

Dallas
CARDIOVASCULAR
INNOVATIONS 2015



Hemodynamic Support: *physiology & application*

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Disclosures

- Consultant honoraria: Medtronic, Merck
- Research grants: Boston Scientific, InfraRedex
- Ownership: Mdcare Global, HygeiaTel

Hemodynamic Support: Topics

- Why and when do we need hemodynamic support?
- Percutaneous hemodynamic support devices during PCI
- Clinical evidence & recommendations for use of hemodynamic support devices
- Interactive Q&A

Q&A

- **Please send a text message
'dallascvi2015' to 37607**
- Upon receipt of a return message you will be enrolled in the mobile audience response system
- Please type in the letter indicative of your response & send your text message

Question 1

- How was tonight's dinner? Please share your experience by selecting one of the following options?
 - A. Just OK
 - B. Good
 - C. Excellent
 - D. Outstanding

Physiology

Myocardial Oxygen Supply and Demand^{a,b}

Myocardial oxygen supply

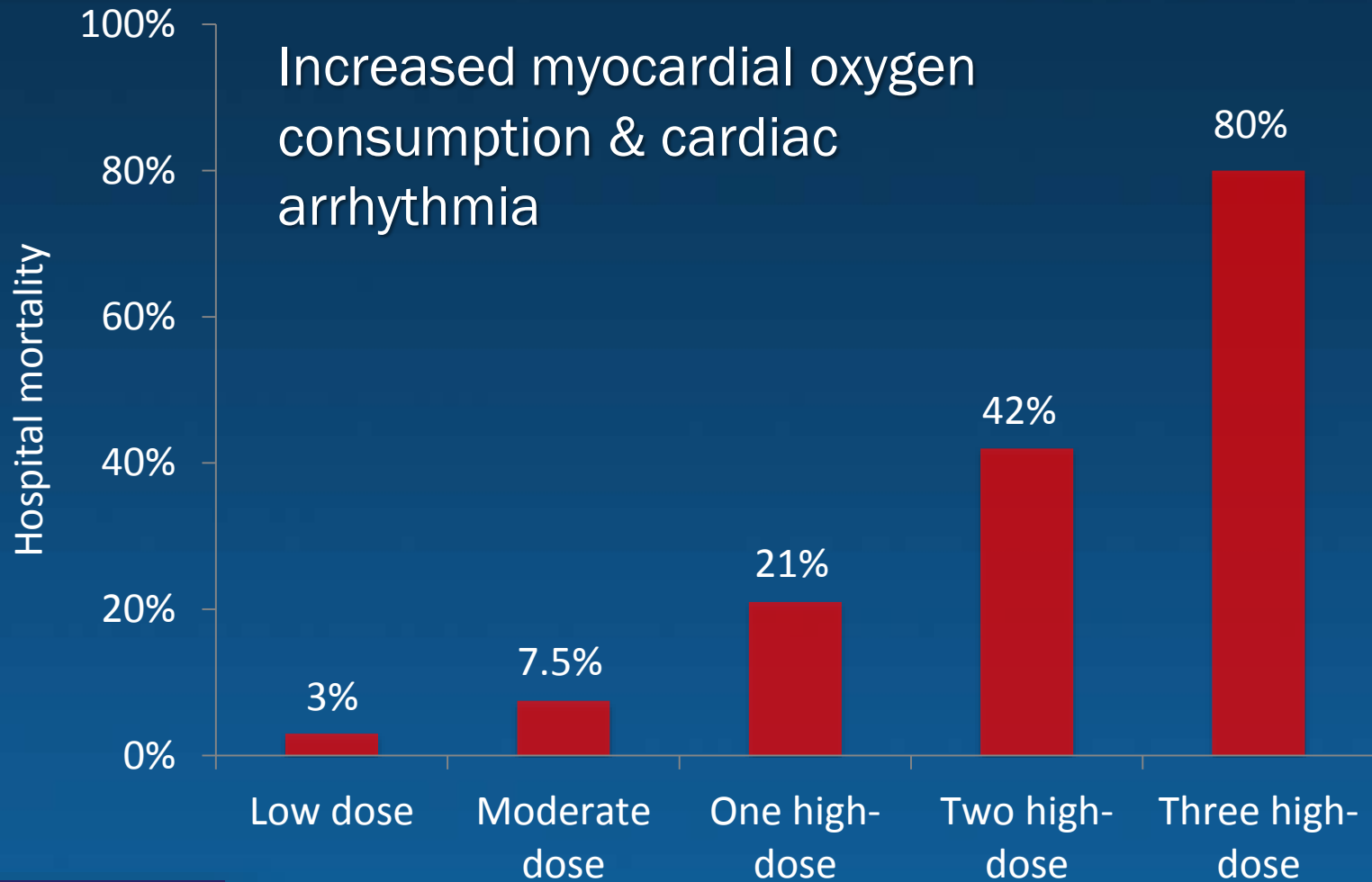
- Normal circulation: blood pressure changes in the aortic root do not affect blood flow/counter pulsation
- Pathologic conditions (eg, cardiogenic shock, post-MI): blood flow is dependent on diastolic pressure in the aortic root

Myocardial oxygen demand

- Heart rate, stroke volume
→ cardiac output
- Wall stress
 - Pressure inside the ventricle
 - Ventricular volume
 - Laplace's law^c

$$\text{Wall Stress} = \frac{(\text{Pressure} \times \text{Radius})}{(2 \times \text{Wall Thickness})}$$

Inotropes and Mortality



Percutaneous Cardiac Assist Devices

TandemHeart

B.



CFP-continuous flow pump

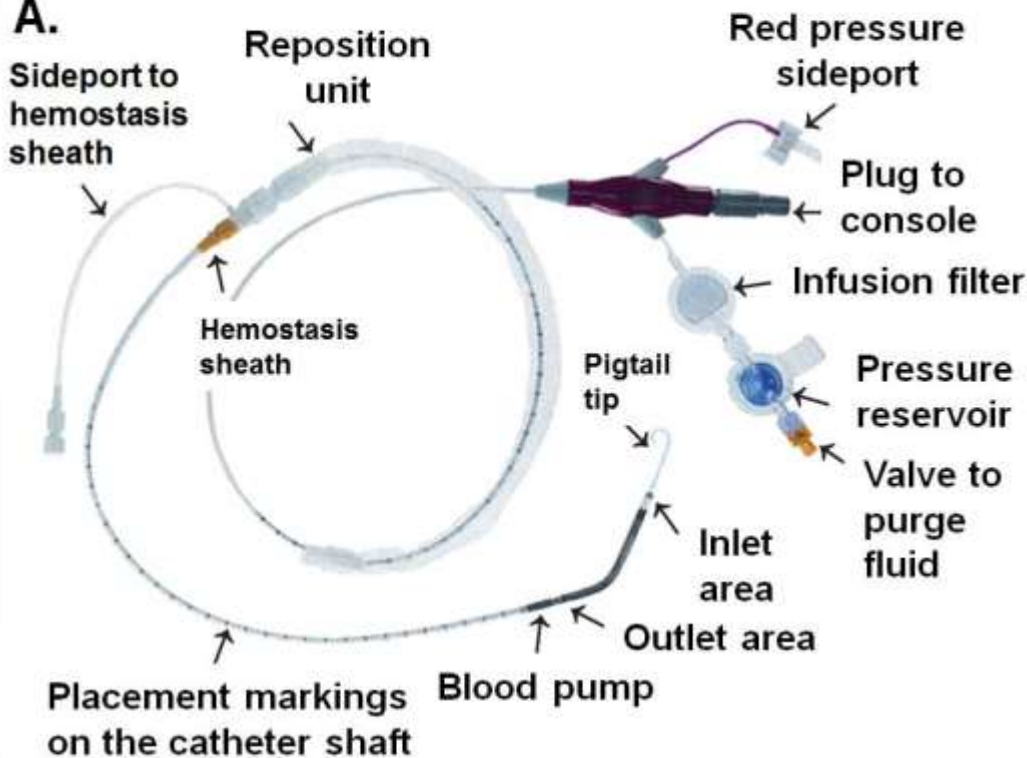
C.



Intra-aortic balloon pump

IABP

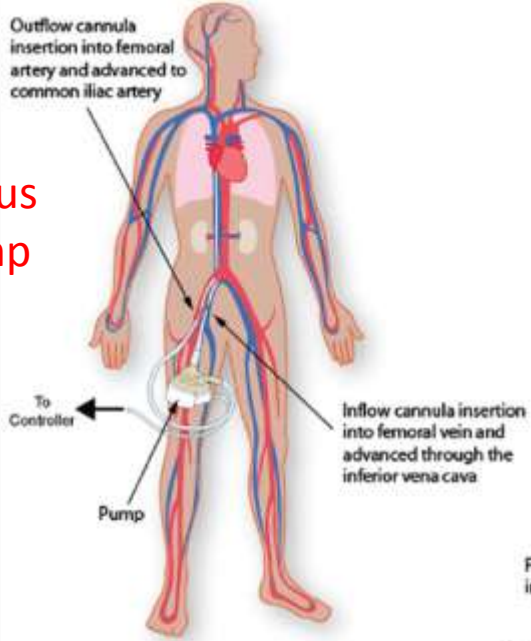
A.



Axial flow pump fitted onto a pigtail catheter

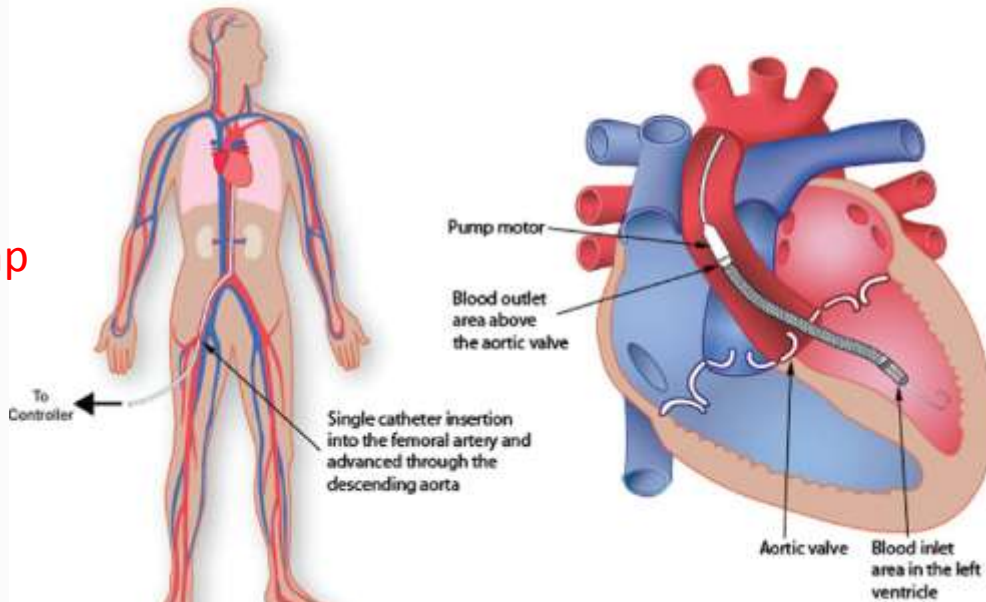
Impella

Continuous flow pump



TandemHeart PVAD

Axial flow pump



Impella Recover 2.5 PVAD

IABP Pressure displacement



Goals of Hemodynamic Support During High-Risk PCI

- Stabilizing systemic perfusion
- Balancing myocardial perfusion against demand and supply
- Augmenting perfusion
- Creating a window to perform complete revascularization, if appropriate

Assist Treatments

Effect on Myocardial Oxygen Demand

Inotropes and vasopressors^a
(eg, dobutamine, digoxin,
vasopressin)

- Increase myocardial oxygen demand
- Increase cardiac workload; potential trigger for arrhythmia
 - Heart rate
 - Contractile function
- Increase mean arterial pressure
- Few benefits, increase in morbidity and mortality

Hemodynamic Target

- Adequate perfusion: cardiac output (CO) & mean arterial pressure (MAP)
- Cardiac power output (CPO) measured in watts, has been elucidated:
 - MAP X CO (watts)
451
 - CO is necessary, but not sufficient for end-organ perfusion; adequate MAP also required

Indications for Cath Lab Hemodynamic Support

Cath Lab hemodynamic support

Elective high-risk PCI

- Impaired LV function
- PCI to a single last patent conduit
- PCI of vessel(s) supplying a large myocardial territory
- Recent high-risk ACS

PCI in Cardiogenic shock

- Heterogeneous
- Non-atherosclerotic CAD
- Underlying LV impairment, scar, valvular disease or dysrhythmia

Question 2

- Which one of the following is a primary goal of hemodynamic support during high-risk PCI?
 - A. Increasing myocardial oxygen supply and demand
 - B. Decreasing myocardial oxygen supply and demand
 - C. Balancing myocardial perfusion against oxygen demand and supply
 - D. Ensuring complete revascularization during stent placement

Question 2

- Which one of the following is a primary goal of hemodynamic support during high-risk PCI?
 - A. Increasing myocardial oxygen supply and demand
 - B. Decreasing myocardial oxygen supply and demand
 - C. **Balancing myocardial perfusion against oxygen demand and supply**
 - D. Ensuring complete revascularization during stent placement

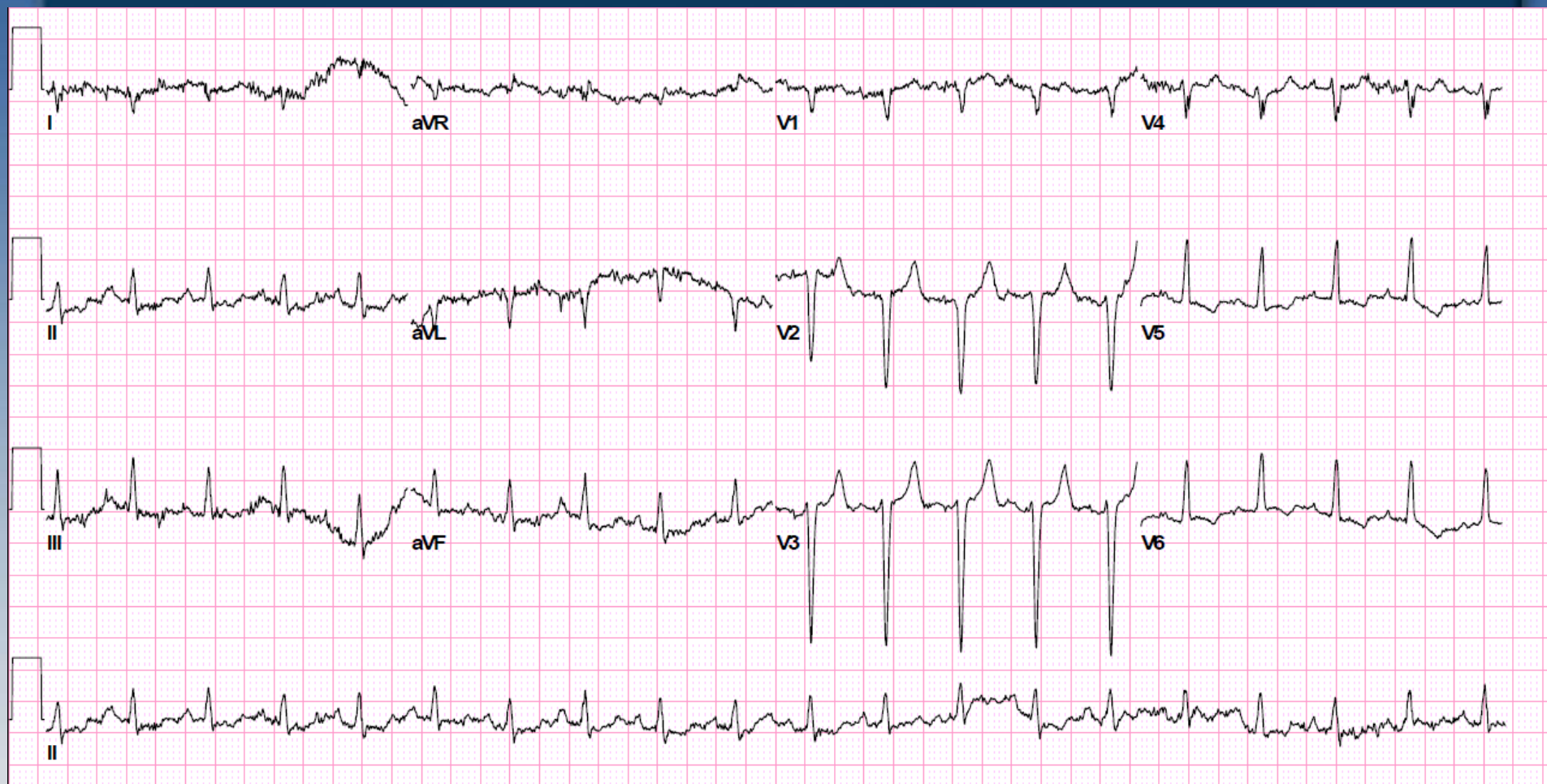
Question 3

- An axial flow pump affects myocardial oxygen demand by:?
 - A. Moving blood from the left ventricle to the aorta
 - B. Moving blood from left atrium into the systemic circulation
 - C. Creating a "pressure sink" in the left ventricle
 - D. Displacing venous blood into the arterial system

