TCTAP 2023
ACS with or without Cardiac Support Devices

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Disclosure

- The author have no financial conflicts of interest todisclose concerning the presentation

Features of ACS

- Rapidly progressive ischemia.

→May not spend enough time on procedure.

- Difficulty of the procedure is unknown or well considered.

→Unexpected difficulties or complications can arise.

- Unlike elective cases, there may be a lack of staff and limited equipment available.

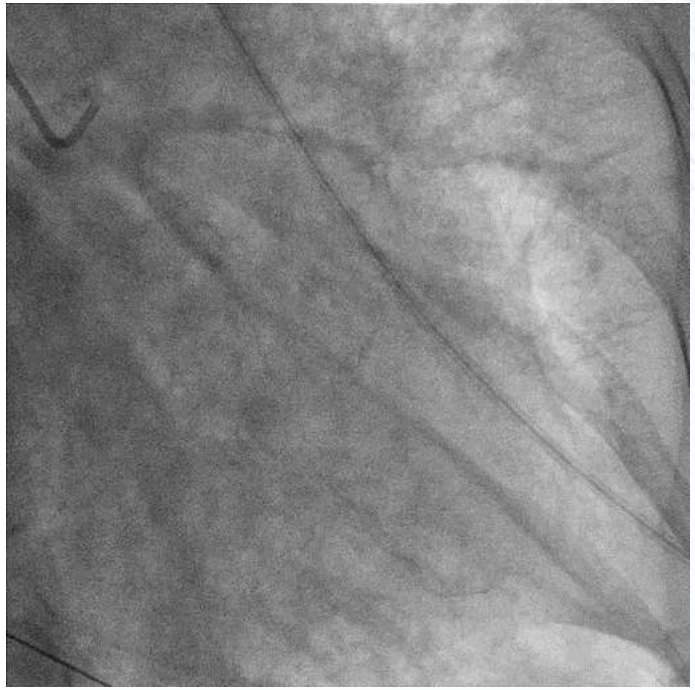
- Hemodynamics may be disrupted or may be disrupted during the procedure

→need cardiac support devices

81F, CPAOA

One of our severest cases of ACS with cardiac support devices

- 81F, cardio-pulmonary arrest on arrival→resuscitated
- LMT/LAD/LCx 99%, RCA: no stenosis
- ECMO→PCI→ECMO+IABP
- Rota to LMT-LAD, LMT-LAD
- After stabilizing CHF, CABG×2(LITA-LAD, SVG-D1-PL)
- Now 18 months after the event,
  she walks to outpatient clinic



