TAVI Procedure Plan and How to Achieve Successful Results

"Practical Technical Tips and Tricks" with SAPIEN 3 Ultra and More

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TAVR: Step-By-Step Approach

Overall Procedural Steps

- Femoral artery access
- Sheath insertion
- Wire crossing of native AV
- Device crossing of native AV
- Valve positioning
- Valve deployment
- Device retrieval
- Femoral artery closure

S3 Ultra “Key Tips and Tricks” to:

- Navigate aortic tortuosity
- Facilitate native valve crossing by the THV
- Achieve optimal valve positioning in tricuspid or bicuspid anatomy
- Minimize the risk of procedural complications (aortic root injury, PPM implantation, PVL, coronary obx etc) during TAVR

1st Step - TAVR Good Planning: "Be Prepared"

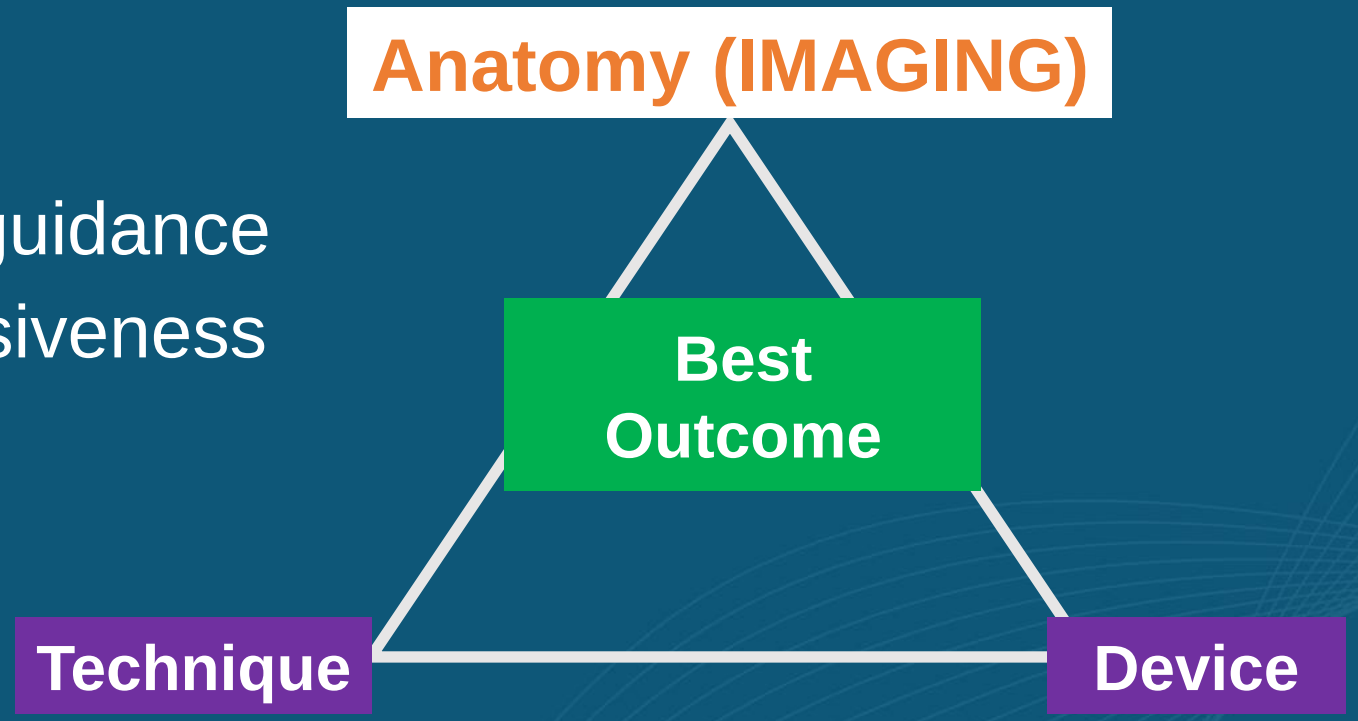
Complications should be anticipated during multidisciplinary evaluation before TAVR.

This will enable prompt recognition and management should such events occur during the procedure.

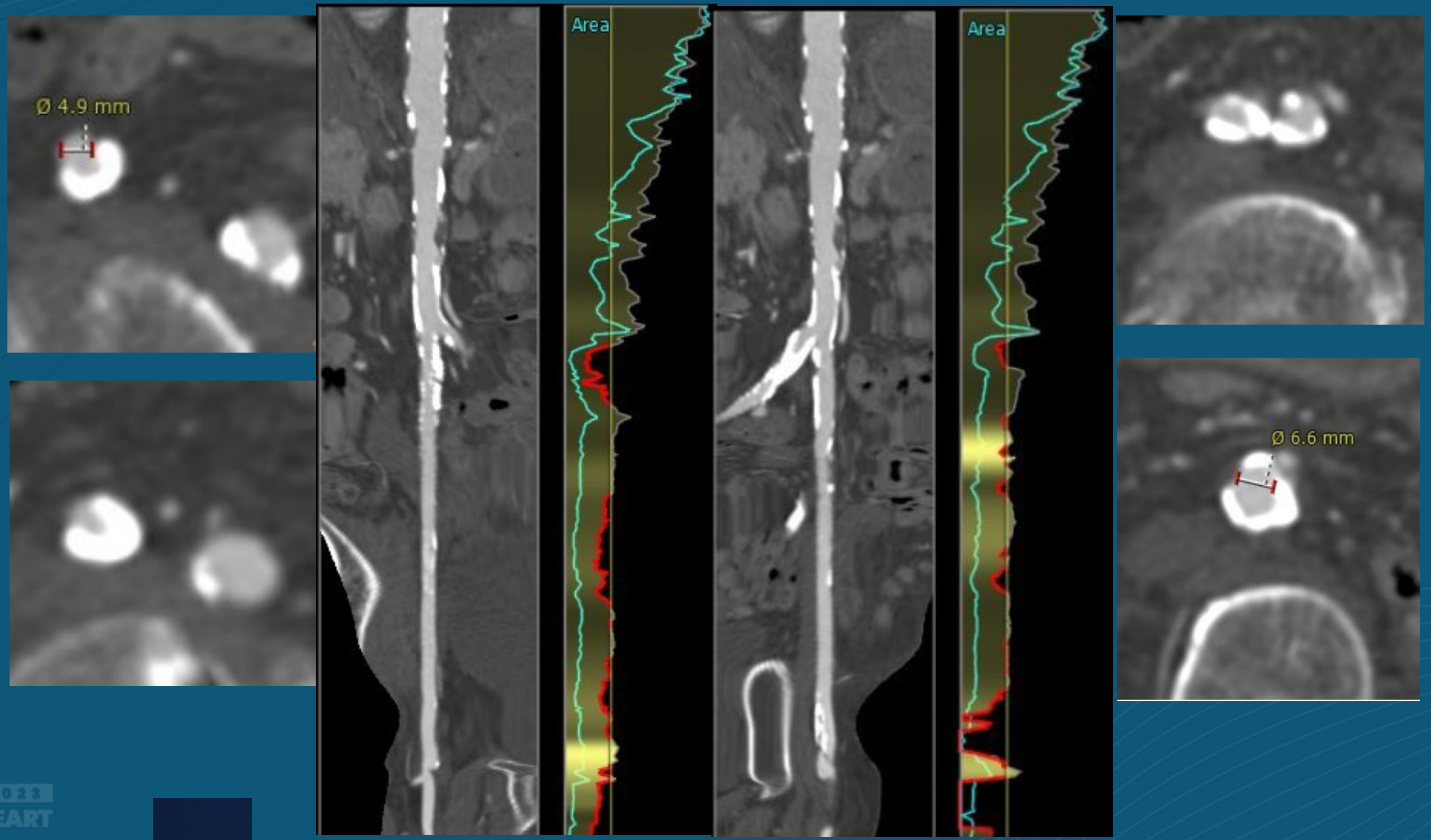
The TAVR team should be ready to perform immediate percutaneous or surgical rescue interventions in the event of serious TAVR-related complications

Progress for TAVR from “imaging”

- Devices and techniques continue to improve but **imaging** crucial in optimization
  - Best Device Selection
  - Best Technique / procedural guidance
  - Best Outcome and least invasiveness to the patient



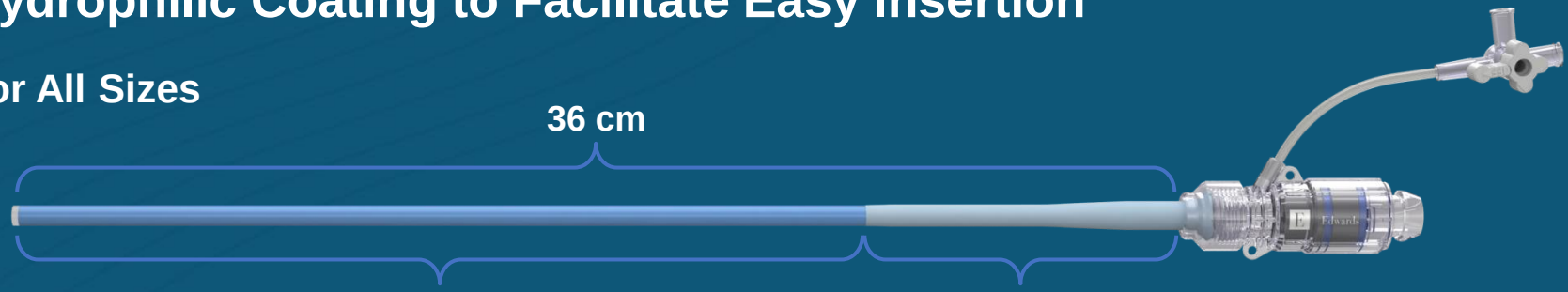
Femoral Access Screening
CT Allows us to Look INSIDE the Arteries

