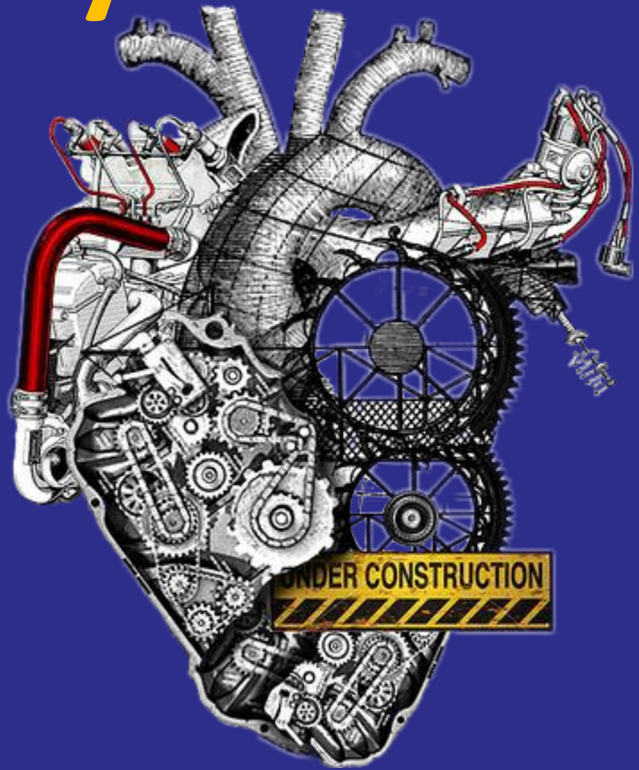
Percutaneous Mechanical Hemodynamic Support



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COAST 2018

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Speaker's Bureau	None
Grant/Research Support	None
Consulting Fees/Honoraria	None

Outline

- Why and in Whom do we use Mechanical support? Back to Basics
- National Trends in Use of Mechanical Cardiac Support (MCS)
- IABP
- Impella
- Tandem Heart/ECMO (briefly)
- Summary

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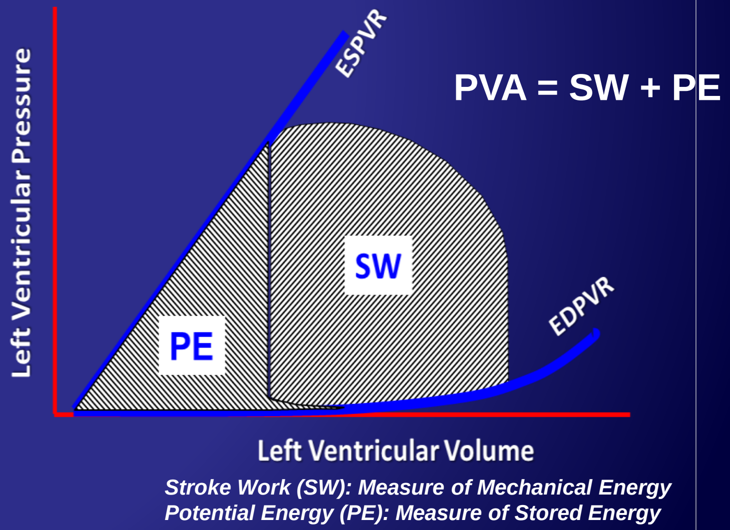
Hemodynamic and Metabolic Goals in Cardiogenic Shock

1. **Normalize hemodynamic profile**
   - CO, MAP
     - Lactate, pH
     - Decrease peri-procedural MI, arrhythmia, increasing coronary and end-organ perfusion, support complex procedures
   - Treat/prevent pulmonary edema (PCWP)
     - O_2 saturation
   - Treat/prevent excessive ↑ CVP



2. **LV Unloading**
   - Prevent/minimize remodeling
   - Minimize myocardial oxygen consumption
     - Determined by HR, Contractility, LV Mass, Pressure Volume Area (PVA)

High Risk Patients

1. Substrate

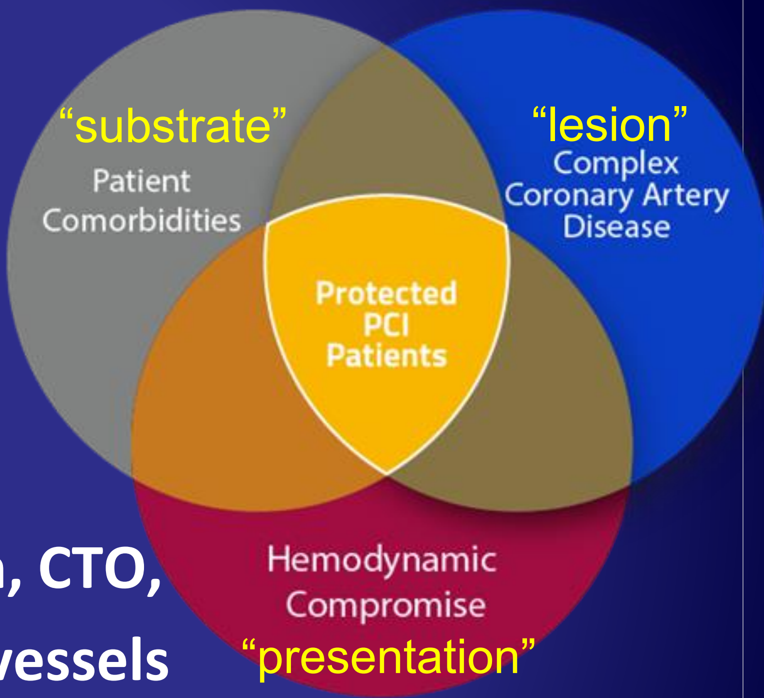
Elderly, low EF (<20-30%), CKD, DM, prior MI, frail

2. Lesion

Unprotected LM, high risk bifurcation, MV PCI, calcification, CTO, No re-flow, SVG, large territory vessels

3. Presentation

ADHF/Acute cardiogenic shock, STEMI/ACS, cardiac arrest, Recalcitrant ventricular arrhythmia



JACC VOL. 65, NO. 19, 2015
MAY 19, 2015:e7-26

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care

Who may benefit from percutaneous hemodynamic support?

- Guidelines:

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

5.6. Percutaneous Hemodynamic Support Devices: Recommendation

CLASS IIb

1. Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients. *(Level of Evidence: C)*

5.2.3. Cardiogenic Shock: Recommendations

CLASS I

1. PCI is recommended for patients with acute MI who develop cardiogenic shock and are suitable candidates (384,421–423). *(Level of Evidence: B)*
2. A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy (384,424–427). *(Level of Evidence: B)*

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care

1. Percutaneous MCS (Impella and TandemHeart) > pharmacologic therapy. Should be reimbursed
2. Cardiogenic shock ↑↑ high mortality despite revascularization/meds. Early MCS *if* fail to rapidly improve
3. High risk PCI: MVD, LM, last patent conduit, inoperable, severely reduced EF, or elevated LVEDP
4. Profound cardiogenic shock: IABP < Impella CP, TandemHeart, ECMO
5. ADHF. Consider MCS > VAD if rapid recovery expected (e.g., fulminant myocarditis, peripartum CM, Takotsubo). Acute severe MR (post MI- ischemic vs papillary rupture)
6. If oxygenation impaired, add oxygenator to a TandemHeart circuit or use ECMO
7. Insufficient data to support or refute routine use of MCSs as adjunct to primary PCI in large AMI to ↓ reperfusion injury or infarct size
8. Failure to wean CPB, RHF s/p OHT, high-risk EP procedures w/ prolonged hypotension, valvular interventions
9. Severe BiV failure : Consider both RV and LV MCS or V-A ECMO. RV support for isolated RV failure
10. Registries and RCTs critically needed!
11. Early analyses suggest cost-effectiveness of MCS for emergent use > surgical ECMO or VAD support, and for elective use vs IABP. Further data are necessary.

JACC VOL. 65, NO. 19, 2015

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Original Investigation

Trends in the Use of Percutaneous Ventricular Assist Devices

Analysis of National Inpatient Sample Data, 2007 Through 2012

JAMA Intern Med. 2015;175(6):941-950.

- Source: National Inpatient Sample
  - Developed by AHRQ (Advanced Healthcare Research Quality)
  - Comprises 20% of all inpatient discharges from US hospitals.
- ICD9 codes used to identify PVAD vs IABP
- PVAD = Impella + Tandem Heart

Original Investigation

Trends in the Use of Percutaneous Ventricular Assist Devices

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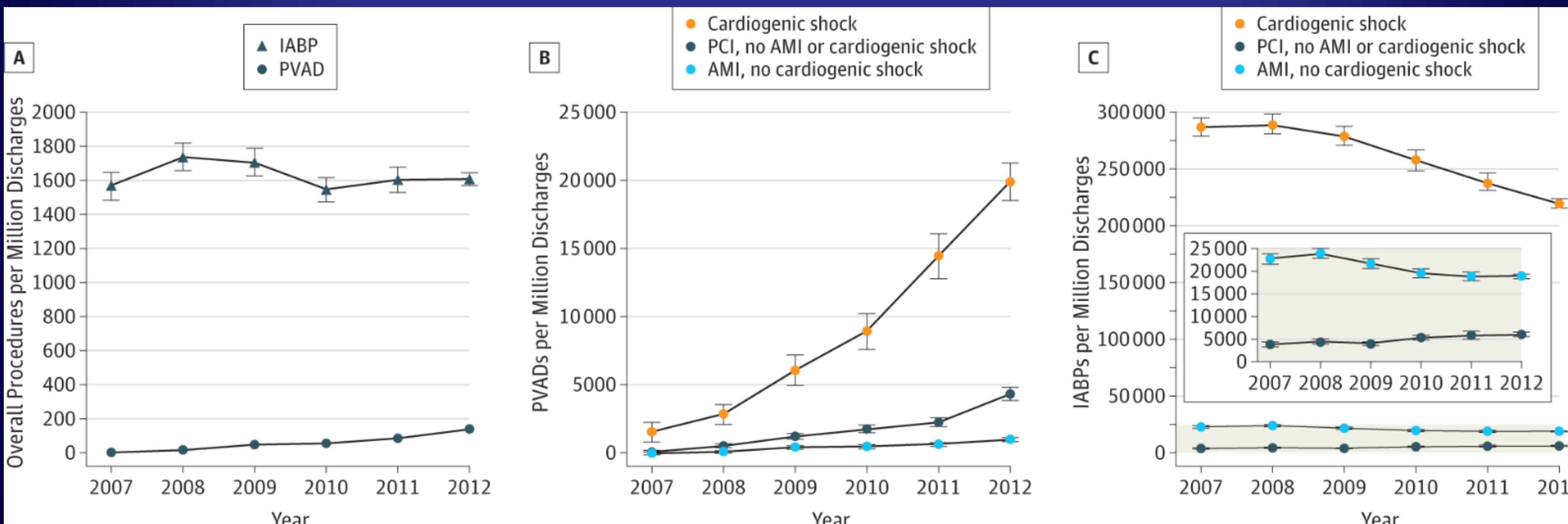
JAMA Intern Med. 2015;175(6):941-950.



- 30 fold increase in pVAD use in 6 yrs
- Increased PCI and Shock, decreased IABP volumes

Original Investigation

Trends in the Use of Percutaneous Ventricular Assist Devices Analysis of National Inpatient Sample Data, 2007 Through 2012

JAMA Intern Med. 2015;175(6):941-950.

- Use of PVAD
  - In 2007, 72 hospitals
  - In 2012, 477 hospitals
- Annual volume of 10 or more PVADs/yr
  - 0 in 2007
  - 102 in 2011
- Propensity Matched Analysis
  - PVADs in older, sicker, worse shock BUT after propensity matching, still ↑ mortality for PVAD vs IABP (OR 1.23, 1.06 – 1.43, p = 0.007)

Temporal Trends and Outcomes of Patients Undergoing Percutaneous Coronary Interventions for Cardiogenic Shock in the Setting of Acute Myocardial Infarction

A Report From the CathPCI Registry

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 9, NO. 4, 2016
FEBRUARY 22, 2016:341-51

- Registry Analysis
- Temporal trends in demographics, clinical characteristics, management strategies, and in-hospital outcomes
- Patient population: Patients with AMI complicated by cardiogenic shock undergoing PCI.
- N ~ 57,000 from 2005 – 2013.

Temporal Trends and Outcomes of Patients Undergoing Percutaneous Coronary Interventions for Cardiogenic Shock in the Setting of Acute Myocardial Infarction

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TABLE 2 Catheterization Laboratory Characteristics in Cardiogenic Shock in the Setting of Acute Myocardial Infarction Patients Undergoing Percutaneous Coronary Intervention

	2005–2006 (n = 5,658)	2006–2008 (n = 10,337)	2009–2010 (n = 13,562)	2011–2013 (n = 26,940)	p Value
STEMI	80.6	81.1	82.1	82.1	0.01
Symptom to presentation (STEMI only)					<0.001
<6 h	88.1	89.6	79.5	77.2	
6–12 h	7.7	6.6	9.2	9.3	
>12 h	4.2	3.8	11.3	13.5	
Thrombolytics	4.0	2.0	1.7	1.2	<0.001
Radial access	0.4	0.6	1.1	4.2	<0.001
>70% stenosis					
Left main	7.1	7.7	8.4	8.9	<0.001
LAD	88.0	87.0	90.0	87.4	<0.001
LCX	44.0	45.0	45.5	45.5	0.004
RCA	66.7	63.6	64.3	63.7	0.02
RI	4.2	4.5	4.1	4.2	<0.001
Grafts	11.1	10.9	10.6	10.0	<0.001
Median fluoroscopy time (min)	14.0	13.0	13.0	12.8	<0.001
Median contrast volume (ml)	200.0	200.0	190.0	180.0	<0.001
High-risk lesion (type C)	69.6	66.2	71.2	72.4	<0.001
>1 lesion treated	31.5	30.7	29.0	25.8	<0.001
IABP	49.5	49.7	49.5	44.9	<0.001
Other LV support devices	NA	NA	5.5	7.2	0.60

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↑ STEMI

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Increase of all lesion types

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IABP ↓
pVAD ↑

Temporal Trends and Outcomes of Patients Undergoing Percutaneous Coronary Interventions for Cardiogenic Shock in the Setting of Acute Myocardial Infarction

A Report From the CathPCI Registry

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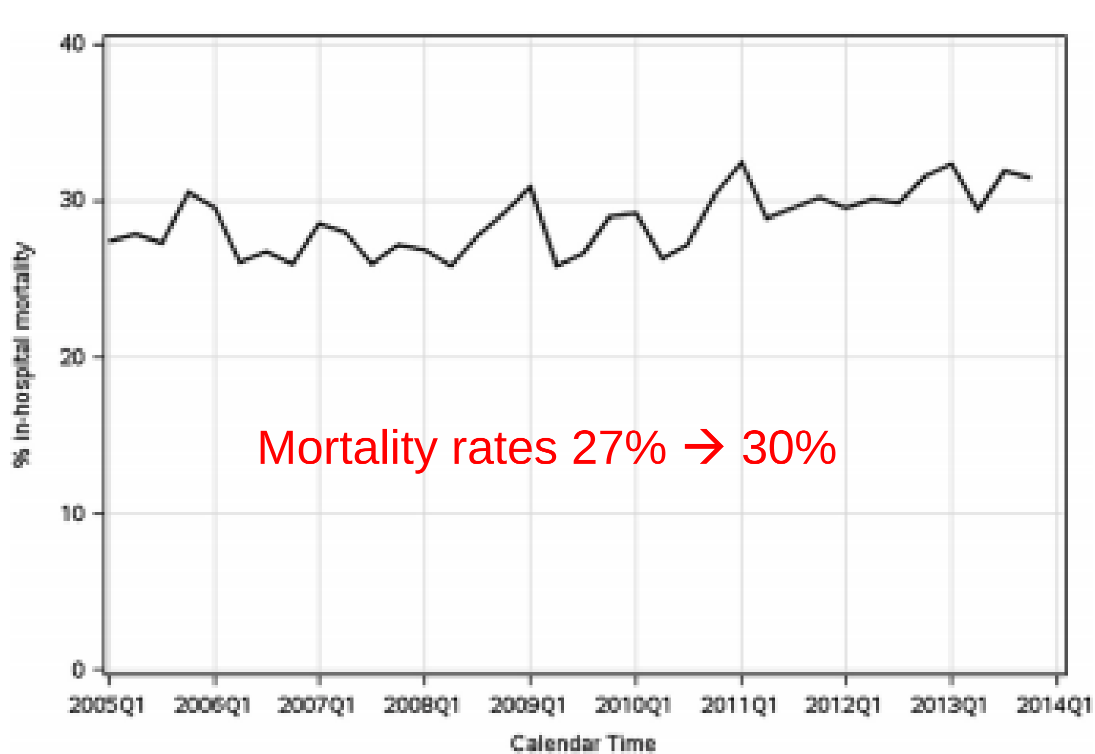
FIGURE 1 Rate of In-Hospital Mortality Over Time



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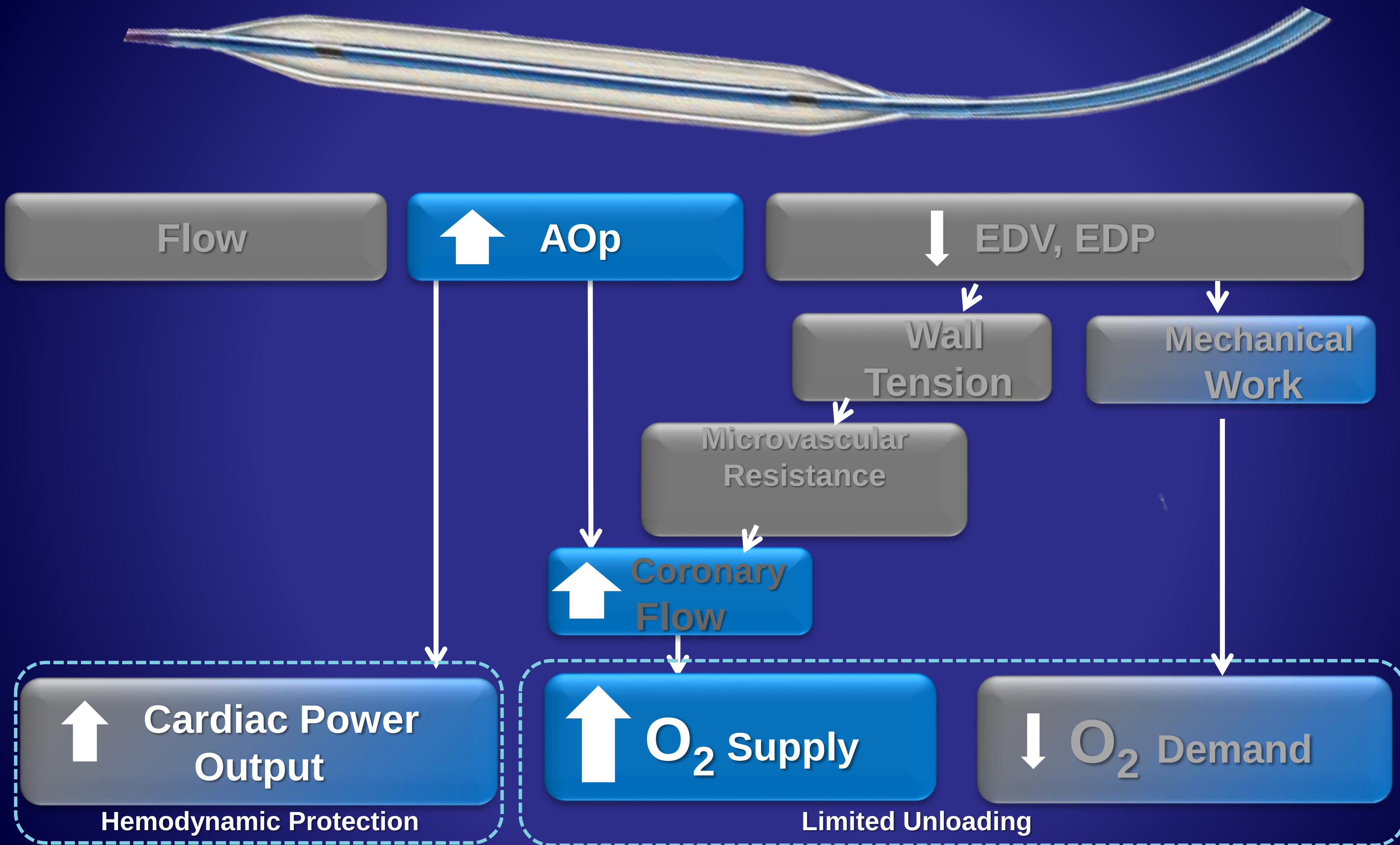
IABP

- Most Common
- Dual lumen (helium, pressure)
- Why do we use helium
  - Low viscosity – shuttles fast in/out of body
  - Absorbs rapidly and non-toxic
- When is the balloon supposed to inflate?
  - Onset of diastole
  - Electrocardiographic repolarization (or the middle of the T wave)
- When is the balloon supposed to deflate?
  - Onset of systole
  - Peak of R wave

Hemodynamic Effects of IABP



Burkhoff D. et.al. J Am Coll Cardiol. 2015 Dec 1
Burkhoff D. et.al. Catheter Cardiovasc Interv. 2012 N

IABP

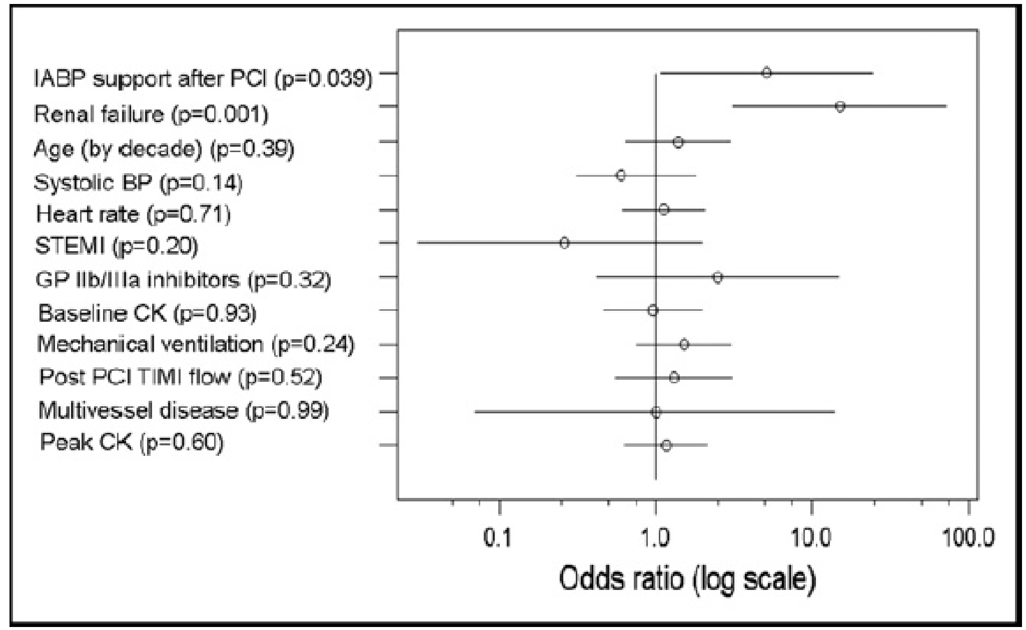
- Pumping inadequate: Pitfalls
  - Poor ECG quality, electrical interference, arrhythmias
  - Tachycardia reduces diastolic filling time
- Hemodynamic effects
  - ↑ DBP and ↓ decreases afterload
  - ↓ MvO2
  - "Modestly" enhances cardiac output
  - "Modest" ventricular unloading

- Contraindications?
  - Mod-severe AI
  - PAD or aortic disease
- Complications
  - Stroke
  - Vascular Injury
  - Thrombocytopenia
    - Plt deposition on IABP membrane
    - Heparin

Patient's <u>must</u> have some level of LV function and electrical stability for IABP to be effective.

Comparison of Hospital Mortality With Intra-Aortic Balloon Counterpulsation Insertion Before Versus After Primary Percutaneous Coronary Intervention for Cardiogenic Shock Complicating Acute Myocardial Infarction

- Retrospective
- N = 48
- AMI c/b CS
- Pre-PCI IABP
  - ↓ peak CK
  - ↓ in-hosp mortality
  - ↓ MACE



- First paper to suggest that Pre-PCI IABP is better than Post-PCI

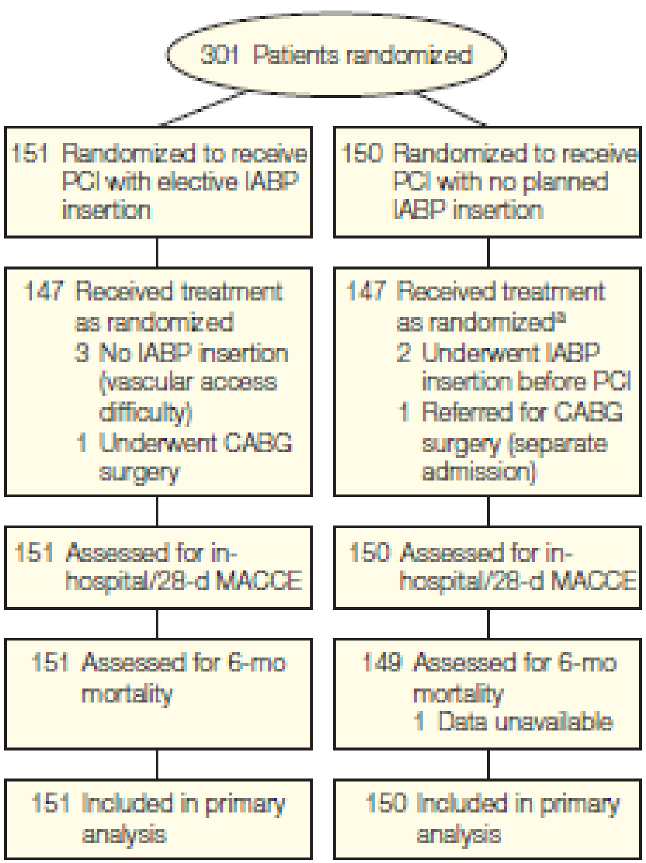
(Am J Cardiol 2010;105:967–971)

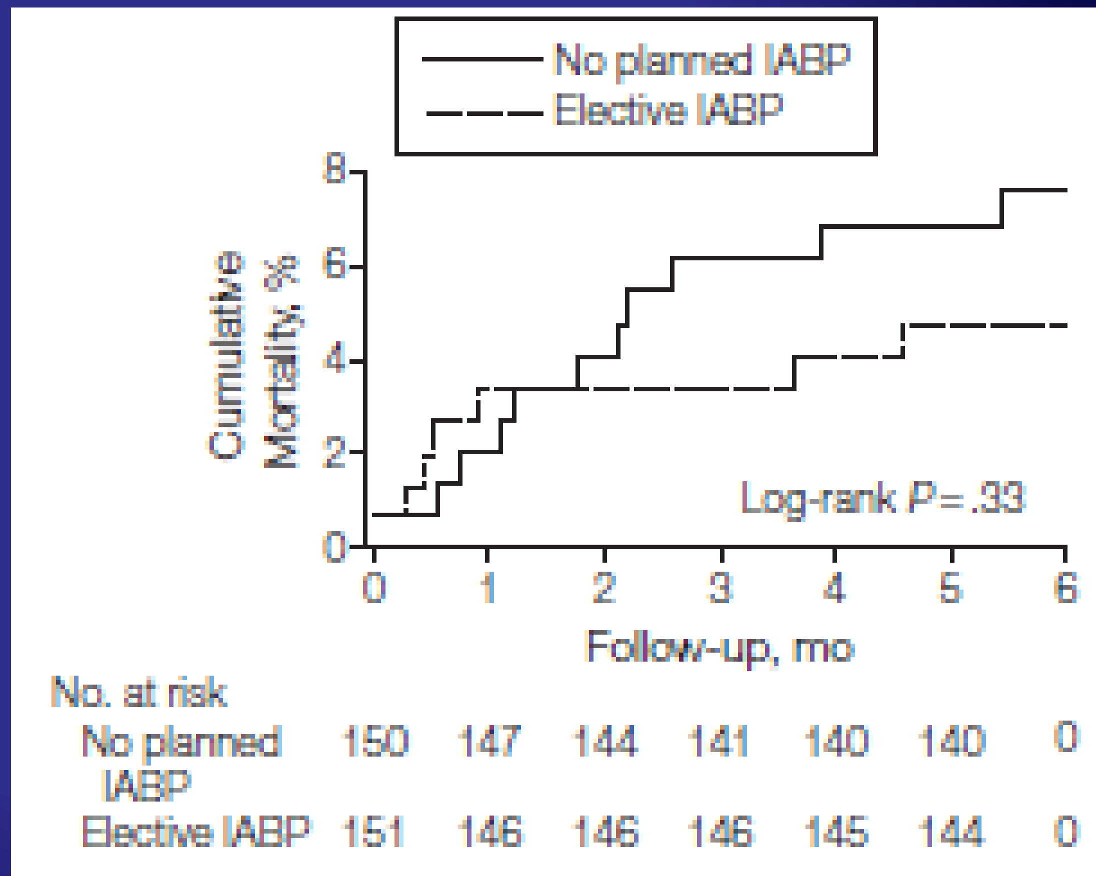
Elective Intra-aortic Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention

A Randomized Controlled Trial

JAMA. 2010;304(8):867-874

Figure 1. Study Flow





Elective Intra-aortic Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention

A Randomized Controlled Trial

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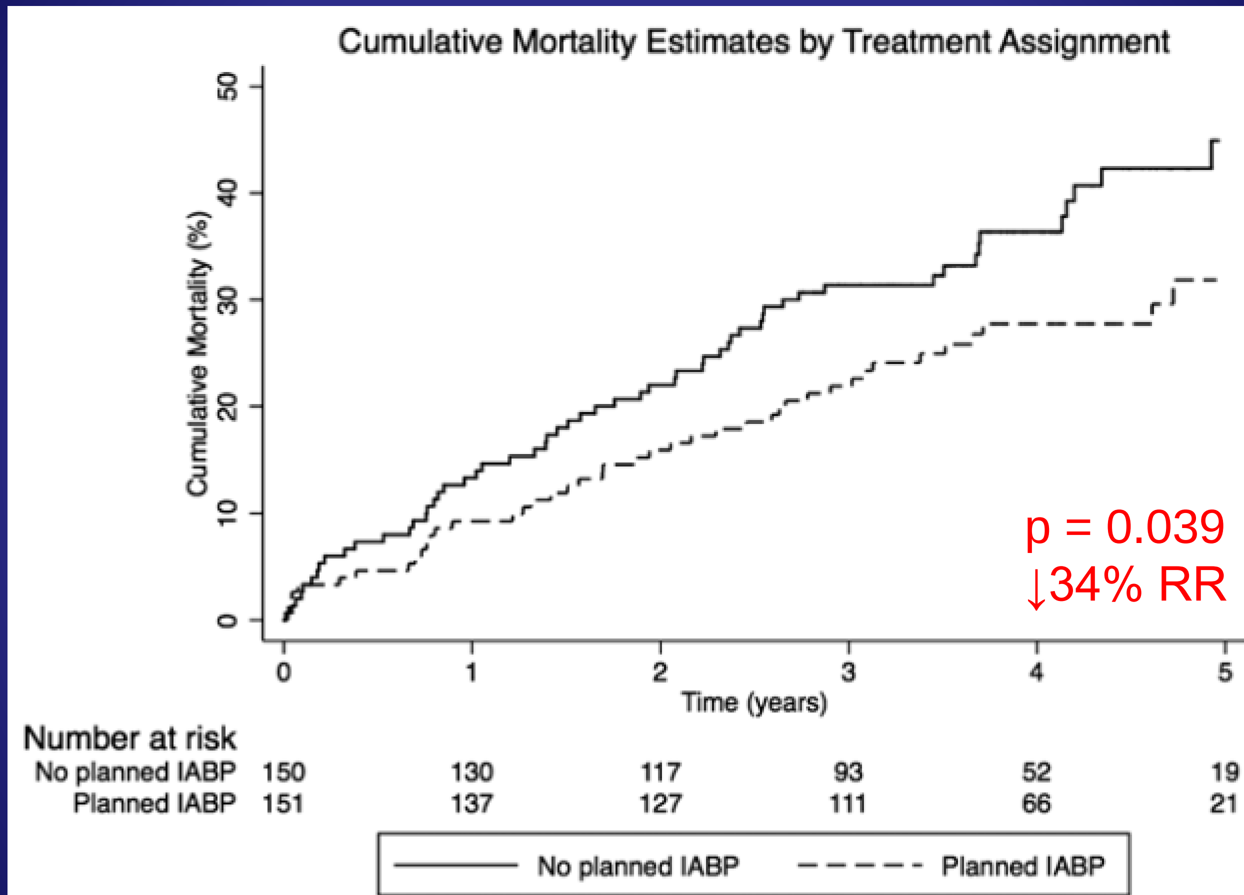
Table 2. Trial Outcomes

Variable	Elective IABP (n = 151) No. (%)	No Planned IABP (n = 150) No. (%)	OR (95% CI)[a]	*P* Value
Primary end point				
MACCE[b]	23 (15.2)	24 (16.0)	0.94 (0.51-1.76)	.85
MI	19 (12.6)	20 (13.3)	0.93 (0.48-1.83)	.85
Death	3 (2.0)	1 (0.7)	3.02 (0.31-29.37)	.34
CVA	2 (1.3)	0		
Further revascularization	1 (0.7)	4 (2.7)	0.24 (0.03-2.20)	.21
Secondary end points				
6-mo mortality	7 (4.6)	11 (7.4)[c]	0.61 (0.24-1.62)	.32
Bleeding				
All	29 (19.2)	17 (11.3)	1.86 (0.93-3.79)	.06
Major	5 (3.3)	6 (4.0)	0.83 (0.20-3.36)	.77
Minor	24 (15.9)	11 (7.3)	2.39 (1.07-5.61)	.02
Procedural complications	2 (1.3)	16 (10.7)	0.11 (0.01-0.49)	<.001
Access-site complications	5 (3.3)	0		.06[d]

- Established that IABPs are generally safe and well tolerated

Long-Term Mortality Data From the Balloon Pump–Assisted Coronary Intervention Study (BCIS-1)
A Randomized, Controlled Trial of Elective Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention



Single-center observational data suggested ↓ mortality and MACE with elective IABP during high risk PCI. (2003, 2006), BCIS-1 was the 1st RCT to investigate safety and efficacy of IABP during high-risk PCI

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

N Engl J Med 2012;367:1287-96.

