

Dallas
CARDIOVASCULAR
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Advanced Hemodynamic Support in the Cath Lab

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Disclosures

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

Background

- While CABG is generally preferred in symptomatic patients with severe, complex multivessel or left main CAD, some patients present with clinical features that make CABG clinically unattractive
- During PCI, repetitive contrast dye injections, balloon inflations, atherectomy passes, and stent manipulations transiently interrupt blood flow to the target coronary artery resulting in a negative inotropic effect

Goals of Hemodynamic Support in the Cath Lab

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

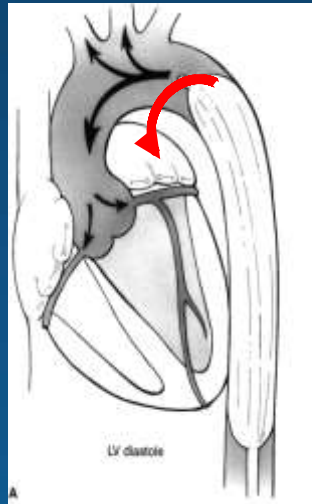
Types of Hemodynamic Support in the Cath Lab

Hemodynamic support in the cath lab

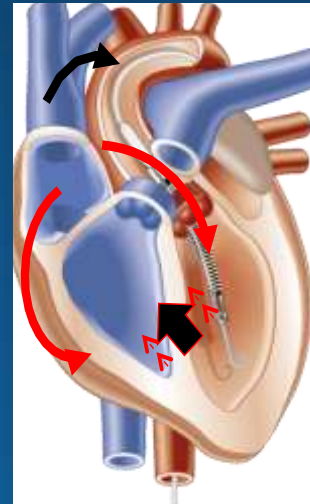
Inotropes



Intra-aortic balloon pump (IABP)



Impella



Tandem Heart



Hemodynamic Support Devices for the Cath Lab

	IABP	Impella	Tandem Heart
High-risk PCI/shock	Yes	Yes	Yes
Location	Descending aorta	LV-AO	Inflow-LA Outflow-CFA
Trans-septal puncture	No	No	Yes
Support	0.5L/min	2.5-5L/min	4-5L/min
Hemodynamic support	↑Diastolic AO Pr.	↓LVEDV, ↓LVEDP, ↑Mean AO Pr.	↓MVO ₂
Largest sheath	9F Fibro-optic-7F	2.5-12F, CP-14F	LA-21F; CFA-15F
Complications	5-10%	5-10%	20-50%

IABP & Impella most frequently used in the cath. lab

Indications for Cath Lab Hemodynamic Support

Cath Lab
hemodynamic
support

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graph TD; A[Cath Lab hemodynamic support] --> B[Elective high-risk PCI]; A --> C[PCI in Cardiogenic shock];
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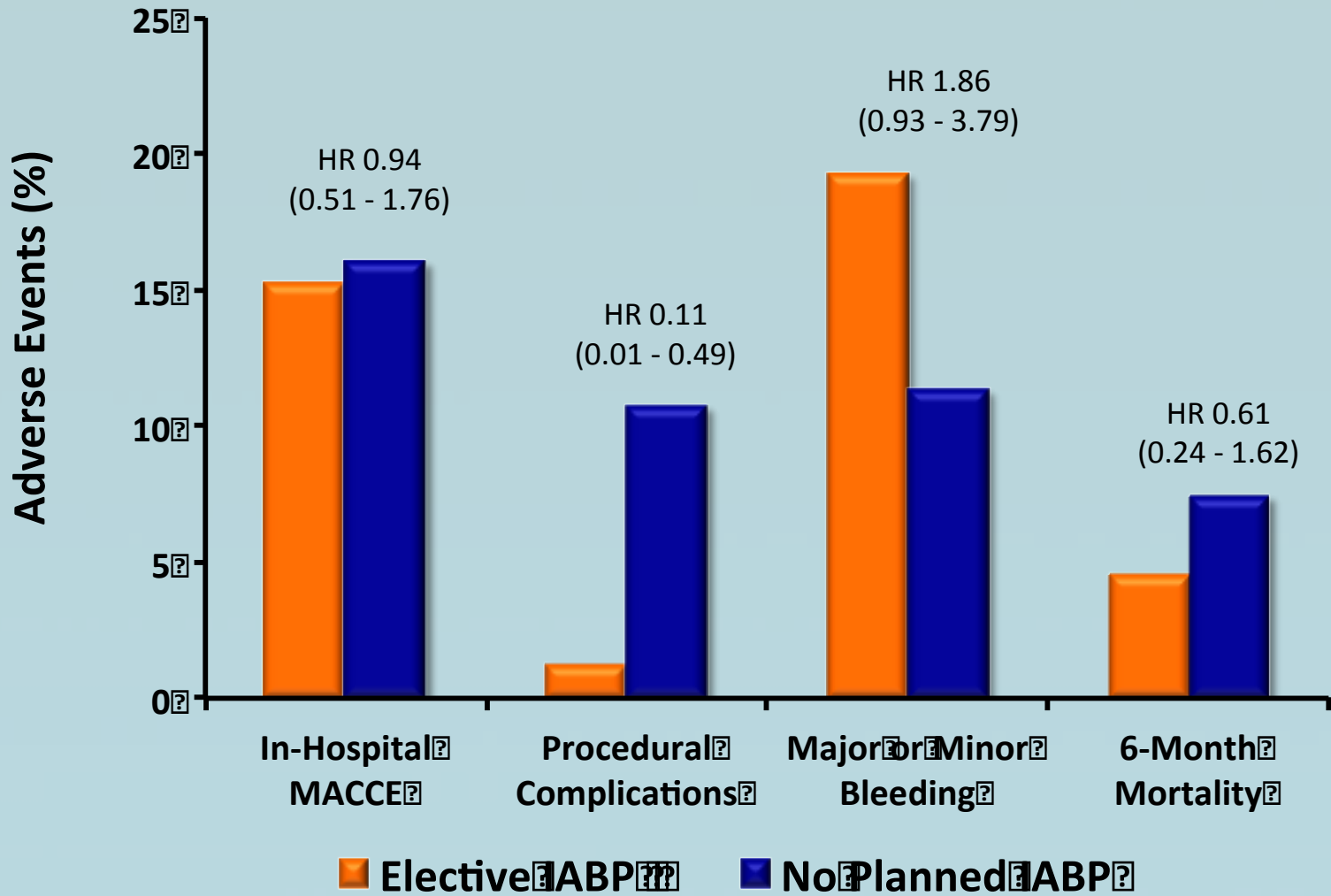
Elective high-risk PCI

- 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

BCIS-1: Major Outcomes



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%*

R

1:1

**IABP +
PCI (n=223)**

**IMPELLA 2.5 +
PCI (n=225)**

Primary Endpoint = 30-day Composite MAE* rate

Follow-up of the Composite MAE* rate at 90 days

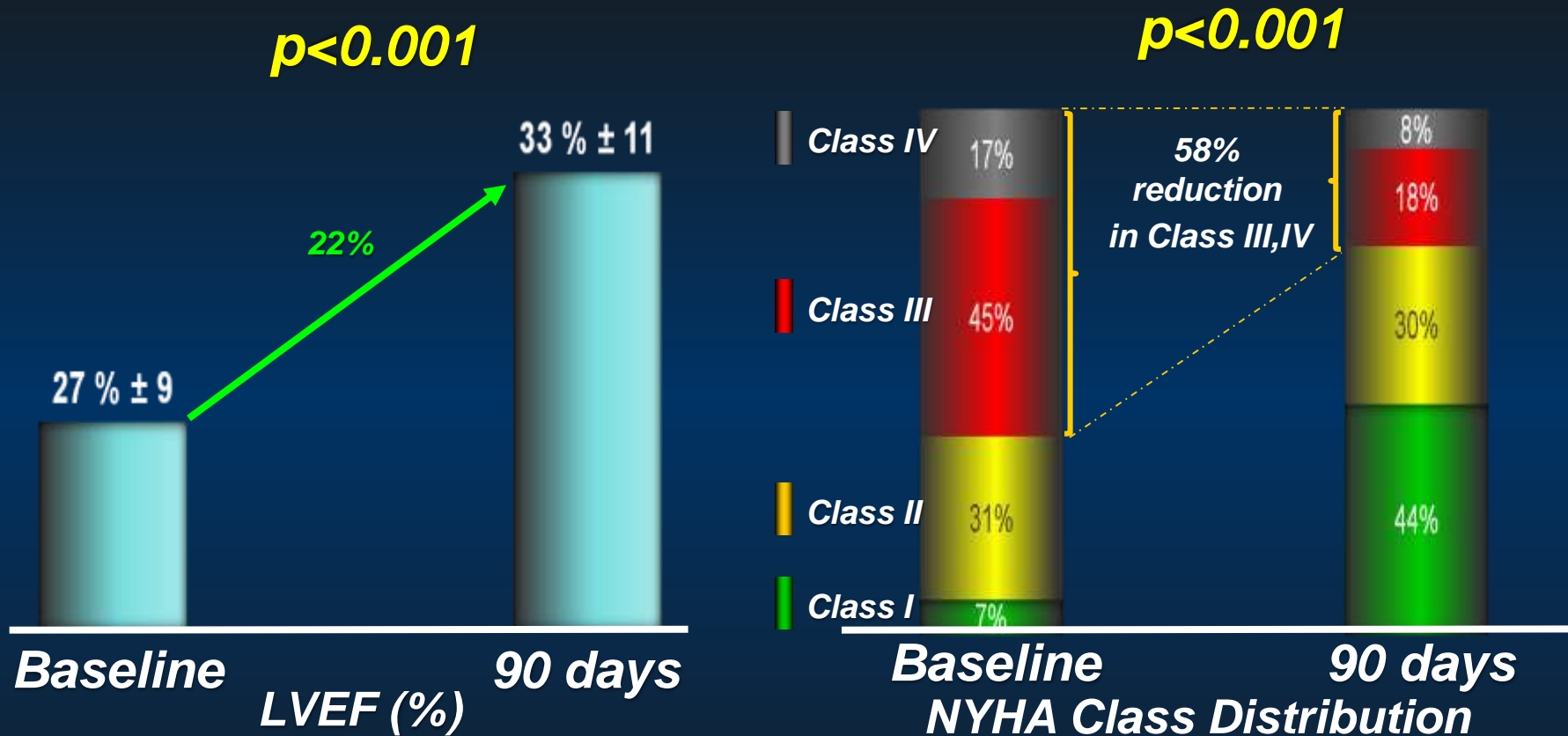
*Major Adverse Events (MAE) :