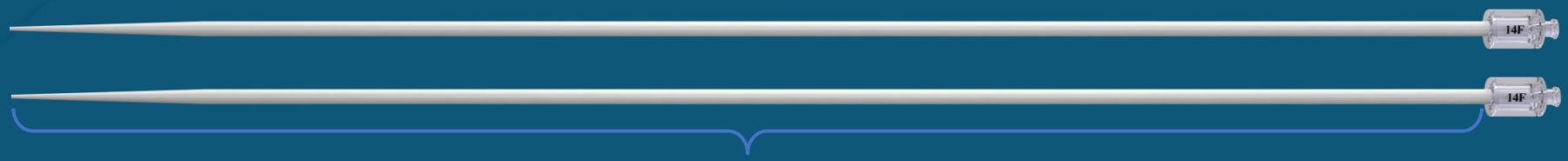


Edwards eSheath Introducer Set

Hydrophilic Coating to Facilitate Easy Insertion

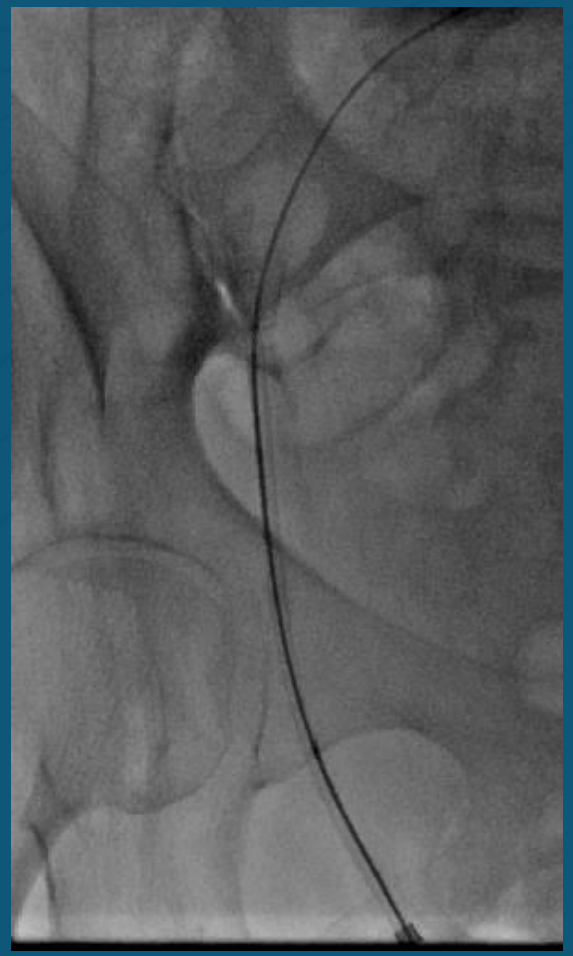
For All Sizes

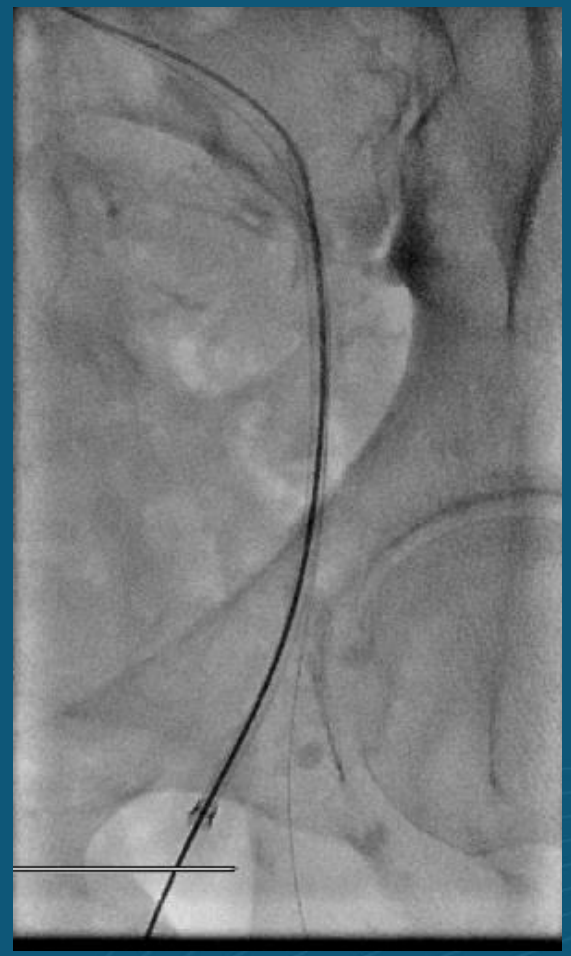




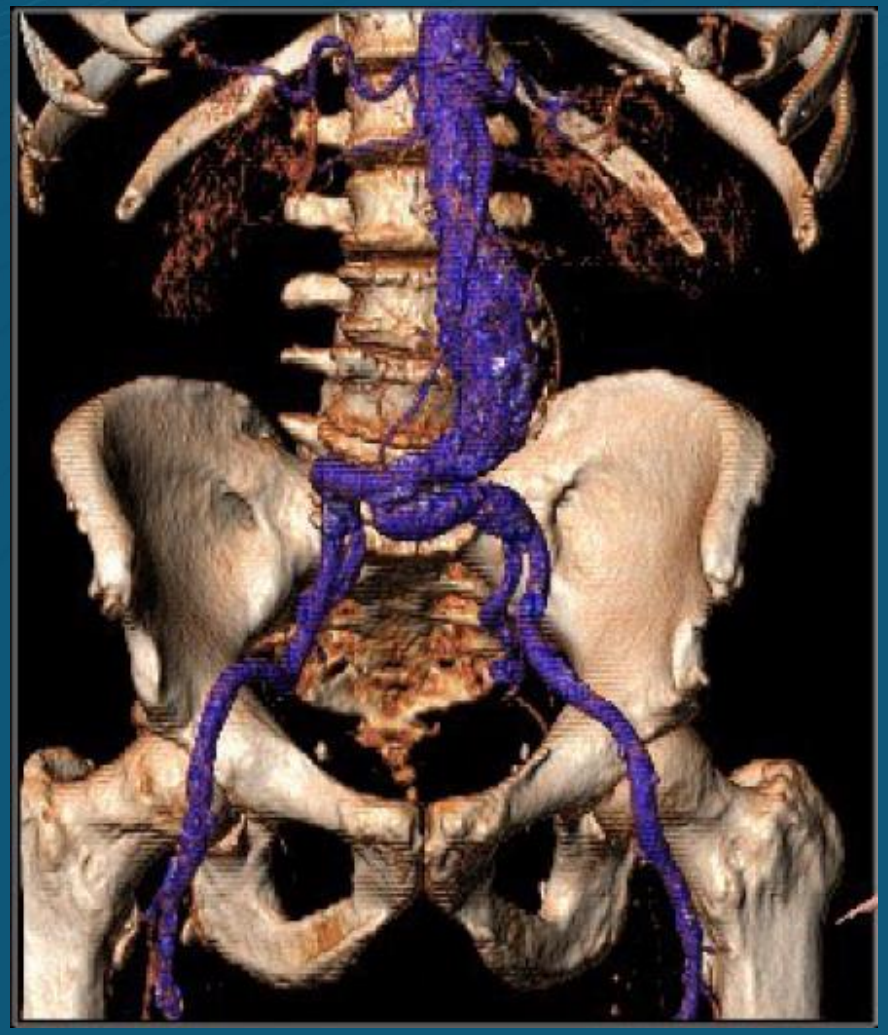
SAPIEN 3 Valve	20 mm	23 mm	26 mm	29 mm
Sheath ID (unexpanded)	14F	14F	14F	16F
Minimum Access Vessel Diameter*	5.5 mm	5.5 mm	5.5 mm	6.0 mm

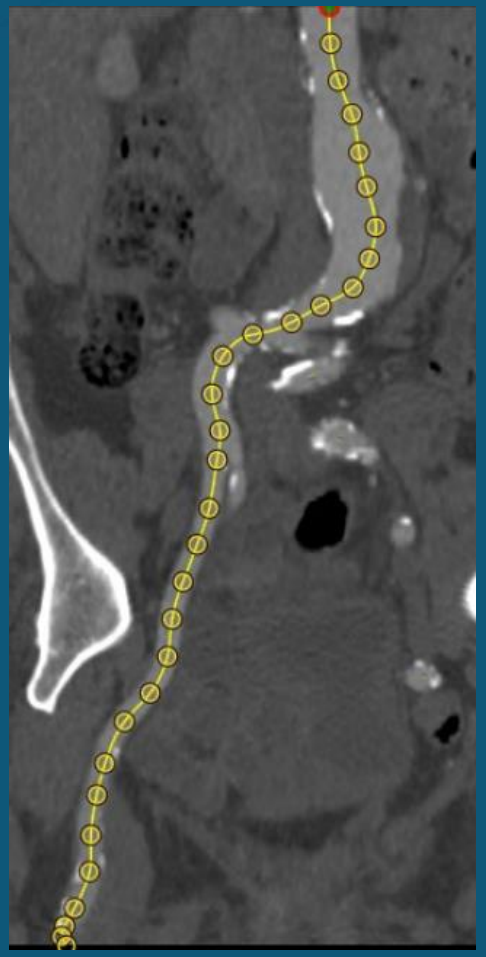
Femoral Access

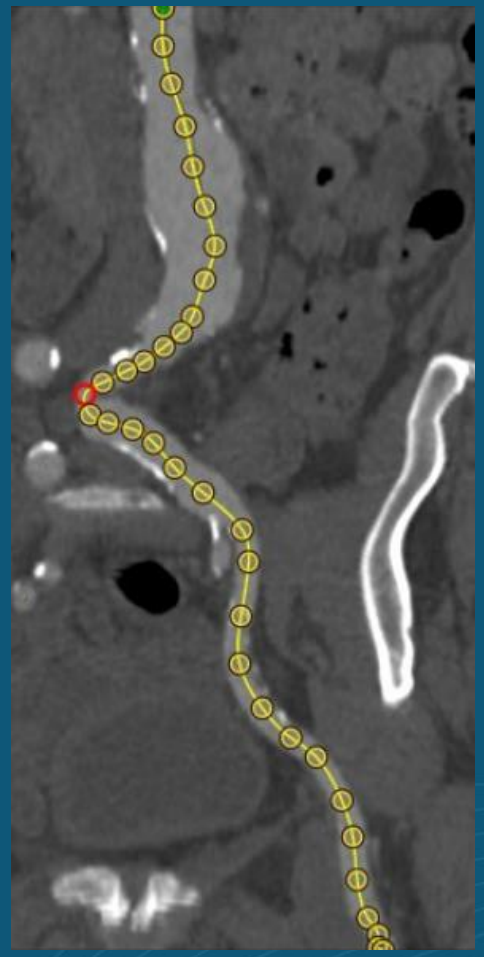




Tortuous Iliac Arteries and AAA

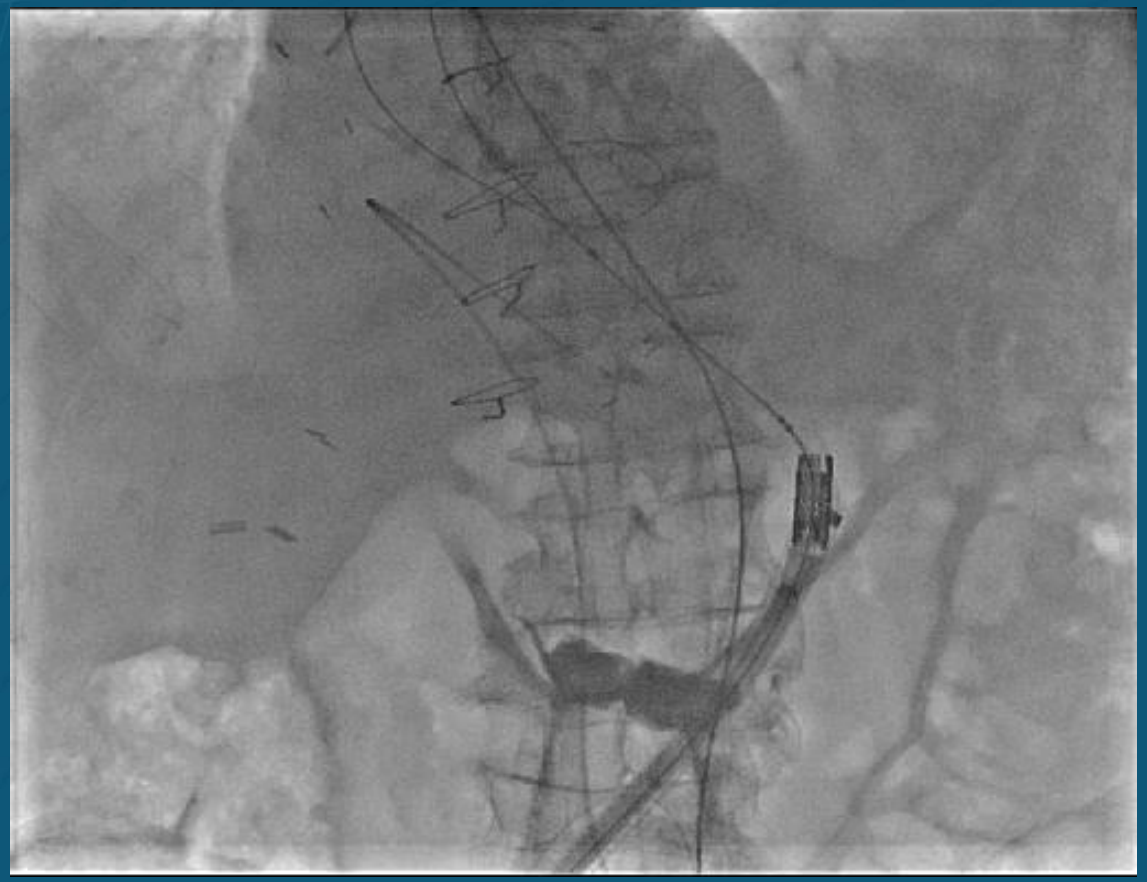


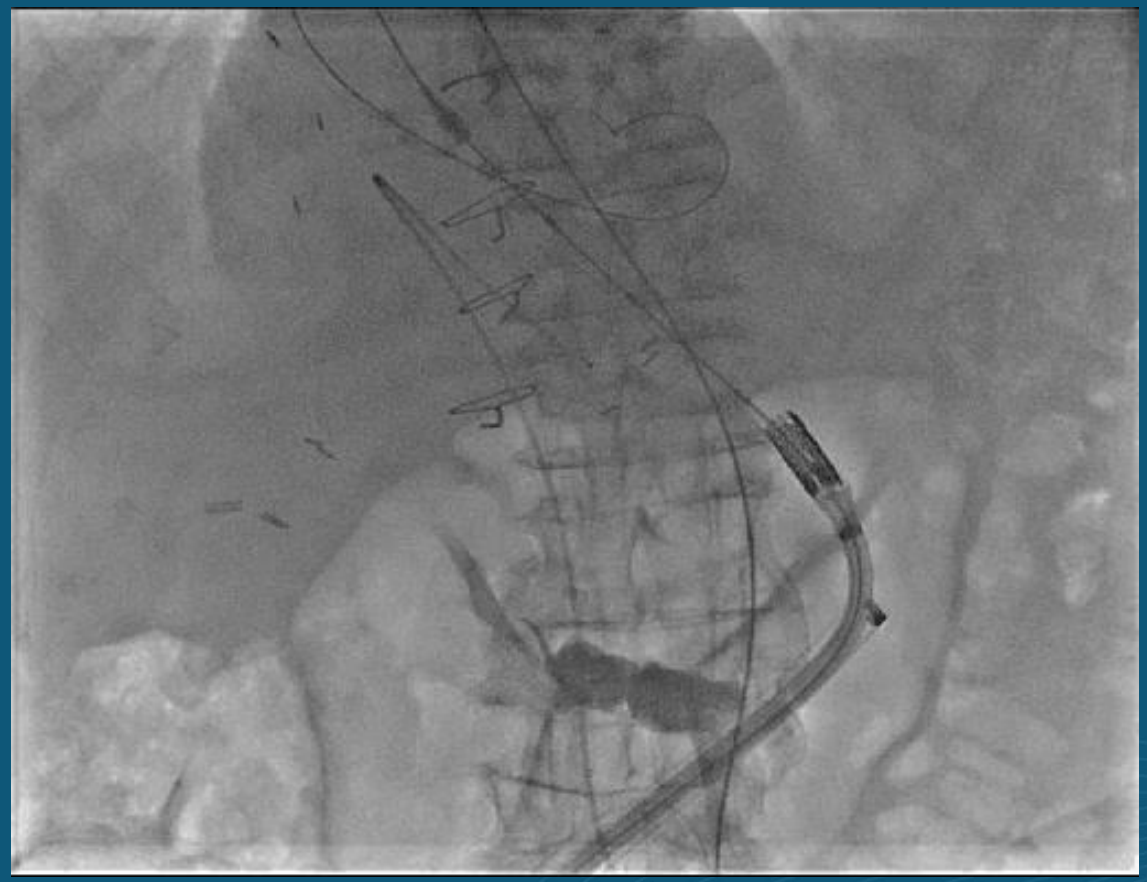




CHALLENGING VASCULAR ANATOMY

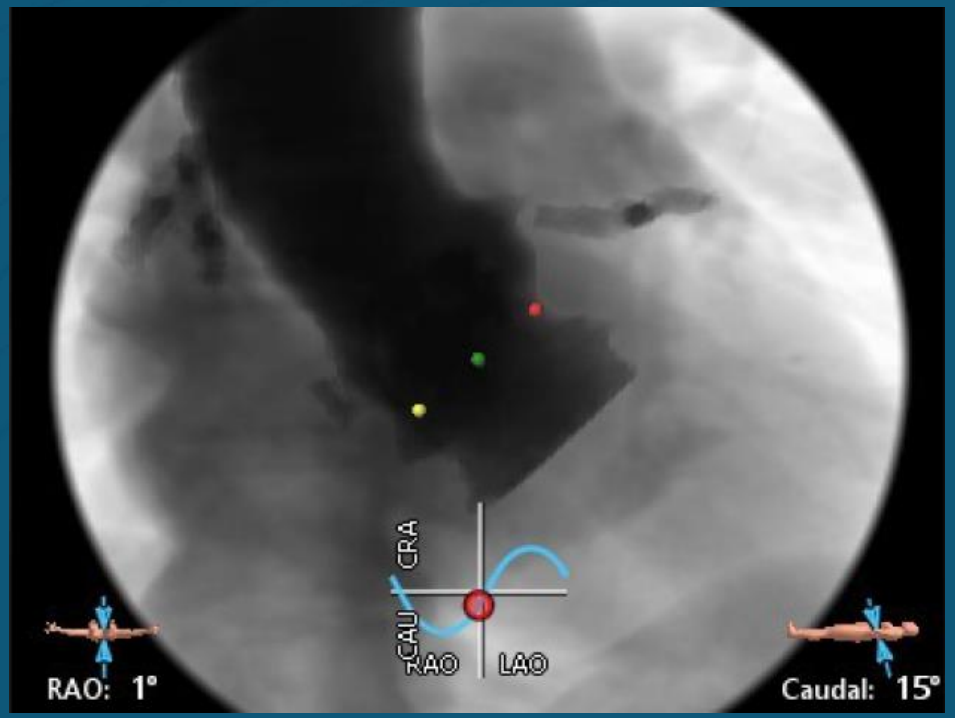
Evaluate entire vascular tree and use caution with Sheath

