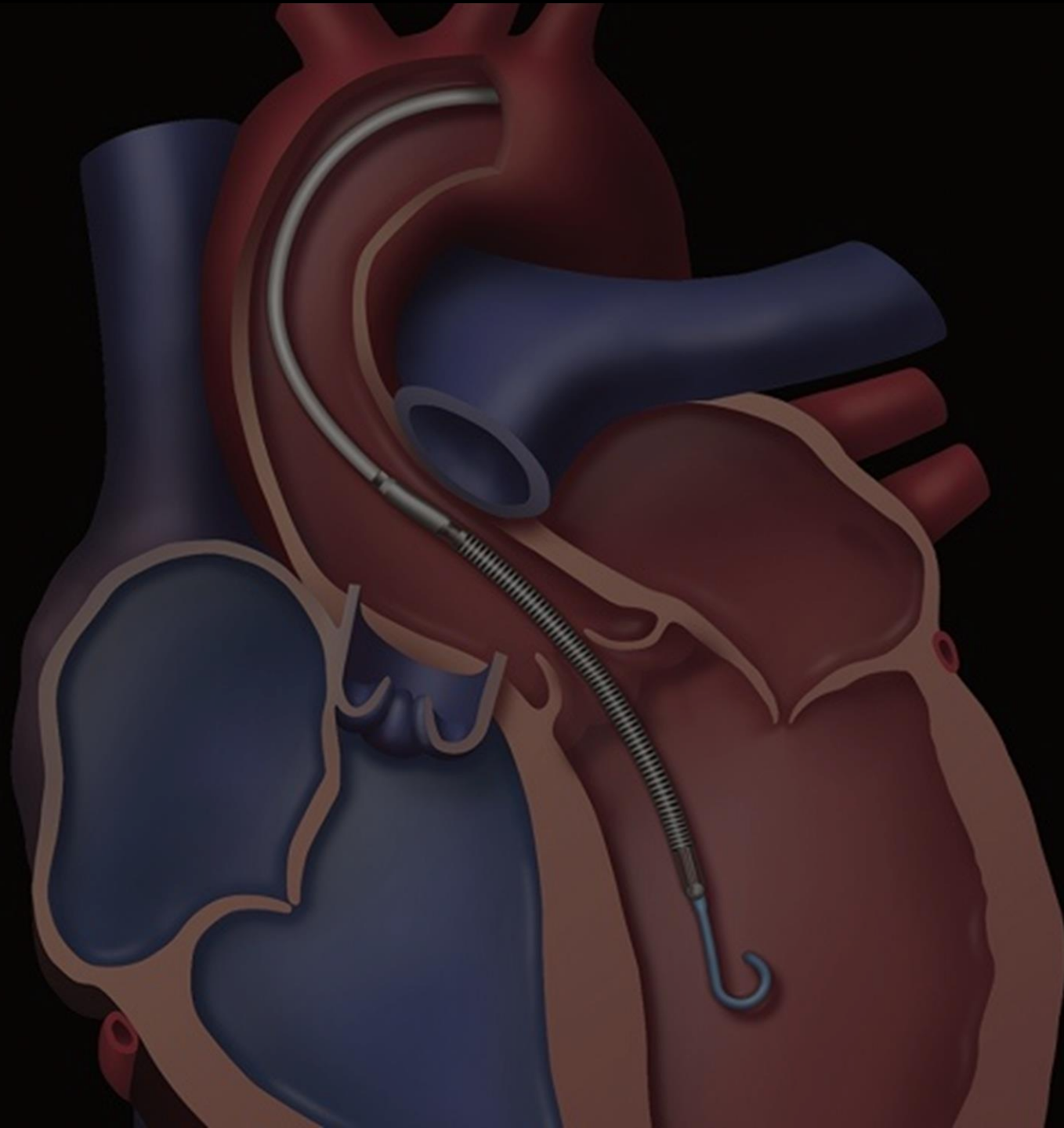


Use of **Mechanical Circulatory Support Devices** Among Patients With **ACS** Complicated by **Cardiogenic Shock**

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Department of Cardiovascular Surgery

Taipei Veterans General Hospital



Outline

- ✓ Cardiogenic shock
- ✓ Mechanical circulatory support device
- ✓ IABP, Intra-arterial balloon pump
- ✓ Impella heart pump
- ✓ ECMO pump

Cardiogenic shock

TABLE 1 Hemodynamic Criteria for Cardiogenic Shock

Clinical

- SBP <90 mm Hg for 30 min
- Supportive measures needed to maintain SBP >90 mm Hg
- End-organ hypoperfusion
- Cool extremities
- UOP <30 mL/h
- HR >60 beats/min

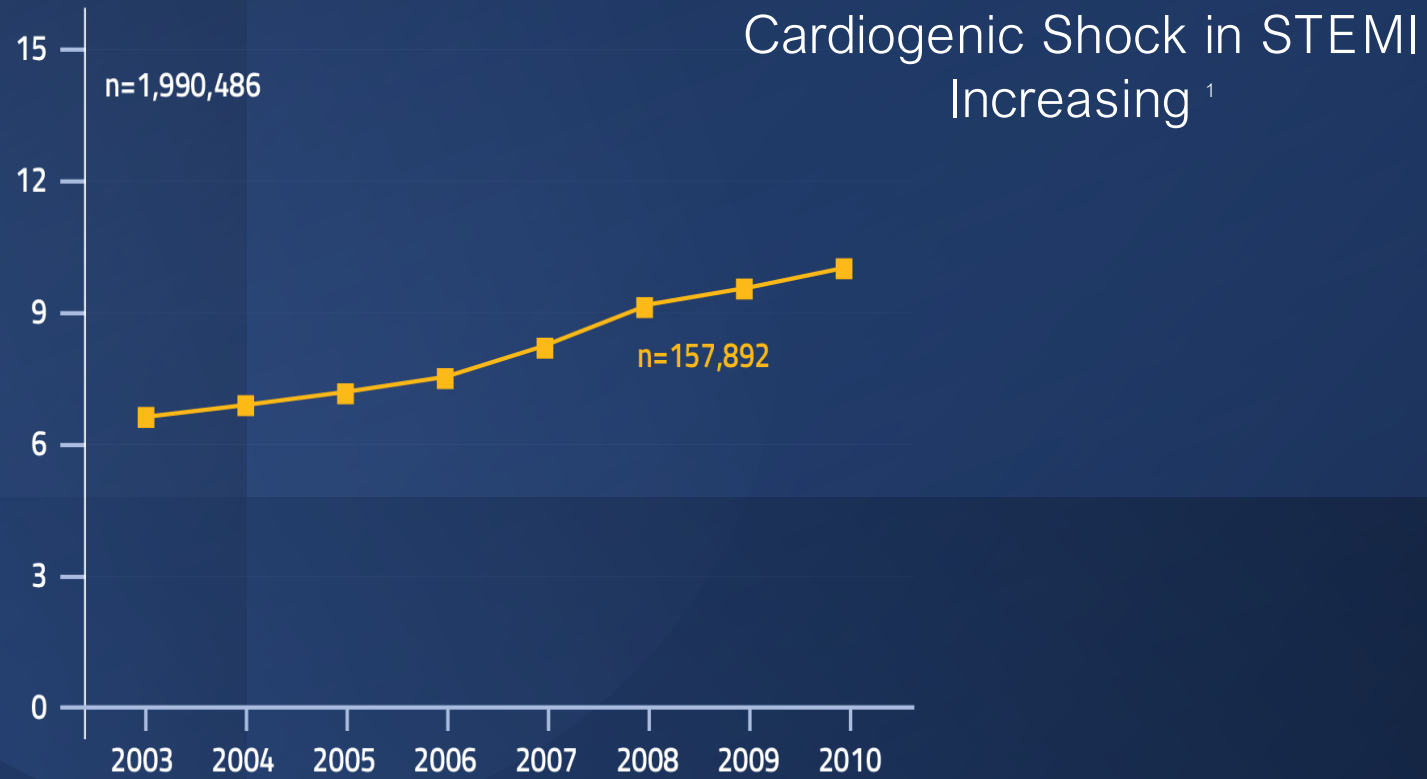
Hemodynamic

- Cardiac index <2.2 mL/min/m²
- PCWP >15 mm Hg

The SHOCK trial defined cardiogenic shock according the clinical and hemodynamic criteria listed (11).

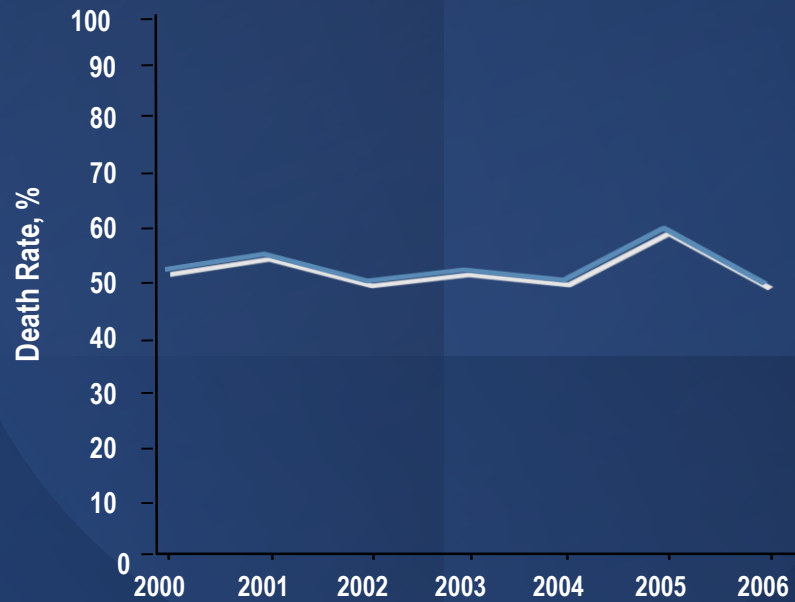
HR = heart rate; PCWP = pulmonary capillary wedge pressure; SBP = systolic blood pressure; UOP = urine output.

Incidence of cardiogenic shock growing

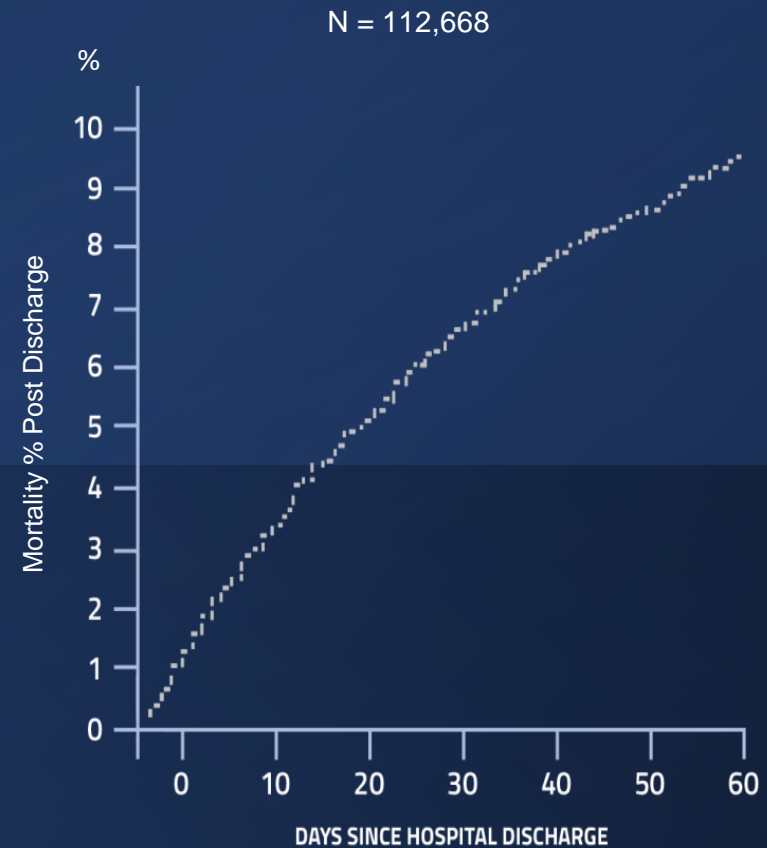


Cardiogenic shock remains leading cause of death

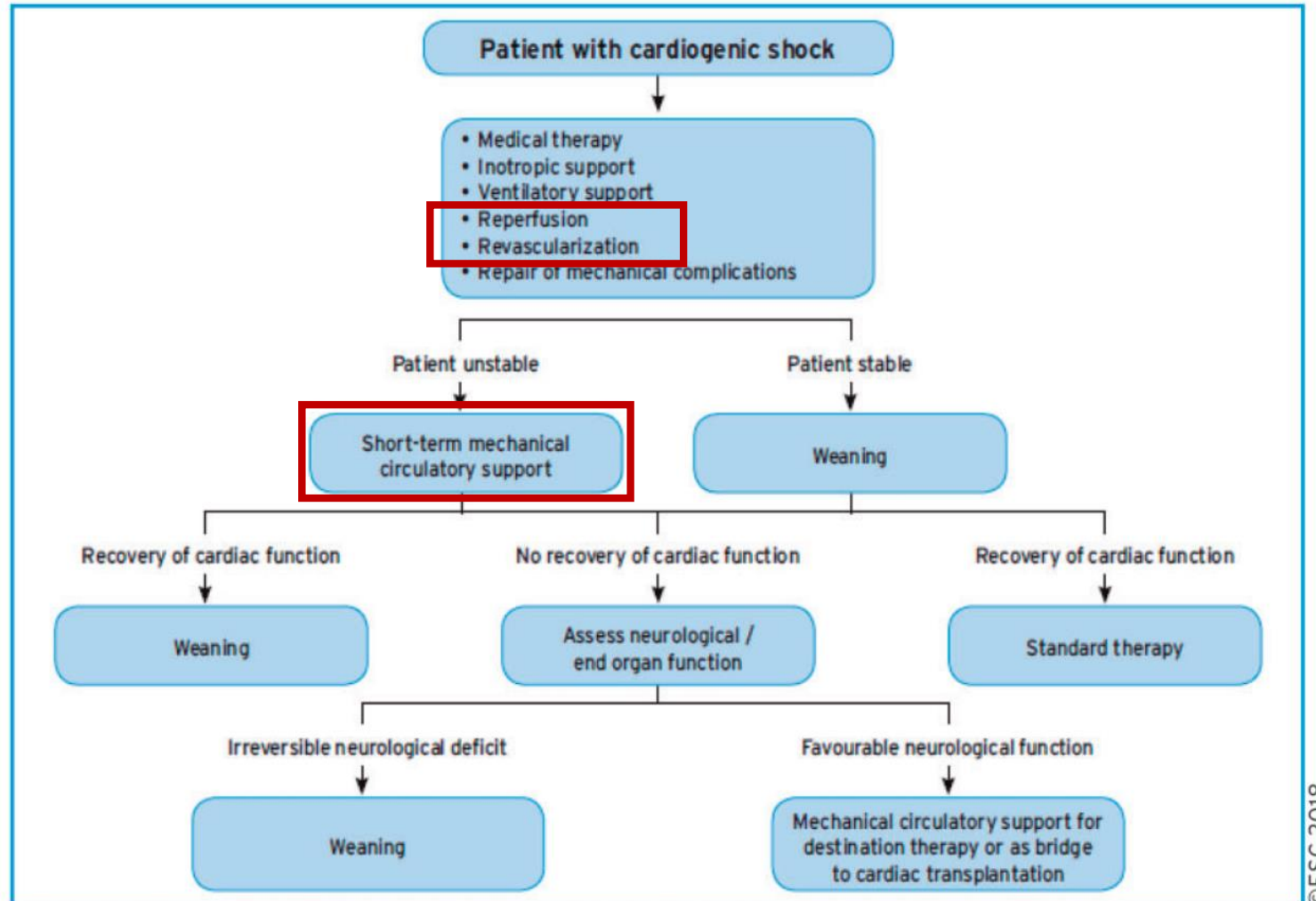
High In-Hospital Mortality
During AMI Cardiogenic Shock¹



