



Brigham and Women's Hospital

Founding Member, Mass General Brigham

Mechanical Circulatory Support Devices

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- Jefferson Medical College – Thomas Jefferson University
- Emergency Medicine Residency @Mount Sinai Hospital
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- Assistant Professor of Emergency Medicine@ HMS
 - Clinical focus: ECMO, Cardiothoracic critical care
 - Research focus: ECMO

DISCLOSURES

- Fresenius Medical Care – Speaker
- LivaNova – Speaker
- Vsee Health Inc- Stock holder



Objectives

- To provide an overview of the wide array of percutaneous mechanical circulatory support devices available to treat acute cardiogenic shock
- Understand the contraindications and complications of each mechanical circulatory support device



Cardiogenic shock

- End organ dysfunction due to inadequate cardiac output secondary to right, left, or biventricular dysfunction.

Clinical Trial/Guideline	CS Criteria
SHOCK Trial (1999) ³	<ul style="list-style-type: none"> • SBP <90 mm Hg for >30 min or vasopressor support to maintain SBP >90 mm Hg • Evidence of end-organ damage (UO <30 mL/h or cool extremities) • Hemodynamic criteria: CI <2.2 and PCWP >15 mm Hg
IABP-SOAP II (2012) ⁴	<ul style="list-style-type: none"> • MAP <70 mm Hg or SBP <100 mm Hg despite adequate fluid resuscitation (at least 1 L of crystalloids or 500 mL of colloids) • Evidence of end-organ damage (AMS, mottled skin, UO <0.5 mL/kg for 1 h, or serum lactate >2 mmol/L)
EHS-PCI (2012) ⁵	<ul style="list-style-type: none"> • SBP <90 mm Hg for 30 min or inotropes use to maintain SBP >90 mm Hg • Evidence of end-organ damage and increased filling pressures
ESC-HF Guidelines (2016) ⁶	<ul style="list-style-type: none"> • SBP <90 mm Hg with appropriate fluid resuscitation with clinical and laboratory evidence of end-organ damage • Clinical: cold extremities, oliguria, AMS, narrow pulse pressure. Laboratory: metabolic acidosis, elevated serum lactate, elevated serum creatinine
KAMIR-NIH (2018) ⁷	<ul style="list-style-type: none"> • SBP <90 mm Hg for >30 min or supportive intervention to maintain SBP >90 mm Hg • Evidence of end-organ damage (AMS, UO <30 mL/h, or cool extremities)



Classification



Etiologies

- **AMI without mechanical complications complicated by CS**
- Acute or acute-on-chronic LV or biventricular failure complicated by CS
- Peripartum cardiomyopathy
- Takotsubo/stress-induced cardiomyopathy
- Cardiac allograft failure/rejection
- Acute myocarditis
- Post-cardiotomy
- Hypertrophic cardiomyopathy with severe outflow tract obstruction
- Acute RV failure complicated by CS
- Post-LVAD implantation
- Post-transplantation
- Pulmonary embolism
- Refractory arrhythmias



Shock Team

- Multidisciplinary, collaborative team that considers issues specific to cardiogenic shock, including selection, implantation, and management of mechanical circulatory support (MCS) devices.

Standardized Team-Based Care for Cardiogenic Shock



Behnam N. Tehrani, MD,^a Alexander G. Truesdell, MD,^{a,b} Matthew W. Sherwood, MD,^a Shashank Desai, MD,^a Henry A. Tran, MD,^a Kelly C. Epps, MD,^a Ramesh Singh, MD,^a Mitchell Psotka, MD, PhD,^a Palak Shah, MD,^a Lauren B. Cooper, MD,^a Carolyn Rosner, NP,^a Anika Raja, BS,^a Scott D. Barnett, PhD,^a Patricia Saulino, RN, MPA,^a Christopher R. deFilippi, MD,^a Paul A. Gurbel, MD,^a Charles E. Murphy, MD,^a Christopher M. O'Connor, MD^a

Circulation

RESEARCH LETTER

Shock Team Approach in Refractory Cardiogenic Shock Requiring Short-Term Mechanical Circulatory Support

