MHIF FEATURED STUDY:

ARIES

OPEN AND ENROLLING

EPIC message: *Research MHIF Patient Referral*

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
Heart Failure	Peter Eckman, MD	Kari Thomas & Sarah Schwager Kari.m.thomas@allina.com 612-863-7493 Sarah.Schwager@allian.com 612-863-6257	Abbott Vascular

DESCRIPTION:

The purpose of this study is to understand if aspirin is needed in subjects implanted with HeartMate 3. Subjects with devices like HeartMate 3 take two blood thinner medicines, specifically warfarin and aspirin. Subjects often experience both clotting and bleeding complications.

Data suggests that the HeartMate 3 may not require as much anticoagulation as are used with similar devices. This study will test if subjects need aspirin together with warfarin or just warfarin alone.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion:

- Subjects will receive the HeartMate 3 as their first LVAD

Exclusion:

- Post implant additional temporary or permanent mechanical circulatory support (MCS)
- Investigator mandated antiplatelet therapy for other conditions

Cardiogenic Shock Update
New Criteria from HF and Interventional Cardiologist Viewpoints

Minneapolis Heart Institute Grand Rounds
November 3, 2020
Kasia Hryniewicz, MD

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- No disclosures

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Outline

- Etiology, new definitions and stages of cardiogenic shock
- Helpful formulas
- Shock Team/Predictors of outcome
- ECMO vs Impella
- Case

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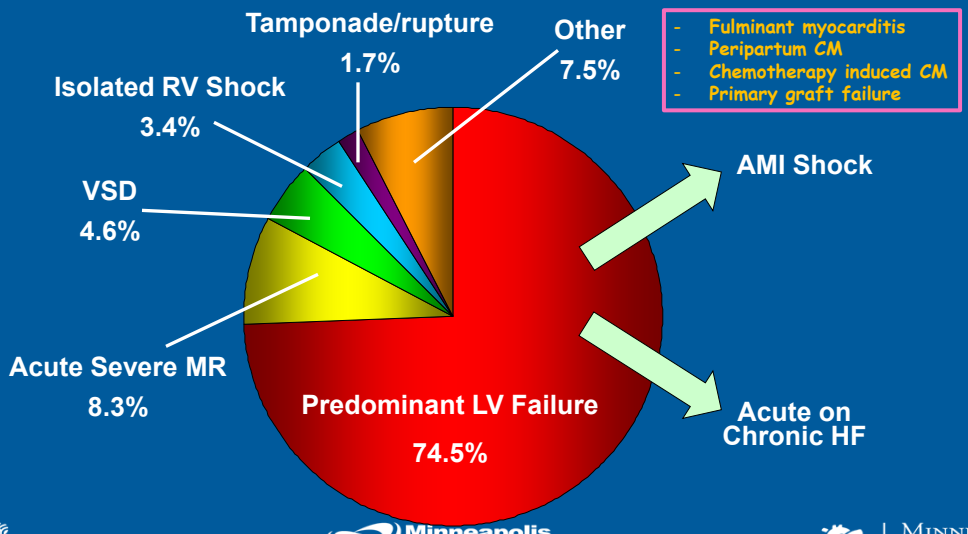
Causes of Cardiogenic Shock



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Adapted From Sanborn T. et al, *JACC*. 2000

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Cardiogenic shock - definition

Clinical / laboratory

- Altered mentation
- SOB
- Abdominal pain/N/V
- Cool periphery
- Pulmonary congestion
- Low urine output
- Lactic acidosis and ↓HCO_3

Based on Hemodynamics

- Persistent hypotension
- Systolic BP < 80-90 mmHg or
- MAP < 60mmHg or 30 mmHg below baseline in pts with HTN
- Cardiac Index