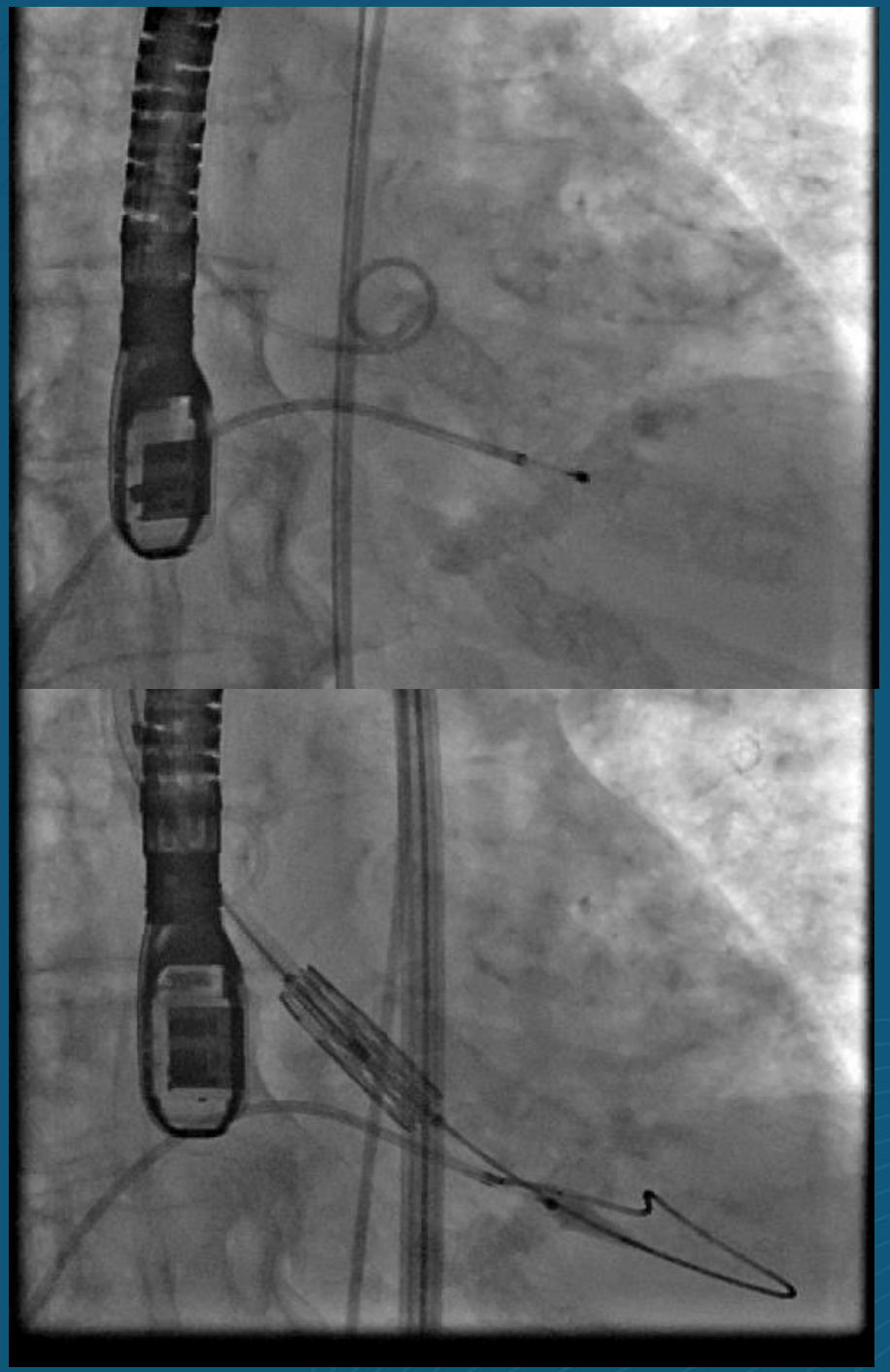




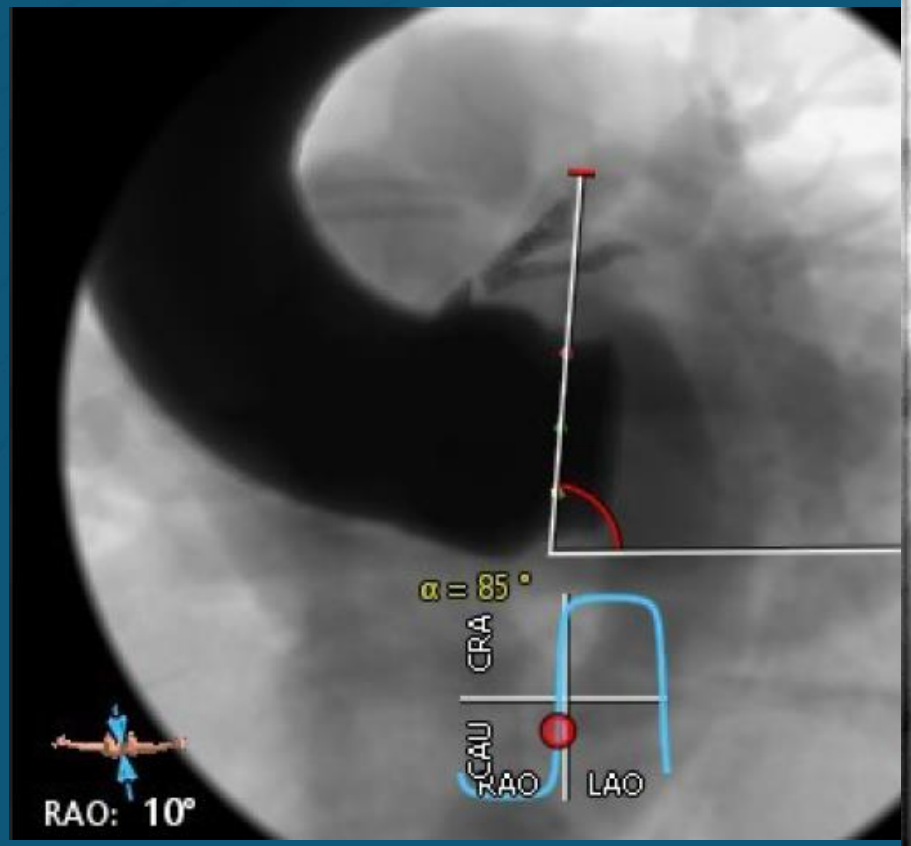
Significant resistance with device exiting sheath

