29th TCTAP2024

Impella, our new friend

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Disclosure

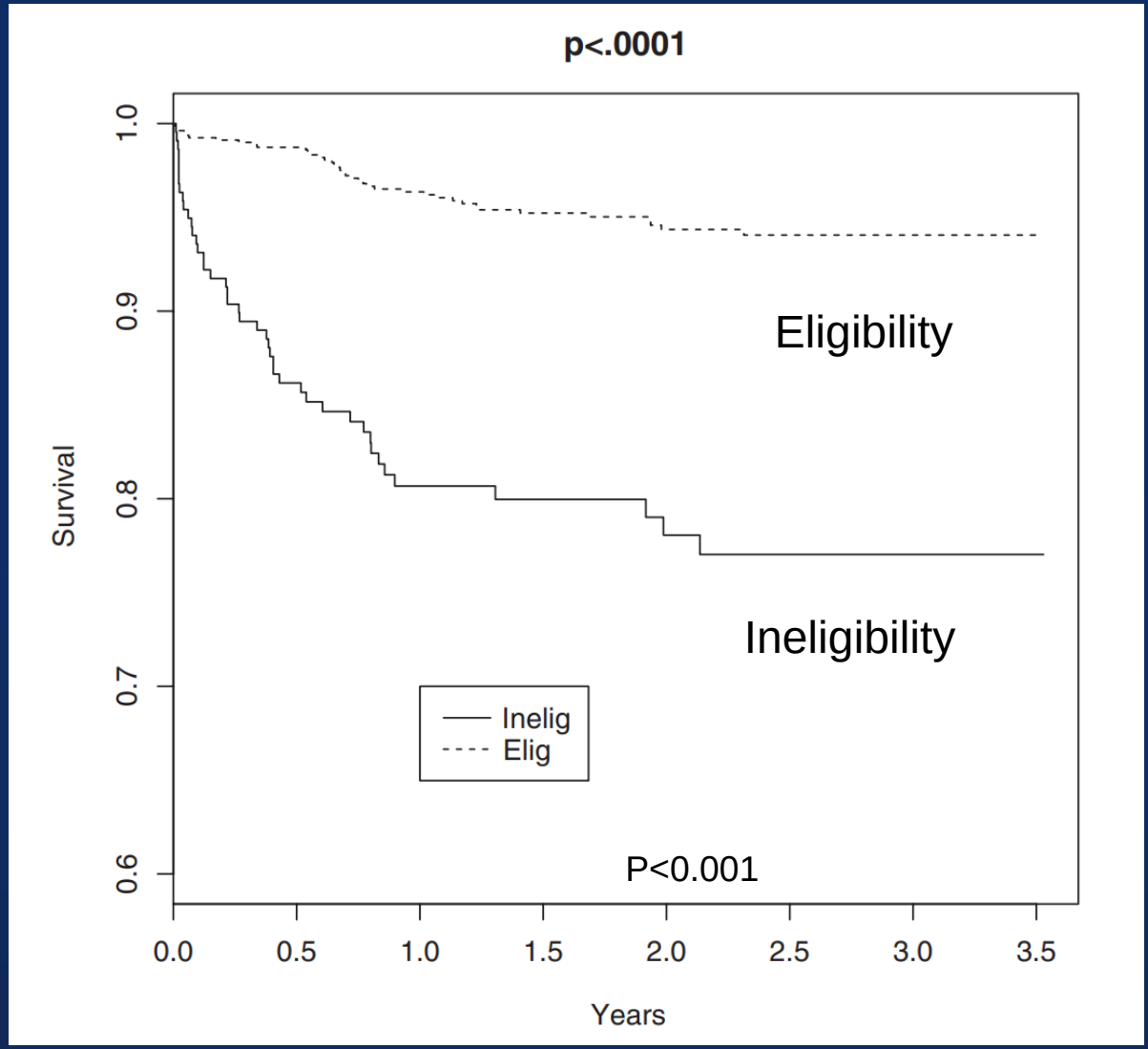
- I have nothing to disclose

Introduction

- CABG provides better outcomes than PCI in patients with intermediate-to-high SYNTAX score
- However, there are patients of surgical ineligibility and those who decline CABG are potential candidates for PCI
- If treated by PCI, these patients are at high risk of major adverse cardiac and cerebrovascular events during or after PCI, classifying as high-risk PCI (HRPCI)
- PCI systematically induces a transient myocardial ischemia, in patients undergoing HRPCI, a prophylactic mechanical circulatory support (MCS) device can provide a more stable hemodynamic profile

Reasons for Surgical Ineligibility

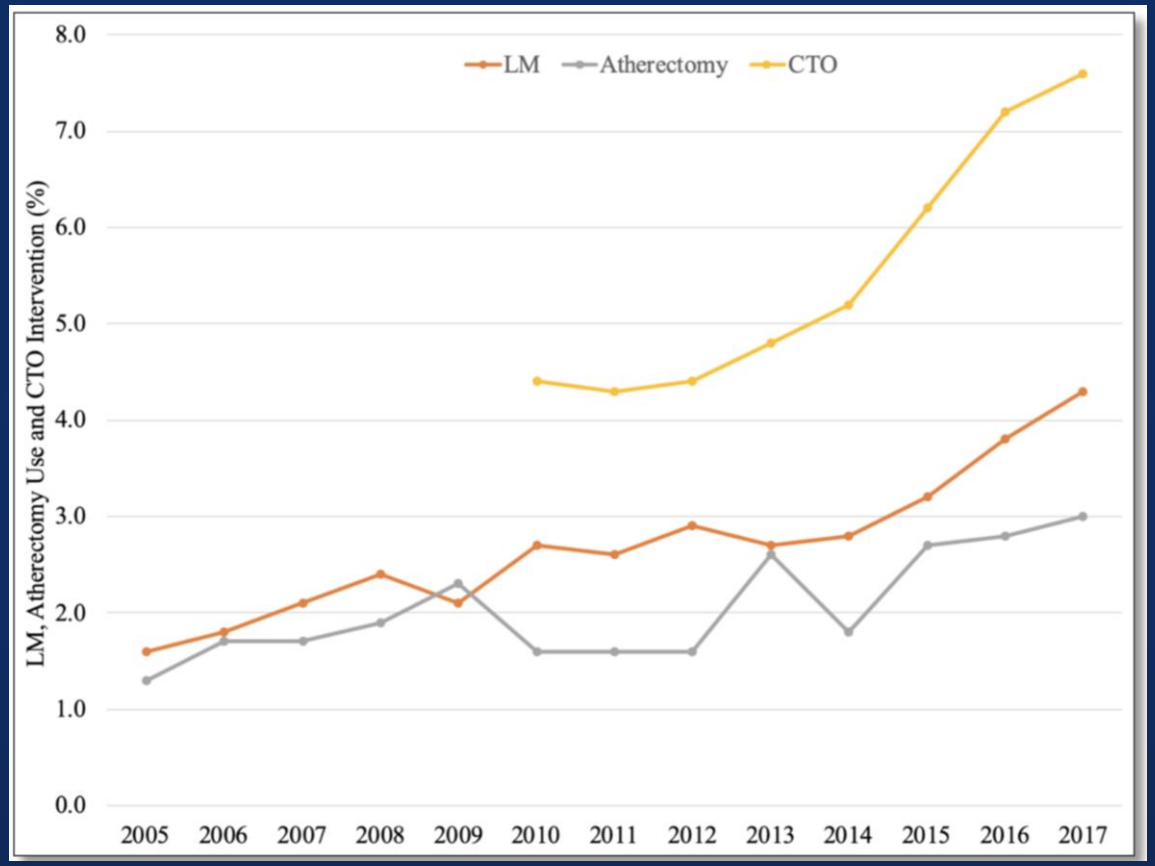
Criterial associated with surgically ineligibility	Prevalence, n(%)
Poor targets/conduits	52(24)
Advanced age	35(16)
Renal insufficiency	35(16)
Severe lung disease	32(15)
Severe systolic dysfunction	31(14)
Malignancy	24(11)
Severe peripheral arterial disease	17(8)
Extensive nonviable myocardium	14(6)
Severe aortic calcification	13(6)
Cachexia	9(4)
Hematologic abnormality	9(4)
End-stage liver disease	8(4)
Morbid obesity	7(3)
Severe cerebrovascular disease	7(3)
Cognitive dysfunction	6(3)
Gastrointestinal bleeding	6(3)
Systemic infection	5(2)
Chest wall abnormality	2(1)
Immunosupressed	2(1)
Pulmonary hypertension	1(1)



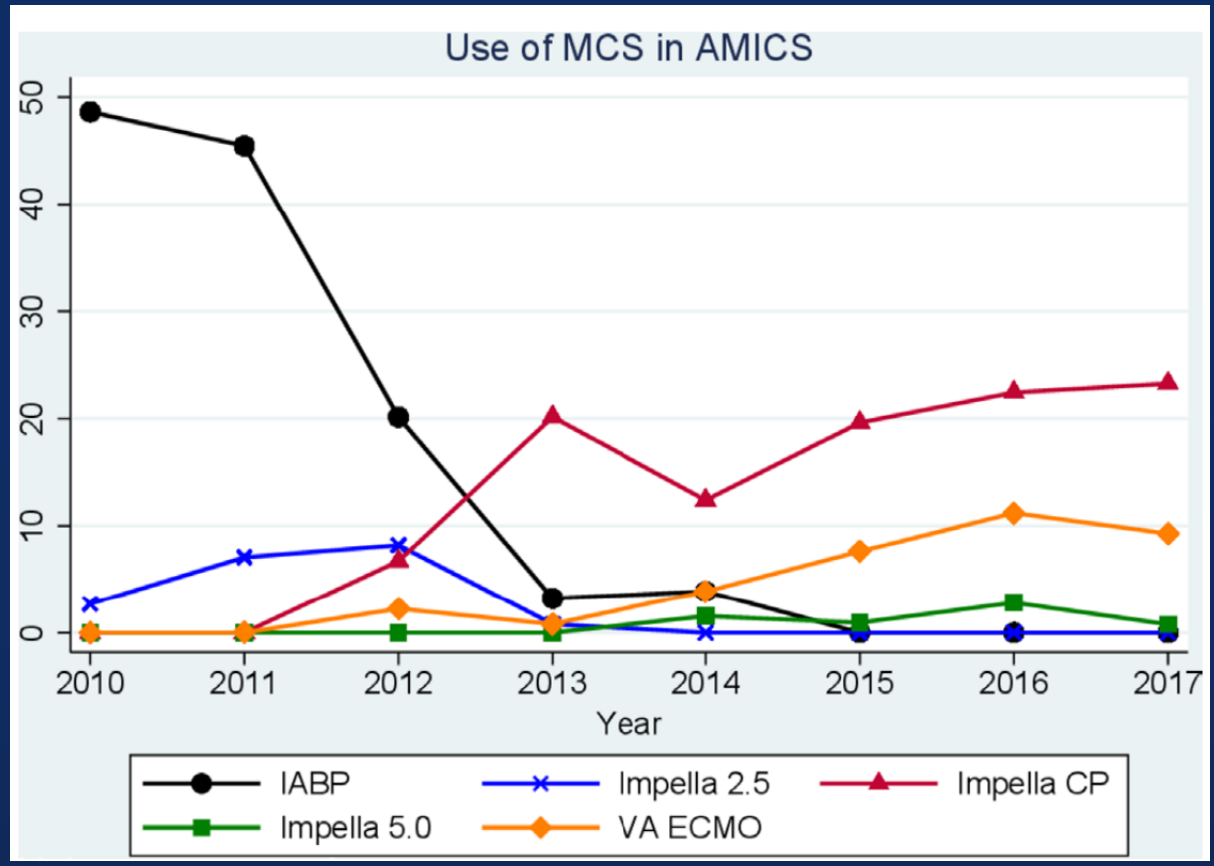
Surgical ineligibility was associated with a significant increase in mortality c/w surgically eligible patients undergoing PCI