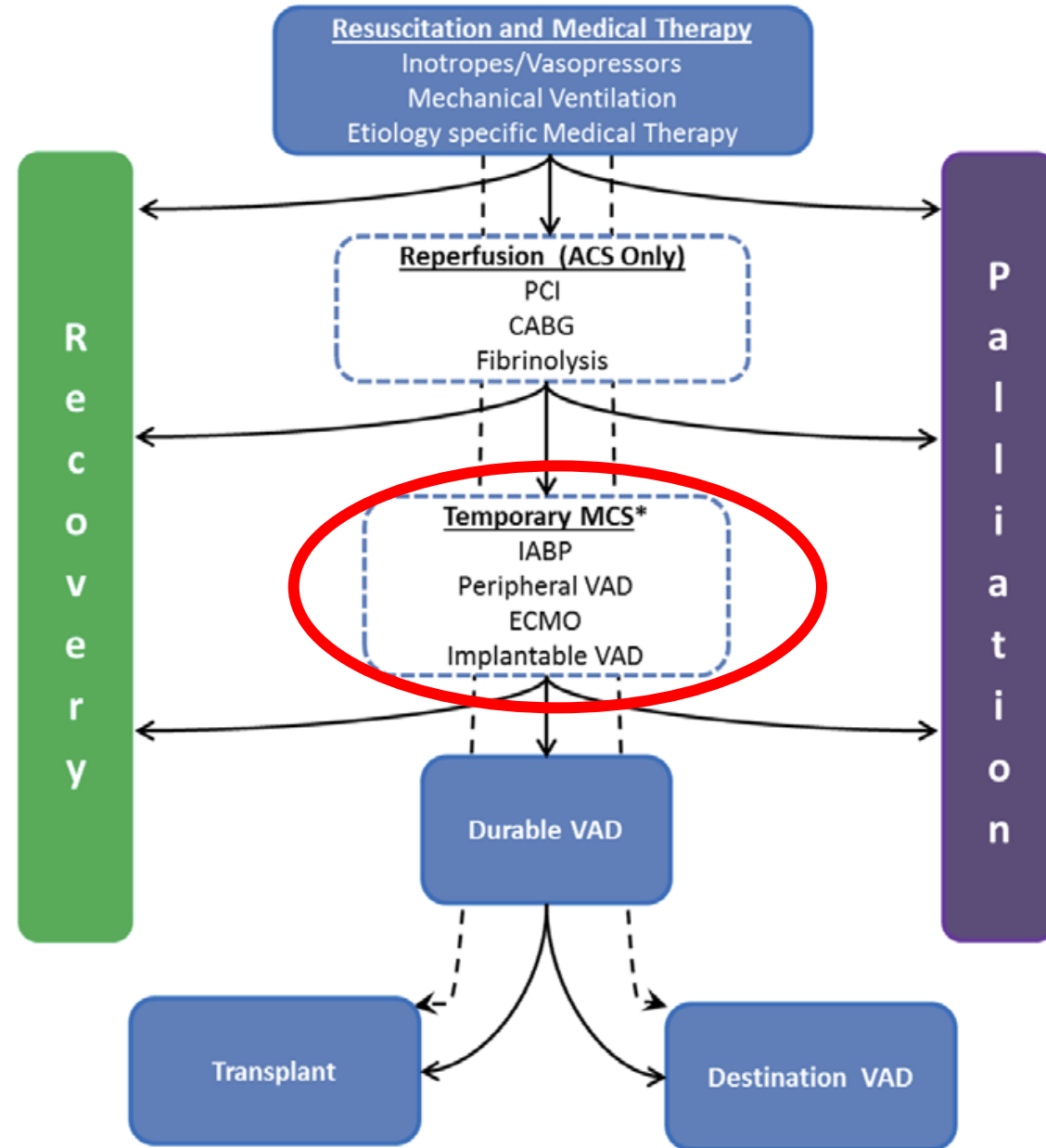




CARE LOCATION



CARDIOGENIC SHOCK MANAGEMENT PATHWAY



Temporal trends of MCS use

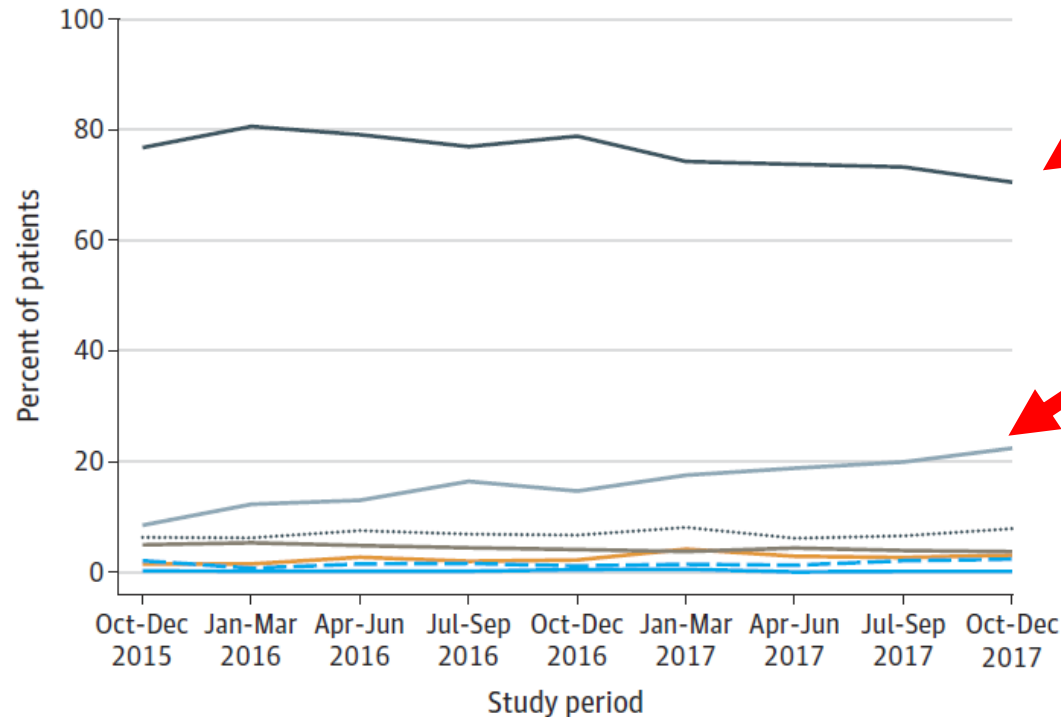
Original Investigation | Cardiology

Use of Mechanical Circulatory Support Devices Among Patients With Acute Myocardial Infarction Complicated by Cardiogenic Shock

Sanket S. Dhruva, MD, MHS; Joseph S. Ross, MD, MHS; Bobak J. Mortazavi, PhD; Nathan C. Hurley, BS; Harlan M. Krumholz, MD, SM; Jephtha P. Curtis, MD; Alyssa P. Berkowitz, MPH; Frederick A. Masoudi, MD, MSPH; John C. Messenger, MD; Craig S. Parzynski, MS; Che G. Nguifo, PhD; Saket Girotra, MD, SM; Amit P. Amin, MD, MSc; Nilay D. Shah, PhD; Nihar R. Desai, MD, MPH



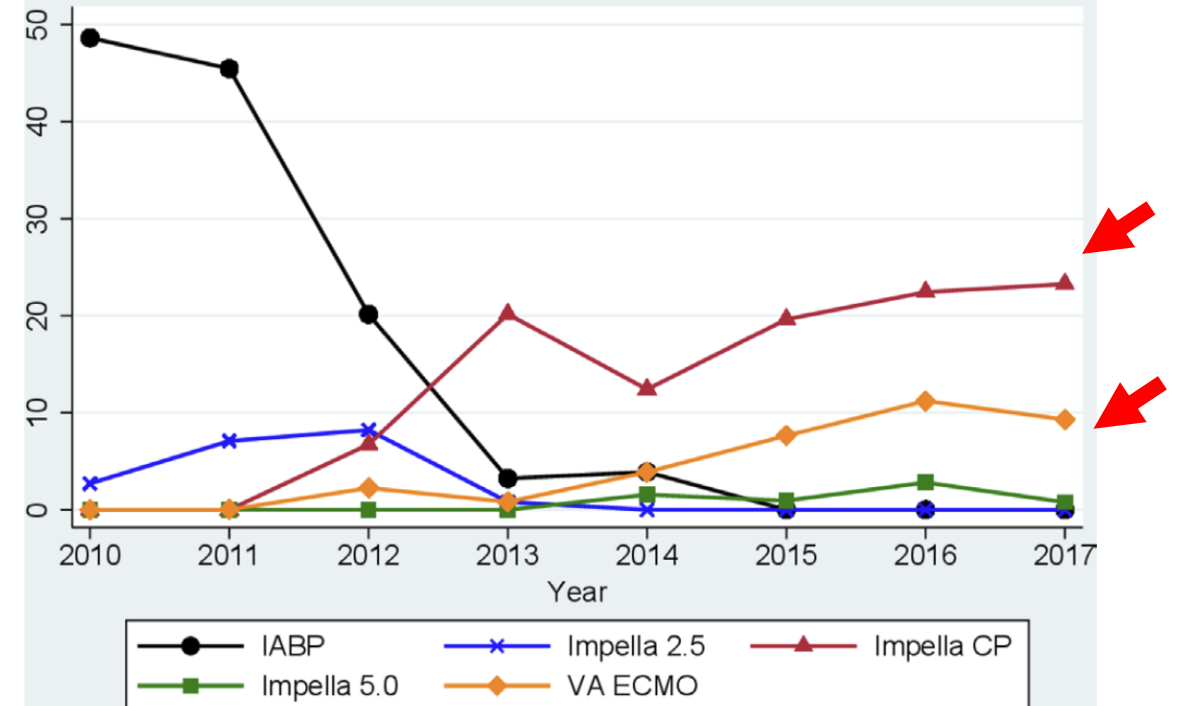
B Subset of patients who received an MCS device, with detail about specific and combinations of MCS devices



Contemporary trends in use of mechanical circulatory support in patients with acute MI and cardiogenic shock

Ole Kristian Lerche Helgestad^{1,2,3}, Jakob Josiassen⁴, Christian Hassager^{4,5}, Lisette Okkels Jensen¹, Lene Holmvang^{4,5}, Nanna Louise Junker Udesen¹, Henrik Schmidt⁶, Hanne Berg Ravn^{5,7}, Jacob Eifer Møller^{1,3}

Use of MCS in AMICS



What is the evidence?



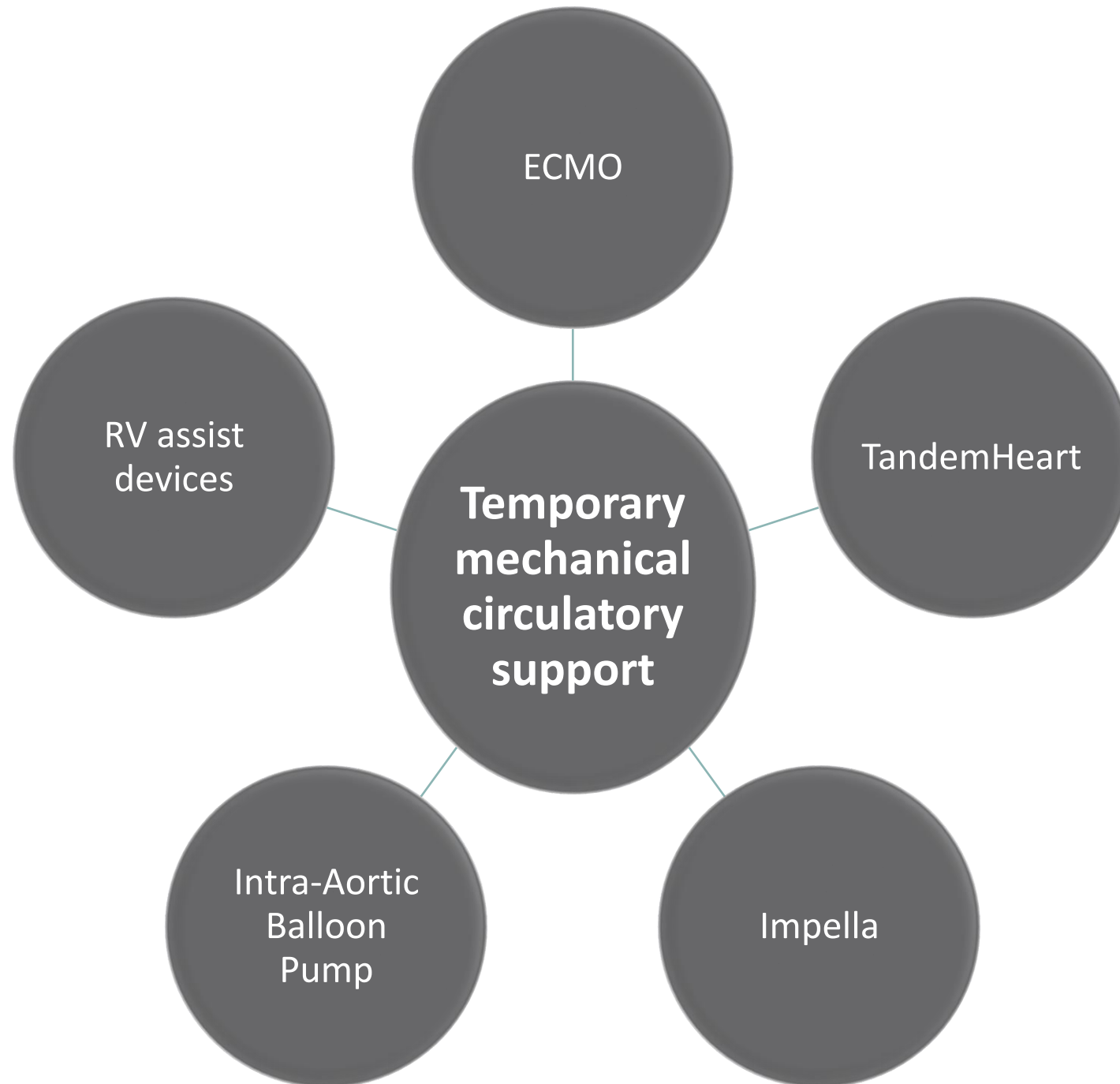
Despite widespread use of mechanical circulatory support (MCS) in cardiogenic shock, high-quality randomized controlled trials (RCTs) demonstrating a clear survival benefit remain limited