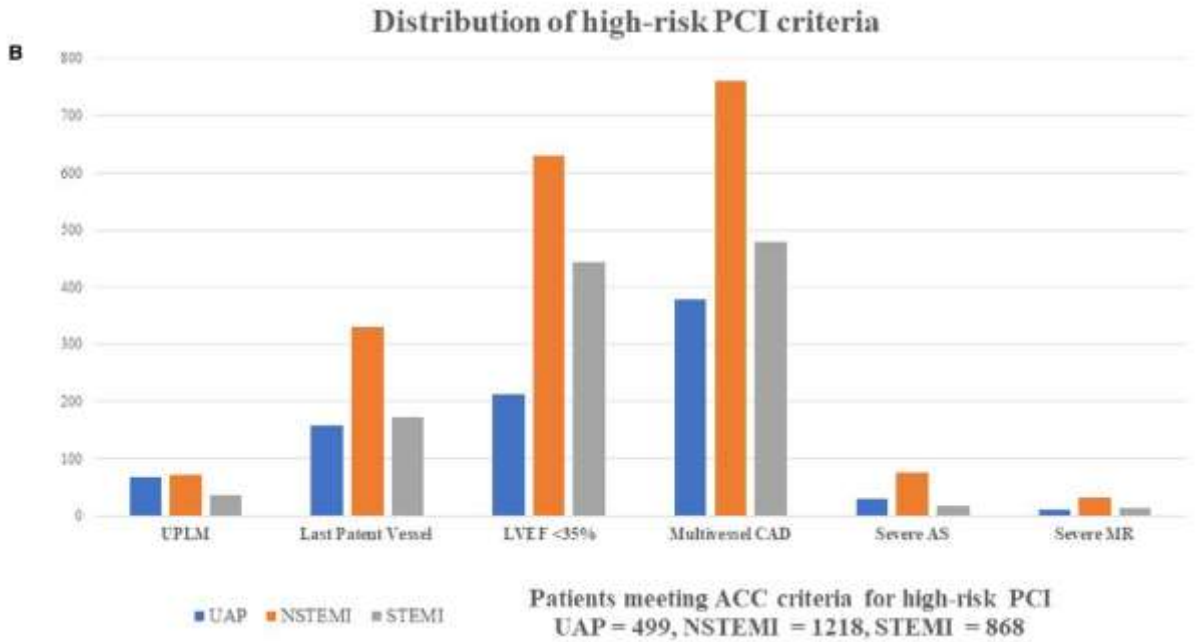
ACS without cardiac support devices

- Rather easy cases. Low risk score by AHA/SYNTAX/GRACE etc.
- Hemodynamics are stable.
- Must keep in mind the possibility of hemodynamic breakdown during procedure.

ACS without cardiac support devices (in high risk cases without shock)

Is it safe or not safe?

- ACS without cardiac support devices had low 30 day mortality not when complicated by shock.



Am J Cardiol
. 2021 Nov 1;158:37-44.

2585 patients(3914 lesions)
In-hospital and 30 day mortality: 2%(UAP), 2.1%(NSTEMI), STEMI(4.7%)

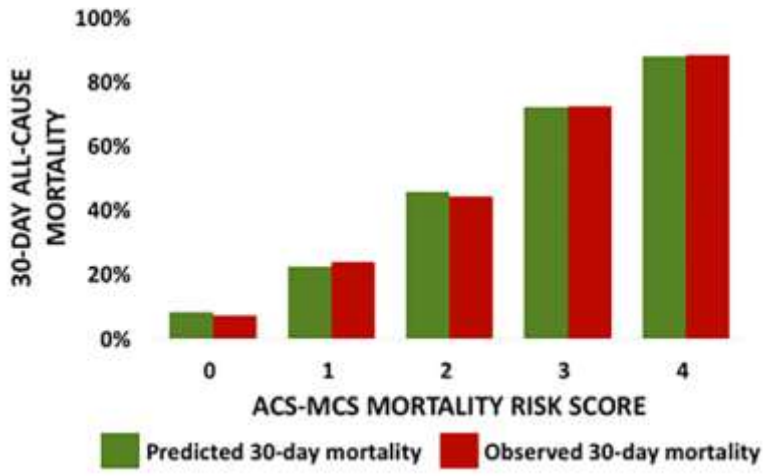
Considering Cadiac Support Devices

Risk score

- ACS-MCS score
- Shock cases due to ACS with **M**echanical **C**ardiac **S**upport(IABP, Impella, ECMO)
- Higher score, higher mortality
- Risk stratification tool
- May help decision

ACS-MCS Mortality Risk Score

Age ≥ 60	1 point
Lactate ≥ 2.5 mmol/L	1 point
SCAI CS stage E	1 point
AKI	1 point



ACS with cardiac support devices

When you consider introducing devices

- Hemodynamics are disrupted. (CPA/CPR cases, Forrester IV, low EF) or may disrupted.
- Extensive ischemia. (LMT, multi vessel disease, proximal or diffuse LAD; preventive use.)

→accurate risk assessment is needed.

