



Dallas
CARDIOVASCULAR
INNOVATIONS 2015

January 16, 2015

Completeness of revascularization and hemodynamic support

Emmanouil S. Brilakis, MD, PhD

Director, Cardiac Catheterization Laboratory

VA North Texas Healthcare System

Associate Professor of Medicine, UTSW

ES Brilakis: Disclosures

**Consulting/speaker honoraria: Abbott
Vascular, Asahi, Boston Scientific,
Elsevier, Somahlution, St Jude
Medical, Terumo**

Employment (spouse): Medtronic

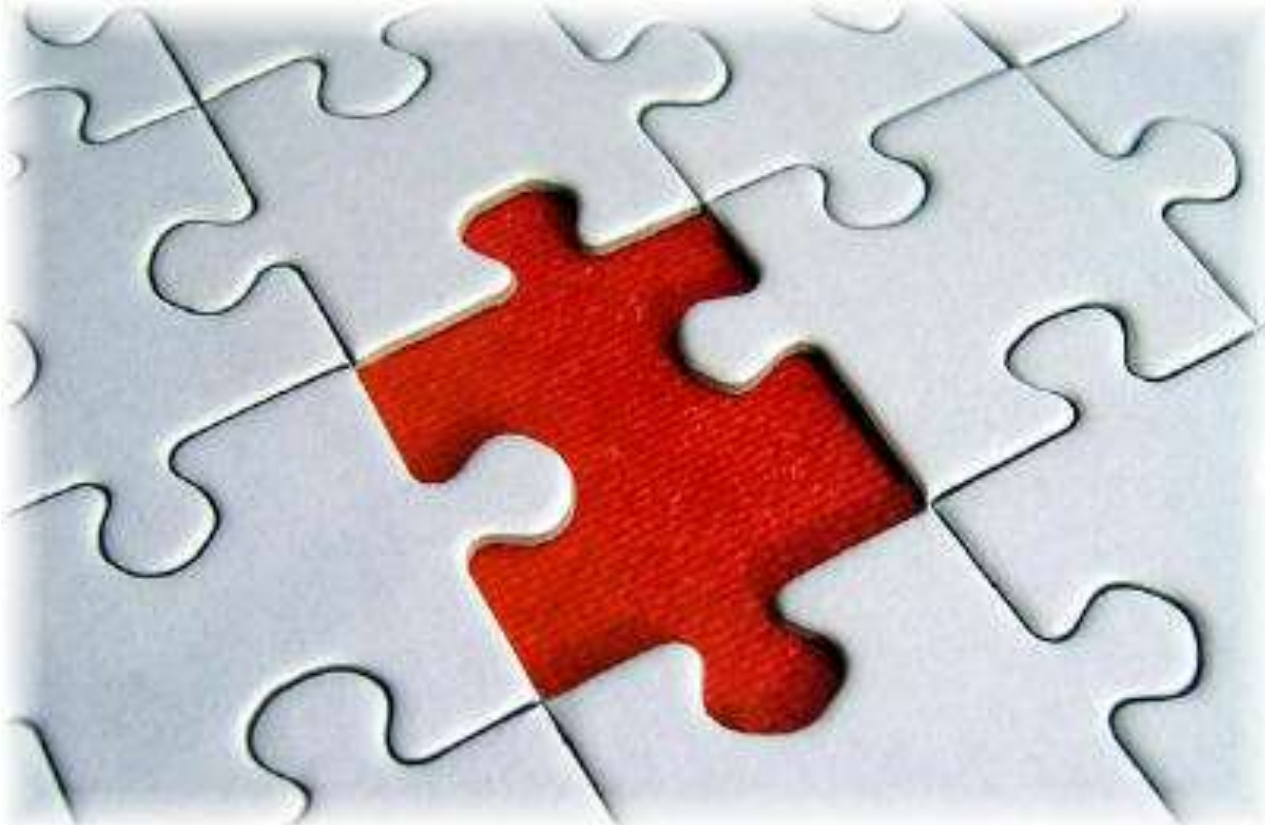
Grants: NIH –1R01HL102442

VA - I01-CX000787-01

VA CSP#571 – DIVA

Guerbet, InfraRedx

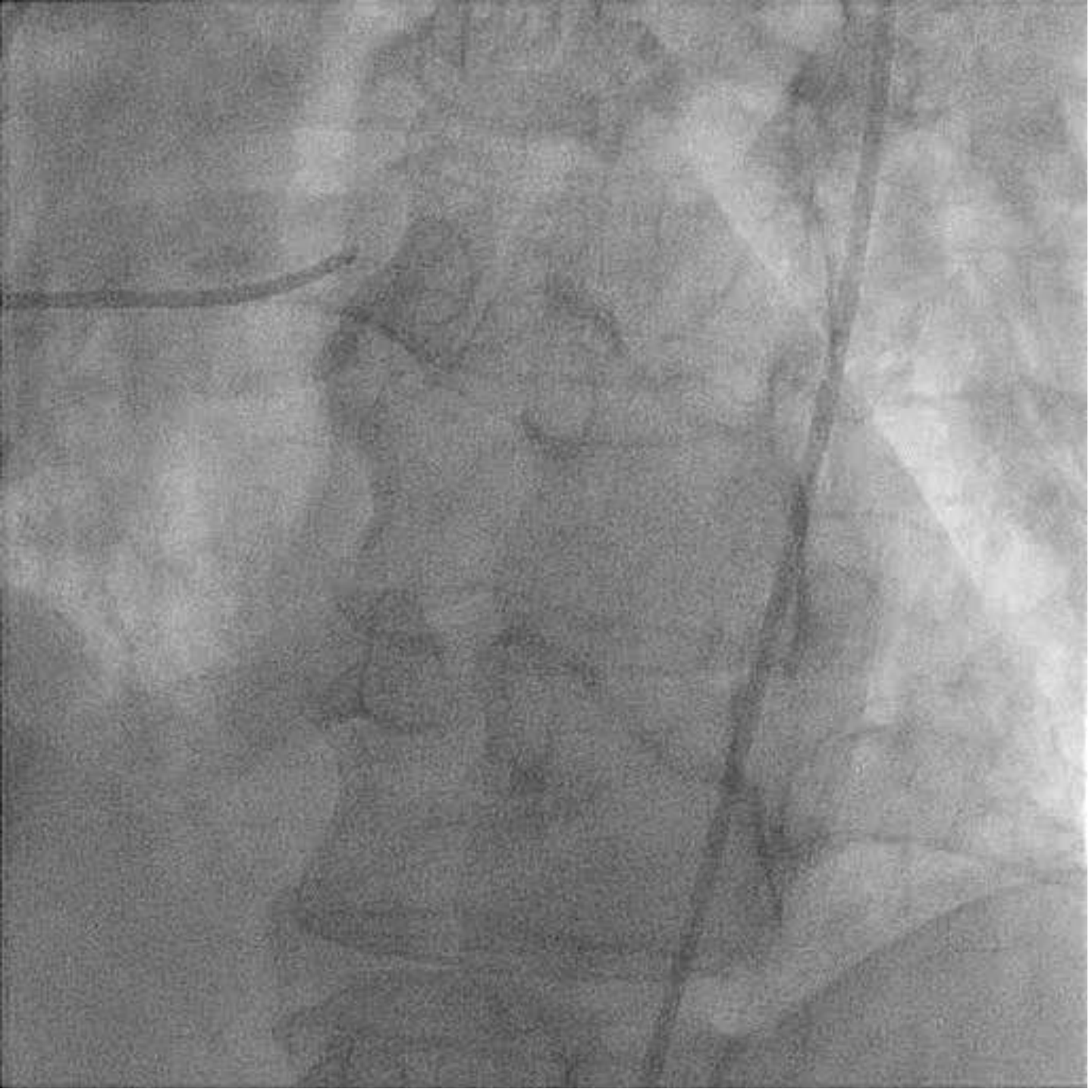
Why complete?



Case

**66-year-old man with
NSTEMI.**

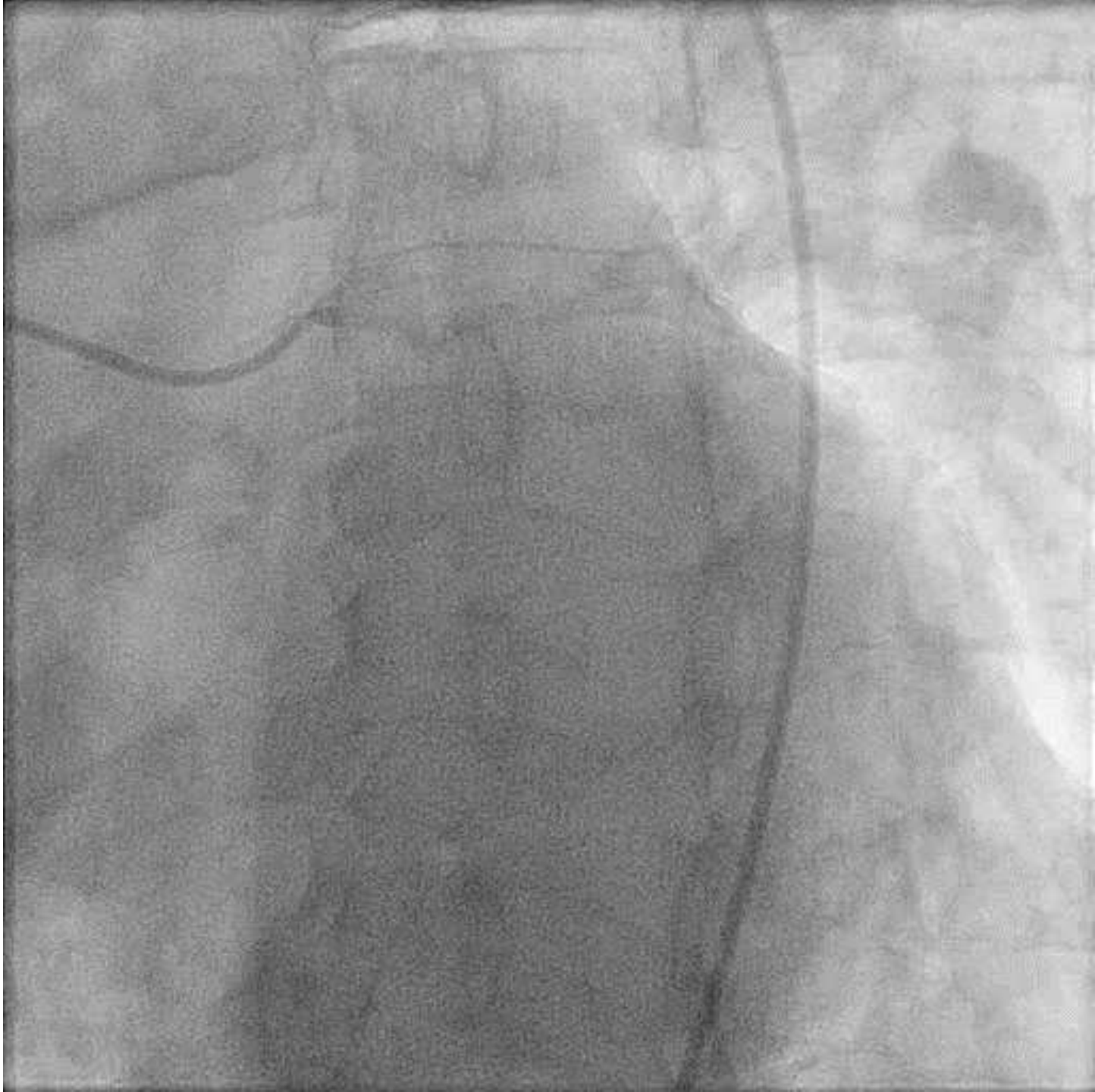
Left main 1



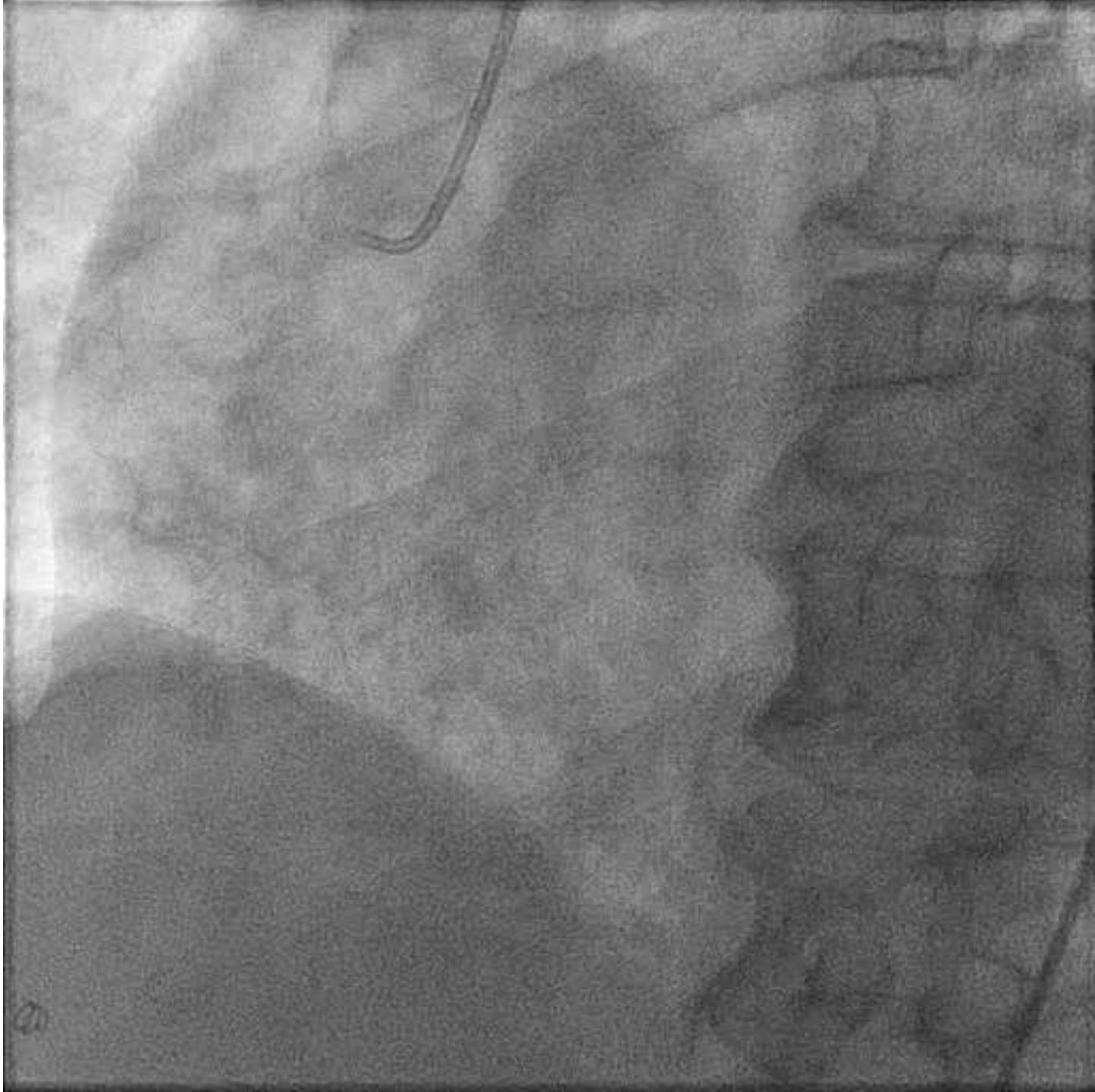
Left main 2



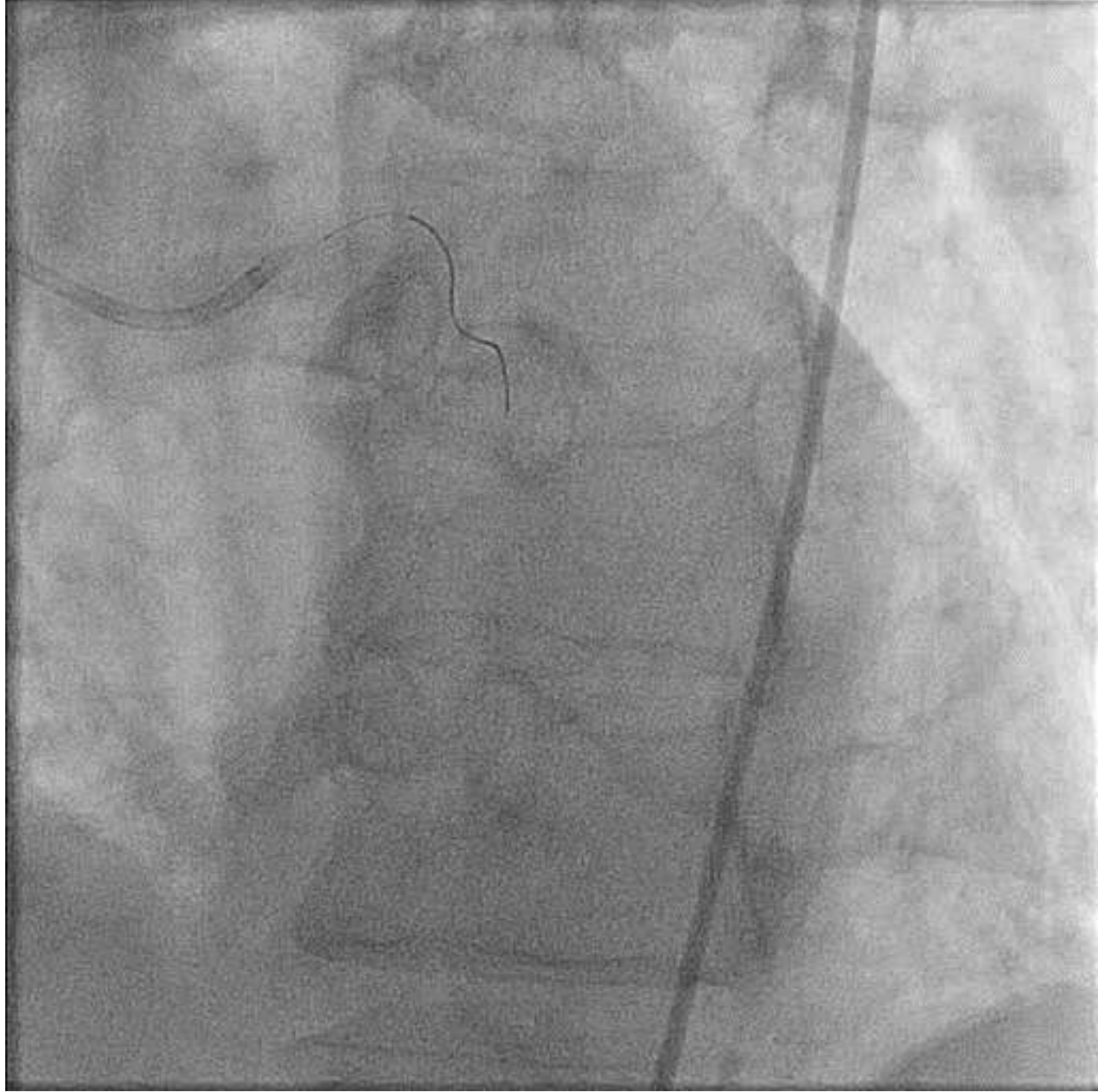
Left main 3



RCA

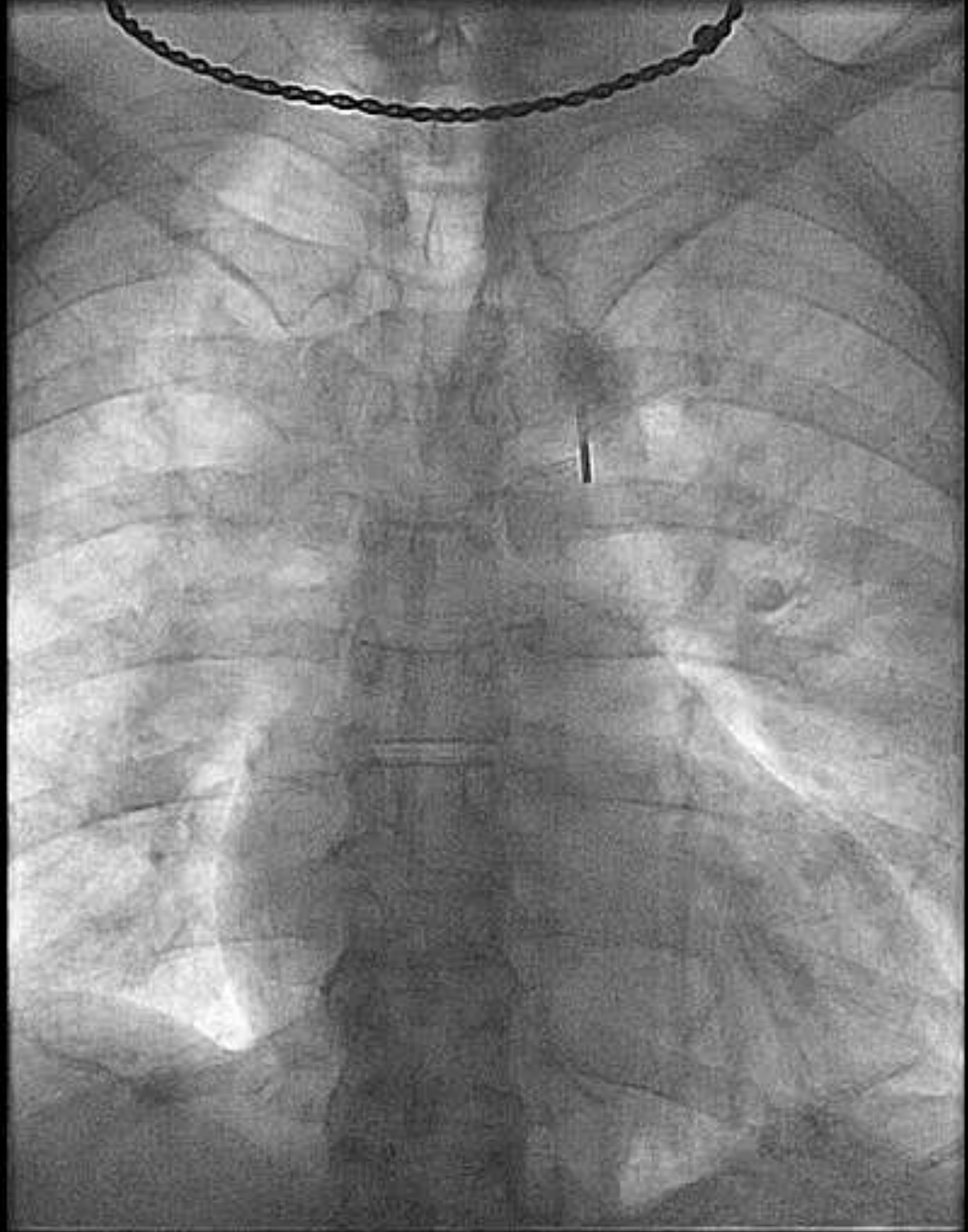


**PCI attempt
failed**



**IABP
Transfer to
Dallas
VAMC**

**Arrives
with SBP in
60s...**



EF=20%

FR 37Hz
24cm

M3

2D
75%
C 45
P Low
HPen



JPEG

102 bpm

Question 1: Immediate next step?