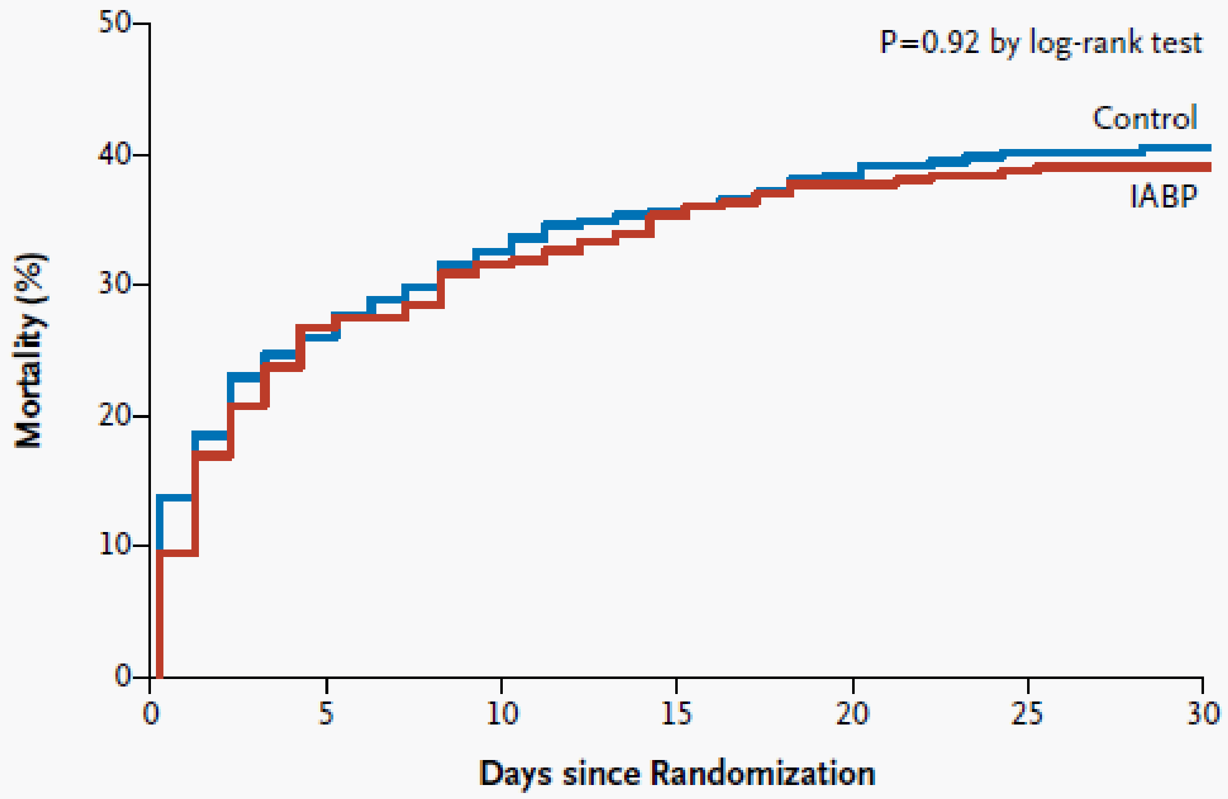


Figure 1. Time-to-Event Curves for the Primary End Point.

Time-to-event curves are shown through 30 days after randomization for the primary end point of all-cause mortality. Event rates represent Kaplan–Meier estimates.

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

N Engl J Med 2012;367:1287-96.

- N=600 (1:1) in Germany, RCT.
  - 95% underwent primary PCI, 90% stent
- Bottom Line:
  - No difference in 30d mortality by ITT.
- No difference in "process of care" outcomes
  - ICU LOS, duration of catecholamines, time to stability
  - Adverse events the same
- Prior to this study, use of IABP for AMI with CS was Class I (B and C) recommendation
  - Change to 2B

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

N Engl J Med 2012;367:1287-96.

Controversies:

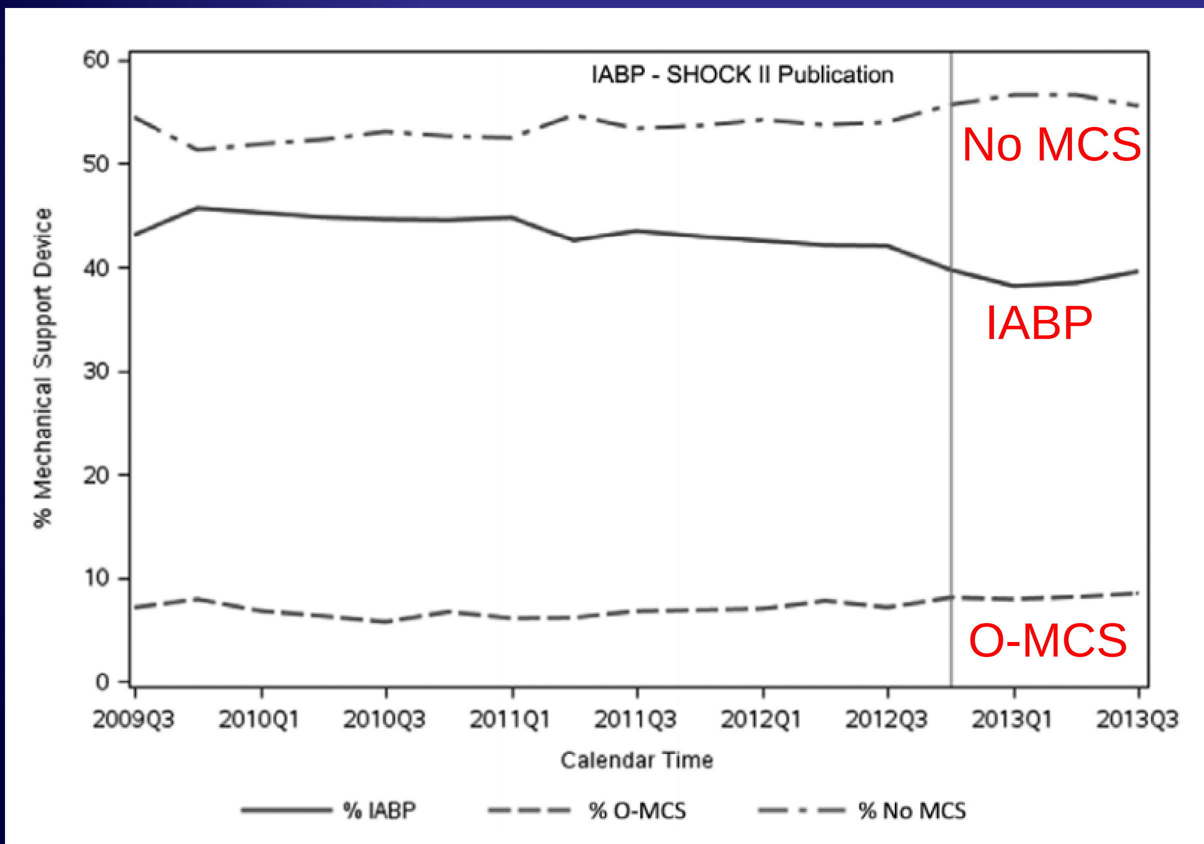
- 96% of IABP group actually got IABP
    - So 4% died before IABP could be inserted
- 10% of control arm got IABP (protocol violation)
- (*Nearly*) more LVAD implantations in control arm
    - 3.7% vs 7.4% (p = 0.053)
- Timing of IABP not controlled
    - 87% if IABPs inserted post PCI
- Mortality rate 40%
    - Other registries at RCT (42 – 48%)
    - ? More mild and moderate CS
- High use of inotropes and low rate of patients with SBP < 90 pre randomization.

Use of Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention

Insights From the National Cardiovascular Data Registry

Amneet Sandhu, MD; Lisa A. McCoy, MS; Smita I. Negi, MD; Irfan Hameed, MD; Prashant Atri, MD; Subhi J. Al'Aref, MD; Jeptha Curtis, MD; Ed McNulty, MD; H. Vernon Anderson, MD; Adhir Shroff, MD; Mark Menegus, MD; Rajesh V. Swaminathan, MD; Hitinder Gurm, MBBS; John Messenger, MD; Tracy Wang, MD; Steven M. Bradley, MD, MPH

2015



- 76464 patients w/ PCI + CS
- 2009-2013
- 54% No MCS
  39% IABP only
  3.5% other MCS (O-MCS)
  3.6% both IABP + O-MCS
- IABP use decreased without increase in MCS
- Majority of O-MCS was clustered in a few hospitals

(Circulation. 2015;132:1243-1251. DOI: 10.1161/
CIRCULATIONAHA.114.014451

Most Recent Guidelines

2013

ACCF/AHA Guideline

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines

Class IIa

1. The use of intra-aortic balloon pump (IABP) coun-ter-pulsation can be useful for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy.[455–459] (*Level of Evidence: B*)

Class IIb

1. Alternative LV assist devices for circulatory support may be considered in patients with refractory cardio-genic shock. (*Level of Evidence: C*)

2017

ESC European Society of Cardiology

European Heart Journal (2018) **39**, 119–177
doi:10.1093/eurheartj/ehx393

ESC GUIDELINES

2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC)

Recommendations for the management of cardio-genic shock in ST-elevation myocardial infarction		
Intra-aortic balloon pumping should be con-sidered in patients with haemodynamic instability/cardiogenic shock due to mechan-ical complications.	IIa	C
Short-term mechanical support[c] may be considered in patients in refractory shock.	IIb	C
Routine intra-aortic balloon pumping is not indicated.[177,437]	III	B

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Impella

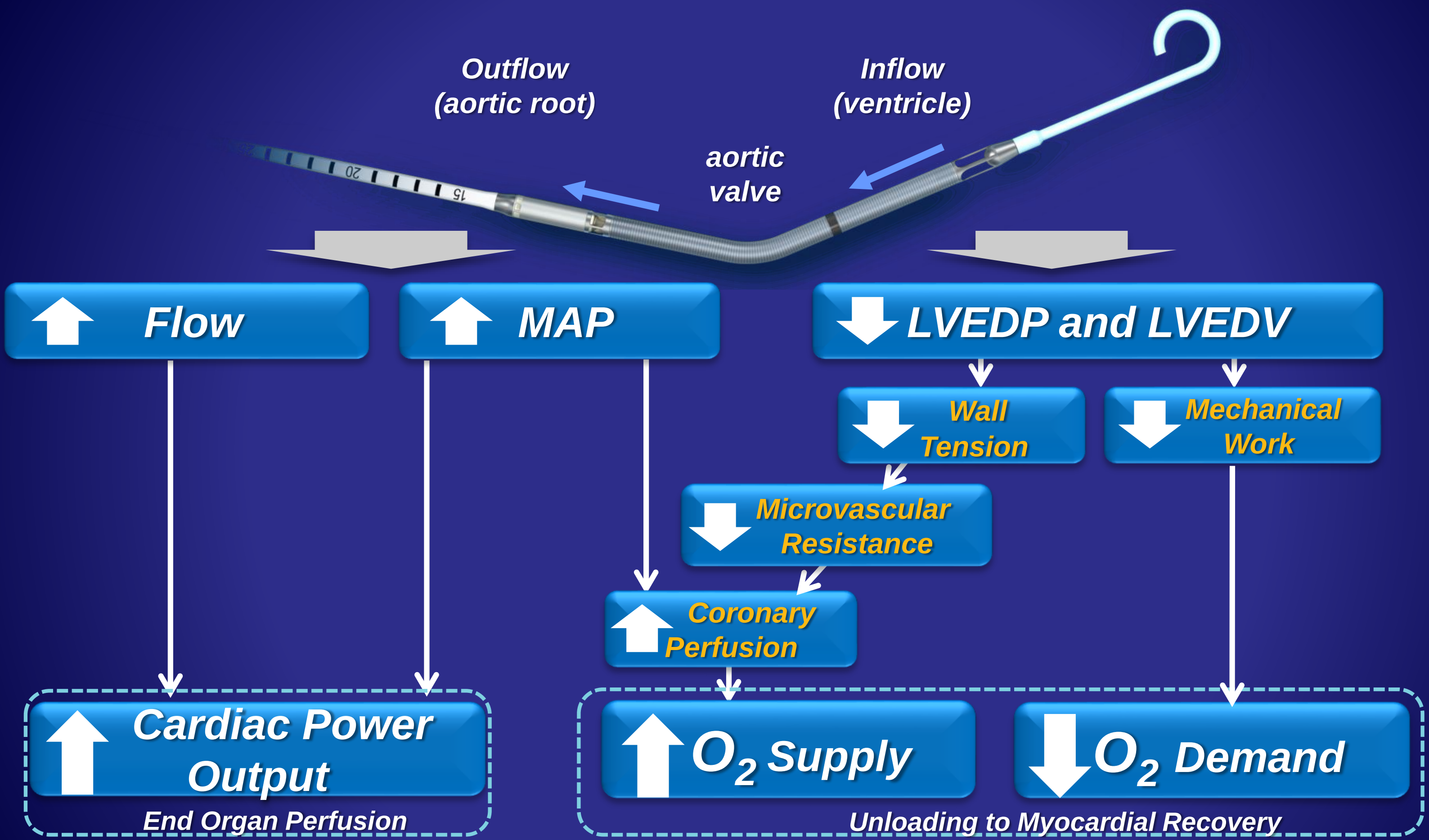
- Non-pulsatile axial flow

- 5 versions
  - 12F – Impella 2.5 (2.5 L/min)
  - 14F – Impella CP (3-4.3 L/min)
  - 21F – Impella 5.0/LD (5L/min)
  - 22F – Impella RP (>4L/min)

- Benefits
  - Does not require timing/trigger
  - Stable during transient arrhythmias

- Negatives
  - Ventricular arrythmias not well tolerated if RV dysfunction
  - Positioning outside cath lab
  - Hemolysis/thrombocytopenia
  - Large bore access

Hemodynamic Effects of Impella® Support



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Impella

- Hemodynamic effects
  - Unload LV – ↑ forward flow
  - ↓ myocardial oxygen demand
  - ↑ MAP
  - ↓ PCWP

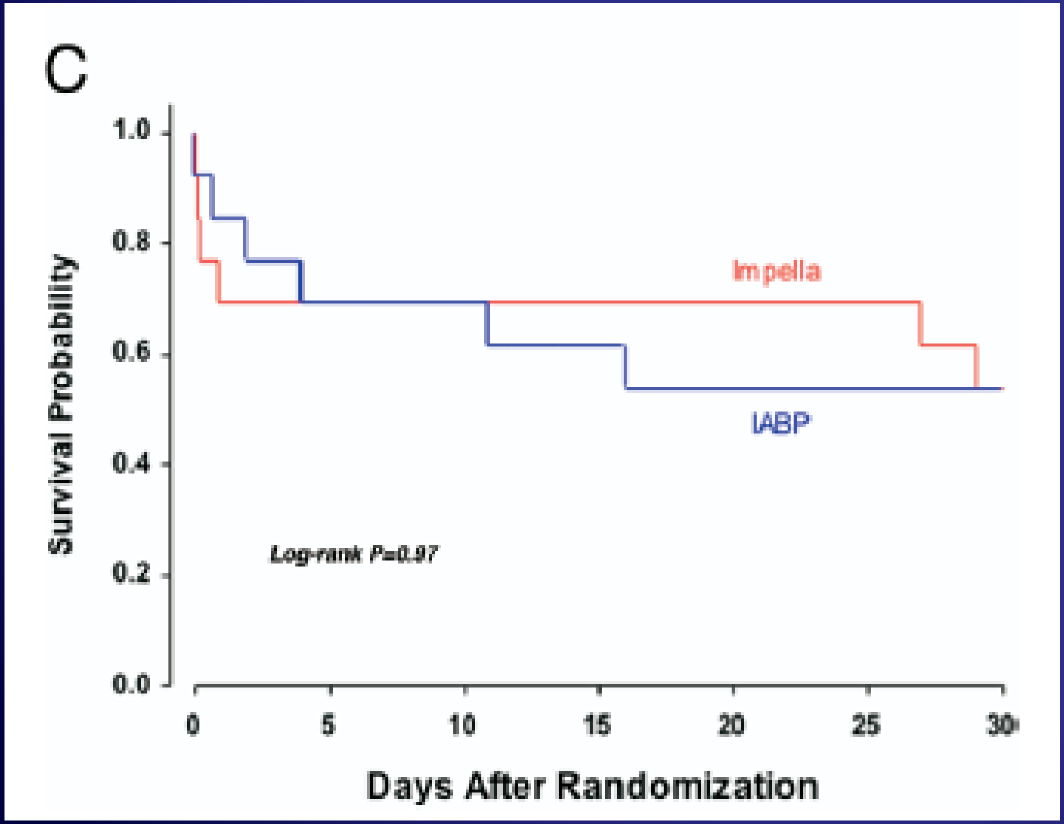
- Contraindications?
  - Mechanical AV
  - LV thrombus
  - ? AS and AI (*Relative* contraindications)
  - PAD
  - Systemic anticoagulation intolerance (ACT goals)

- Complications:
  - Vascular Injury
  - Hemolysis
    - 5-10% in first 24h. Reposition.
  - Thrombocytopenia

A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

(J Am Coll Cardiol 2008;52:1584–8)

ISAR-SHOCK

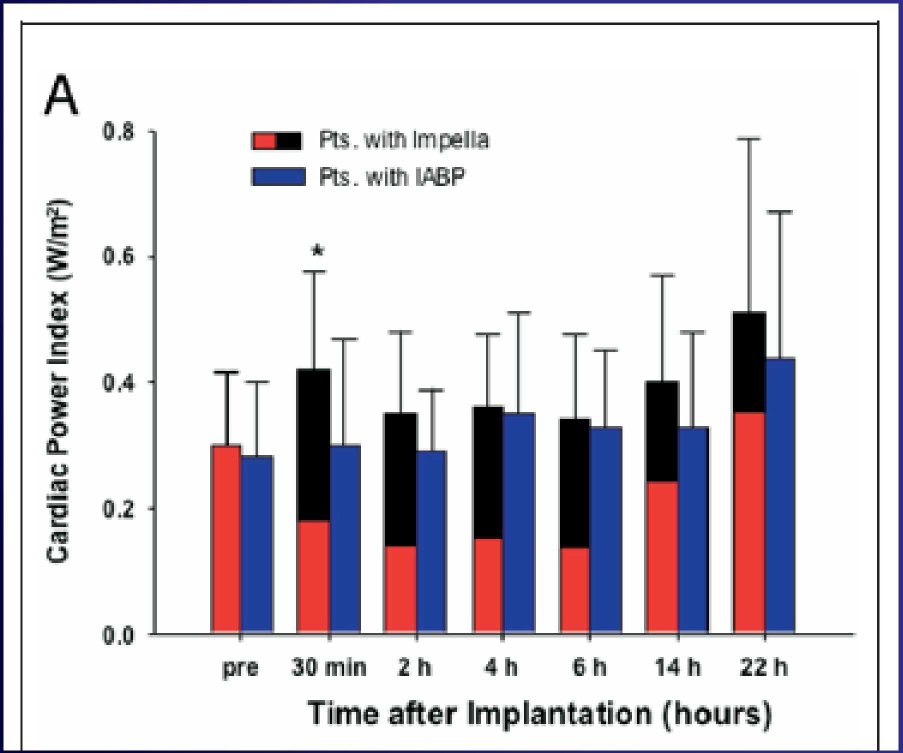


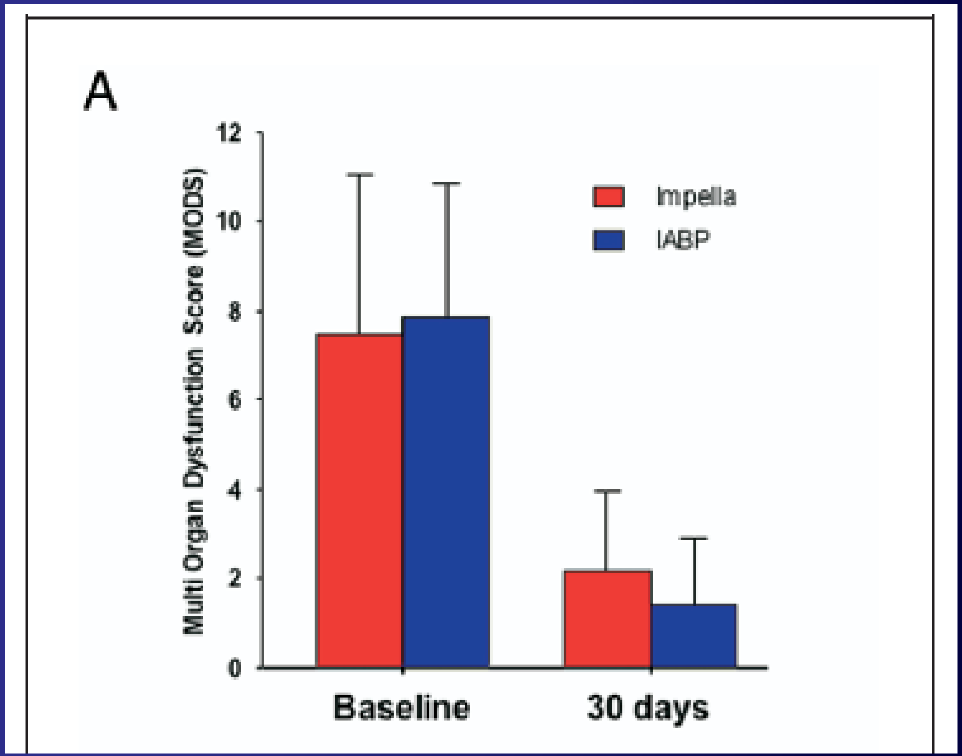
- Feasible
- Safe
- Impella > IABP for cardiac ouput
- Both had 54% Mortality

Impella 2.5, Prospective, Randomized, n = 25

A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

(J Am Coll Cardiol 2008;52:1584-8)





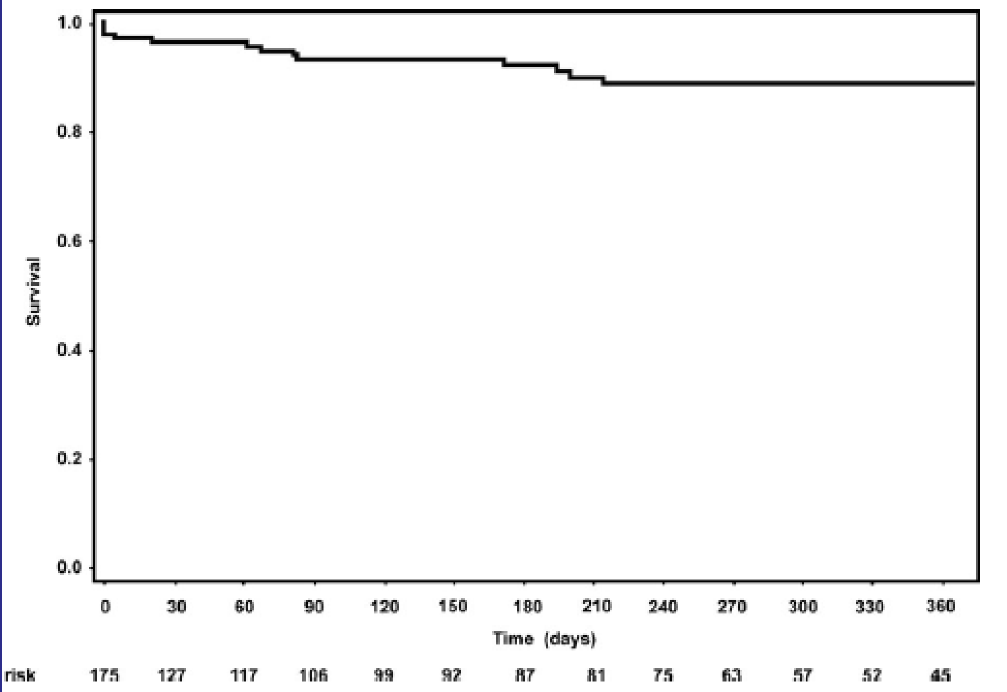
CI increased at 30 minutes, but overall mortality was the same.

Real-World Use of the Impella 2.5 Circulatory Support System in Complex High-Risk Percutaneous Coronary Intervention: The USpella Registry

2012

TABLE I. Baseline Demographics and Patient Characteristics

	Mean ± SD (range) or %
Age (years)	70 ± 10 (43–91)
Male	74
Multivessel disease	89
Unprotected left main	51
Last remaining patent conduit	10
Prior MI	56
Prior PCI	48
Prior CABG	28
Diabetes	47
Cerebrovascular disease	22
Chronic renal insufficiency	33
Chronic obstructive pulmonary disease	30
New York Heart Association	
Class III	35
Class IV	31
LVEF	31 ± 17 (5–76)
LVEF < 35%	69



- n = 175
- Syntax Scores 37-39
- Procedural Success was 90%
- 30d MACE = 8%
- 1 year survival 88%

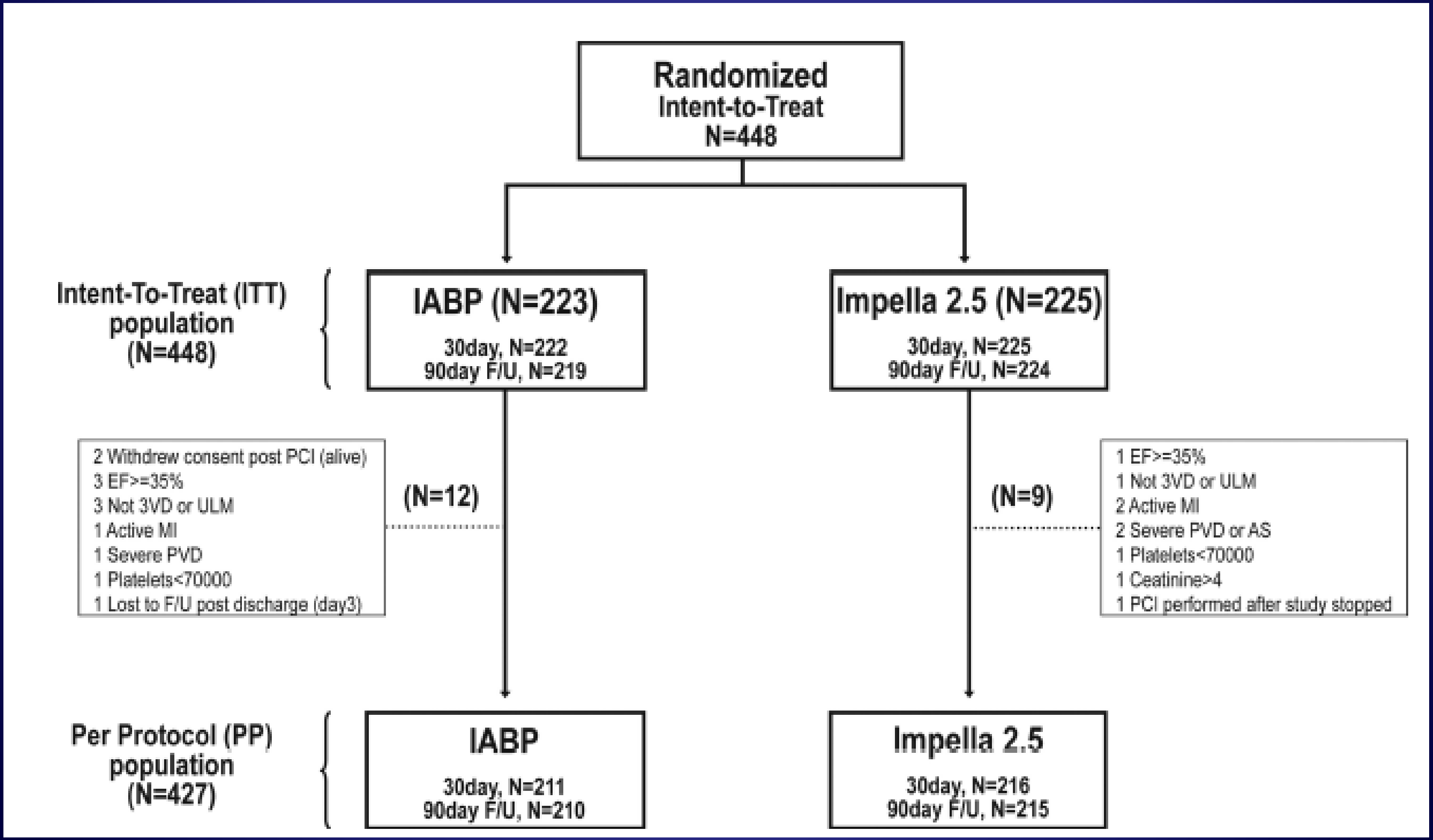
Safe for high risk PCI with high survival rates

Catheterization and Cardiovascular Interventions 80:717–725 (2012)

A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention

The PROTECT II Study

2012



*ABIOMED Funded

(*Circulation*. 2012;126:1717-1727.)