Defining the Deployment Angle

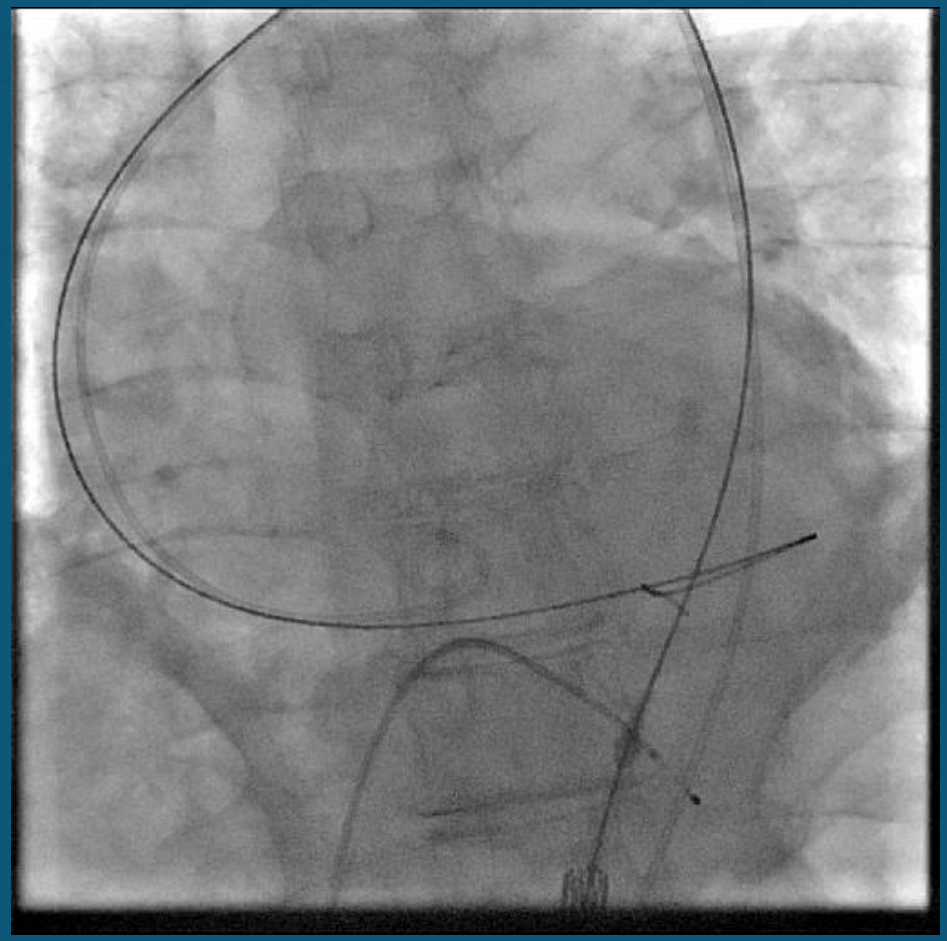


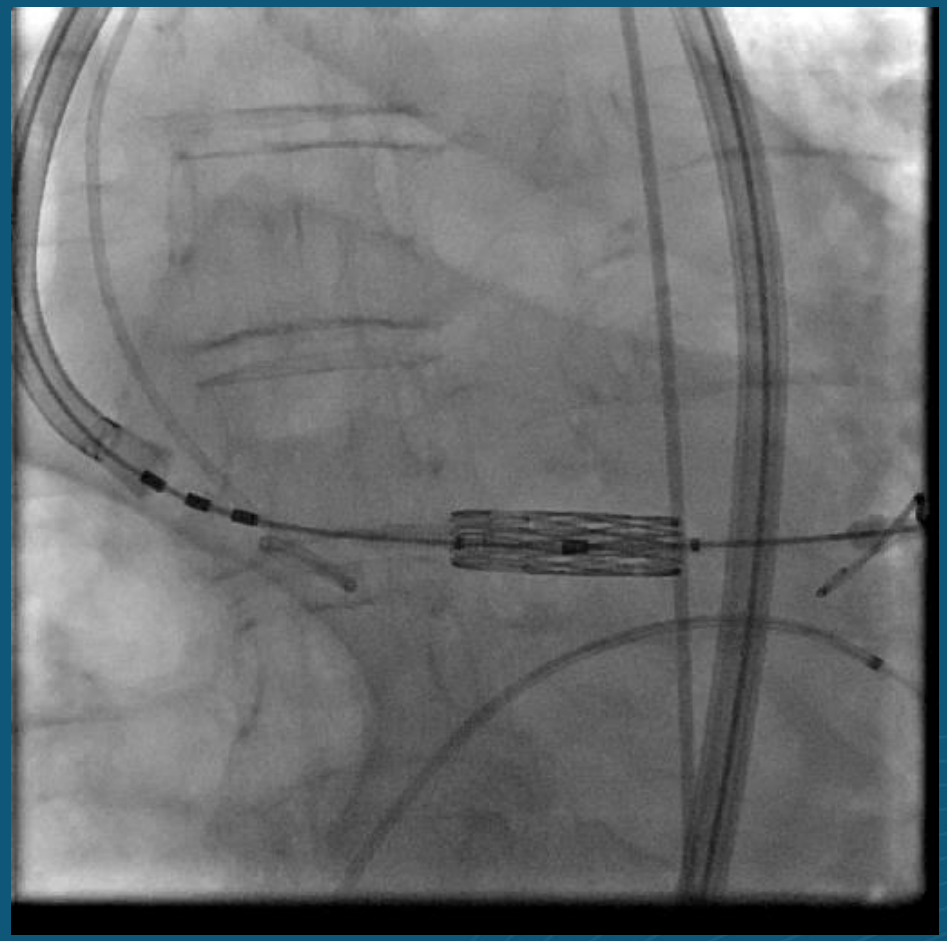


Horizontal Aorta



Horizontal Aorta

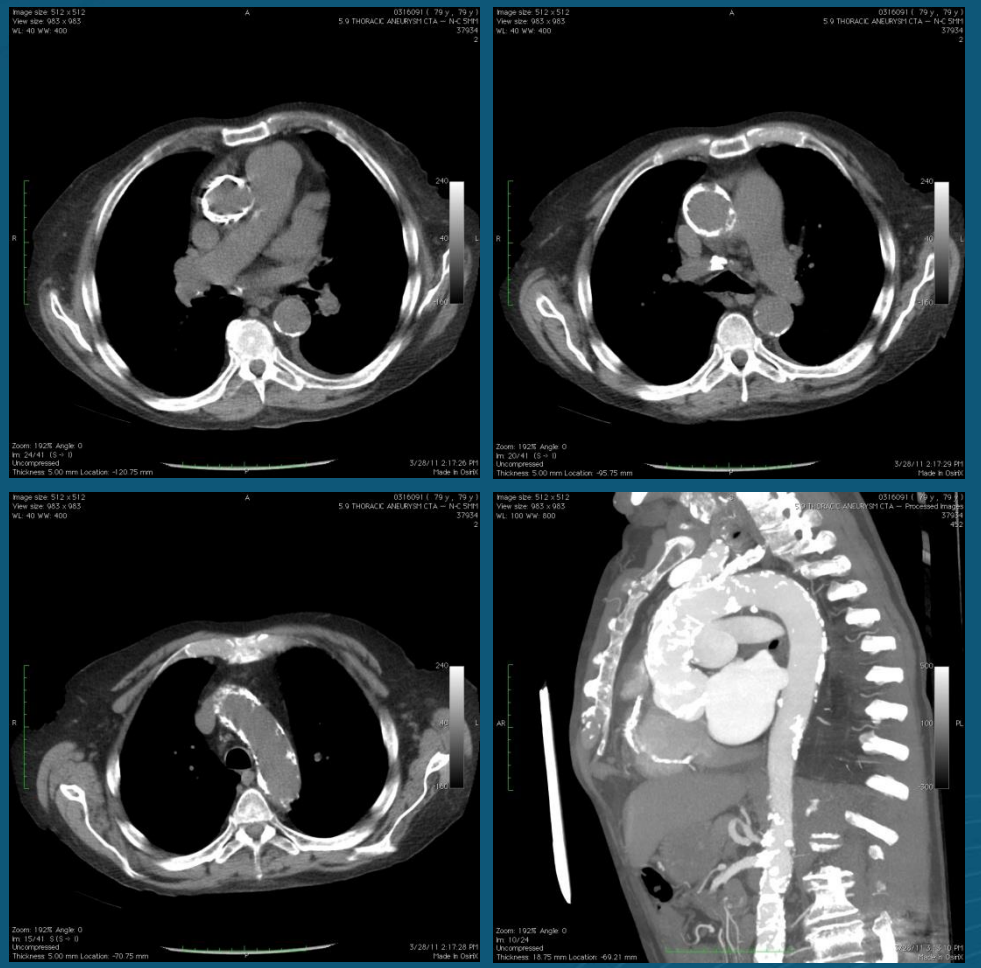




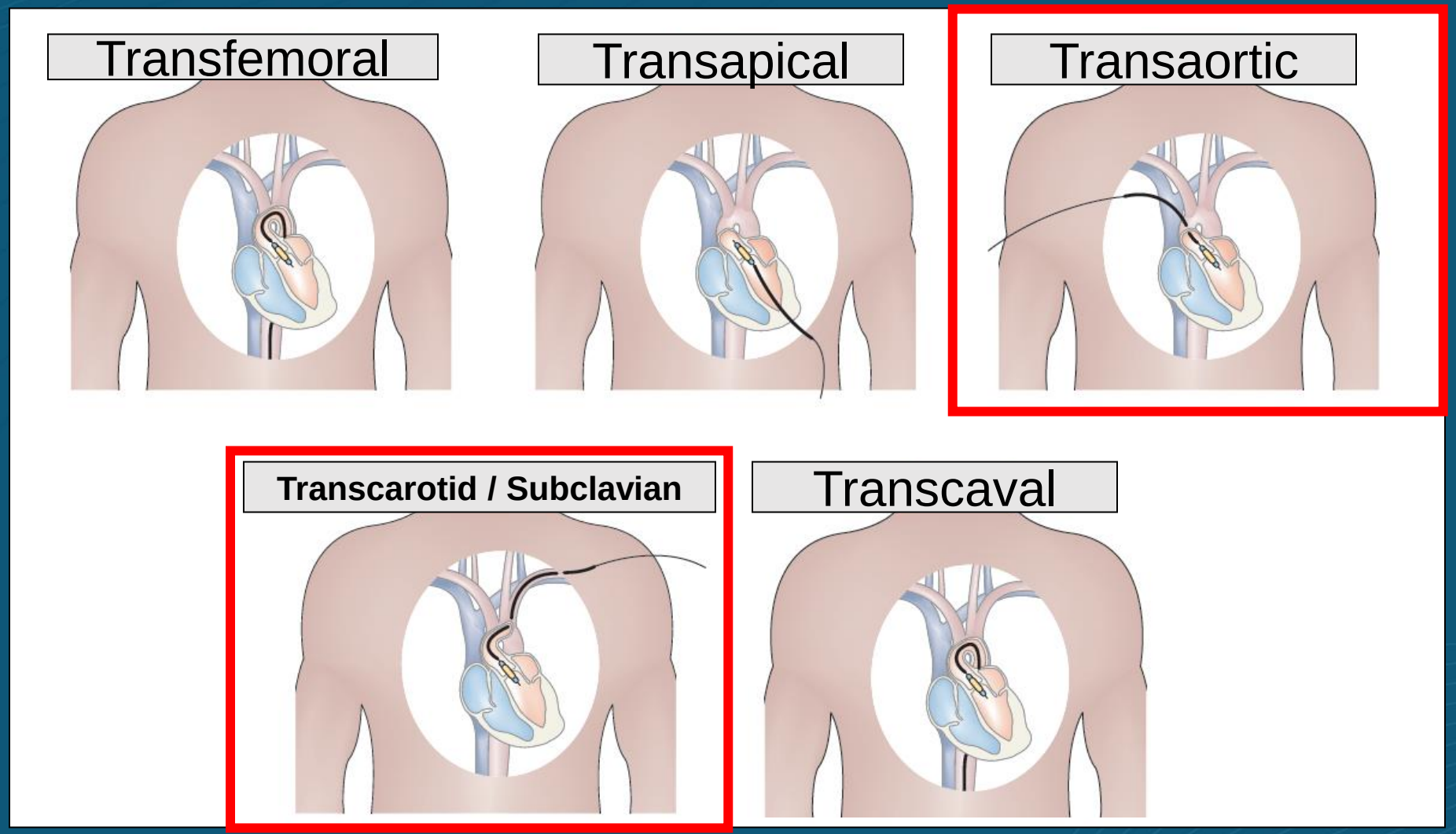
Access Risk Assessment

Porcelain Aorta:

Multiple axial cuts which demonstrate circumferential calcification as well as sagittal or coronal imaging showing extent of calcification over entire aortic arch



Other TAVR Access Choice

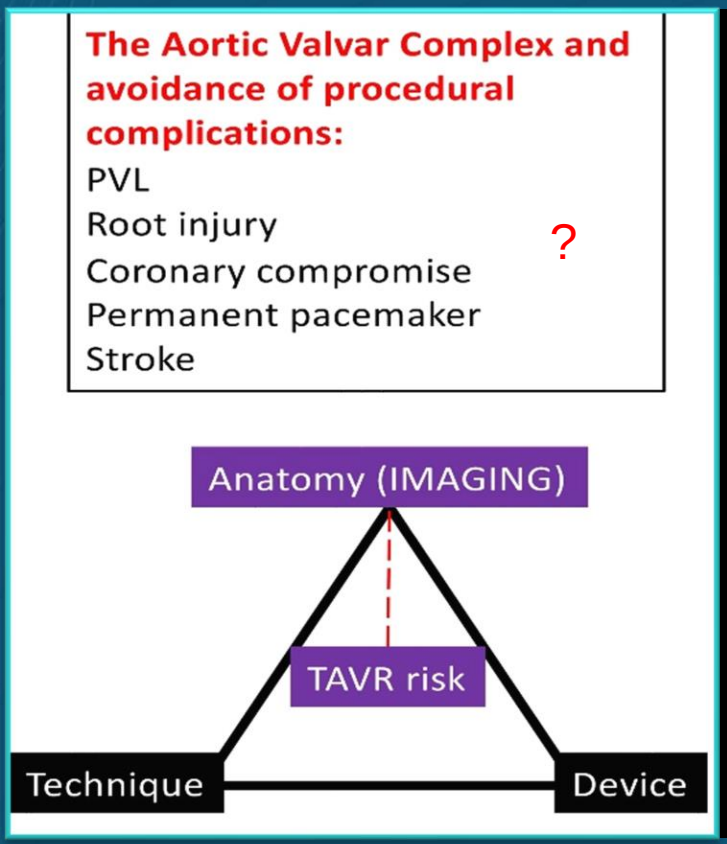


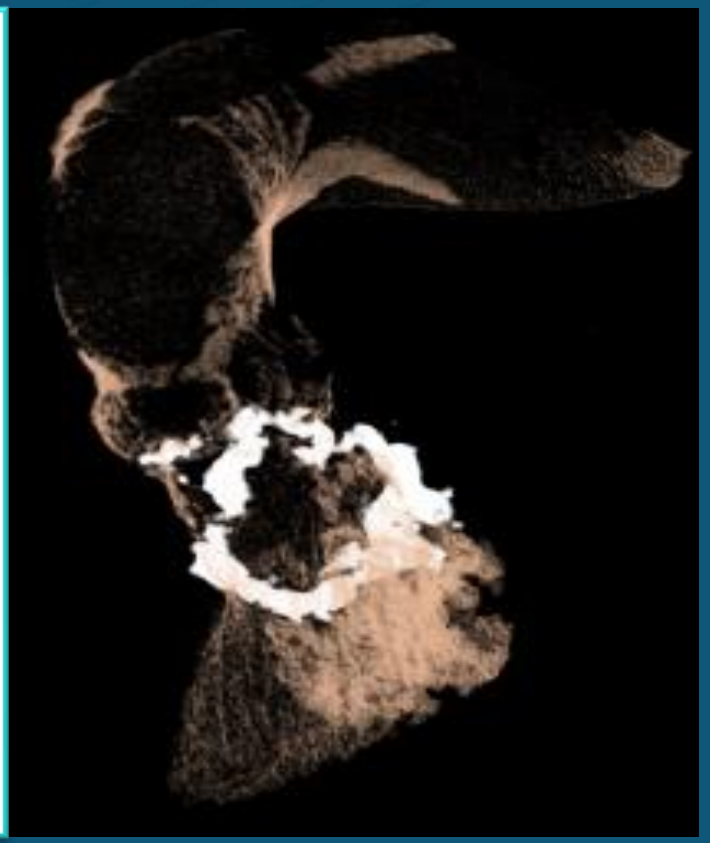
Understanding the Aortic Valvar Complex (AVC)

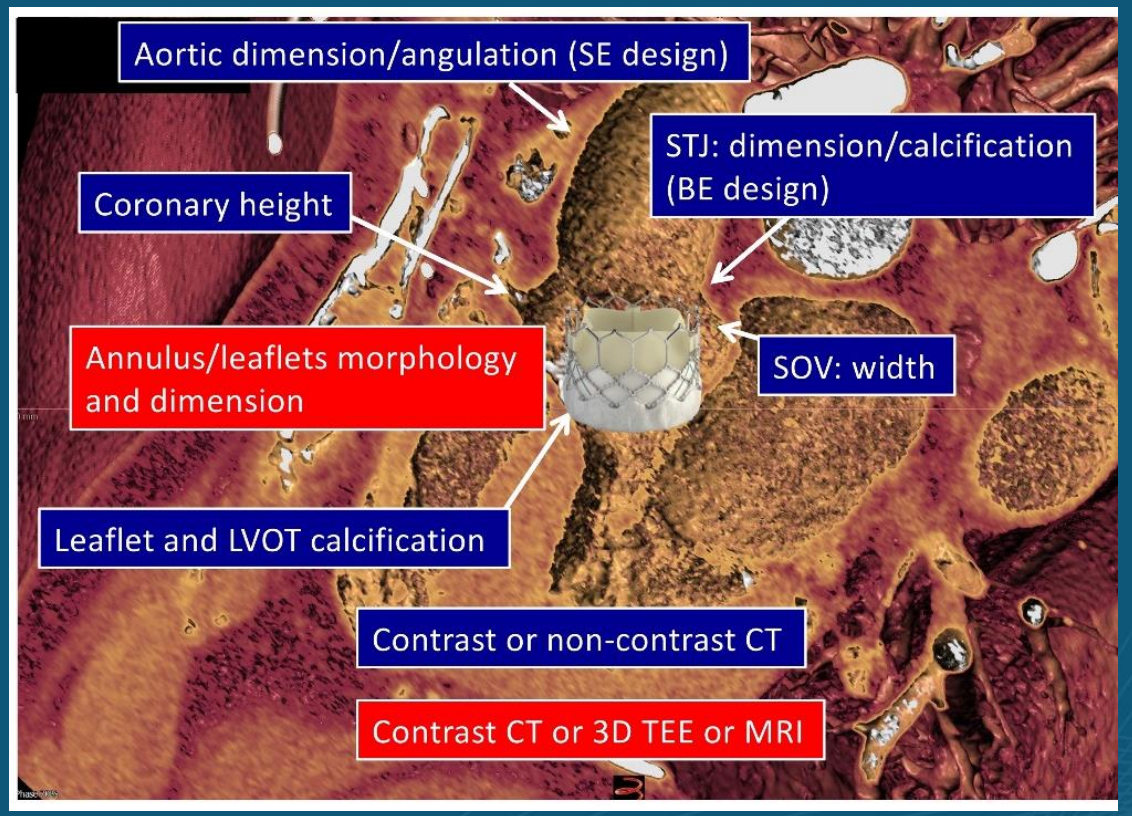
The Aortic Valvar Complex and avoidance of procedural complications:

PVL
Root injury
Coronary compromise
Permanent pacemaker
Stroke

?