1. Emergent CABG

2. PCI with IABP

3. PCI with Impella

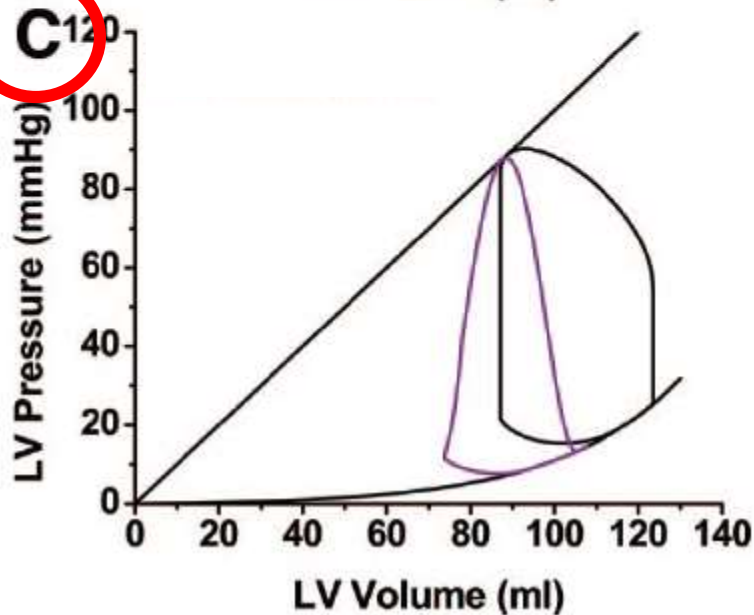
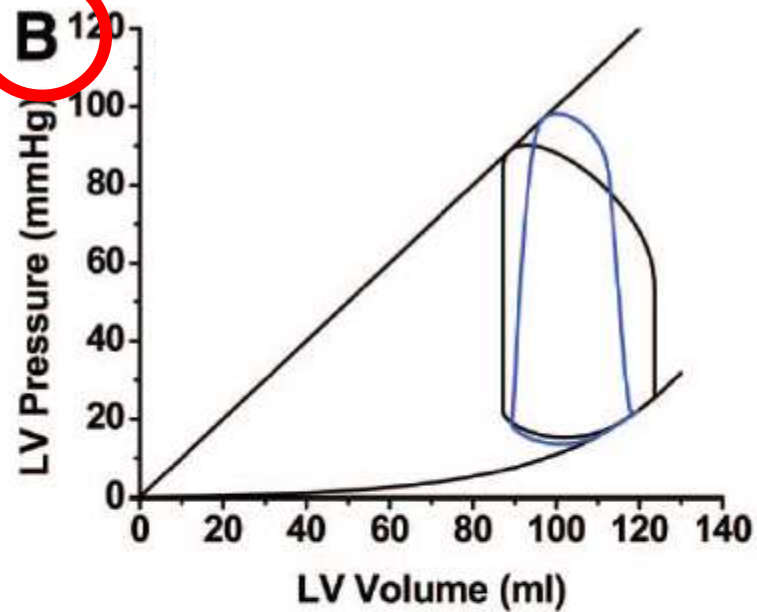
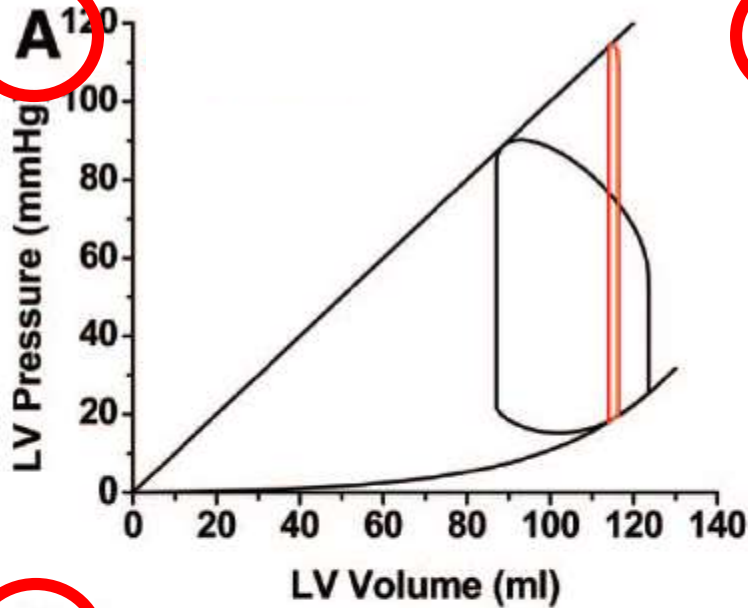
4. PCI with Tandem Heart

Emergent surgical consult

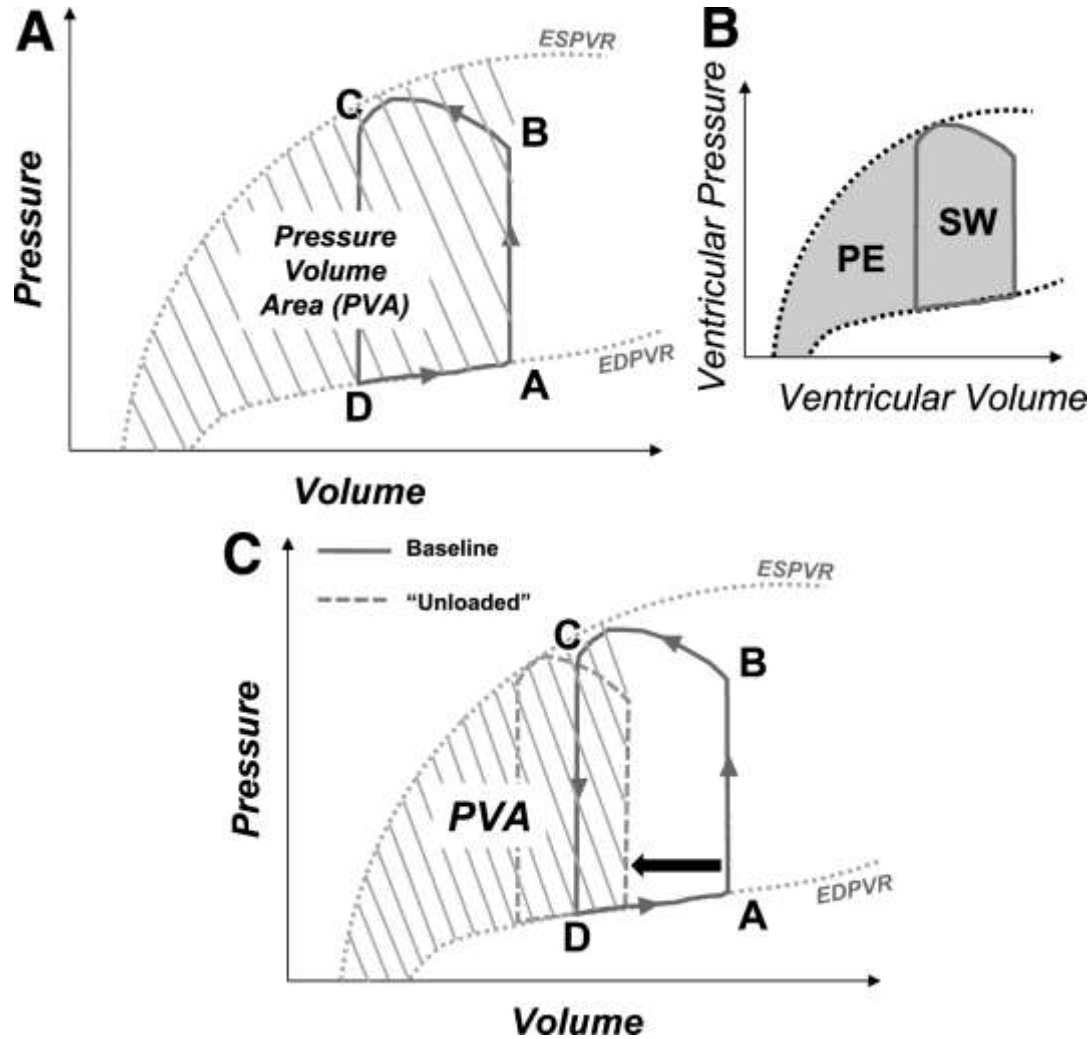
- **Patient received clopidogrel**
- **ACS**
- **Unstable hemodynamics**
- **Low EF**

Proceed with PCI

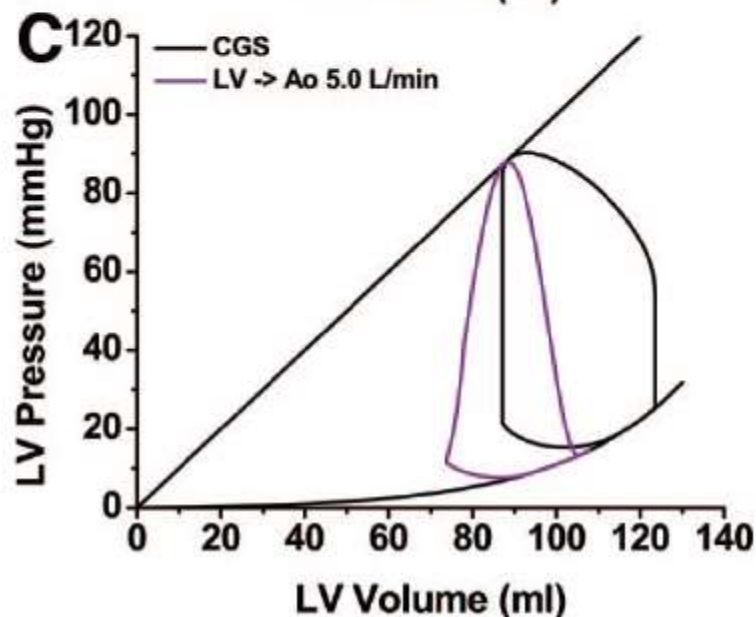
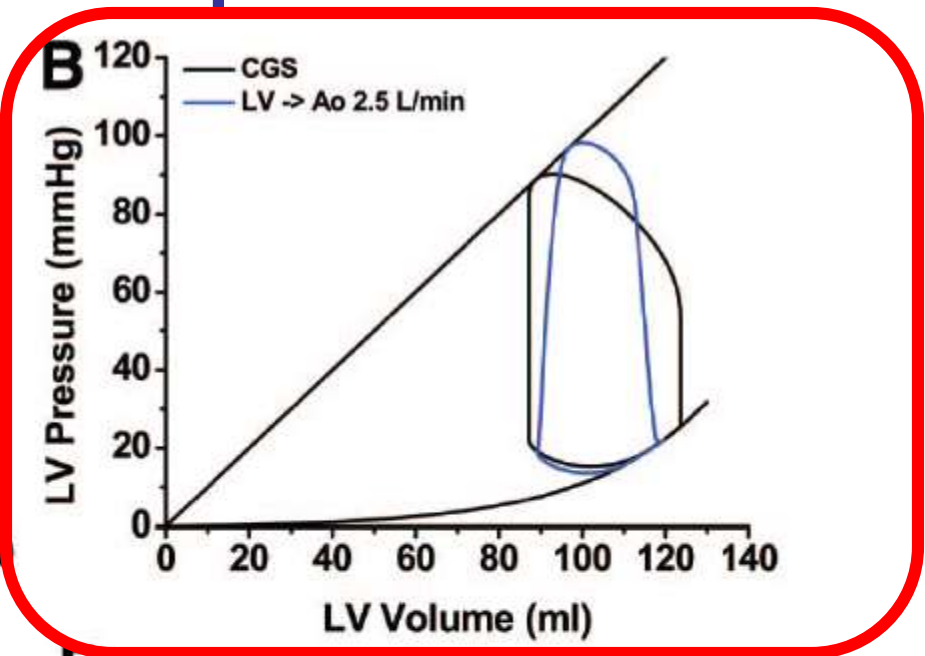
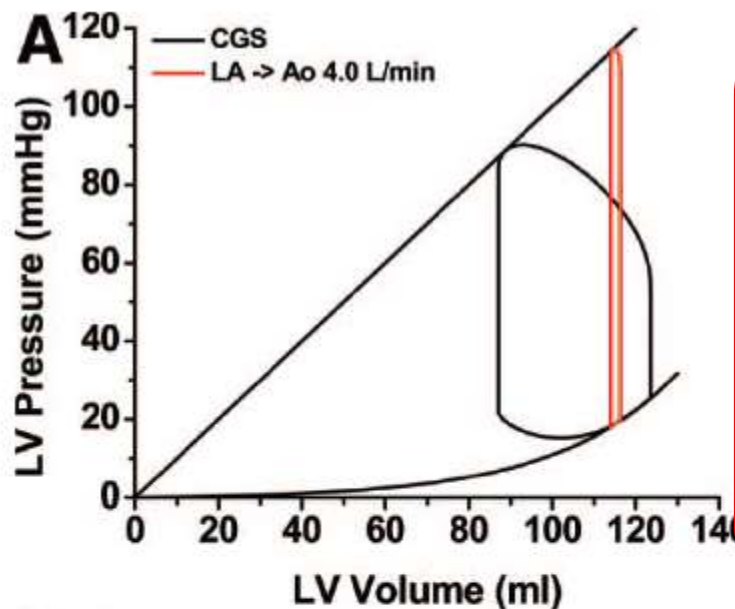
Question 2. Support in cardiogenic shock. Which one is the Impella 2.5 device?



PVA as a measure of oxygen consumption per beat



Question 2. Support in cardiogenic shock. Which one is the Impella 2.5 device?



D

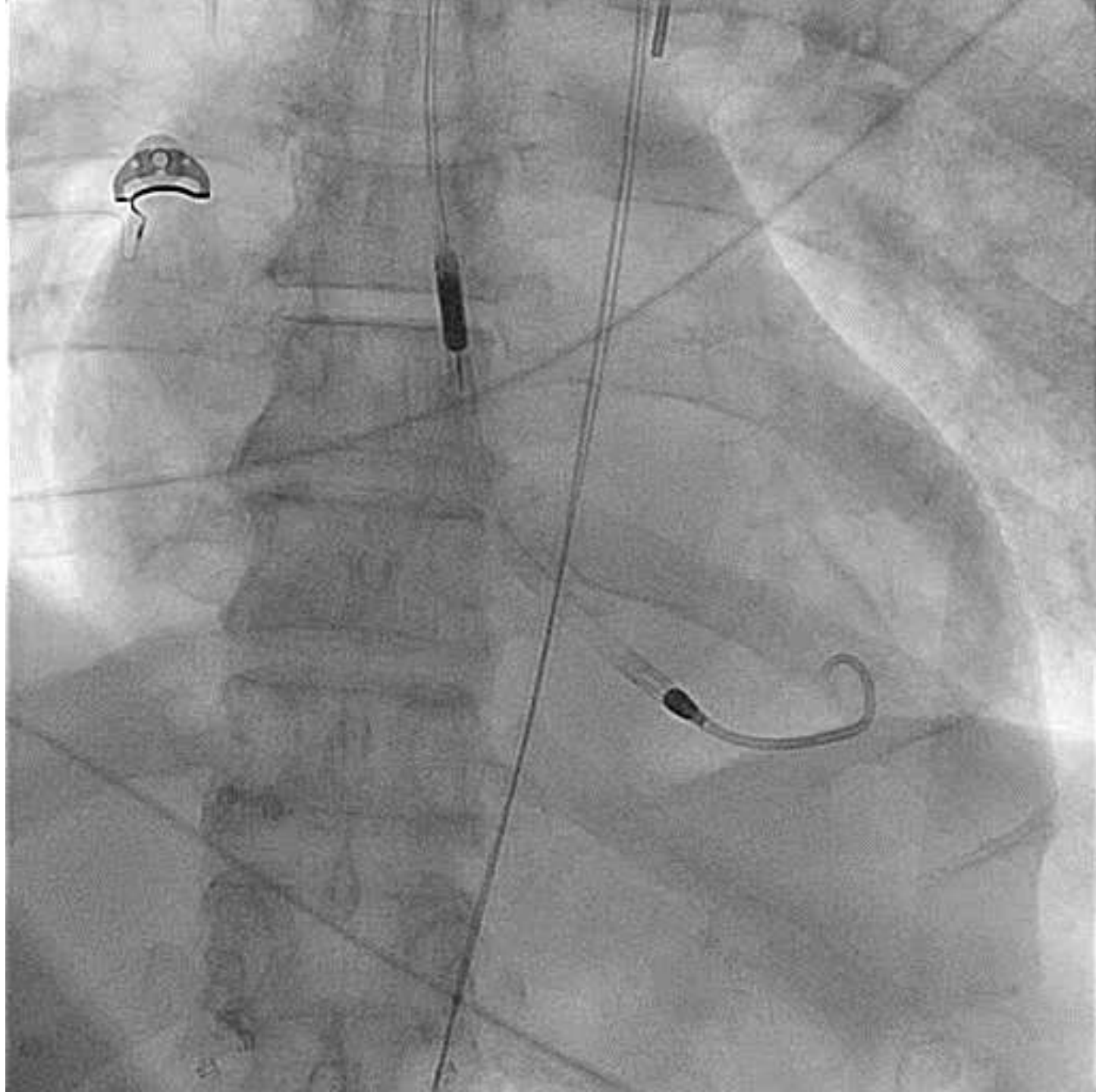
		CGS	LV->Ao 2.5 L/min	LV->Ao 5.0 L/min	LA-> Ao 4.0 L/min
CO:	LV	2.55	0.79	0.00	0.16
	VAD	<u>0.00</u>	<u>2.50</u>	<u>5.00</u>	<u>4.00</u>
	Total	2.55	3.29	5.00	4.16
EDP		25	21	13	20
MAP		70	89	134	112
PVA		6093	5897	4455	6244

Question 3. Would you check femoral angiogram before Impella 2.5 insertion?

1. Yes

2. No





Question 4. What size guide catheter would you use?

- A. 5 French**
- B. 6 French**
- C. 7 French**
- D. 8 French**

CTO basics

1. Approach: femoral – consider **45 cm sheath**

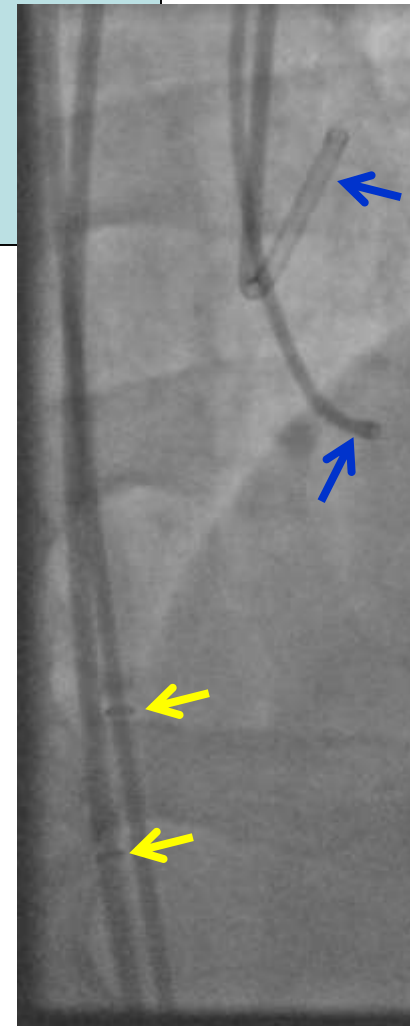
2. Guide: **8 French** – support short/shortened **90 cm**

3. Virtually always: **dual injections**

4. Anticoagulation: **heparin**

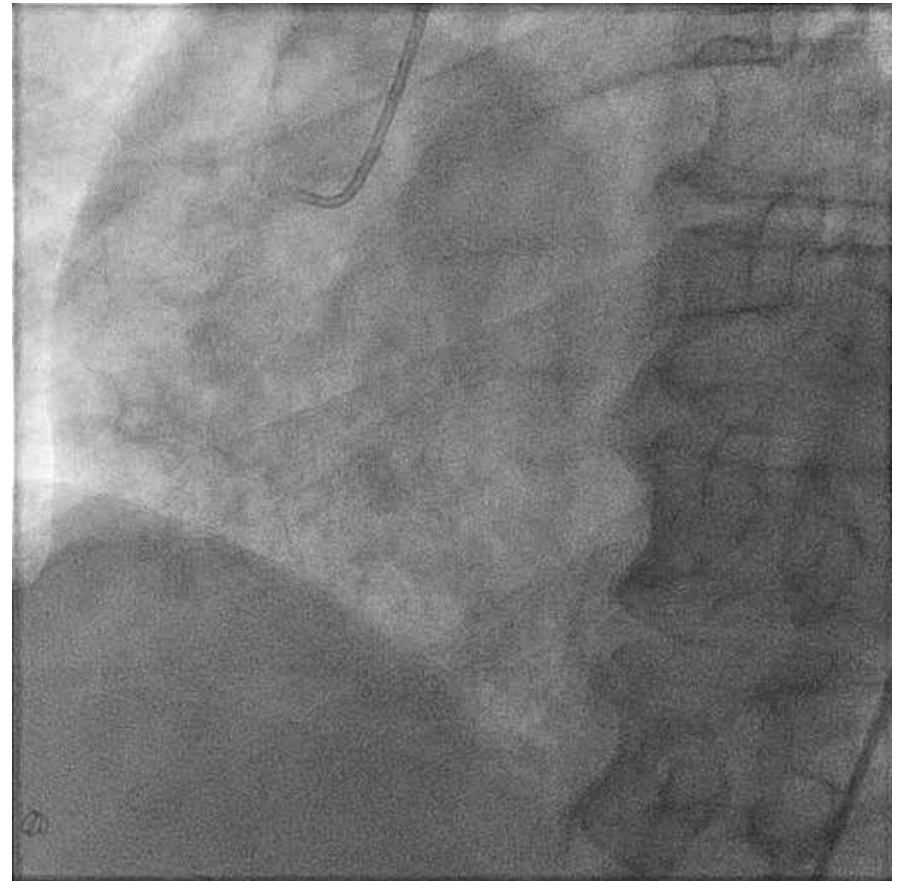
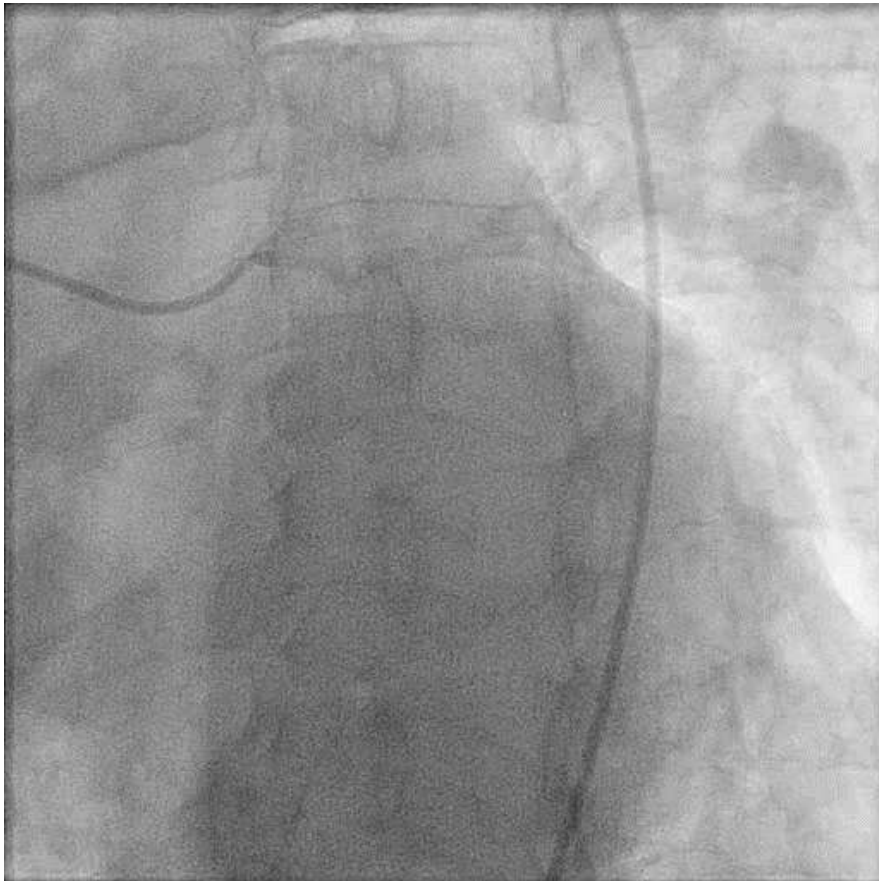
5. Monitor radiation: **AK**

6. Ready to manage complications: **perforation - tamponade**

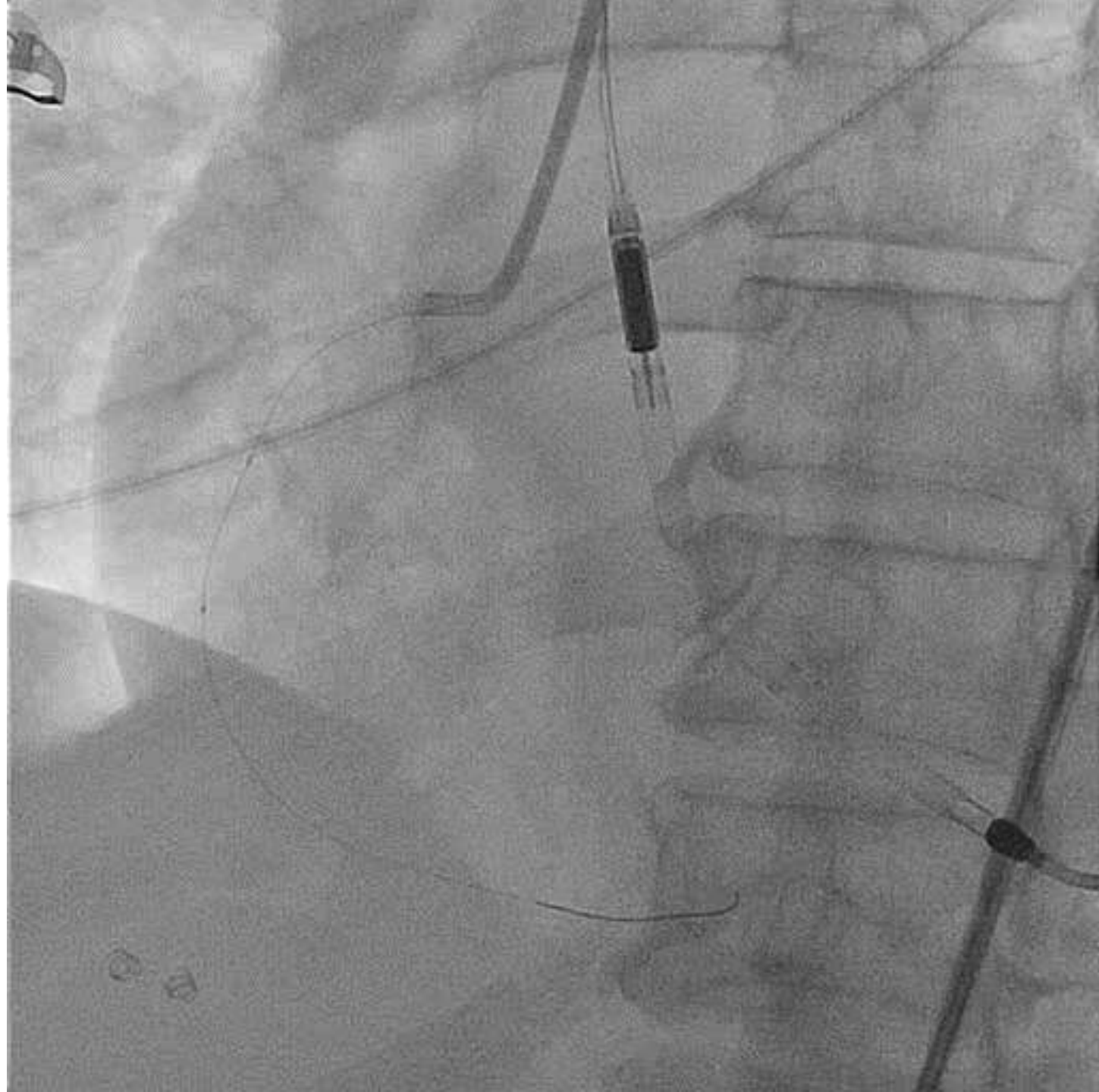


Question 5. Which vessel first?

