

**A joint meeting of the Working Group on
Myocardial & Pericardial Diseases in
collaboration with Israel Working
Group on Heart Failure**



MCS as bridge to recovery: When and for Whom

tMCS & dMCS

Tuvia Ben Gal (Blachinsky)

Heart Failure Unit

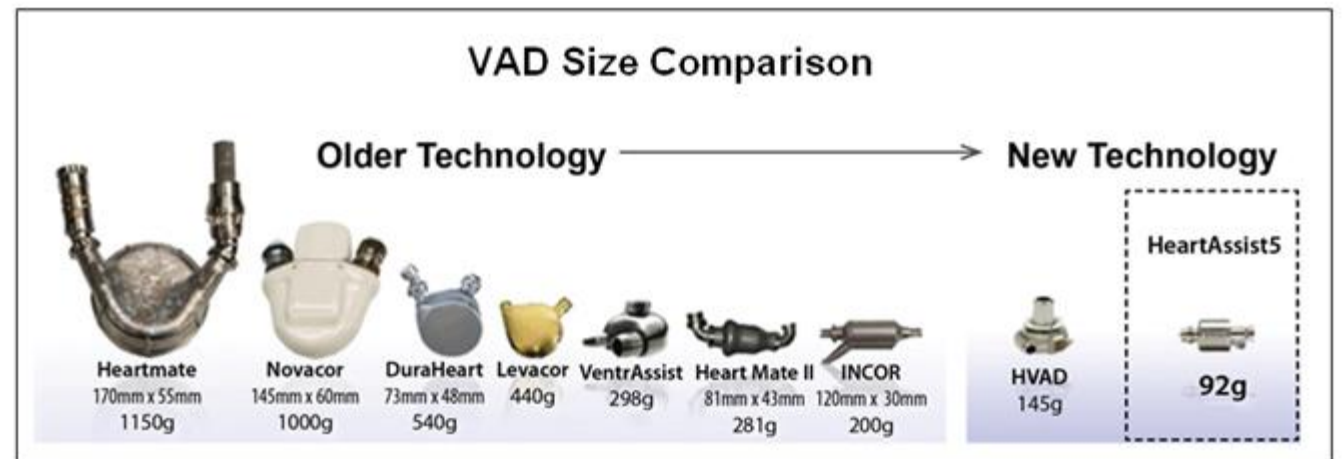
Rabin Medical Center



Content

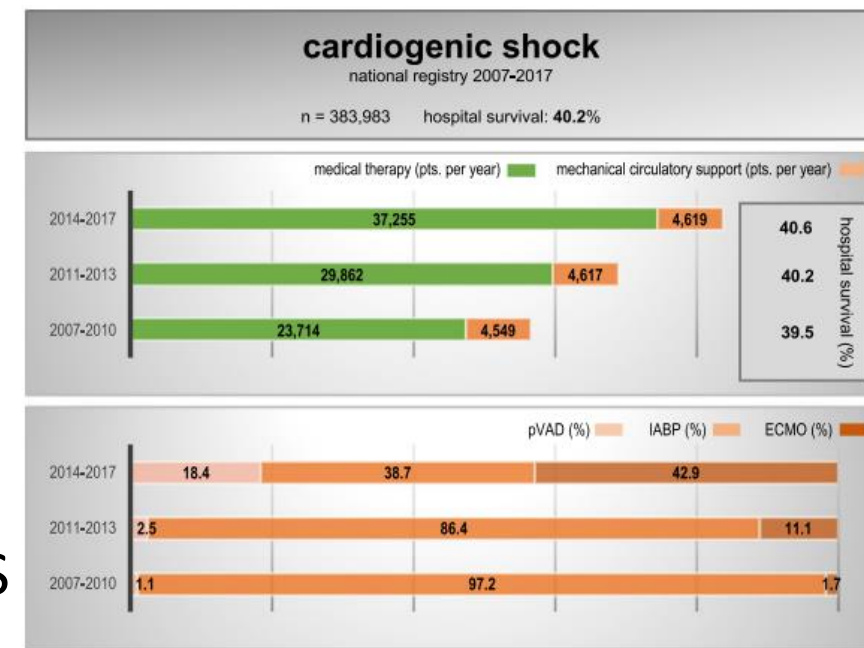


- tMCS:
 - Indications for implantation: Cardiogenic shock
 - tMCS: different devices for different patients
 - tMCS: recovery
- dMCS: recovery



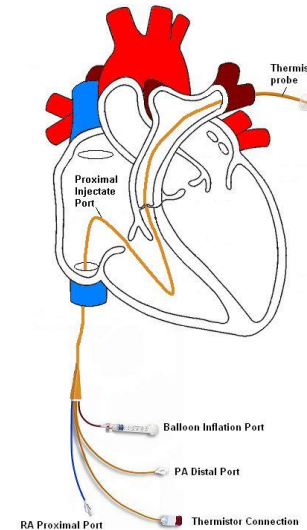
Cardiogenic Shock

- Significantly low survival rates.
- MCS: fundamental role in the contemporary treatment of CS
- Device selection is a key element in determining optimal treatment
- Different MCS specific nominal flow, potential complications, and expected durations.
- A simultaneous or consecutive combination of MCS.
- Correct timing and indications for implantation: early use pMCS = improved outcomes.
- Escalation & de-escalation.



CS: Management

- Intensive care unit with haemodynamic invasive and non-invasive monitoring.
- The use of pulmonary artery catheters is strongly advised
- Continuous monitoring of
 - Cardiac output
 - Blood pressure
 - Cardiac filling pressures
 - Residual LVEF
 - Shock parameters: lactate, metabolic acidosis, mixed venous oxygen saturation.
- Inotropes: increased myocardial O₂ cons. & arrhythmic risk, to maintain SBP, Class IIb.



CS: Management when to consider MCS?

- Considering several inotropes
- Inadequate response to the inotropic support
- Inotropic score >20 (5.5) consider MCS
- Inotropes for >48 h
- Persistent elevated LVEDP, pulmonary congestion, metabolic decompensation, & end-organ damage

IS = Dopamine dose ($\mu\text{g}/\text{kg}/\text{min}$) 5-20

+ Dobutamine dose ($\mu\text{g}/\text{kg}/\text{min}$) 2.5-20

+ 100 \times Epinephrine dose ($\mu\text{g}/\text{kg}/\text{min}$) 0.01-0.5

VIS = IS + 10 \times Milrinone dose ($\mu\text{g}/\text{kg}/\text{min}$) 0.125-0.75

0.02-0.04 + 10,000 \times Vasopressin dose (units/kg/min)

0.05-0.4 + 100 \times Norepinephrine dose ($\mu\text{g}/\text{kg}/\text{min}$)

preCS
Hypoperfusion and SBP > 90 mm Hg without circulatory support

CS
Hypoperfusion and SBP < 90 for > 30 min or the need for pharmacologic or IABP to maintain SBP > 90 mm Hg or MAP with 30 mm Hg lower than baseline.

Refractory CS
Ongoing evidence of tissue hypoperfusion despite administration of adequate doses of 2 vasoactive medications and treatment of the underlying etiology