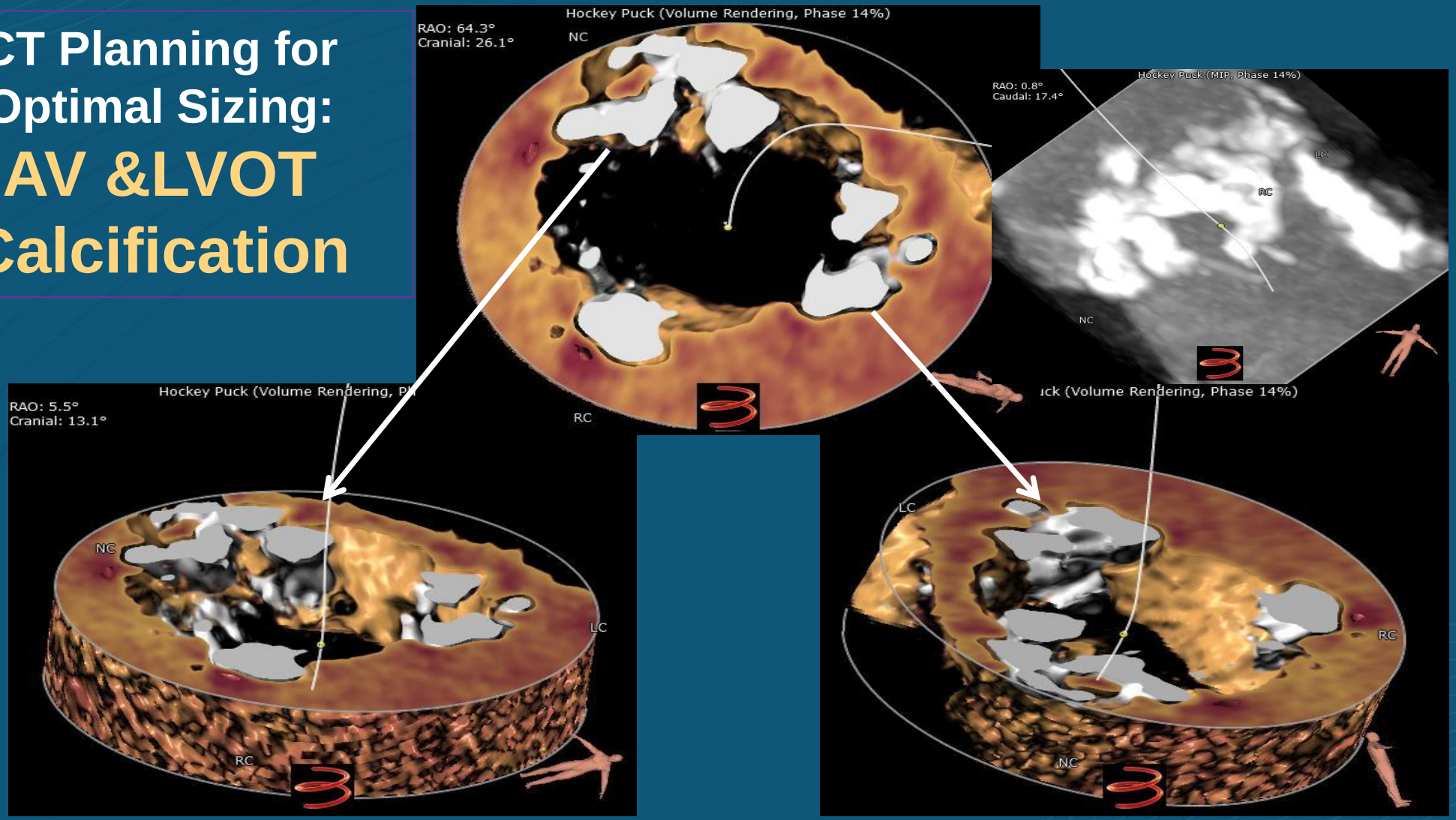




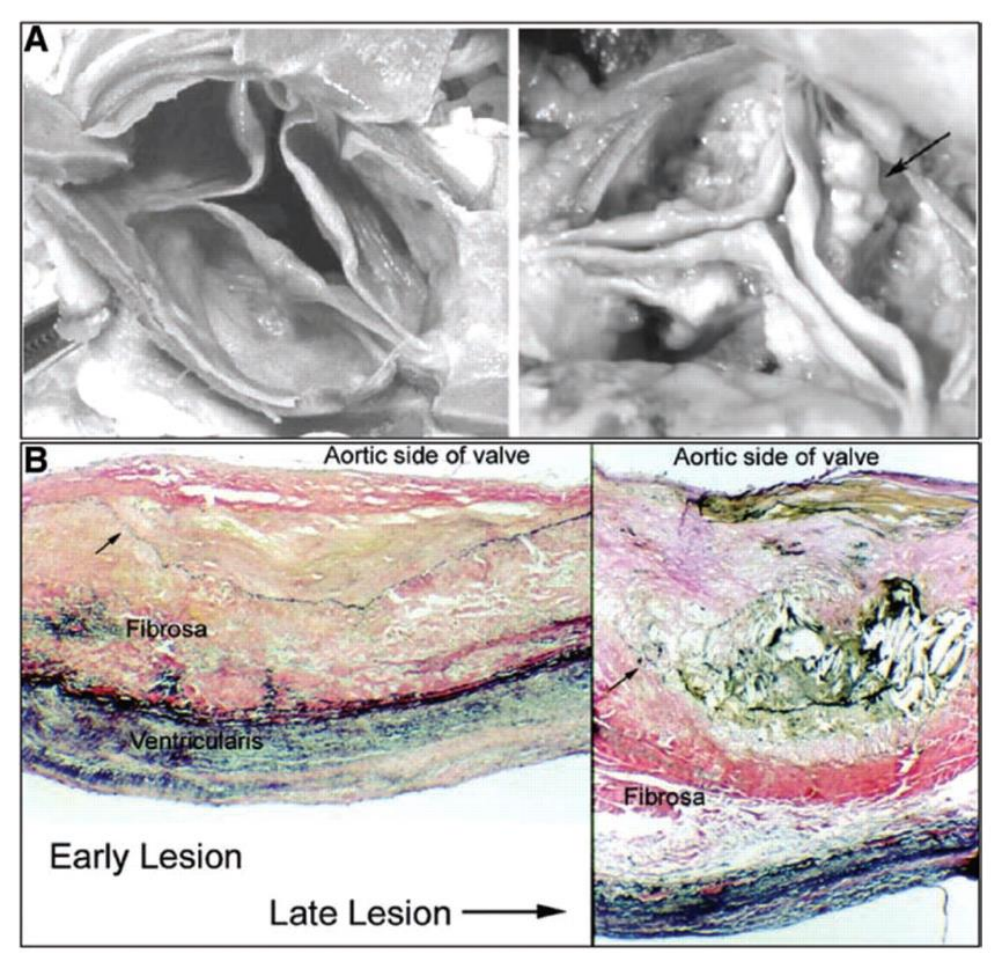
AVC Check List

Most Critical Part for TAVR Planning

CT Planning for Optimal Sizing:
AV &LVOT Calcification



AV Complex Calcification: "Friends and Foes"
- Leaflet, Annular, LVOT Calcium

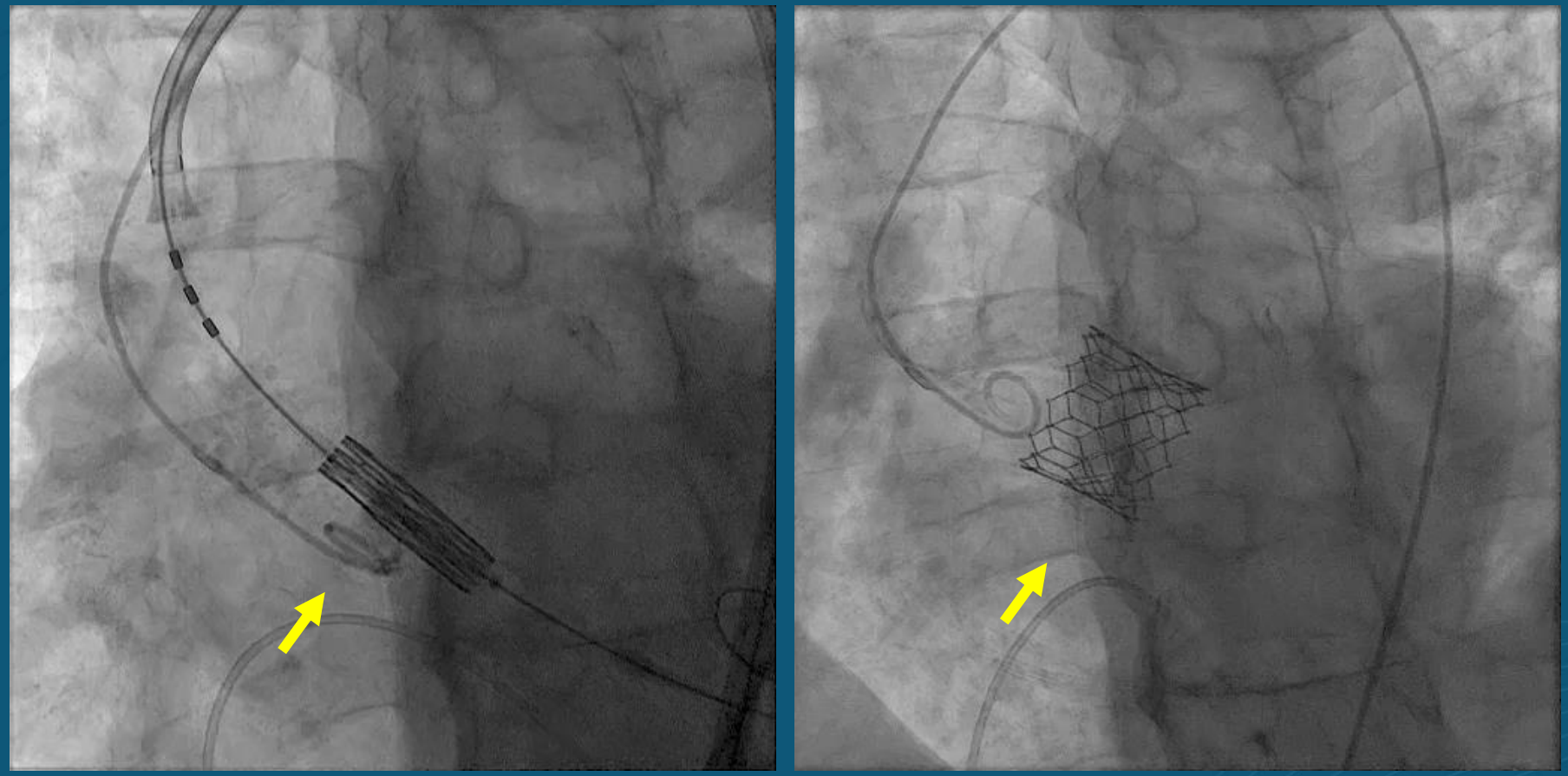


Calcification

- Anchoring

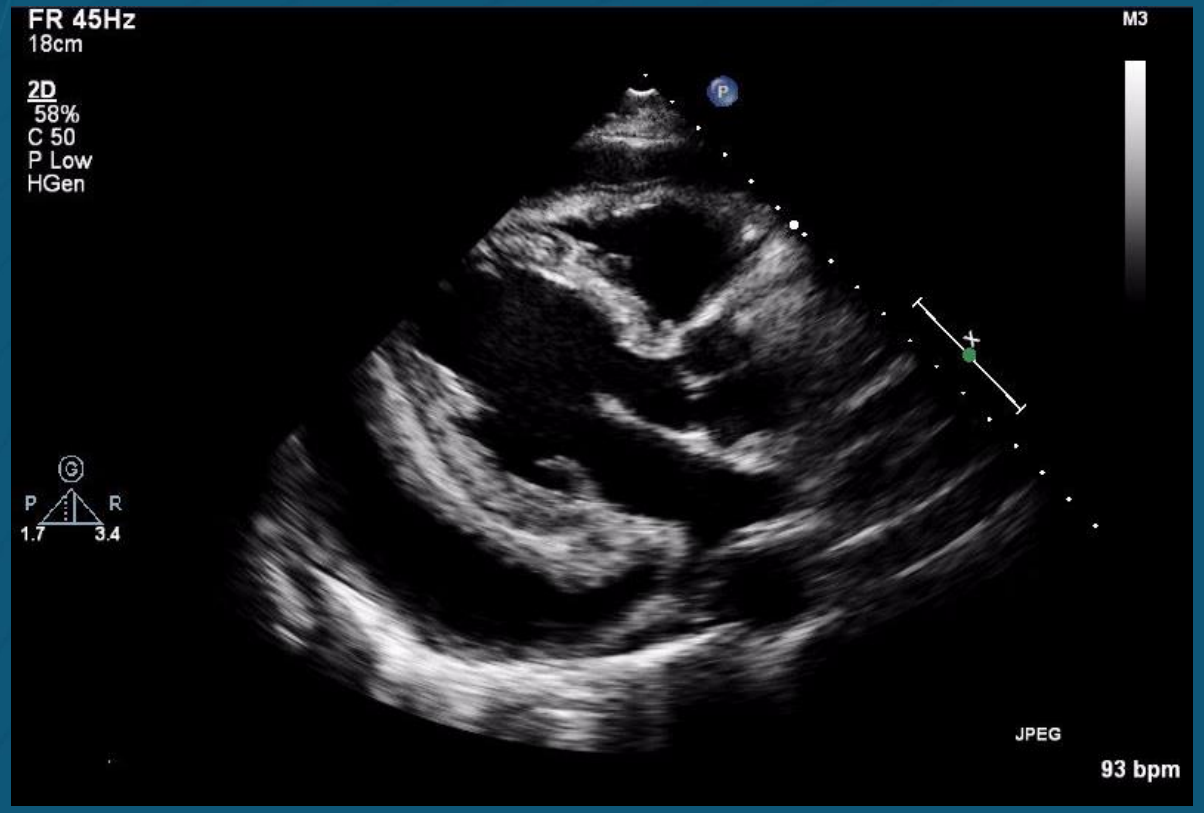
- **Associated Complications**
  1. Paravalvular leakage (PVL)
  2. Aortic injury: annulus rupture
  3. Coronary obstruction
  4. Pacemaker implantation
  5. etc…

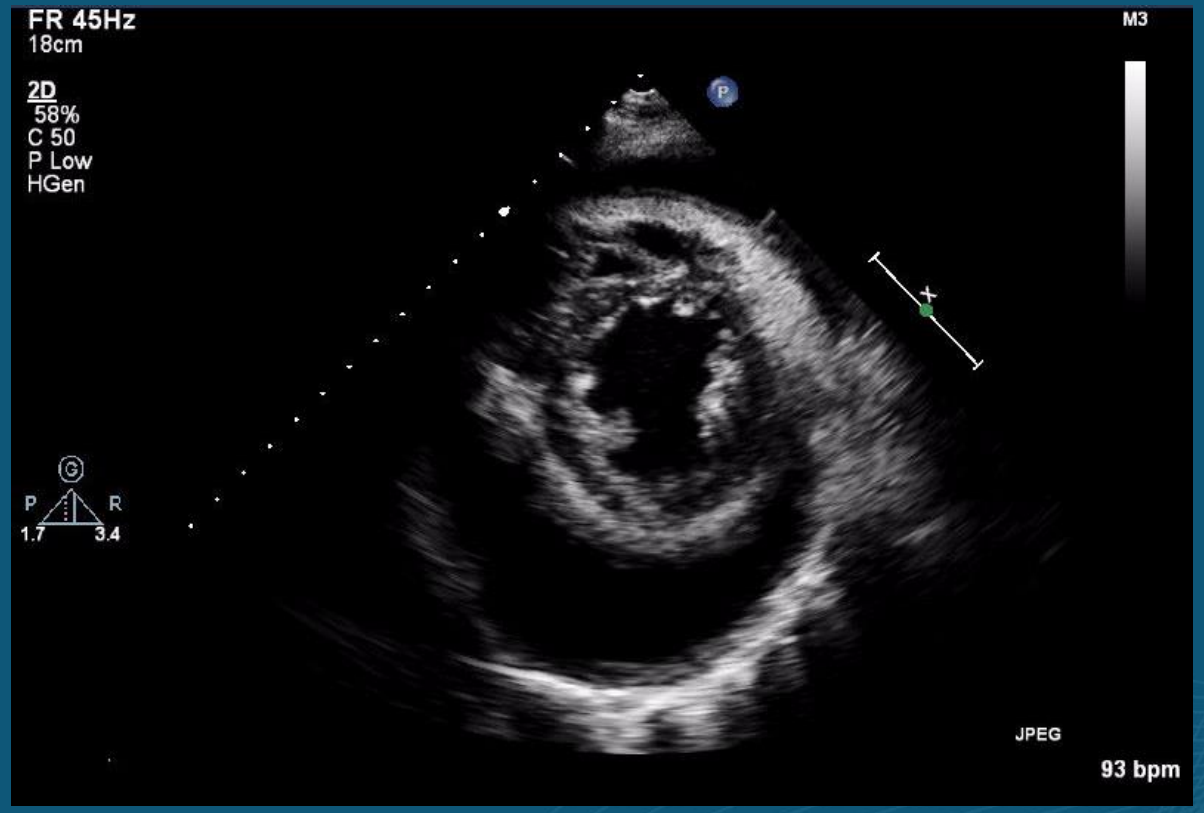
TAVR Disaster: Aortic Root Injury



Aortic Root Injury

Cardiac Tamponade





Severe LVOT Calcification

“Vulnerable area”

