Company
Exchange	035" Angled Terumo wire	260cm	Terumo
	035" Complete J Terumo wire	150cm	Terumo
	035" Amplatze Extra Stiff wire	260cm	Cook
AV Crossing	035" Straight Stiff Terumo wire	260cm	Terumo
	035" Straight Tefron wire	150cm	Merit medical
	035" Ring Torque wire	145cm	Cook
Main	035" Amplatze Super Stiff Wire Straight tip 1cm	260cm	Boston
	035" Amplatze Extra Stiff wire	260cm	Cook
	035" Safari pre shape small curve	300cm	Boston
Extra stiff	035" Lunderquist extra stiff wire	260cm	Cook

Usage	Order
Angio	Pigtail catheter 6Fr (or Marked Pigtail)
Exchange	JR4 diagnostic catheter 6Fr
AV Crossing	AL1 , 2 diagnostic catheter 6Fr
	AL1 , 2 Guiding catheter 6Fr
Wire shape	Pigtail catheter 6Fr



3rd Valve embolization

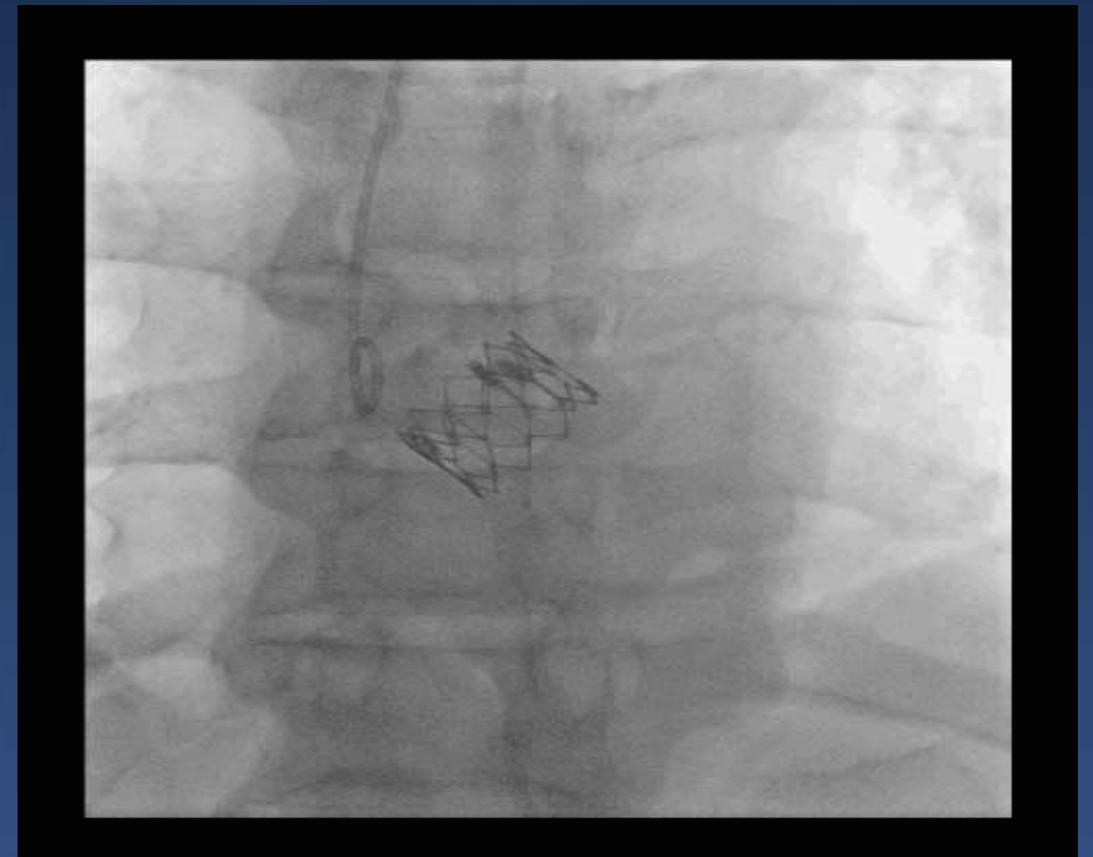
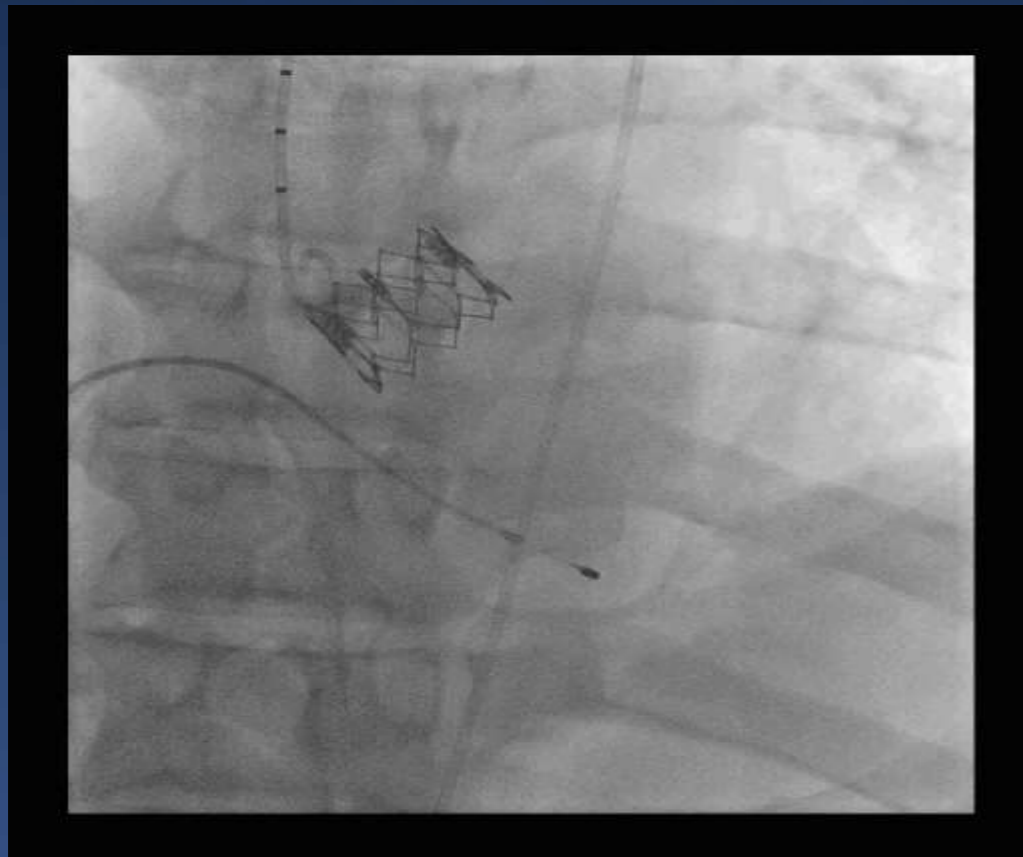
3rd Ventricular Embolization after 1day



Annulus area 495



Sapien XT 26mm



3rd-2 Aortic embolization during implantation

A rare complication with Edwards Sapien: Aortic valve embolization in TAVI

Hüseyin Ayhan¹, Tahir Durmaz¹, Telat Keleş¹, Hacı Ahmet Kasapkara¹, Kemal Eşref Erdoğan² and Engin Bozkurt¹

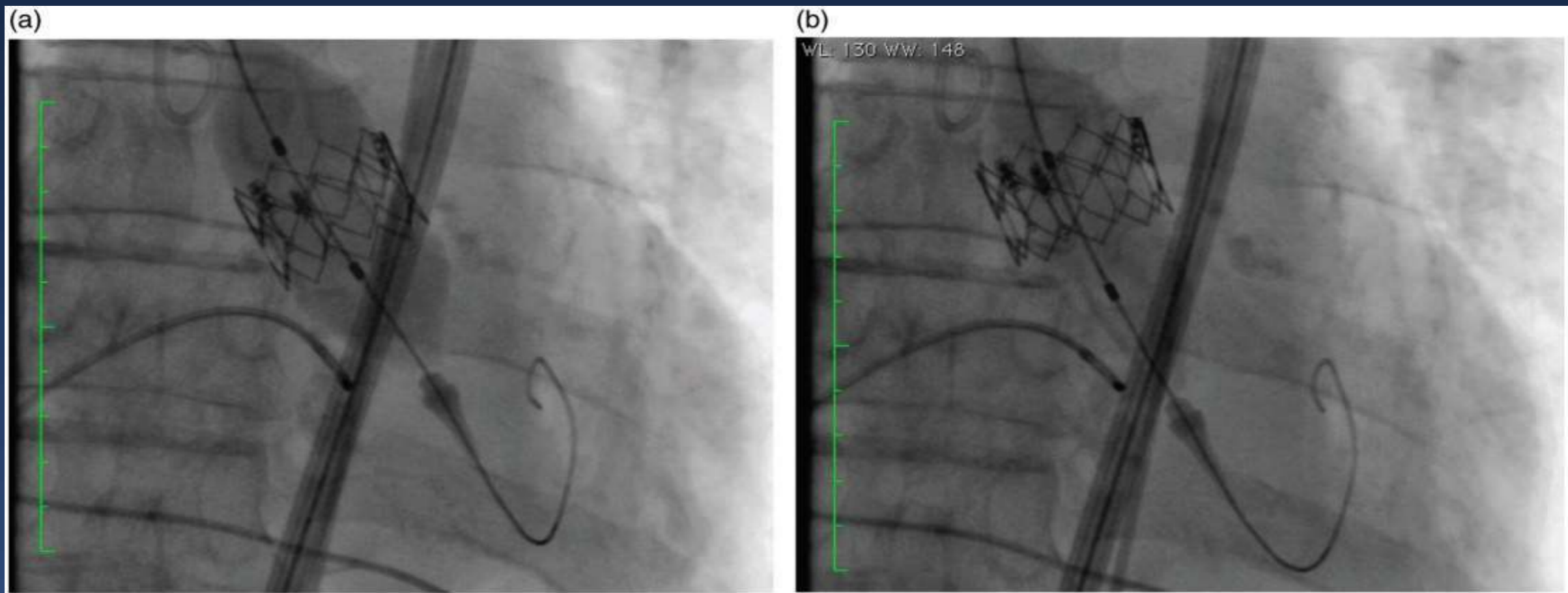


Figure 1. (a and b) Fluoroscopic image of implantation of Edwards Sapien XT prosthesis under rapid pacing, both of them are same angle but the valve in (b) is higher than in (a).

3rd-2 Aortic embolization during implantation

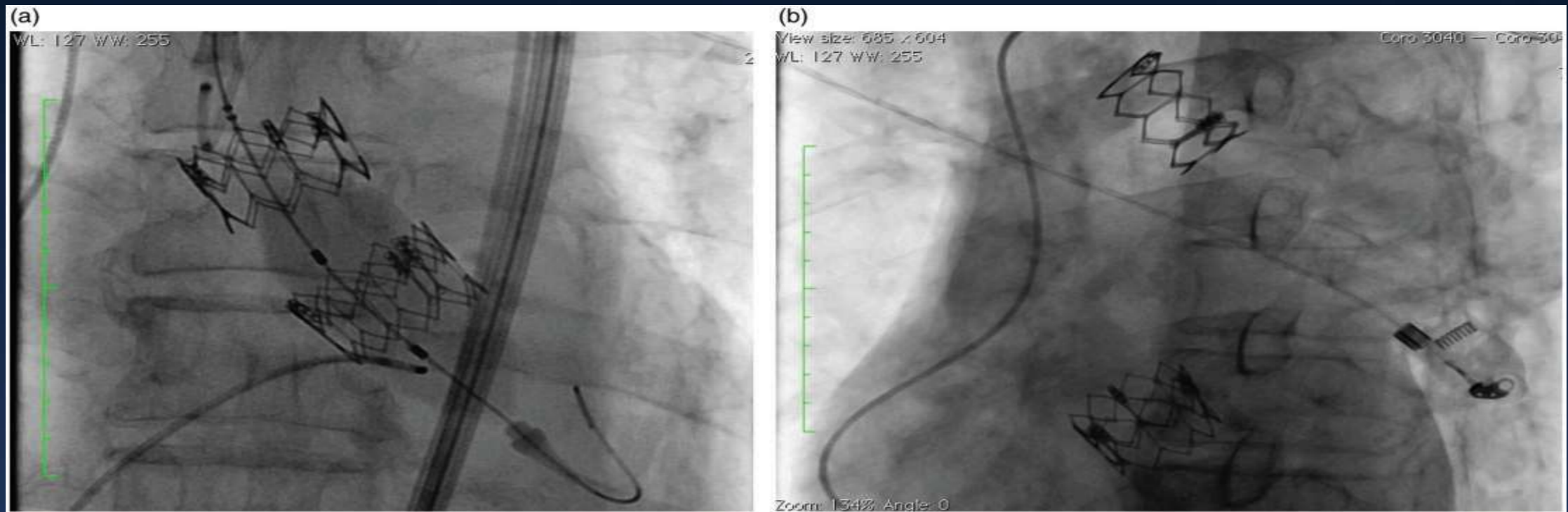


Figure 2. (a) Fluoroscopic image of implantation of the second Edwards Sapien XT prosthesis under rapid pacing, (b) Fluoroscopic image showing the angiogram after deployment of the embolized valve in aorta with no evidence of obstruction of truncus brachiocephalicus and left common carotid artery.