... and Ongoing Hazard Post Discharge
after AMI Cardiogenic Shock²

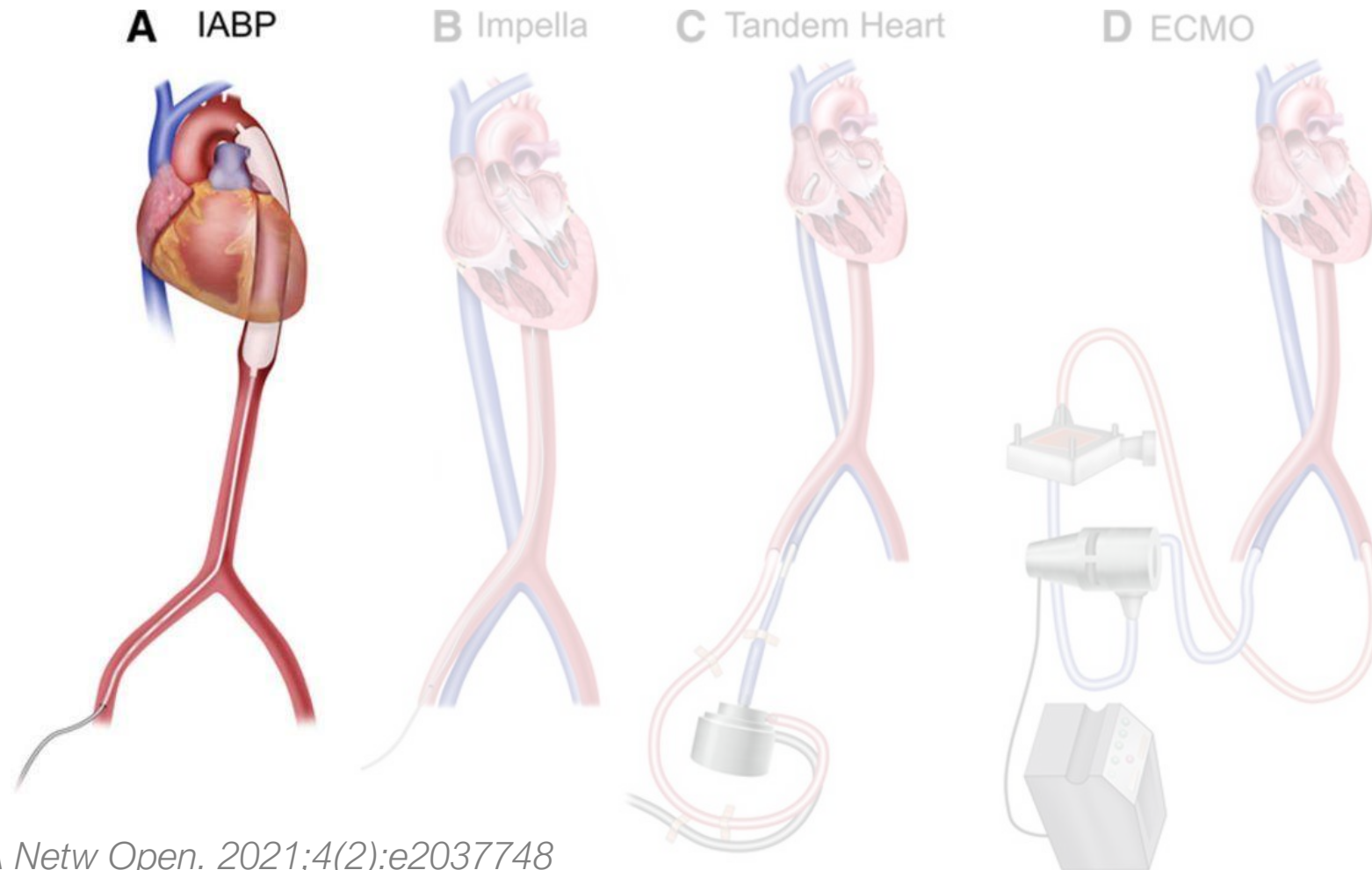


Algorithm for the management of Cardiogenic shock

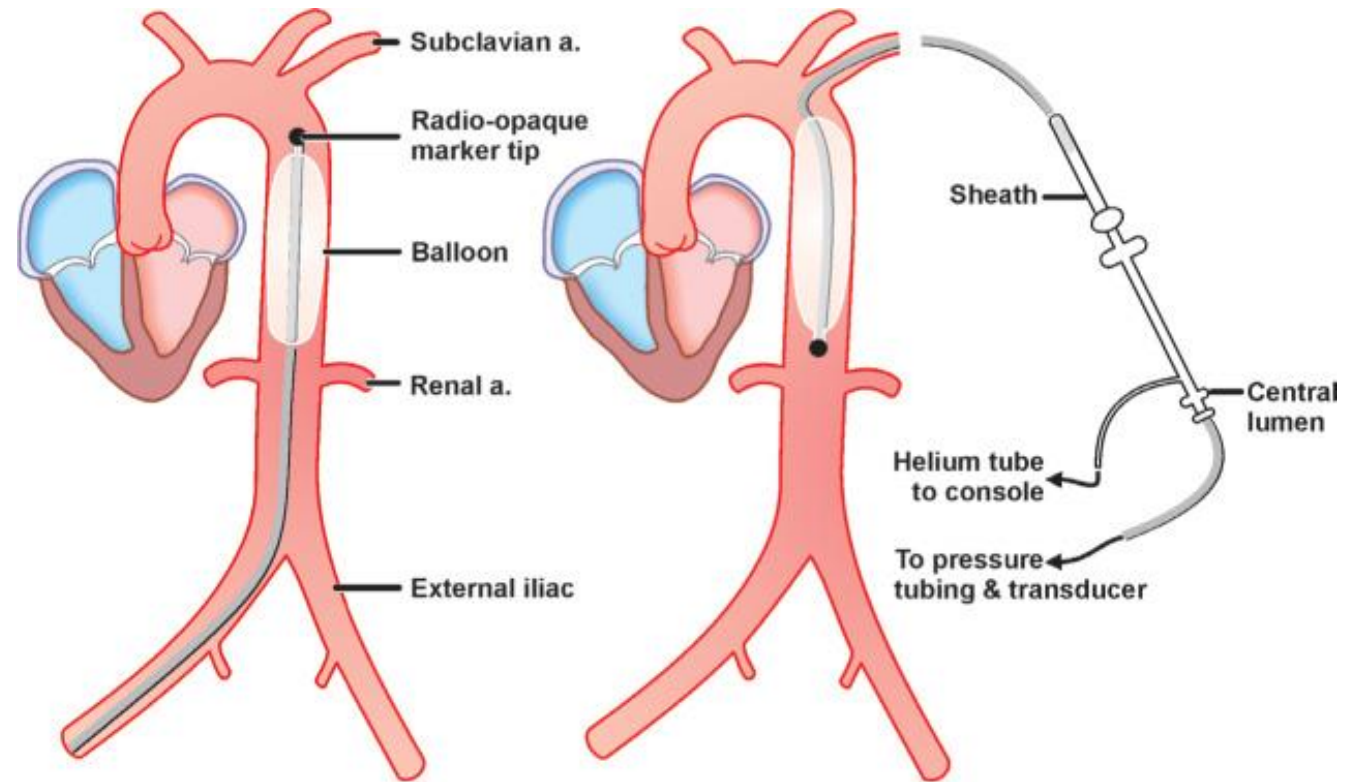


2018 ESC guideline

Mechanical circulatory support

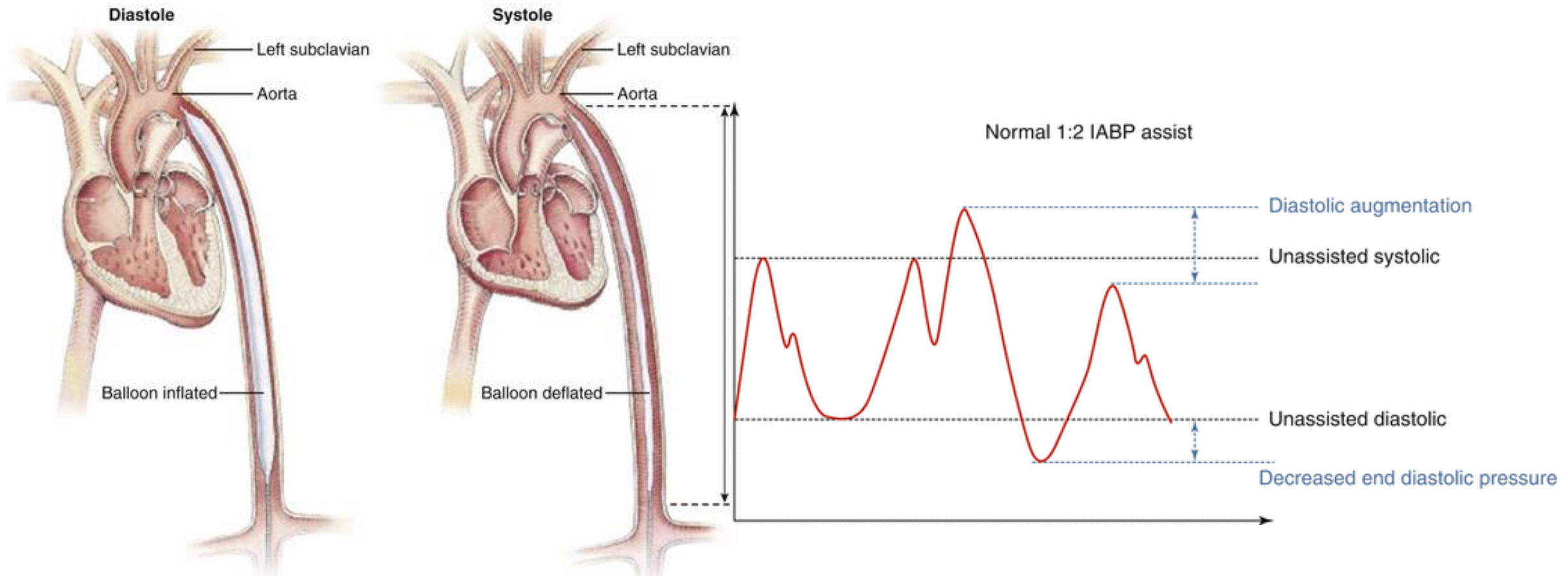


Intra-arterial balloon pump, IABP



<https://thoracickey.com/intra-aortic-balloon-pump-iabp-placement/>

Arterial waveform with IABP support



Hemodynamic change after IABP



| | |
|----------------|---|
| Aorta | ↓systolic pressure, ↑diastolic pressure |
| Left ventricle | ↓systolic pressure, ↓end-diastolic pressure, ↓volume, ↓wall tension |
| Heart | ↓afterload, ↓preload, ↑cardiac output |
| Blood flow | ↑→ coronary blood flow |

Increasing coronary major and micro-perfusion

Unloading LV and cardiac workload

Timing of using IABP

Indication

Cardiogenic shock after MI
Cardiac failure after surgery
Refractory angina
Refractory ventricular arrhythmia
Acute MR or VSD
Short-term bridge to heart transplant

Contraindication

Aortic valve insufficiency
Severe PAD
Aortic aneurysm or dissection

The role of IABP in ACS cardiogenic shock

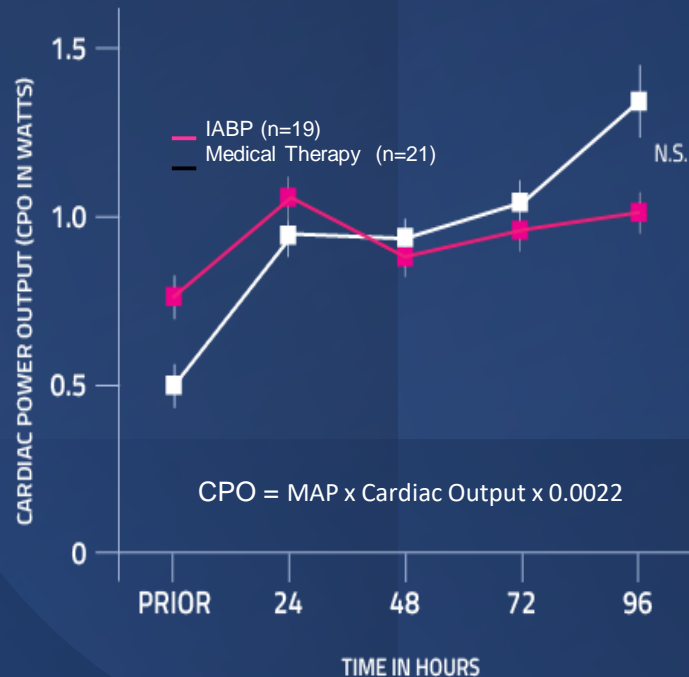
IABP shock I & IABP shock II trial

Randomized, prospective, open-label, multicenter trial,

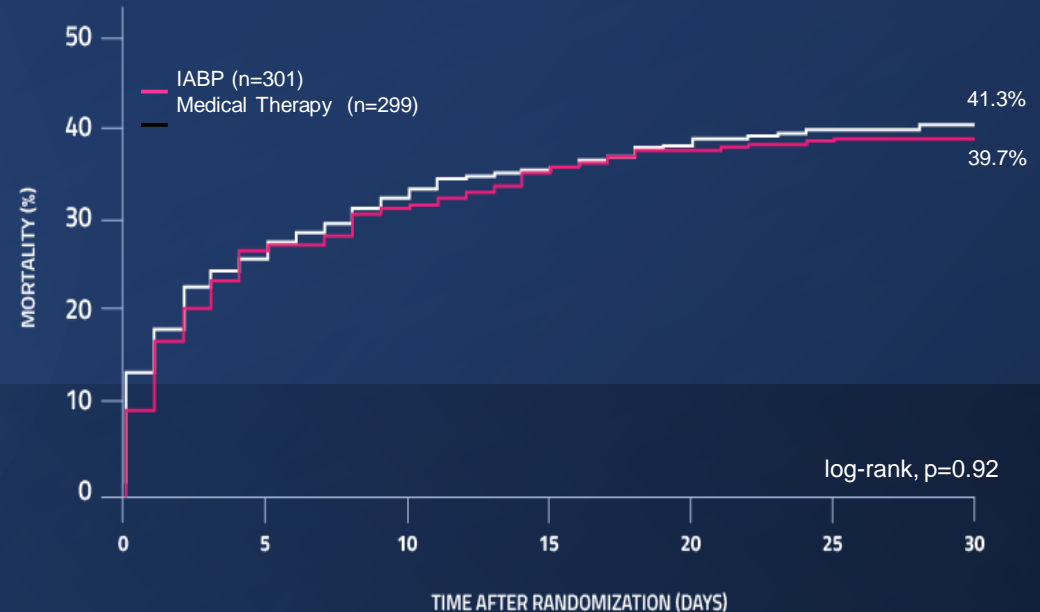
600 patients with cardiogenic shock complicating AMI were randomized to receive IABP (pre-PCI or post-PCI per operator discretion) or no IABP.