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

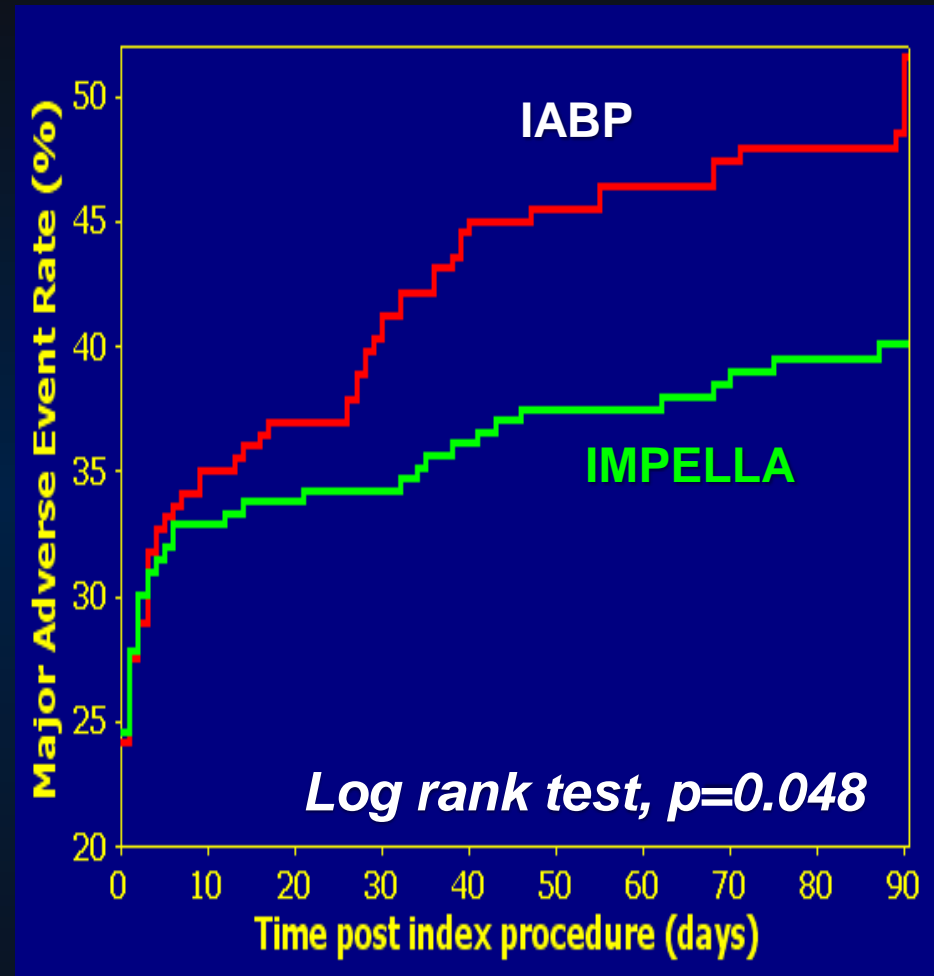
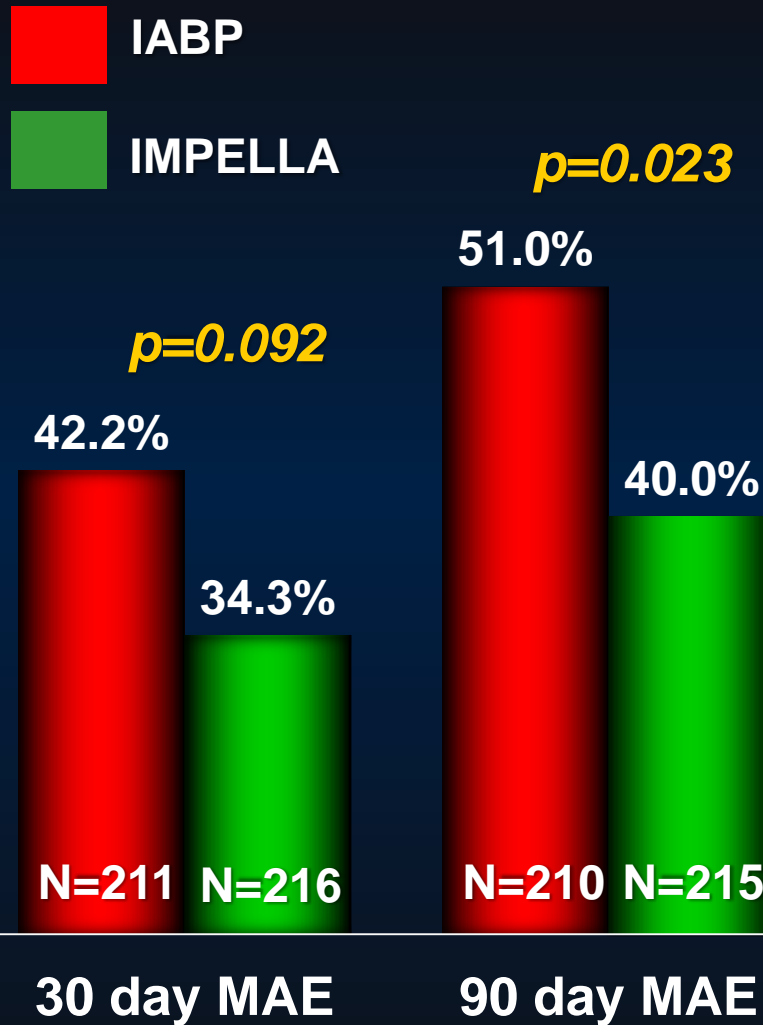
Procedural Characteristics

Procedural Characteristics	IABP (N=223)	Impella (N=225)	p- value
Use of Heparin	83.3%	93.3%	<0.001
IIb/IIIa Inhibitors	26.0%	13.8%	0.001
Total Contrast Media (cc)	241±114	267±142	0.036
Rotational Atherectomy (RA)	9.0%	14.2%	0.083
Median # of RA Passes/lesion (IQ range)	1 (1-2)	3 (2-5)	0.001
Median # of RA passes/pt (IQ range)	2.0 (2.0-4.0)	5.0 (3.5-9.5)	0.003
Median RA time/lesion (IQ range sec)	40 (20-47)	60 (40-118)	0.004
RA of Left Main Artery	3.1%	8.0%	0.024
Total Support Time (hours)	8.4±21.8	1.9±2.7	<0.001
Discharge from Cath Lab on device	36.7%	5.9%	<0.001

LVEF and NYHA Improvement Post PCI

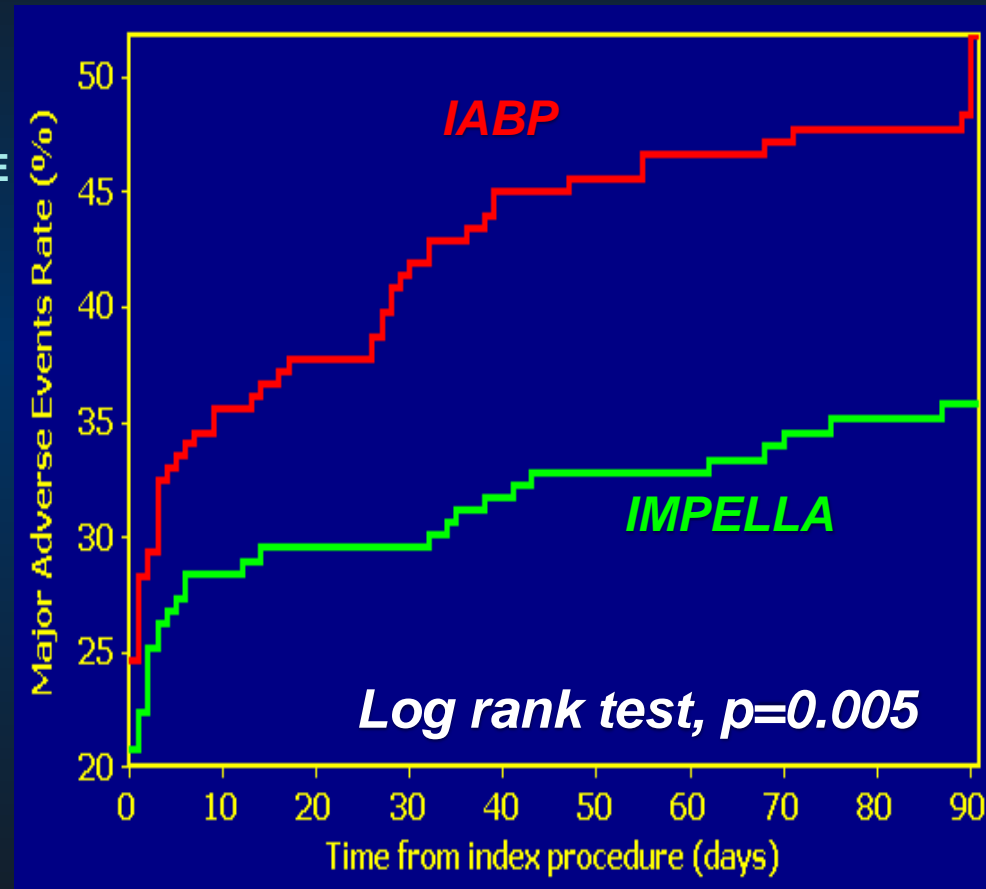
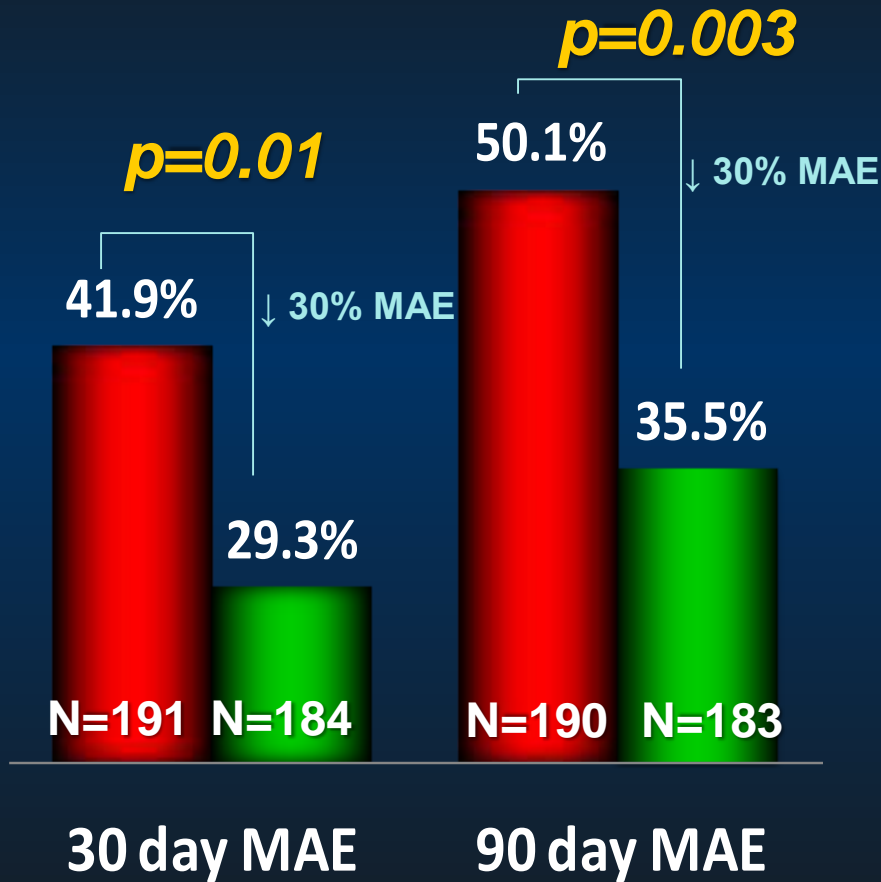