- (1) attending your surgeon for any complications
- (2) measuring the valve size accurately
- (3) imaging of optimal valve plane
- (4) controlling ventricular pacing before valve deployment
- (5) preparing the second valve quickly.

3rd CASE Review - Consequences of TAV embolization

- ✓ Annular trauma
- ✓ Severe paravalvular leaks
- ✓ Increased risk of permanent pacemaker implantation
- ✓ **LV outflow obstruction**
- ✓ Stroke
- ✓ **Aortic obstruction**
- ✓ Coronary occlusion
- ✓ Vascular injury
- ✓ Mitral valve injury
- ✓ Ventricular septal defects

2014 TCT Valvular Migration During TAVR Dr Ganes/h Manoharan

3rd CASE Review - How / Why does it happen?

- ✓ Learning curve / technique – new device
- ✓ **Valve size mismatch**
- ✓ Sub-optimal wire control
- ✓ Sub-optimal valve release/deployment – too fast
- ✓ Sub-optimal valve fixation
 - Low degree of annular calcification: Aortic regurgitation
 - Degree of valve over-sizing
- ✓ **I:I capture** and arterial pressure drop not **maintained** before inflating
- ✓ Hyperdynamic circulation
- ✓ Severe septal hypertrophy/septal bulge

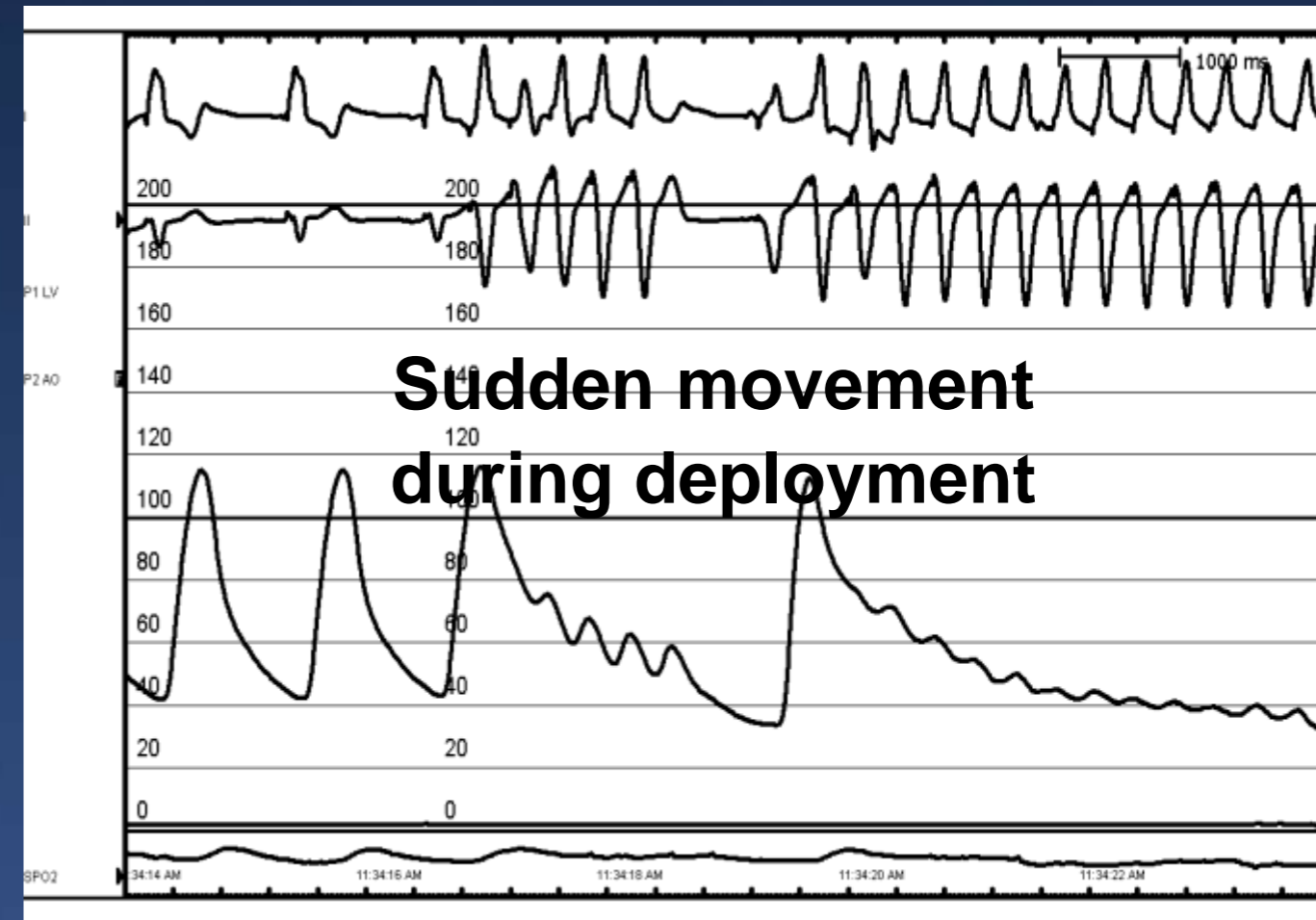
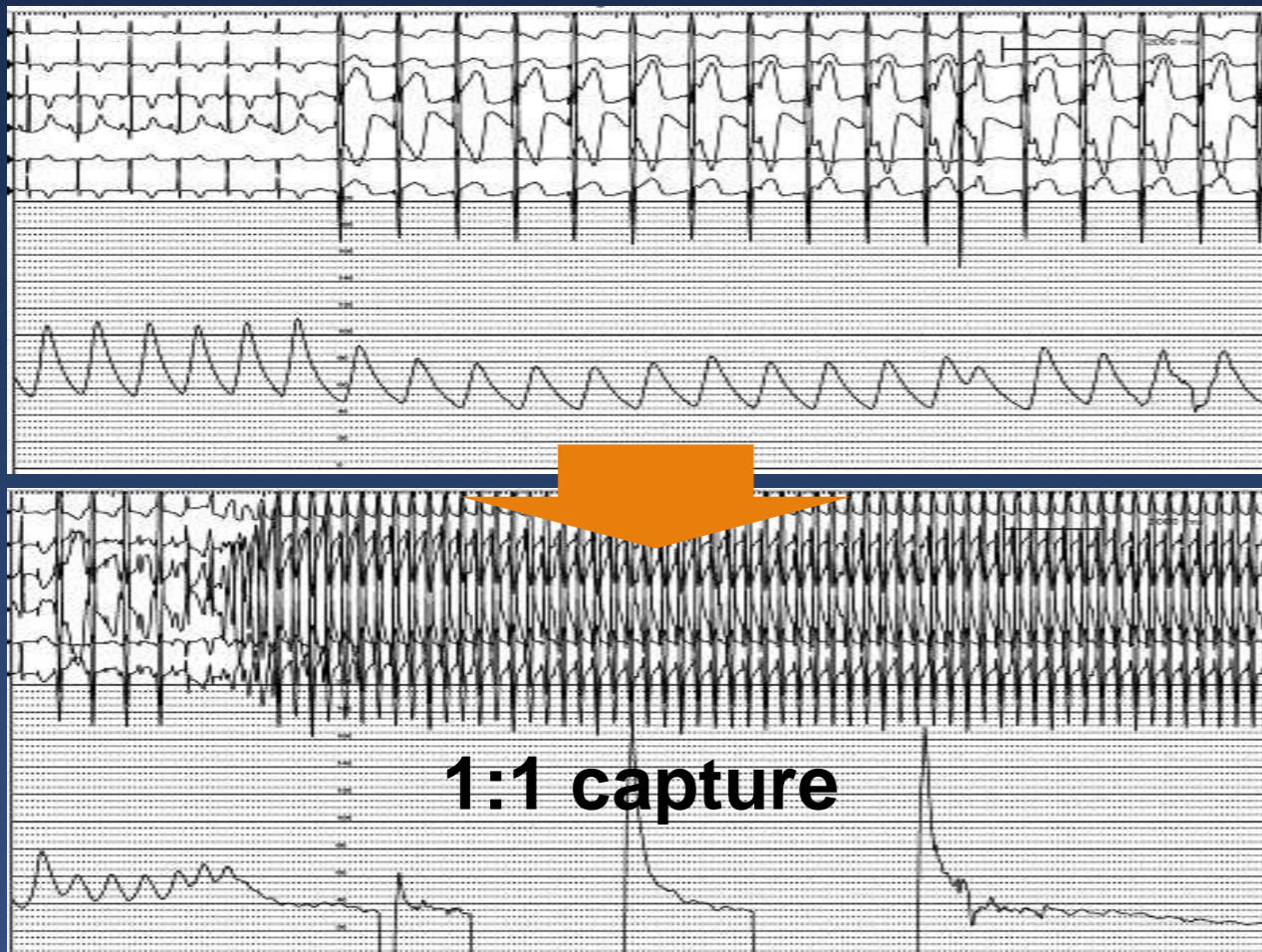
2014 TCT Valvular Migration During TAVR Dr Ganes/h Manoharan

3rd CASE Review - Lessons for Nurse & Tech

✓ CT Review

- Valve size mismatch
- Severe septal hypertrophy / septal bulge → Selection of SE of BE

✓ **1:1 capture** and arterial pressure drop not **maintained** before inflating



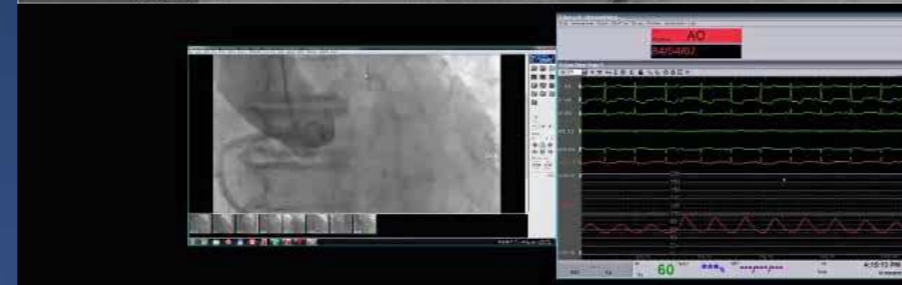
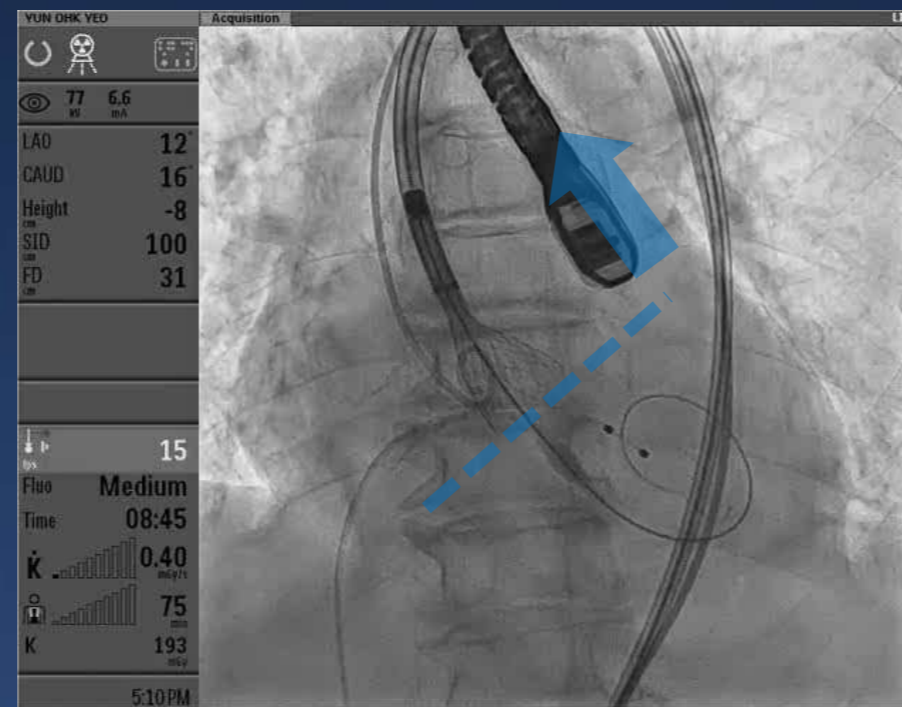
3rd CASE Review - Lessons for Nurse & Tech