Question 3

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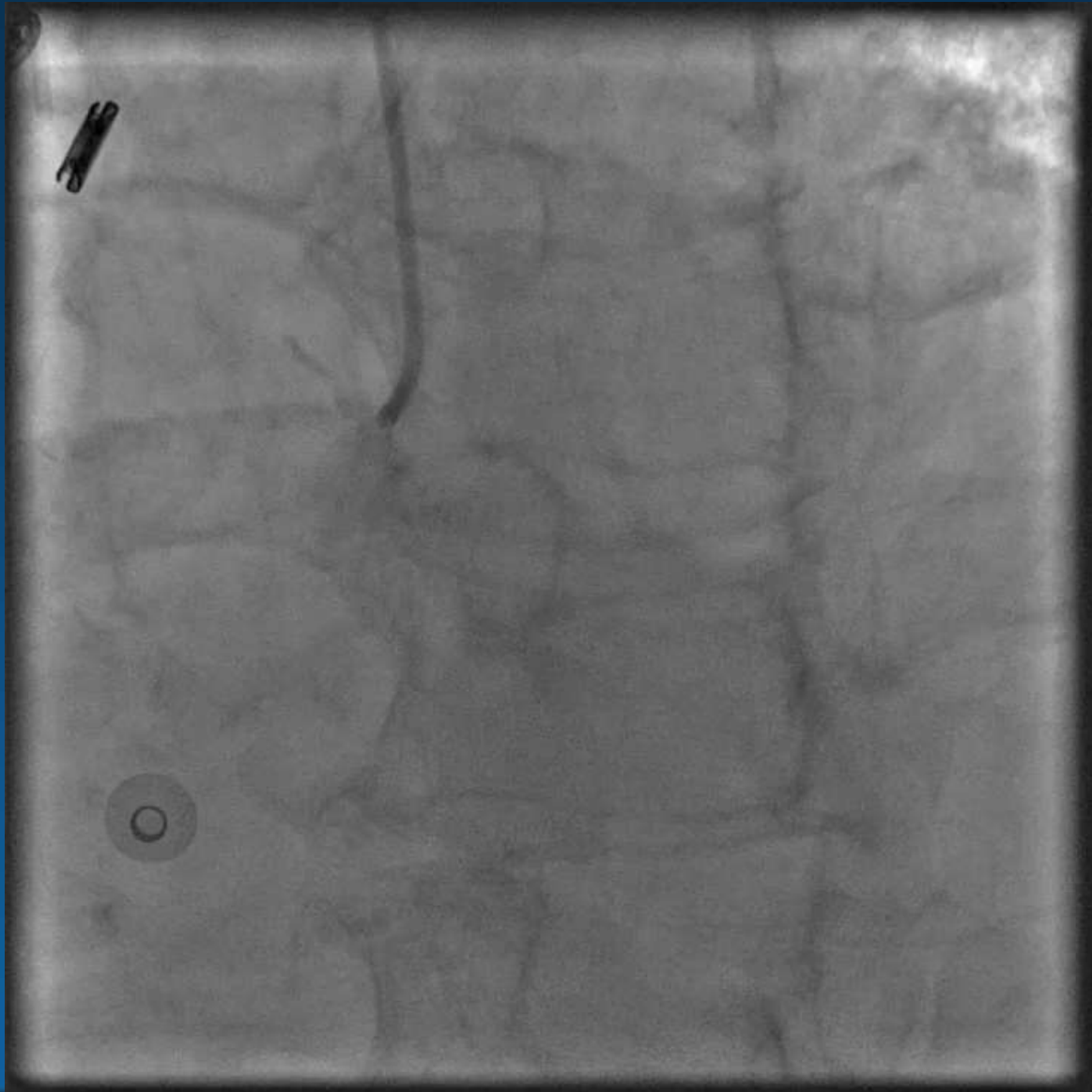
**67 male, DM, smoker, PAD, prior stroke,
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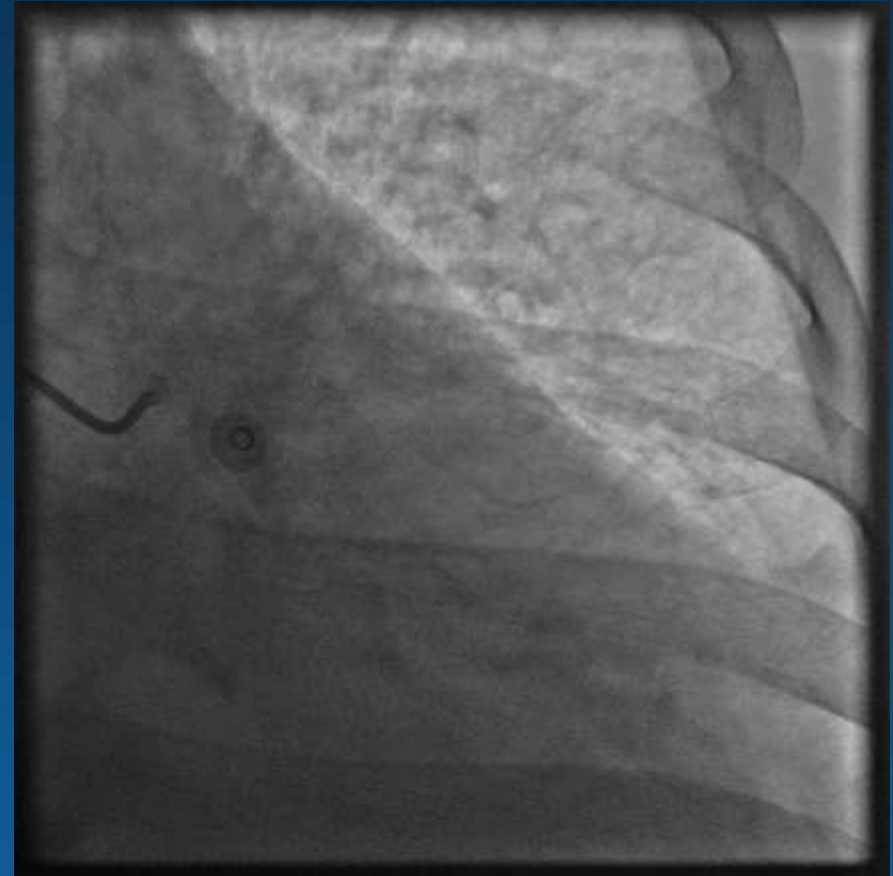
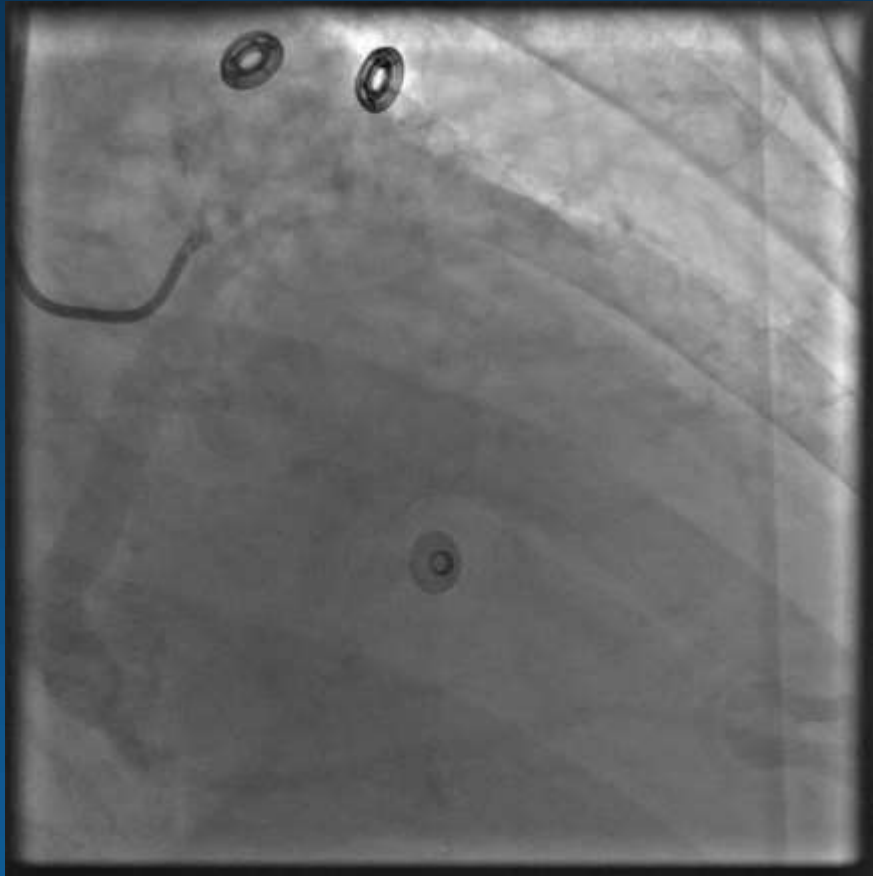
Echocardiogram



RCA Angiogram



Left Coronary Angiogram



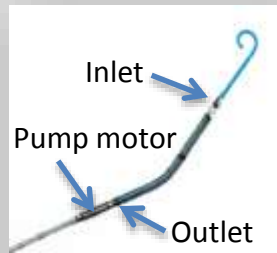
Question 4

Which of the following revascularization strategies would you recommend? Choose one of the following:

- A. CABG
- B. PCI with IABP support
- C. PCI with Impella 2.5 support
- D. PCI with TandemHeart
- E. PCI with an additional arterial access for IABP, if needed

Impella™ Hemodynamic Support Catheters

Impella 2.5



9F
catheter
2.5 L/min
12F
pump
motor

Impella CP



9F
catheter
2.5 L/min
14F
pump
motor

Impella 5.0



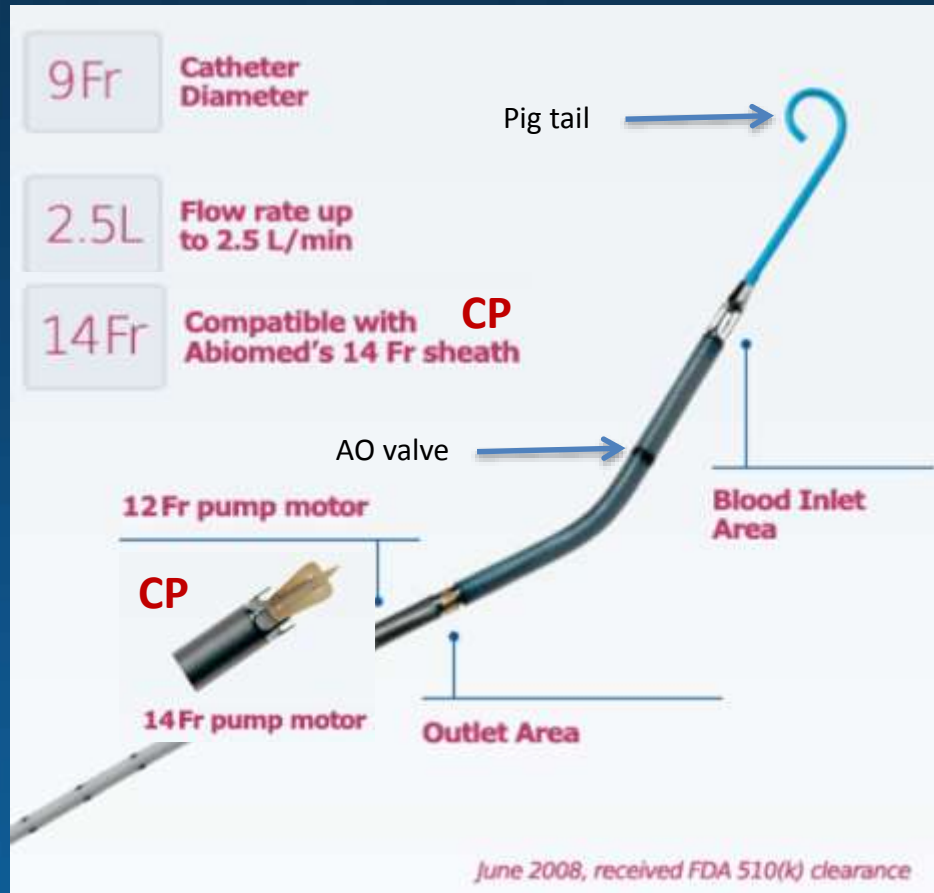
9F
catheter
5.0 L/min
21F
pump
motor

Impella LD



9F
catheter
5.0 L/min
21F
pump
motor

Impella™ 2.5/CP



Migration of Impella CP catheter

- The Impella 2.5 catheter is an intravascular microaxial blood pump that delivers up to 2.5 L/min of forward flow blood from the left ventricle (LV) to the aorta (AO)
- Reduces LV end-diastolic volume
- Reduces LV end diastolic pressure
- Increases mean AO pressure & flow



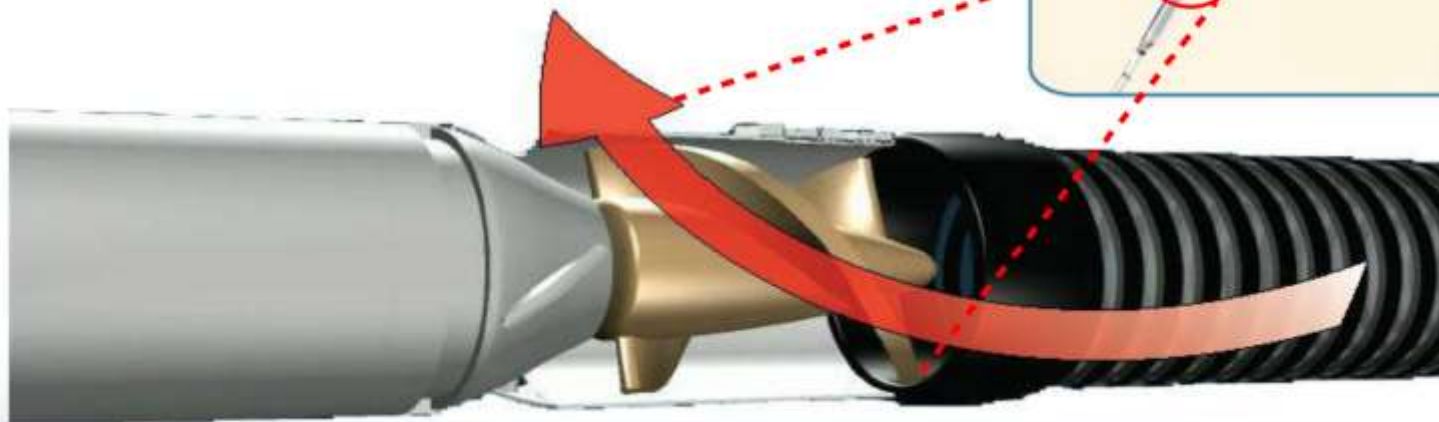
Impella®
World's Smallest Heart Pump

Impella™ Rotating Pump

Moving the Blood

Rotating impeller pulls blood through the cannula

Faster rotation= Higher flow



Motor

Impeller

Cannula

Impella™ Controller



- Interface for monitoring & controlling the Impella catheter & purge system
 - Purge system prevents blood from entering the catheter motor
- Hands-on demonstration



Question 5

When correctly inserted and placed in the LV, Impella catheters reduce? Choose one of the following:

- A. Aortic diastolic pressure
- B. Left ventricular end diastolic volume
- C. Left ventricular end diastolic pressure
- D. All of the above
- E. Only B and C

Question 5

When correctly inserted and placed in the LV, Impella catheters reduce? Choose one of the following:

- A. Aortic diastolic pressure
- B. Left ventricular end diastolic volume
- C. Left ventricular end diastolic pressure
- D. All of the above
- E. Only B and C

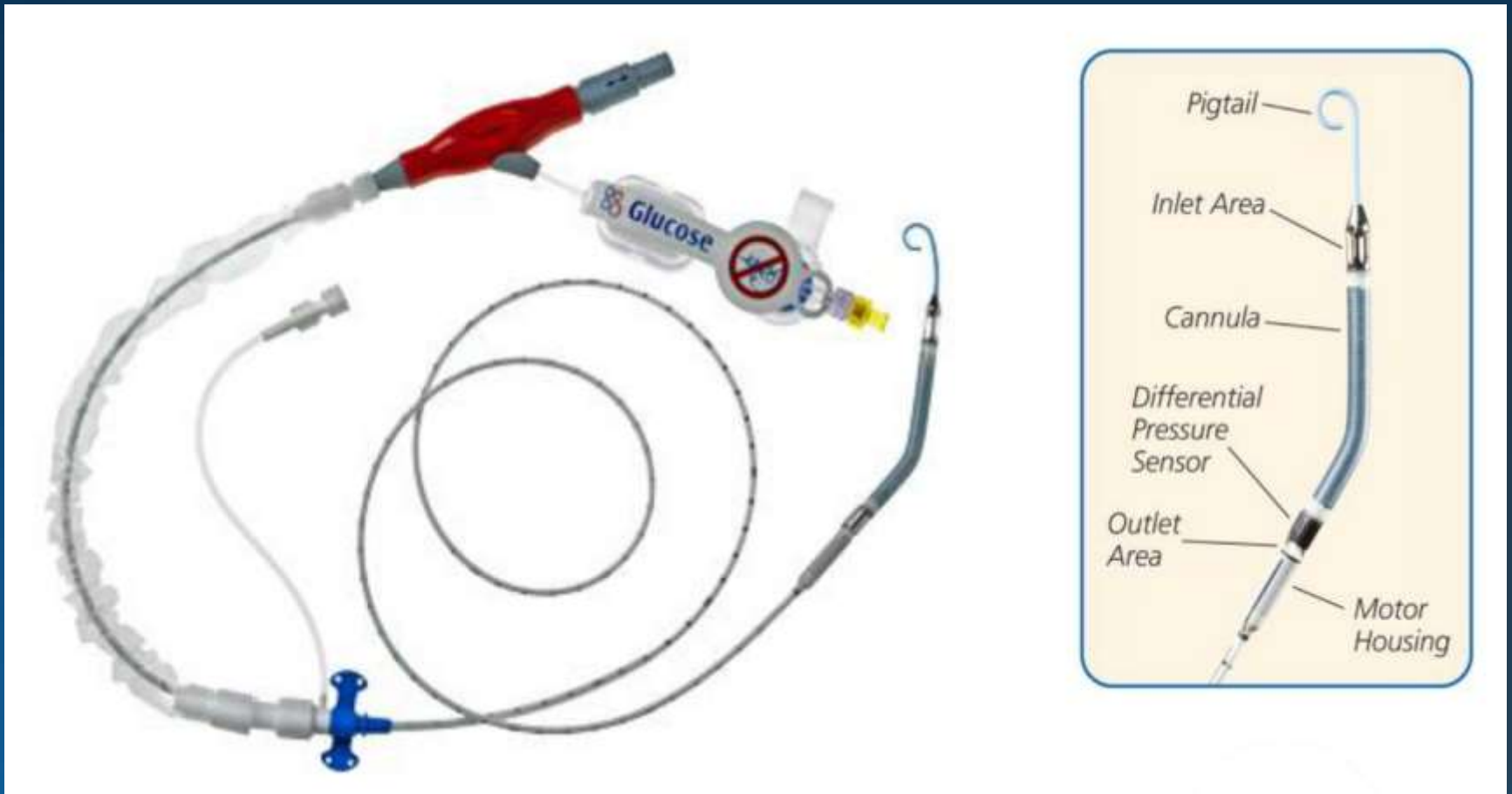
Target Hemodynamics

- Low CVP could precipitate a suction alarm
- Controller may reduce motor speed if a low volume state exists
- Rapid infusion of appropriate crystalloid or colloid solution may resolve the alarm
- Is Swan in place: $SG\ CO = Impella\ flow + LV\ ejection$
- Native LV will be in competition for volume with Impella & will normally be reduced (unloaded)

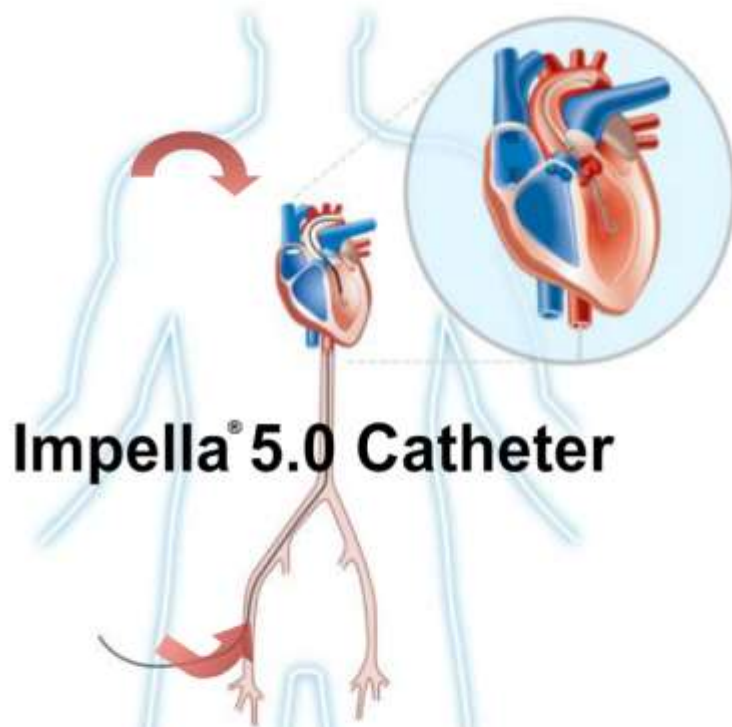
Impella Management

- Identify controller alarms
- Echocardiography to assess positioning in addition to controller placement indicators
- Purge pressure & flow alarms
- CPR
- Removal & access site management
- Hemolysis, HIT, vascular complications

Impella™ 5.0

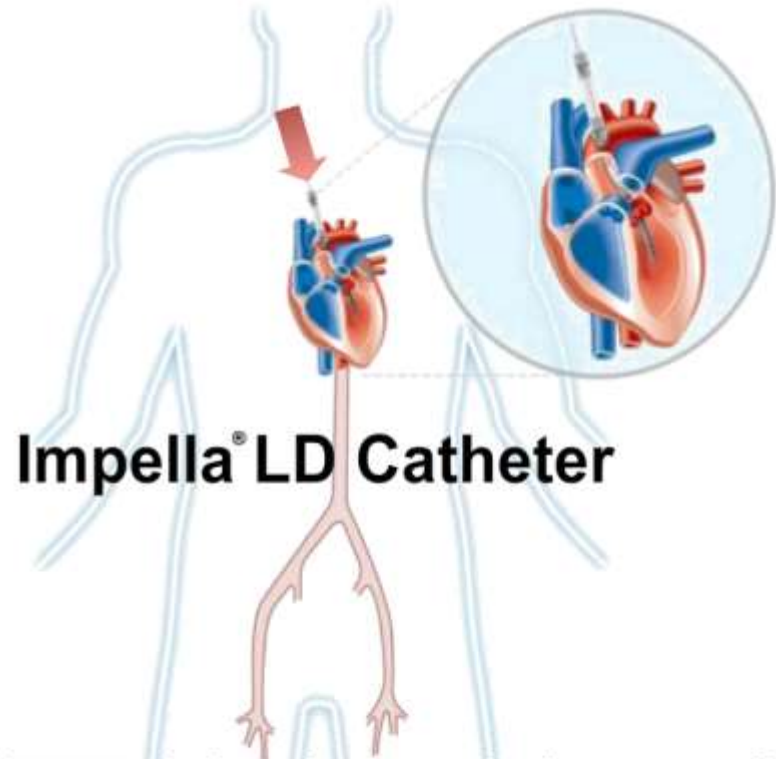


Impella™ 5.0 and LD Technology



Impella® 5.0 Catheter

Inserted through the femoral or axillary artery into the left ventricle



Impella® LD Catheter

Inserted directly through the ascending aorta into the left ventricle

Question 6

Which one of the Impella catheters is correctly matched with its insertion description? Choose one of the following:

- A. Impella 2.5 – percutaneous femoral artery
- B. Impella 2.5 – only surgical cut down of femoral or axillary artery
- C. Impella 5.0 – direct aortic insertion
- D. Impella LD catheter – exclusively via femoral artery cut down

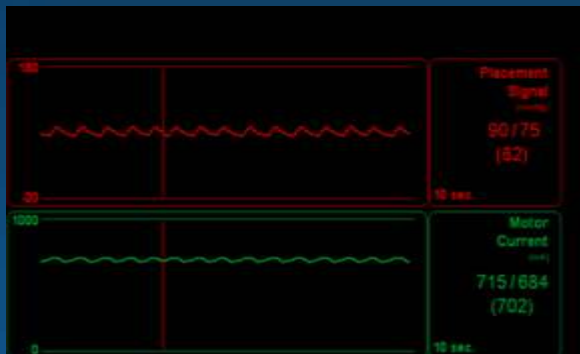
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- D. Impella LD catheter – exclusively via femoral artery cut down

Question 7

Which one of the Impella controller placement screens indicate that the Impella cannula is too far into the LV?