A-At risk
At risk of CS; SBP=N; CI>2.5; Lactate=N
No hypoperfusion

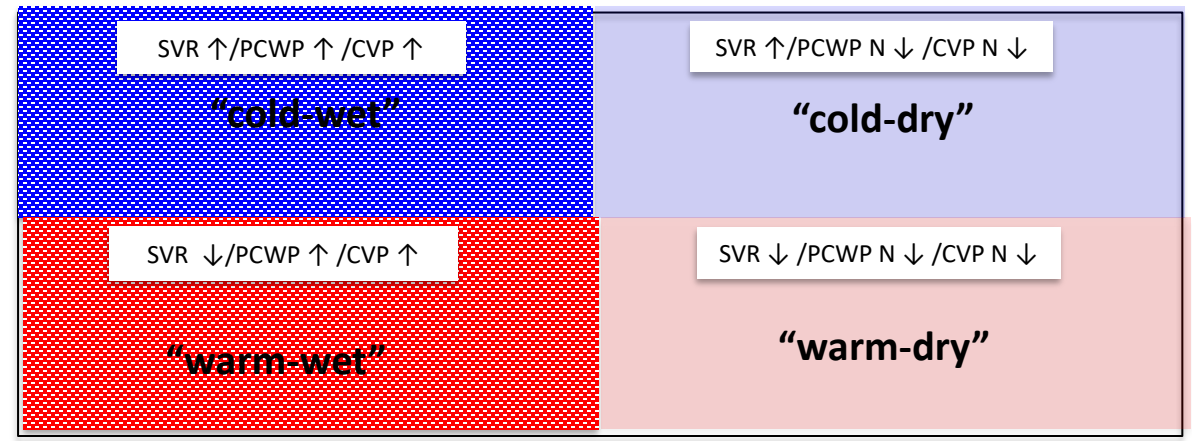
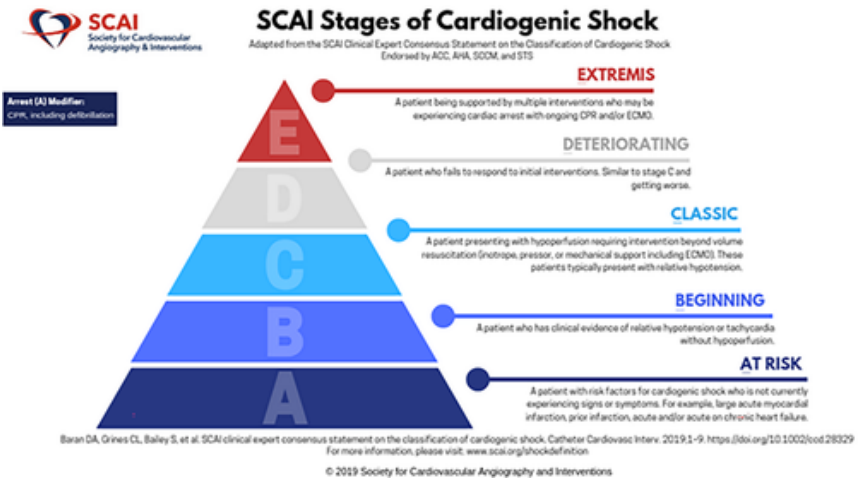
B-Beginning
Relative hypotension or tachycardia without hypoperfusion; CI<2.2, PA sat ≥65%. Lactate<2mmol/l

C-Classic
Hypoperfusion that requires an initial set of Interventions (inotropes, pressors, MCS, or ECMO) beyond volume resuscitation to restore perfusion; CI<2.2, PA sat <65%. Lactate>2mmol/l

D-Deteriorating
Failed to stabilize despite intense initial efforts. After >30 minutes the patient has not responded with resolution of hypotension or end-organ hypoperfusion. Further escalation (increase in the number or intensity of IV therapies to address hypoperfusion, or addition of MCS) is required; Lactate>5mmol/l

E-Extremis
refractory cardiac arrest with ongoing CPR or are being supported by multiple acute interventions including ECMO-facilitated CPR

Society for cardiovascular angiography and interventions



CS: Management when to consider escalation?



- Inotropic score >20 + MCS.
- Persistent elevated LVEDP, pulmonary congestion, metabolic decompensation, & end-organ damage + MCS
- Repeated complete clinical, haemodynamic, and echocardiographic evaluations
- Prompt MCS escalation should be considered when criteria are matched.
- Early use of appropriate MCS correlates with better clinical outcomes.

CS: Management escalation

- Stage 1: Transfemoral IABP or Impella 2.5/CP
- Stage 2: Upper body surgical approach: Impella 5/5.5

CI for performing the procedure:

- a vessel artery diameter <6 mm
- the presence of heavy calcifications
- obstruction or dissection
- pre-existing upper extremity ischaemia
- previous arterial axillary open cannulations
- Infraclavicular infections
- Arteriovenous fistulae for dialysis
- A patent internal mammary artery graft.

The right axillary artery is preferred

CS: Management escalation due to RV failure

- Primary Biventricular dysfunction
- LV with concomitant RV failure development
- Definition of RV failure:
 - CVP (RAP) > 16 mmHg
 - Reduced TAPSE
 - Invasive low pulmonary artery pulsatility index (PAPi) < 1.85 $[(sPA-dPA)/RA]$
 - High RAP/pulmonary capillary wedge pressure ratio > 0.59.

Common DD of RV failure must be ruled out:

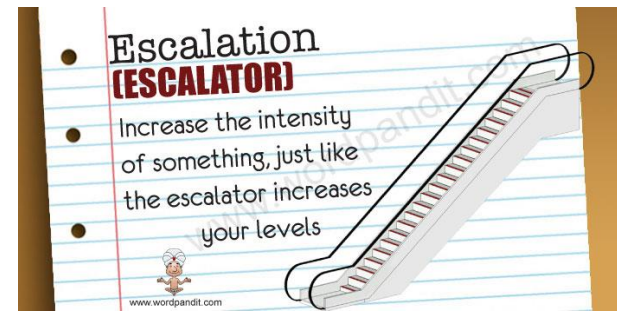
- pulmonary complications
 - pneumothorax, pleural effusion, atelectasis.
 - PE.
- Non-pulmonary complications
 - RV outflow tamponade.
 - persistence of metabolic decompensation.

CS: Management

escalation due to 1^{ary} vs 2^{ary} RV failure

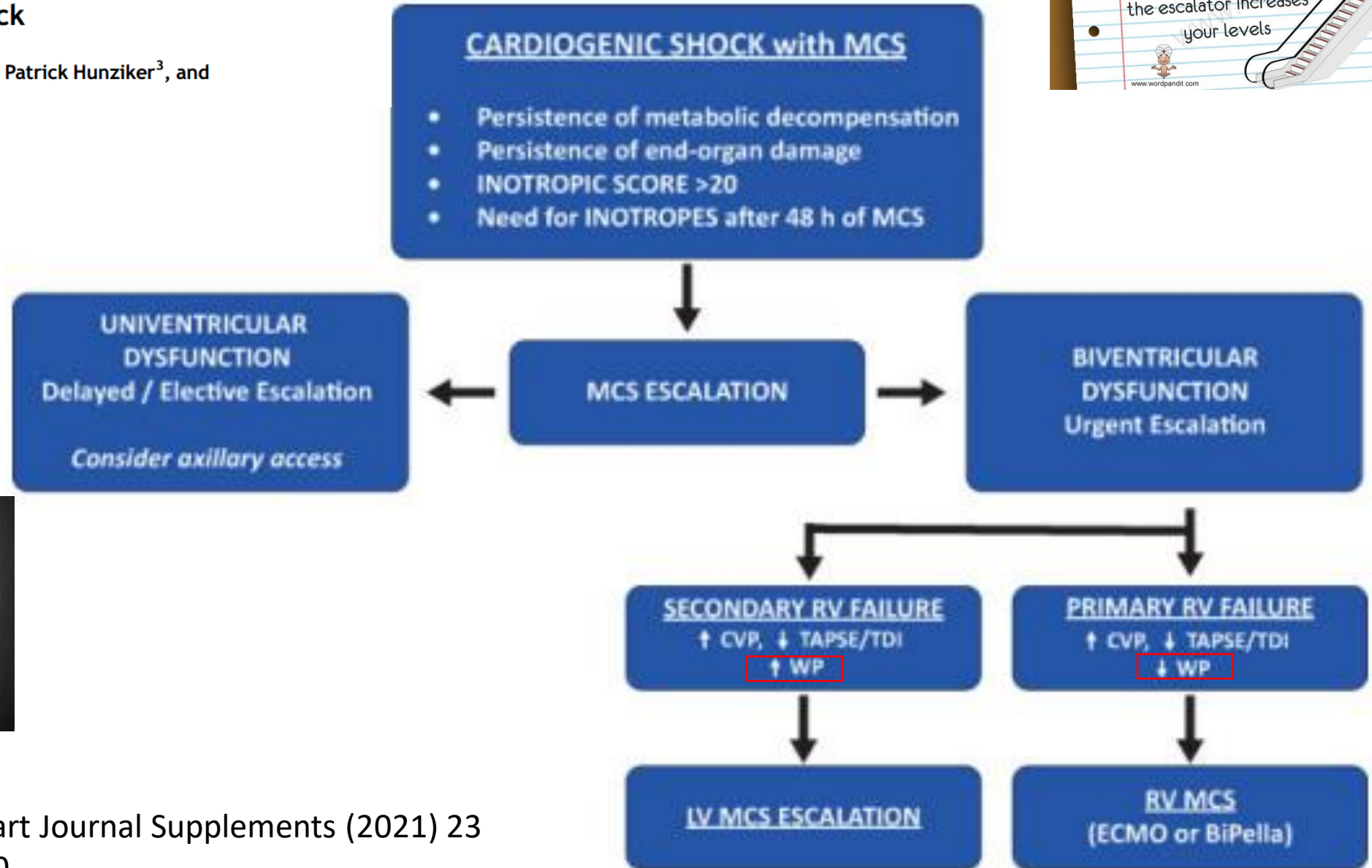
- 1^{ary} RV failure: normal LV pressures: escalation with RV MCS
- The biventricular MCS strategies:
 - VA-ECMO support.
 - Addition of an RV assist device with ProtekDuo cannula.
 - BiPELLA support: LV Impella (CP/5.0/5.5) and RV Impella (RP).
- When upgrading with VA-ECMO, concomitant LV unloading with a transaortic pump (ECpella strategy) is strongly recommended.
- 2^{ary} RV failure: improve/escalate LV support