Circulation. 2014;130:2295-2301

Increasing CAD complexity and HRPCI



The trends in the use of MCS in AMICS from 2010 to 2017

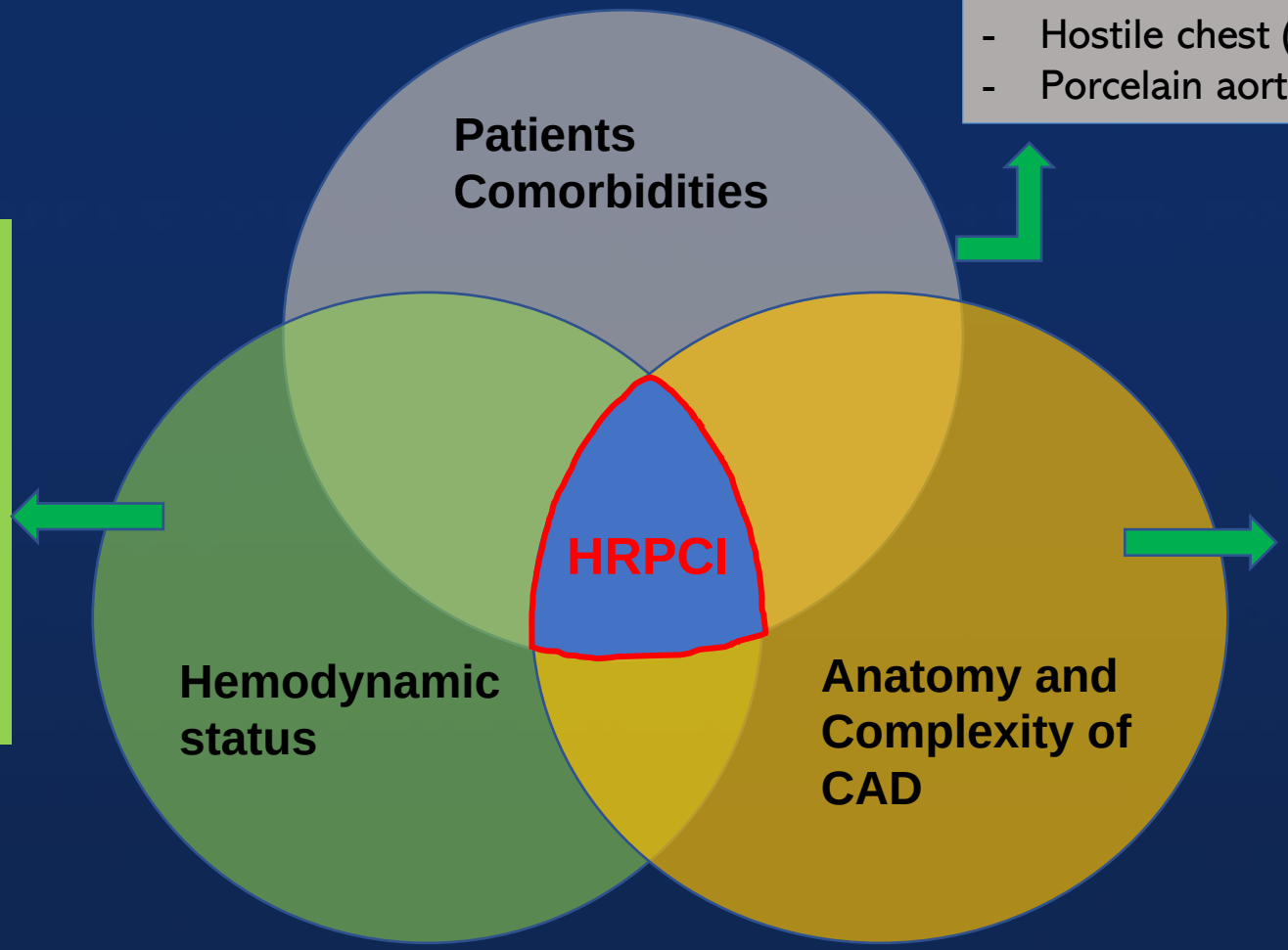


High risk PCI such as atherectomy use and LM intervention increased from 2005 to 2017. PCI for CTOs also increased from 2010 to 2017

European Heart Journal Open (2024) 4, 1–9

There is no universal consensus definition for HRPCI
Three categories are widely accepted:

Increased risk for CABG compared with PCI:
- Advanced age
- COPD
- Severe liver disease
- Prior stroke, carotid artery disease
- Frailty
- Prior CABG
- Hostile chest (deformities, prior R/T)
- Porcelain aorta



Increased the risk for CABG and PCI
- LVEF ≦35%
- LVEDP/PCWP ≧ 15 mmHg
- Cardiac index ≦ 2.2 L/min/m^2
- Significant VHD
- Pul. HTN
- RVF

Challenging PCI
- Unprotected LMD
- Complex bifurcations
- CTO
- Heavily calcified lesion
- SVGs
- Thrombus containing lesion
- High syntax score

Compex High-Risk PCI

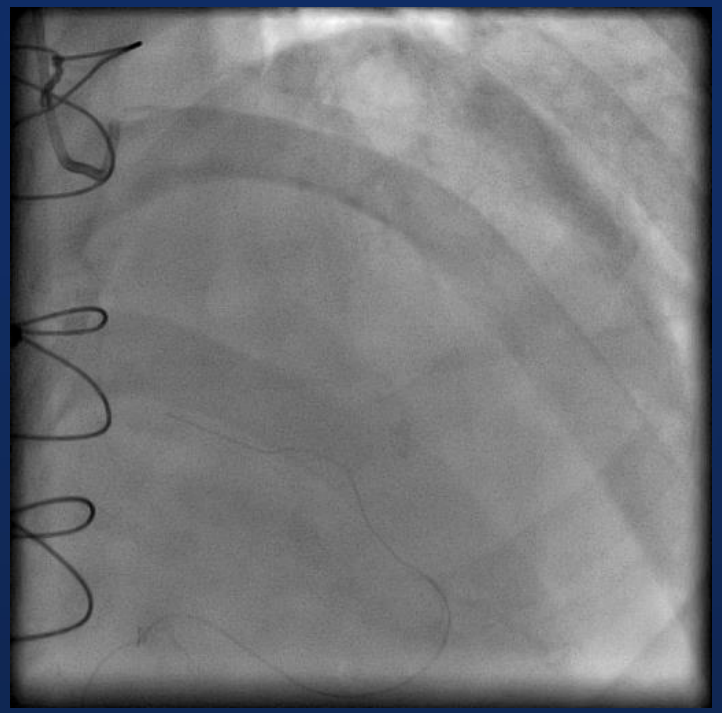
Complex PCI ≠ High Risk PCI

Complex PCI but not at high risk

A 70/M with calcified ostial LAD disease

High Risk PCI but not complex

A 60/F, all bypass grafts occluded; RCA: CTO, LVEF 35%



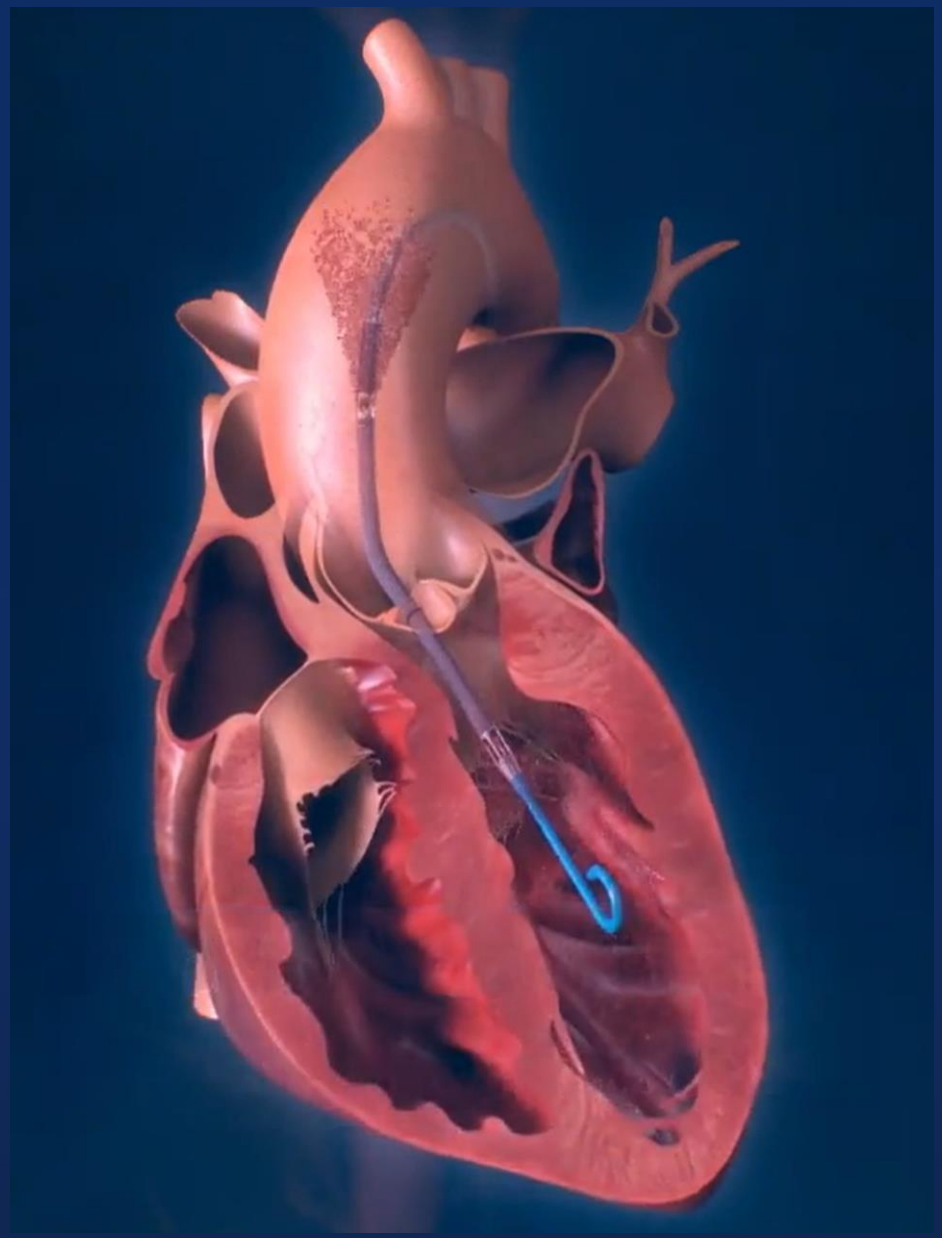
BP 66/40
Chest pain with cold sweating

MCS is needed

Mechanical circulatory support Devices

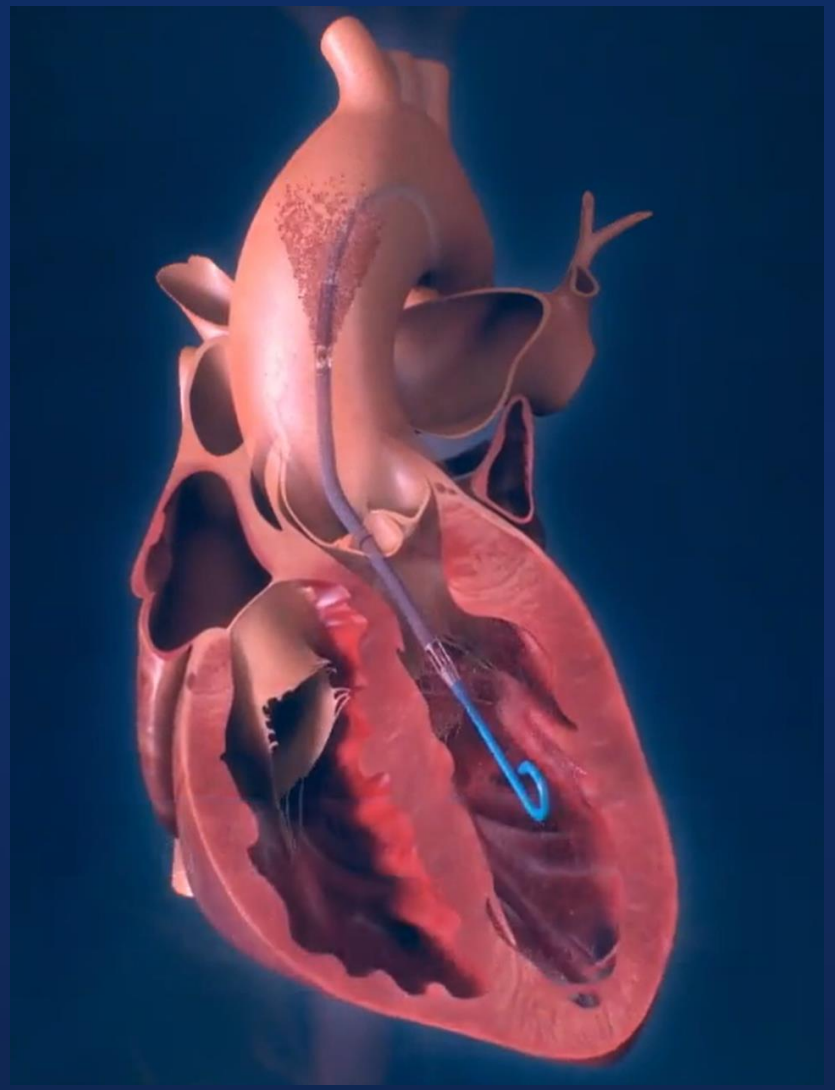
Characteristics	IABP	Impella CP	iVAC 2 l	HeartMate PHP	TandemHeart	VA ECMO
Inflow→outflow	Aorta	LV→aorta	LV→aorta	LV→aorta	LA→aorta	RA→aorta
Mechanism	Pneumatic	Axial flow	Pulsatile flow	Axial flow	Centrifugal flow	Centrifugal flow
Maximum cardiac flow	0.5 l/min	4.3 l/min	2.8 l/min	5.0 l/min	4.0 l/min	7.0 l/min
Sheath size	7–8 Fr	14 Fr	17 Fr	14 Fr	Arterial: 12–19 Fr Venous: 21 Fr	Arterial: 16–19 Fr Venous: 17–21 Fr
LV unloading	+	+++	+	+++	+++	–
Afterload	↓	↓	↓	↓	↑	↑↑↑
MAP	↑	↑↑	↑↑	↑↑	↑↑	↑↑
LVEDP	↓	↓↓	↓↓	↓↓	↓↓	↔
Coronary perfusion	↑	↑	↑	↑	↔	↔
Myocardial oxygen demand	↓	↓↓	↓↓	↓↓	↔	↔
Complications	• Limb ischaemia • Bleeding	• Limb ischaemia • Bleeding • Haemolysis	• Limb ischaemia • Bleeding • Haemolysis	• Limb ischaemia • Bleeding	• Limb ischaemia • Bleeding • Haemolysis	• Limb ischaemia • Bleeding • Haemolysis
Contraindications	• Moderate to severe AR • Severe PAD	• Severe AS/AR • Mechanical AV • LV thrombus • Severe PAD	• Severe AS/AR • Mechanical AV • LV thrombus • Severe PAD	• Severe AS/AR • Mechanical AV • LV thrombus • Severe PAD	• Moderate to severe AR • LA thrombus • Severe PAD	• Moderate tosevere AR • Severe PAD

Characteristics of mechanical circulatory support devices most commonly used during high-risk percutaneous coronary intervention. AS=aortic stenosis; AR=aortic regurgitation; AV=aortic valve; IABP=intra-aortic balloon pump; LA=left atrium; LV=left ventricle; LVEDP=LV end-diastolic pressure; MAP=mean arterial pressure; PHP=percutaneous heart pump; RA=right atrium; VA ECMO=venoarterial extracorporeal membrane oxygenation. Glossary: AR=aortic regurgitation; AV=aortic valve; LA=left atrium; MAP=mean arterial pressure; PHP=percutaneous heart pump; RA=right atrium.