✓ CT Review

- Valve size mismatch

- **Severe septal hypertrophy / septal bulge → Selection of SE of BE**

✓ I:I capture and arterial pressure drop not maintained before inflating

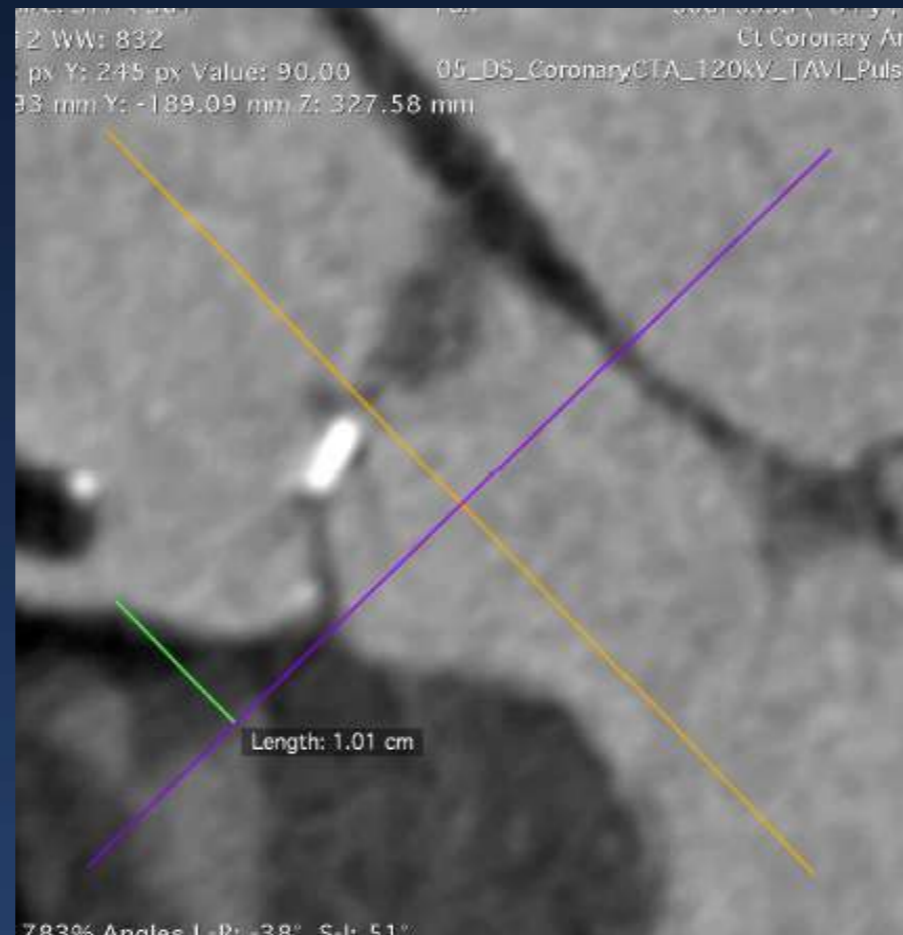
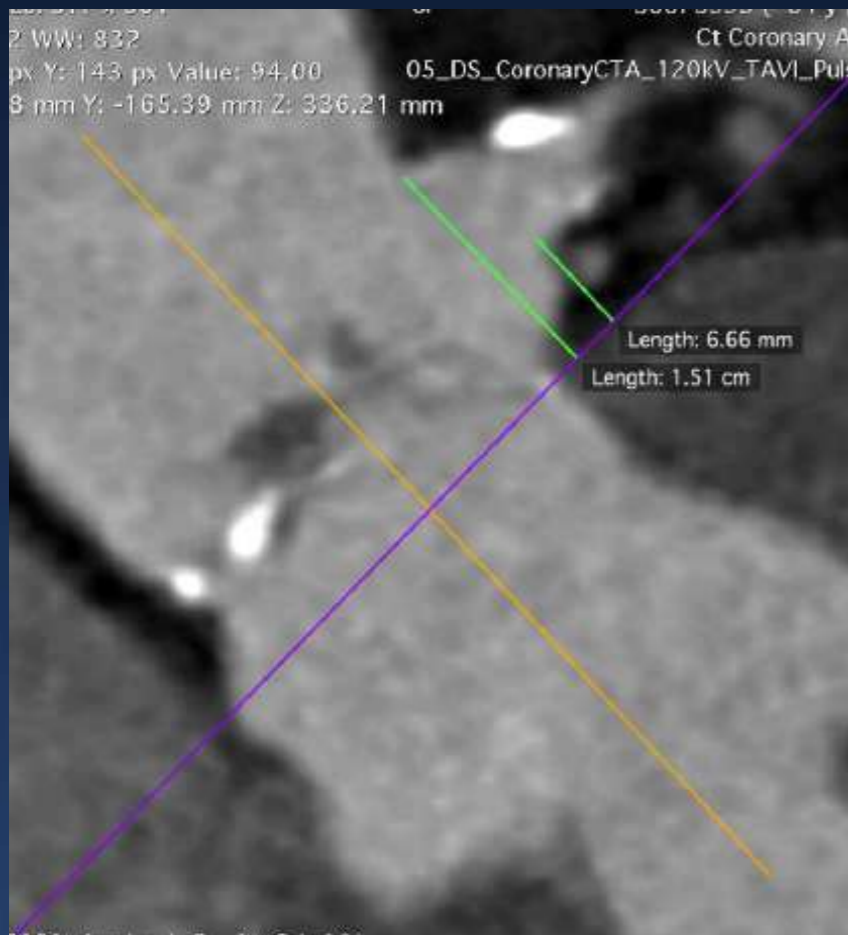


4th Coronary Artery Occlusion

(Shallow SOV & Low coronary ostium)

