



# Mechanical Circulatory Support in Thailand: What Are Our Options?

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*Thailand*

# Disclosure

- I have no conflict of interest related to this presentation



# Topic

Why do we need MCS devices

What are our options

Device characteristic

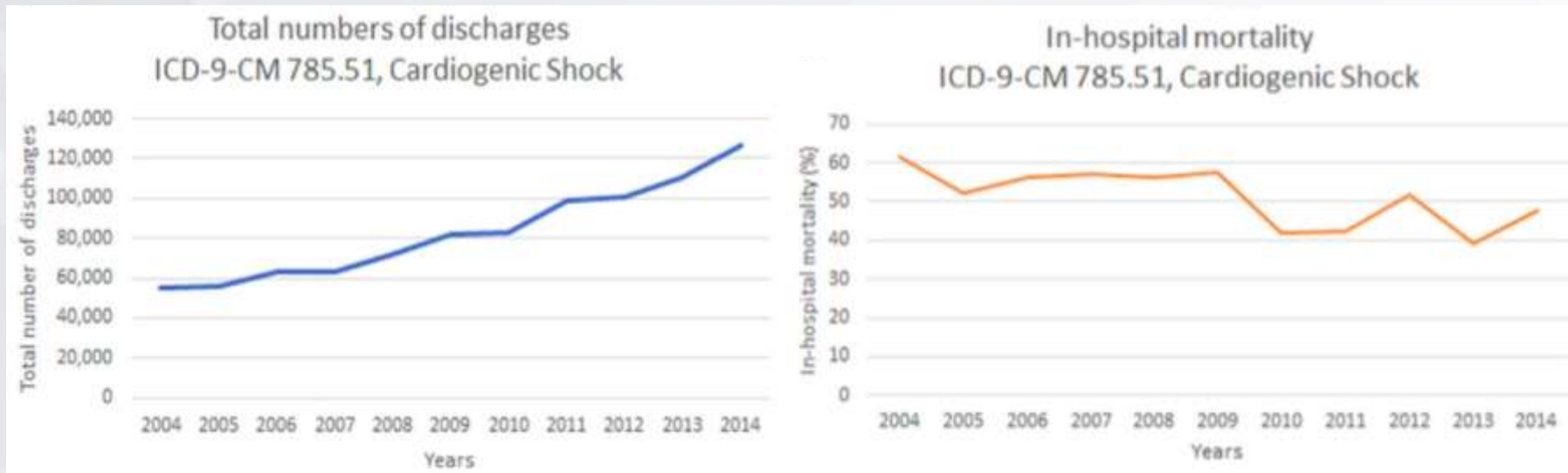
Clinical application & Evidence

Upcoming study



# Why do we need mechanical circulatory support device ?

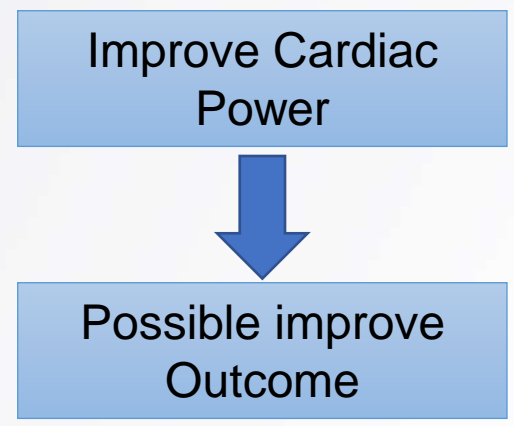
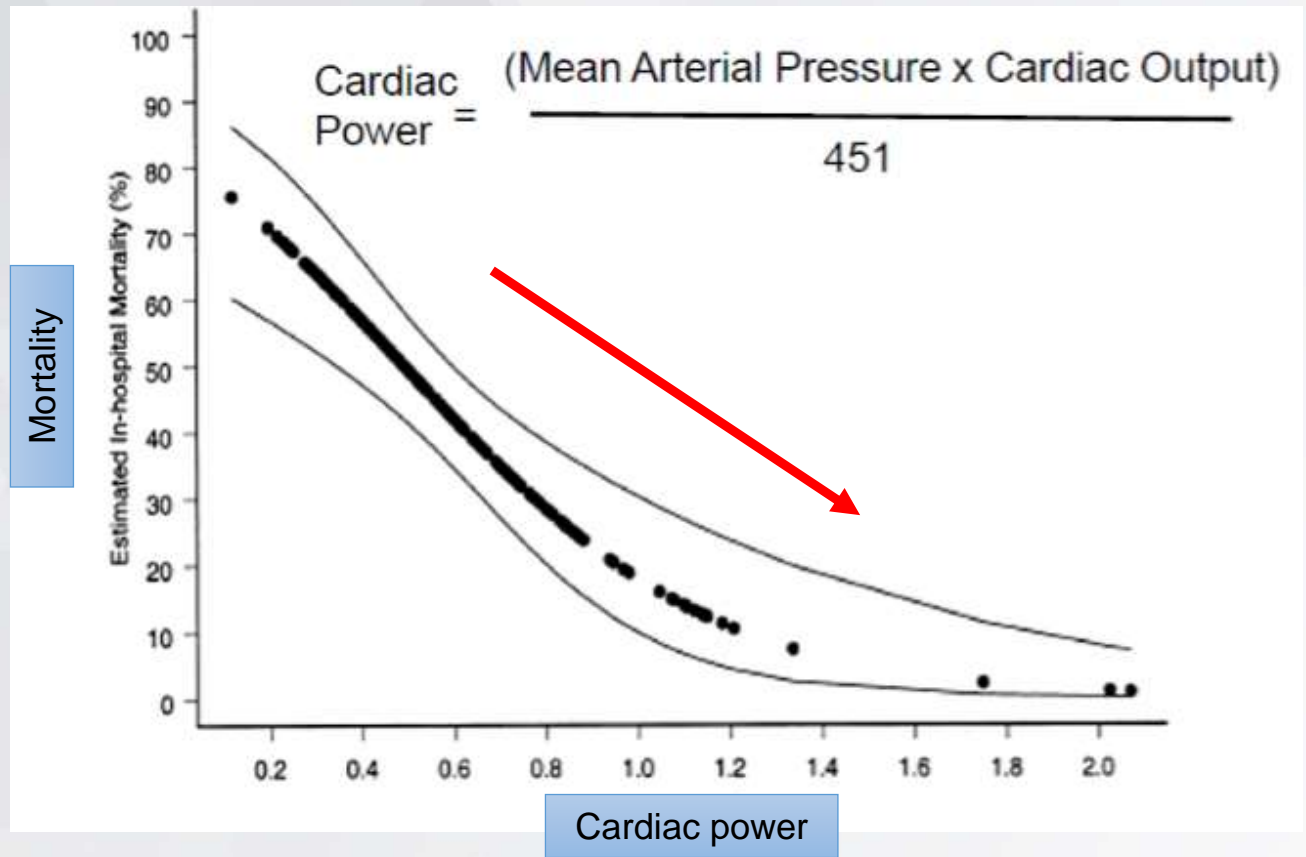
- We are getting more & more CHIP case
- Mortality in cardiogenic shock stable despite improve in quality of care esp. AMI-CS ( Primary PCI , DTB , Network )





# Cardiac power

## -Predictor of mortality in shock patient





## Why do we need mechanical circulatory support device ?

Mechanical support devices have an ability to stabilize hemodynamic and bridge to

- Bridge to recovery
- Bridge to transplant
- Bridge to decision







# Percutaneous Circulatory Support - Clinical application-

- **Cardiogenic shock ( +/- AMI ) / Decompensated heart failure**
  - Normalize CO/BP/Cardiac power
  - Decrease PCWP
  - Minimized myocardial damage & optimize myocardial recovery
- **High risk PCI**
  - Protection from temporary hemodynamic compromise
  - facilitate complete revascularization
  - Lower risk of acute kidney injury
- **Myocardial Salvage in Setting of AMI**
  - Reduce LV workload ( and oxygen demand ) to minimize necrosis and optimize myocardial recovery