PROTECT II: Per Protocol MAE (N=427)



PROTECT II MAE Outcome

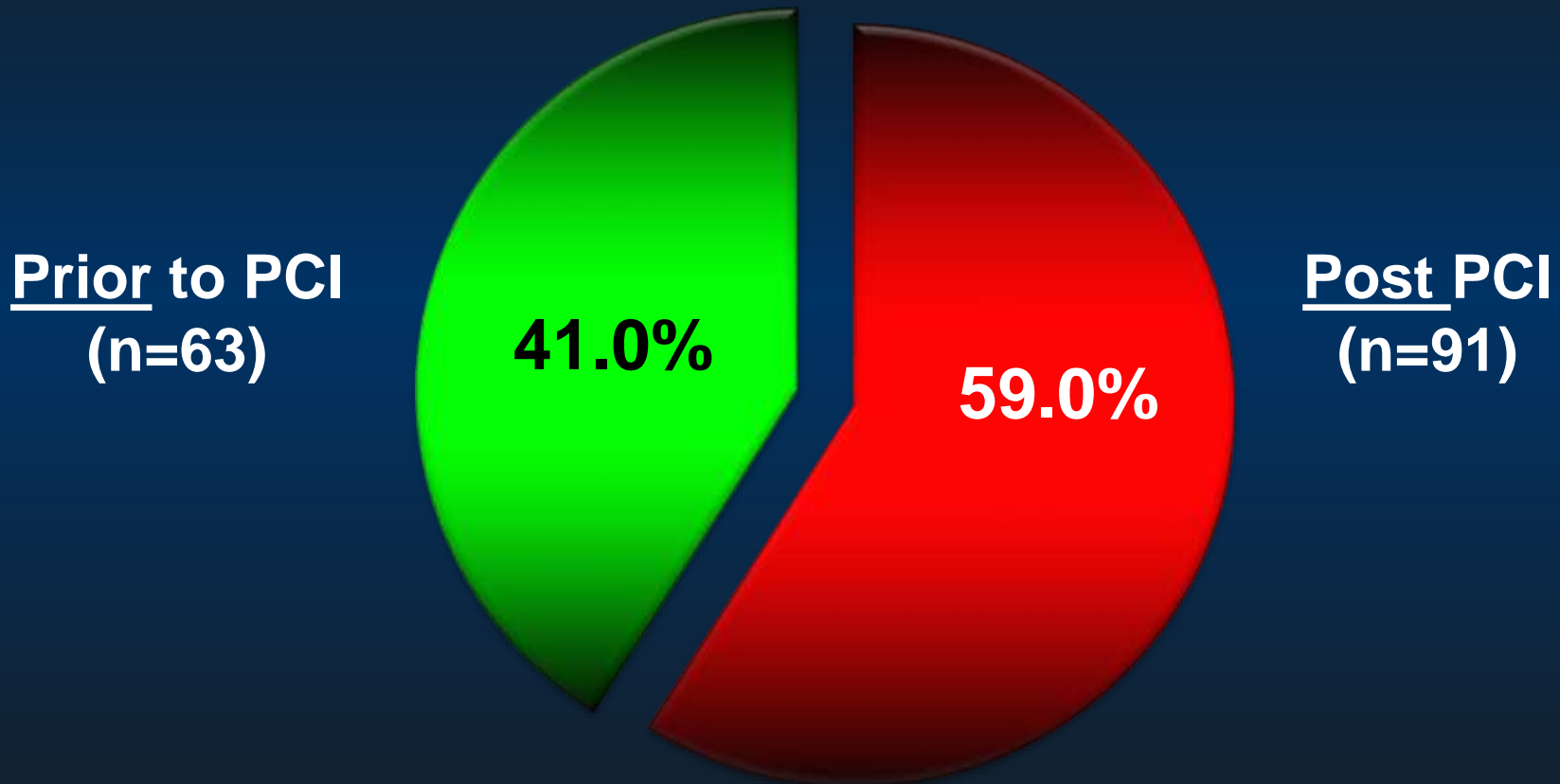
Pre-specified High Risk PCI Without Atherectomy Group
Per Protocol (N=374)



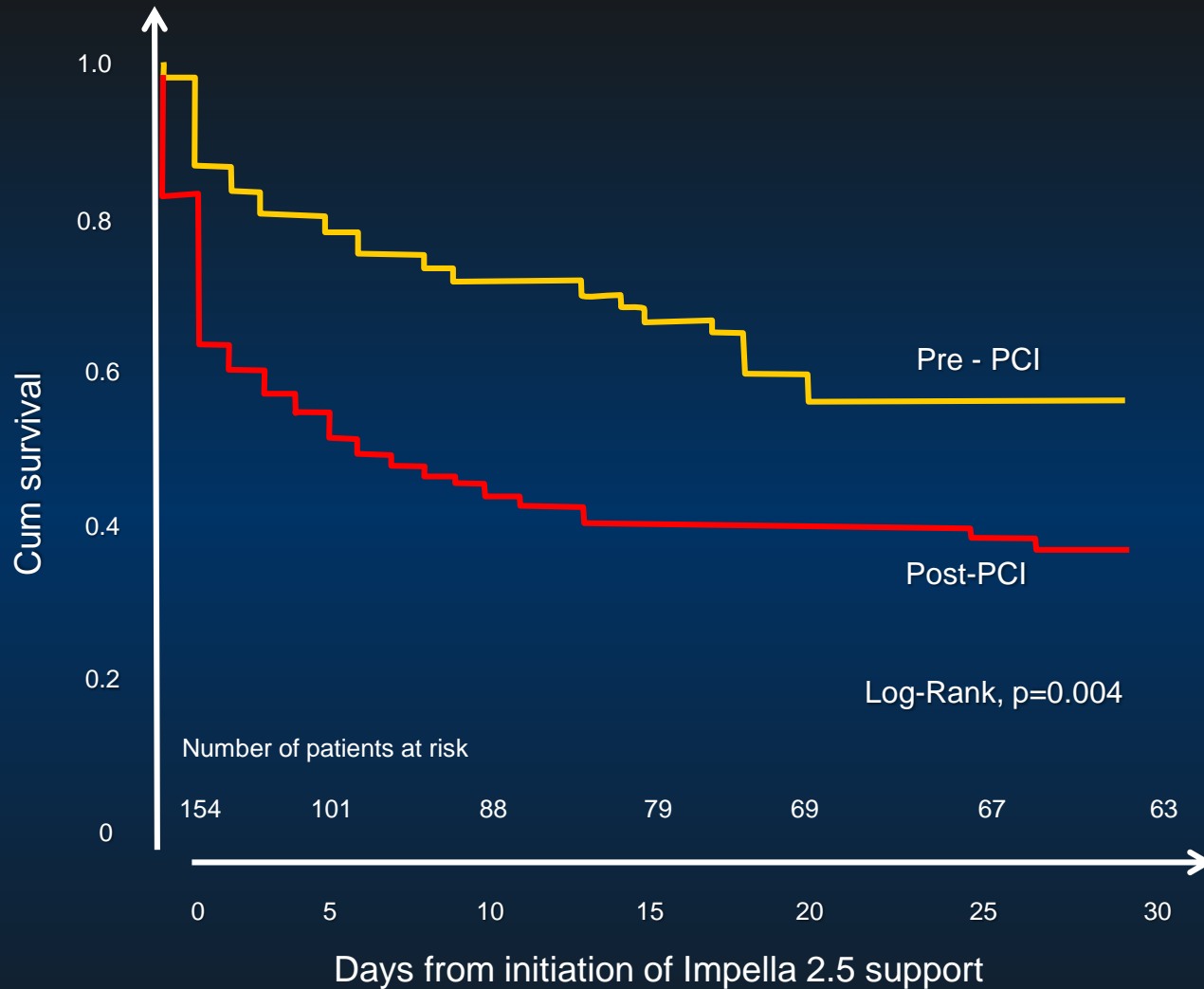
Cohen et al, Catheter Cardiovasc Interv. 2013 (In press)

MAE= Major Adverse Event Rate

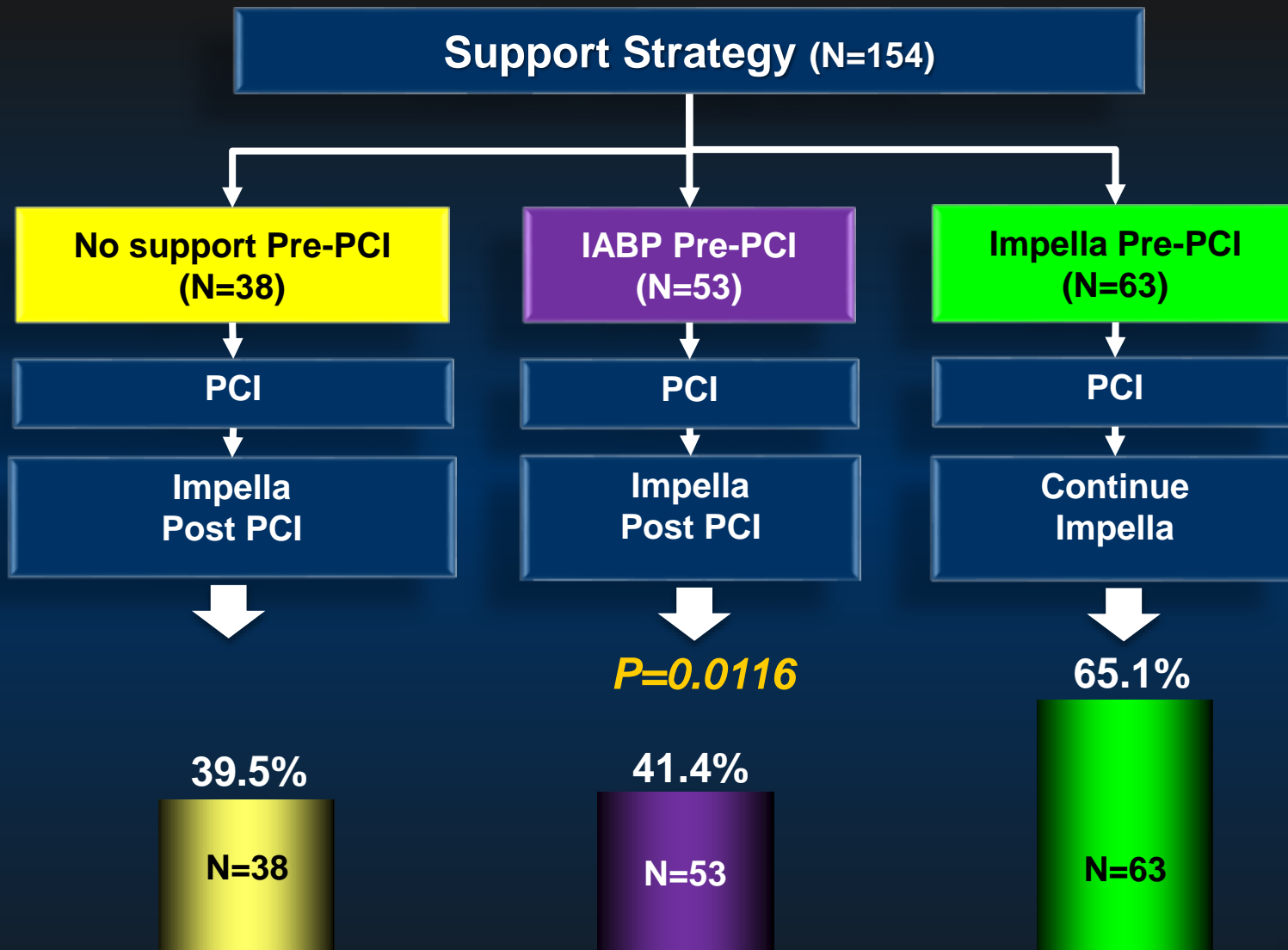
USPELLA Registry: Impella[®] Insertion Timing (N= 154)