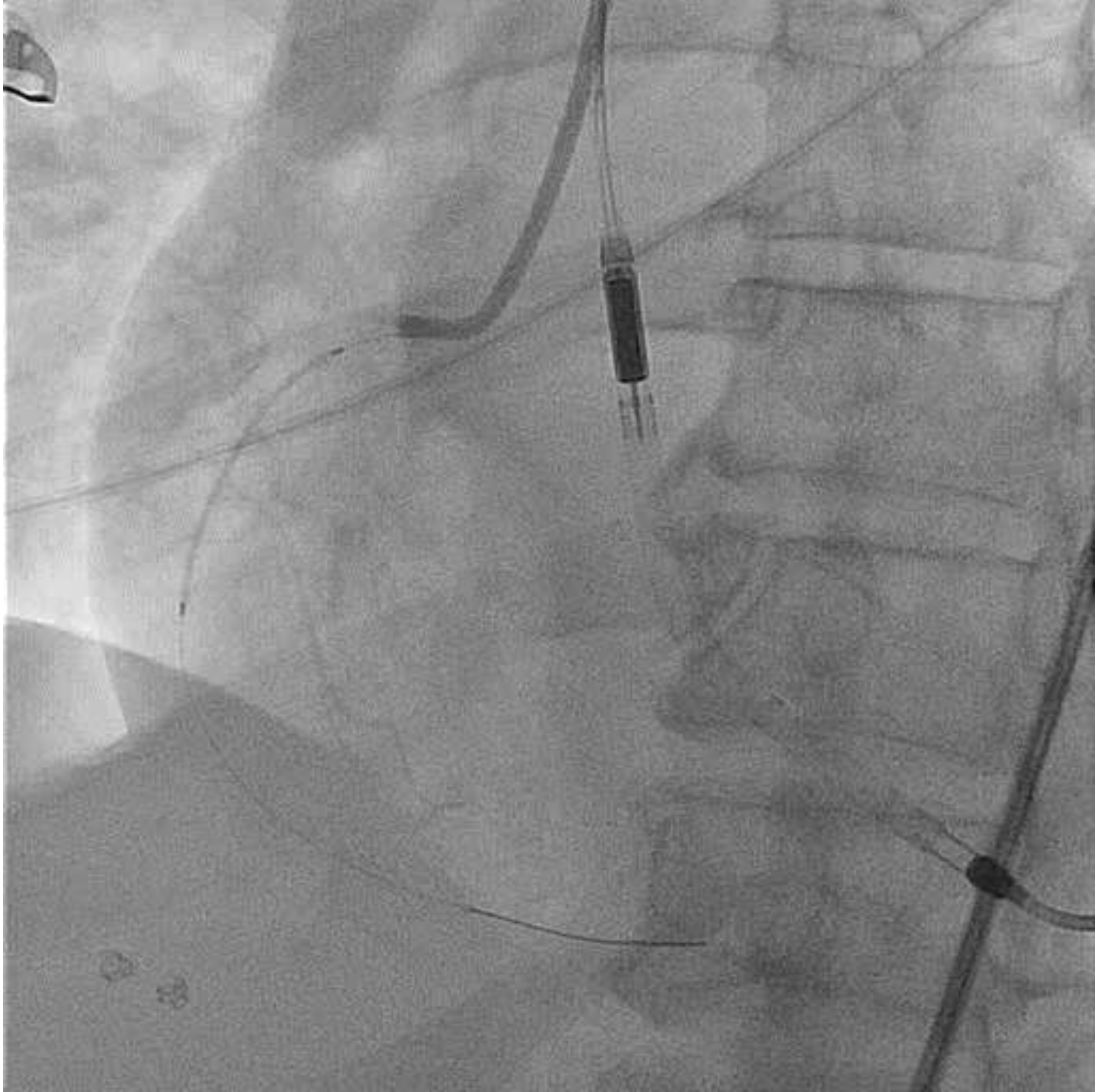
1. LAD - 2. Circumflex - 3. RCA



**RCA
crossing –
Asahi soft**

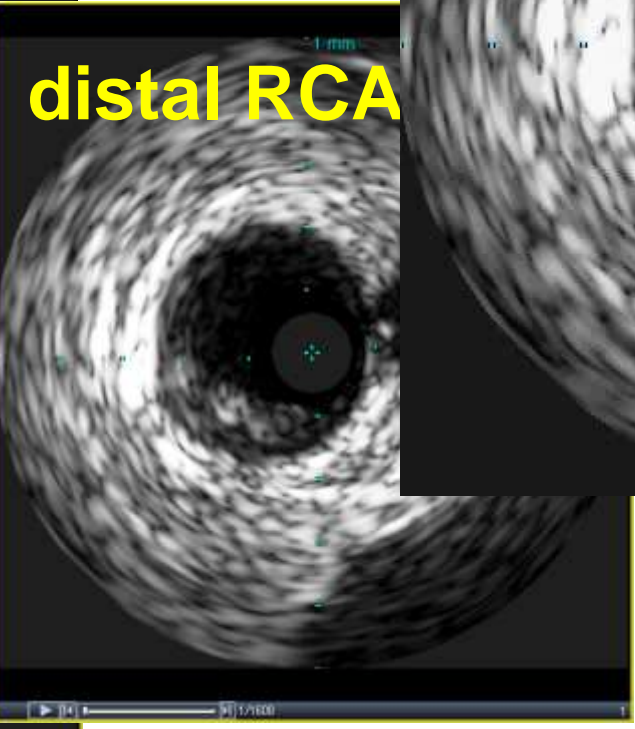
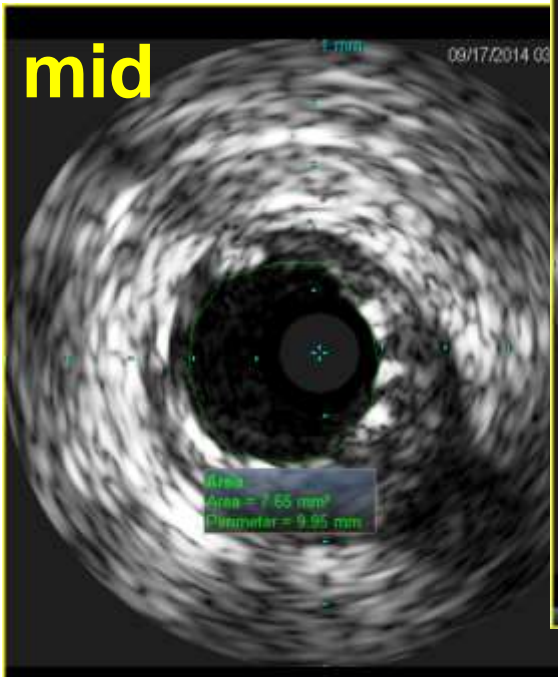
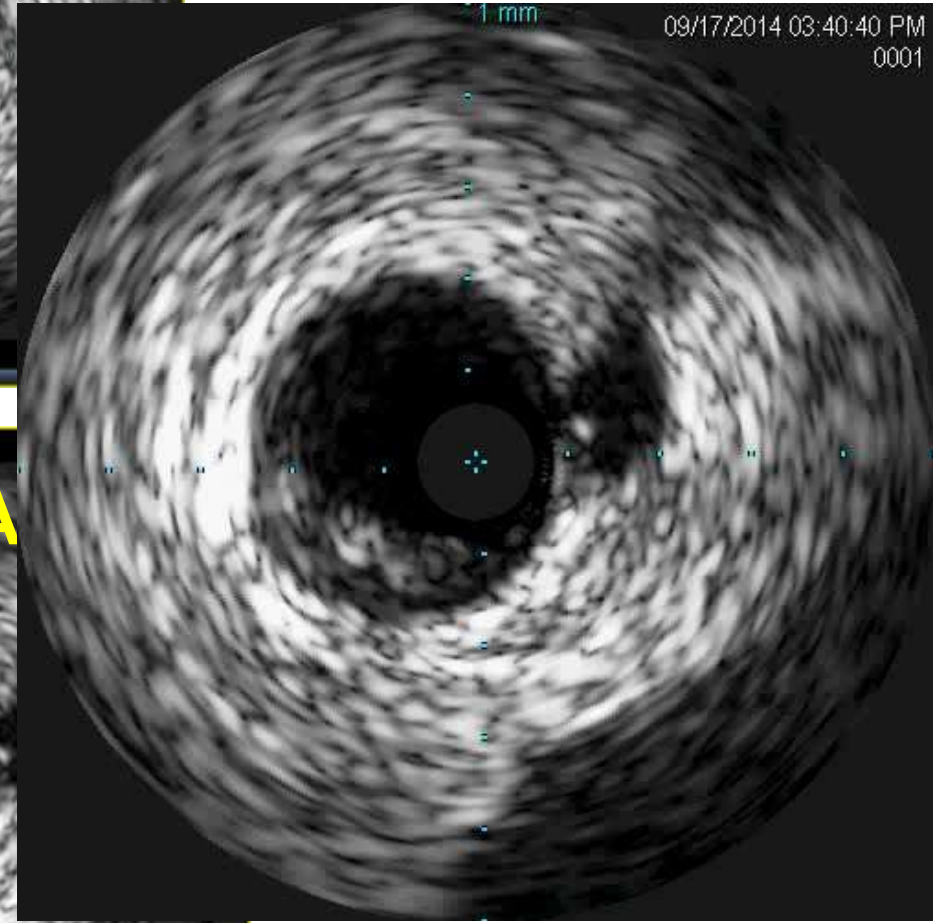
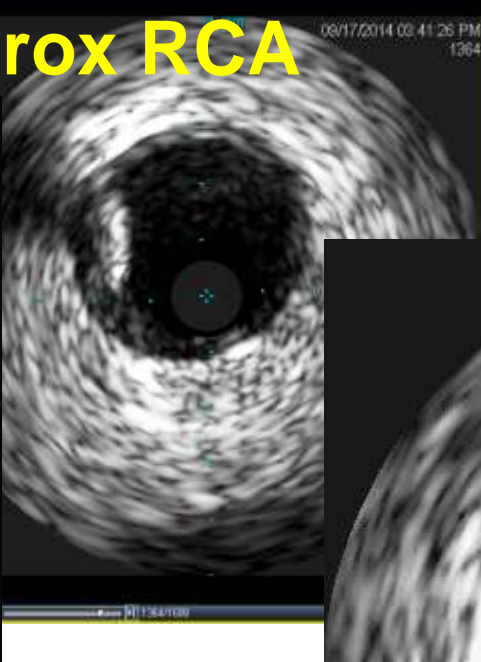


**3.0x38 mm
DES**

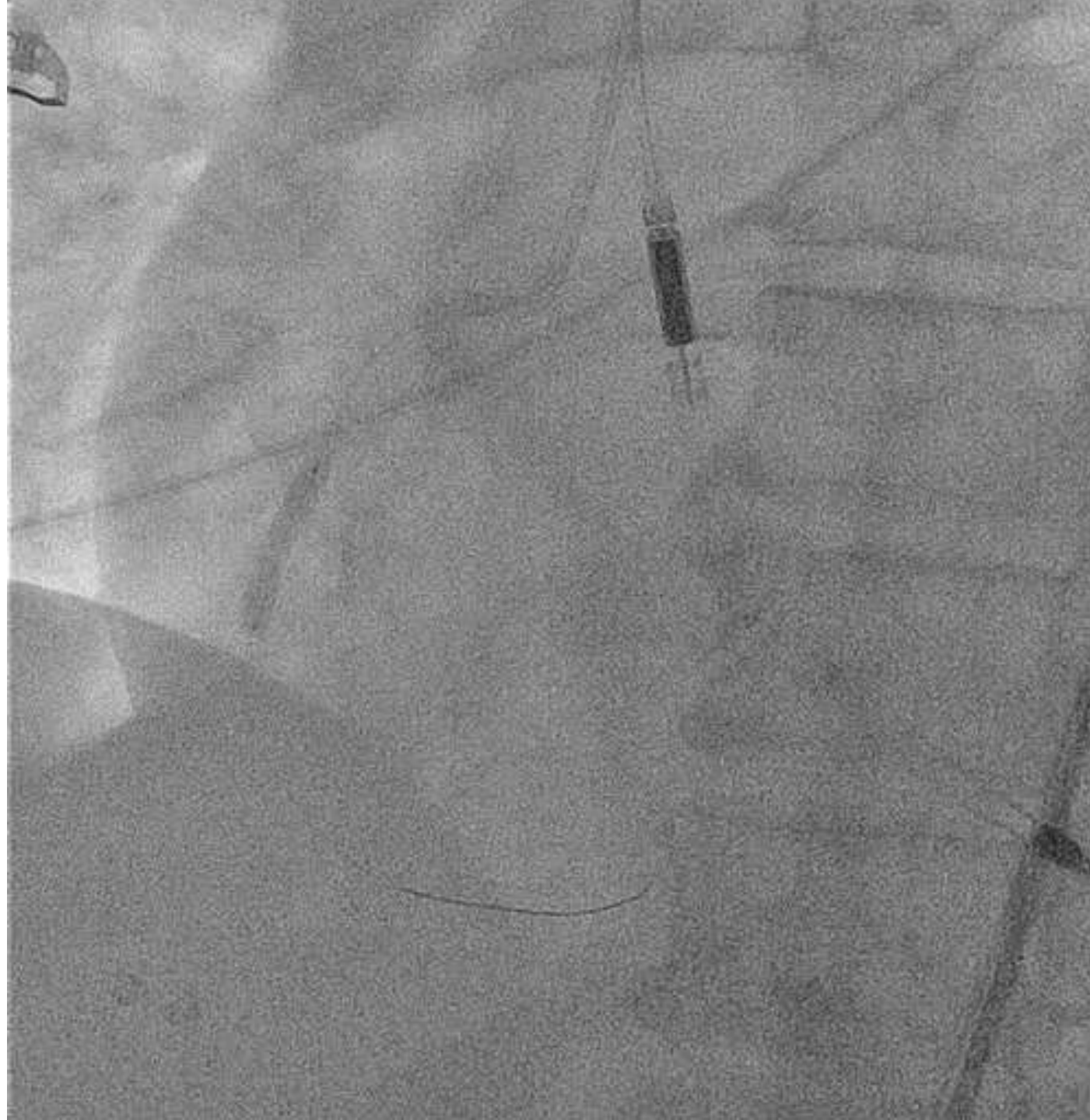


underexpansion prox RCA

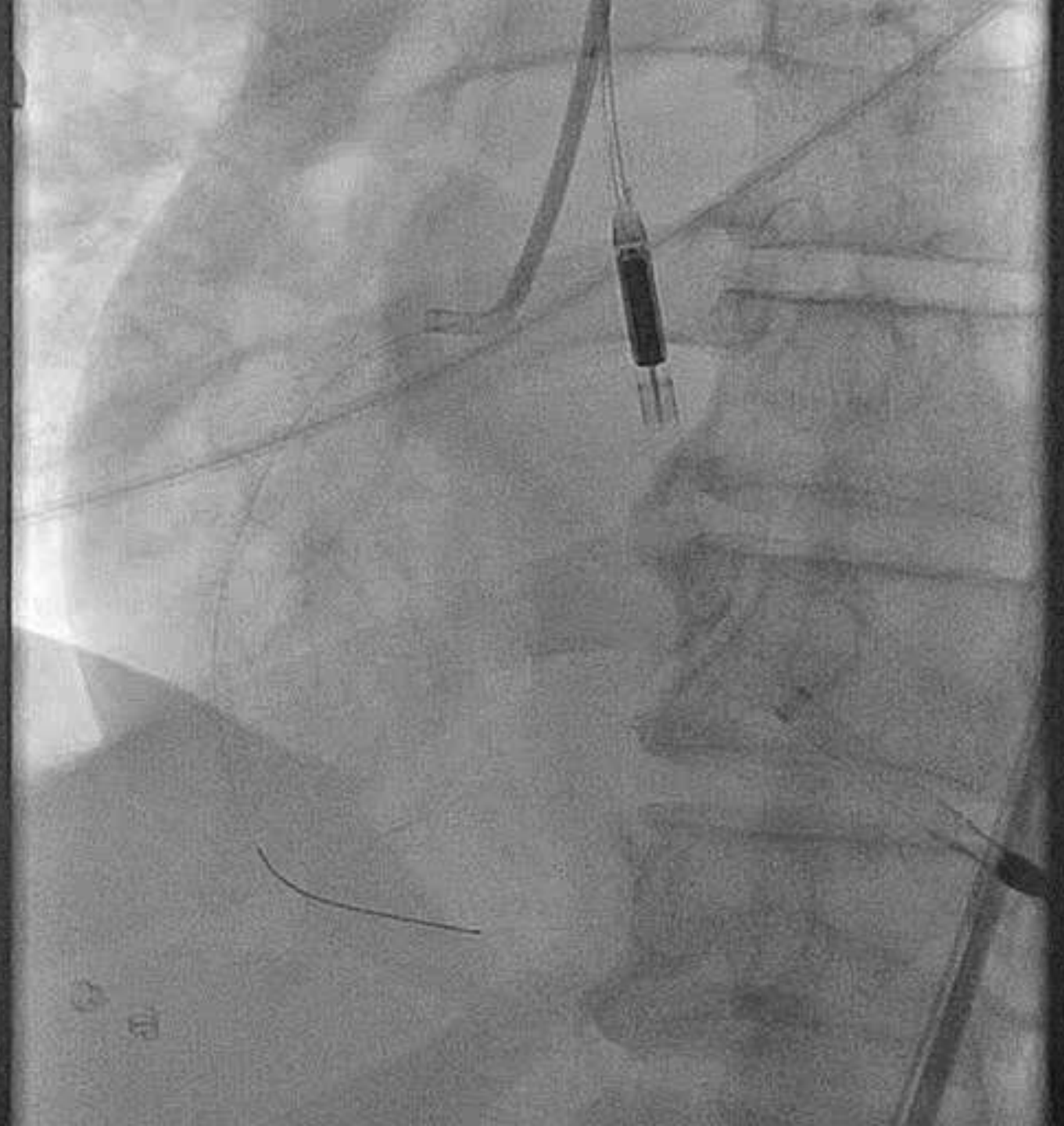
09/17/2014 03:41:26 PM
1364



**Multiple
high-
pressure
postdilations**

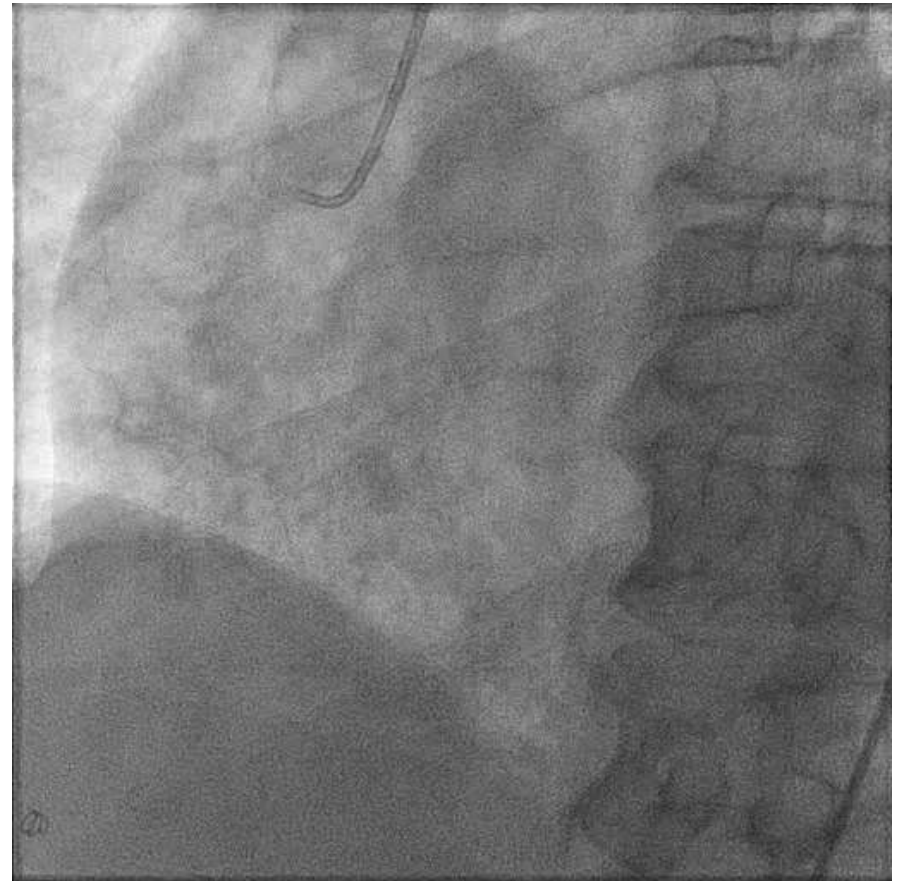
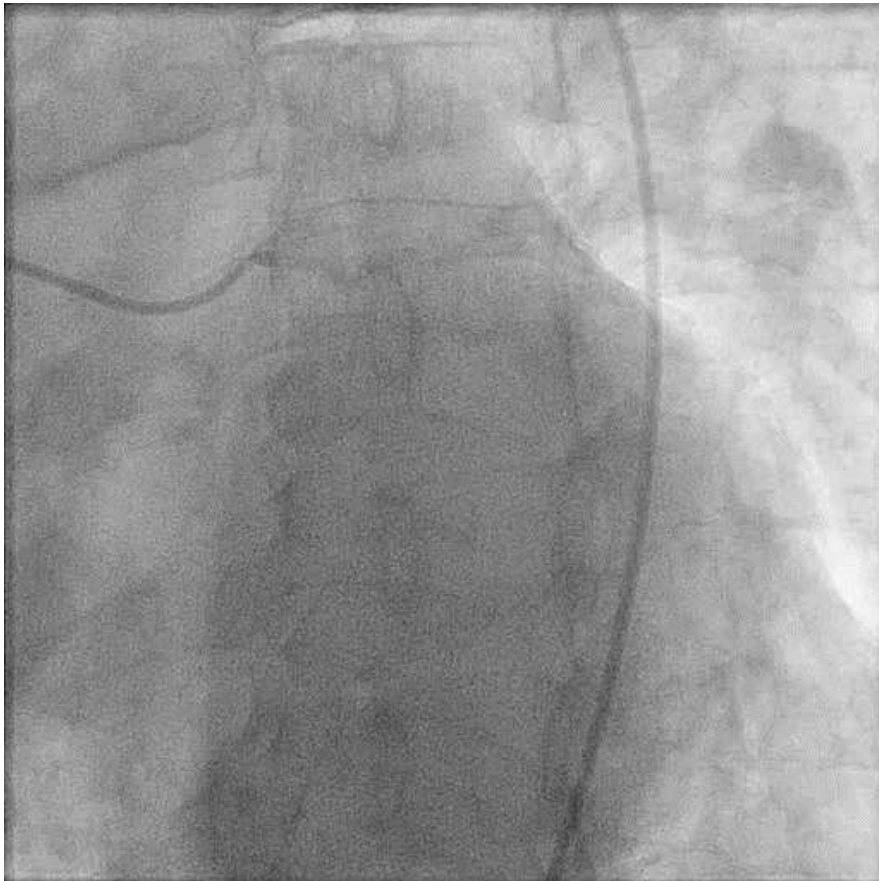


RCA final

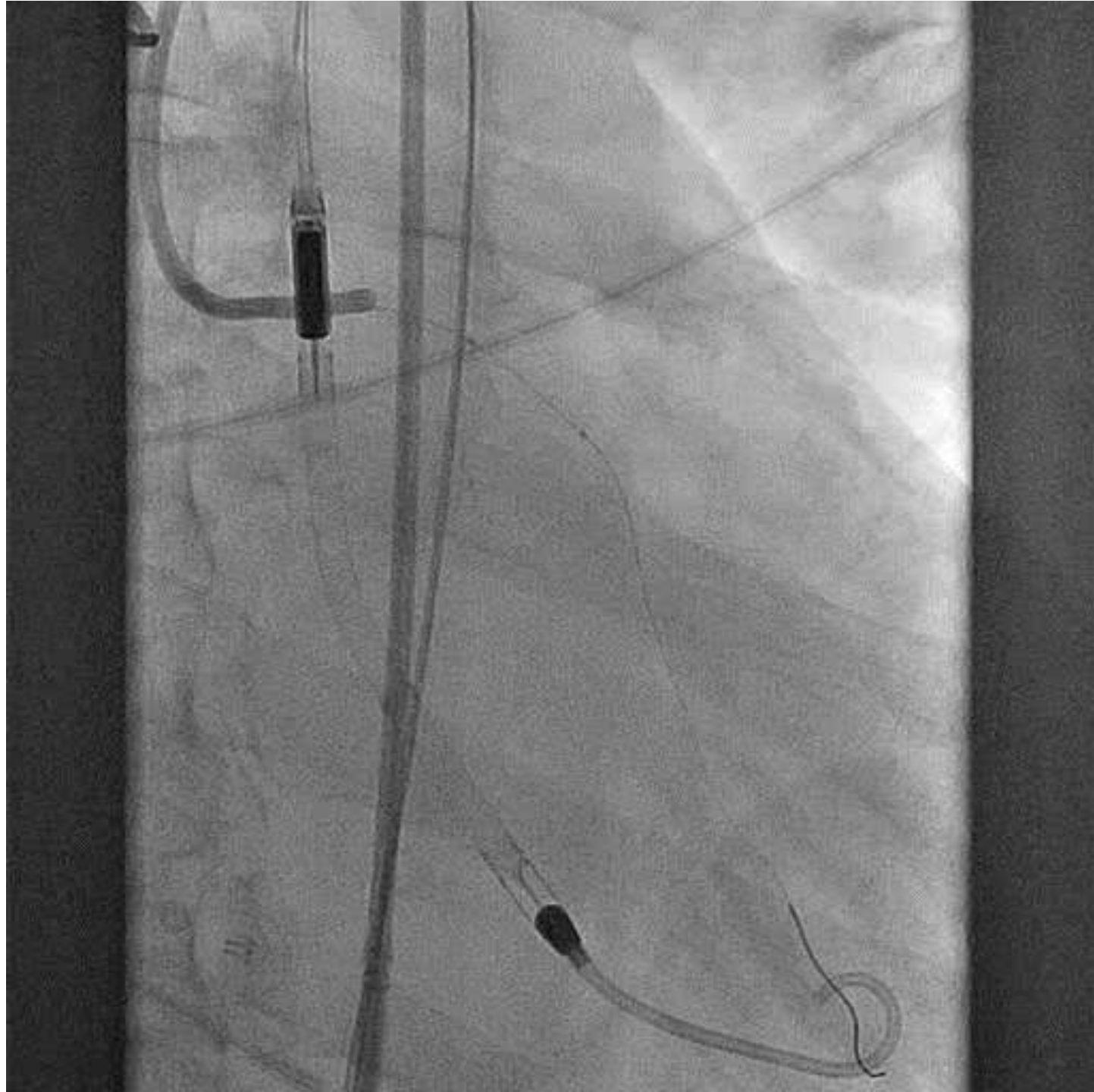


Question 6. Which vessel next?