The role of IABP in ACS cardiogenic shock

IABP SHOCK I
Randomized Controlled Trial¹
N = 40



IABP-SHOCK II
Randomized Controlled Trial²
N = 600



The role of IABP for planned PCI (BCIS-1 Study)

MACCE at Discharge
 $p=0.85$

15.2%

16.0%

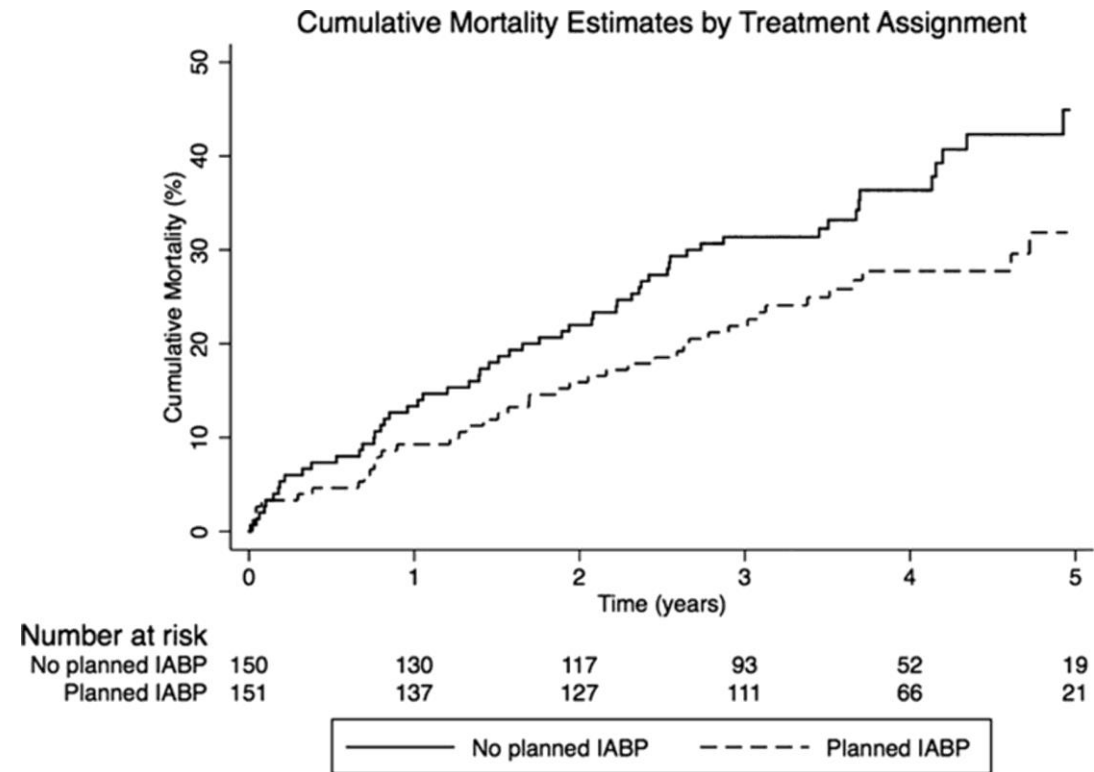
N= 151

N= 150

Elective
IABP

Not Planned IABP

Result do not support prophylactic use of IABP



Limited role of using IABP in ACS patients

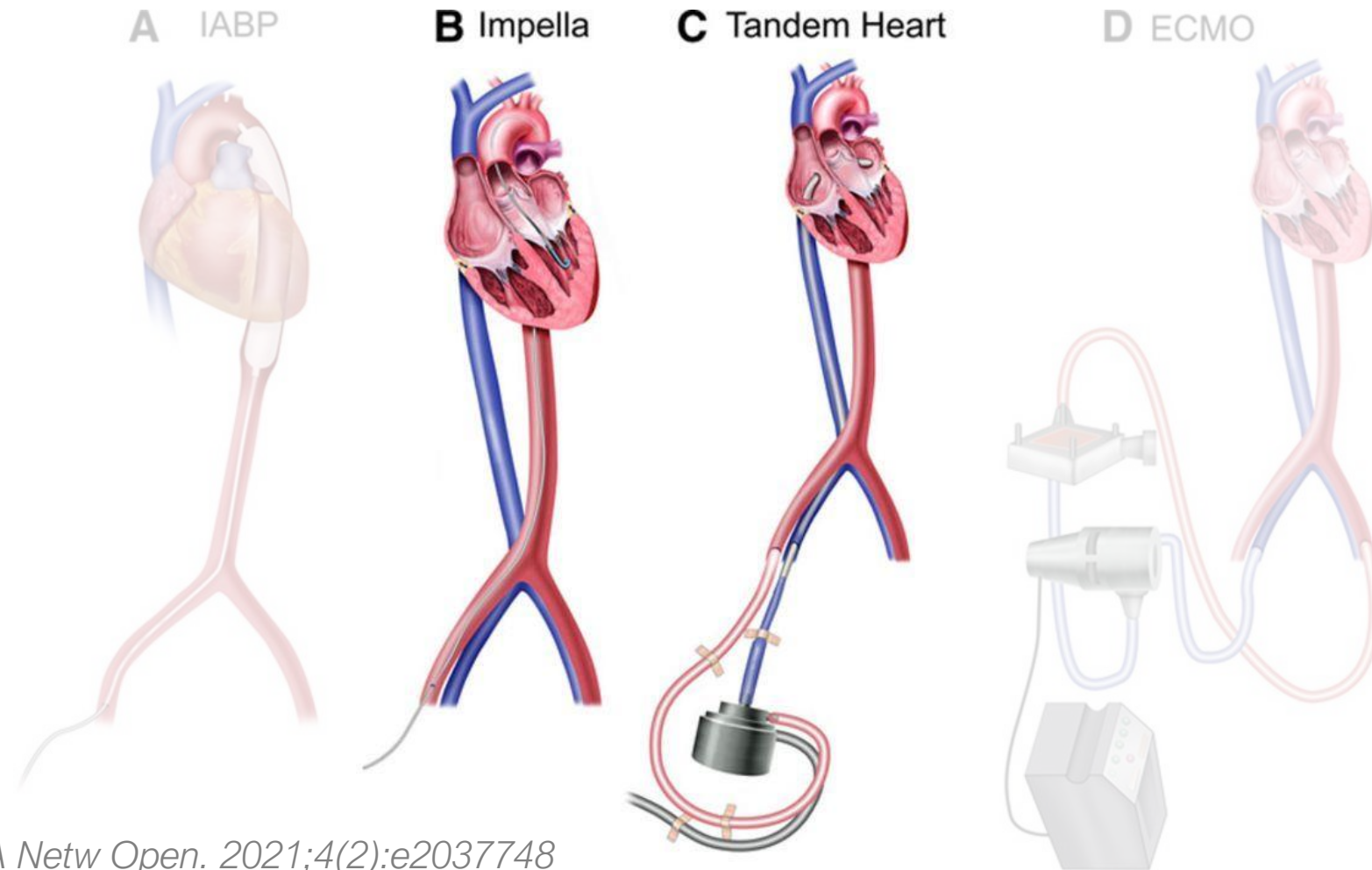
2018 ESC guideline in myocardial revascularization

PAMI-II Trial:

IABP increased hazard risk of stroke and ischemia

| | | |
|---|------------|----------|
| In selected patients with ACS and cardiogenic shock, short-term mechanical circulatory support may be considered, depending on patient age, comorbidities, neurological function, and the prospects for long-term survival and predicted quality of life. | IIb | C |
| Routine use of IABPs in patients with cardiogenic shock due to ACS is not recommended. ^{260–262} | III | B |

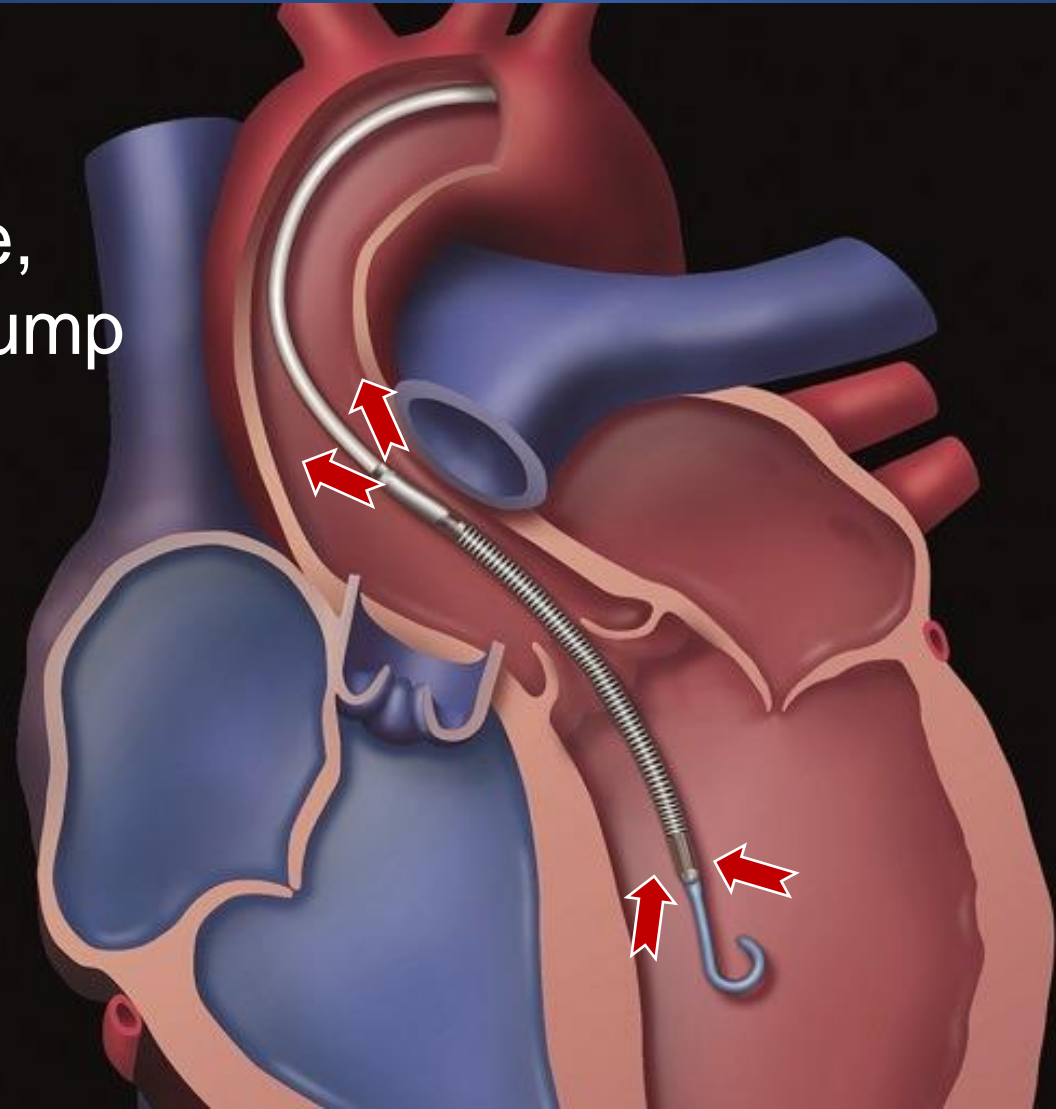
Mechanical circulatory support



Impella heart Pump



Continuous,
Nonpulsatile,
Axial flow pump

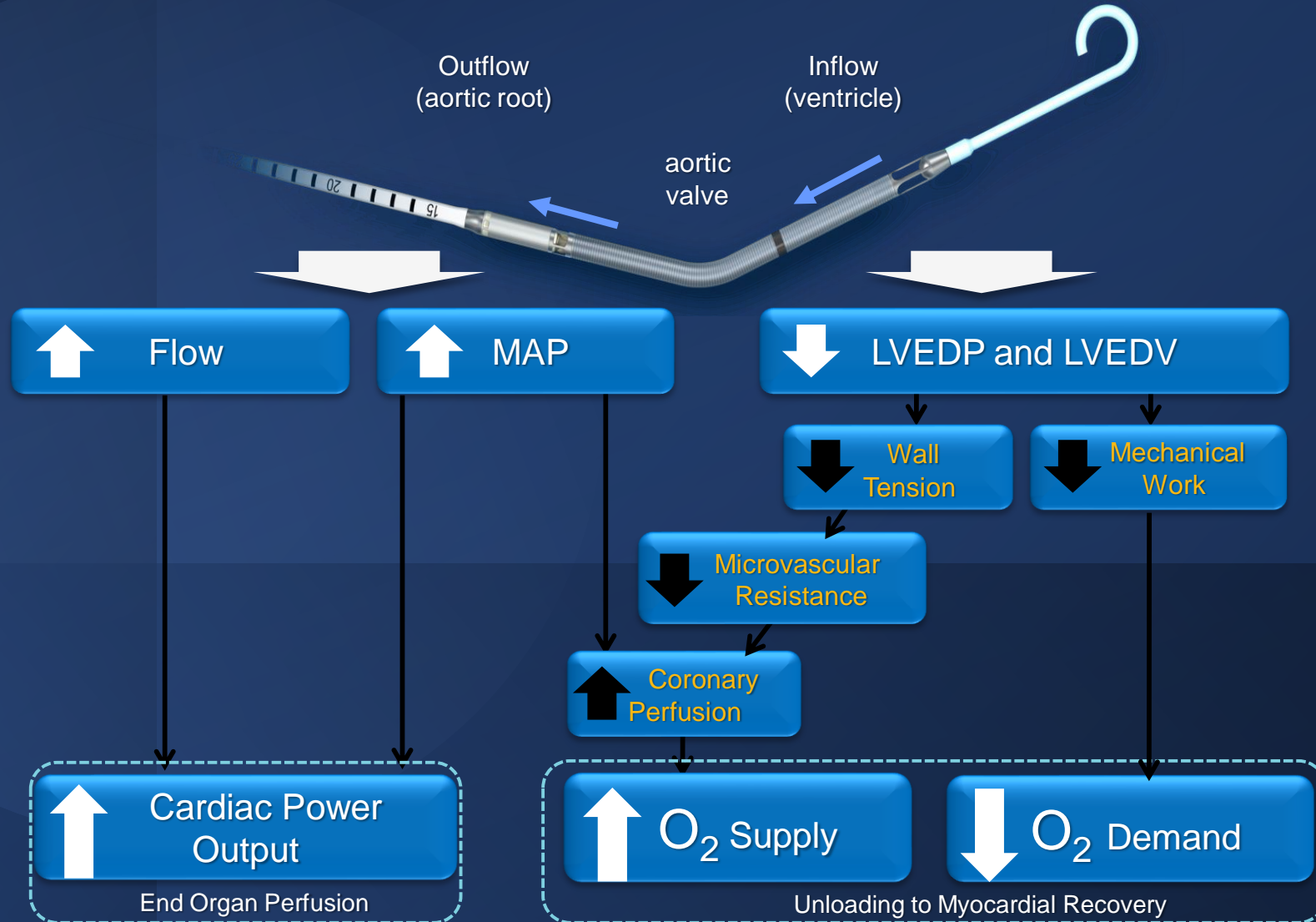


Impella heart Pump

| Impella Device | 2.5 | CP | 5.0 | LD | 5.5 | RP |
|------------------------------|----------------------------------|----------------------------------|-----------------------------|--------------------------|--|-----------------------------------|
| Indication | HRPCI and CS | HRPCI and CS | CS | CS | CS | RHF or decompensation |
| Introducer diameter | 13 Fr | 14 Fr | 23 Fr | -- | 23 Fr | 23 Fr |
| Pump motor | 12 Fr | 14 Fr | 21 Fr | 21 Fr | 19 Fr | 22 Fr |
| Access | Percutaneous femoral or axillary | Percutaneous femoral or axillary | Femoral cutdown or axillary | Direct insertion into AA | Axillary cutdown or direct insertion into AA | Percutaneous femoral vein (to PA) |
| Maximum average flow (l/min) | 2.5 | 3.7 | 5.0 | 5.3 | 5.5 | 4.4 |
| Maximum duration of support | HRPCI: ≤6 hours CS: ≤4 days | HRPCI: ≤6 hours CS: ≤4 days | 14 days | 14 days | 14 days | 14 days |
| SmartAssist? | N | Y | N | N | Y | N |

All catheter diameters are 9 Fr, with the exception of the Impella RP (11 Fr). AA = ascending aorta; CS = cardiogenic shock; HRPCI = high-risk percutaneous coronary intervention; PA = pulmonary artery; RHF = right heart failure.

