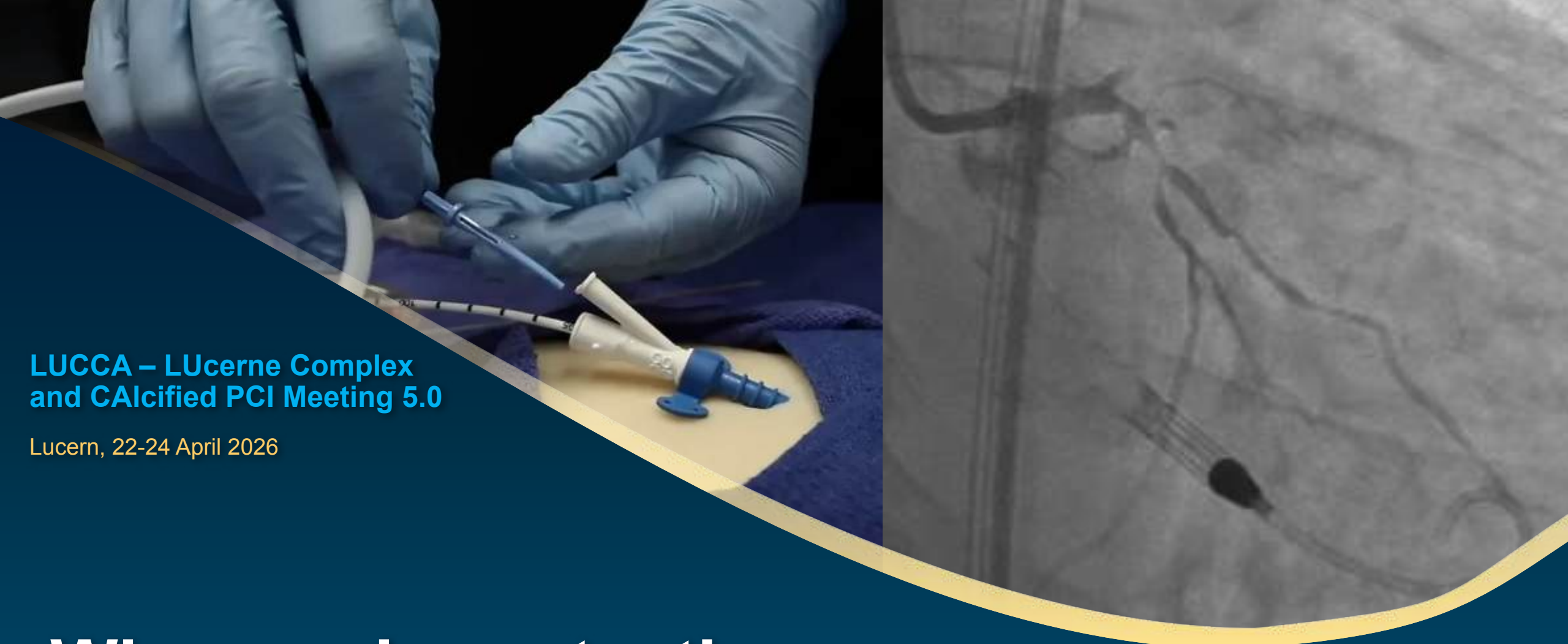




**LUCCA – LUcerne Complex
and CAIcified PCI Meeting 5.0**

Lucern, 22-24 April 2026

Who needs protection for complex PCI



Università
di **Genova**



OSPEDALE POLICLINICO SAN MARTINO
Sistema Sanitario Regionale Liguria
Istituto di Ricovero e Cura a Carattere Scientifico

Rocco Vergallo

Interventional Cardiology Unit
Ospedale Policlinico San Martino IRCCS, Genova
Università di Genova



- Consulting or lecturing fees from: Abbott Vascular, Abiomed, Amarin, Amgen, Boston Scientific, Daiichi Sankyo, Edwards Lifesciences, Medtronic, Philips, Novartis, Novo Nordisk, and SIS Medical.



In-hospital Mortality Risks*

**Surgical
Ineligibility**

6-7x

increase in mortality^{2,3}

**Chronic Kidney
Disease**

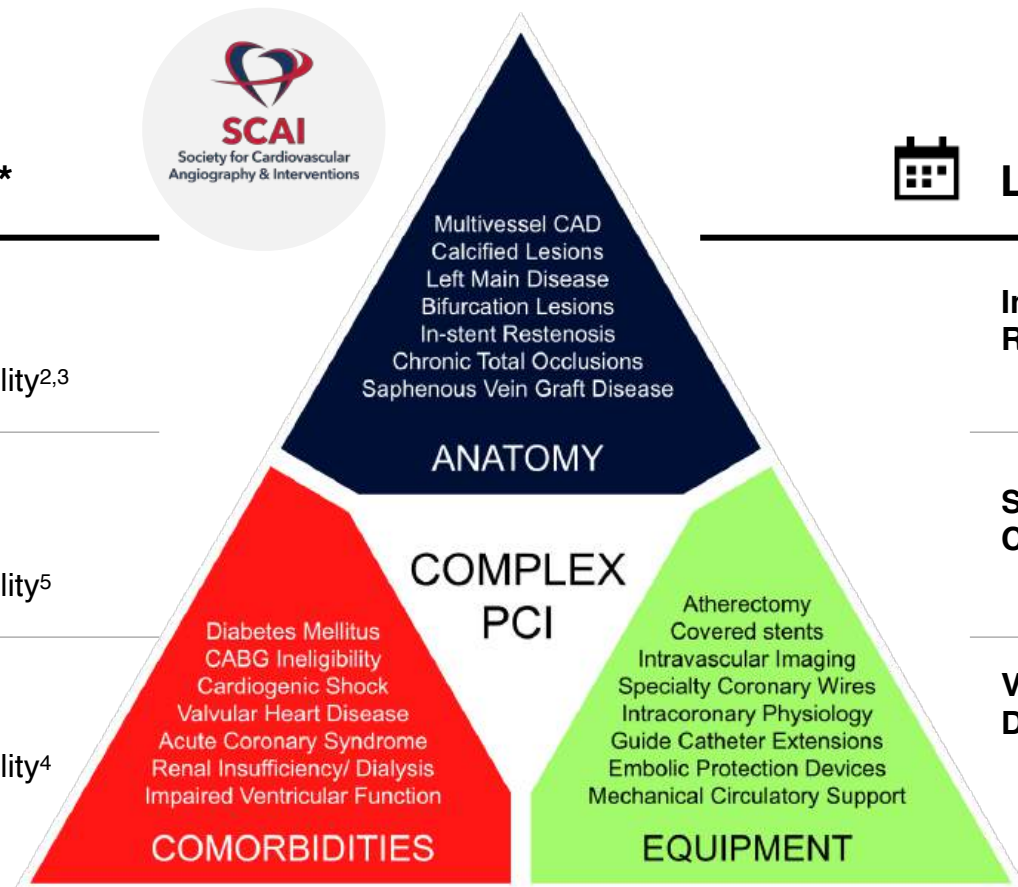
2-3x

increase in mortality⁵

**Impaired LV
(<50% EF)**

15%

increase in mortality⁴



Long-Term Mortality Risks*

**Incomplete
Revascularization**

3x

increase in 5-year mortality¹

**Severe
Calcification**

72%

increase in 5-year mortality⁶

**Valvular Heart
Disease**

increase in 1-year mortality⁷

Riley, R. et al. (2020). SCAI Position Statement, Catheter Cardiovasc Interv, doi: 10.1002/ccd.28994

1. Farooq, V. et al. (2013). J Am Coll Cardiol, 61(3),282-294

2. Waldo, S. et al. (2014). Circulation,130(25), 2295-2301

3. McNulty, E. et al. (2011). JACC Cardiovasc Interv, 4(9), 1020-1027

4. Ye, Z. et al. (2018). Biomed Res Int, 2018, 1-8. doi.org/10.1155/2018/8753176

5. Charytan, D. et al. (2006). Am Heart J, 152(3), 558-564

6. Bourantas, C. et al. (2015). Catheter Cardiovasc Interv, 85(2), 199-206

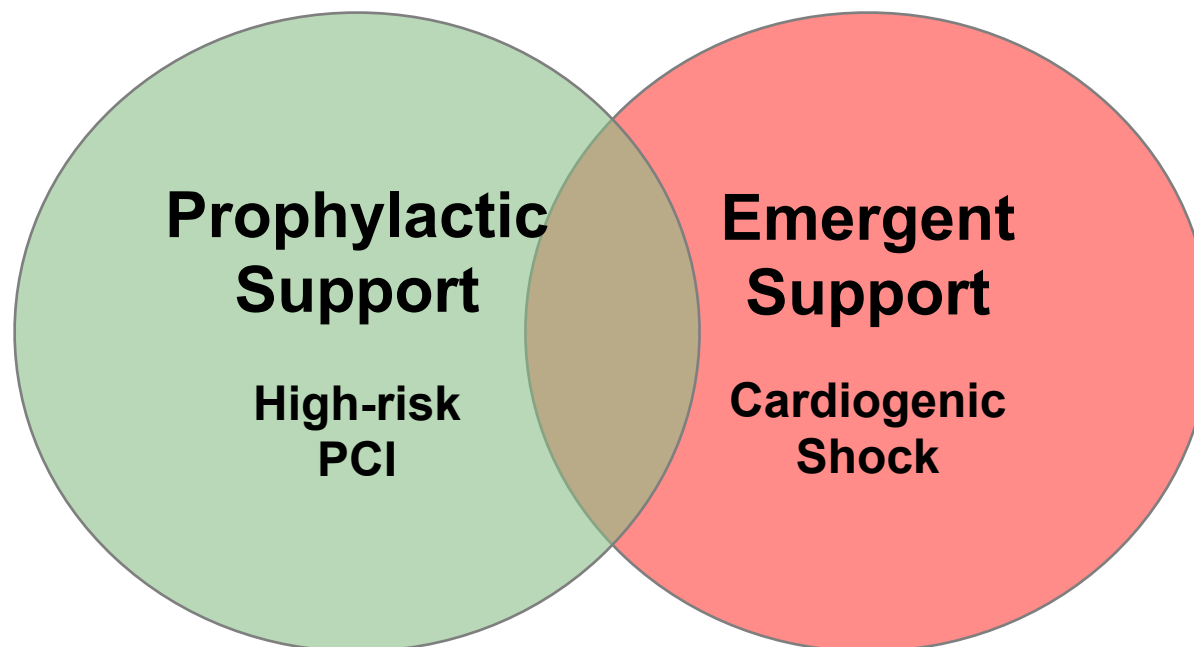
7. Stefanini, G. et al. (2014). Eur Heart J, 35(37), 2530-2540



Clinical Settings for Percutaneous Hemodynamic Support

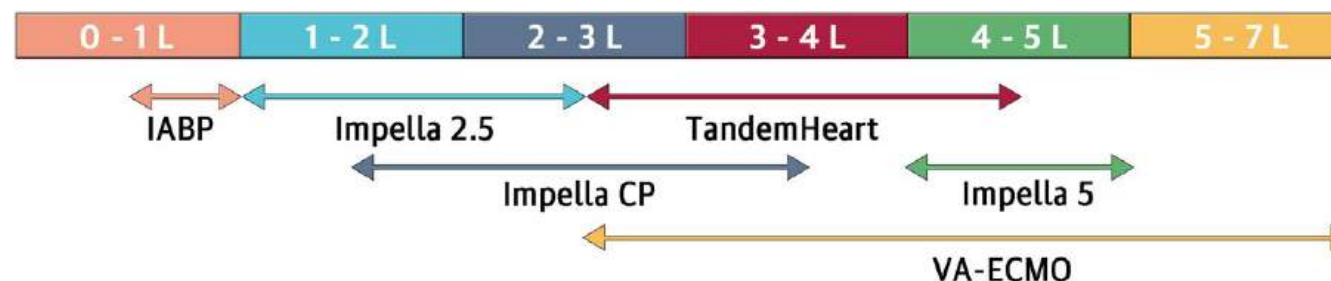
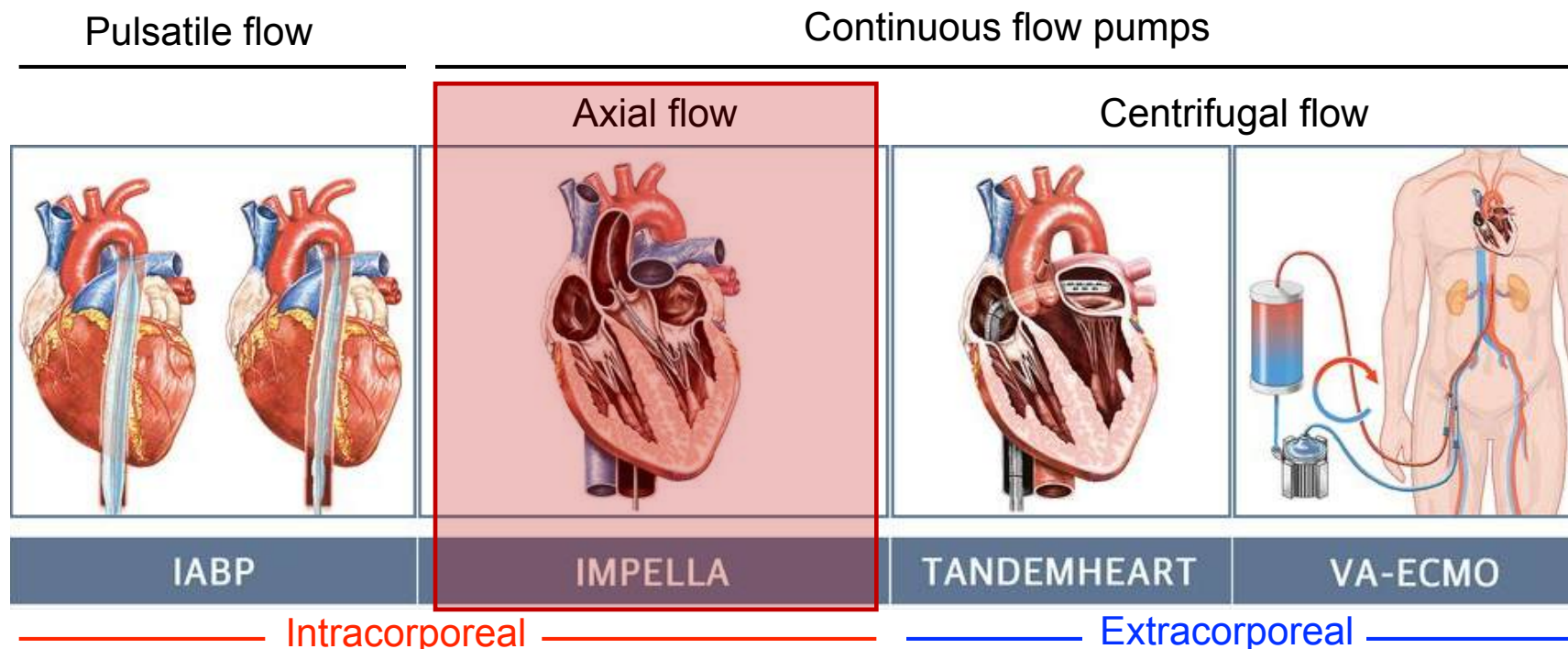
Prophylactic Setting

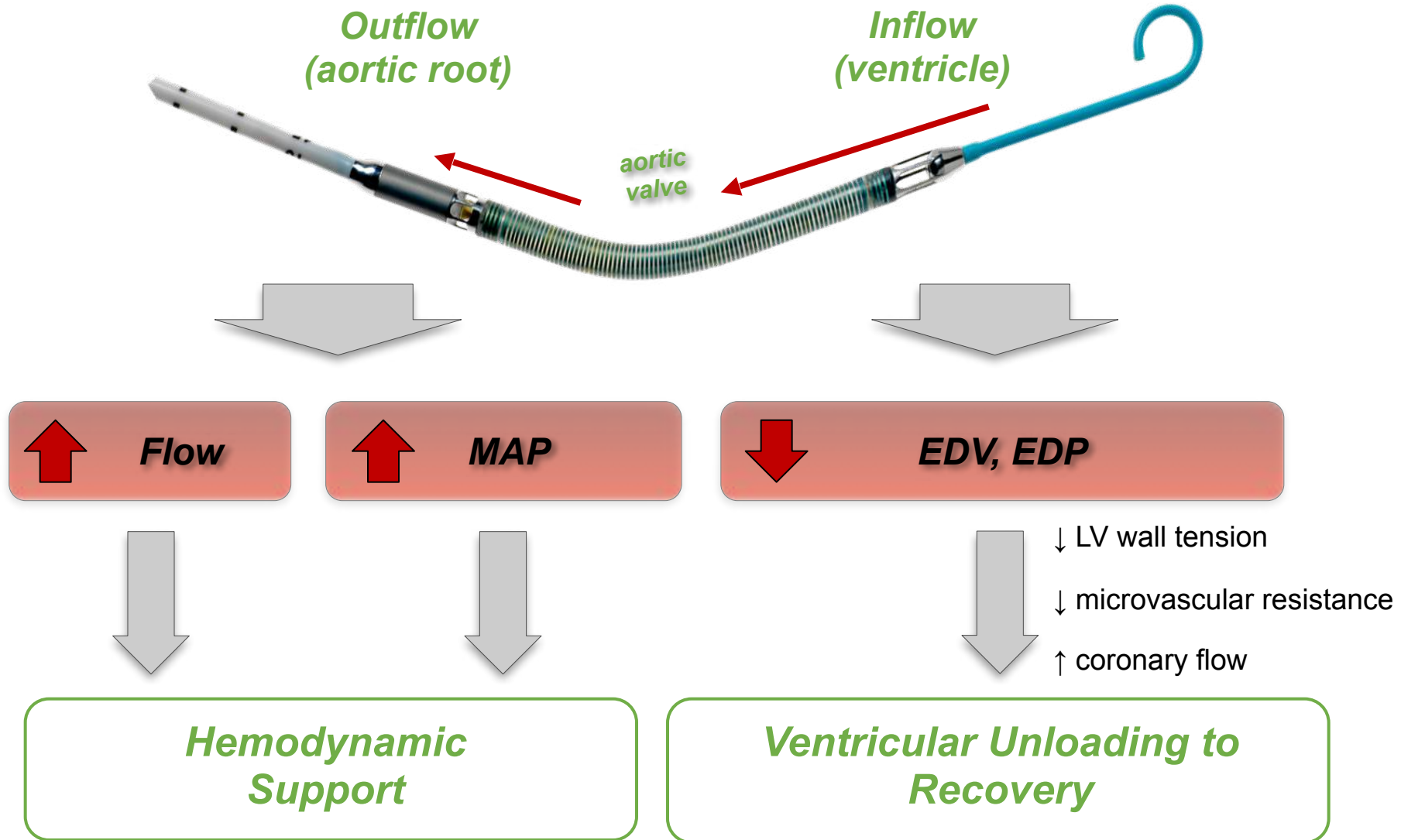
- Maintain BP and CO during high-risk procedure to maximize CBF to other myocardial regions and blood flow to the body

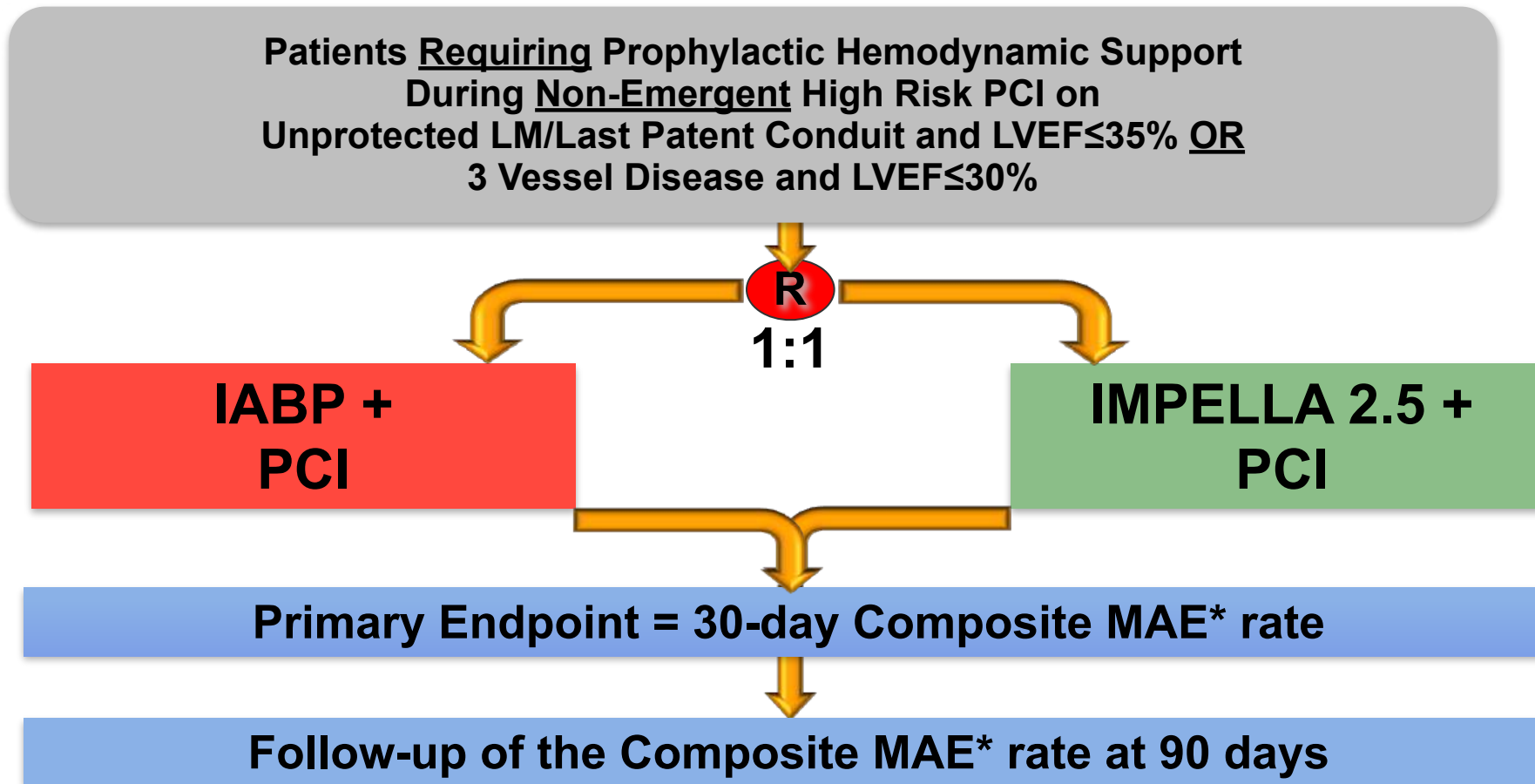
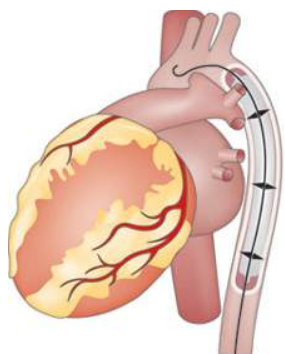


Emergent Setting

- Normalize CO, BP, Cardiac Power Output ($CPO = MAP \times CO$)
- Decrease PCWP
- Decrease myocardial work and oxygen consumption
- Minimize myocardial damage and optimize recovery



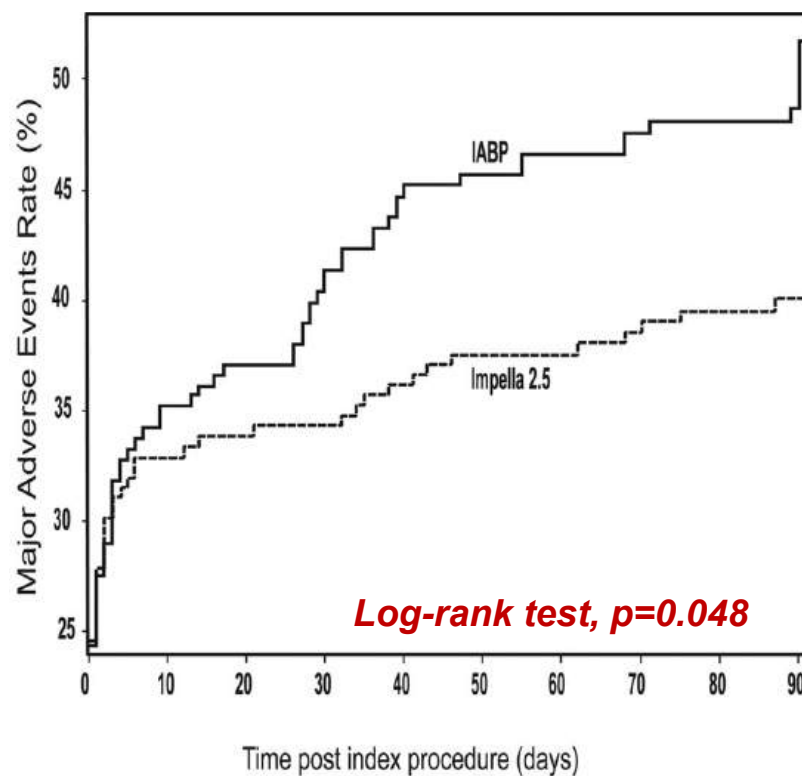


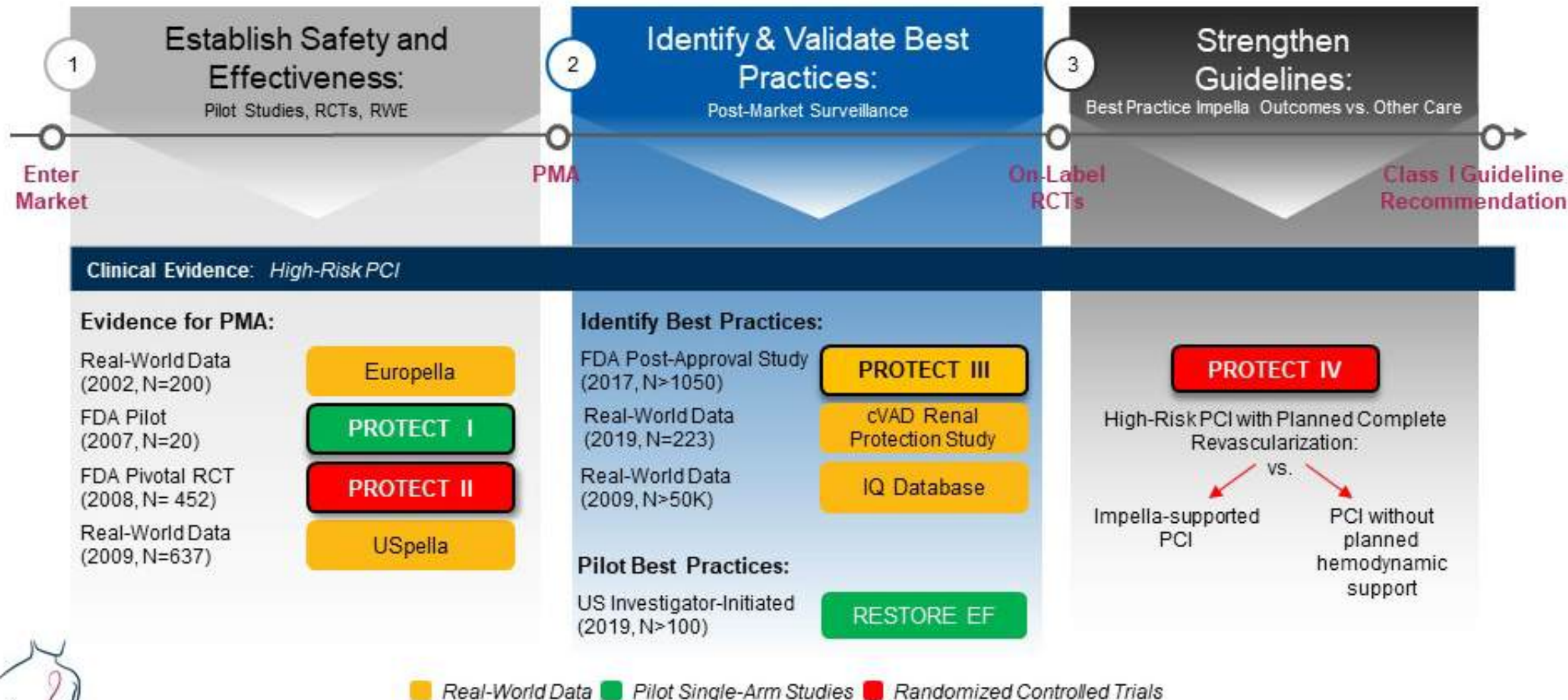


**Major Adverse Events (MAE) :*

Death, Stroke/TIA, MI (>3xULN CK-MB or Troponin), 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

IABP versus Impella: PROTECT II trial





2024 ESC Guidelines for the management
 of chronic coronary syndromes

Management of chronic coronary syndrome patients with chronic heart failure—Section 5		
In HF patients with LVEF ≤35% in whom obstructive CAD is suspected, ICA is recommended with a view towards improving prognosis by CABG, taking into account the risk-to-benefit ratio of the procedures.	I	B
In HF patients with LVEF >35% and suspected CCS with low or moderate (>5%–50%) pre-test likelihood of obstructive CAD, CCTA or functional imaging is recommended.	I	C
In patients with HFpEF with angina or equivalent symptoms and normal or non-obstructive epicardial coronary arteries, PET or CMR perfusion or invasive functional coronary testing should be considered to detect or rule out coronary microvascular dysfunction.	IIa	B
In selected patients with HFrEF undergoing high-risk PCI for complex CAD, the use of a microaxial flow pump may be considered in experienced centres.	IIb	C
It is recommended that CCS patients with heart failure be enrolled in a multidisciplinary heart failure management programme to reduce the risk of heart failure hospitalization and to improve survival.	I	A
Sacubitril/valsartan is recommended as a replacement for an ACE-I or ARB in CCS patients with HFrEF to reduce the risk of heart failure hospitalization and death.	I	B