Outcome: Impella Pre or Post PCI

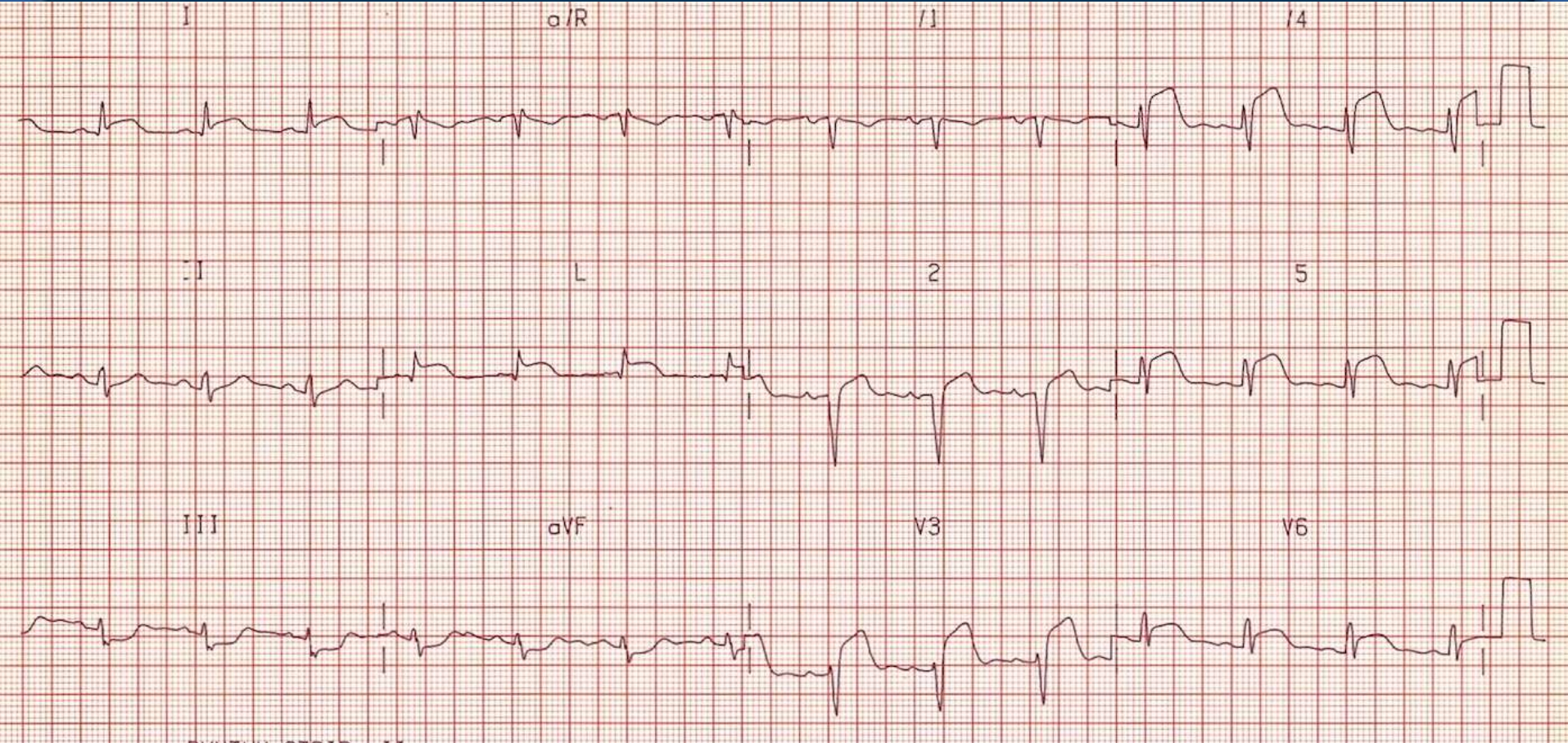


Outcome By Support Strategy

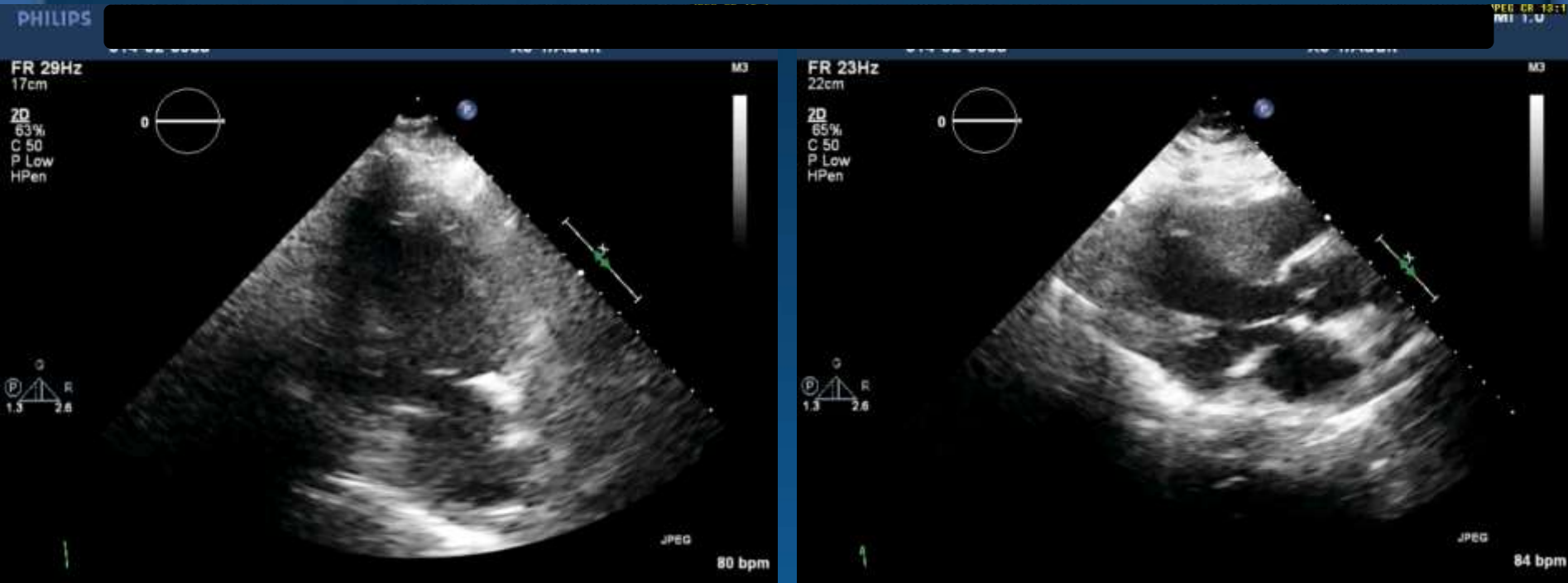


Survival to discharge

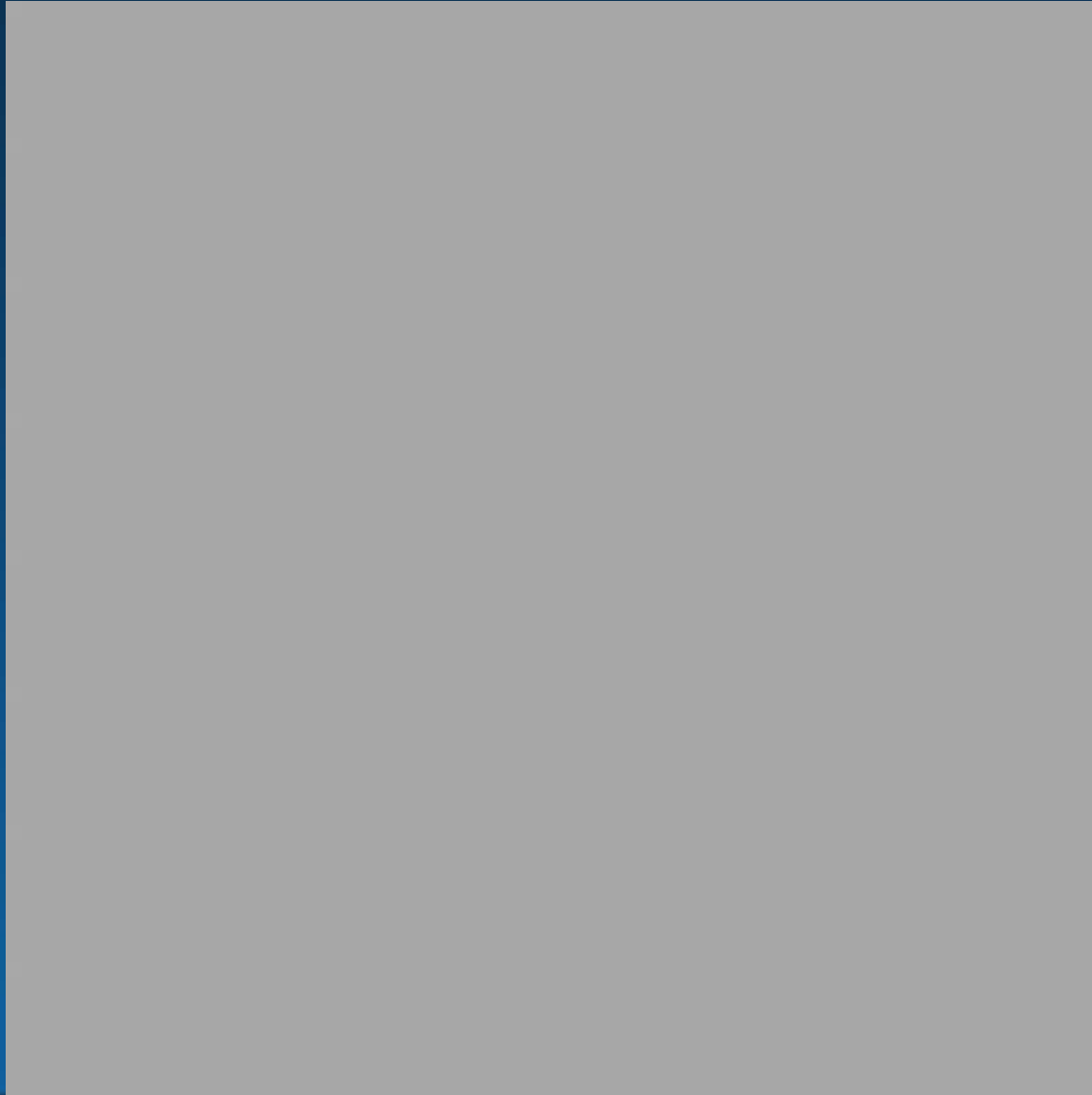
67y female, DM, PAD, Anterior STEMI at OSH, Trop I=16 hypotension, LVEF=35%