Is Impella our friend?

Impella (microaxial flow pump)

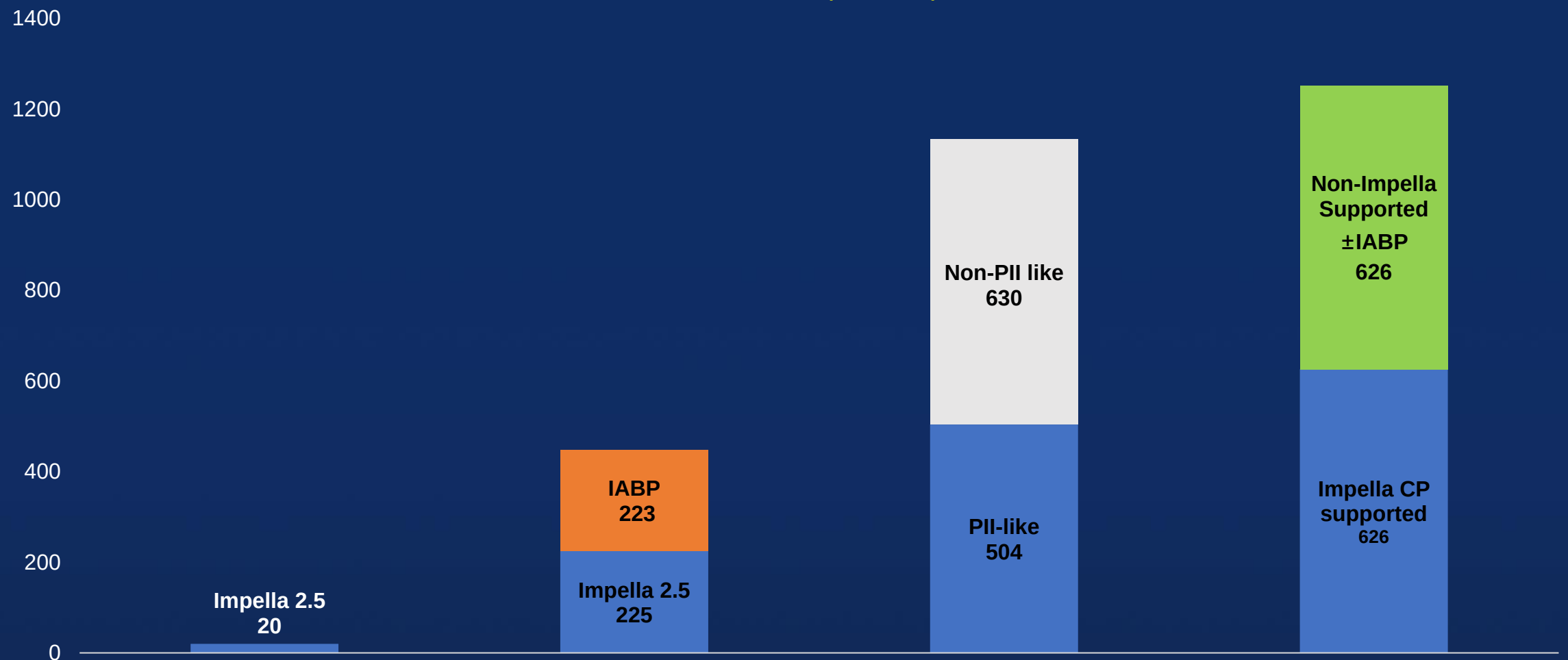


- Unload LV
- ↑ Flow
- ↑ MAP
- ↓ LVEDP and LV wall stress
- ↓ O2 demand

- However, Impella has disadvantages:
  - the lack of active oxygenation
  - the need for adequate RV output to provide adequate LV filling
  - less efficient in prolonged cardiac arrest situations, including arrhythmic storms

PROTECT Study Series

Patient enrolled (n=2854)



LVEF≦ 35%
+ ULM or last
Patent conduit

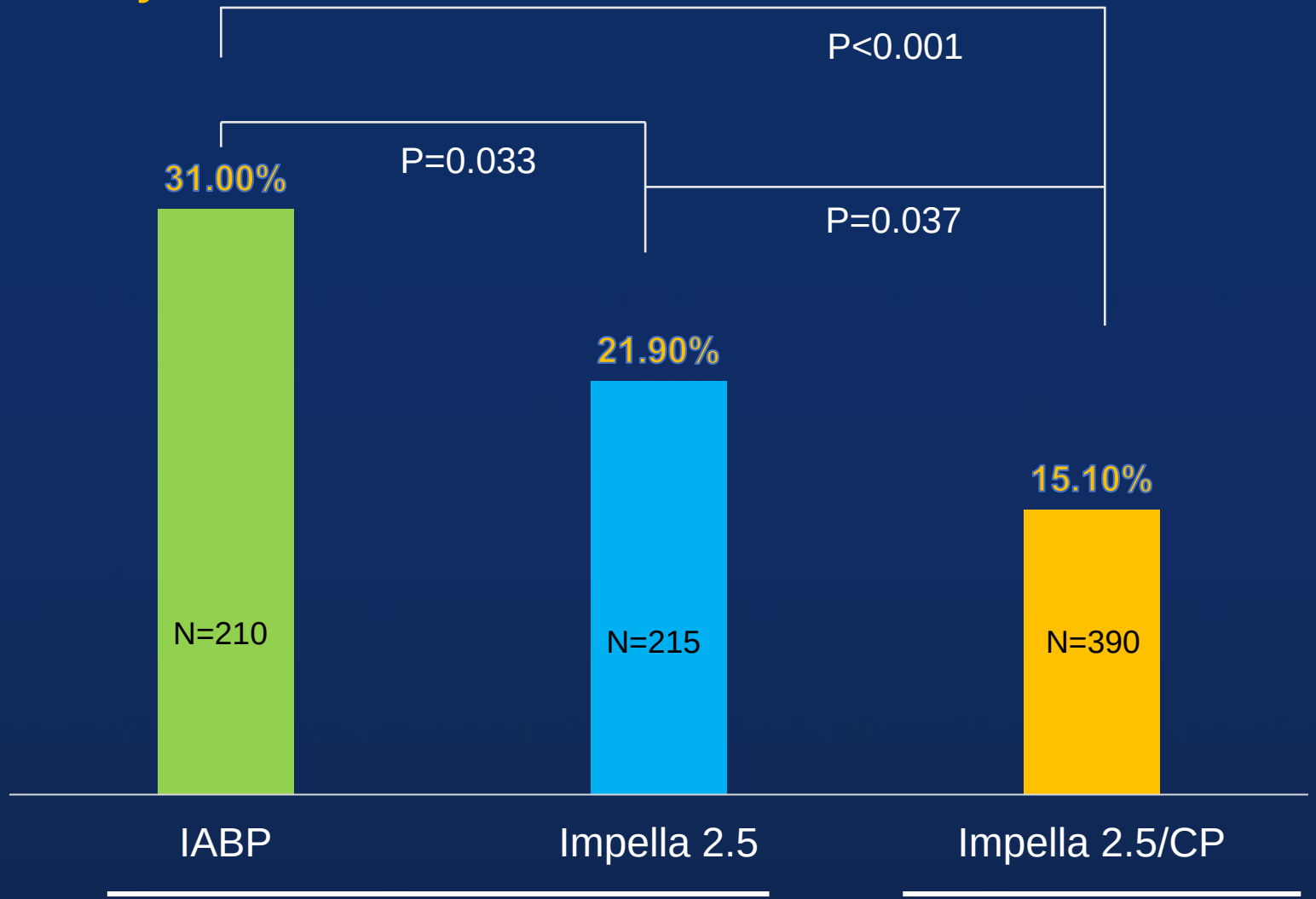
LVEF≦ 35%
+ ULM or last
patent conduit
or LVEF≦ 30%
+ 3VD

PROTECT II-LIKE
Impella 2.5: 32%
Impella CP: 68%

Ongoing RCT

PROTECT III outcome compared to PROTECT II

Composite MACCE at 90 days



N= number of patients with 90-day follow up

Impella-supported HRPCI improved LVEF and survival

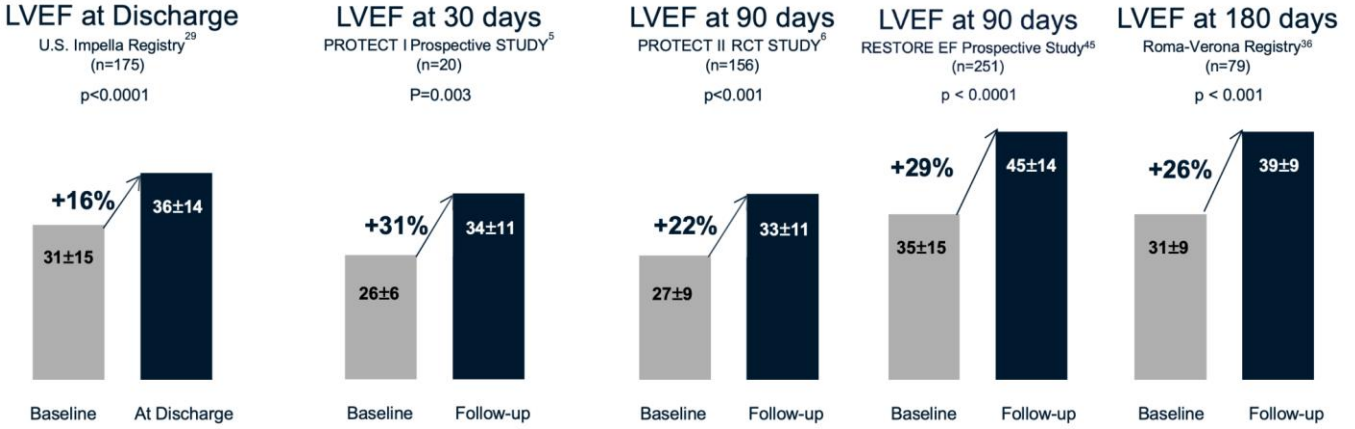


Figure 8: LVEF Improvement Demonstrated in High-risk Patients. Several PCI studies utilizing the Impella heart pump have demonstrated improvement in LVEF.[5,6,29,36,45]