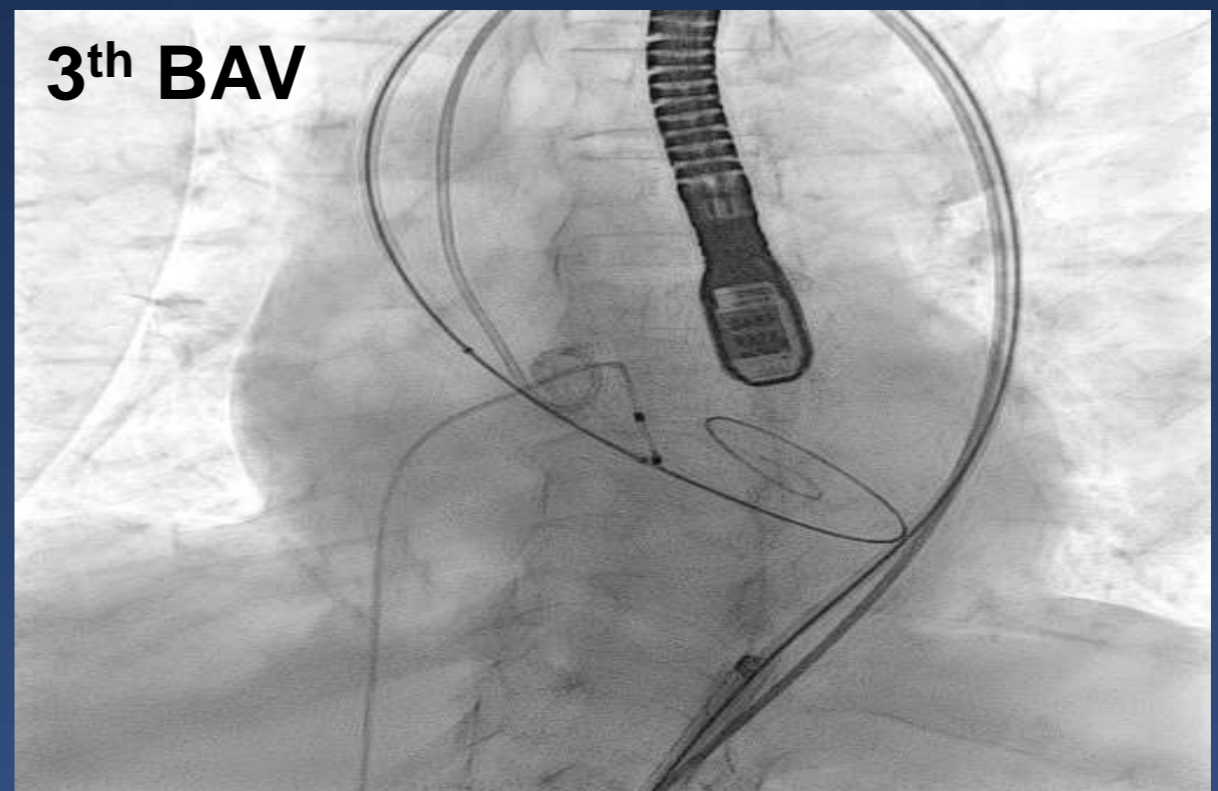
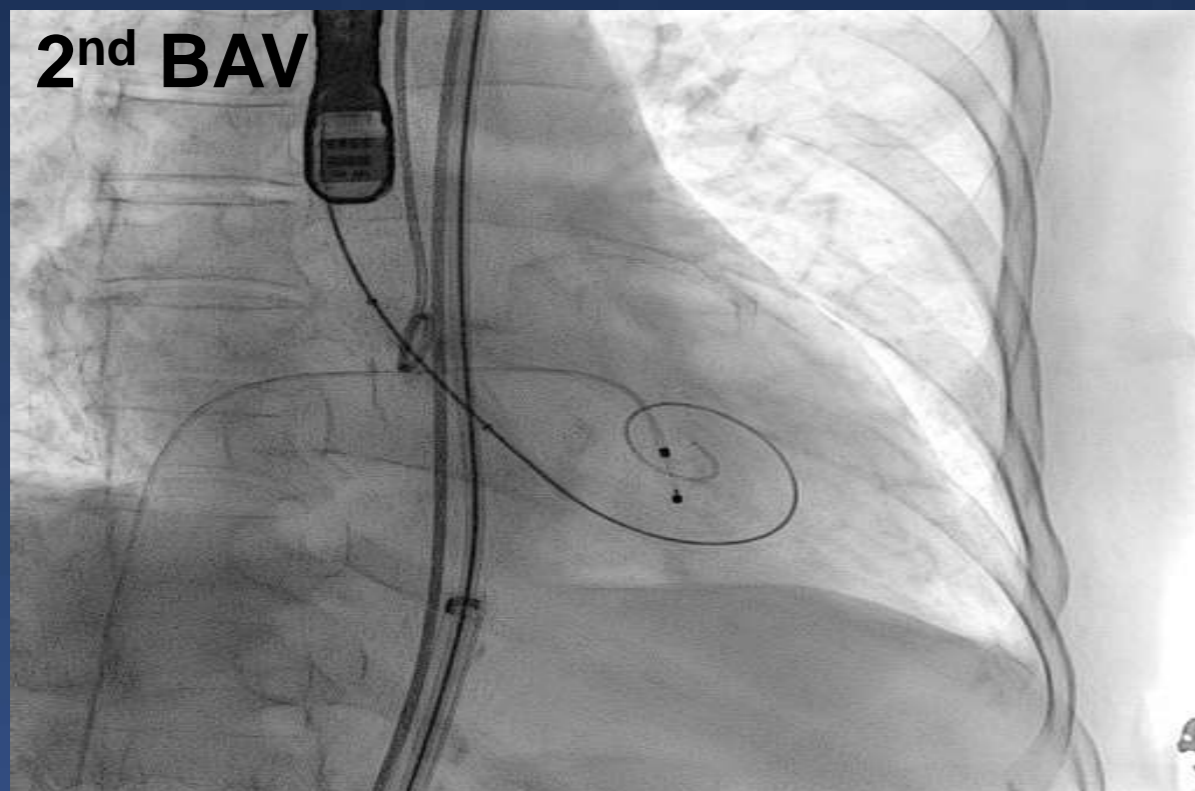
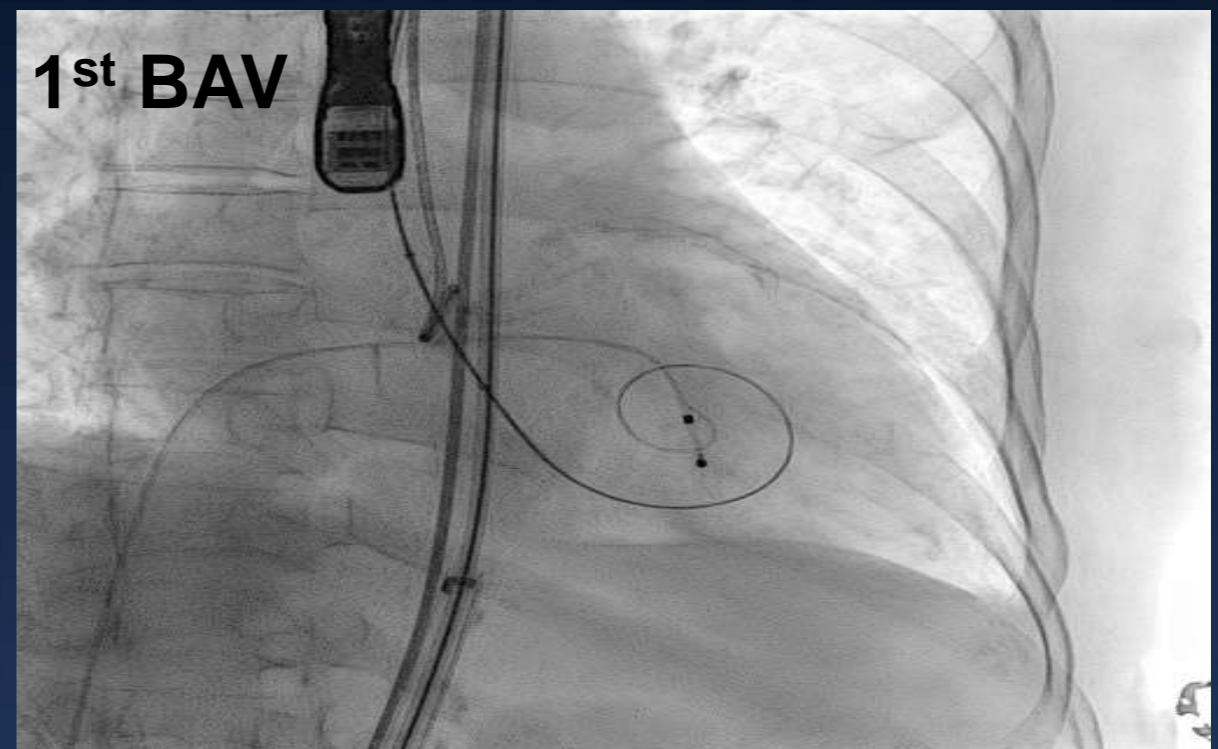
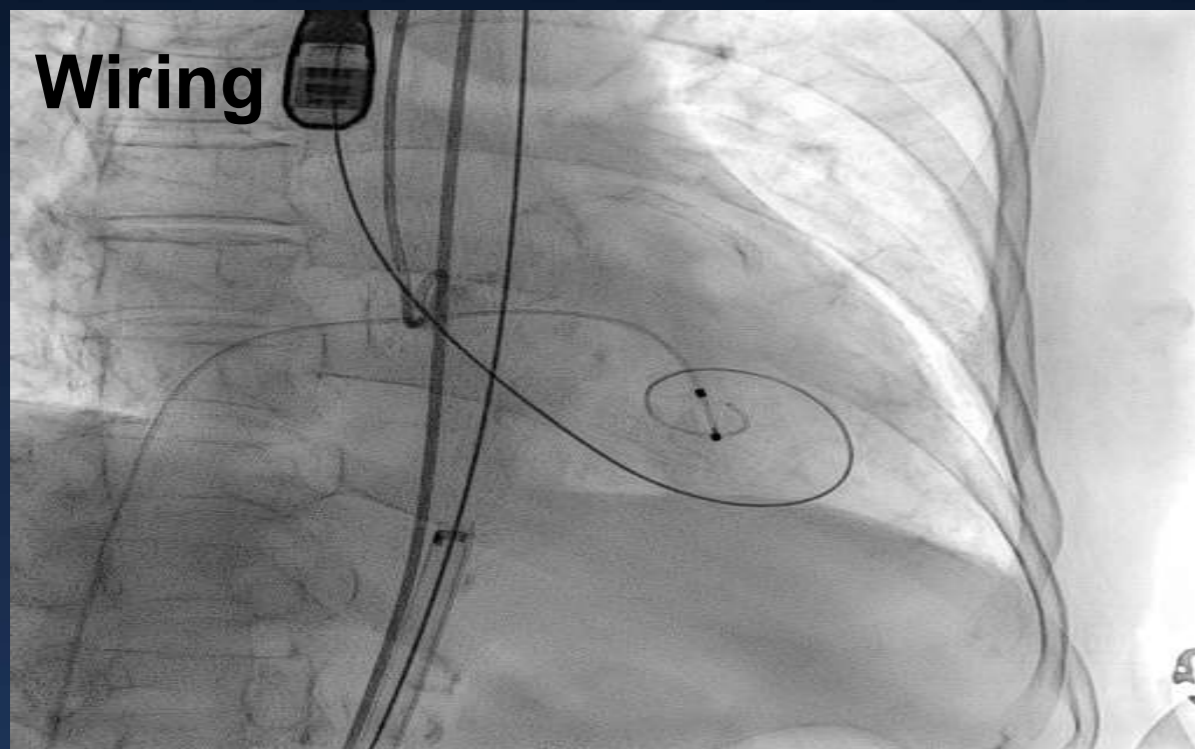
4th CASE Coronary Artery Occlusion

Shallow SOV & Low coronary ostium



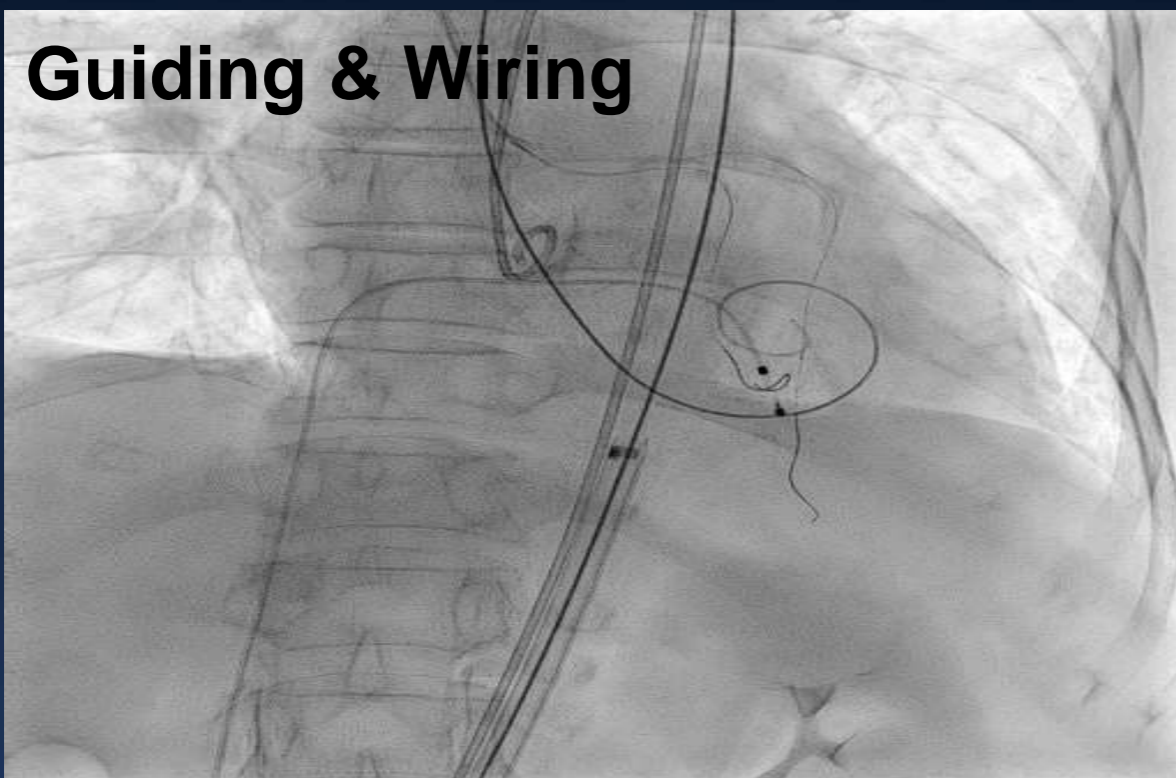
- LM Height 6.7 mm / RCA Height 10.1 mm
- Annulus area 466.3 mm² / Diameter 20.6 * 28.3 mm
- SOV 28.5 * 29 mm