Hemodynamic change of Impella support



Sahil K., et al. Cardiac Interventions Today 2018.

The role of Impella in ACS cardiogenic shock

Randomization of AMI patients with CS is challenging

| Study | Condition | Pts Required (n) | Pts Enrolled (n) | Duration (months) | Status | Reason for Discontinuation |
|--------------------------|-----------|------------------------|------------------------|----------------------|--------------|-------------------------------|
| FRENCH TRIAL (2006) | AMI CS | 200 | 19 | 52 | Discontinued | Low Enrollment |
| ISAR-SHOCK (2006) | AMI CS | 26 | 26 | 19 | Completed | N/A |
| RECOVER I FDA (2008) | PCCS | Up to 20 | 17 | 28 | Completed | N/A |
| RECOVER II FDA (2009) | AMI CS | 384 | 1 | 18 | Discontinued | Low Enrollment |
| RELIEF I (2010) | ADHF | 20 | 1 | 33 | Discontinued | Low Enrollment |
| DANSHOCK (2012) | AMI CS | 360 | ~50 | 40 | Enrolling | N/A |

The role of Impella in ACS cardiogenic shock

ISAR-SHOCK trial

Randomized, prospective, two-center trial, till 2006

26 patients with cardiogenic shock complicating AMI

IMPRESS trial

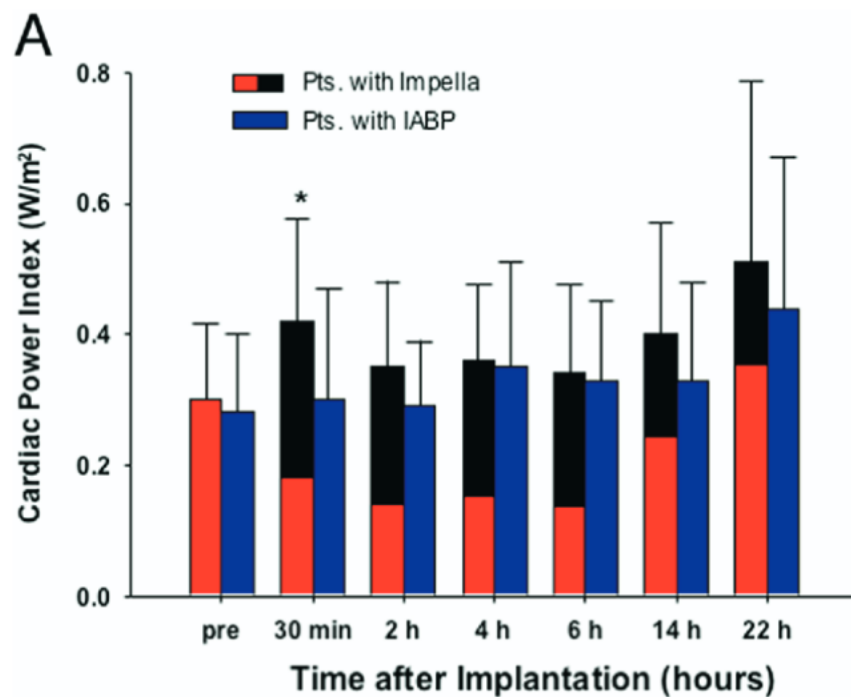
Randomized, prospective, multicenter trial, till 2014

48 patients with cardiogenic shock complicating AMI

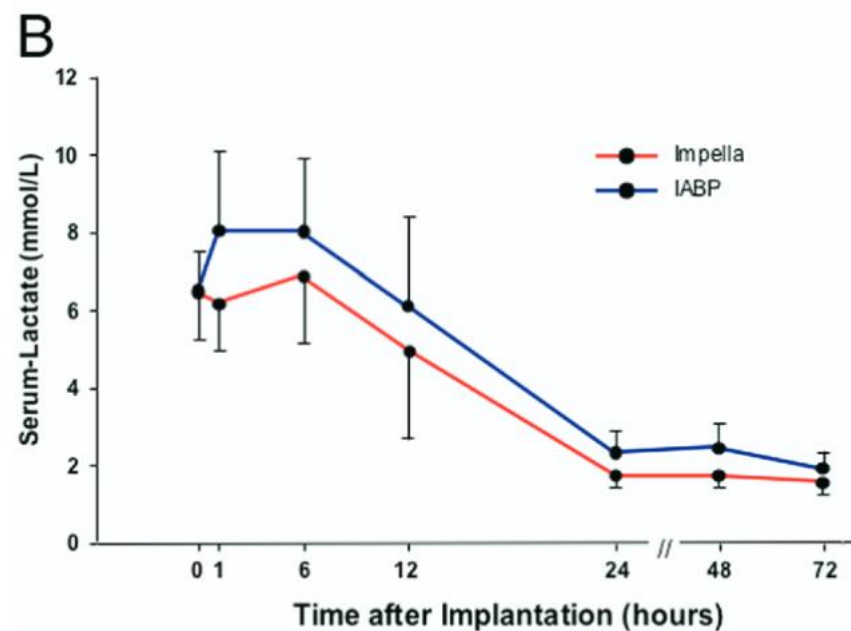
Melchior S., et al. J Am Coll Cardiol. 2008 Nov 4;52(19):1584-8.

Dagmar M., et al. J Am Coll Cardiol. 2017 Jan 24;69(3):278-287

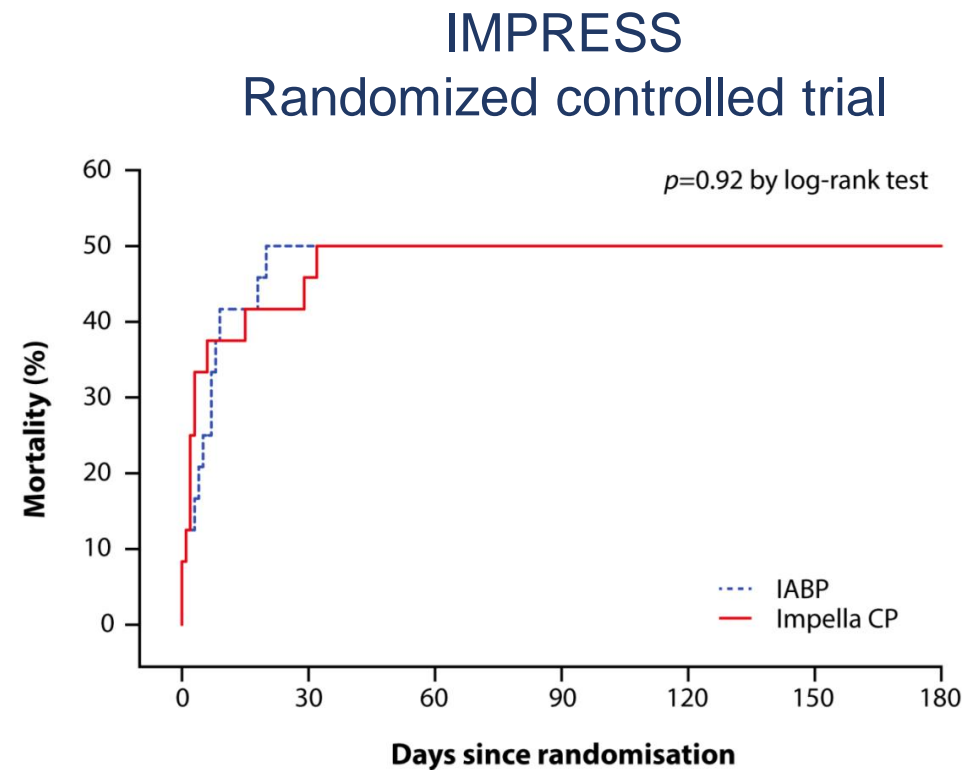
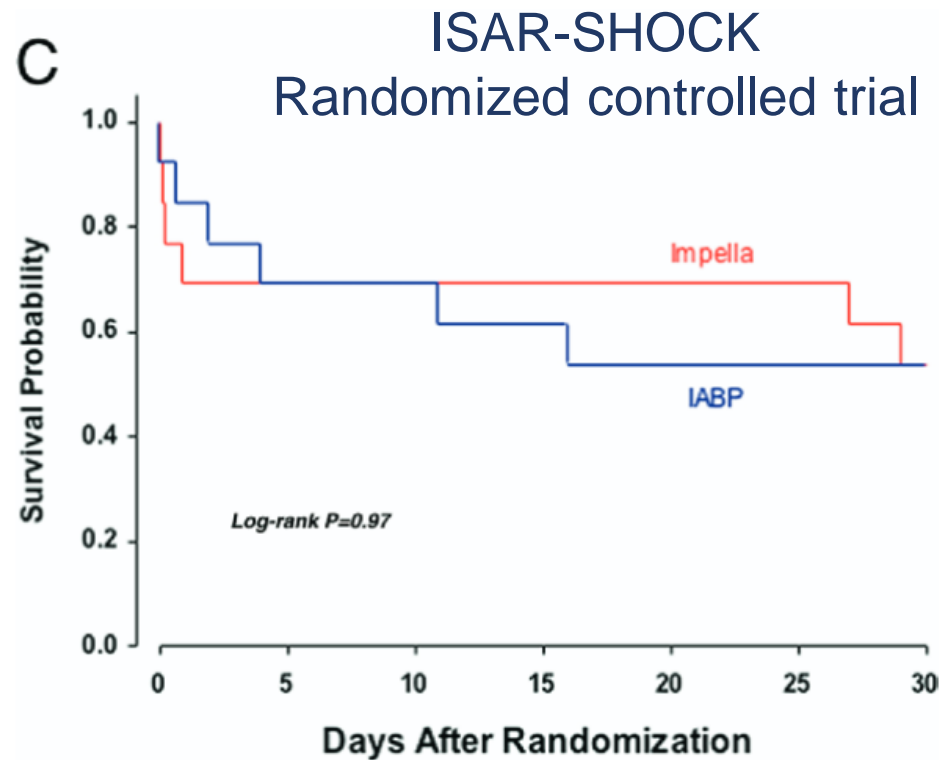
The role of Impella in ACS cardiogenic shock



ISAR-SHOCK Randomized controlled trial



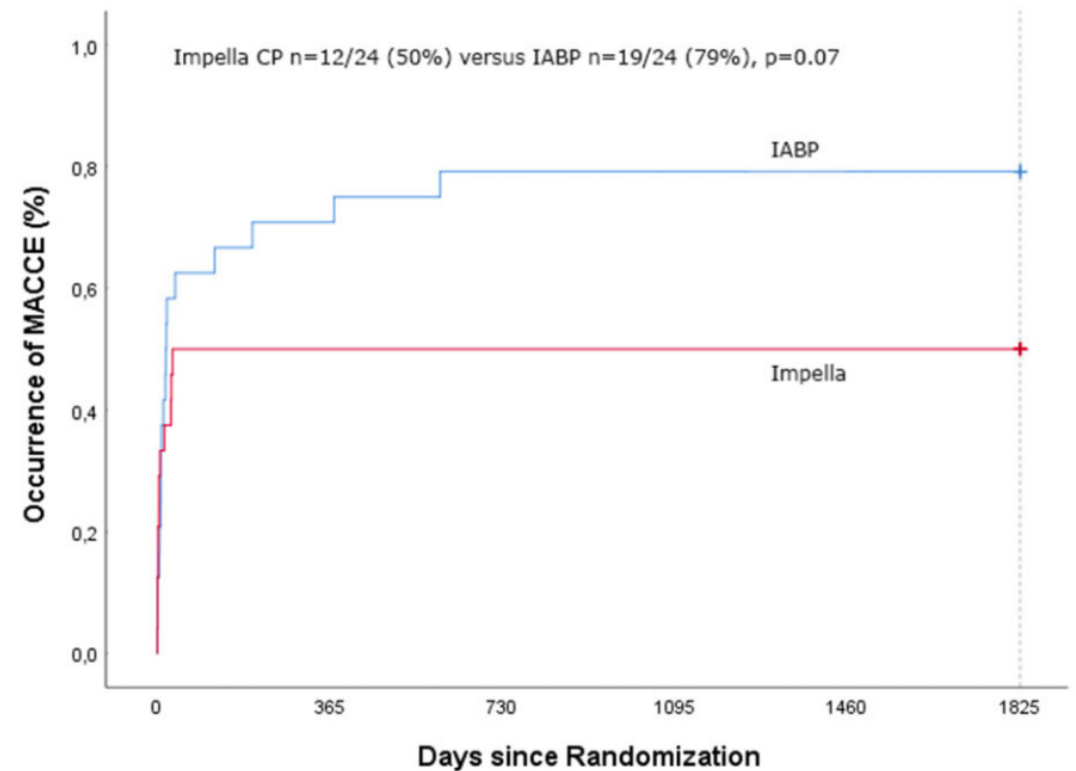
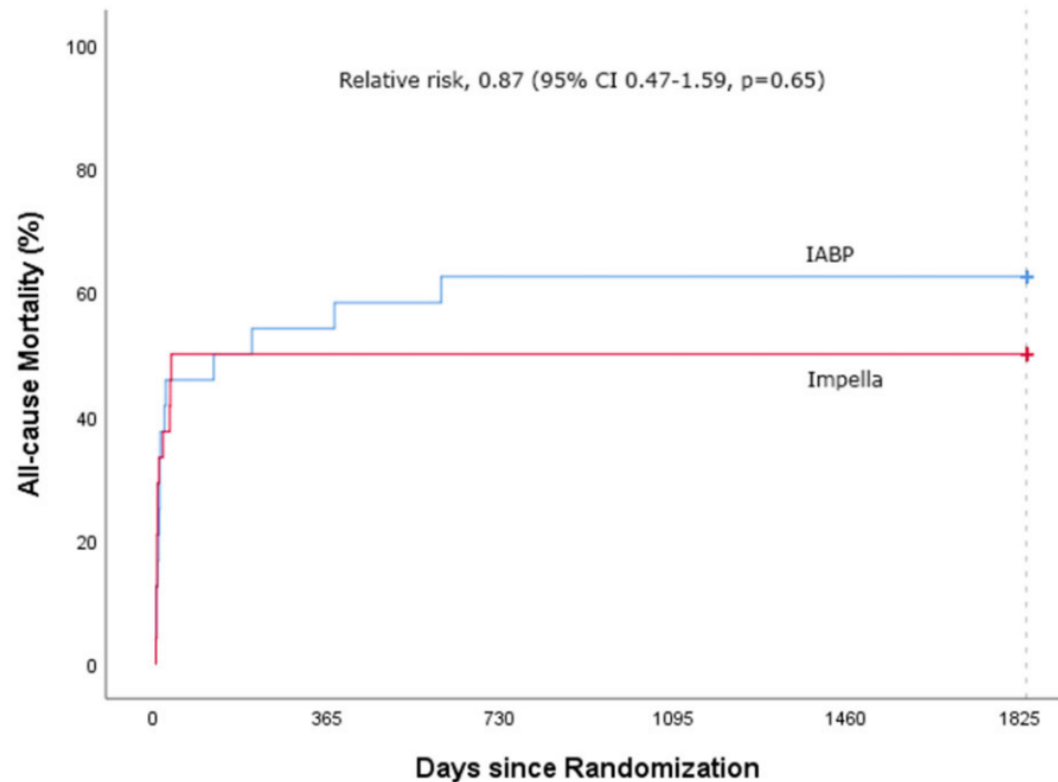
The role of Impella in ACS cardiogenic shock