Epicardial fat segment is not covered by cardiac structures and leads directly to the epicardial fat and the pericardium

LVOT Calcification & TAVR: Annular Rupture

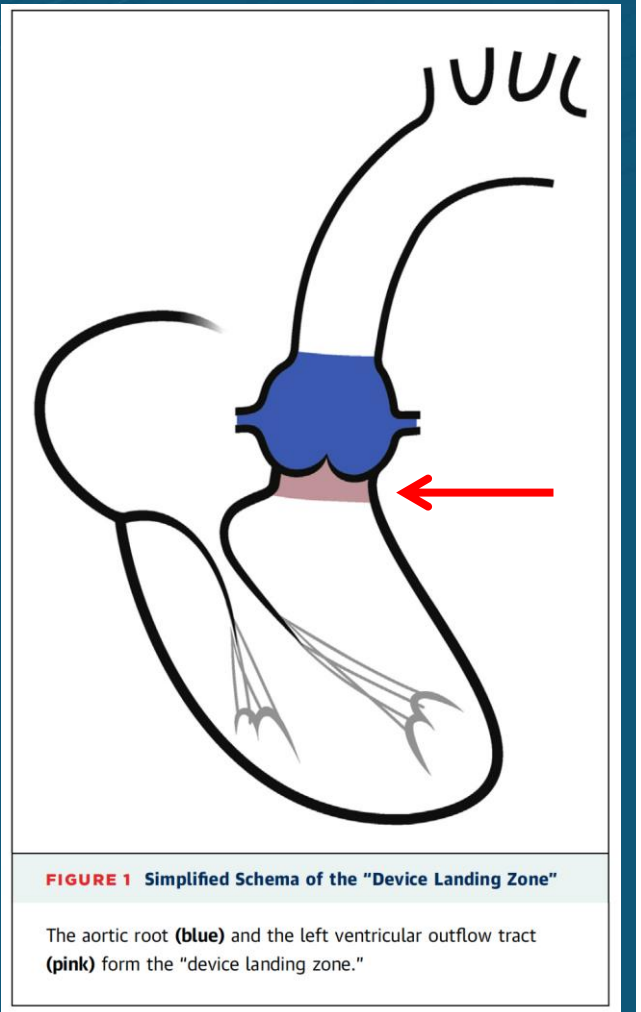


FIGURE 1 Simplified Schema of the "Device Landing Zone"

The aortic root **(blue)** and the left ventricular outflow tract **(pink)** form the "device landing zone."

TABLE 1 Classification of Annular Rupture According to the Anatomical Location

1. Intra-annular

2. Subannular
   - a. Injury of the free myocardial wall
   - b. Injury of the anterior mitral leaflet
   - c. Injury of the interventricular septum

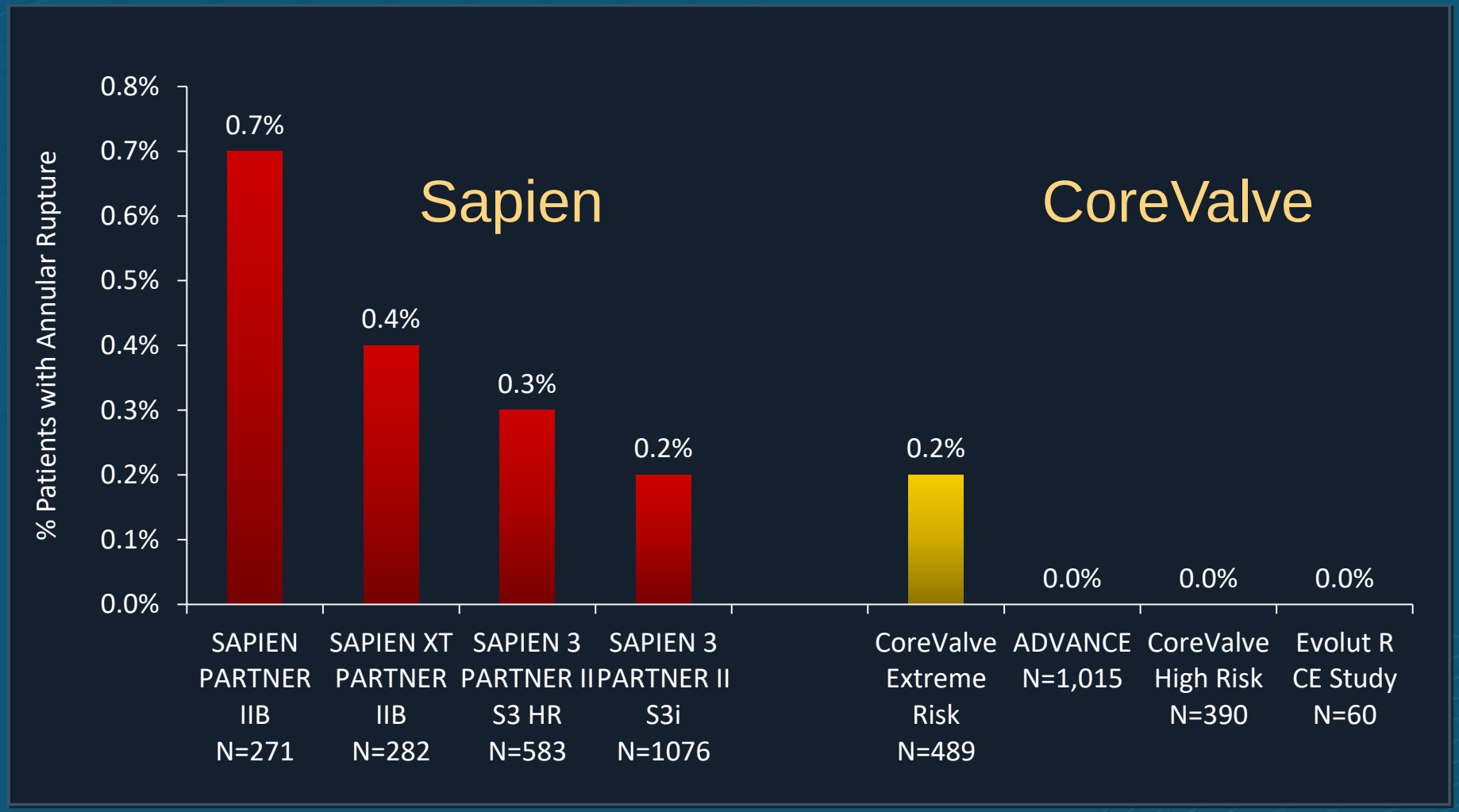
b. Injury of the ostium of a coronary artery

c. Injury of the sinotubular junction

4. Combined
   - a. Intra-annular and supra-annular
   - b. Intra-annular and subannular
   - c. Intra-annular, supra-annular, and subannular

Pasic M et al. JACC Intv. 2015; 8(1): 1-9

Risk of Annular Rupture



[1]Leon, et. al. presented at ACC 2013; [2]Kodali, et al., presented at ACC 2015; [3]Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; [4]Linke, et al. , *Eur Heart J* 2014; 35: 2672-84; [5]Adams, et al., *N Engl J Med* 2014; 370: 1790-8; [6]Meredith, et. al. presented at EuroPCR 2015

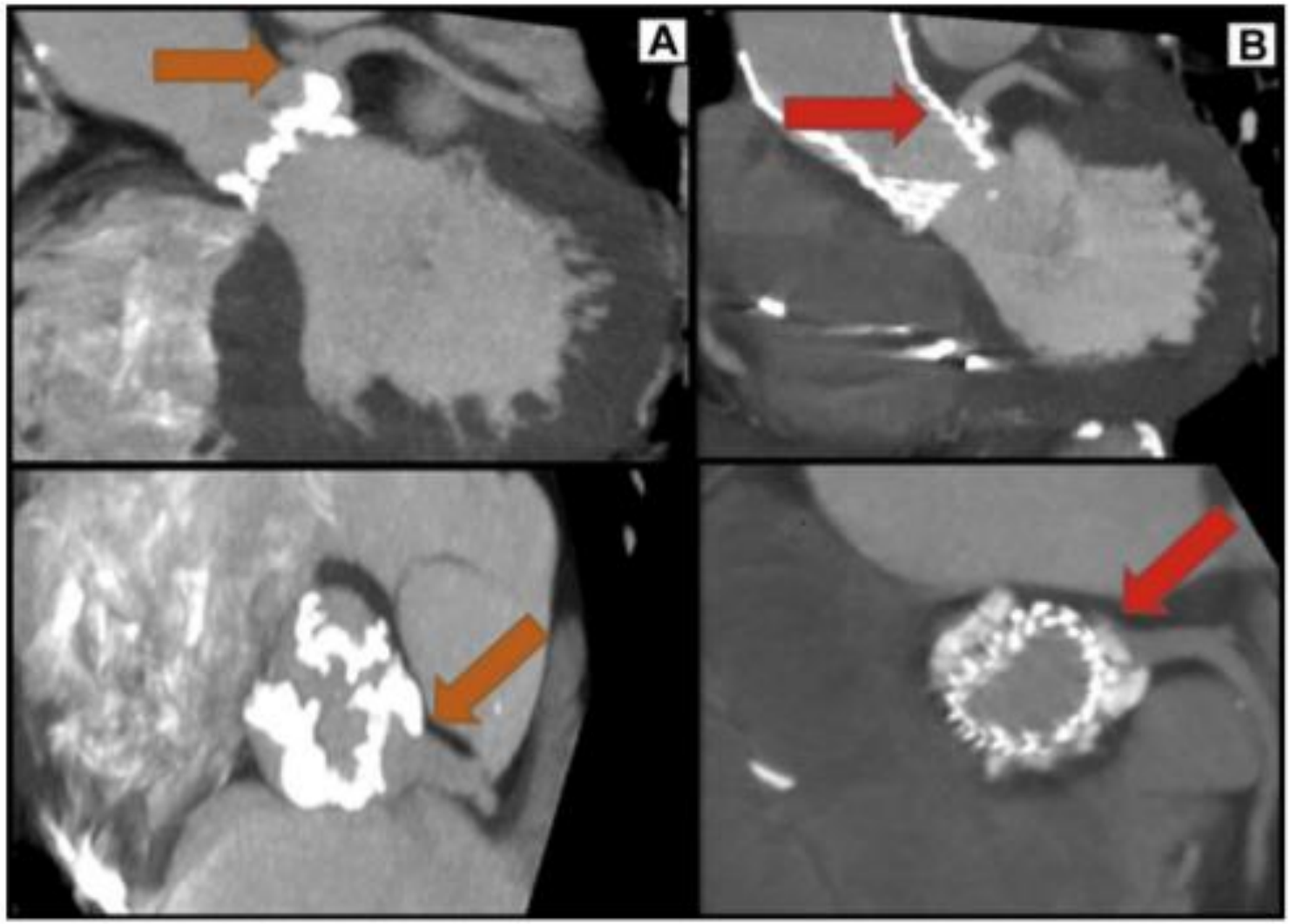
Causes of Coronary Obstruction

- The displacement of a ***Bulky Calcified Native Valve*** over a coronary ostium: The most cases

- An obstruction by a portion of the THV frame or the sealing cuff placed directly over a coronary ostium (hypothetically)

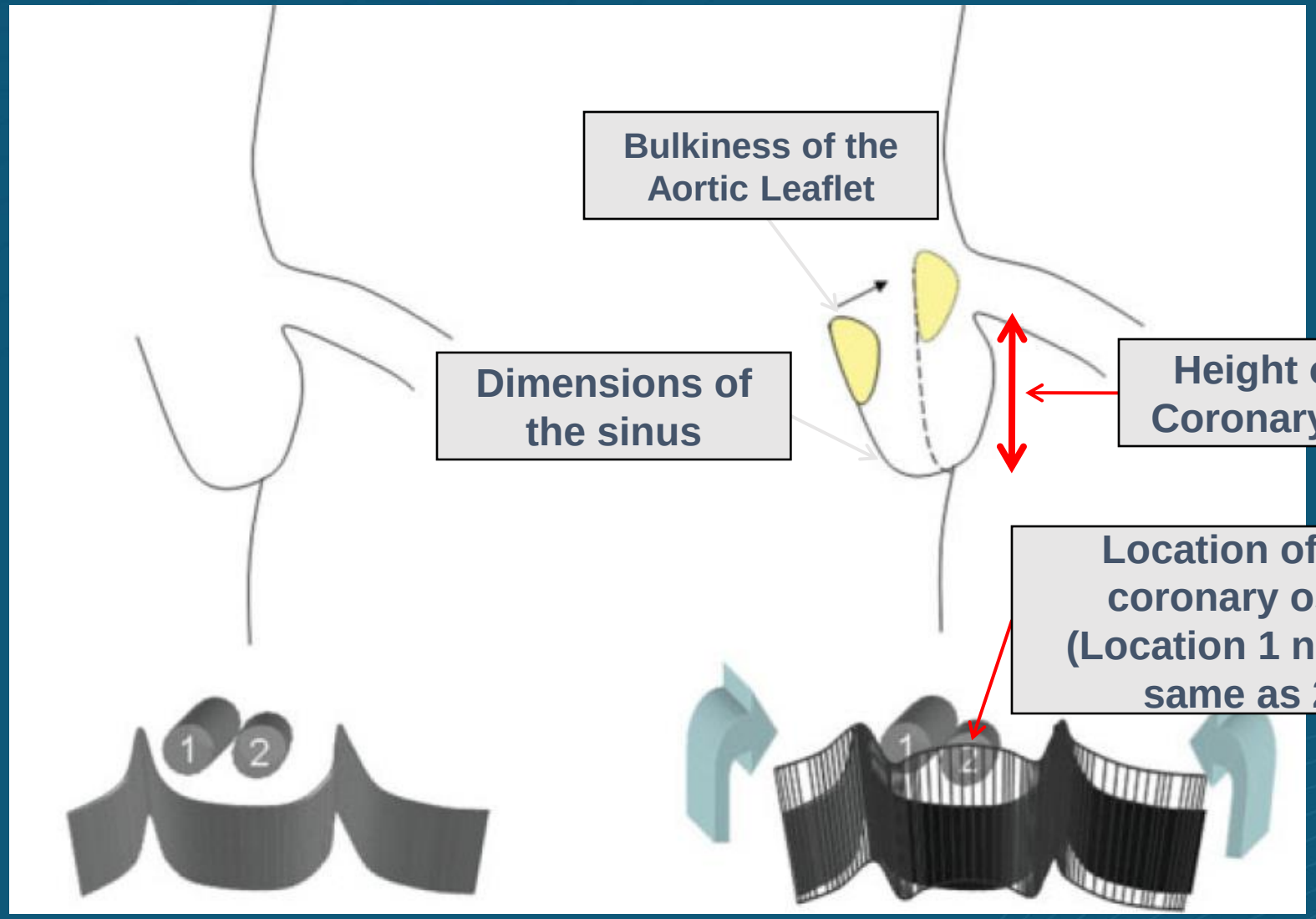
Interventional Cardiology Review, 2015;10(2):94–7
Yamamoto M, et al. Int J Cardiol. 2016 May 4;217:58-63