A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention

The PROTECT II Study

2012

Table 1. Patient Baseline Characteristics

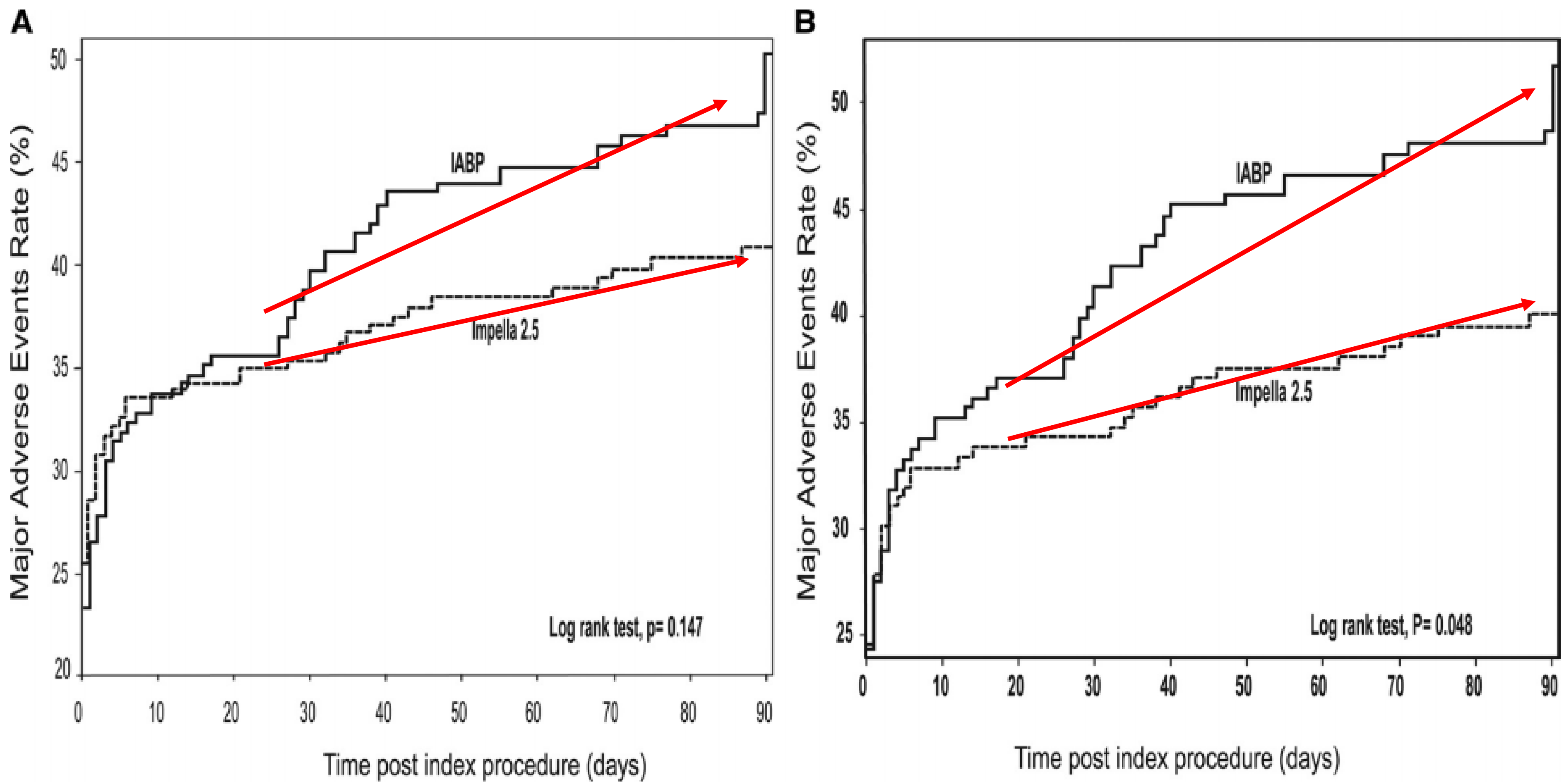
	IABP (n=223)	Impella 2.5 (n=225)	P
Age, y	67±11	68±11	0.488
Sex, male, %	81.2	80.0	0.668
History of CHF, %	83.4	91.1	0.014
Current NYHA (class III/IV), %	64.6	67.0	0.632
Diabetes mellitus, %	50.7	52.0	0.779
Renal insufficiency, %	30.2	23.1	0.091
Peripheral vascular disease, %	26.5	25.7	0.851
Implantable cardiac defibrillator, %	31.1	34.7	0.420
Previous CABG, %	28.7	38.2	0.033
LVEF, %	24.1±6.3	23.4±6.3	0.244
STS mortality score, %	6±7	6±6	0.809
SYNTAX score	29.3±13.5	30.3±13.1	0.514
Mayo PCI score, %	8.4±3.6	8.8±3.4	0.154
New York PCI score, %	10.8±3.4	11.2±3.3	0.207
Not surgical candidate, %	64.6	63.6	0.822

(*Circulation*. 2012;126:1717-1727.)

A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention

The PROTECT II Study

2012



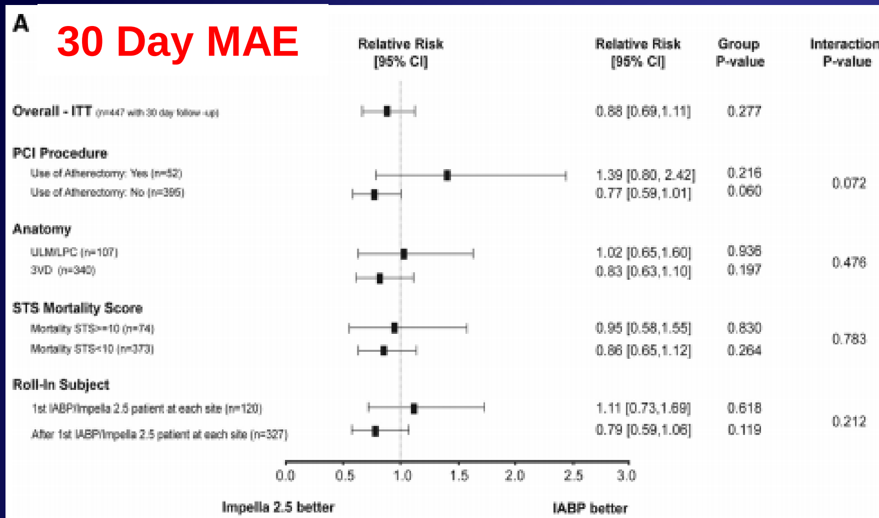
Intention to Treat **Per Protocol**

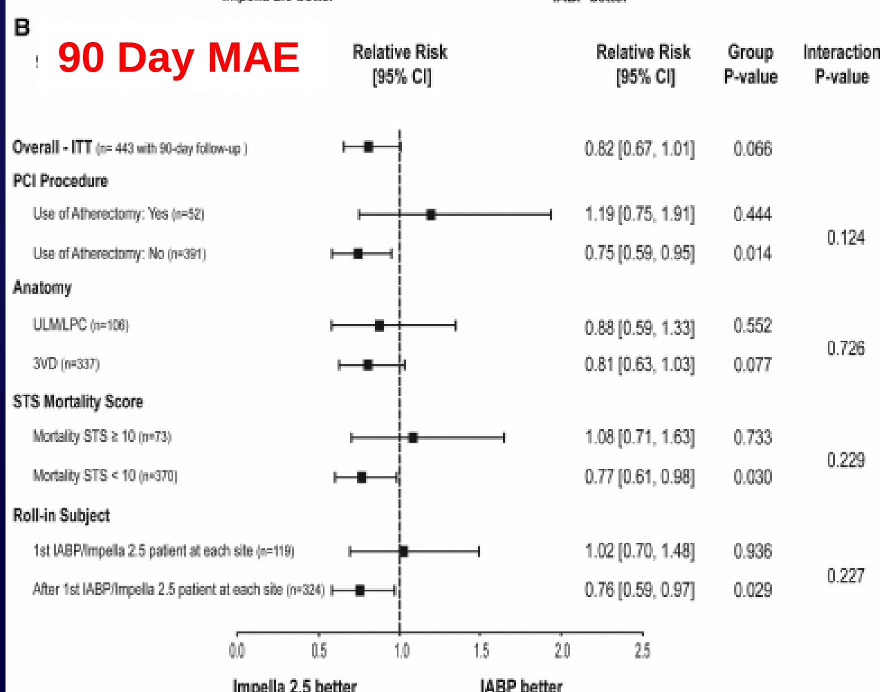
(*Circulation*. 2012;126:1717-1727.)

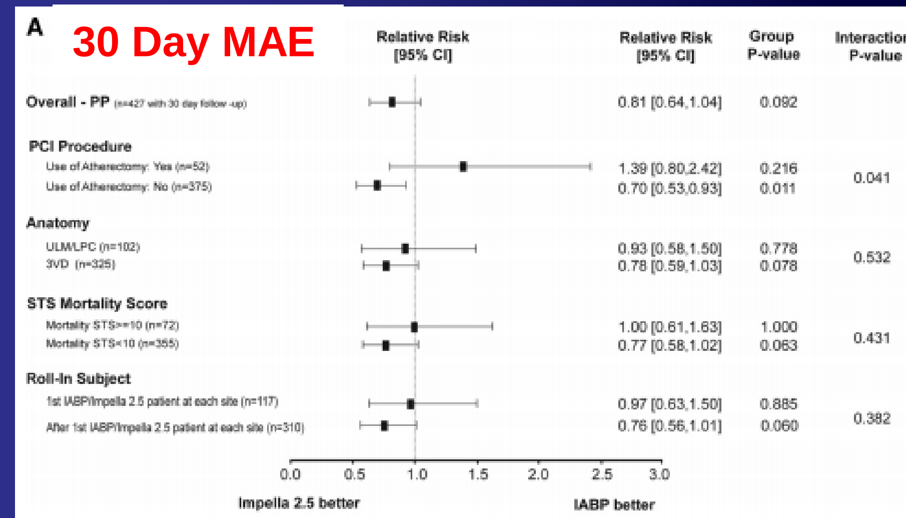
A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention

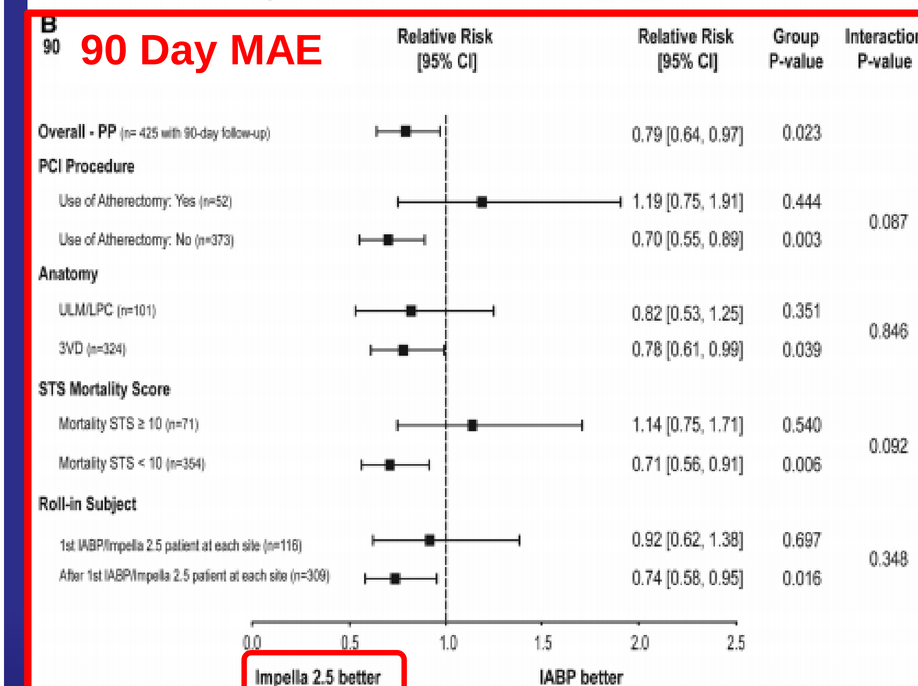
The PROTECT II Study

(*Circulation*. 2012;126:1717-1727.)







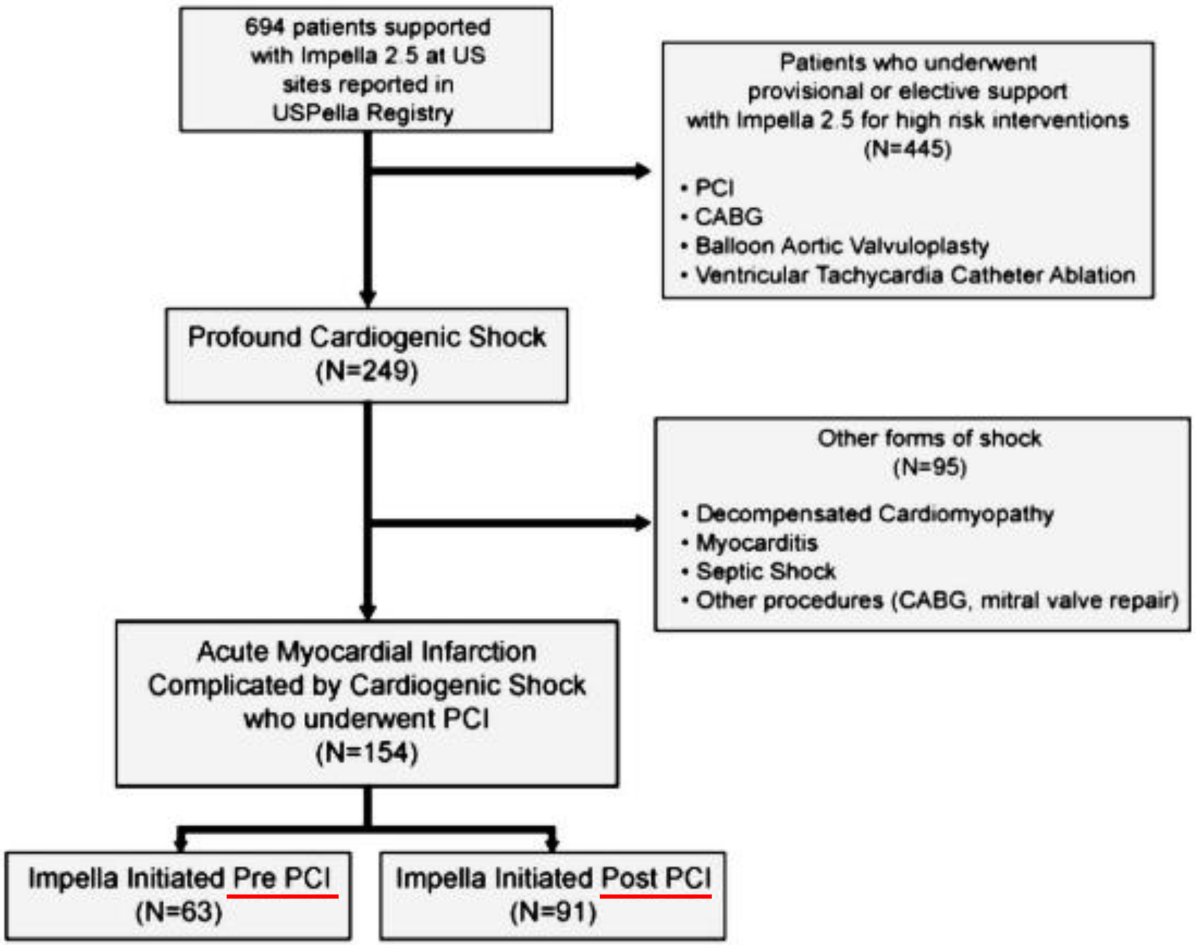


Intention to Treat

Per Protocol

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

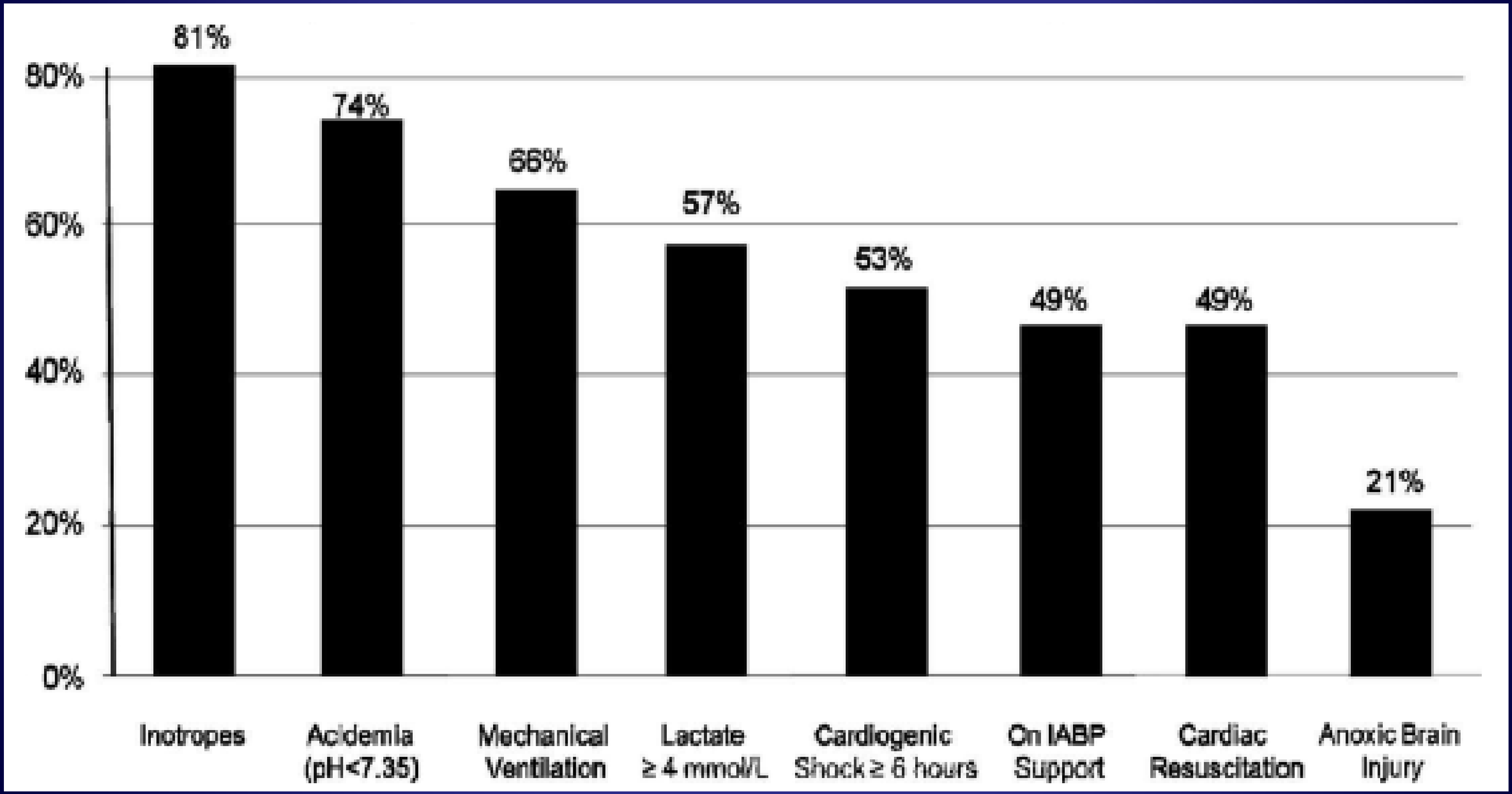
(J Interven Cardiol 2014;27:1–11)



Abbreviations: CABG: Coronary artery bypass grafting; PCI: Percutaneous coronary intervention

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

(J Interven Cardiol 2014;27:1–11)



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

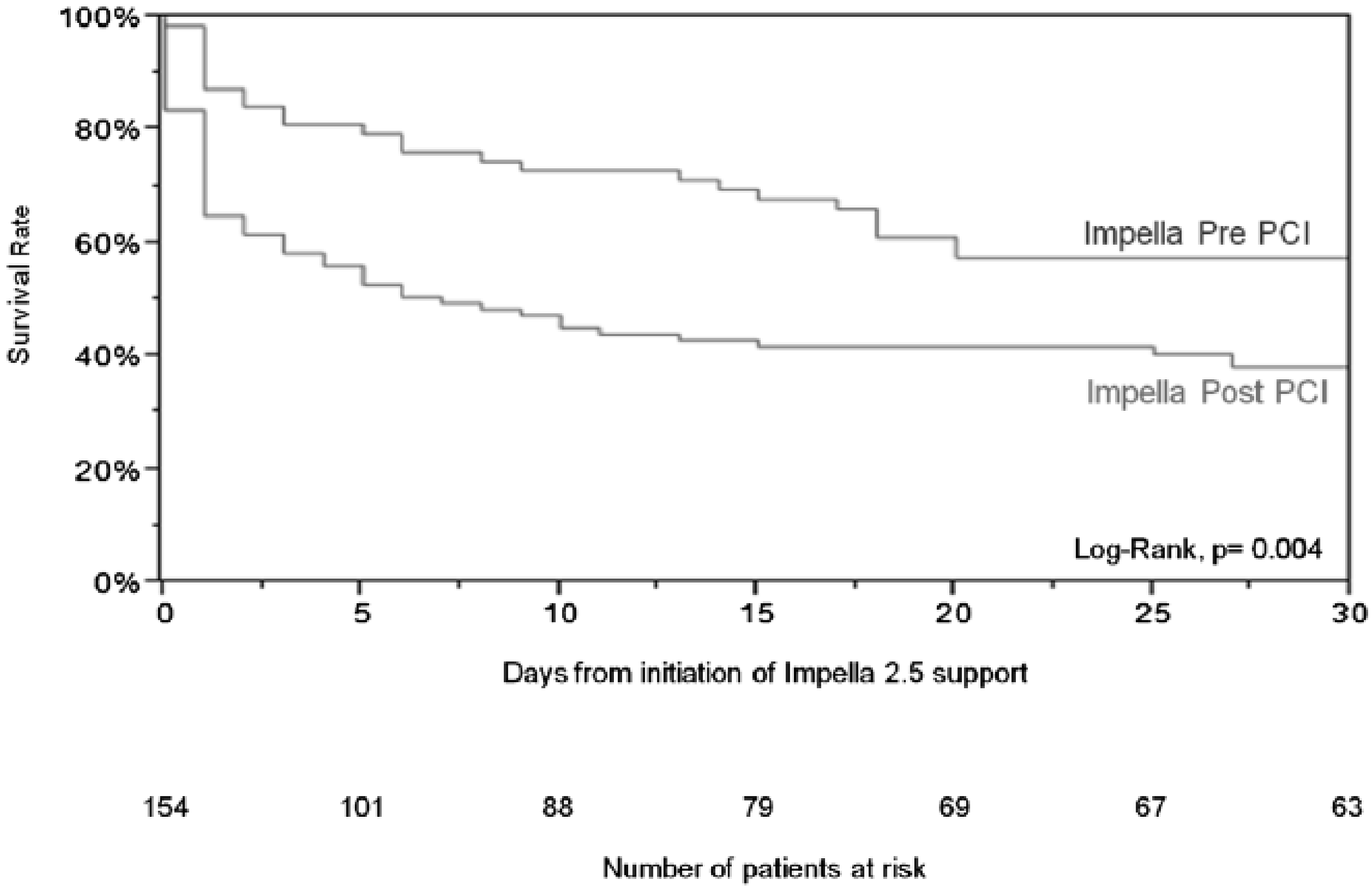
(J Interven Cardiol 2014;27:1–11)

Table 2. Procedural Characteristics

	All N = 154 (mean ± SD, median [IQR], or %)	Impella Pre-PCI N = 63 (mean ± SD, median [IQR], or %)	Impella Post-PCI N = 91 (mean ± SD, median [IQR], or %)	P-Value
Duration of Impella support, hours	23.7 [3.5 62.7]	22.8 [1.6 52.8]	24.2 [4.2 69.2]	0.39
Median door-to-balloon time,* min	63.5 [40.3 113.5]	112 [79 112]	52 [34 81]	<0.0001
Suspected infarct related artery territory				
Left main	16.1%	23.8%	9.5%	0.02
Left anterior descending	52.6%	53.9%	51.4%	0.76
Left circumflex	10.9%	4.8%	16.2%	0.03
Right coronary	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 (≥70%)	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
Number of lesions treated	2.02 ± 1.24	2.33 ± 1.40	1.77 ± 1.02	0.006
Number of stents	1.68 ± 1.02	1.94 ± 1.15	1.47 ± 0.85	0.007
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

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

(J Interven Cardiol 2014;27:1–11)



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

(J Interven Cardiol 2014;27:1–11)

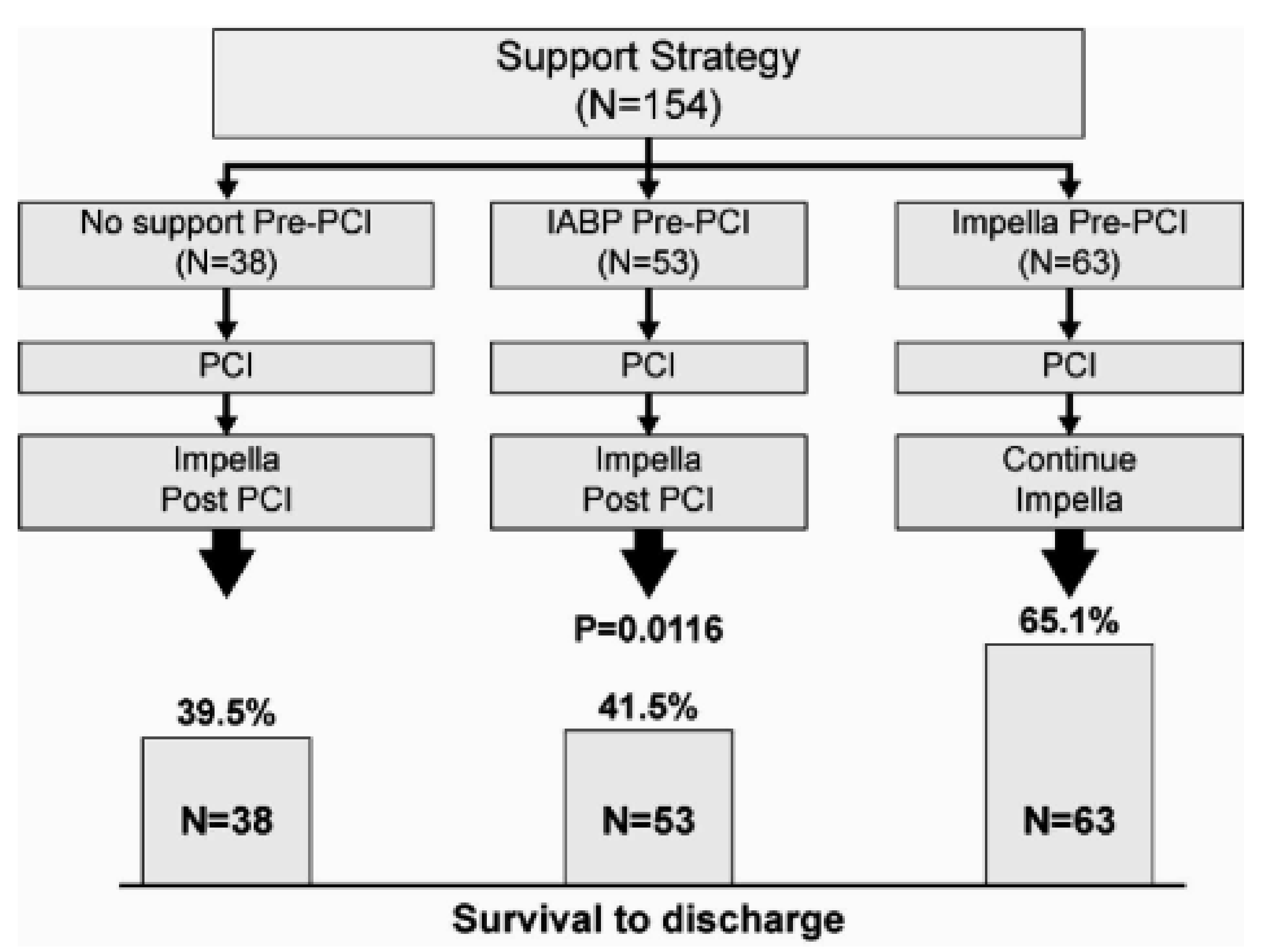
Table 4. Multivariate Analysis for Predictors of In-Hospital Mortality

	Odds Ratio	95% Confidence Interval	P-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	11–2.18	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

increases

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

(J Interven Cardiol 2014;27:1–11)



Earlier MCS is BETTER!