MULTICENTER, RANDOMIZED, OPEN-LABEL TRIAL

700

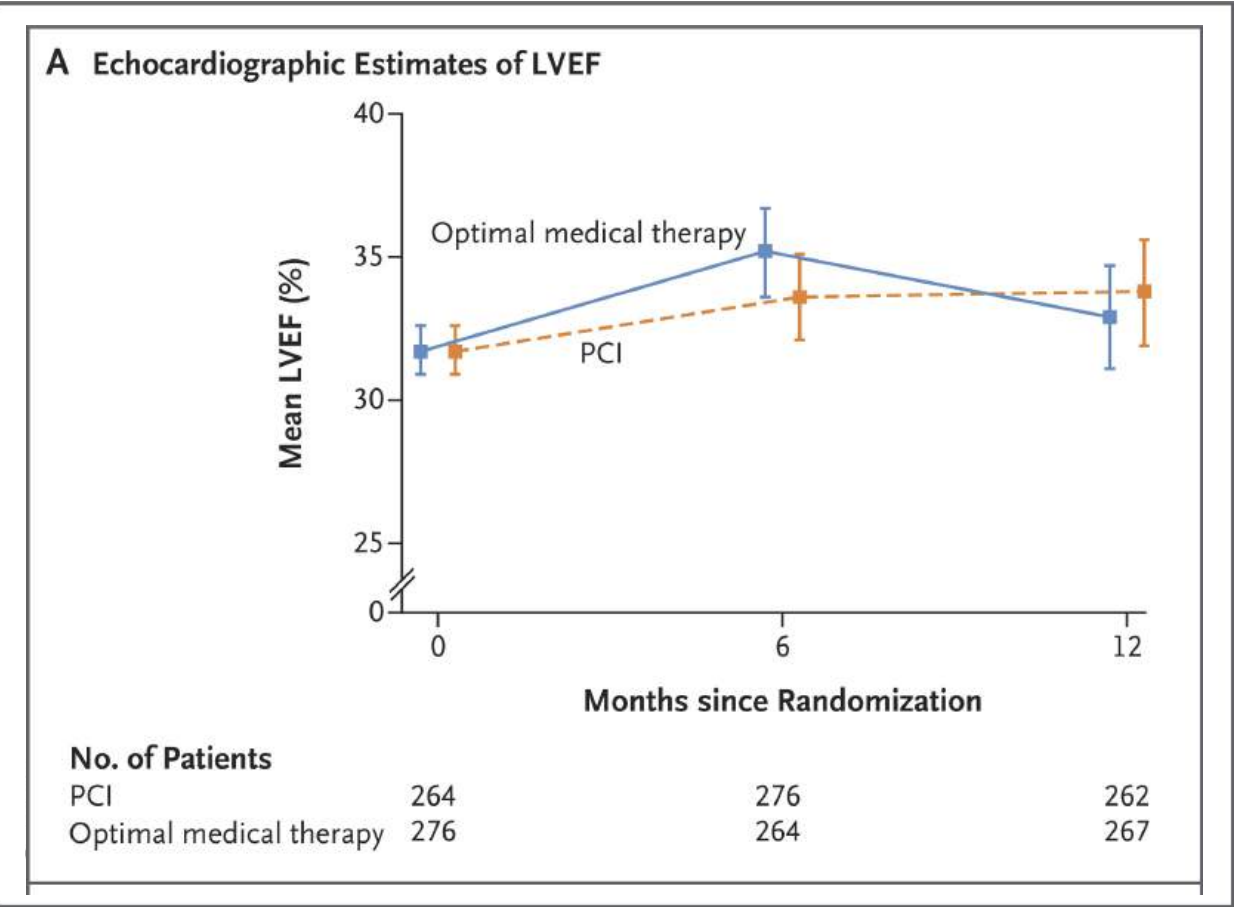
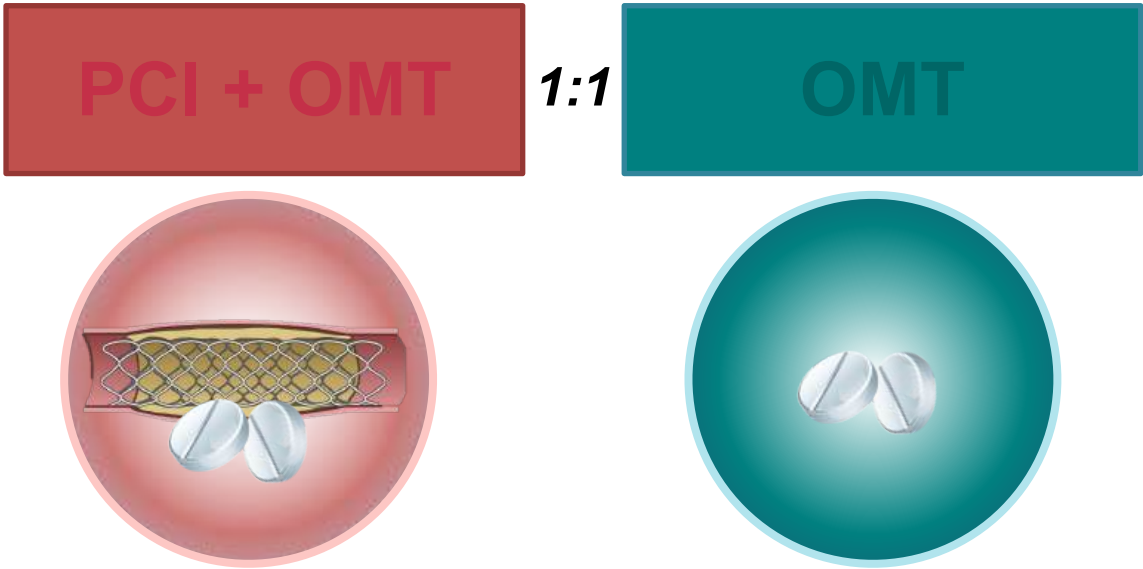
Patients with

ISCHEMIC LV DYSF (EF< 35%)

BCIS JS ≥6

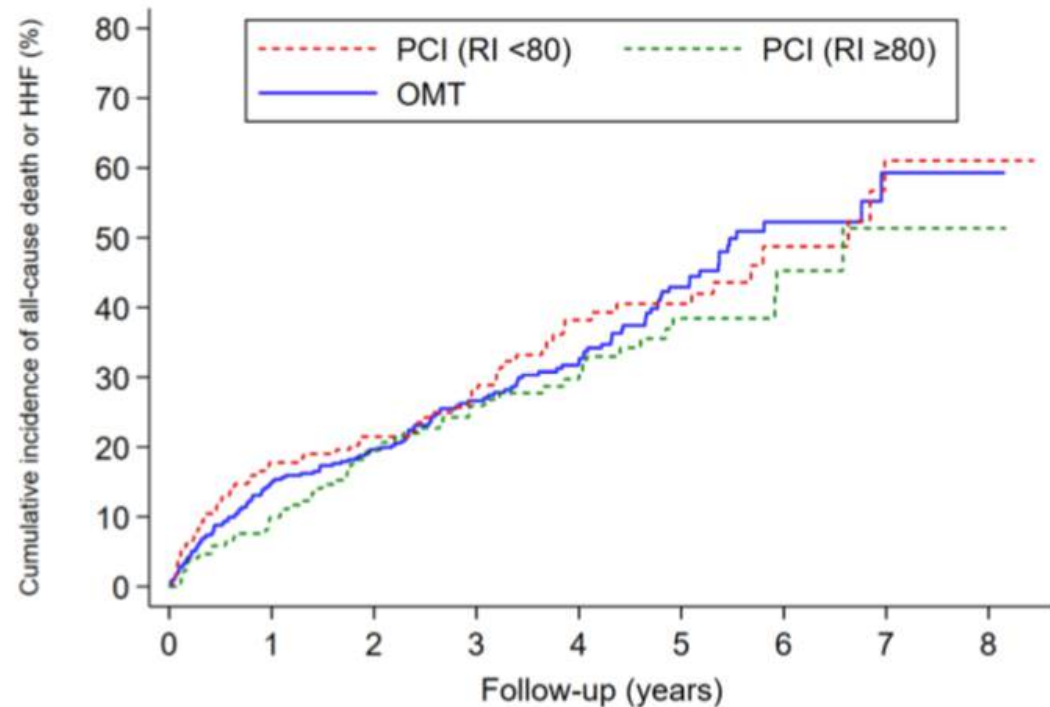
Myocardial viability in ≥ 4 segments

RANDOMIZED



Death or hospitalization for HF

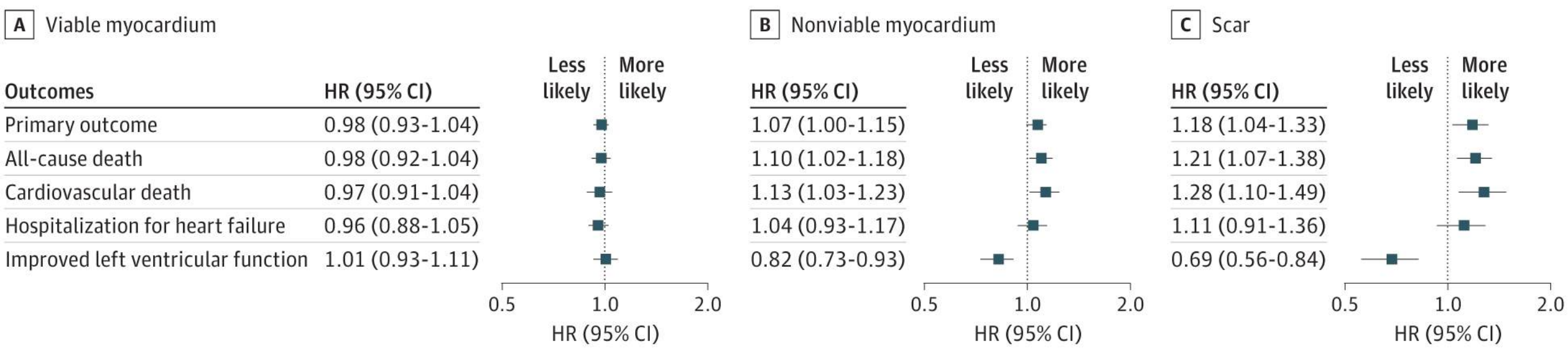
Complete versus incomplete revascularization in REVIVED-BCIS trial



Number at risk									
PCI (RI <80)	163	134	126	88	60	41	16	9	1
PCI (RI ≥80)	171	154	132	87	68	39	16	5	2
OMT	353	299	276	191	142	82	33	10	1

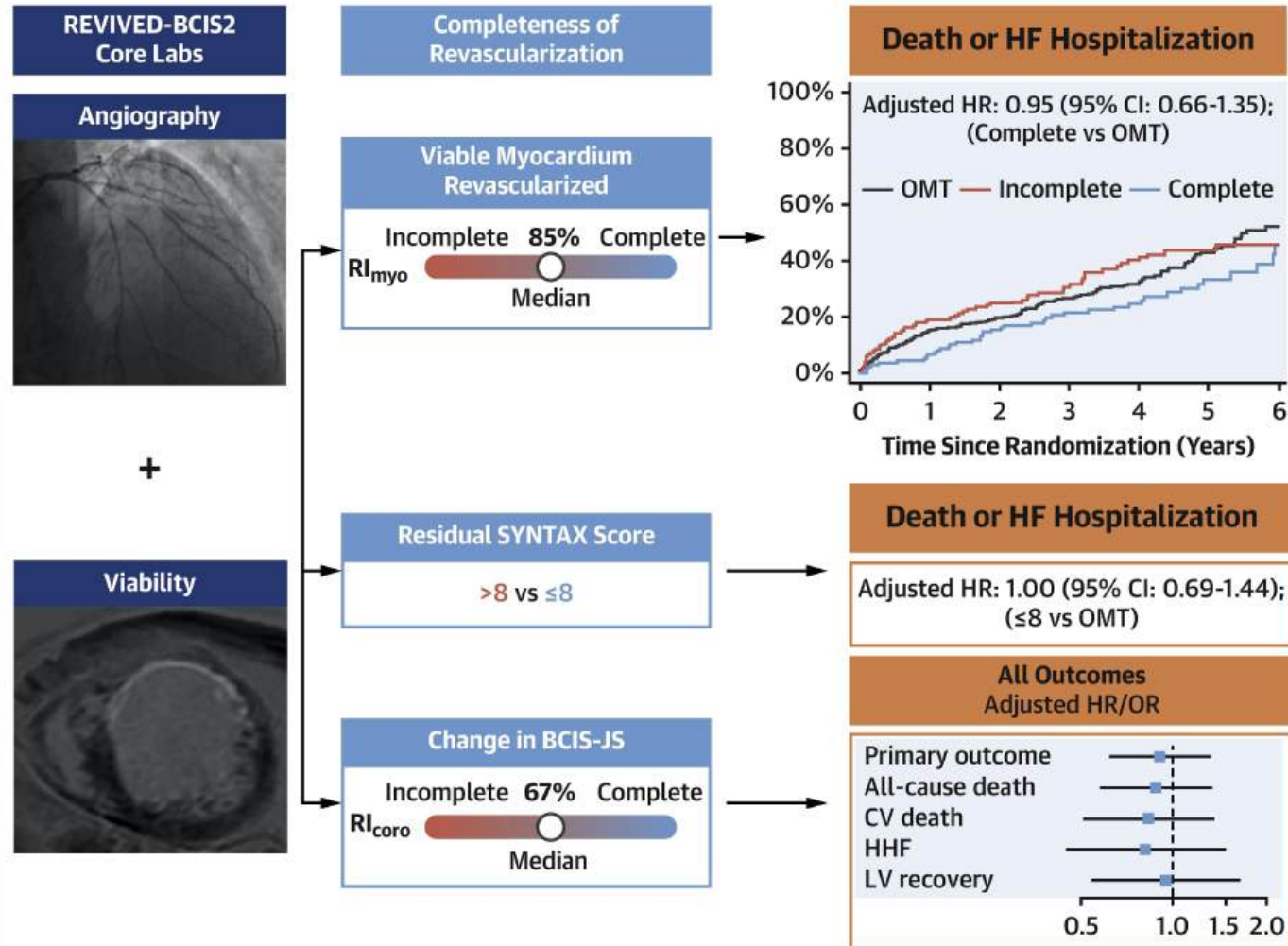
	PCI	OMT	Hazard Ratio (95% CI)
RI >80	56/171	134/353	0.87 (0.64 to 1.19)
RI <80	64/163		1.02 (0.76 to 1.37)

MCS used in only 3%
of patients
randomized to PCI



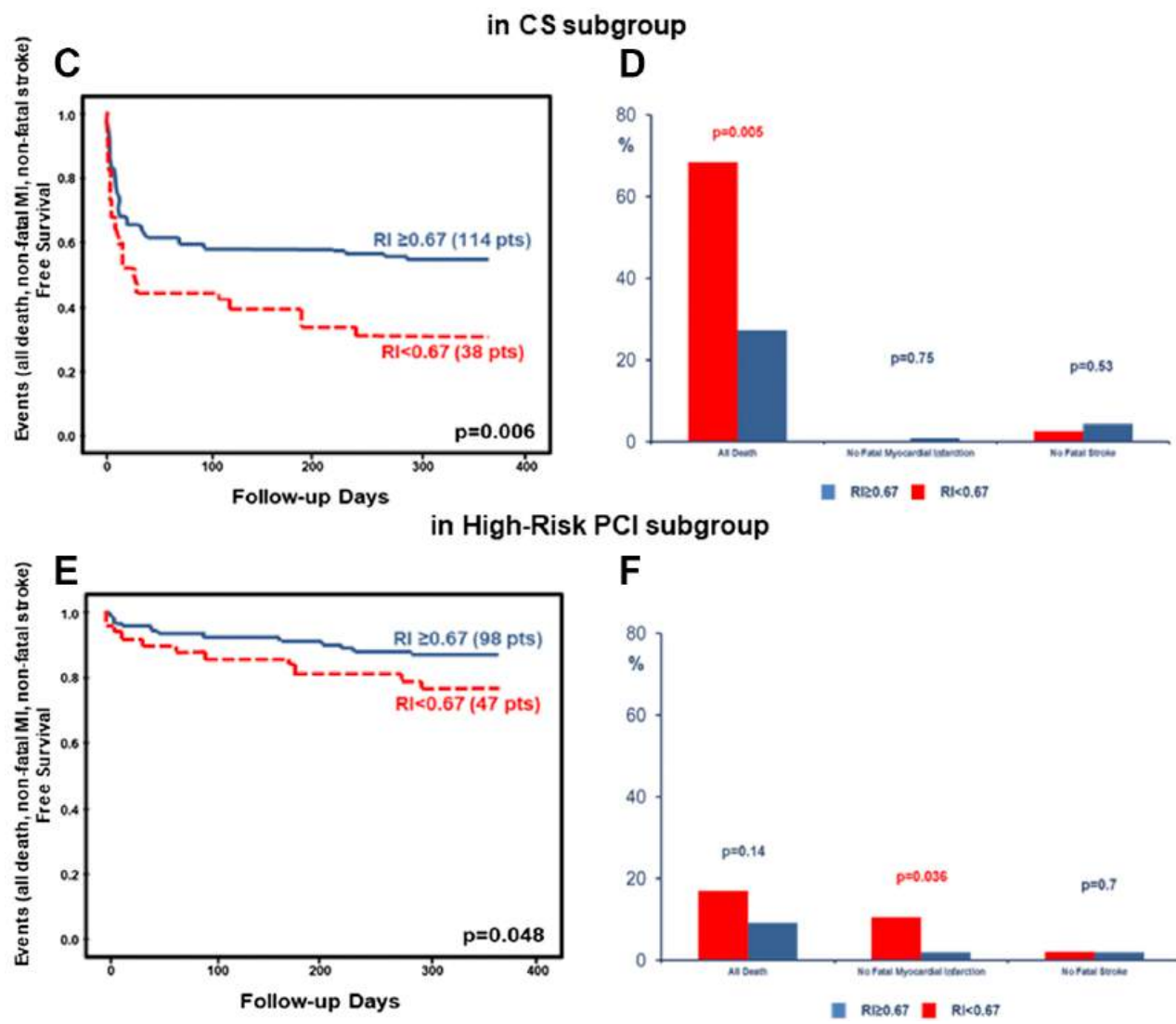
Viability, completeness of revascularization and outcomes in REVIVED-BCIS trial

CENTRAL ILLUSTRATION: Completeness of Revascularization in Revascularization for Ischemic Ventricular Dysfunction



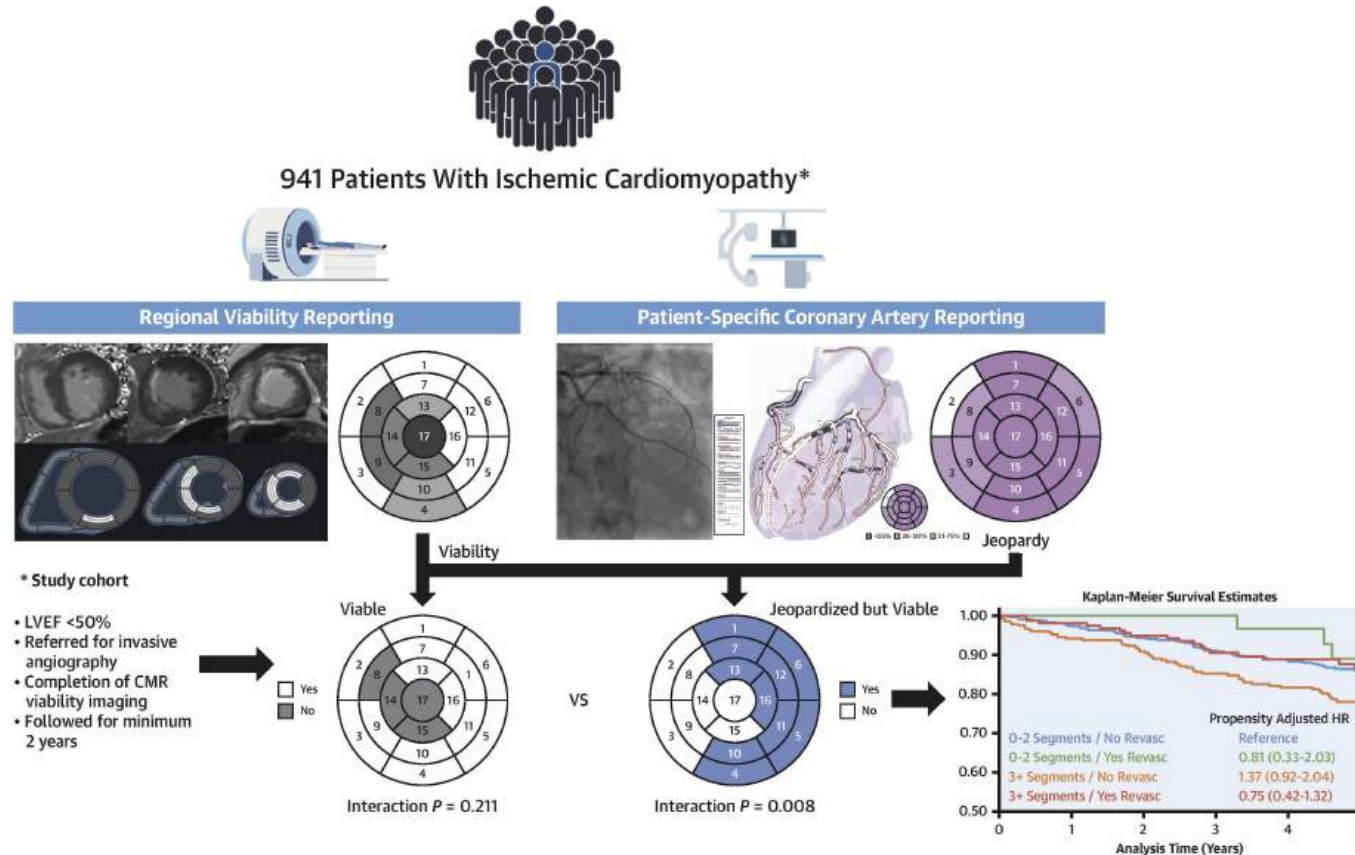


Extent of revascularization and outcome in Impella-supported interventions



Patient-specific coronary tree-based to define jeopardized but viable myocardium

CENTRAL ILLUSTRATION: Analysis of Patient-Specific Vascular Tree and Viability Reporting to Guide Revascularization



Abdaem J, et al. JACC Cardiovasc Imaging. 2026;19(4):463-474.

Map coronary jeopardy to viable territories:

The key is not global viability or global CAD burden, but whether significant viable myocardium is supplied by vessels with critical stenoses amenable to PCI

Clinical case





Piano

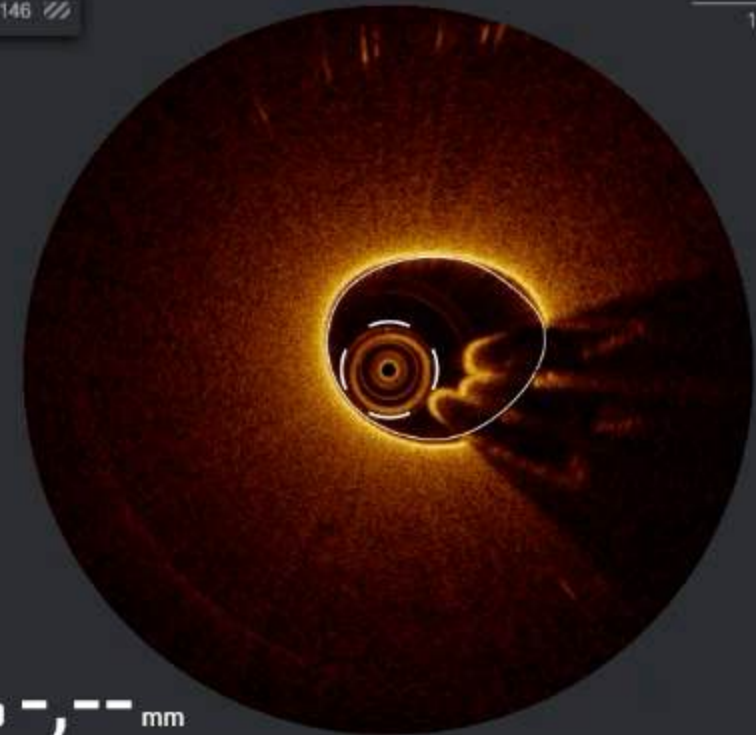
Revisione



Protocollo rai
kV mA ms RAO CRAN SID FO

F:146

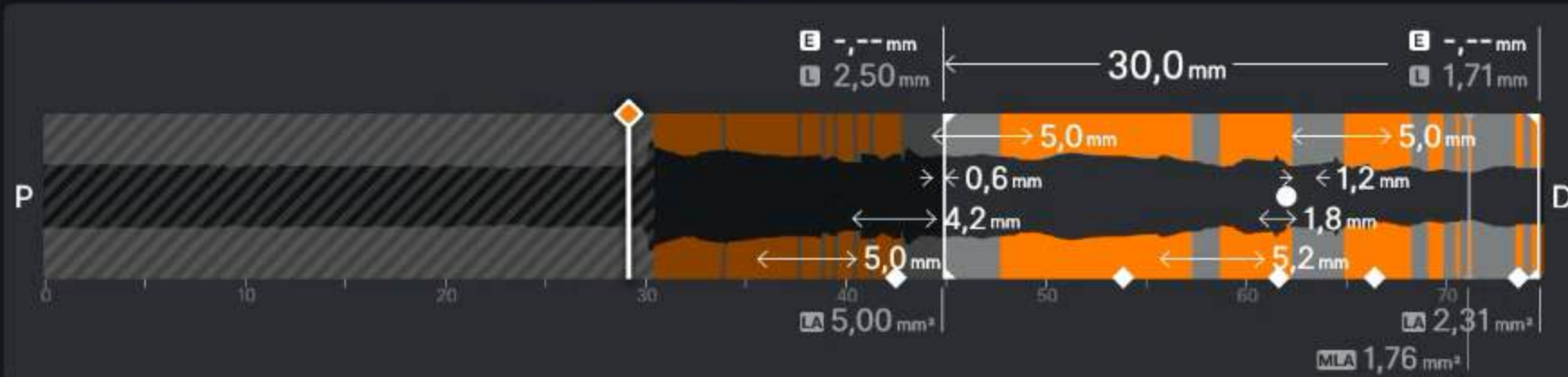
1 mm



E --- mm

L 1,88 mm

LA 2,79 mm²

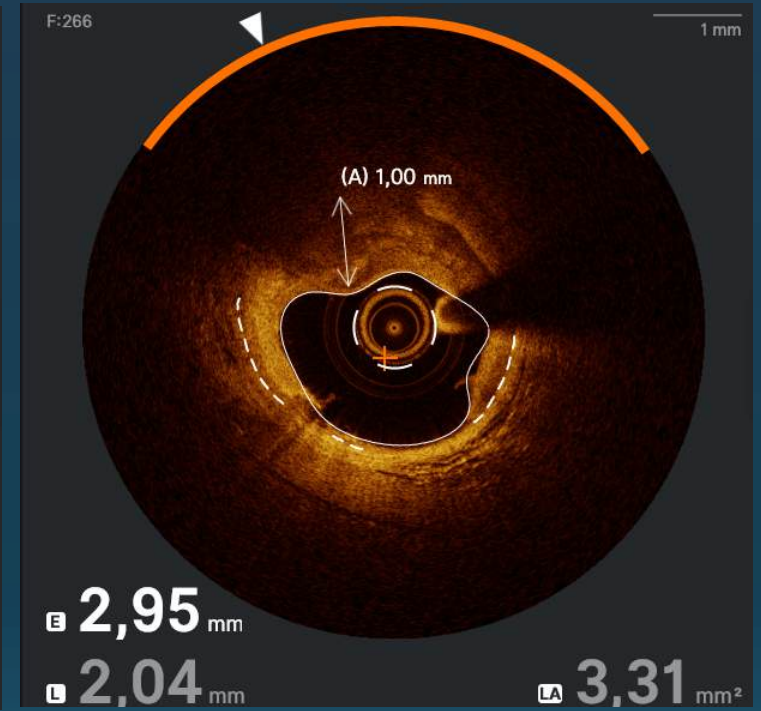
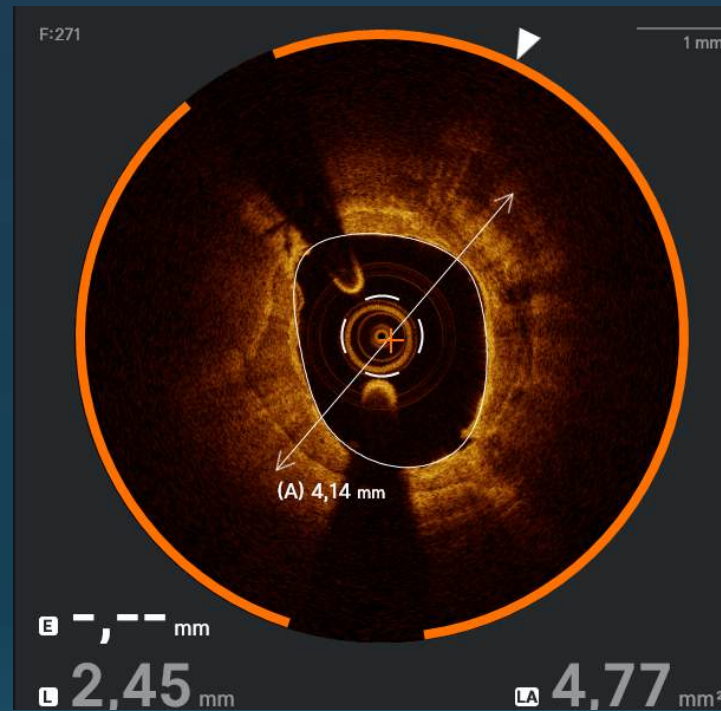
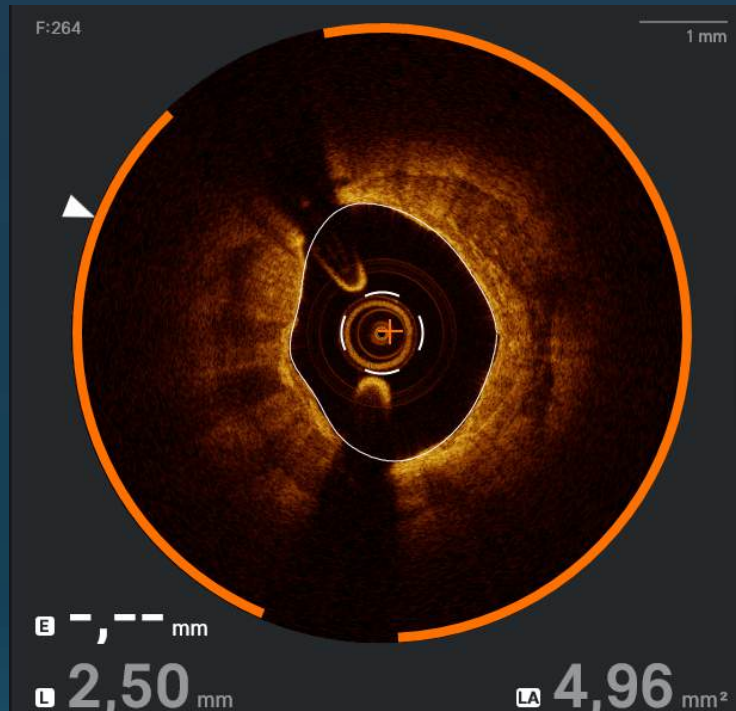