LVEF improvement demonstrated after Protected PCI

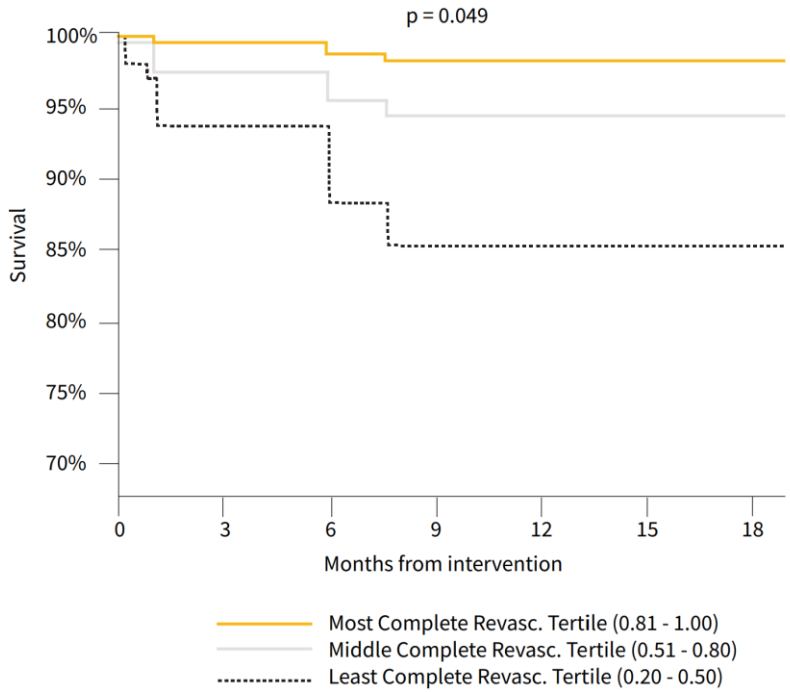
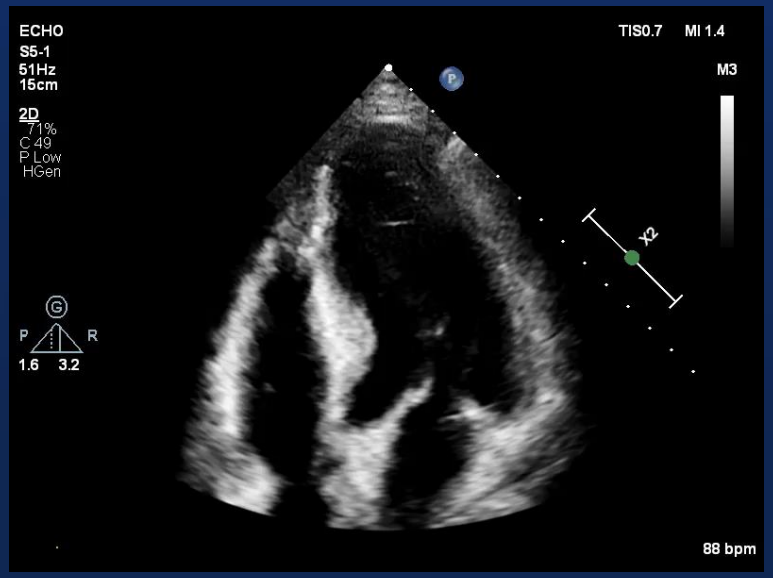
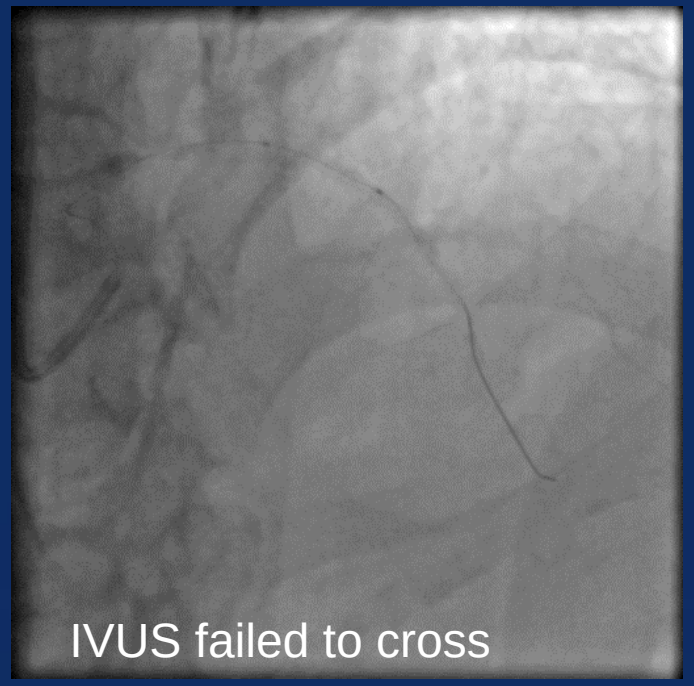


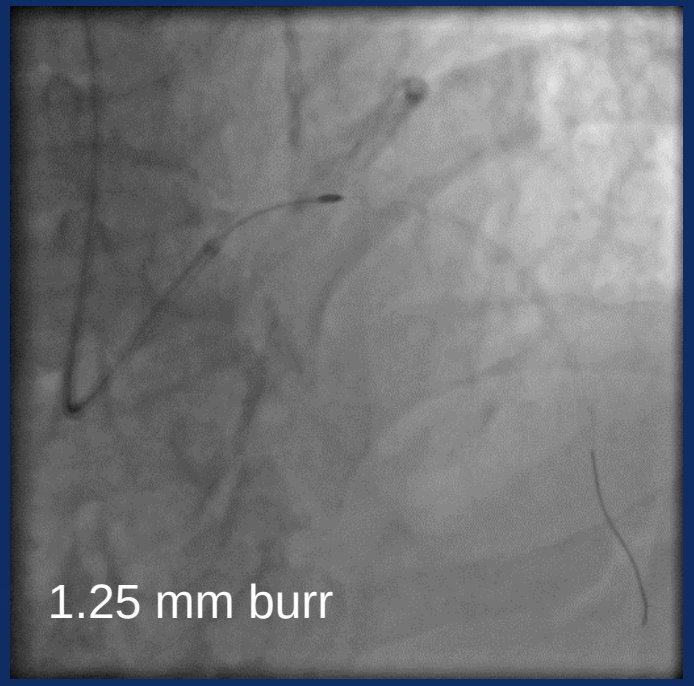
Figure 13: Adjusted survival curves according to BCIS-JS tertile extent of revascularization

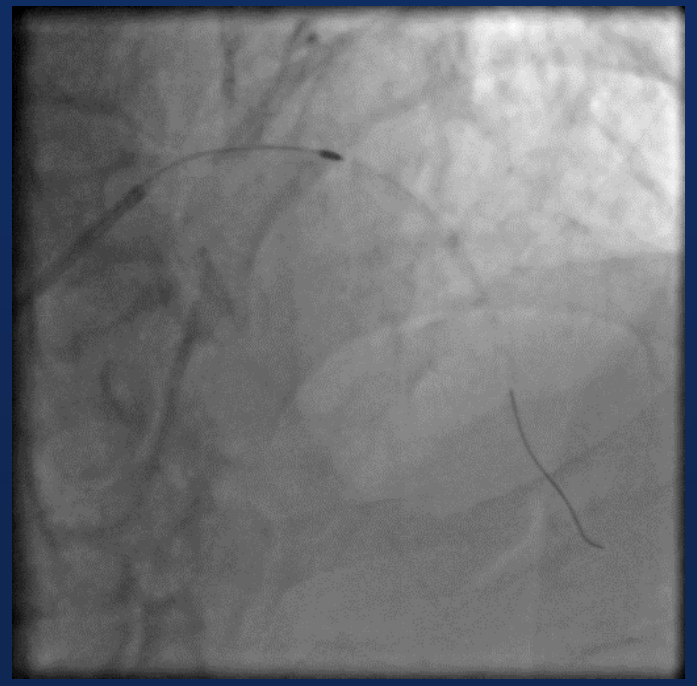
Roma-Verona Impella Protected PCI Registry showed complete revascularization was associated with significant improvement in LVEF and long-term survival

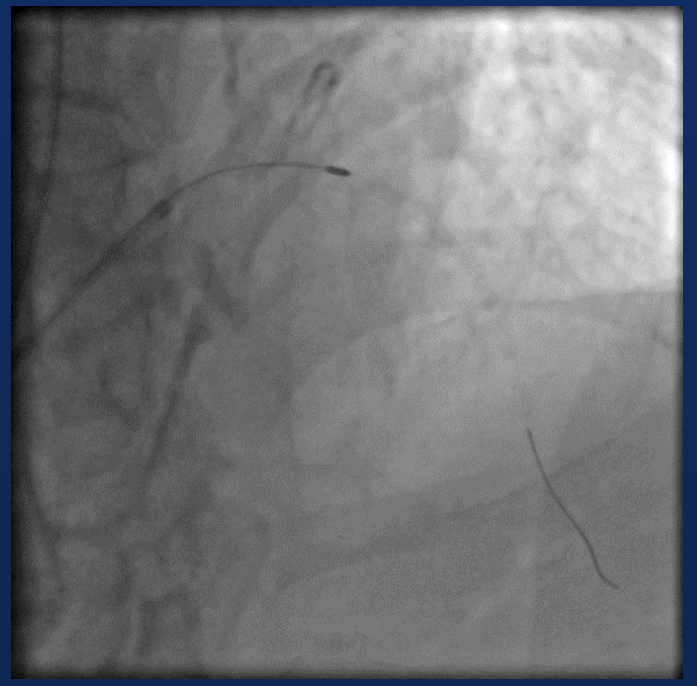
A 80/M, diffuse LAD lesion with calcification. Cr: 4.0, Preserved LVEF