- Non coronary complications (valvular disease, cardiomyopathy)

Common cardiac support devices used during ACS PCI

- IABP (Intra Aortic Balloon Pumping)
- Impella
- ECMO (Extracorporeal Membrane Oxygenation)

- Recently, Implella use is increasing

Features of each devices

IABP/IMPELLA/ECMO

Intra-Aortic Balloon Pump

Advantages:
- Ubiquitous – available in most cardiac catheterization laboratories throughout the world
- Ease of percutaneous implantation
- Available in 7Fr, 7.5Fr, and 8Fr catheter sizes minimizing threat of vascular complications
- Contemporary systems use fiber-optic technology negating risks associated with a fluid-filled pressure line
- Newer systems calibrate automatically in vivo accelerating the time to effective diastolic augmentation
- Range of balloon sizes available to accommodate patients of all heights
- Larger volume balloons displace more blood providing enhanced diastolic augmentation and systolic unloading

Potential disadvantages:
- Can only supplement cardiac output by up to 0.3-0.5 l/min and requires a degree of native cardiac output to function
- Relies on synchronization with the cardiac cycle so circulatory support may not be reliable with dysrhythmia
- Risk of balloon displacement, rupture, leak, or entrapment
- Twisting/kinking of and clot formation in the pressure line or catheter
- Small but tangible risk of aortic dissection or rupture
- Systemic embolization (e.g. cholesterol, helium)
- Stroke
- Infection
- *Lower limb ischemia +
- *Hemolysis +
- *Bleeding at insertion site +

Impella

Advantages:
- Can augment cardiac output by 2.5 l/min (Impella 2.5) to 4 l/min (Impella CP™/cVAD)
- Can be used to support the circulation for up to 7 days
- Does not require a stable cardiac rhythm or native cardiac output/blood pressure signal for optimal function – the device does, however, require adequate filling of the left ventricle for optimal function

Potential disadvantages:
- Not universally available
- Requires 12-14Fr catheters for implantation thus increasing the risk of vascular complications
- Non-pulsatile flow
- Risk of displacement of inflow from the left ventricle to the aorta
- Insufficient flow to the periphery in larger patients (>100 kg body mass)
- Systemic embolization
- Stroke
- Infection
- *Lower limb ischemia ++
- *Hemolysis ++
- *Bleeding at insertion site ++

*Denotes relative grading between all three devices.

TandemHeart

Advantages:
- Can augment native cardiac output by up to 4-5 l/min
- Can be used to support the circulation for up to 14 days
- Does not require a stable cardiac rhythm or native cardiac output/blood pressure signal for optimal function

Potential disadvantages:
- Not universally available
- Requires specific expertise with transseptal punctures for implantation of a 21Fr cannula
- Relatively long implantation time
- Implantation cannot be performed during cardiopulmonary resuscitation
- Relatively complex post-implantation management
- Risk of left atrial cannula tip displacement into the right atrium causing profound desaturation
- 17Fr femoral arterial cannula increases risk of vascular complications
- Systemic embolization
- Stroke
- Infection
- *Lower limb ischemia +++
- *Hemolysis ++
- *Bleeding at insertion site ++

But how to choose each devices?

JACC Cardiovasc Interv . 2015 Feb;8(2):229-244.

IABP-SHOCK II trial

- AMI with shock patients

(1:1 with IABP/without IABP)

- randomized, prospective, open-label, multicenter trial
- Primary endpoint: 30 days mortality
- No significant differences between IABP group and control group

(relative risk 0.96; 95%; P=0.69)