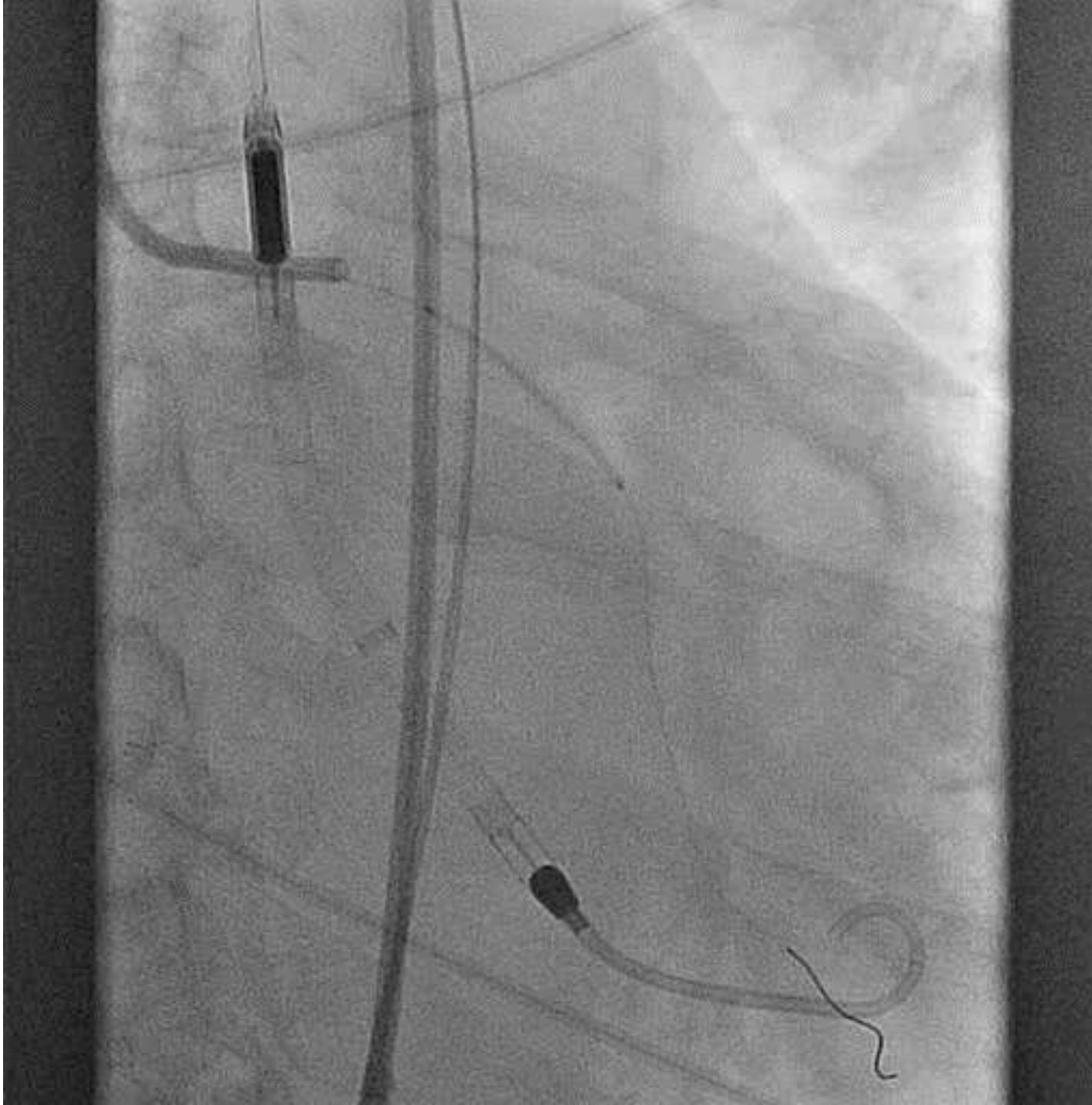
1. LAD - 2. Circumflex



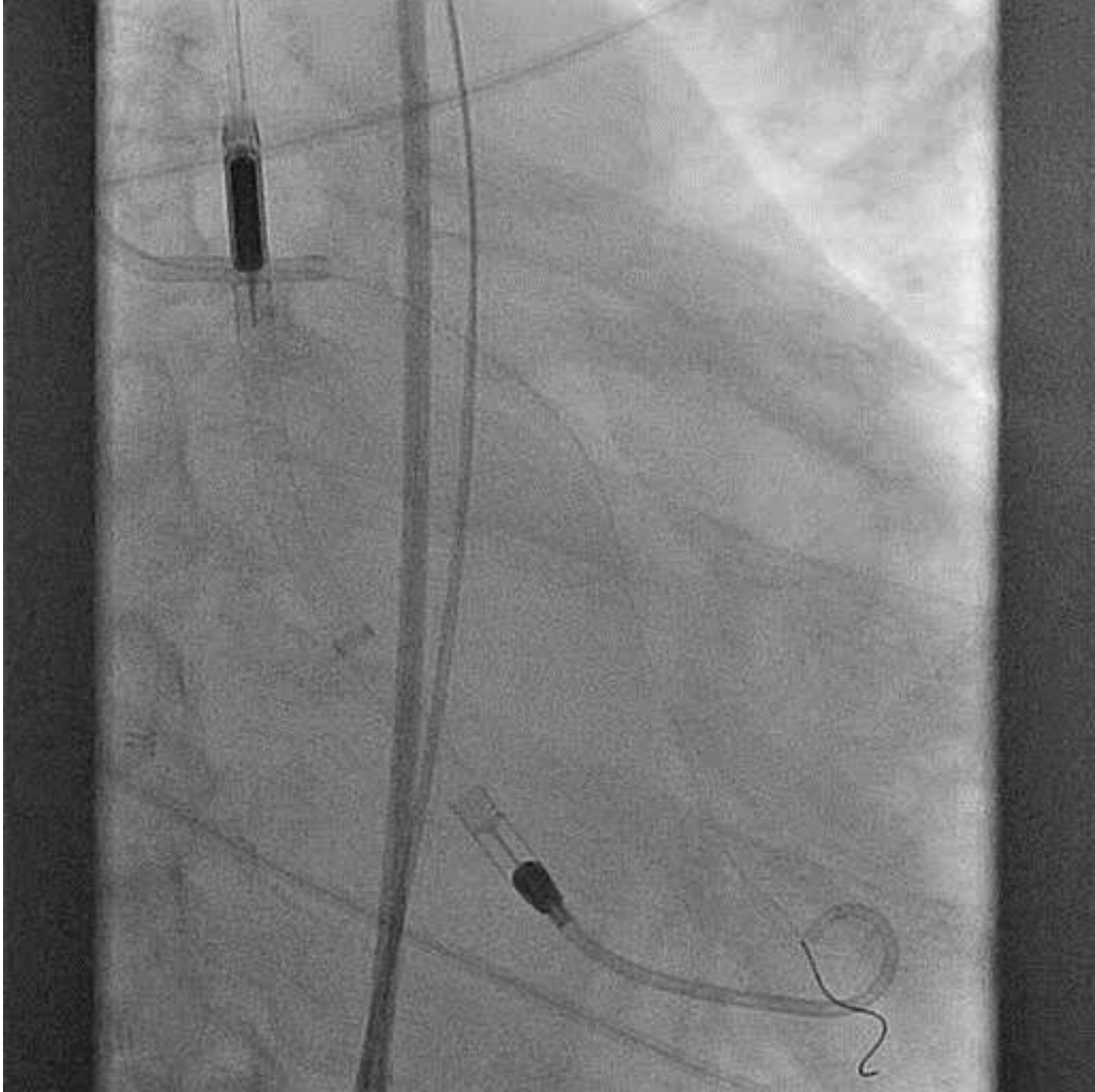
Circumflex wiring



**2.75x28 mm
DES**



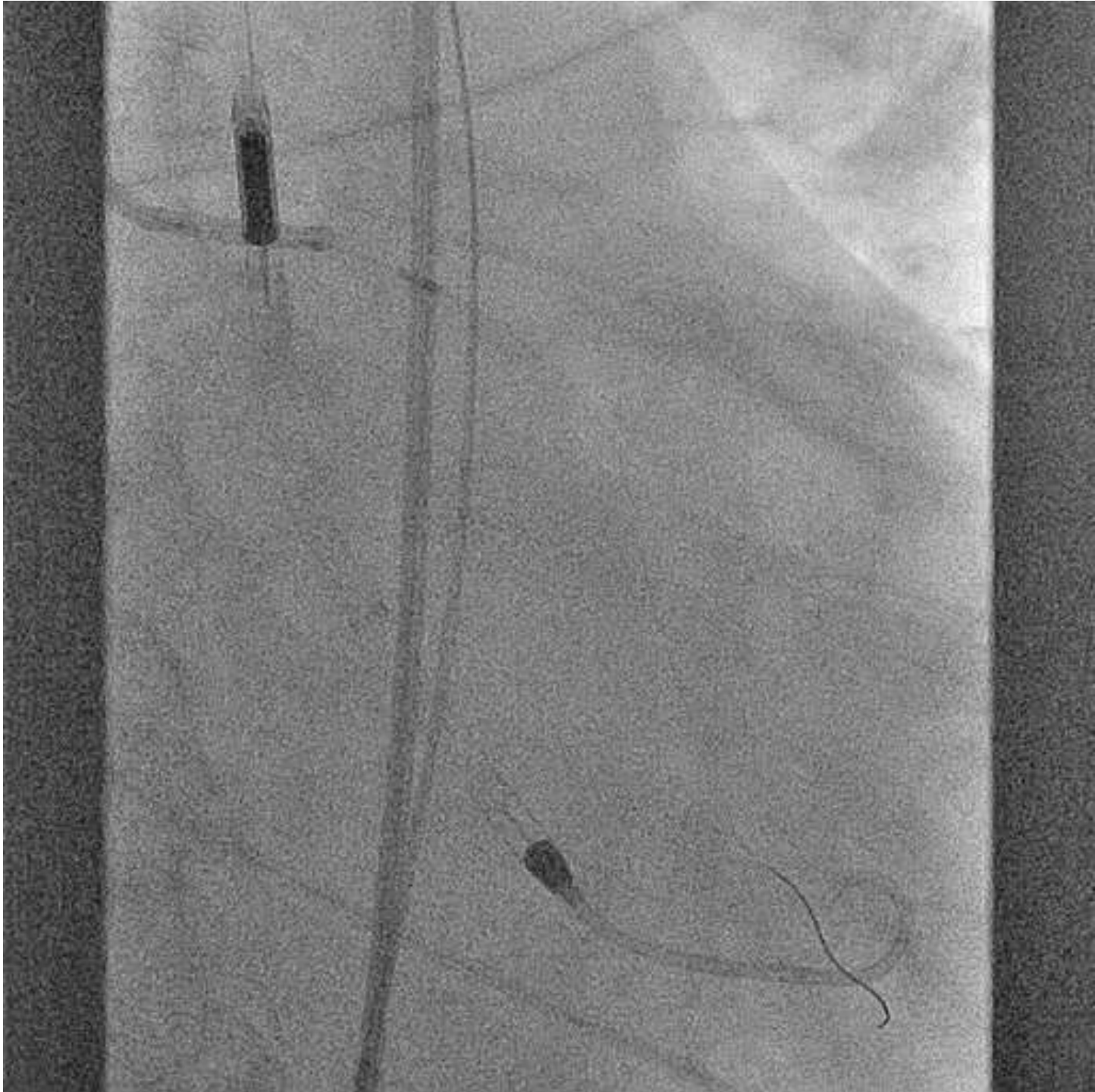
Post stent



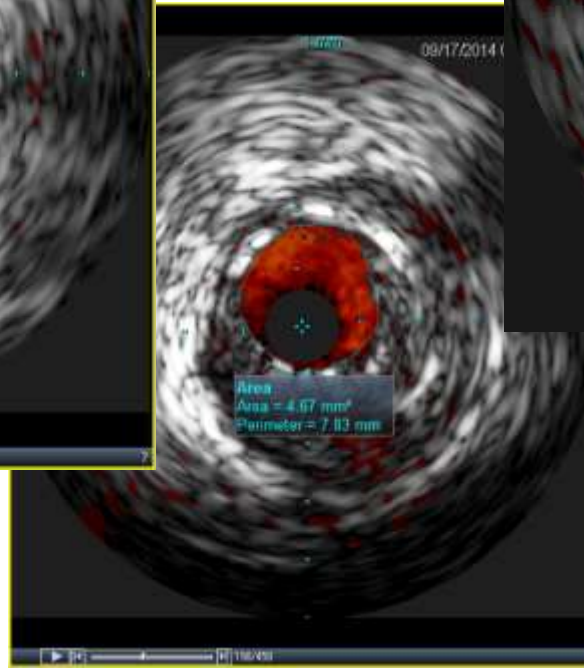
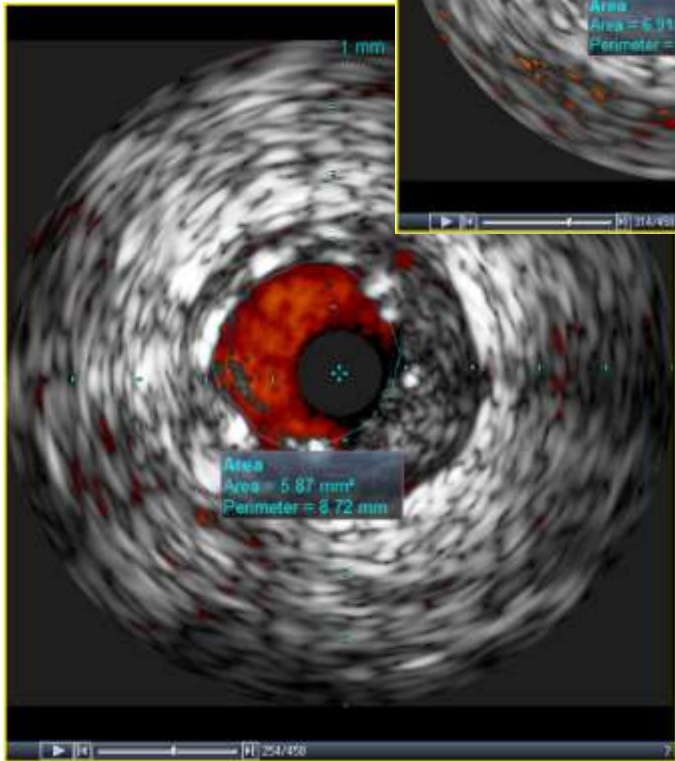
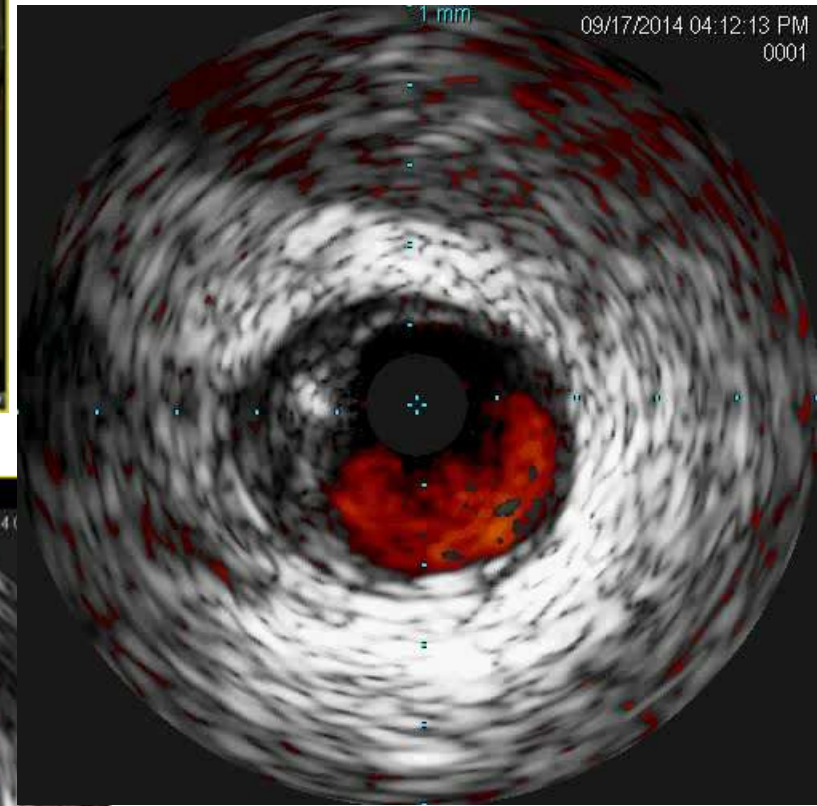
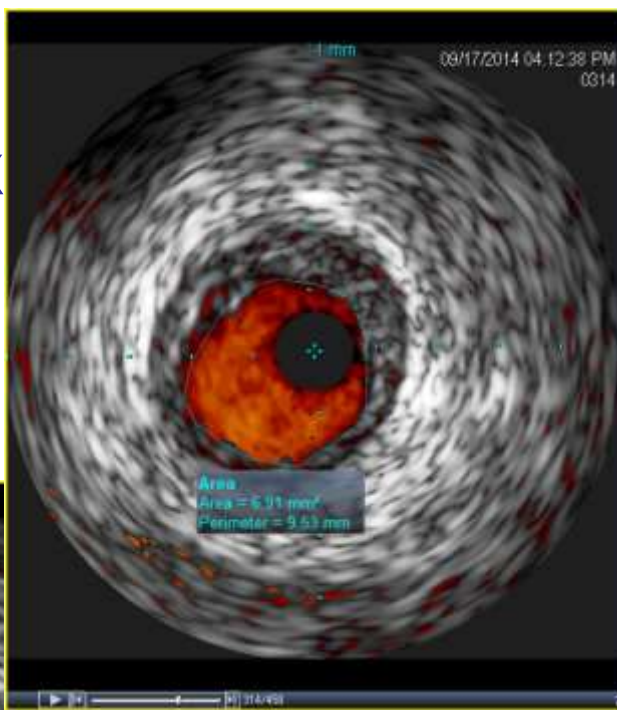
Question 7. What next?

- A. Call it a day**
- B. LAD PCI**
- C. IVUS**
- D. FFR**

IVUS



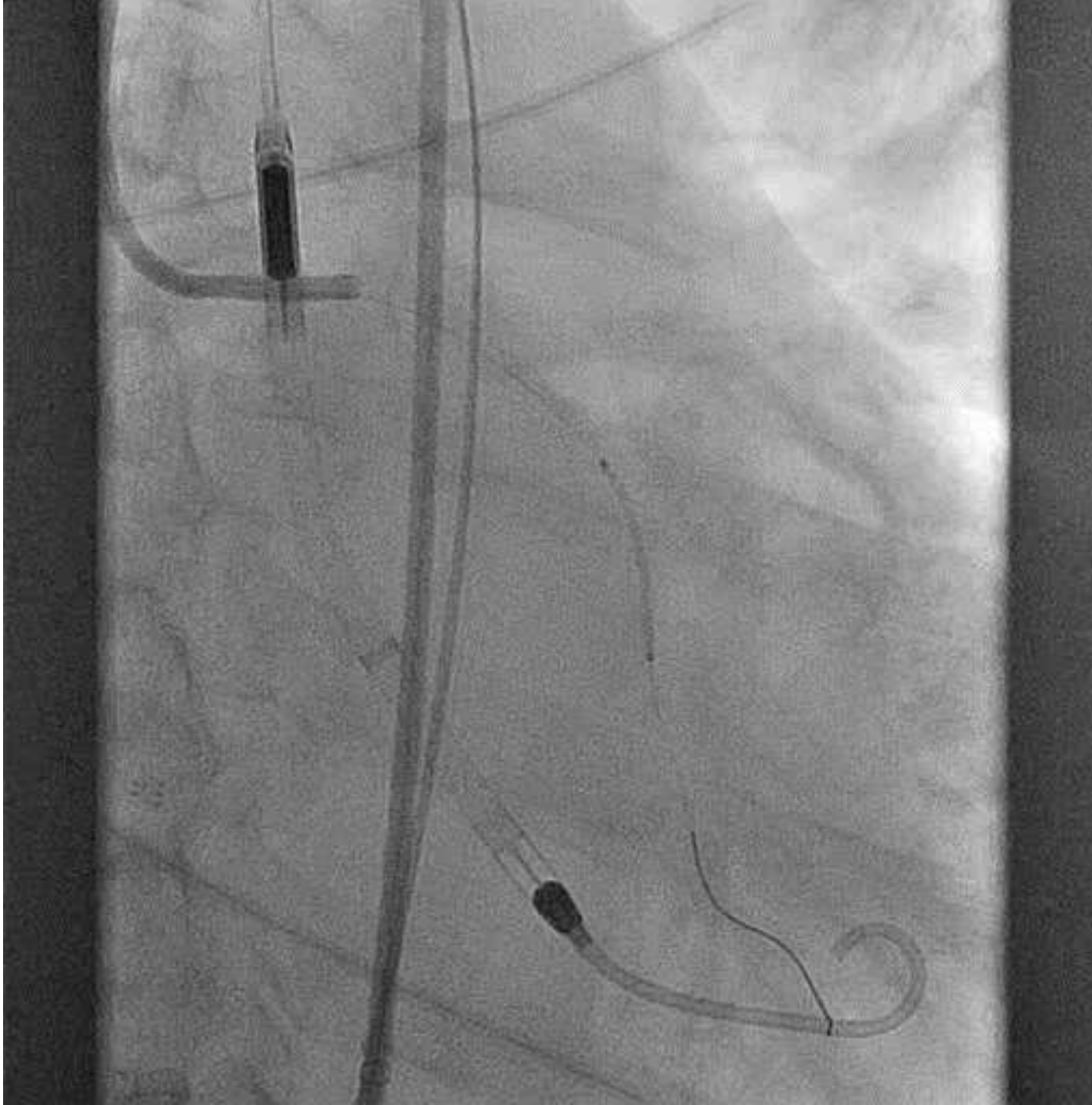
circumflex



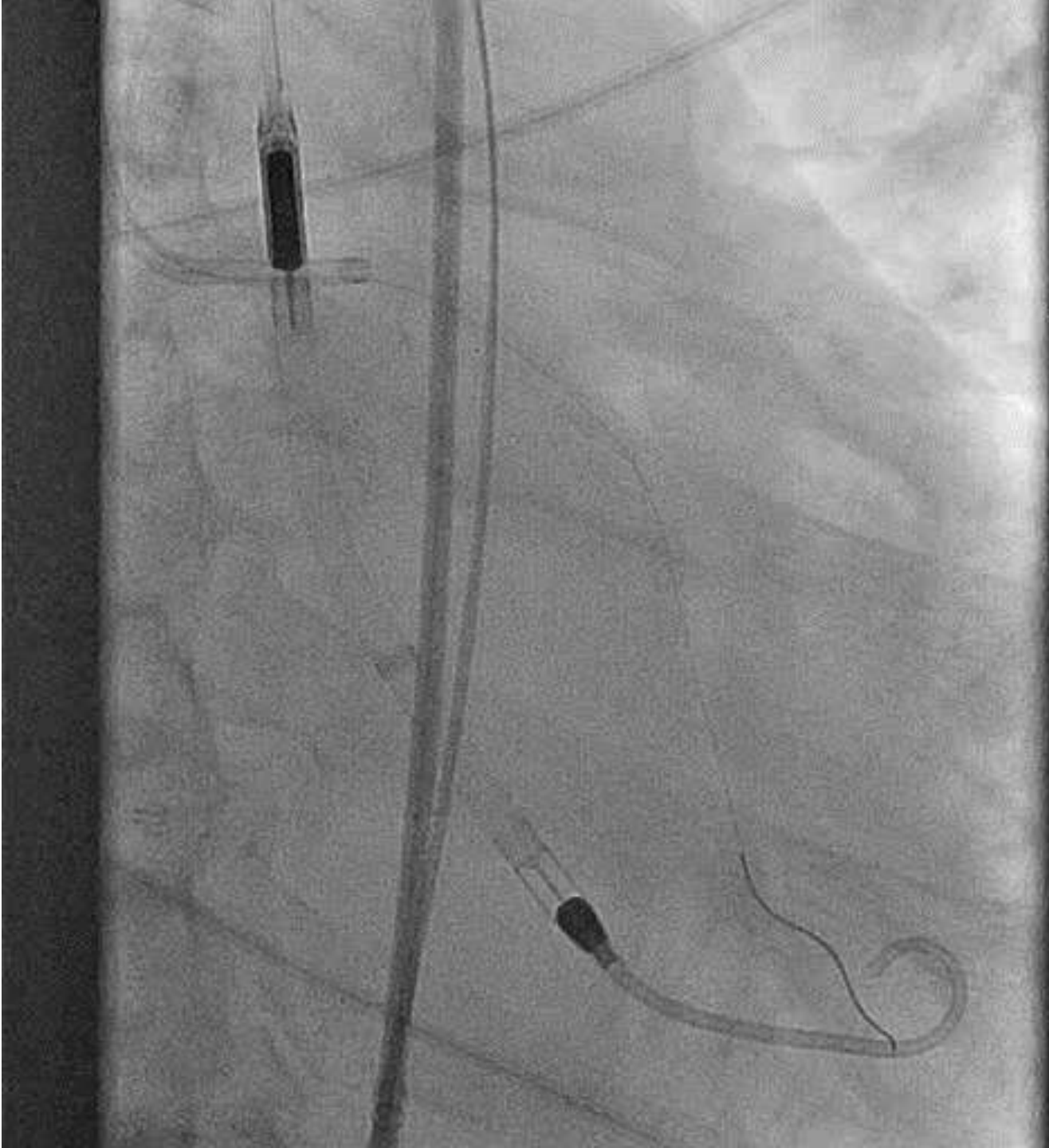
**Multiple
high-
pressure
postdilations**



**2.75x23 mm
DES**



**Circumflex
final**

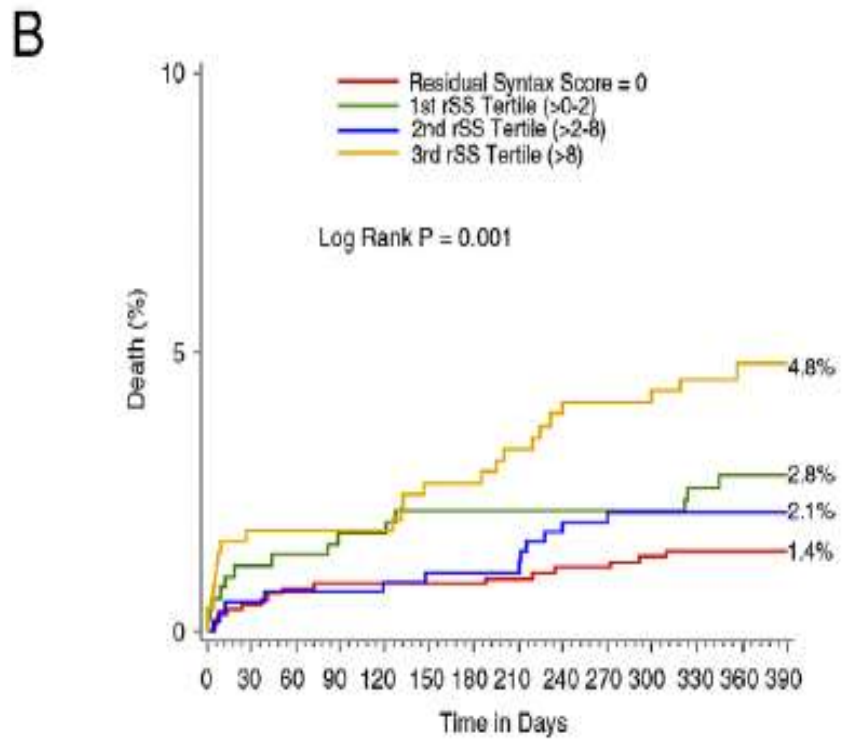


**Question 8. Would you fix the
LAD?**

A. YES

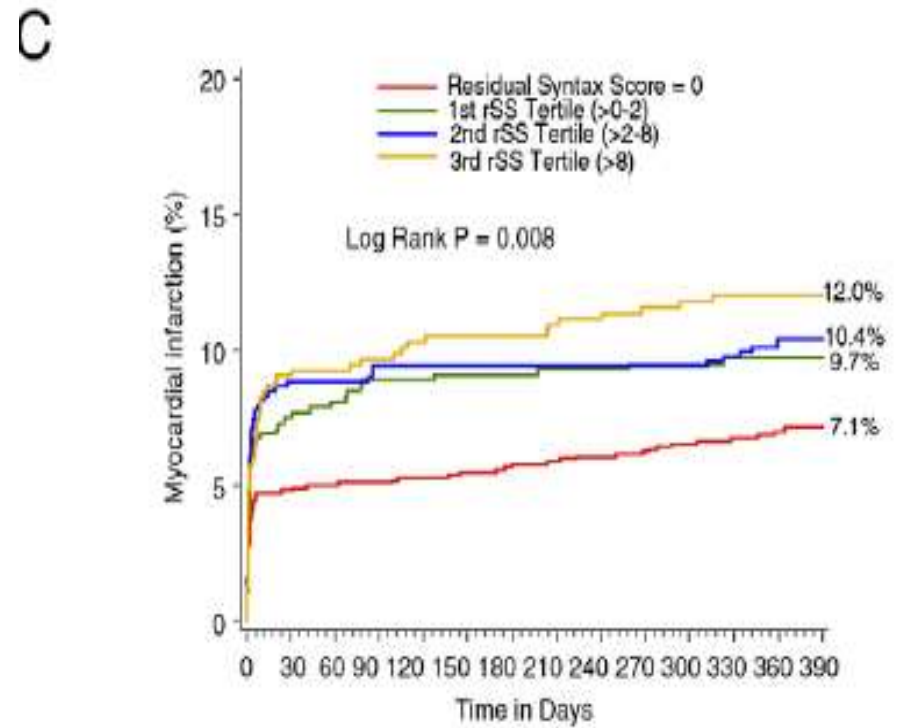
B. NO

Why complete?