Coronary Obstruction With Bulky Calcium



JACC: cardiovascular interventions. 2014:7(8); e105 – 7

Factors determining the Risk of Coronary Complications



Kapadia et al. Catheterization and Cardiovascular Interventions 2009

“Key Practical Recommendation”: TAVR with SAPIEN for Severely Calcified AV

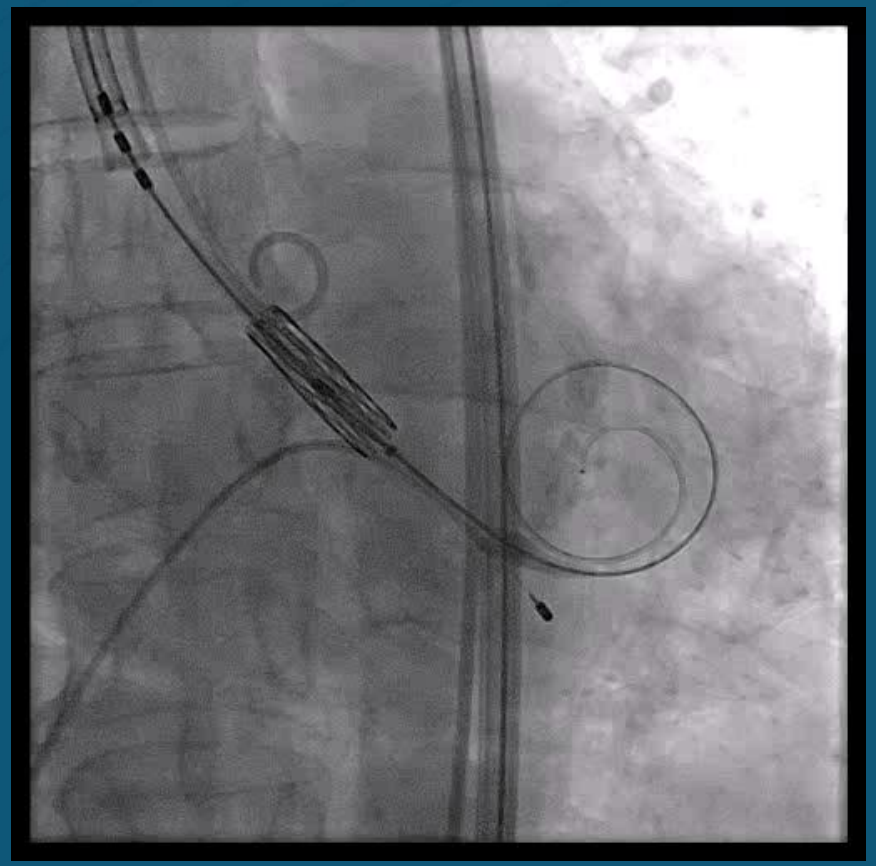
1. Identify risk factor for annular injury
2. Do not oversize
3. Modify implantation plan, such as higher valve positioning
4. Avoid performing valve reballooning for paravalvular leak in the presence of significant calcification **(“perfect is an enemy of good”)**
5. Consider the use of other type of valve rather than a balloon-expandable valve

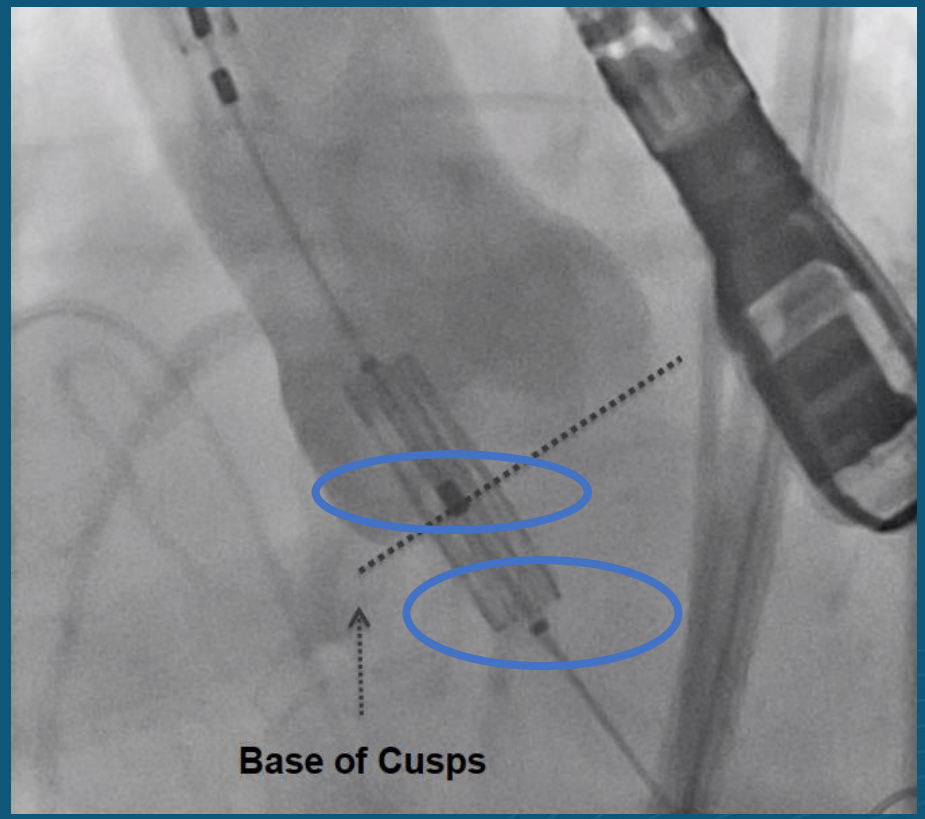
Sizing Algorithm
Based on the CT Assessment

Severe AS with Tricuspid	***10~15% Area Oversizing***
Severe AS with Bicuspid	0-5% Lesser Oversizing
Heavy Calcification (Ca volume > 1000 mm^3)	**0-5% Lesser Oversizing**
Small Sinus of Valsalva to Annulus Area ratio	0-5% Lesser Oversizing
Small LVOT	Consider Lesser Oversizing

Conventional Valve Positioning and Implantation

Bottom of Center Marker at Base of Cusps





ORIGINAL ARTICLE

Systematic Approach to High Implantation of SAPIEN-3 Valve Achieves a Lower Rate of Conduction Abnormalities Including Pacemaker Implantation

Circ CV Interv 2021

Yasser Sammour, MD; Kinjal Banerjee, MD; Arnav Kumar, MD, MSCR; Hassan Lak, MD; Sanchit Chawla, MD; Cameron Incognito, MD; Jay Patel, MD; Manpreet Kaur, MD; Omar Abdelfattah, MD; Lars G. Svensson, MD, PhD; E. Murat Tuzcu, MD; Grant W. Reed, MD, MSc; Rishi Puri, MD, PhD; James Yun, MD; Amar Krishnaswamy, MD; Samir Kapadia, MD

- 1,028 TF-TAVR Patients at CCF (‘15 – ‘18)
- 622 traditional deployment
- 406 “high” deployment
- No difference in major clinical outcomes (AR, valve embolization, survival, stroke)

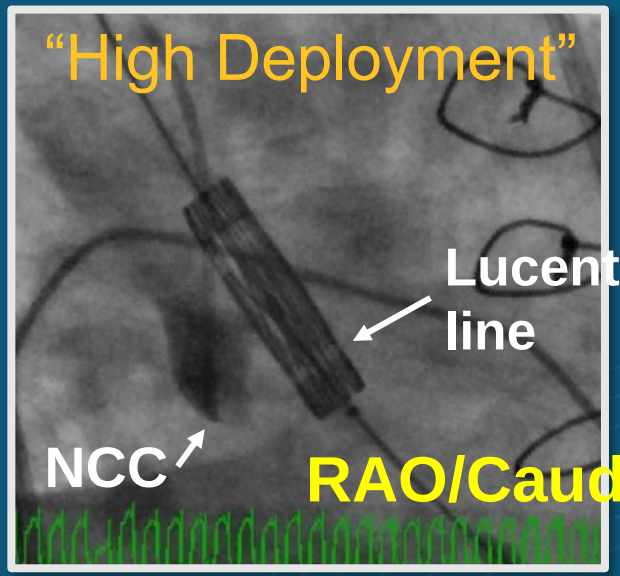
during transcatheter aortic valve replacement. One patient (0.2%) had valve embolization with HDT (P=0.216). Thirty-day permanent pacemaker rates were lower with HDT (5.5% versus 13.1%; P<0.001), as were rates of complete heart block (3.5% versus 11.2%; P<0.001) and new-onset left bundle branch block (5.3% versus 12.2%; P<0.001). There were no differences in mild (16.5% versus 15.9%; P=0.804), or moderate-to-severe aortic regurgitation (1% versus 2.7%; P=0.081) at 1 year. HDT was associated with slightly higher 1-year mean gradients (13.1±6.2 versus 11.8±4.9 mm Hg; P=0.042) and peak gradients (25±11.9 versus 22.5±9 mm Hg; P=0.026). However, Doppler velocity index was similar (0.47±0.15 versus 0.48±0.13; P=0.772).

CONCLUSIONS: Our novel technique for balloon-expandable S3 valve positioning consistently achieves higher implantation resulting in substantial reduction in conduction abnormalities and permanent pacemaker requirement after transcatheter aortic valve replacement without compromising procedural safety or valve hemodynamics. Operators should consider this as an important technique to improve patient outcomes.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: atrioventricular block ■ hemodynamics ■ high deployment ■ implantation depth ■ transcatheter aortic valve replacement