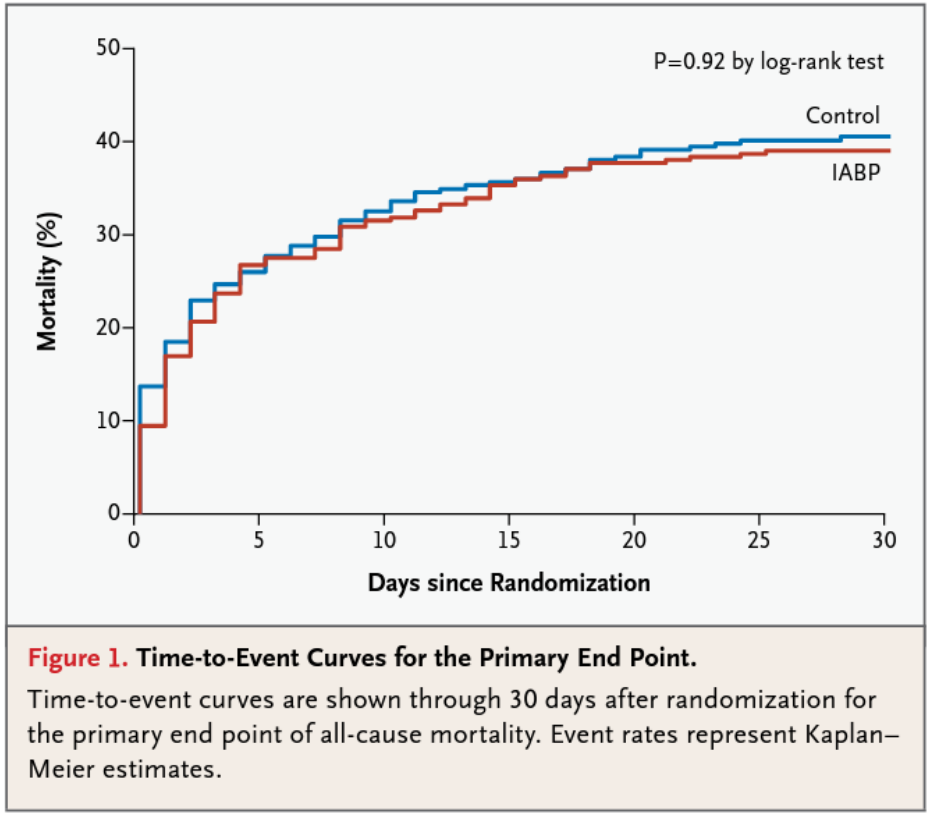
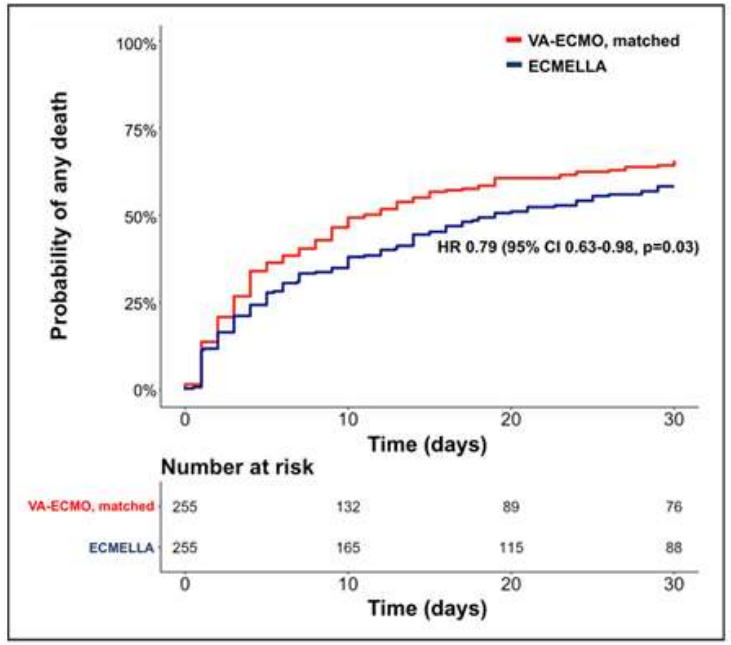