>= 180°

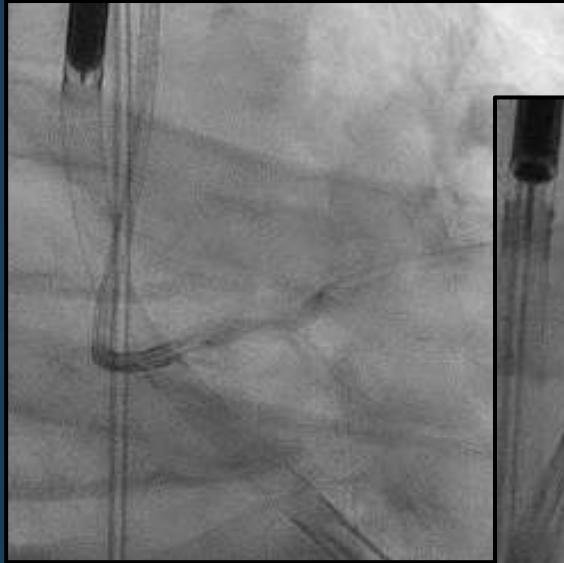
PBK 2: LAD, Proximale, Pre-PCI

Anonymous Anonymous

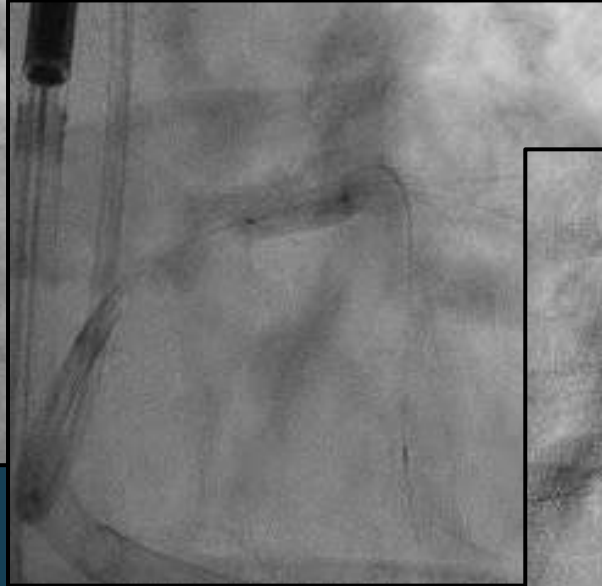
Baseline OCT (selected frames)



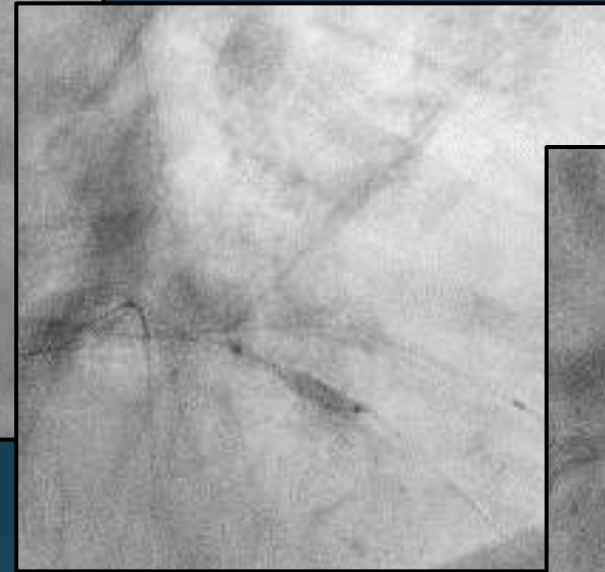
Lesion preparation



NC 3.0x12
mm



Shockwave
3.5x12 mm



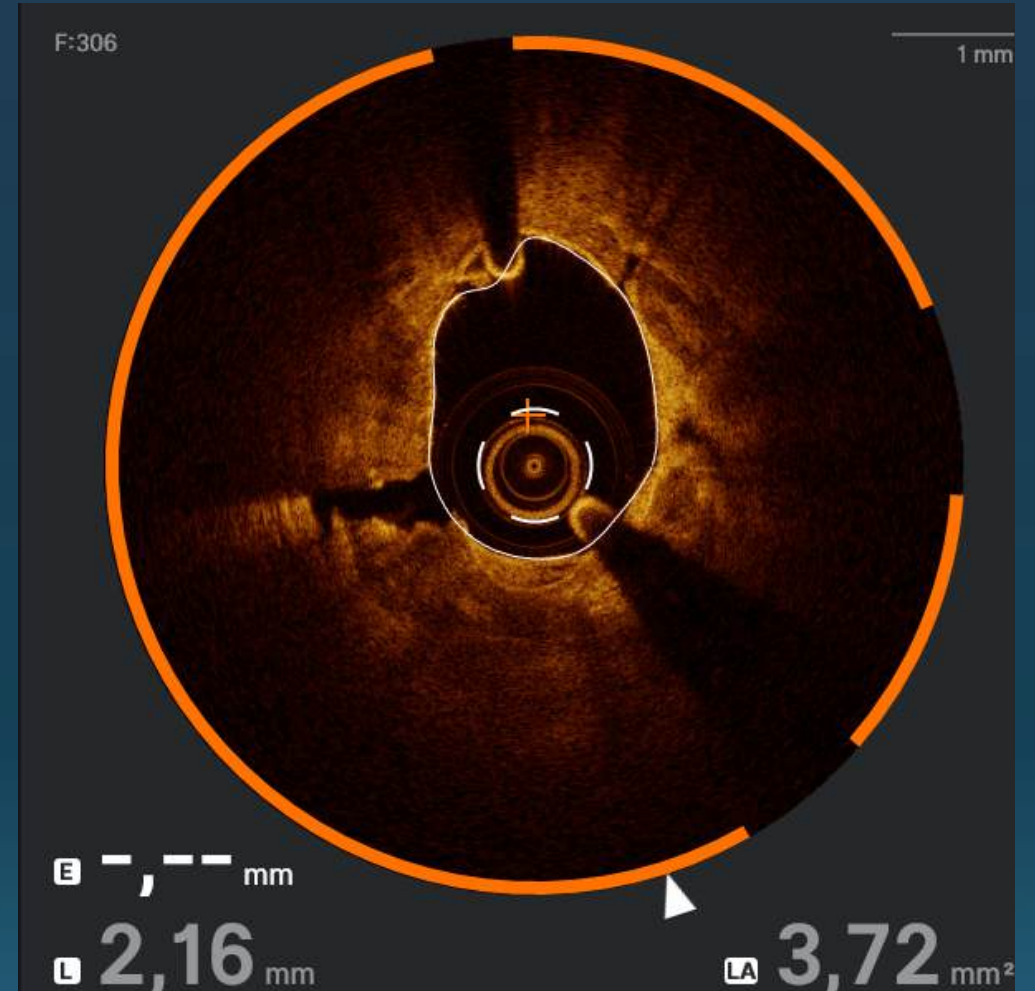
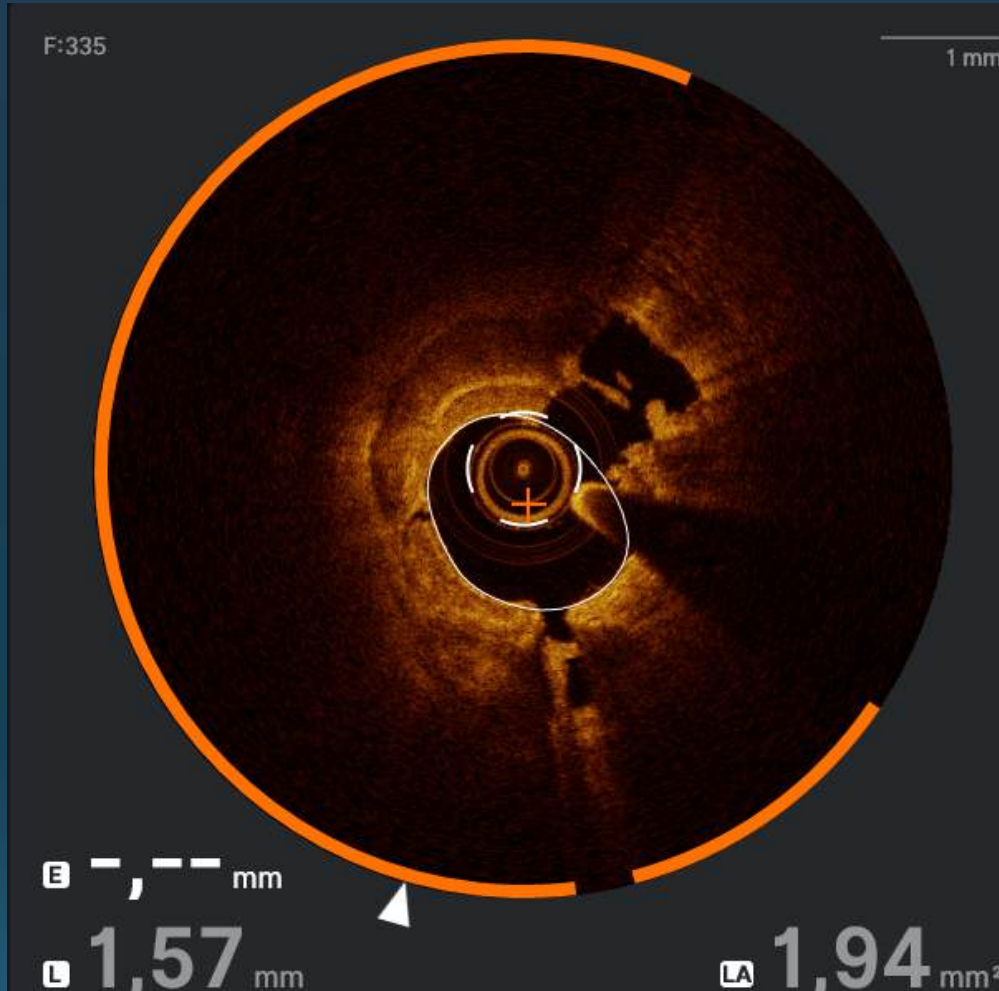
OPN 2.5x10 mm
(30 atm)



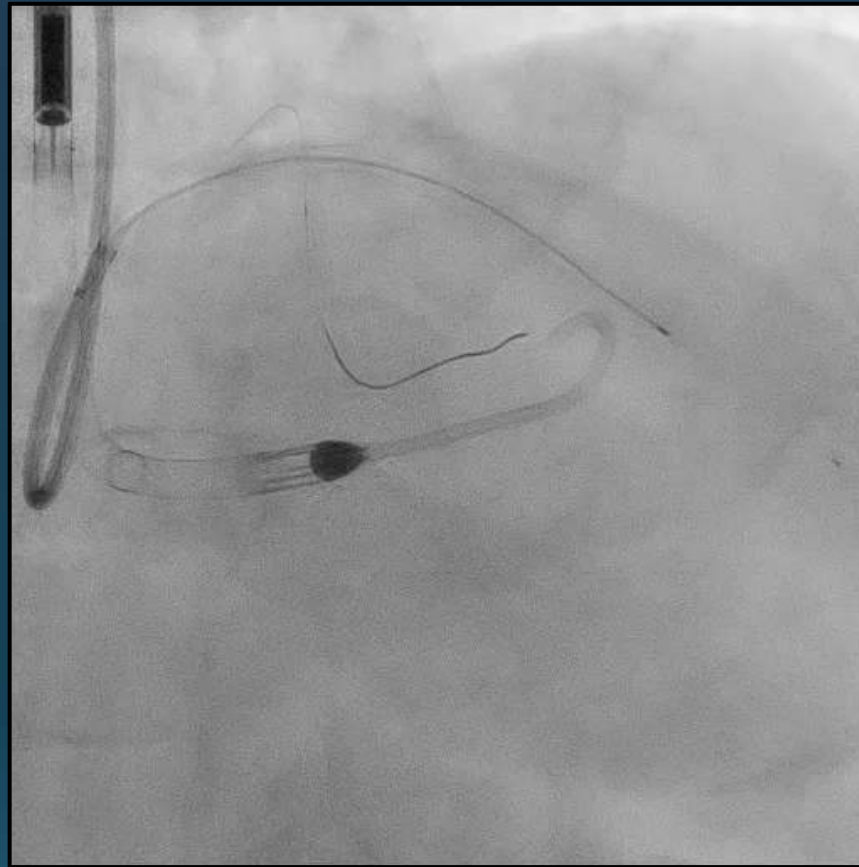
OPN 2.5x10
(40 atm)



Cracking after IV (multiple fractures)

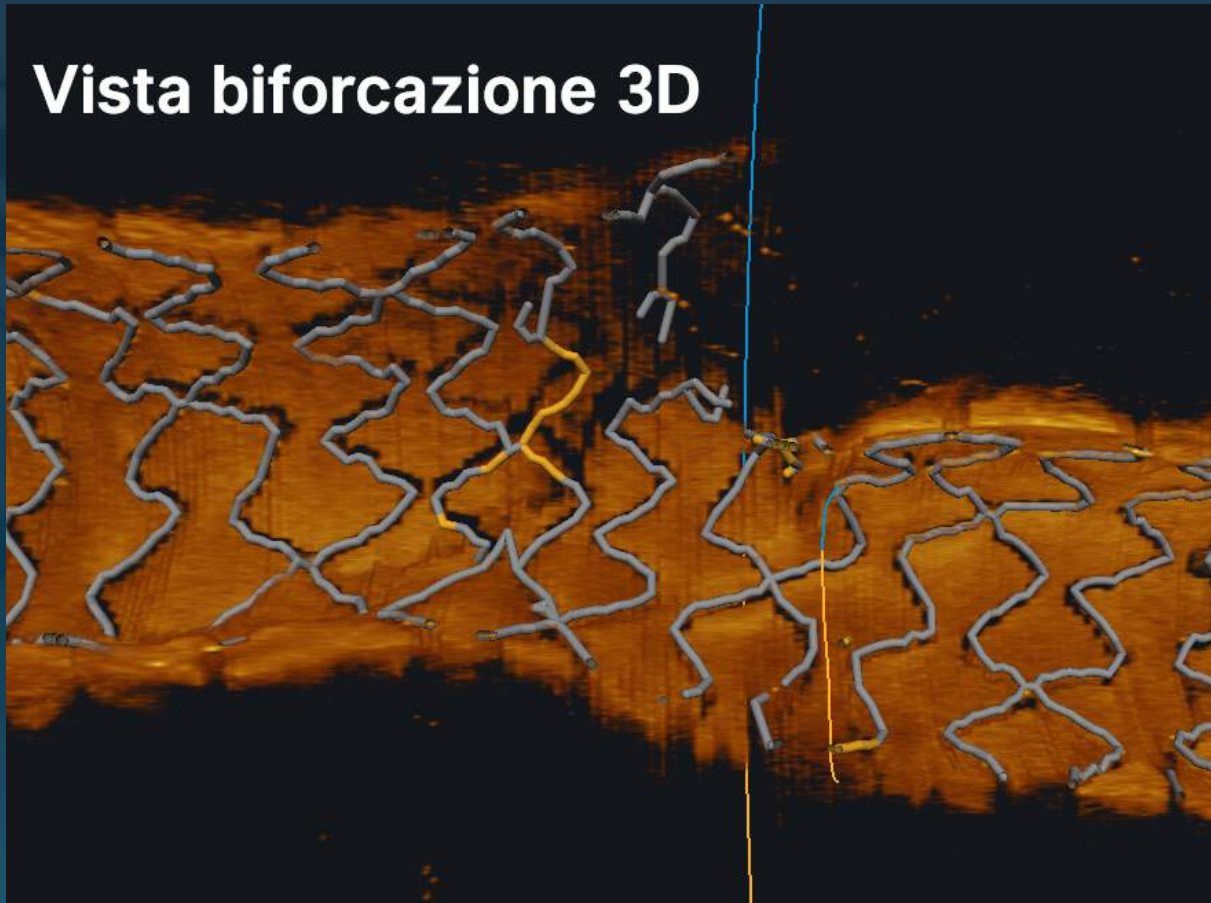


Final result

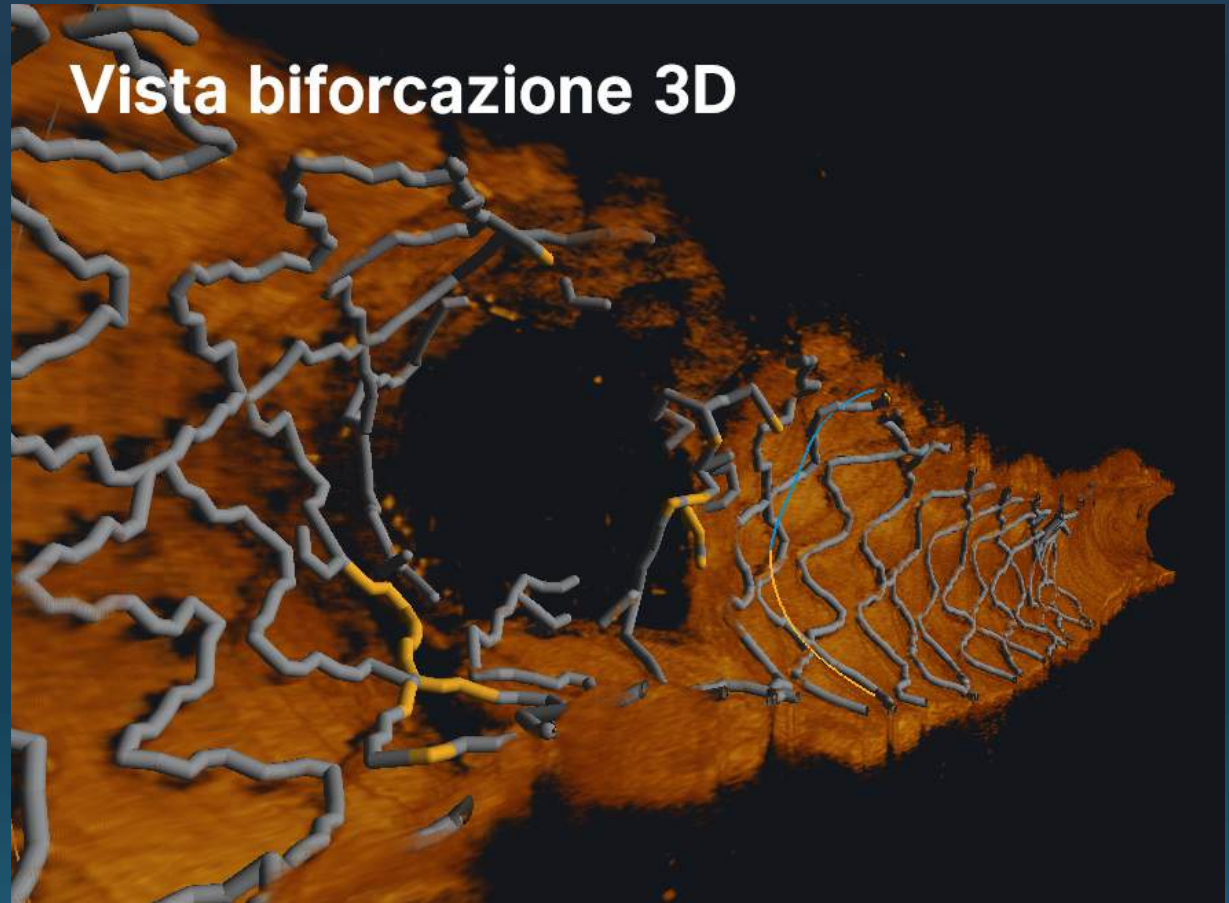


Final result

Vista biforcazione 3D



Vista biforcazione 3D





LV function recovery after protected PCI with Impella



Original article

INFOGRAPHIC

Left ventricular functional recovery after complex high-risk indicated percutaneous coronary intervention supported with microaxial flow pump

Marco Lombardi^{a,b,*}, Juan Guido Chiabrando^{c,*}, Pietro Ameri^{a,d}, Marco Canepa^{a,d}, Nieves Gonzalo^b, Javier Escaned^b, Italo Porto^{a,d} and Rocco Vergallo^{a,d}

**Meta-analysis
9 studies**

2370 patients

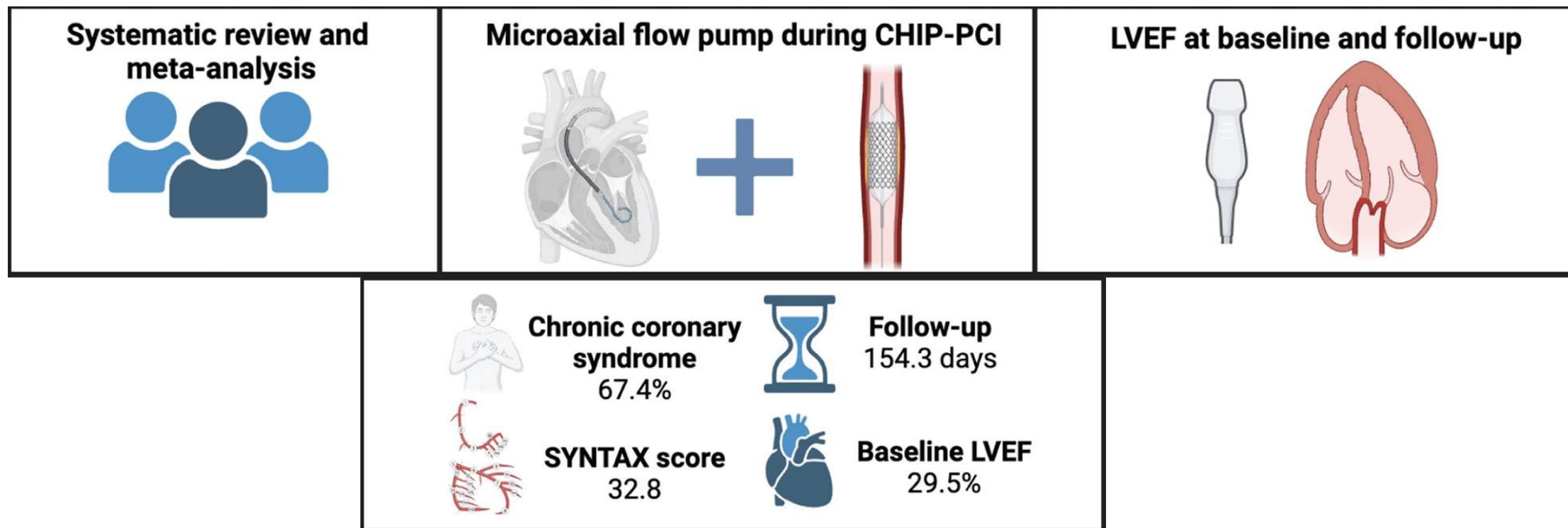
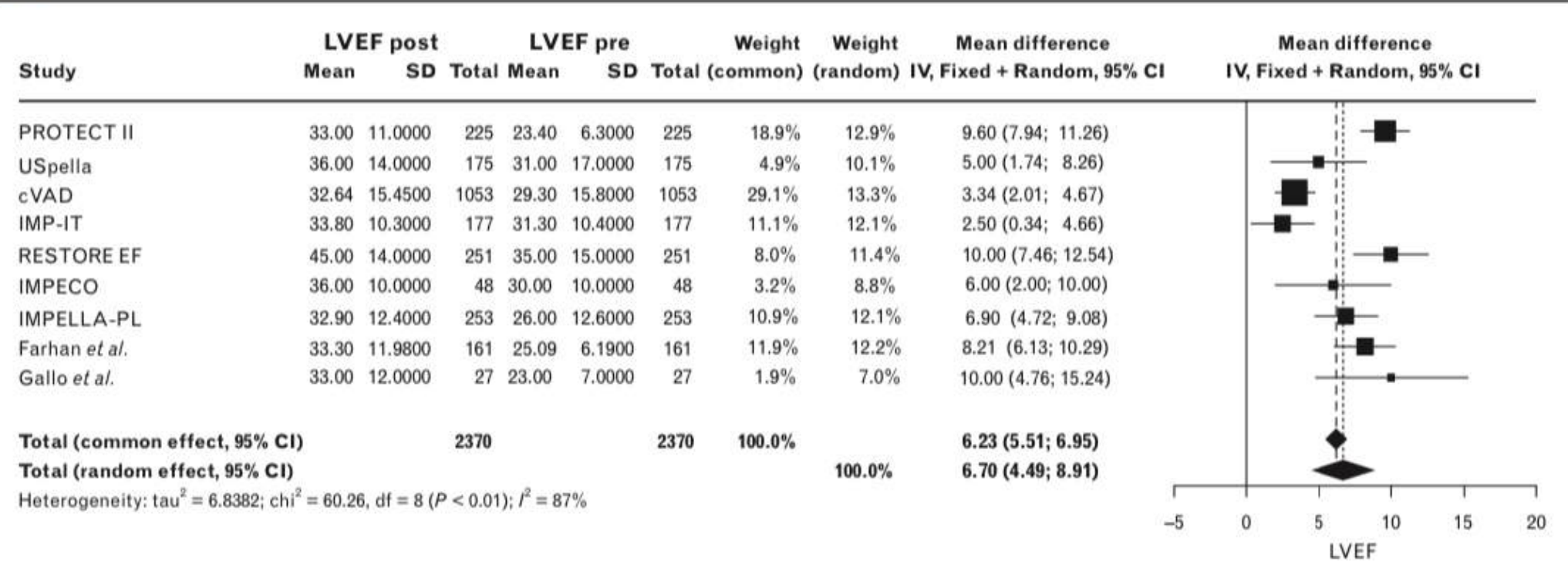


Fig. 2



Change in left ventricular ejection fraction (LVEF) before and after complex high-risk indicated percutaneous coronary interventions (CHIP-PCI) procedures supported by a microaxial flow pump device, with follow-up measurements.

CHIP-PCI assisted by Impella associated with significant increase in LVEF at follow-up (median, 154 days) (MD, +6.70%; 95% confidence interval, 4.49 to 8.91, P = 0.0001).

MULTICENTER, RANDOMIZED, OPEN-LABEL TRIAL

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Left Ventricular Unloading in High-Risk Percutaneous Coronary Intervention

Divaka Perera, M.D.,^{1,2} Matthew Ryan, Ph.D.,^{1,2} Saad M. Ezad, Ph.D.,^{1,3}
Sohail Q. Khan, M.D.,⁴ Ian Webb, Ph.D.,^{1,5} Peter D. O'Kane, M.D.,³
Roshan Weerackody, Ph.D.,⁶ Matthew Dodd, Ph.D.,⁷ Matthew Kwok, M.Sc.,⁷
Lynn Laidlaw, B.A.,⁷ Laura Van Dyck, B.Sc.,⁷ Benjamin Wrigley, M.D.,⁸
Julian W. Strange, M.D.,⁹ Alan Bagnall, Ph.D.,¹⁰ Farzin Fath-Ordoubadi, M.D.,¹¹
Vasileios F. Panoulas, Ph.D.,² Andrew Ladwiniec, M.D.,¹² John R. Davies, Ph.D.,¹³
Alexander Chase, Ph.D.,¹⁴ Colum G. Owens, M.D.,¹⁵ Stuart Watkins, M.D.,¹⁶
Haseeb Rahman, Ph.D.,^{1,2} Nilesh Pareek, Ph.D.,^{1,5} Krishnaraj Rathod, Ph.D.,⁶
John Rawlins, M.D.,¹⁷ Richard Evans, B.A.,⁷ Stephen P. Hoole, M.D.,¹⁸
Rod H. Stables, D.M.,¹⁹ Nick Curzen, Ph.D.,¹⁷ and Tim Clayton, M.Sc.,⁷
for the CHIP-BCIS3 Investigators*

PRIMARY ENDPOINT: hierarchical composite including all-cause death, disabling stroke, spontaneous MI, CV hospitalizations for CV causes, or periprocedural MI at a minimum of 12 months



300

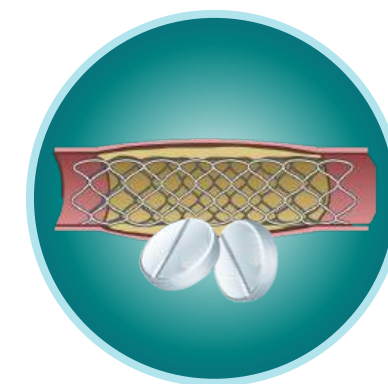
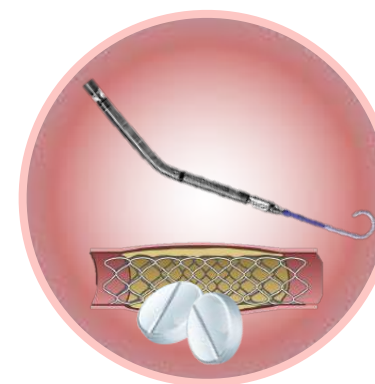
Patients with **severe LV dysfunction and extensive CAD** undergoing **complex PCI**

RANDOMIZED

LV unloading with
Impella CP

1:1

Standard care



Advanced/decompensated heart failure, low-reserve biology

- NT-proBNP subgroup split at 3545 pg/mL.
- LVEF 27%
- Elevated Pre-PCI hs-troponin: 5× ULN with mAFP vs 13× ULN with standard care, biasing biomarker-defined PPMI (rise in hs-troponin by ≥20% or 5× ULN after PCI)
- Risk is likely driven substantially by HF physiology, not anatomy alone.