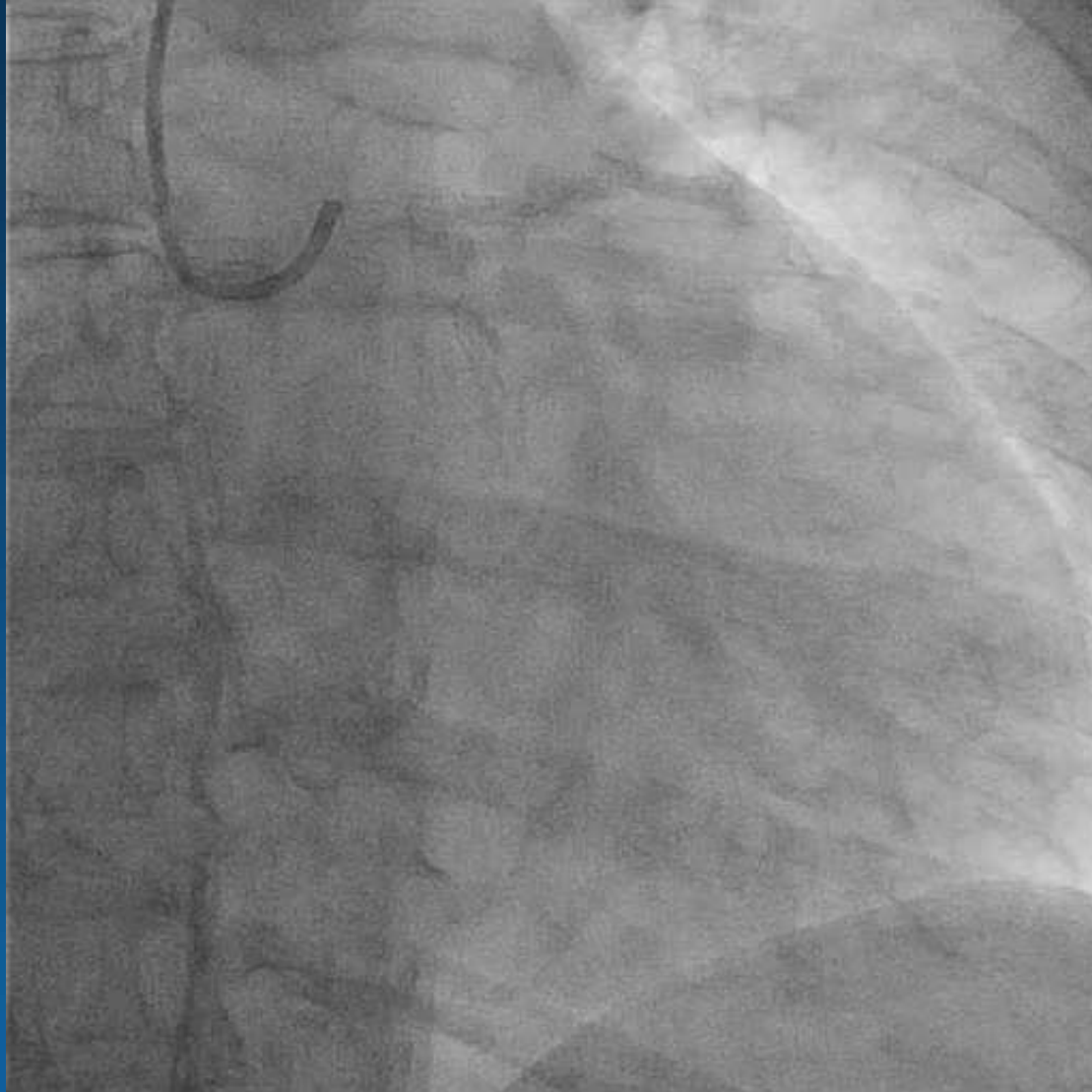
Transthoracic echocardiogram



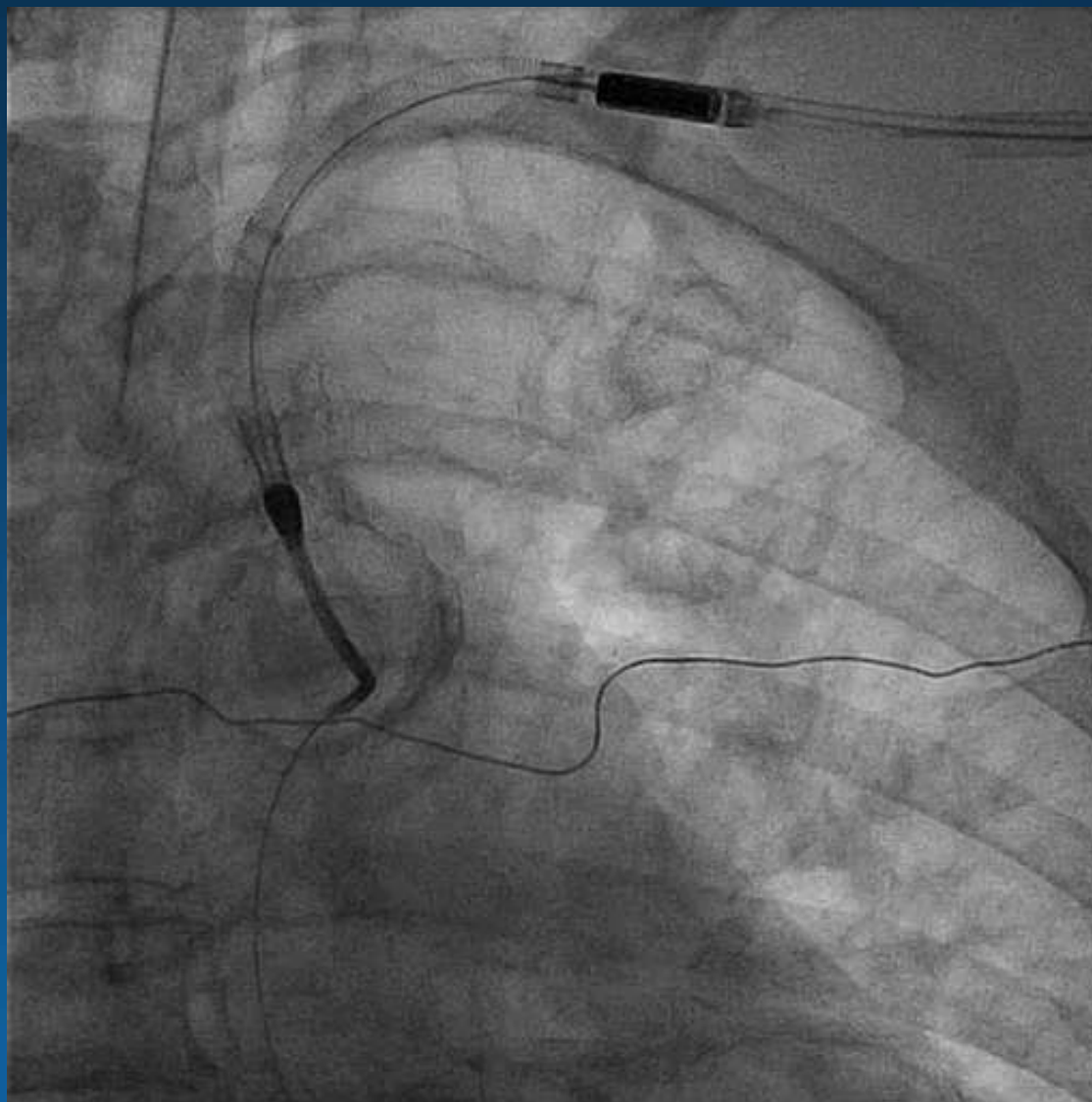
Distal Aortogram



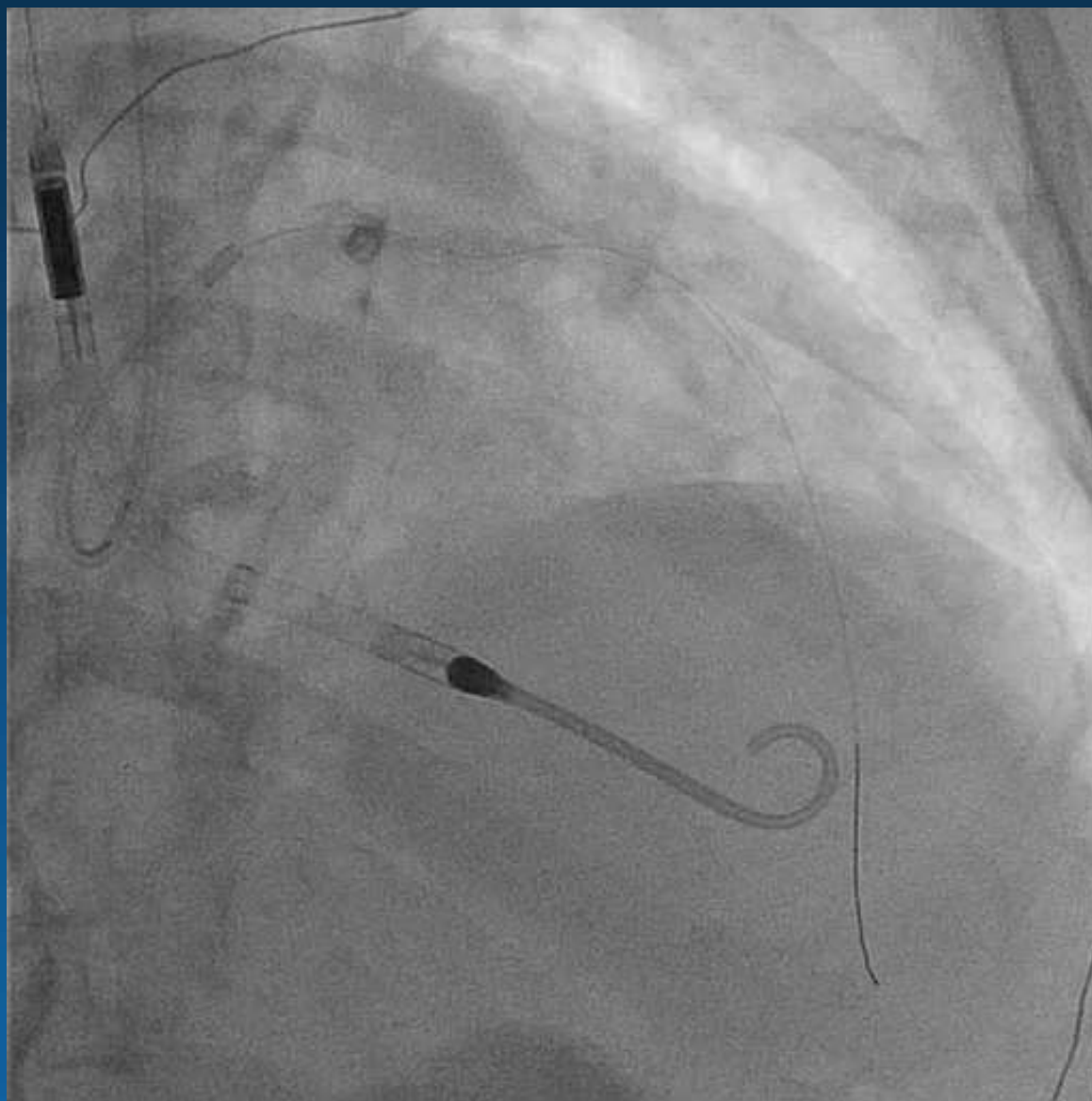
Diagnostic coronary angiogram