Melchior S., et al. *J Am Coll Cardiol.* 2008 Nov 4;52(19):1584-8.
Dagmar M., et al. *J Am Coll Cardiol.* 2017 Jan 24;69(3):278-287

Less Major Adverse Cardiac and Cerebrovascular Events (MACCE) in Impella compared to IABP

5-years follow-up of IMPRESS randomized controlled trial

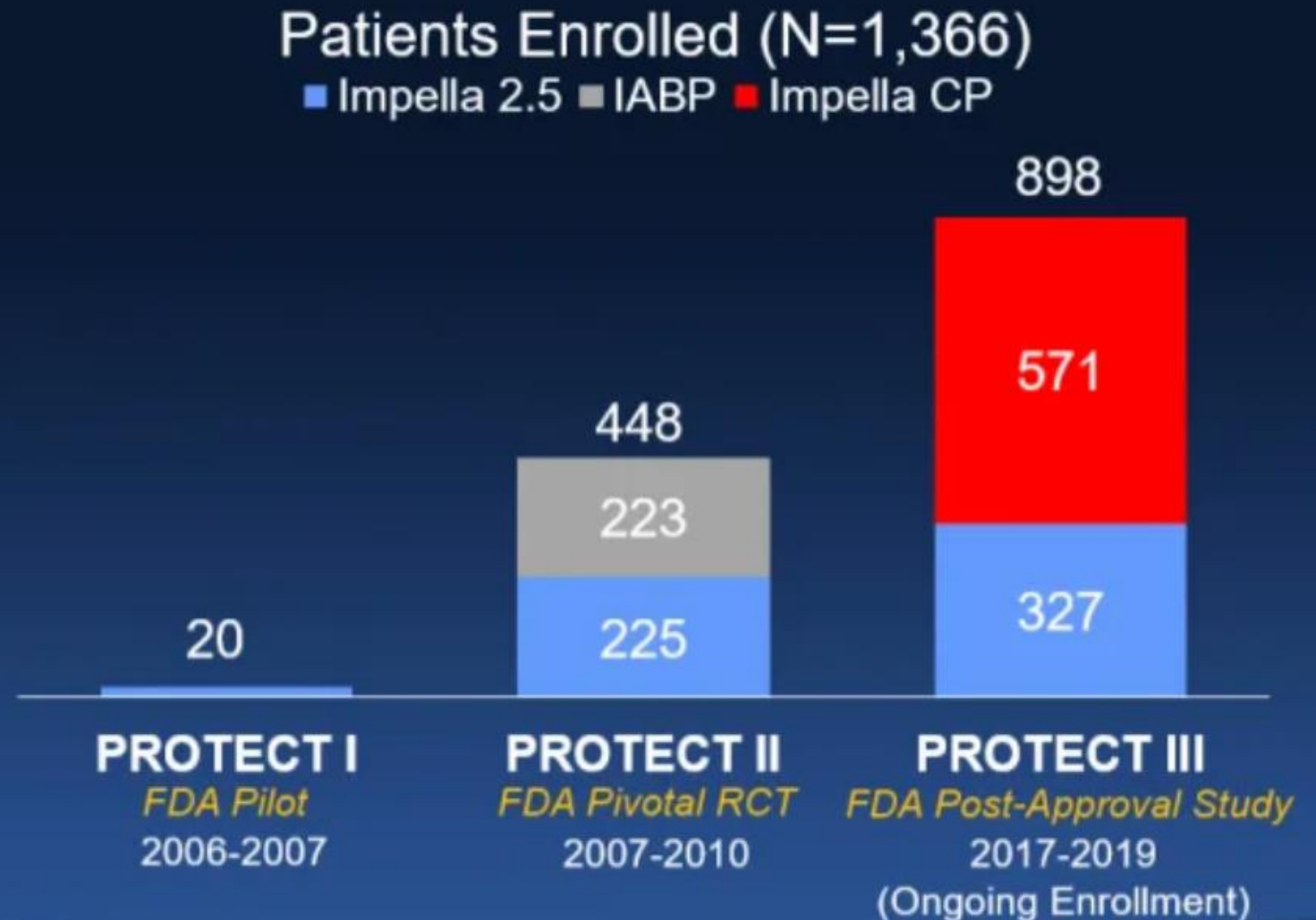


The role of Impella in high-risk PCI

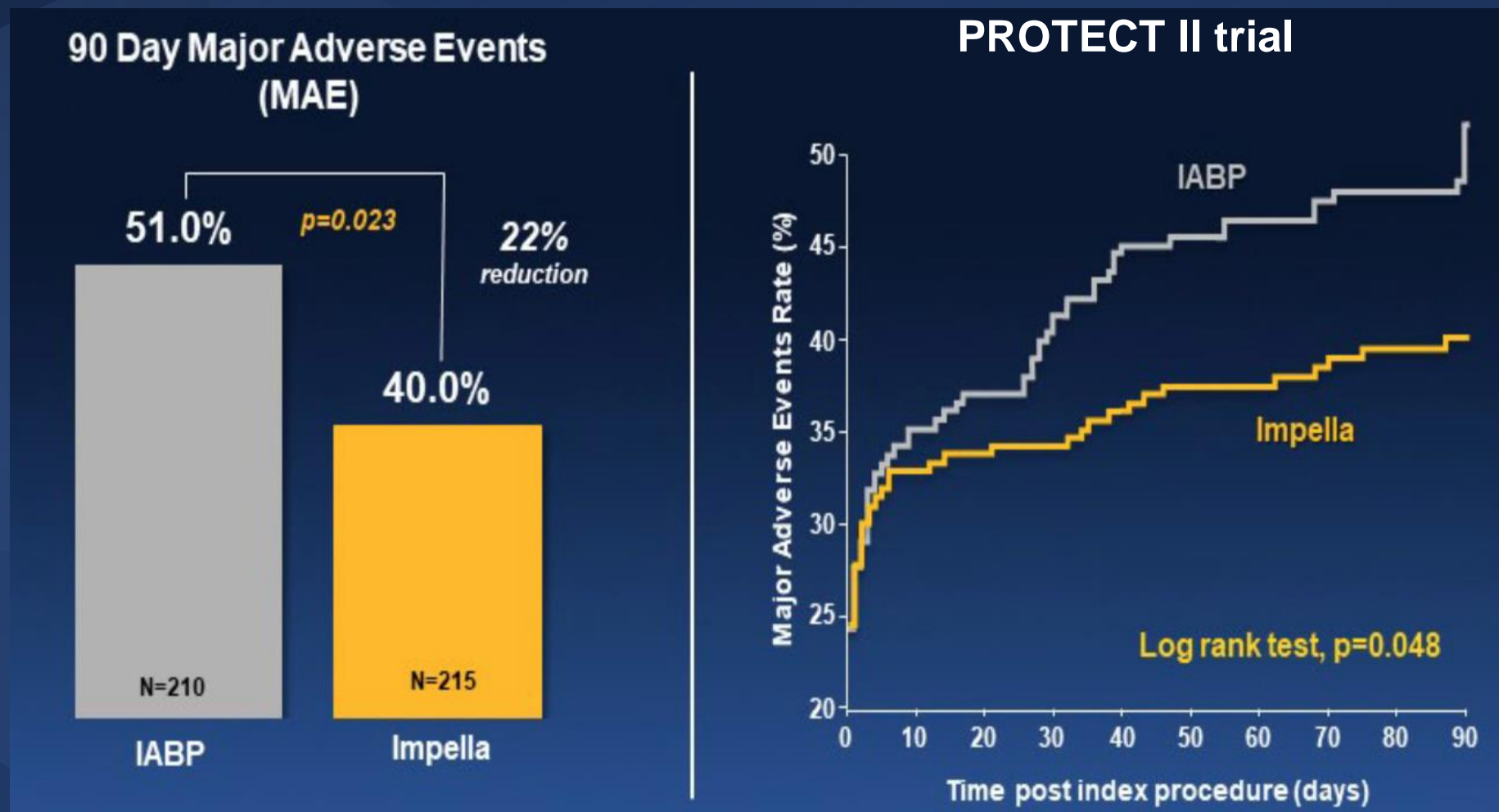
PROTECT trial

Randomized, prospective

High-risk PCI with
Impella-supported
compared to
IABP-supported

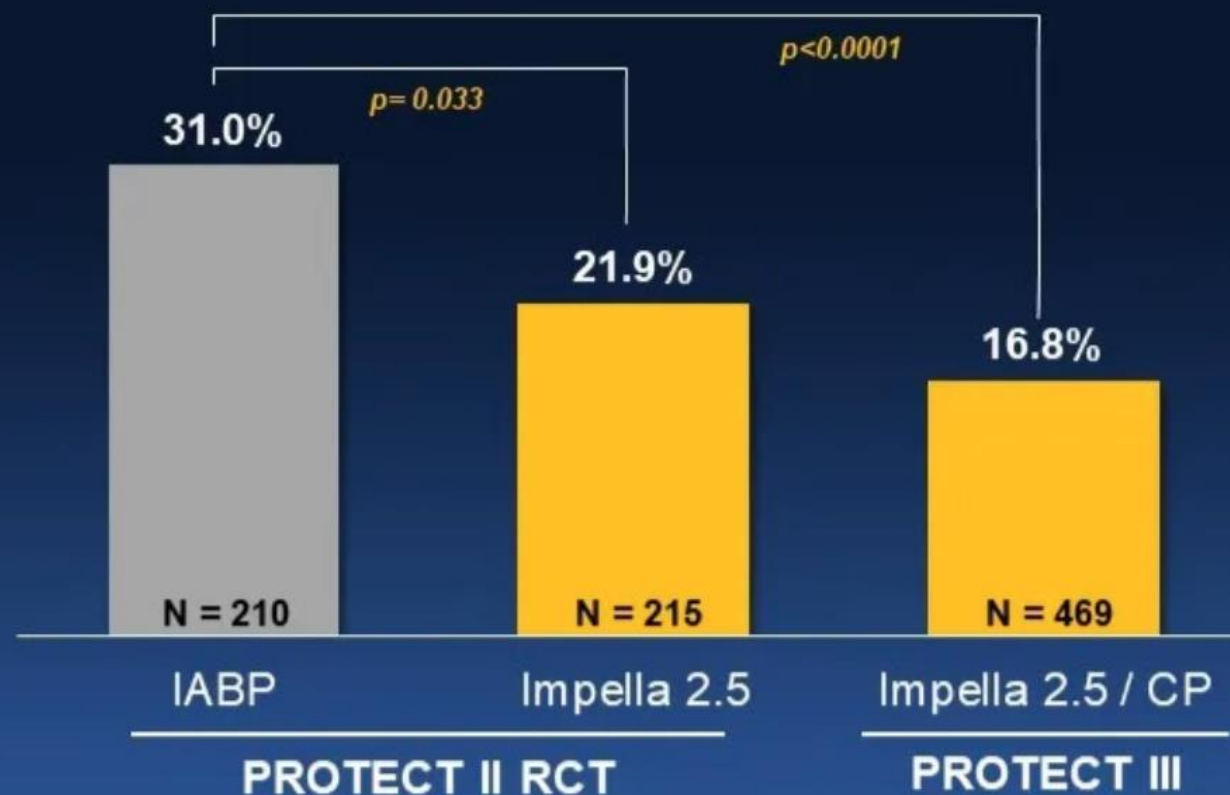


Better outcome of Impella in high-risk PCI



Better outcome of Impella in high-risk PCI

Composite Major Adverse Cardiac and Cerebrovascular Events (MACCE) at 90 Days



The role of Impella in ACS patients

2021 AHA guideline in myocardial revascularization

| COR | LOE | RECOMMENDATION |
|-----|-----|---|
| 2b | B-R | 1. In selected high-risk patients, elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable to prevent hemodynamic compromise during PCI (1,2). |

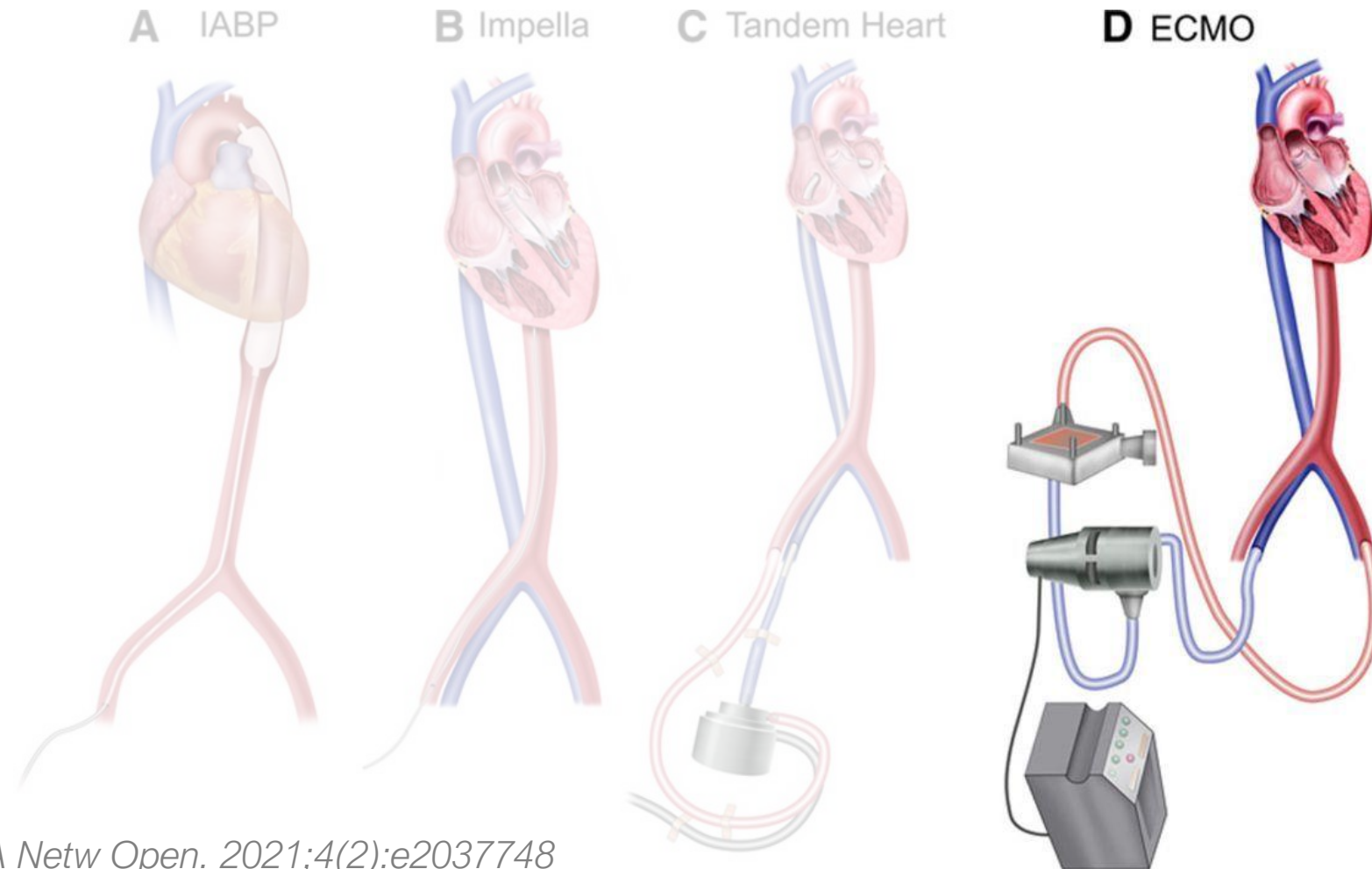
| | | SURGICAL RISK | | |
|---------------|--------|---------------|-------------|---------------|
| | | Low | Medium | High |
| ANATOMIC RISK | Low | PCI | PCI | PCI |
| | Medium | CABG or PCI | CABG or PCI | Support & PCI |
| | High | CABG | CABG or PCI | Support & PCI |