Urgent / ACS-heavy case mix

- Urgent PCI: 72.3% with mAFP and 79.6% with standard care.
- Within urgent cases, myocardial infarction and acute/worsening HF were common.
- This is not a typical elective HRPCI cohort.

High-risk ≠ right-risk: Unclear Heart Team or CABG-ineligibility criterion.

- SYNTAX: 38, BCIS-JS: 12
- Low prior CABG: 7.4% in the mAFP arm and 3.3% in standard care.
- Very high event risk ≠ right-risk phenotype for prognostic PCI benefit.

Urgent NSTEMI, ADHF, Heterogenous Phenotype

Urgent PCI
72–80%

CCS 0
23%

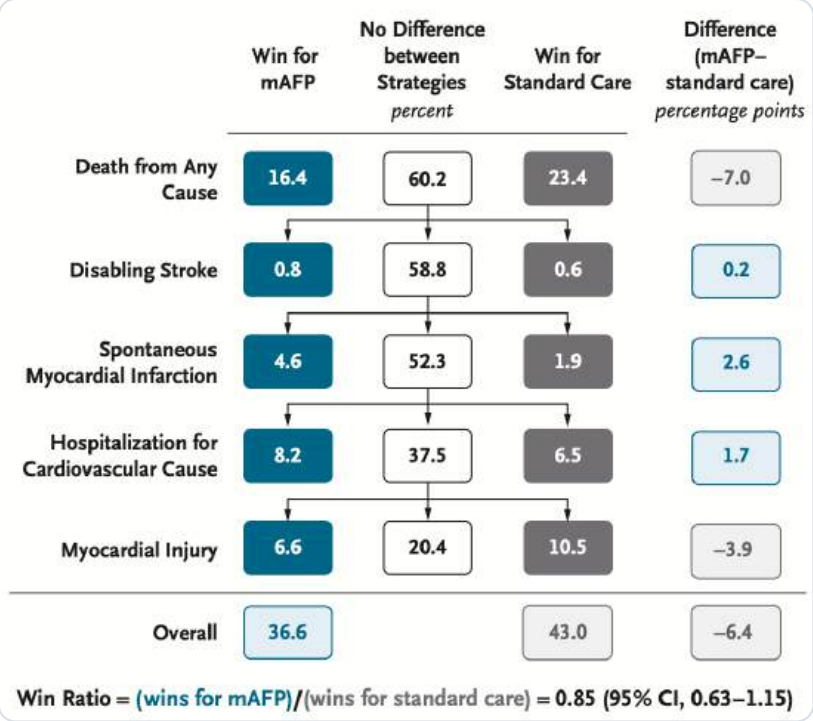
NT-proBNP split
3545
pg/mL

Different from prior HR-PCI Studies

Study	Population	Results
PROTECT II	Non-emergent HR-PCI requiring Impella vs IABP	Impella better at 90 day
PROTECT III	Non-emergent Impella HR-PCI, contemporary cohort	Modern outcomes superior
RESTORE EF	Non-emergent Impella HR-PCI, EF recovery study	EF and Symptom Improvements
IABP-BCIS1	Elective HR-PCI; EF ≤30%	Neutral
REVIVED-BCIS2	PCI vs OMT in stable ischemic LV dysfunction	Neutral
CHIP-BCIS3	urgent + HF-enriched + heterogeneous	Neutral

	Microaxial flow pump (n=148)	Standard care (n=152)
Indication for urgent PCI — no./total no. (%)	107/148 (72.3)	121/152 (79.6)
Myocardial infarction	87/107 (81.3)	103/121 (85.1)
Unstable angina	8/107 (7.5)	11/121 (9.1)
Acute or worsening heart failure	55/107 (51.4)	51/121 (42.1)
Ventricular arrhythmia	7/107 (6.5)	10/121 (8.3)
Number who received planned PCI — no./total no. (%)	148/148 (100.0)	151/152 (99.3)*
Number of PCI stages — no./total no. (%)		
1	138/148 (93.2)	124/151 (82.1)
2	10/148 (6.8)	25/151 (16.6)
3	0/148 (0.0)	2/151 (1.3)
Time from randomization to first PCI (IQR) — days [#] range	1 (0,4) 0-48	1 (0,3) 0-53
Time from randomization to last PCI in those who had staged PCI (IQR) — days [#] range	122 (53,190) 4-221 n=10	67 (36,136) 2-455 n=27

	Microaxial flow pump (n = 148)	Standard care (n = 151)
Procedure duration (IQR) — minutes	188 (152, 232)	139 (111, 185)
Duration of mAFP support (IQR) — minutes*	134 (113, 182)	-
Contrast volume (ml)	220 (180, 300)	200 (160, 270)
Radiation dose (IQR) — cGycm ²	7290 (2997, 12122)	6428 (3229, 11724)
Number of lesions treated — IQR	3 (2,3)	2 (2,3)
Number of vessels treated — IQR	2 (2,3)	2 (2,3)
Number of stents used — IQR	3 (2,4)	3 (2,3)
Intravascular imaging used — no./total no. (%)	136/148 (91.9)	141/151 (93.4)
Calcium modification — no./total no. (%)	106/148 (71.6)	107/151 (70.9)
Rotational atherectomy	59/106 (55.7)	64/107 (59.8)
Intravascular lithotripsy	86/106 (81.1)	71/107 (66.4)
Laser atherectomy	2/106 (1.9)	1/107 (0.9)
Left mainstem PCI — no./total no. (%)	107/148 (72.3)	111/151 (73.5)
Single stent	59/107 (55.1)	64/111 (57.7)
Two stents	48/107 (44.9)	47/111 (42.3)
Attempted CTO PCI — no./total no. (%)	38/148 (25.7)	35/151 (23.2)

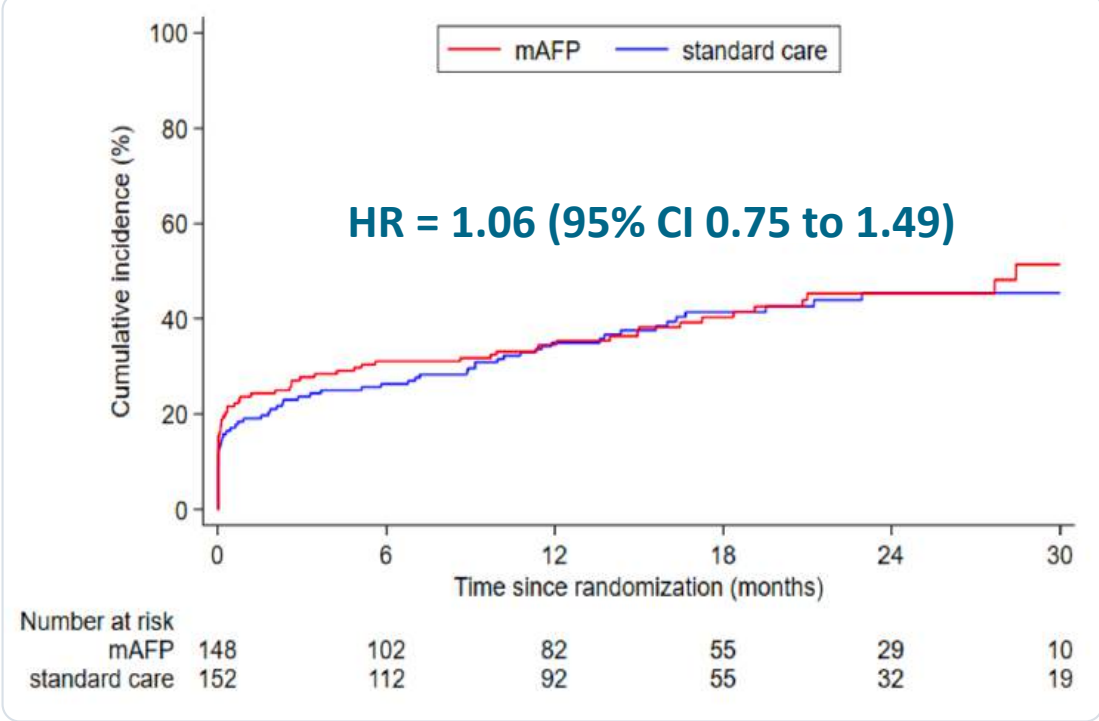


WR 0.85



Excluding PPMI
WR 0.92

95% CI 0.65–1.32;
win diff. –2.5 pct points



TTFE composite including PPMI
79.3% vs 73.6%

111/140 vs 100/139;
HR 1.24 (0.94–1.62)



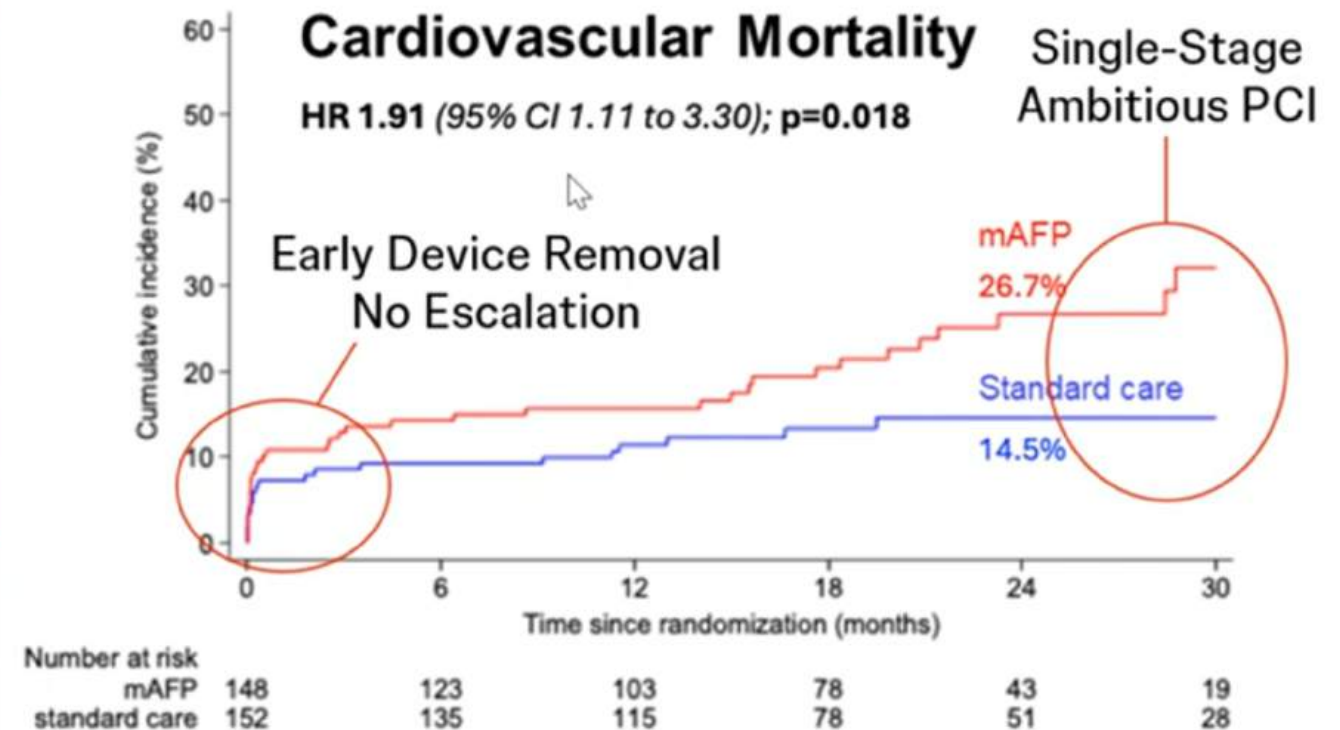
Excluding PPMI
45.3% vs 45.4%

64/148 vs 65/152;
HR 1.06 (0.75–1.49)

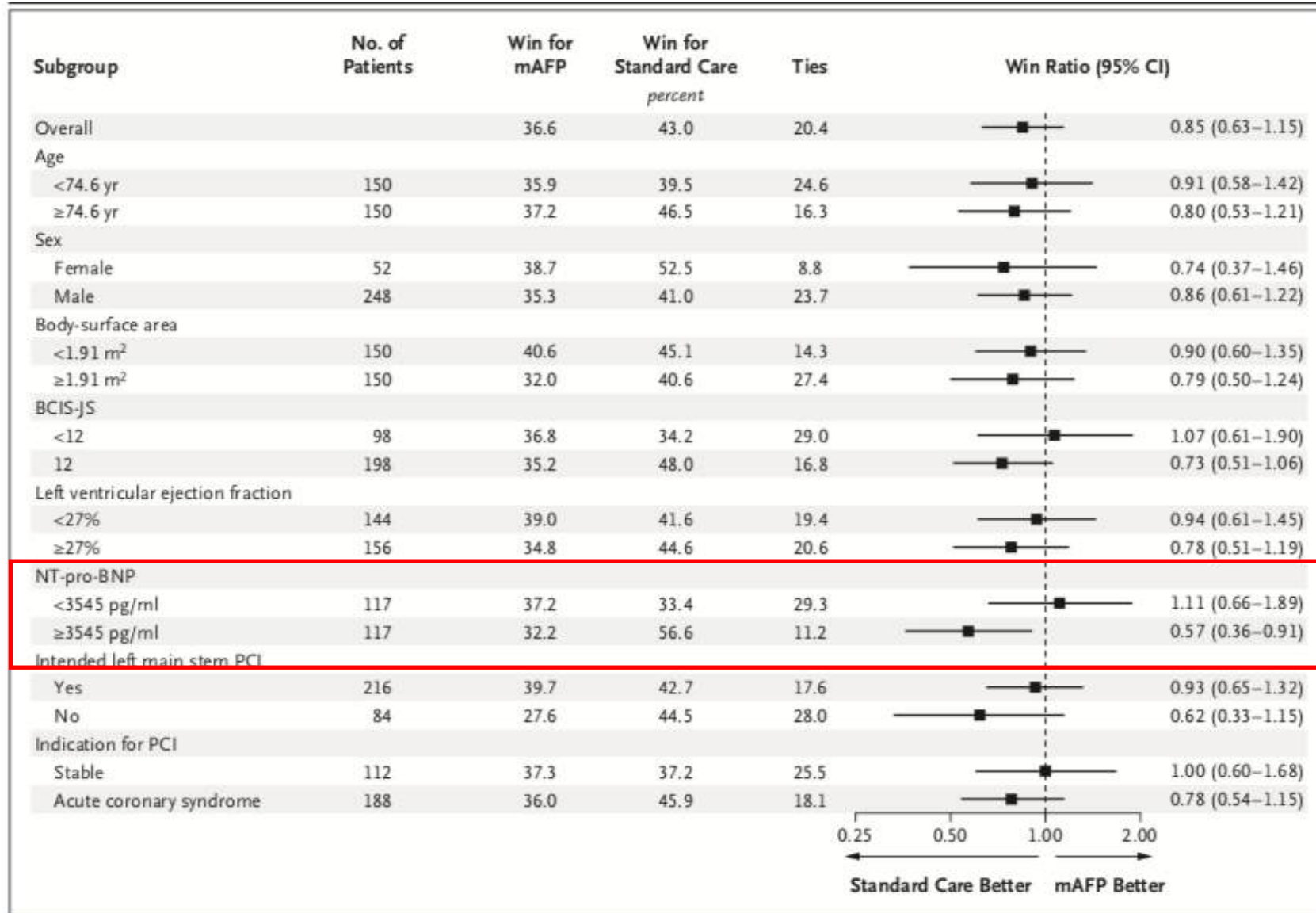
* Higher Pre-PCI hs-troponin in standard care (13× ULN vs 5× ULN) complicates interpretation of PPMI defined as rise in hs-troponin by ≥20% or 5× ULN after PCI in favor of the standard care.

Index procedure intensity

Measure	mAFP	Standard
Procedure duration (median, IQR)	188 min (152–232)	139 min (111–185)
No. of lesions treated (median, IQR)	3 (2–3)	2 (2–3)
Single-stage PCI	93.2%	82.1%
2-stage PCI	6.8%	16.6%
3-stage PCI	0.0%	1.3%
Time to last staged PCI (among staged cases)	122 d (53–190)	67 d (36–136)
Bailout MCS in control strategy	0.7%	6.0% total

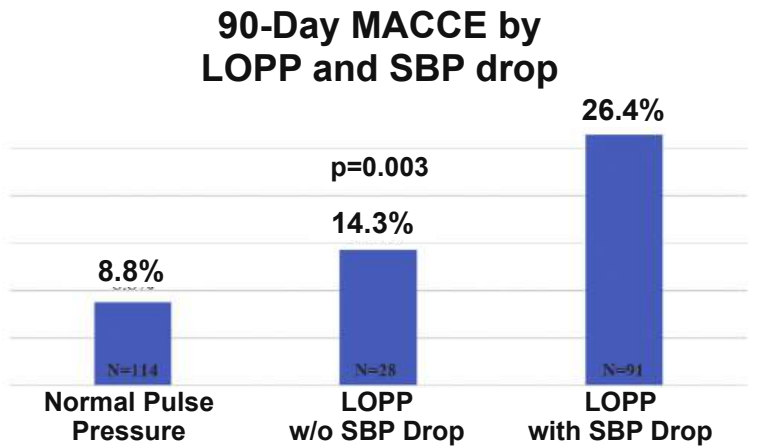
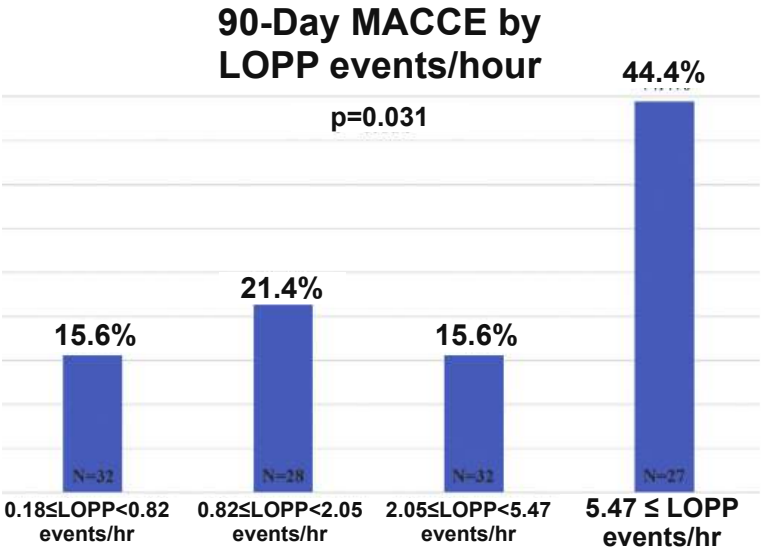


CHIP-BCIS3 trial: subgroup analysis





PROTECT III: Hemodynamic stability provides a window for higher quality intervention – not simply more interventions



PROTECT III Sub Study: LOPP vs No LOPP

Loss of Pulse Pressure (LOPP) is a physiologic warning sign of residual myocardial vulnerability despite Impella support.

49%
experienced
LOPP

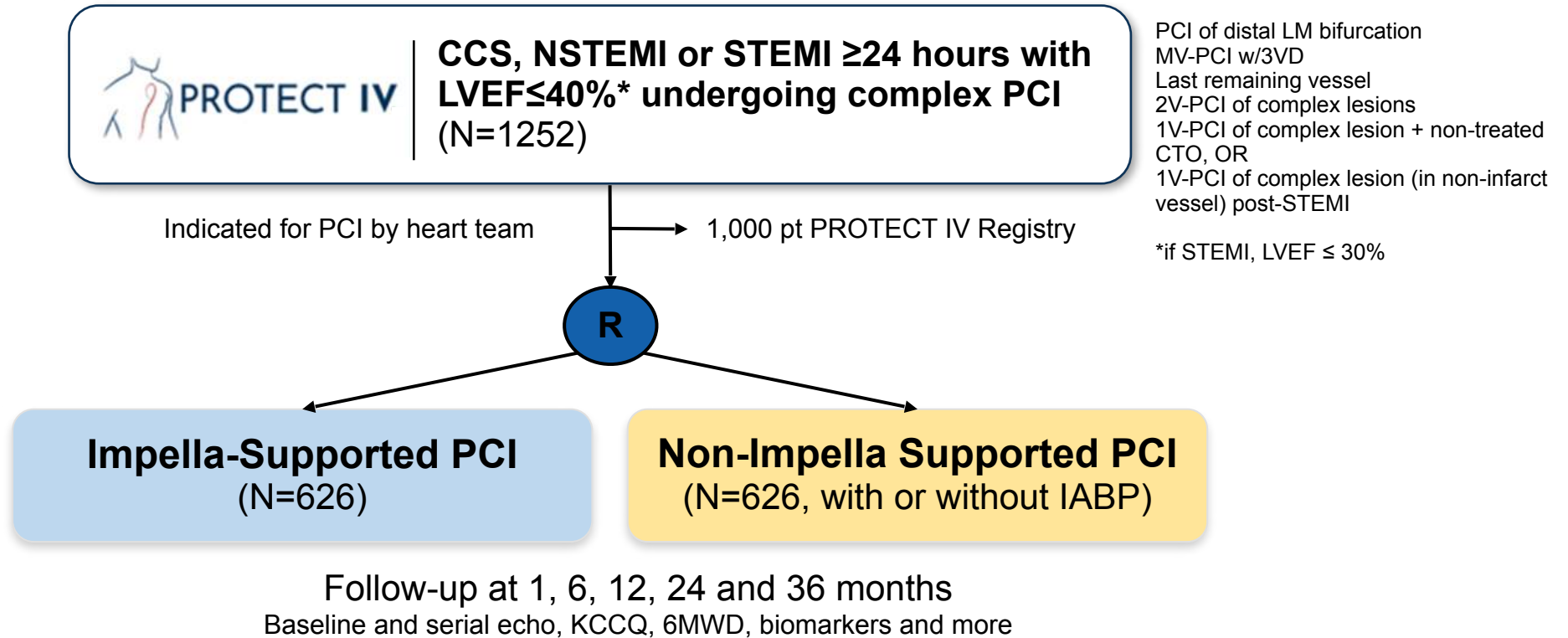
**90-day
MACCE
23.5% vs
8.8%**

**90-day
mortality
20.2% vs 7.9%**

LOPP patients should be identified as ultra-high-risk patients, warranting consideration of:

- Right heart catheterization (if not already performed)
- Limiting or ceasing further revascularization
- Support beyond the lab with CICU admission
- Consultation and close long-term follow-up with advanced HF specialists to optimize GDMT and other therapies.

LOPP provides a mechanistic reason to pace revascularization in low-reserve patients, even when support is present.

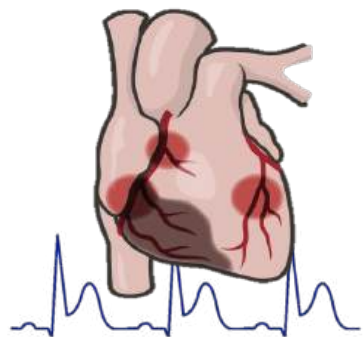


Hypothesis: By providing effective hemodynamic support in high-risk patients with complex CAD and reduced left ventricular function, PCI with Impella will be safer and will facilitate higher rates of optimal and complete revascularization, which will lead to improved long-term event-free survival, quality of life and functional outcomes

Primary Endpoint: The composite of all-cause death, stroke, durable LVAD implant or heart transplant, MI or hospitalization for cardiovascular (CV) causes

Major Sub-Studies: Right heart catheterization, renal function, viability (CMR at baseline and 6 months)

MULTICENTER, RANDOMIZED, OPEN-LABEL TRIAL



355

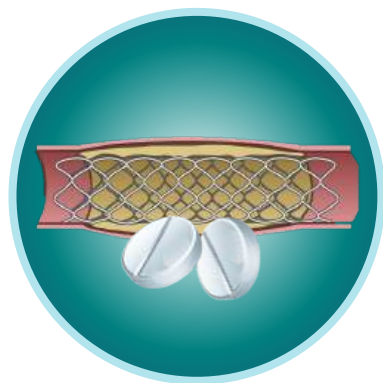
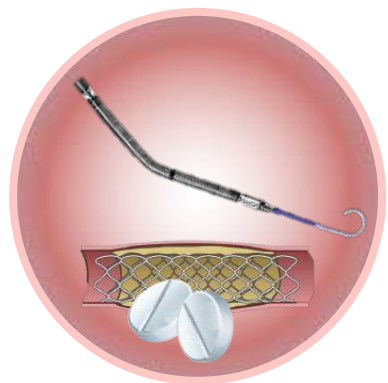
Patients with **AMI-related
CARDIOGENIC SHOCK**

RANDOMIZED

Impella CP

1:1

Guideline-directed
therapy only

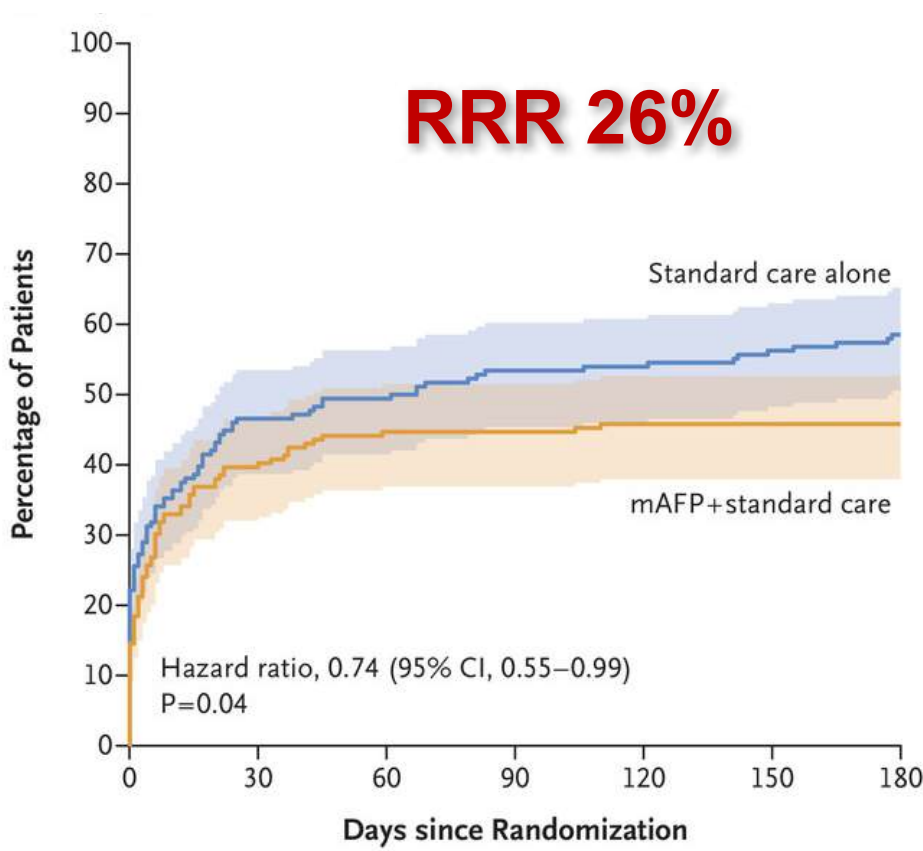


Baseline characteristics:

- Median lactate levels: 4.6 mmol/l
- Median LVEF: 25%
- RV failure, OHCA, comatous pts: excluded
- SCAI class: C (classic) 55%, D (deteriorating) 28% and E (extremis) 16%.