4th CASE Coronary Artery Occlusion

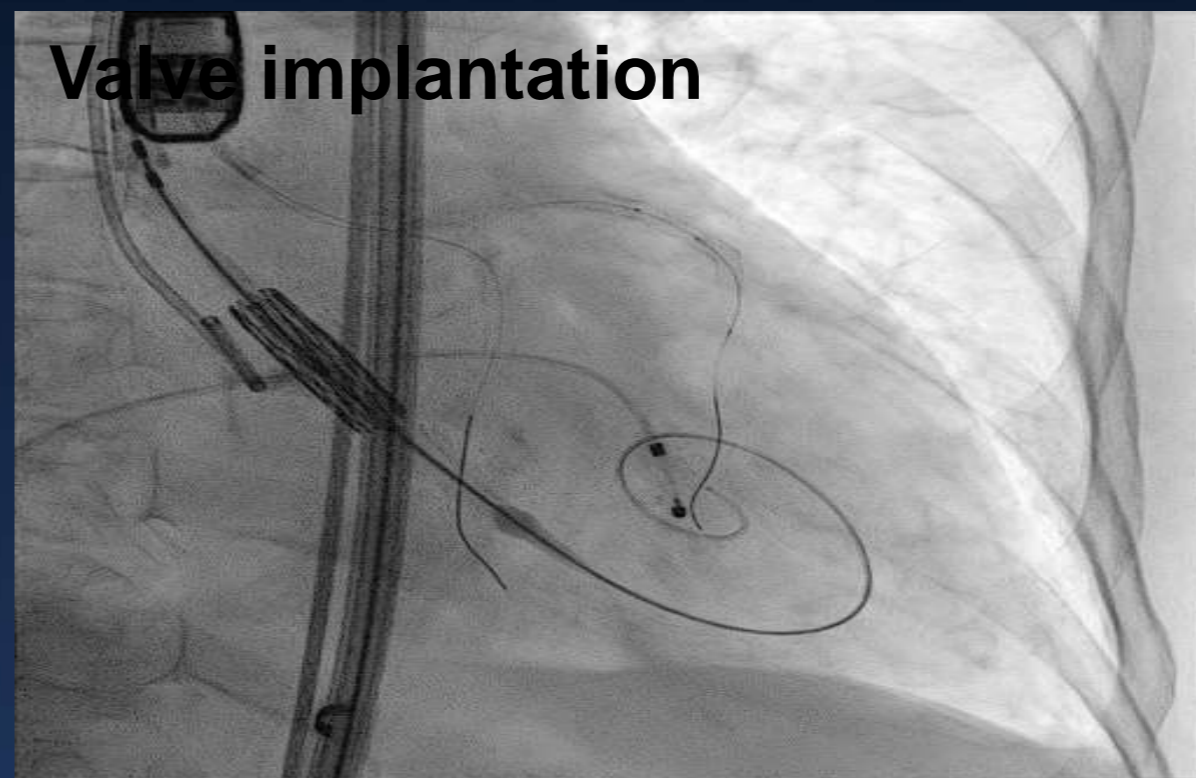


4th CASE Coronary Artery Occlusion

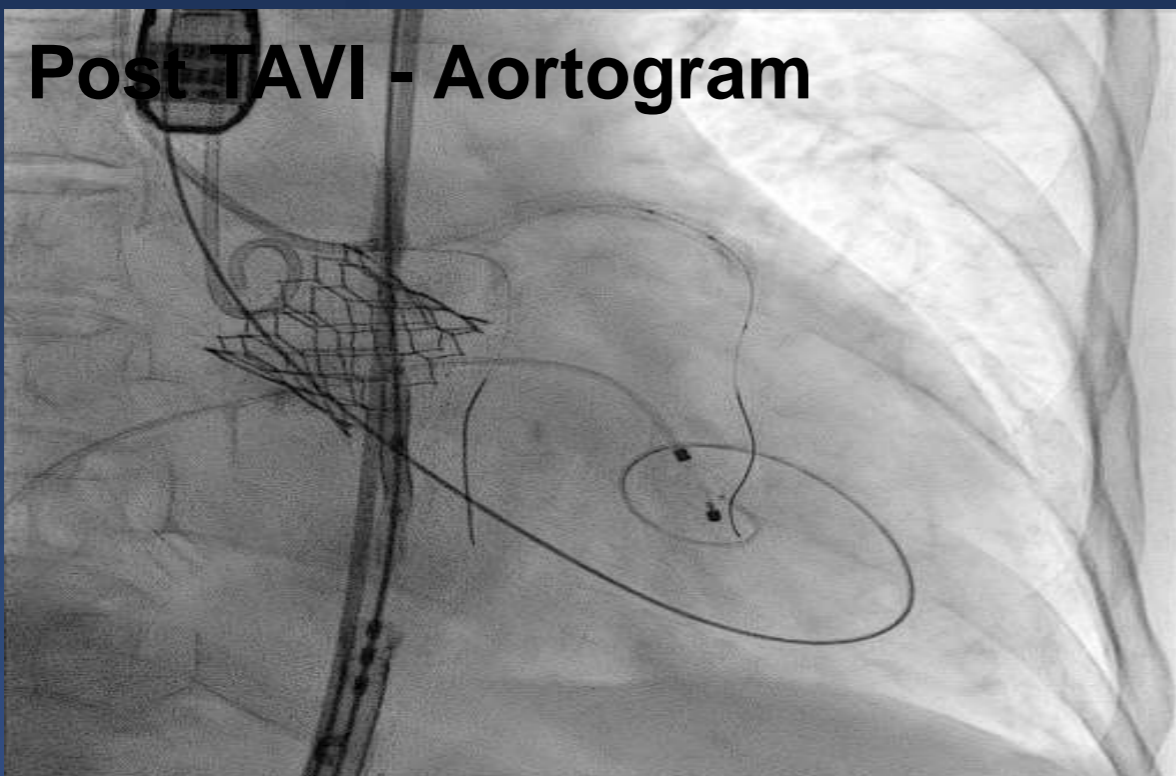
Guiding & Wiring



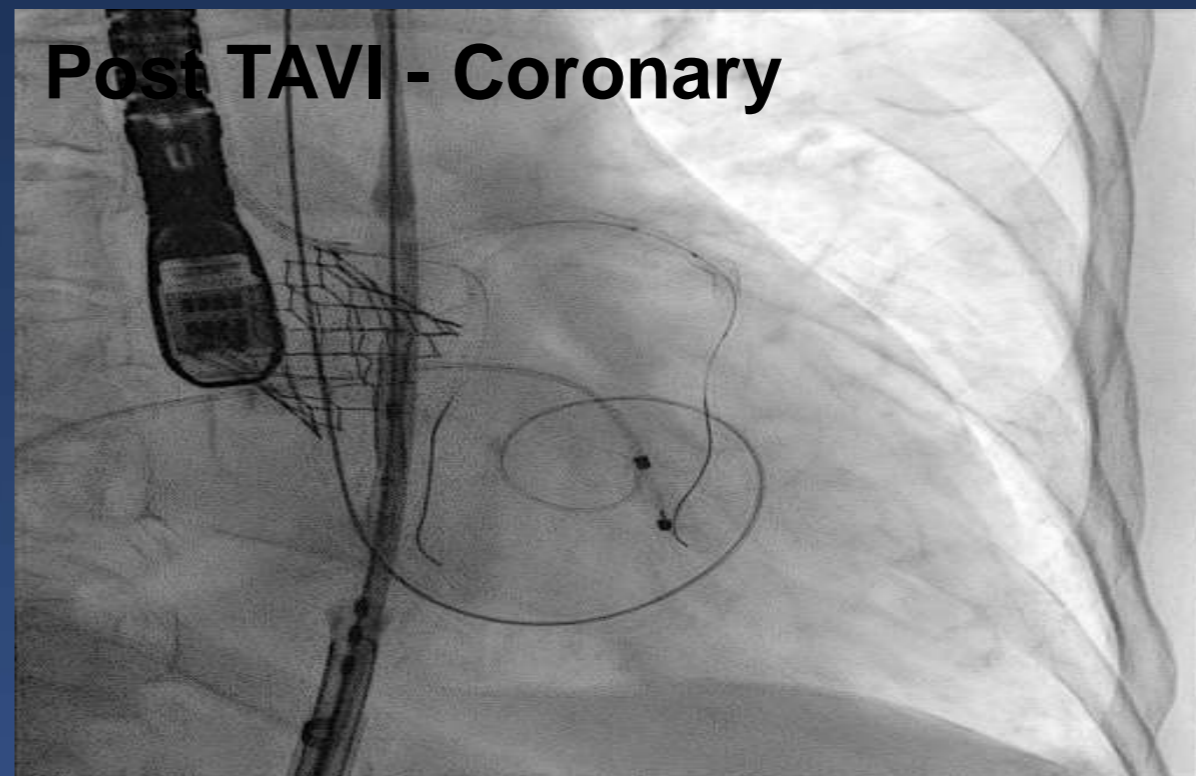
Valve implantation



Post TAVI - Aortogram

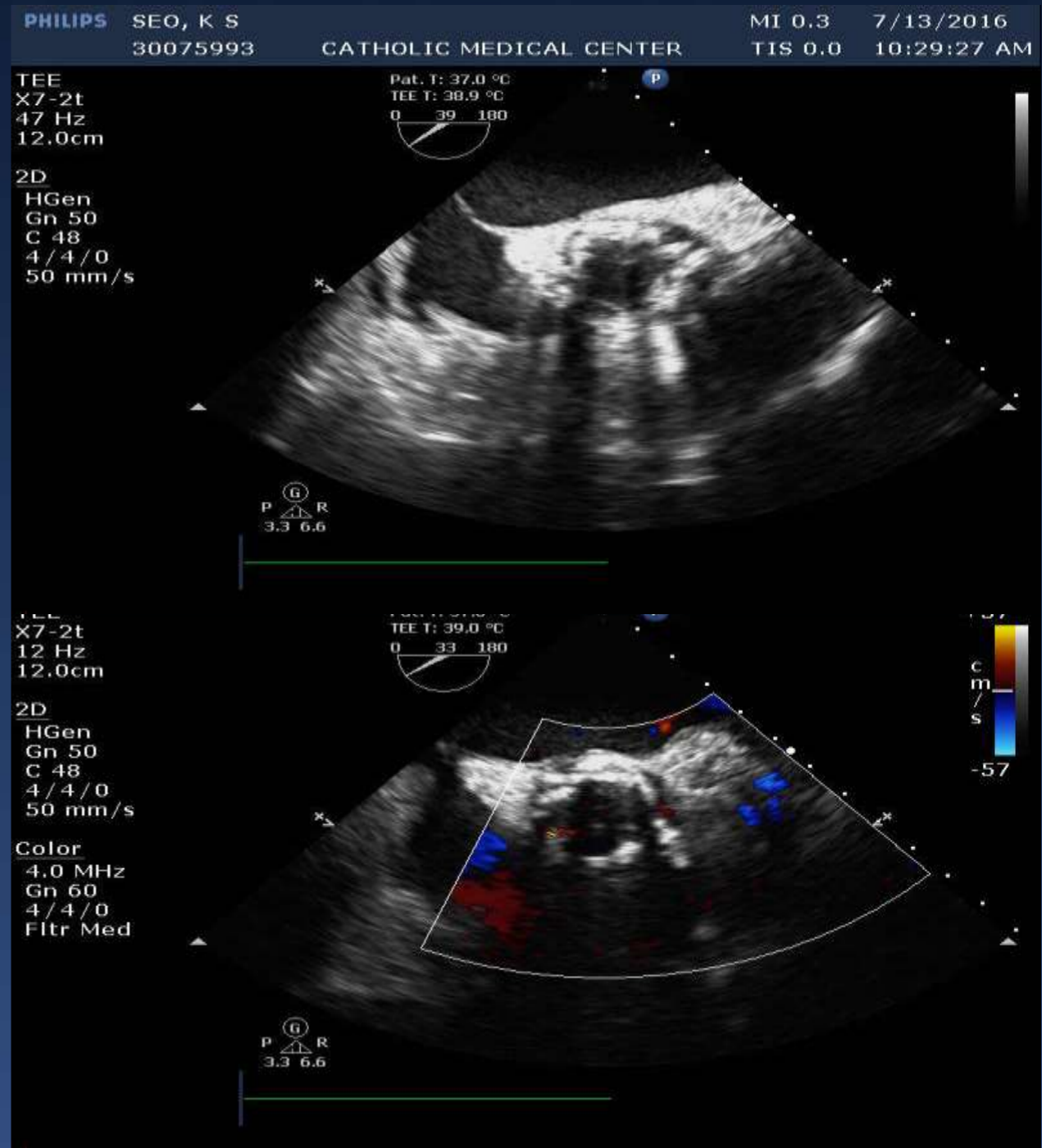
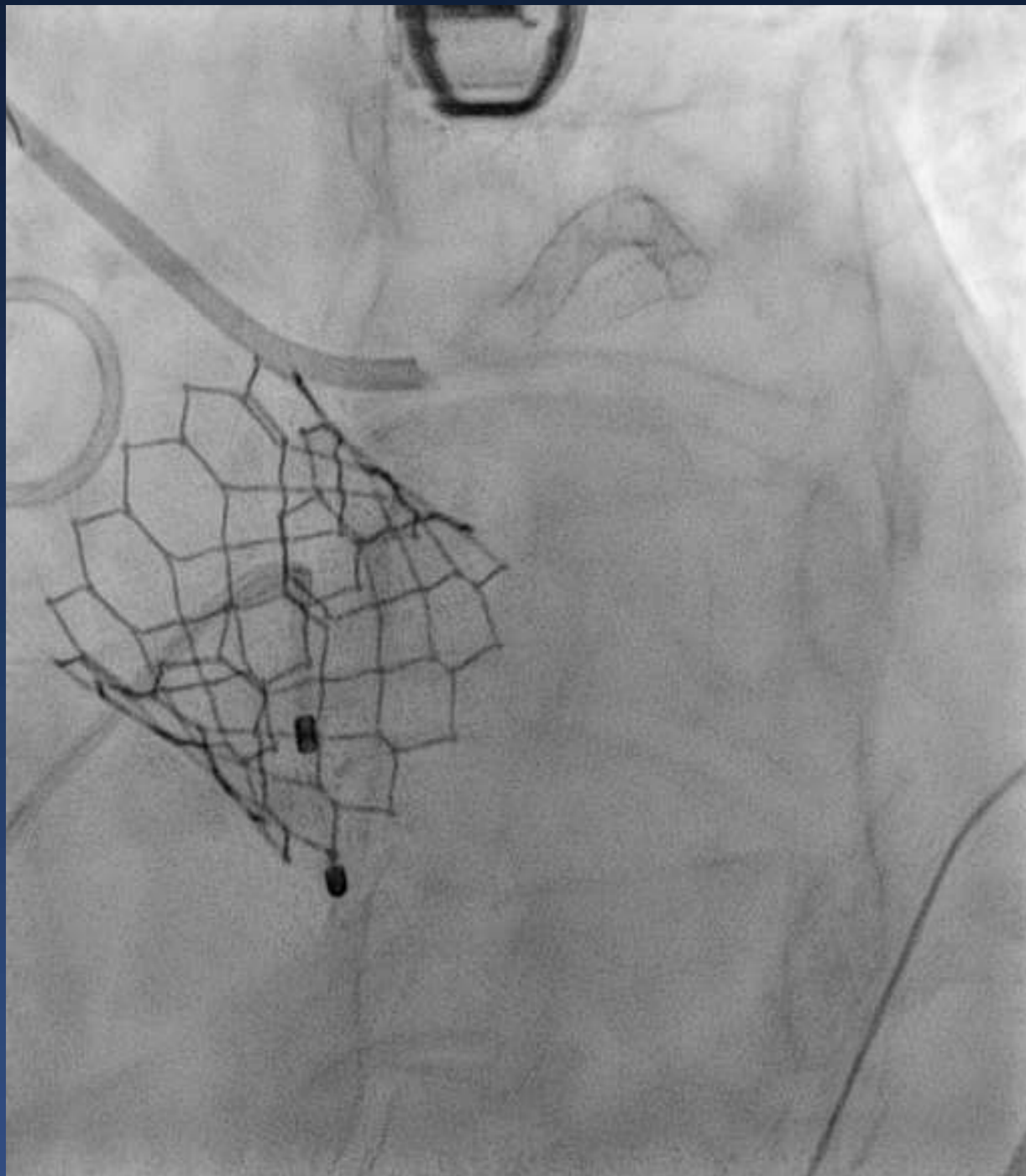