A



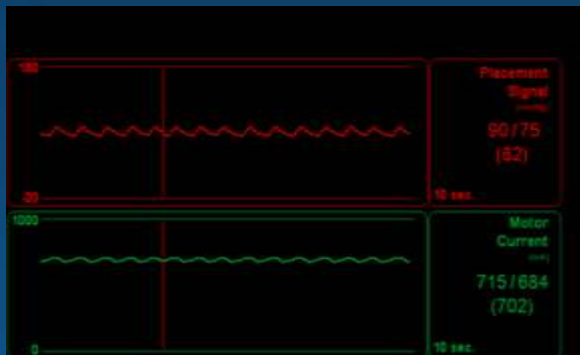
B



C

Question 7

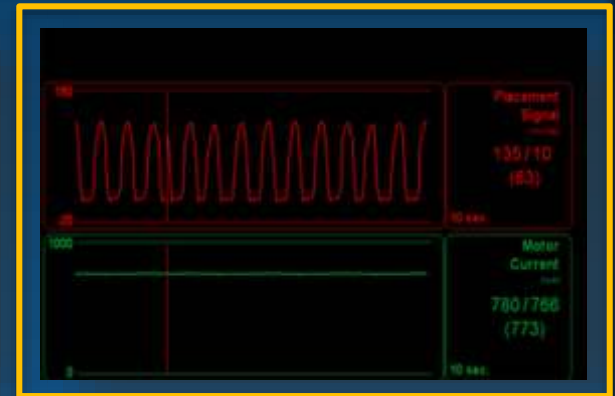
Which one of the Impella controller placement screens indicate that the Impella cannula is too far into the LV?



A



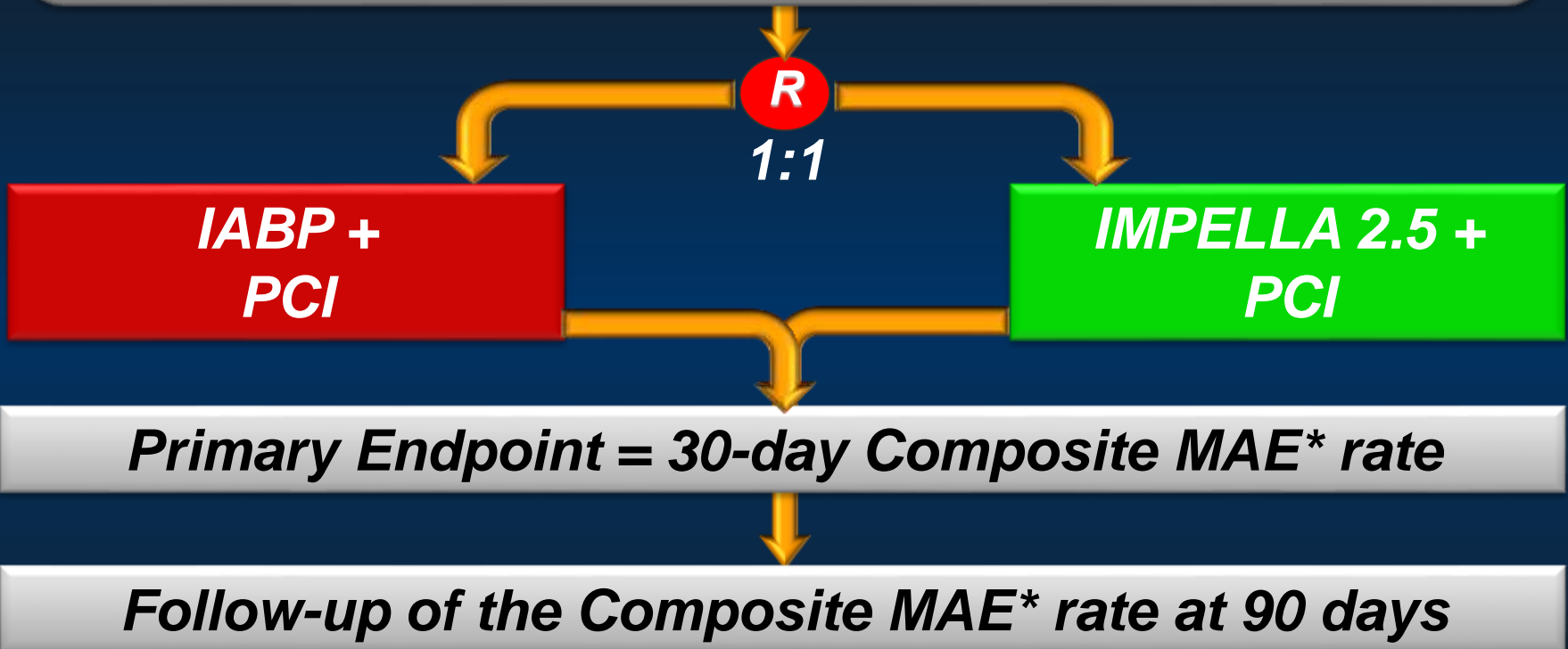
B



C

PROTECT II Trial Design

*Patients Requiring Prophylactic Hemodynamic Support
During Non-Emergent High Risk PCI on
Unprotected LM/Last Patent Conduit and LVEF \leq 35% OR
3 Vessel Disease and LVEF \leq 30%*



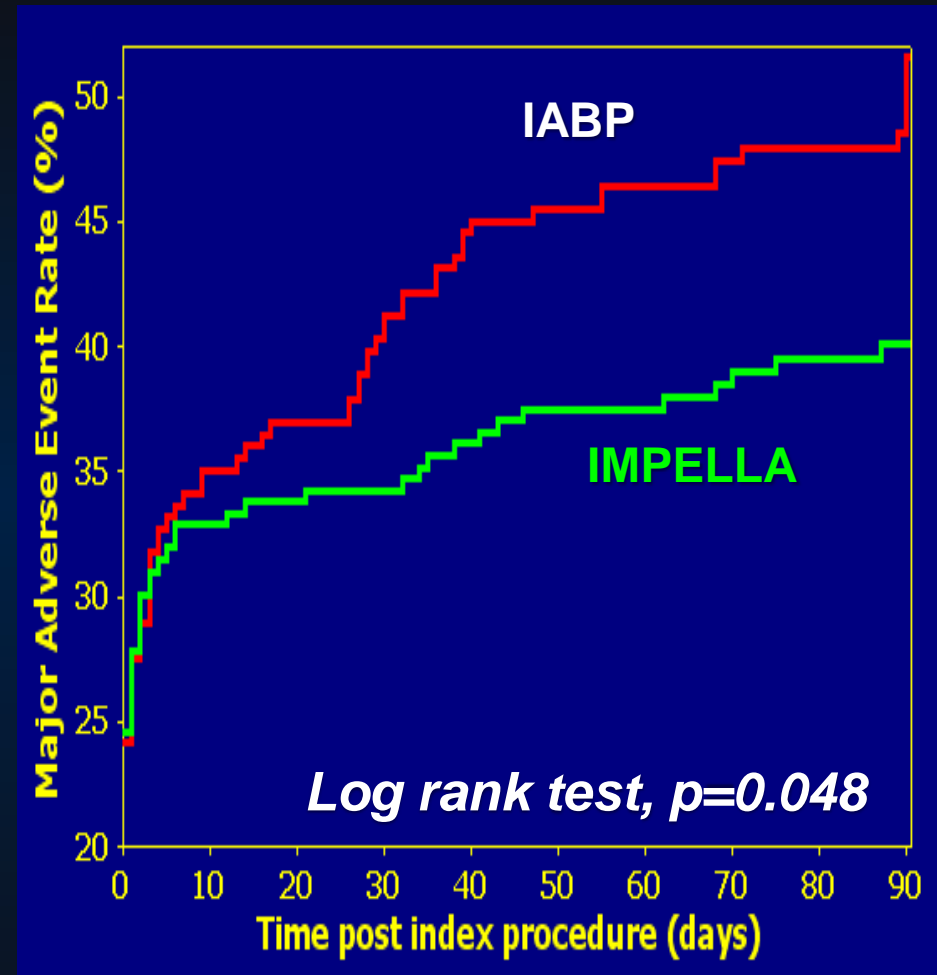
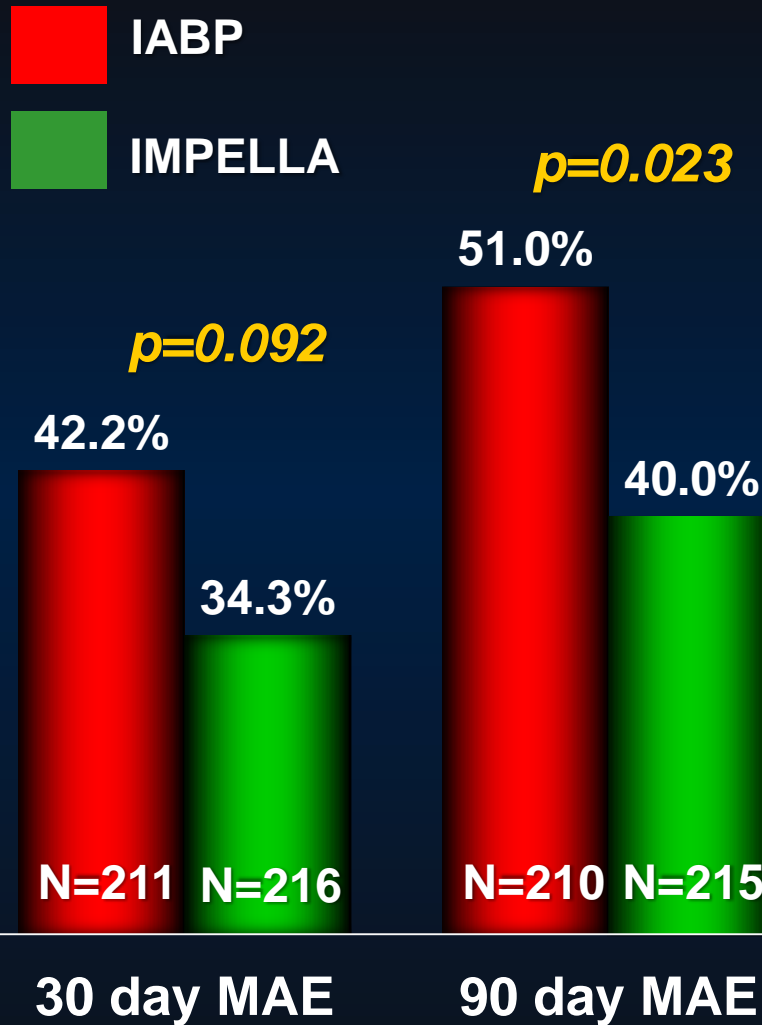
**Major Adverse Events (MAE) :*

Death, MI (>3xULN CK-MB or Troponin) , Stroke/TIA, Repeat Revasc, Cardiac or Vascular Operation or Vasc. Operation for limb ischemia, Acute Renal Dysfunction, Increase in Aortic insufficiency, Severe Hypotension, CPR/VT, Angio Failure

PROTECT II: Results

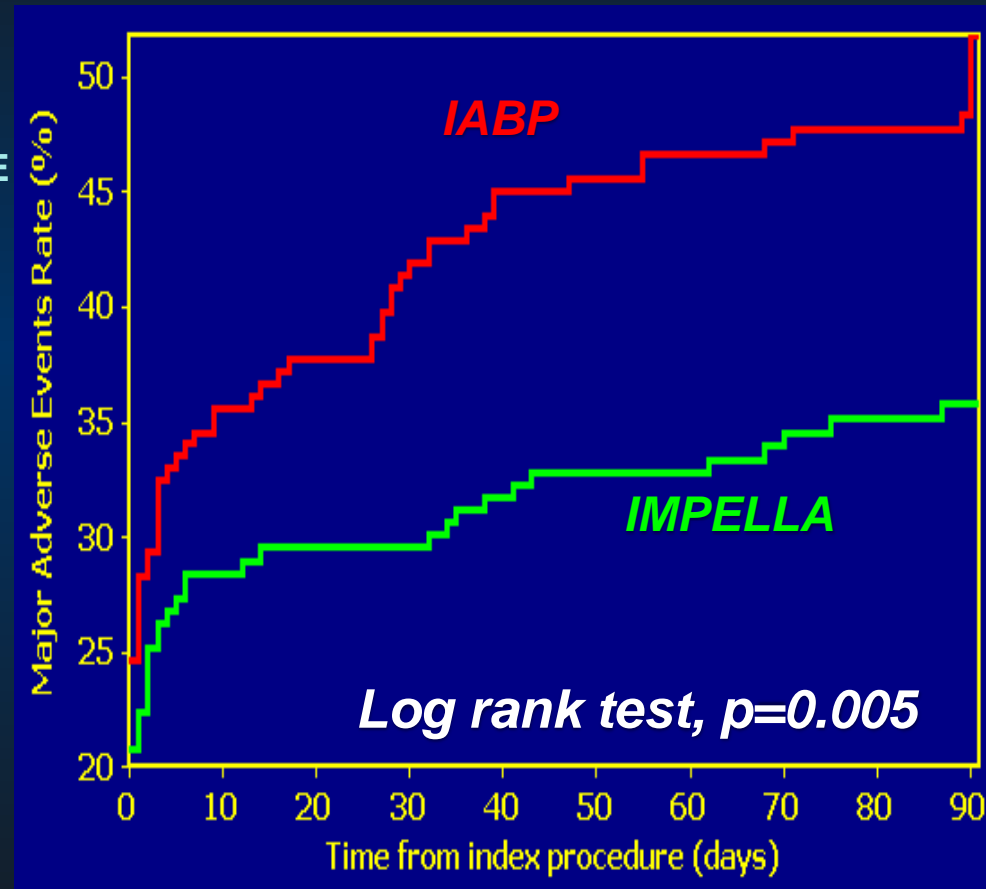
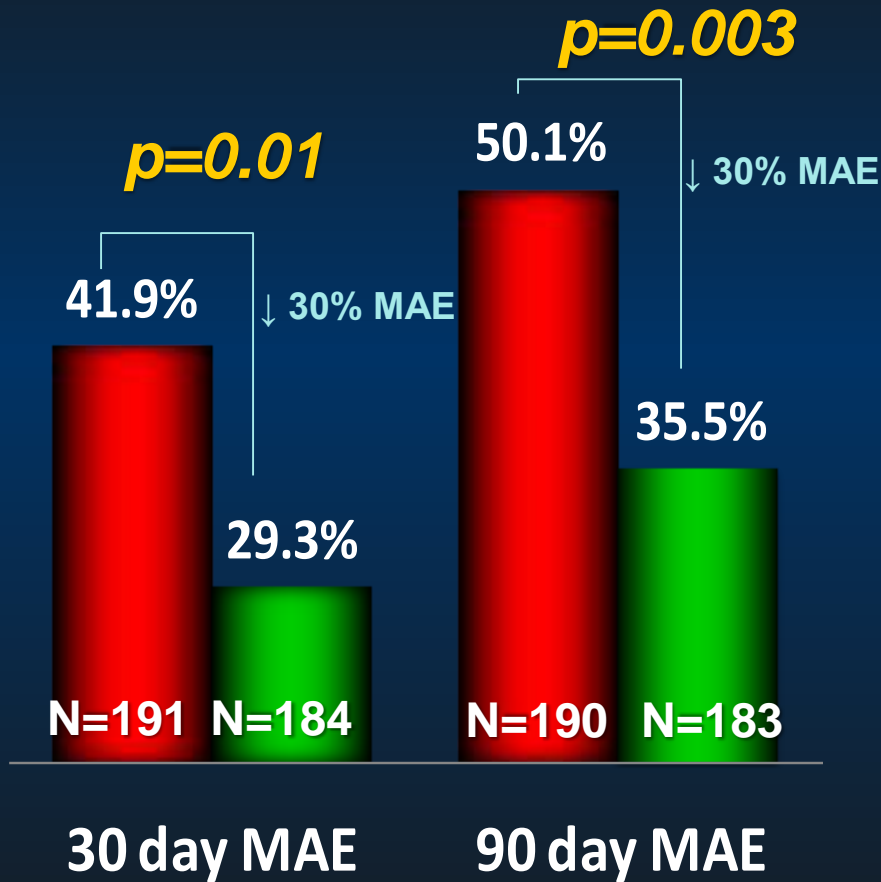
- Final cohort 452 patients
 - 3 withdrew consent (IABP arm)
 - 1 died (Impella 2.5 arm) before PCI
 - Full cohort included all 448 ITT patients randomly assigned to either Impella 2.5 (n=225) or IABP (n=223)
 - Pre-specified PP population: 427 –met eligibility criteria (216 for Impella 2.5 and 211 for IABP).