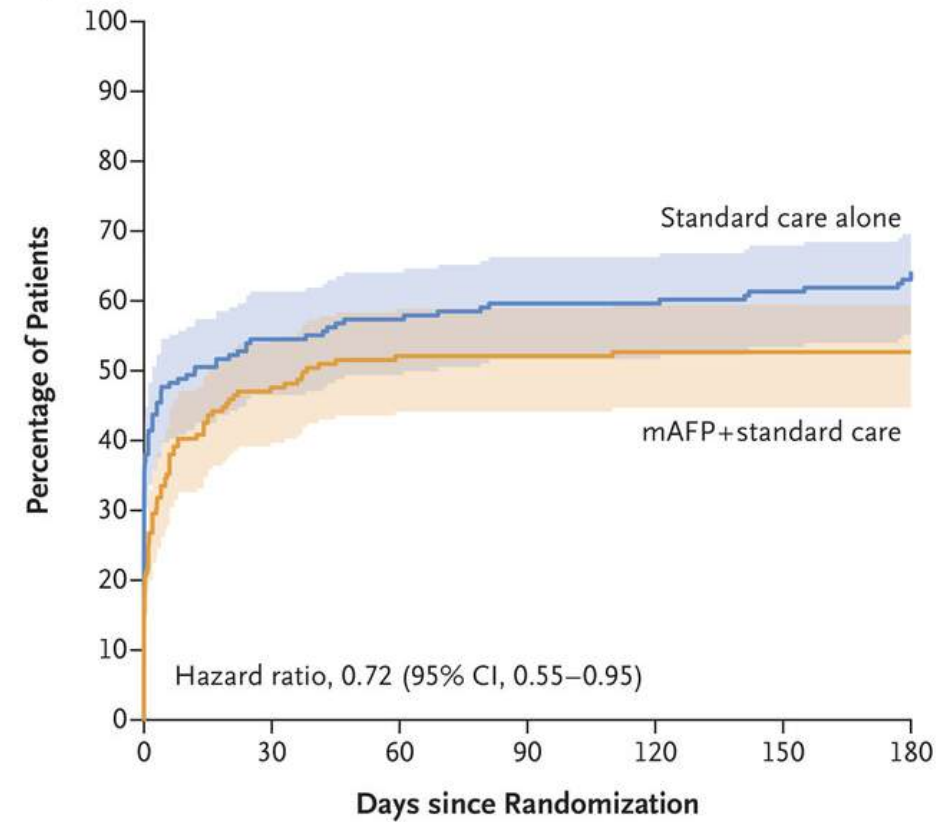


- **Primary EP:** All-cause death at 180 days



No. at Risk							
Standard care	176	94	89	82	81	77	72
mAFP+standard care	179	108	99	99	97	97	97

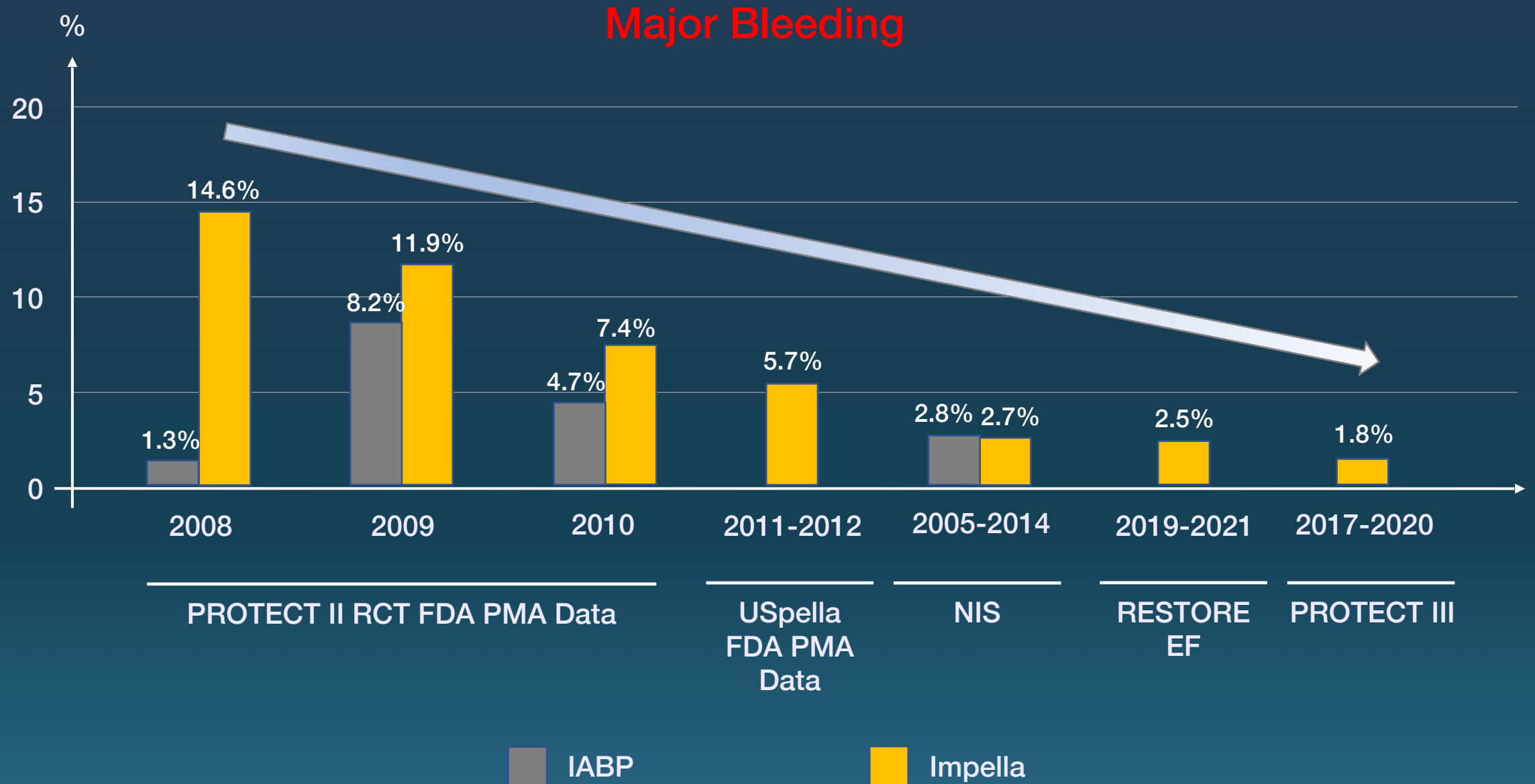
ALL-CAUSE DEATH



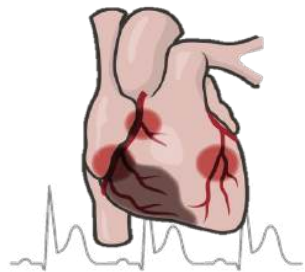
No. at Risk							
Standard care	176	80	75	71	71	68	64
mAFP+standard care	179	93	85	85	84	84	84

COMPOSITE SECONDARY EP: escalation of treatment to additional MCS, heart transplantation, or death.

CONTINUOUS SAFETY IMPROVEMENT OVER TIME IN HR-PCI



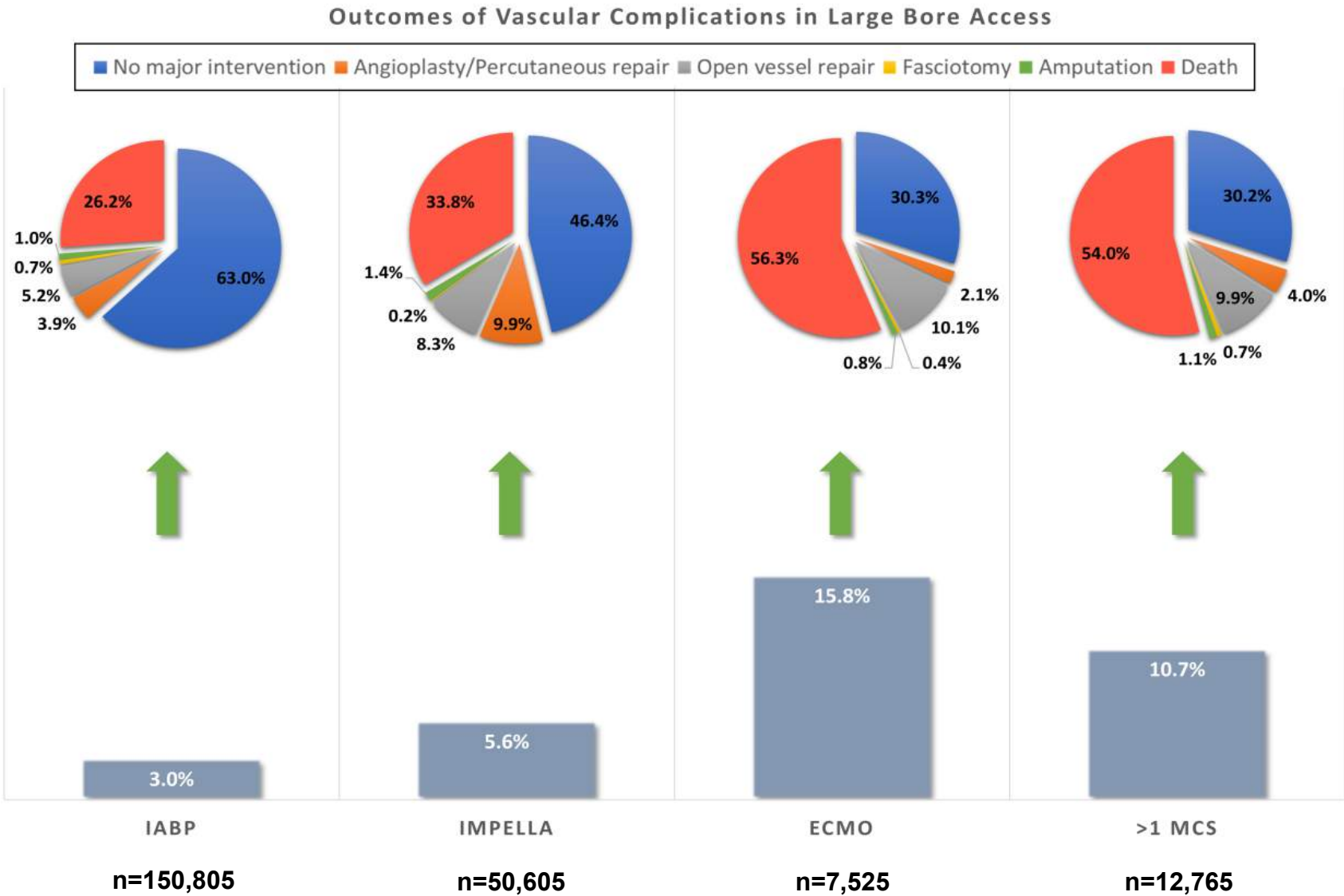
Rates and impact of vascular complications in MCS



221,700

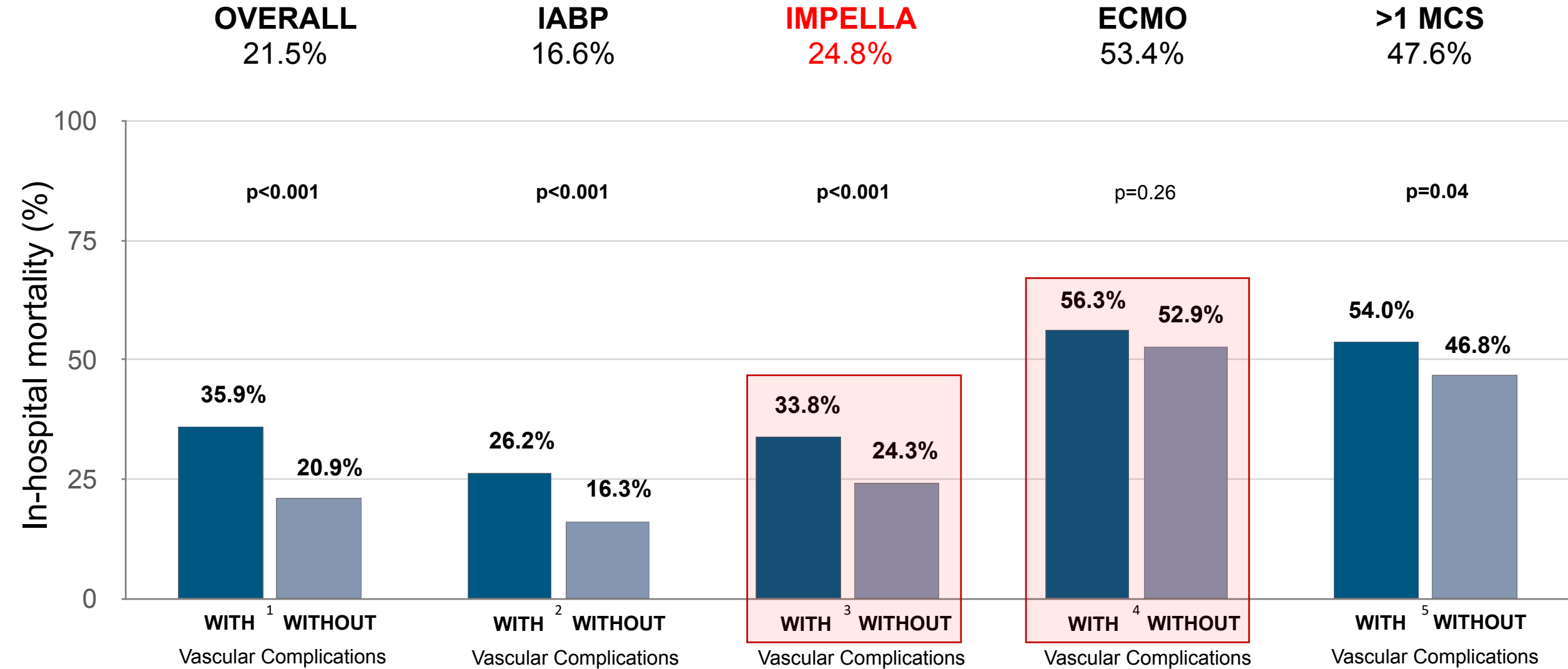
Patients requiring **MCS**
(17% elective admission)
including
AMI
Acute HF
VHD
Cardiac arrest
Ventricular arrhythmias
Cardiomyopathy

Frequency of vascular complications

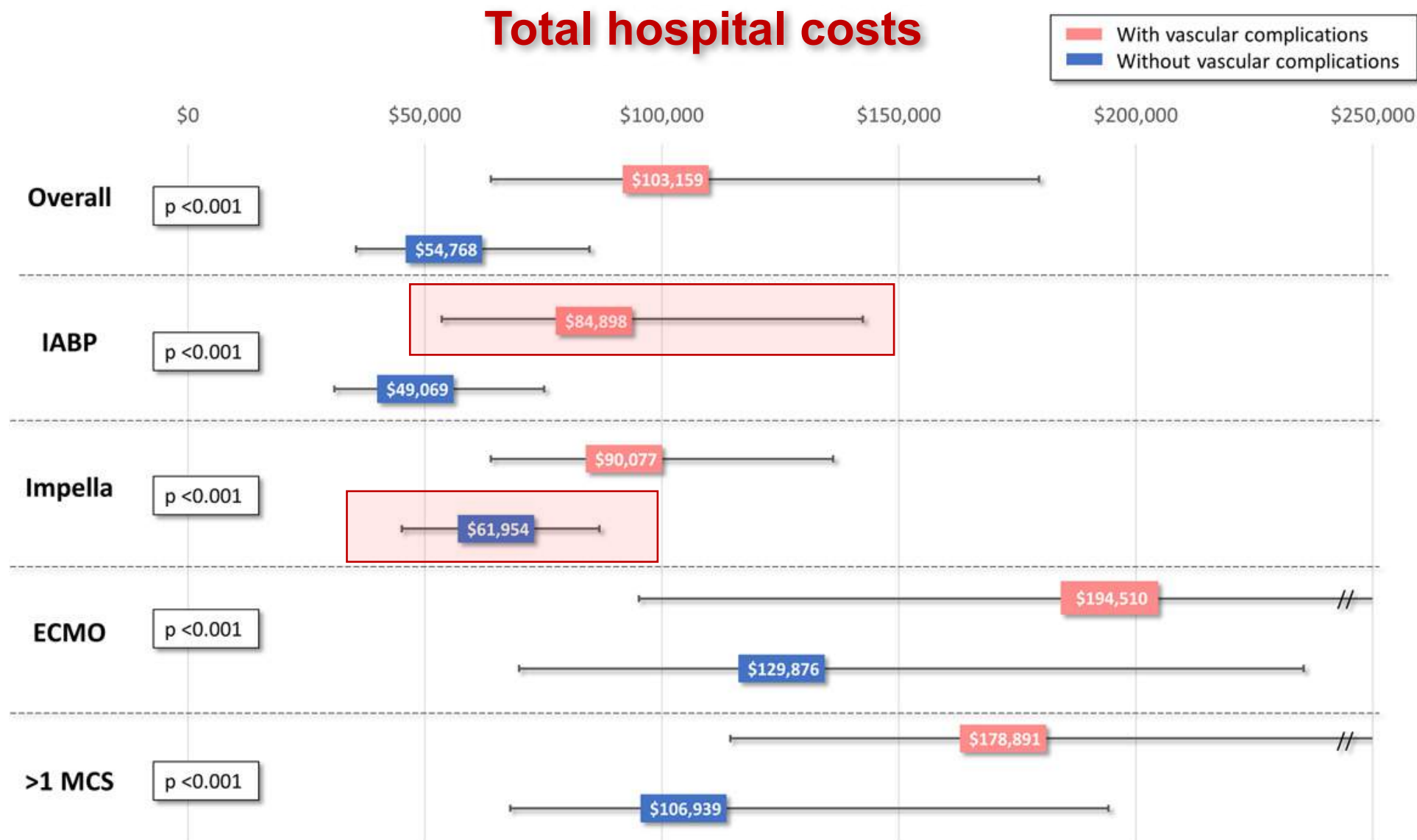


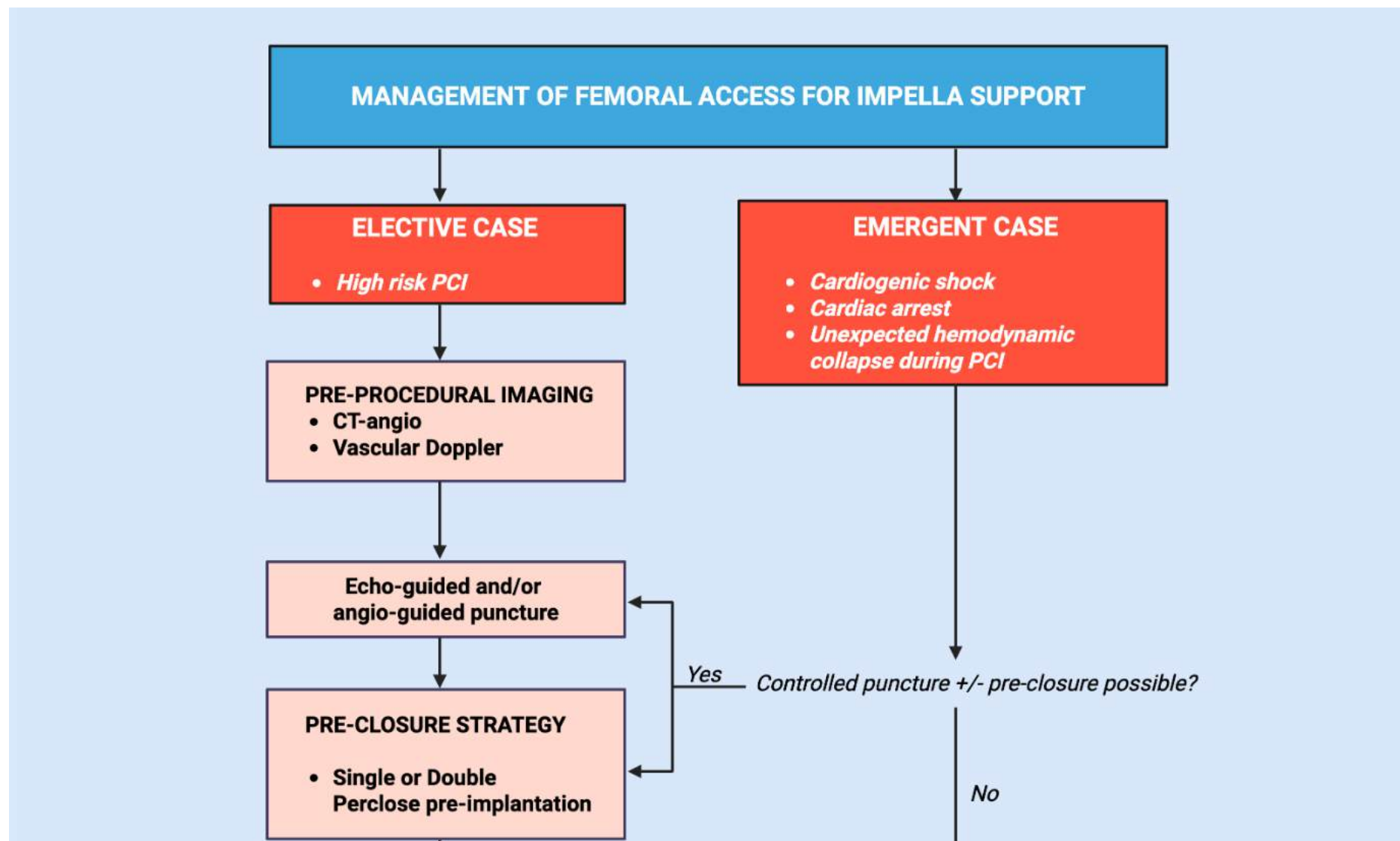


Rates and impact of vascular complications in MCS



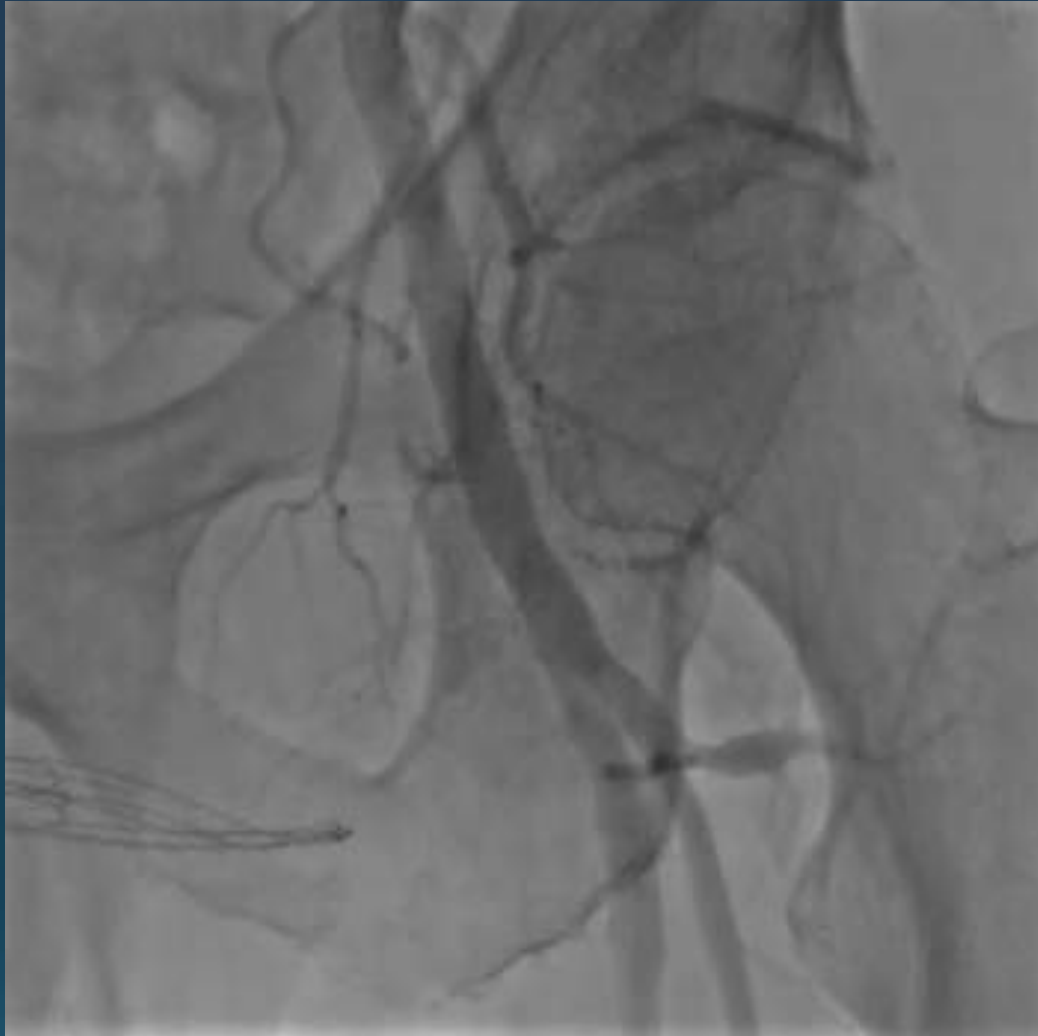
Rates and impact of vascular complications in MCS





