



EXPERIENCE OF IMPELLA SUPPORTED PCI IN CARDIOGENIC SHOCK AND HIGH RISK PATIENT

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Case presentation

1 *Non-STEMI: Impella 2.5 device*

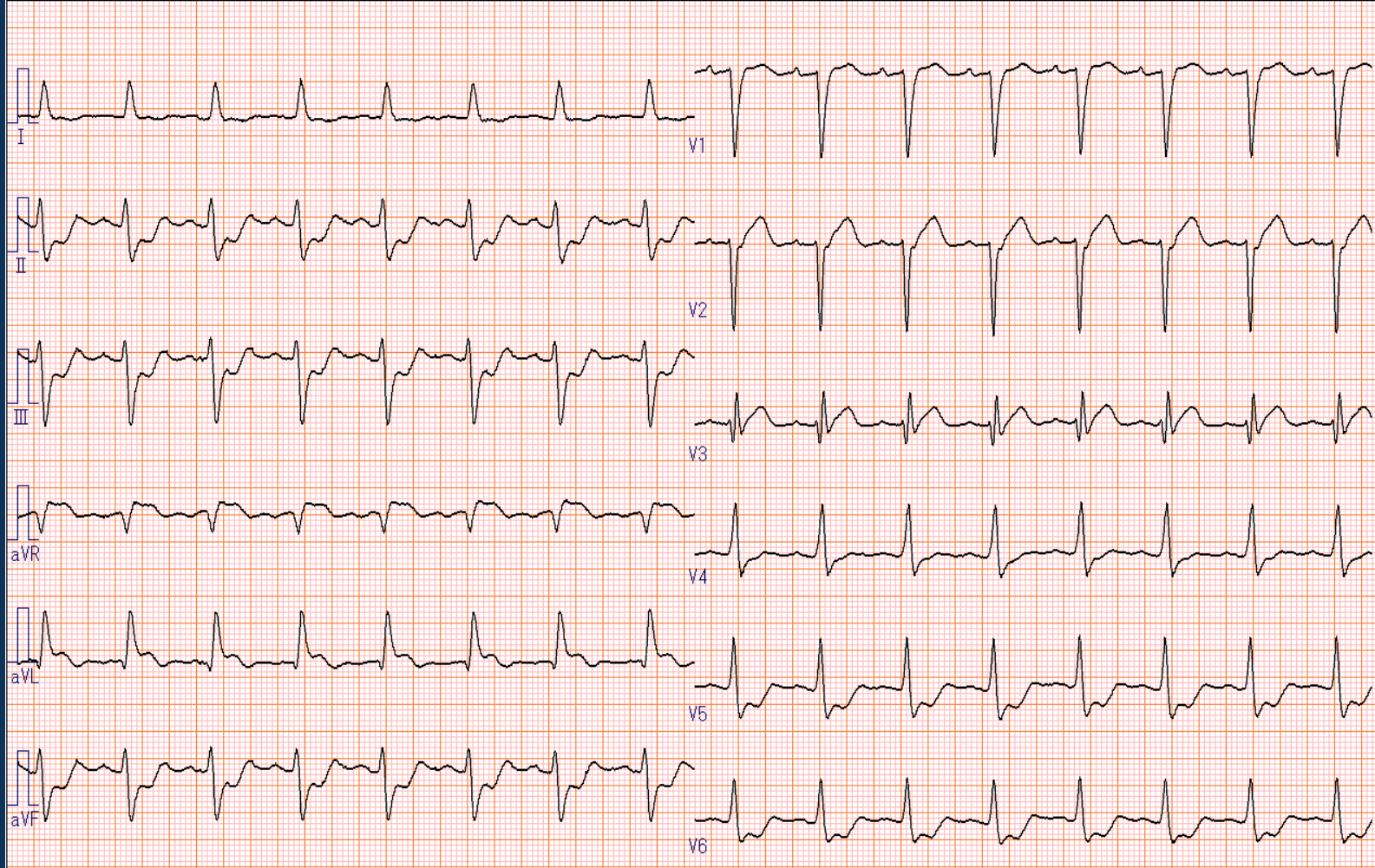
2 *Non-STEMI: Intra Aortic Balloon Pumping*



Case 1: Non-STEMI

- ***A 66-year old woman presented to the ER with chest pain***
- ***Coronary risk factors***
Hypertension, Diabetes mellitus
- ***Renal function***
Chronic kidney disease: Stage 5 on hemodialysis
- ***TTE***
 - ***Ejection fraction: 49%***
 - ***Dyskinesia: anterior-septal-apex of the left ventricle***
- ***Blood pressure: 86/64 mmHg***

ECG

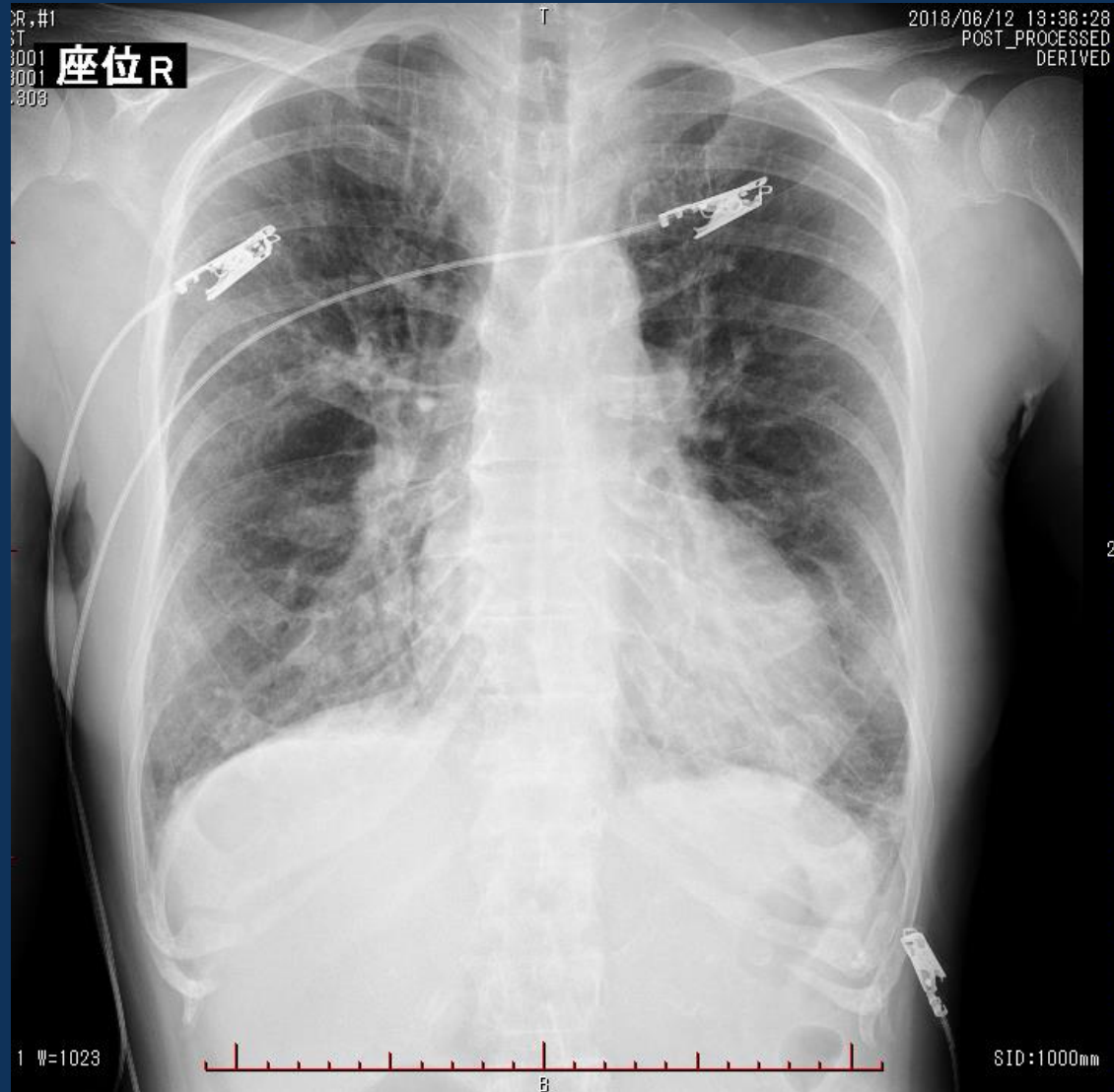


ST segment depression in the inferior, lateral leads and ST segment elevation in lead aVR