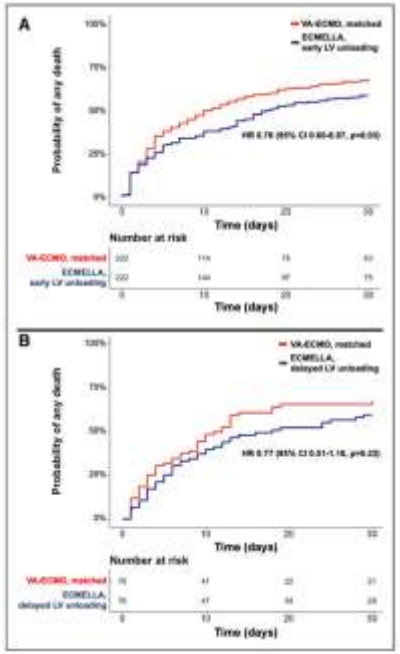
Figure 1. Time-to-Event Curves for the Primary End Point.
Time-to-event curves are shown through 30 days after randomization for the primary end point of all-cause mortality. Event rates represent Kaplan–Meier estimates.

N Engl J Med. 2012 Oct 4;367(14):1287-96.

ECPELLA better than ECMO only

- Shock treatment study (not limited to ACS: AMI 59.3%/63.5%)
- Multicenter, international cohort
- ECMO+Impella had lower rate or death from any cause.

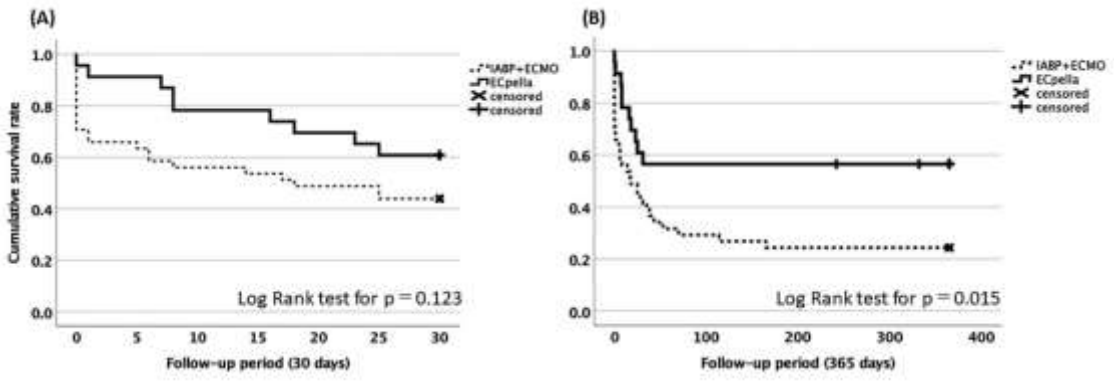




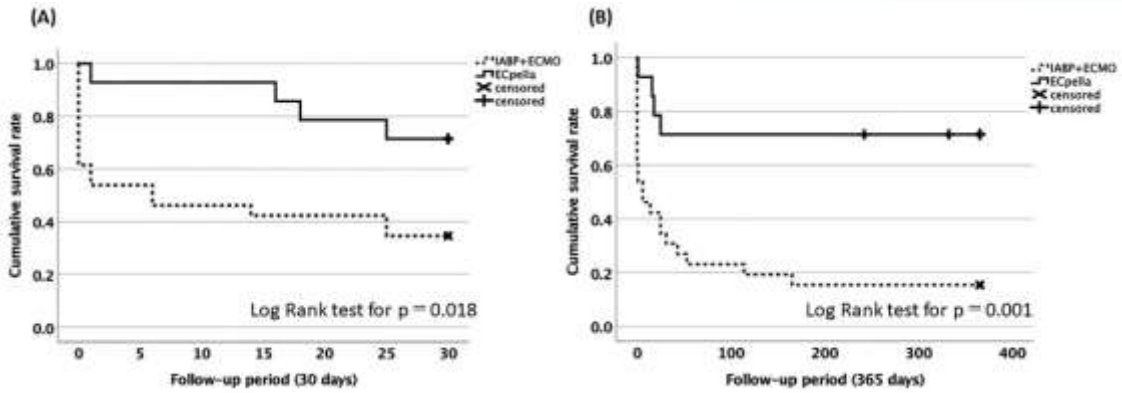
Circulation. 2020 Dec;142(22):2095-2106.

ACS with shock; ECMO+IABP or ECMO+Impella?