Impella showed non-inferior results compared to IABP in supporting ACS cardiogenic shock

Protected PCI

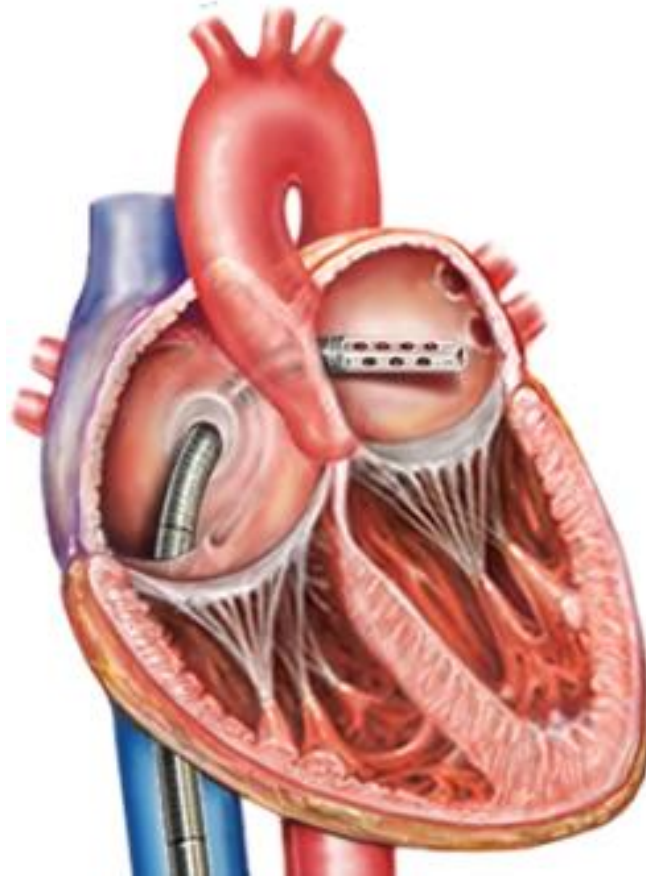
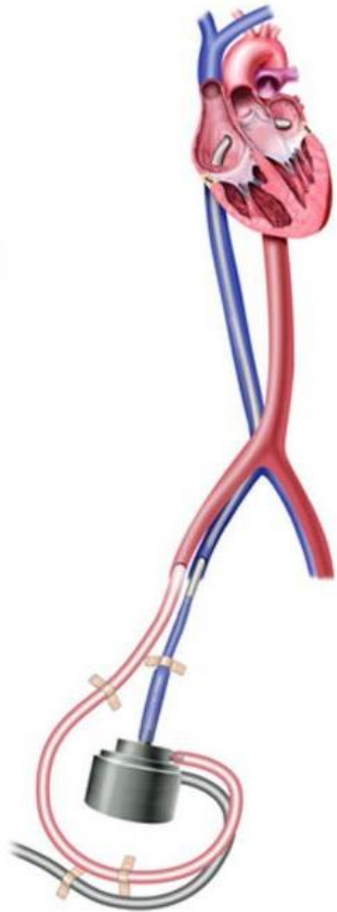
FDA-indicated
Safe & effective
ACC/AHA PCI Guidelines

Mechanical circulatory support



Tandem Heart

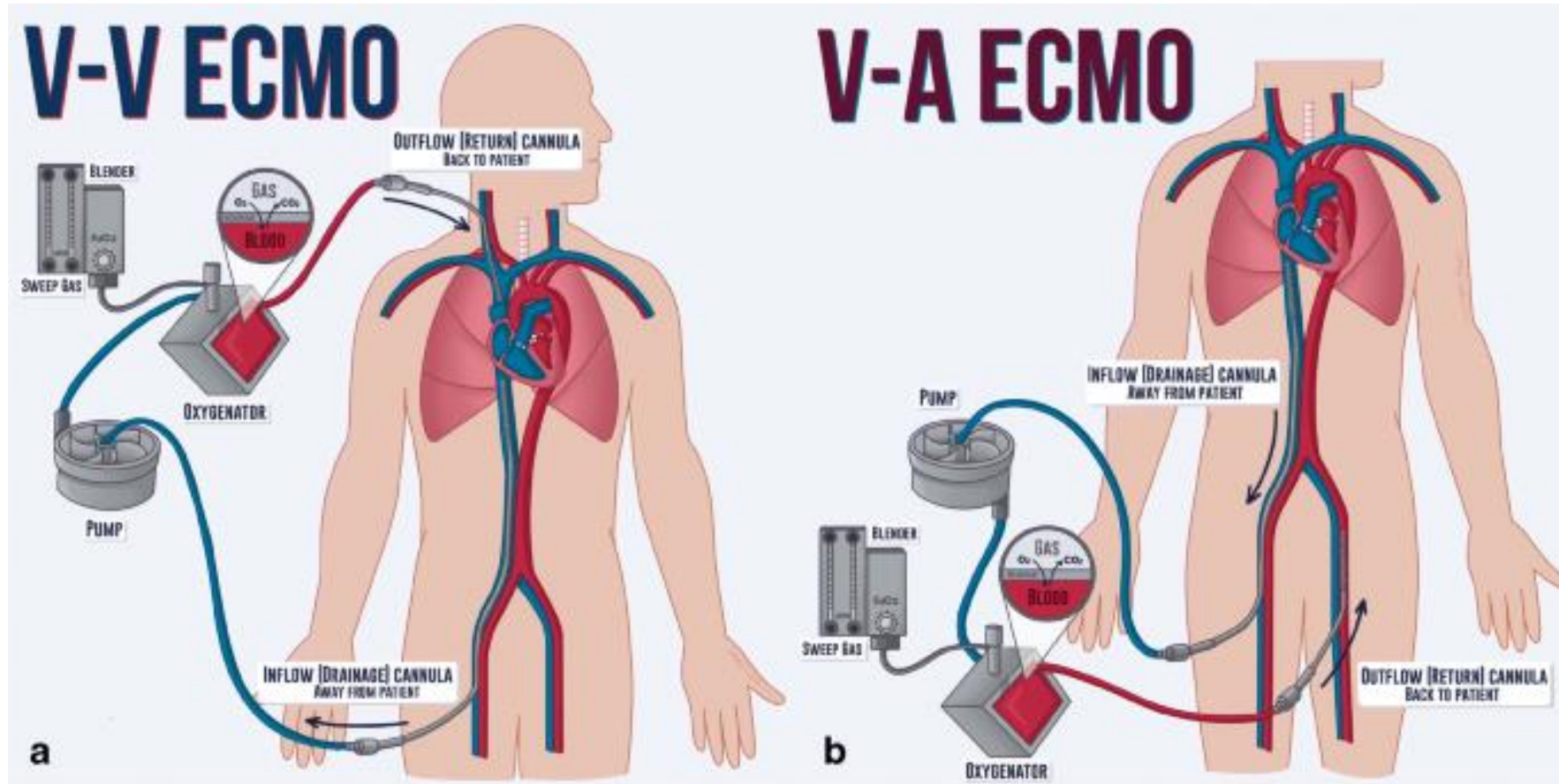
C Tandem Heart



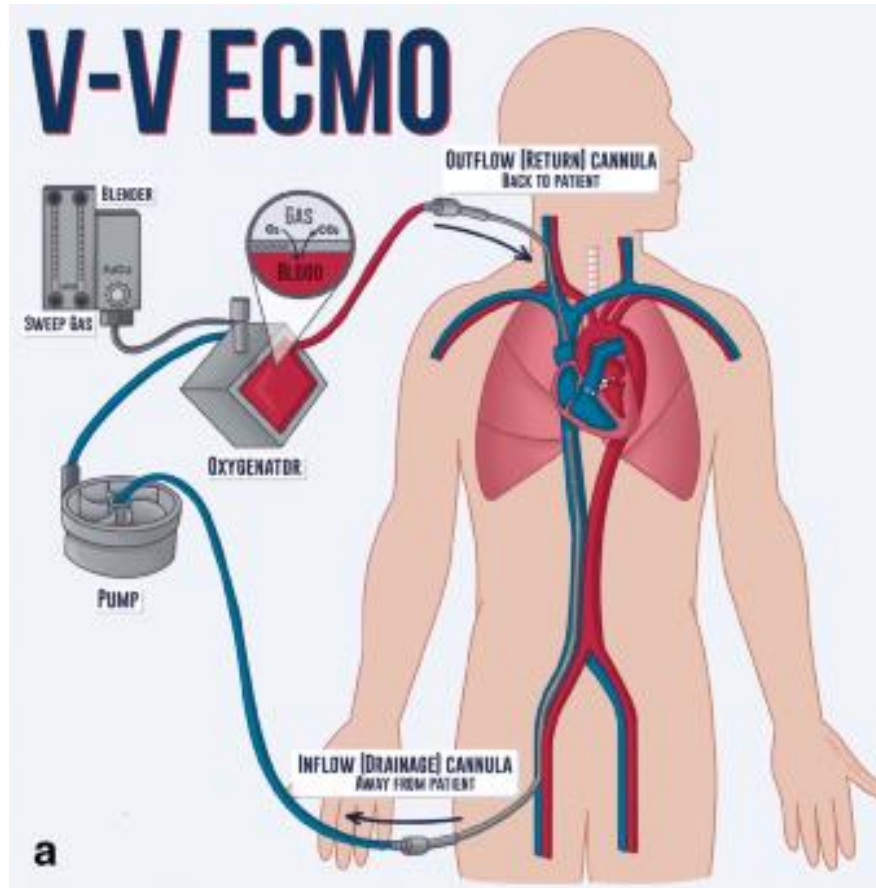
Extracorporeal Membrane Oxygenation , ECMO



Venous-Venous and Venous-Arterial ECMO



Differences between VV and VA ECMO



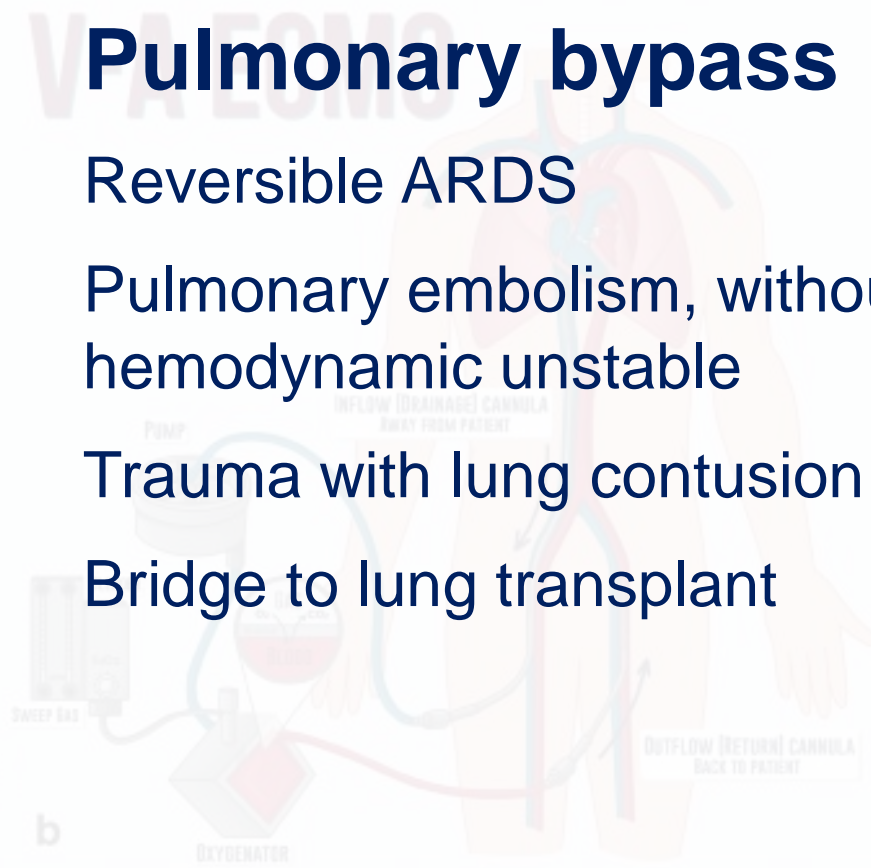
Pulmonary bypass

Reversible ARDS

Pulmonary embolism, without hemodynamic unstable

Trauma with lung contusion

Bridge to lung transplant



Differences between VV and VA ECMO

Cardiopulmonary bypass (more than 4.5L/min)