Chest X-ray

Pulmonary congestion and cardiomegaly





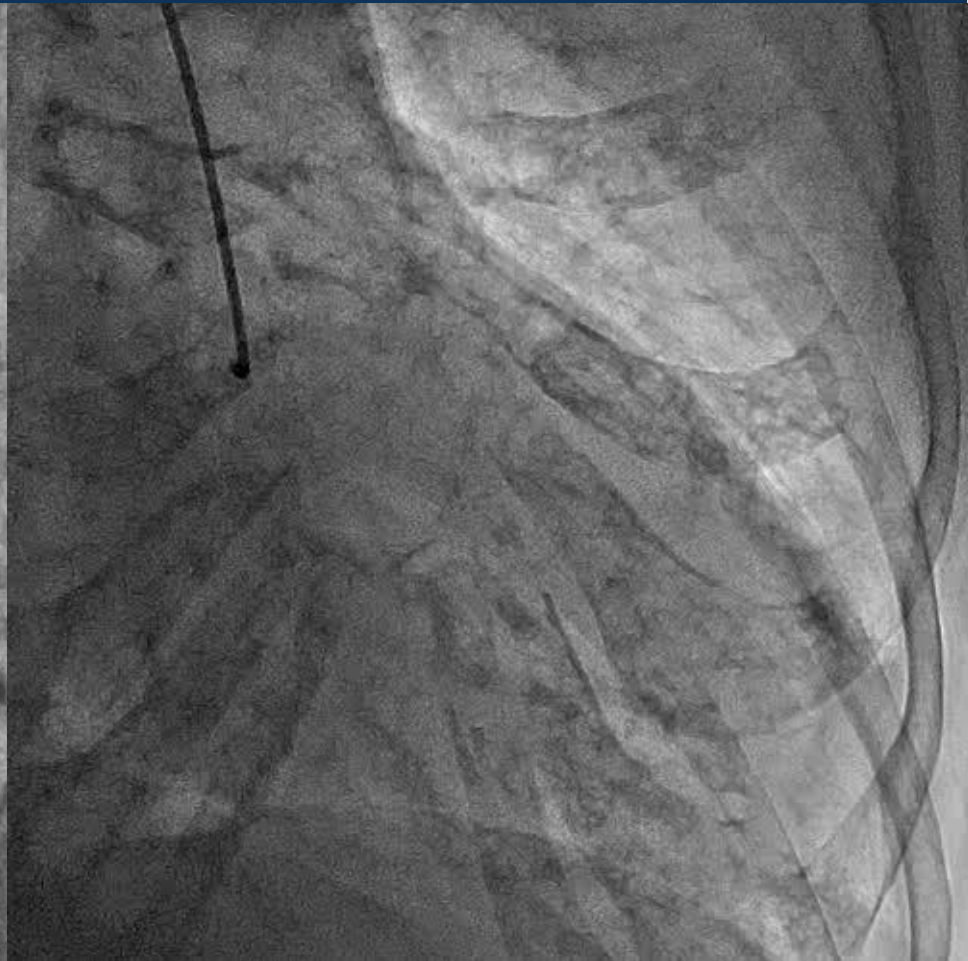
Complex Cardiovascular Therapeutics

Emergent CAG-LCA



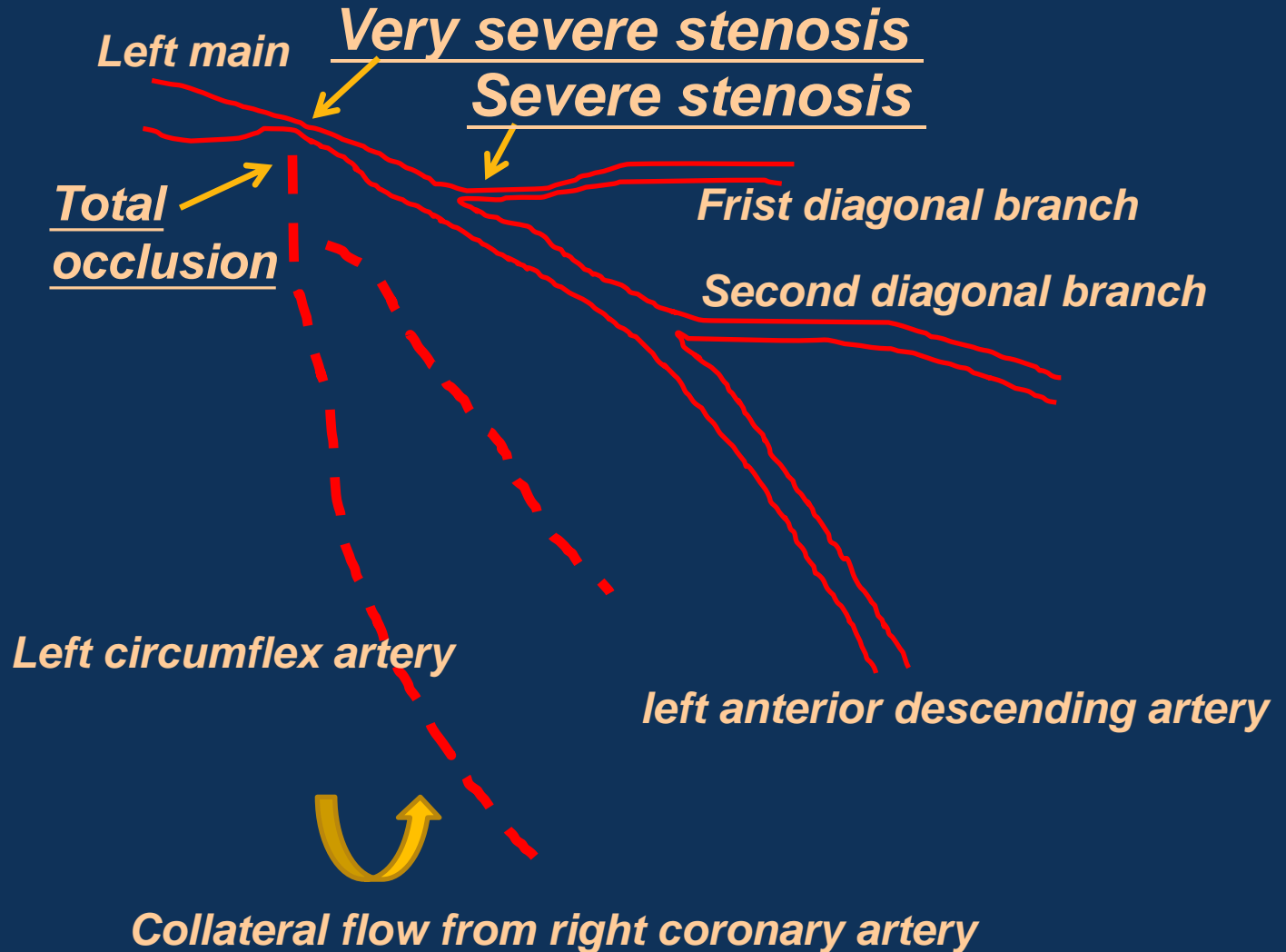


Emergent CAG-RCA

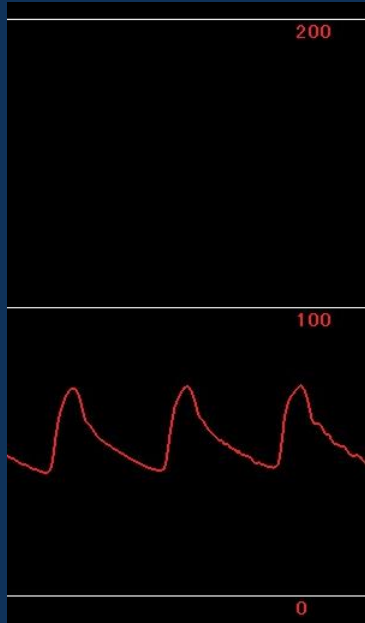




Left coronary system



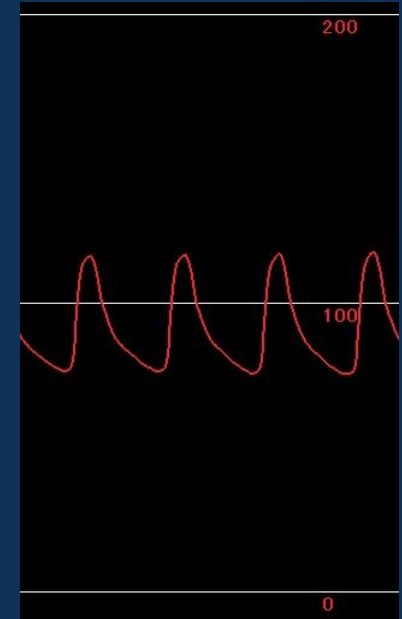
Cardiogenic shock with low blood pressure