PROTECT II: Per Protocol MAE (N=427)



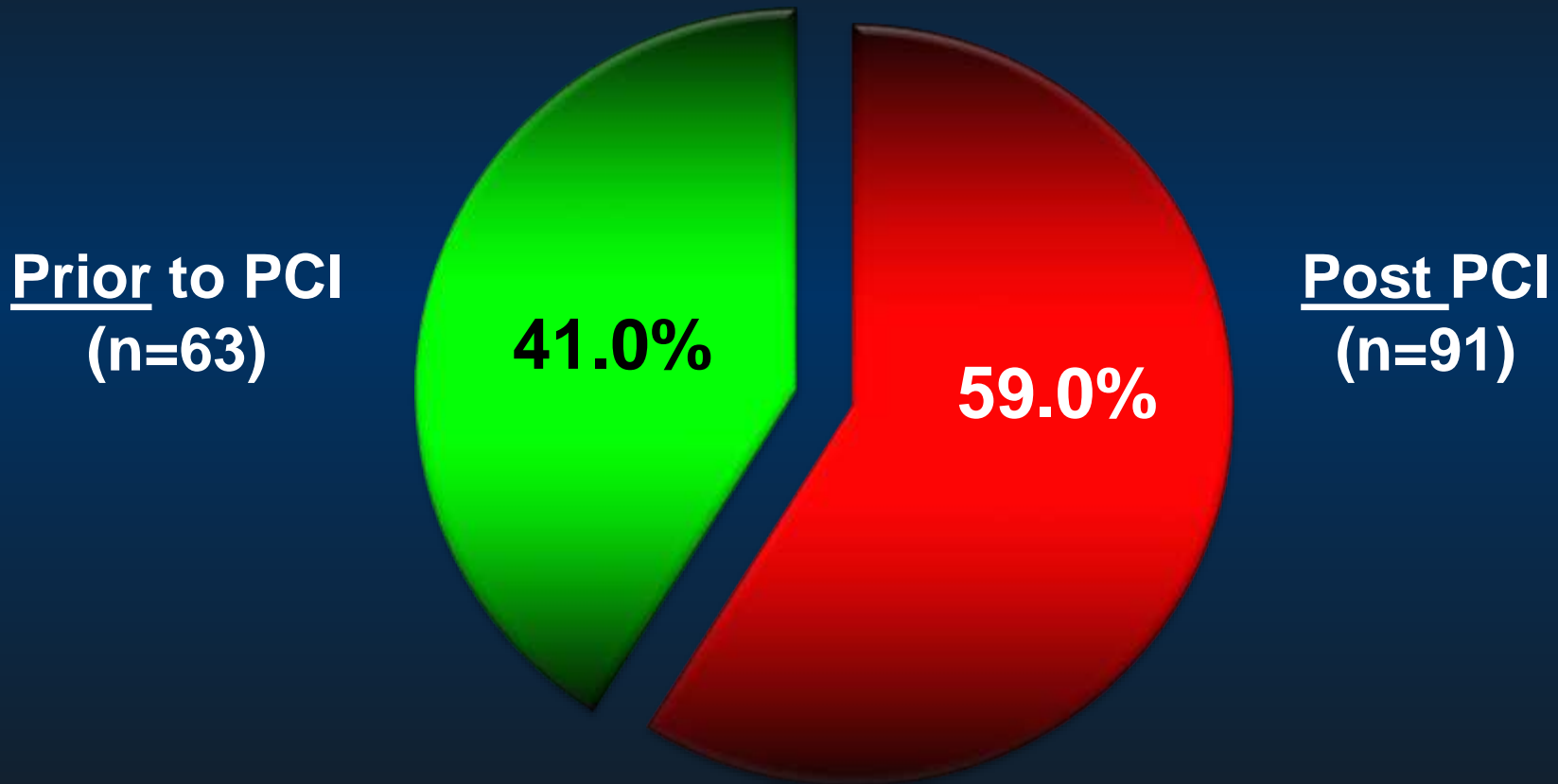
PROTECT II MAE Outcome

Pre-specified High Risk PCI Without Atherectomy Group
Per Protocol (N=374)

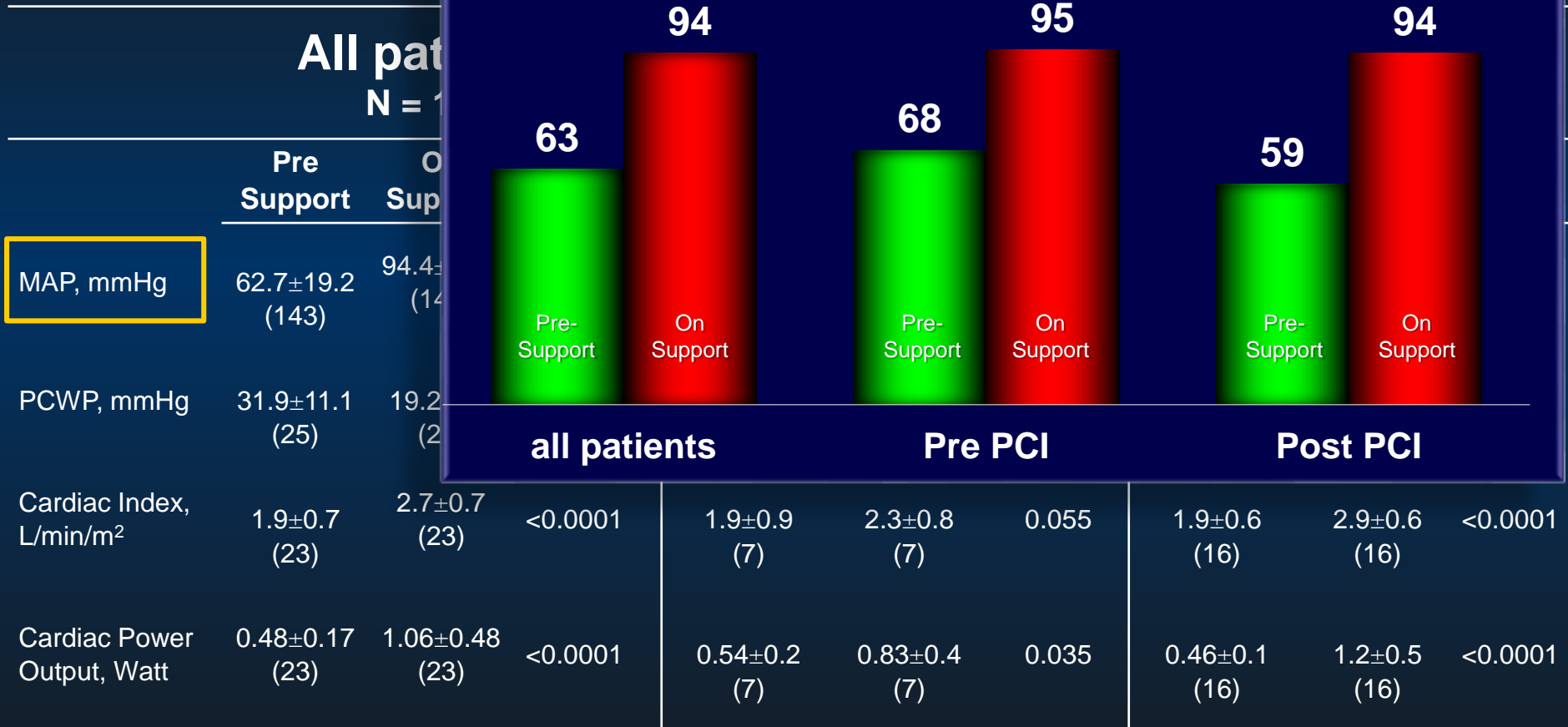


Cohen et al, Catheter Cardiovasc Interv. 2013 (In press)

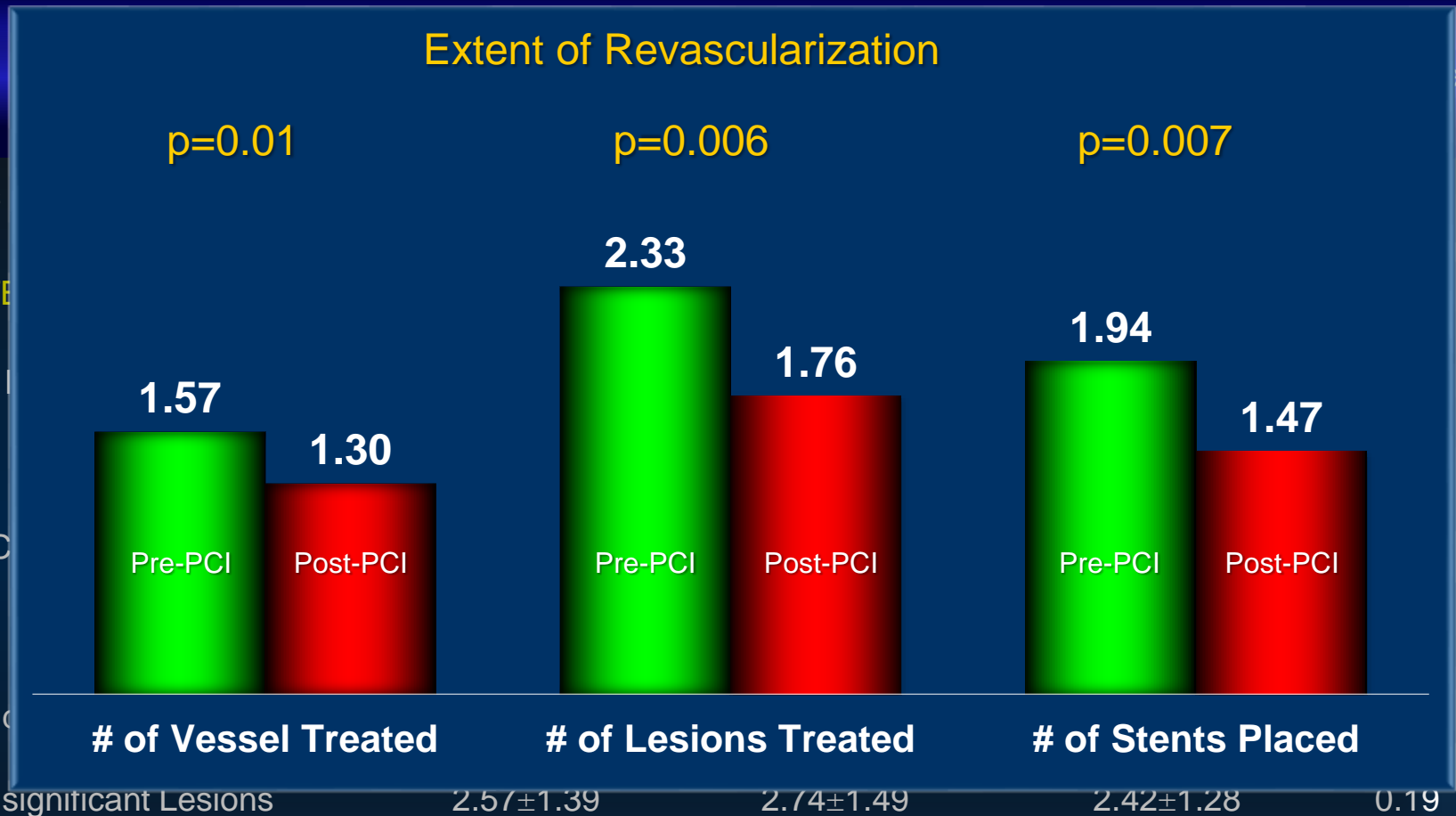
Impella[®] Insertion Timing (N= 154)



Hemodynamics



Procedural Characteristics

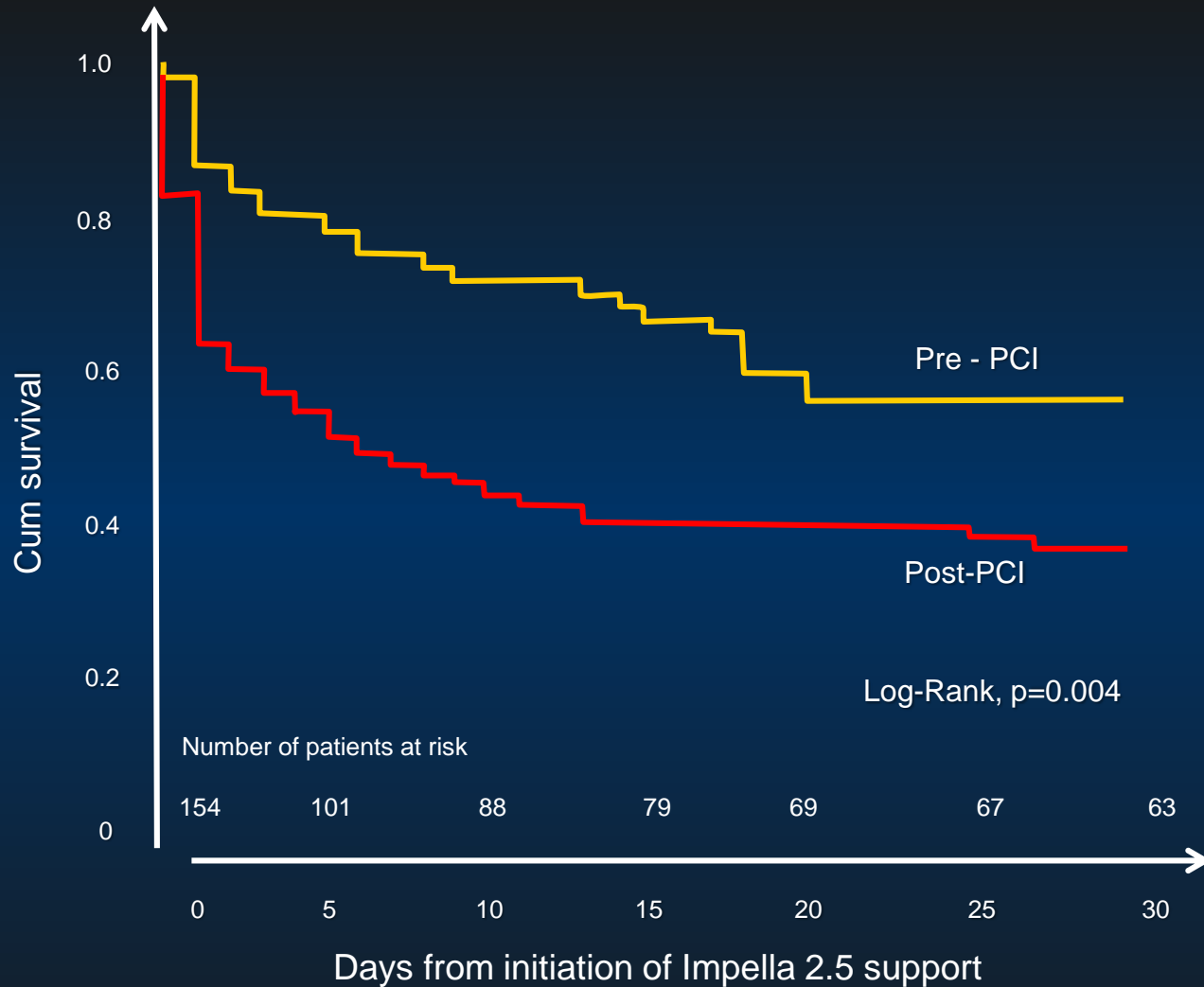


Number of vessel treated	1.42±0.63	1.57±0.67	1.30±0.57	0.01
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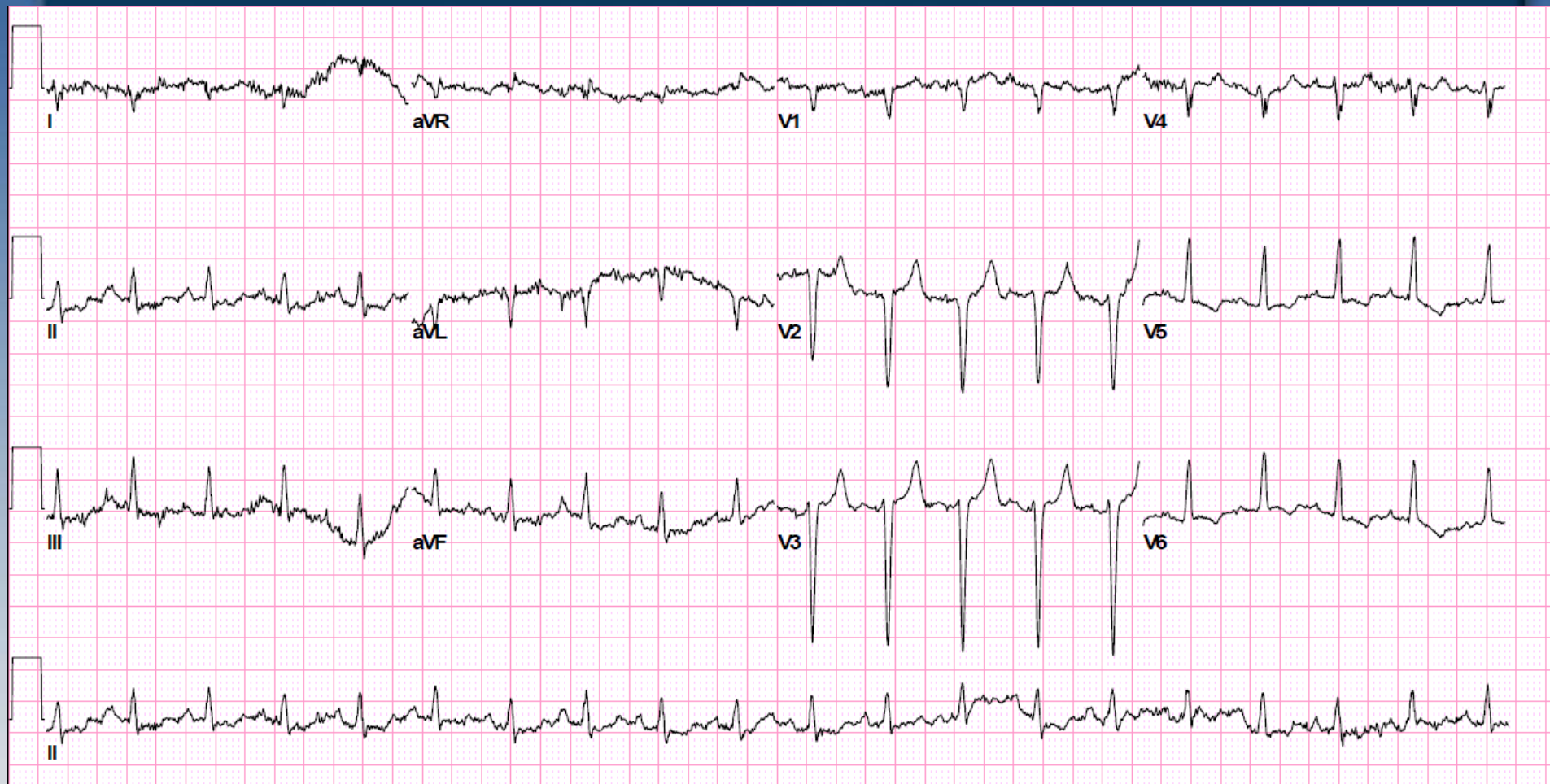
TIMI Flow [0-1] Prior to PCI	80.2%	71.9%	84.8%	0.14
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TIMI Flow [0-1] Post PCI	8.7%	4.6%	11.9%	0.19
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Outcome: Impella Pre or Post PCI