MCS escalating



Escalation and de-escalation of mechanical circulatory support in cardiogenic shock

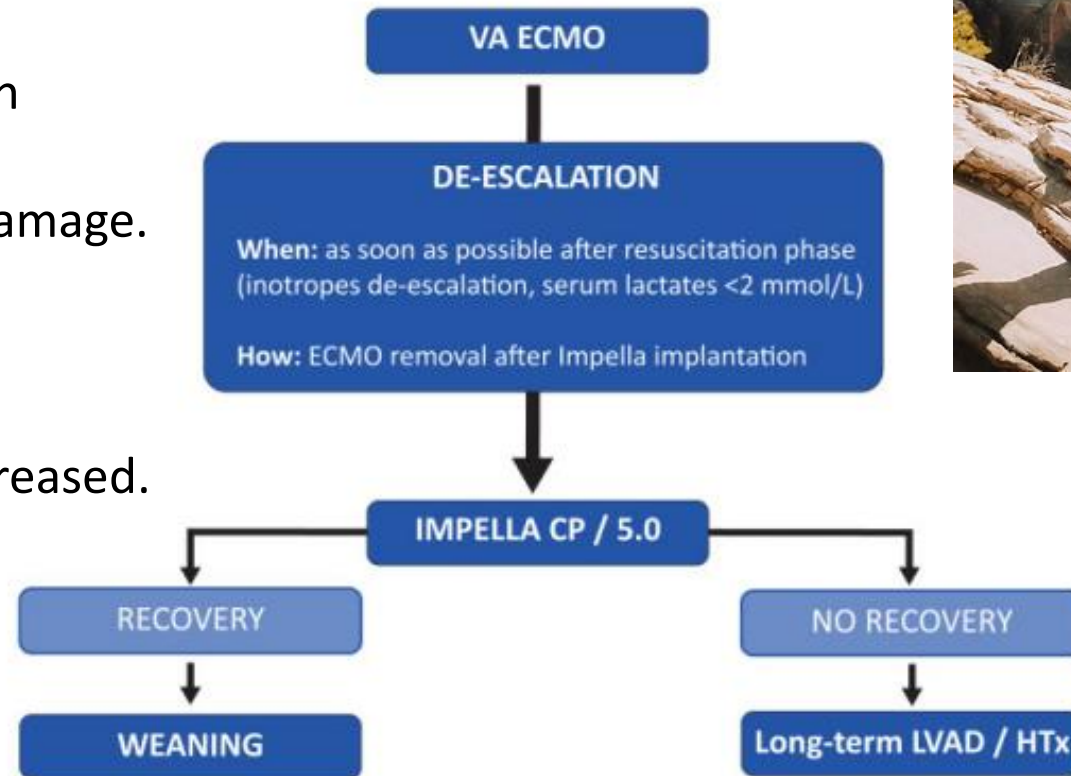
Letizia F. Bertoldi^{1*}, Clement Delmas², Patrick Hunziker³, and Federico Pappalardo⁴



tMCS di-escalating



1. Haemodynamic and metabolic stabilization
2. Reduction in serum lactate & end-organ damage.
3. Implant Impella 5.0 at maximum flow.
4. In hours, VA-ECMO flow progressively decreased.
5. Invasive haemodynamic monitoring

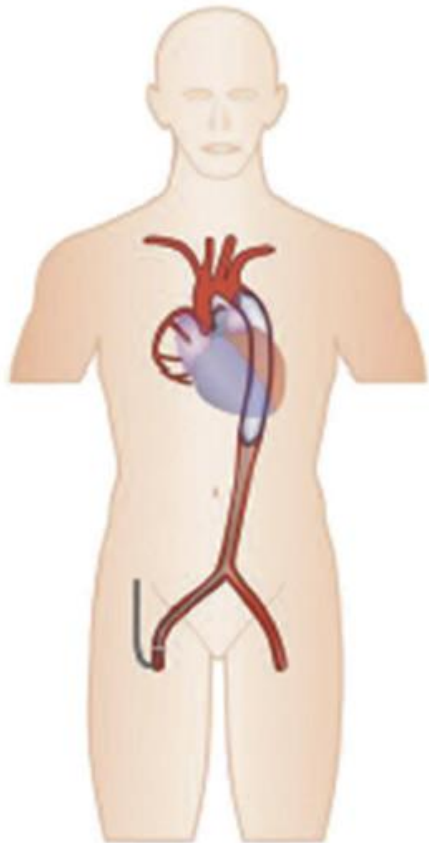


Echo parameters must drive ECMO de-escalation and appropriate ECMO removal timing