Post TAVI - Coronary

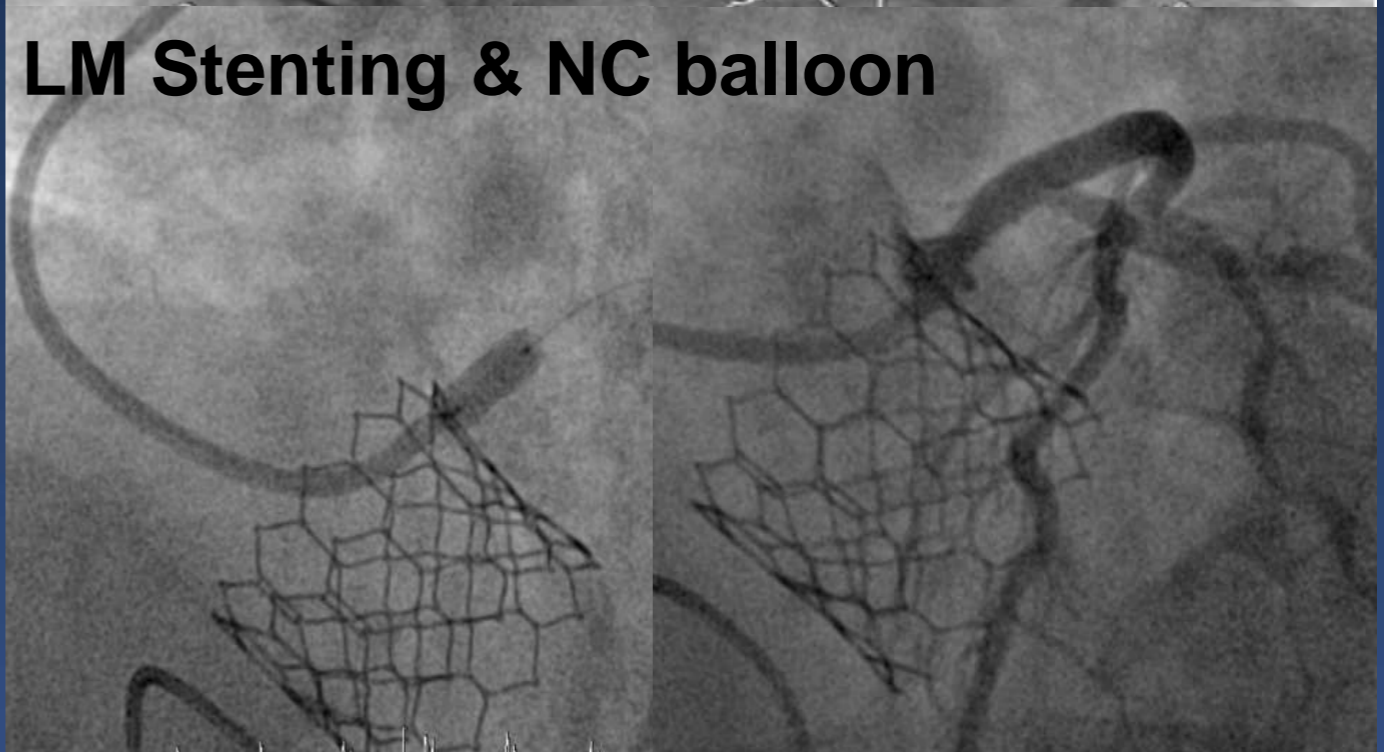
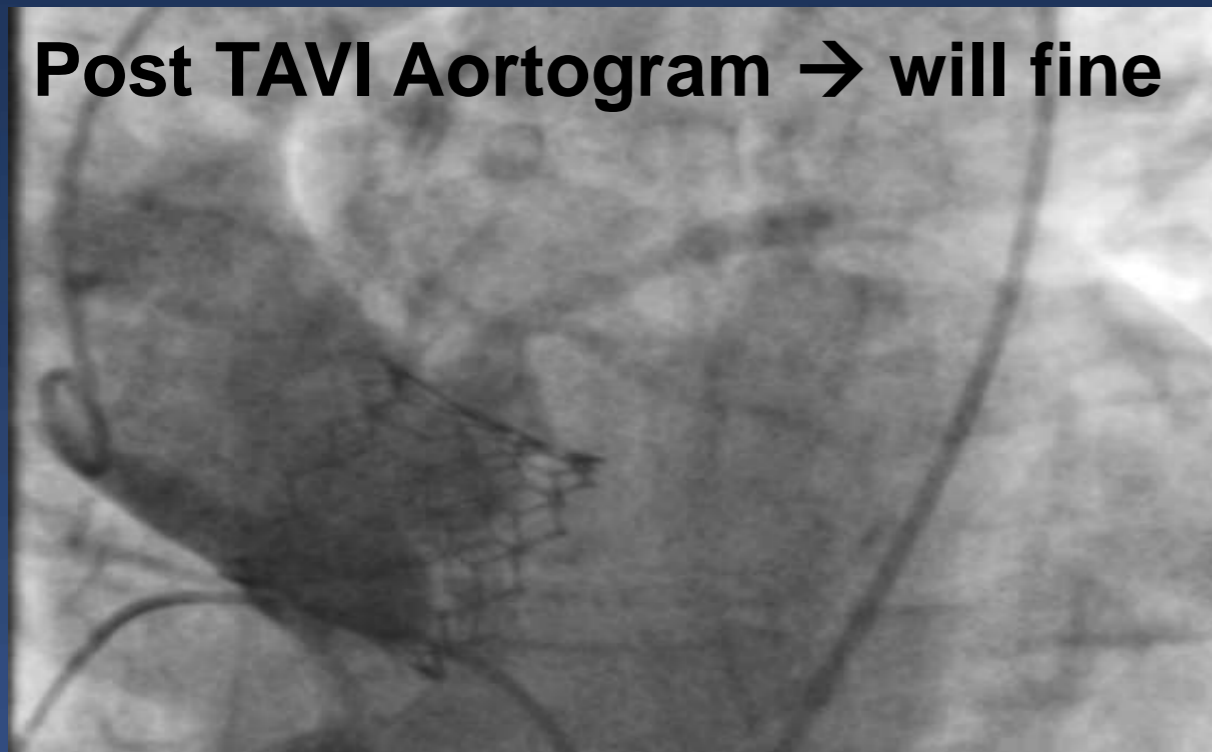
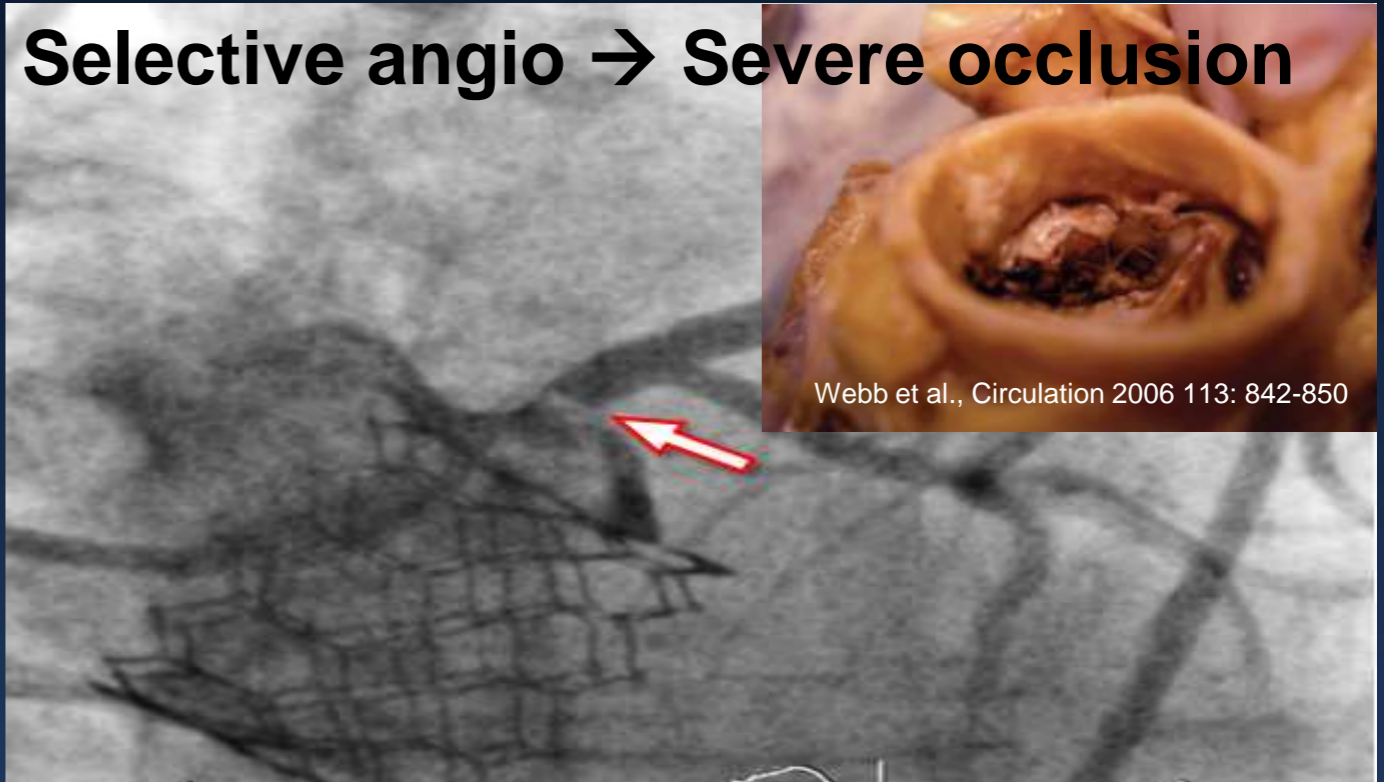
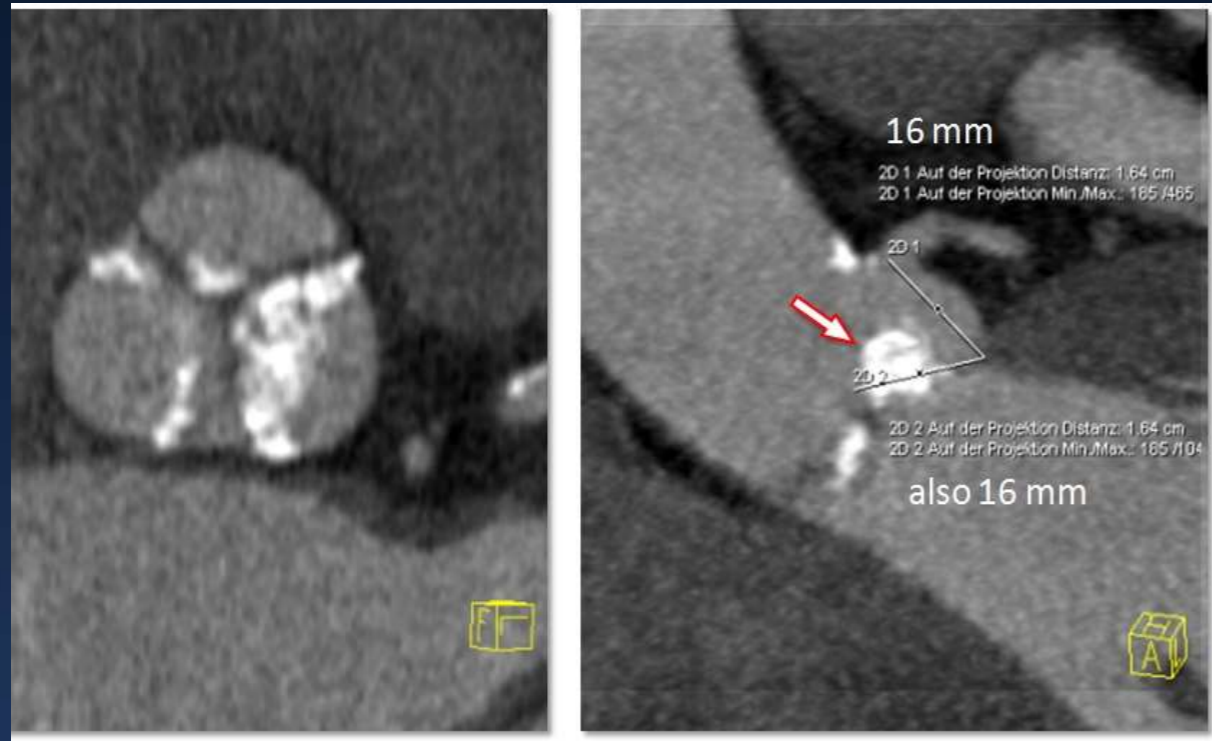