72/42 (52) mmHg
NAd 0.3µg+ Nad iV

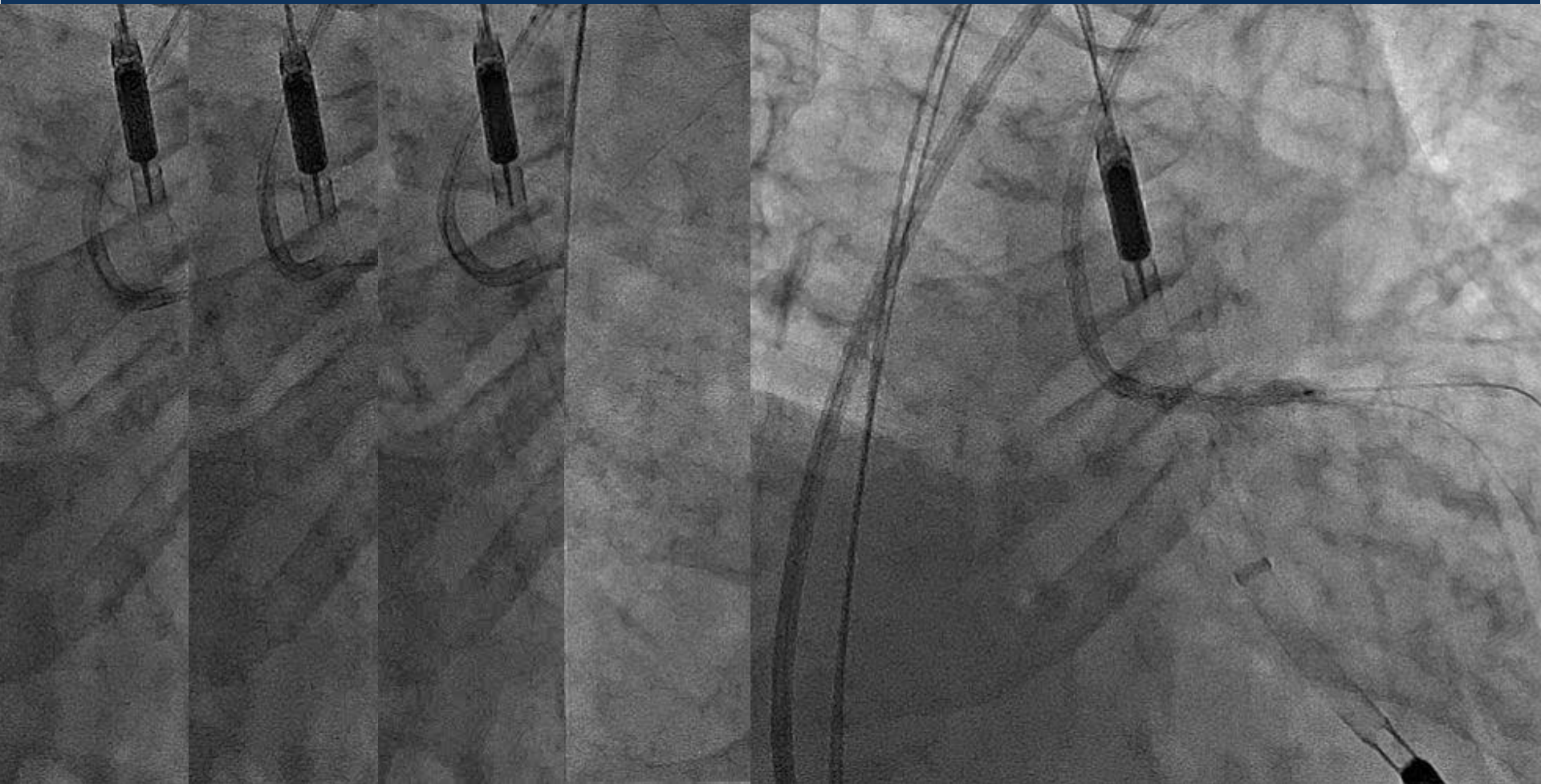


IMPELLA 2.5



116/76 (89) mmHg
NAd 0.3µg

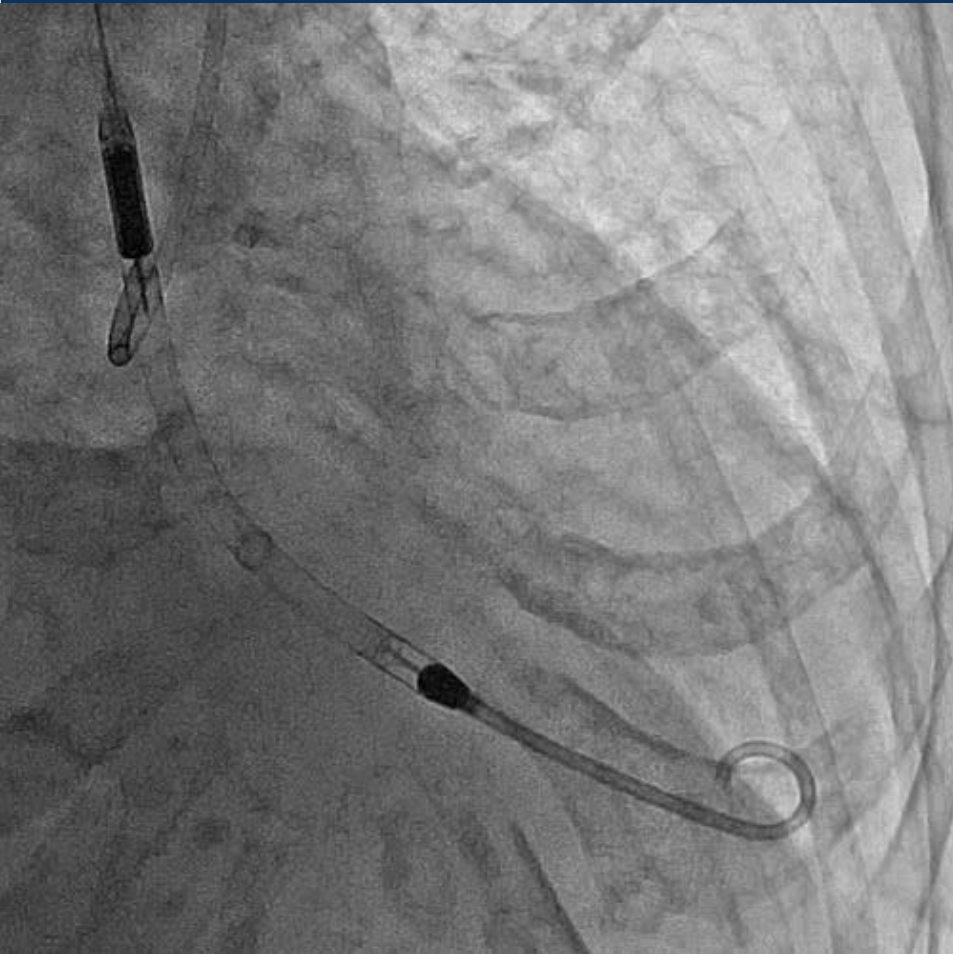
In light of the sustained hemodynamic compromise while using noradrenaline, Impella 2.5 was inserted via left femoral artery.



■ **Right femoral artery approach 7Fr Short tip JL 3.5 SH guiding catheter**



Final angiograms

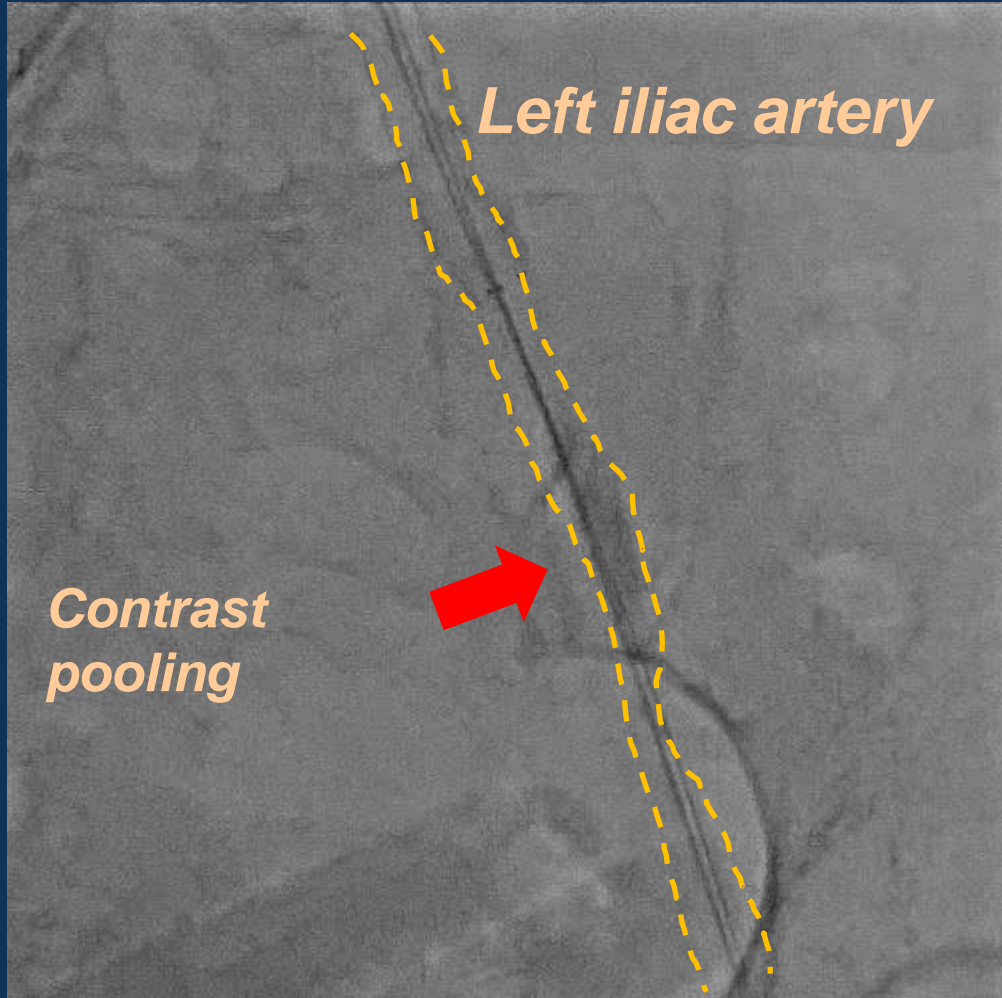




Clinical course

- ***IMPELLA 2.5 was set at P7 with cardiac output of 2.0-3.0 L/min***
- ***The device was removed 2 days later in the ICU.***
- ***Complications due to Impella 2.5 device in this patient***
 1. ***Lower limb ischemia***
 2. ***Pump displacement***
 3. ***Hemolysis***

Lower limb ischemia



It is thought that using a large sheath (13Fr) in patient with stenosis of the iliac artery caused a lower limb ischemia.



Recovery of blood flow



Sheath inserting portion

Femoral artery

Blood flow

Iliac artery

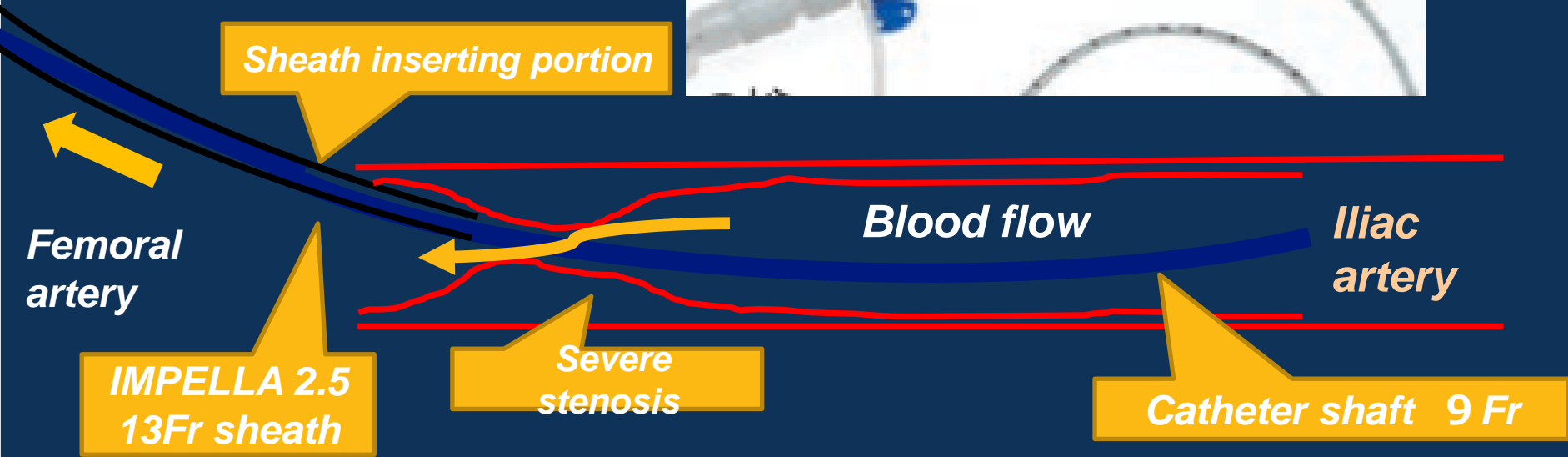
IMPELLA 2.5
13Fr sheath

Severe stenosis

Catheter shaft 9 Fr

Blood flow was recovered by pulling back the sheath.

Recovery of blood flow



Blood flow was recovered by pulling back the sheath.