# Currently Available MCS



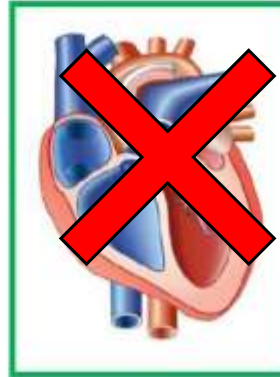
## Continuous Flow Pumps

### Pulsatile



IABP

### Axial-Flow

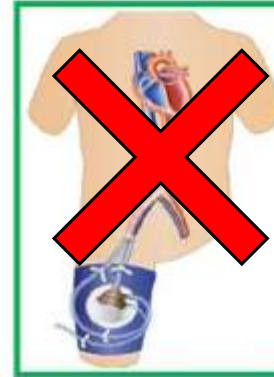


Impella CP

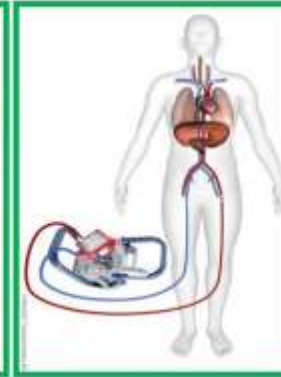


PHP \*

### Centrifugal Flow



TandemHeart

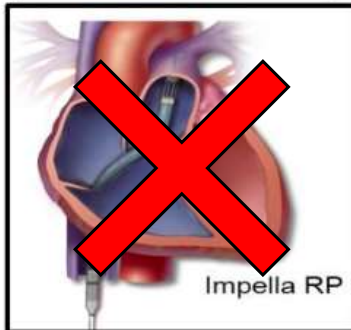


VA-ECMO

Left Ventricle

### Intracorporeal

#### Axial Flow

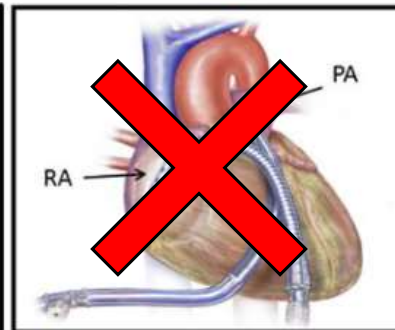


Impella RP

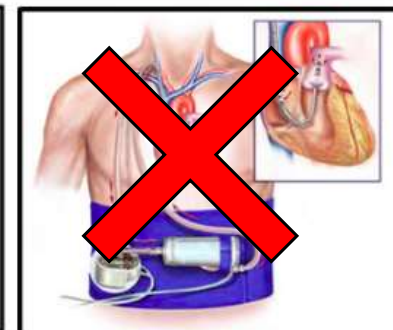


VA-ECMO

#### Centrifugal Flow



Tandem pRVAD

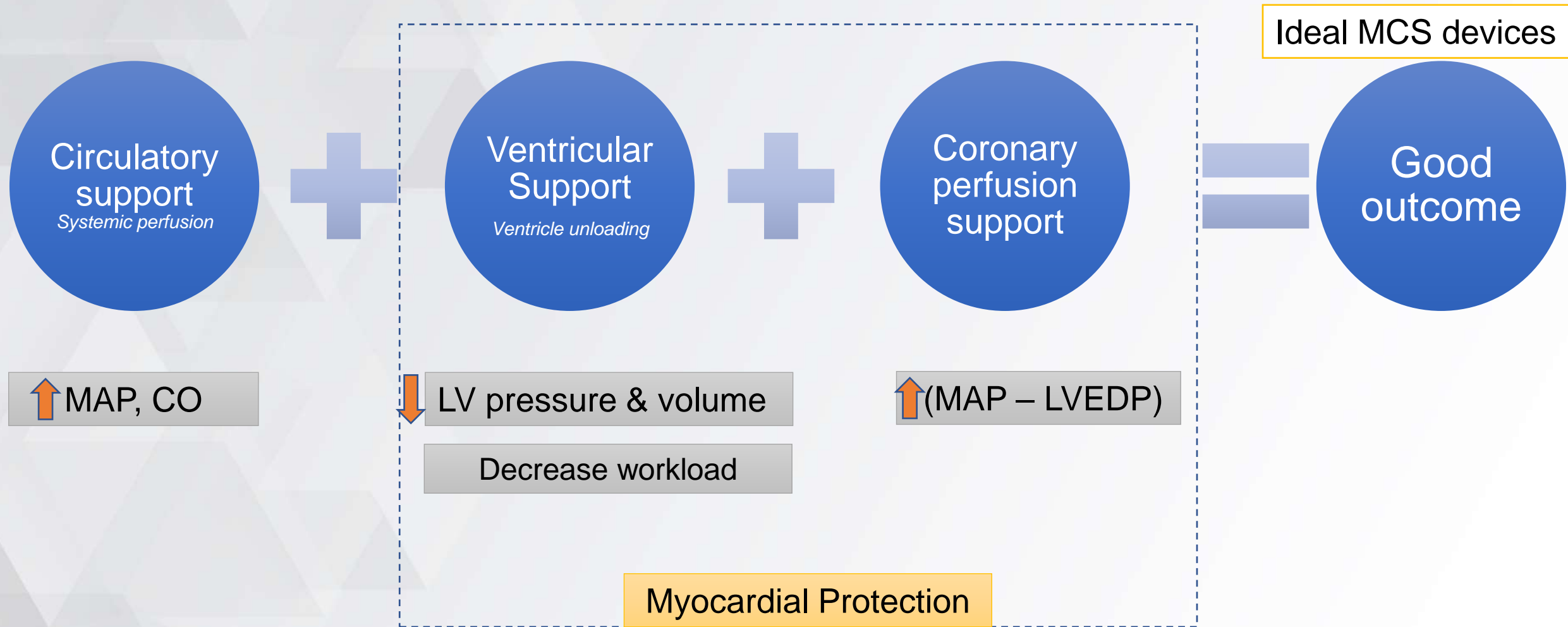


Protek Oxy-RVAD

Right Ventricle

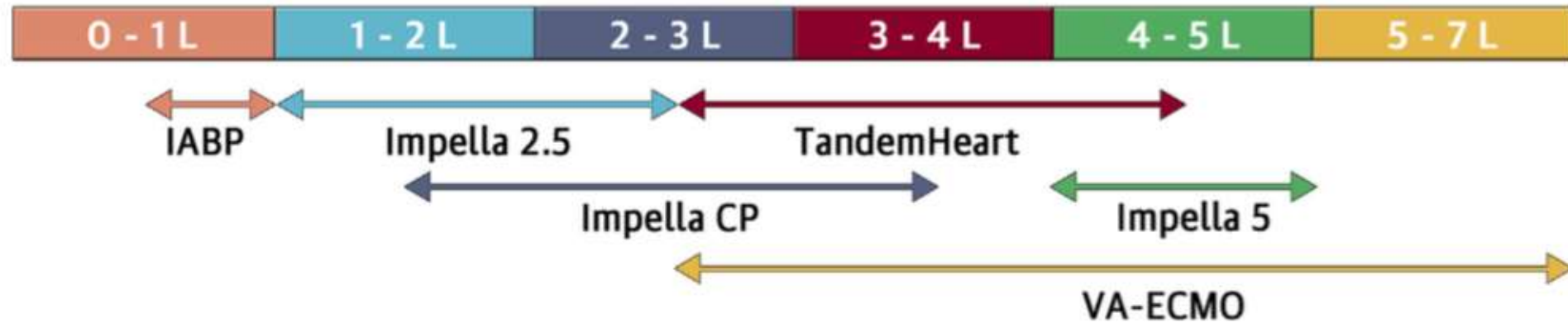


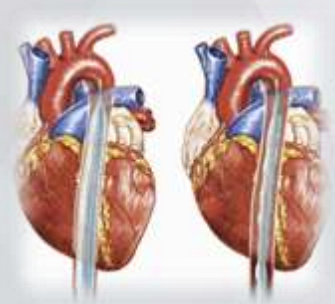
# The hemodynamic support equation



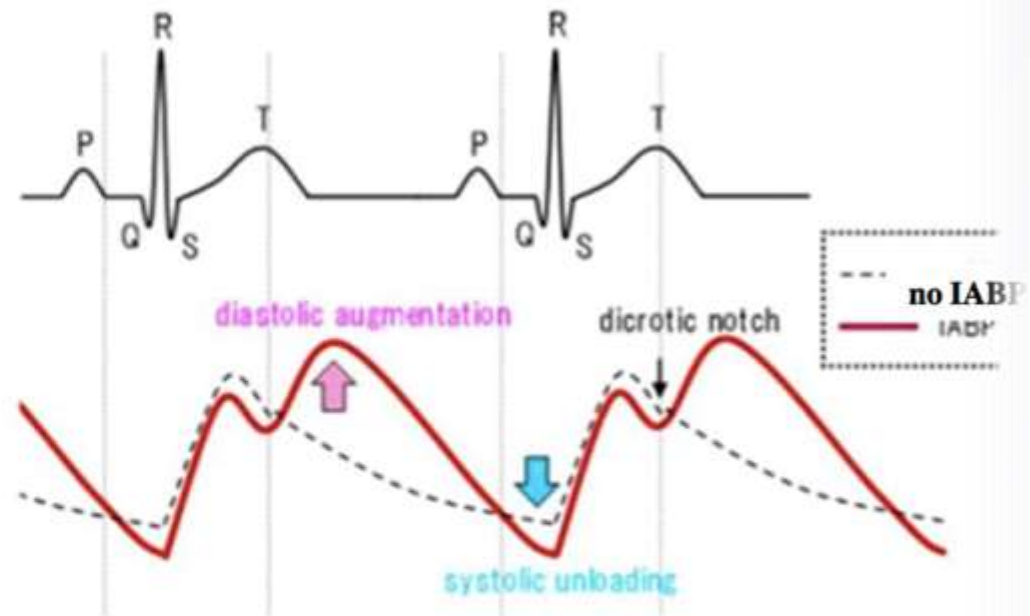
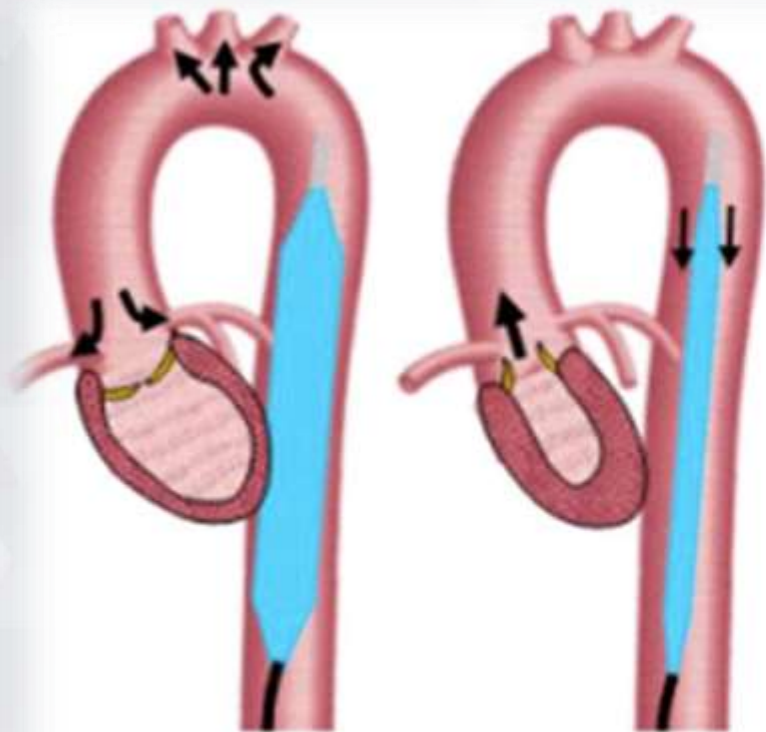


# Level of circulatory support from MCS devices





# Intra-Aortic Balloon Pump (IABP)



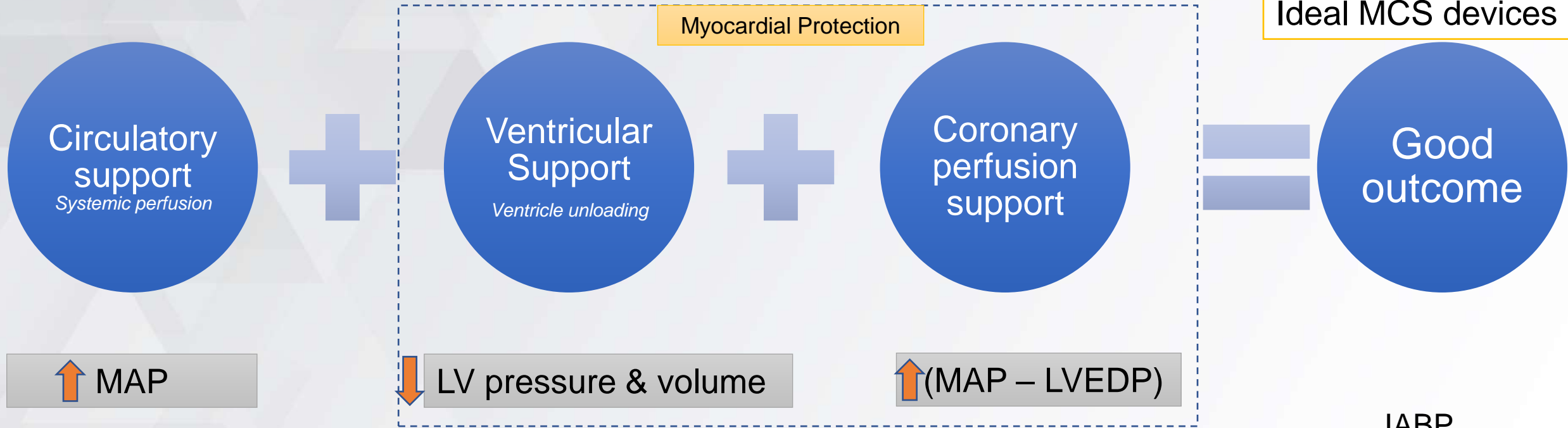
improved coronary perfusion  
increase in myocardial oxygen supply  
**no active mechanical augmentation of cardiac output**