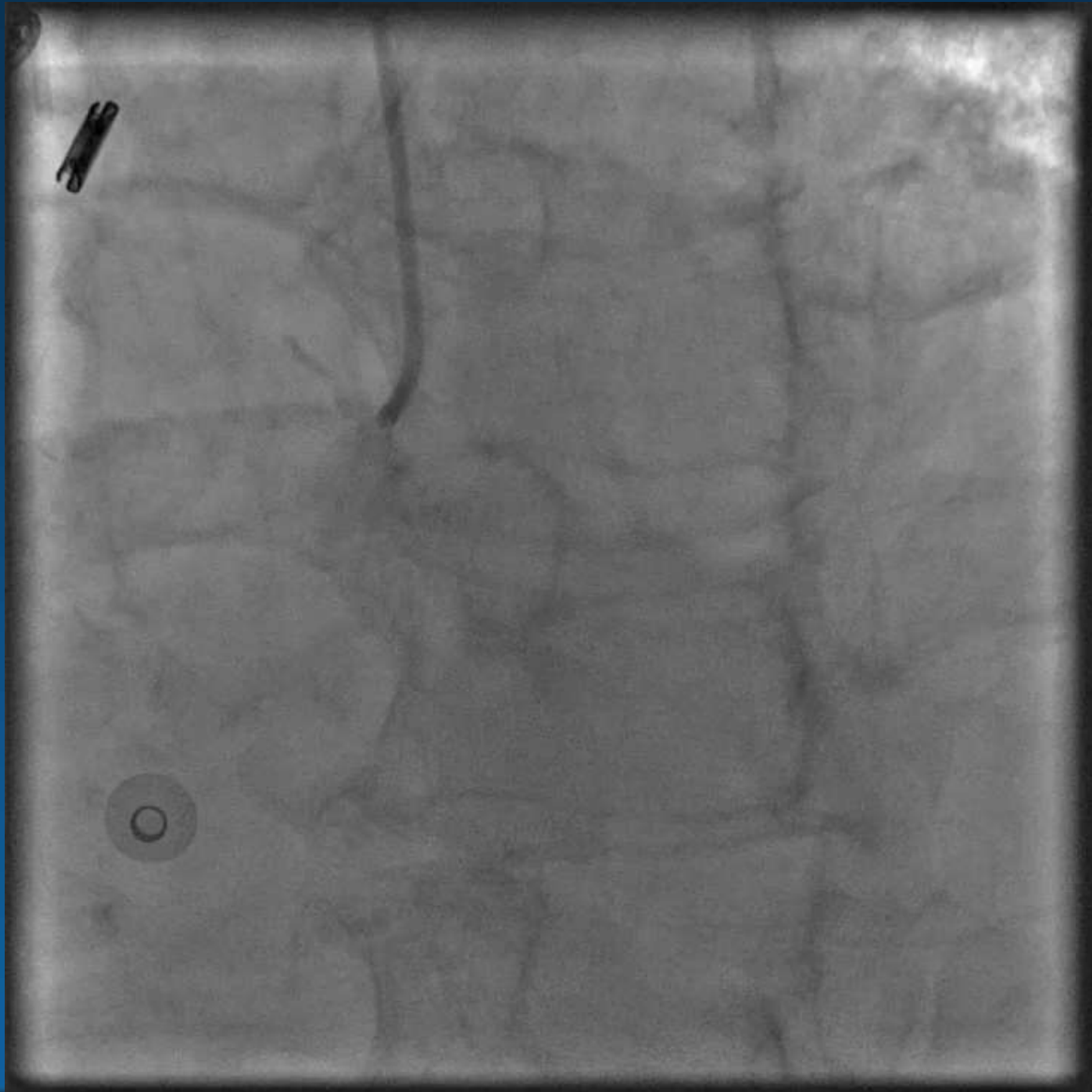
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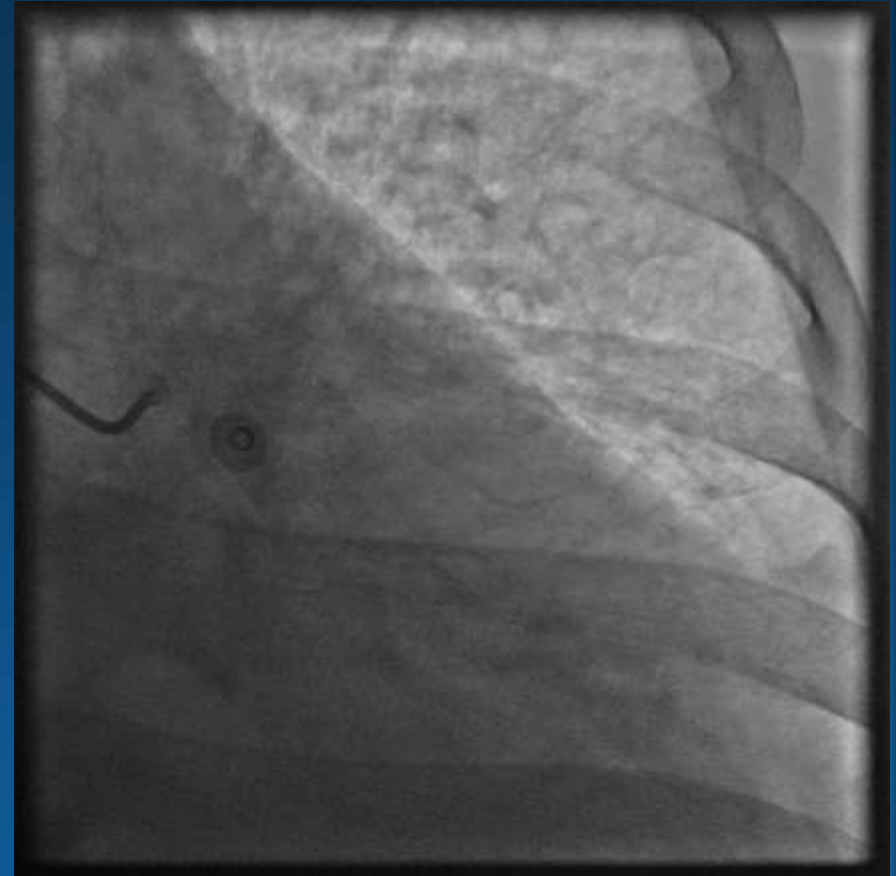
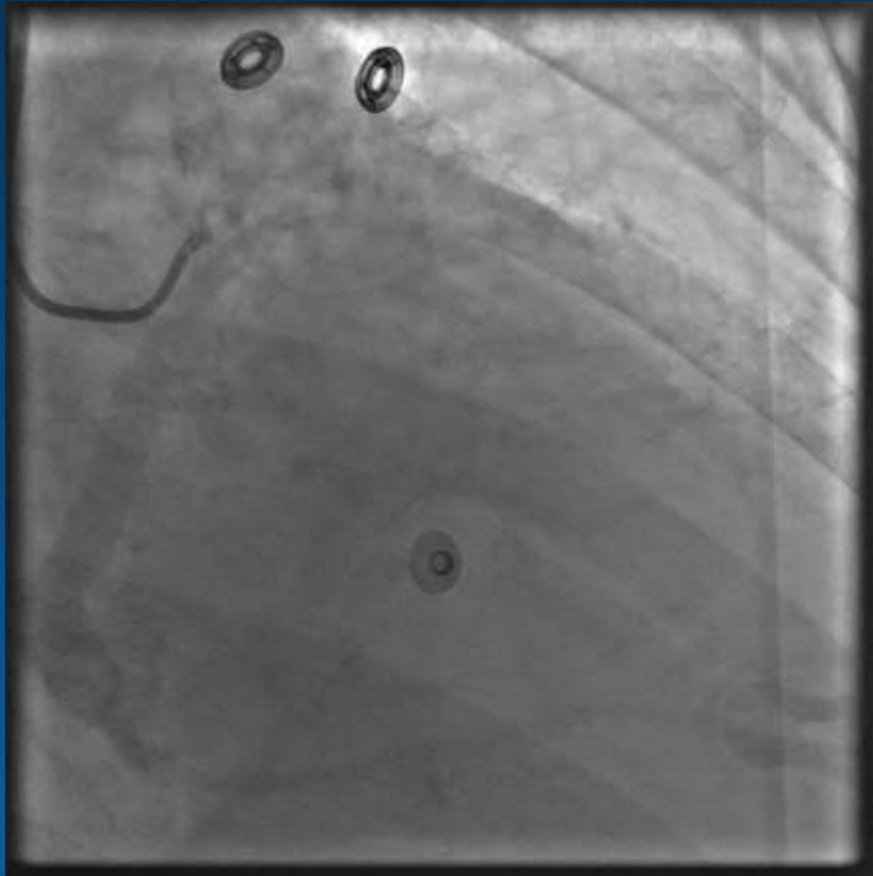
Echocardiogram



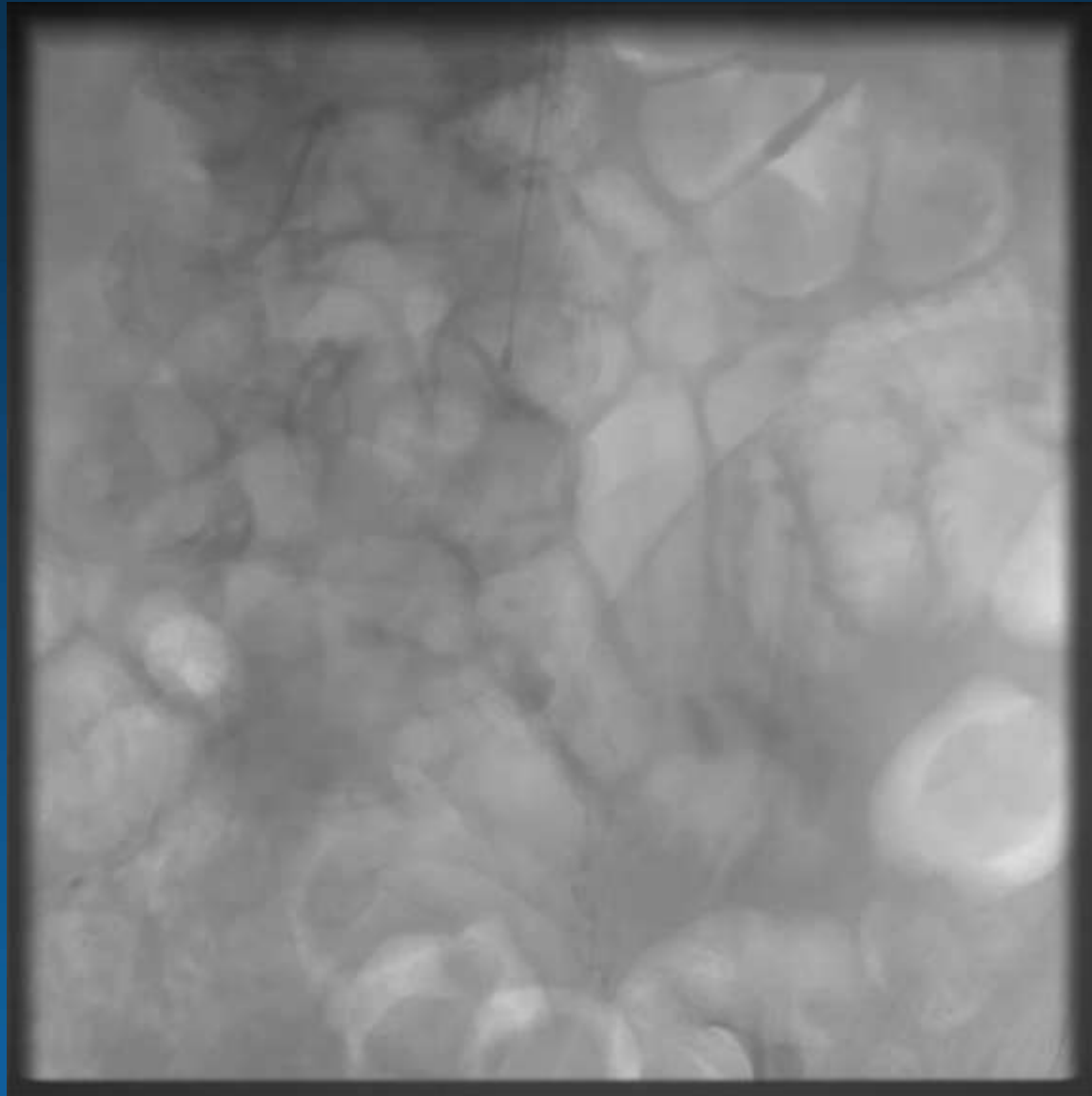
RCA Angiogram



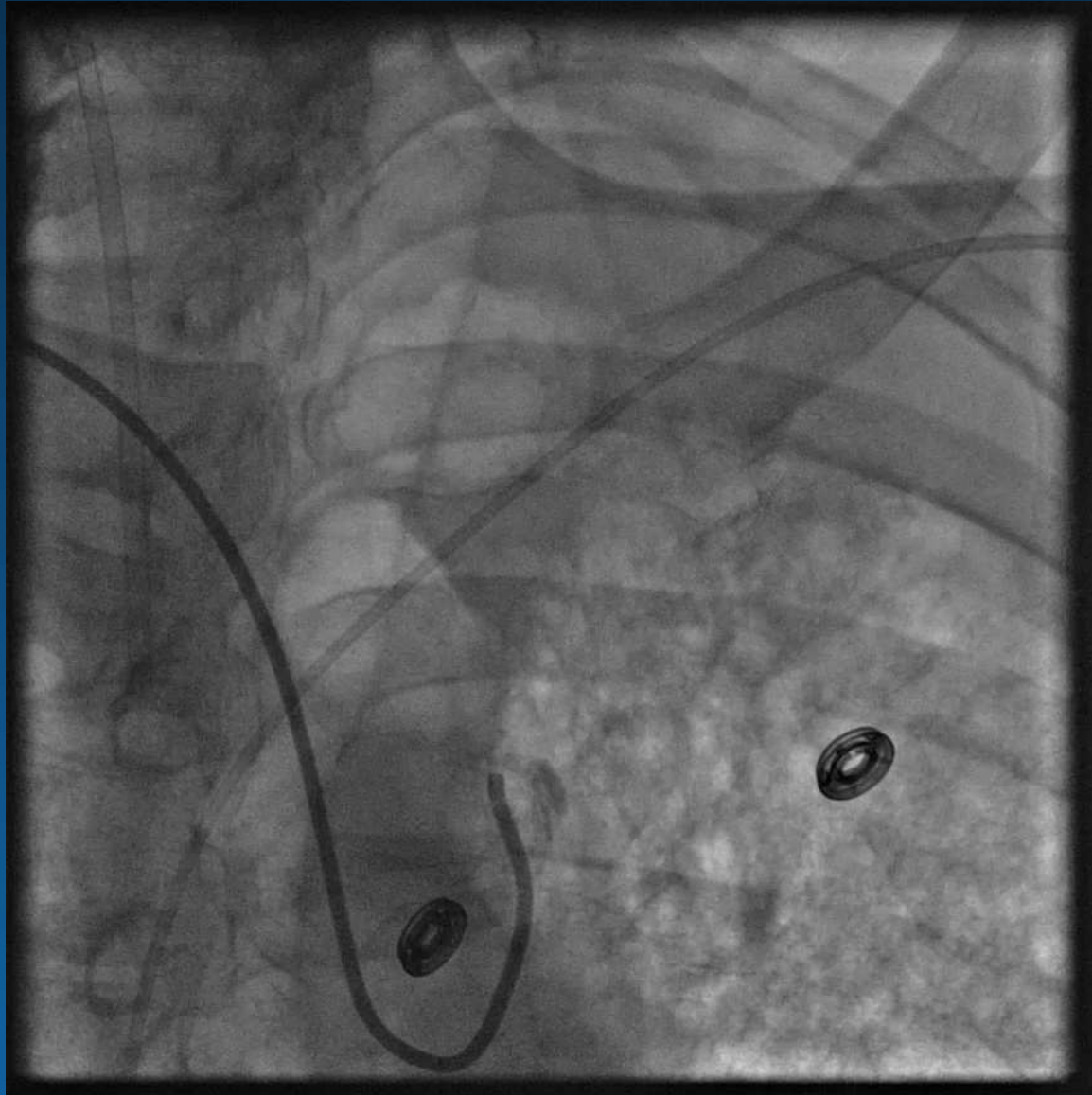
Left Coronary Angiogram



Distal Aortogram



Left Subclavian Artery Angiogram



Left Axillary Artery Percutaneous Access with Pre-closure



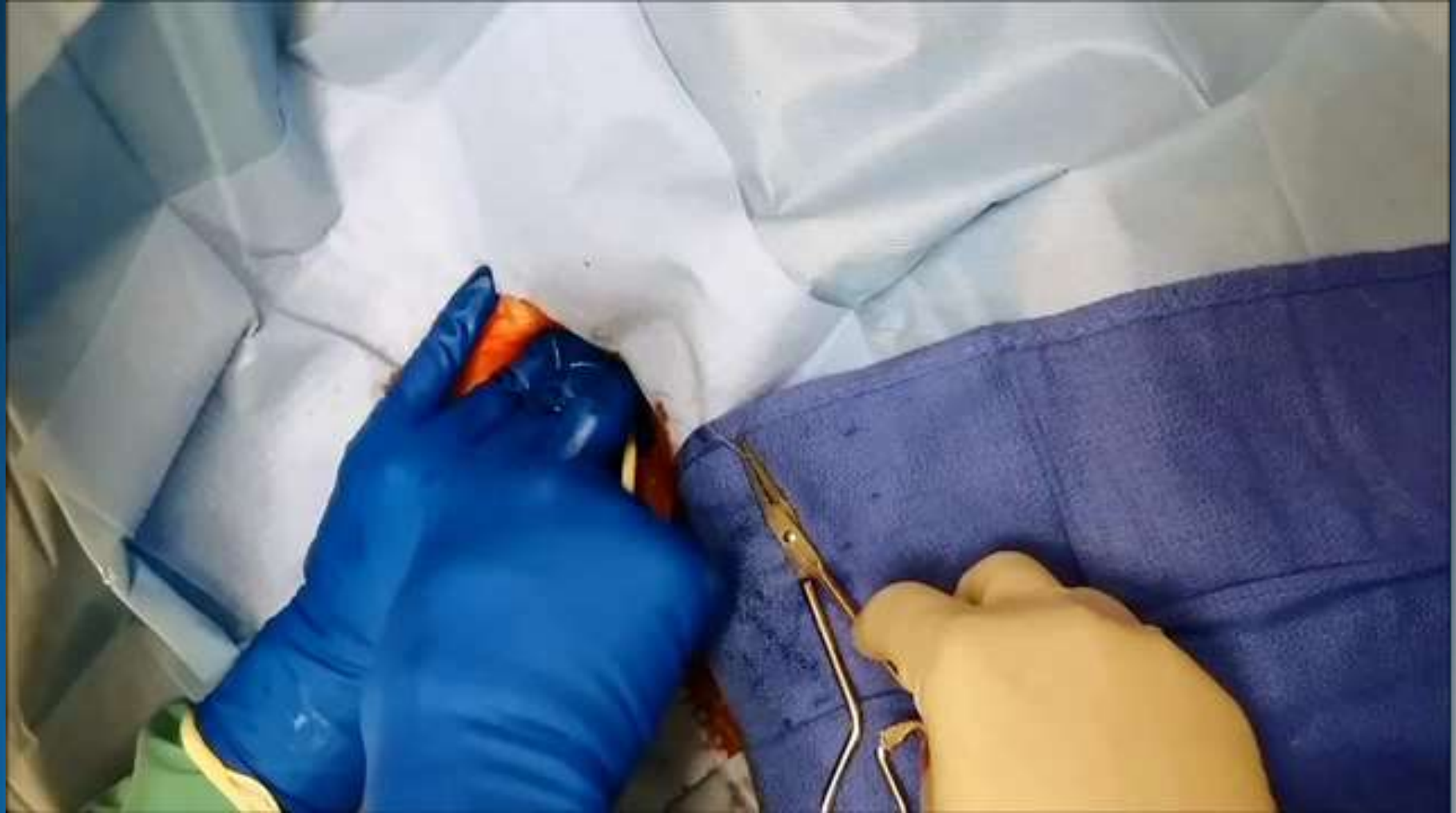
Left Axillary Artery Percutaneous Access with Pre-closure



Left Axillary Artery Percutaneous Access with Pre-closure



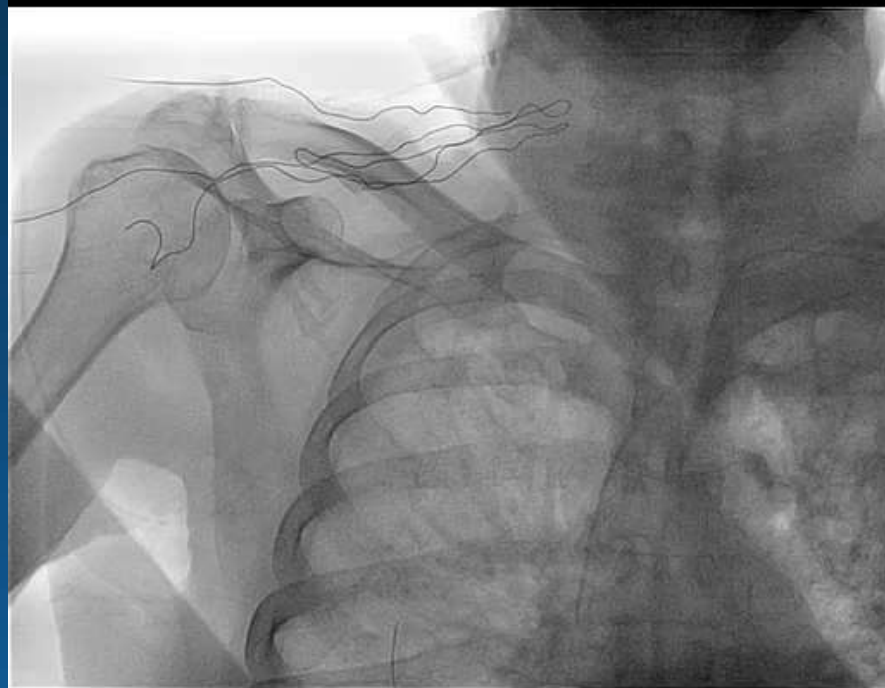
Left Axillary Artery Percutaneous Access with Pre-closure