Recovery of blood flow

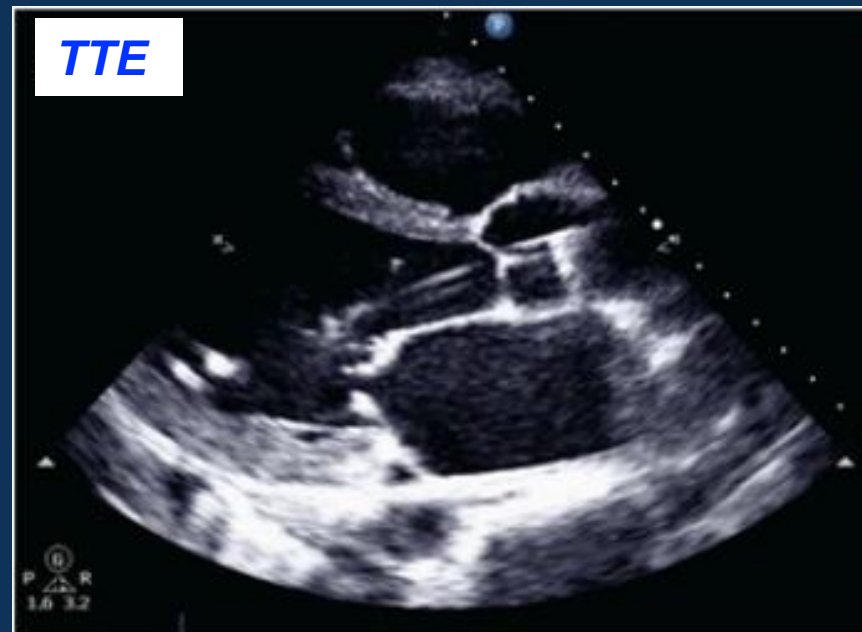




Pump displacement

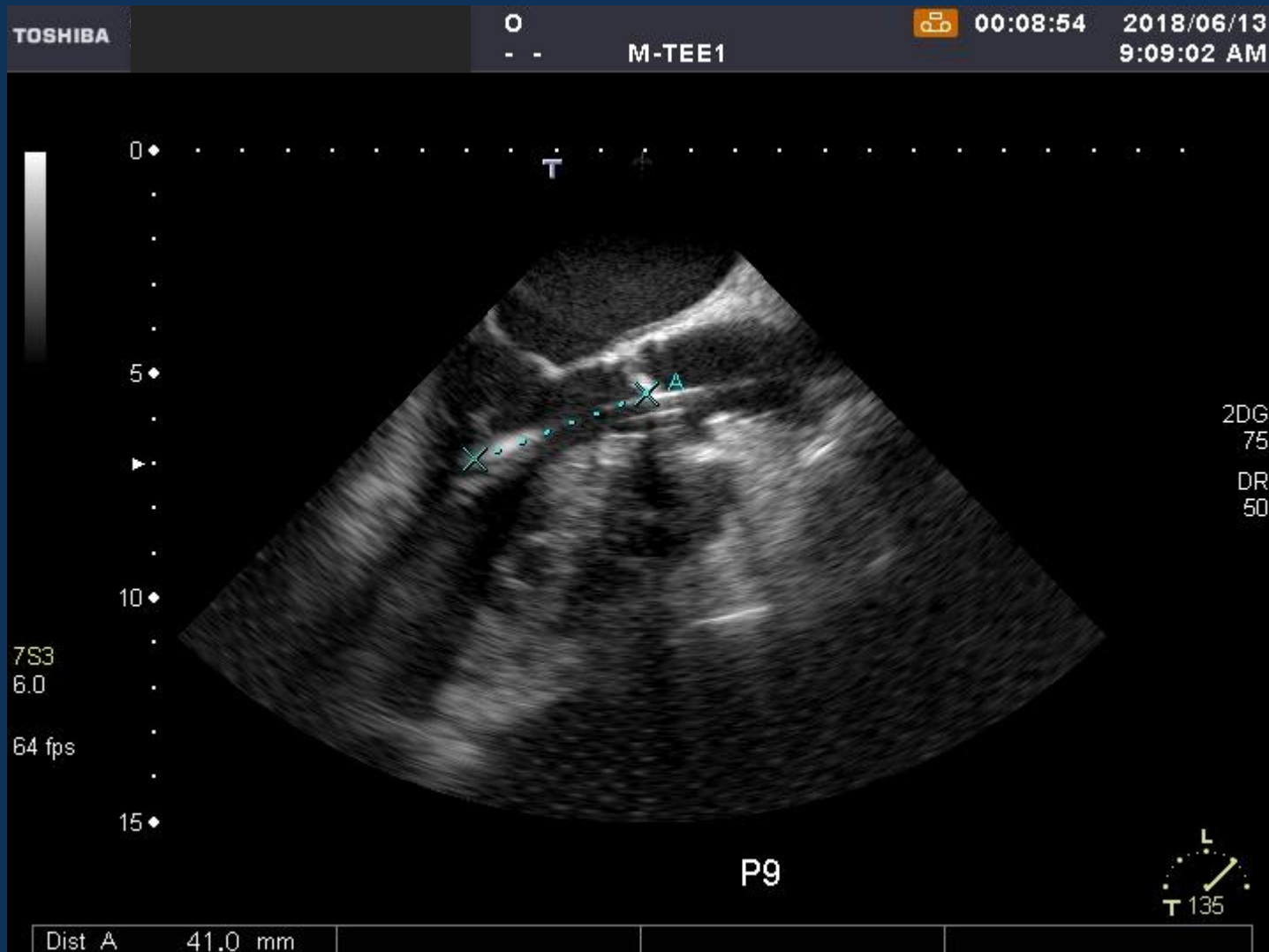
Knee movement of the patient caused a pump displacement and led to shock.

- Appropriate IMPELLA catheter position
Catheter inlet area around 3.5cm below the aortic valve





TTE of this patient





Pump displacement

If patient moves one's own body, pump displacement could occur.

→ We put the patient under sedation, after that, pump displacement did not happen.

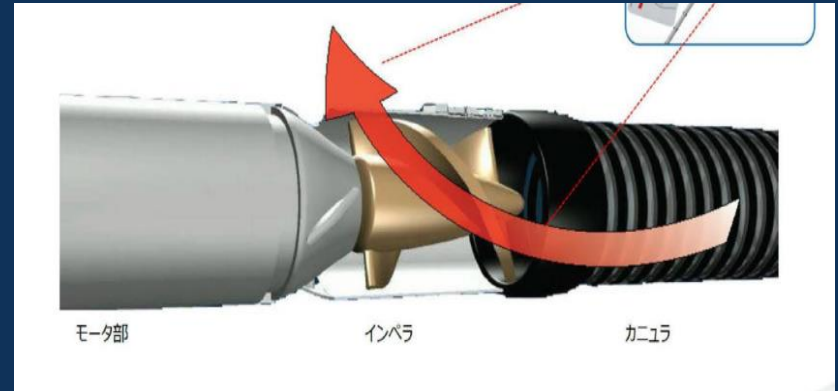
■ *It is thought that sedation is requisite for use IMPELLA*

Hemolysis

The blood cells may be damaged by mechanical force of the IMPELLA.

【The main causes of hemolysis】

- Wrong pump position
- Inadequate filling volume
- Higher than needed flow setting



☞ In this case

◇ Dialyze wastewater by continuous hemofiltration

➡ Transparent pale pink

➡ Reduce P-level from P8 to P7

➡ Color transparent

☞ At an early stage, we eliminated the cause of the hemolysis.

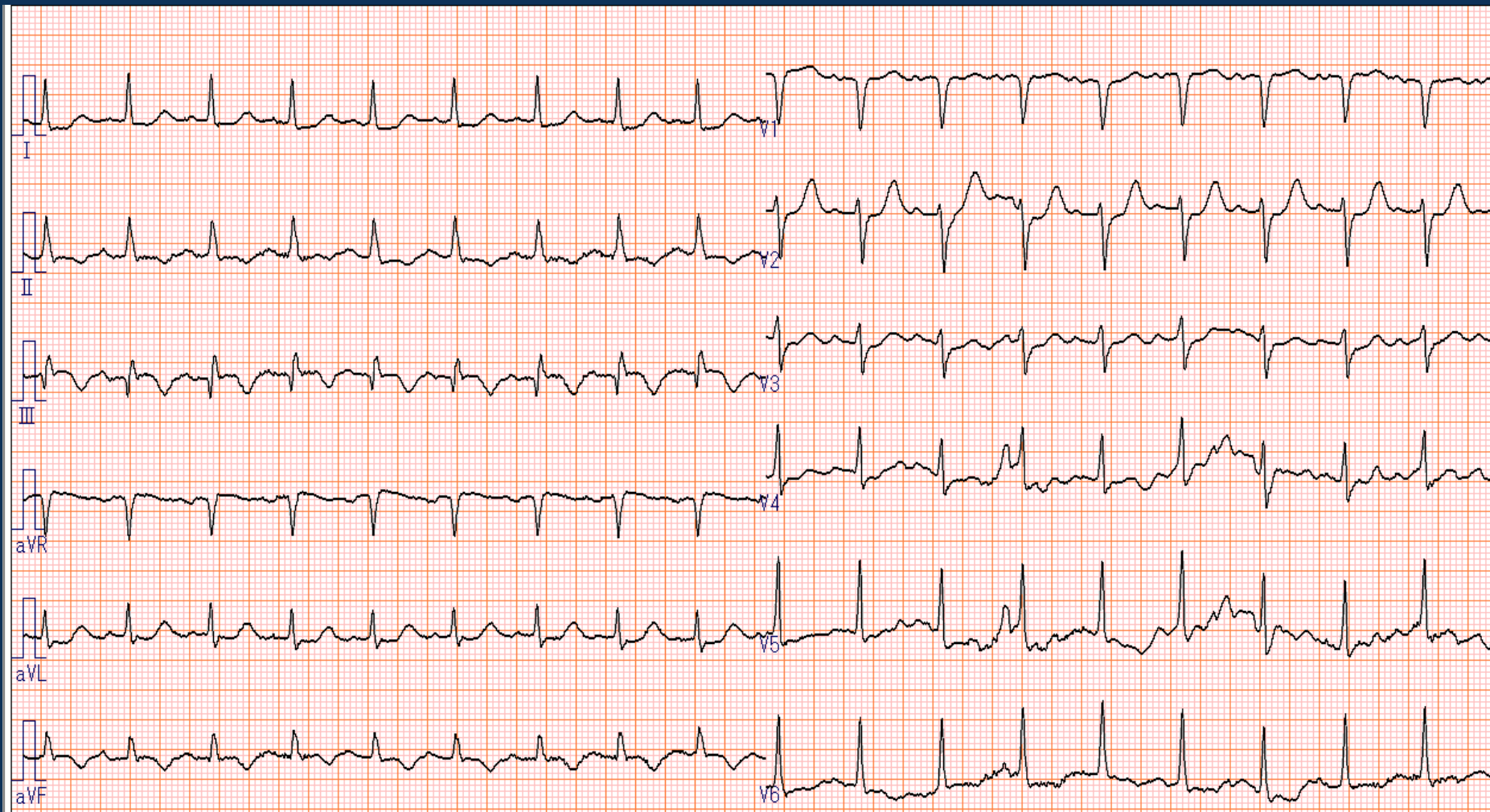


Case 2: OMI + AP

- *A 83-year old woman presented to the ER with dyspnea*
- *Coronary risk factors*
Hypertension
- *Comorbidity*
Bronchial asthma, Frailty score 5
- *Failed PCI to total occlusion of RCA*
- *TTE*
 - *Ejection fraction: 48%*
 - *Dyskinesis: infero-posterior wall of the left ventricle*