# Intra-Aortic Balloon Pump (IABP)

- Advantage
  - Available in most lab & Easy to implantation
  - Available in 7 – 8 Fr Catheter sizes minimizing threat of vascular complication
  - Range of balloon sizes available to accommodate all patient height
  - Require only > 4 mm femoral artery
- Disadvantage
  - Only supplement cardiac output by upto 0.3-0.5 l/min and requires a degree of native cardiac output to function
  - Relies on synchronization with cardiac cycle ( may not be reliable in dysrhythmia) + need native Left ventricular function
  - Risk of systemic embolization ( Cholesterol , Helium)
  - Stroke , Infection , hemolysis , Bleeding at insertion , lower limb ischemia

# The hemodynamic support equation



↑ MAP

↓ LV pressure & volume

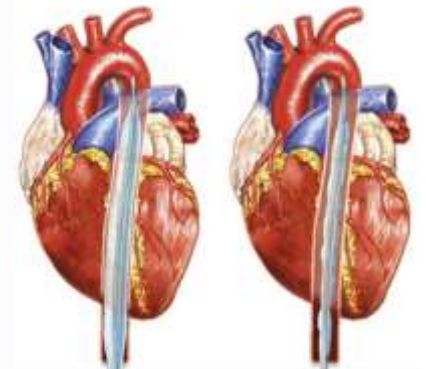
↑ (MAP - LVEDP)



Minimal only CO 0.5 l/m

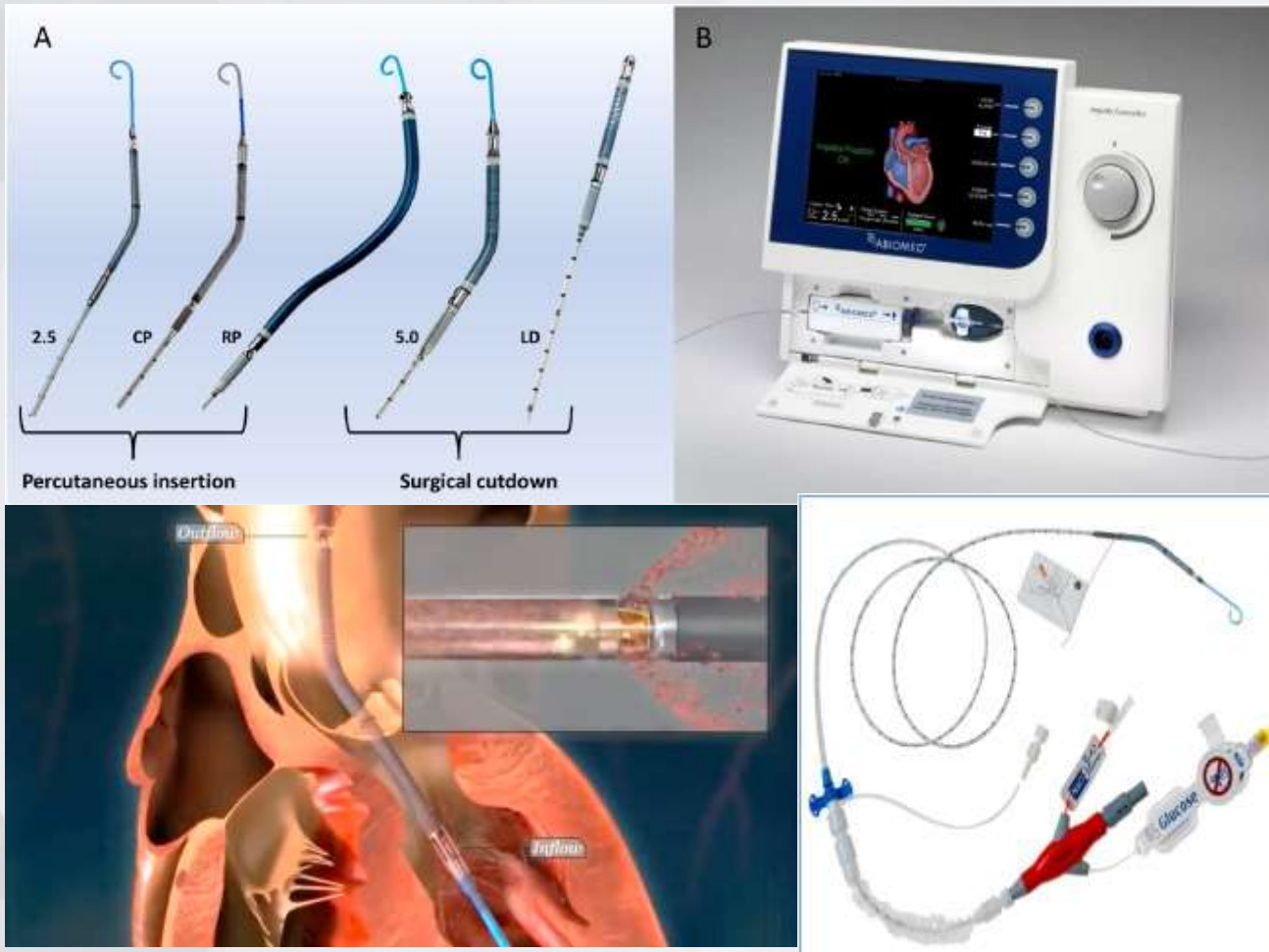


IABP





# Impella device



- Flow 1-5 l/min.
- LV to AO
- Single vascular access
- Sheath size
  - 12 Fr for impella 2.5
  - 14 Fr for impella CP
  - 21 Fr for impella 5.0
- Device shaft 9 Fr
- Femoral artery size
  - Impella 2.5 & CP => 5 – 5.5 mm
  - Impella 5.0 => 8 mm



↓ EDV, EDP

↑ AOP

↑ Flow

↓ O<sub>2</sub> Demand

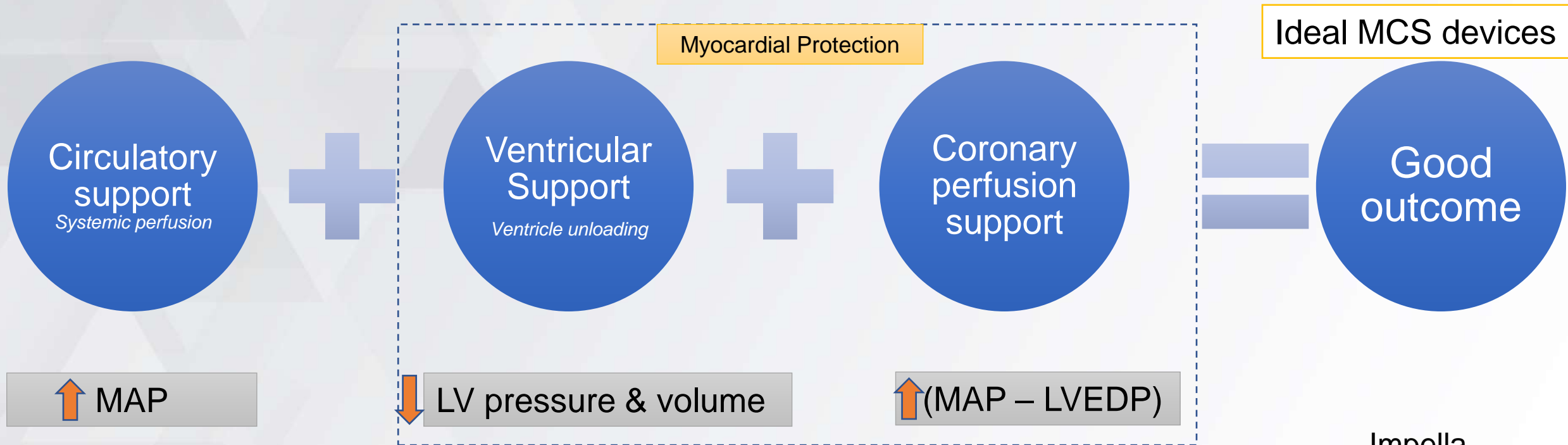
↑ O<sub>2</sub> Supply

*Direct Unloading*

↑ Cardiac Power Output

*Systemic Hemodynamic Support*

# The hemodynamic support equation

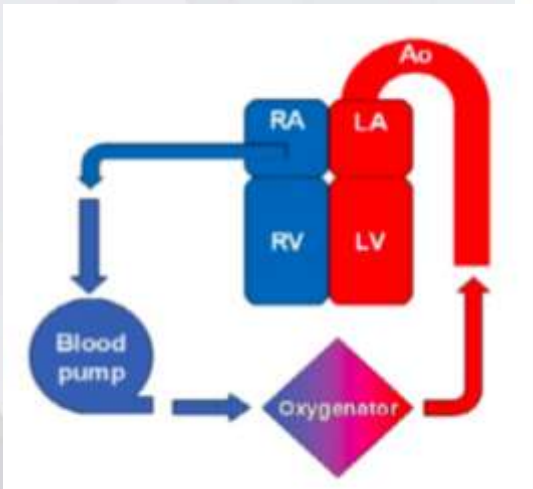
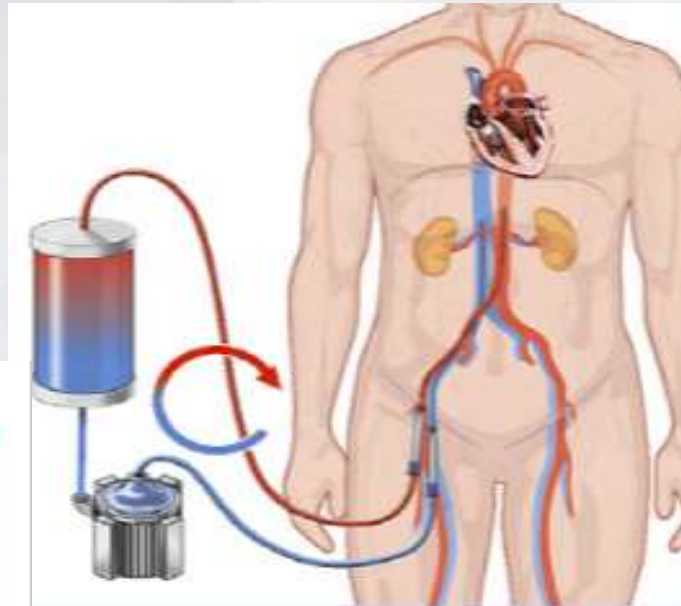