Cardiogenic shock, with/without ACS

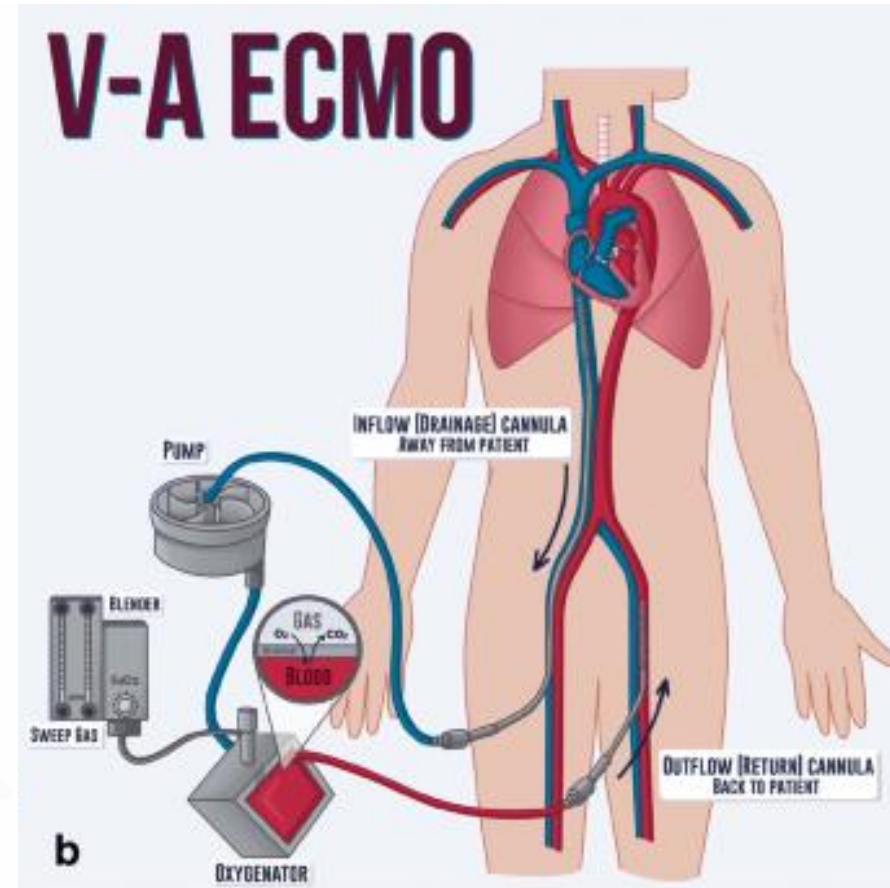
Intractable arrhythmia

Acute myocarditis

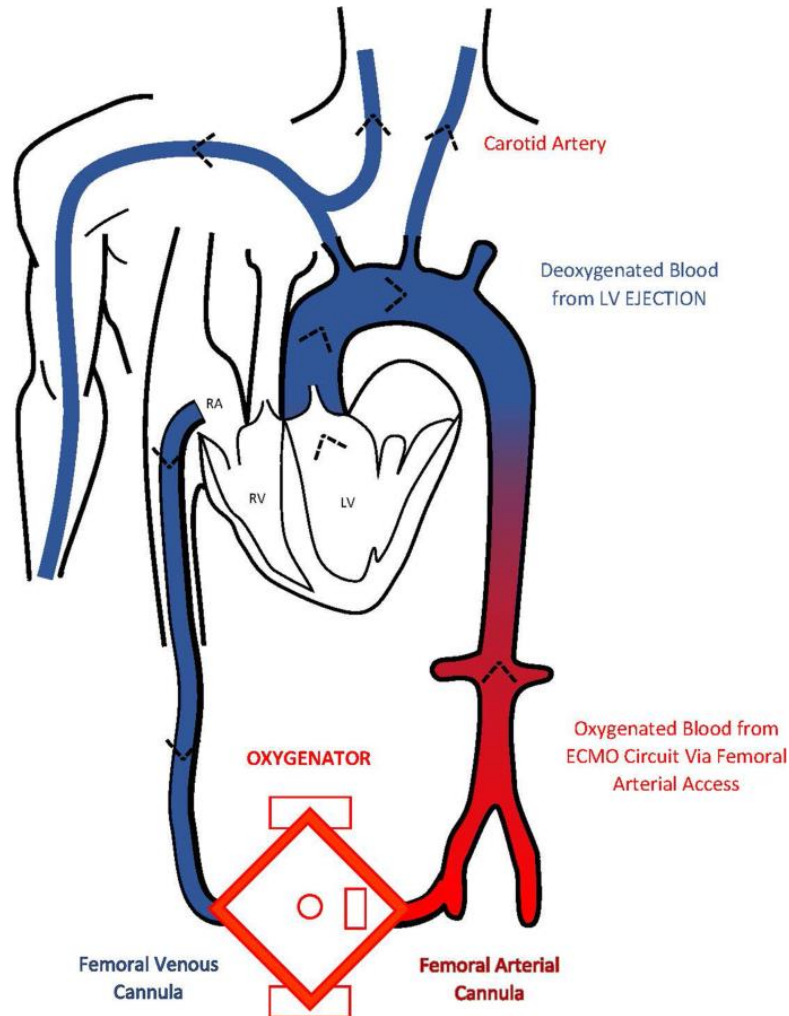
Post-cardiac arrest (ROSC)

Pulmonary embolism

Short-term bridge to heart transplant



Hemodynamic change after VA ECMO

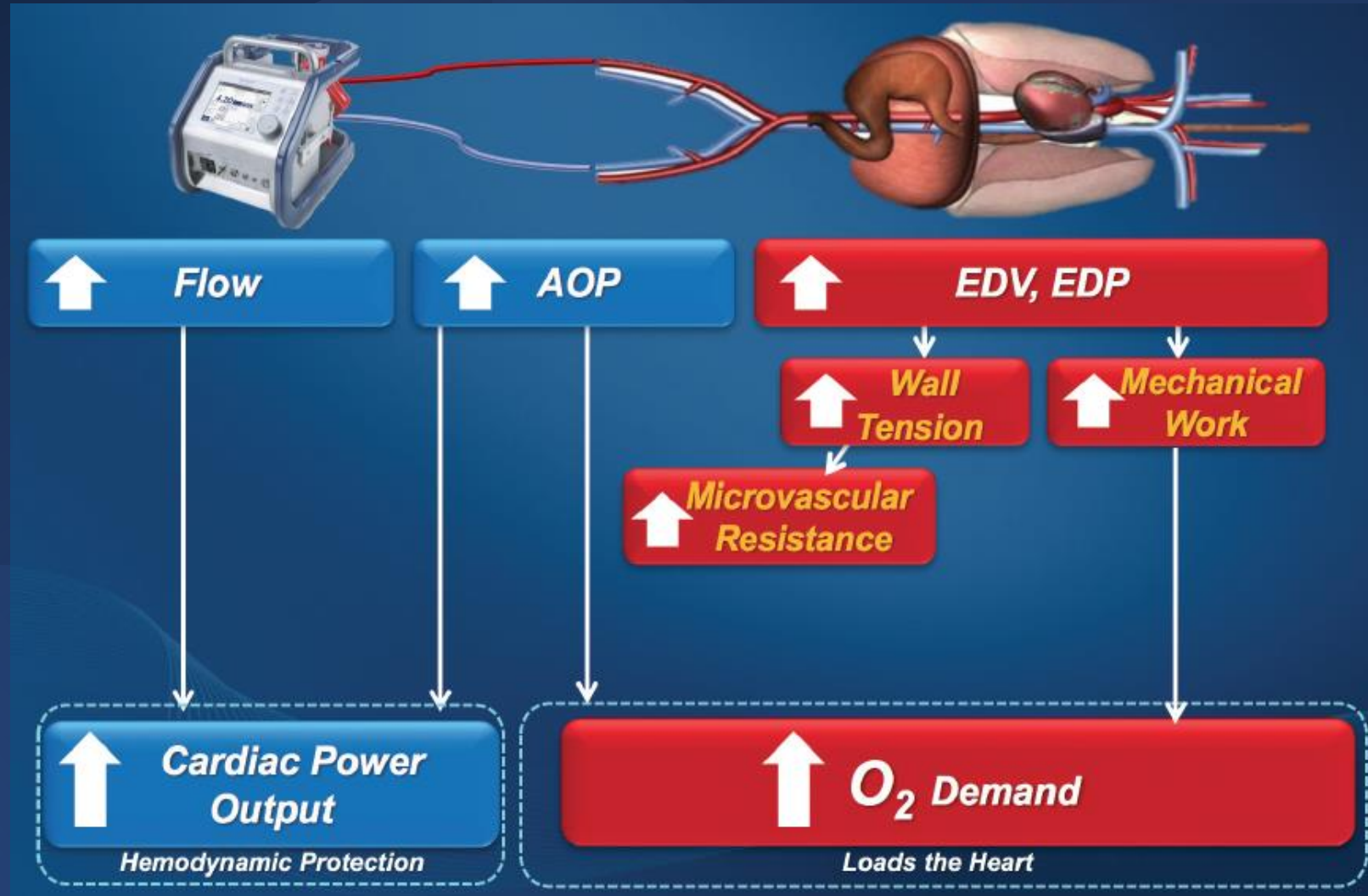


North-South Syndrome

Two circulation syndrome

Harlequin Syndrome

Hemodynamic change after VA ECMO

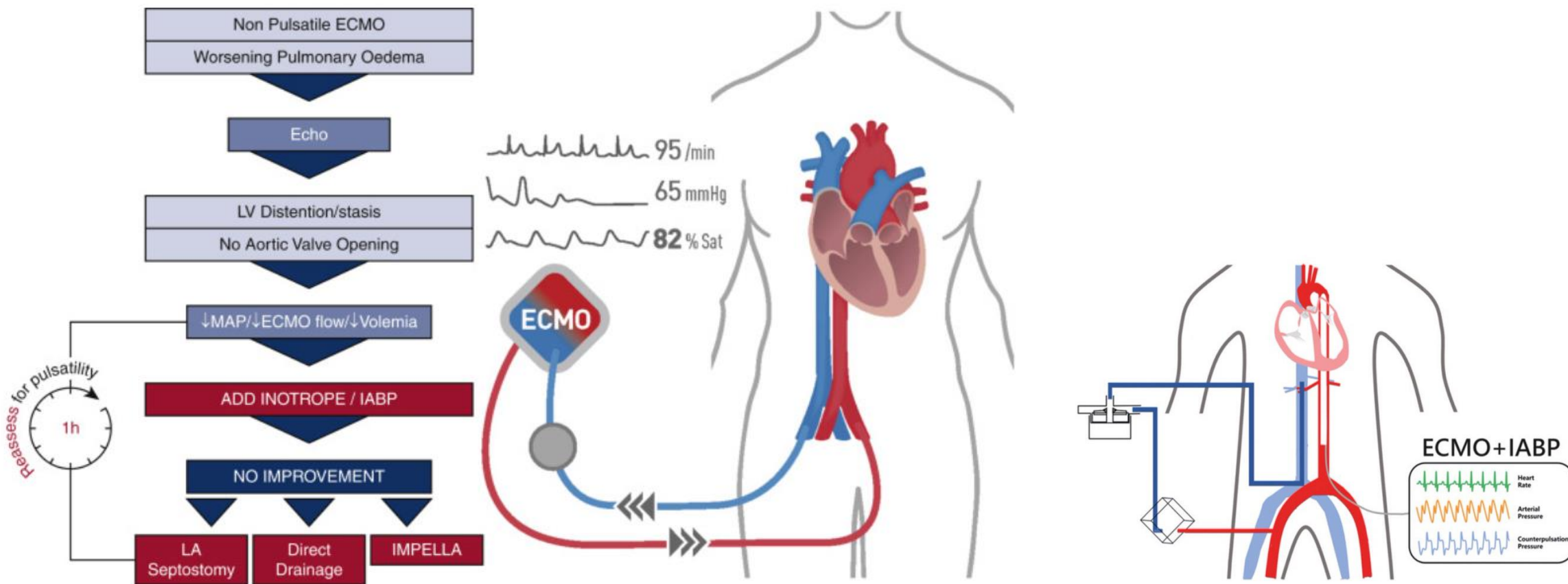


Aortic regurgitation

LV distention

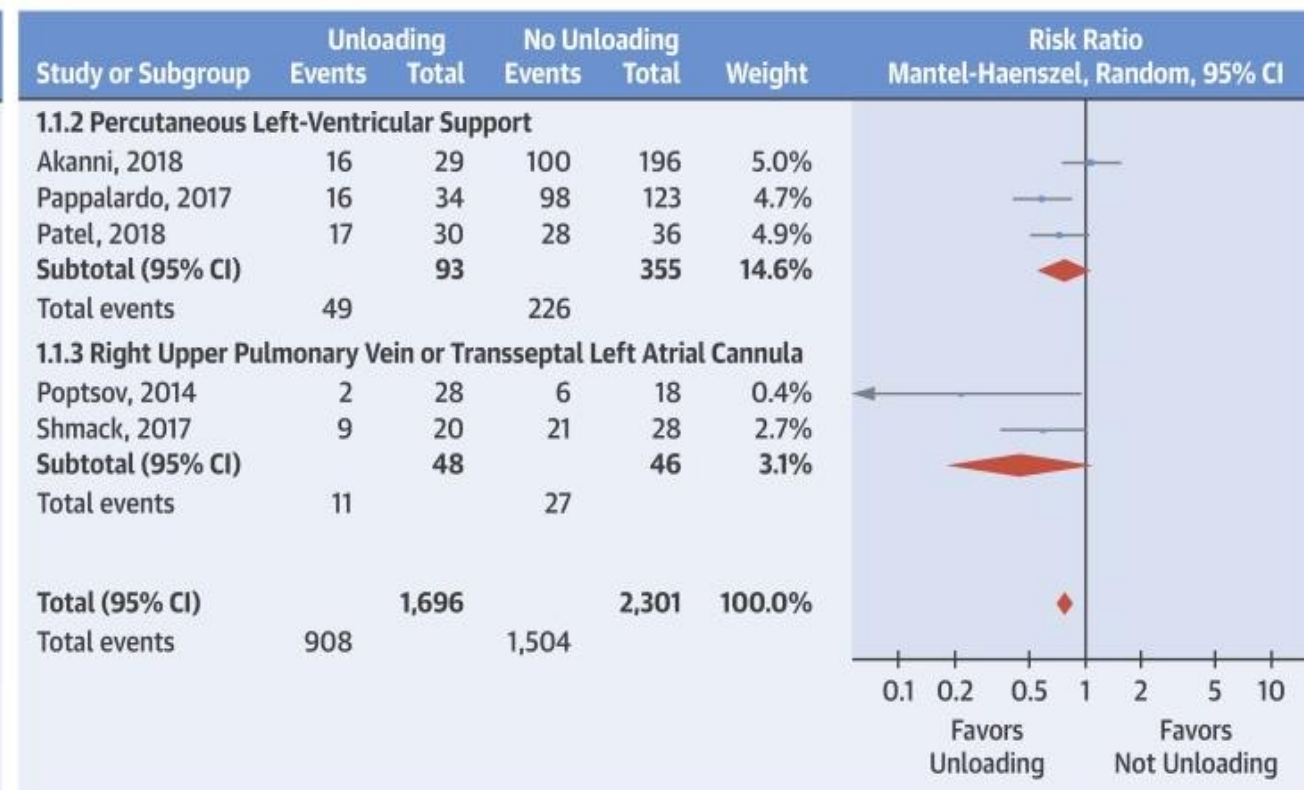
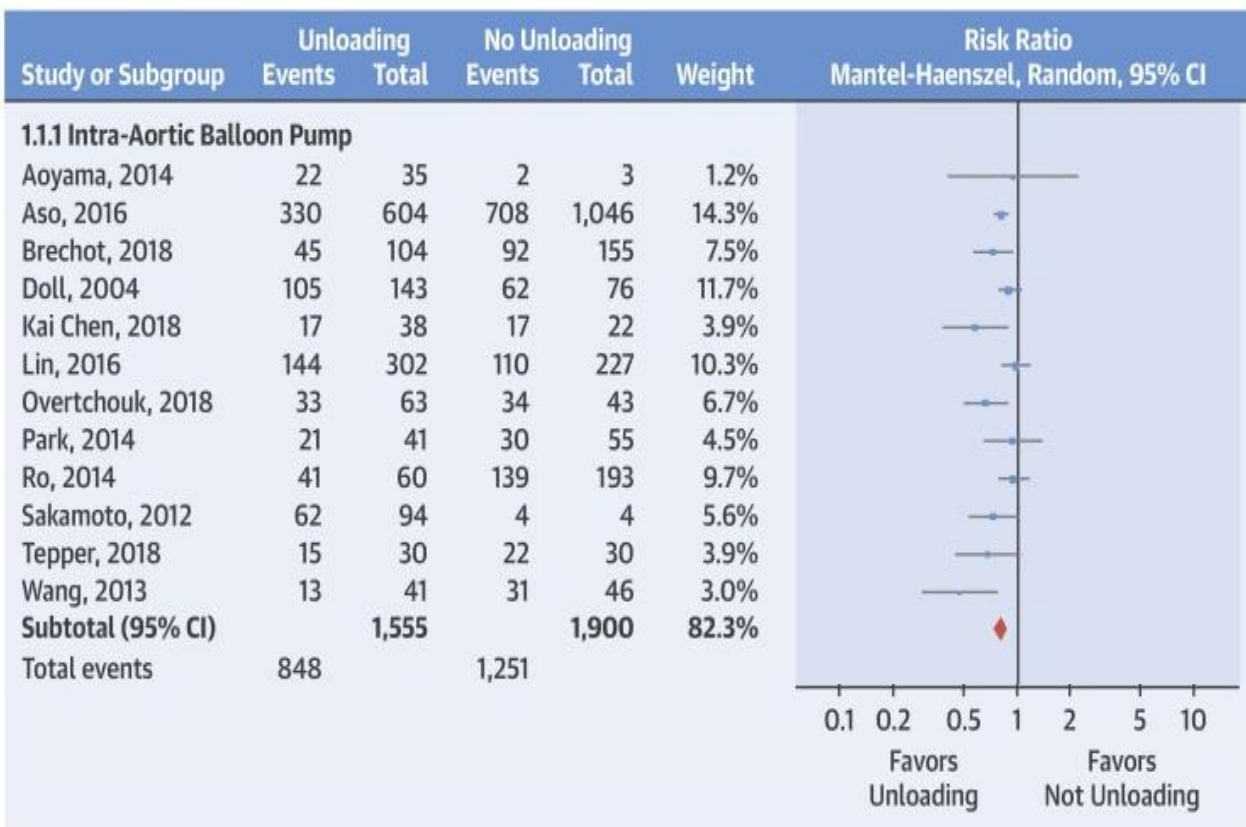
Pulmonary edema