ECG



Q wave in lead III and negative T wave in the inferior and lateral leads



CAG





Coronary anatomy

Severe stenosis / Moderate stenosis

Frist diagonal branch

A very high risk PCI

**A multi-vessel disease of Left main to LAD
with CTO at proximal RCA**



**Impella is not approved for a high risk PCI without
cardiogenic shock.**

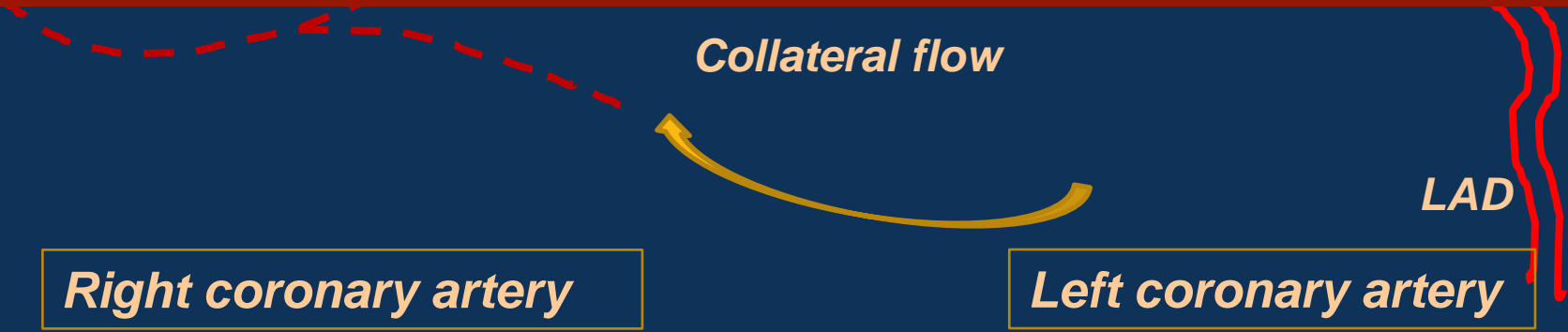
**Intra-Aortic Balloon Pumping was chosen for a support
device during this high risk procedure.**

Collateral flow

LAD

Right coronary artery

Left coronary artery

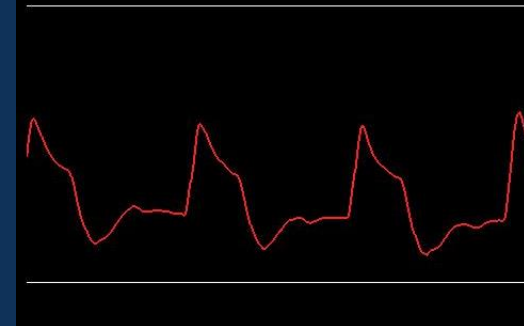




PCI



Cardiogenic shock
sBP
25mmHg





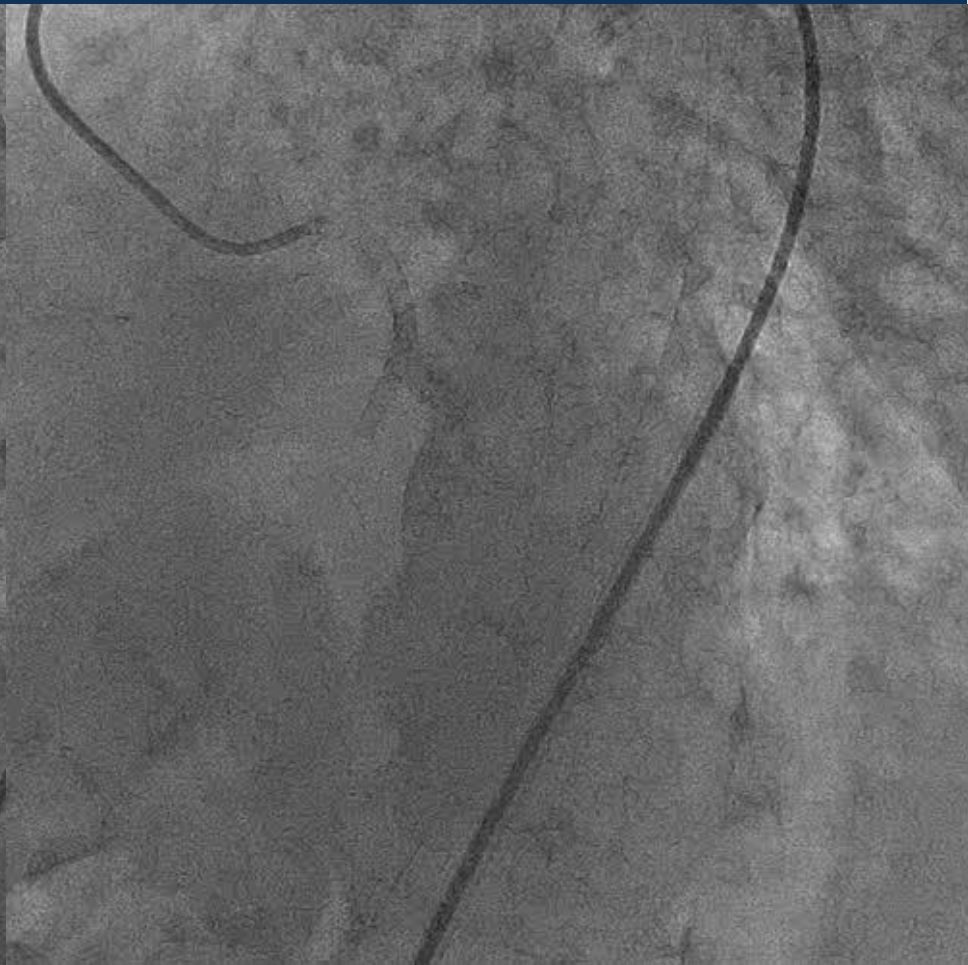
Urgent stenting



Urgent stenting (no time for delicate positioning) to the left main stabilized hemodynamics.



Final angiograms





Summary

◆ Case 1

- *A high risk PCI of left main to LAD in patient with cardiogenic shock*
- *Procedure supported by the Impella was successful*
- *We experienced several complications associated with this device*
 1. *Lower limb ischemia*
 2. *Pump displacement*
 3. *Hemolysis*

◆ Case 2

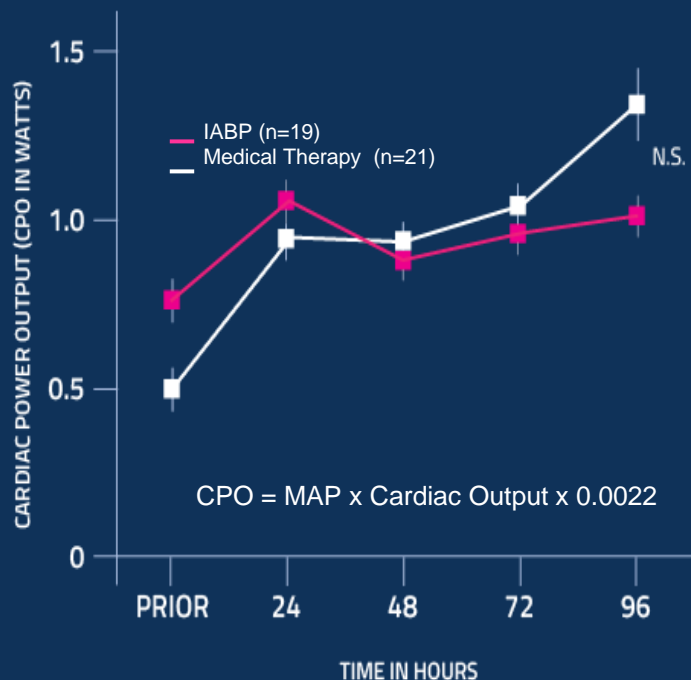
- *A very high risk PCI of left main to LAD with a CTO at proximal RCA in frail patient.*
- *Cardiogenic shock occurred during procedure even on the support of IABP.*