Impella



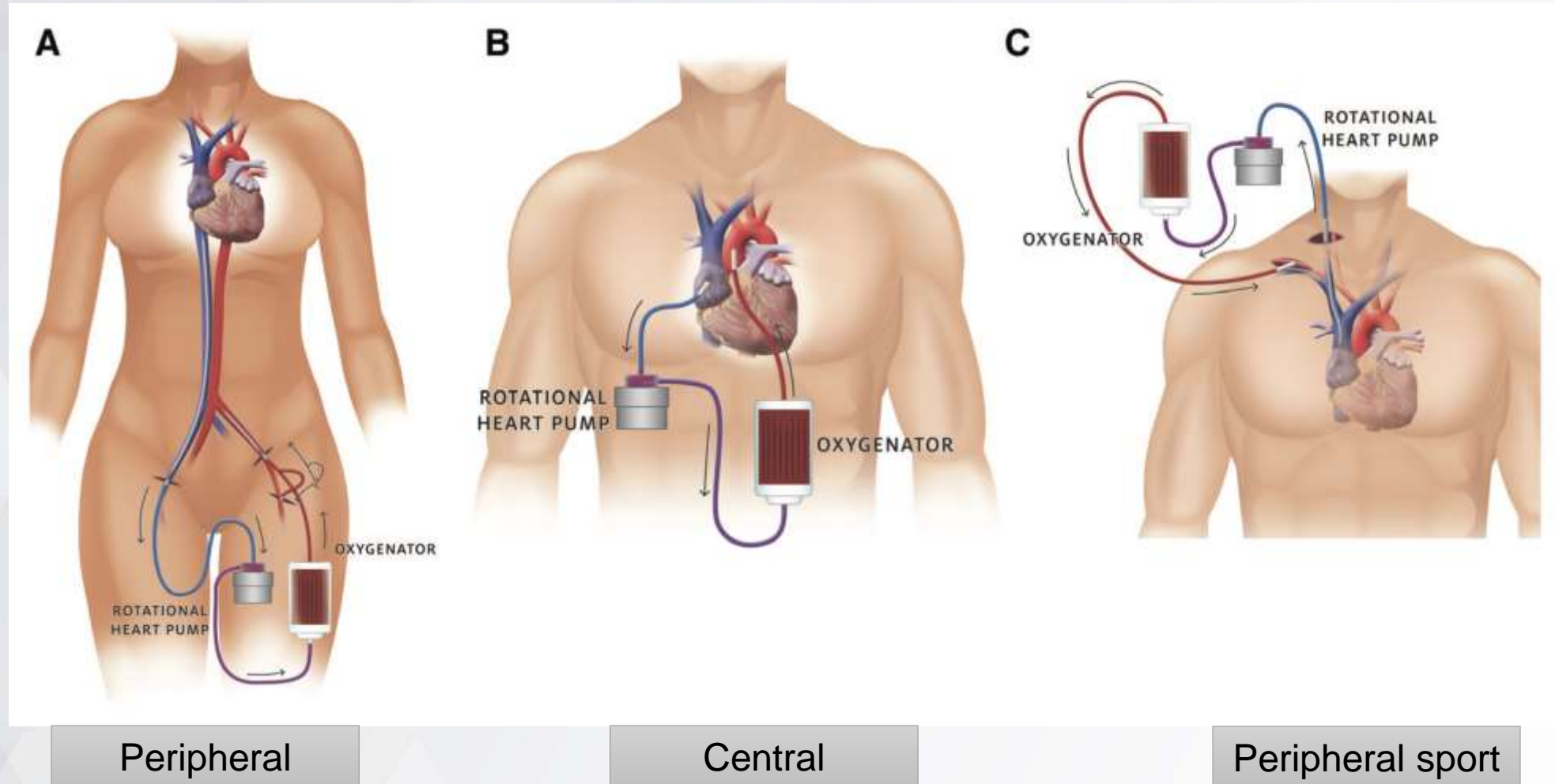
# VA ECMO

- 3-7 L / min
- RA to AO
- Dual vascular access points
- 18 – 24 Fr venous cannula
- 14 – 16 Fr arterial cannula
- Incorporate
  - Oxygenator
  - Heat exchanger
- Complex management



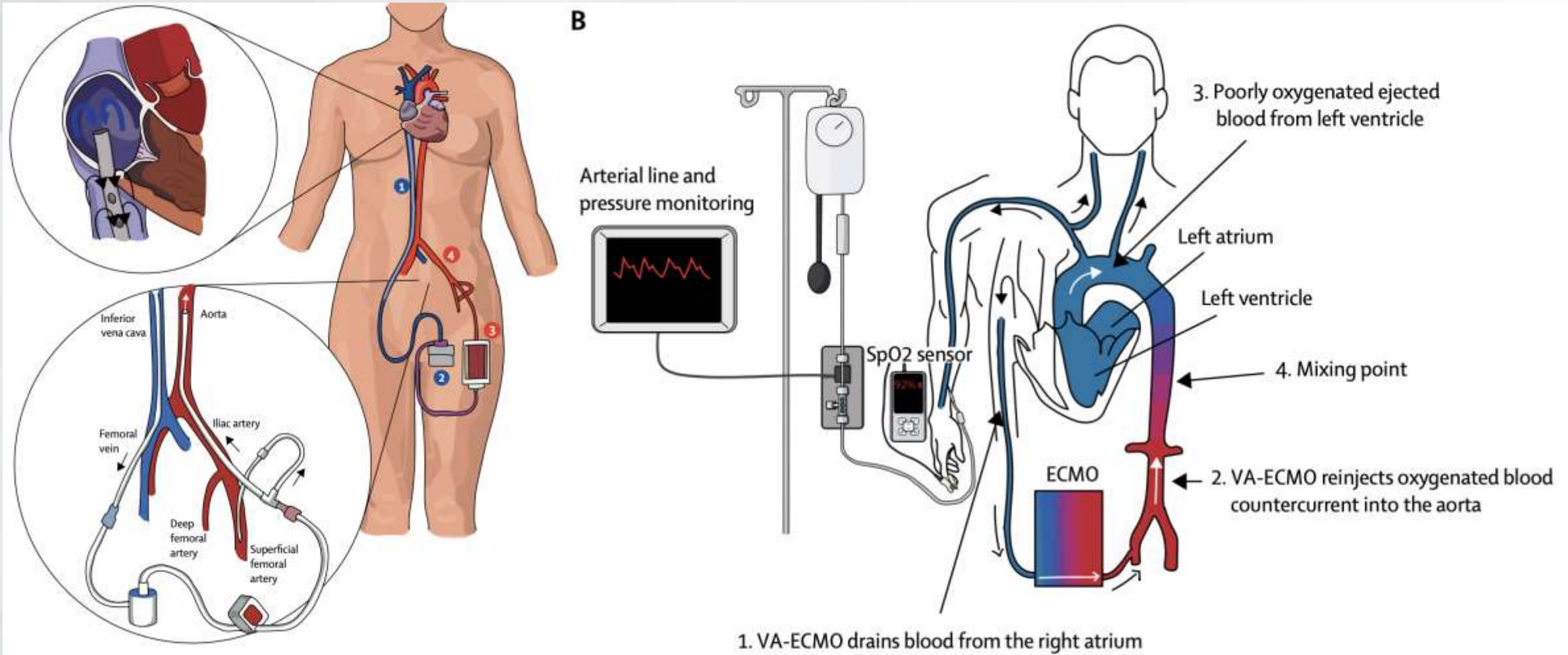


# VA- ECMO cannulation strategy

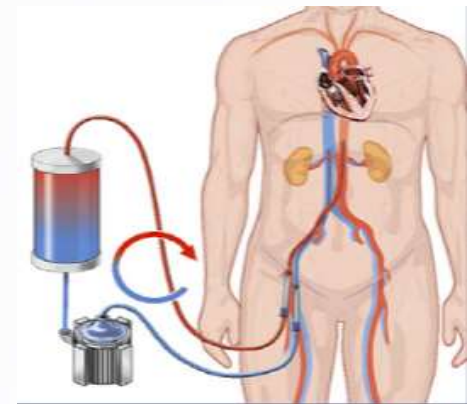
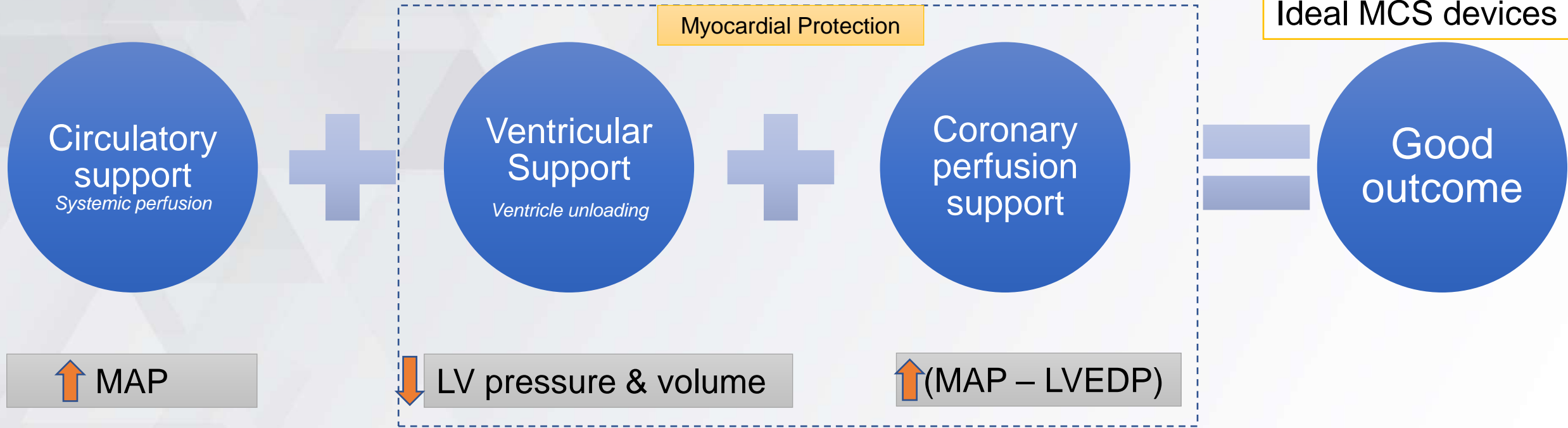