- ECMO+Impella may improve overall survival of patients with shock due to ACS.
- Limitation: single center study, not randomized, small number of cases(without CPA: 40, with CPA 24)



Without CPA

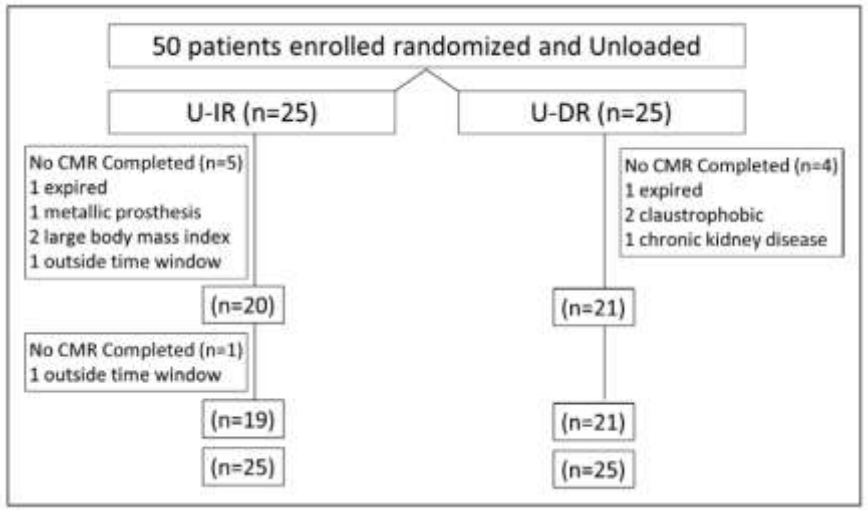


With CPA

J Cardiol. 2022 Aug;80(2):116-124.

STEMI-DTU pilot trial

- Unloading(Impella CP) before PCI may be better than PCI before unloading
- Small size, pilot study
- 30 min. delay of PCI in U-DR group
- Not statistically significant but first proved feasibility of Unloading first strategy.



Circulation. 2019 Jan 15;139(3):337-346.

STEMI-DTU pilot trial

- U-DR group(Impella first) had smaller infarct size(estimated by CMR), higher EF, smaller EDV/ESV.
- U-DR group had equal CV mortality but higher major vascular events, thus higher MACCE.
- Differences are not significant maybe because of small study population.

Results	U-DR	U-IR	*P* Value
30 days			
Infarct size, number assessed, n (%)	21 (84.0)	19 (76.0)	
Mean (±SD), %	13.1 (11.3)	15.3 (11.5)	0.53
Median (IQR), %	10.4 (5.0–26.1)	13.0 (3.8–22.9)	
LVEF, number assessed, n (%)	21 (84.0)	19 (76.0)	
Mean (±SD), %	49.2 (12.9)	48.5 (13.4)	0.87
Median (IQR), %	47.4 (39.4–61.0)	47.2 (35.9–59.9)	
LVESV, number assessed, n (%)	20 (80.0)	19 (76.0)	
Mean (±SD), mL	76.0 (43.9)	78.3 (34.4)	0.86
Median (IQR), mL	69.0 (38.7–100.6)	65.5 (50.2–106.0)	
LVEDV, number assessed, n (%)	20 (80.0)	19 (76.0)	
Mean (±SD), mL	140.9 (50.8)	147.9 (37.1)	0.63
Median (IQR), mL	147.8 (97.8–171.6)	149.6 (119.2–171.0)	

Table 4. MACCE at 30 Days

Events	U-DR n=25	95% CI	U-IR n=25	95% CI	*P* Value
MACCE, n (%)	3 (12)	2.55%–31.22%	2 (8)	0.98%–26.03%	0.99
CV mortality, n (%)	1 (4)	0.10%–20.35%	1 (4)	0.10%–20.35%	0.99
Reinfarction, n (%)	0 (0)	0.00%–13.72%	0 (0)	0.00%–13.72%	—
Stroke/TIA, n (%)	0 (0)	0.00%–13.72%	1 (4)	0.10%–20.35%	0.99
Major vascular events, n (%)	2 (8)	0.98%–26.03%	0 (0)	0.00%–13.72%	0.49

Circulation. 2019 Jan 15;139(3):337-346.