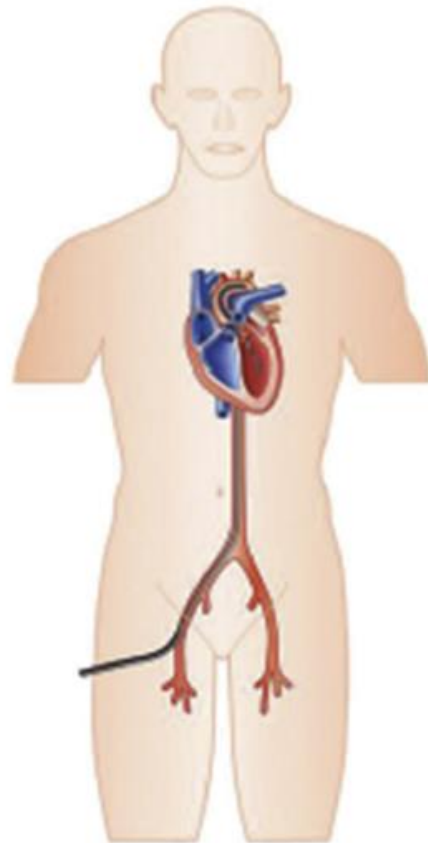
Temporary MCS: tMCS

Percutaneous mechanical support

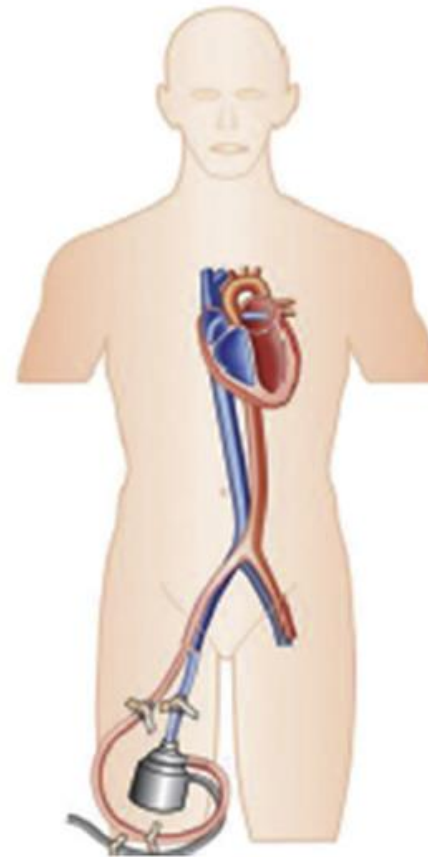
A IABP



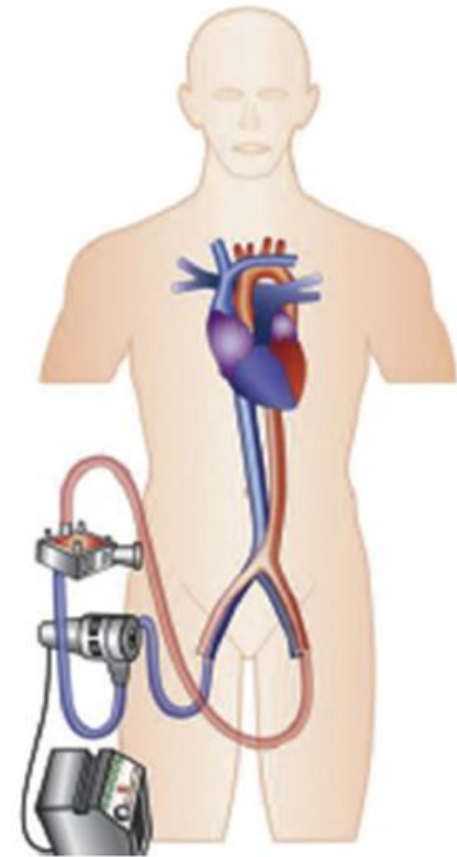
B Impella



C TandemHeart

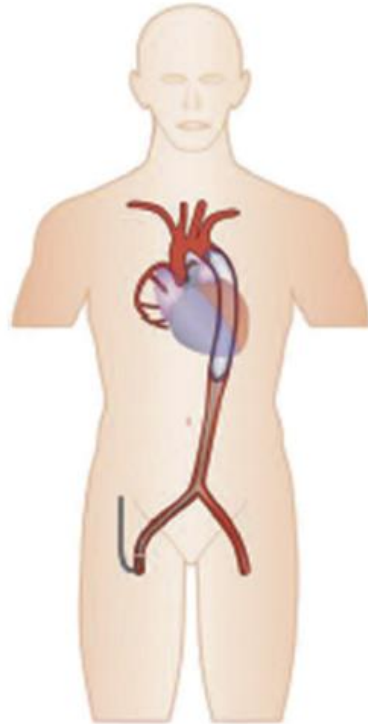


D ECMO



Percutaneous mechanical support

A IABP



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Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

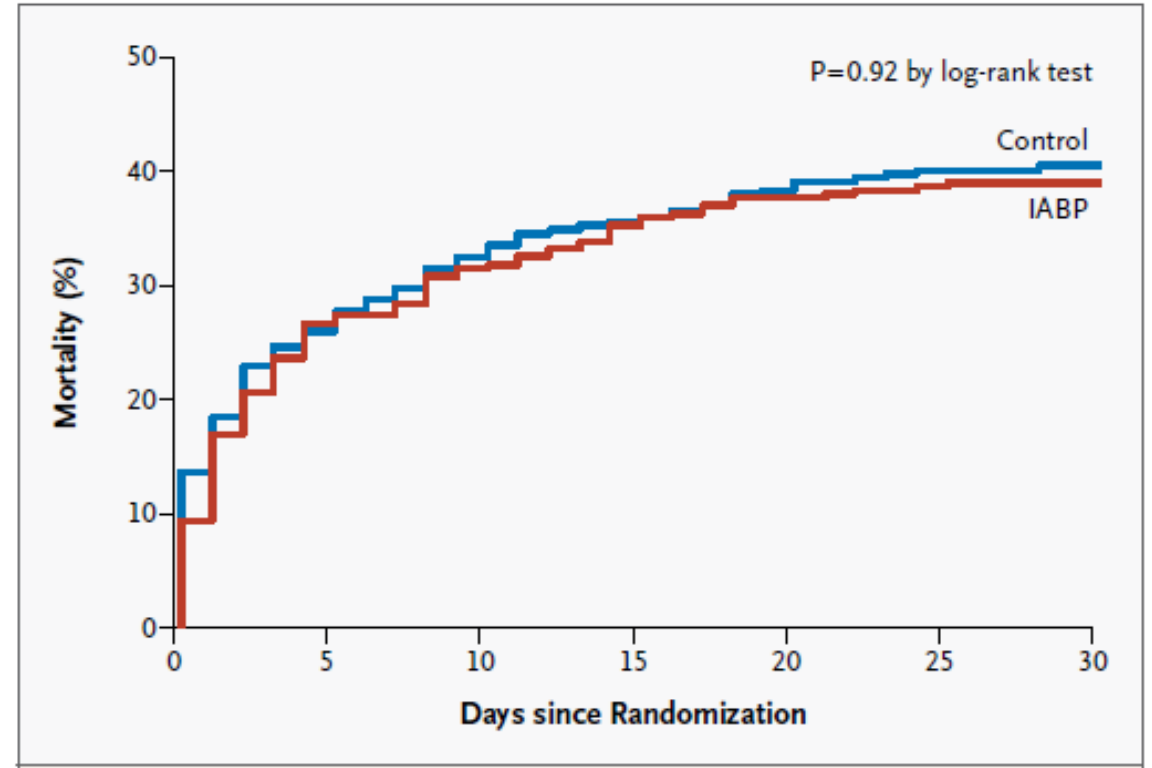
Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Miroslaw Ferenc, M.D., Hans-Georg Olbrich, M.D., Jörg Hausleiter, M.D., Gert Richardt, M.D., Marcus Hennersdorf, M.D., Klaus Empen, M.D., Georg Fuernau, M.D., Steffen Desch, M.D., Ingo Eitel, M.D., Rainer Hambrecht, M.D., Jörg Fuhrmann, M.D., Michael Böhm, M.D., Henning Ebel, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D.,
for the IABP-SHOCK II Trial Investigators*

Tewelde SZ, Liu SS, Winters ME. Cardiogenic Shock. *Cardiol Clin.* 2018 Feb;36(1):53-61.

IABP-SHOCK II

Table 3. Clinical Outcomes.

Outcome	IABP (N=300)	Control (N=298)	P Value	Relative Risk with IABP (95% CI)
	number (percent)			
Primary end point: all-cause mortality at 30 days	119 (39.7)	123 (41.3)	0.69	0.96 (0.79–1.17)
Reinfarction in hospital	9 (3.0)	4 (1.3)	0.16	2.24 (0.70–7.18)
Stent thrombosis in hospital	4 (1.3)	3 (1.0)	0.71	1.32 (0.30–5.87)
Stroke in hospital	2 (0.7)	5 (1.7)	0.28	0.40 (0.08–2.03)
Ischemic	2 (0.7)	4 (1.3)	0.45	0.49 (0.09–2.71)
Hemorrhagic	0	1 (0.3)	0.50	—
Peripheral ischemic complications requiring intervention in hospital	13 (4.3)	10 (3.4)	0.53	1.29 (0.58–2.90)
Bleeding in hospital*				
Life-threatening or severe	10 (3.3)	13 (4.4)	0.51	0.76 (0.34–1.72)
Moderate	52 (17.3)	49 (16.4)	0.77	1.05 (0.74–1.50)
Sepsis in hospital	47 (15.7)	61 (20.5)	0.15	0.77 (0.54–1.08)



CS –AMI: 50% mortality D/T

1. Hemodynamic deterioration
2. Multiorgan dysfunction syndrome
3. systemic inflammatory response syndrome.

IABP: used in 25%-40%

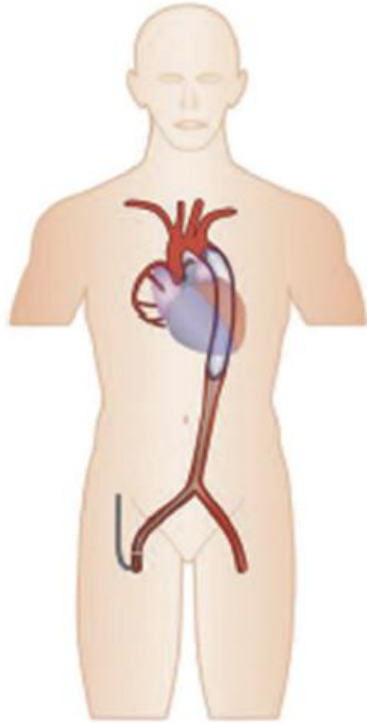
Tissue perfusion ↑

LV afterload ↓

Myoc. O₂ supply ↑

IABP in CS post AMI

A IABP



The recent studies affected clinical practice:

- Decline in IABP use
- Increase use of Impella, Tandem-Heart, and VA-ECMO

The 2017 ESC STEMI GL:

- Routine use of the IABP in CS III B
- Consider IABP only in Post AMI & mechanical complications. IIa

IMPELLA

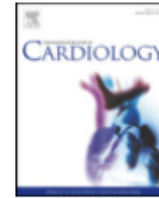
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Review

Impella ventricular support in clinical practice: Collaborative viewpoint from a European expert user group



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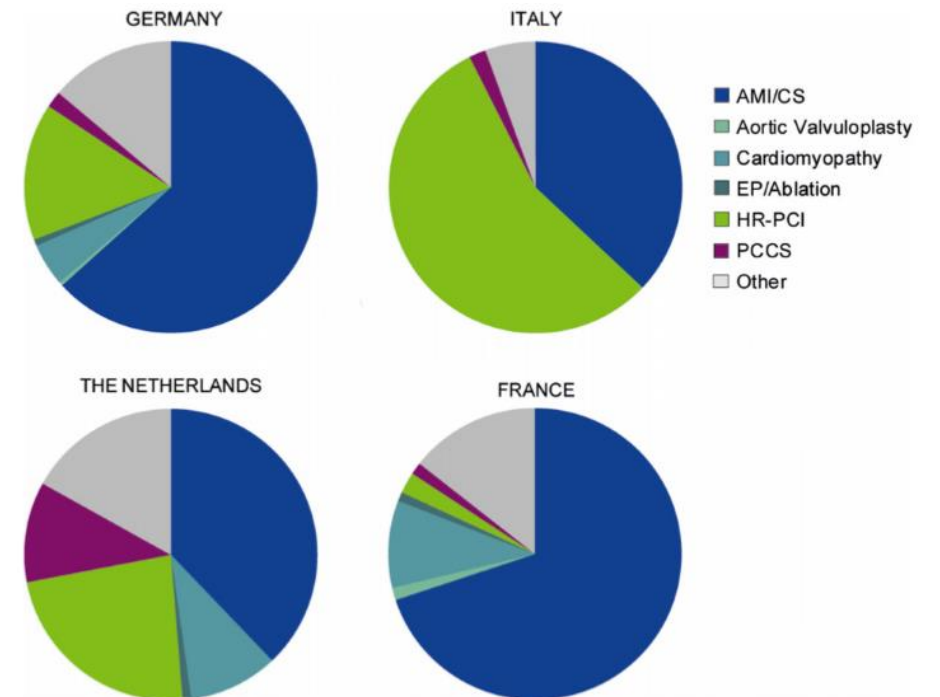
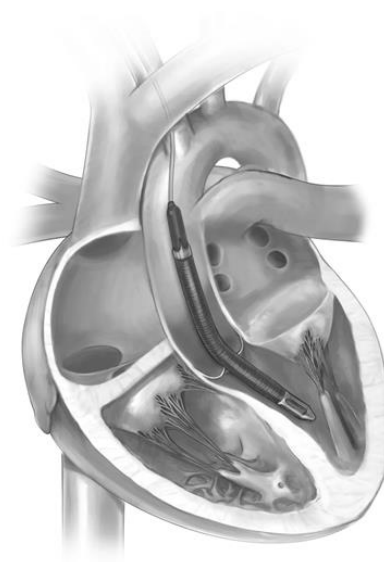
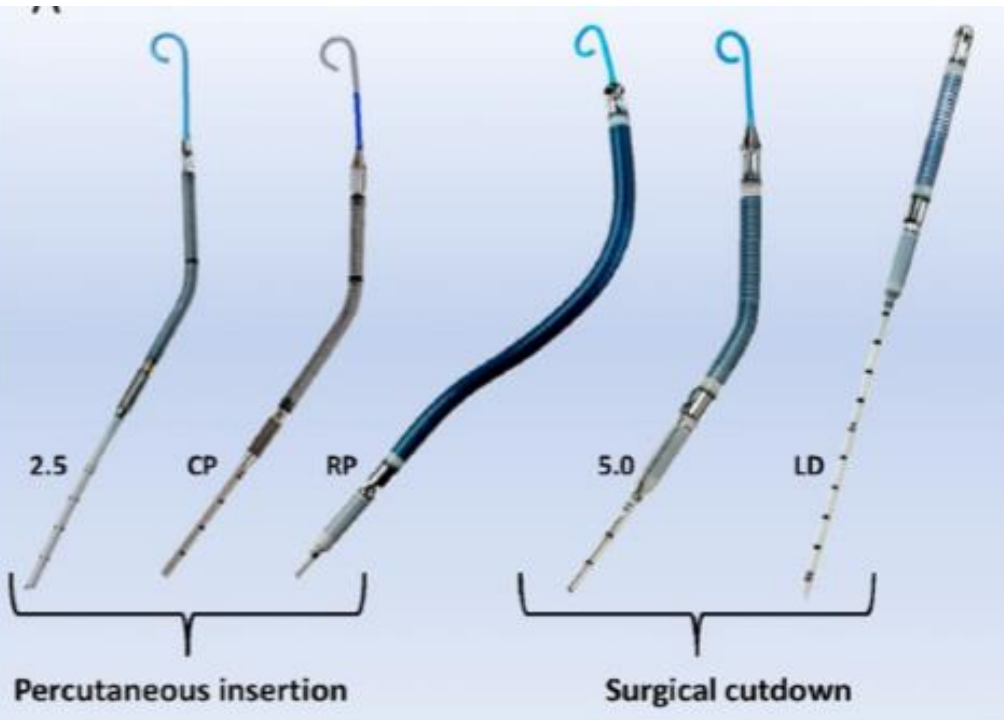


Fig. 1. Geographic distribution of Impella per indication comparing Germany, France, The Netherlands and Italy.

Percutaneous mechanical support

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Percutaneous Mechanical Circulatory Support Versus Intra-Aortic Balloon Pump in Cardiogenic Shock After Acute Myocardial Infarction



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ABSTRACT

BACKGROUND Despite advances in treatment, mortality in acute myocardial infarction (AMI) complicated by cardiogenic shock (CS) remains high. Short-term mechanical circulatory support devices acutely improve hemodynamic conditions.

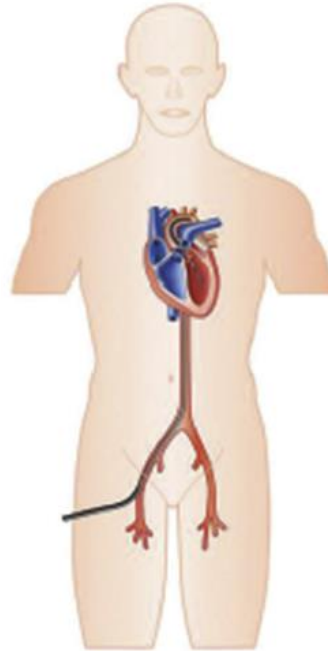
OBJECTIVES The aim of this study was to determine whether a new percutaneous mechanical circulatory support (pMCS) device (Impella CP, Abiomed, Danvers, Massachusetts) decreases 30-day mortality when compared with an intra-aortic balloon pump (IABP) in patients with severe shock complicating AMI.

METHODS In a randomized, prospective, open-label, multicenter trial, 48 patients with severe CS complicating AMI were assigned to pMCS (n = 24) or IABP (n = 24). Severe CS was defined as systolic blood pressure <90 mm Hg or the need for inotropic or vasoactive medication and the requirement for mechanical ventilation. The primary endpoint was 30-day all-cause mortality.

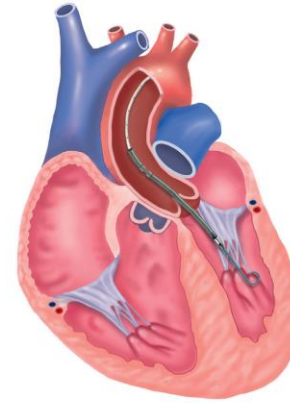
RESULTS At 30 days, mortality in patients treated with either IABP or pMCS was similar (50% and 46%, respectively; hazard ratio with pMCS: 0.96; 95% confidence interval: 0.42 to 2.18; p = 0.92). At 6 months, mortality rates for both pMCS and IABP were 50% (hazard ratio: 1.04; 95% confidence interval: 0.47 to 2.32; p = 0.923).