# Peripheral ECMO circulation consideration



# The hemodynamic support equation





	Baseline	IABP	Impella	ECMO	IABP + ECMO	Impella + ECMO	
French		8–9	13 (2.5) 14 (CP)	14–19 (A) 17–21 (V)	8–9 (IABP) + 14–19 (A) 17–21 (V)	13–14 (Impella) + 14–19 (A) 17–21 (V)	
HR, bpm	100	100	100	100	100	100*	
PCWP, mmHg	23	-4%	-9%	-13%	+17%	+13%	+9%*
AoP, mmHg	81/46 (61)	+2%	+8%	+15%	+28%	+31%	+39%*
CO, L/min	3.93	+5%	+13%	+28%	+43%	+48%	+60%*
CPO, watts	0.53	+7%	+21%	+34%	+81%	+91%	+118%*
PVA, mmHg × mL	4989	-3%	-7%	-13%	+16%	+14%	+7%*
CBF, mL/min/g	0.09	+10%	+10%	+20%	+40%	+50%	+70%*
Approved duration of assistance		No limitations (vascular complications increases after 2 days)	4 days (US) 5 days (EU)	Usually < 7 days <sup>1</sup> (poor survival if > 7 days)	See IABP and ECMO columns	See Impella and ECMO columns	



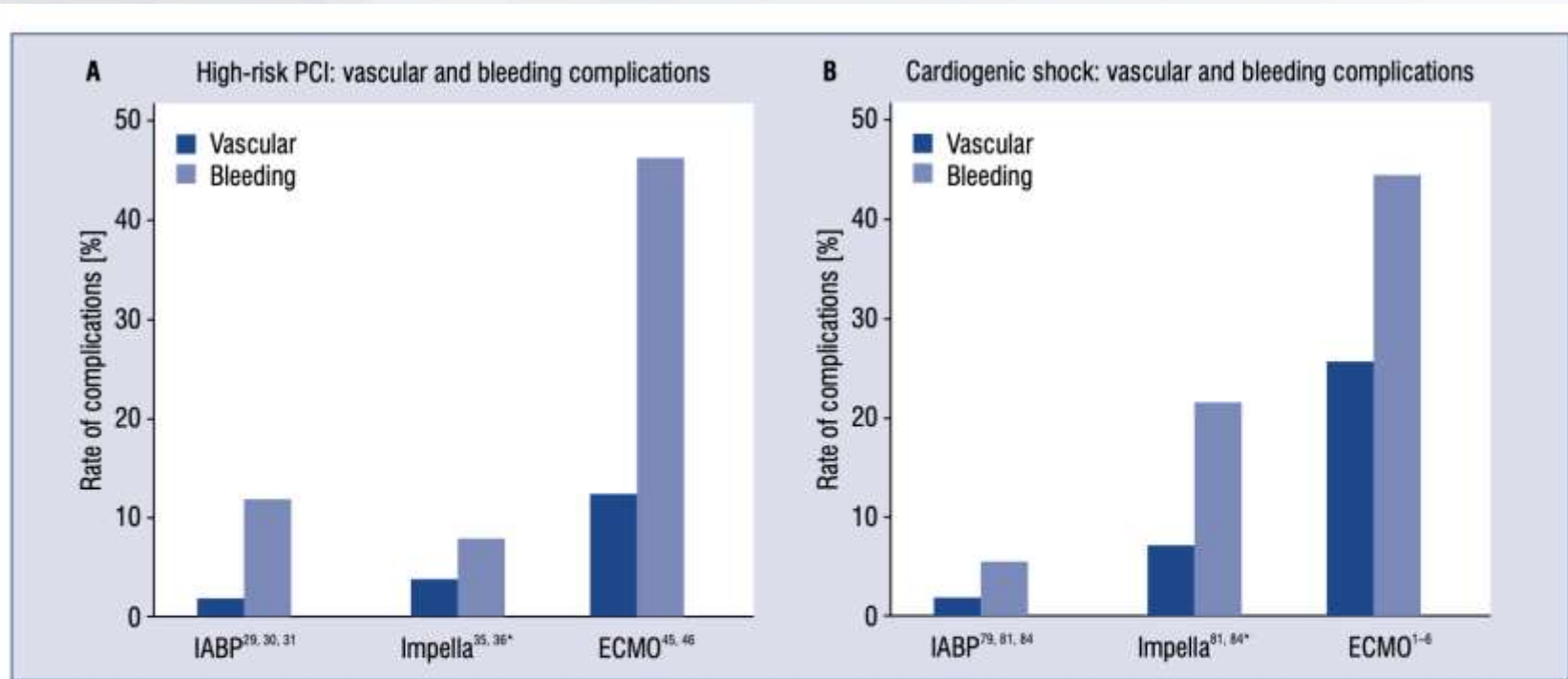


# Contraindications & complication

**TABLE 5 MCS Device Contraindications and Complications**

	<b>IABP</b>	<b>Impella</b>	<b>TandemHeart</b>	<b>VA-ECMO</b>
<b>Contraindications</b>	Moderate to severe AR Severe PAD Aortic disease	LV thrombus Mechanical aortic valve Aortic stenosis with AVA <0.6 Moderate to severe AR Severe PAD Contraindication to anticoagulation	Severe PAD HIT DIC Contraindications to anticoagulation LA thrombus VSD Moderate to severe AR	Contraindications to anticoagulation Moderate to severe AR Severe PAD
<b>Complications</b>	Stroke Limb ischemia Vascular trauma Balloon rupture Thrombocytopenia Acute kidney injury Bowel ischemia Infection	Device migration Device thrombosis Limb ischemia Vascular trauma Hemolysis Infection Stroke	Air embolism Thromboembolism Device Dislodgement Cardiac tamponade Limb ischemia Vascular trauma Hemolysis Infection Stroke	Bleeding Vascular trauma Limb ischemia Compartment syndrome Acute kidney injury Hemolysis Thromboembolism Air embolism Infection Neurological Injury
<b>Bleeding/hemolysis</b>	+	++	++	++
<b>Vascular complications</b>	+	++	+++	++++

# Vascular access site & bleeding complication



**Figure 4. A.** Access-site-related vascular and bleeding complication rate in high-risk percutaneous coronary intervention according to different percutaneous ventricular assist device (averaged mean value); **B.** Access-site-related vascular and bleeding complication rate in cardiogenic shock according to different percutaneous ventricular assist device (averaged mean value). Note: Major and minor vascular/bleeding complications are pooled together; PCI — percutaneous coronary intervention; IABP — intra-aortic balloon pump; ECMO — extracorporeal membrane oxygenation; \*data from both Impella 2.5 and CP were considered. For references [1–6] see dedicated reference list.