Number at Risk:

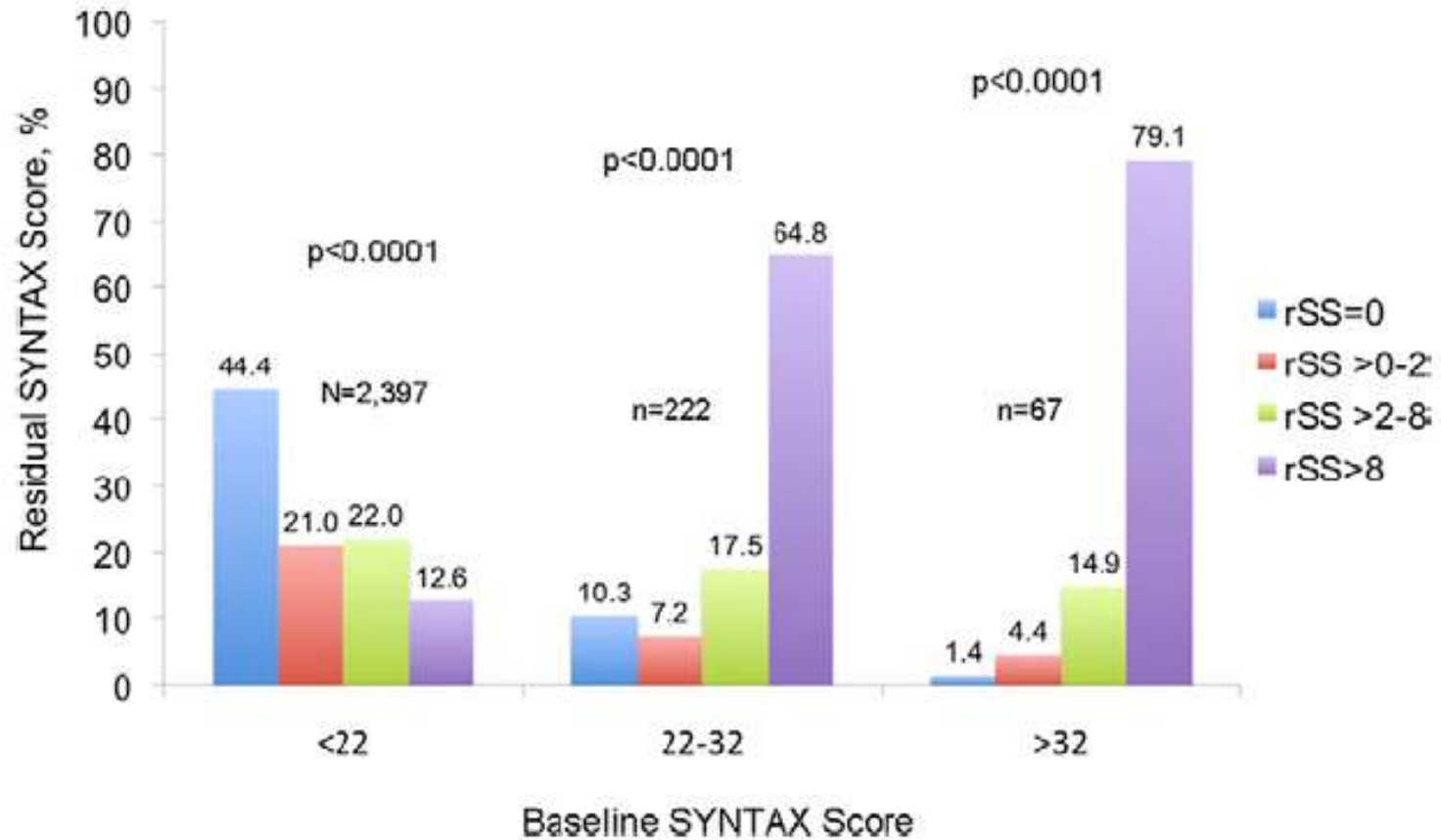
rSS = 0	1084	1047	1044	1038	756
1st rSS Tertile	523	494	490	486	355
2nd rSS Tertile	578	558	555	549	408
3rd rSS Tertile	501	473	469	460	330



Number at Risk:

rSS = 0	1084	995	986	975	709
1st rSS Tertile	523	455	453	449	327
2nd rSS Tertile	578	506	504	500	368
3rd rSS Tertile	501	430	425	414	299

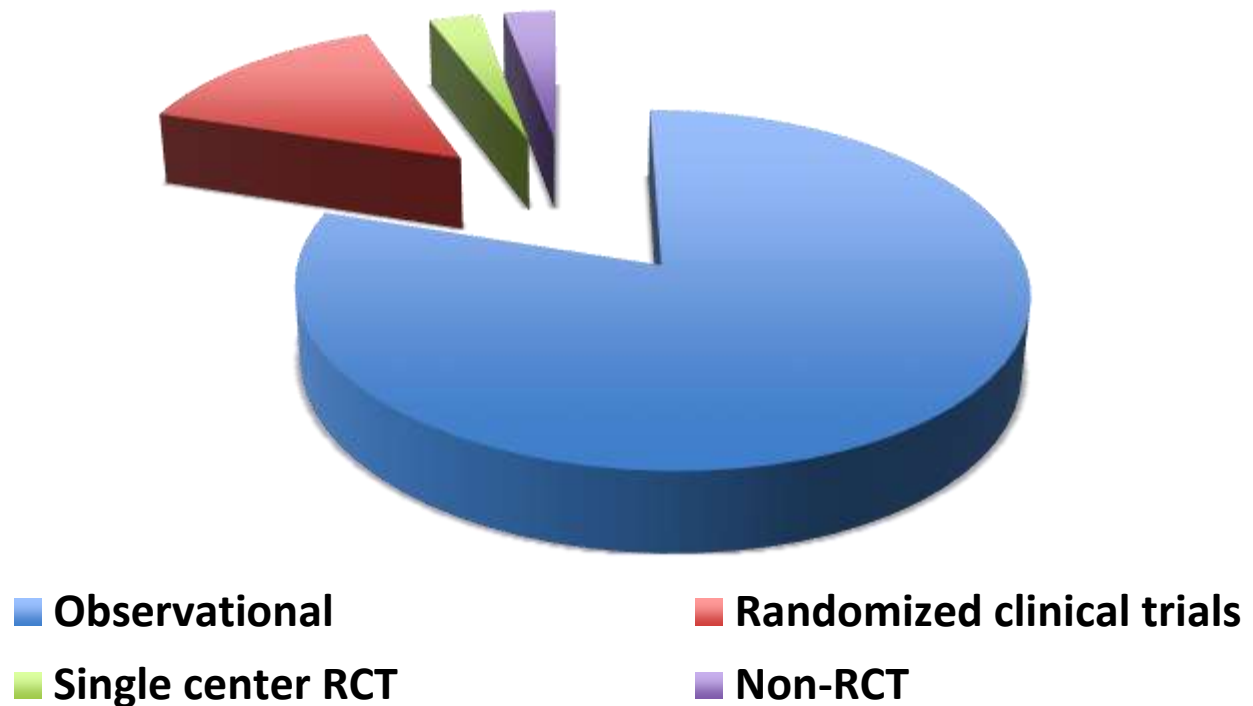
Completeness of PCI in SYNTAX



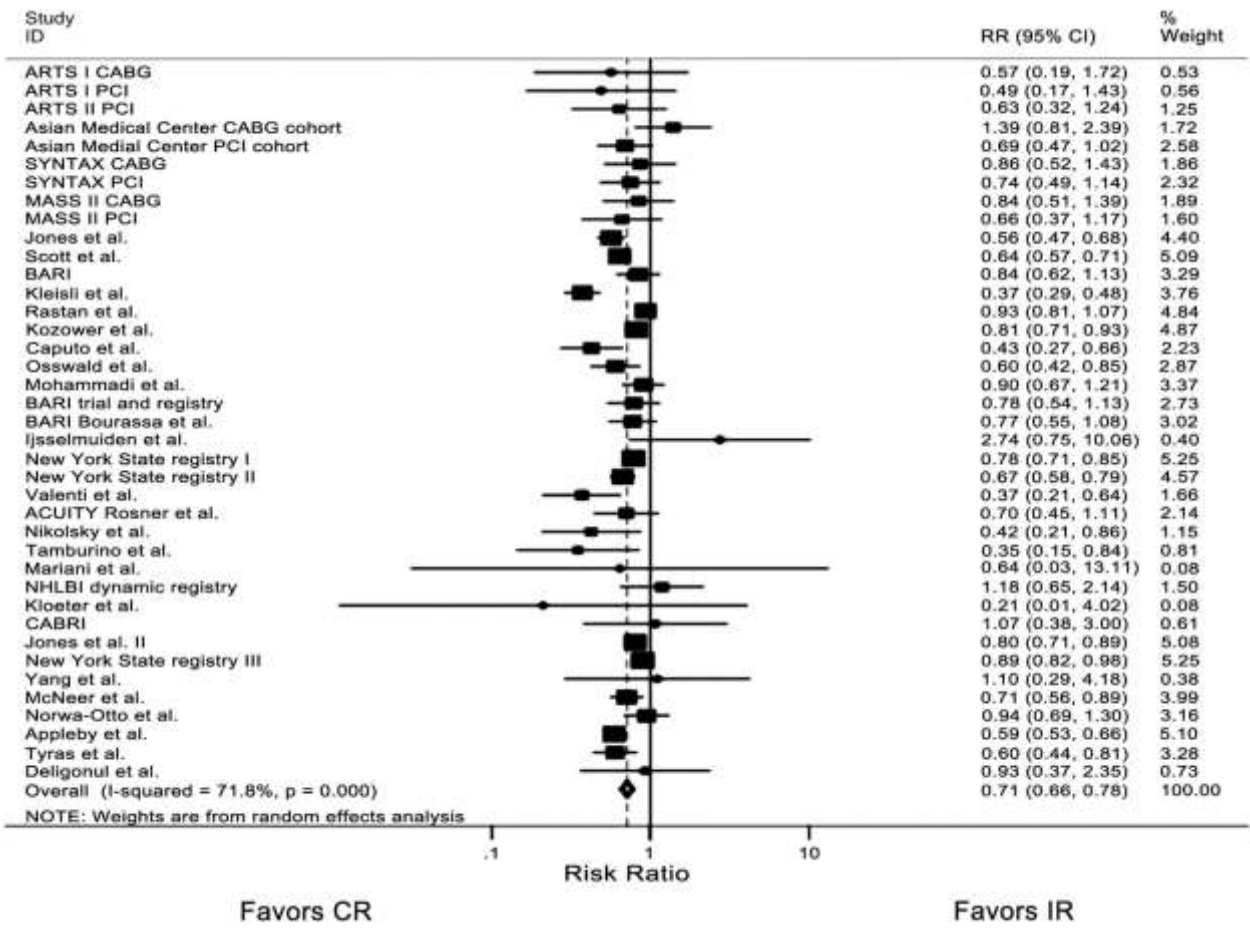
Outcomes After Complete Versus Incomplete Revascularization of Patients With Multivessel Coronary Artery Disease

A Meta-Analysis of 89,883 Patients Enrolled in Randomized Clinical Trials and Observational Studies

Santiago Garcia, MD,*† Yader Sandoval, MD,‡ Henri Roukoz, MD, MS,† Selcuk Adabag, MD, MS,*† Mariana Canoniero, MD,§ Demetris Yannopoulos, MD,† Emmanouil S. Brilakis, MD, PhD||¶
Minneapolis, Minnesota; and Dallas, Texas



Complete vs. incomplete revascularization: Mortality



**12,259 out of
 89,883 (13%) died
 during follow up.**

**Mortality benefit
 did not vary with
 definition of CR.**

RR: 0.71

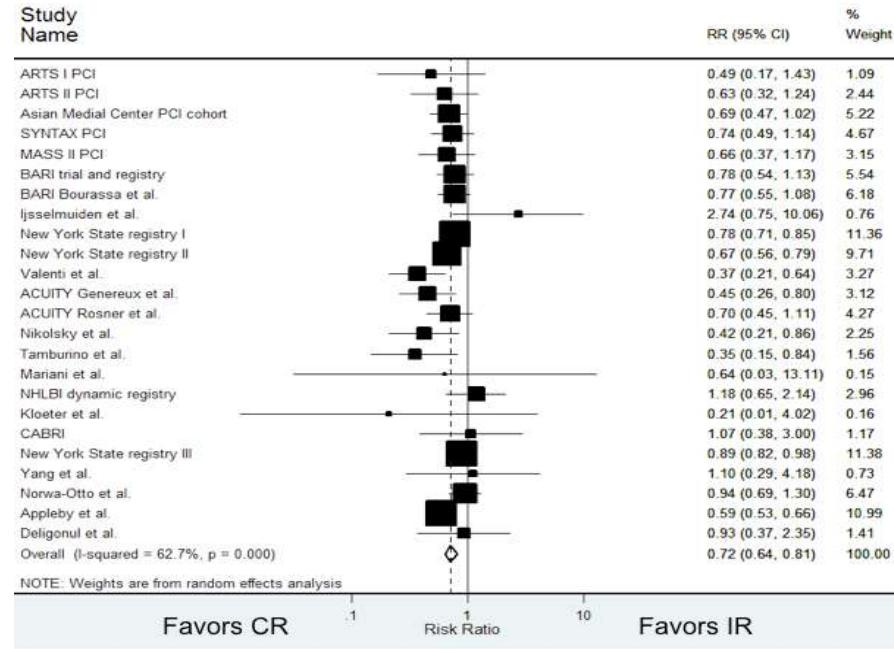
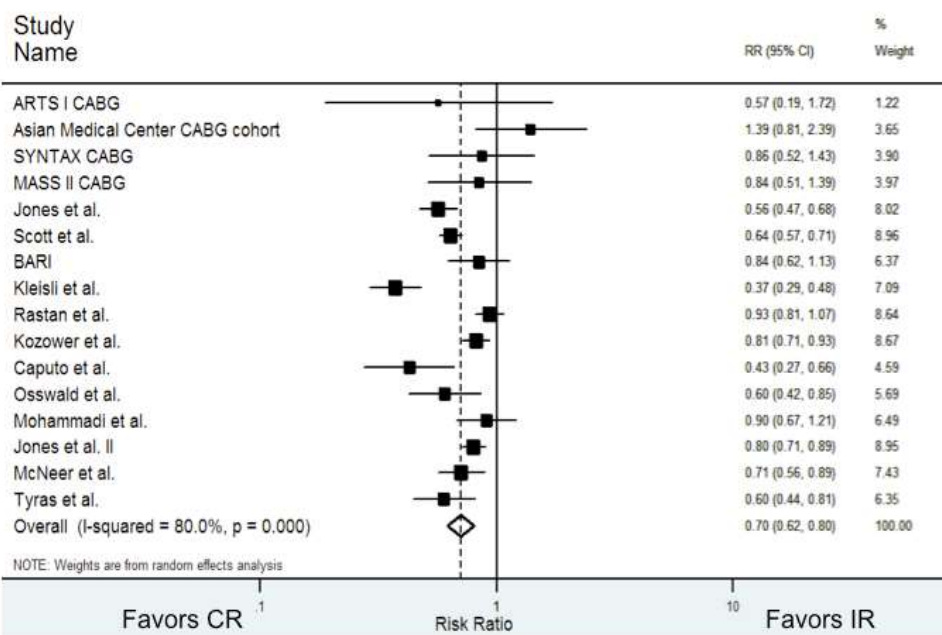
95% CI: 0.65-0.77, p<0.001

Complete vs. incomplete revascularization:

Mortality

CABG

PCI



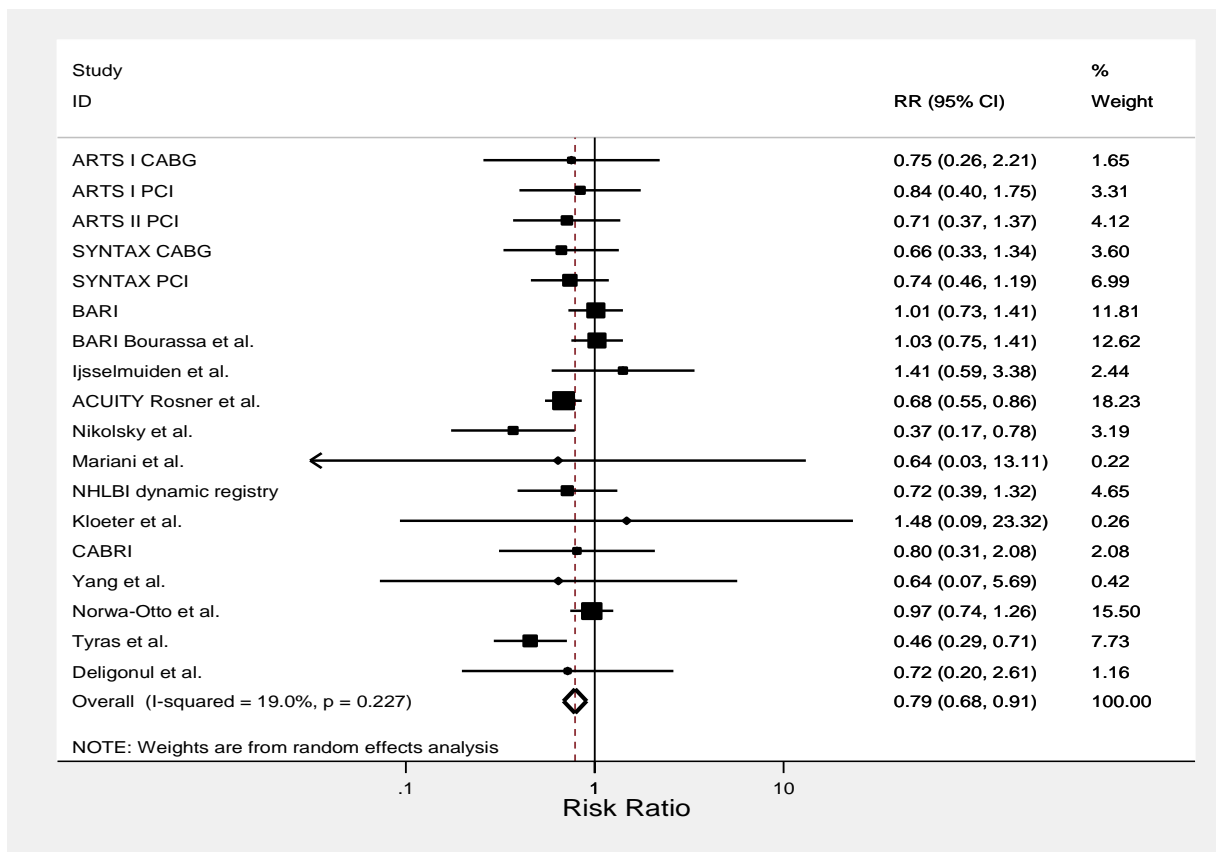
RR: 0.70

RR: 0.72

95% CI: 0.61-0.80, p<0.001

95% CI: 0.64-0.81, P<0.001

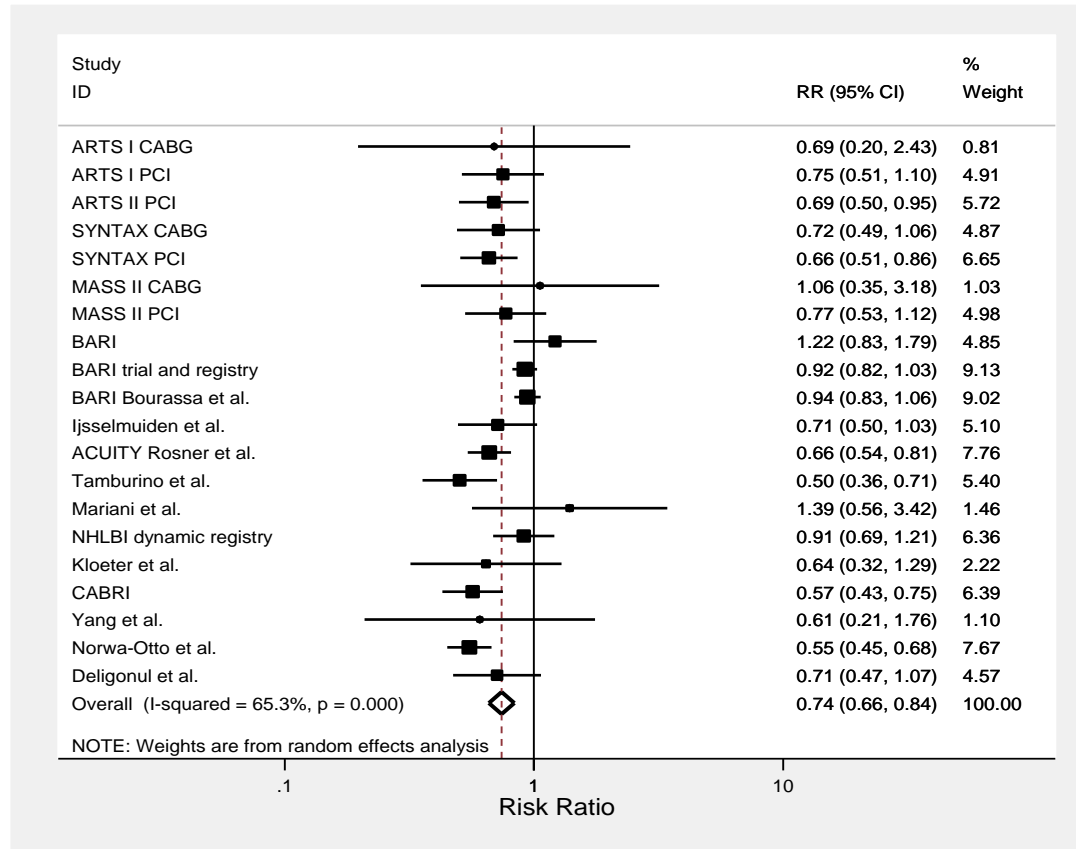
Complete vs. incomplete revascularization: Mortality



RR: 0.78

95% CI: 0.68-0.90, p = 0.001

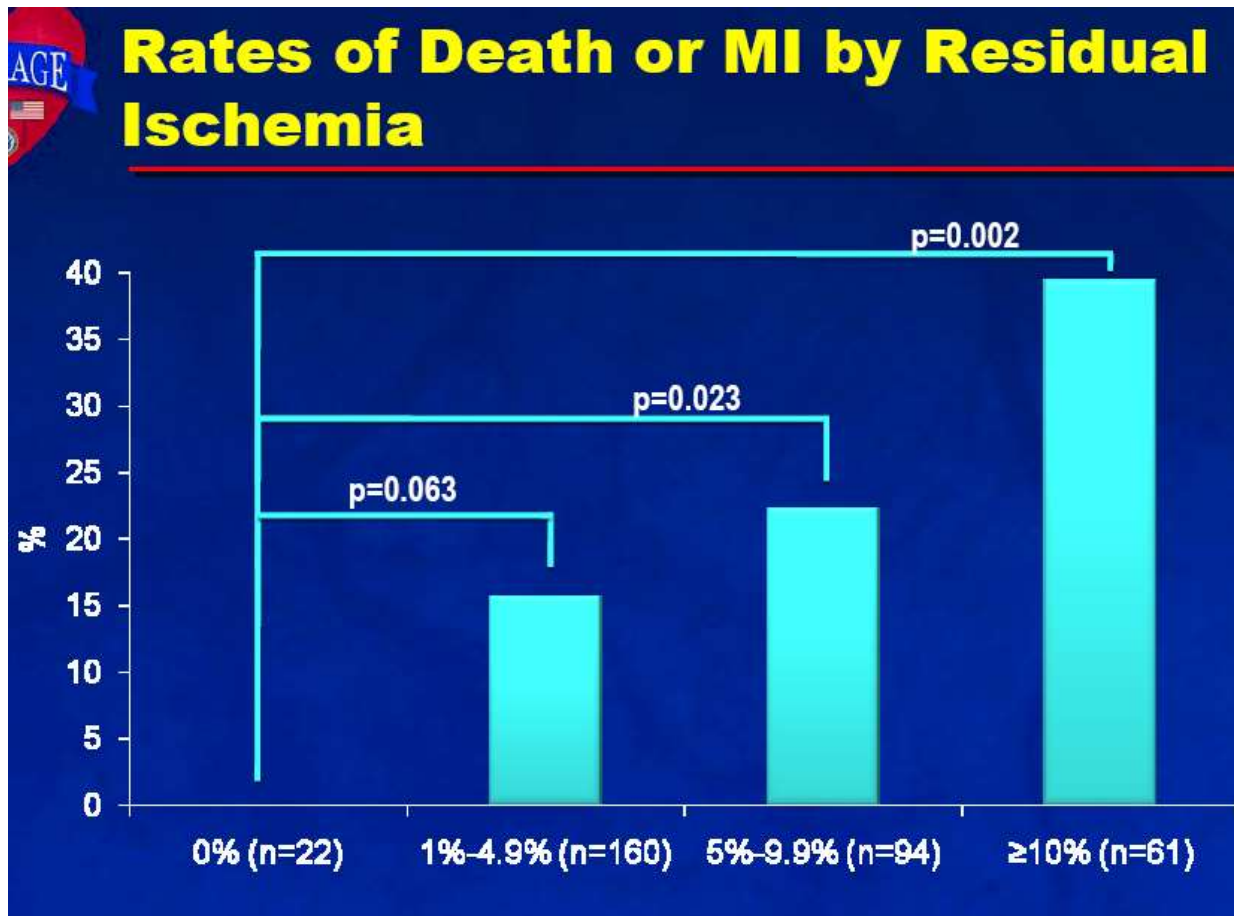
Complete vs. incomplete revascularization: Repeat Revascularization