4th CASE Coronary Artery Occlusion

Final TAVI - Coronary artery



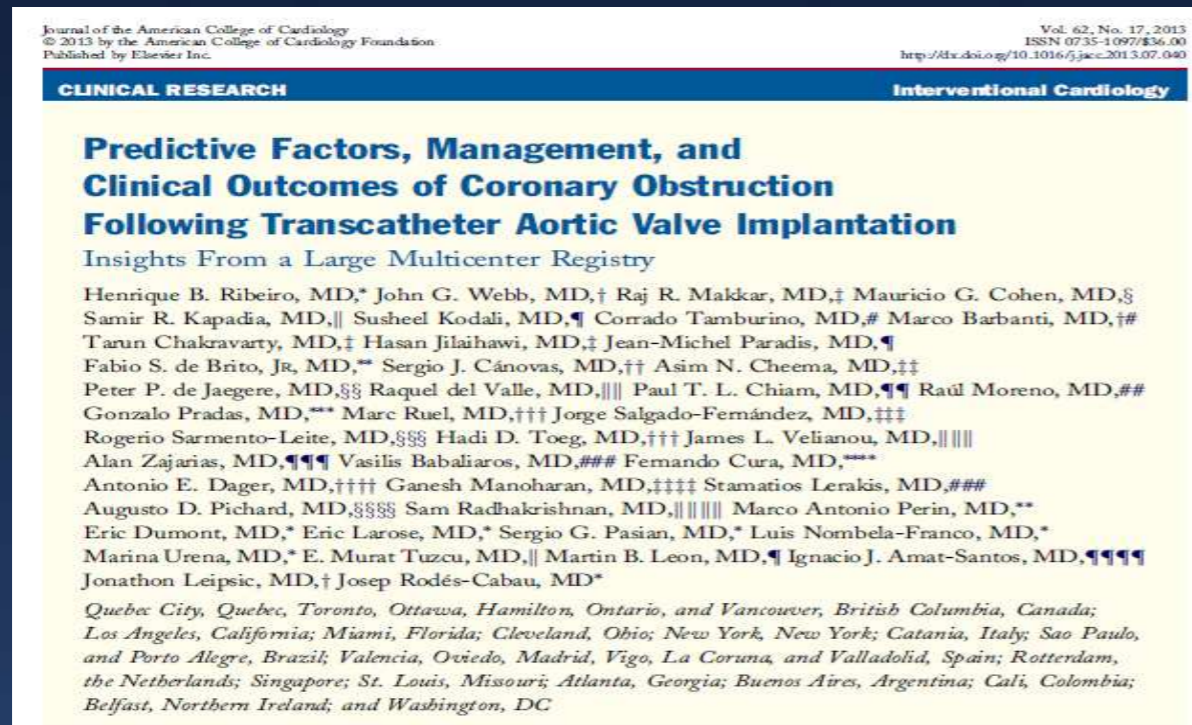
4th-2 CASE Coronary Artery Occlusion



4th CASE Review – Coronary artery occlusion

Anatomical Predictors of Coronary occlusion

Multi-center register

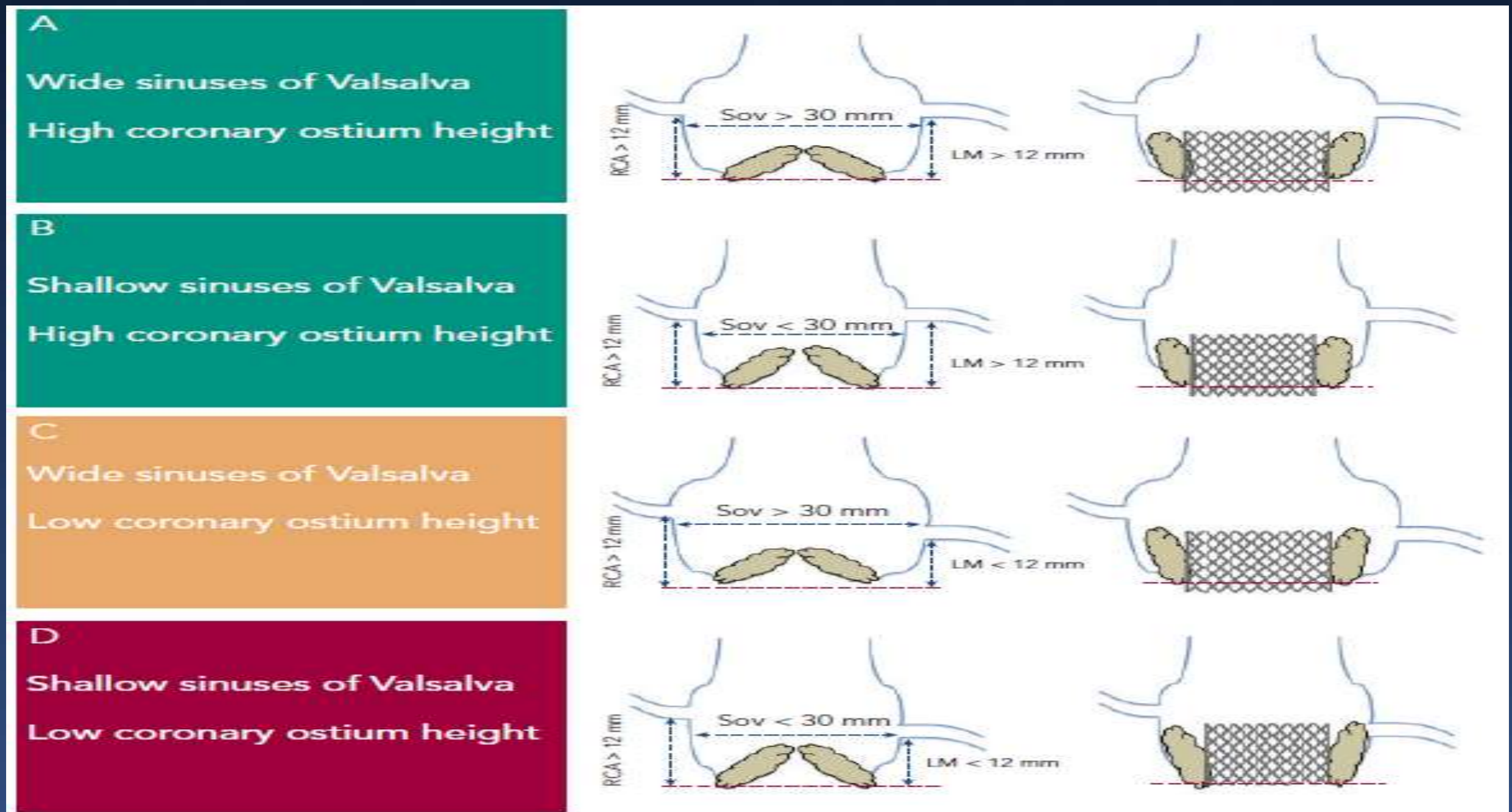


- 44/6688 (0.66%)
- Predominantly LM
- More common in
 - Women
 - Balloon-expandable TAVI
 - Valve-in-Valve

- **LMH:**
 - 10.6±2.1mm vs. 13.4±2.1mm
 - <12mm – in obstruction 86%
 - <12mm – controls 26%
- **SOV:**
 - 28.1±3.8mm vs. 31.9±4.1 mm
 - <30mm – in obstruction 71%
 - <30mm – controls 33%
- **LMH <12mm and SOV <30mm**
 - obstruction 68%
 - controls 13%