See Editorial by Vora and Gada

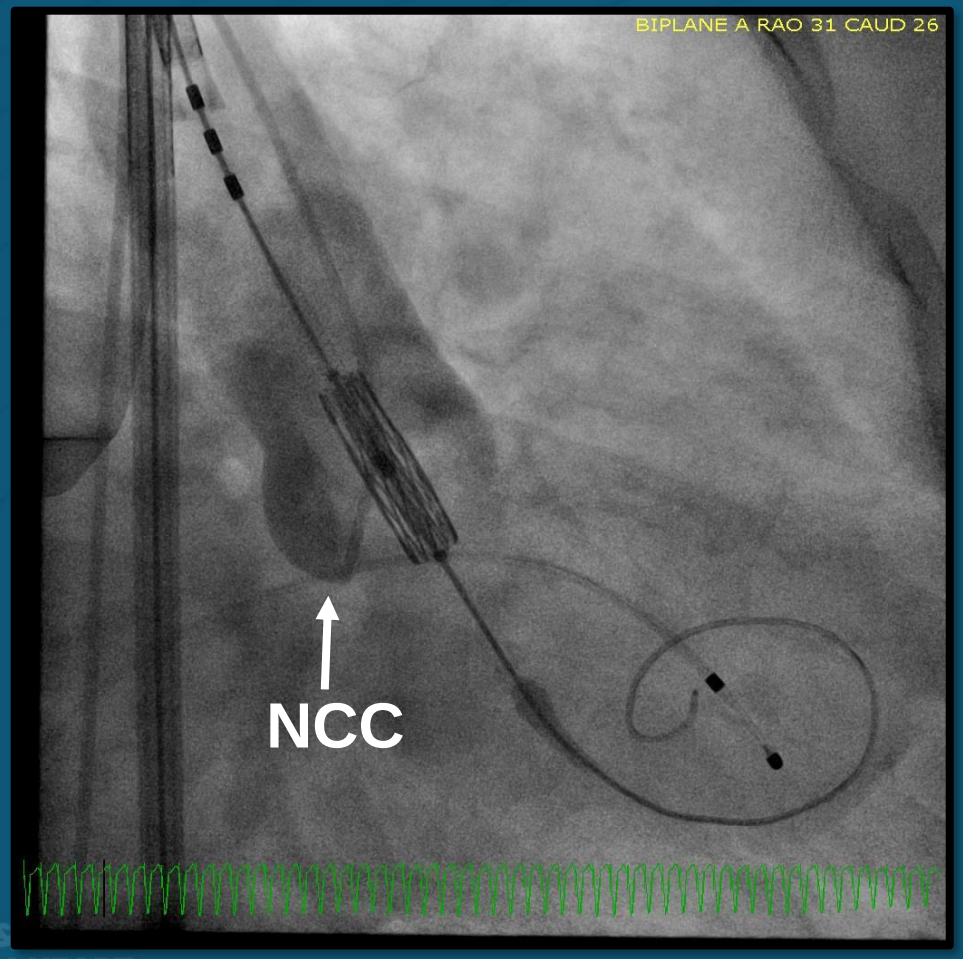


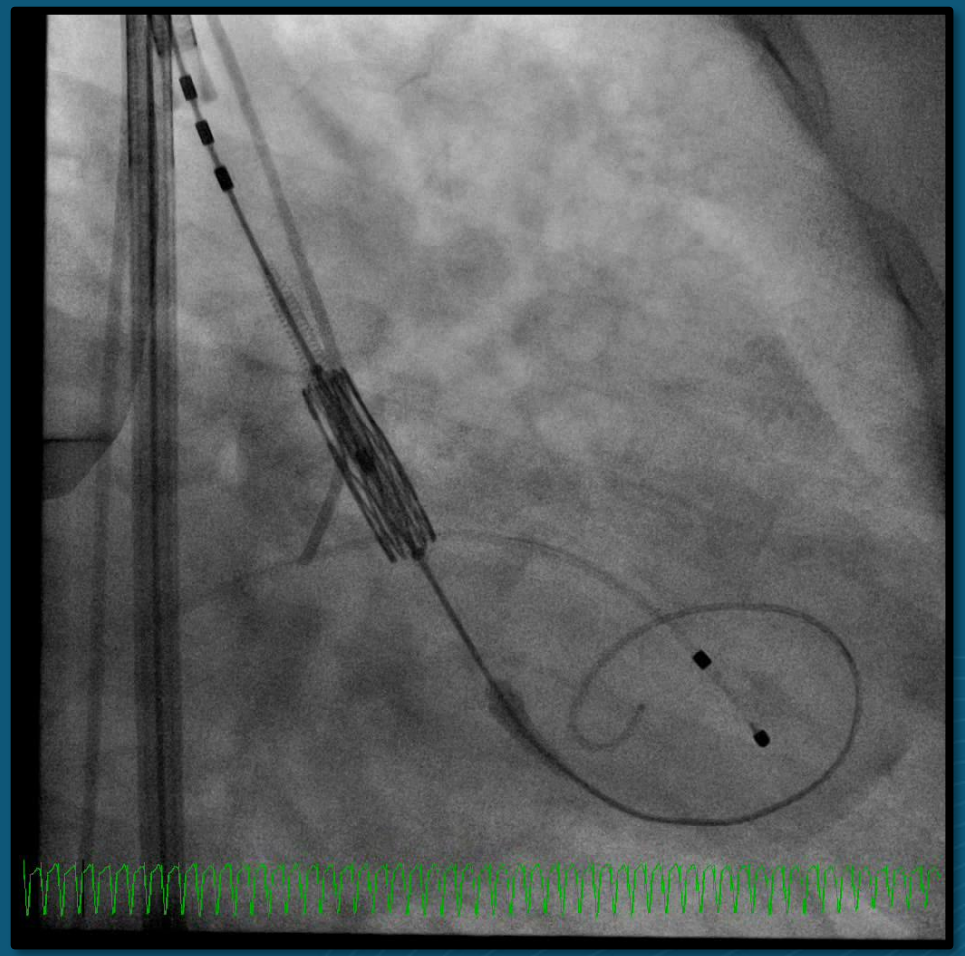
Avg Depth

3.2 ± 1.9mm

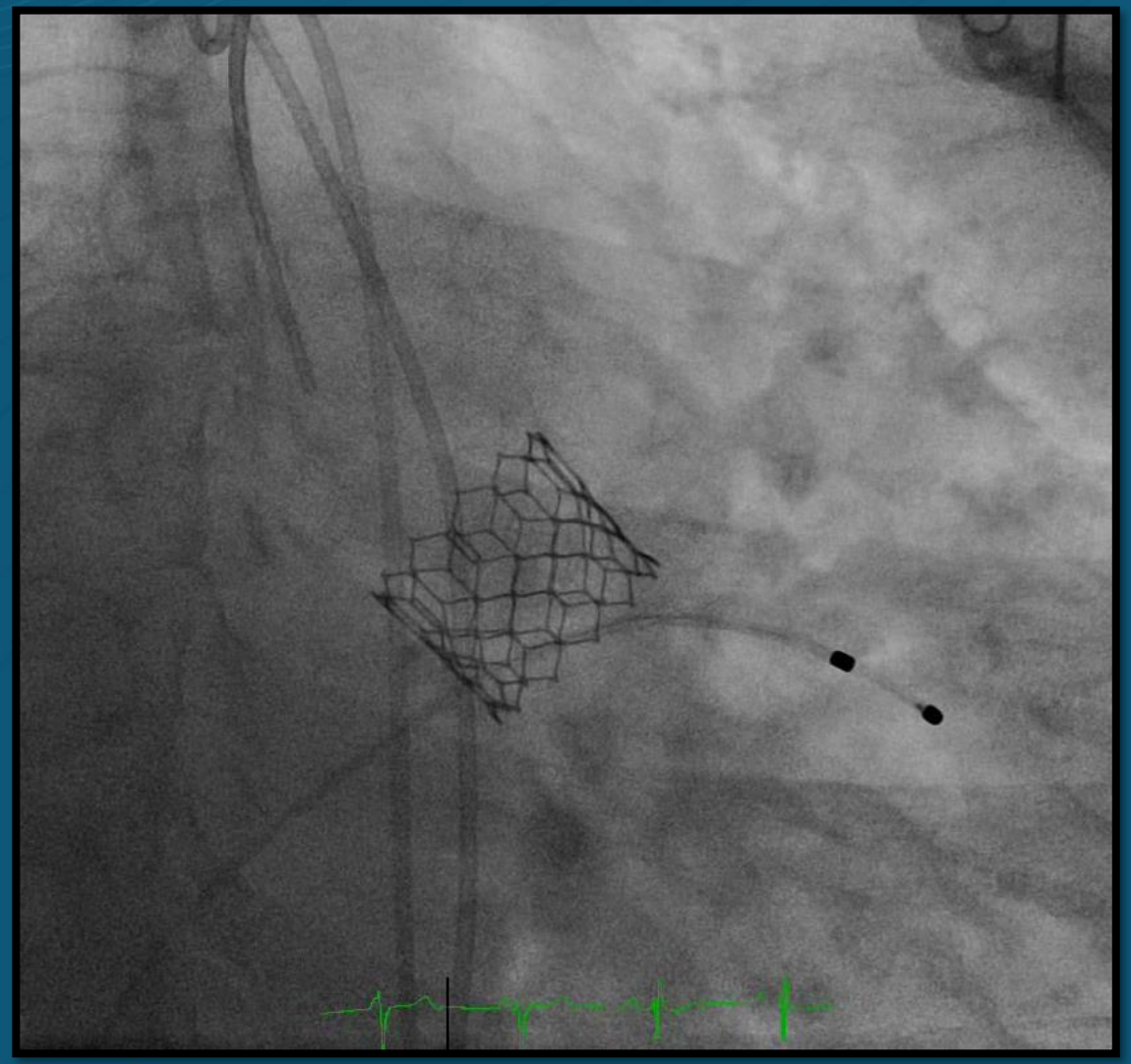
1.5 ± 1.6mm

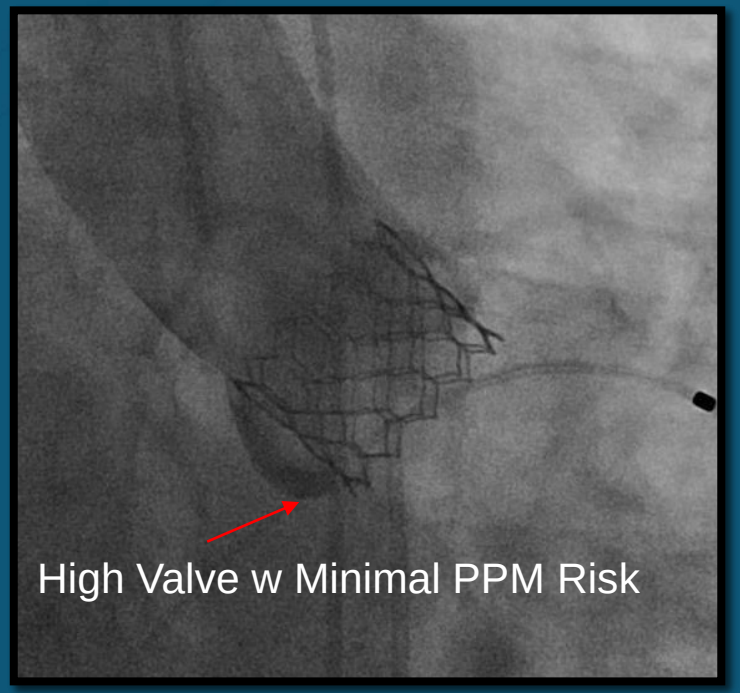
Positioning and Slow/Controlled Valve Deployment

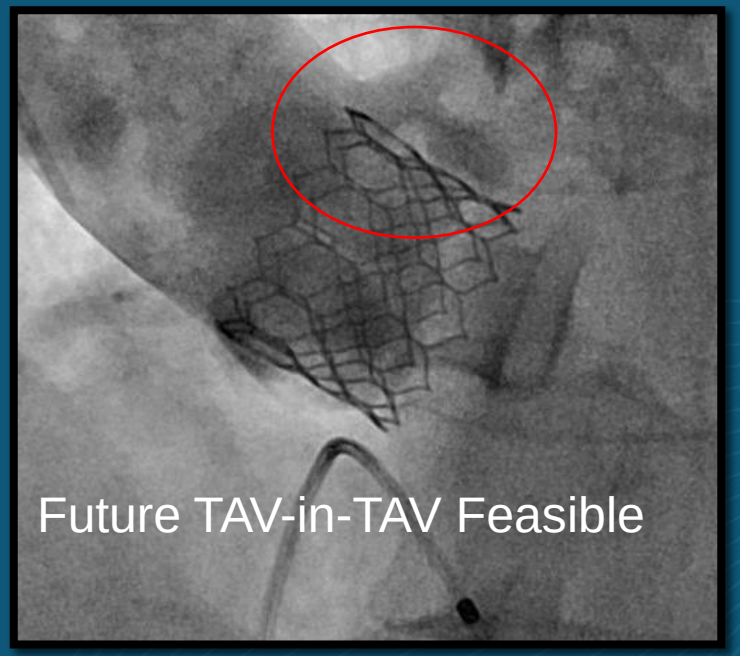




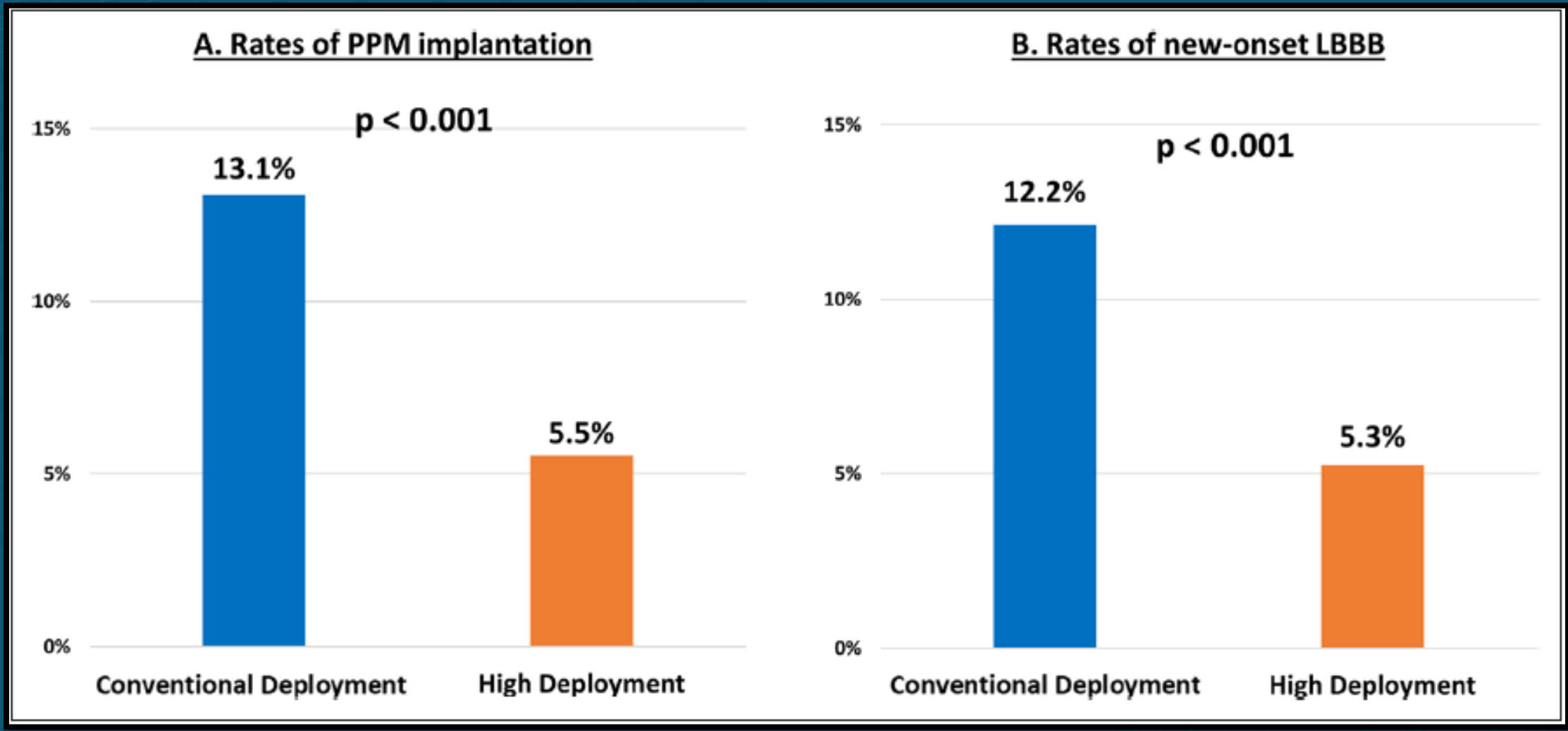
Final Result: Valve at 100:0







Substantial Reduction in Pacemaker Implantation and LBBB



Sammour Y, Krishnaswamy A, Kapadia SR et al Circ CV Int 2021

Summary

TAVR with SAPIEN Ultra: Procedural Tips and Tricks

- Comprehensive screening by the ‘heart team’ before TAVR is important for the prevention and management of TAVR-related complications.
- Structural heart procedures require skills in coronary and peripheral interventions.
- A proper balance between degree of PVL vs. potentially fatal annular injury in the implant strategy, especially in TAVR for severely calcified AV.
- Procedural safety: Pre-expect and Should know “When to Say No”.