Left Axillary Artery Percutaneous Access with Pre-closure



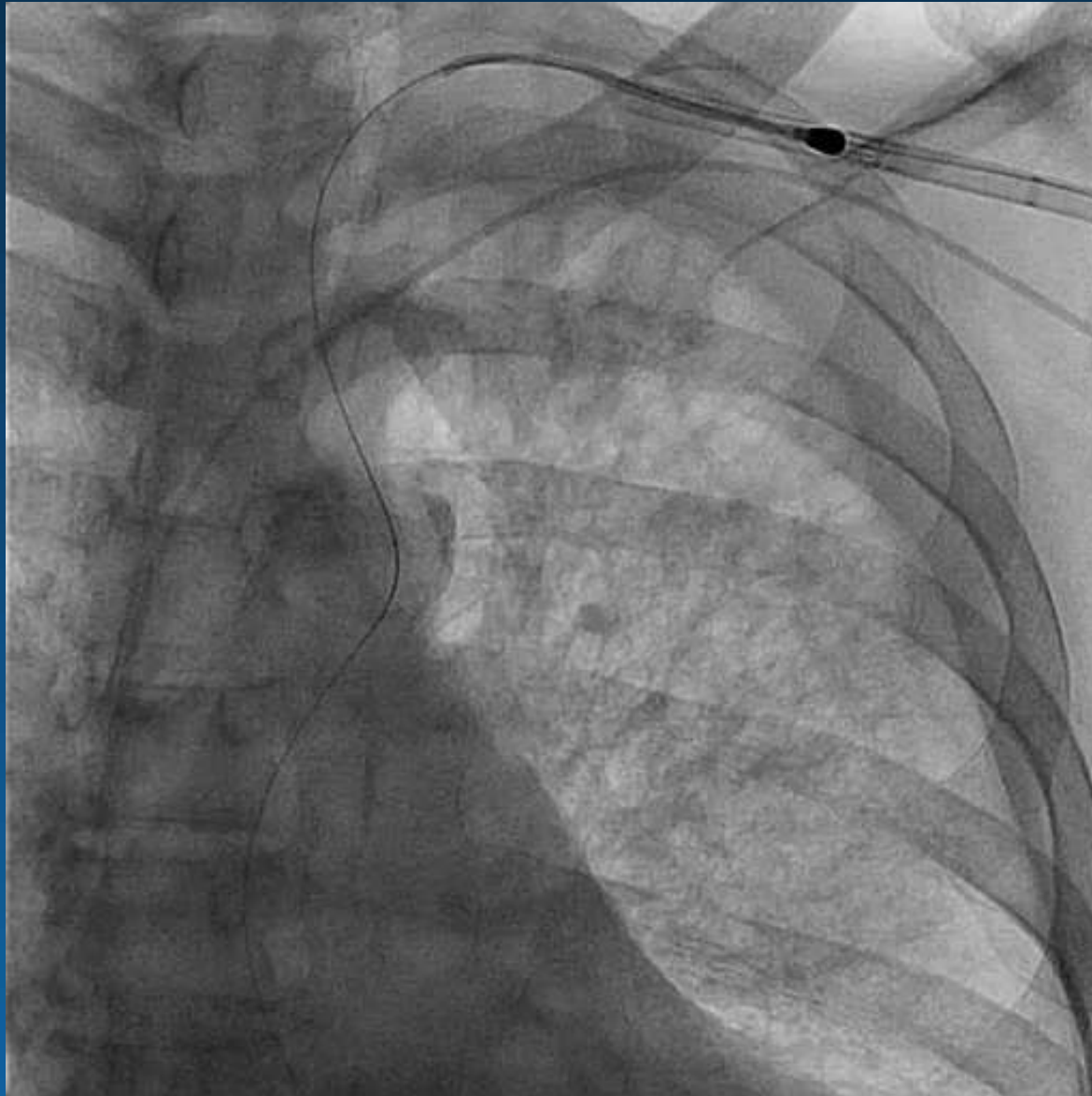
LSCA Access



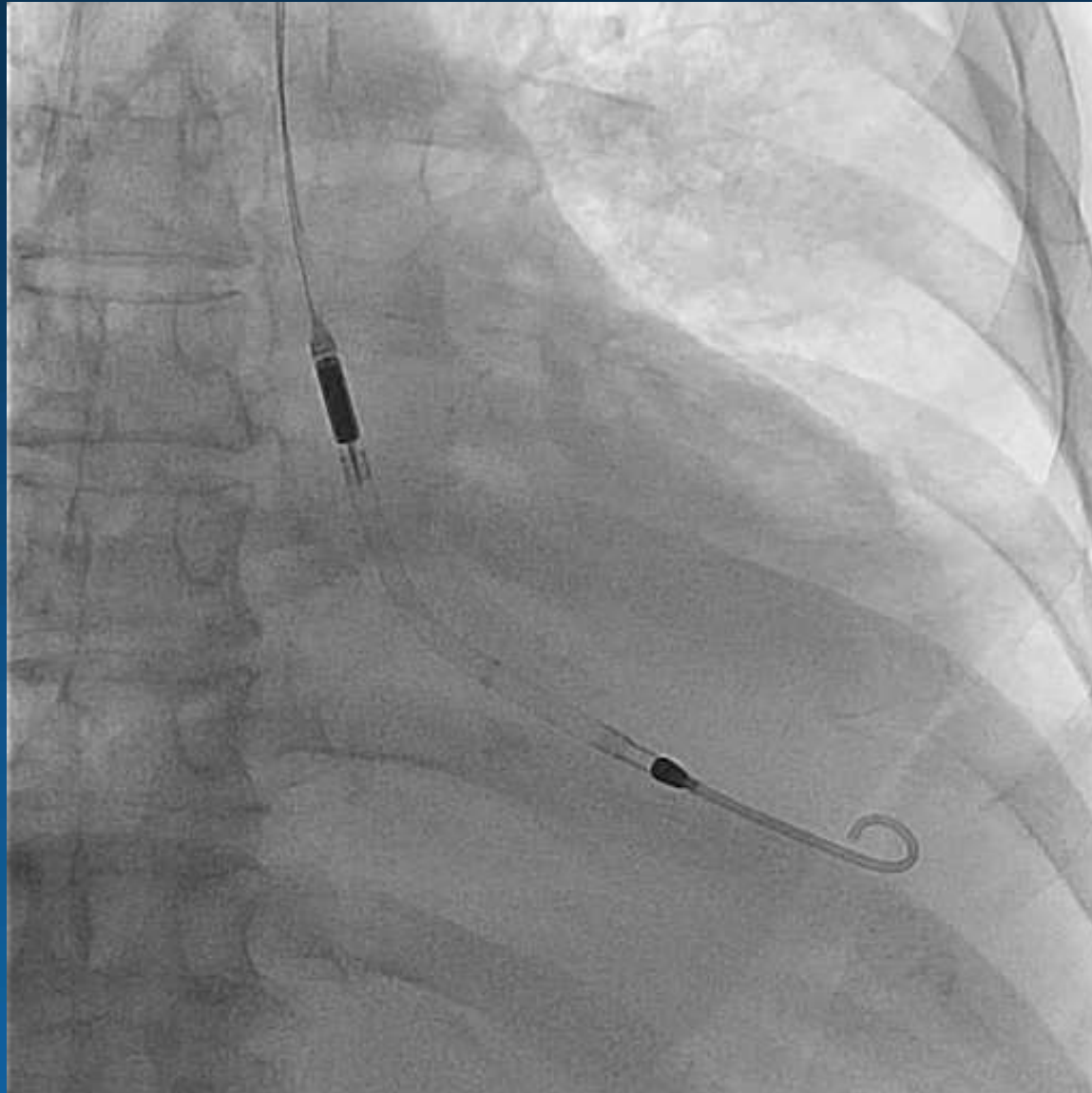




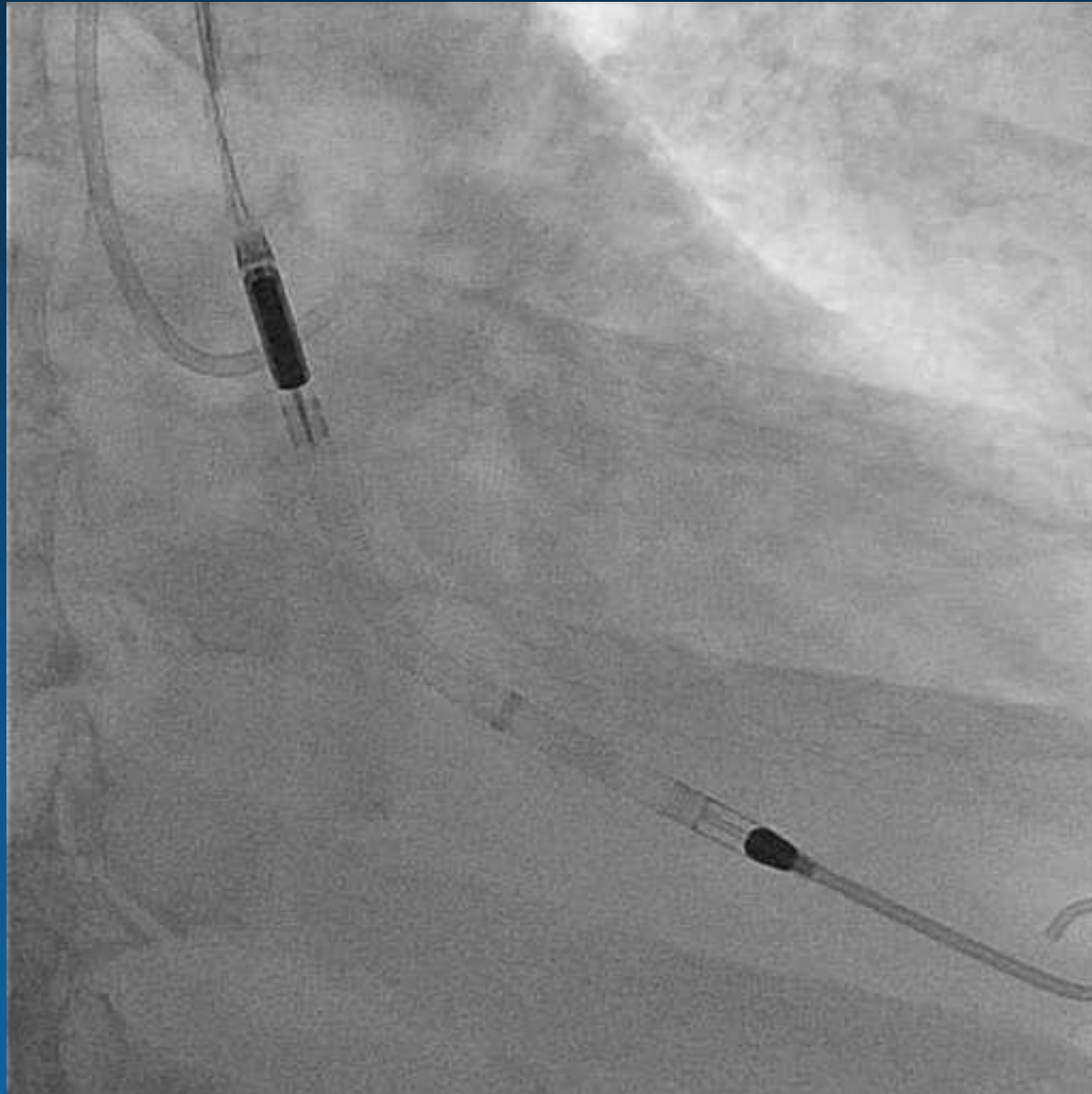
Impella 2.5 Insertion



Impella 2.5 Insertion



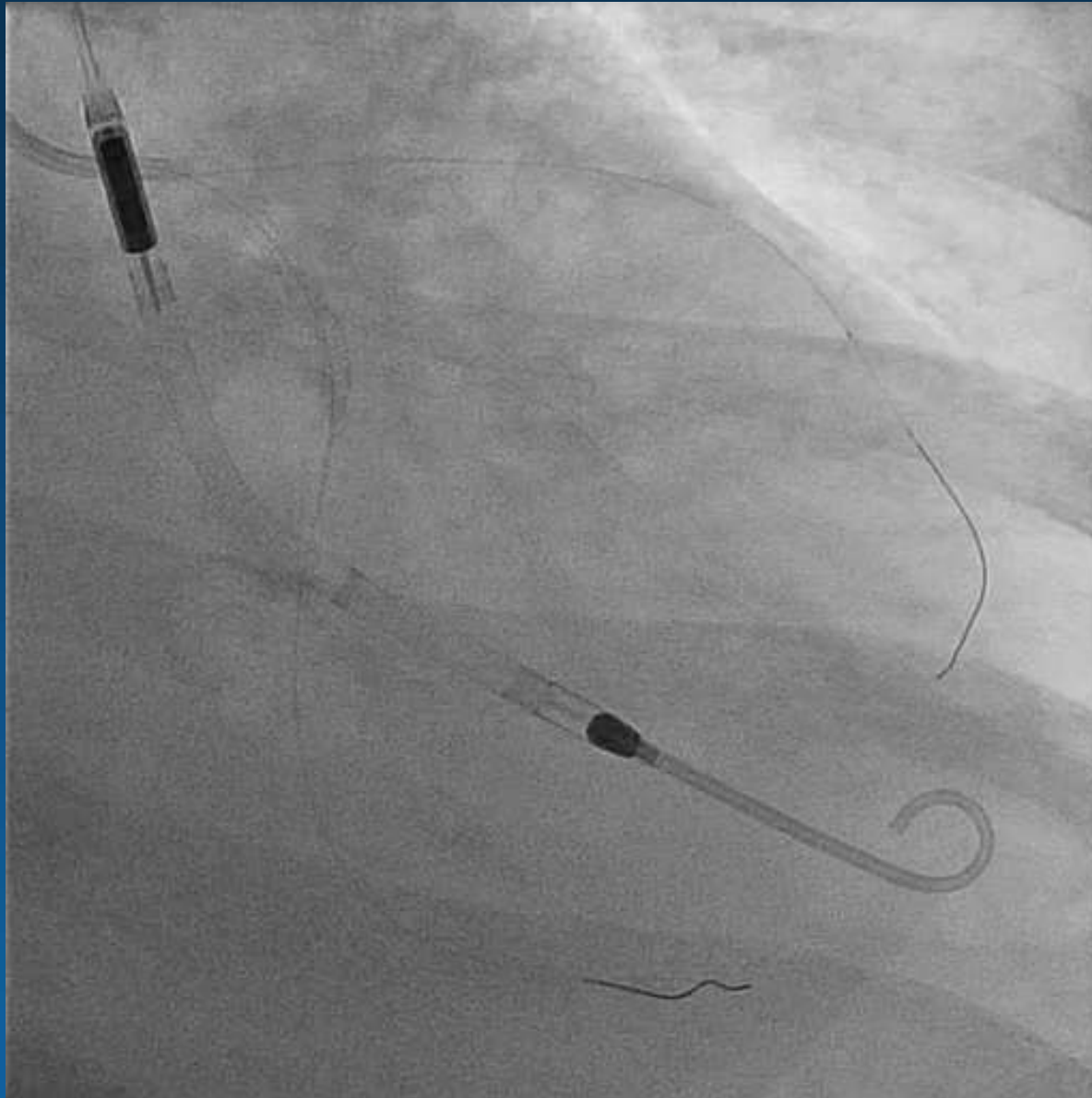
LM Guide Injection



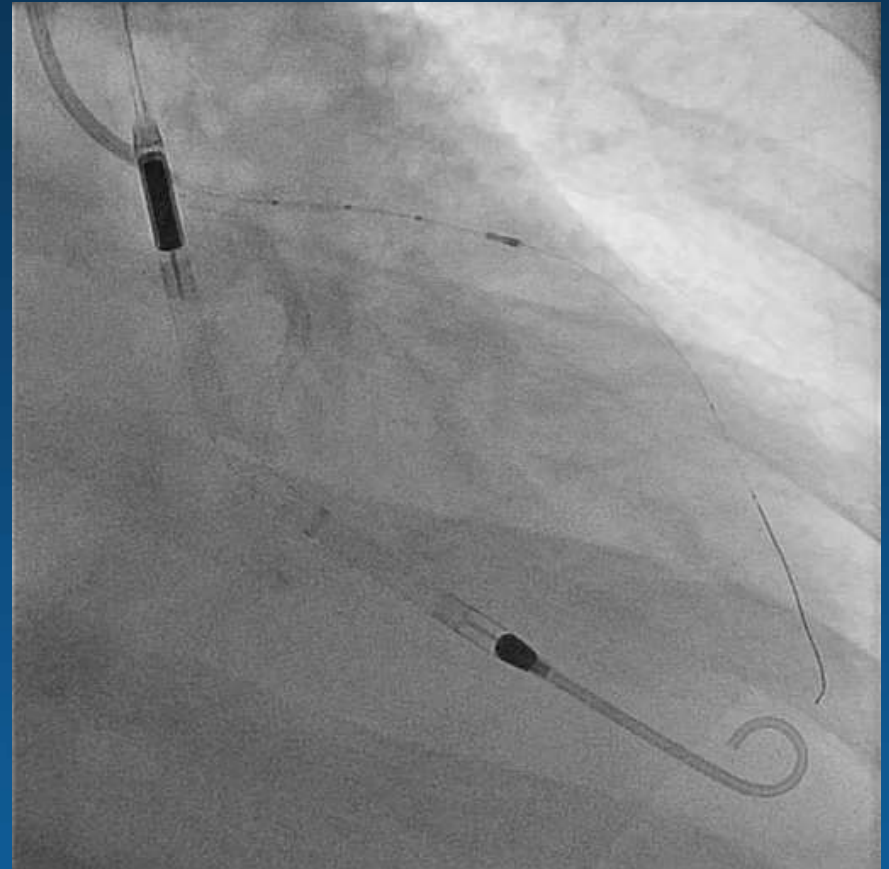
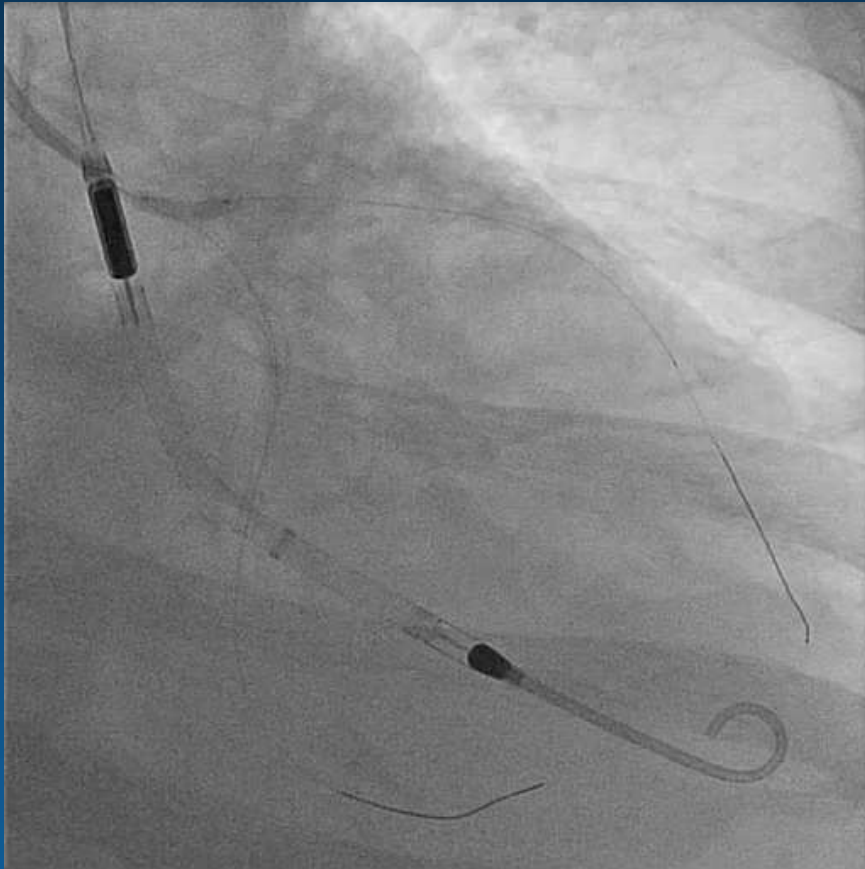
Left Circumflex Artery DES