4th CASE Review – Coronary artery occlusion

Schematic Representation of four aortic root scenarios

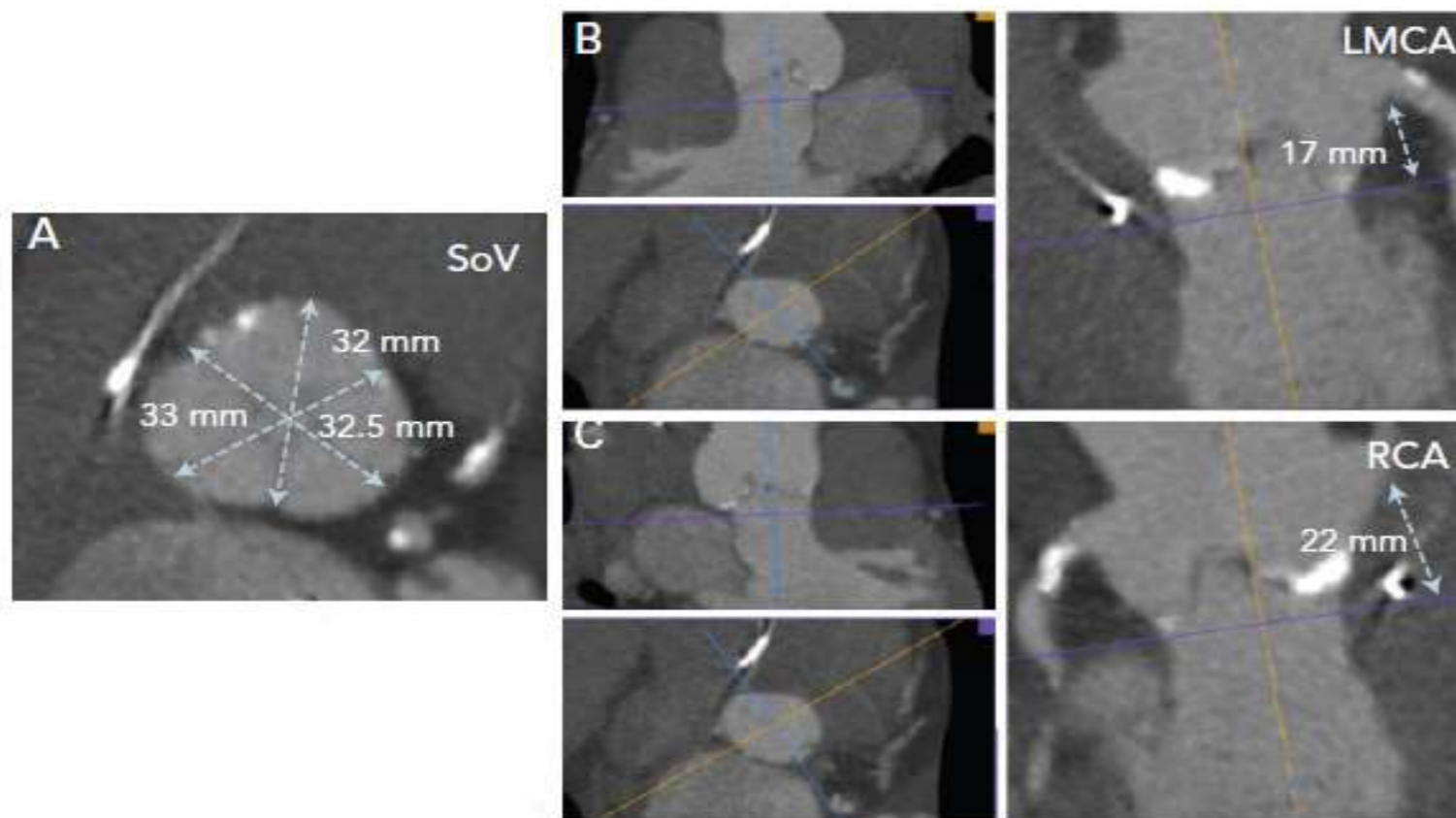


4th CASE Review – Coronary artery occlusion

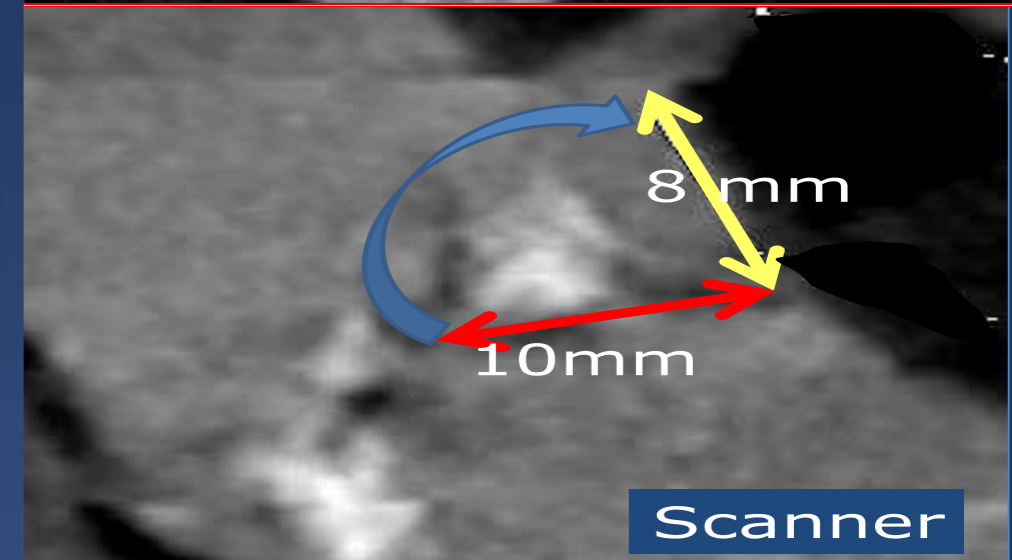
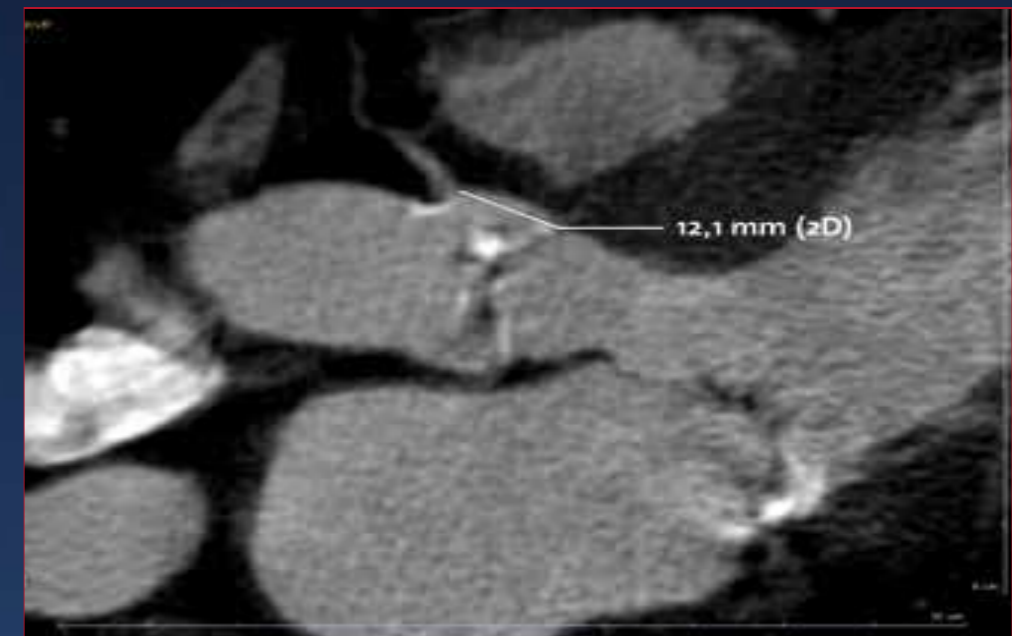
Evaluation pre TAVI

SOV & Coronary Height & Length of Leaflet

Figure 2: Multidetector Computed Tomography Reconstruction of the Aortic Root in One Patient Undergoing Evaluation Pre-transcatheter aortic valve implantation (TAVI)



(A) Double-oblique transverse at the level of the sinuses of Valsalva; (B) measurement of (B) left main coronary artery (LMCA); (C) right coronary artery (RCA).

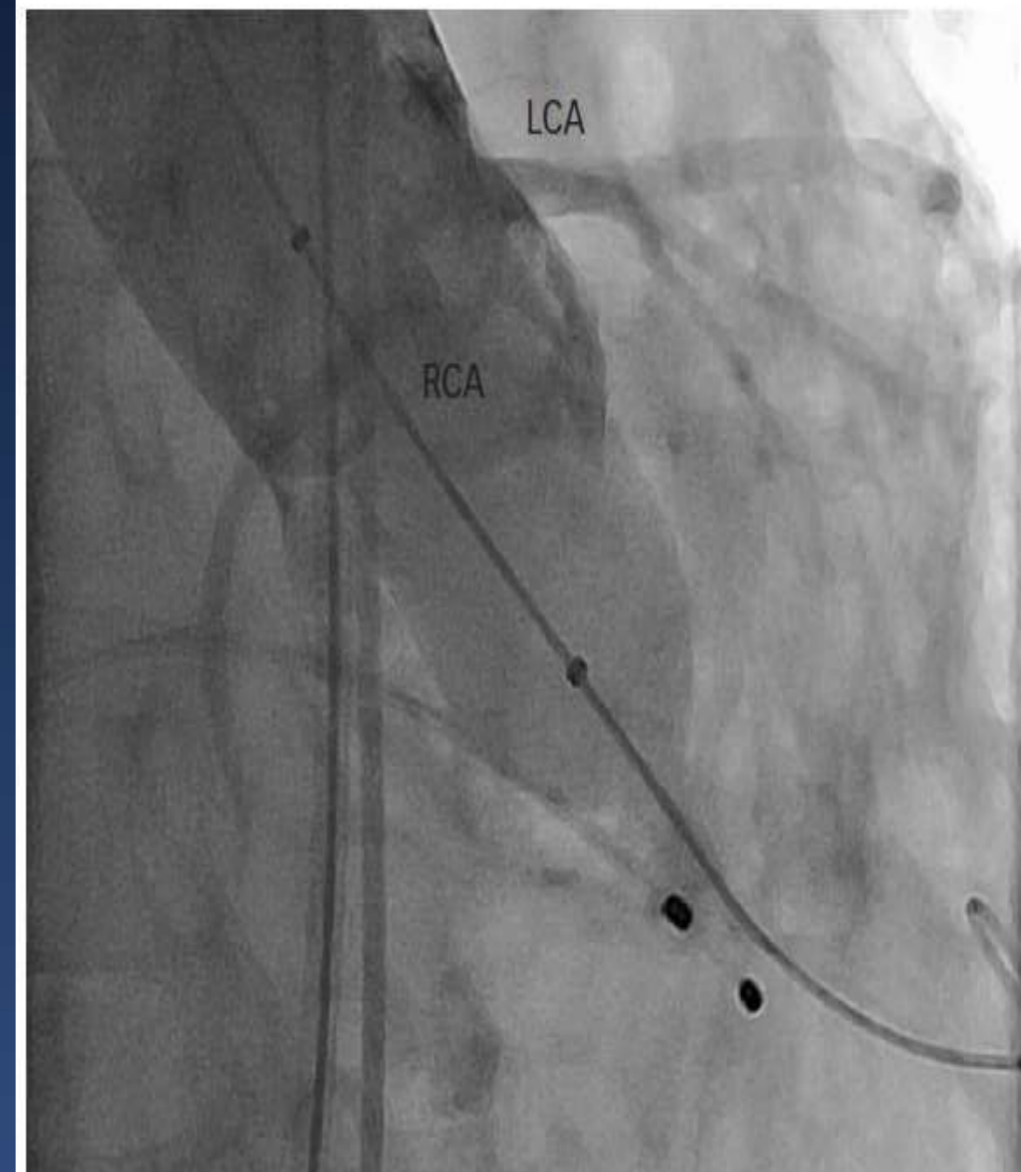


4th CASE Review – Lessons for Nurse & Tech

- ✓ Prediction from work up CT
(**narrow SOV, bulky leaflet calcifications, low-lying coronary ostia**)
- ✓ During BAV & **Simultaneous Aortogram** & Echo, bulky calcification noted to move toward left main
- ✓ Finally both check from angio (Aortogram and CAG)
- ✓ Decision made to maintain access to coronary during THV deployment
- ✓ Need to prepare of Guiding catheter, wire, balloon & stent quickly.

Especially, it is necessary to strong backup guiding & very stiff wire

Figure 3: Simultaneous Aortography and Balloon Aortic Valvuloplasty Showing the Patency of Both Left Coronary Artery (LCA) and Right Coronary Artery (RCA) while the Balloon is Fully Inflated



(A) Double-oblique transverse at the level of the sinuses of Valsalva; (B) measurement of (B) left main coronary artery (LMCA); (C) right coronary artery (RCA).

Take home message

- ✓ **Size measure is also as important as the **quality measure****
 - Quantitative (Aorta & Access diameter, Annulus area & perimeter)
 - Qualitative (Aortic valve calcification amount & distribution,
LVOT protruding calcification, SOV leaflet calcification
Aorta angulation & Access route)
- ✓ **Keep the necessary supplies in the cath lab**
 - Various wire & catheter, Covered stent, PTA Balloon
- ✓ **TAVI team is responsible to the sustainable management**

Thank you for your attention