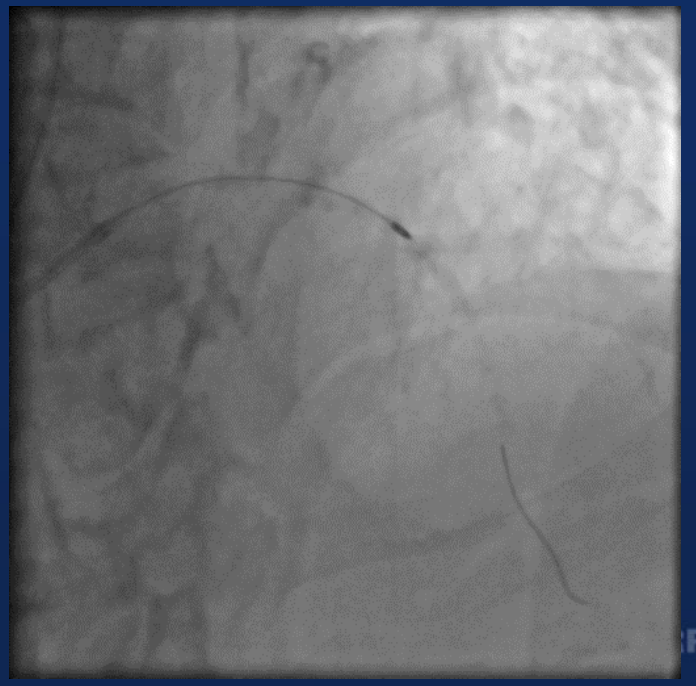



IVUS failed to cross


1.25 mm burr

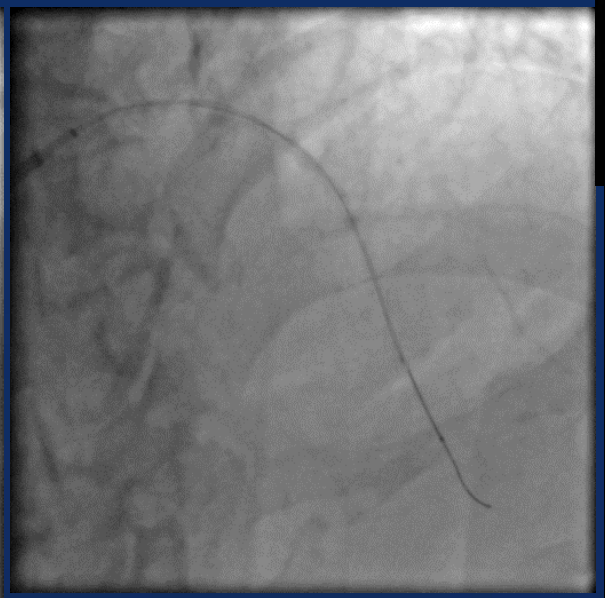


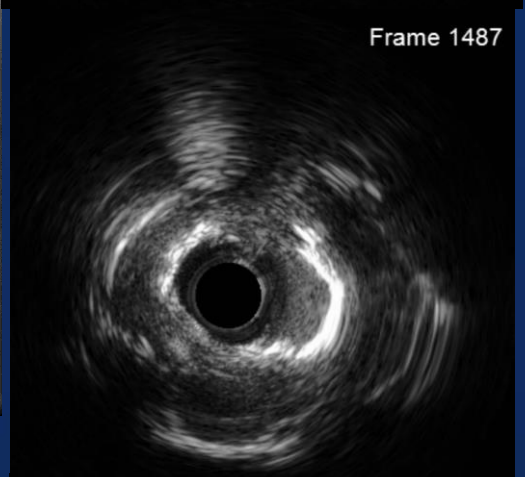


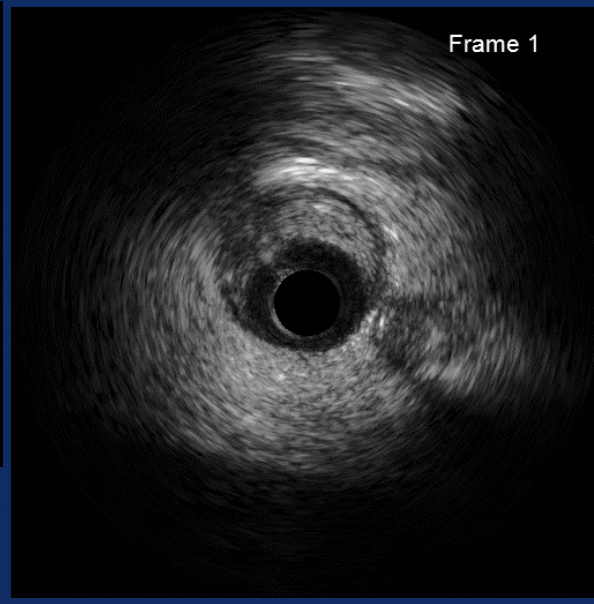


Angio. after Rota

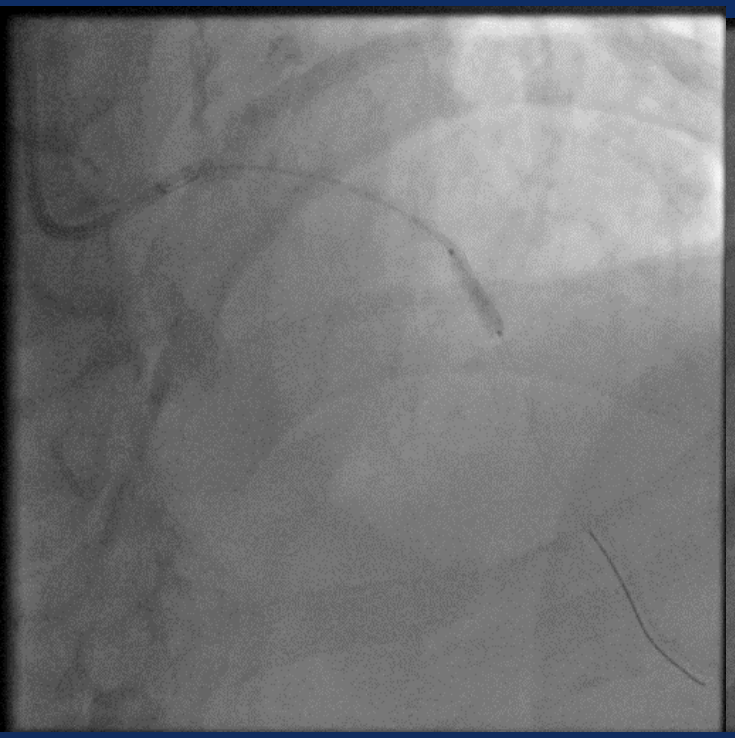
IVUS







IVL 3.0 x 12

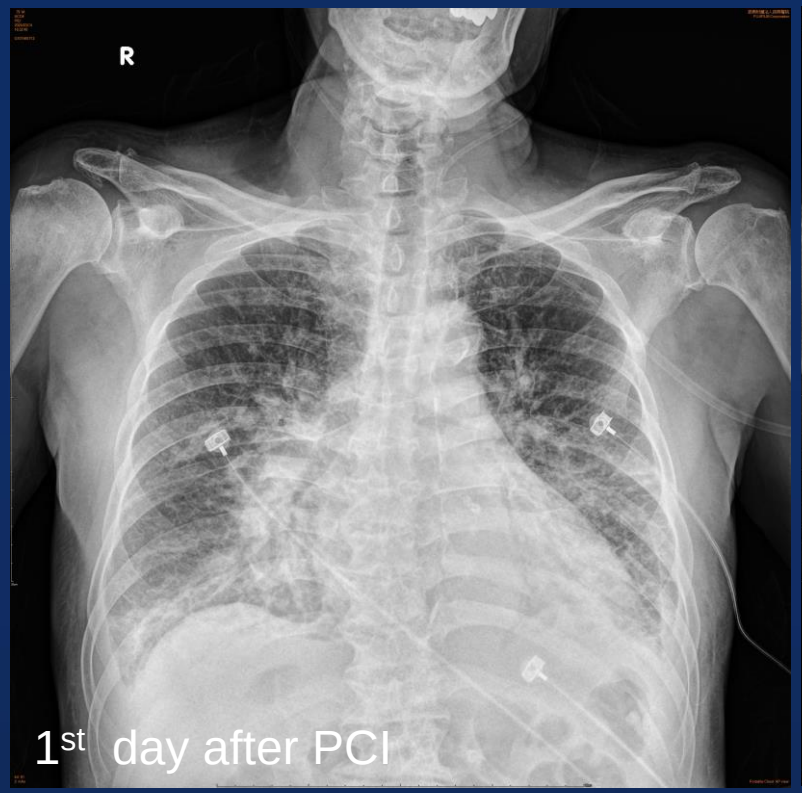


IVL 3.0 x 12

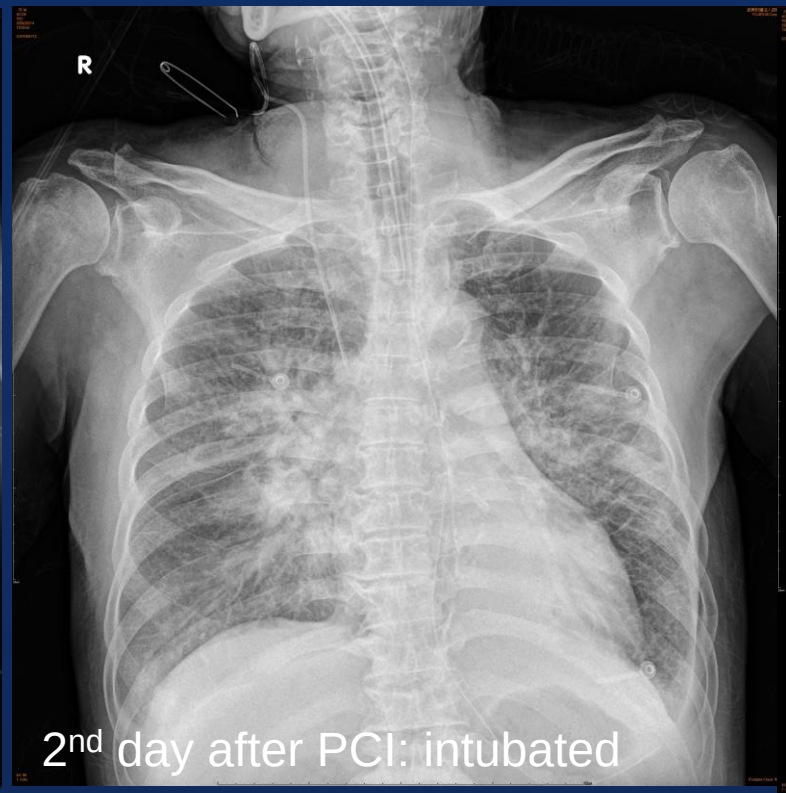
Post-IVL angio.

Angio. after 2 DES

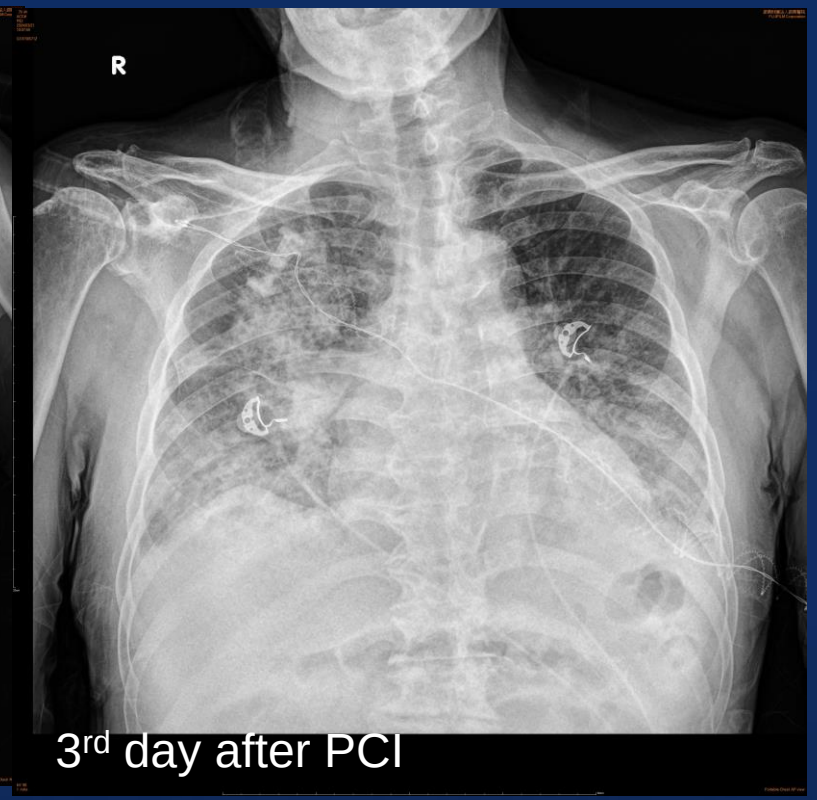
Successful procedure, but……



1st day after PCI

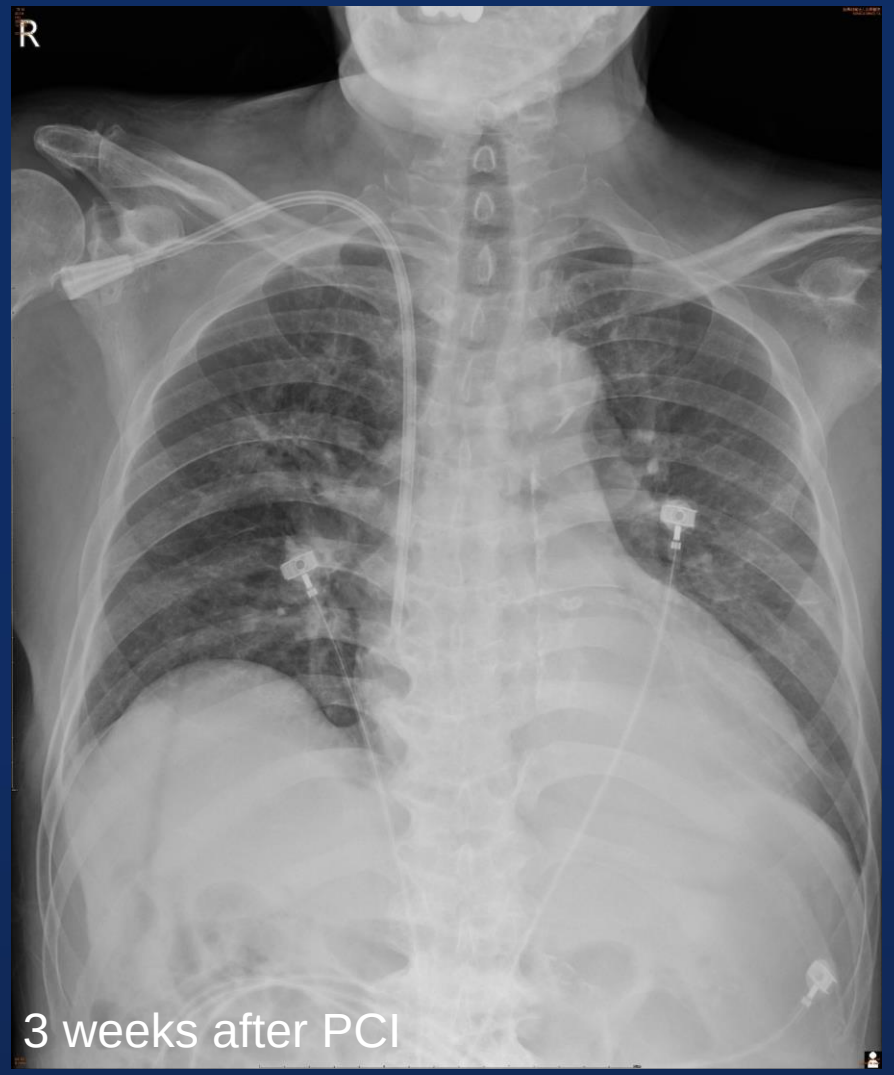


2nd day after PCI: intubated

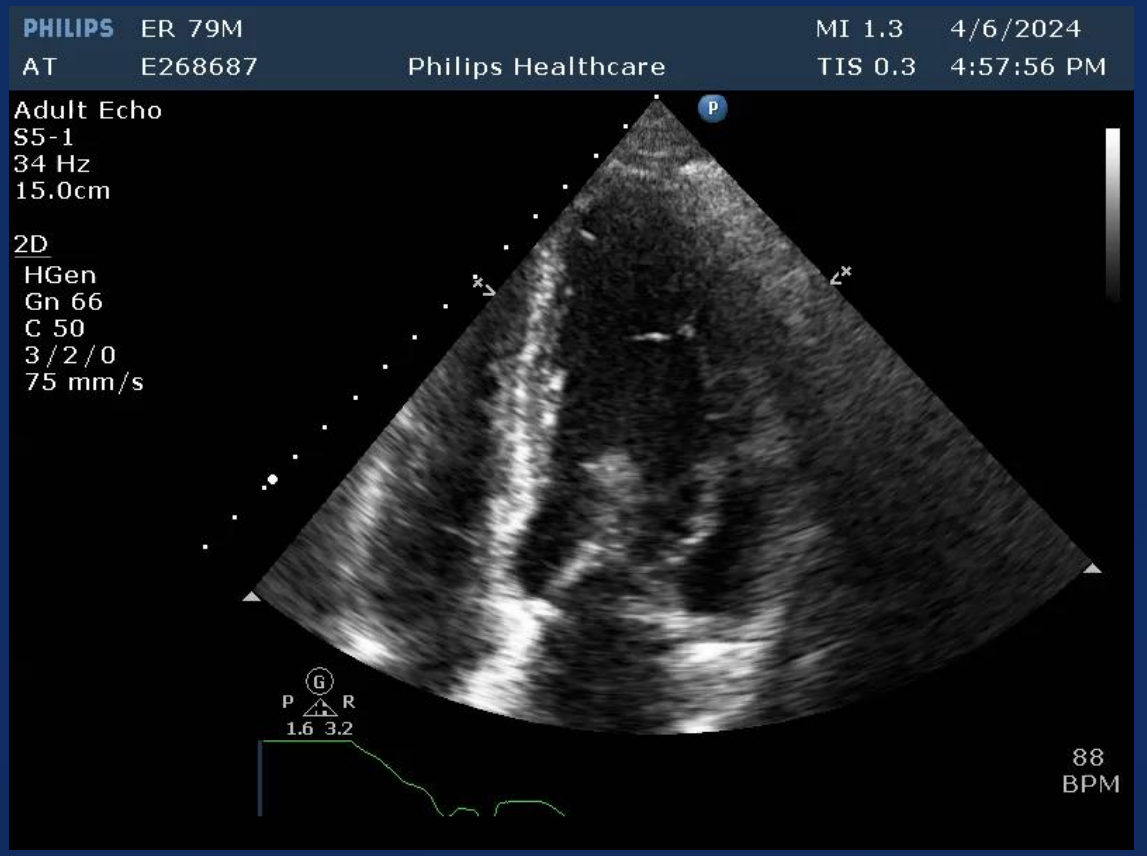


3rd day after PCI

Serial complications: Peri-procedural MI (Troponin I: 125,000 ng/dl) heart failure, acute pulmonary edema, pneumonia and renal failure, prolonged length of stay in hospital (21 days), renal failure on hemodialysis