IABP IN AMI CARDIOGENIC SHOCK: NO HEMODYNAMIC OR SURVIVAL BENEFIT

IABP SHOCK I

Randomized Controlled Trial¹

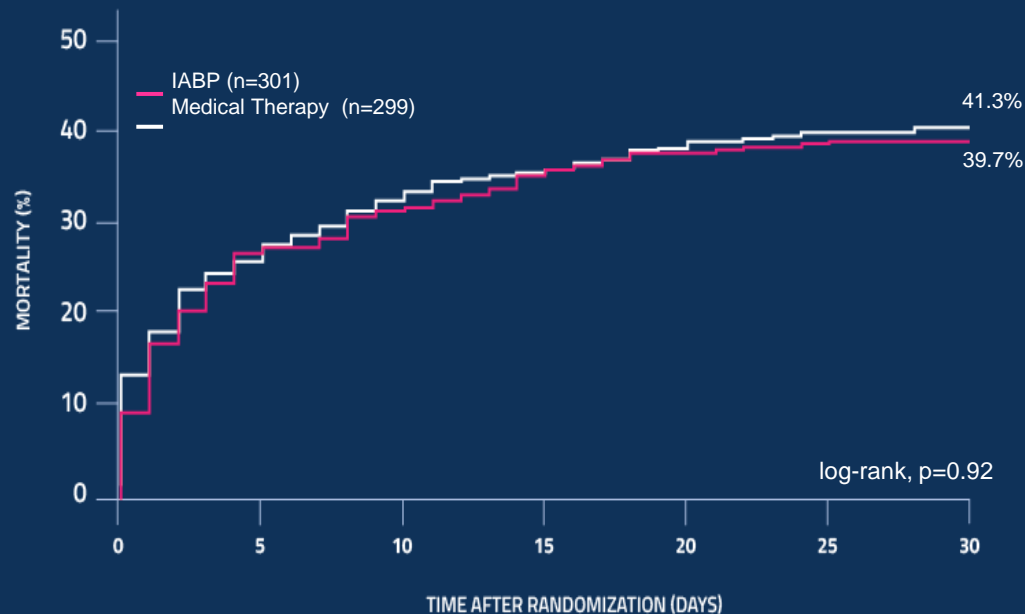
N = 40



IABP-SHOCK II

Randomized Controlled Trial²

N = 600

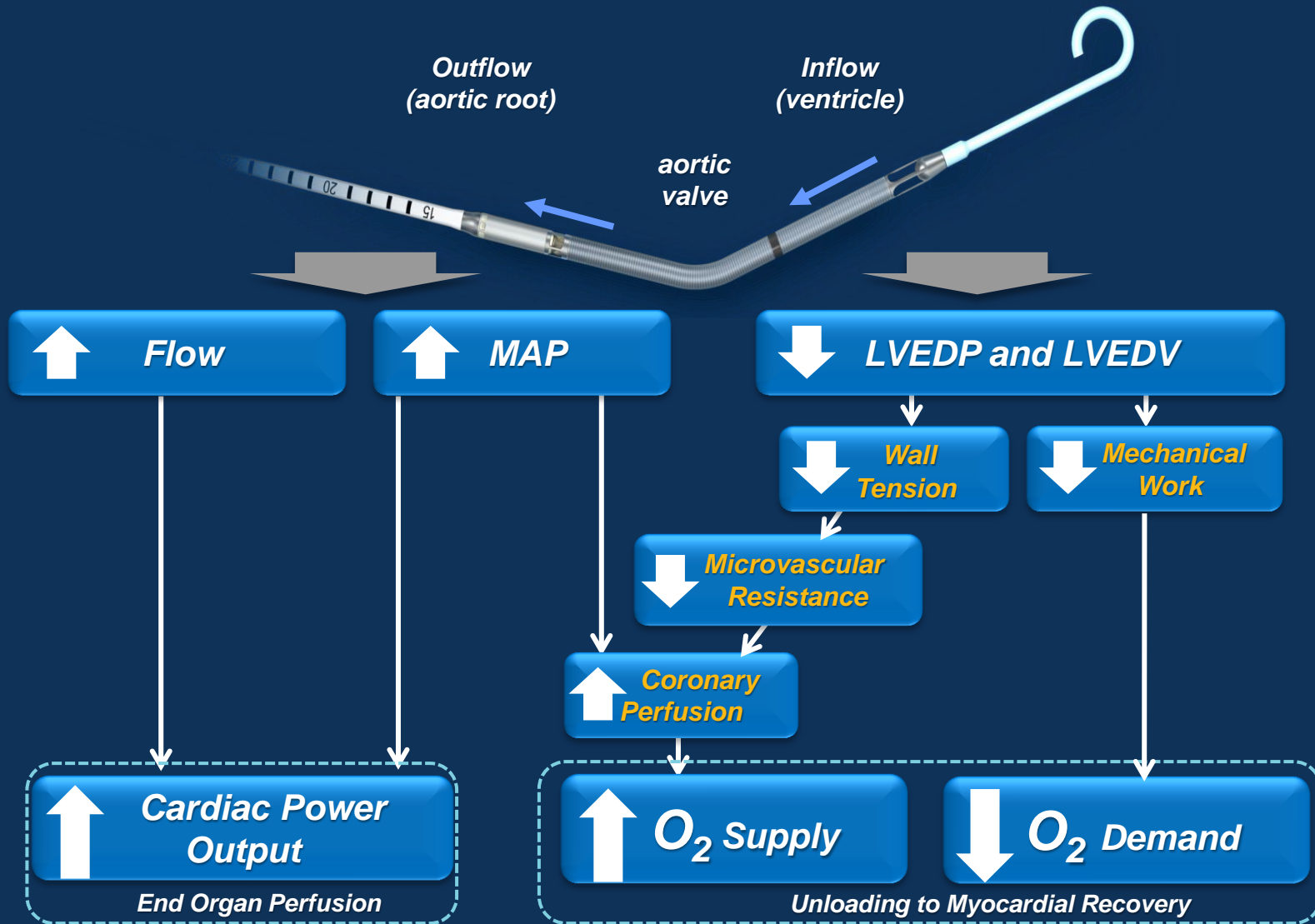


IABP Increased hazard risk of stroke, downgraded to Class III (harm), Level of Evidence A, ESC STEMI Guidelines 2014

1. Prondzinsky R. et al. Jn Critical Care Medicine IABP SHOCK I 2010 – Clinicaltrial.gov # NCT00469248
 2. Thiele H et al. NEJM 2012 - Clinicaltrial.gov # NCT00491036

NEW CARDIOGENIC SHOCK INDICATED THERAPY: *IMPELLA*[®] *DEVICES*

HEMODYNAMIC EFFECTS OF IMPELLER® DEVICE SUPPORT



Fincke J, et al. *Am Coll Cardiol* 2004
 den Uil CA, et al. *Eur Heart J* 2010
 Mendoza DD, et al. *AMJ* 2007
 Torgersen C, et al. *Crit Care* 2009
 Torre-Amione G, et al. *J Card Fail* 2009

Suga H, et al. *Am J Physiol* 1979
 Suga H, et al. *Am J Physiol* 1981
 Burkhoff D, et al. *Am J Physiol Heart Circ* 2005
 Burkhoff D, et al. *Mechanical Properties Of The Heart And Its Interaction With The Vascular System. (White Paper)* 2011

Sauren LDC, et al. *Artif Organs* 2007
 Meyns B, et al. *J Am Coll Cardiol* 2003
 Rimmelink M, et al. *atherter Cardiovasc Interv* 2007
 Aqel RA, et al. *J Nucl Cardiol* 2009
 Lam K, et al. *Clin Res Cardiol* 2009

Reesink KD, et al. *Chest* 2004
 Valgimigli M, et al. *Catheter Cardiovasc Interv* 2005
 Rimmelink M, et al. *Catheter Cardiovasc Interv* 2010
 Naidu S, et al. *Novel Circulation*.2011
 Weber DM, et al. *Cardiac Interventions Today Supplement Aug/Sep 2009*

HEMODYNAMIC STABILITY & LV UNLOADING WITH IMPELLA® DEVICES

Improvement in Cardiac Index

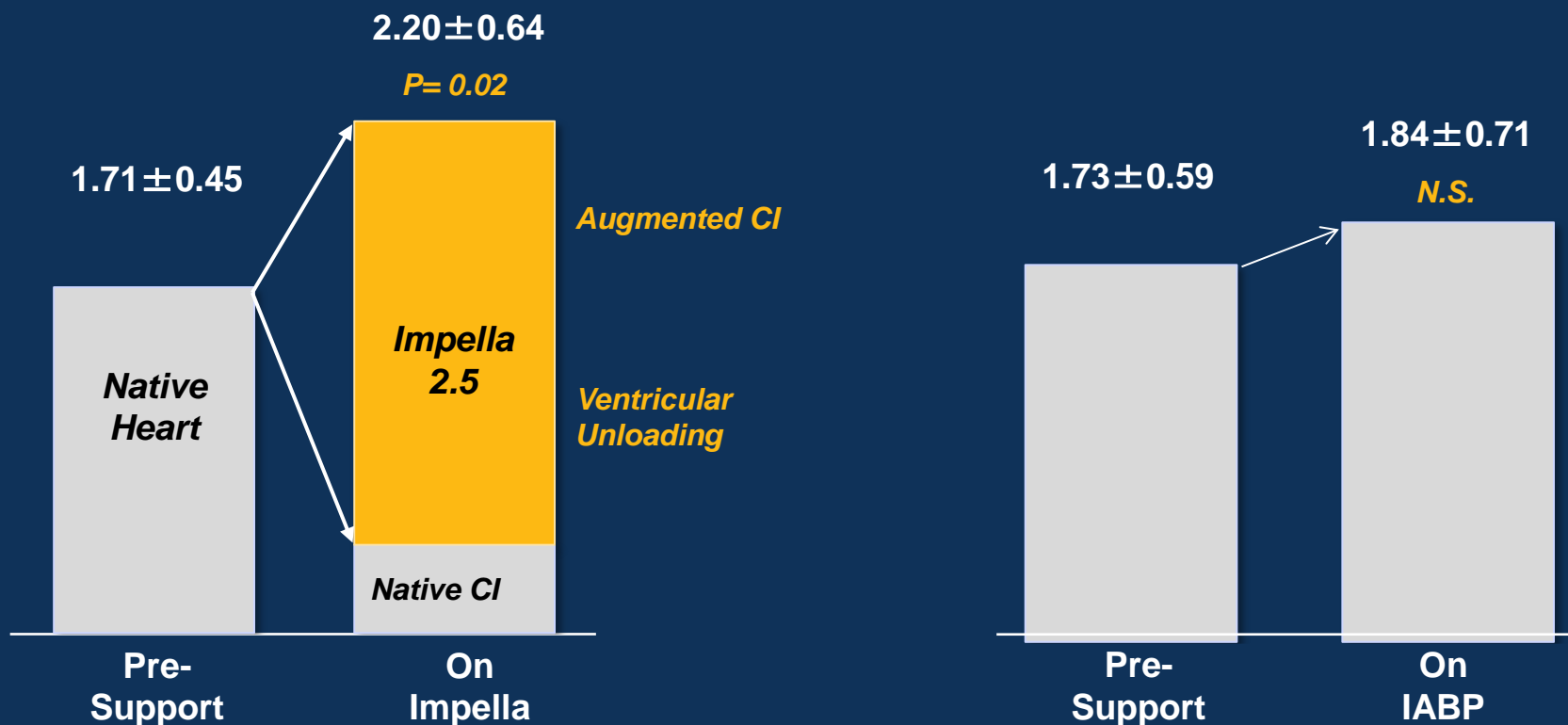
ISAR SHOCK Randomized Controlled Trial

(L/min/m²)