Purpose of temporary MCS

- To promote ventricular unloading as well as **restore systemic perfusion** to maintain end-organ function and patient viability
- **Bridge** patient to reach end destination
 - Recovery
 - Transplant
 - Durable VAD
 - Decision





Intra-aortic balloon pump

- Placed percutaneously via the femoral artery, balloon position in descending aorta.
- It uses counterpulsation - **inflation of balloon during diastole and active deflation of balloon in systole.**
 - Inflation causes blood to be displaced into the proximal aorta during diastole.
 - Afterload is reduced during systole through rapid balloon deflation (vacuum effect)
- Increases coronary artery blood flow
- Reduces LV afterload
- Decreases myocardial oxygen demand and increases myocardial oxygen supply
- Relatively modest increase in cardiac output



Contraindications

- Significant aortic regurgitation
- Aortic dissection
- Severe PAD
- Uncontrolled bleeding
- Septic shock

Complications

- Limb ischemia
- Major bleeding
- Other ischemia
 - Spinal cord
 - Renal
 - Mesenteric
 - Stroke



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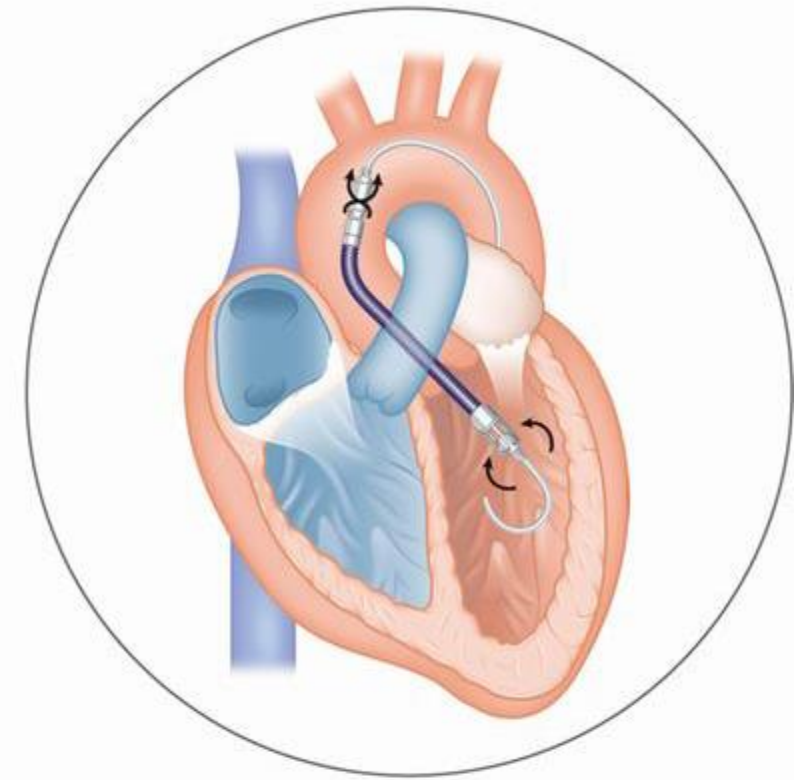
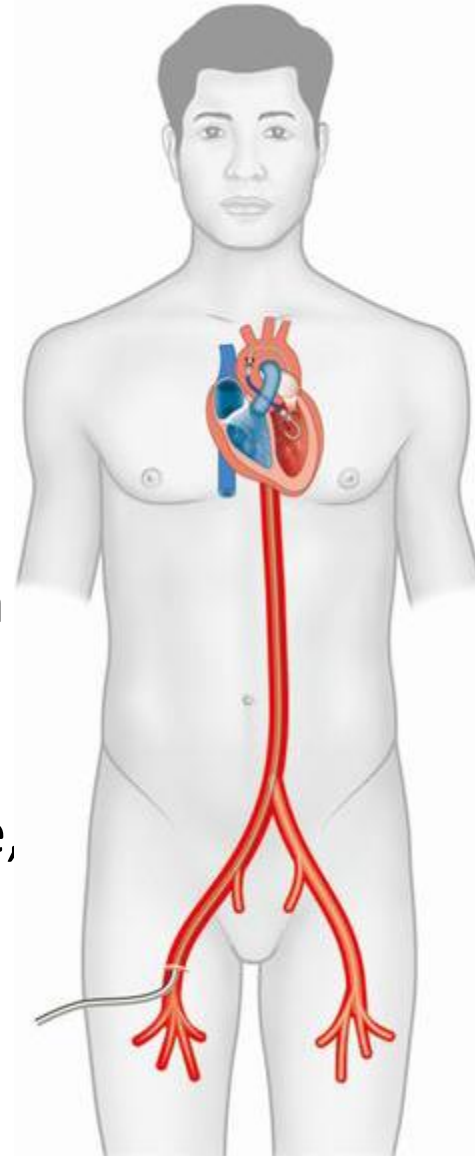
Intraaortic Balloon Support for Myocardial Infarction
with Cardiogenic Shock

- The IABP-SHOCK II
- Primary outcome: 30-day mortality
 - 39.7% in the IABP group vs. 41.3% in the optimal medical therapy group
 - Relative risk [RR], 0.96; 95% CI, 0.79–1.17; **P=0.69**
- No difference in:
 - Time to hemodynamic stabilization
 - ICU LOS
 - Adverse events (eg, bleeding, stroke, peripheral ischemic complications requiring intervention, or infection).



Impella

- Catheter based axial flow pump that is placed percutaneously via femoral artery or surgically via axillary artery.
- Inflow is positioned retrograde across aortic valve in the left ventricle.
- **The axial flow pump draws blood from left ventricle and ejects into aorta**
- Directly delivers blood to the aorta
- Decreases left ventricular size, pressure, and wall tension
- Decreases oxygen consumption



Contraindications

- LV thrombus
- Mechanical aortic valve
- Severe peripheral arterial disease
- Ventricular septal defect

Complications

- Device migration
- Device malfunction due to thrombosis
- Hemolysis
- Bleeding requiring transfusion
- Arrhythmias
- Limb ischemia
- Tamponade
- Aortic or mitral valve injury
- Stroke