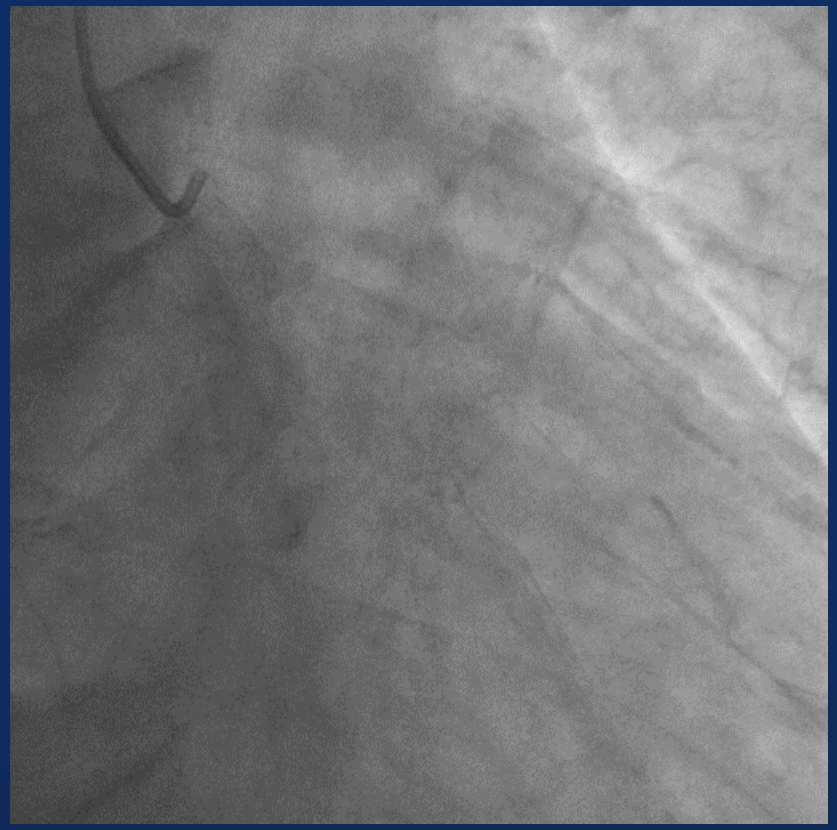
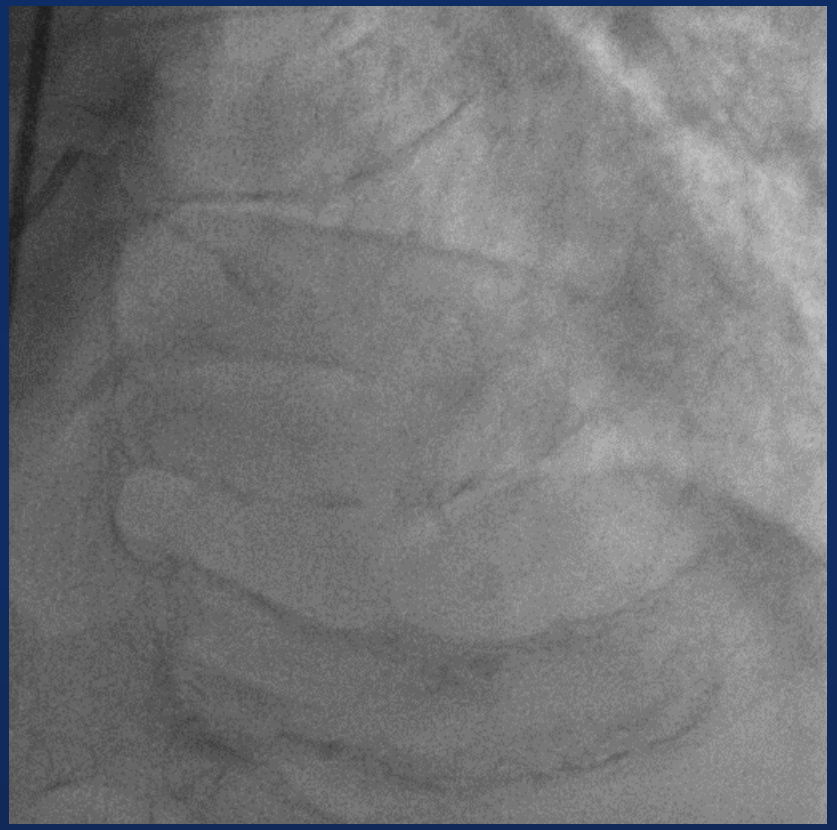
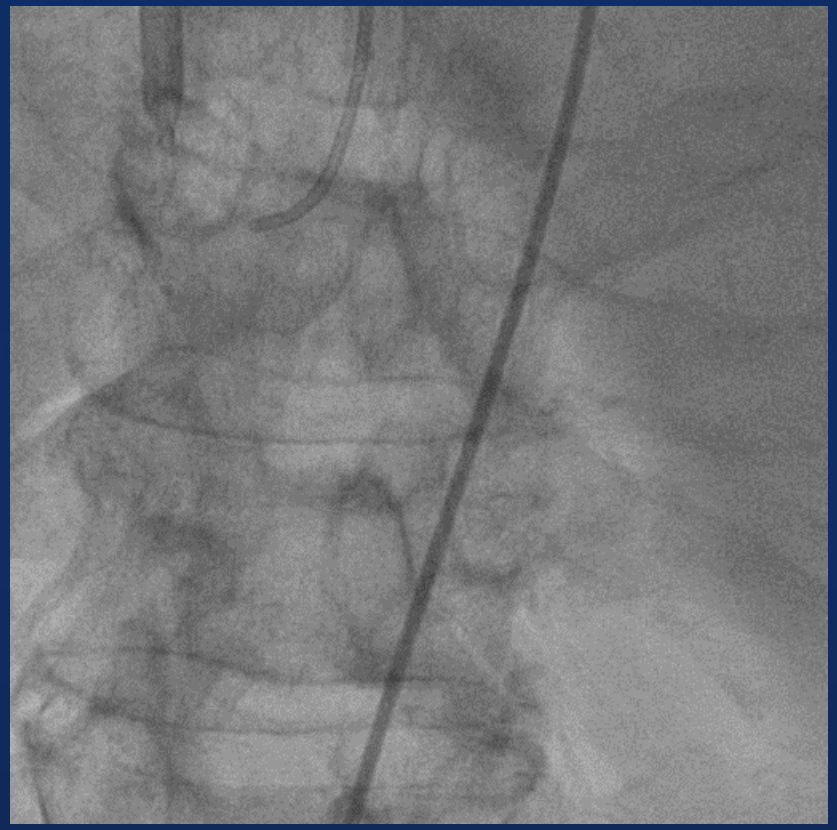


On Hemodialysis

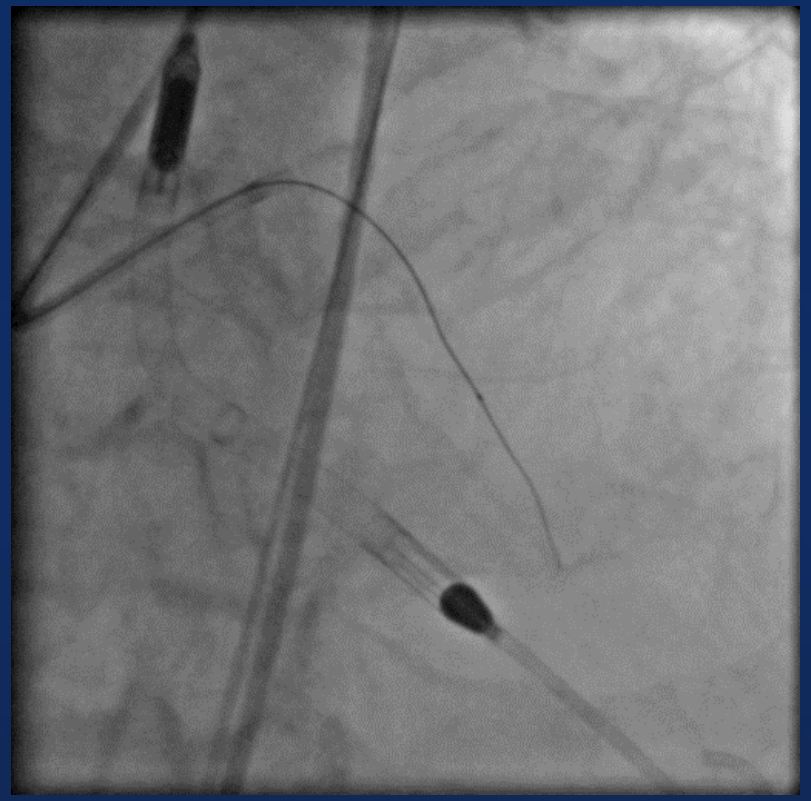


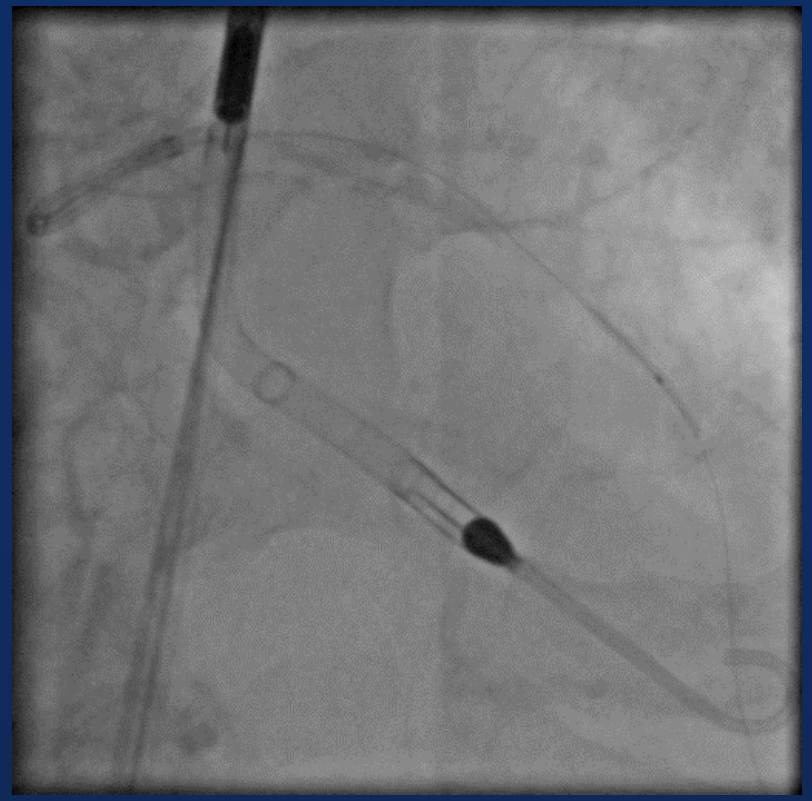
Followed up echo

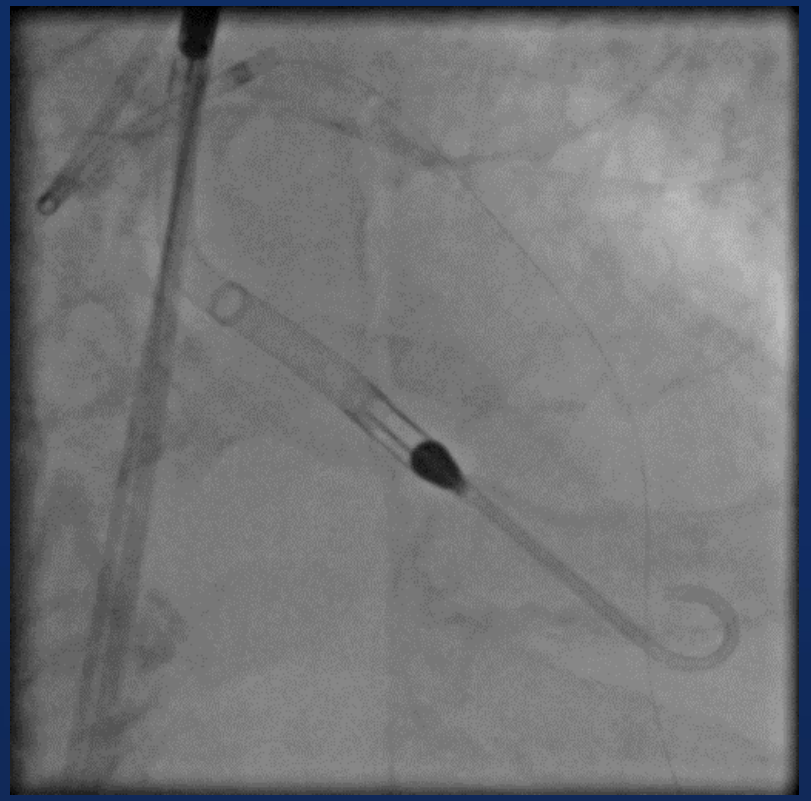
54/M, DM and ESRD, LVEF 25%, Declined CABG