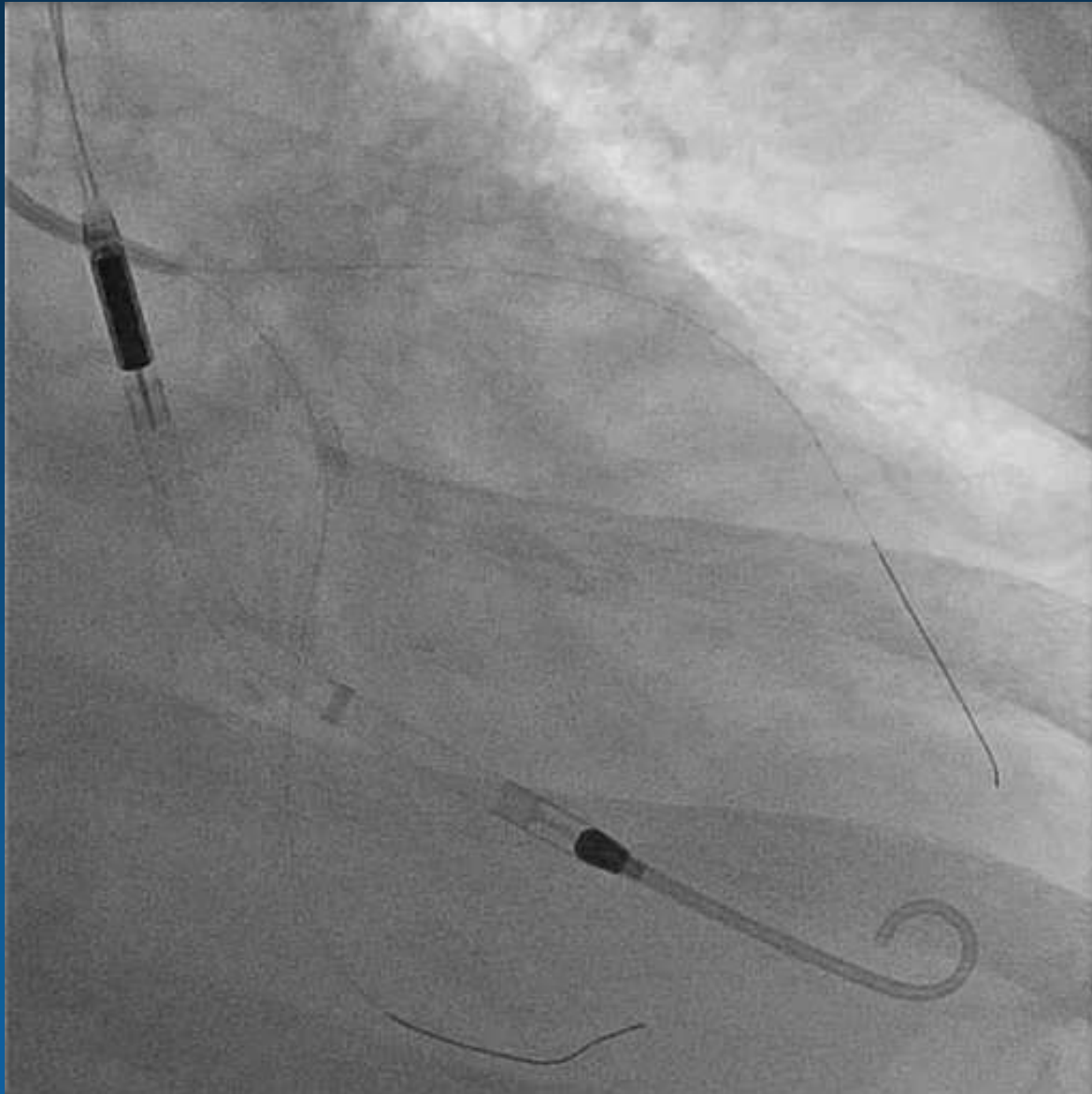
Post-LCX DES Implantation



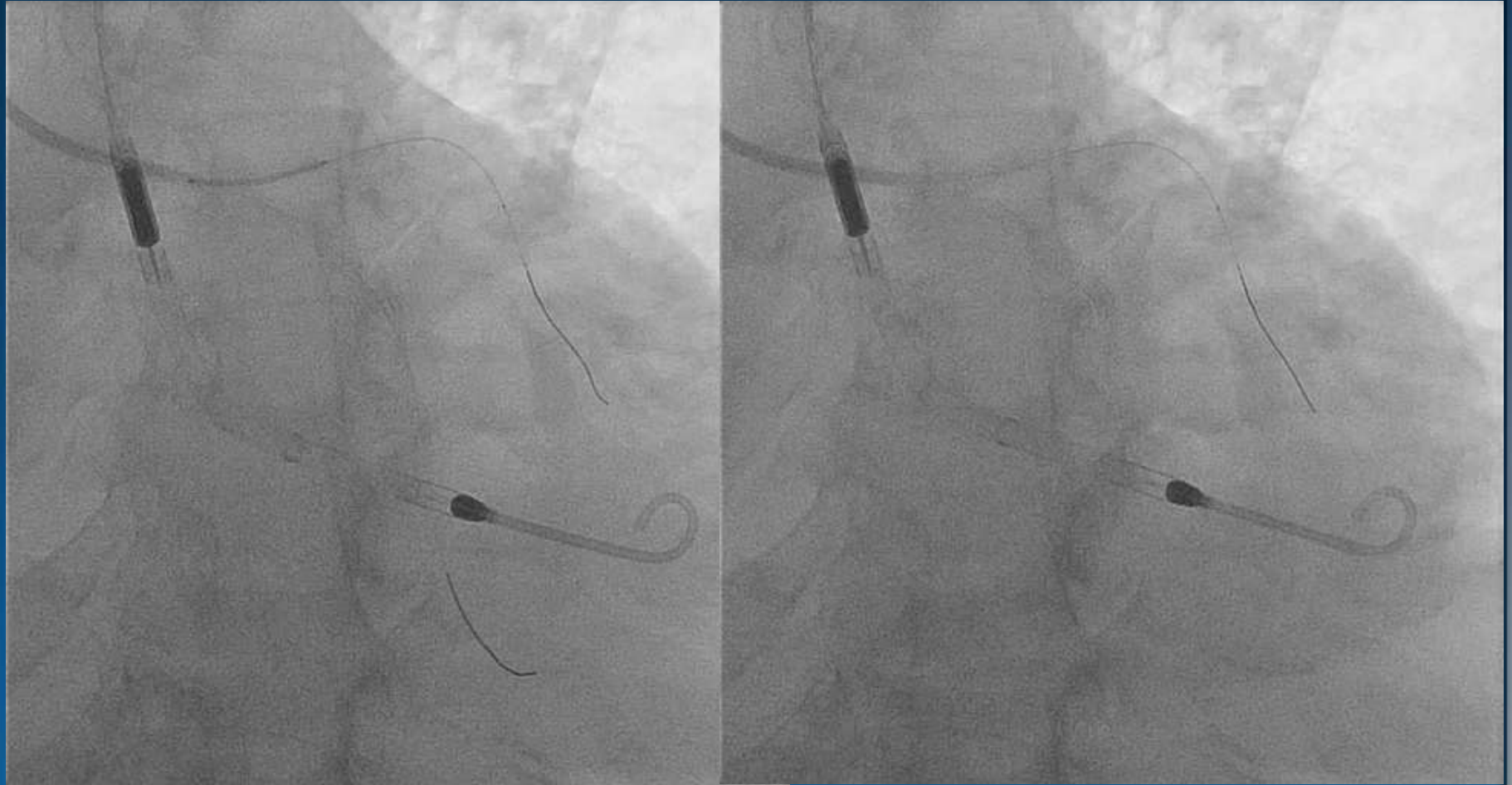
LM PTCA & IVUS



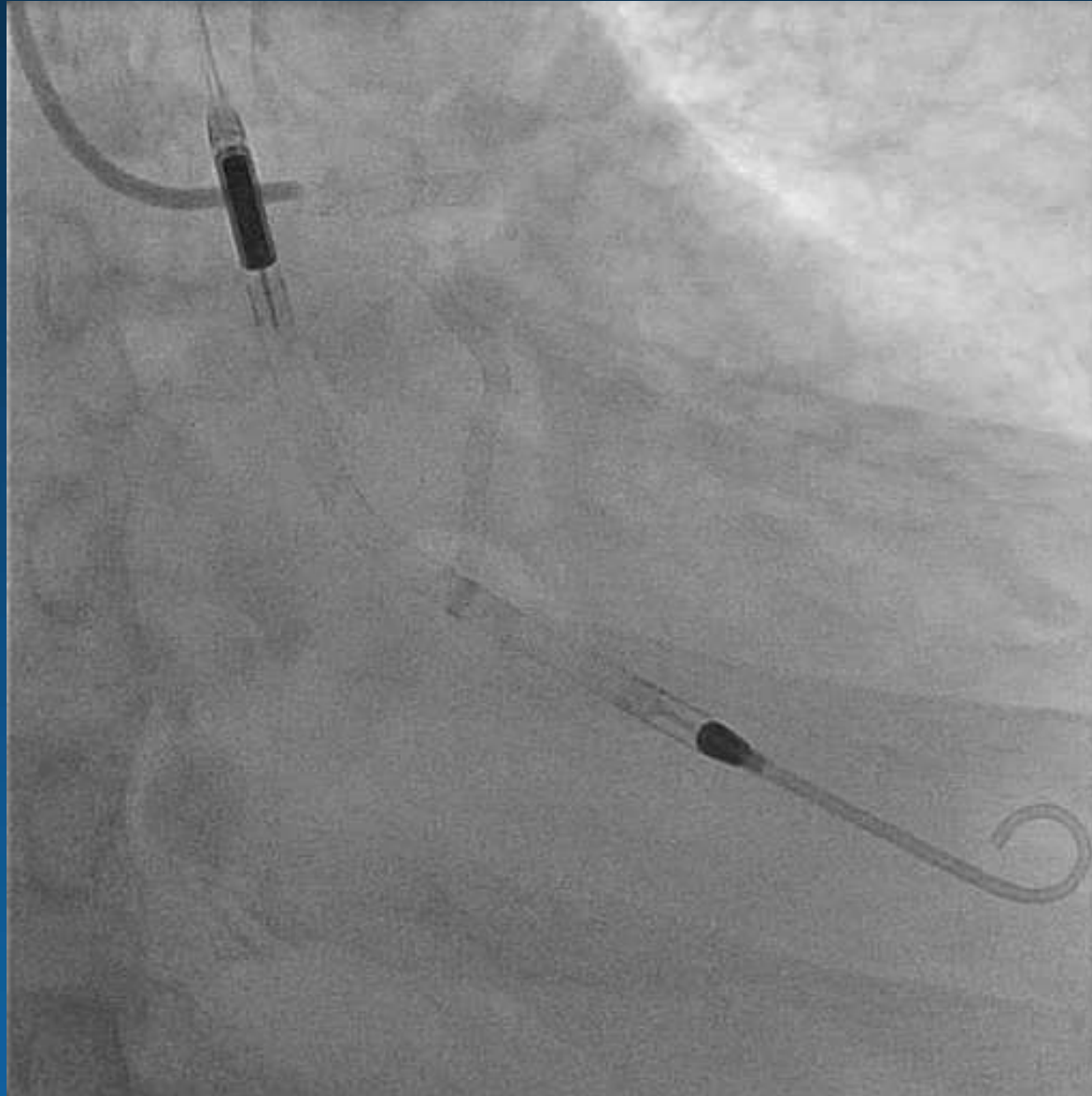
Post-LM PTCA



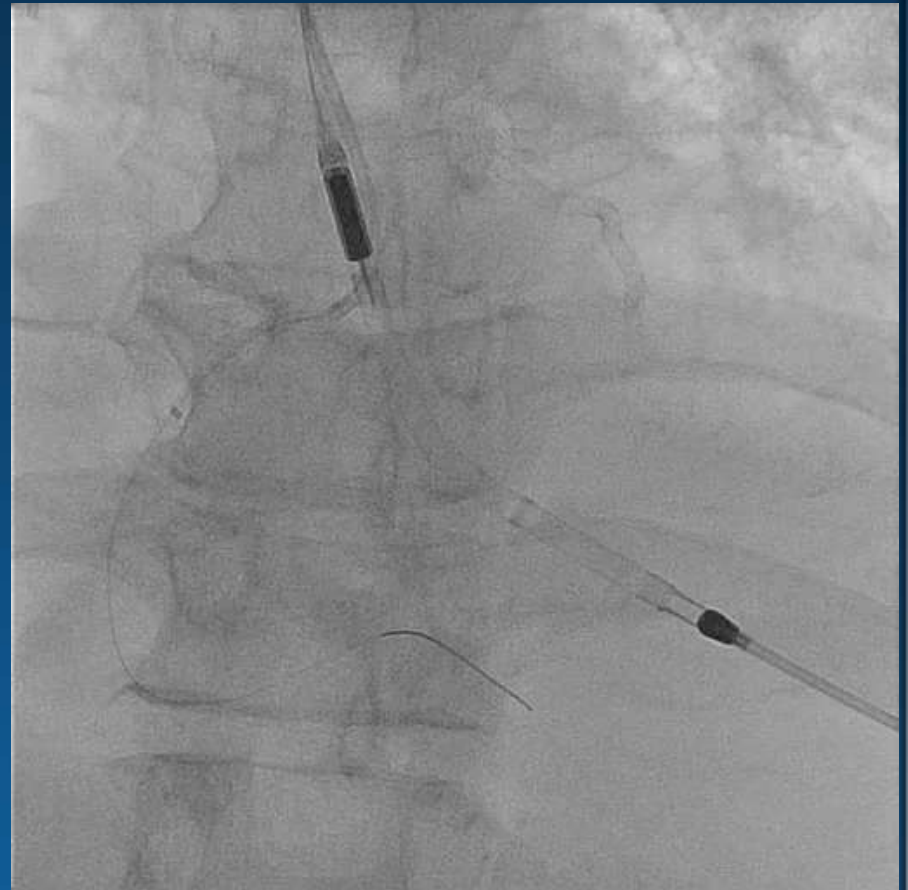
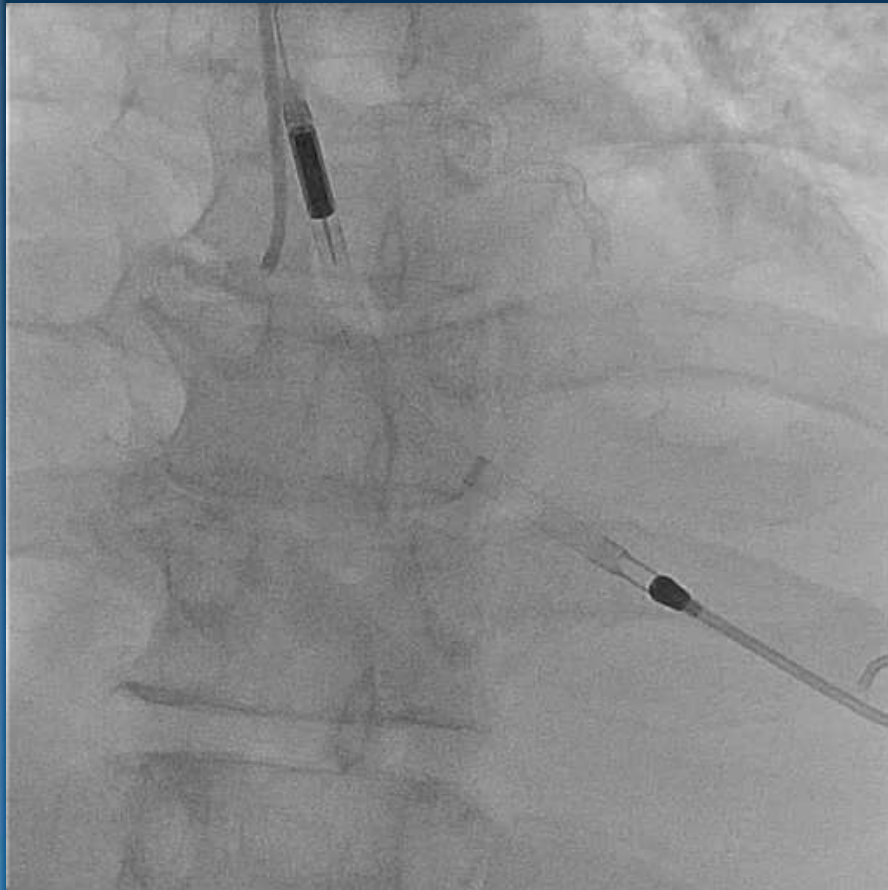
LAD DES