Analysis of outcomes for 15,259 US patients with acute myocardial infarction cardiogenic shock (AMICS) supported with the Impella device

William W. O'Neill MD, FACC [a], Cindy Grines MD, FACC [b], Theodore Schreiber MD, FACC [c], Jeffrey Moses MD, FACC [d], Brijeshwar Maini MD, FACC [e], Simon R. Dixon MBChB, FACC [f], E. Magnus Ohman MD, FACC [g]

2018

- Jan 2009-Dec 2016
- 15,259 identified as having acute MI with cardiogenic shock
- 51% survived to explantations of pVAD
- Hospital volume predicted survival: Lowest volume (quintile) had 30% survival vs 76% in the top quintile ($p < 0.001$)
- 59% survival as first line treatment vs 52% in salvage cases

Am Heart J. 2018 Aug;202:33-38. doi: 10.1016/j.ahj.2018.03.024. Epub 2018 Apr 7

High Risk PCI Expanded FDA Indication:

(Now includes mild and mod reduced LVEF)

The Impella 2.5 and Impella CP are indicated for providing temporary (< 6 hours) ventricular support during elective or urgent high risk percutaneous coronary interventions (PCI) performed in hemodynamically stable patients with severe coronary artery disease, [~~and depressed left ventricular ejection fraction~~] when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option.

Use of the Impella 2.5 and the Impella CP in these patients may prevent hemodynamic instability which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

The Impella® platform is the only percutaneous temporary ventricular support devices that are FDA-approved for High Risk PCI

Data Supporting Protected PCI Indication

Scientific Evidence to Support PMA Applications*	Total Number of Patients in the Cohort	Number of Impella Protected PCI Patients
Severely Reduced LVEF ≤35%		
Protect I	20	**20**
Protect II	452	**225**
U.S. Impella Registry	1,322	**709**
Literature review	2,537	**756**
Mild, Moderately Reduced LVEF >35%		
cVAD Registry Study	693	**464 / 229** LVEF ≤35% / LVEF >35%
Total	5,024	**2,403**

* Patient data may be provided in multiple PMA applications

Accepted Manuscript

Title: The Role of Mechanical Circulatory Support during Percutaneous Coronary Intervention in Patients Without Severely Depressed Left Ventricular Function

Author: Khaldoon Alaswad, Mir Babar Basir, Akshay Khandelwal, Theodore Schreiber, William Lombardi, William O'Neill

PII: S0002-9149(17)31923-9
DOI: https://doi.org/10.1016/j.amjcard.2017.11.045
Reference: AJC 23036

To appear in: *The American Journal of Cardiology*

Baseline Characteristics

Baseline Characteristics	LVEF <=35% (N=661 Patients)	LVEF >35% (N=230 Patients)	P-Value
Age Mean ±SD(N)	68.68±11.01	72.12±11.70	<.001
Gender - Male	78%	67%	<.001
Hypertension	88%	94%	0.017
Diabetes Mellitus	53%	45%	0.042
Angina	41%	42%	0.696
Prior Stroke	7%	6%	0.879
Renal Insufficiency	34%	25%	0.010
Dialysis	24%	30%	0.378
CHF	65%	34%	<.001
Prior MI	53%	38%	<.001
Prior PCI	50%	42%	0.059
Prior CABG	30%	29%	0.848
LVEF %	21.18±7.84	51.94±9.31	<.001
STS Mortality Score	6.37±7.11	4.87±5.84	0.007
Creatinine (mg/dL)	1.58±1.26	1.35±1.02	0.015

Patient cohort >35% was older, more often female, had more hypertension

Alaswad, O'Neill, et al. American Journal of Cardiology 2018

Procedural Characteristics

Procedural Characteristics	LVEF <=35% (N=661 Patients)	LVEF >35% (N=230 Patients)	P-Value
Number of diseased vessels	1.73±0.79 (649)	1.90±0.71 (220)	0.005
Number of vessels treated	1.55±0.73 (649)	1.81±0.60 (216)	<.001
Use of rotational atherectomy (RA)	14.90%	21.21%	0.046
Average number of passes per lesion	2.51±1.63	3.33±2.09	0.017
Number of lesions treated	1.67±0.76 (604)	1.87±0.80 (212)	0.001
Coronary vessel involved:			
Left anterior descending artery	35.50% (662/1865)	33.84% (245/724)	0.428
Left Main:	13.08% (244/1865)	23.62% (171/724)	<.001
Distal LM and proximal LAD	8.02% (53/661)	18.70% (43/230)	<.0001
Distal LM and proximal LCx	7.11% (47/661)	18.70 (43/230)	<.0001
LCx	28.36% (529/1865)	26.93% (195/724)	0.467
RCA	18.34% (342/1865)	11.74% (85/724)	<.001
Graft	4.72% (88/1865)	3.87% (28/724)	0.347
SVG	4.29% (80/1865)	3.31% (24/724)	0.257

Patient cohort >35% had more diseased vessels, more RA, more lesions treated, more Left Main

Alaswad, O'Neill, et al. American Journal of Cardiology 2018

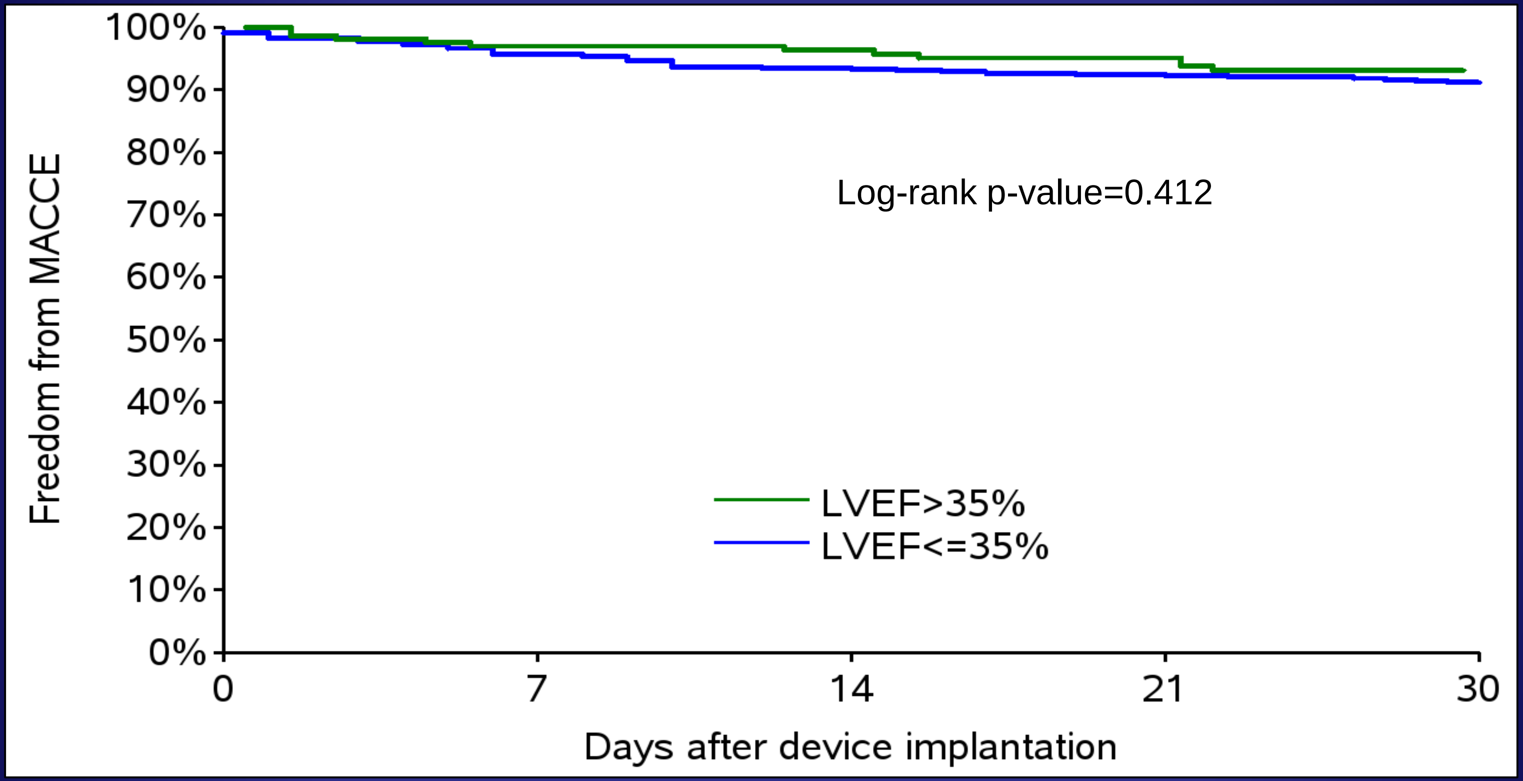
Favorable MACCE in Both Cohorts

Adverse Events	**LVEF <=35%** (N=661 Patients)	**LVEF >35%** (N=230 Patients)	**P-Value**
MACCE	4.54%	3.48%	0.574
Death	3.78%	1.74%	0.193
Myocardial Infarction	0.30%	1.30%	0.112
CVA/Stroke	0.00%	0.00%	--
Revascularization	0.61%	1.30%	0.383
Acute Renal Dysfunction	6.05%	2.61%	0.055
Bleeding requiring Surgery	0.76%	0.43%	1.000
Vascular Complication requiring Surgery	1.06%	2.17%	0.201
Device Malfunction	0.15%	0.00%	1.000
Failure to Achieve Angiographic Success (Residual Stenosis <30% after stent implant)	0.30%	0.87%	0.275

MACCE and adverse event rates favorable and consistent between two patient cohorts

Alaswad, O'Neill, et al. American Journal of Cardiology 2018

Favorable MACCE in Both Cohorts



MACCE and adverse event rates favorable and consistent between two patient cohorts

Alaswad, O'Neill, et al. American Journal of Cardiology 2018

Title: The Role of Mechanical Circulatory Support during Percutaneous Coronary Intervention in Patients Without Severely Depressed Left Ventricular Function

Conclusions

Patients with LVEF >35% when compared to patients with LVEF ≤35% were:

1. Older age (72 vs 69 years, $p<0.001$)
2. More extensive CAD, more diseased vessels (1.9 vs 1.7; $p=0.005$)
3. More LM (13% vs 24% <.0001) and more MVD intervention
4. More use of rotational atherectomy (21% vs 15% $p=0.046$)
5. Prevalence of high-risk clinical features; renal failure (25%) and DM (45%)

Despite high-risk features, MACCE favorable overall – No differences between groups (3.48% vs 4.54%; p = 0.574).

PCI with elective MCS was feasible and safe

Alaswad, O'Neill, et al. American Journal of Cardiology 2018

Revascularization Strategy by Risk Category

Surgical Risk

Anatomic Risk	Low	Medium	High (Often inoperable)
Low	PCI	PCI	PCI
Medium	CABG or PCI	PCI or CABG	Support & PCI
High	CABG	CABG or PCI	Support & PCI

SYNTAX Study

Protected PCI
FDA Indicated
Safe & Effective

Severe, Moderate, Mild
Reduced LVEF

ACC/AHA PCI Guidelines

1. Levine GN, et al. J Am Coll Cardiol, 2011 Dec 6;58(24):e44-122,
2 Amsterdam EA, et al. Circulation. 2014 Dec 23; 130(25):e344-426

Patients Most Appropriate for Revascularization

Coronary Revascularization Appropriateness Guidelines

ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT[1]

Heart Failure

High Risk Findings on Noninvasive Study					
Symptoms Med. Rx / **Coronary Anatomy**	CTO of 1 vz.; no other disease	1-2 vz. disease; no Prox. LAD	1 vz. disease of Prox. LAD	2 vz. disease with Prox. LAD	3 vz. disease; no Left Main
Class III or IV Max Rx	A	A	A	A	A
Class I or II Max Rx	A	A	A	A	A
Asymptomatic Max Rx	U	A	A	A	A
Class III or IV No/min Rx	A	A	A	A	A
Class I or II No/min Rx	U	A	A	A	A
Asymptomatic No/min Rx	U	U	A	A	A

A = Appropriate, U = Uncertain, I= Inappropriate

Protected PCI Patients
=
More Heart Failure
More Angina
More Complex
=
More likely to be appropriate

Angina

CCS Class III or IV Angina					
Stress Test Med. Rx / **Coronary Anatomy**	CTO of 1-vz; no other disease	1-2-vz. disease; no prox. LAD	1-vz. disease of prox. LAD	2-vz. disease with prox. LAD	3-vz. disease; no left main
High Risk Max Rx	A	A	A	A	A
High Risk No/min Rx	A	A	A	A	A
Int. Risk Max Rx	A	A	A	A	A
Int. Risk No/min Rx	U	U	A	A	A
Low Risk Max Rx	U	A	A	A	A
Low Risk No/min Rx	I	U	A	A	A

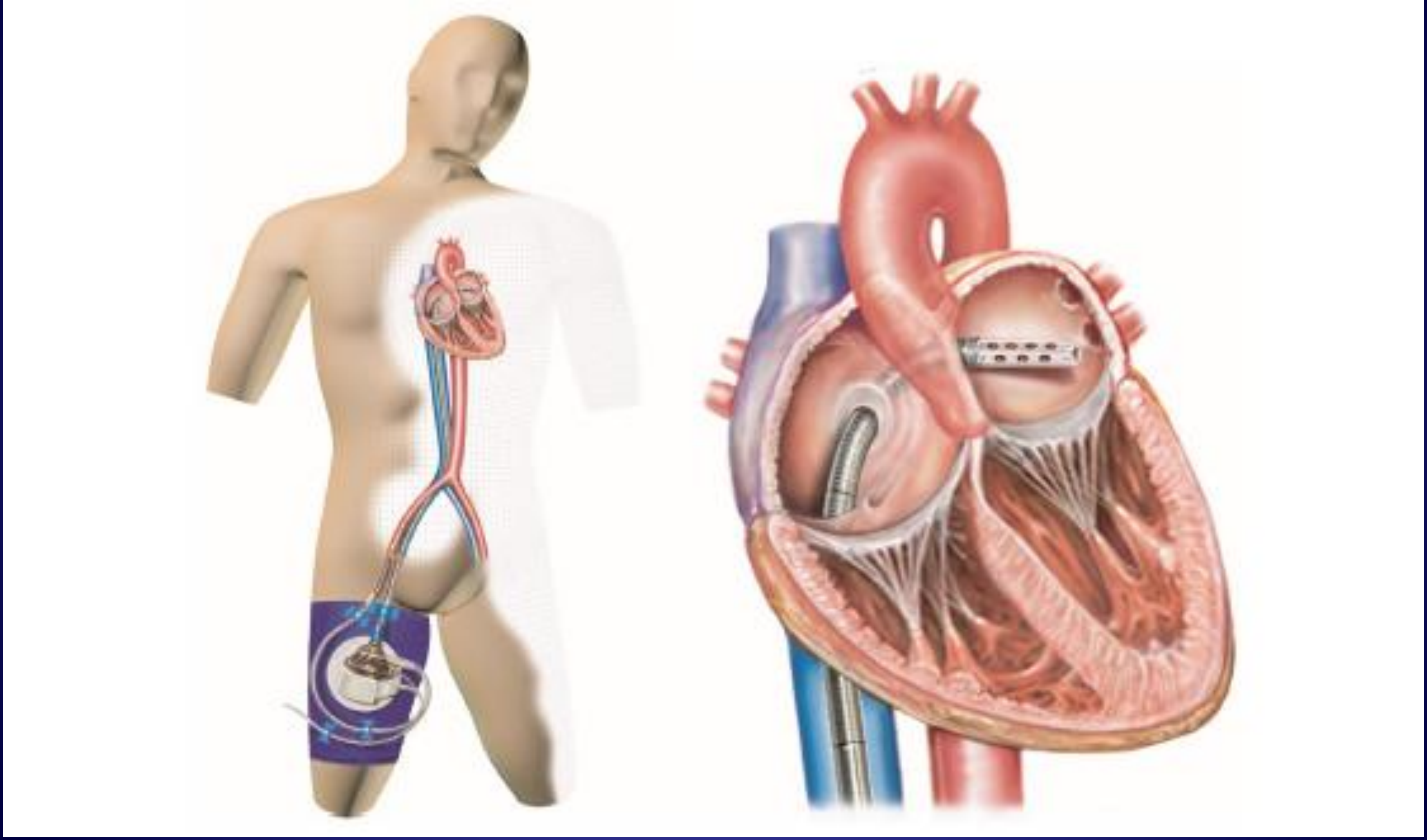
A = Appropriate, U = Uncertain, I= Inappropriate

1. Patel MR, et al, J AM Coll Cardiol. 2012;59(9); 857-881

Outline

- Why and in Whom do we use Mechanical support? Back to Basics
- National Trends in Use of Mechanical Cardiac Support (MCS)
- IABP
- Impella
- Tandem Heart/ECMO (briefly)
- Summary

Tandem Heart



Tandem Heart

- Four components
  - 21 F transseptal cannula
  - Centrifugal pump
  - Femoral arterial cannula
    - 15F – 19F (3.5 - 5L/min)
  - Control Console

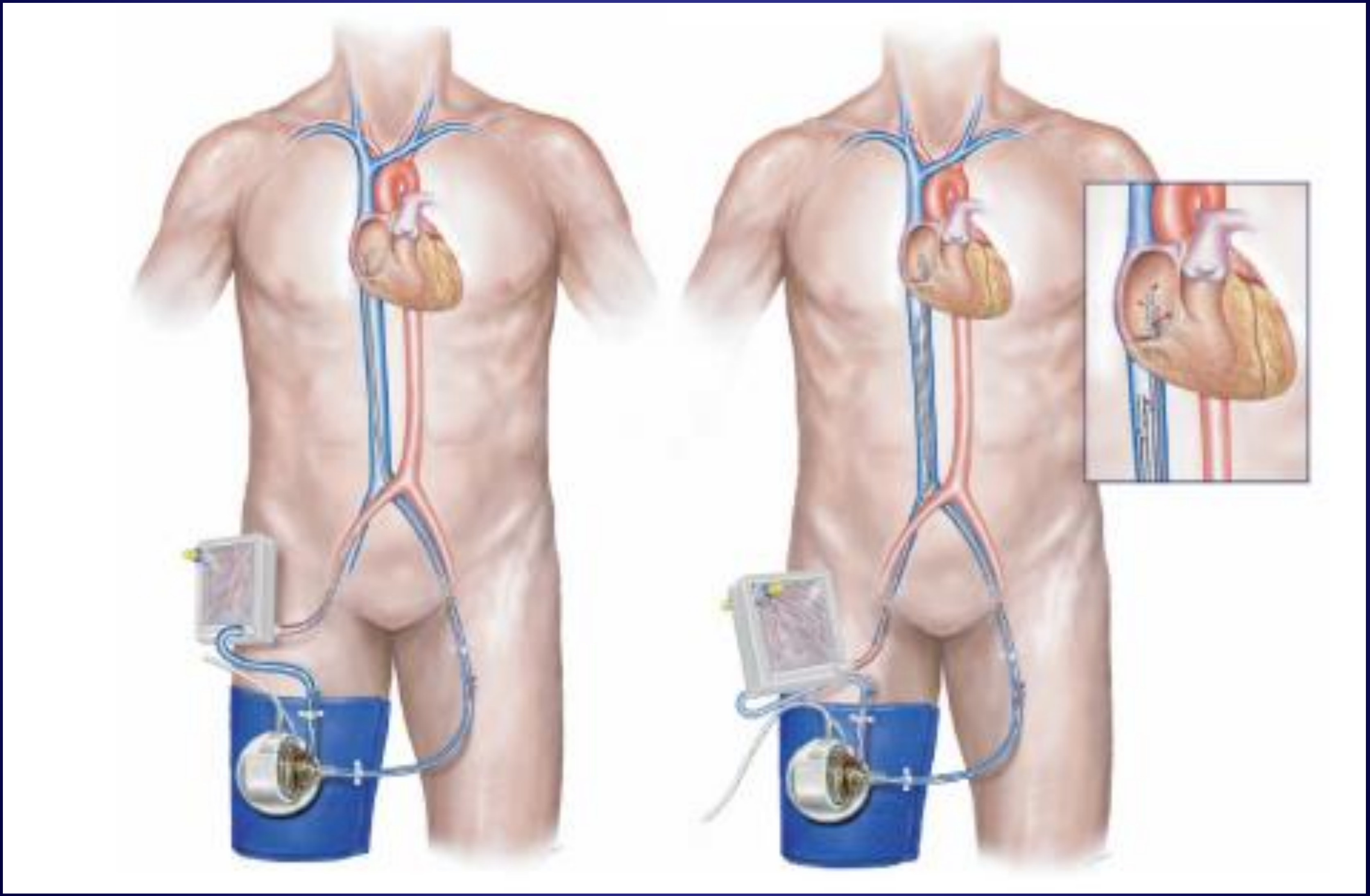
- Both LV and pump contribute flow to aorta in "tandem" (CO is additive)
  - ↓ blood from LA to LV
  - ↓ LV preload, workload, filling pressures, wall stress and MvO2
  - Severity of LV dysfunction determines dependency on tandem heart– *flat line* for some patients

- Do not tolerate VT/VF very well
  - Still need RV function

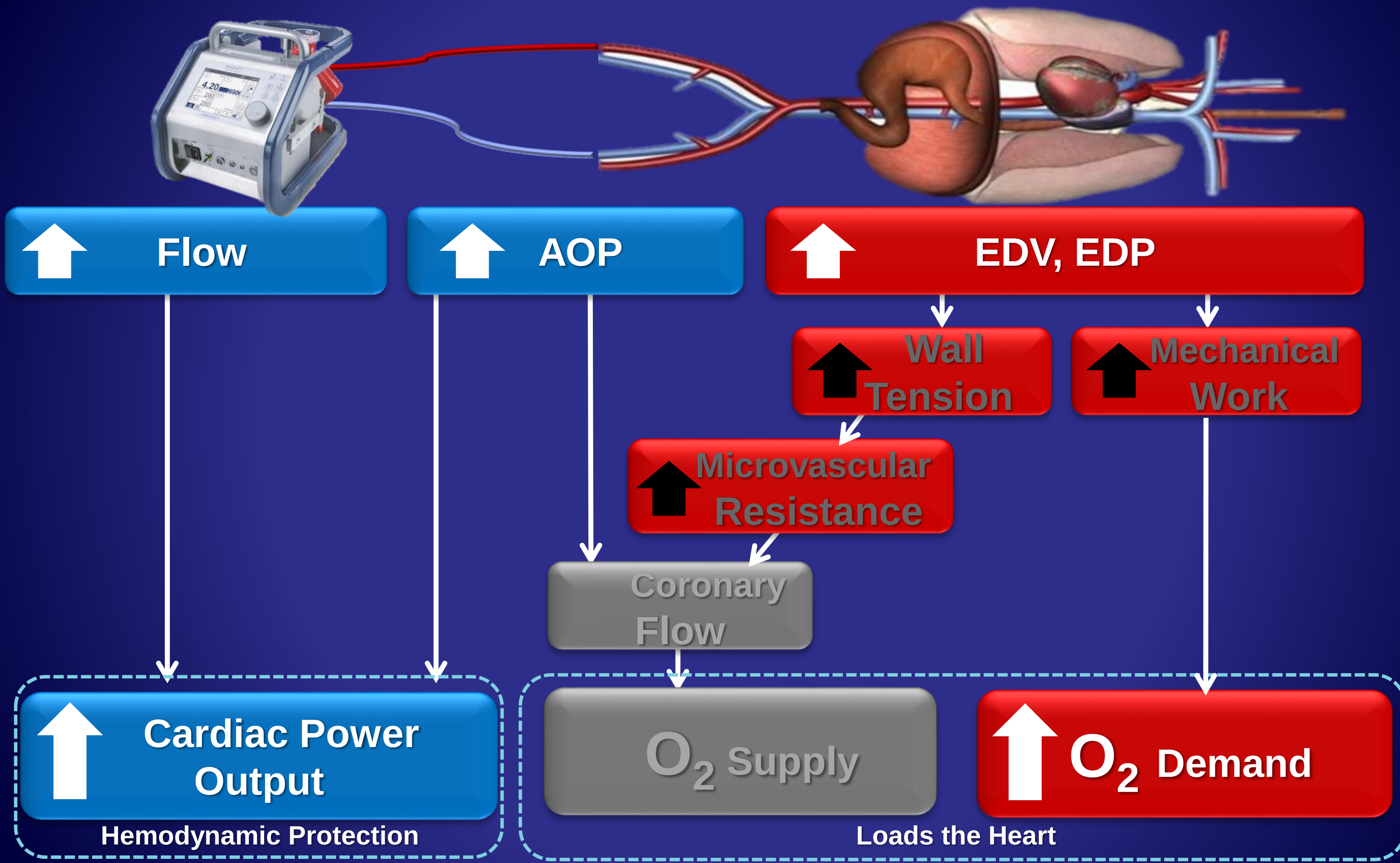
- Contraindications
  - Severe RV dysfunction
  - VSD vs severe AI?
  - Intolerance to anticoagulation (ACT > 300 required)

- Complications
  - Coagulopathies (DIC, HITT), Hemolysis
  - Vascular

ECMO



Hemodynamic Effects of ECMO

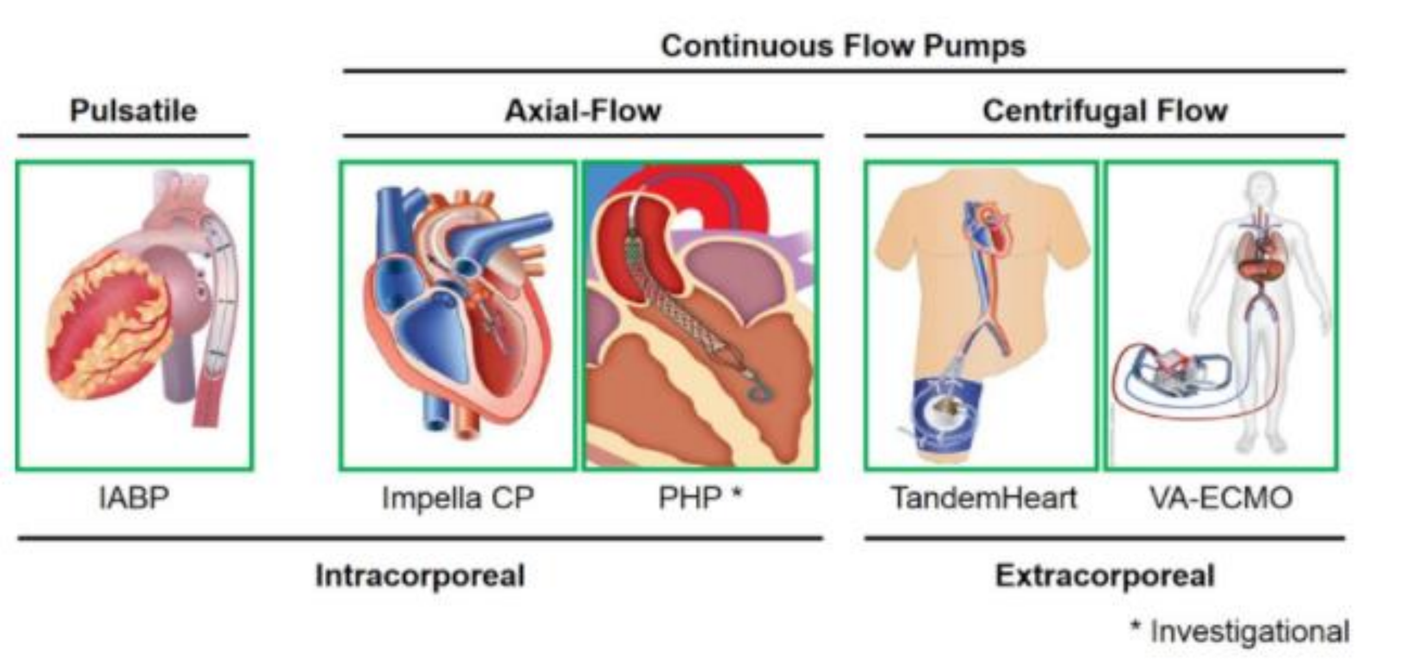


Burkhoff D. et.al. J Am Coll Cardiol. 2015 De
Burkhoff D. et.al. Catheter Cardiovasc Interv

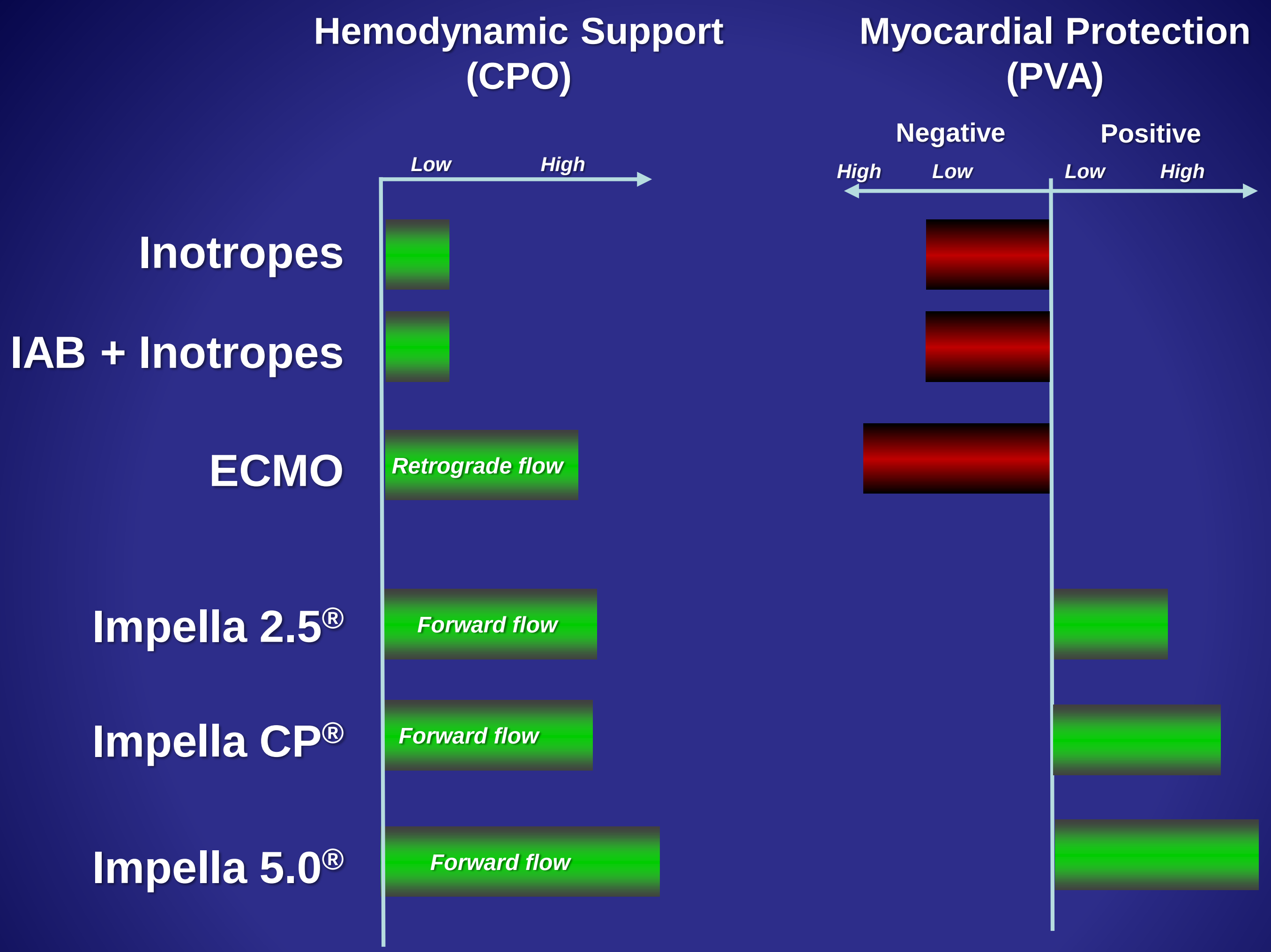
Differences

TABLE 1. SAFETY AND EASE-OF-USE CHARACTERISTICS OF CARDIAC ASSIST DEVICES

	ECMO/CPS	TandemHeart	IABP	Impella 2.5
Vascular surgery required	Yes	Yes	No	No
Vascular access points	Multiple	Multiple	Single	Single
Catheter/cannula size	20–28 F	17–21 F	7–8 F	9 F
Cardiac wall puncture	No	Yes	No	No
Inotropic drug dependency	No	No	Yes	No
Physiologic timing	No	Yes	Yes	No



Therapy / Device Summary



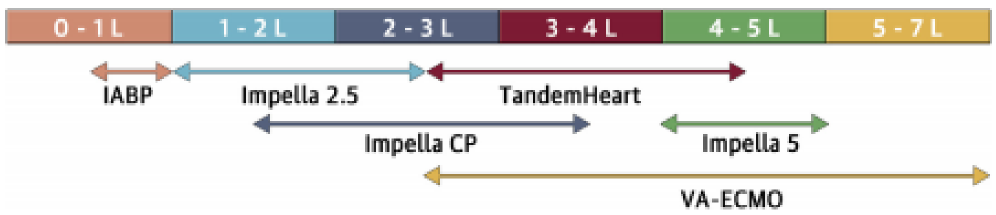
Outline

- Why and in Whom do we use Mechanical support? Back to Basics
- National Trends in Use of Mechanical Cardiac Support (MCS)
- IABP
- Impella
- Tandem Heart/ECMO (briefly)
- Summary

Summary

- MCS intended to improve hemodynamic profile, improve coronary and end organ perfusion, support complex procedures
- Trends: IABP on the decline, pVADs on the rise
- IABP: Quick, easy. Mild support. Cheap. Decent data
- Impella: More support, more expensive. Slightly more robust data, though this is industry driven
- For high risk patients, earlier MCS is better than later

FIGURE 2 Comparison of MCS Devices and Their Impact on Cardiac Flow



Four main families of devices exist for percutaneous MCS, which includes IABP, Impella (Abiomed Inc., Danvers, Massachusetts), TandemHeart (CardiacAssist, Inc., Pittsburgh, Pennsylvania), and VA-ECMO. Each device provides a different level of cardiac flow and device selection should be tailored to the level of support needed. Abbreviations as in Figure 1.