Evidence

Table 4
Summary of Major Impella Studies

	MACH II ⁴⁵	ISAR-SHOCK ⁴⁷	PROTECT II ⁴⁹	IMPRESS ⁴⁸	DanGer Shock ⁵⁰
Enrollment period	December 2005 to June 2006	September 2004 to January 2007	November 2007 to December 2010	May 2012 to September 2015	January 2013 to July 2023
Enrolled patients	20	25	452	48	355
Study population	First anterior STEMI within 6 h of symptom onset with primary PCI revascularization	CS complicating AMI, revascularization by PCI	Symptomatic 3-vessel CAD (or unprotected left main CAD) with severely reduced LVEF, revascularization by PCI	CS complicating AMI, revascularization by PCI	CS complicating AMI, revascularization by PCI or CABG
Main exclusion criteria	Presence of LV thrombus, presence of CS	Age <18; presence of LV thrombus, severe valvular disease, or mechanical heart valve; Resuscitation >30 min; hypertrophic obstructive cardiomyopathy; CS from AMI-related mechanical complications (ie, MR, ruptured ventricle); RV failure; cerebral disease; pulmonary embolism; sepsis; known coagulopathy; severe aortic regurgitation; bleeding requiring surgical intervention; pregnancy	Recent MI, presence of LV thrombus, platelets $\leq 75,000$; creatinine ≥ 4 mg/dL, severe peripheral vascular disease	Severe peripheral arterial disease, severe aortic valvular disease, projected life expectancy <1 y from severe accompanying disease, recent CABG <1 wk	Resuscitated out-of-hospital and remained comatose at time of arrival to cardiac catheterization lab, RV failure
Intervention	Impella (immediately after PCI)	Impella (following PCI)	Impella (during PCI)	Impella (before or immediately after PCI)	Impella (before or after revascularization)
Control	Standard therapy (IABP allowed)	IABP (following PCI)	IABP (during PCI)	IABP (before or immediately after PCI)	Standard therapy
Key endpoints	Major adverse cardiac and cerebral events at time of Impella support and at 4 mo. LVEF at 3 d and 4 mo	Changes in CI at 30 min postimplantation, 30-d all-cause mortality	30- and 90-d major adverse events (including all-cause mortality, stroke, repeat revascularization)	30-d and 6-mo all-cause mortality	180-d all-cause mortality, subsequent need for additional MCS or heart transplant
Main findings	Increase LVEF in Impella group at 3 d and 4 mo	Increased CI in Impella-supported patients but no significant 30-d mortality difference	No difference in 3-d major adverse events; however, a trend toward improved outcomes in Impella group at 90 d	No difference in 30-d or 6-mo all-cause mortality in patients assigned to Impella CP compared with IABP	Lower 180-d all-cause mortality rate in Impella CP group compared with standard care alone



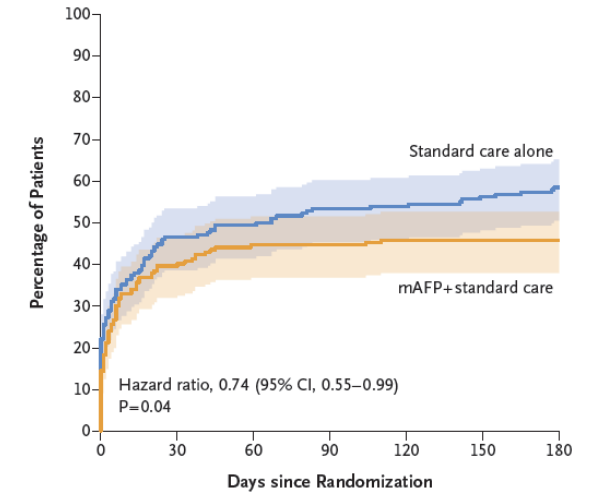
ORIGINAL ARTICLE

Microaxial Flow Pump or Standard Care in Infarct-Related Cardiogenic Shock

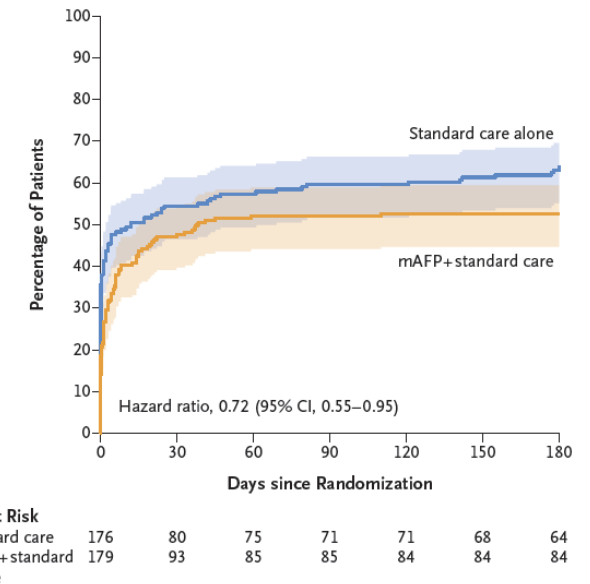
J.E. Møller, T. Engstrøm, L.O. Jensen, H. Eiskjær, N. Mangner, A. Polzin, P.C. Schulze, C. Skurk, P. Nordbeck, P. Clemmensen, V. Panoulas, S. Zimmer, A. Schäfer, N. Werner, M. Frydland, L. Holmvang, J. Kjærgaard, R. Sørensen, J. Lønborg, M.G. Lindholm, N.L.J. Udesen, A. Junker, H. Schmidt, C.J. Terkelsen, S. Christensen, E.H. Christiansen, A. Linke, F.J. Woitek, R. Westenfeld, S. Möbius-Winkler, K. Wachtell, H.B. Ravn, J.F. Lassen, S. Boesgaard, O. Gerke, and C. Hassager, for the DanGer Shock Investigators*

- Who? Cardiogenic shock post STEMI
 - SBP < 100 mm Hg or an ongoing need for vasopressor support
 - Lactate > 2.5 mmol/L
 - LVEF < 45%
- Results:
 - **Mortality was lower** with the use of impella vs. standard care alone
 - **More complications:**
 - A composite safety end-point event (severe bleeding, limb ischemia, hemolysis, device failure, or worsening of aortic regurgitation) occurred more often in impella group than in the standard-care group.
 - Renal-replacement therapy was more with impella vs. standard care.

A Death from Any Cause

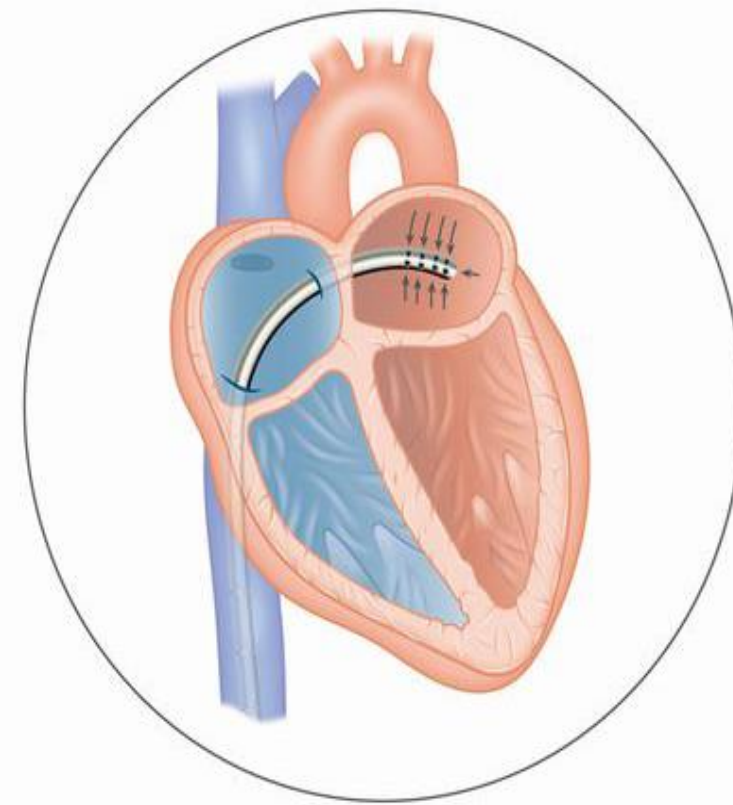
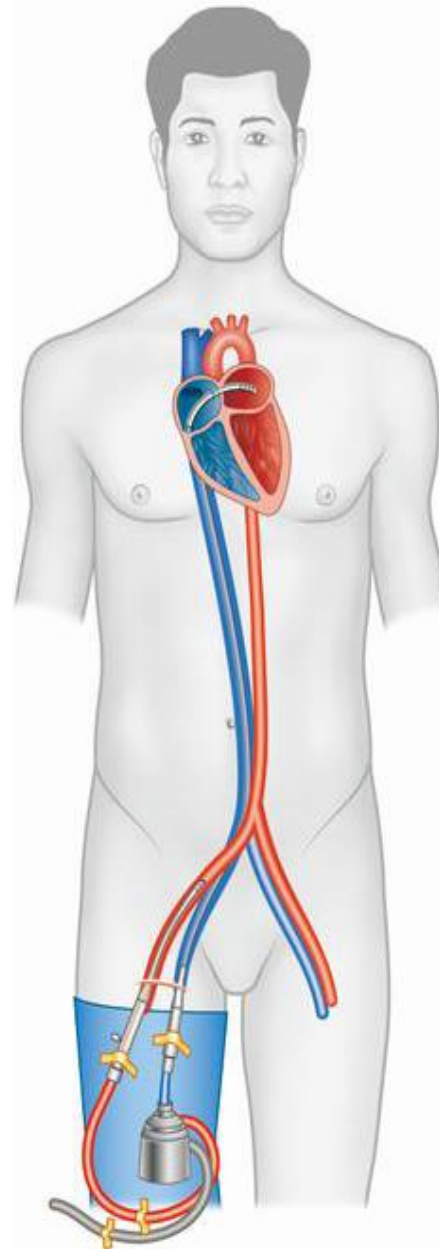