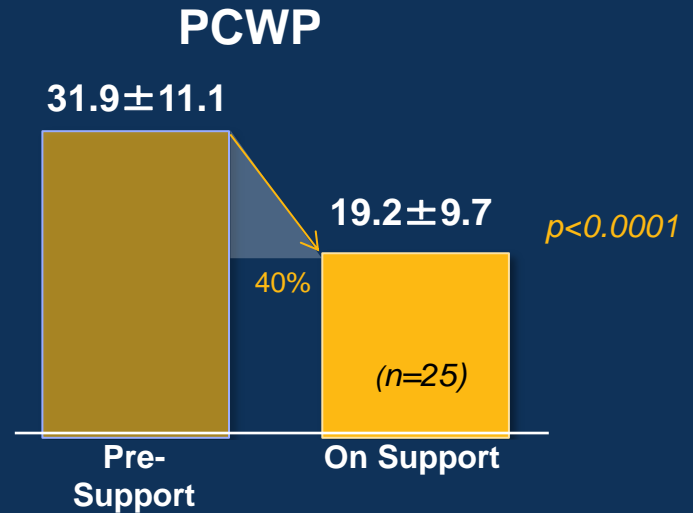
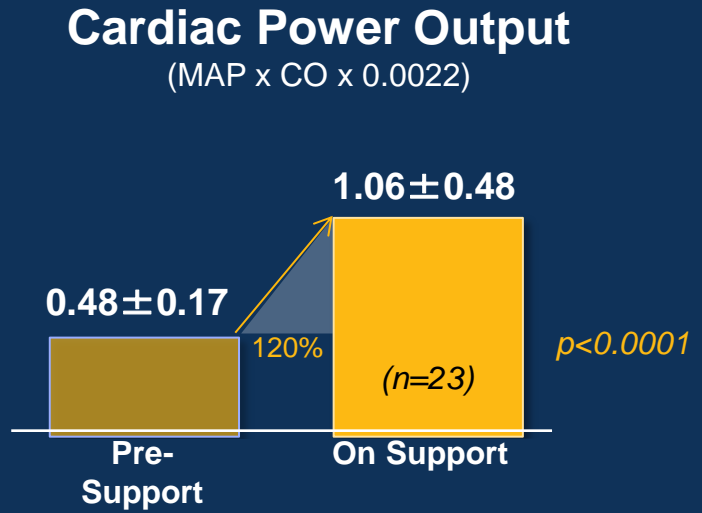
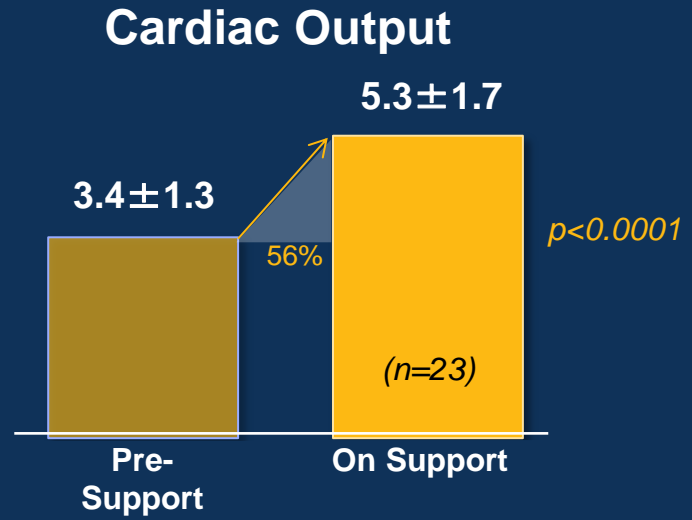
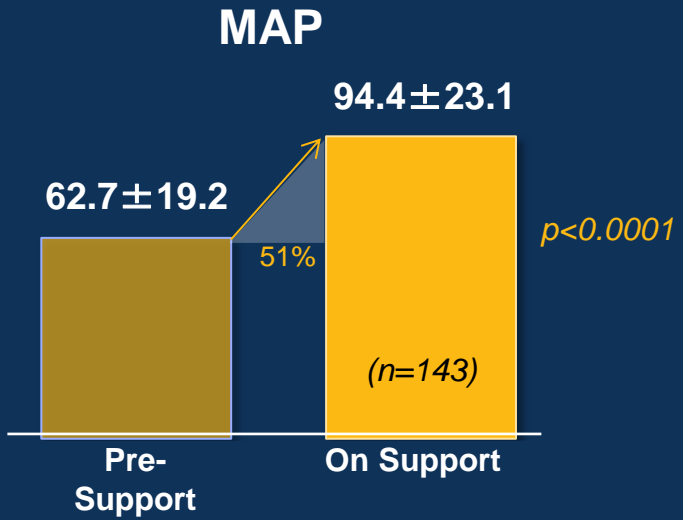
N=26

Impella 2.5

IABP



HEMODYNAMIC IMPROVEMENT IMPELLA[®] DEVICES - cVAD REGISTRY[™]

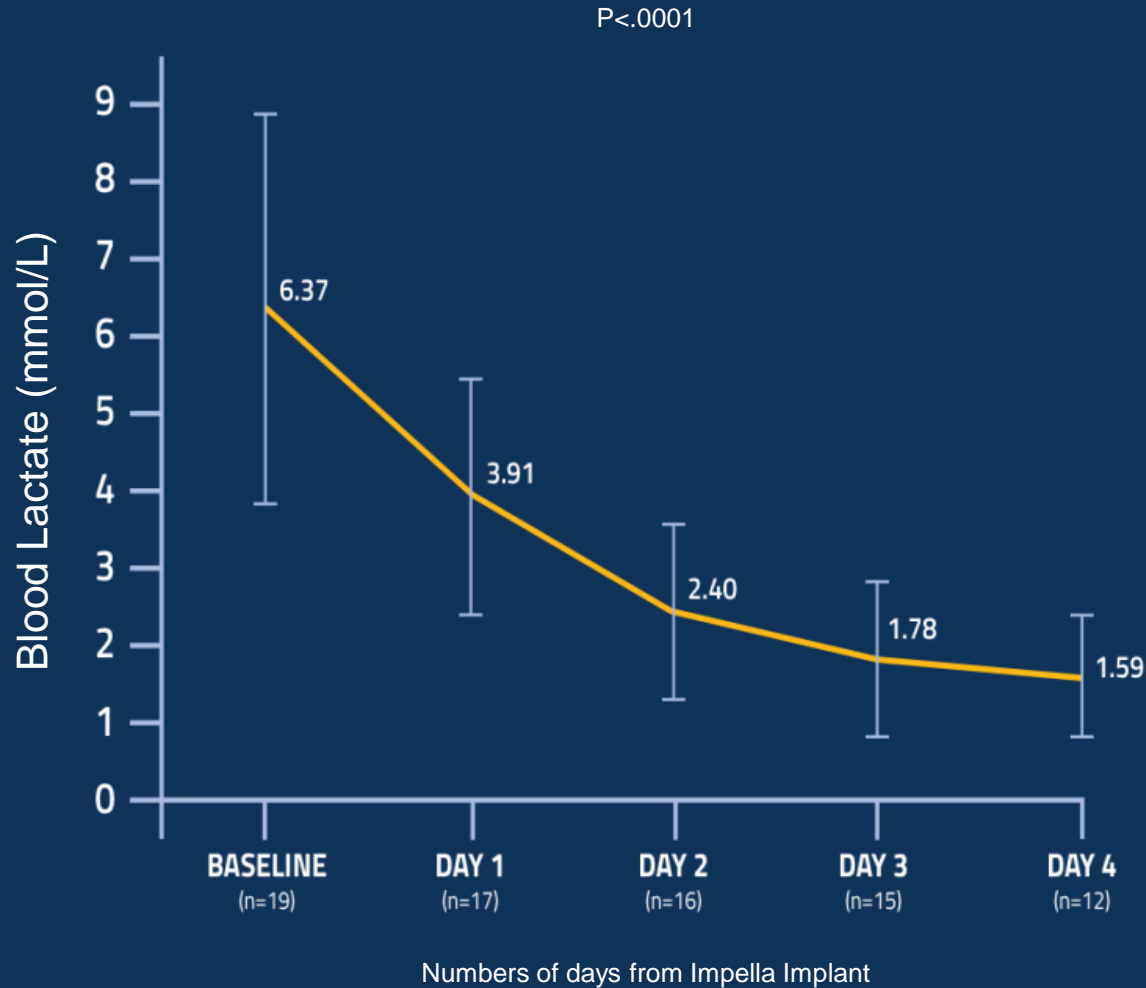


The catheter based VAD Registry is a worldwide, multicenter, IRB approved, monitored clinical registry of all patients at participating sites; registry data is used for FDA PMA submissions

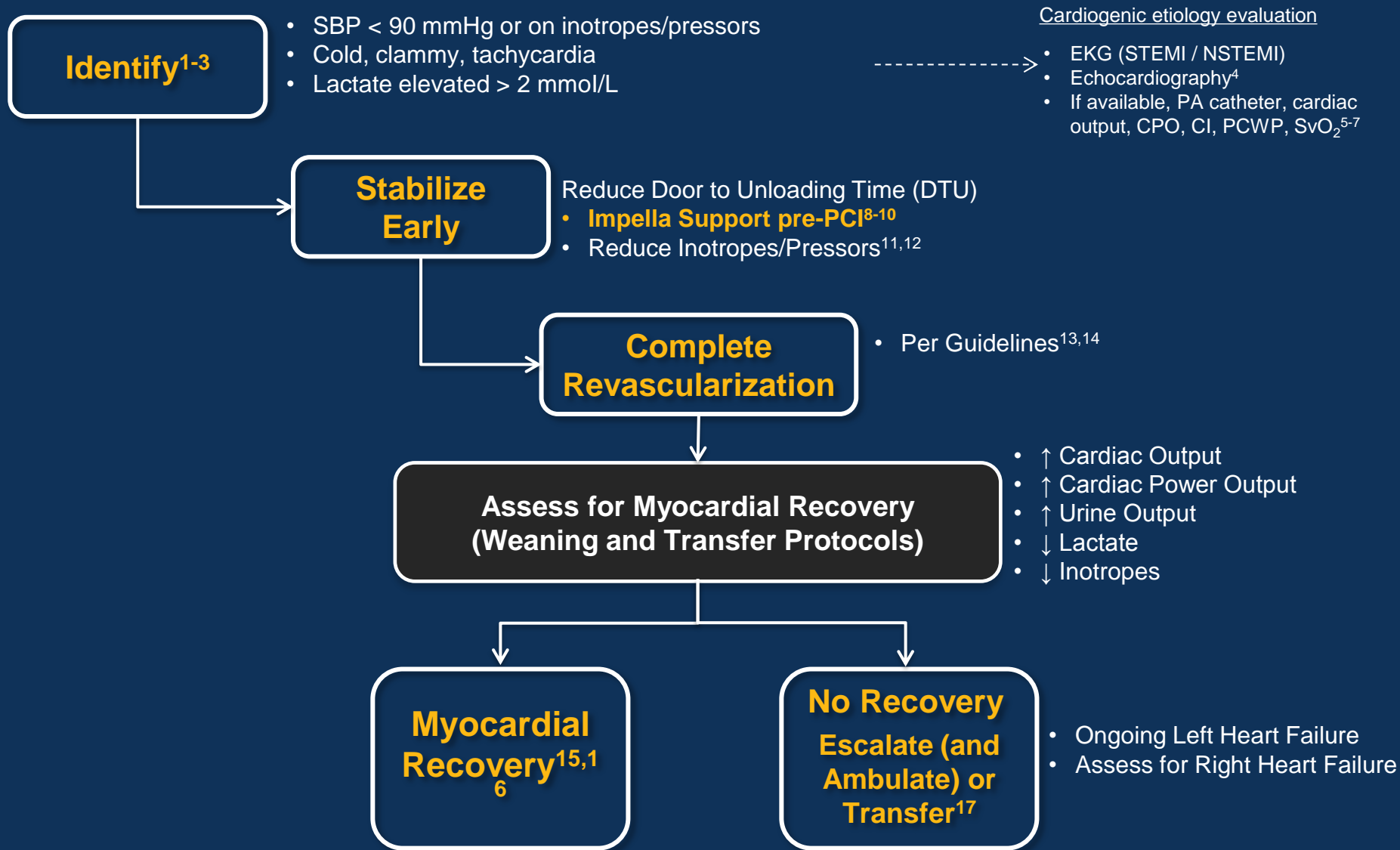
O'Neill, et. al. J Interven Cardiol, 2013