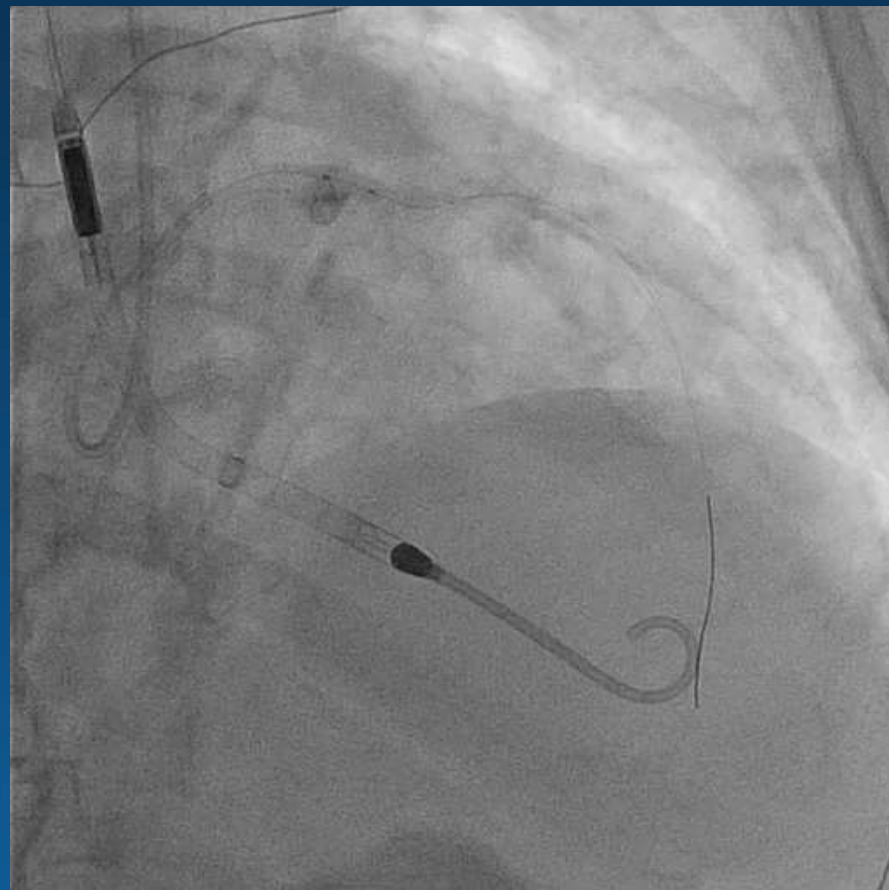
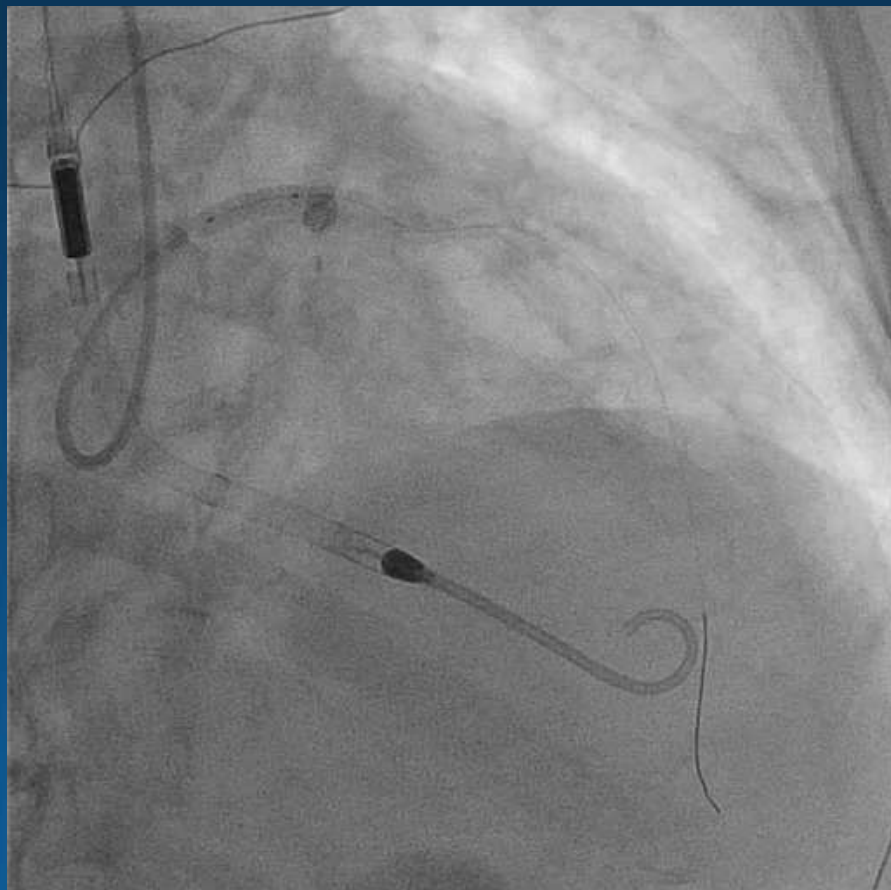
Impella 2.5 Insertion Via Left Axillary Artery Access



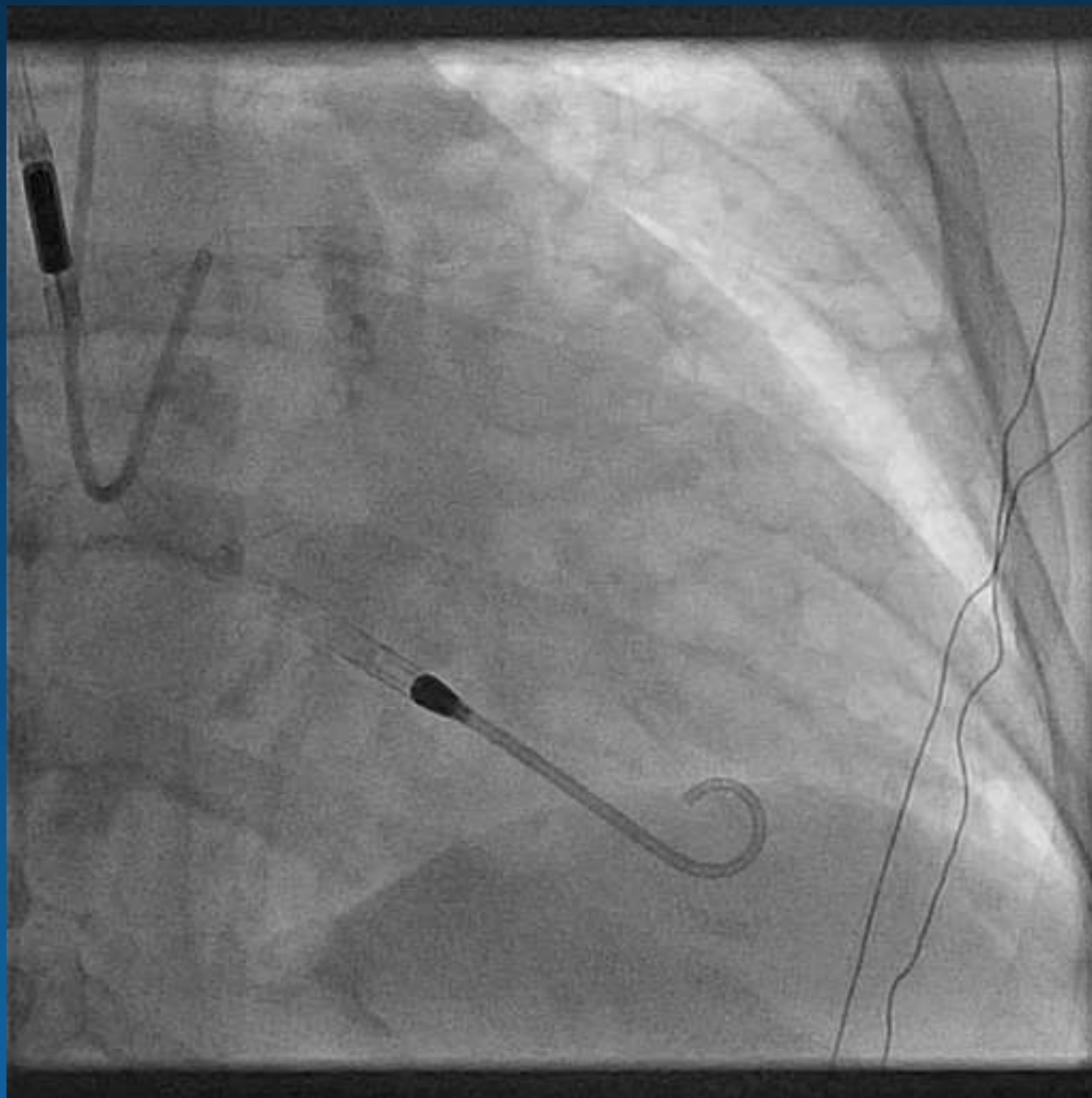
Coronary Angiogram Post-Balloon Angioplasty