B Secondary Composite Cardiac End-Point Event



TandemHeart

- Percutaneous device with continuous flow centrifugal.
- Inflow cannula placed into left atrium (LA) via femoral vein and then transseptal puncture.
- Outflow cannula placed in ilio/femoral artery
- **Blood is withdrawn from the LA and then returned in a retrograde fashion to the aorta via the femoral artery**



Hemodynamics

- Increases cardiac output and mean arterial pressure and
- Decreases cardiac filling pressure by venting the left atrium
- Increases LV afterload from retrograde blood flow up the aorta



Contraindications

- Severe peripheral arterial disease
- Severe bleeding inability to tolerate anticoagulation
- Severe RV failure

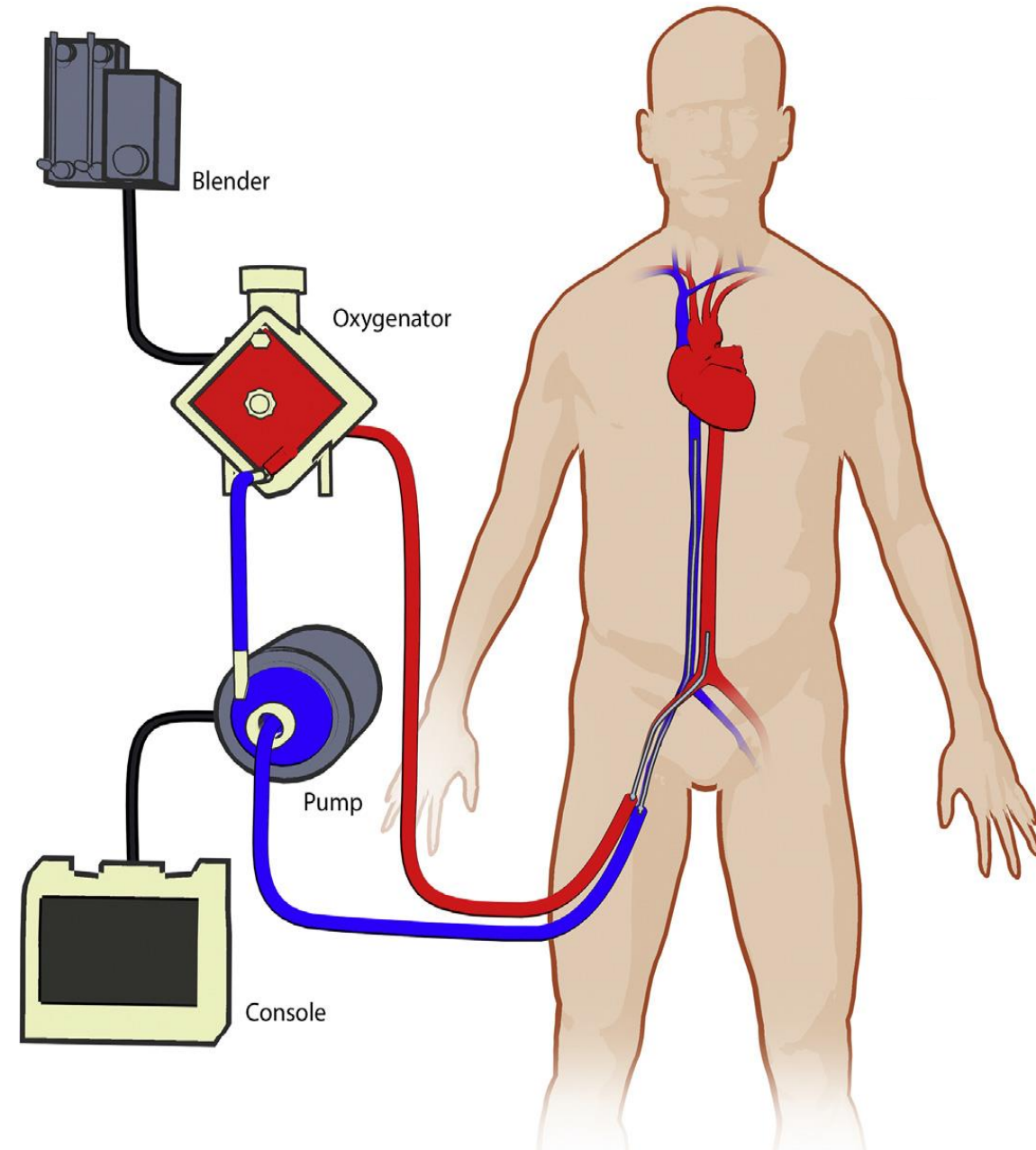
Complications

- Device malfunction due to thrombosis
- Hemolysis
- Bleeding requiring transfusion
- Limb ischemia
- Cardiac tamponade
- Stroke



Peripheral VA-ECMO

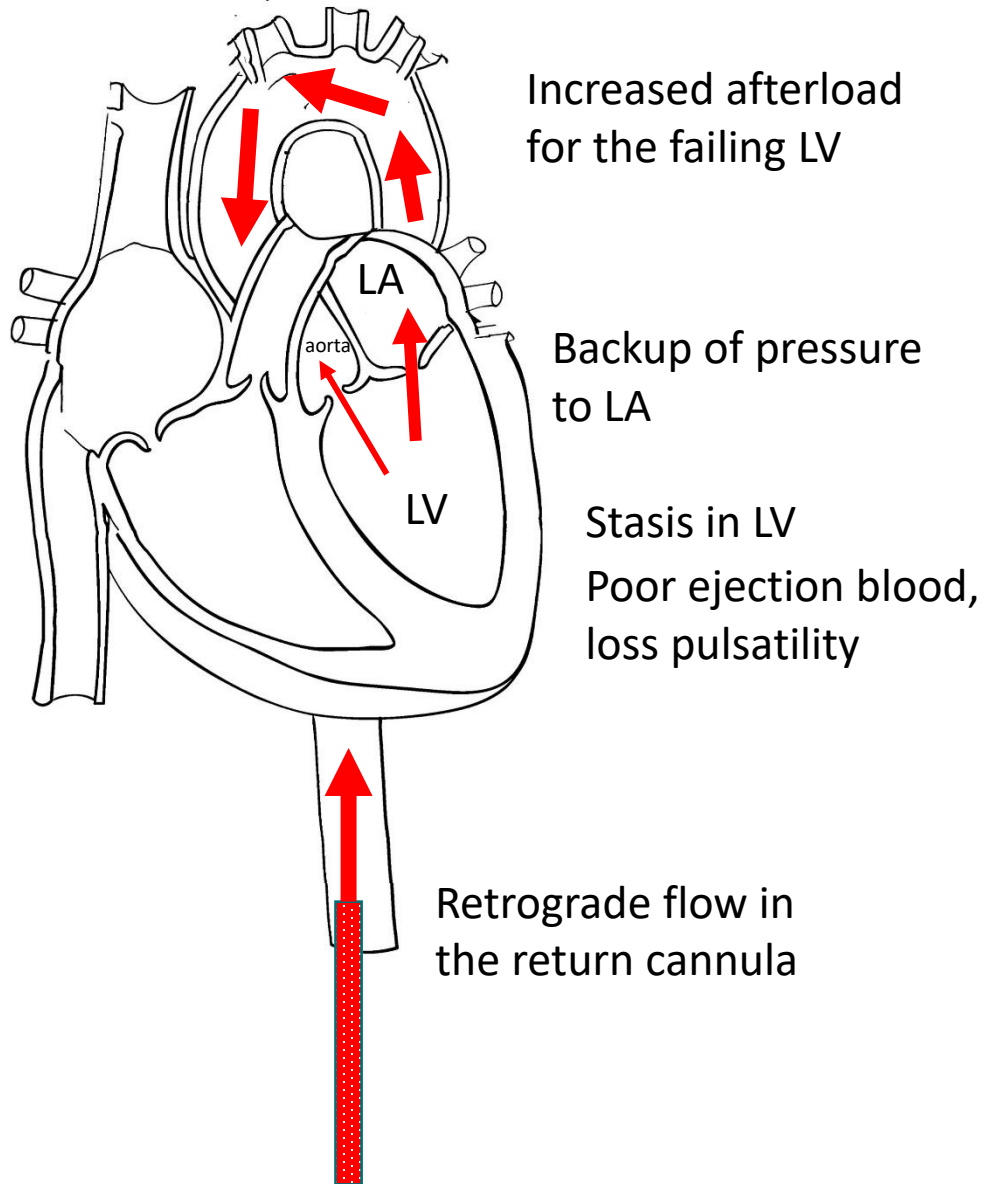
- Centrifugal pump
- Drainage cannula in IVC via femoral vein
- Return cannula in femoral artery
- **Deoxygenated blood is drained from RA/IVC and returned in a retrograde fashion via the femoral artery**
- Bypasses heart and lungs to give partial support for both