CONCLUSIONS In this explorative randomized controlled trial involving mechanically ventilated patients with CS after AMI, routine treatment with pMCS was not associated with reduced 30-day mortality compared with IABP. (IMPRESS in Severe Shock; NTR3450) (J Am Coll Cardiol 2017;69:278-87) © 2017 by the American College of Cardiology Foundation.

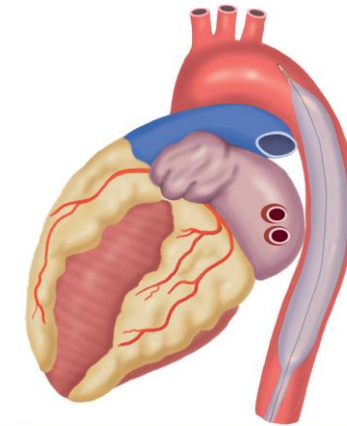
B Impella



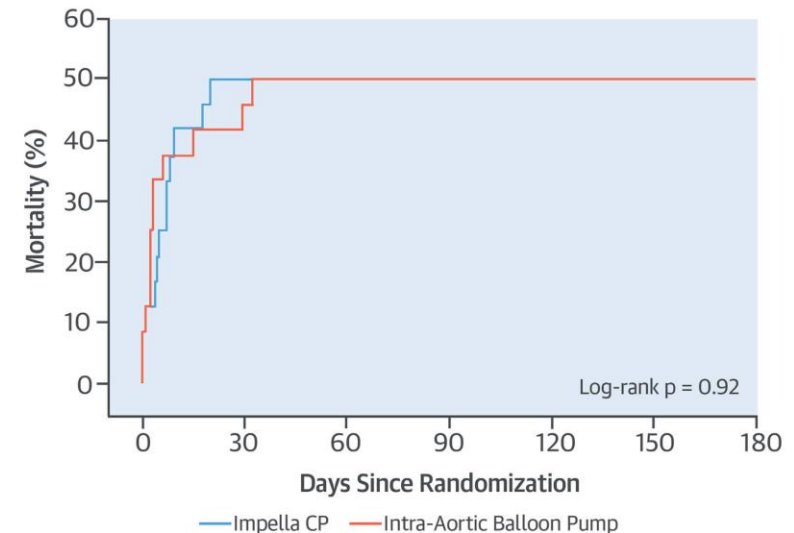
A. Impella CP



B. Intra-Aortic Balloon Pump



C. All-cause Mortality, ≤6 Months



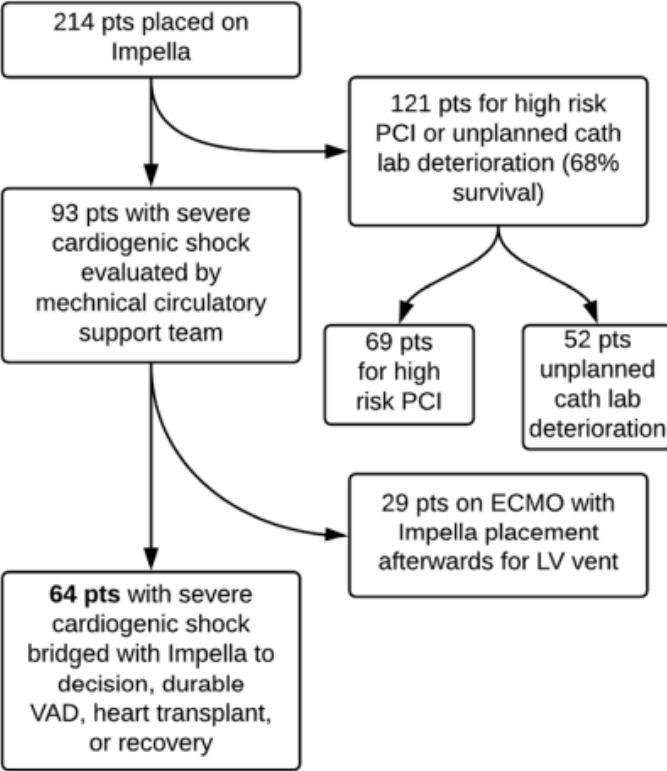
Impella CP

Pre PCI in STEMI & CS??
 < 6 days
 Expensive

Clinical Outcomes of Impella Microaxial Devices Used to Salvage Cardiogenic Shock as a Bridge to Durable Circulatory Support or Cardiac Transplantation

Impella 2.5, one pt.
Impella CP, 43 pts.
Impella 5.0, 36 pts.

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JON A. KOBASHIGAWA,* JAIME D. MORIGUCHI,* AND FRANCISCO A. ARABIA‡



INTERMACS 1 “crashing & burning” 48.4%

INTERMACS 2 “sliding on inotropes” 51.6%

Escalating:

- Impella CP to Impella 5.0
- Add or replace with an ECMO circuit
 - Impella left as a LV vent.
- To durable VAD

Mean clinical follow-up was 232.6±328.3 days.

Survival to next therapy occurred in 68.8%

30 & 60 day survival: 67.2% & 65.6%

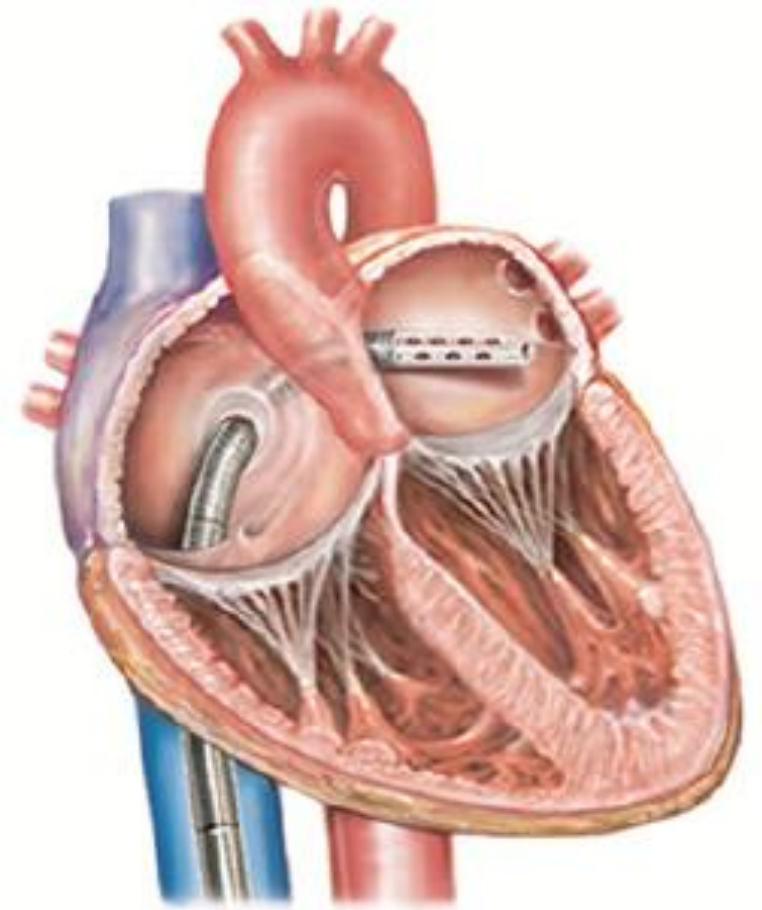
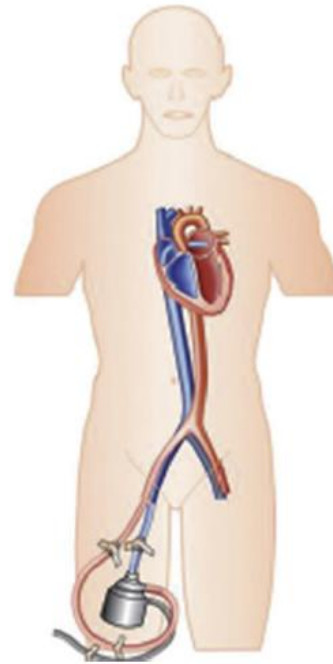
Primary etiology of CS (%)

- ADHF 61%
- Acute MI 34%

TandemHeart

- Flow: up to 4 l/m
- Trans septal approach
- Oxygenation possible
- Complications:
 - Limb ischemia
 - Bleeding
 - Hemolysis

C TandemHeart



VA-ECMO

levitronix



D ECMO

Drains venous blood from the RA + oxygenator

Pumps back: to the ascending aorta

-central cannulation.

to the iliac artery

-peripheral cannulation.