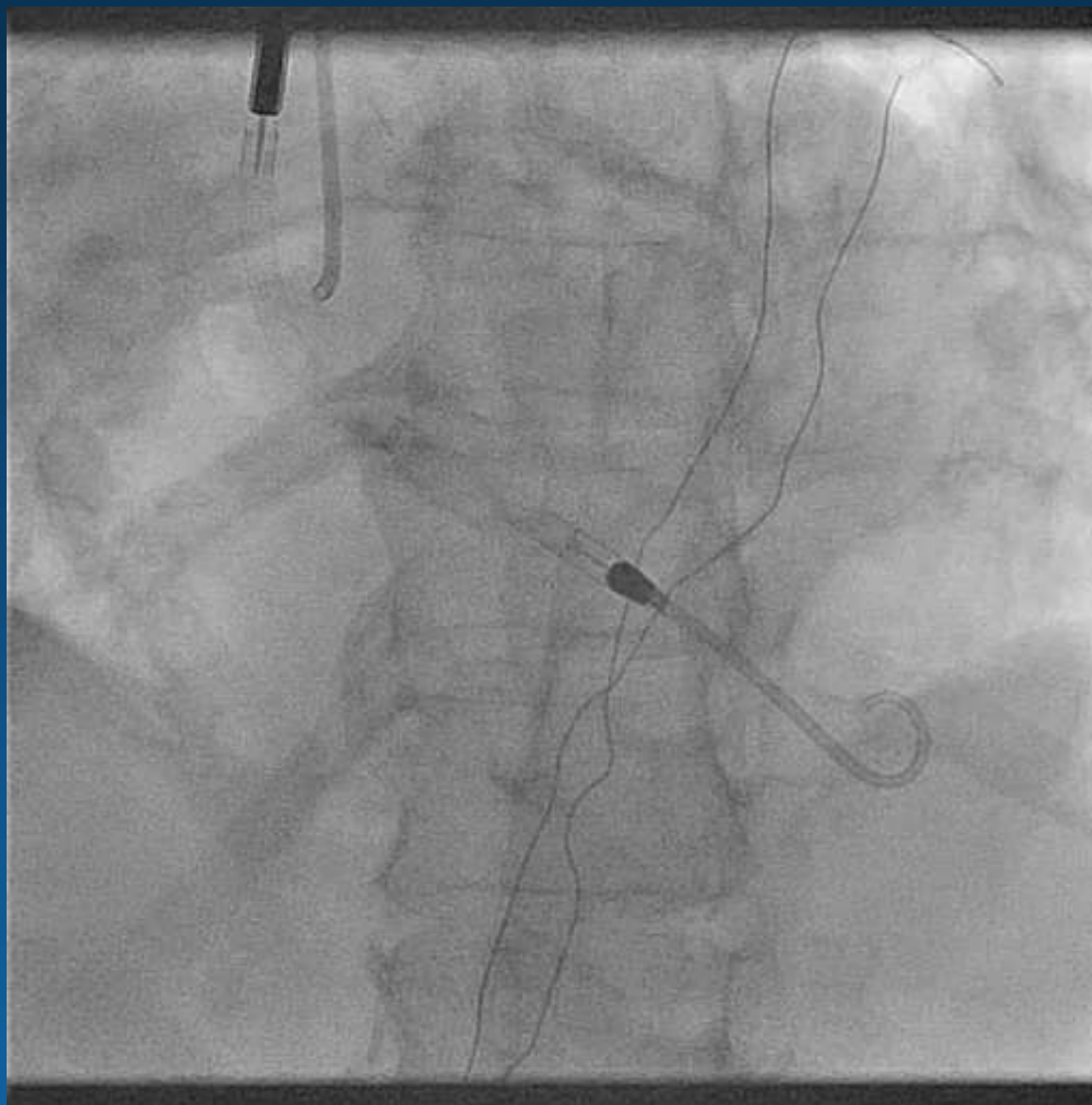
LM DES Implantation & Post-dilation



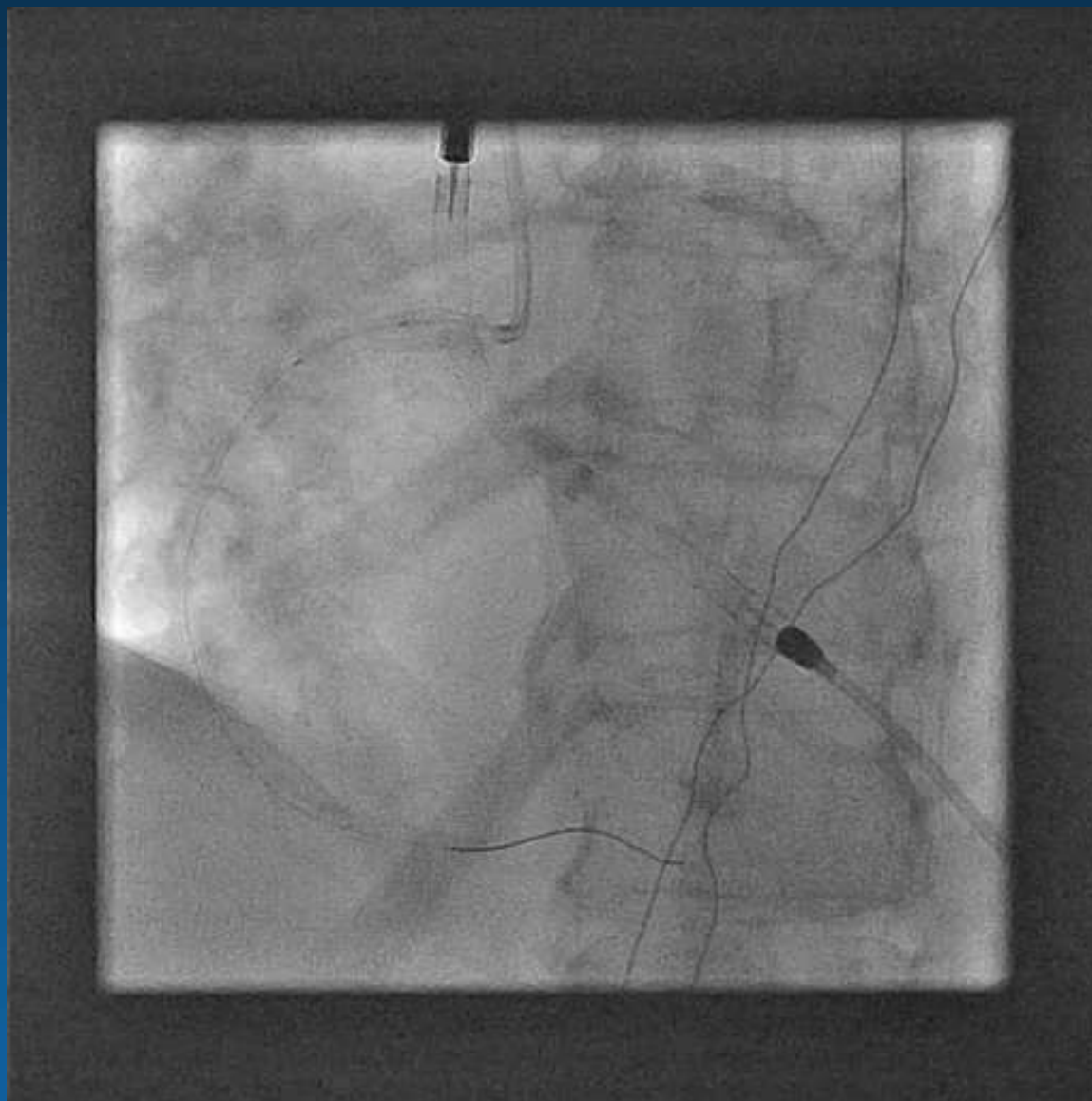
Final Left Coronary Angiogram



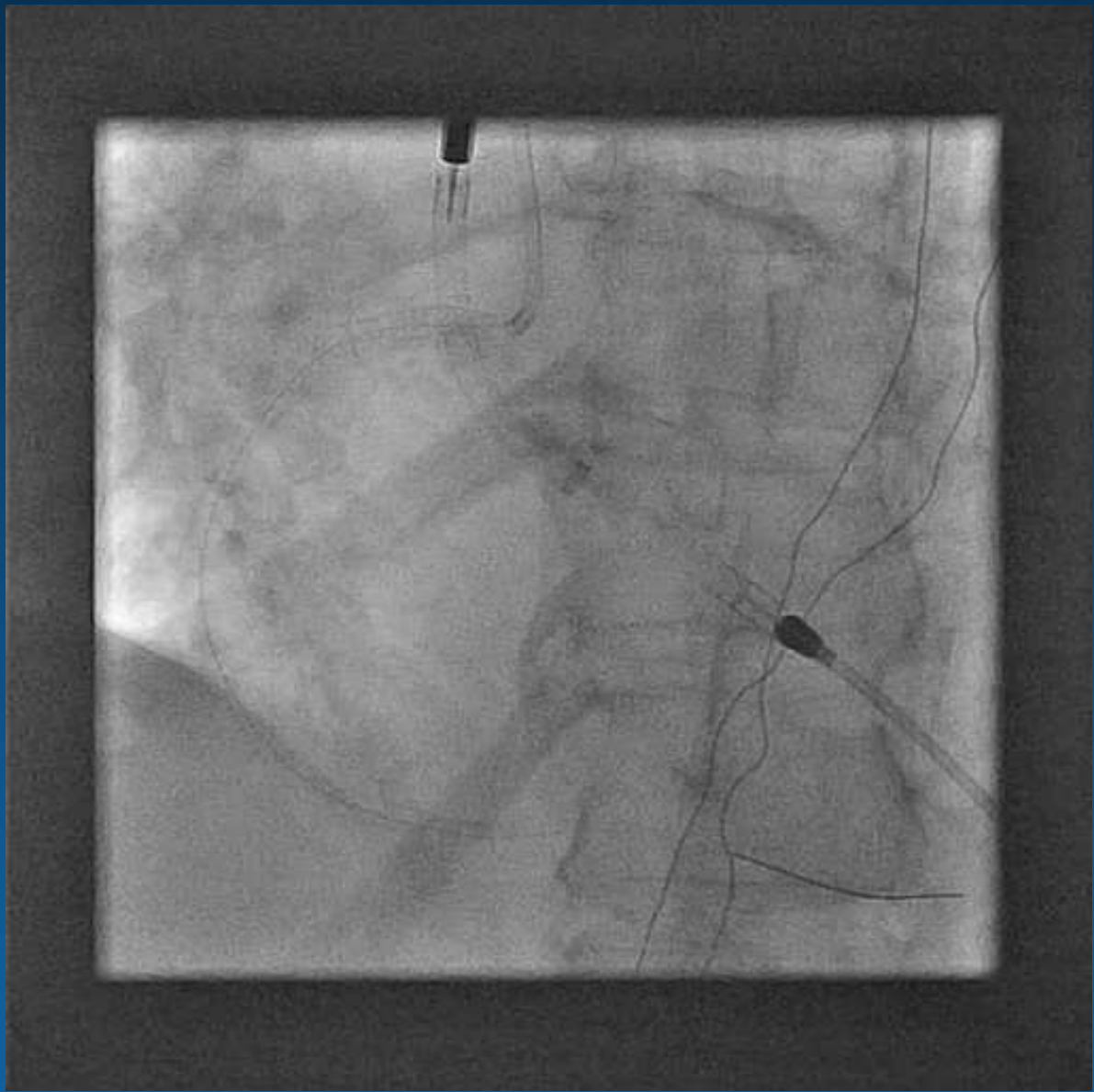
Right Coronary Angiogram



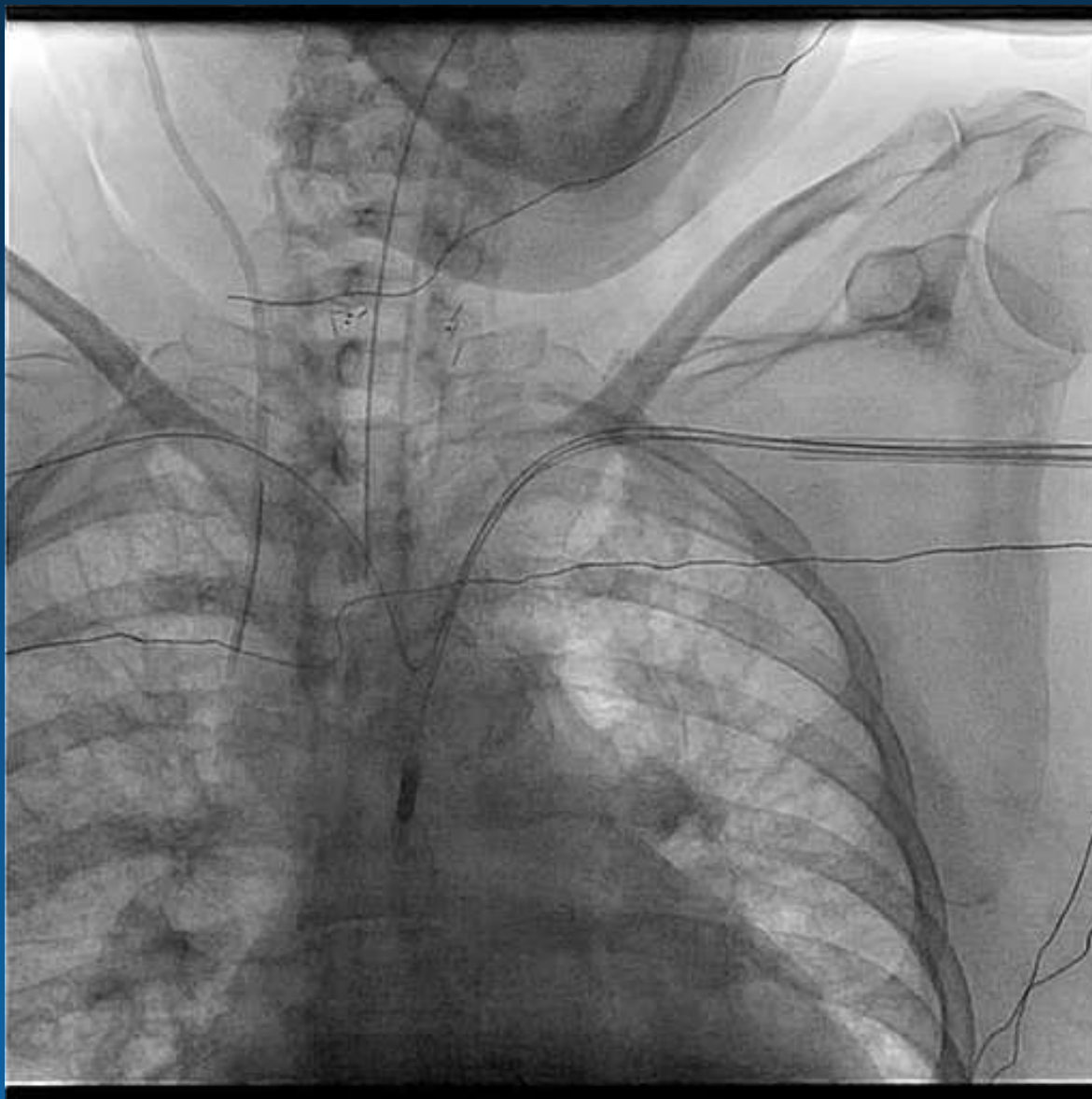
RCA Balloon Angioplasty & DES



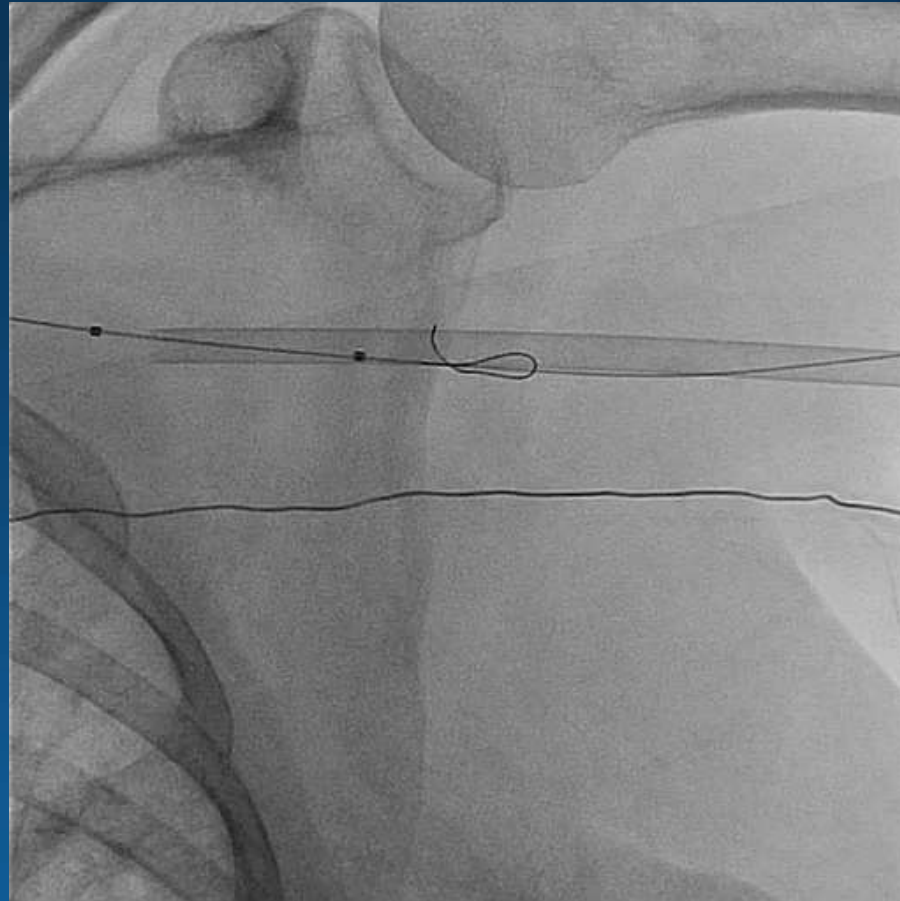
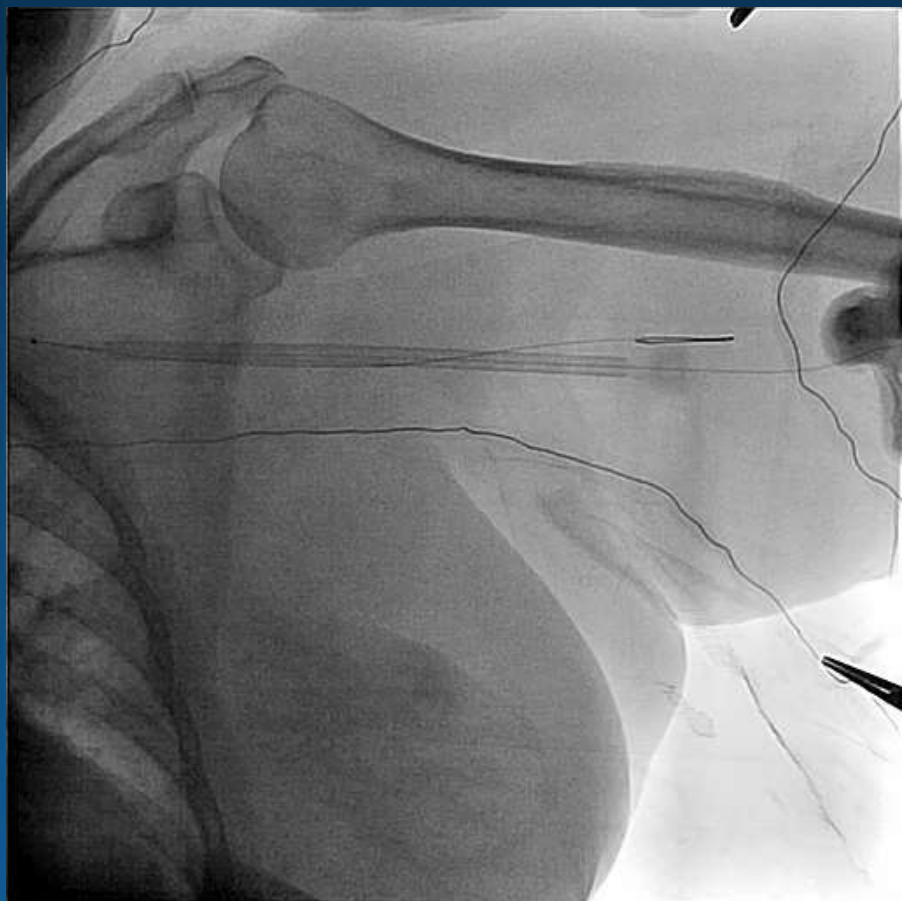
Final Right Coronary Angiogram



Impella Removal



Balloon Placement in LSCA



Final LSCA Angiogram After Sheath Removal



Conclusions

- Impella & IABP are most frequently used hemodynamic support devices in the cath lab that facilitate performance of high-risk elective PCI & during cardiogenic shock
- Impella provides better balance of efficacy, safety & feasibility during high risk PCI, and provides superior hemodynamic support compared to IABP, especially if placed pre-PCI

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- OUR PATIENTS