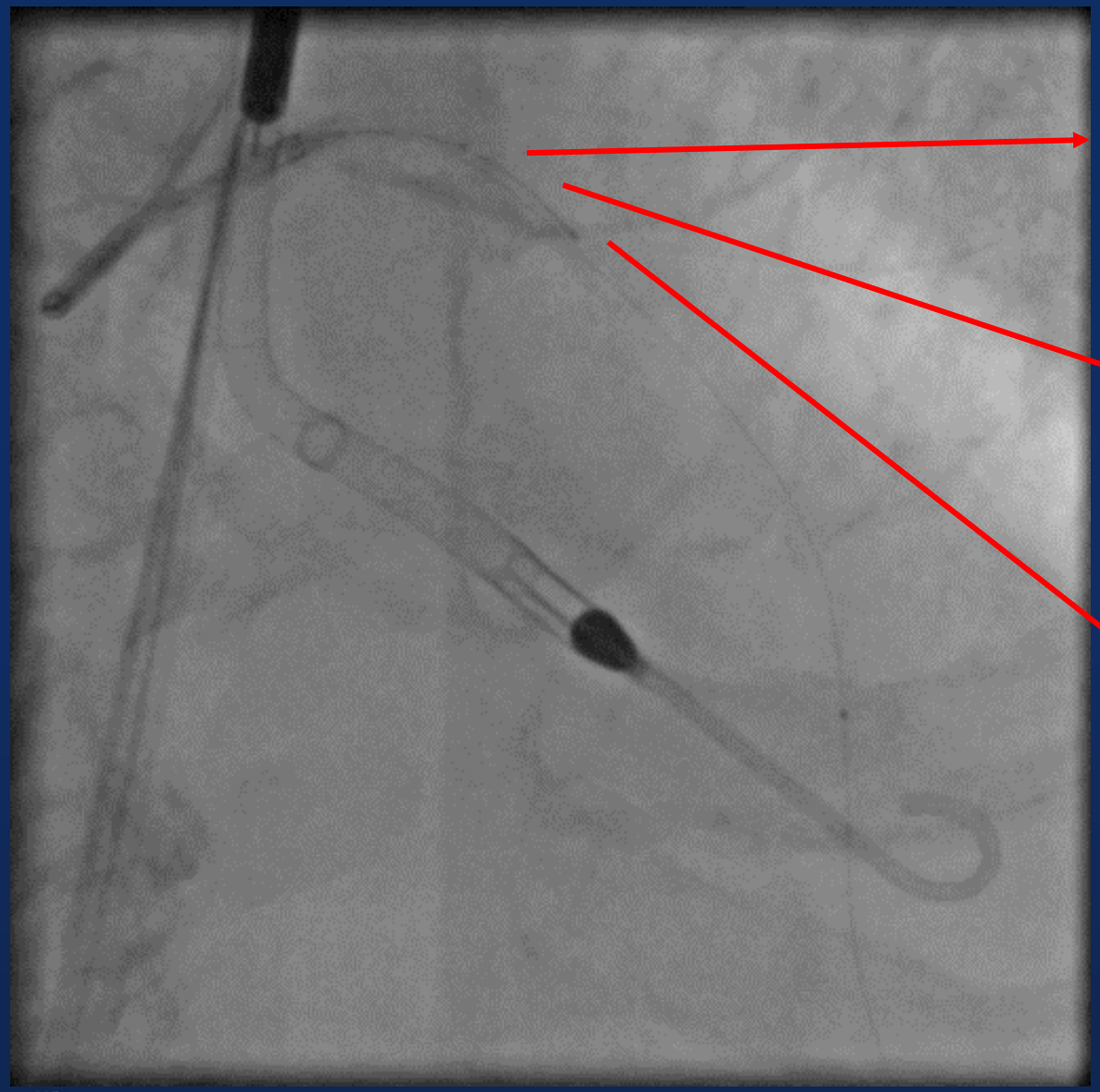
Impella CP with SmartAssist for high-risk PCI