Flow: more than 7 l/m

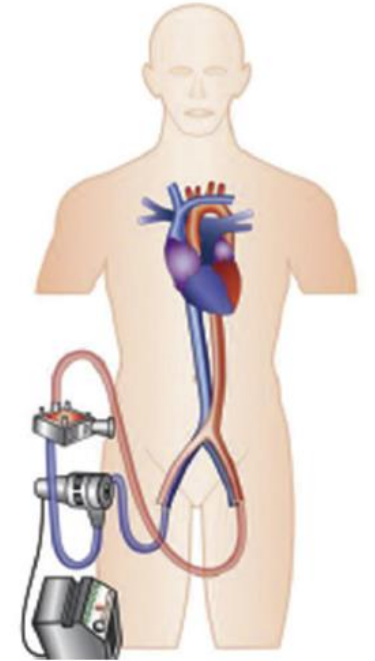
Significant increase in BP

Strongly improves end-organ perfusion.

Increases LV afterload.

Absent or low arterial pulsatility: LV is not ejecting, leading to blood stasis and thrombus formation,

Higher pulsatility indicates possible myocardial recovery.



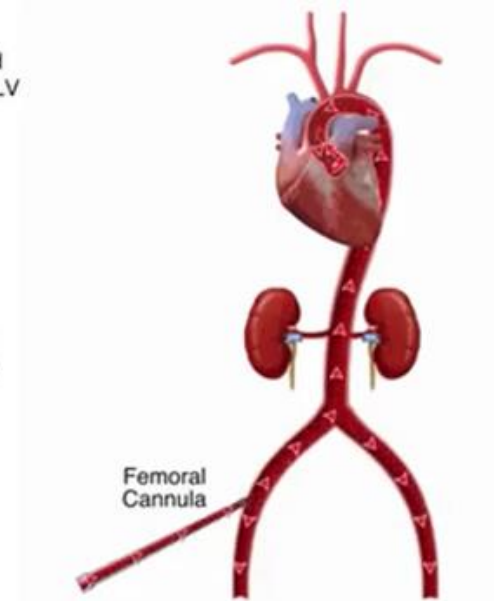
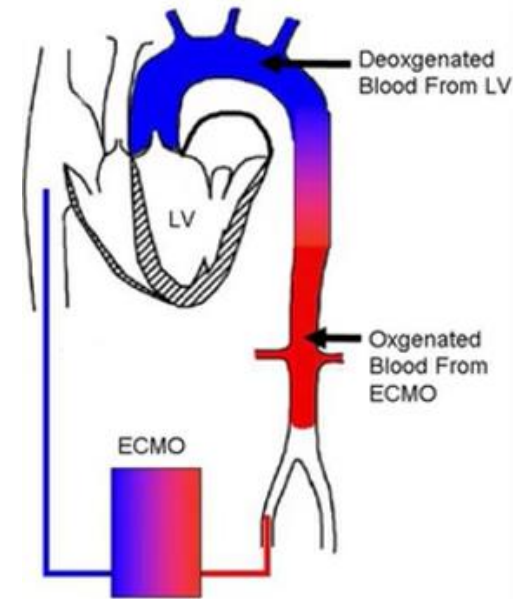
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VA-ECMO

- Rapid insertion, no need for catheterization lab, bedside...Ambulance
- Even for the cardiologist..
- Ability to cool for hypothermia Tx
- Ambulatory with RSCA and RIJ cannulations
- Main complications: Bleeding & limb ischemia
- Less expensive
- LV unloading: Combined with IABP or Impella

Atrial septostomy



- 32 studies comprising 12756 pats: 62% of patients died in the hospital
- Harlequin syndrome

Tissue perfusion ↑ RV preload ↓ LV afterload ↑ LVP ↑ Myoc. O2 demand ↓ Myoc. O2 supply ↑

tMCS: Characteristics

	IABP	Impella 2.5/CP	Impella 5	TandemHeart	ECMO
Hemodynamics	LV press or Volume unloading	LV press or Volume unloading	LV press or Volume unloading	Volume unloading	Biv press & volume unloading
TPR	Decreased	Decreased	Decreased	Mild increase	High increased
Bridge to rec.	Yes	Yes	Yes	Yes	No
<i>Hem. support</i>	<i>Low (0.5-1 l/m)</i>	<i>Mod. (2.5/3.5 l/m)</i>	<i>High (4-5.5 l/m)</i>	<i>High (5 l/m)</i>	<i>High (4-8 l/m)</i>
Cannula size	7.9 fr	13 fr	22 fr	21V 15-17A fr	18-21V 15-22A fr
Impl. time	Very low	Low	Moderate	High	Moderate
Limb ischemia	Very low	Low	Low	High	High
Anticoagulation	Very low	Very low	Very low	High	High
Hemolysis	Very low	low	Low	Low	Low
Support time	5-7 days	<4 days	<6 days	<7 days	2-4 weeks

Adult Heart Allocation Criteria for Medical Urgency Status

The Organ Procurement and Transplantation Network announced that a new, six-tier adult heart allocation system will be implemented this year.

Status 1

- VA ECMO
- Non-dischargeable, surgically implanted, non-endovascular biventricular support device
- MCSD with life-threatening ventricular arrhythmia

Status 2

- Non-dischargeable, surgically implanted, non-endovascular LVAD
- IABP
- V-tach / V-fib, mechanical support not required
- MCSD with device malfunction/mechanical failure
- TAH, BiVAD, RVAD, or VAD for single ventricle patients
- Percutaneous endovascular MCSD

Status 3

- Dischargeable LVAD for discretionary 30 days
- Multiple inotropes or single high-dose inotrope with continuous hemodynamic monitoring
- VA ECMO after 7 days; percutaneous endovascular circulatory support device or IABP after 14 days
- Non-dischargeable, surgically implanted, non-endovascular LVAD after 14 days
- MCSD with one of the following: device infection, hemolysis, pump thrombosis, right heart failure, mucosal bleeding, aortic insufficiency

Status 4

- Dischargeable LVAD without discretionary 30 days
- Inotropes without hemodynamic monitoring
- Retransplant
- Diagnosis of one of the following: congenital heart disease (CHD), ischemic heart disease with intractable angina, hypertrophic cardiomyopathy, restrictive cardiomyopathy, amyloidosis

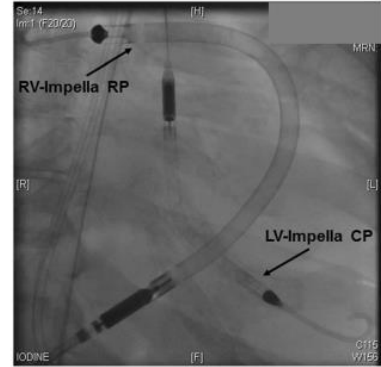
Status 5

- On the waitlist for at least one other organ at the same hospital

Status 6

- All remaining active candidates

Impella-based strategy to CS due to fulminant myocarditis



- ECMELLA: ECMO+Impella
 - BI-PELLA: LV Impella + RV Impella RP.
 - PROPELLA: prolonged Impella support (weeks)
 - Unloading strategy provides the required circulatory support but also provides additional disease-modifying effects important for myocardial recovery (bridge-to-recovery).
 - Escalating & Di-escalating
- (1) Ease of access
 - (2) Nonsurgical percutaneous insertion
 - (3) Rapid deployment
 - (4) Potent biventricular support
 - (5) Stepwise weaning of uni- or biventricular support
 - (6) Can be used as a bridge to a durable LVAD if needed