# Clinical application

High risk PCI  
*Protected PCI*

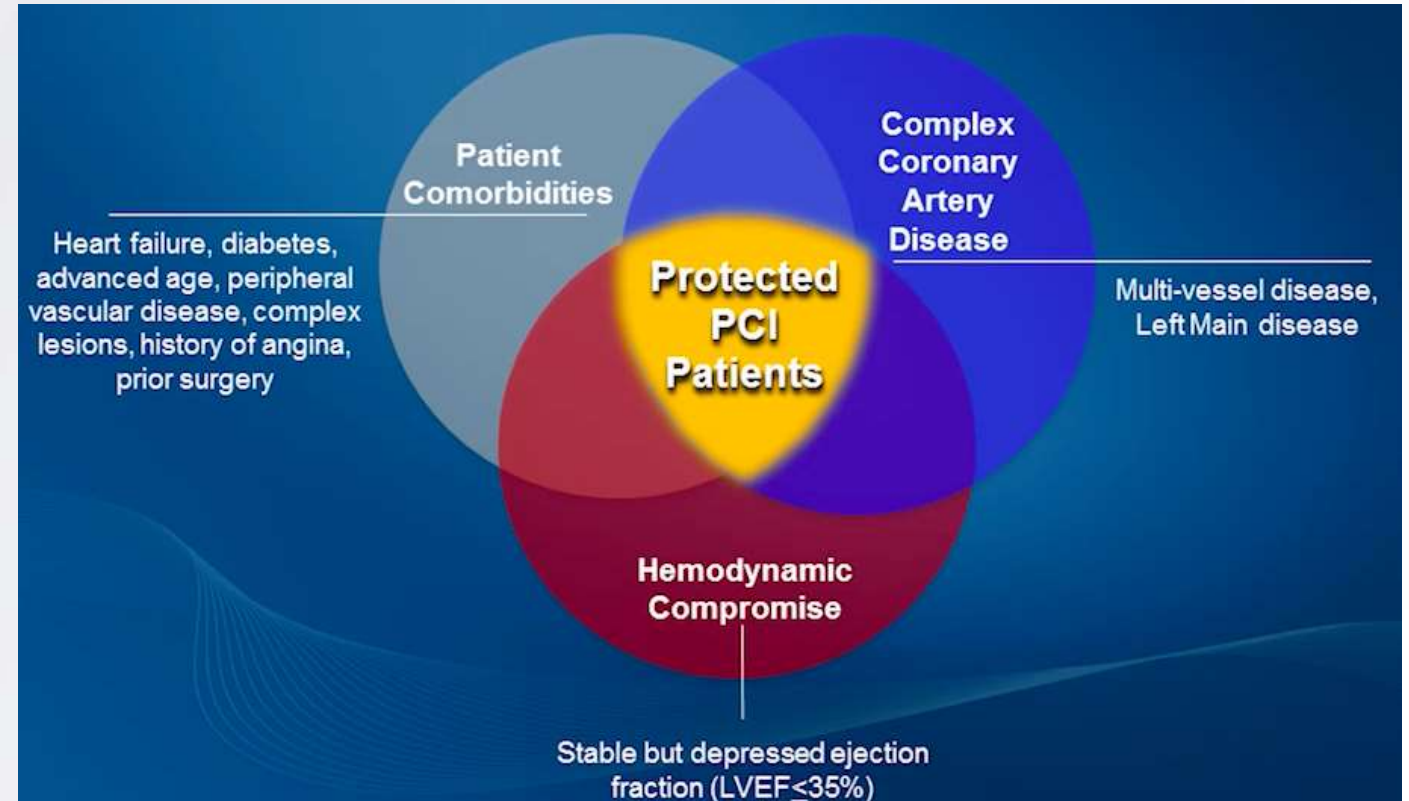
Cardiogenic  
shock



# Definition of High risk PCI

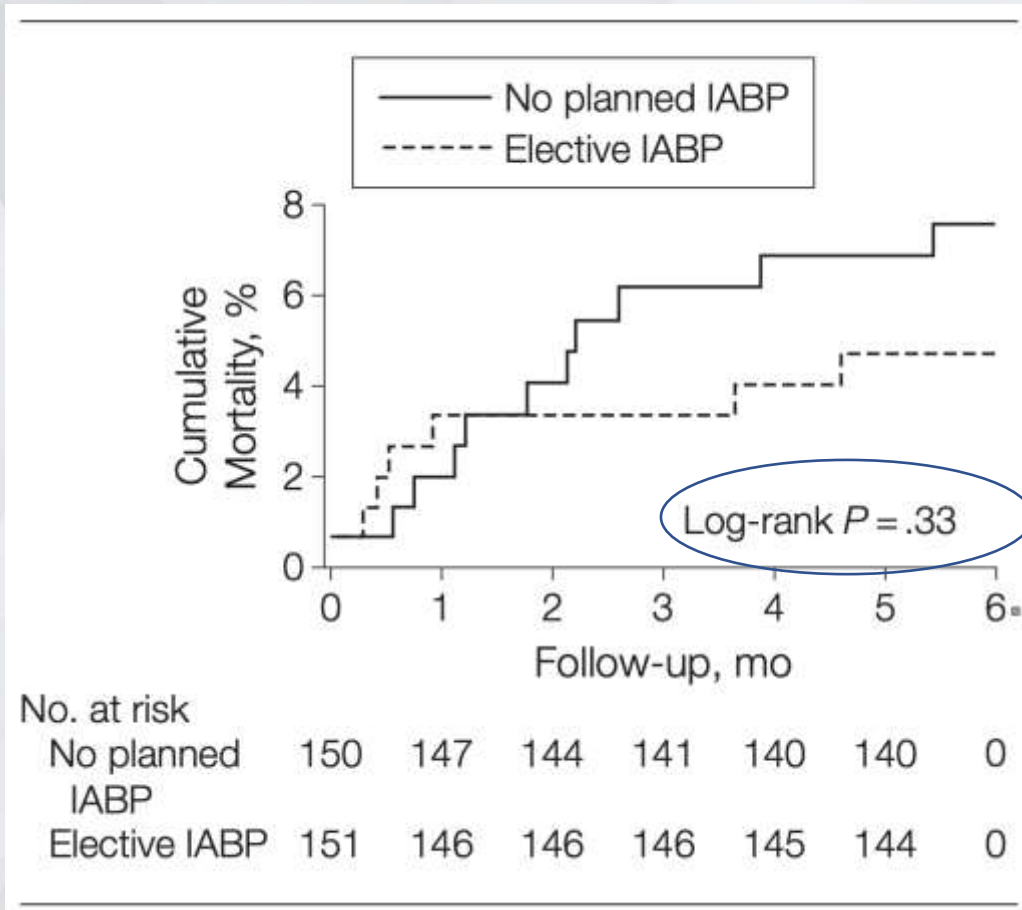
**TABLE 3 High-Risk PCI**

Clinical	
LVEF <35%	hemodynamic
Electrical instability	
Congestive heart failure	
Comorbidities	
Severe aortic stenosis	
Severe mitral regurgitation	
Chronic obstructive pulmonary disease	
Chronic kidney disease	Comorbidities
Diabetes	
Cerebrovascular disease	
Peripheral vascular disease	
Age >75 yrs	
Acute coronary syndrome	
Coronary anatomy	
Last patent vessel	Complex anatomy
UPLMN	
3 vessel disease, SYNTAX score >33	
Target vessel providing collaterals to a territory, which supplies >40% of the myocardium	
Distal left main bifurcation	





# IABP in High risk PCI



RCT in UK , multicenter  
N = 301

High risk definition

LVEF < 30%

Extensive coronary disease ( Jeopardy Score >8/12)

12% Bail-out IABP

No different in MACCE at discharge &  
mortality @ 6 month

BCIS – I study



# Impella in high risk PCI

First Author/Trial (Ref. #)	Indication	HR-PCI/Shock Definition	N	Devices	Outcomes	Complications
USPella (30)	Prophylactic HR-PCI	Severe 3VD, UPLMN, last patent vessel, low EF No STEMI or shock, mean SYNTAX score 36	175	Impella 2.5	12-month survival: 88%	MACE: 8%
EuroPella (52)	Prophylactic HR-PCI	Severe 3VD, UPLMN, last patent vessel, EF <30% No STEMI or shock	144	Impella 2.5	30-day survival: 94.5%	MI: 0%, stroke 0.7%, bleeding 6.2%, vascular complication 4%
Protect I (7)	HR-PCI	Last patent vessel, UPLMN, EF <35% No STEMI or shock	20	Impella 2.5		MACE 20%
PROTECT-II (23)	HR-PCI	UPLMN, last patent vessel, EF <35%, 3VD, and EF <30%	452	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%





# ECMO in high risk PCI

First Author/Trial (Ref. #)	Indication	HR-PCI/Shock Definition	N	Devices	Outcomes	Complications
Teirstein et al. (55) registry	HR-PCI and VA-ECMO	1) Stable or unstable angina pectoris; 2) at least 1 coronary artery stenosis amenable to PCI; 3) EF <25%; or 4) angioplasty target vessel supplying >50% of the viable myocardium, or both	389: prophylactic CPS 180: standby 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
Schreiber et al. (56)	HR-PCI	Low EF, culprit vessel supplying the majority of myocardium, or intended multivessel angioplasty	CPS: 58 IABP: 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%)

ECMO should not be the front line MCS device in HR -PCI



## High Risk PCI

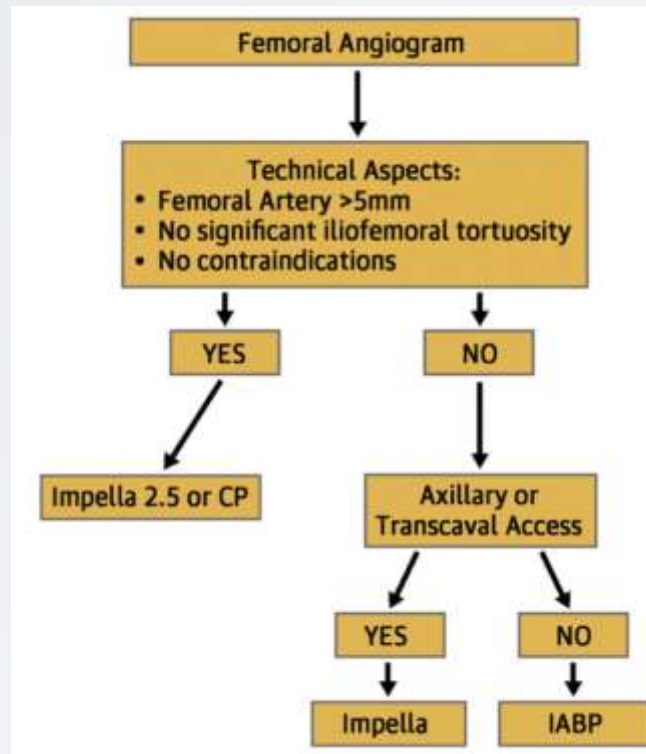
UPLMN  
Last patent vessel  
EF <35%  
Complex 3VD  
Comorbidities - severe AS/MR

### Multidisciplinary Heart Team Consultation - Interventional Cardiology, Cardiothoracic Surgery, Advanced Heart Failure, Intensive Care

#### Protected PCI planning

Which device should we use ?

- Degree of support needed ?
- Any contraindication for specific device ?
- Arterial acces suitability?



Bail – out device preparation

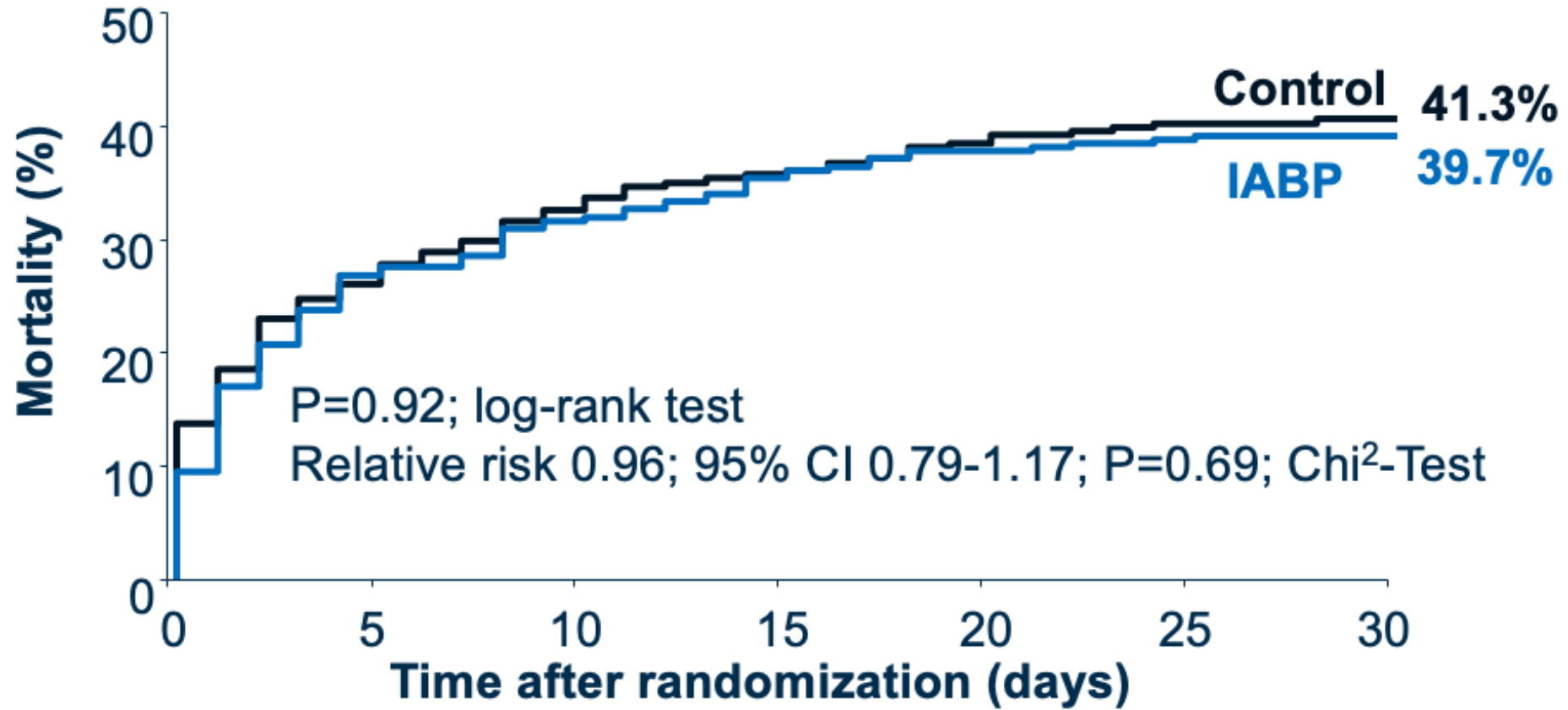
*Insert 5Fr sheath for rapid exchange in femoral artery*