Results from Japanese registry

- impella alone (293 patients) vs ECMO+Impella (300 patients)
- Impella alone group showed better 30 days mortality rate(80.9% vs 45.7%)

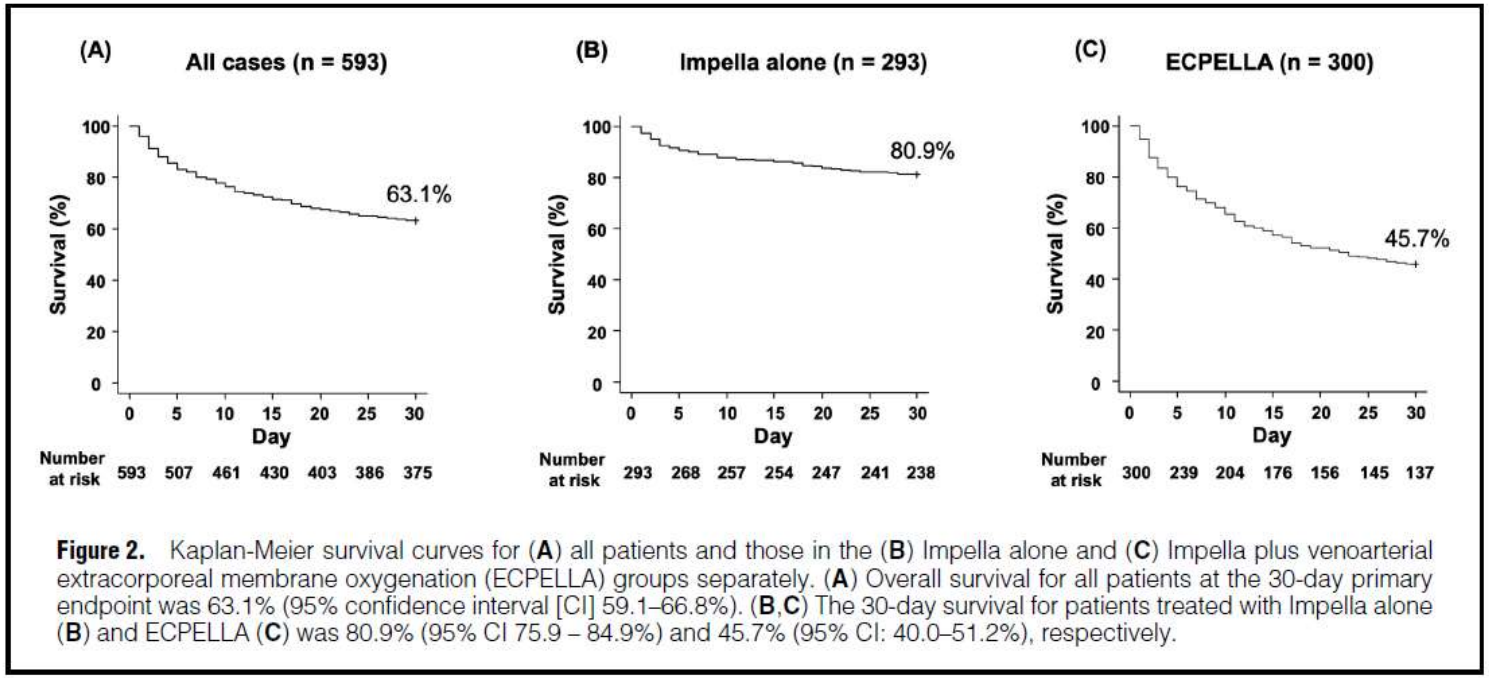


Figure 2. Kaplan-Meier survival curves for (**A**) all patients and those in the (**B**) Impella alone and (**C**) Impella plus venoarterial extracorporeal membrane oxygenation (ECPELLA) groups separately. (**A**) Overall survival for all patients at the 30-day primary endpoint was 63.1% (95% confidence interval [CI] 59.1–66.8%). (**B**,**C**) The 30-day survival for patients treated with Impella alone (**B**) and ECPELLA (**C**) was 80.9% (95% CI 75.9 – 84.9%) and 45.7% (95% CI: 40.0–51.2%), respectively.