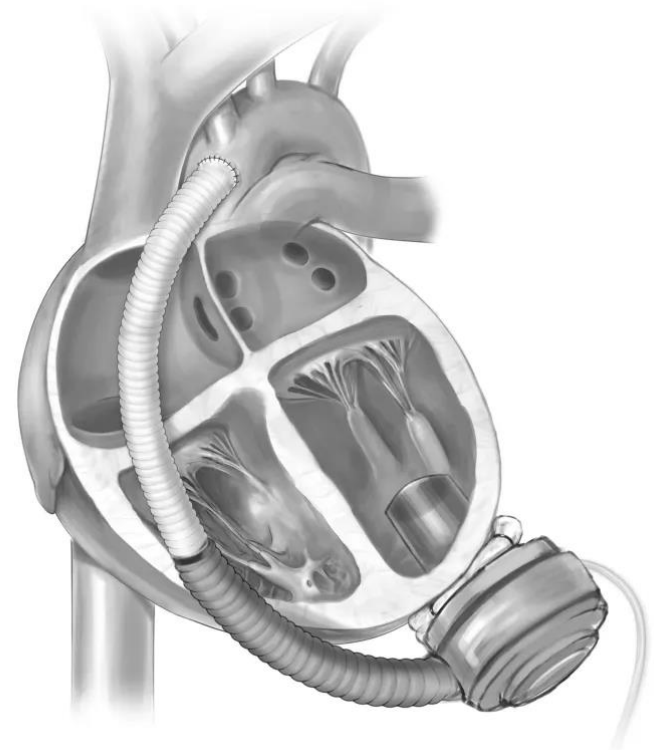
Weaning Under Temporary Mechanical Circulatory Support with Impella

- Stage 1: baseline RV and LV function are measured by echo on full LV-Impella support.
- Stage 2: Impella RPMs (flow) is decreased in single steps (e.g., P8 to P7...) with the goal of achieving half of the original RPMs with maintenance of adequate hemodynamics.
- At every flow level, RV and LV function and hemodynamic responses are monitored over 5–10 minutes.
- If, at any period in the weaning protocol, RV or LV distension occurs or significant hypotension or increase in heart rate is observed, the weaning protocol is stopped and Impella support is returned to full flow.

Weaning Under Temporary Mechanical Circulatory Support with Impella

- Stage 3: If stage 2 was successful, Impella support will continue to be reduced by one step for 24 h and then reevaluated like described under stage 2.
- Stage 4: If stable RV and LV function, hemodynamics and volume status are maintained for 48 h on P2 Impella support, inotrope stress test with dobutamine will be performed in which RV and LV functions and hemodynamics are observed for responses over 30 min.
- If both, RV and LV function are recovered, the patient will be considered for Impella removal.
- This procedure is not performed in patients who spontaneously increase their LV function during pump reduction flow, as is often detectable in myocarditis patients with recovery.
- Time for explanations approximately 4 weeks

Durable MCS: dMCS



LVAD Vest



Studies on Cardiac Functional and Structural Improvement during Chronic LVAD Support.

Group, Year	No. of Patients	HF Etiology	Standardized Pharmacologic Therapy	Heart Function Monitoring Protocol	LVAD Support Duration (months)	Cardiac Recovery *	Freedom from LVAD Reimplantation or HTx, Follow-Up Duration
Pittsburgh, 2003 [37]	18	NICM: 72% ICM: 28%	No	Yes	8	NICM: 38% ICM: 20%	67%, 16.5 months
Texas Heart Institute, 2003 [38]	16	NICM: 75% ICM: 25%	Yes	Yes	8	NICM: 58% ICM: 50%	78%, 14.3 months
Gothenburg, 2006 [40]	18	NICM: 83% ICM: 17%	No	Yes	7	NICM: 17% ICM: 0%	33%, 8 years
Harefield, 2006 [6]	15	NICM: 100%	Yes	Yes	11	NICM: 73%	100% and 89%, 1 and 4 years, respectively
U.S. LVAD Working Group, 2007 [30]	67	NICM: 55% ICM: 45%	No	Yes	4.5	NICM: 13.5% ICM: 3.3%	100%, 6 months
University of Athens, 2007 [22]	8	NICM: 100%	Yes	Yes	7	NICM: 50%	100%, 2 years
Berlin, 2008 and 2010 [7,27]	188	NICM: 100%	No	Yes	4	NICM: 19%	74% and 66%, 3 and 5 years, respectively
Vancouver, 2011 [39]	17	Not reported	No	Yes	7	NICM and ICM: 23%	100%, 2 years
Harefield, 2011 [5]	20	NICM: 100%	Yes	Yes	9	NICM: 60%	83%, 3 years
U.S. IMAC, 2012 [36]	14	NICM: 100%	No	Yes	3.5	NICM: 67%	87.5%, 17.5 months
Montefiore, 2013 [23]	21	NICM: 62% ICM: 38%	Yes	Yes	9	NICM: 23% ICM: 0%	100%, 57 months
Utah Cardiac Recovery Program, 2016 [31]	154	NICM: 60% ICM: 40%	No	Yes	6	NICM: 21% ICM: 5%	N/A
RESTAGE-HF Multicenter Trial, 2020 [4]	40	NICM: 100%	Yes	Yes	13	NICM: 48%	90% and 77%, 1 and 3 years, respectively

LVAD Bridge to recovery

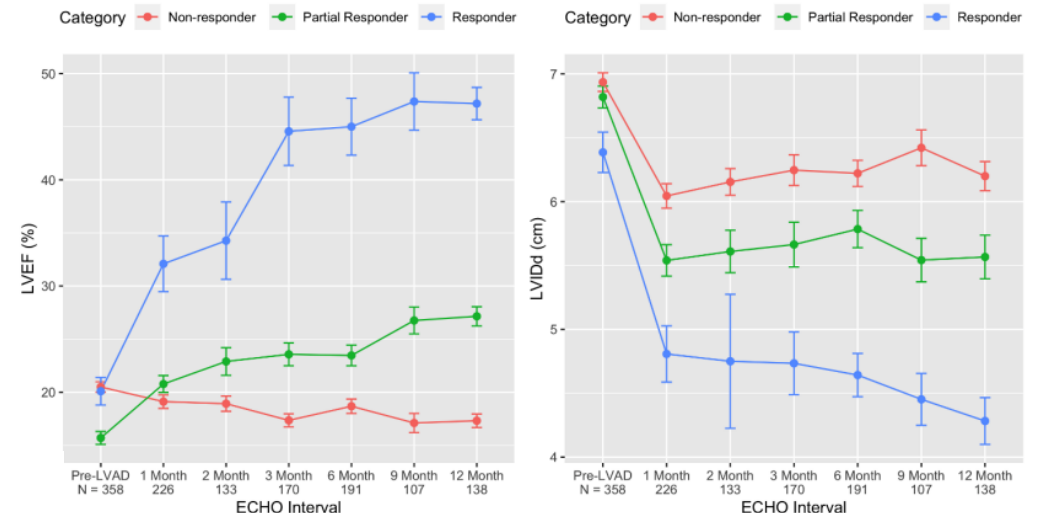
Ventricular Assist Device Weaning Assessment Protocols

Stage 1—Screening phase: serial cardiac structural and functional evaluation (suggested duration 6–12 months)

- Serial echocardiography
 - Monthly or bimonthly
 - Full LVAD support and minimal LVAD support for 15–30 min
- Patients revealing favorable findings (e.g., LVEF > 40–45% and LVEDD < 60 mm) proceed to Stage 2

Stage 2—Weaning phase

- Exercise capacity testing and hemodynamic evaluation
 - Right heart catheterization: full and minimal LVAD support for 15–30 min
 - Exercise capacity and myocardial reserve (6-min walk test or cardiopulmonary exercise test or dobutamine stress test): minimal LVAD support
- LVAD weaning criteria: structure, function, and hemodynamics (values at minimal LVAD support and/or peak exercise)
 - Echocardiogram
 - LVEDD < 60 mm
 - LVESD < 50 mm
 - LVEF > 45%
 - Right heart catheterization
 - PCWP < 15 mm Hg
 - CI > 2.4 L/min/m²
 - Cardiopulmonary exercise test
 - VO₂ max > 16 mL/kg/min
 - VE/VCO₂ < 40



THANK YOU FOR



YOUR ATTENTION