Hemodynamics

- Unloads RV, by draining blood from systemic venous system
- Provides systemic perfusion with increase in MAP
- Retrograde flow up aorta **increases left ventricular afterload**
 - Can prevent left ventricular ejection -> leading to stasis and thrombosis within the cardiac chambers
 - Increased left ventricular end-diastolic pressure -> pulmonary edema





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L9E-904 WALLENSTEINKEL



PVC 0	53	ECG
		130
		25
74/	74	ART 1
RATE 0	74	160
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18/	18	PA 2
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	17	CVP 4
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		-99
PEEP 8	14	VNT
MV 3.6		
FIO2 41	PT-RR	
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VNT ALARM	07:01	
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MORE
MENUS

ALARMS:

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T2-F

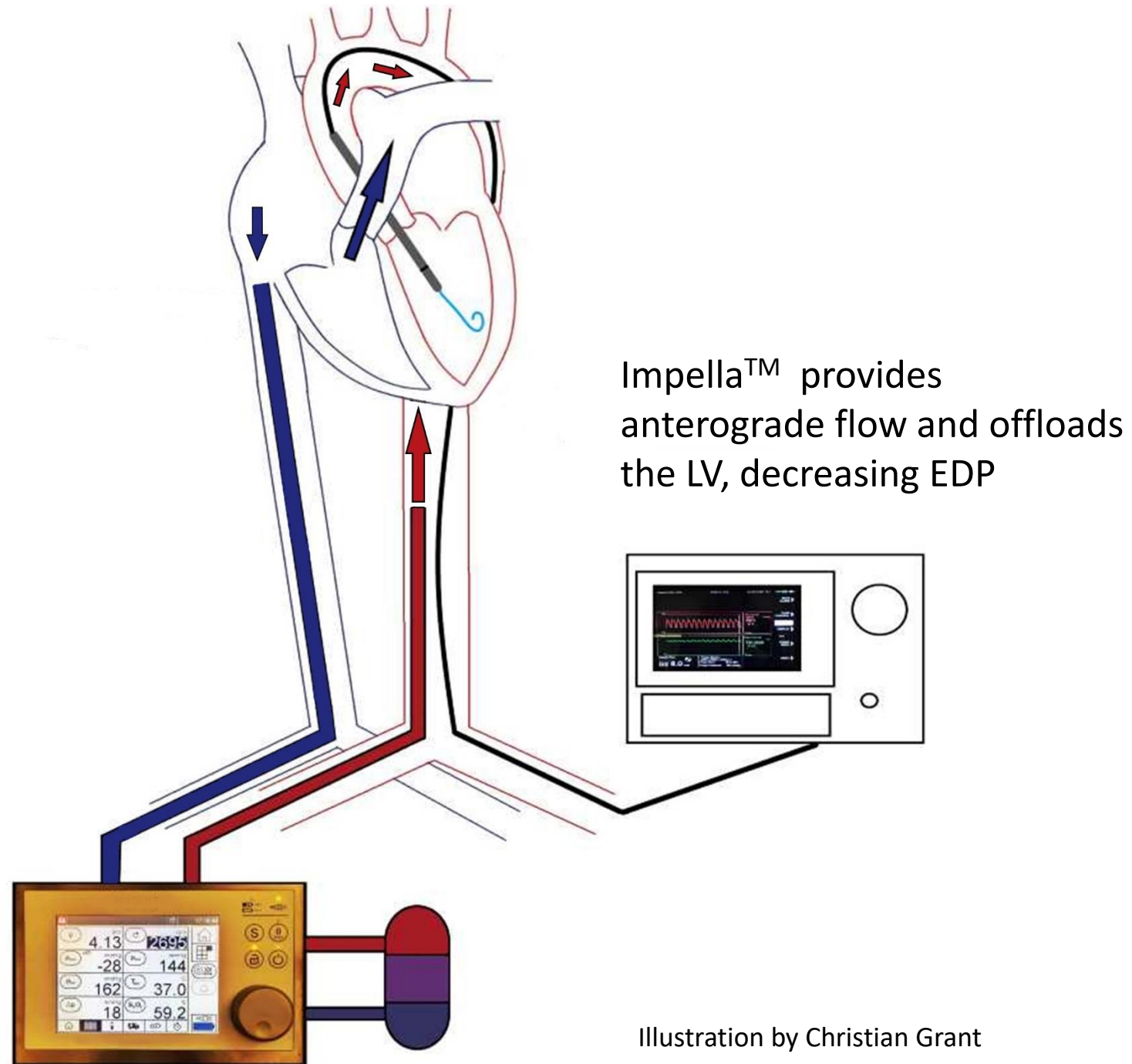
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Contraindications

- Significant baseline comorbidities (end stage cardiopulmonary disease and not a transplant or VAD candidate, ESRD, ESLD)
- Aortic dissection
- Severe aortic regurgitation
- Unwitnessed or prolonged cardiac arrest
- Severe bleeding inability to tolerate anticoagulation

Complications

- Bleeding
- Thrombosis
- Hemolysis
- Stroke
- AKI
- Infection
- Tamponade
- Circuit-related complications



Extracorporeal life support during cardiac arrest and cardiogenic shock: a systematic review and meta-analysis

Dagmar M. Ouweneel¹, Jasper V. Schotborgh¹, Jacqueline Limpens², Krischan D. Sjauw¹, A. E. Engström¹, Wim K. Lagrand³, Thomas G. V. Cherpanath³, Antoine H. G. Driessen¹, Bas A. J. M. de Mol¹ and José P. S. Henriques^{1*}

Cardiogenic shock - 30-day survival

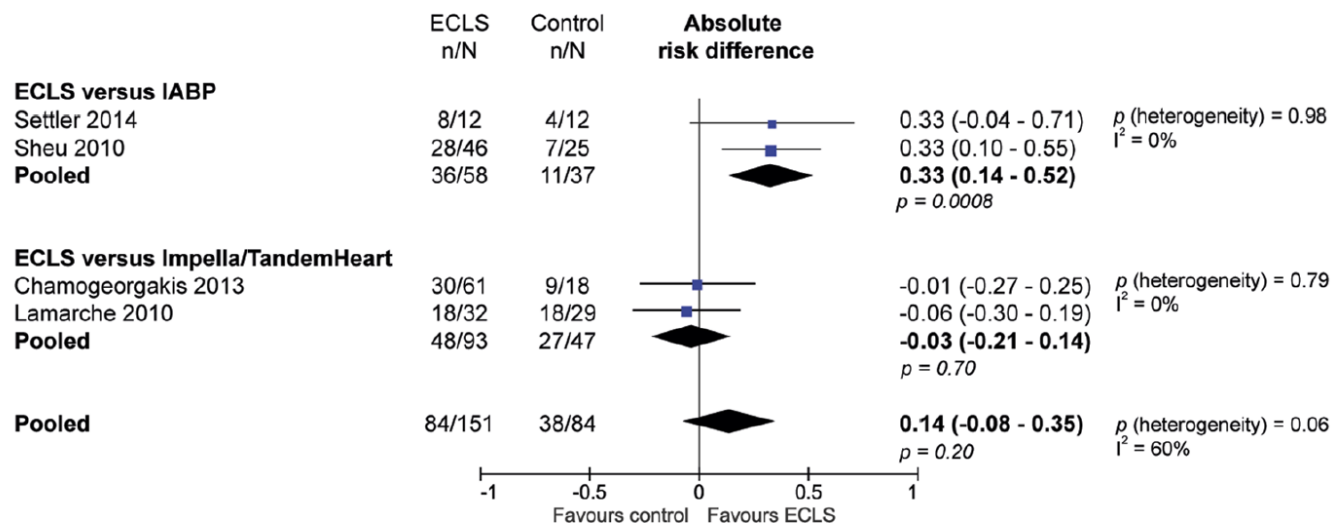


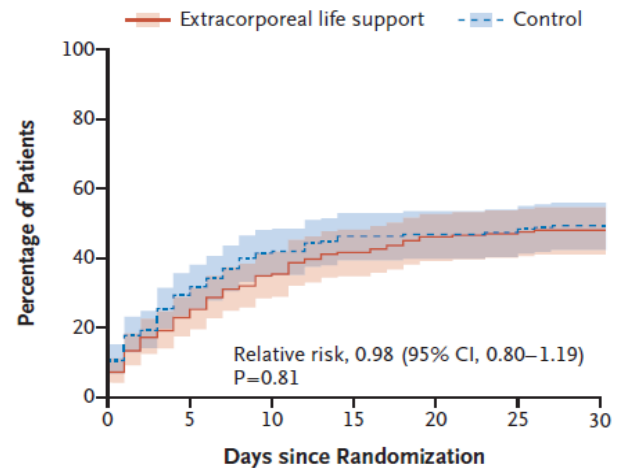
Fig. 3 Difference of 30-day survival of patients with cardiogenic shock, stratified according to different control therapies (IABP or Impella/Tandem-Heart)