How Do I Decide?

Which To Use:

1. Substrate

- Elderly
- Low EF
- Renal failure
- Vasculature adequate
- Frail

2. Lesion +/- Low EF

- Unprotected LM
- Multivessel PCI
- Prolonged ischemia expected
  (rotational atherectomy, diffuse disease)

3. Presentation

- Shock
- Large STEMI
- CHF

What To Use:

- How much support needed?
- Adequate access? Ischemic limb risk?
- Clinical factors favoring or going against device (ie afib, aortic stenosis or insufficiency, LV thombus)

Thank You

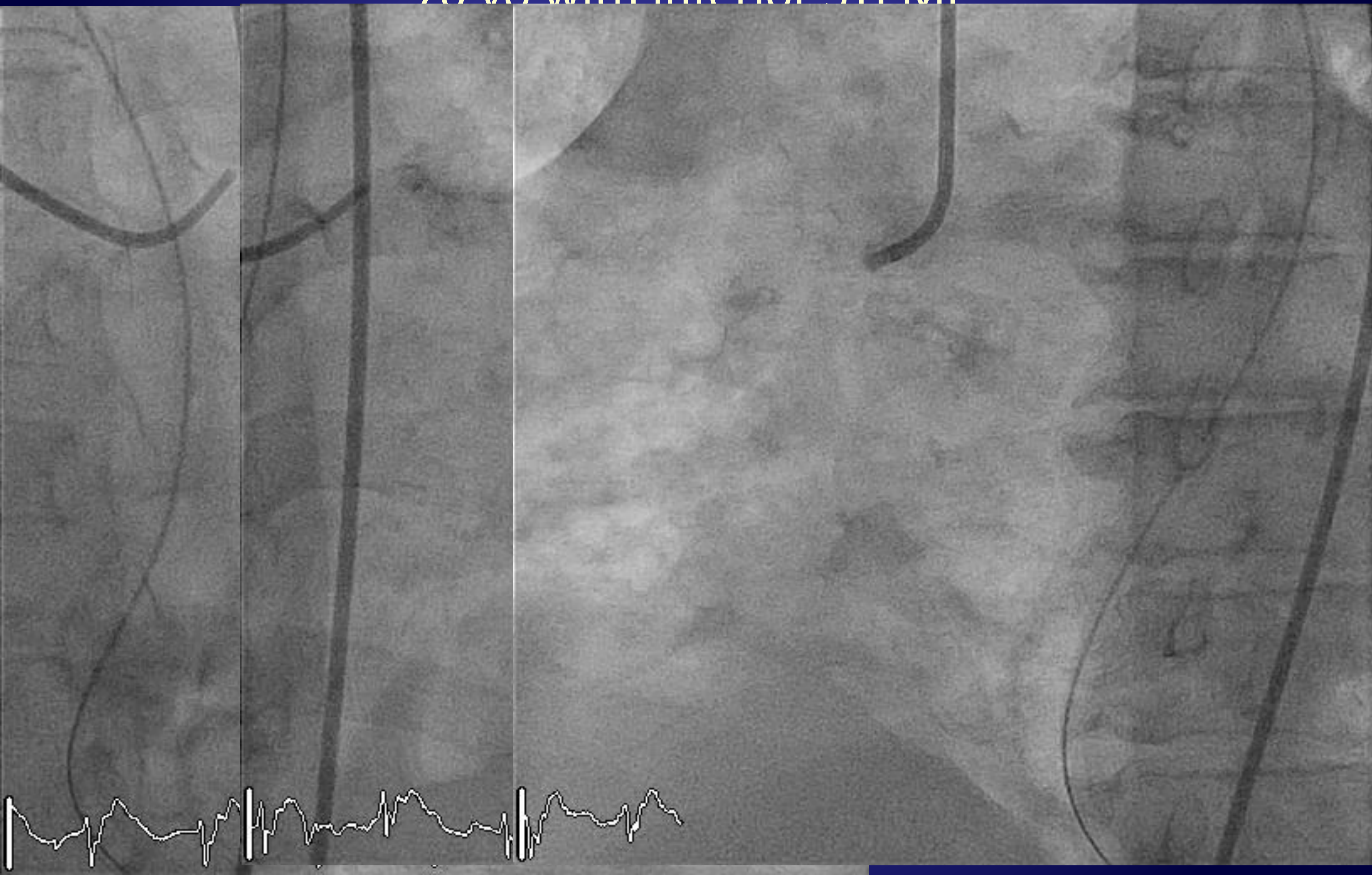
Questions?

Manu Uberoi

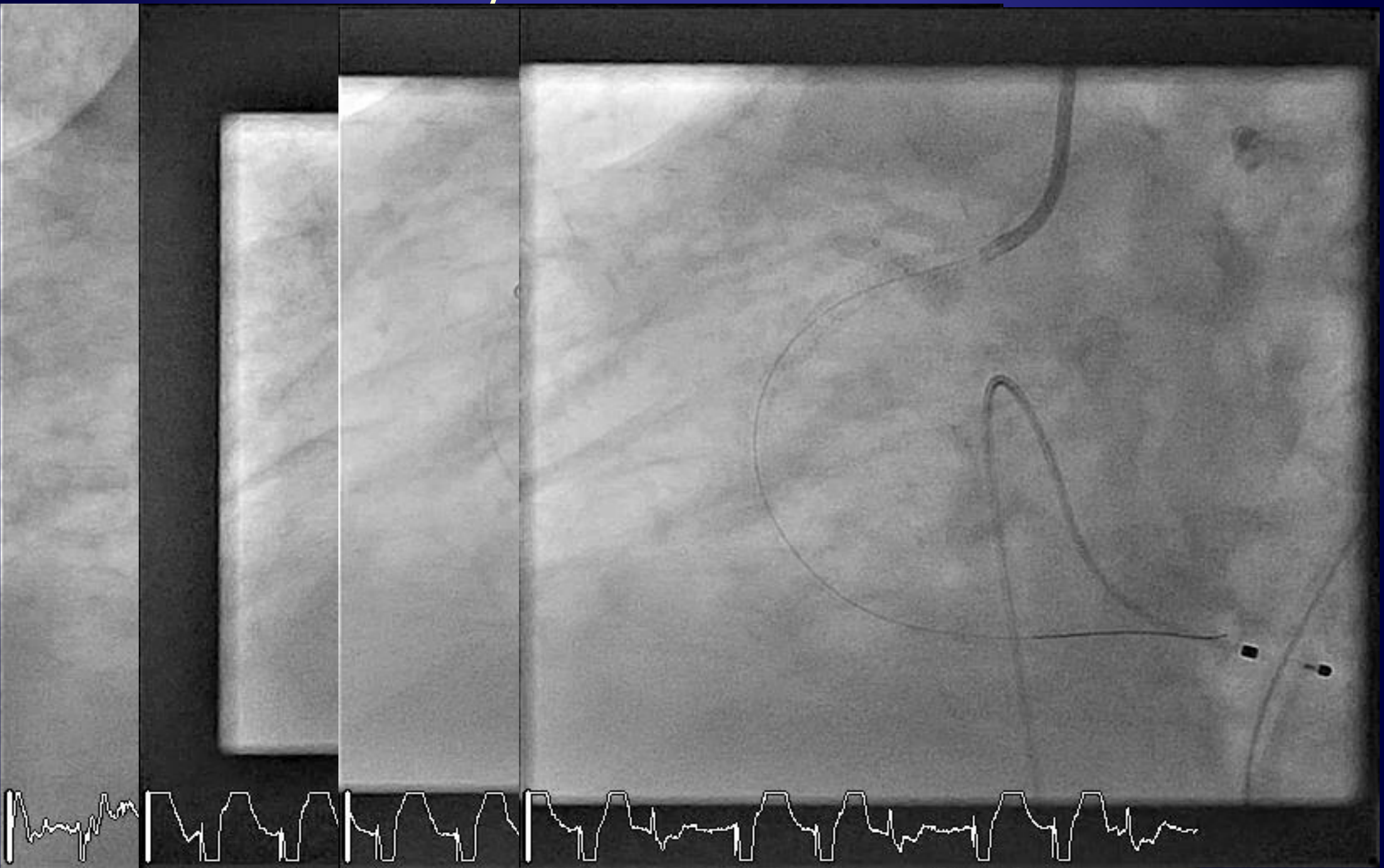
Abhimanyu.Uberoi@kp.org

(971) 278 - 8259

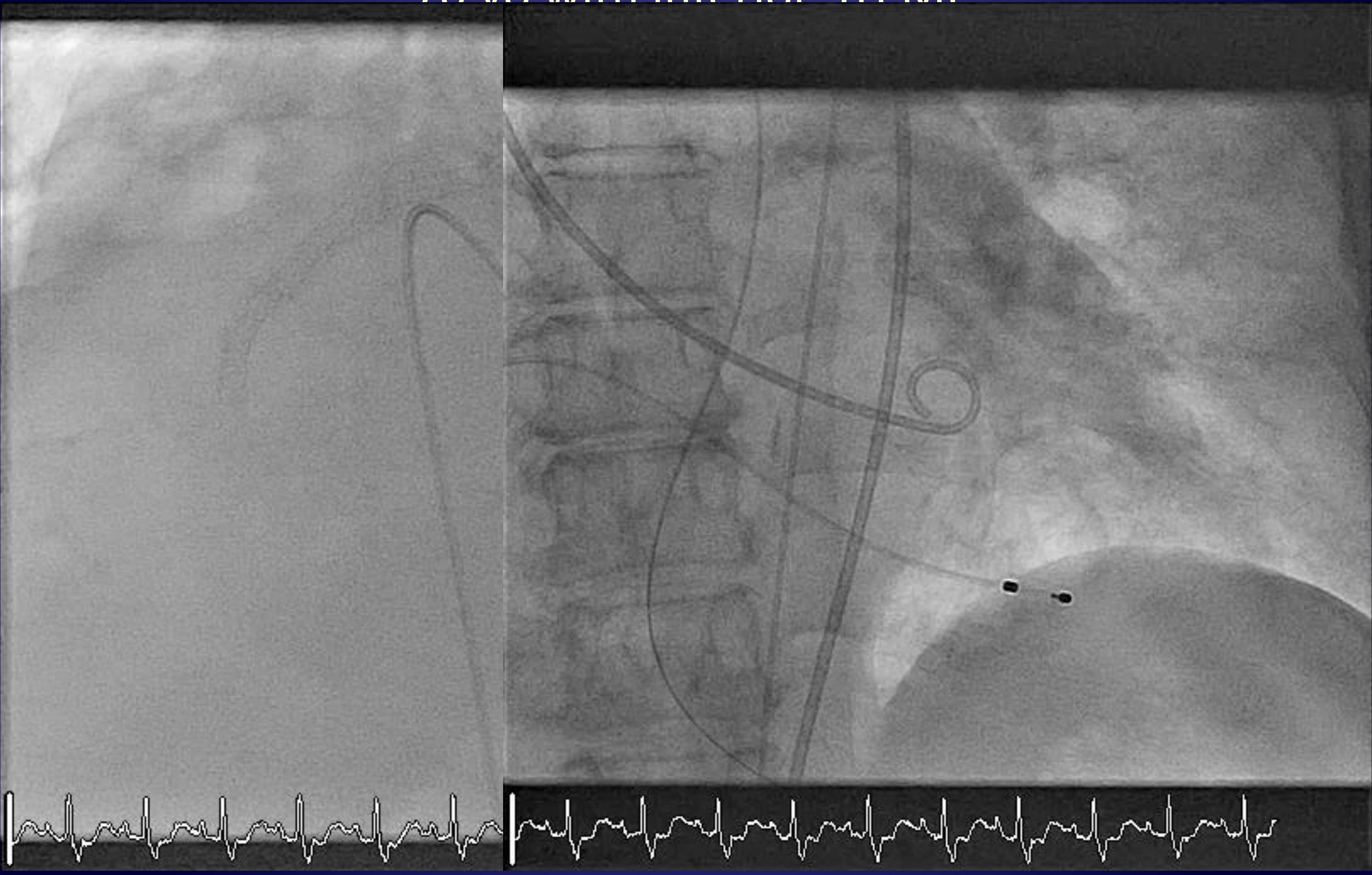
70 yo with inferior STEMI



70 yo with inferior STEMI



70 yo with inferior STEMI



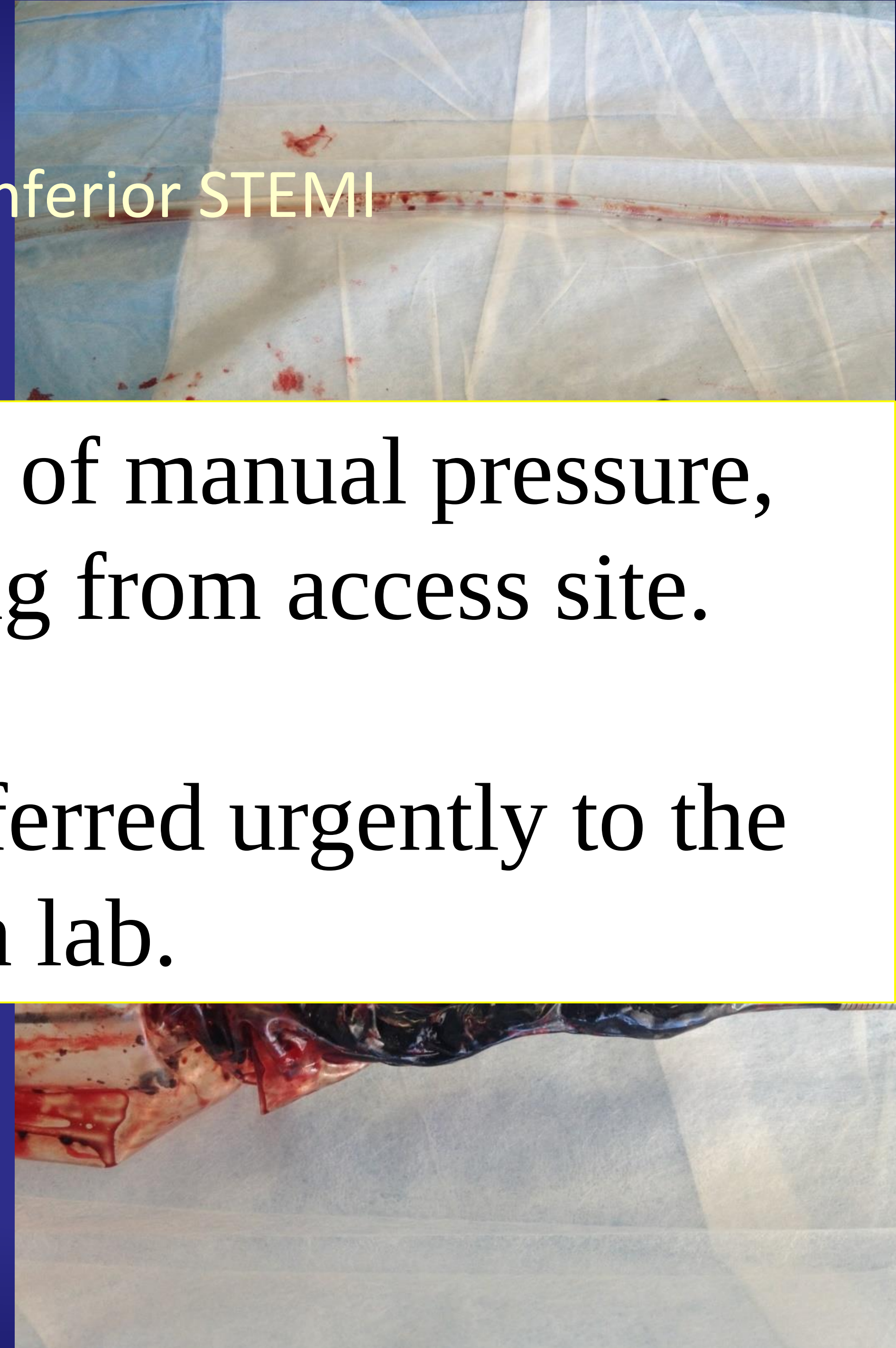
70 yo with inferior STEMI

- On HD 3, RNs call noting blood in the gas line

Despite 30 minutes of manual pressure, continued bleeding from access site.

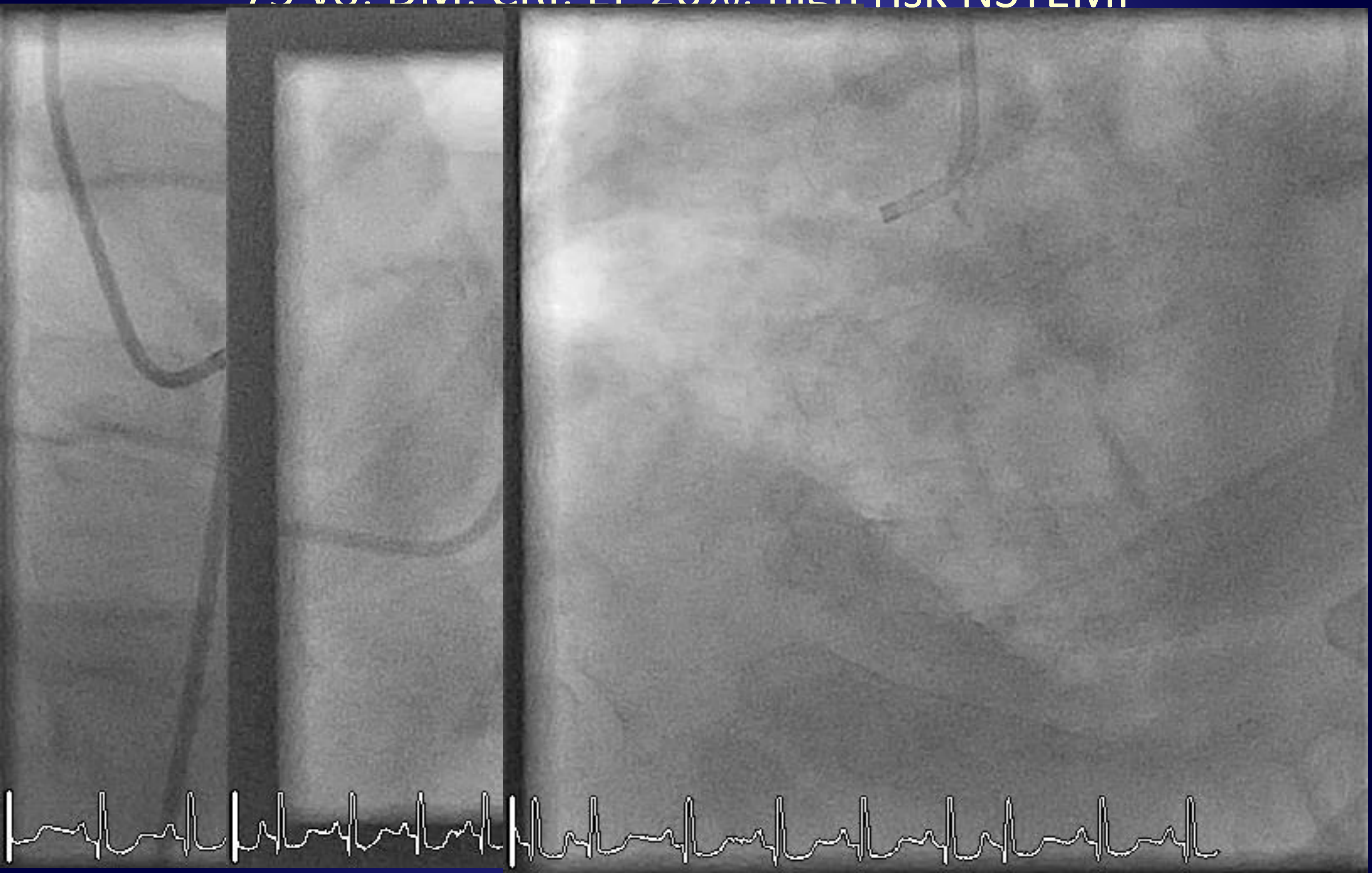
The patient is transferred urgently to the cath lab.

in retracting IABP

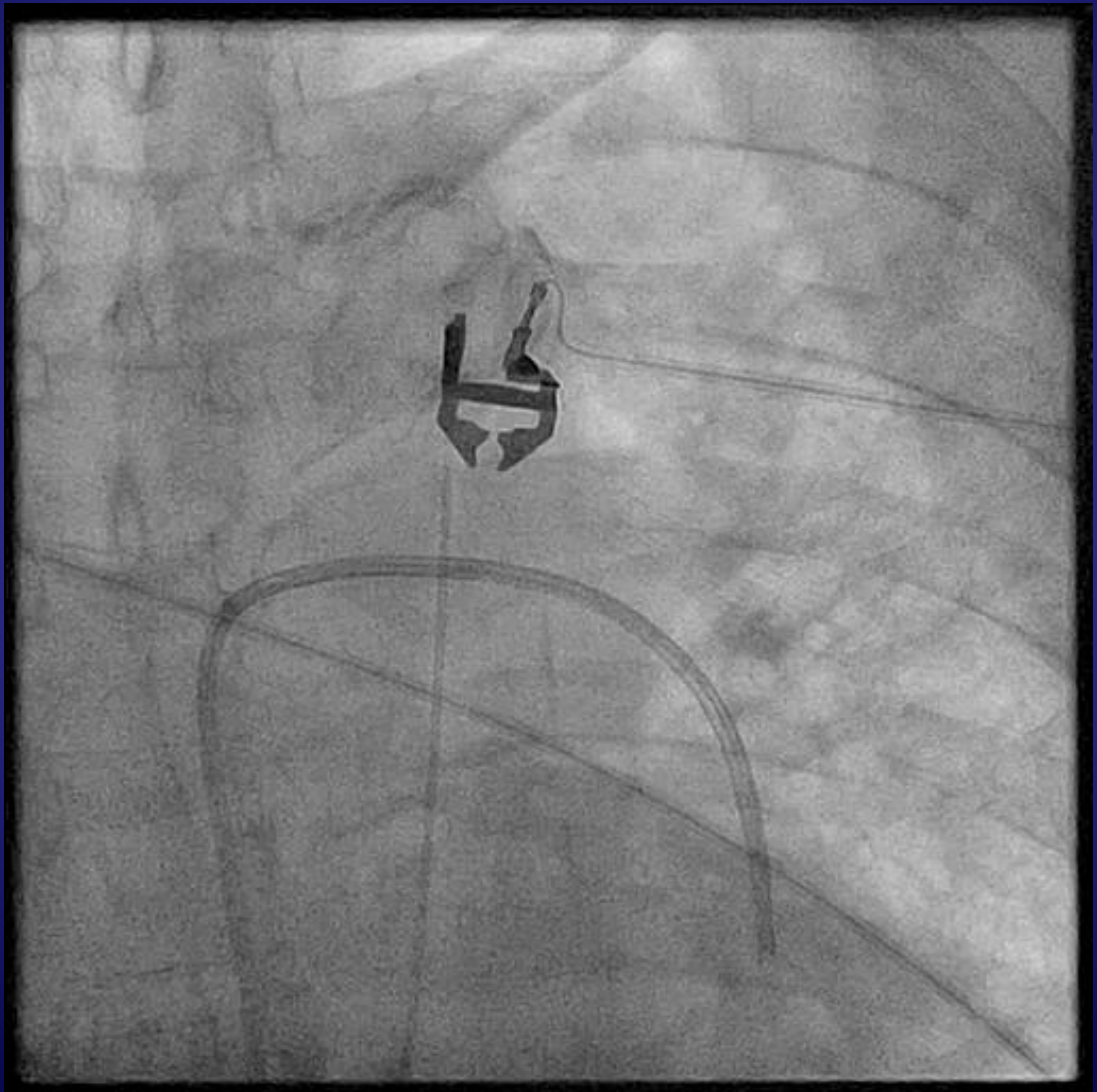


70 yo with inferior STEMI

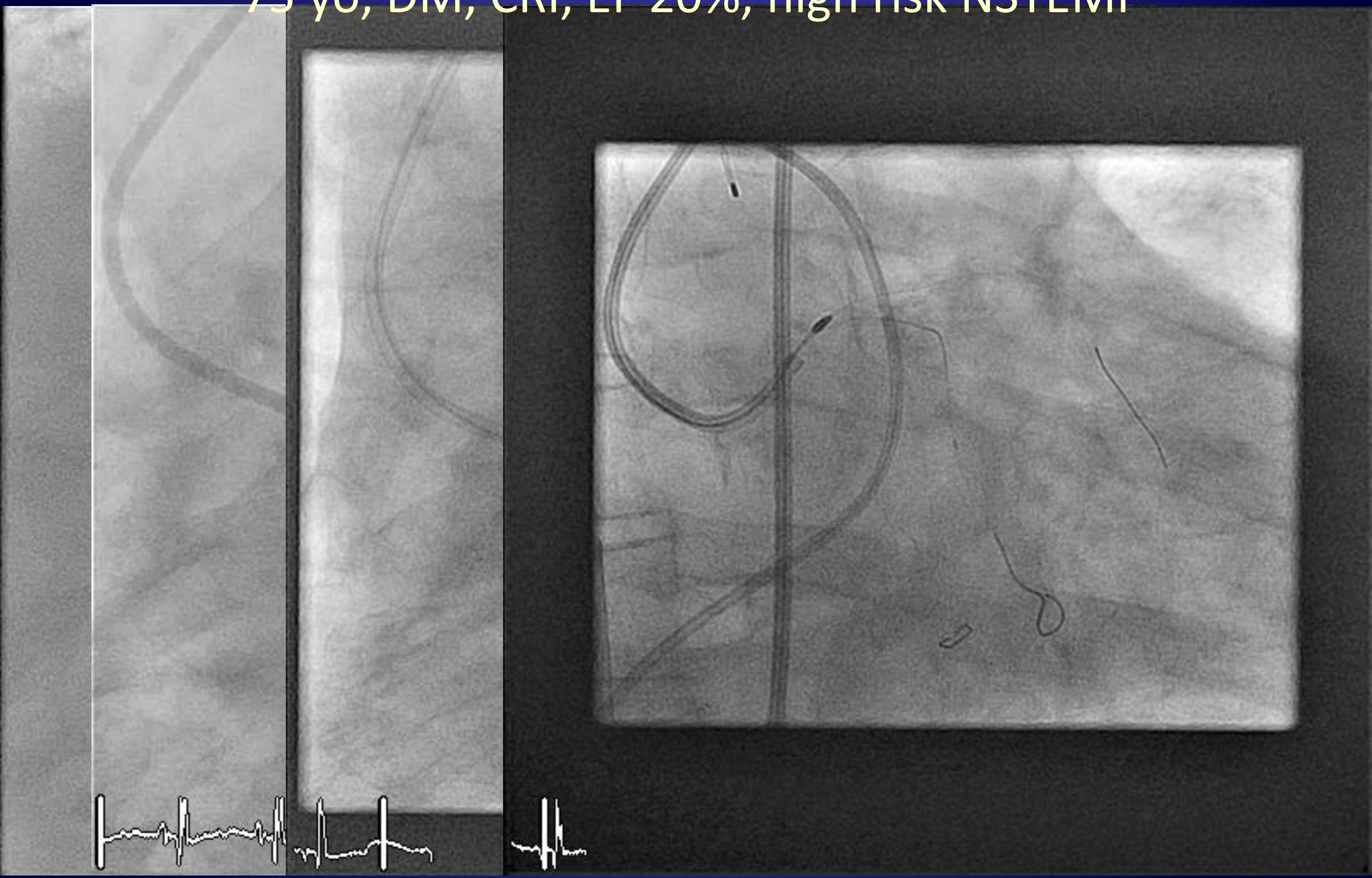
75 yo, DM, CRI, EF 20%, high risk NSTEMI