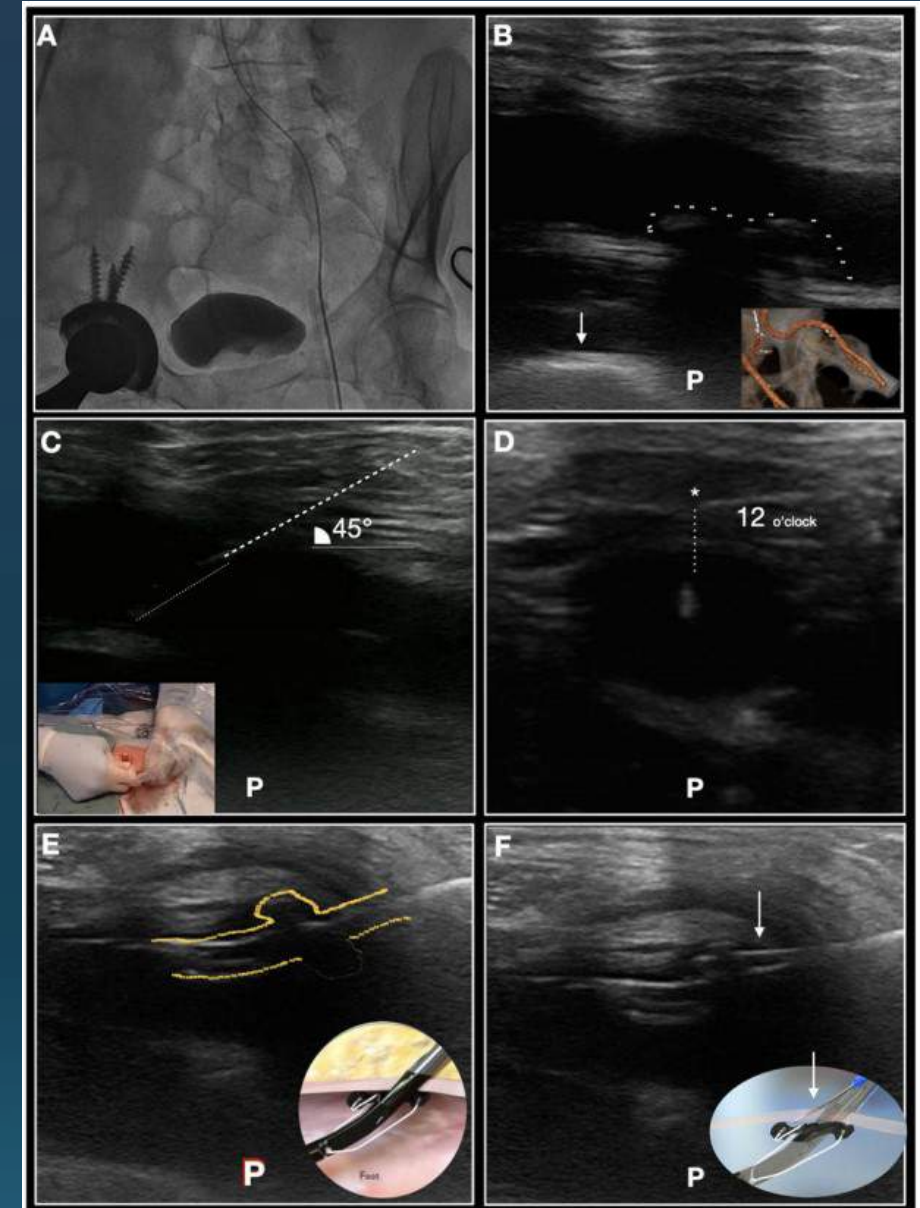
CLINICAL VASCULAR ACCESS PRE-CLOSURE SCENARIO #1





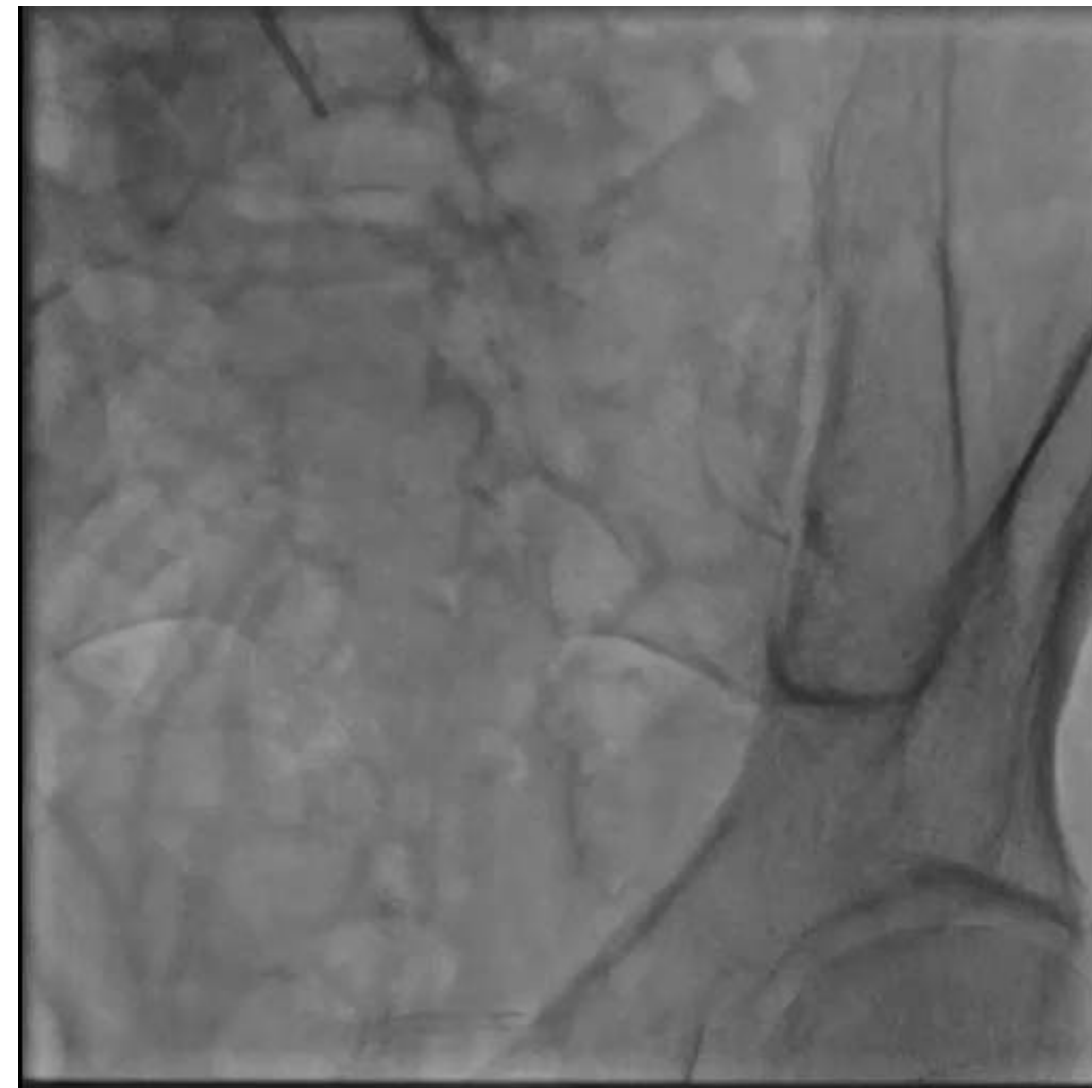
Angio + US guided puncture

2 ProStyle pre-implanted



Advantages of pre-closure

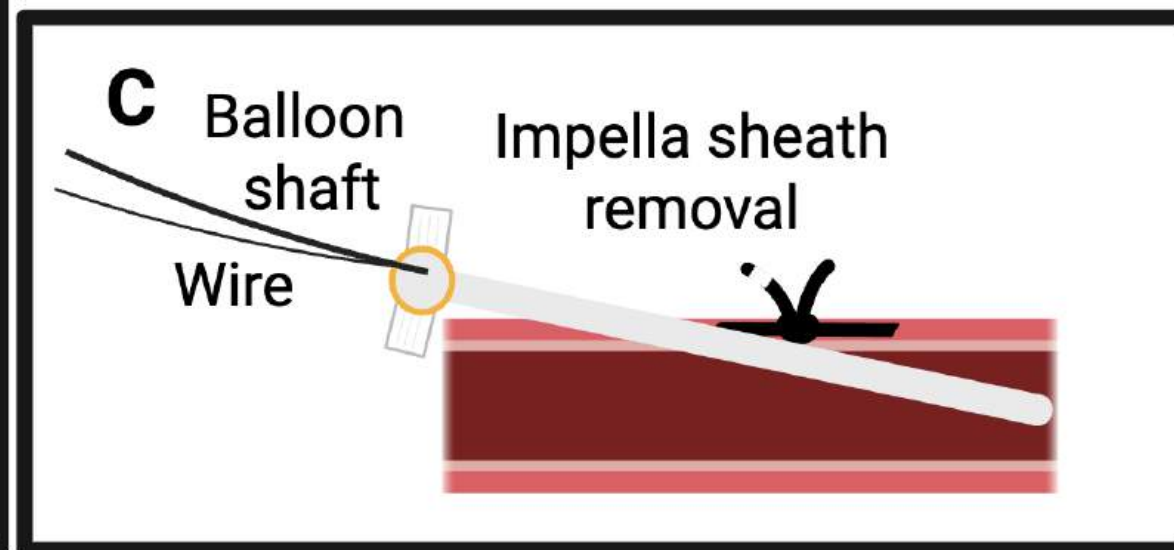
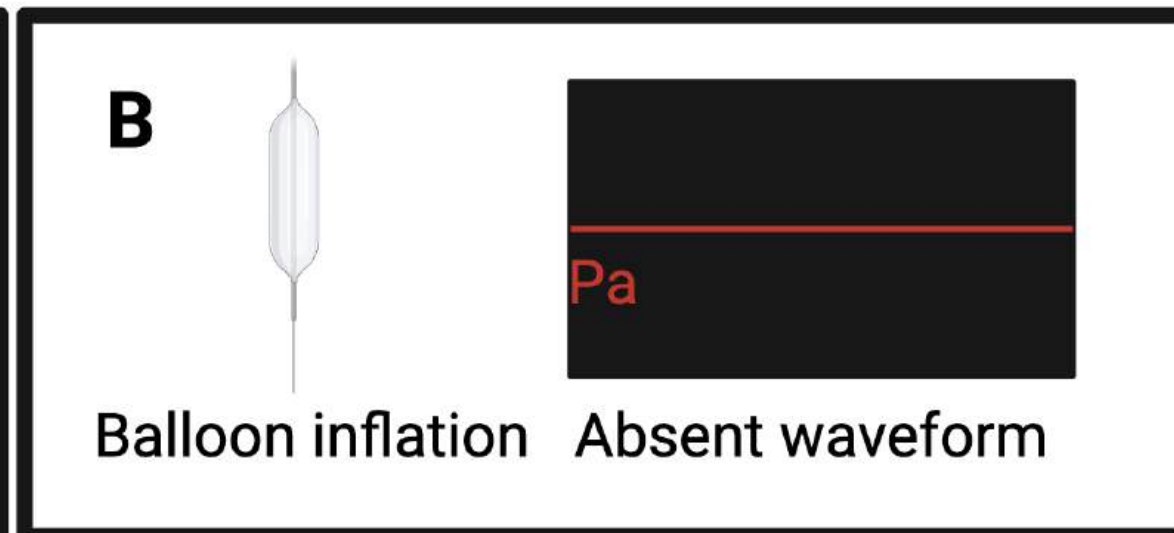
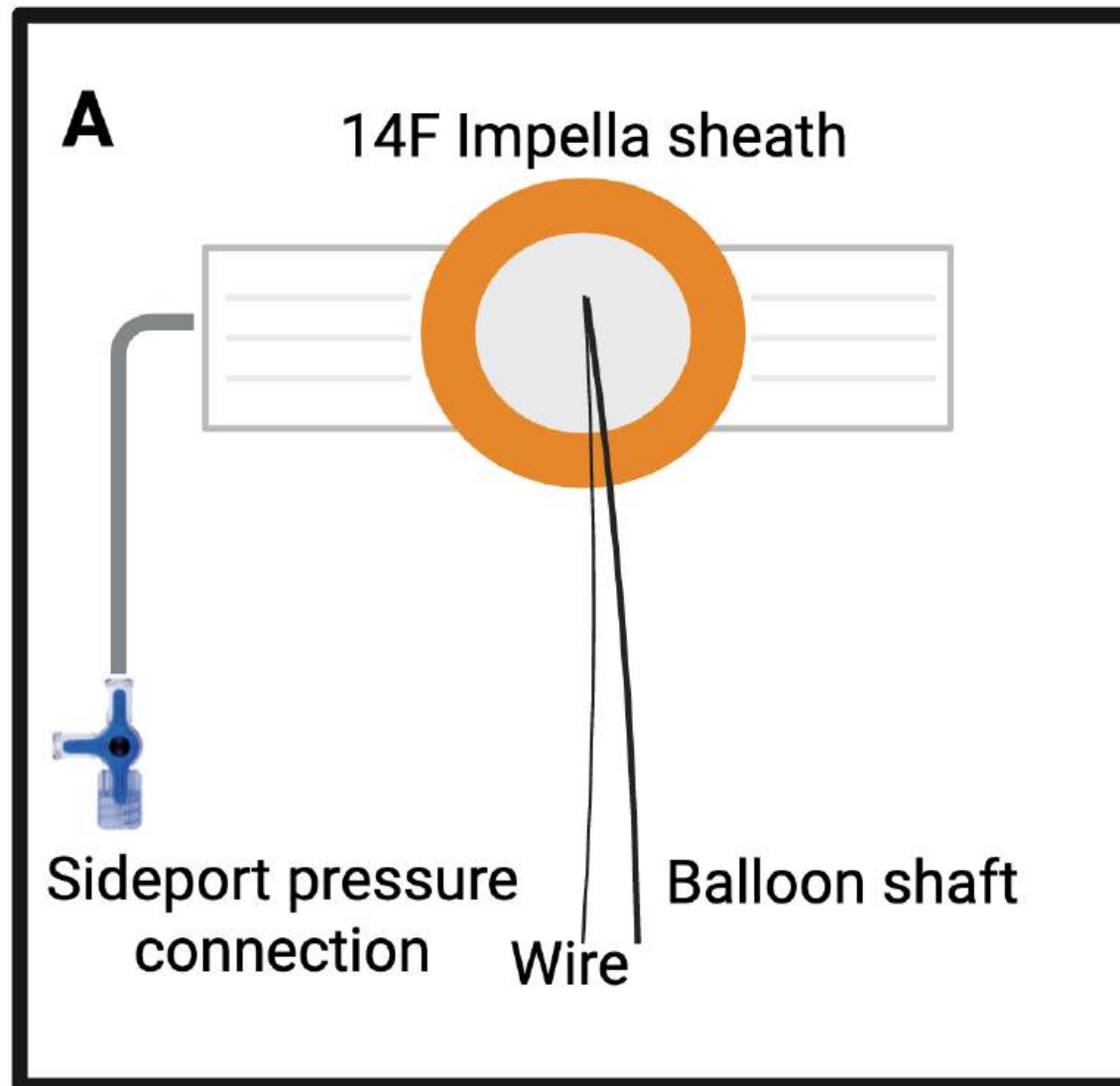
- ❖ **Careful pre-procedural work-up:**
assess and prepare femoral access site → imaging (CTA, angiography, US) and imaging-guided access.
- ❖ **Ready for access closure** after Impella and 14Fr sheath removal (with or without balloon-assisted hemostasis) → minimize bleeding.



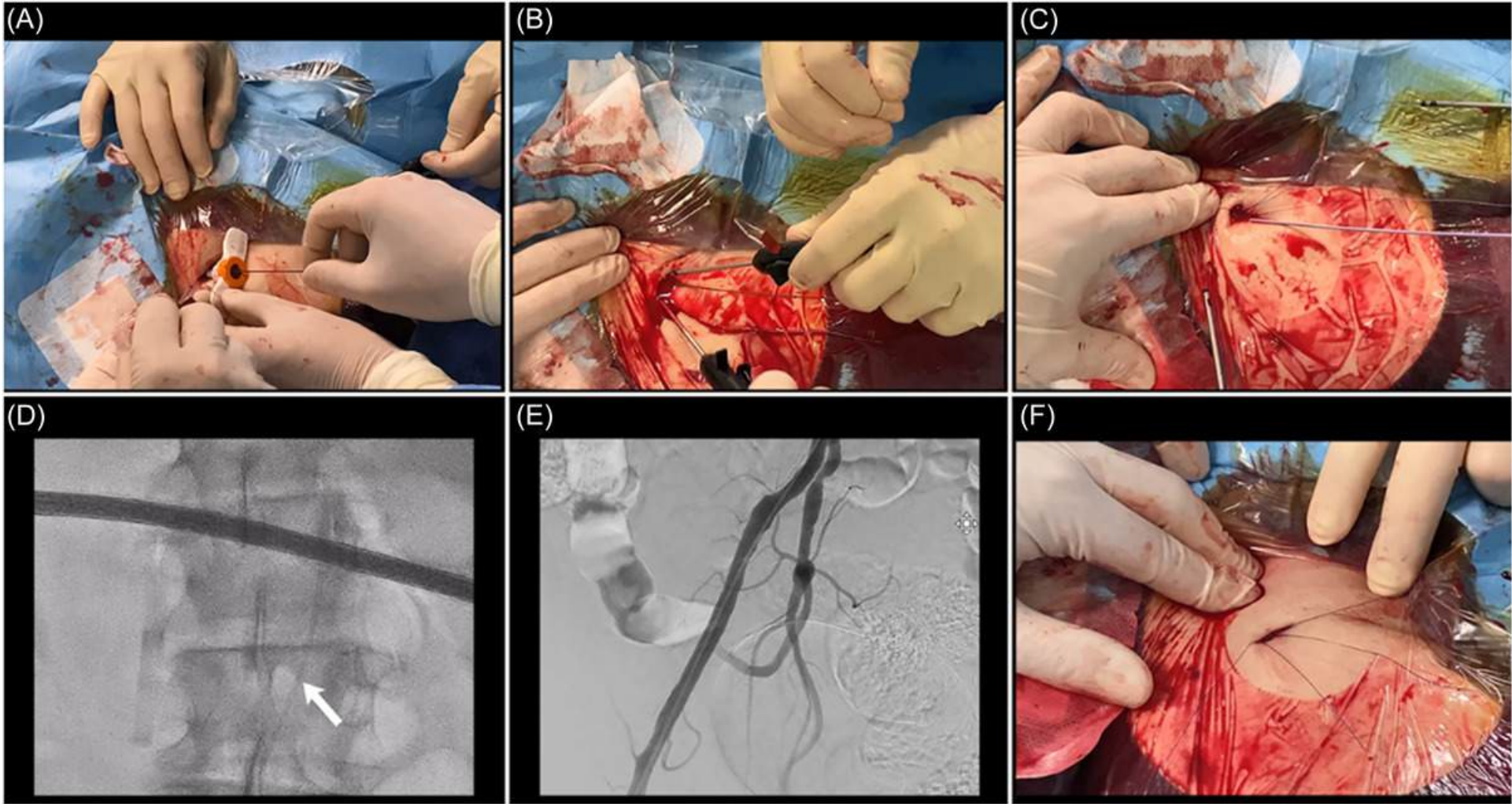
Hemostasis with 2 pre-implanted ProStyles and final angio result

Balloon-assisted hemostasis

From ipsilateral access (through the Impella 14 Fr sheath)



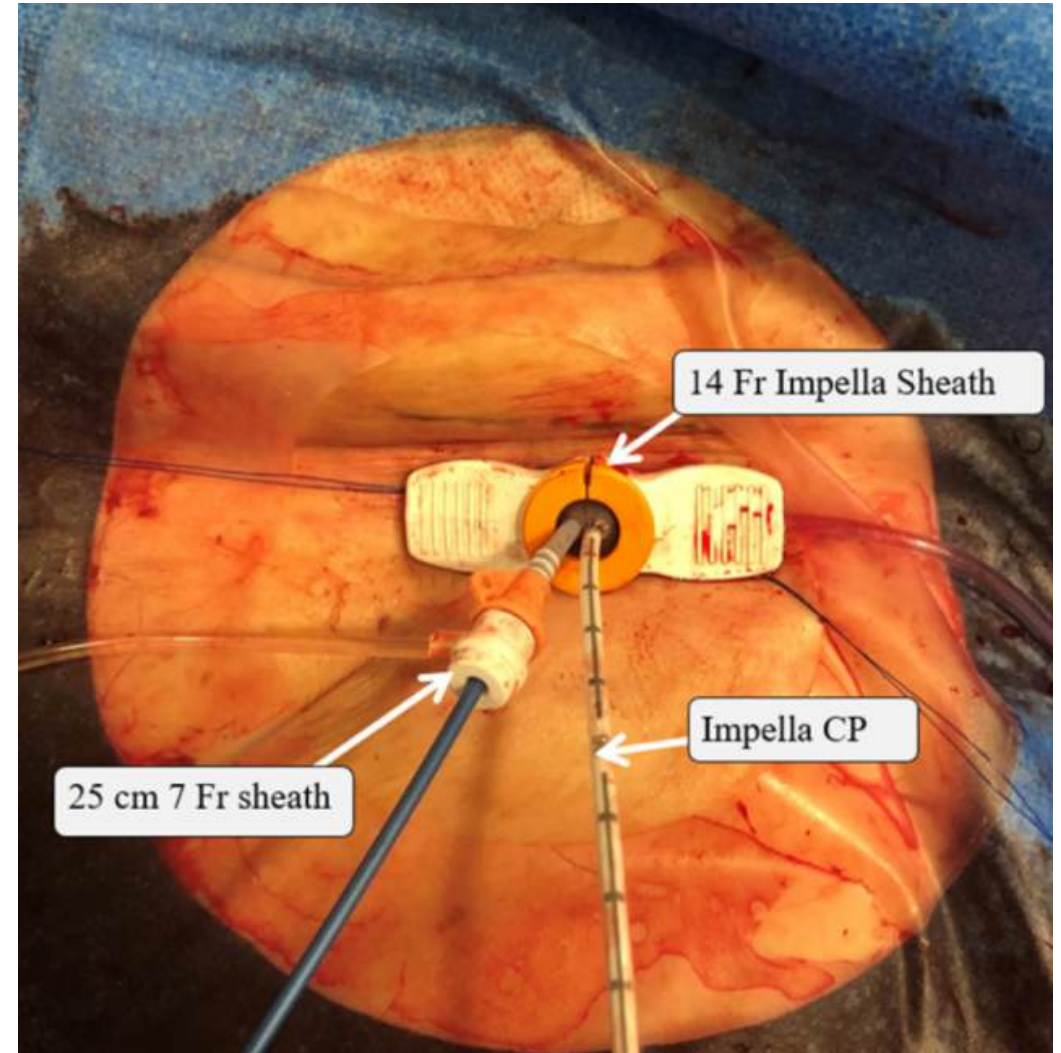
Antegrade angiographic control

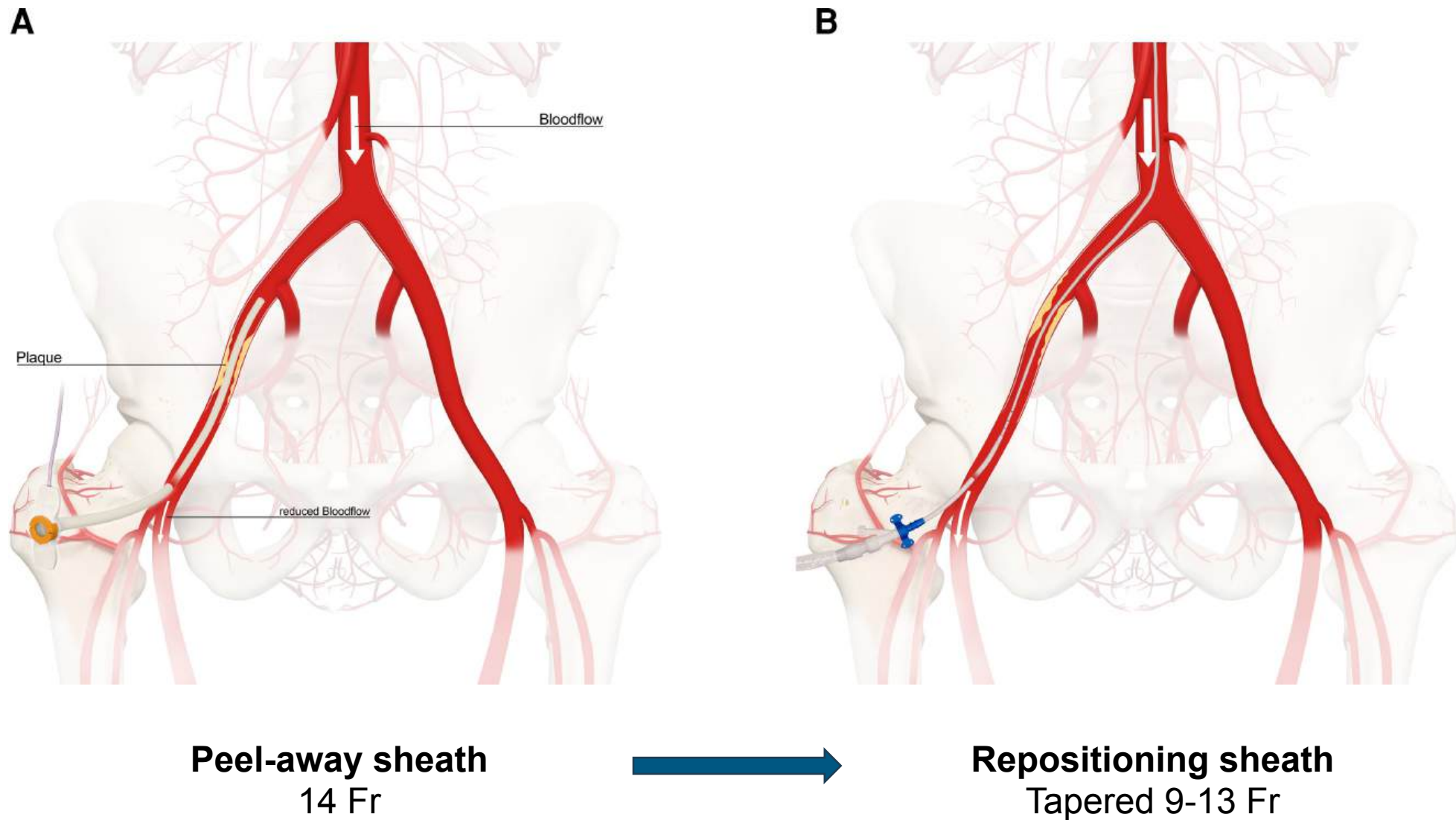


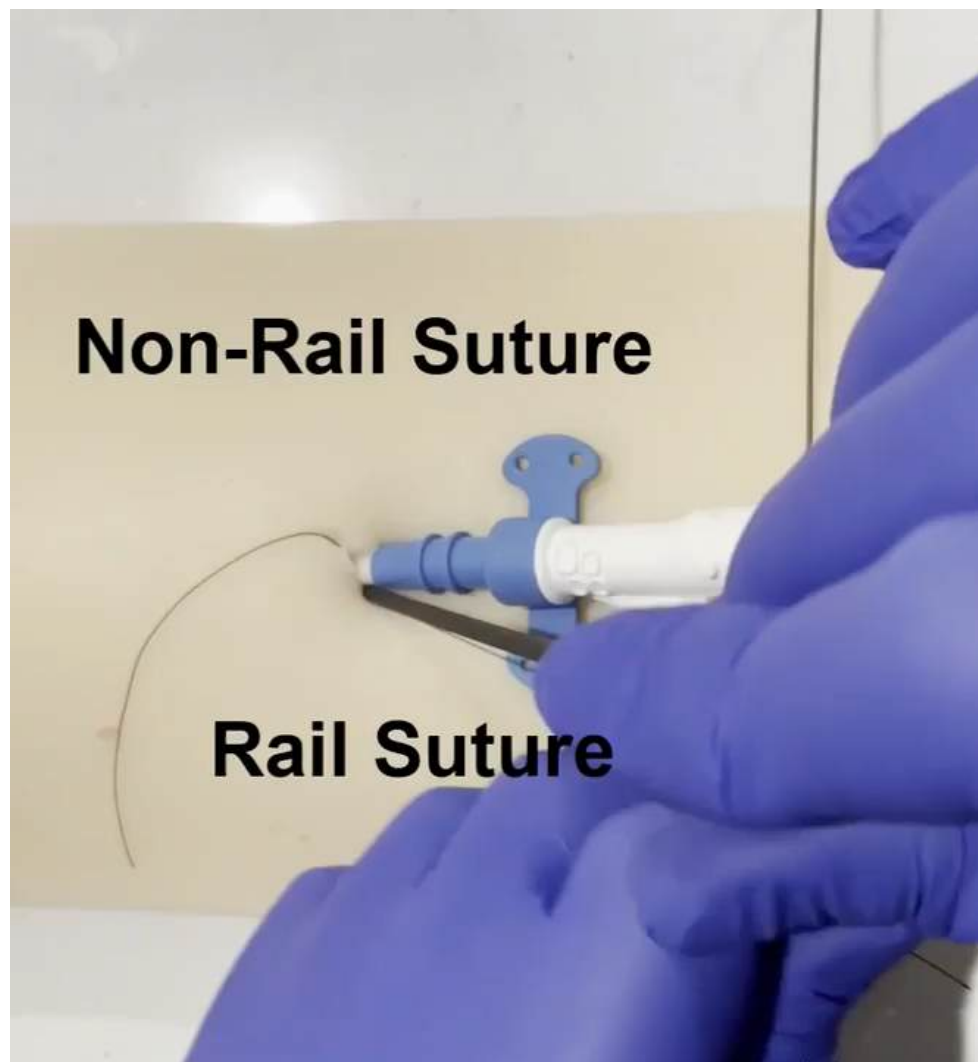
Antegrade angiographic control using a JR4 4Fr over a 0.035" guidewire
after single access Impella protected PCI

Advantages of preclosure

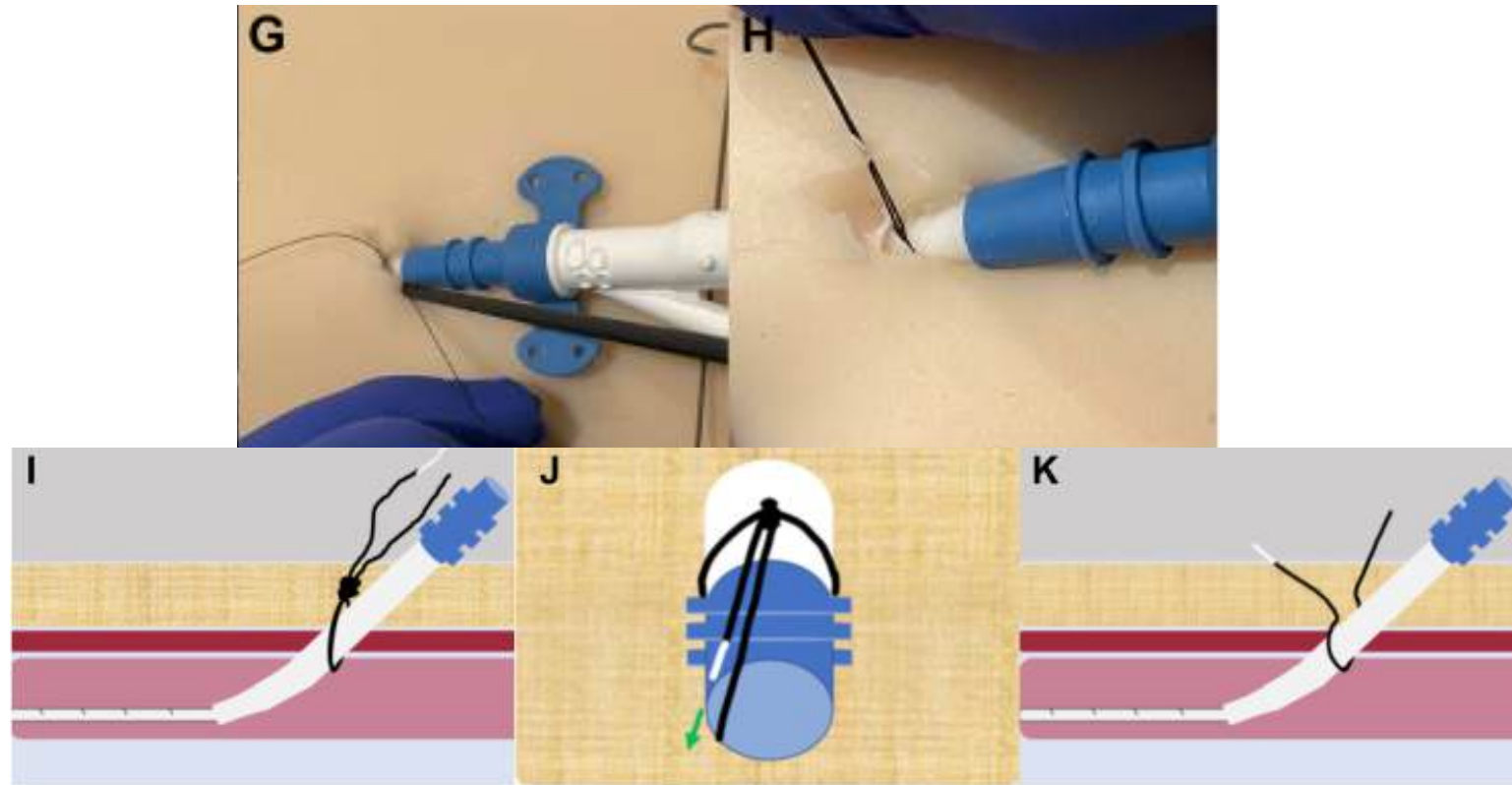
- ❖ Careful pre-procedural work-up: assess and prepare femoral access site → imaging (CTA, angiography, US) and imaging-guided access.
- ❖ Ready for access closure after Impella and 14Fr sheath removal (with or without balloon-assisted hemostasis) → minimize bleeding.
- ❖ Allows to **tighten the ProStyle sutures over the 9-Fr repositioning sheath**, once the 14-Fr peel-away sheath has been removed → prevent bleeding around Impella sheath