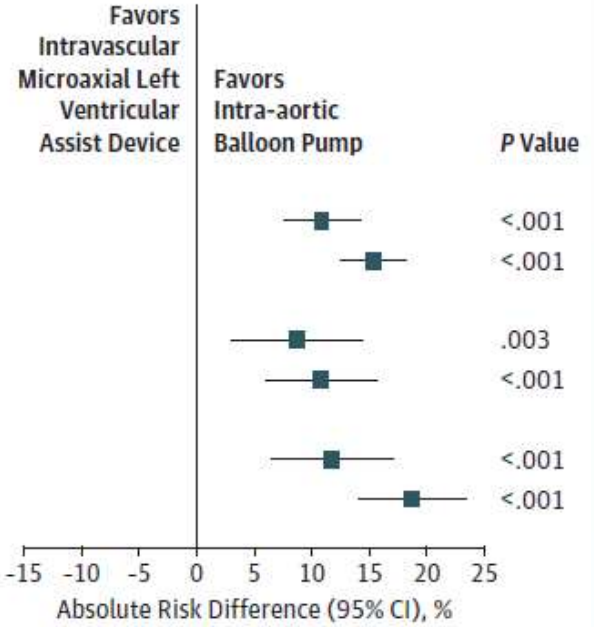
Circ J. 2023 Apr 25;87(5):588-597.

Evidence supporting superiority of IABP

- AMI with shock patients(retrospective study)
- Between 1680 matched pairs, Impella group had higher 30 days mortality and higher major bleeding.

Figure 2. In-Hospital Outcomes Among Propensity-Matched Patients With Acute Myocardial Infarction Complicated by Cardiogenic Shock Undergoing Percutaneous Coronary Intervention With Intravascular Microaxial Left Ventricular Assist Device vs Intra-aortic Balloon Pump

	Intravascular Microaxial Left Ventricular Assist Device		Intra-aortic Balloon Pump		Absolute Risk Difference (95% CI), %	*P* Value
	No. of Patients	Patients, %	No. of Patients	Patients, %		
Overall (n = 1680 matched pairs)						
Mortality	756	45.0	573	34.1	10.9 (7.6-14.2)	<.001
Major bleeding	526	31.3	268	16.0	15.4 (12.5-18.2)	<.001
Device placement before initiation of percutaneous coronary intervention (n = 573 matched pairs)						
Mortality	261	45.5	211	36.8	8.7 (3.1-14.4)	.003
Major bleeding	157	27.4	95	16.6	10.8 (6.1-15.6)	<.001
Device placement after initiation of percutaneous coronary intervention (n = 662 matched pairs)						
Mortality	291	44.0	213	32.2	11.8 (6.6-17.0)	<.001
Major bleeding	228	34.4	104	15.7	18.7 (14.2-23.3)	<.001



JAMA. 2020 Feb 25;323(8):734-745.

Conclusion

- There are no clear criteria or evidence regarding the use of cardiac support devices during ACS treatment and which devices to use.
- Impella-based circulatory support is becoming the mainstay in cases of shock complications
- Impella requires caution because bleeding complications may define the life prognosis.
- IABP has difficulty demonstrating efficacy since the IABP-SOCK II trial, but has advantages in terms of relatively easier introduction, management, and rapidity of initiation, thus use with ACS is acceptable under certain circumstances.
- ECMO is essential in cases of right heart failure or respiratory failure even when using impella
- Further accumulation of basic and clinical findings is needed.