VA ECMO with concomitant LV unloading

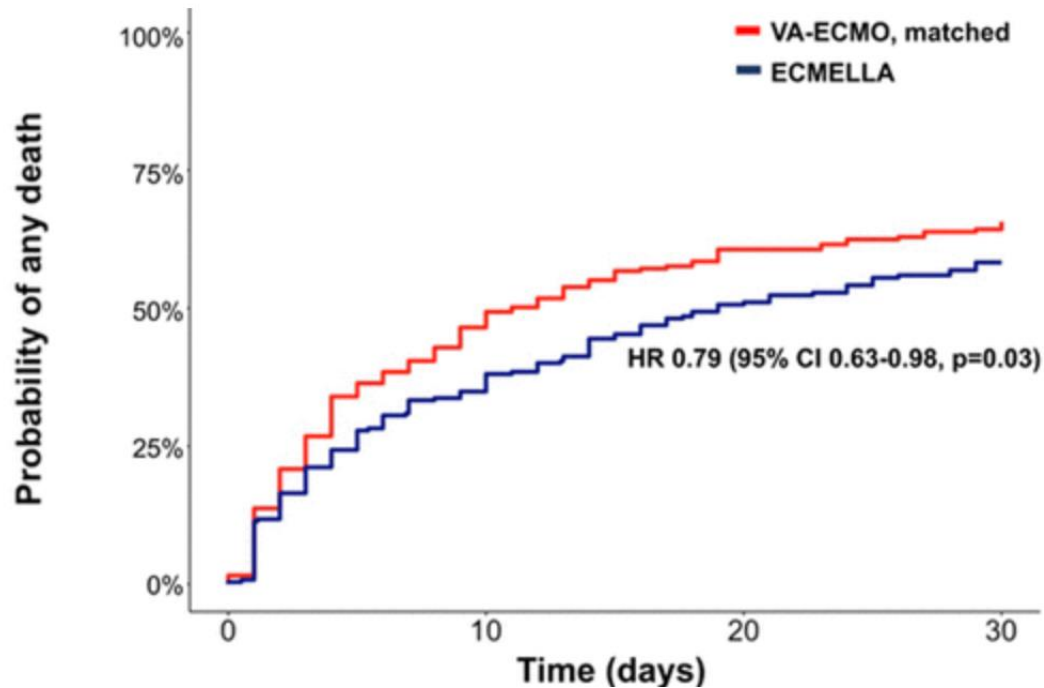


Cavayas YA, et al. JTCVS Open. 2021;8:70-76.

VA ECMO with concomitant LV unloading



VA ECMO with Impella LV unloading

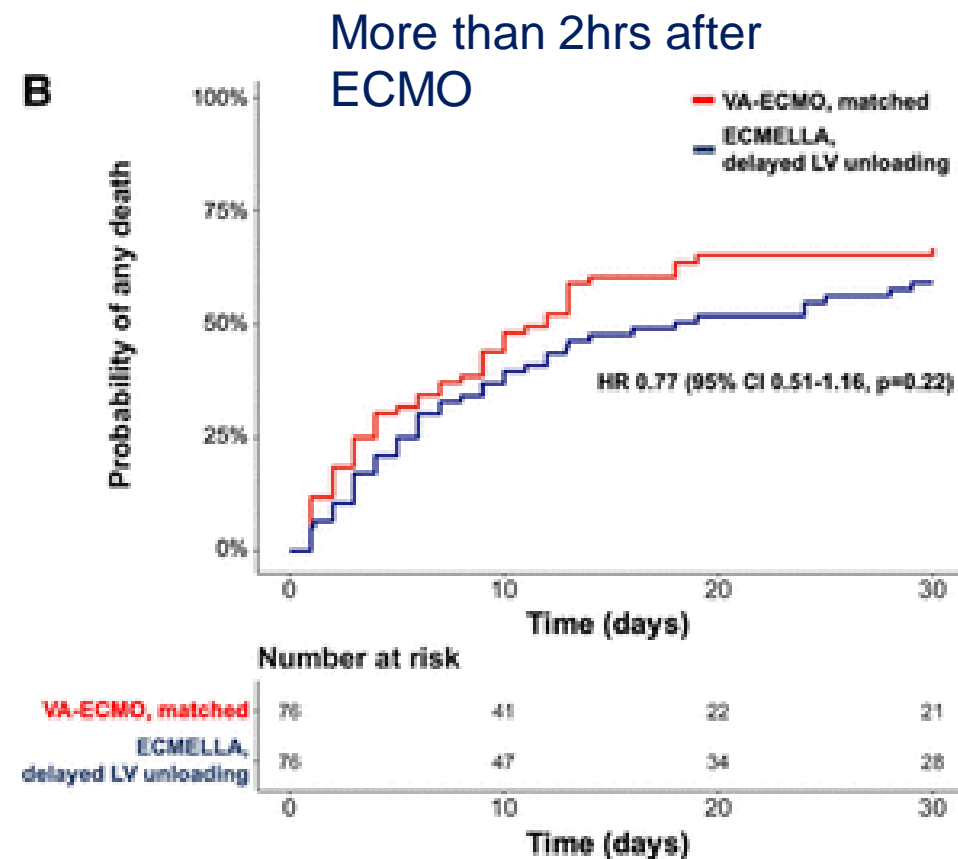
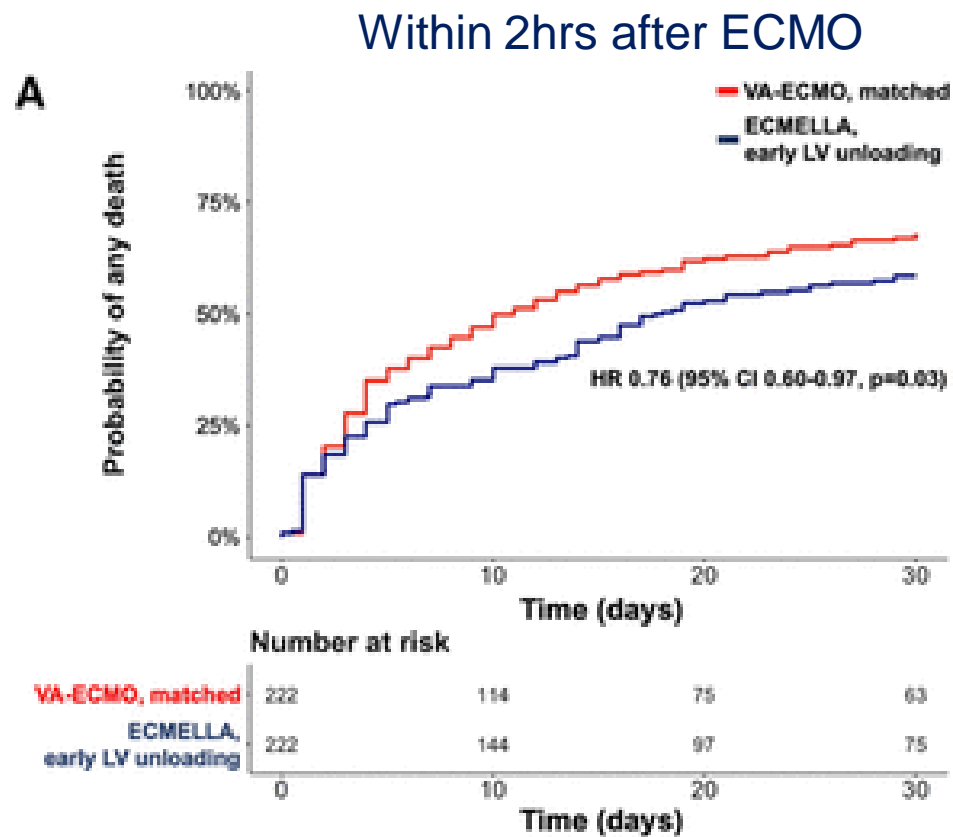


Randomized, Multicenter trial

Propensity matched

444 patients with CS

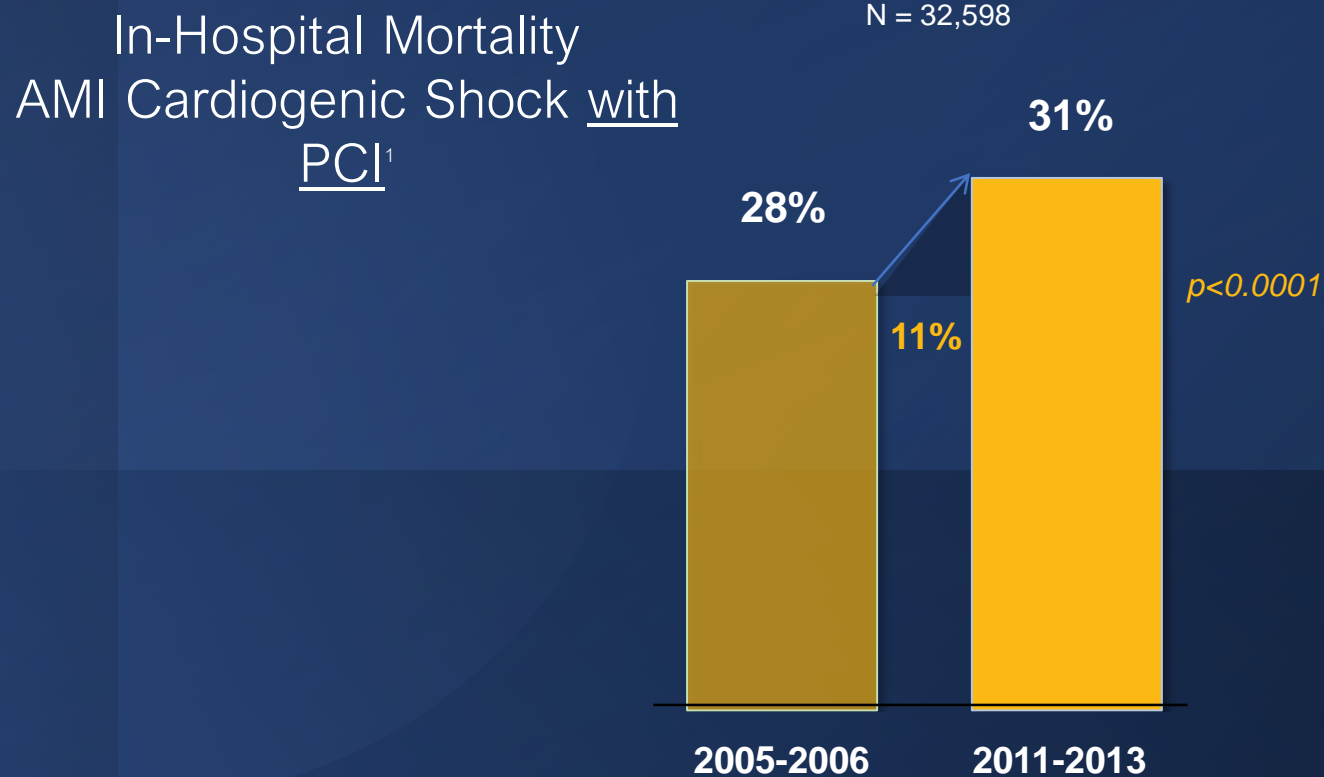
VA ECMO with **early** Impella LV unloading



Take Home Message

- ❑ ACS with cardiogenic shock remains challenge to be treated

Mortality in PCI with cardiogenic shock remains challenge at all time



Take Home Message

- ❑ ACS with cardiogenic shock remains challenge to be treated

Wise choice of Mechanical Circulatory Support

| pLVAD | Access | Cardiac Output Support | Indications | Limitation | Contraindications |
|----------|---|------------------------|--|---|---|
| IABP | 8–9 Fr through femoral artery | Up to 0.5 l/min | -Cardiogenic shock - High-risk PCI | Requires stable rhythm | -Aortic insufficiency -Aortic pathology (aneurysm/dissection) |
| Impella® | 12–21 Fr typically femoral possible axillary artery | 2.5 to 5.0 l/min | -Cardiogenic shock following AMI -High-risk PCI | Large cannula | -LV mural thrombus - Significant ASD or VSD -Moderate to severe aortic stenosis |
| VA-ECMO | 15–23 Fr through femoral artery and femoral vein | Up to 7.0 l/min | -Acute, severe cardiac failure/cardiogenic shock with high risk of death. -Typically used for bridging to LVAD/transplant | Requires two access sites and usually requires venous/arterial cut-down | -non-recoverable cardiac disease -Unwitnessed arrest -Advanced malignancy |

AMI = acute myocardial infarction; ASD = atrial septal defect; ECMO = extracorporeal membrane oxygenation; IABP = intra-aortic balloon pump; LV = left ventricular; LVAD = left ventricle assisting devices; PAD = peripheral arterial disease; PCI = percutaneous coronary intervention; pLVAD = percutaneous left-ventricle-assisting devices; RV = right ventricular; VSD = ventricular septal defect.

Take Home Message

- ❑ ACS with cardiogenic shock remains challenge to be treated
- ❑ In selected ACS with cardiogenic shock patients, MCS may be considered