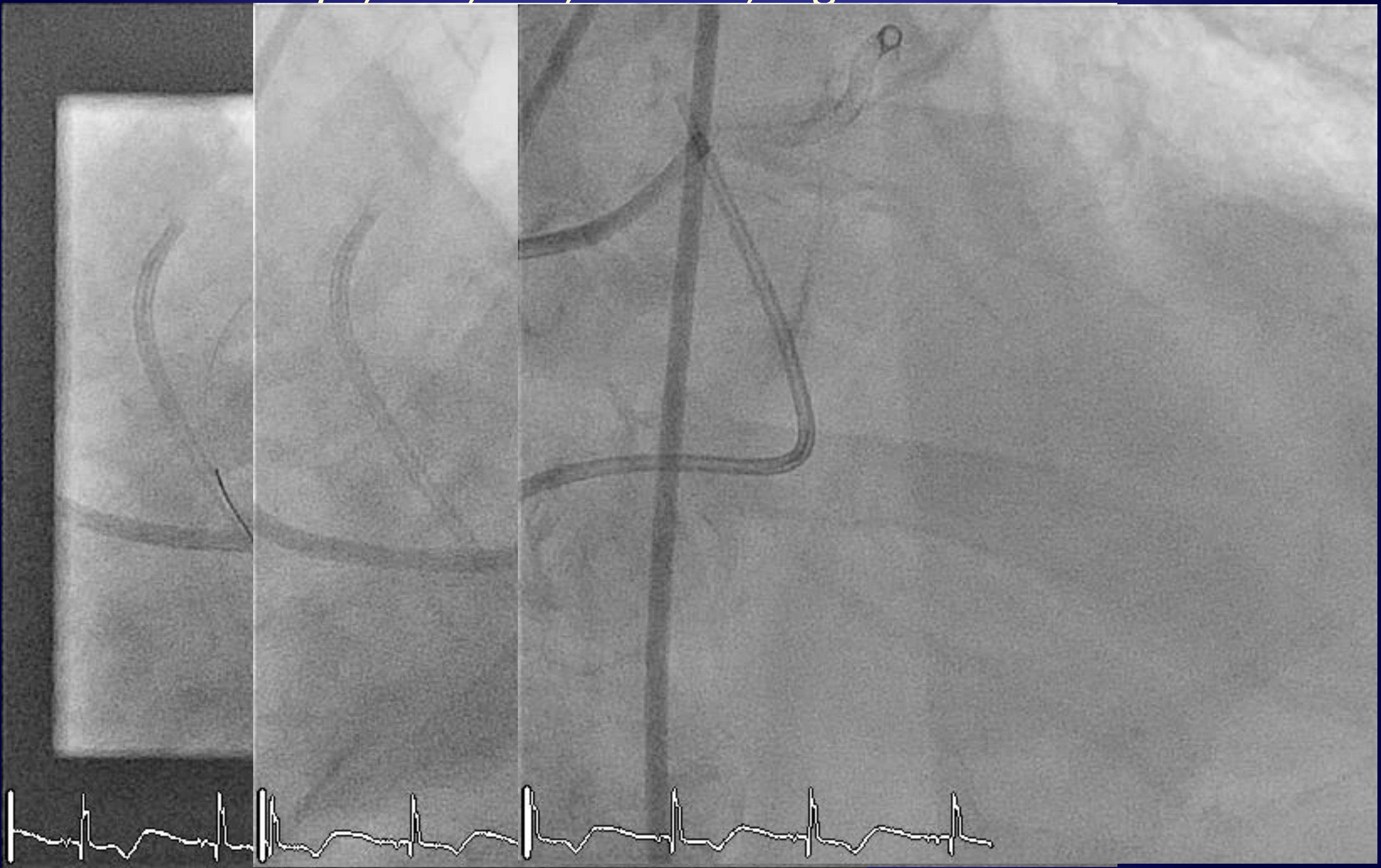
75 yo, DM, CRI, EF 20%, high risk NSTEMI



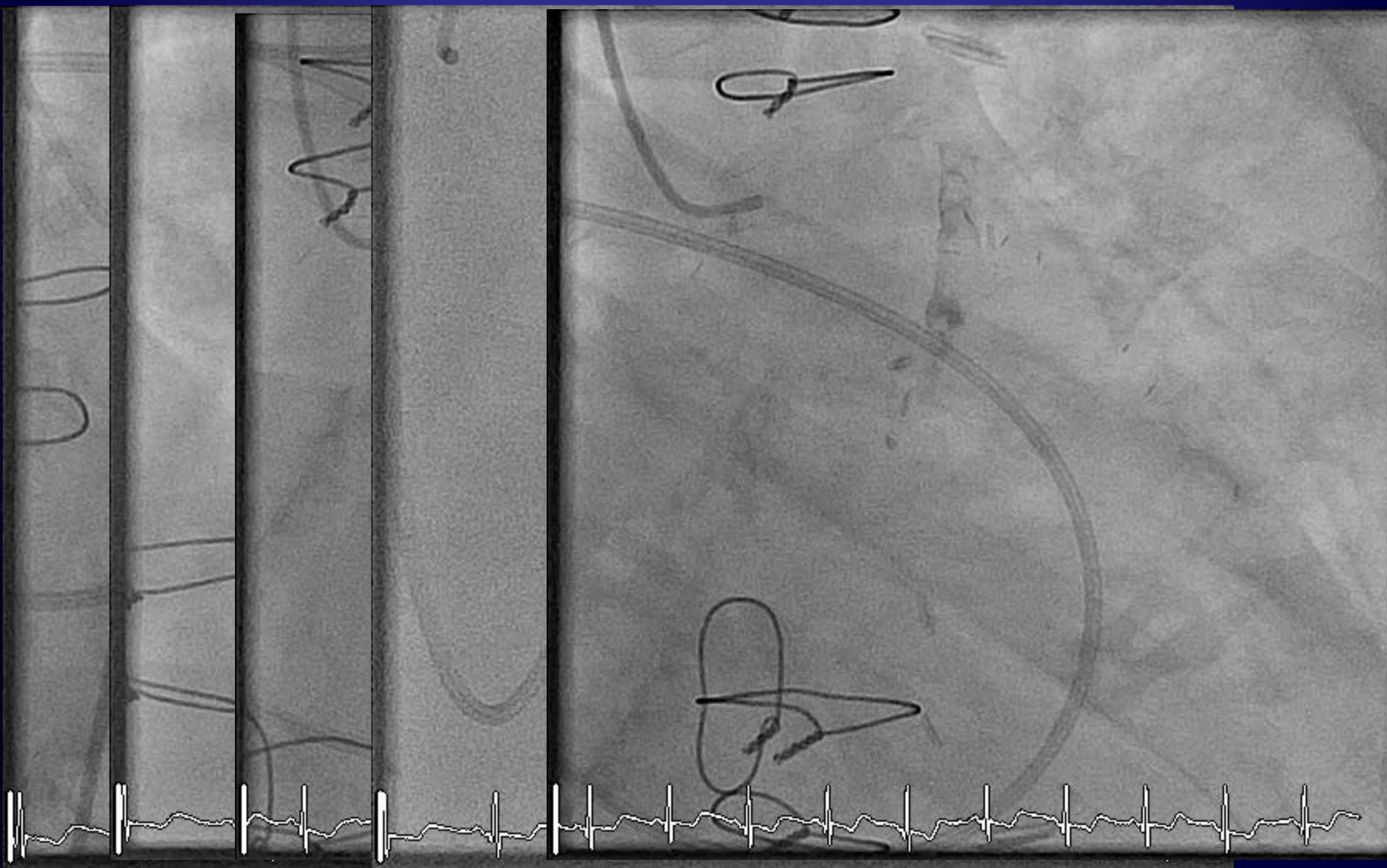
75 yo, DM, CRI, EF 20%, high risk NSTEMI



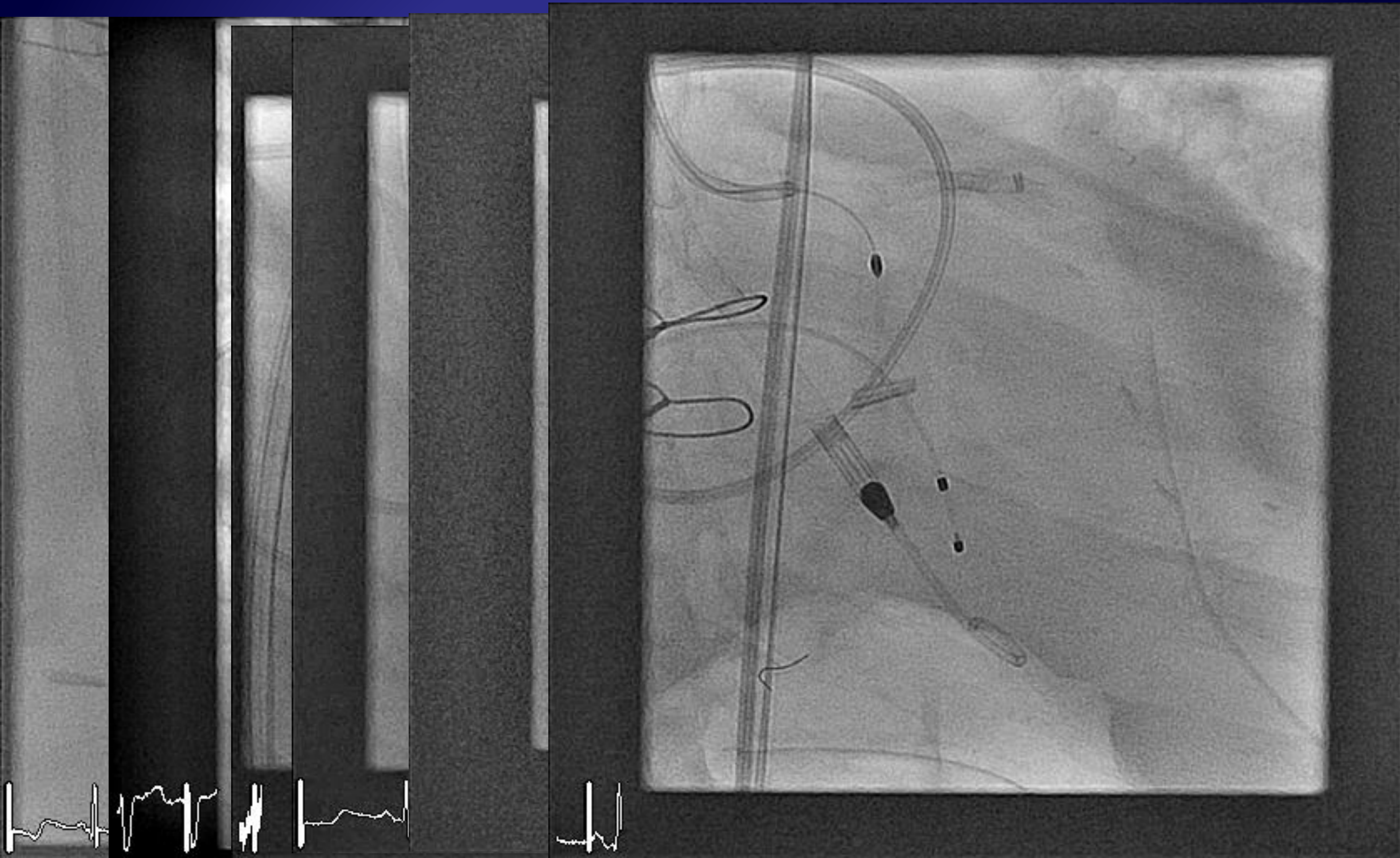
75 yo, DM, CRI, EF 20%, high risk NSTEMI



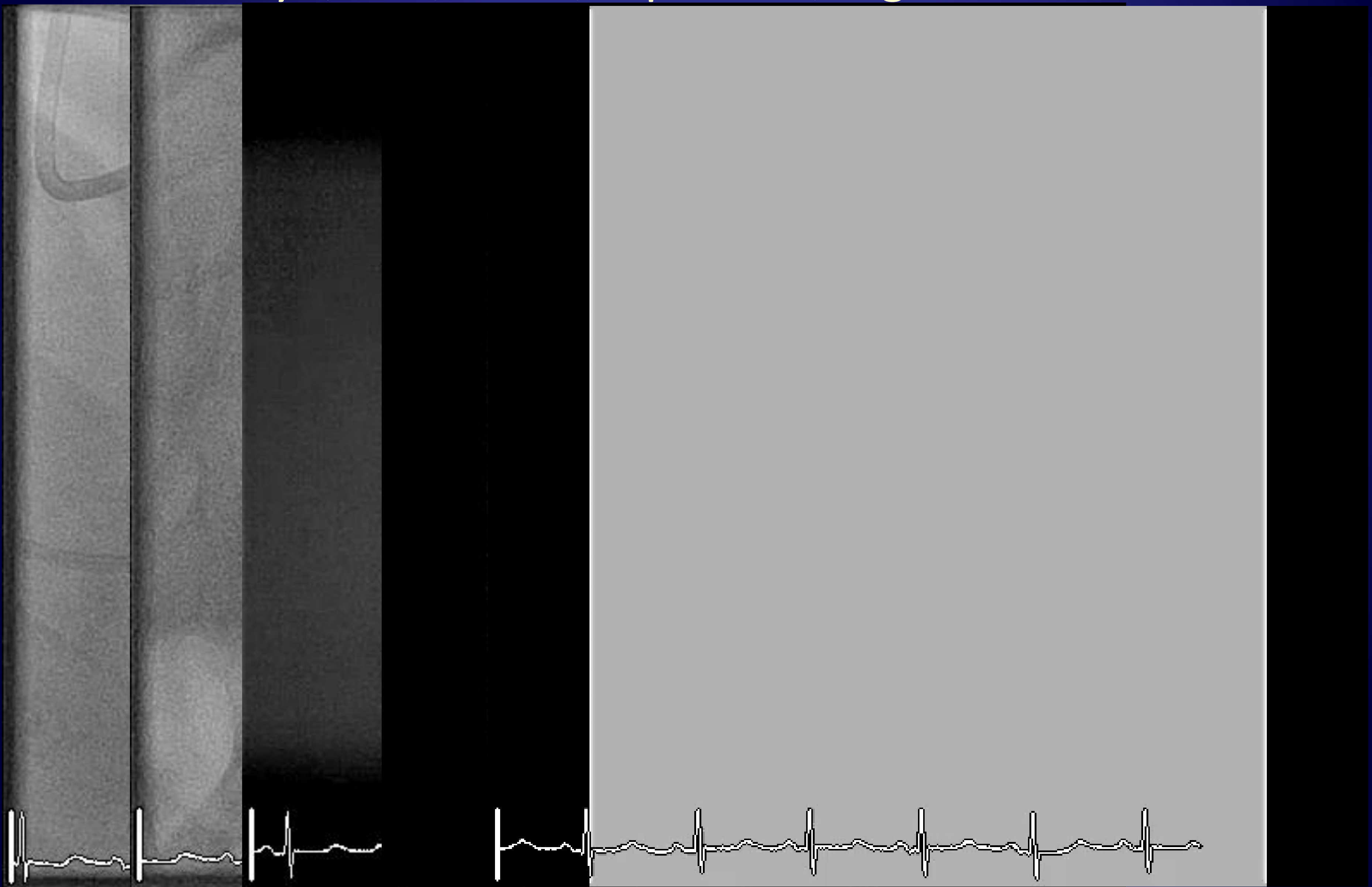
60 yo, DM, ESRD, s/p CABG, high risk NSTEMI



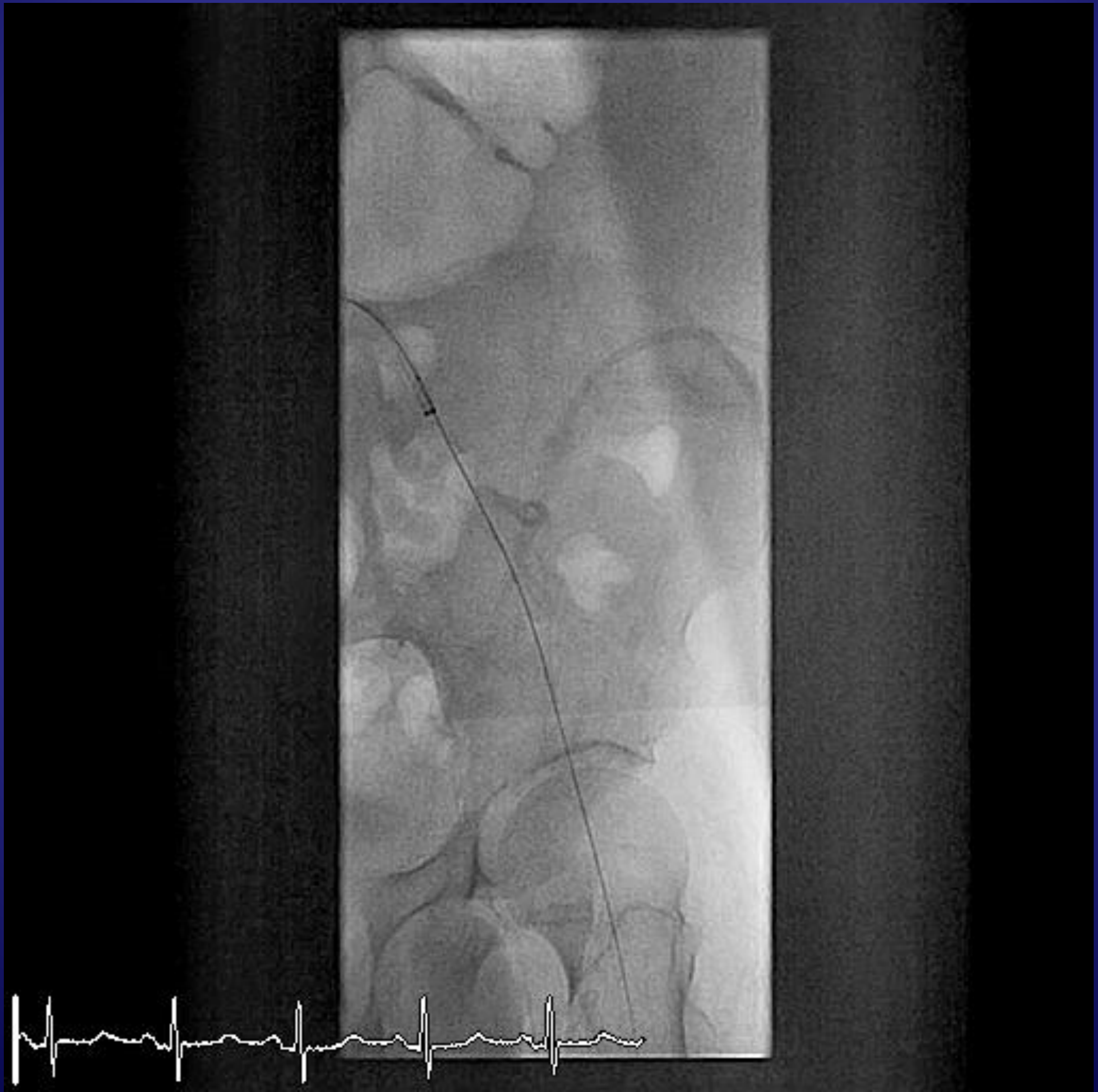
60 yo, DM, ESRD, s/p CABG, high risk NSTEMI



60 yo, DM, ESRD, s/p CABG, high risk NSTEMI



60 yo, DM, ESRD, s/p CABG, high risk NSTEMI



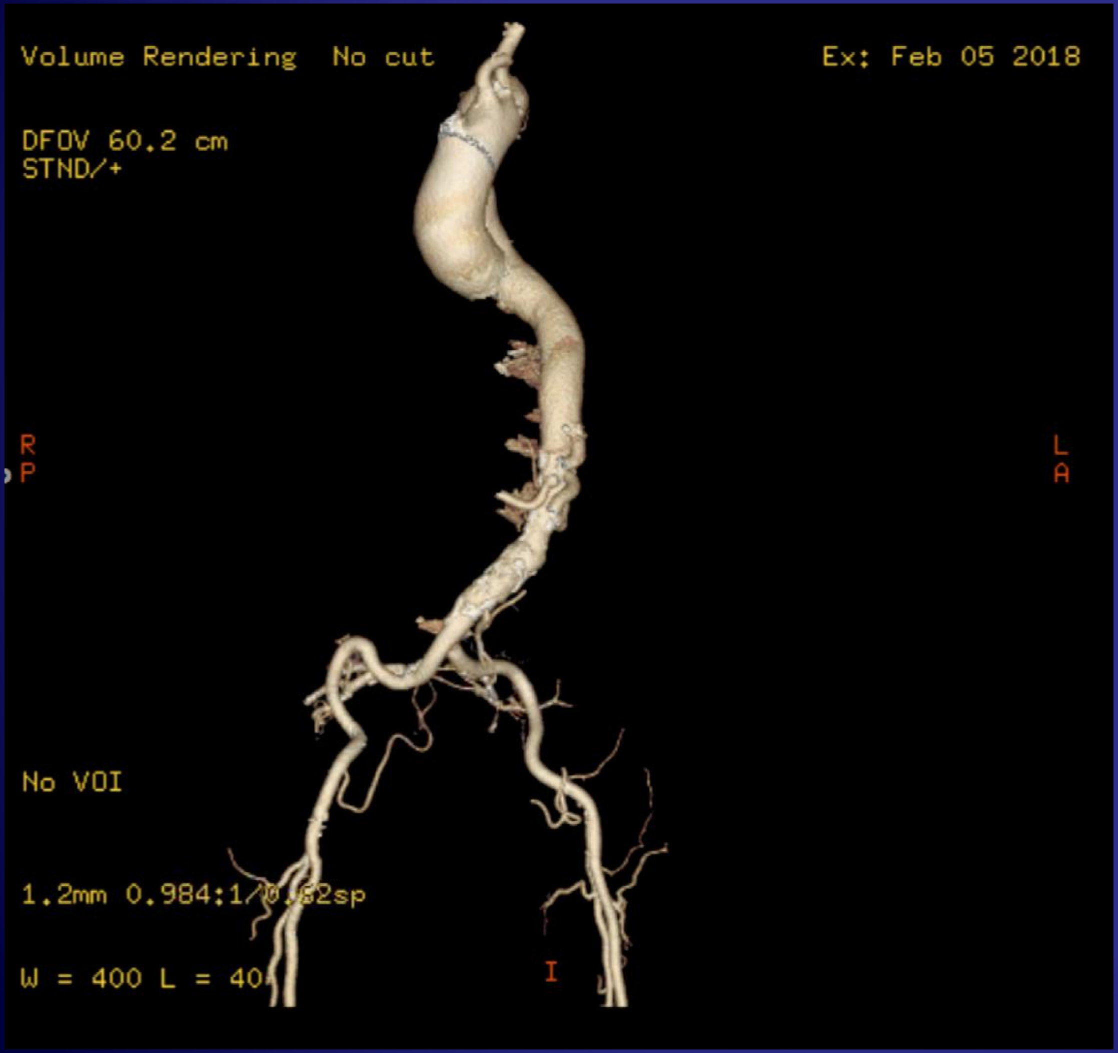
75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

Extreme angulation
Severe AI
EF 35%

75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

Short LM
Severe LM disease
Severe prox-mid LAD disease
Severe diagonal disease
Significant Calcium
L dominant

75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.



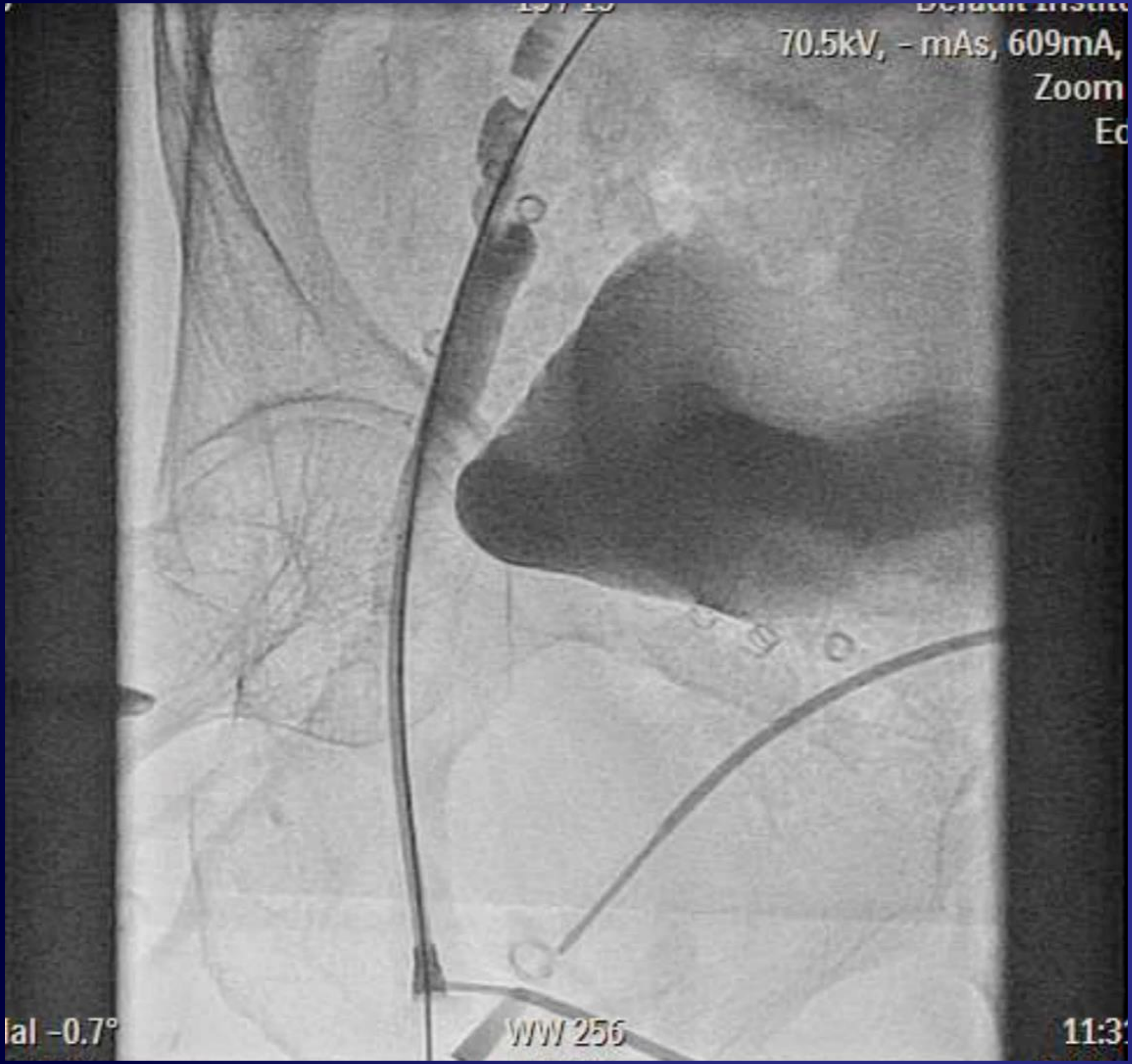
Severe kyphoscoliosis
Severe iliofem tortuosity

75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

After PreClose Attempt

75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.



R Femoral Angio

75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

Decision Time

1. Stop everything, let groins heal
2. Send for surgery?
3. Proceed with PCI? Without support?
4. If with support, how would you do it?