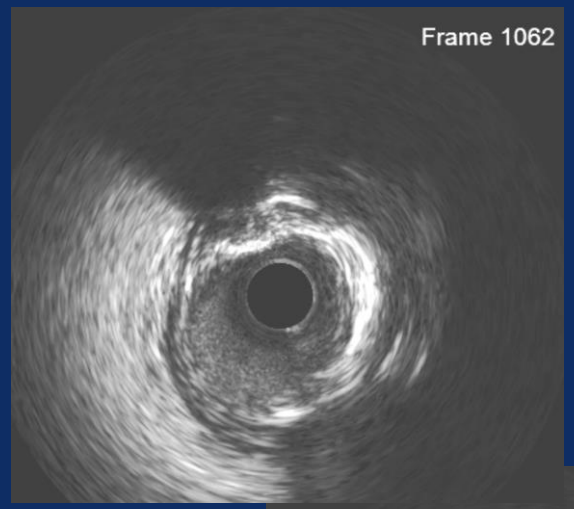


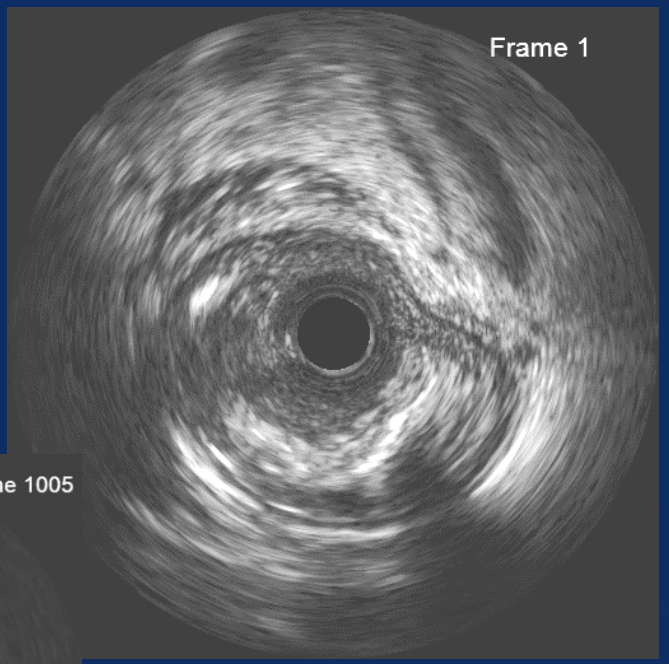


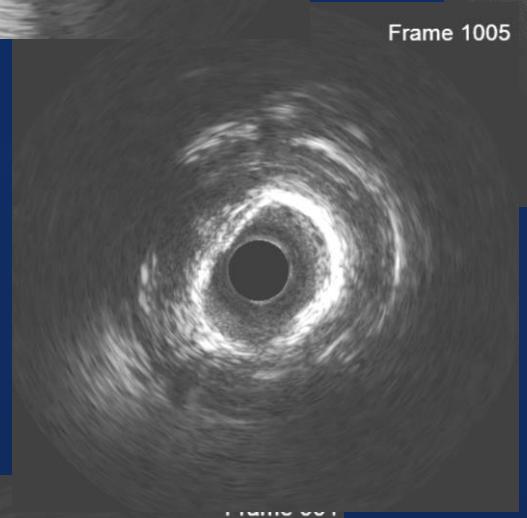


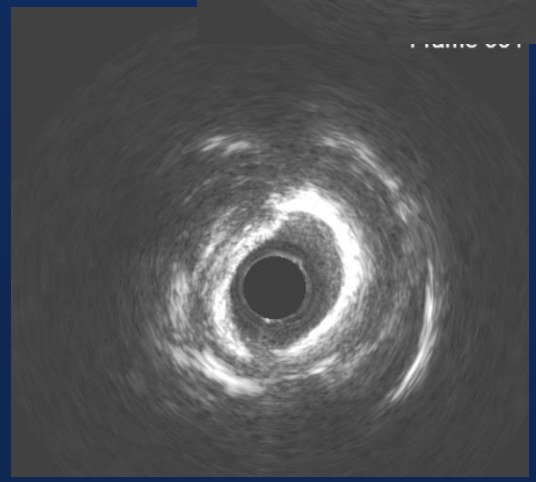
IVUS



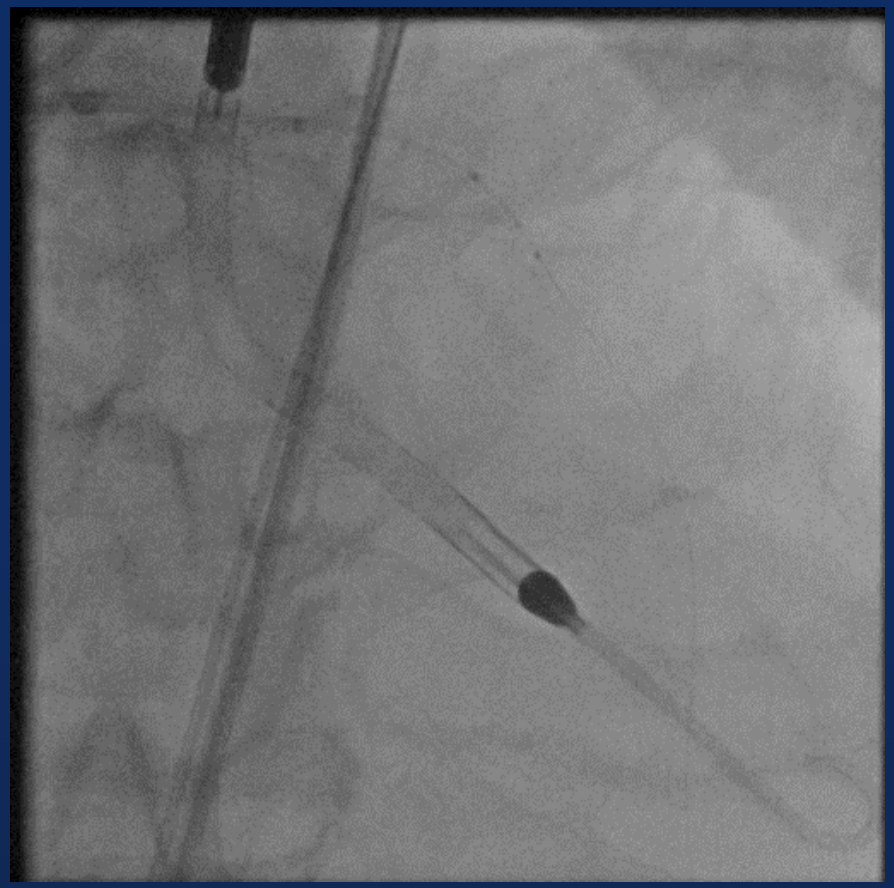




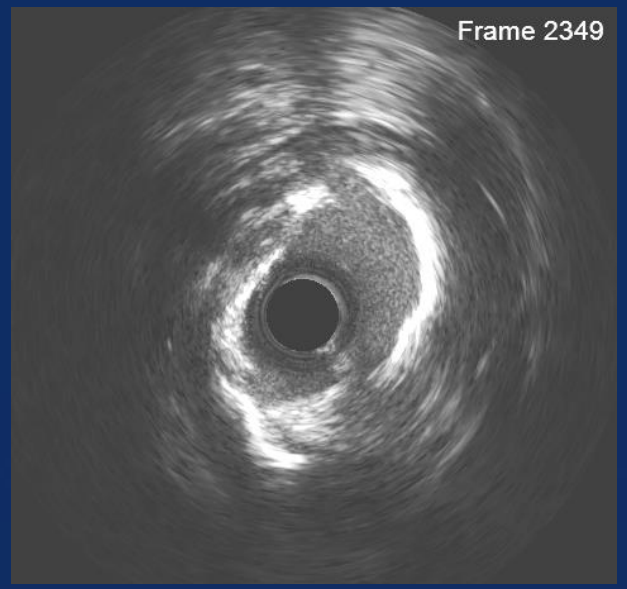




IVL 3.0 x 12 mm



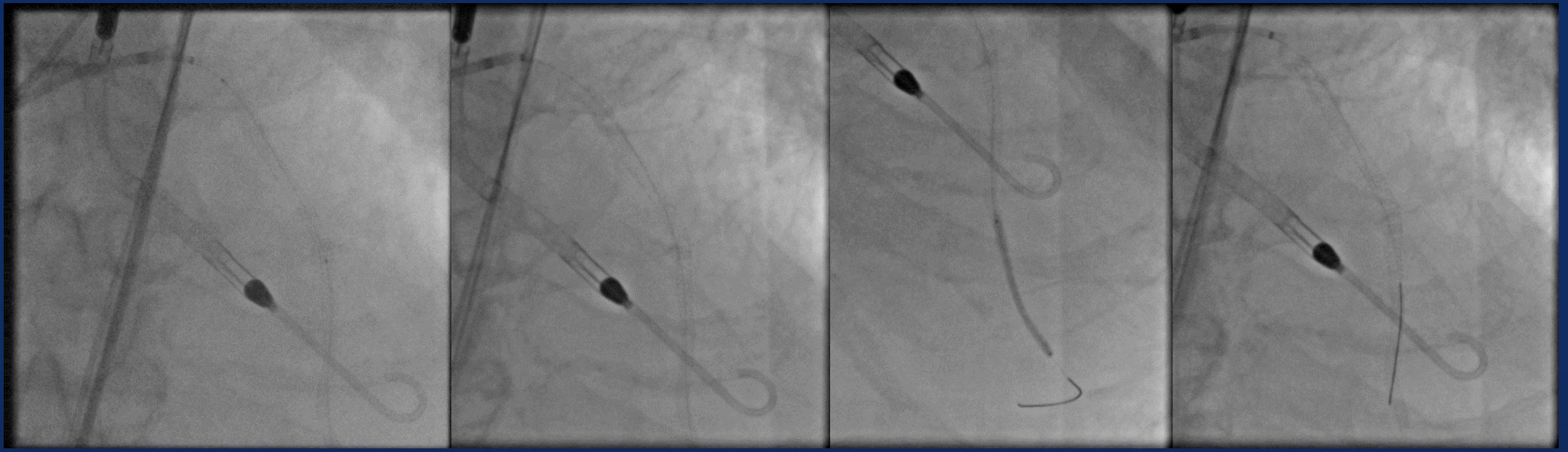
Post IVL IVUS



Good stent expansion (1st and 2nd DES)

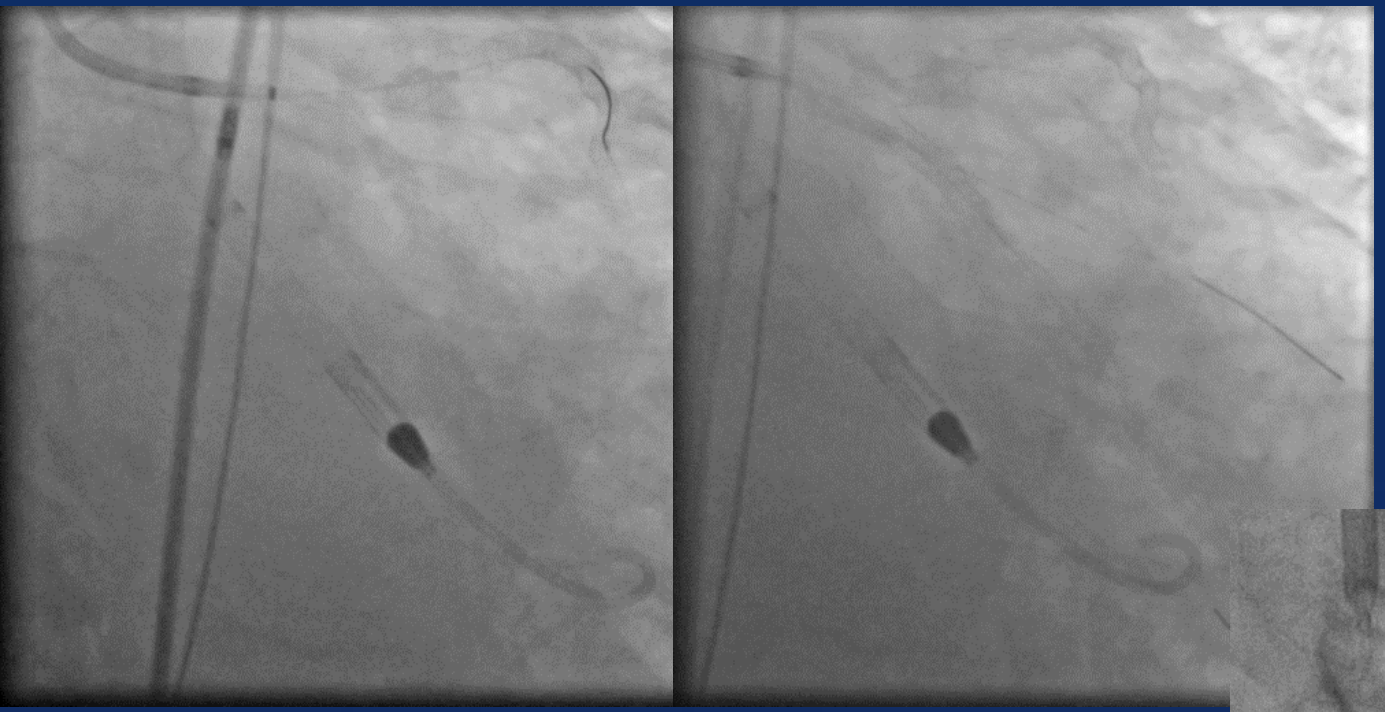
DEB

Final Results

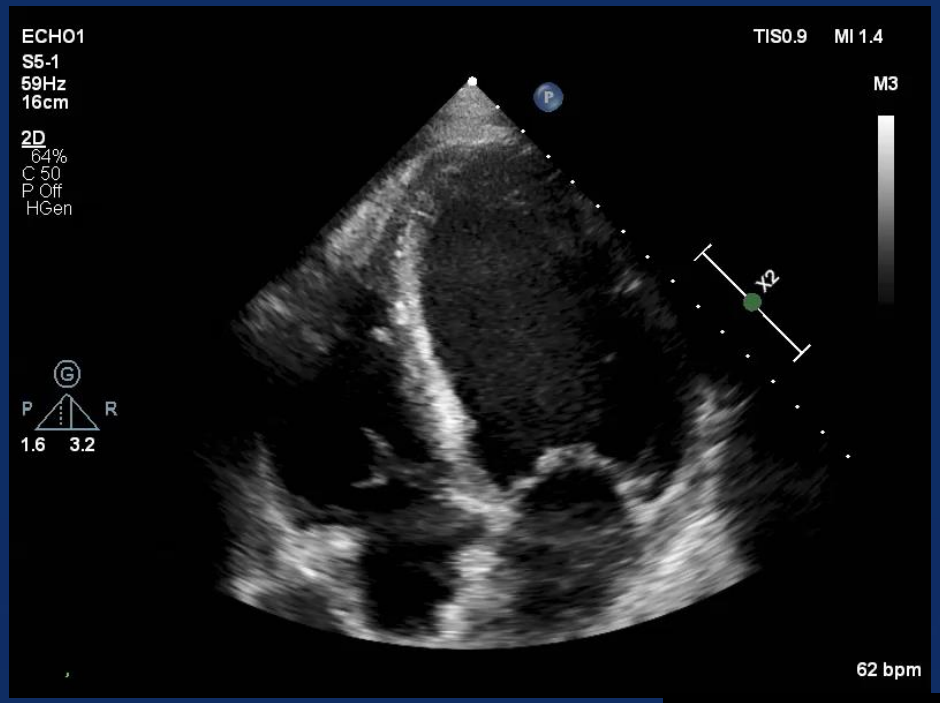


LCx - Pre

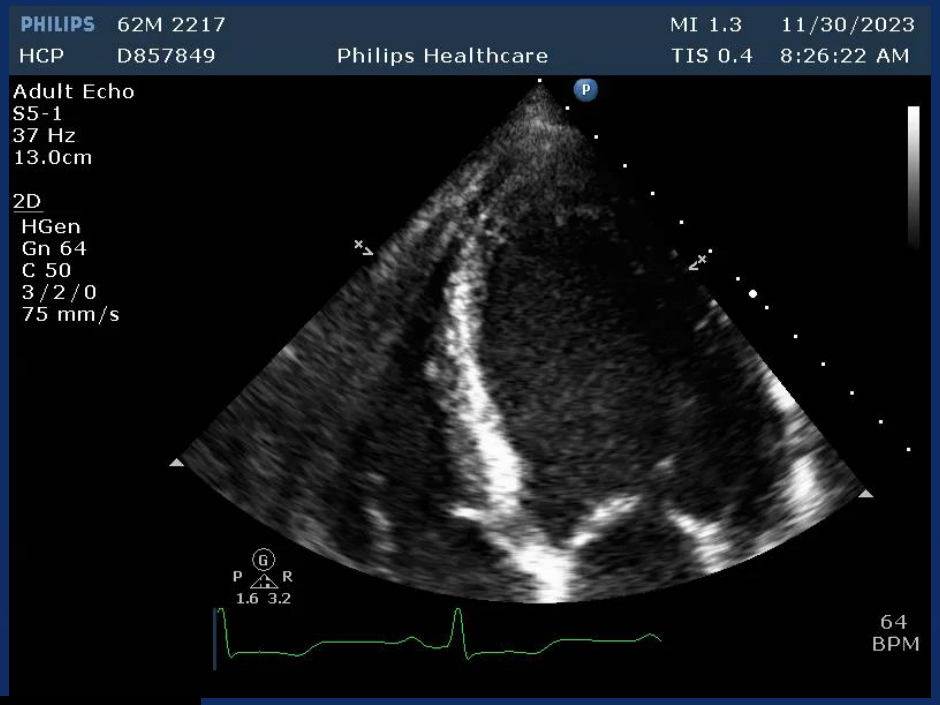
LCx - Post stenting (3rd and 4th DES)



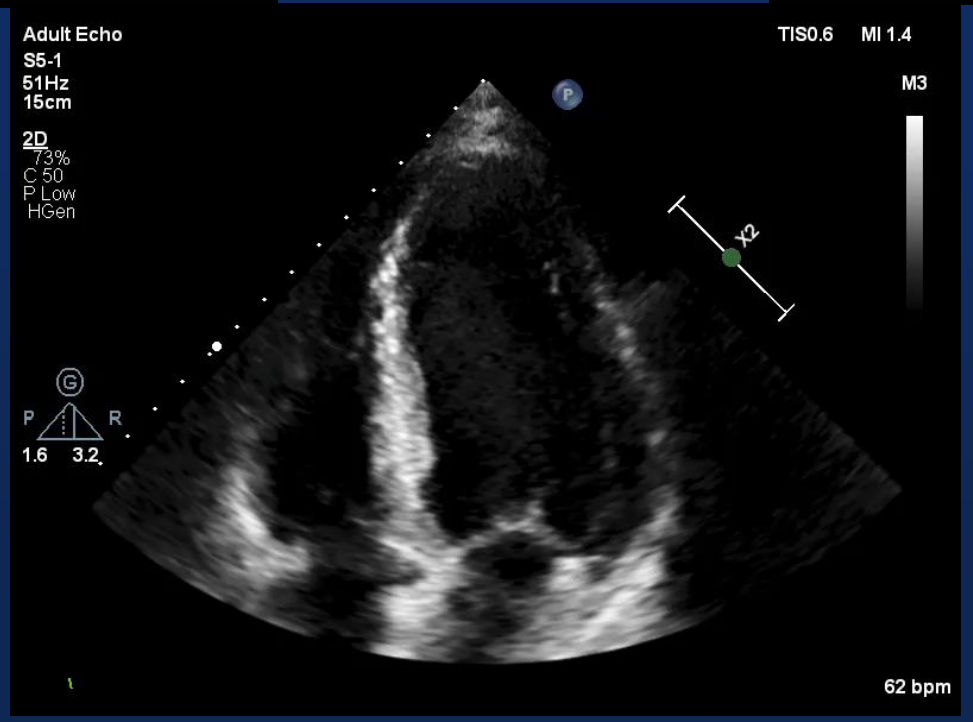
RCA - Pre and Post stenting
(5th – 7th DES)



LVF Pre - PCI



LVF - Post PCI (the next day)



LVF- 5 months after PCI

Conclusion

- Impella is designed to increase cardiac flow, unload the LV, and stablize the hemodynamics during HRPCI
- The PROTECT PCI studies have demonstrated the prophylactic use of Impella 2.5 or Impella CP during HRPCI reducing the MACCE rates
- There is still unmet need for CHIP population, the decision to treat those patients should carefully weigh the risks, benefits, and complications with or without MCS
- The PROTECT IV randomized clinical trial aims to clarify the use of Impella in HR-PCI

I believe Impella is our new friend and also the patient's good friend in HRPCI