RR: 0.74

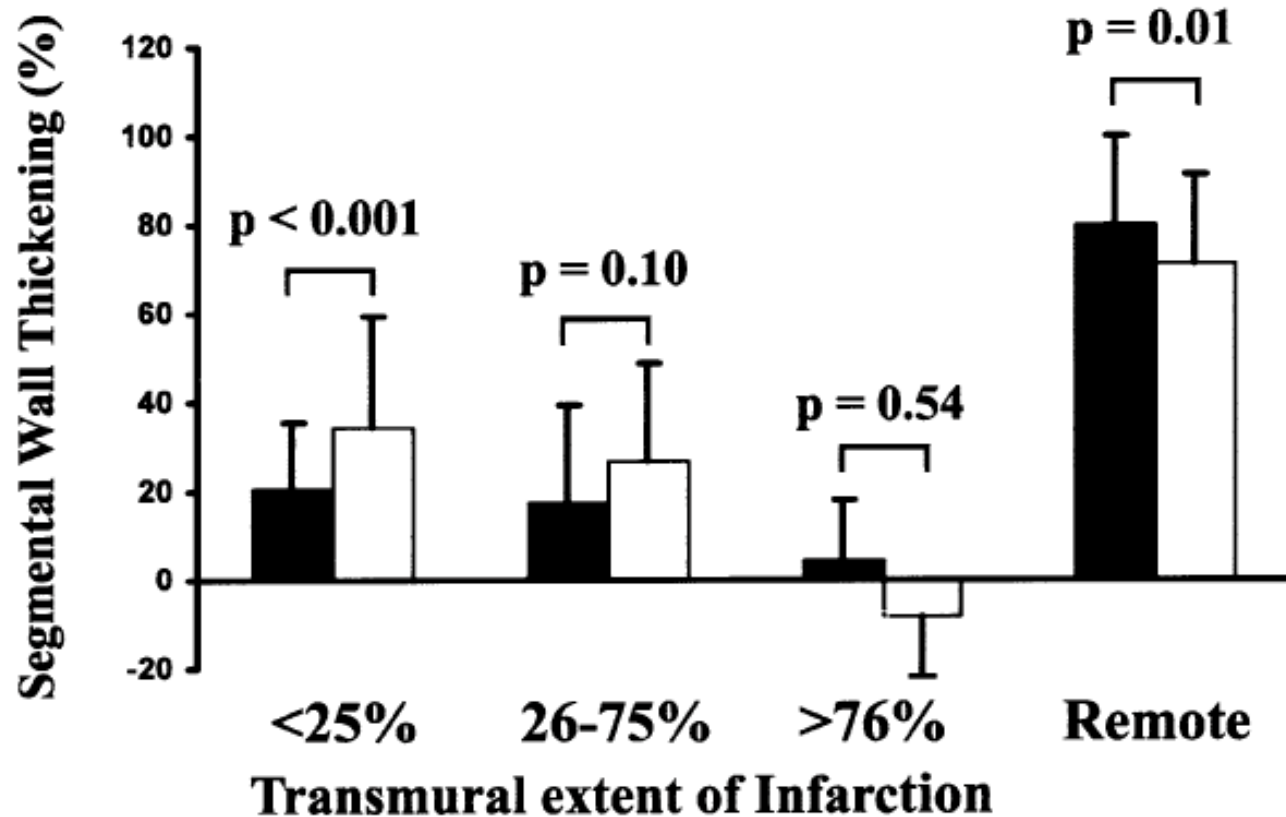
95% CI: 0.65-0.83, p < 0.001

1- Ischemia Reduction COURAGE Nuclear Sub Study



2- LV Function

Improvement of regional LV thickness as a function of transmural extent of MI before CTO recanalization



Barriers To Complete Revascularization

✓ PCI

- **Chronic Total Occlusions**
- **Bifurcation disease**
- **Small vessel size (2.0-2.8 mm)**

✓ CABG

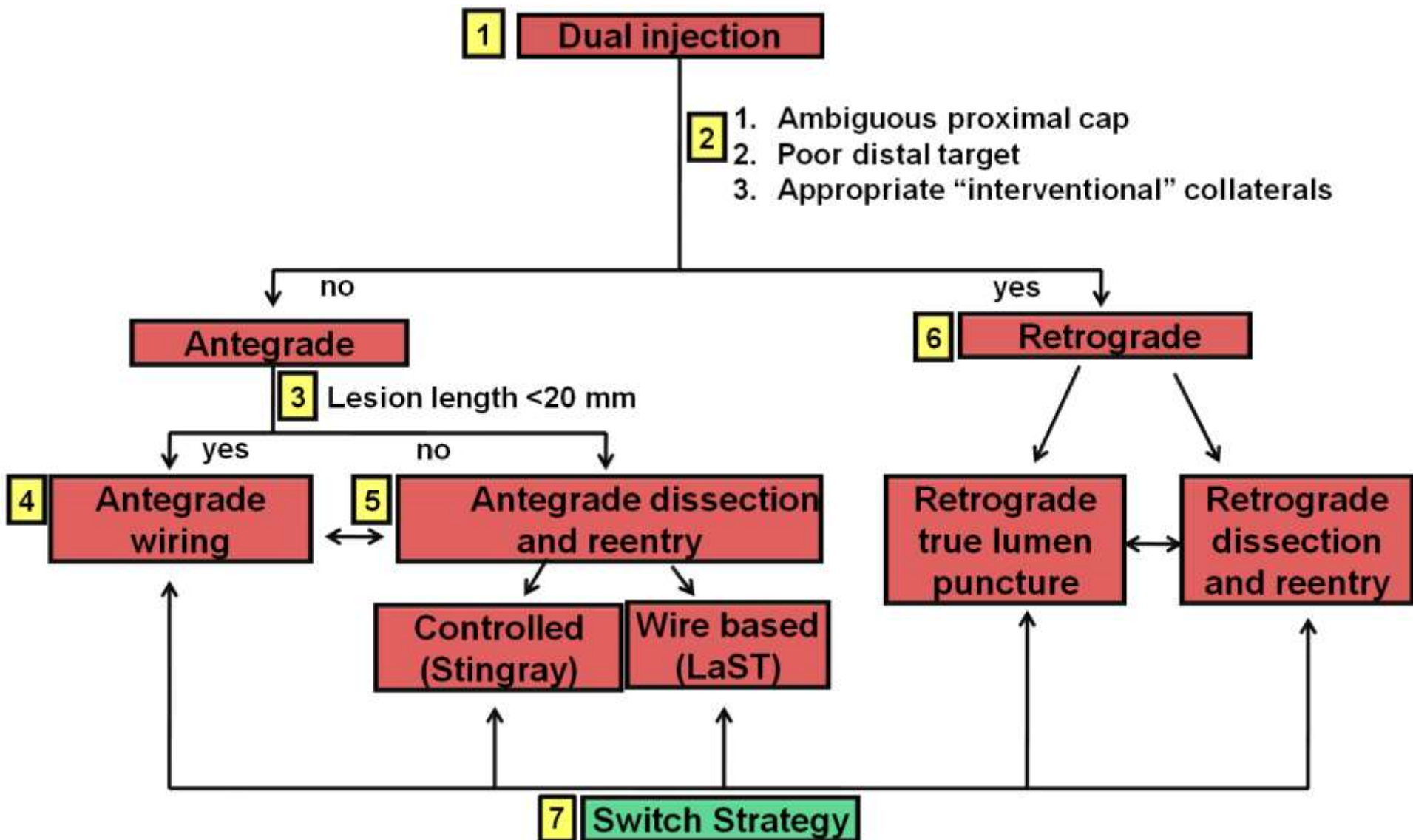
- **ACS presentation**
- **Small vessel size in particular with severe coronary calcification**
- **Diffuse disease**
- **Number of lesions (lack of conduits)**

Question 9: how would you cross the LAD?

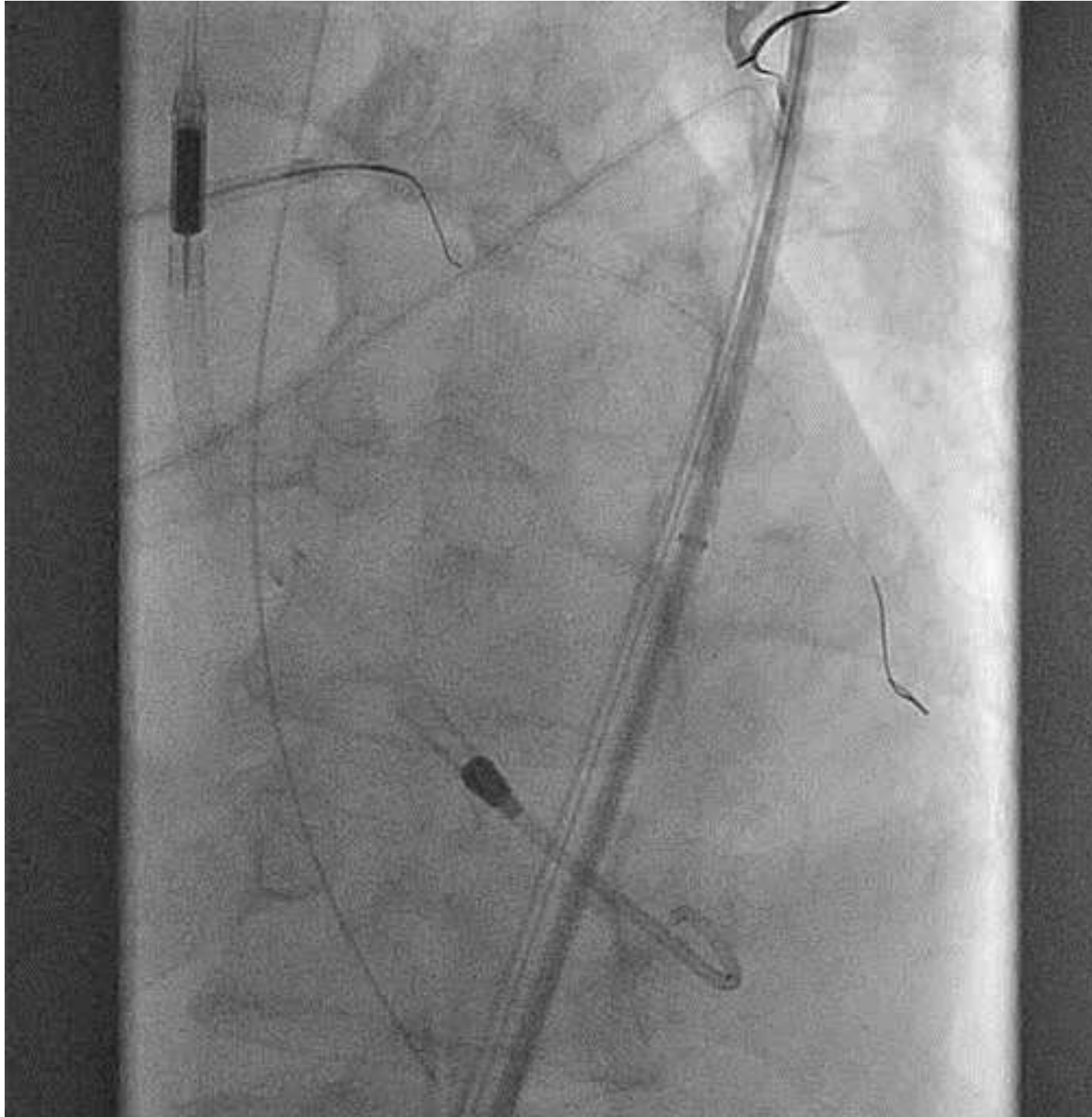
1. Antegrade wire escalation
2. Antegrade dissection/re-entry
3. Retrograde



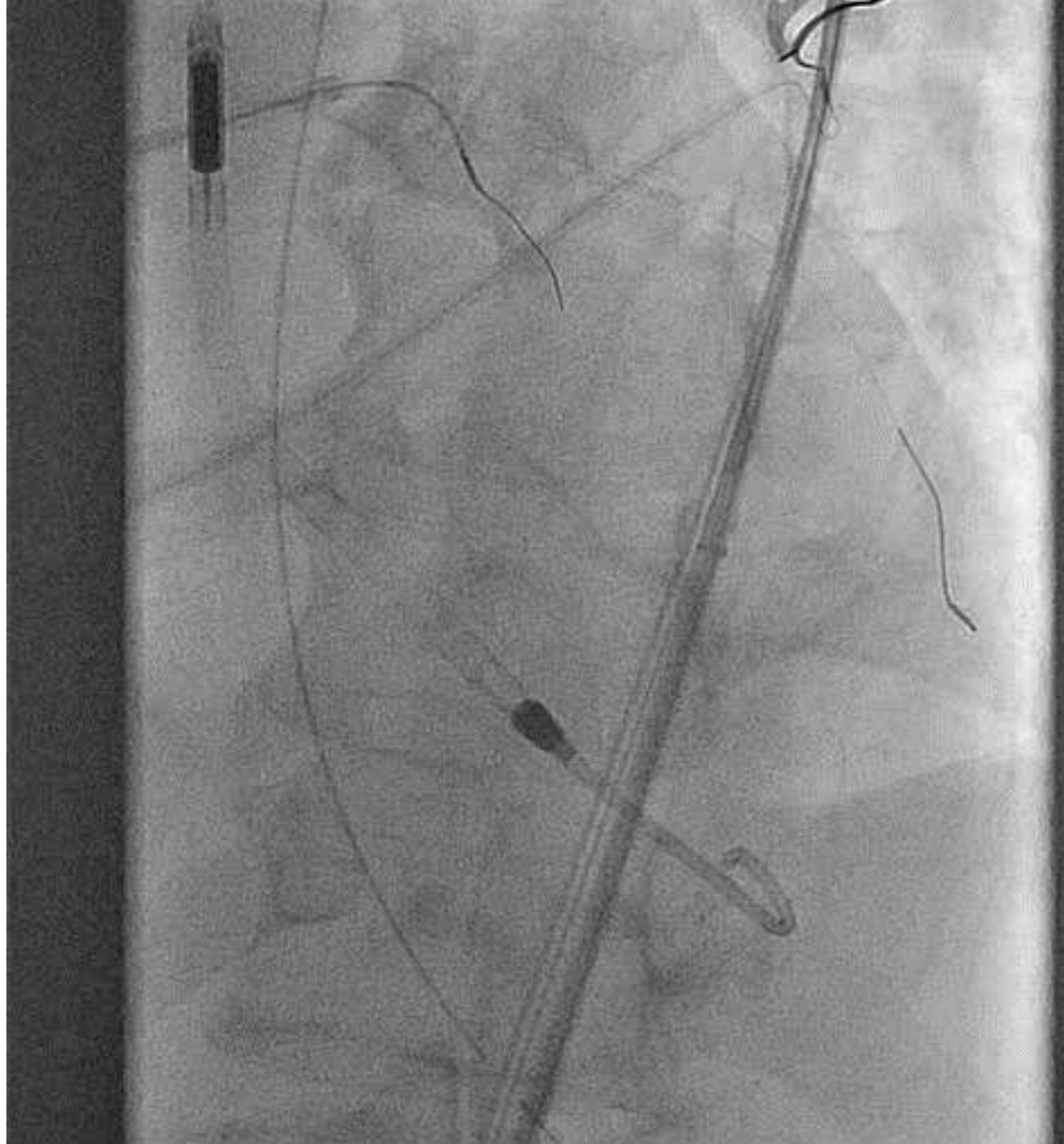
Hybrid CTO crossing algorithm



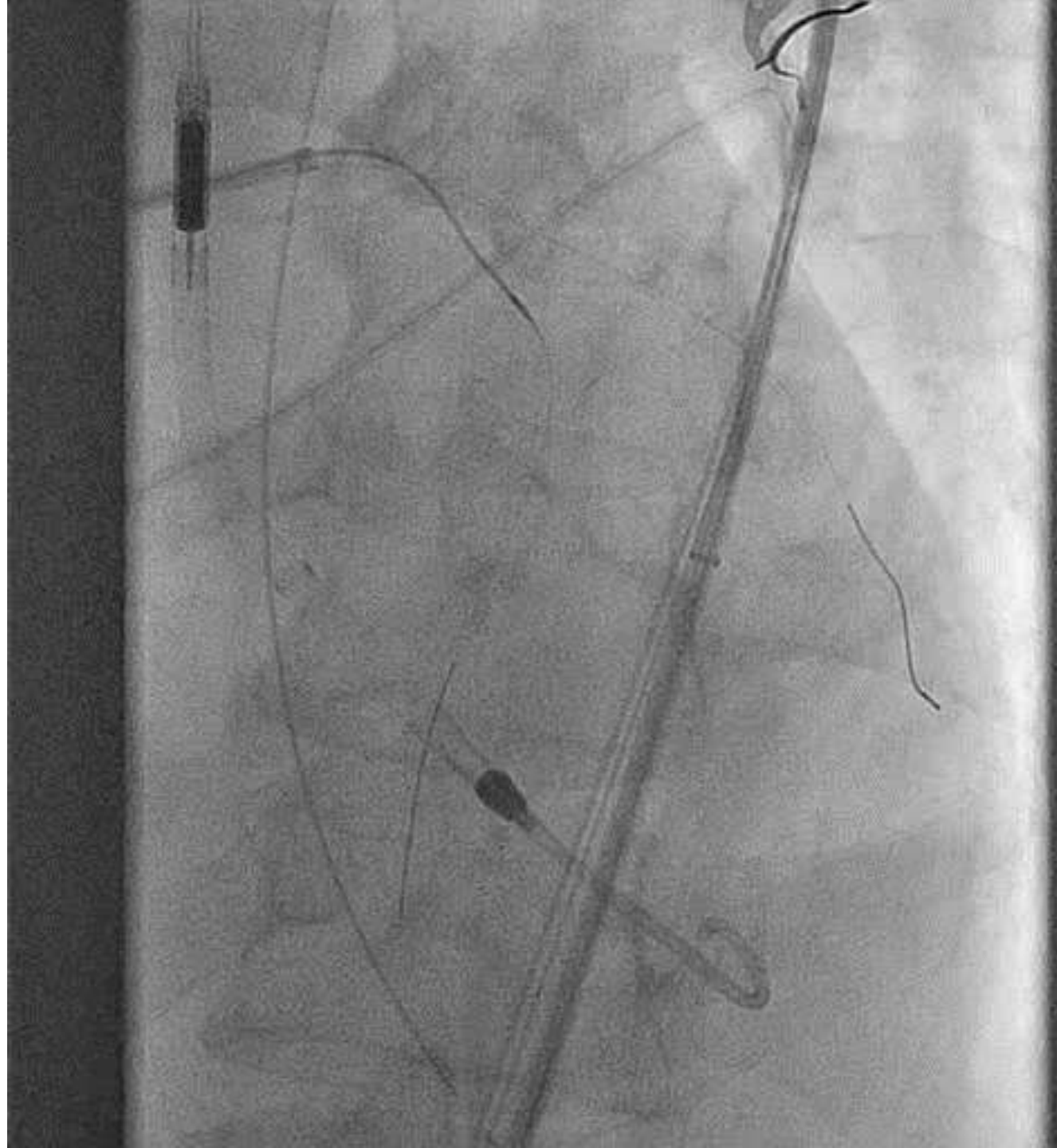
Corsair and workhorse



Corsair and Fielder XT



Corsair and Pilot 200



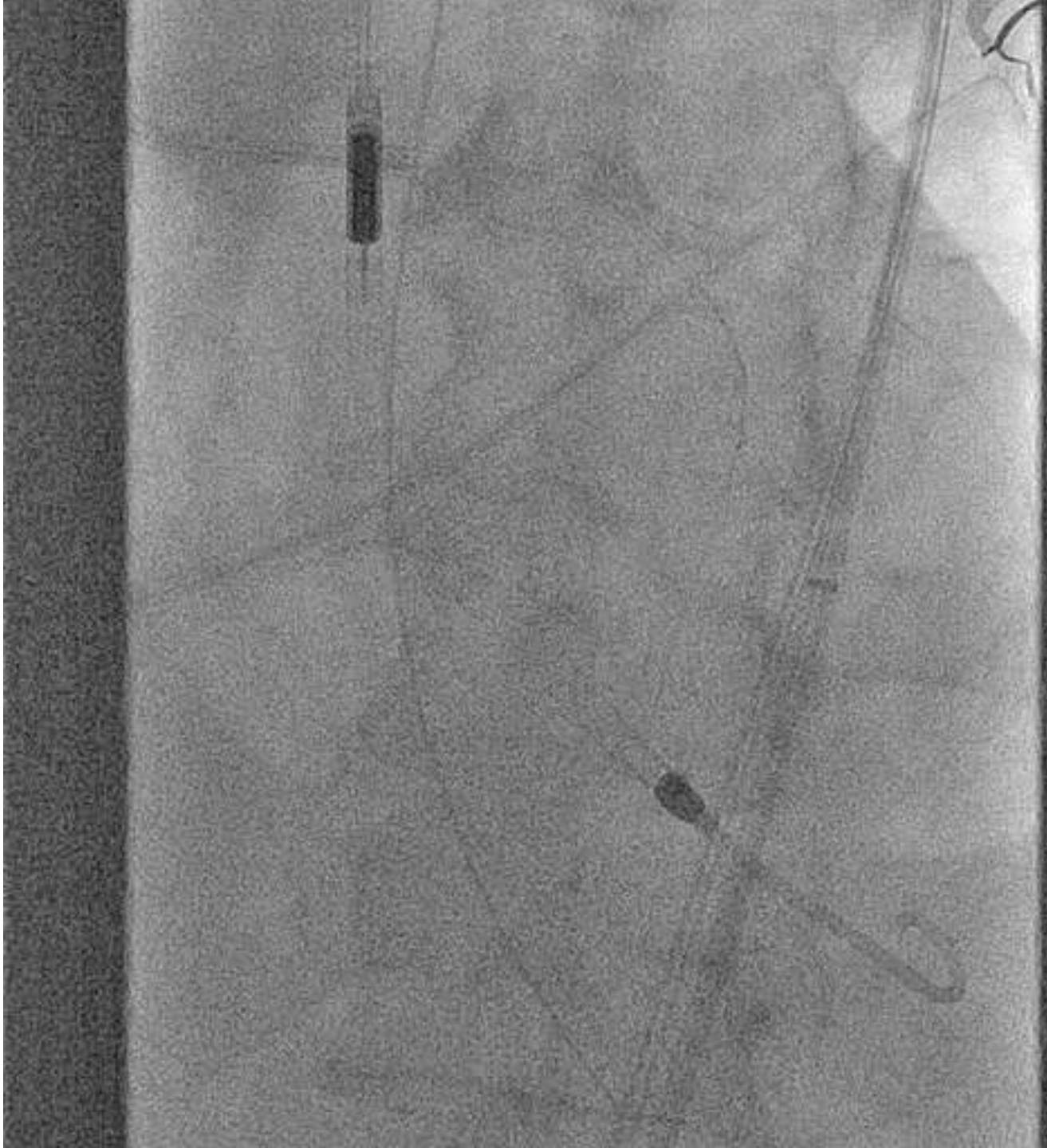
Question 10: what next?

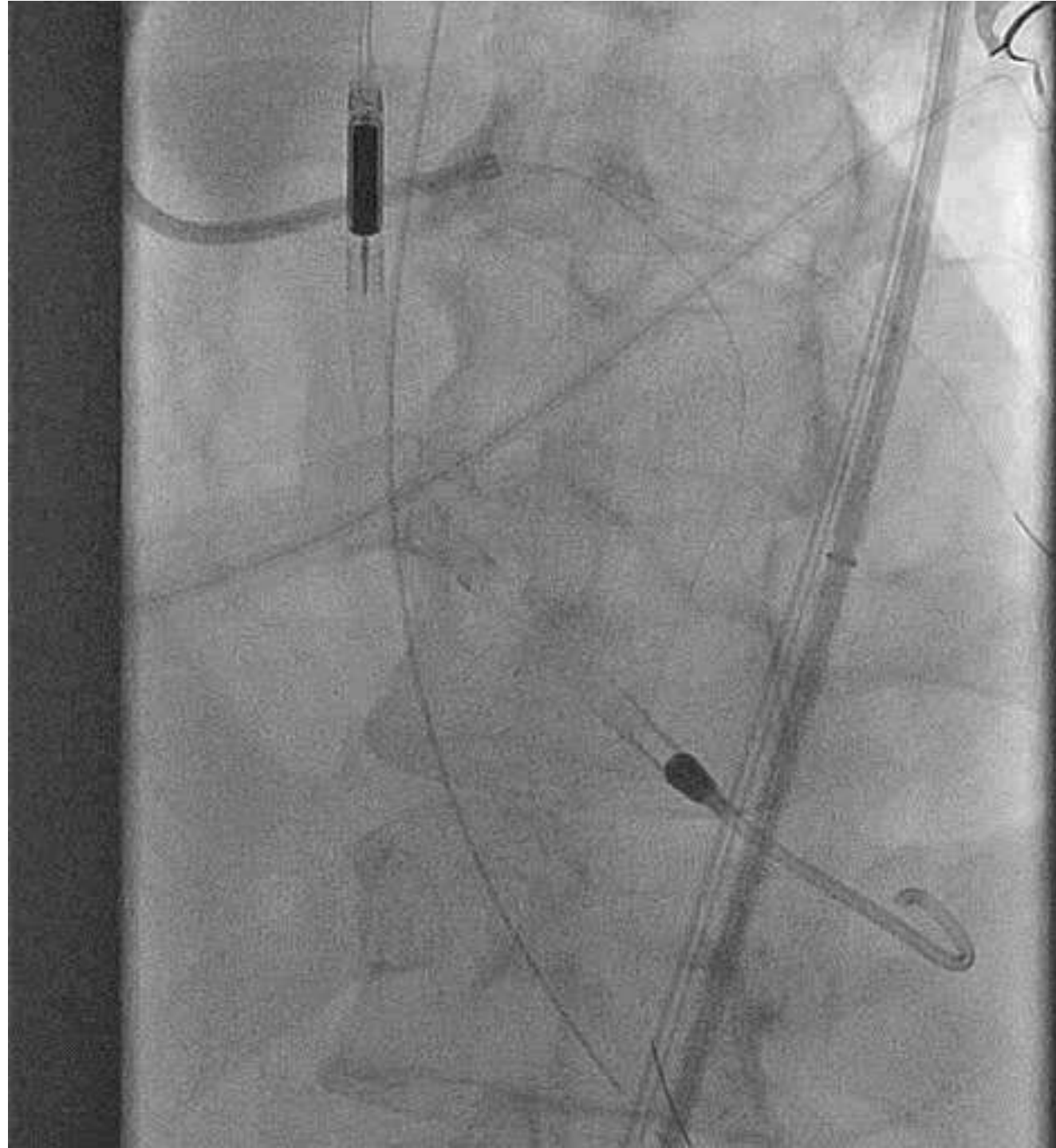
- 1. Antegrade**
- 2. IVUS**
- 3. Inject
contrast**
- 4. Orthogonal
view**