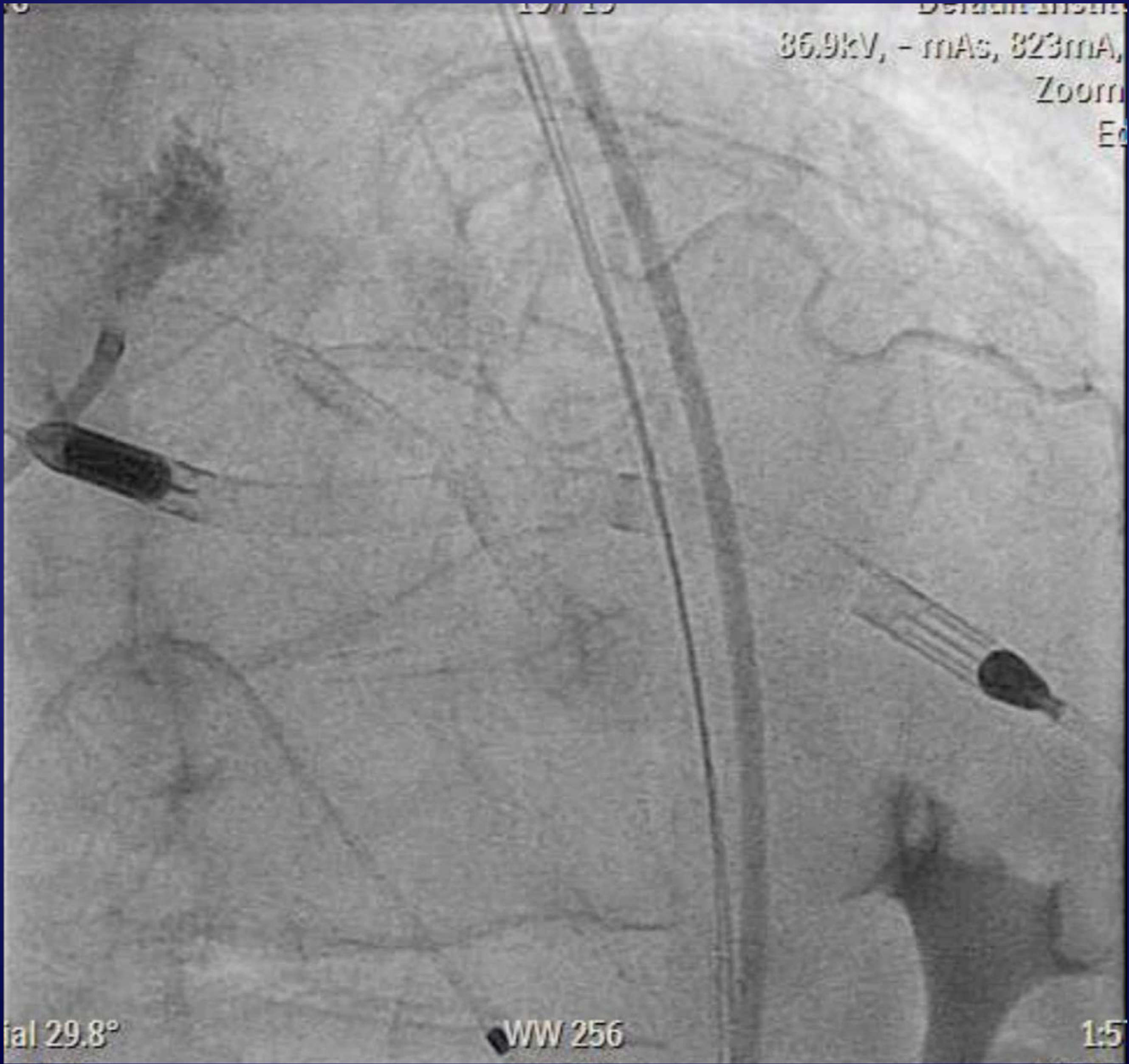
75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

What We Did

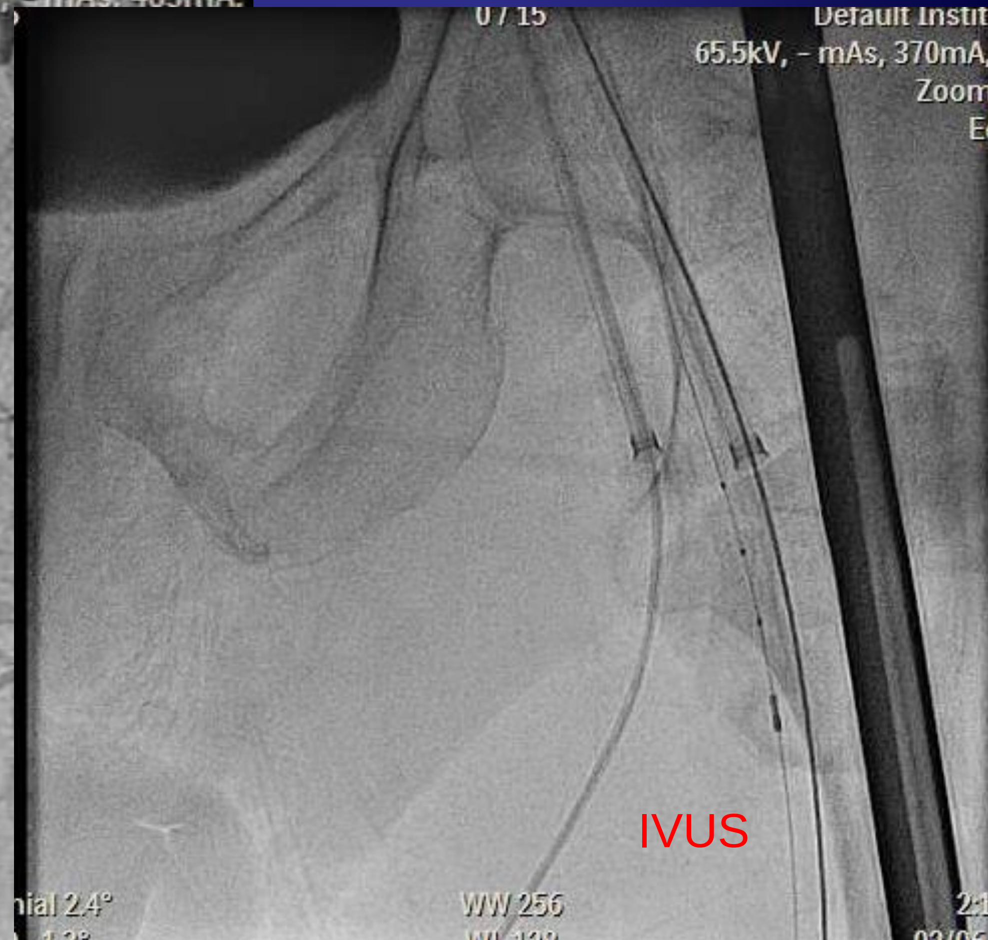
1. Upsized R sheath to 14Fr Impella Sheath
2. Used L CFA access for 7 Fr Guide
3. Insert Impella
4. Roto PCI of LM/LAD/Diag
5. Remove Impella
6. Endovascular Repair of L CFA
7. Manual pull of R CFA Sheath in ICU

75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

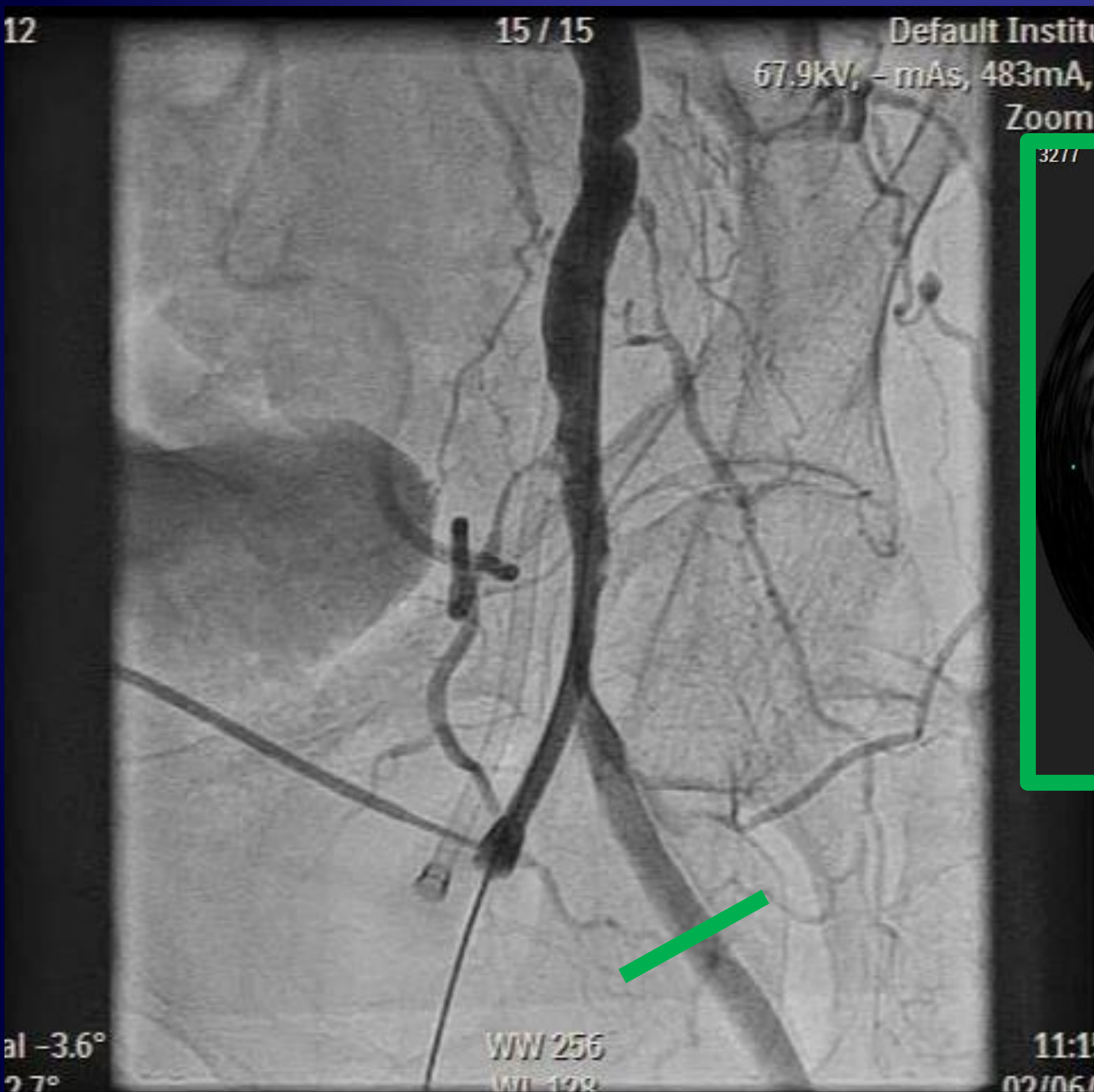
75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

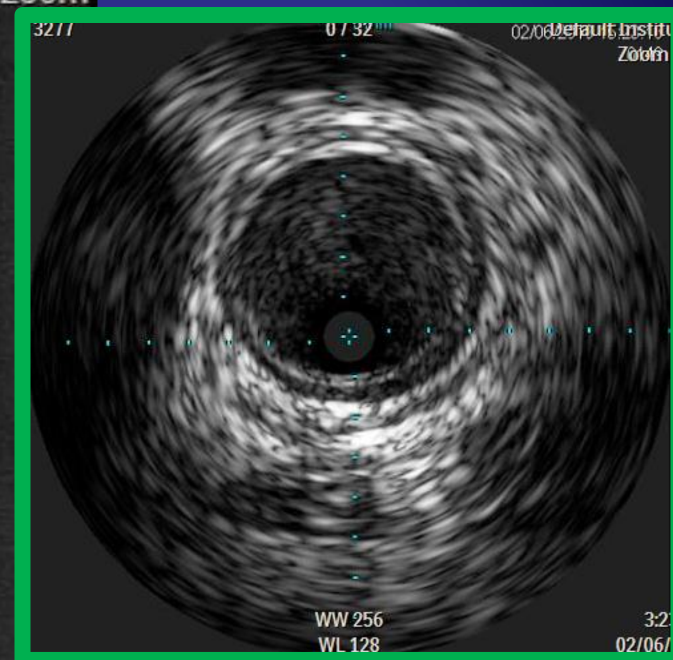


75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

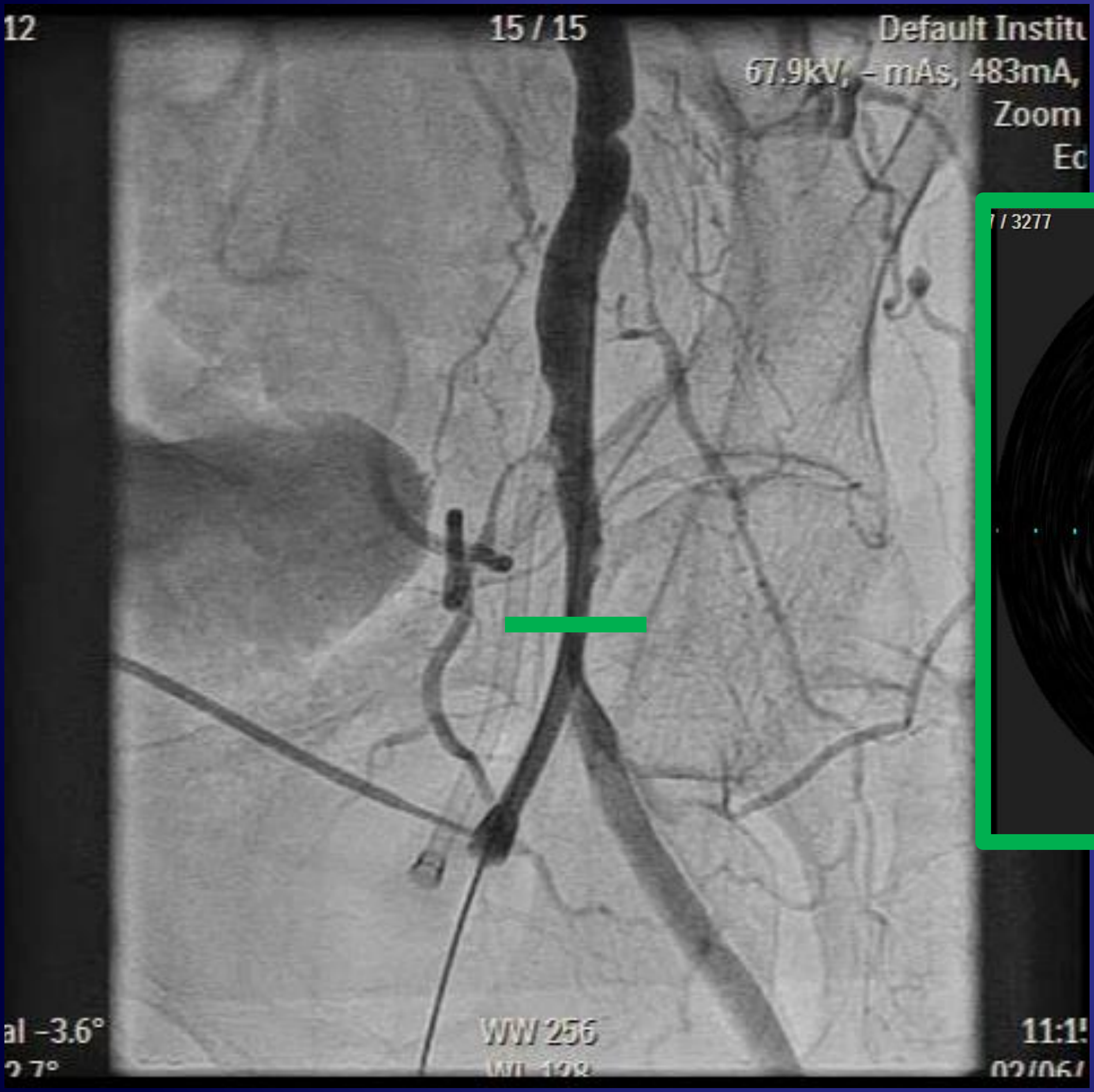


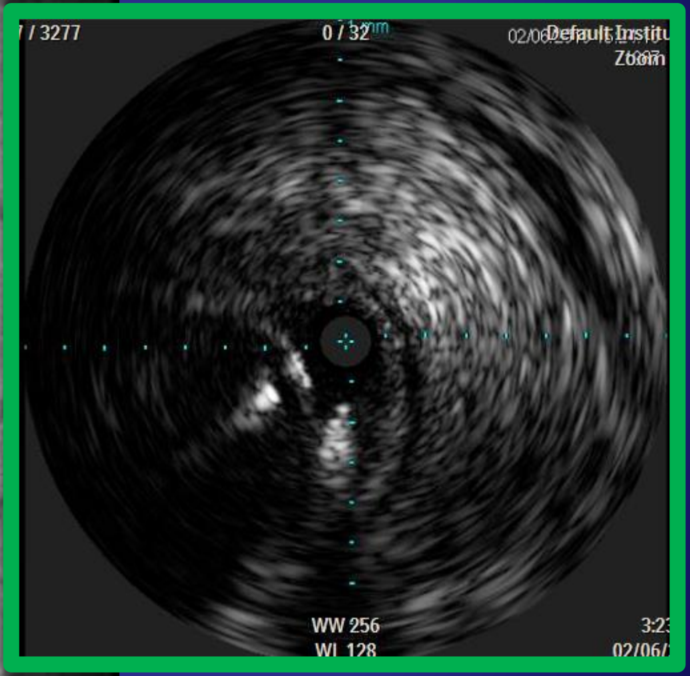
75 yo male, severe scoliosis, Parkinson's, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.





75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.





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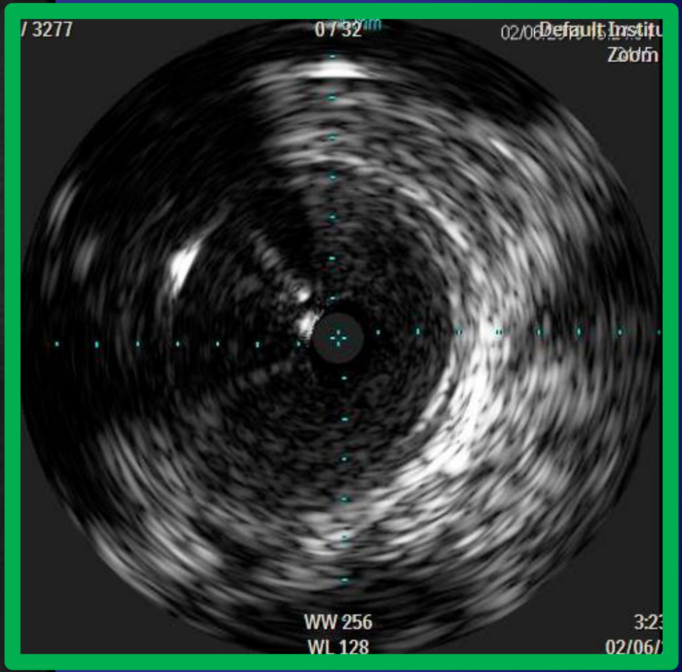

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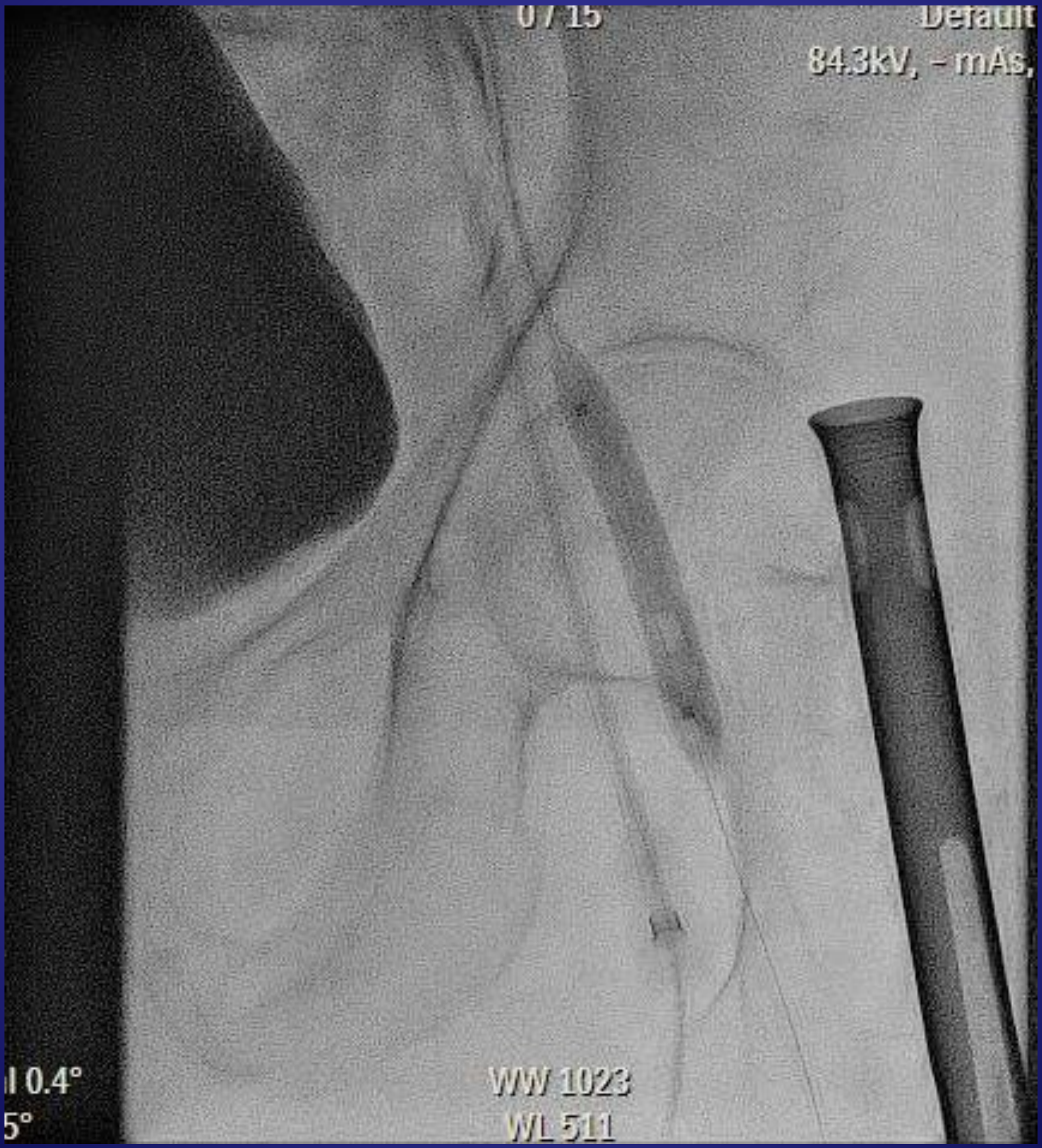

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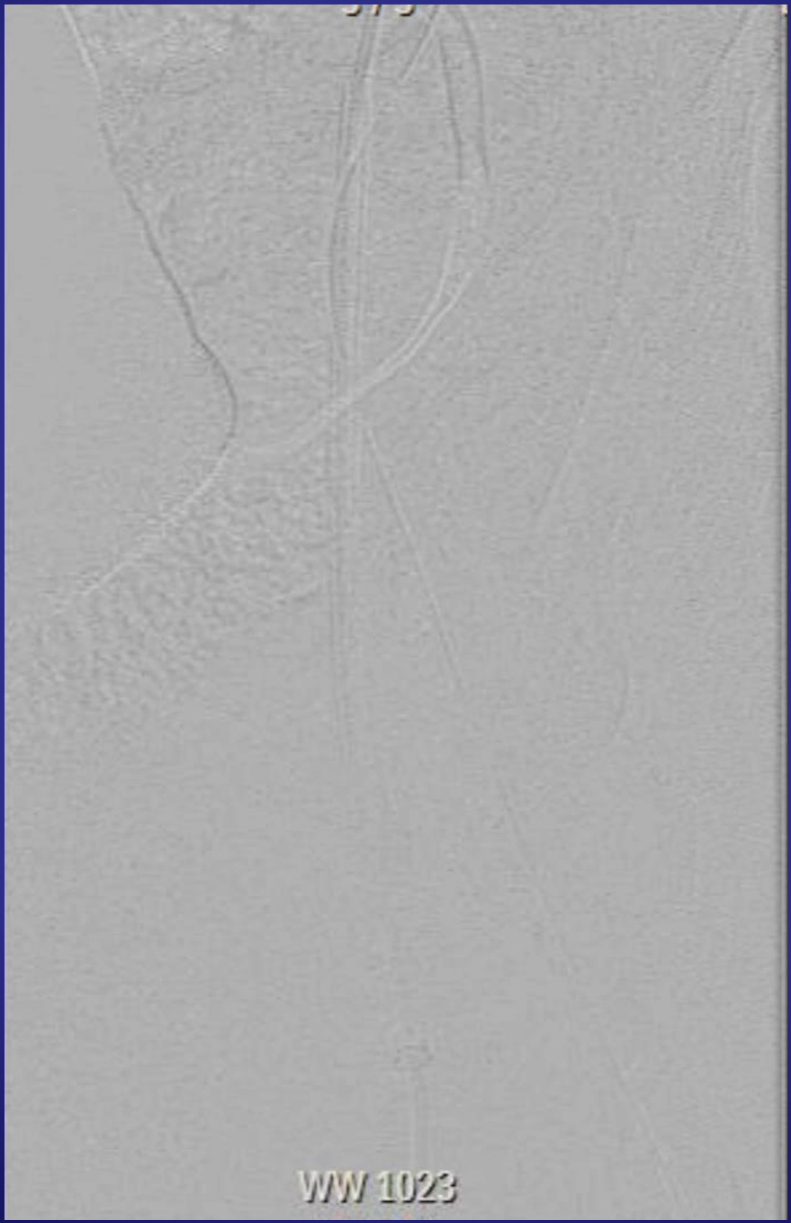
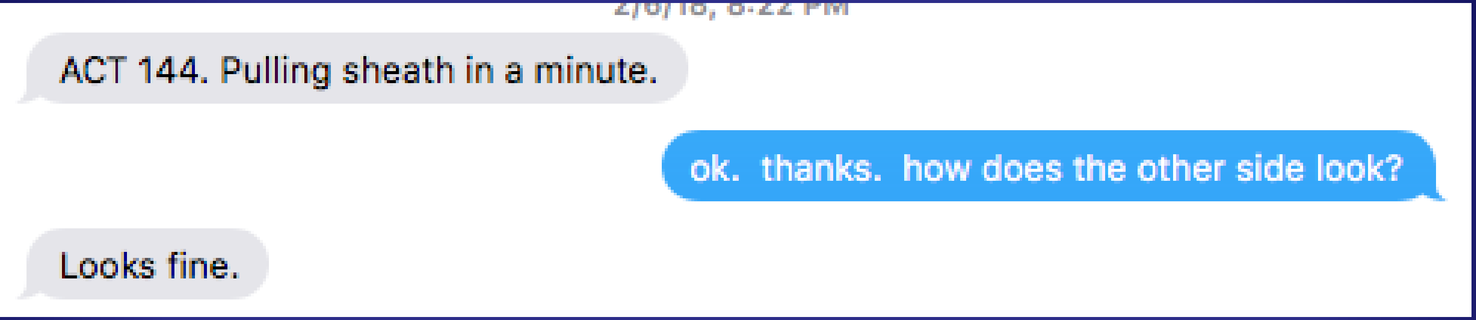
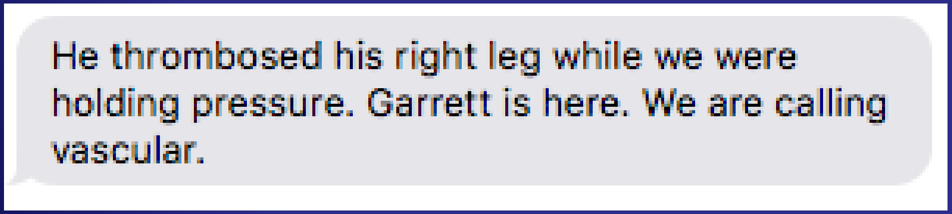


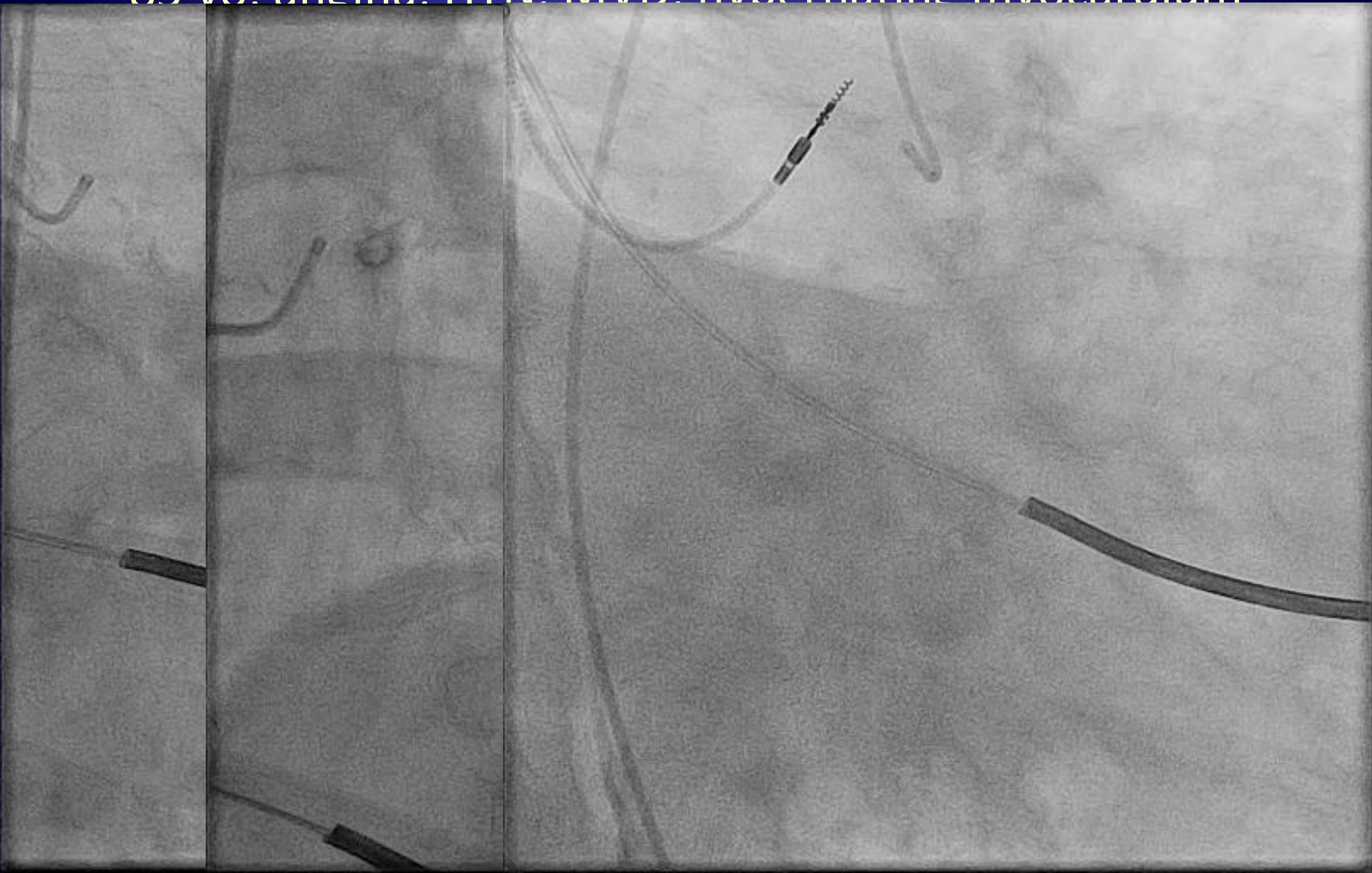
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

What happened to R groin?