 ***There are no adequately powered RCT's that support the use of ECMO in patients with cardiogenic shock.***

ORIGINAL ARTICLE

Extracorporeal Life Support in Infarct-Related Cardiogenic Shock

H. Thiele, U. Zeymer, I. Akin, M. Behnes, T. Rassaf, A.A. Mahabadi, R. Lehmann, I. Eitel, T. Graf, T. Seidler, A. Schuster, C. Skurk, D. Dierschmied, P. Clemmensen, M. Hennersdorf, S. Fichtlscherer, I. Voigt, M. Seyfarth, S. John, S. Ewen, A. Linke, E. Tigges, P. Nordbeck, L. Bruch, C. Jung, J. Franz, P. Lauten, T. Goslar, H.-J. Feistritz, J. Pöss, E. Kirchhof, T. Ouarrak, S. Schneider, S. Desch, and A. Freund, for the ECLS-SHOCK Investigators*



No. at Risk							
Control	208	146	120	109	105	104	100
Extracorporeal life support	209	161	136	119	109	107	105

Figure 1. Death from Any Cause at 30 Days.

Shown are the time-to-event curves for death from any cause at 30 days (the primary outcome) among the patients who received extracorporeal life support plus medical therapy as compared with those who received only medical therapy (control). The shaded areas indicate the 95% confidence intervals.

- Who? AMI associated cardiogenic shock
 - SBP < 90 mm Hg for more than 30 minutes
 - On catecholamines to maintain SBP > 90 mm Hg
 - Lactate > 3 mmol/L
 - Signs of impaired organ perfusion with at least one:
 - altered mental status,
 - cold or clammy skin and limbs
 - urine output of less than 30 ml/hr
- Results:
 - **No difference in 30-day mortality**
 - Complications:
 - Moderate or severe bleeding and peripheral ischemic vascular complications warranting surgical or interventional therapy occurred **more often in the ECLS group**.

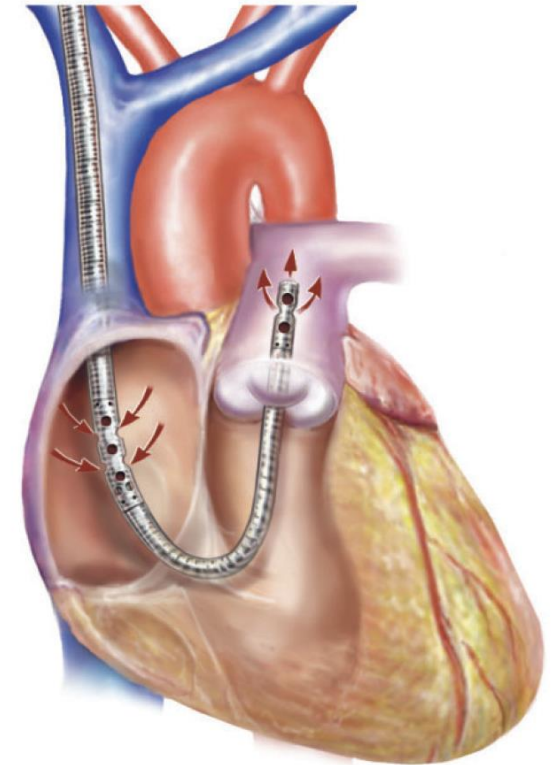
Right Ventricular Assist Devices

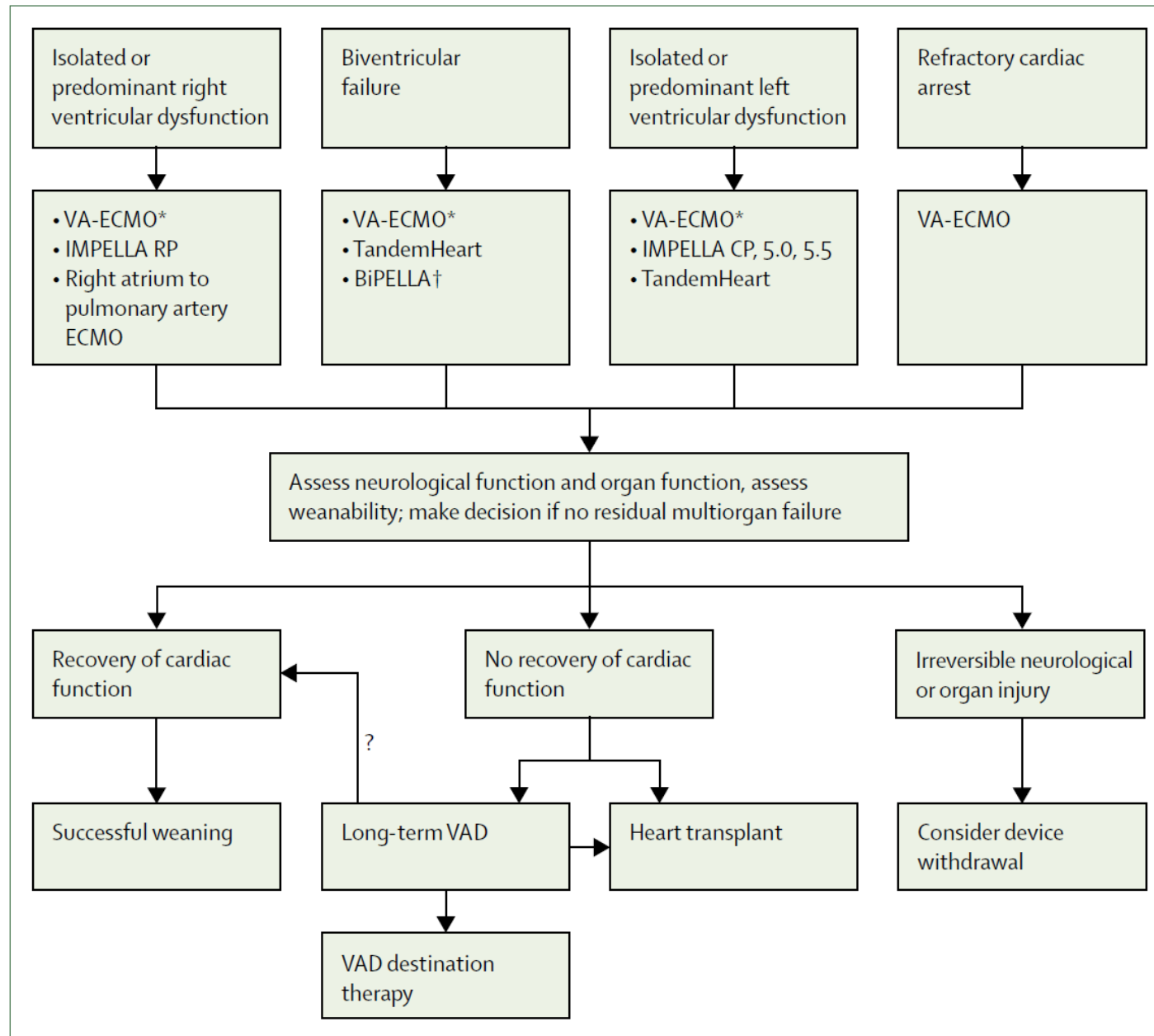
- Percutaneously placed via the internal jugular vein or femoral vein
- Draws blood from the right atrium and ejects into the pulmonary artery
- Commonly used scenarios: RV AMI, RV failure post-cardiotomy, RV failure post LVAD placement, RV failure post heart transplant