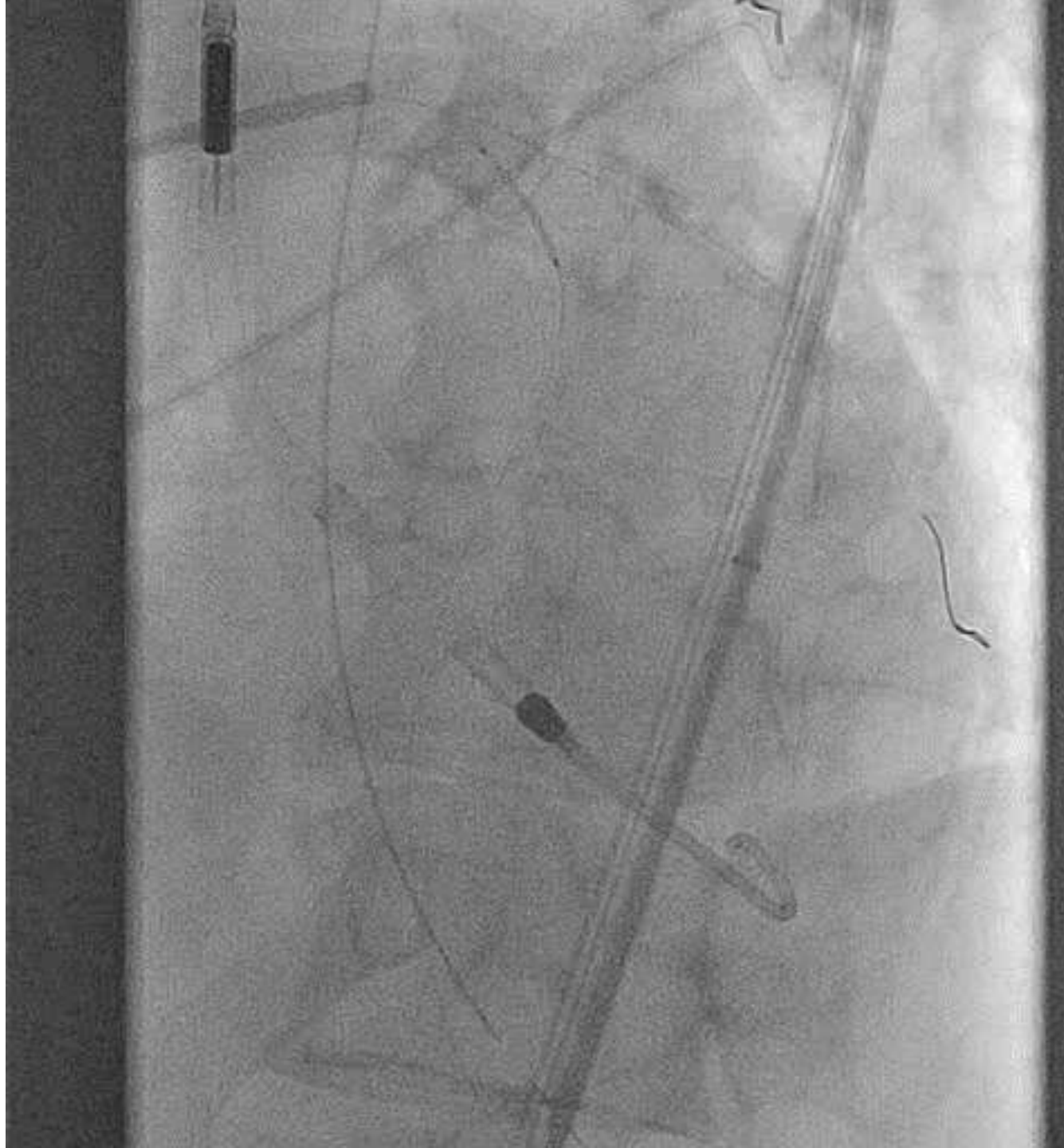
Orthogonal view

Predilation



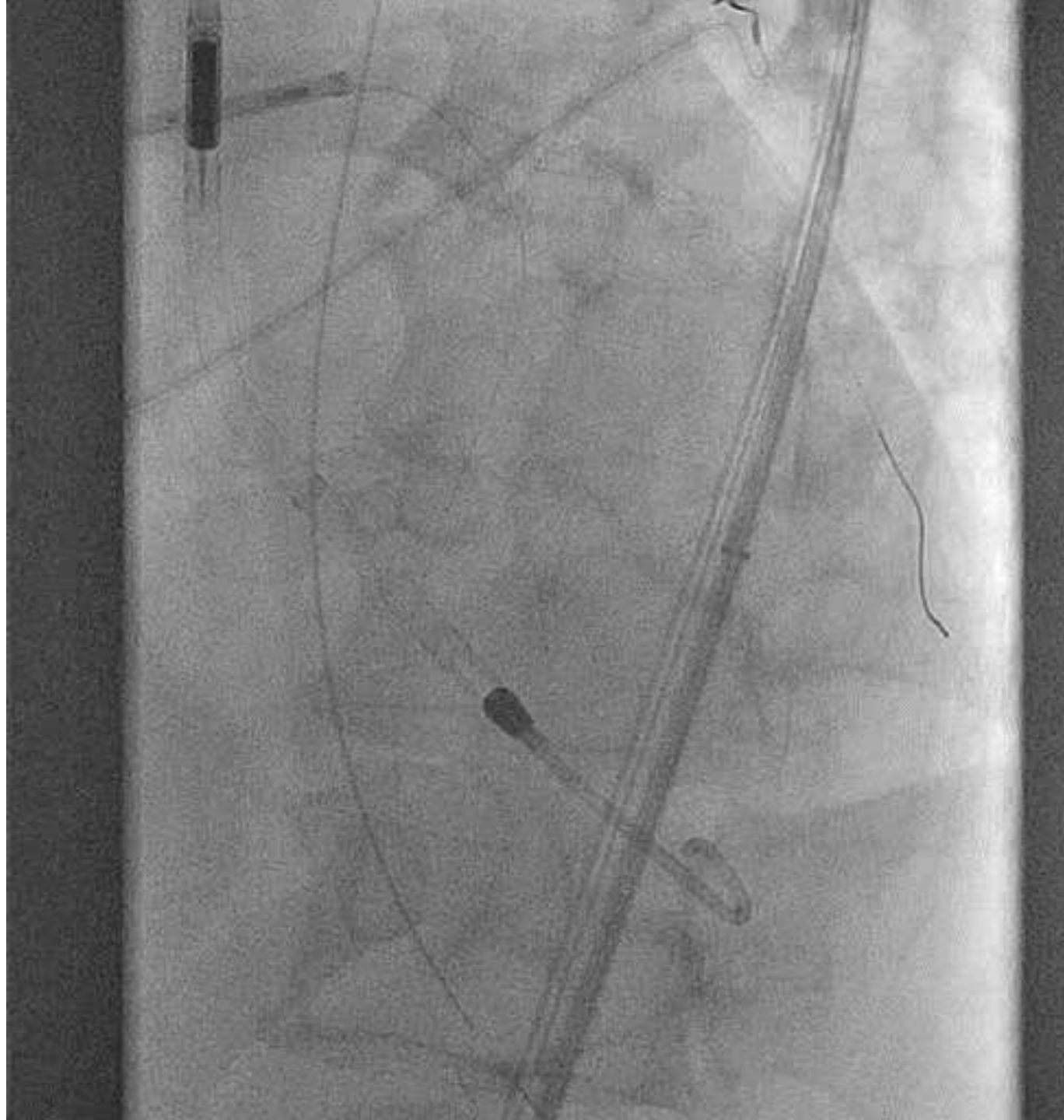


**2.75x23 mm
DES**

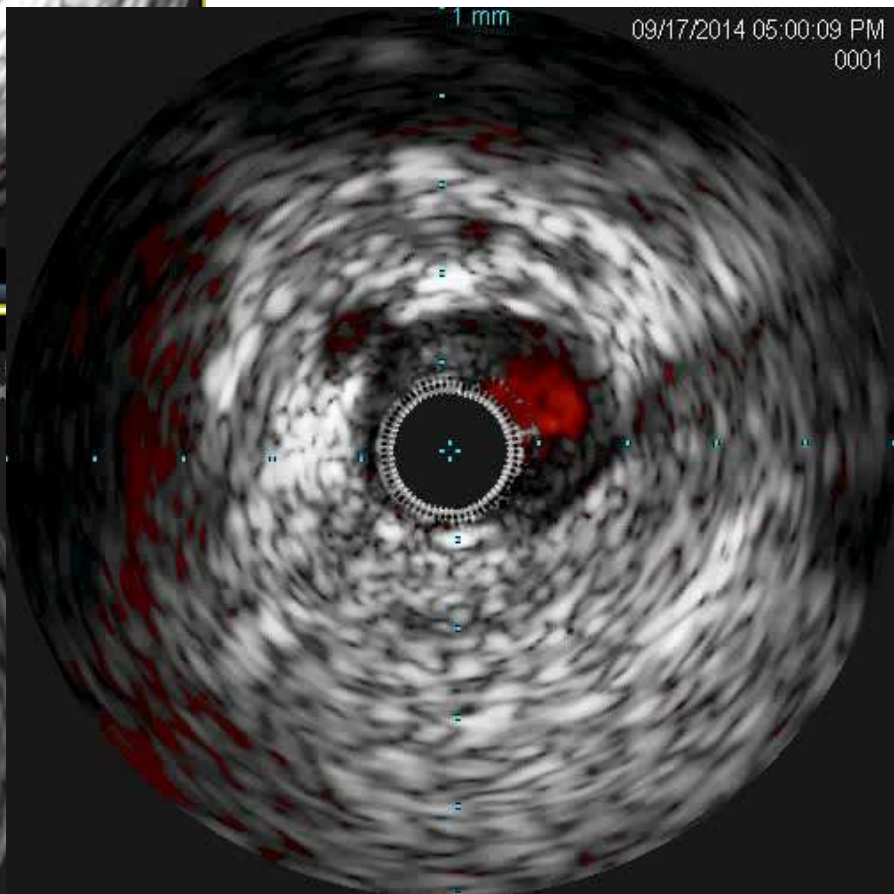
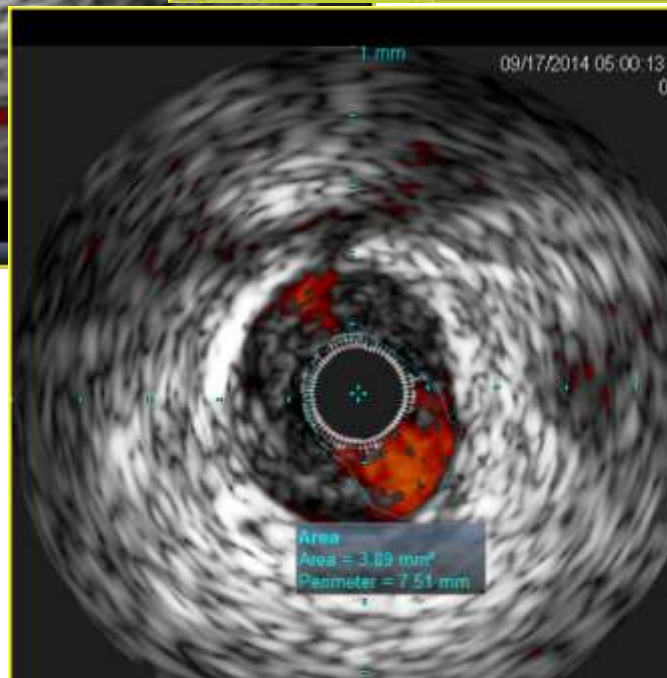
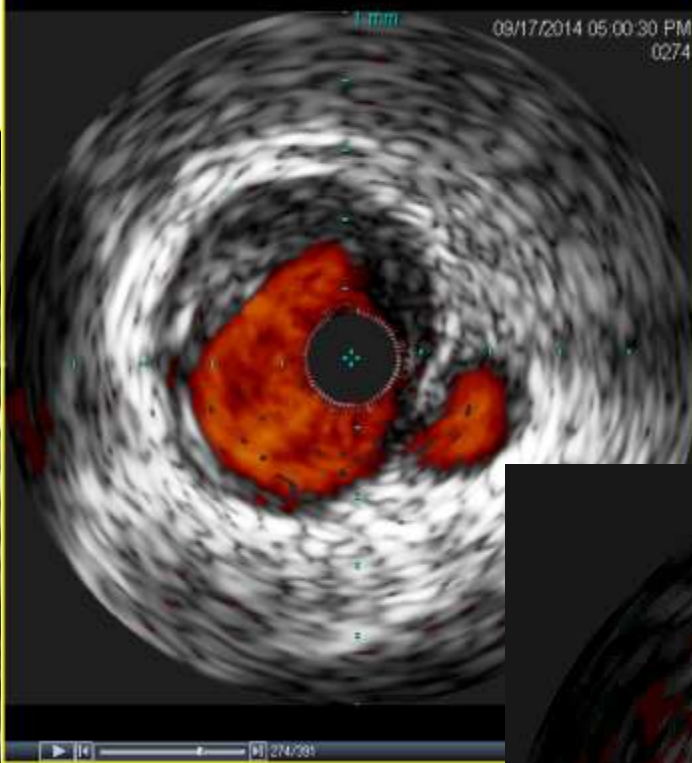
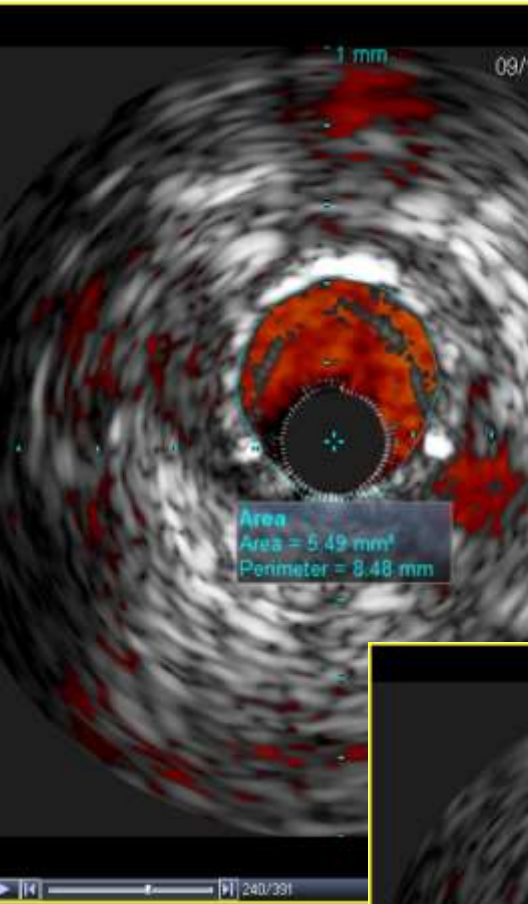


Question 11.
Now what?

- 1. Done**
- 2. IVUS**
- 3. OCT**



**Fluoroscopy
time: 24.3 min
AK: 2.2 Gray
Contrast: 300 mL**



Post PCI course

- 1. Impella removed the following day**
- 2. Nosocomial pneumonia**
- 3. Dismissed 2 weeks later**
- 4. Currently doing well on cardiac rehab**

Largest Cohort To Study The Current Use of Impella in Cardiogenic Shock

ORIGINAL INVESTIGATION

The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

WILLIAM W. O'NEILL, M.D.,¹ THEODORE SCHREIBER, M.D.,² DAVID H. W. WOHNS, M.D.,³ CHARANJIT RIHAL, M.D.,⁴ SRIHARI S. NAIDU, M.D.,⁵ ANDREW B. CIVITELLO, M.D.,⁶ SIMON R. DIXON, M.B., Ch.B.,⁷ JOSEPH M. MASSARO, Ph.D.,⁸ BRIJESHWAR MAINI, M.D.,⁹ and E. MAGNUS OHMAN, M.D.¹⁰

From the ¹Henry Ford Hospital, Detroit, Michigan; ²Detroit Medical Center, Detroit, Michigan; ³Spectrum Health, Grand Rapids, Michigan; ⁴Mayo Clinic, Rochester, Michigan; ⁵Winthrop University Hospital, Mineola, New York; ⁶Texas Heart Institute, Houston, Texas; ⁷Beaumont Hospital, Royal Oak, Michigan; ⁸Harvard Research Institute, Boston, Massachusetts; ⁹Pinnacle Health Medical Center, Wormleysburg, Pennsylvania; and ¹⁰Duke University Medical Center, Durham, North Carolina

Objectives: To evaluate the peri-procedural characteristics and outcomes of patients supported with Impella 2.5 prior to percutaneous coronary intervention (Pre-PCI) versus those who received it after PCI (Post-PCI) in the setting of cardiogenic shock (CS) complicating an acute myocardial infarction (AMI).

Background: Early mechanical circulatory support may improve outcome in the setting of CS complicating an AMI. However, the optimal timing to initiate hemodynamic support has not been well characterized.

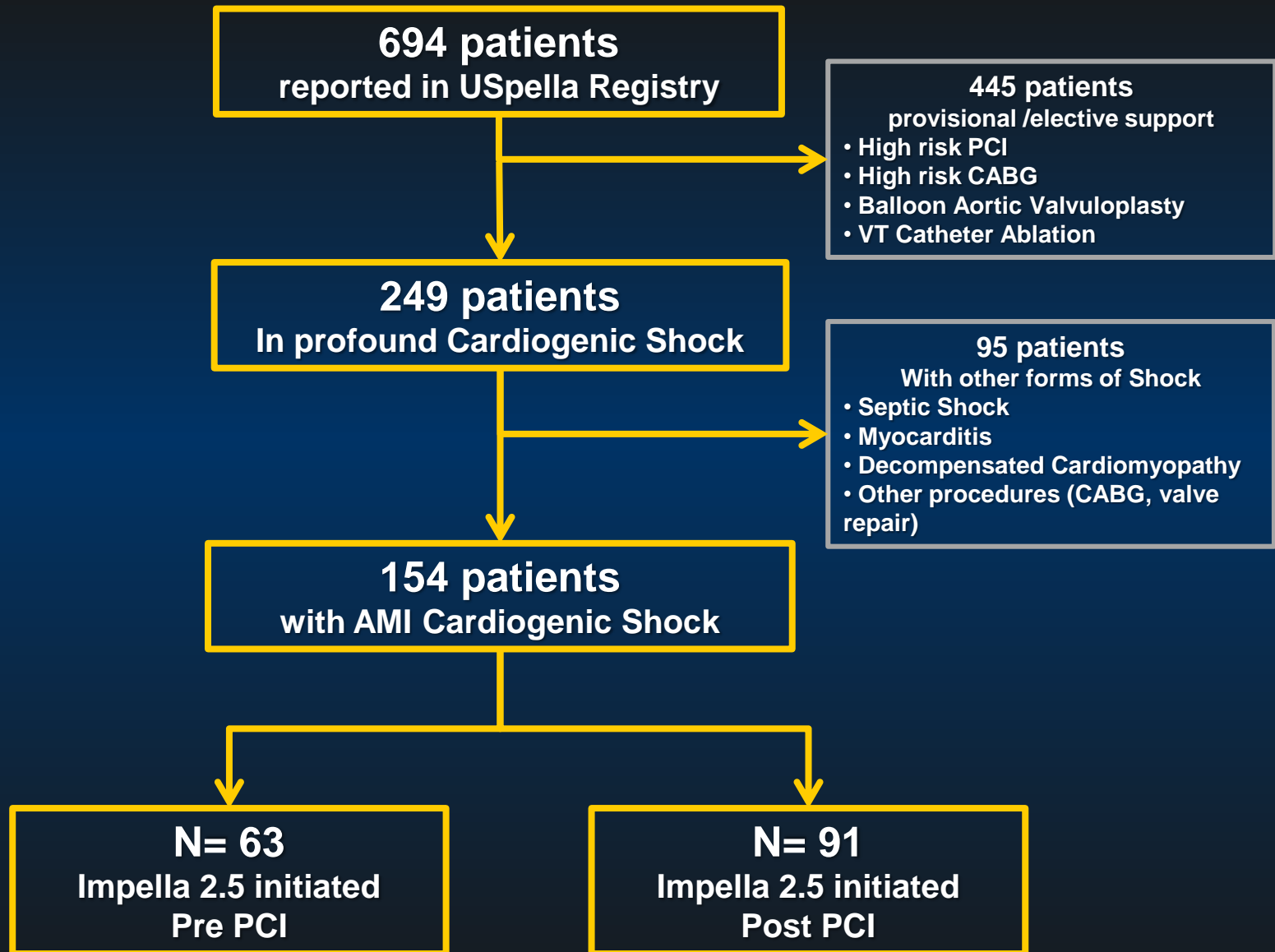
Methods: Data from 154 consecutive patients who underwent PCI and Impella 2.5 support from 38 US hospitals participating in the USpella Registry were included in our study. The primary endpoint was survival to discharge. Secondary endpoints included assessment of patients' hemodynamics and in-hospital complications. A multivariate regression model was used to identify independent predictors for mortality.

Results: Both groups were comparable except for diabetes ($P = 0.02$), peripheral vascular disease ($P = 0.008$), chronic obstructive pulmonary disease ($P = 0.05$), and prior stroke ($P = 0.04$) all of which were more prevalent in the Pre-PCI group. Patients in the Pre-PCI group had more lesions ($P = 0.006$) and vessels ($P = 0.01$) treated. These patients had also significantly better survival to discharge compared to patients in the Post-PCI group (65.1% vs. 40.7%, $P = 0.003$). Survival remained favorable for the Pre-PCI group after adjusting for potential confounding variables. Initiation of support prior to PCI with Impella 2.5 was an independent predictor of in-hospital survival (Odds ratio 0.37, 95% confidence interval: 0.17–0.79, $P = 0.01$) in multivariate analysis. The incidence of in-hospital complications included in the secondary endpoint was similar between the two groups.

Conclusions: The results of our study suggest that early initiation of hemodynamic support prior to PCI with Impella 2.5 is associated with more complete revascularization and improved survival in the setting of refractory CS complicating an AMI. (J Intervent Cardiol 2013;9999:1–12)

Study Flow Chart

(06/08-05/12)



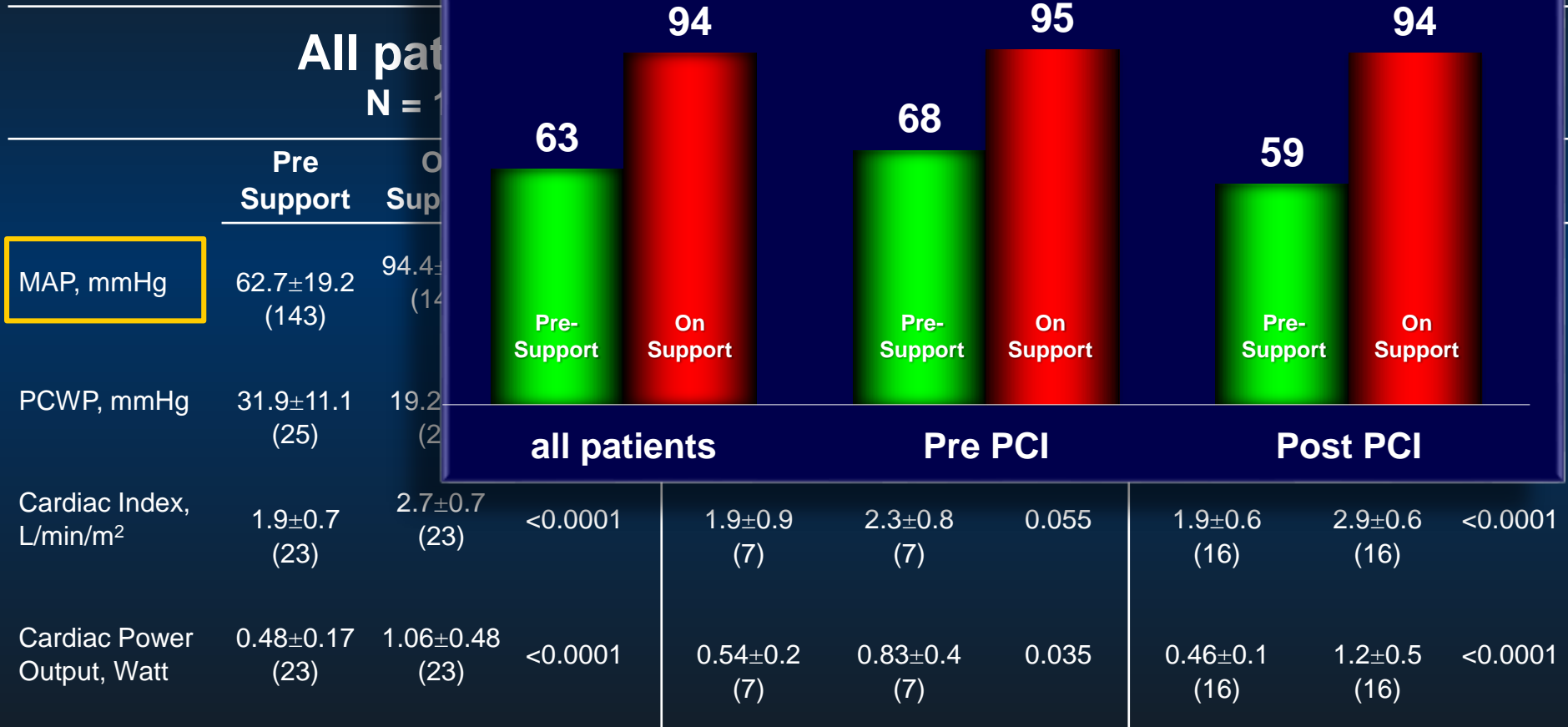
Baseline Clinical Characteristics

	All N = 154	Impella Pre-PCI N = 63	Impella Post-PCI N = 91	p value
Age, years	64.0±12.7	66±12	63±13	0.12
Gender, Male	71.4%	73.0%	70.3%	0.73
Hypertension	77.3%	82.3%	73.9%	0.23
Diabetes	44.6%	56.7%	36.4%	0.02
PVD	21.4%	32.2%	13.6%	0.008
COPD	15.9%	22.9%	10.7%	0.05
Stroke	9.4%	15.3%	5.1%	0.04
Renal Insuff.	23.9%	27.9%	21.2%	0.35
Prior AMI	38.6%	43.3%	35.3%	0.33
STEMI presentation	74.7%	55.6%	87.9%	<.0001
Prior CABG	14.2%	19.4%	10.5%	0.13
Prior PCI	38.5%	37.1%	39.5%	0.77

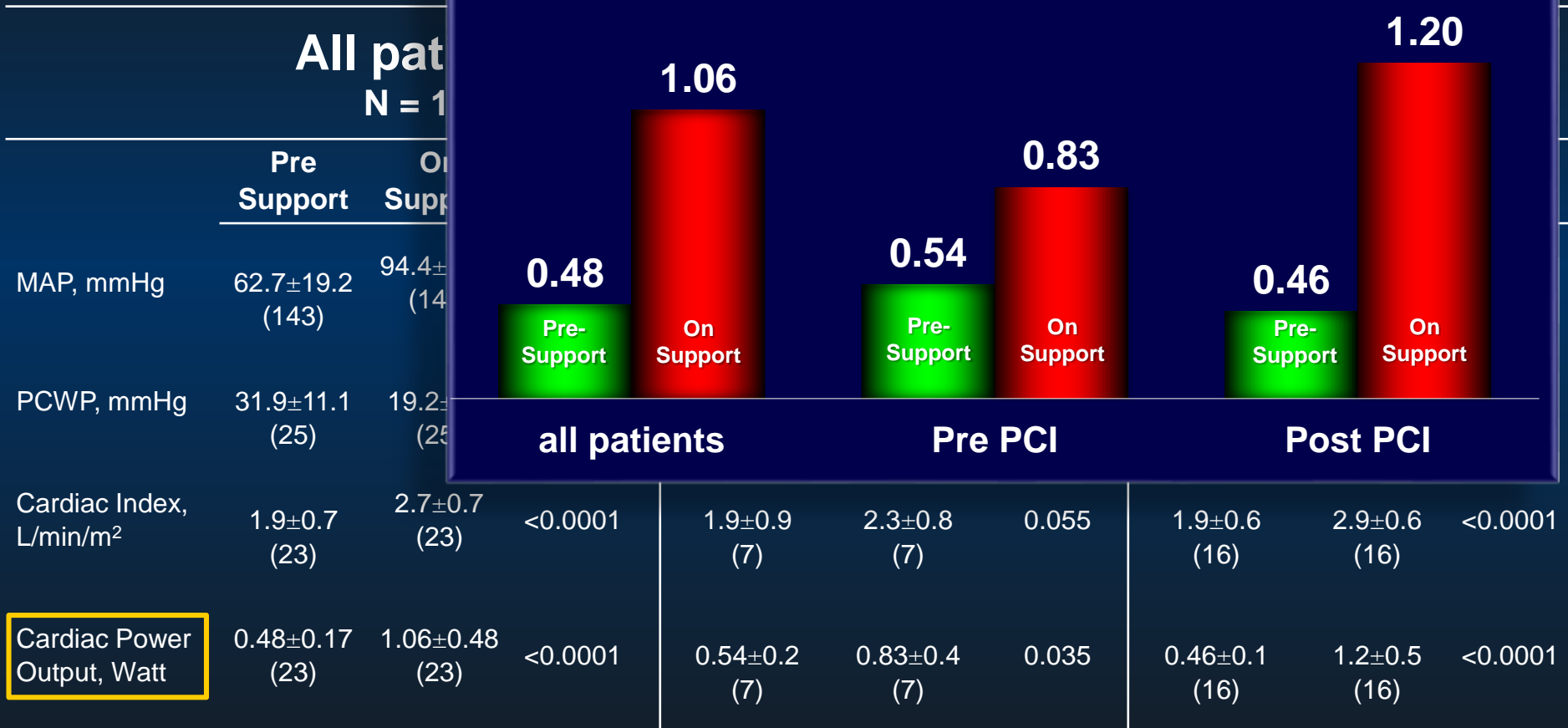
Baseline Clinical Characteristics

	All N = 154	Impella Pre-PCI N = 63	Impella Post- PCI N = 91	p value
IABP prior to Impella	48.7%	34.9%	58.2%	0.004
Mechanical Ventilation	65.5%	54.8%	73.3%	0.02
LVEF (%)	26.4±13.4	25.6±12.9	27.0±13.8	0.56
Troponin ng/mL	5.7 [0.6 23.1]	5.7 [0.9 24.7]	5.7 [0.4 23.3]	0.82
eGFR mL/min/m ²	49 [27.5 60]	49 [25 60]	48 [29.5 60]	0.91
Serum Lactate mmol/L	4.1 [2.4 7.2]	4.3 [1.6 10.2]	3.8 [2.5 5.9]	0.65
STS Mortality score	21.7±15.2	22.6±14.4	21.0±15.8	0.55
STS Morbidity score	64.2±18.2	67.1±16.9	62.1±18.9	0.11