# Clinical application

High risk PCI  
*Protected PCI*

Cardiogenic  
shock

# Primary Study Endpoint (30-Day Mortality)



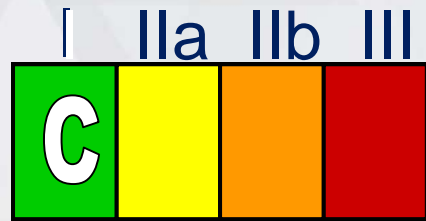


# ESC Guidelines 2012-2017

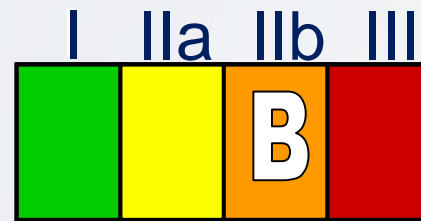


## IABP in cardiogenic shock

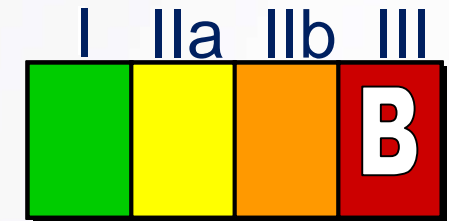
2010



2012

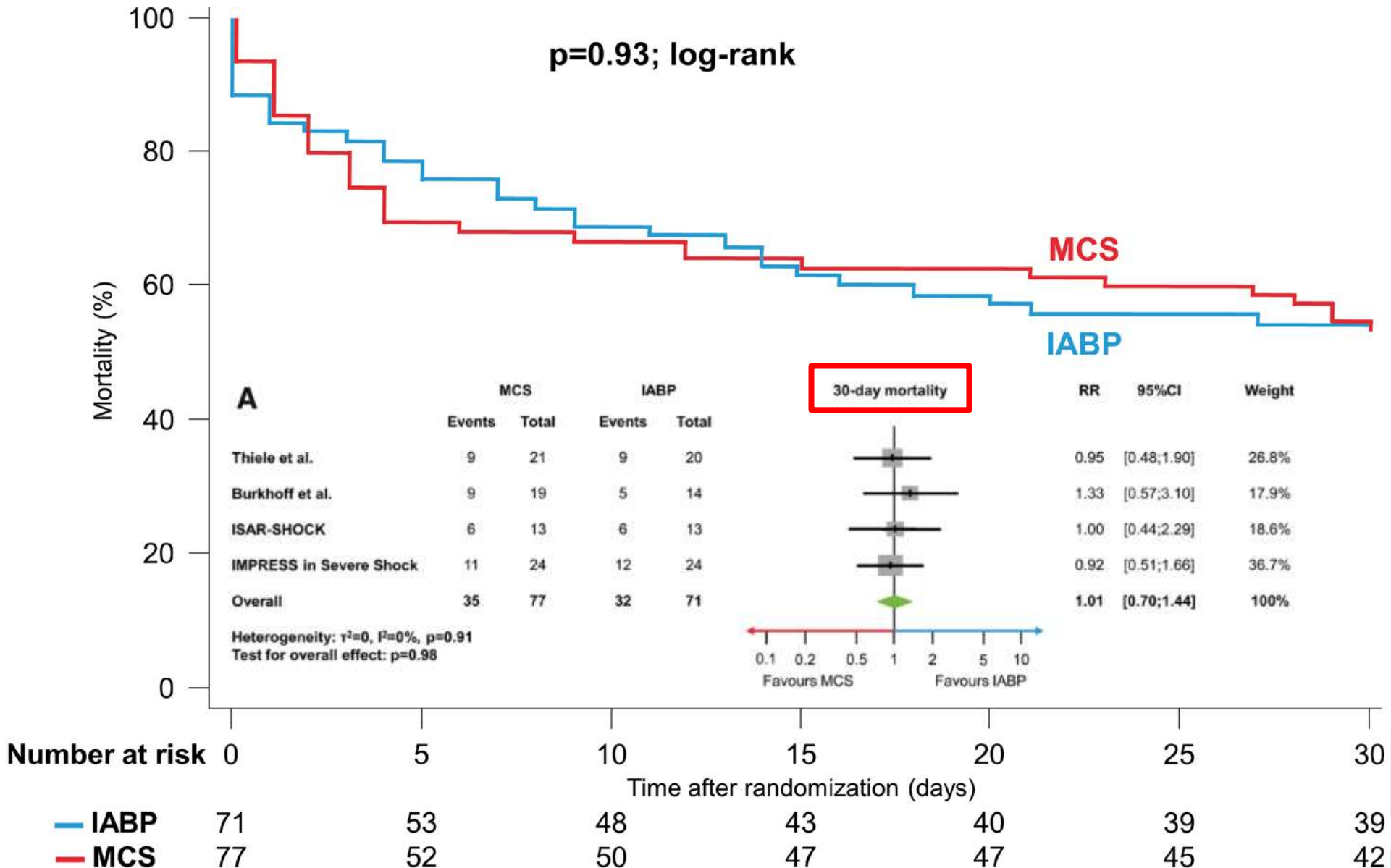


2017



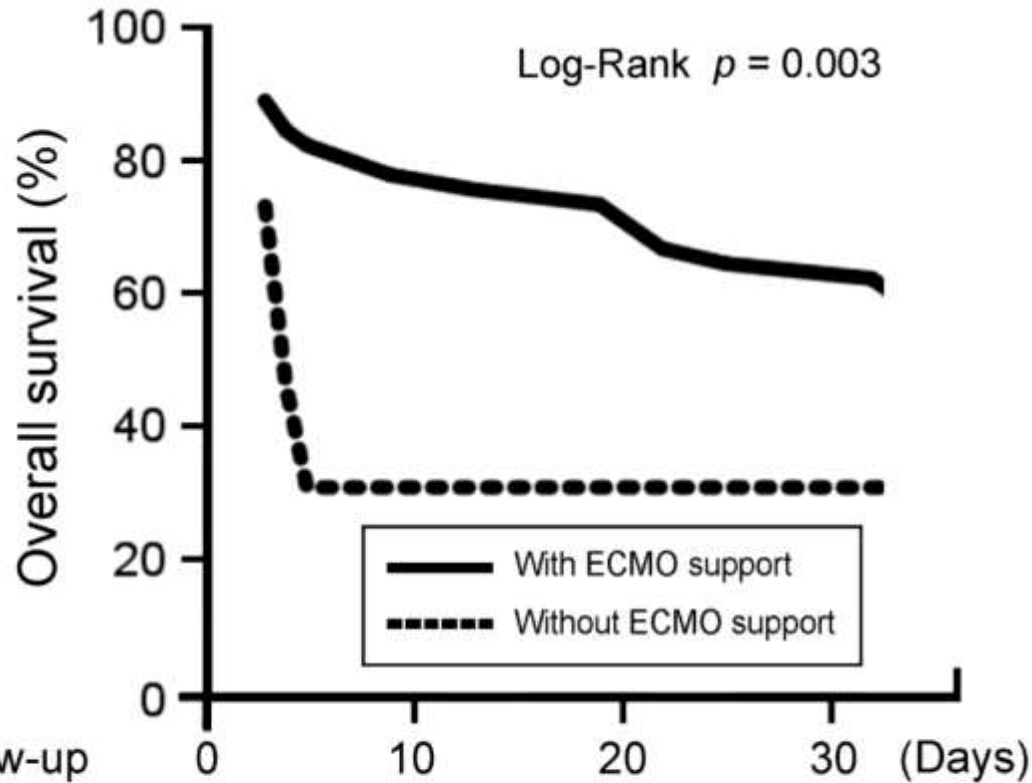
Roffi et al. Eur Heart J. 2016;37:267-315  
Windecker et al. Eur Heart J. 2014;35:2541-2619  
Ponikowski et al. Eur Heart J. 2016;37:2129-2200  
ESC STEMI Leitlinien 2017. Eur Heart J 2017; epub