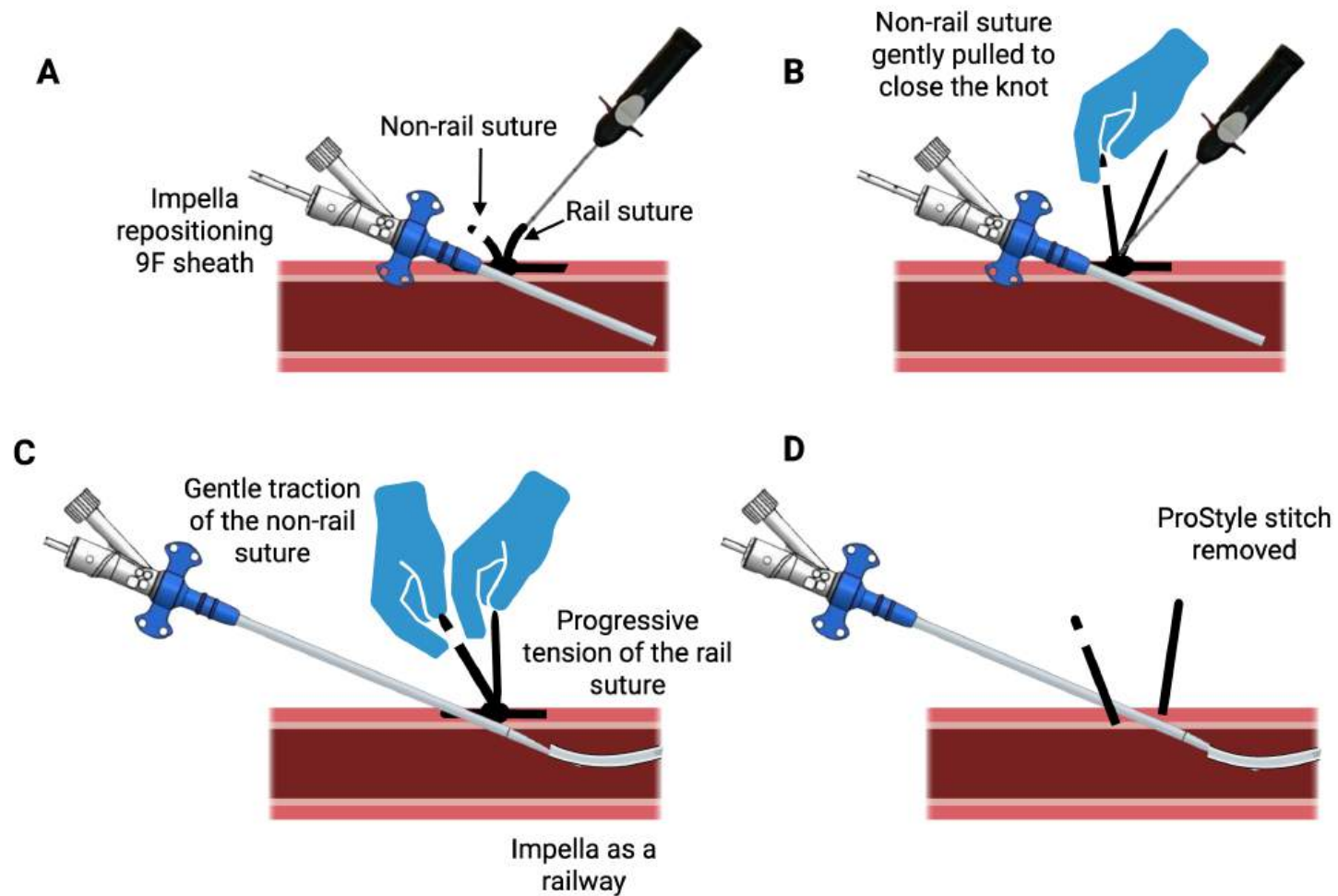






Preclose Cinching “C-Stitch” to Aid Hemostasis After Impella Insertion



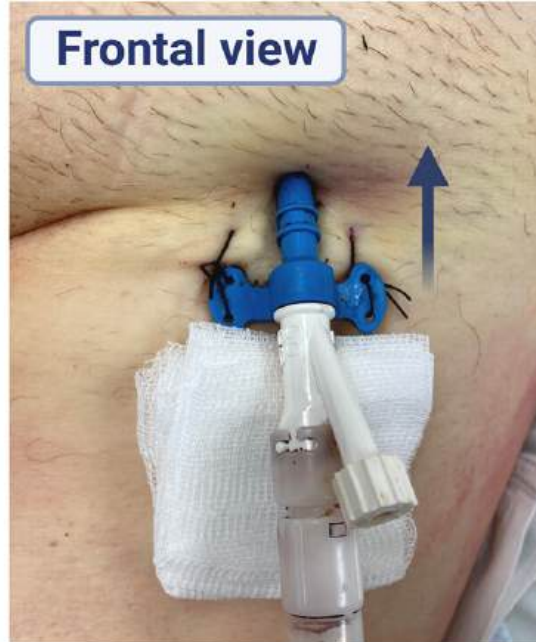


Proper positioning of the femoral Impella-sheath to avoid cannula-related oozing

Lateral view

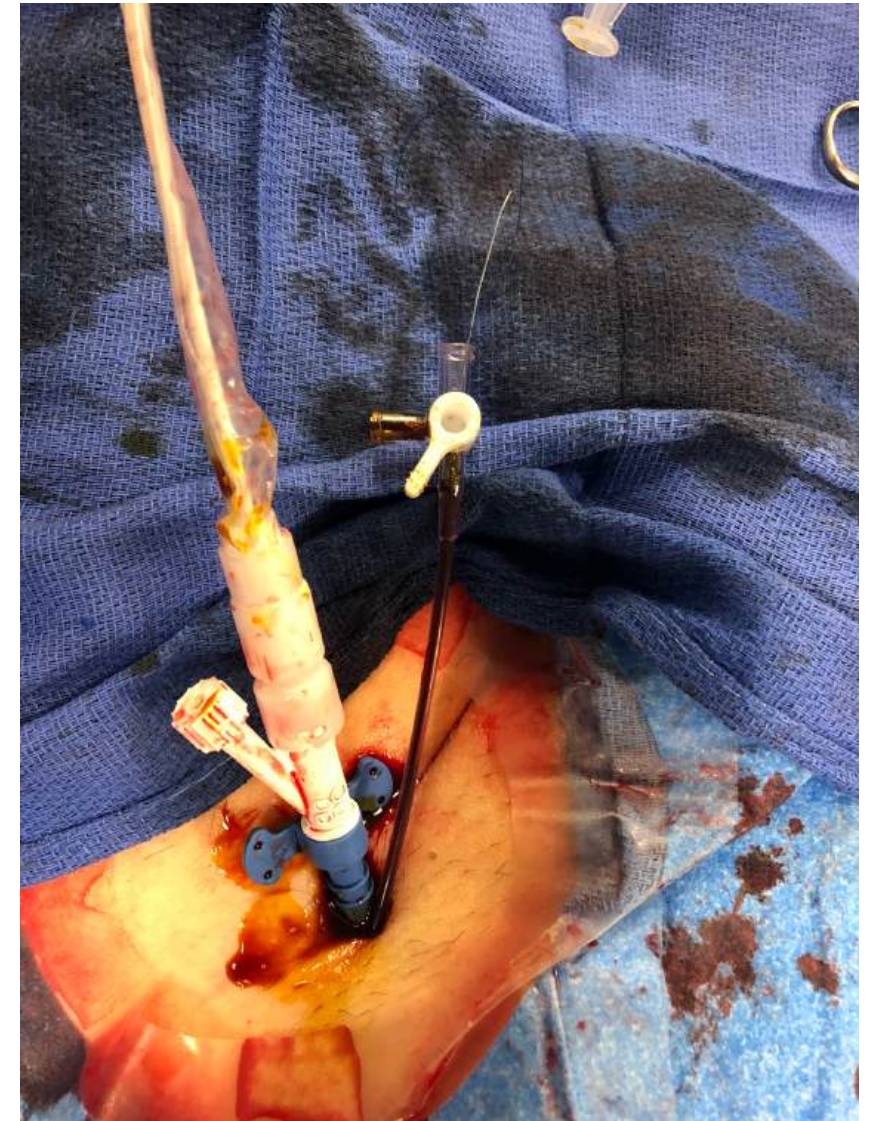
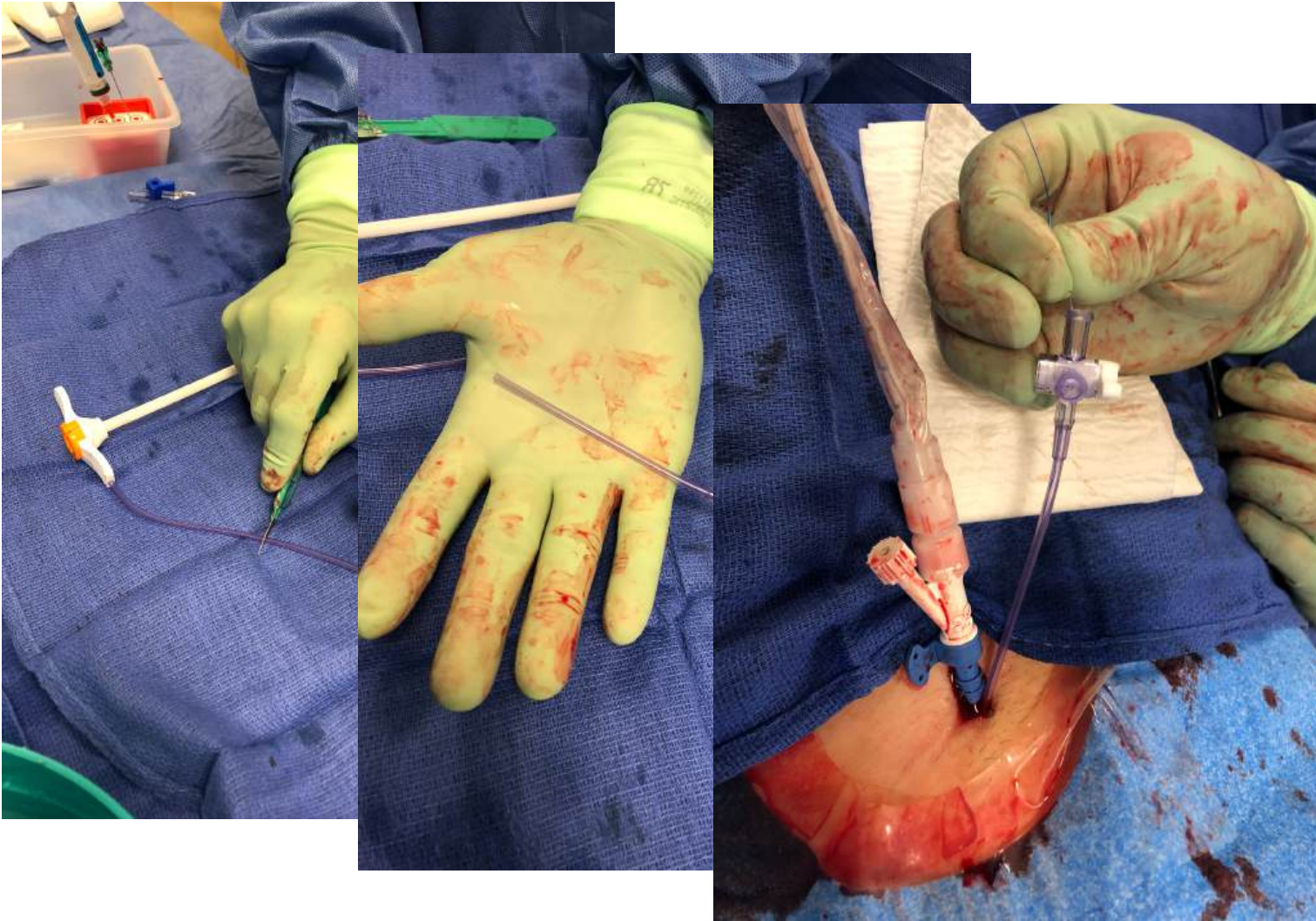


Frontal view



- ✓ Echo-guided cannulation
- ✓ Pull-up stitching technique pushing the cannula well into the skin
- ✓ Gauze to maintain the angle of insertion

Potential drawbacks associated to (not due to) pre-closure

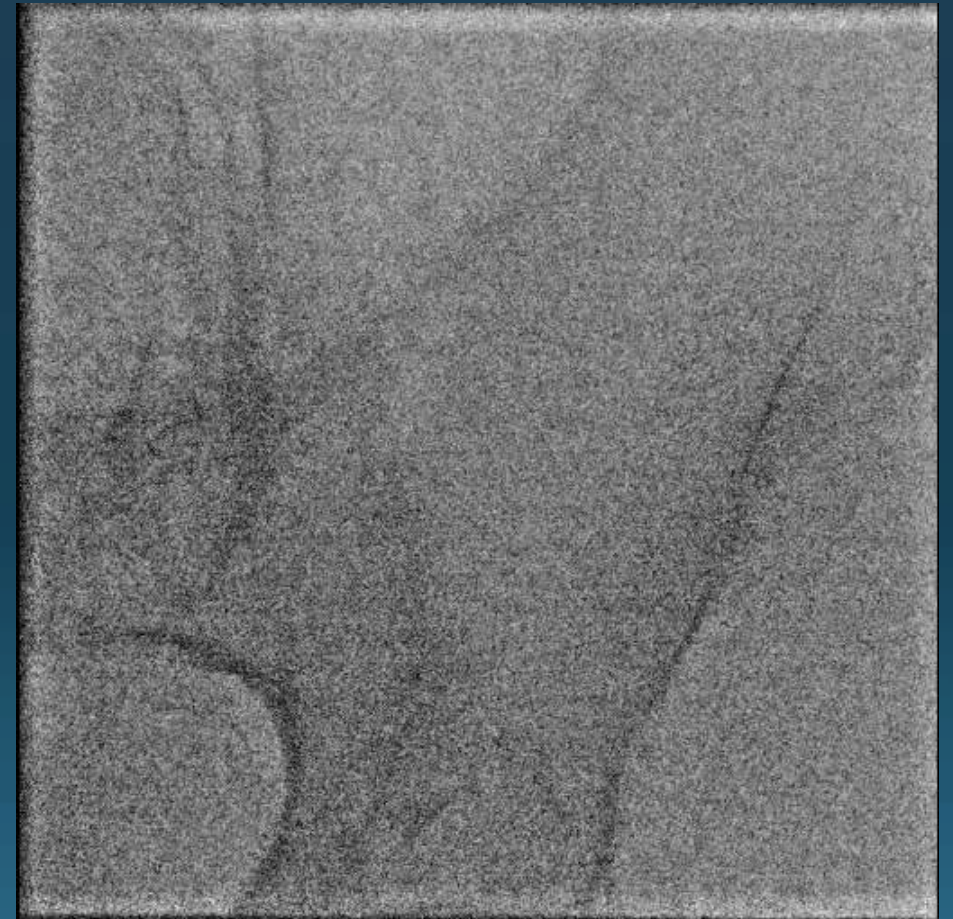
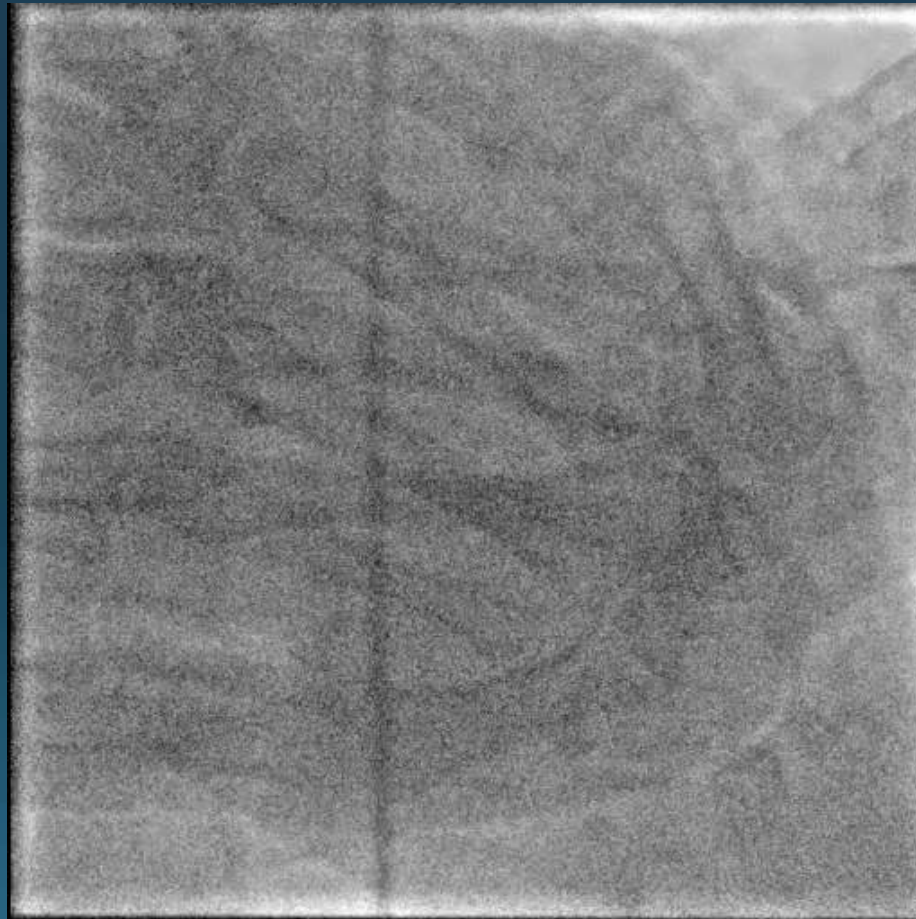


CLINICAL VASCULAR ACCESS POST-CLOSURE SCENARIO #2

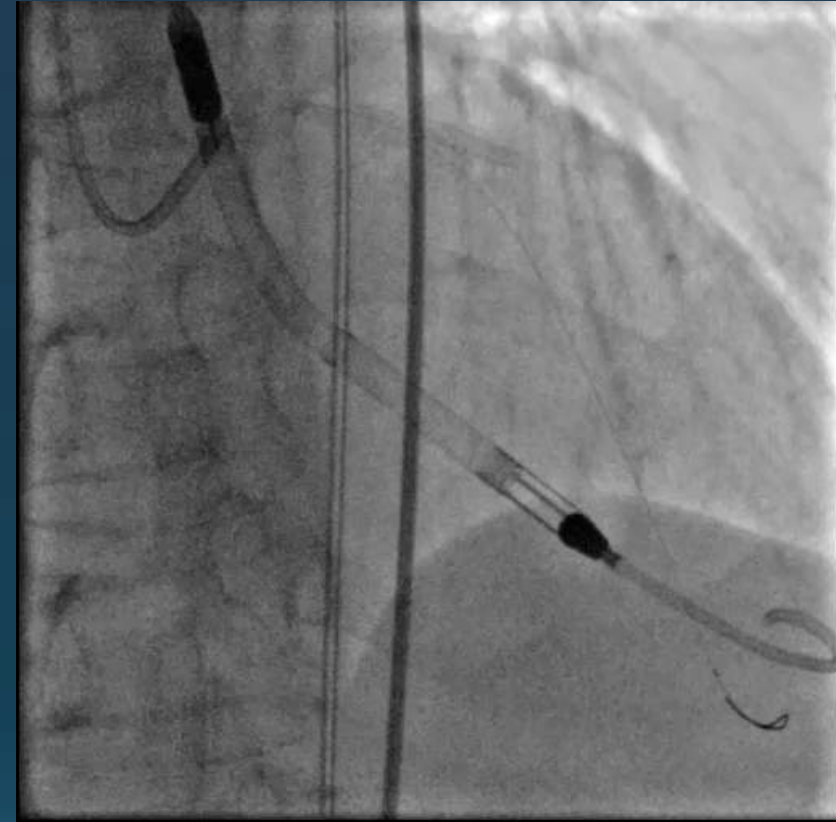
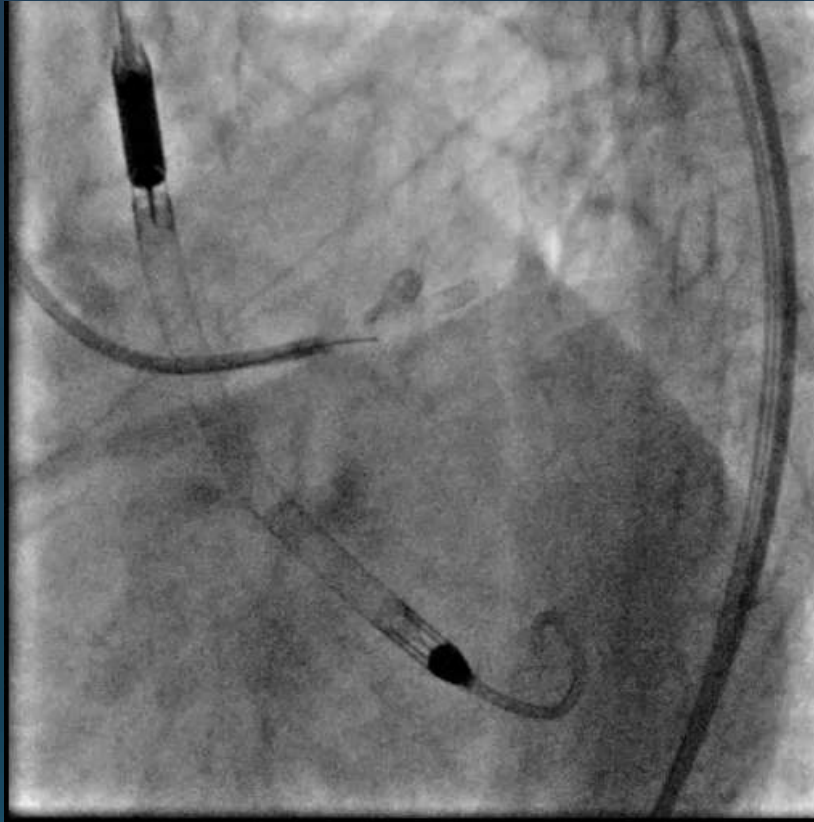
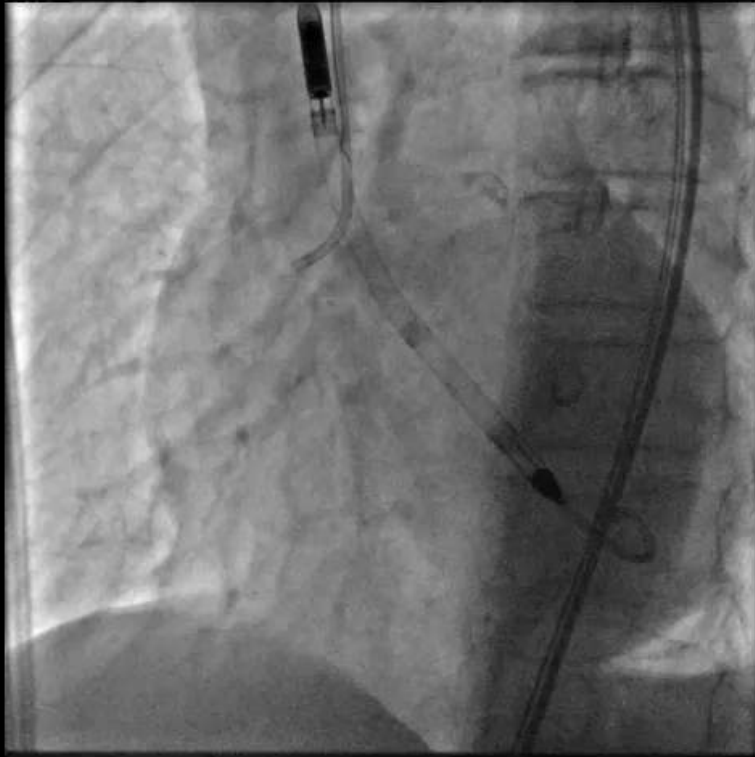


Clinical presentation

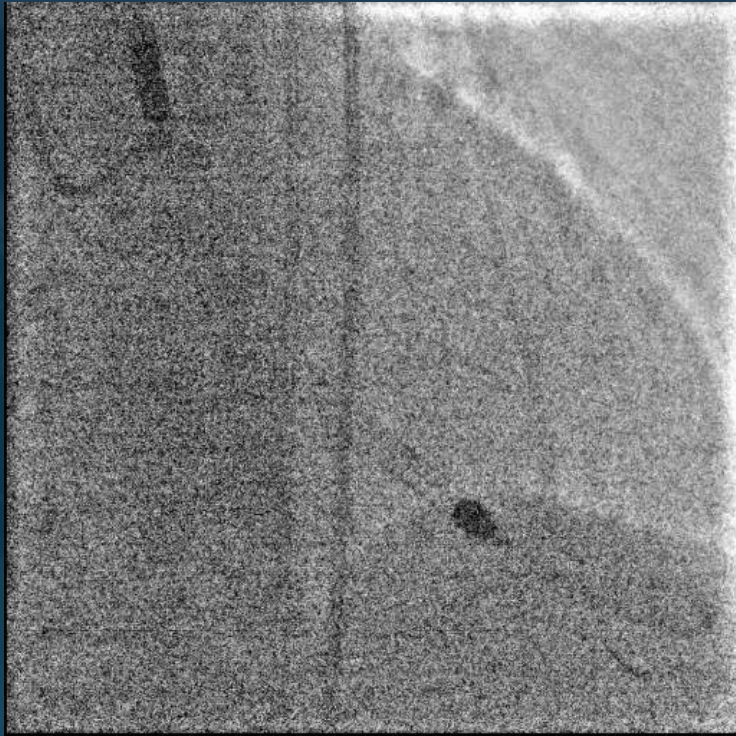
- ❖ 79 y.o. woman
- ❖ Prior PCI to LAD-D1
- ❖ Presentation with antero-lateral STEMI, PA 90/50 mmHg, Lac 2.9



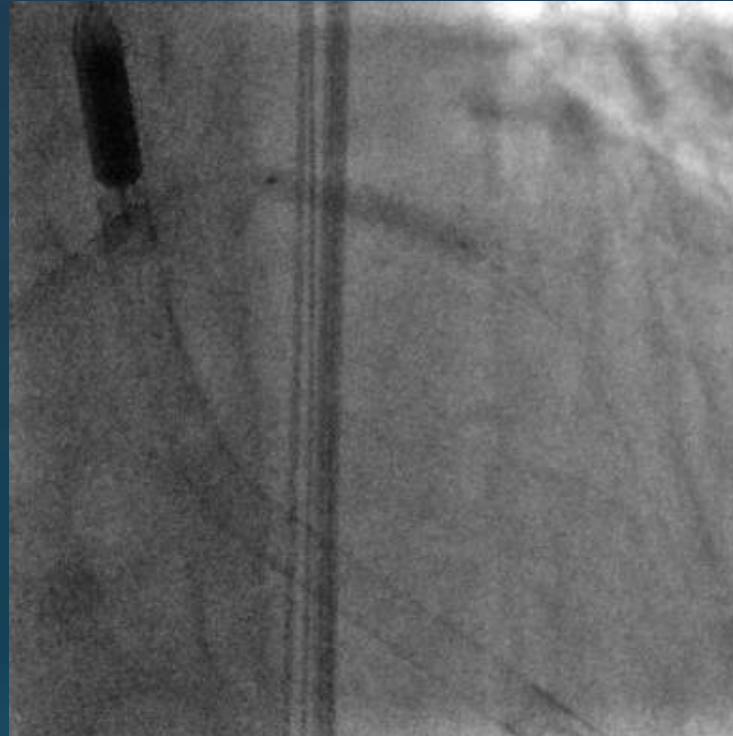
Coronary angiography



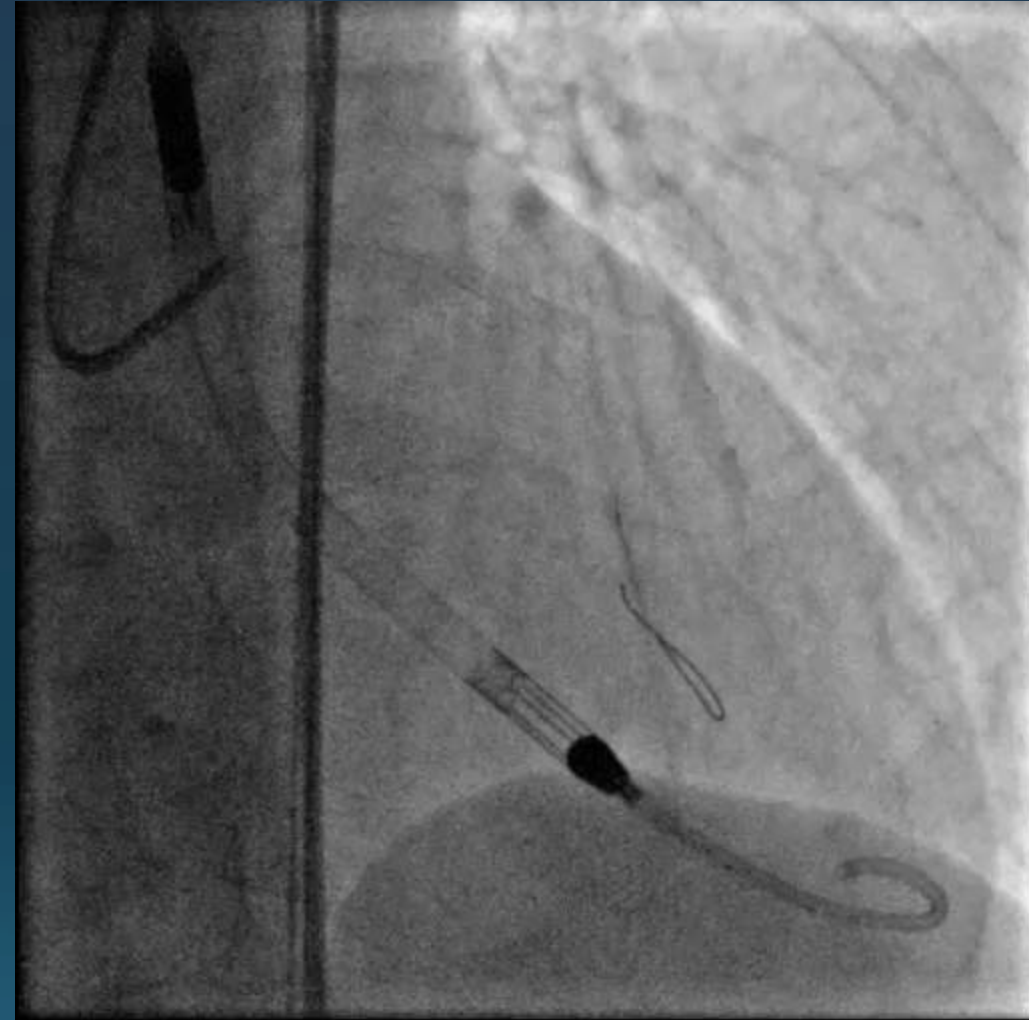
PCI



Thrombus aspiration



POBA with 3.0 - 3.5 mm NC balloons



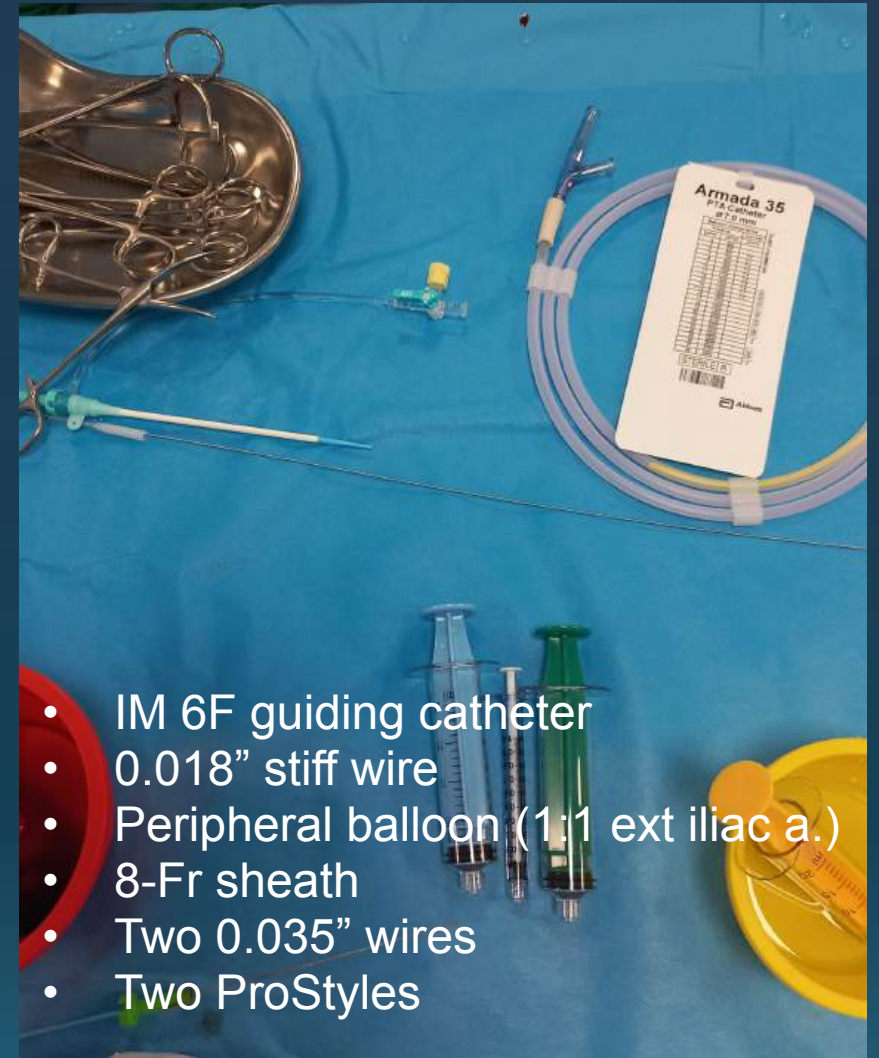
Good final angiographic result → patient sent to ICU with Impella