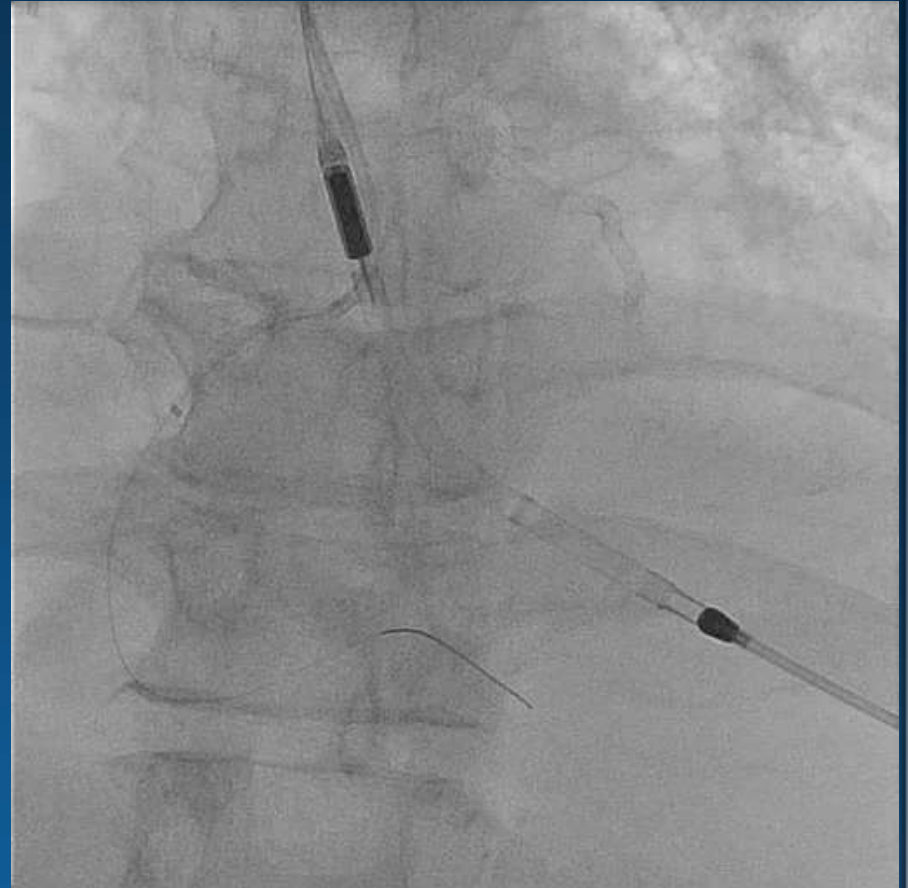
Final LAD Angiogram



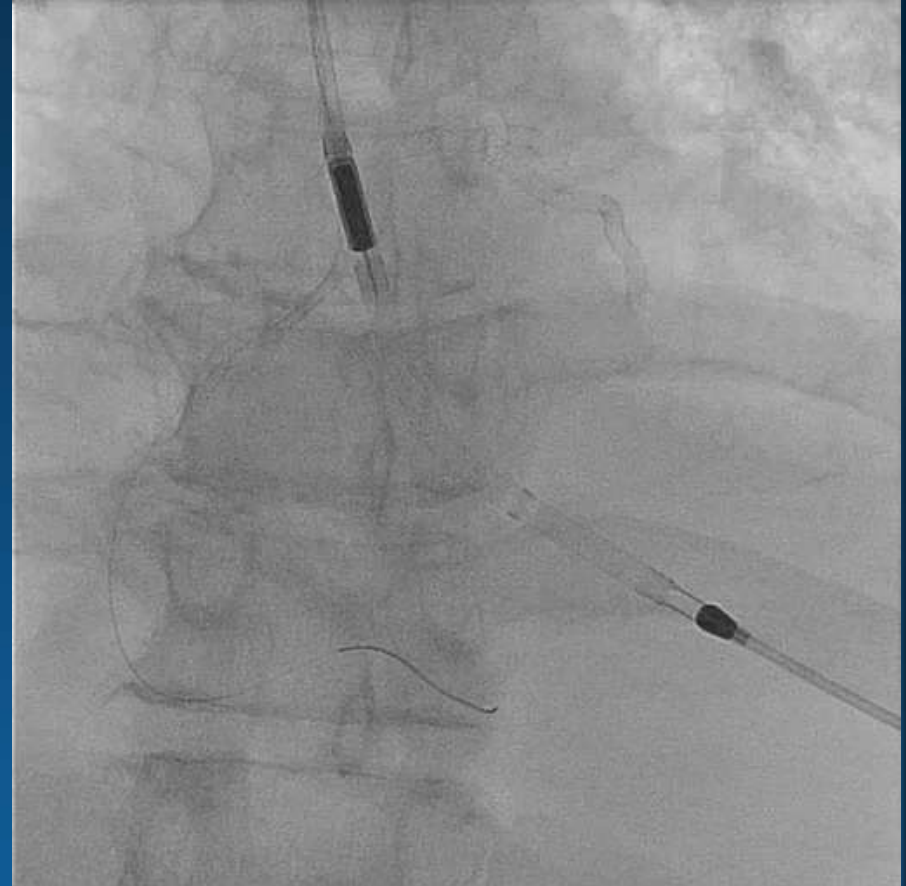
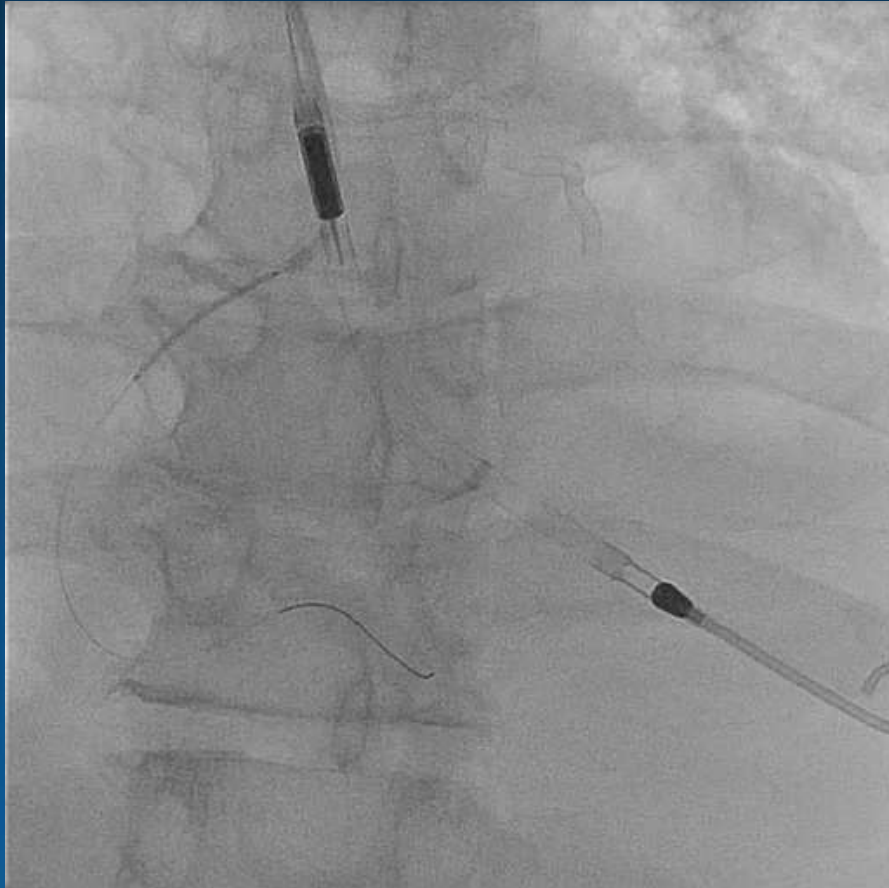
RCA PCI



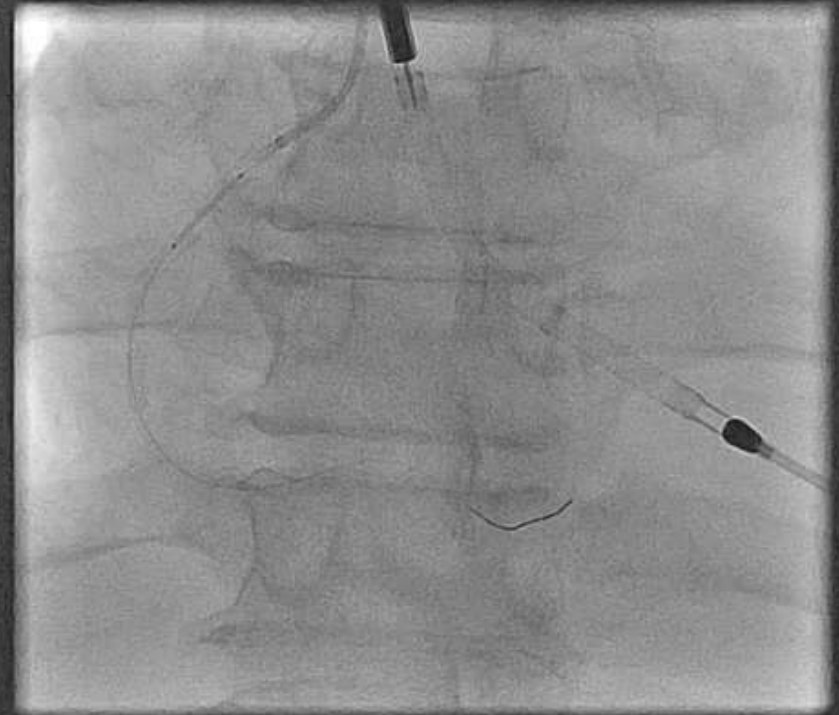
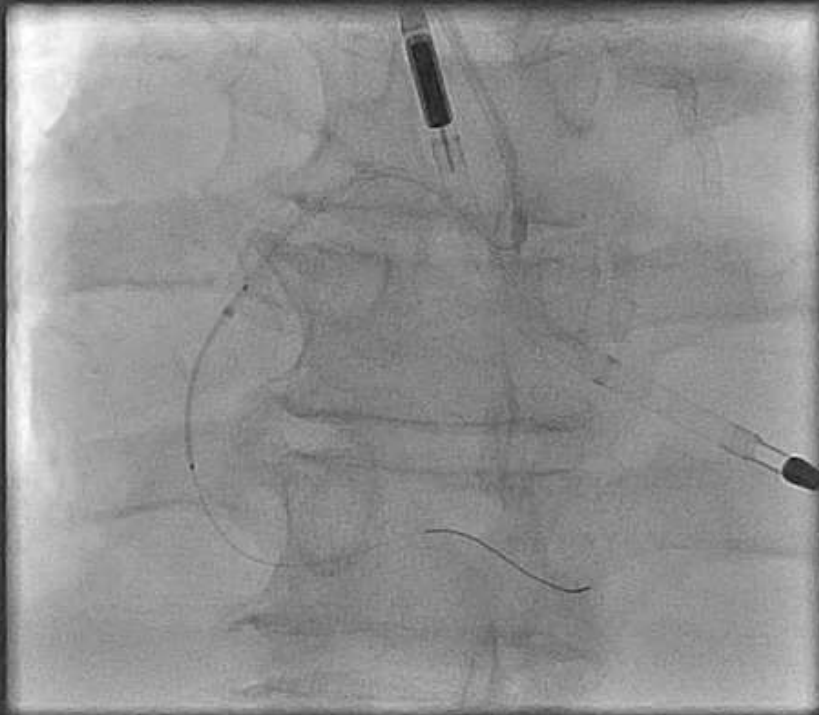
RCA PCI-Guideliner



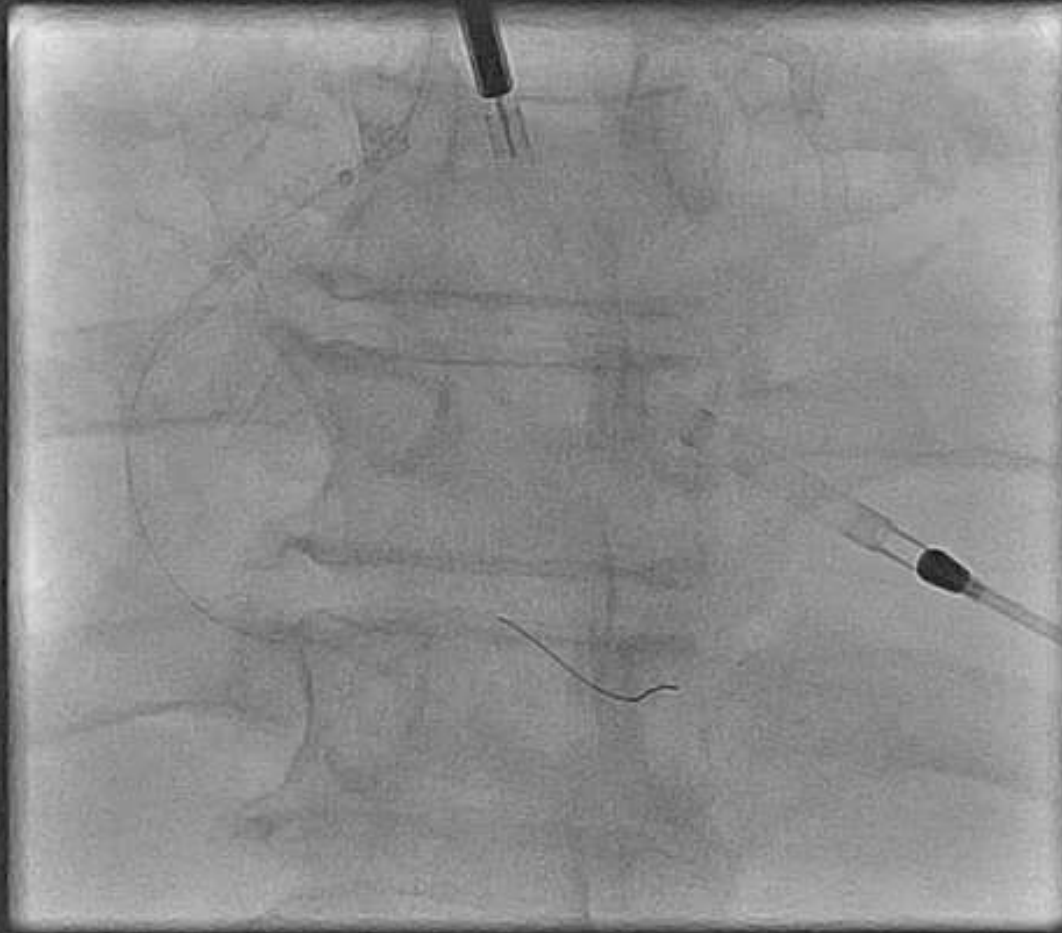
RCA PCI-Proximal DES



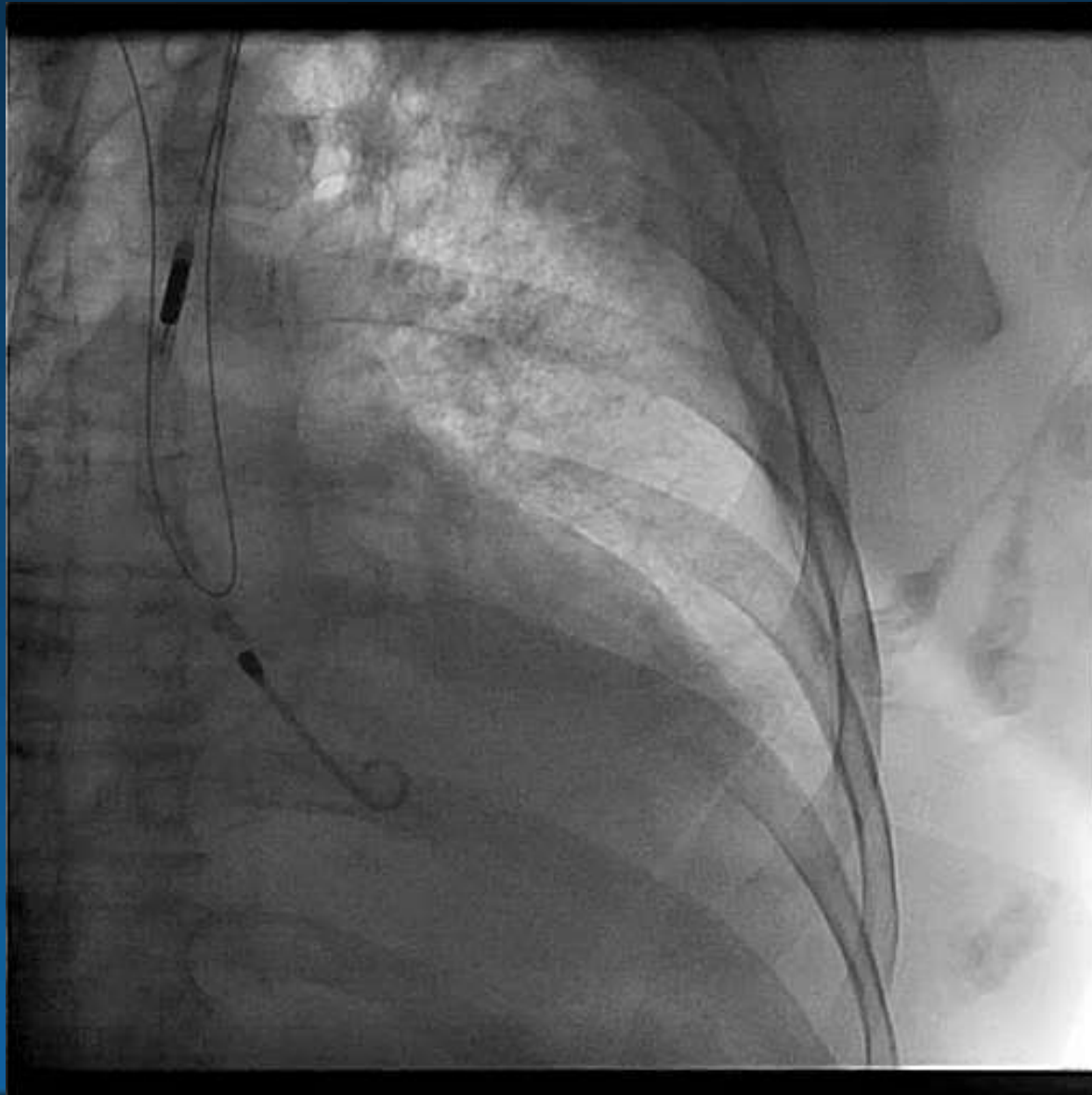
RCA PCI-Proximal DES



RCA DES-Final Angiogram



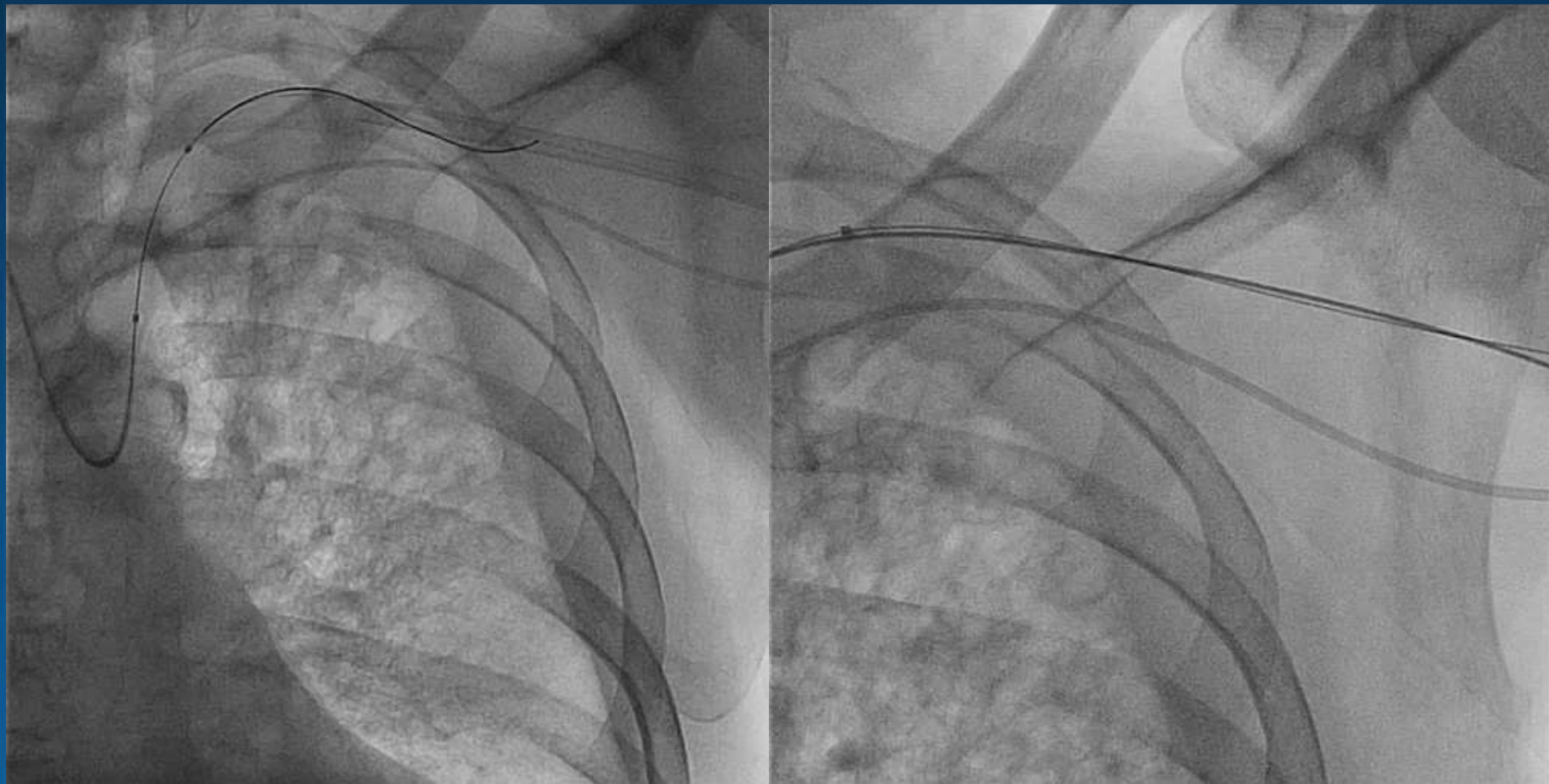
Impella Removal



LSCA Guidewire Placement



Left Axillary Artery Sheath Removal



Conclusions

- Hemodynamic support may be readily delivered during high-risk PCI or PCI in cardiogenic shock with Impella, IABP & TandemHeart
- Impella provides the highest level of hemodynamic support, facilitating more complete revascularization, with no additional harm

Acknowledgements

- Emmanouil S. Brilakis, MD, PhD
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- Tayo Addo, MD
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- Swagata Das, MBBS
- Karan Sarode, BS
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- Teresa Jeong, RN
- Susan Droughty, RN
- Lauren Makke, RVT
- Dwaine William
- Tina Terry, RN
- Smitha Thomas, RN
- Diana Lacey, RN
- OUR PATIENTS