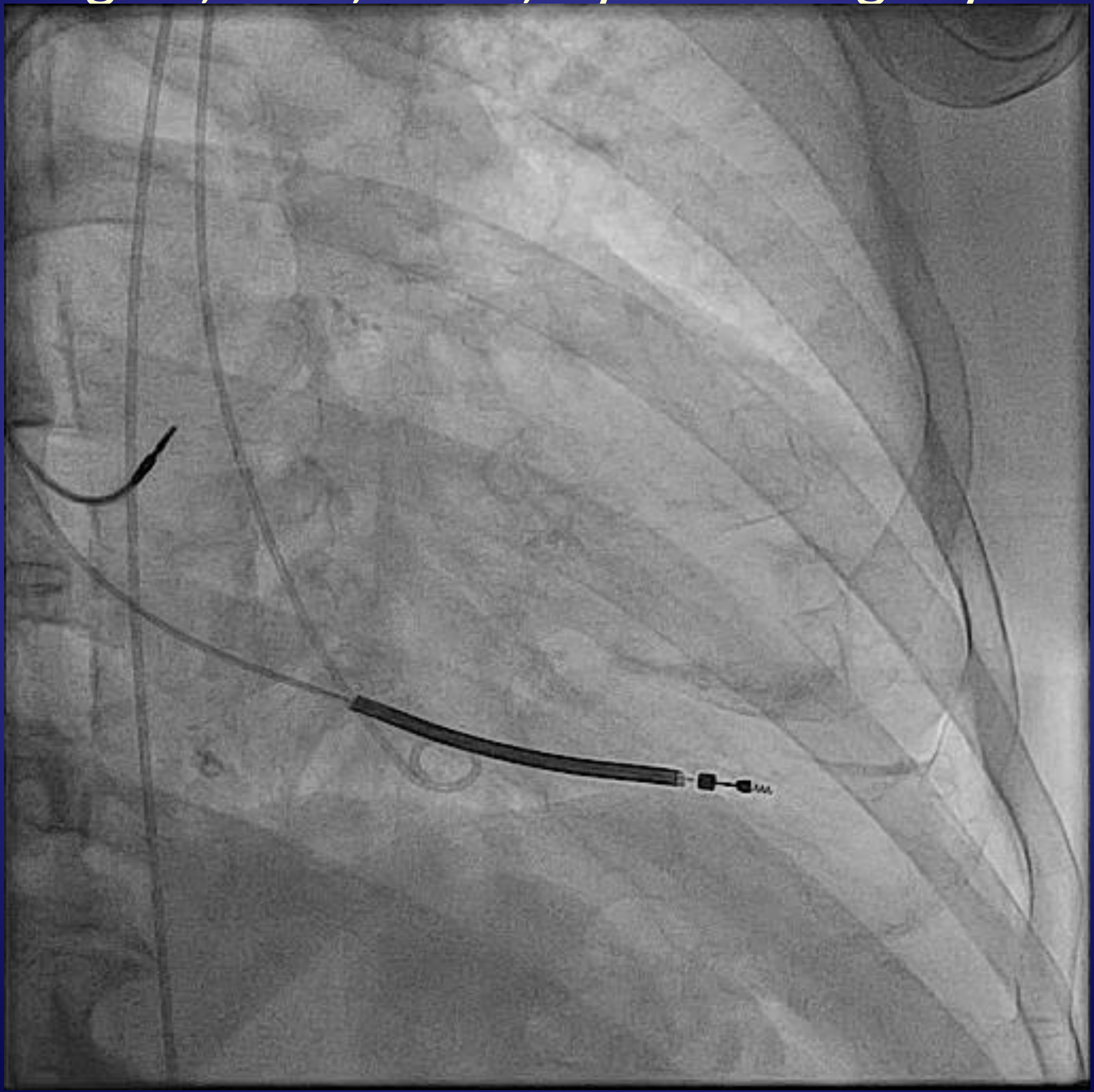




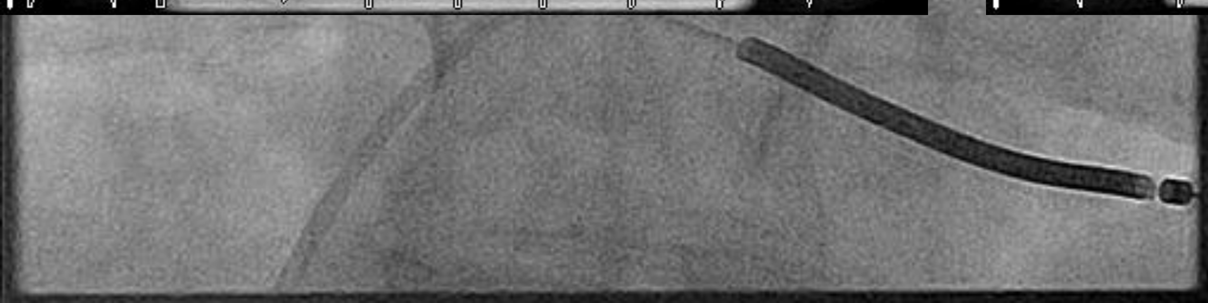
85 yo, angina, HTN, MVD, hybernating myocardium



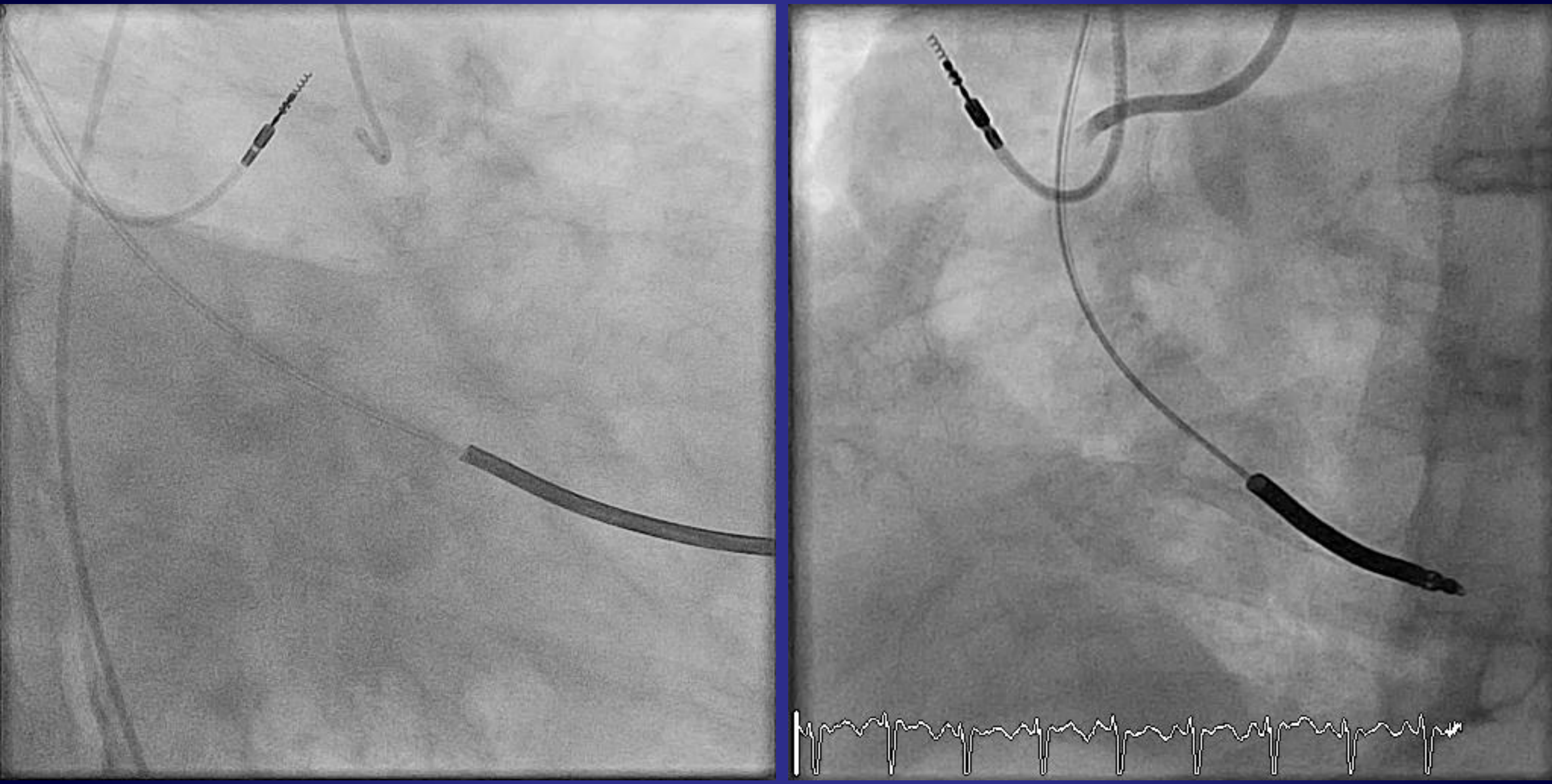
85 yo, angina, HTN, MVD, hybernating myocardium



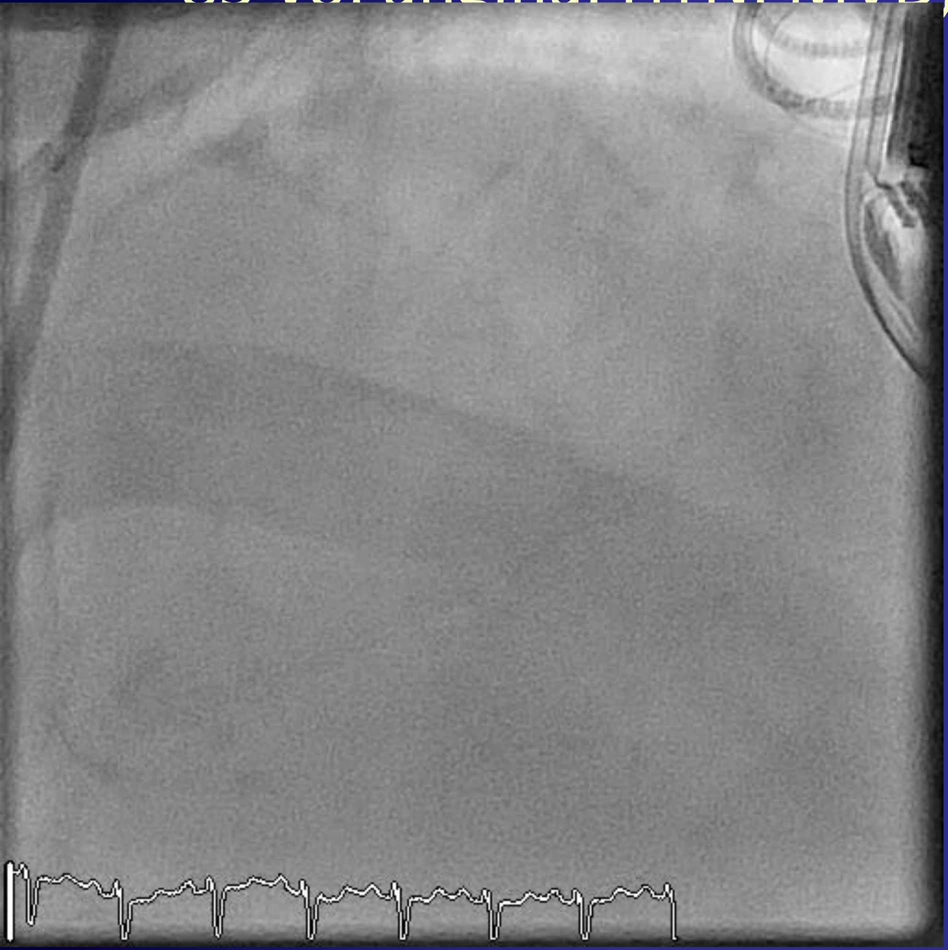
85 yo, angina, HTN, MVD, hybernating myocardium

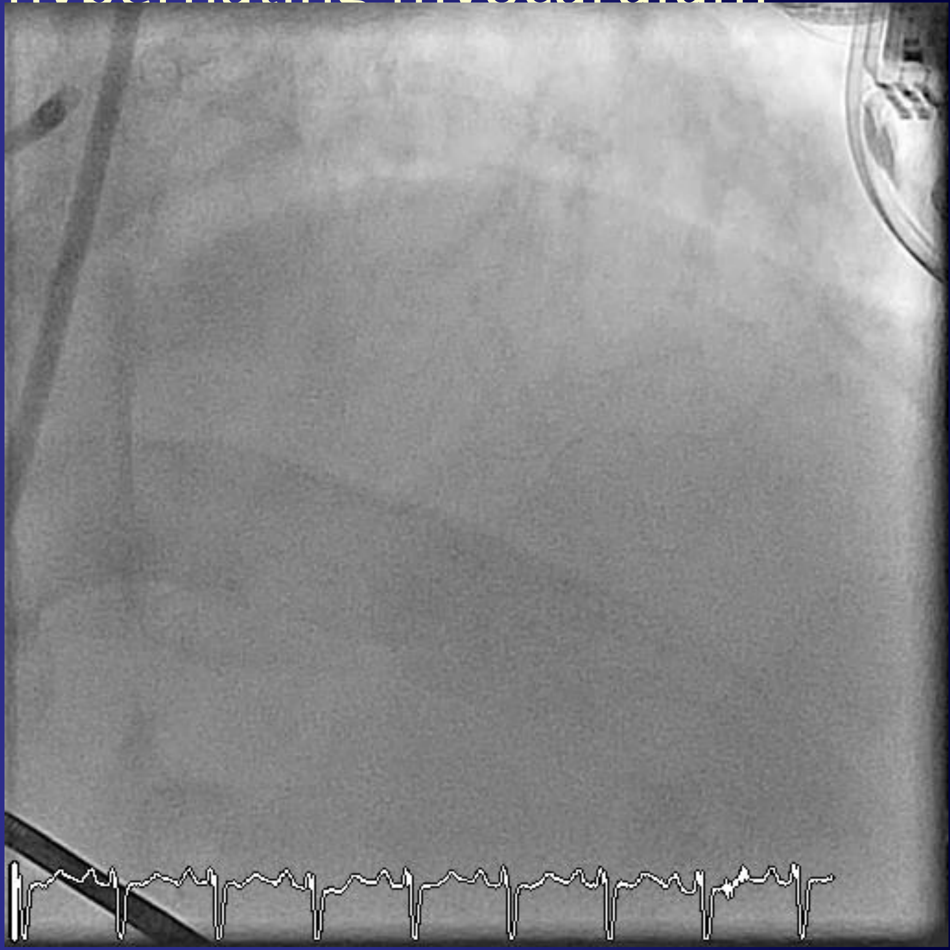


85 yo, angina, HTN, MVD, hybernating myocardium



85 yo, angina, HTN, MVD, hybernating myocardium





When I think Mechanical Support is needed?

- For HR PCI
  - Hemodynamic condition of patient at time of PCI
  - Anticipated risk of hemodynamic compromise during procedure
  - Need for support after revascularization
- In Acute MI, STEMI and high risk NSTEMI
  - Myocardial Ischemia
    - LV systolic and diastolic dysfunction
    - Elevated intracardiac pressures
  - Potential for thrombotic microembolization
    - Infarct extension
  - Hemodynamic decompensation
  - Procedural Complication

THANK YOU

IABP

- STEMI and high risk NSTEMI
- Myocardial Ischemia
  - LV systolic and diastolic dysfunction
  - Elevated intracardiac pressures
- Potential for thrombotic microembolization
  - Infarct extension
  - Hemodynamic decompensation
- Procedural Complication

- MCS may:
  - Reduces myocardial oxygen consumption
  - Improve coronary perfusion

Cases

- Torress, MRN 2215483 IABP for RCA
  - --IVUS guided re-entry for RCA
  - --Inferior STEMI
- Richard Vincent
- Sammy Donnahoe
- Lan Thi
- Michael Hall
- Wanda Simpson
- Albert Fischer
- Khanhnhay
- Robb

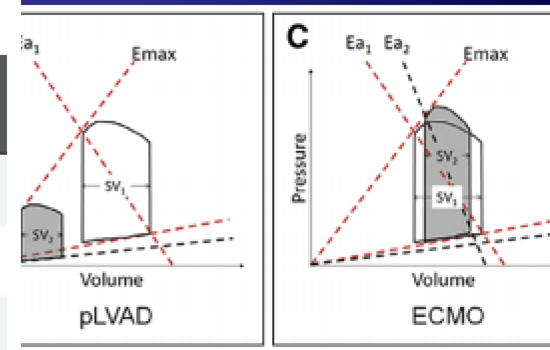
- https://insights.ovid.com/pubmed?pmid=28857849
- Miller PE[1], Solomon MA, McAreavey D. 28857849
- Although introduction of IABP counterpulsation was hailed as a major advance, there was no mortality benefit at 30-day or 12-month follow-up in a major randomized controlled trial of IABP versus medical therapy in 600 subjects eligible for revascularization (IABP in Cardiogenic Shock II [IABP-SHOCK II]) (6, 8). The IABP-SHOCK II trial has been criticized because of a high crossover rate, relatively smaller sample size, timing of IABP insertion, and lower mortality (40%) than reported earlier. Notably, there were positive trends in certain subsets that some hypothesize could benefit from IABP support (9). Nevertheless, the recommendation for IABP use has been downgraded from class I to IIa in the United States (US) and European guidelines. Percutaneous mechanical circulatory
- Currently in development, the i-cor system (Xenios AG, Heilbronn, Germany) is similar to an ECMO circuit and provides up to 8L/min of blood flow. Novel to the i-cor device, continuous flow or diastolic augmentation with electrocardiogram-triggered pulsatile flow can be provided. The HeartMate PHP (Percutaneous Heart Pump, St. Jude, St. Paul, MN) is an axialflow circulatory device, which expands when across the aortic valve and provides up to 5L/min of blood flow. It is currently being compared with the Impella 2.5 in high-risk PCI patients. The Reitan Catheter Pump (CardioBridge GmbH, Hechingen, Germany), placed in the descending thoracic aorta distal to the subclavian artery, creates a pressure gradient similar to the IABP counterpulsation resulting in decreased afterload and increased perfusion distally. Also positioned in the descending aorta, the Aortix device (Procyrion, Houston, TX) has expanding anchors and a transcutaneous charger allowing for sheath removal and potentially provides durable support (36).

- 6. Thiele H, Zeymer U, Neumann FJ, et al; IABP-SHOCK II Trial Investigators: Intraaortic balloon support for myocardial infarction with cardiogenic shock. N Engl J Med 2012; 367:1287–1296
- 7. Unverzagt S, Buerke M, de Waha A, et al: Intra-aortic balloon pump counterpulsation (IABP) for myocardial infarction complicated by cardiogenic shock. Cochrane Database Syst Rev 2015; (3):CD007398
- 8. Thiele H, Zeymer U, Neumann FJ, et al; Intraaortic Balloon Pump in cardiogenic shock II (IABP-SHOCK II) trial investigators: Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): Final 12 month results of a randomised, open-label trial. Lancet 2013; 382:1638–1645
- 9. O'Connor CM, Rogers JG: Evidence for overturning the guidelines in cardiogenic shock. N Engl J Med 2012; 367:1349–1350

TABLE 2. Randomized Controlled Trials of Percutaneous Ventricular Assist Devices Compared With Intra-Aortic Balloon Counterpulsation for Cardiogenic Shock

Study	Date	Condition	Device	Control	Total Sample Size	Primary Outcome	Mortality at 30 d, IABP Vs Percutaneous Ventricular Assist Device
Ouweneel et al (17)	2017	Cardiogenic shock	Impella CP, $n = 24$	IABP, $n = 24$	48	30-d mortality	50% vs 46%[b]
Ouweneel et al (23)	2016	Cardiogenic preshock	Impella 2.5, $n = 12$	IABP, $n = 9$	21	Left ventricular ejection fraction at 4 mo	11% vs 25%[b]
Seyfarth et al (22)	2008	Cardiogenic shock	Impella 2.5, $n = 12$[a]	IABP, $n = 13$	26	Cardiac index	46% vs 46%[b]
Thiele et al (32)	2005	Cardiogenic shock	TandemHeart, $n = 21$	IABP, $n = 20$	41	CP index	45% vs 43%[b]
Burkhoff et al (33)	2006	Cardiogenic shock	TandemHeart $n = 19$	IABP, $n = 14$	33	Hemodynamic improvement	64% vs 53%[b]

CP = Cardiac Power, IABP = intra-aortic balloon pump.
[a]One patient died prior to implant.
[b]Not significant.



ous mechanical circulatory support devices. Cardiac effects o
ume (PV) loops before (*nonshaded loops*) and after activatio
independent contractility, defined as the maximal slope of th
ditions. **A**, Intra-aortic balloon pump (IABP) counterpulsation
nd diastolic pressures and increases LV stroke volume (SV).
e (Ea) (from Ea_1 to Ea_2). (**B**) Percutaneous LV assist devices
y reduce LV pressures, LV volumes, and LV SV. The net effec
enoarterial extracorporeal membrane oxygenation (ECMO) w
nd diastolic pressure, while reducing LV SV. The net effect is

https://www.cathlabdigest.com/article/Role-Percutaneous-Mechanical-Circulatory-Support-Devices-High-Risk-Percutaneous-Coronary

- recent CathPCI registry analysis of 56,497 patients with acute myocardial infarction (AMI) complicated with cardiogenic shock (CS) revealed increased in-hospital mortality from 27.6% in 2005 to 2006, to 30.6% in 2011 to 2013 ($P<0.01$)[2], possibly indicating the increased complexity of patients presenting with AMI and CS. Of the 1,249,547 PCI procedures performed between July 2009 and June 2011 in the United States, 17% were emergent cases.[3] The American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) guidelines support the use of these devices in various settings, including hemodynamic support during high-risk PCI, patients presenting with cardiogenic shock as a bridge to recovery, or during revascularization.[4-6] Despite widespread use and availability of these devices, there is a paucity of randomized, controlled trials data demonstrating unequivocal superiority of these devices in the aforementioned settings.[7-9] A contemporary review by the Interventional Scientific Council of the ACC outlines an elegant algorithm providing various scenarios where use of mechanical circulatory support may be appropriate and helpful in patients undergoing high-risk PCI with CS.[10]

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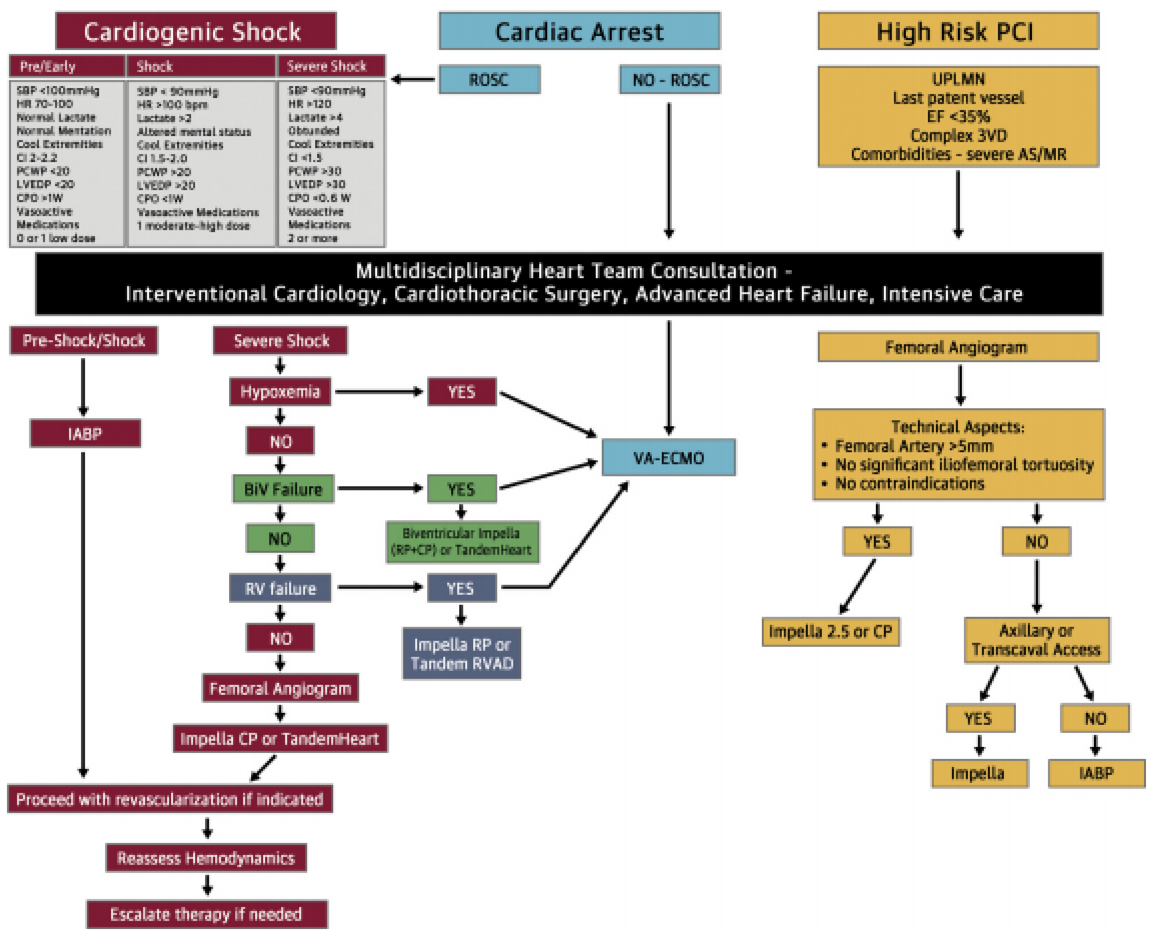
TABLE 4 Contemporary Outcomes for MCS Devices

First Author/Trial (Ref. #)	Indication	HR-PCI/Shock Definition	N	Devices	Outcomes	Complications
Burkhoff et al. (48)	CS	CI <2.2 l/min/m², PCWP >15, end organ hypoperfusion (low UOP, AMS), high dose vasopressor or inotrope, failed IABP	42	IABP versus TandemHeart	No difference in survival or 30-day adverse events. Better hemodynamics with TandemHeart (CI, MAP)	
Kar et al. (49)	Severe CS	SBP <90 mm Hg, CI <2 l/min/m², end organ failure despite IABP/pressors/inotropes	117	TandemHeart (82% had IABP prior to TandemHeart)	30-day survival: 60%	Bleeding around cannula sites 29% Blood transfusions: 59.8%
Thiele et al. (57)	CS in AMI (95% PCI)	SHOCK trial definition, lactate >2, CI <2.1 l/min/m²	41	IABP = 20 TandemHeart = 21	Superior hemodynamic support with TandemHeart: ↑ CPI, ↓ lactate, PCWP Similar 30-day mortality	Increased bleeding and limb ischemia
Alli et al. (50)	Prophylactic HR-PCI	EF <30% with a Jeopardy score >8 in which occlusion of the target	54	TandemHeart	6-month survival: 87%	13% vascular complications
			25	IABP versus Impella	30-day survival: 54% in both Superior hemodynamics with Impella (CI, CPI)	Hemolysis
			5	Impella 2.5	12-month survival: 88%	MACE: 8%
			4	Impella 2.5	30-day survival: 94.5%	MI: 0%, stroke 0.7%, bleeding 6.2%, vascular complication 4%
			0	Impella 2.5		MACE 20%
			2	IABP (226) versus IMPELLA 2.5 (226)	Superior hemodynamics with Impella (CPO) No statistical difference in MAE	MAE: MAE 30 & 90 days: (ITT) Impella: 35.1%, 40.6% IABP: 40.1%, 49.3%
			94 udies	VA-ECMO	50% survival to hospital discharge	Vascular injury, bleeding and stroke
			33: CPR	VA-ECMO 91%	27% survival to hospital discharge	Neurologic complications 33%
			0	VA-ECMO	49% survival to hospital discharge	Bleeding and stroke: 26% and 18% LV distention and pulmonary edema
			phylactic CPS dby CPS	CPS	↑ Procedural morbidity prophylactic 41.3 versus 9.4% standby, no improvement in outcome	7.2% required initiation of standby CPS Standby CPS: provided excellent support and recommended over prophylactic CPS
			58 91	IABP versus CPS	No difference in MACE (MI, stroke, death, CABG) Multivessel angioplasty success rates higher in CPS (40% vs. 20%)	Increased vascular repair with CPS (14 v. 3%) Increased transfusion with CPS (60 versus 27%)
			1: 115 2: 219	In Group 1 ECMO: 100% IABP, 25 profound CS, no ECMO In Group 2: 46 profound CS + ECMO	60.9% 30-day survival in ECMO group versus 28% 30-day survival in non-ECMO group	PCI completed with stent in 70%

CENTRAL ILLUSTRATION Algorithm for Percutaneous MCS Device Selection in Patients with Cardiogenic Shock, Cardiac Arrest, and HR-PCI



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REVIEW

Novel devices

Mechanical circulatory support in cardiogenic shock

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Table 5 **Meta-analysis of RCTs: effects of left ventricular assist devices—TandemHeart[55,56] and Impella PL2.5 pump[63]—in comparison with the effects of IABP on haemodynamics; 30-day-mortality and adverse events in patients with cardiogenic shock, mainly due to myocardial infarction**

	Thiele *et al.*[55]		Burkhoff *et al.*[56]		Seyfarth *et al.*[63]		Pooled (fixed effect model)		Pooled (random effects model)	
	LVAD (*n* = 21)	IABP (*n* = 20)	LVAD (*n* = 19)	IABP (*n* = 14)	LVAD (*n* = 13)	IABP (*n* = 13)	Mean difference/ relative risk	*P*-value	Mean difference/ relative risk	*P*-value
Haemodynamics										
CI ± SD (L min^{-1} m^{-2})	2.3 ± 0.6	1.8 ± 0.4	2.2 ± 0.6	2.1 ± 0.2	2.2 ± 0.6	1.8 ± 0.7	0.35 (0.14; 0.55)	<0.001	0.35 (0.09; 0.61)	<0.01
MAP ± SD (mmHg)	76 ± 10	70 ± 16	91 + 16	72 ± 12	87 ± 18	71 ± 22	12.1 (6.3; 17.9)	<0.001	12.8 (3.6; 22.0)	<0.01
PCWP ± SD (mmHg)	16 ± 5	22 ± 7	16 ± 4	25 ± 3	19 ± 5	20 ± 6	−6.2 (−8.0; −4.3)	<0.001	−5.3 (−9.4; −1.2)	<0.05
Clinical outcome										
30-day mortality, *n* (%)	9 (43)	9 (45)	9 (47)	5 (36)	6 (46)	6 (46)	1.06 (0.68; 1.66)	0.80	1.06 (0.68; 1.66)	0.80
Reported adverse events										
Leg ischaemia, *n* (%)	7 (33)	0 (0)	4 (21)	2 (14)	1 (8)	0 (0)	2.59 (0.75; 8.97)	0.13	2.59 (0.75; 8.97)	0.13
Bleeding, *n* (%)	19 (90)	8 (40)	8 (42)	2 (14)			2.35 (1.40; 3.93)	<0.01	2.35 (1.40: 3.93)	<0.01
Fever of sepsis, *n* (%)	17 (81)	10 (50)	4 (21)	5 (36)			1.38 (0.88; 215)	0.16	1.11 (0.43; 290)	0.83

CI, cardiac index; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MAP, mean arterial pressure; PCWP, pulmonary capillary wedge pressure. From Cheng et al.[60] For details on the statistical analysis please refer to the original

- The major IABP trials, meanwhile, have been disappointing. In the 37-center, randomized IABP-SHOCK II trial of patients with acute myocardial infarction (AMI) complicated by cardiogenic shock, IABPs failed to show a benefit over standard care in terms of all-cause mortality. In the randomized BCIS-1 trial, planned IABP use failed to improve short-term survival or MACCE rates over no planned use of the device in patients with multivessel coronary disease and severe left ventricular dysfunction (LVEF ≤ 30%) undergoing PCI, although longer-term survival was inexplicably improved.

Outline

- Why and in Whom do we use Mechanical support? Back to Basics
- National Trends in Use of Mechanical Cardiac Support (MCS)
- IABP: iabp shock (2010), bcis-1 (2012), CRISP-AMI (2015), iabp shock 2 (2015). decreasing trends (2015, NCDR)
- Impella: ISAR SHOCK (2008), Protect II (2012), Uspella HRPCI (2012), Uspella shock (2014), Oneill mild/mod LVEF(2018), German Impella Study (2018), AMICS (2018)
- Tandem Heart/ECMO (briefly)
- Summary