2 days later: Impella removal and post-closure



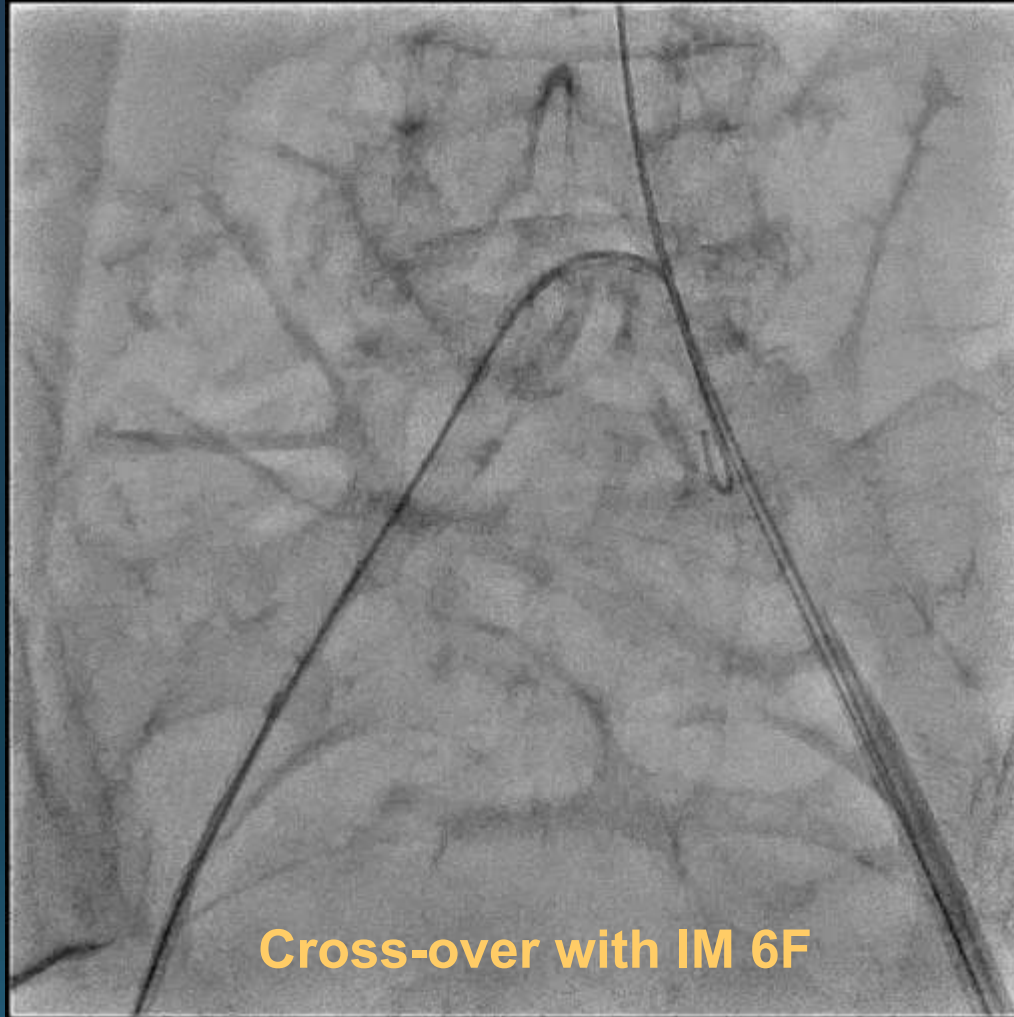
US-guided puncture of right CFA
6F sheath insertion



- IM 6F guiding catheter
- 0.018" stiff wire
- Peripheral balloon (1:1 ext iliac a.)
- 8-Fr sheath
- Two 0.035" wires
- Two ProStyles



Impella removal and post-closure



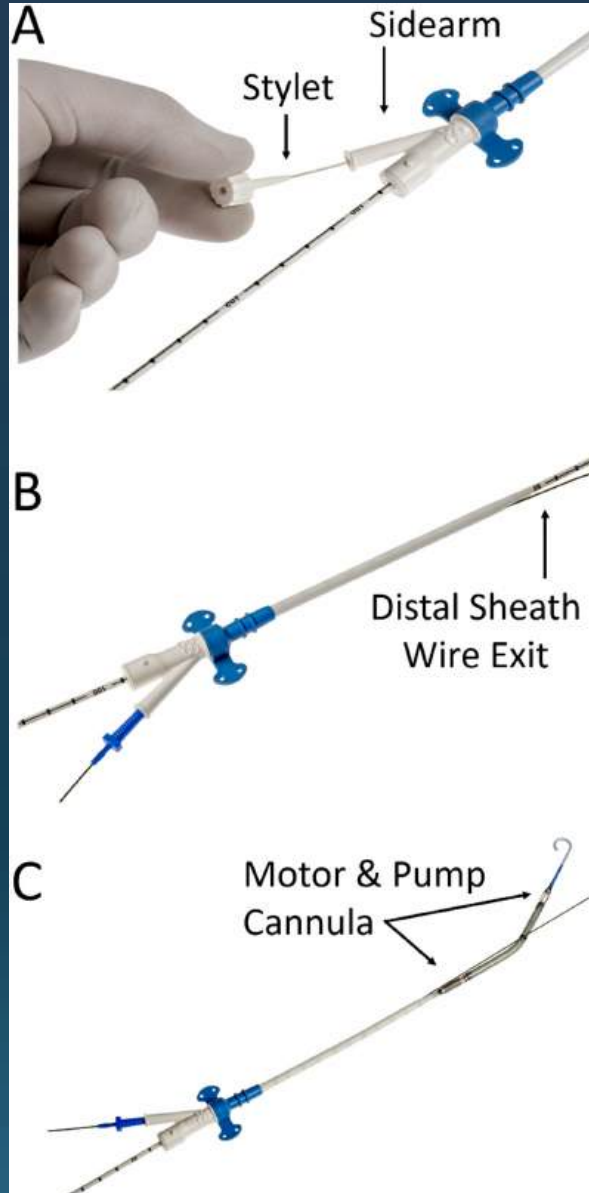
Cross-over with IM 6F



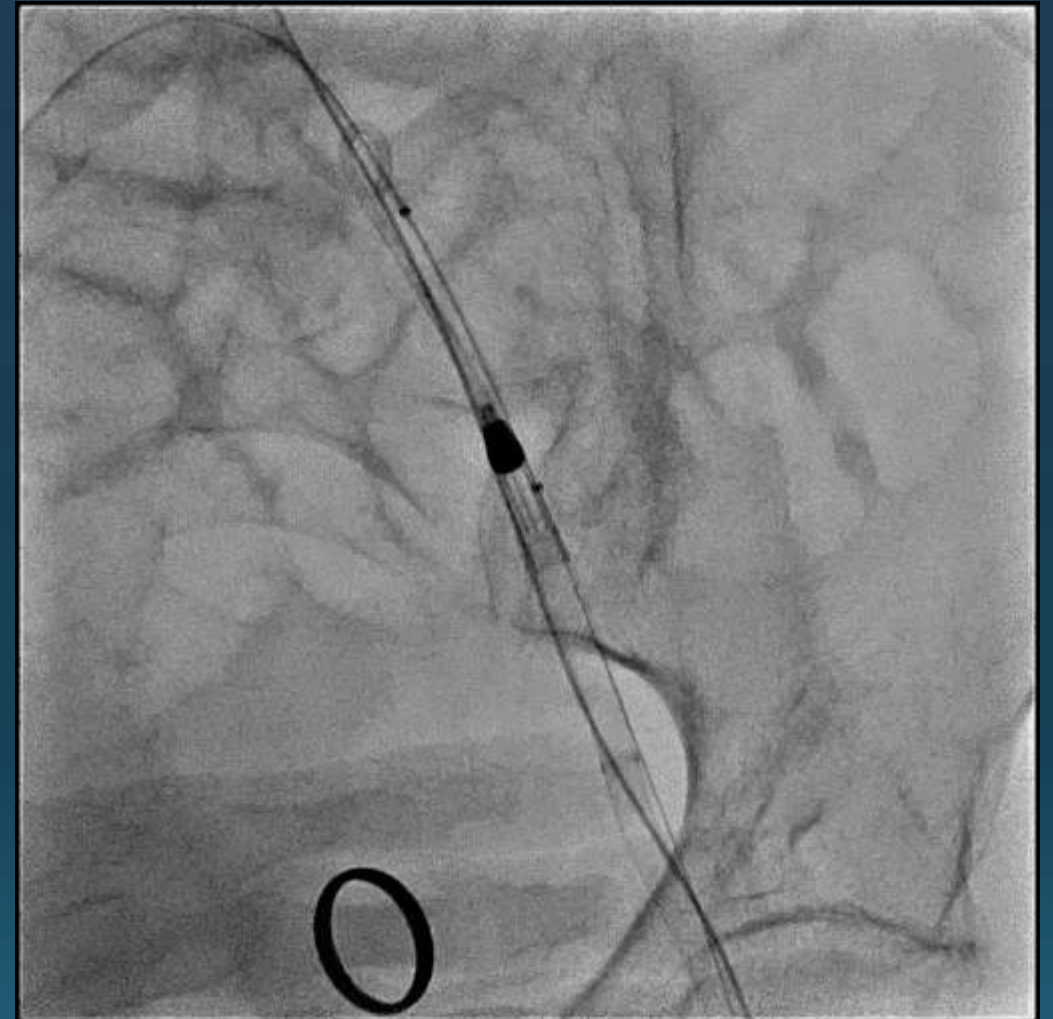
0.018" wire in SFA



Impella removal and post-closure



Impella removal and post-closure



Balloon deflation and Impella removal

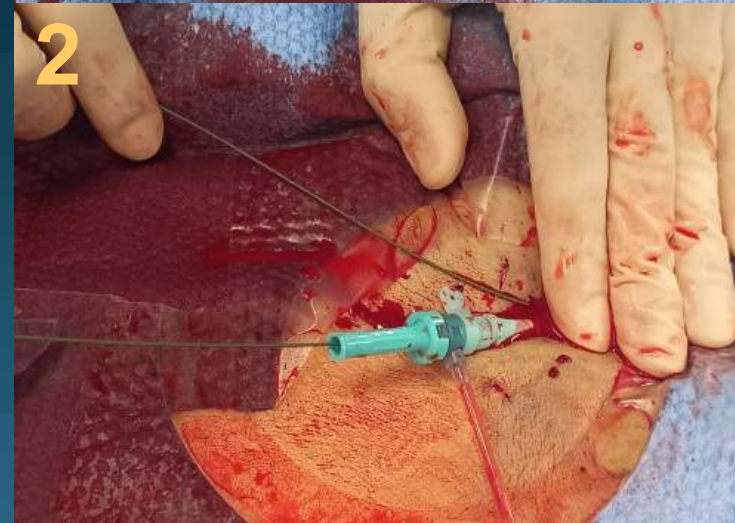


Impella removal and post-closure

1



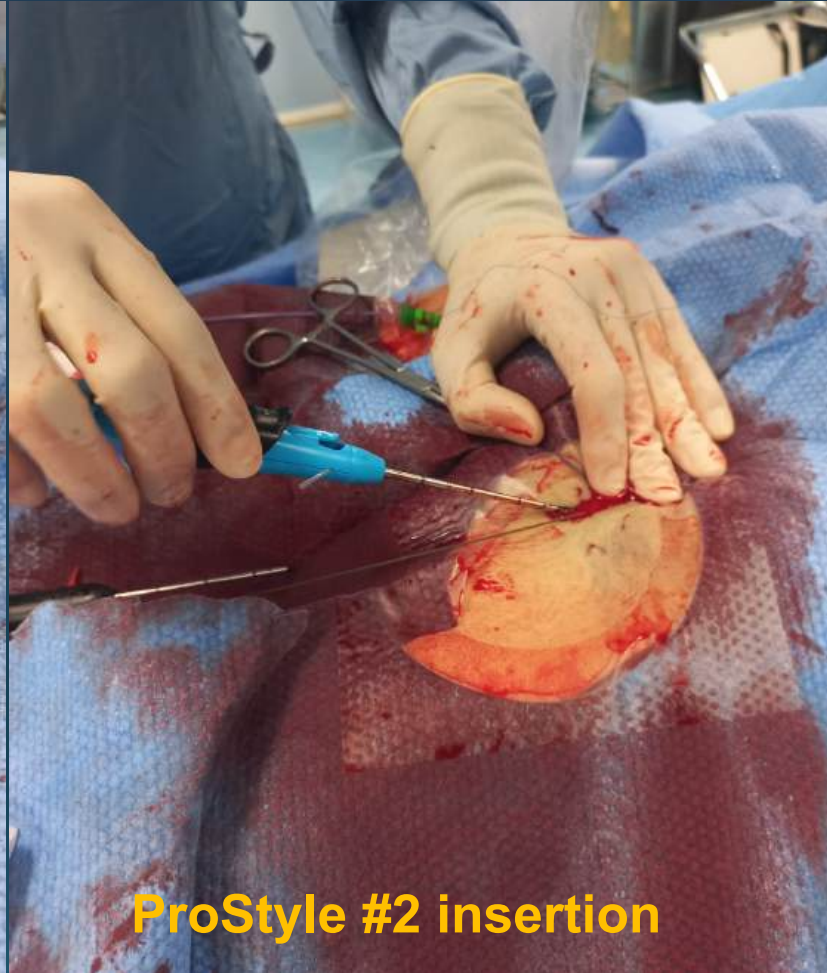
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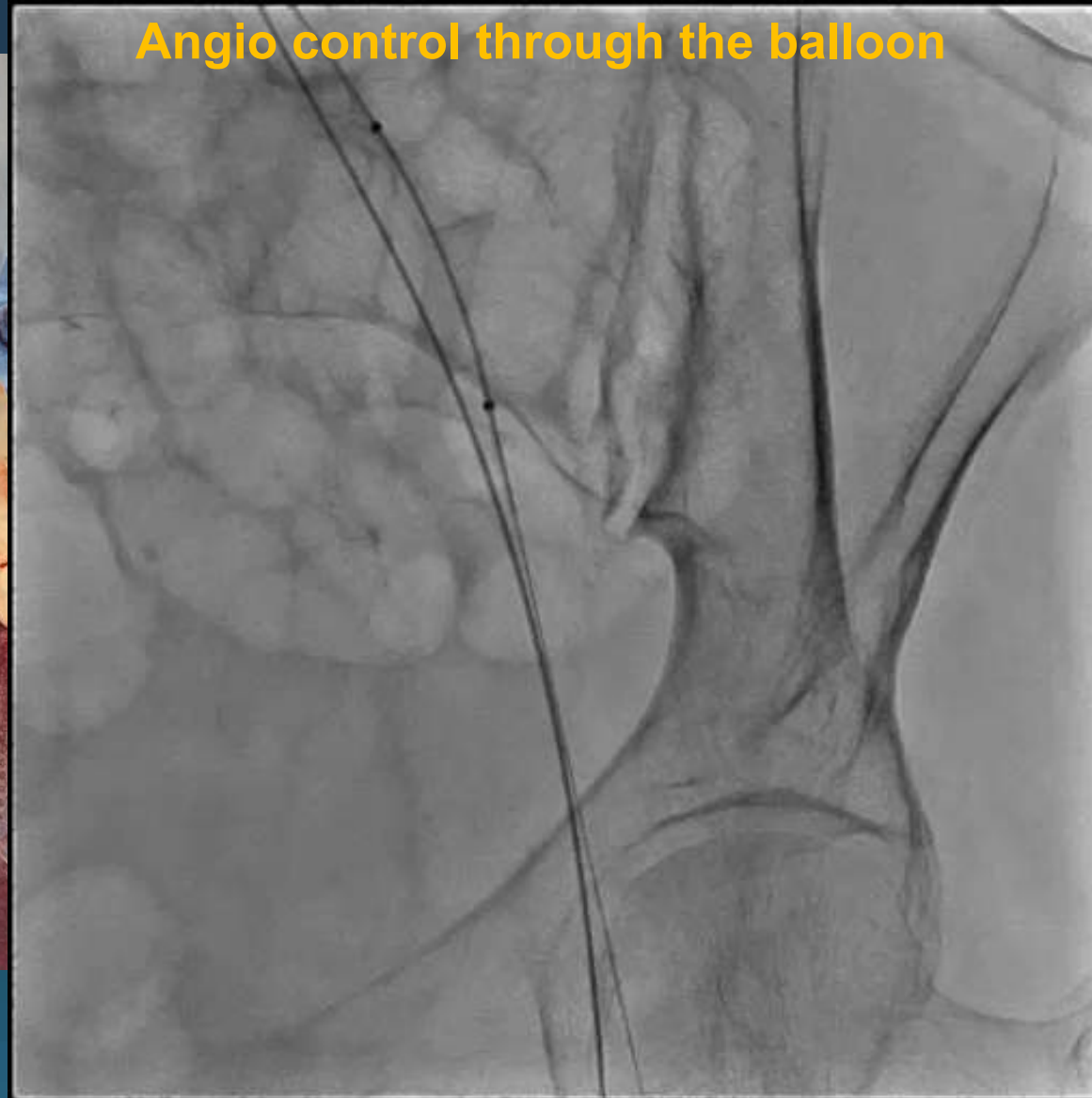
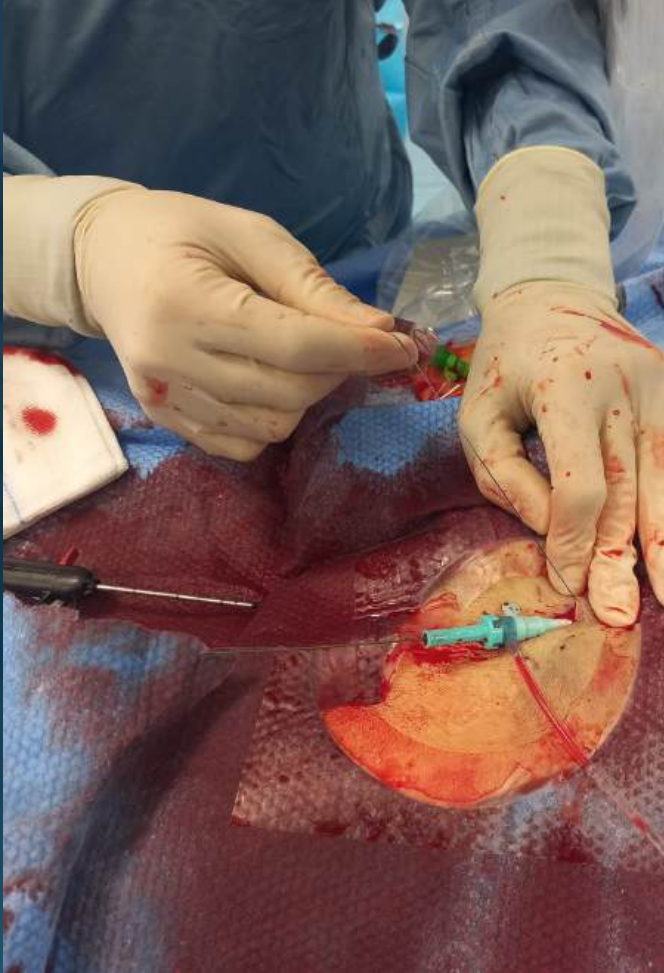
3



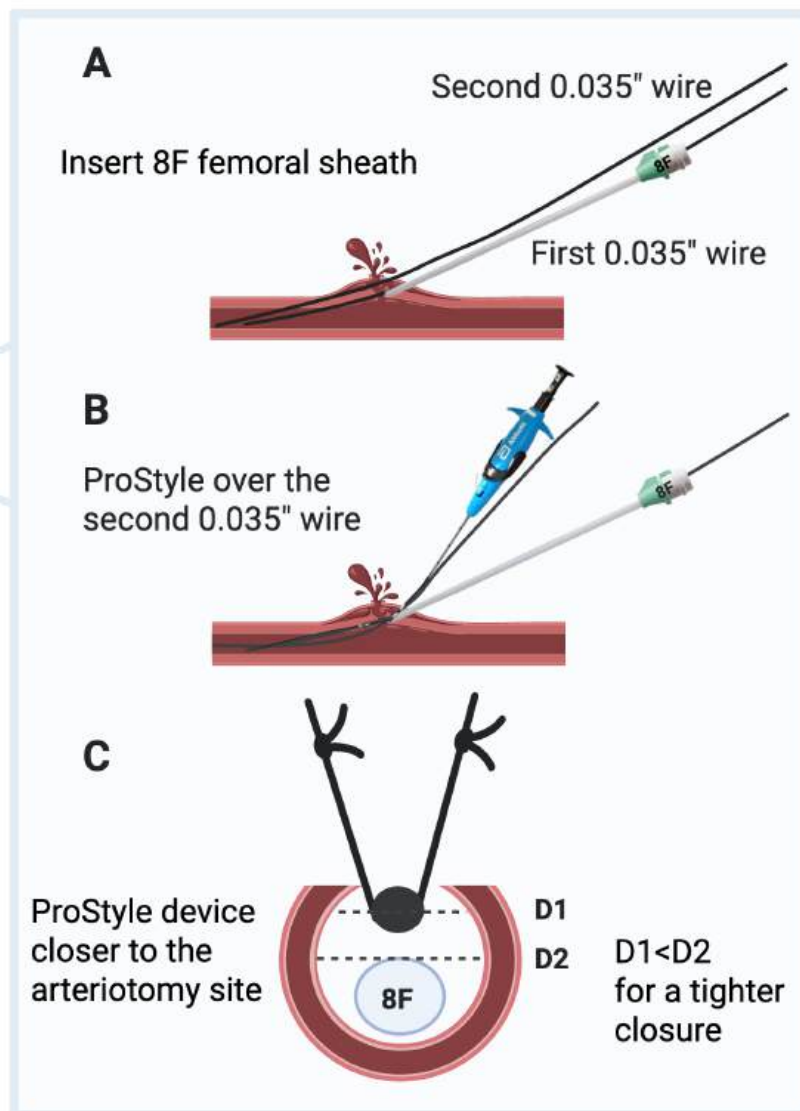
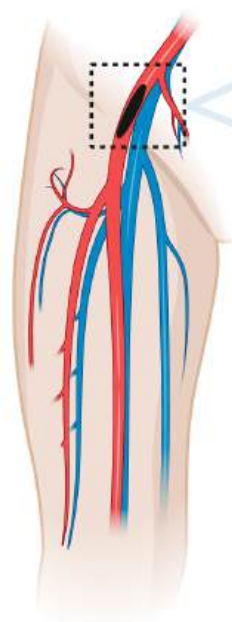
Impella removal and post-closure



Impella removal and post-closure

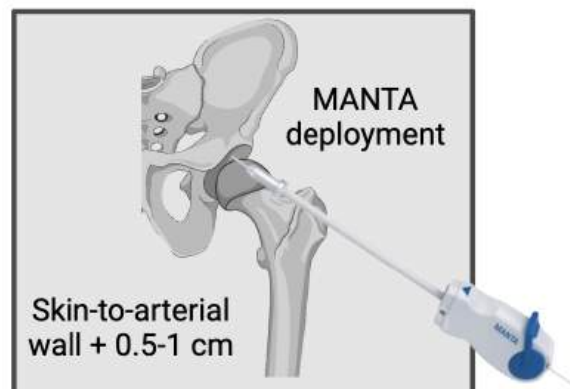
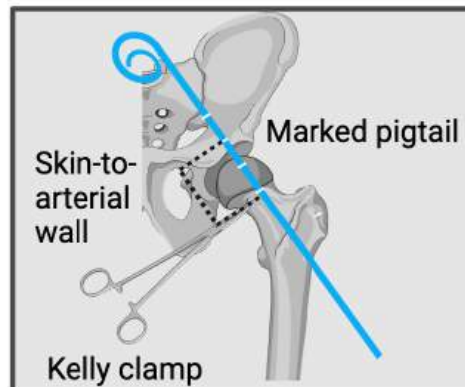


Facilitated post-closure of large bore access

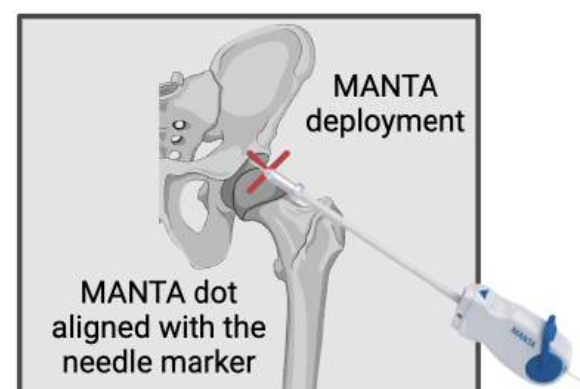
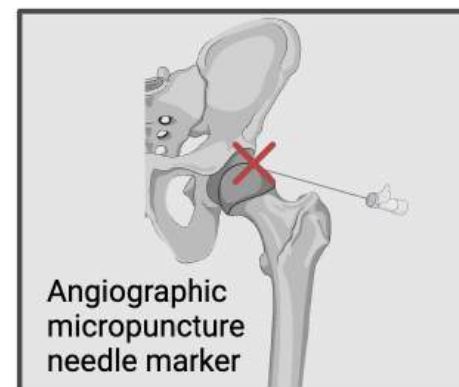


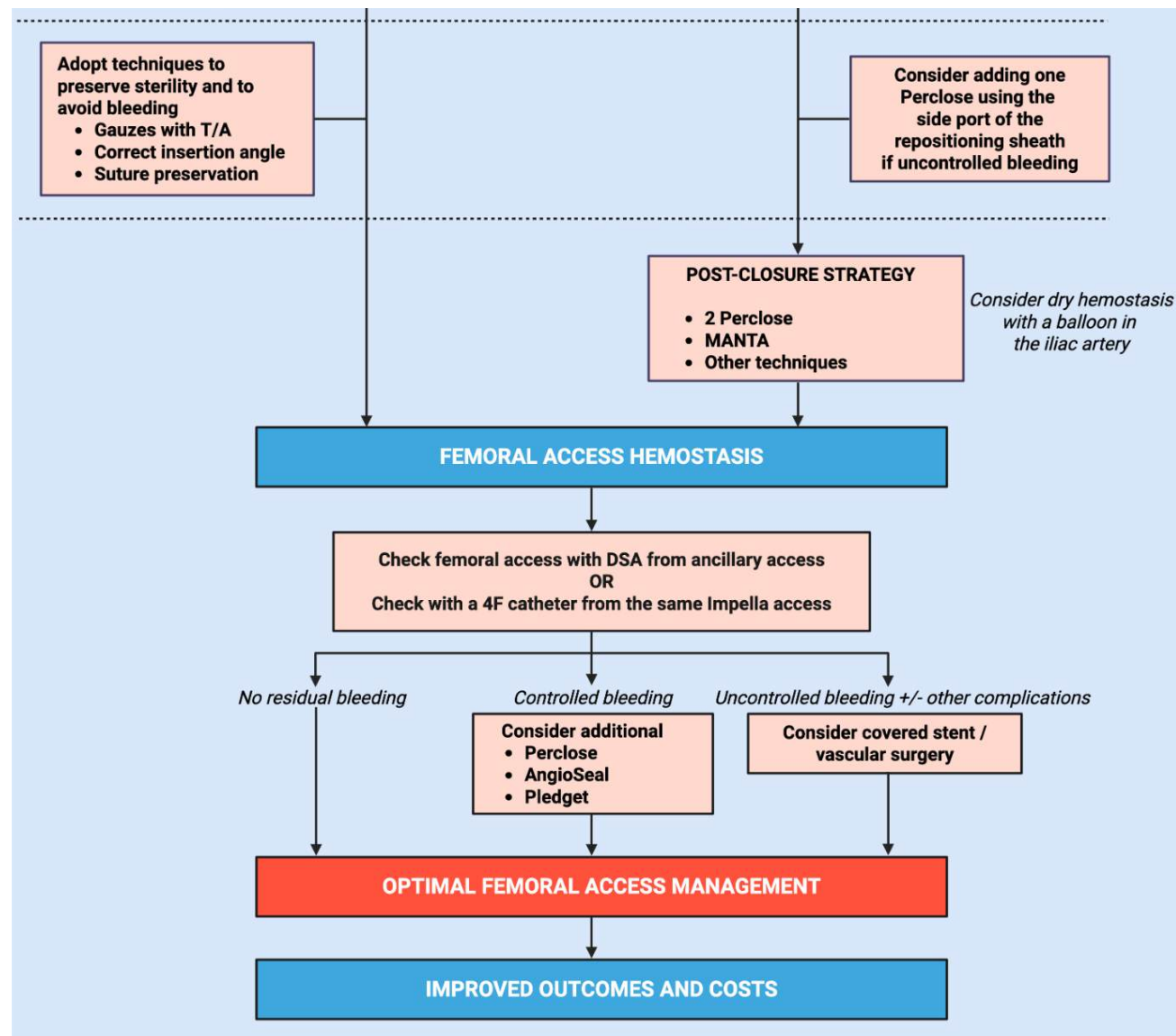
Post-closure with Manta

A Pigtail technique



B MANTA dot technique





Closing remarks

- ❖ Impella use in high-risk PCI should be selective, not routine.
- ❖ Protected PCI in patients where extensive/complete revascularization is the goal and would otherwise be limited by hemodynamic instability (PROTECT II subanalysis and R-IMPIT registry) – this does not mean that all lesions should be treated during index procedure. Aim at higher quality intervention, not simply more interventions.
- ❖ **PROTECT IV** will provide the most robust data to define which subgroup of patients undergoing high-risk PCI truly benefit from MCS.
- ❖ **Contemporary CHIP-PCI is an integrated strategy-based care** spanning patient selection, optimization, physiology, revascularization decision, access management, recovery and HF management (GDMT, ICD, etc.)



Thank you