Hemodynamics



Hemodynamics



Procedural Characteristics

	All N = 154	Impella Pre-PCI N = 63	Impella Post- PCI N = 91	p value
Duration of support, (hrs)	23.7 [3.5 62.7]	22.8 [1.6 52.8]	24.2 [4.2 69.2]	0.39
Median DTB Time*, min	63.5 [40.3 113.5]	112 [79 276]	52 [34 81]	<.0001
Suspected IRA Territory				
LM	16.1%	23.8%	9.5%	0.02
LAD	52.6%	53.9%	51.4%	0.76
Left Cx.	10.9%	4.8%	16.2%	0.03
RCA	16.8%	12.7%	20.3%	0.24
Graft	3.7%	4.8%	2.7%	0.52
Number of diseased vessels	1.8±0.76	1.94±0.72	1.70±0.79	0.07
Number of significant Lesions	2.57±1.39	2.74±1.49	2.42±1.28	0.19
Number of vessel treated	1.42±0.63	1.57±0.67	1.30±0.57	0.01
TIMI Flow [0-1] Prior to PCI	80.2%	71.9%	84.8%	0.14
TIMI Flow [0-1] Post PCI	8.7%	4.6%	11.9%	0.19

*: DTB time for patients admitted for STEMI

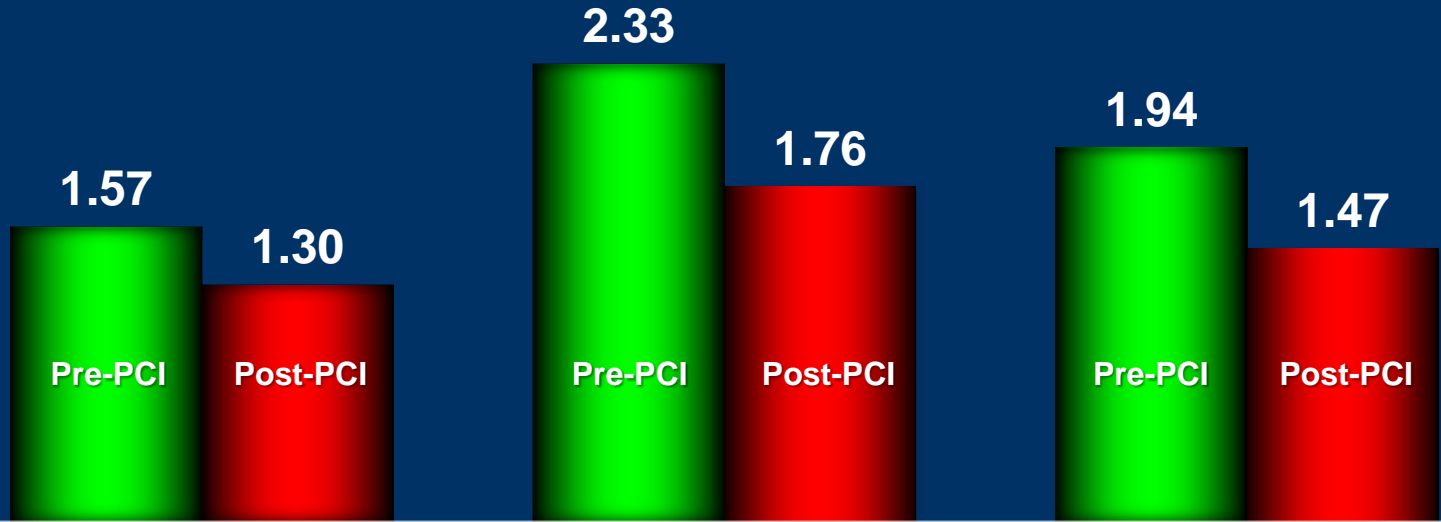
Procedural Characteristics

Extent of Revascularization

p=0.01

p=0.006

p=0.007



of Vessel Treated

of Lesions Treated

of Stents Placed

Number of significant Lesions 2.57±1.39 2.74±1.49 2.42±1.28 0.19

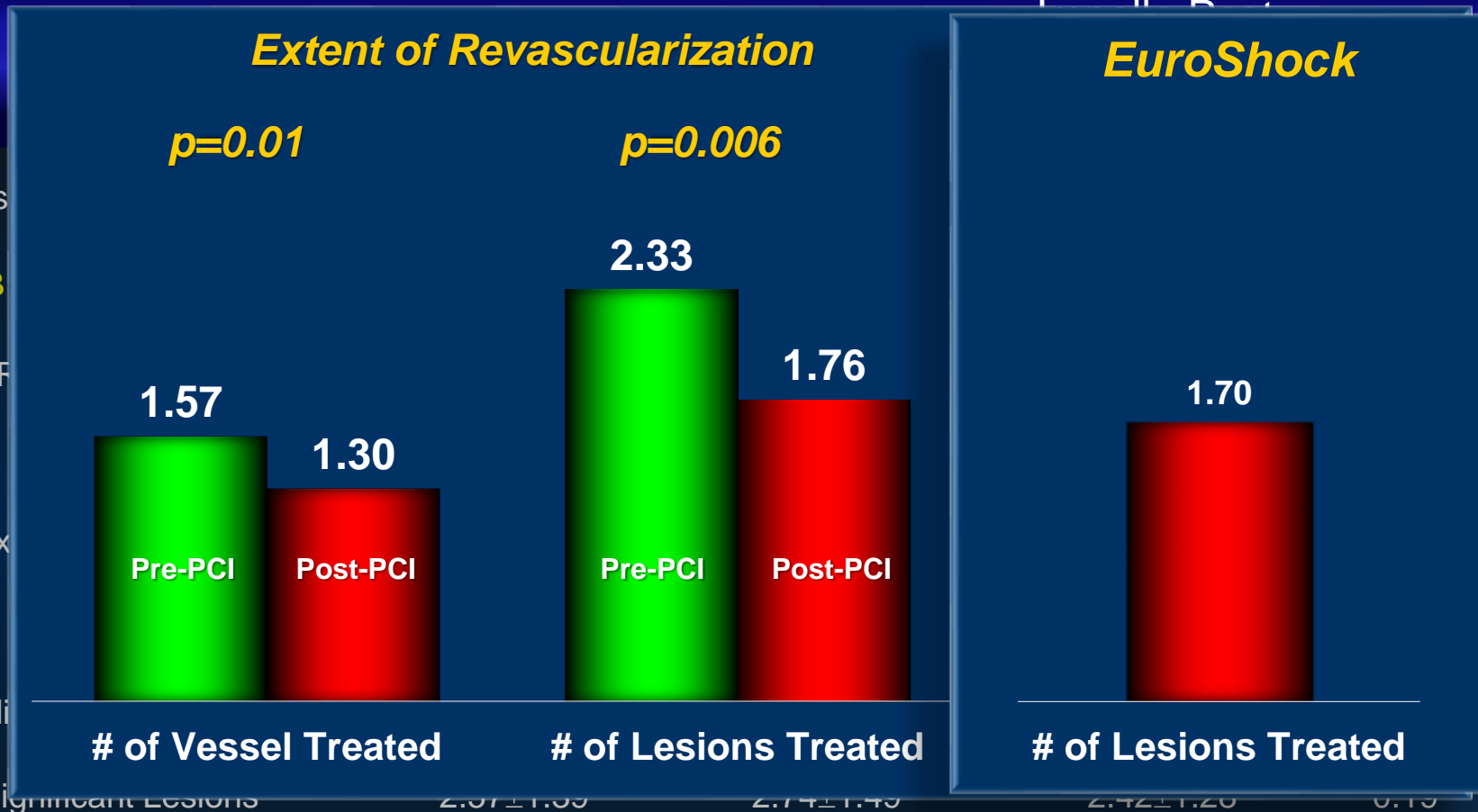
Number of vessel treated 1.42±0.63 1.57±0.67 1.30±0.57 0.01

TIMI Flow [0-1] Prior to PCI 80.2% 71.9% 84.8% 0.14

TIMI Flow [0-1] Post PCI 8.7% 4.6% 11.9% 0.19

*: DTB time for patients admitted for STEMI

Procedural Characteristics

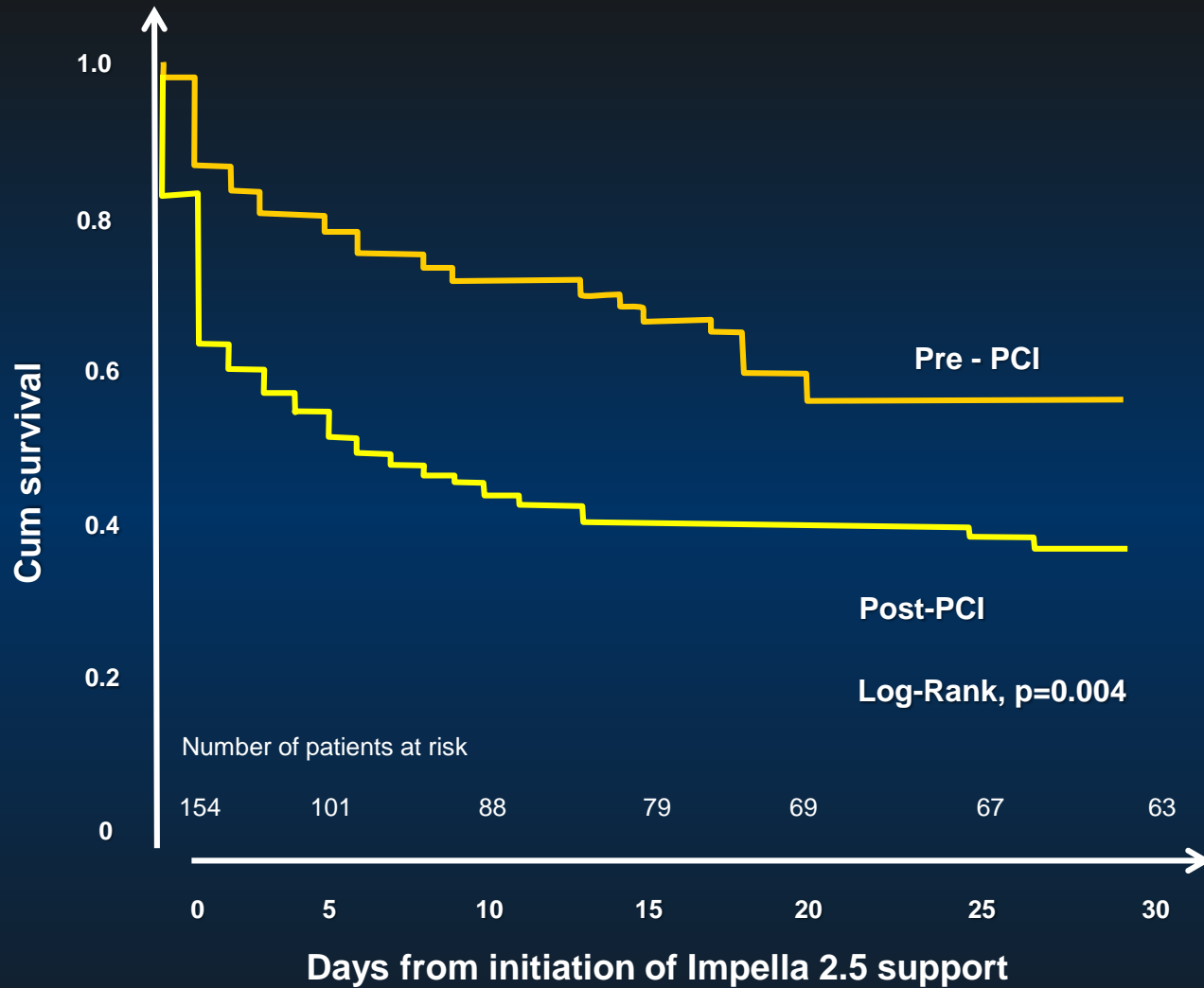


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O'Neill et al, J Interven Cardiol 2013;9999:1-11

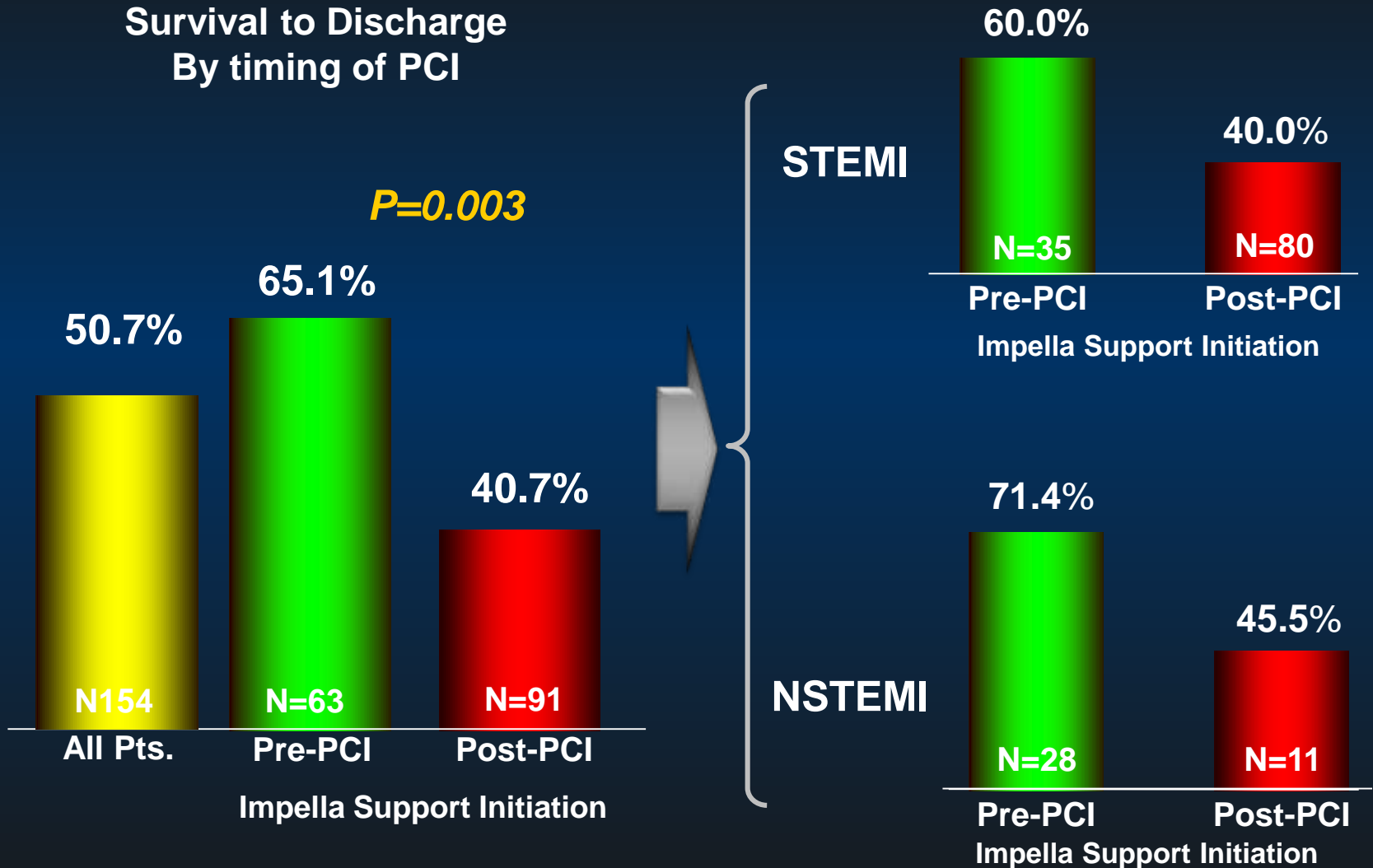
Outcome



Survival to Discharge by Timing of PCI

Timing of Support Initiation (154)

Survival to Discharge
By timing of PCI



Independent Predictors of In-Hospital Mortality Using a Multivariate Analysis*

Parameter Tested*	Odds-ratio	[CI 95%]	<i>p</i> -value
Initiation of Impella support prior to PCI	0.37	0.17 - 0.79	0.01
Age	1.05	1.02 - 1.08	0.003
Number of inotropes	1.56	1.1 - 2.18	0.01
Cardiogenic shock onset prior to admission	2.42	1.12 - 5.24	0.03
Mechanical ventilation	4.59	2.02 - 10.42	0.0003

* The multivariate analysis logistic model included the following as candidates for entry age, gender, history of chronic obstructive pulmonary disease, diabetes, peripheral vascular disease or prior stroke, STEMI vs. NSTEMI, cardiac arrest prior to admission, onset and duration of CS, patient transfer from outlying facility, evidence of anoxic brain injury pre-Impella support, need for mechanical ventilation, systolic and diastolic blood pressure, level of inotropic support pre-Impella support and potential use of IABP prior to Impella support, and baseline serum creatinine levels.

Conclusion and Limitations

These results are in favour of early initiation of hemodynamic support with active unloading of the LV prior to PCI in terms of completeness of revascularization and survival in the setting of CS complicating an AMI.

- Retrospective data, therefore hypothesis generating and no definite conclusion on causality
- Decision for the timing to implant Impella and extent of revascularization was operator
- Although multivariate analysis reduces the bias of potential confounding factors there might be still some biases

How did hemodynamic support help?

Patient hemodynamically stable throughout procedure enabling:

- a. Complete revascularization**
- b. Meticulous attention to quality (IVUS)**

Subhash Banerjee, MD
Shuaib Abdullah, MD
Jerrold Grodin, MD
Jeffrey Hastings, MD
R Tyler Miller, MD
James LePage, PhD
Clark Gregg, MD

Research Team

Bavana Rangan, BDS, MPH
Michele Roesle, RN
Michelle Harper, BSA
Ameka Coleman, MS
Amy Atwell, LVN
Deborah Shorrock

UT Southwestern
Medical Center

James de Lemos, MD
Darren Mc Guire, MD
Milton Packer, MD
Joseph Hill, MD, PhD
Michael Luna, MD
Tayo Addo, MD
Dharam Kumbhani, MD
Sarah Gualano, MD

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Dallas VAMC

Cath Lab Team

Don Haagen
Susan Dougherty
Theresa Jeong
Dwaine Williams
Loren Makke
Kathleen Hazelton
Diana Lacy
Smitha Thomas
Tina Terry
Alexis Rodriguez Torres
Linell Garnsey
Shibu Mathew
Cheryl Webb-Singh
Latoya Armont
Pamela Alexander



Phyllis Adelle Bilbrey
Helen Jones
Elvin Franklin

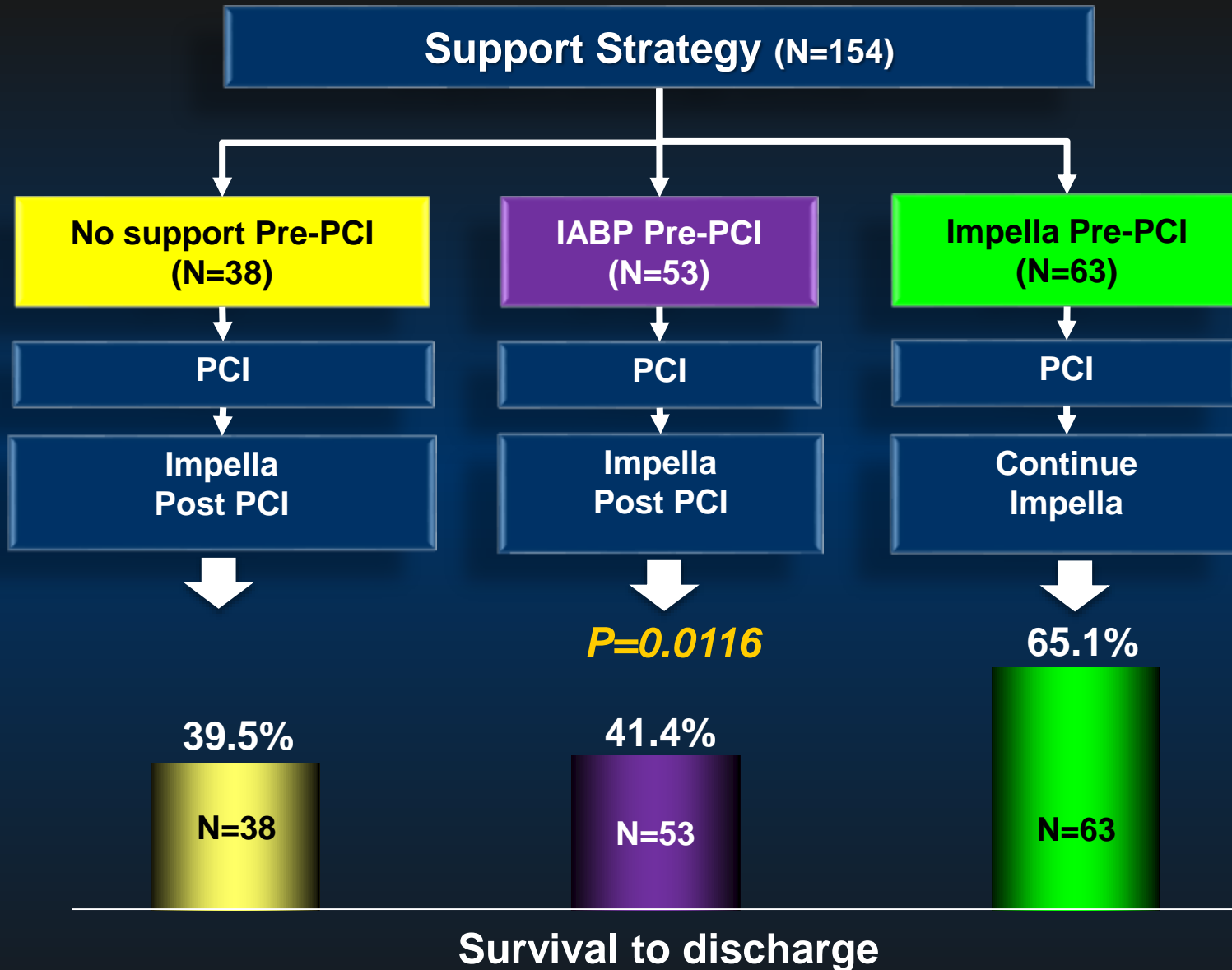
Trainees

George Christopoulos, MD
George Christakopoulos, MD
Nauman Tarar, MD
Anna Kotsia, MD
Vijay Raja, MD
Houman Khalili, MD
Omar Jeroudi, MD
Thao Duong, MD
Jedrek Wosik, MD
Howard Chao, BS
Henry Han, BS
Andres Guerra, BS
Alan Sosa, BS
Emily Spaedy, BS



Steven Goldman, MD
Kendrick Shunk, MD
Deepak Bhatt, MD
Sunil Rao, MD
David Holmes, MD
Palo Alto CSPCC
All 25 participating sites

Outcome By Support Strategy

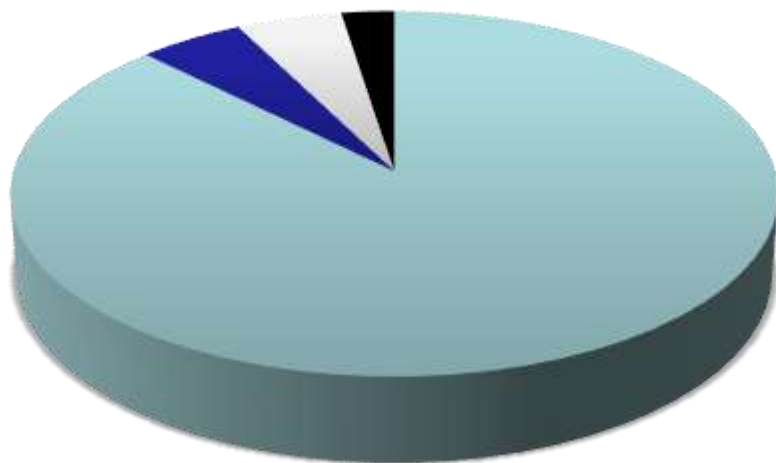


Complete Revascularization Definitions

Anatomical or Traditional	All diseased arterial systems with vessel size ≥ 1.5 (2.0-2.25 mm for PCI) with at least one significant stenosis $> 50\%$ receive a graft (or stent)
Functional	All ischemic myocardial territories are grafted (or stented); areas of old infarction with no viable myocardium are not required to be reperfused
Numerical	Number of distal anastomosis \geq number of diseased coronary segments/systems
Score-based	Scoring of stenosis in different vessels. Different weight given to different vessels according to number of myocardial segments supplied. A residual score of 0 is usually considered equivalent to CR
Physiology-Based	All coronary lesions with fractional-flow reserve $\leq 0.75 - 0.80$ receive a graft or stent

Complete revascularization: definition

■ Anatomical ■ Functional
■ Numerical ■ Multiple



**Anatomical: Used in 87%
of published studies**

Main limitations:

1. Angiography is not performed routinely after CABG (relies heavily on surgical impression)
2. Threshold to define significance: 50% (FAME, DEFER)
3. Does not take into account the functional status of the myocardium (OAT)

Angiographic vs. Functional Severity of Coronary Artery Stenoses