# 30-day mortality between MCS vs IABP





# Early ECMO-assist primary PCI



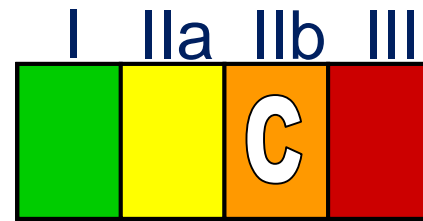
Few data  
only registry , no RCT

At risk (n)	With ECMO	46	32	31	28
	Without ECMO	25	7	7	7

# ESC STEMI Guidelines 2017

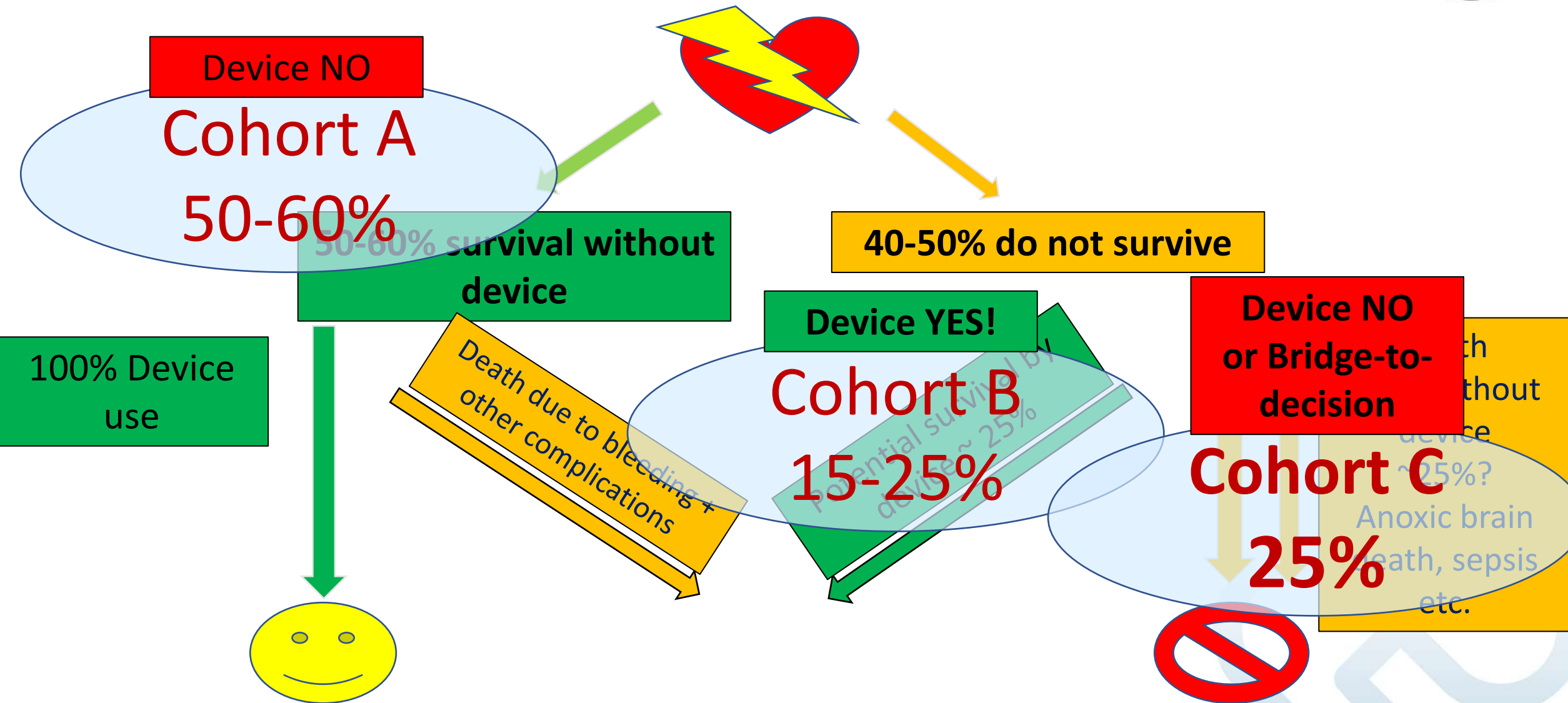


## MCS in cardiogenic shock



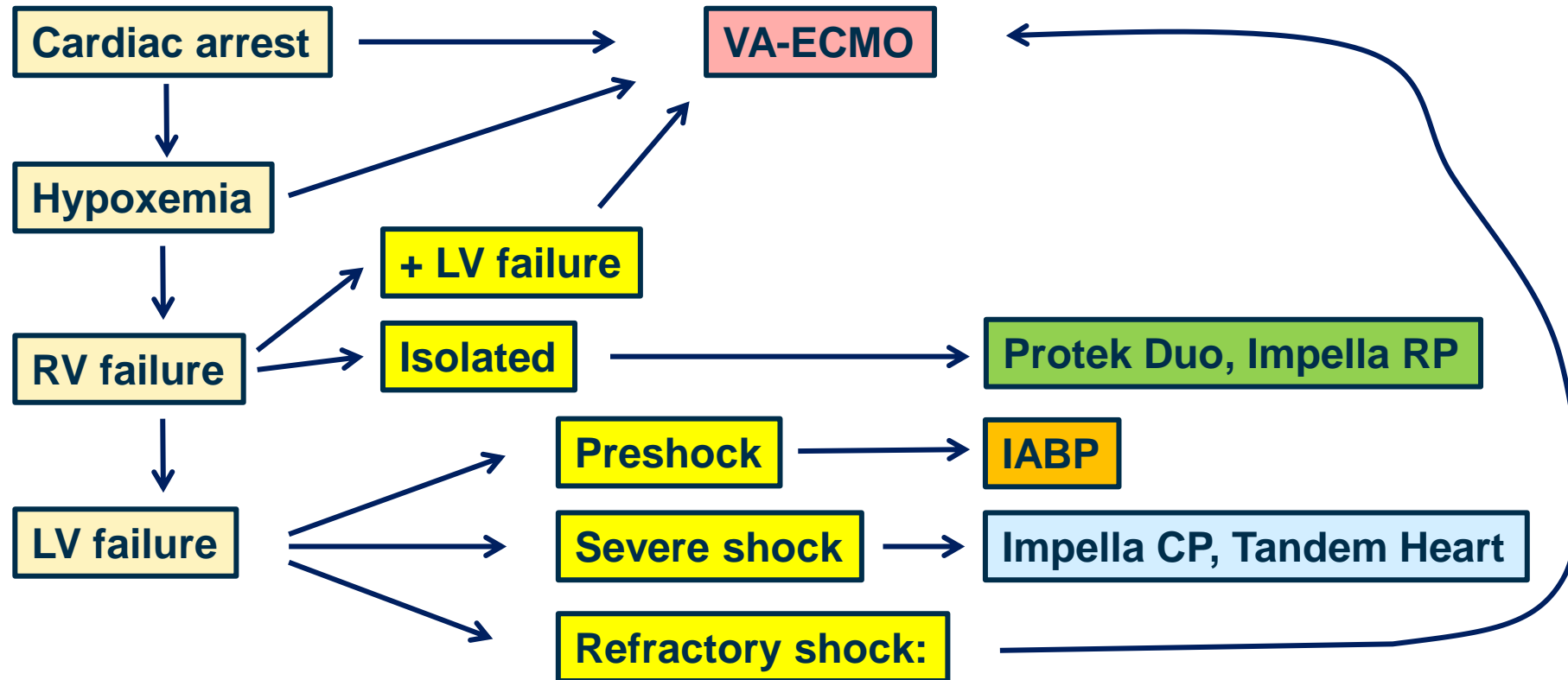


# Patient Selection?





# MCS device selection



STATEMENT FROM THE INTERVENTIONAL COUNCIL OF THE ACC

A Practical Approach to Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention

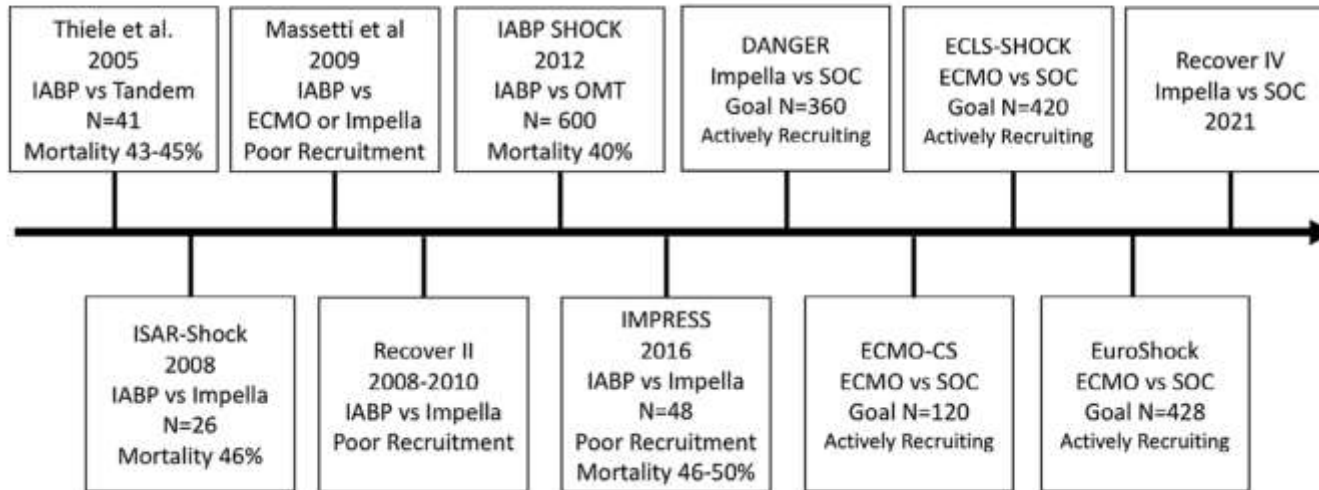
An Interventional Perspective

Tamara M. Atkinson, MD,<sup>a</sup> E. Magnus Olsson, MD,<sup>b</sup> William W. O'Neill, MD,<sup>c</sup> Tanveer Rab, MD,<sup>d</sup> Joaquin E. Cigarroa, MD,<sup>e</sup> on behalf of the Interventional Scientific Council of the American College of Cardiology

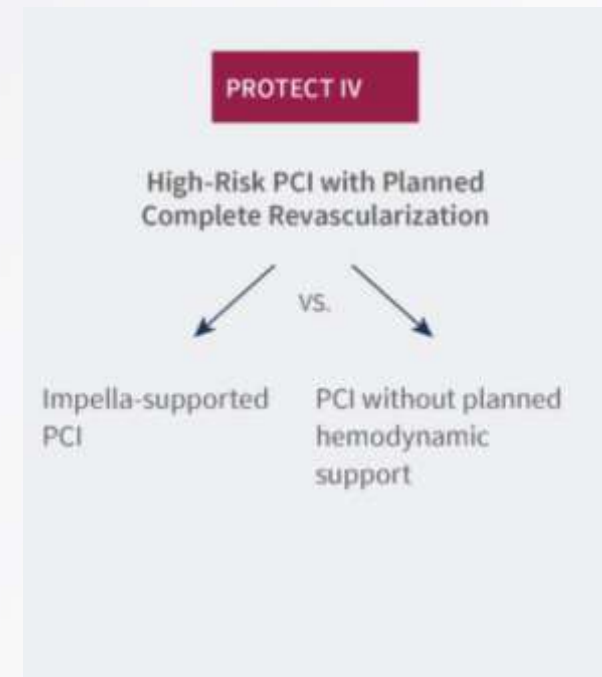


# Upcoming trial for answer the question

## Randomized Control Trials Evaluating Mechanical Circulatory Support in Acute Myocardial Infarction and Cardiogenic Shock



Cardiogenic shock



High risk PCI



# Conclusion / Take-home Message

- All MCS devices have some limitation /contraindications
- Careful case selection is the key to improve the patient outcome
- In High risk PCI
  - Planning and prepare for the worst
  - Bail out MCS device is another option ( better to have arterial access and standby device )
- In CS
  - Monitoring & early escalate therapy with MCS device is the key to break the spiral
  - Implementing "best practices" and developing "shock team" is associate with improve outcome

Choose the right mechanical circulatory support device to the right patient.