Impella RP



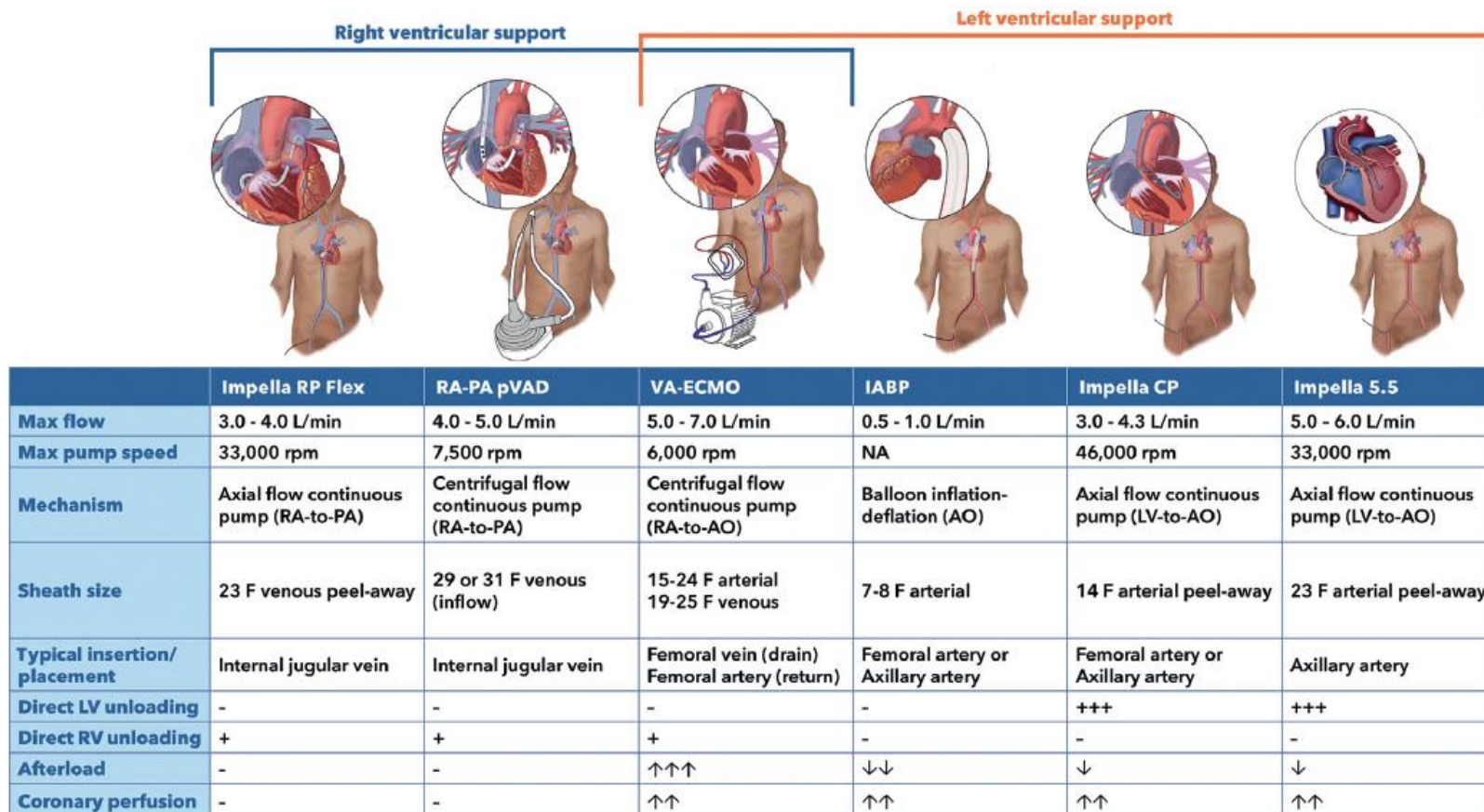
Protek-Duo





Device	Flow (l/min)	Mechanism	LV support	RV support	Oxygenation	Contraindications	Complications
IABP	0.5 l/min	Pulsatile flow	Yes	No	No	Aortic dissection Aortic regurgitation Severe peripheral vascular disease	Limb ischemia Bleeding
Impella 2.5 Impella CP Impella 5.5	2.5 l/min 3.0–3.5 l/min 6 l/min	Axial Flow	Yes	No	No	Severe aortic valve disease Mechanical aortic valve Left ventricular thrombus	Limb ischemia Hemolysis Bleeding
VA-ECMO	4–7 l/min	Centrifugal flow	Yes	Yes	Yes	Severe peripheral vascular disease Moderate to severe aortic regurgitation	Limb ischemia Hemolysis Bleeding
TandemHeart	3.5–4 l/min	Centrifugal flow	Yes	No	No	Aortic regurgitation Ventricular septal defect Severe peripheral vascular disease	bleeding Cannula dislodgement Atrial-septal defect Limb ischemia Thromboembolism
Impella RP	2–4 l/min	Axial flow	No	Yes	No	Severe tricuspid/pulmonic stenosis Severe tricuspid/pulmonic regurgitation Mechanical tricuspid or pulmonic valve Mural thrombus of right atrium or IVC Vena cava filter	Atrial fibrillation Bleeding Hemolysis Pulmonic valve insufficiency Venous thrombosis
TandemLife Protek Duo	4–5 l/min	Centrifugal flow	No	Yes	Yes	Severe tricuspid/pulmonic stenosis Mechanical tricuspid/pulmonic valve Mural thrombus of right atrium	Myocardial wall injury/perforation Venous thrombosis Air embolism Arrhythmias Hemolysis

FIGURE 6 Common tMCS Devices Used in CS



Adapted with permission from Tehrani BN, et al.²¹ AO = aorta; CP = cardiac power; CS = cardiogenic shock; F = French; IABP = intra-aortic balloon pump; LV = left ventricular; NA = not applicable; PA = pulmonary artery; pVAD = percutaneous ventricular assist device; RA = right atrium; RA-PA = right atrium to pulmonary artery; RP = right percutaneous; rpm = revolutions per minute; RV = right ventricular; tMCS = temporary mechanical circulatory support; VA-ECMO = venoarterial extra-corporeal membrane oxygenation.

Summary

- Temporary percutaneous mechanical circulatory assist devices improve hemodynamics by supporting the failing LV and or RV.
- Despite improvement in hemodynamic parameters large RCT data do not exist that demonstrate a survival benefit in cardiogenic shock
- These devices include: IABP, Impella, TandemHeart, peripheral VA-ECMO, Protek-Duo, Impella RP
- Common complications include severe bleeding, limb ischemia, hemolysis, stroke and device specific complications.



MOC REFLECTIVE STATEMENT (BRIEF TAKE HOME NOTES FOR REFERENCE)

- Temporary percutaneous mechanical circulatory assist devices improve hemodynamics by supporting the failing LV and or RV.
- Despite improvement in hemodynamic parameters large RCT data do not exist that demonstrate a survival benefit in cardiogenic shock
- These devices include: IABP, Impella, peripheral VA-ECMO, Protek-Duo, Impella RP flex
- Common complications include severe bleeding, limb ischemia, hemolysis, stroke and device specific complications.



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Question

- A 50 y.o. male was admitted to the ICU with the diagnosis of viral myocarditis. He was treated with inotropes and vasopressors to target a mean arterial pressure of 65 mm Hg. Despite these interventions he had a cardiac index of 1.5 l/min/m² and a lactic acid level of 5.5 mmol/L. His urine output started to trend down to less than 10 cc/hour despite appropriate dose of diuretics. He had an echocardiogram performed that demonstrated severe biventricular dysfunction. The shock team was activated, and decision was made to place the patient on temporary mechanical circulatory support. Which of the following is the most appropriate form of support for this patient?
 - A. VA-ECMO
 - B. Impella CP
 - C. Impella RP Flex
 - D. Intra-aortic balloon pump
 - E. Protek-Duo



Answer Explanation

- Answer A is correct because it is the only form of MCS listed that provides biventricular support.
- Impella 2.5 and IABP only provide LV support. The Impella RP and Protek-Duo only provide RV support.



Question

- A 65 y/o M with an anterior STEMI is taken emergently to the cardiac catheterization lab. In the catheterization lab, the patient is successfully revascularized but develops hypotension. A PA catheter is placed, and hemodynamic measurements are consistent with cardiogenic shock. The decision is made to place an intra-aortic balloon pump (IABP). Which following statements regarding IABP is correct?
- A. There is strong evidence from randomized control trials that demonstrate IABP use in cardiogenic shock due to acute myocardial infarction leads to decreased mortality.
- B. IABP provides up to 5 L/min of cardiac output support.
- C. IABP Increases coronary artery blood flow and reduces LV afterload
- D. IABP is safe to use in patients with aortic dissections.
- E. IABP mechanism of action is via a centrifugal pump.



Answer Explanation

- Answer C is correct. The IABP inflates during diastole displacing blood into the proximal aorta which increased coronary blood flow and deflates in systole which decreases LV afterload.
- There is no RCT evidence to support the use of IABP in cardiogenic shock secondary to acute MI.
- IABP does not lead to a considerable increase in cardiac output.
- Aortic dissection is a contraindication for IABP use.
- IABP functions via counterpulsation not a centrifugal pump.