IMPROVED END ORGAN PERFUSION WITH IMPELLA® DEVICES

Reduction of Blood Lactate Concentration



IMPELLA® BEST PRACTICES IN AMI CARIOGENIC SHOCK



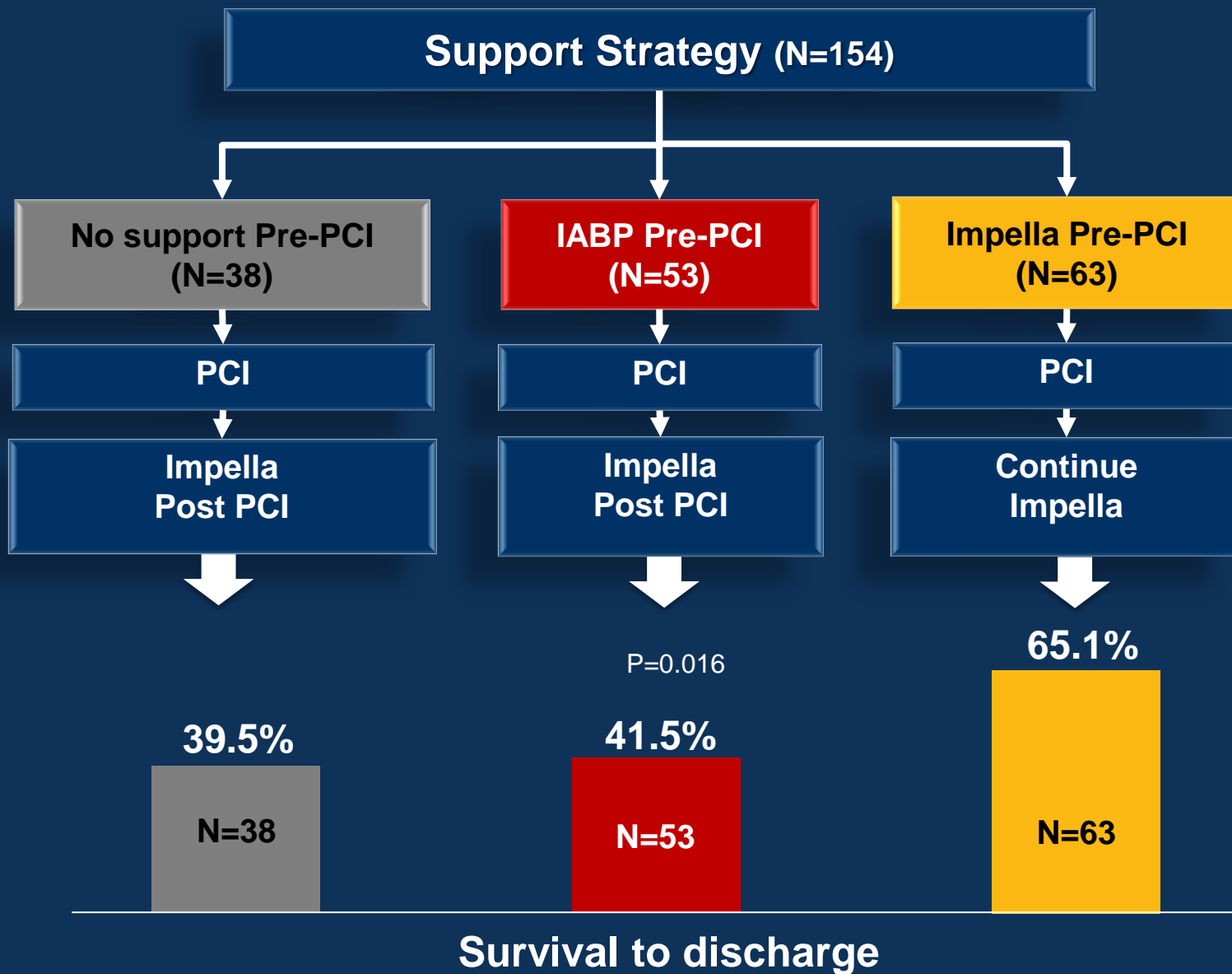
1. Reventovich A, et al. *Nat Rev Cardiol*. 2016;13(8):481-492.
 2. Hochman JS, et al. *N Engl J Med*. 1999;341(9):625-634.
 3. Rihal CS, et al. *J Am Coll Cardiol*. 2015;65(19):e7-e26.
 4. Picard MH, et al. *Circulation*. 2003;107(2):279-284.
 5. Cohen MG, et al. *Am J Med*. 2005;118(5):482-488.

6. Kahwash R, et al. *Cardiol Clin*. 2011;29(2):281-288.
 7. Chatterjee K. *Circulation* 2009;119(1):147-152.
 8. O'Neill WW, et al. *J Interv Cardiol*. 2014;27(1):1-11.
 9. Joseph SM, et al. *J Interv Cardiol*. 2016 Jun;29(3):248-56.

10. Schroeter MR, et al. *J Invasive Cardiol*. 2016 Aug 15. [Epub ahead of print]
 11. Samuels LE, et al. *J Card Surg*. 1999;14(4):289-293.
 12. De Backer D, et al. *N Engl J Med*. 2010;362(9):779-789.
 13. O'Gara PT, et al. *J Am Coll Cardiol*. 2013;61(4):e78-e140.

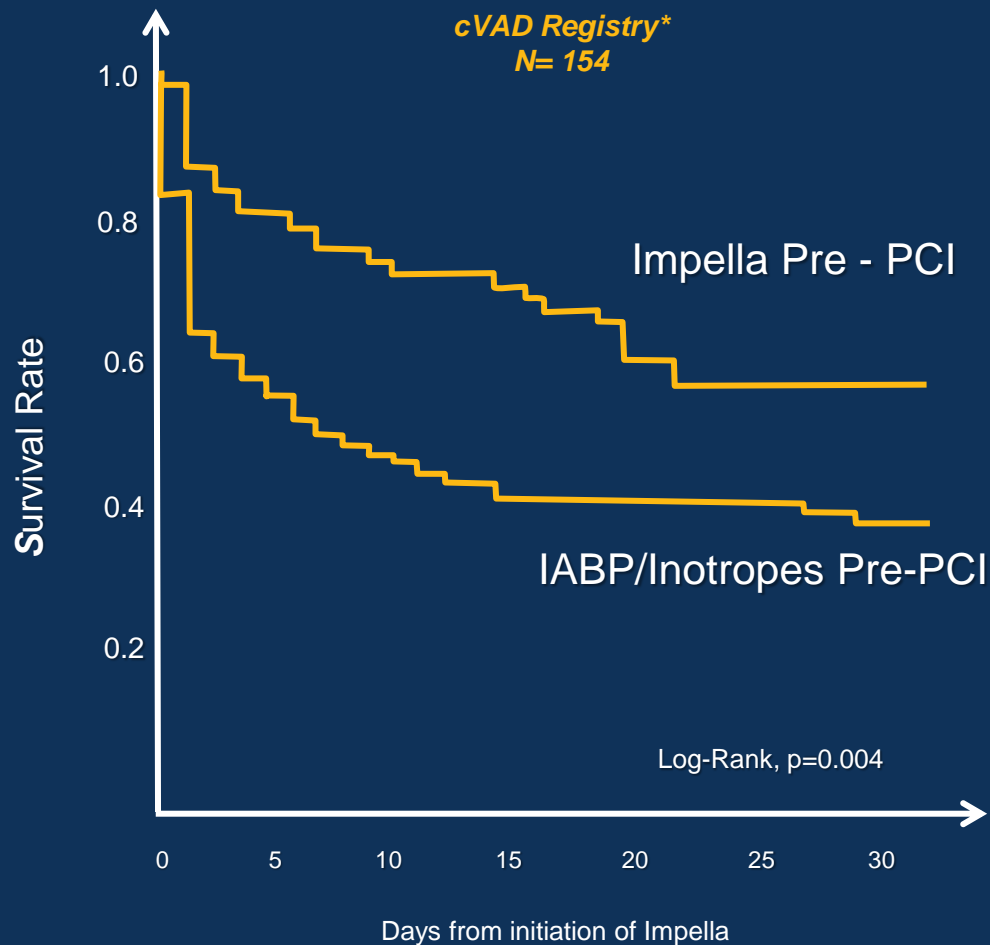
14. Steg PG, et al. *Eur Heart J*. 2012;33(20):2569-2619.
 15. Casassus F, et al. *J Interv Cardiol*. 2015;28(1):41-50.
 16. Lemaire A, et al. *Ann Thorac Surg*. 2014;97(1):133-138.
 17. Anderson MB, et al. *J Heart Lung Transplant*. 2015;34(12):1549-1560.

CLINICAL OUTCOMES BY SUPPORT STRATEGY



TIMING OF SUPPORT IMPACTS OUTCOMES

30 Day Survival



Door to Balloon Metric - Cardiogenic Shock & hemodynamic support are excluded from Door to Balloon (DTB) metrics Source: CMS, SCAI & ACC

*The catheter based VAD Registry is a worldwide, multicenter, IRB approved, monitored clinical registry of all patients at participating sites; registry data is used for FDA PMA submissions

HEMODYNAMIC EFFECTS OF ECMO