< 2.2 without support or < 2.0L/min/m^2 with moderate/maximal support

- Elevated Filling Pressures
- LVEDP > 18 mmHg
- RVEDP > 10-15 mmHg

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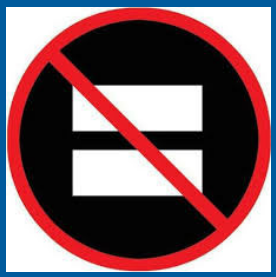
Cardiogenic shock is not all created equal



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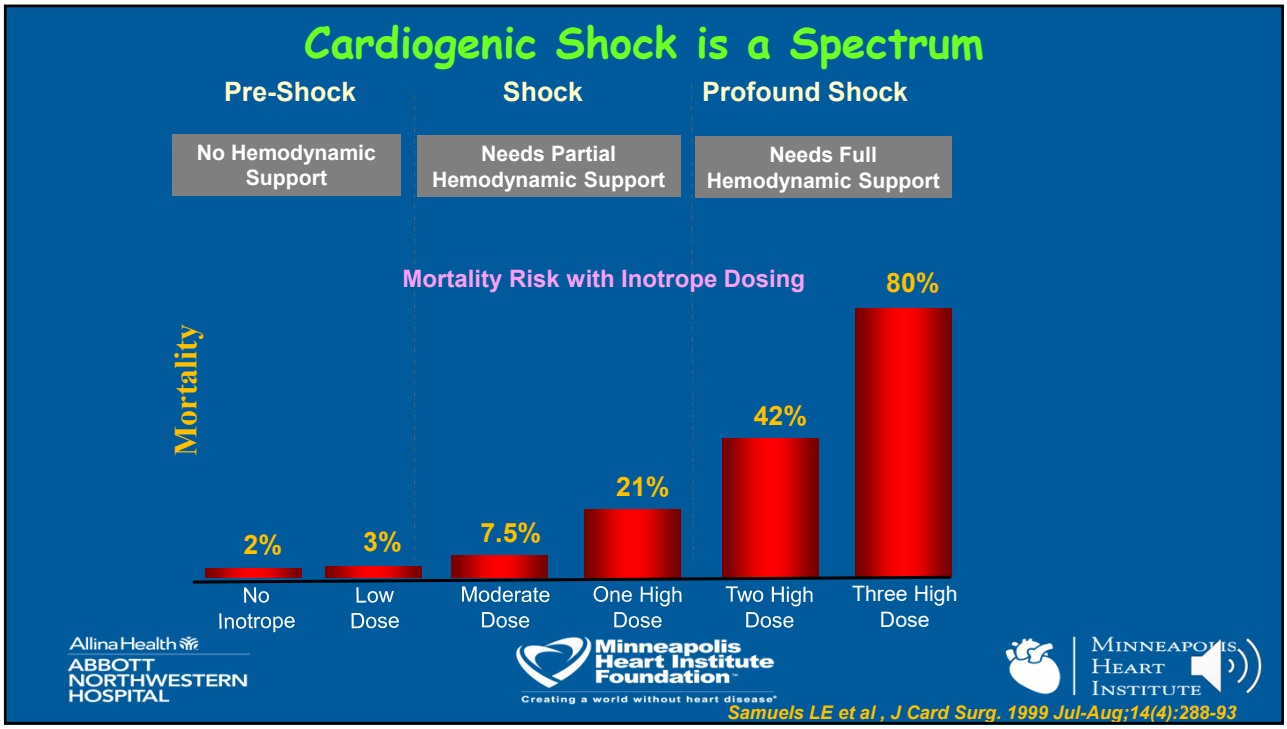
Cardiogenic Shock is a Spectrum
Pre-Shock
Shock
Profound Shock
No Hemodynamic Support
Needs Partial Hemodynamic Support
Needs Full Hemodynamic Support
Mortality Risk with Inotrope Dosing
Mortality
2%
3%
7.5%
21%
42%
80%
No Inotrope
Low Dose
Moderate Dose
One High Dose
Two High Dose
Three High Dose
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Samuels LE et al , J Card Surg. 1999 Jul-Aug;14(4):288-93

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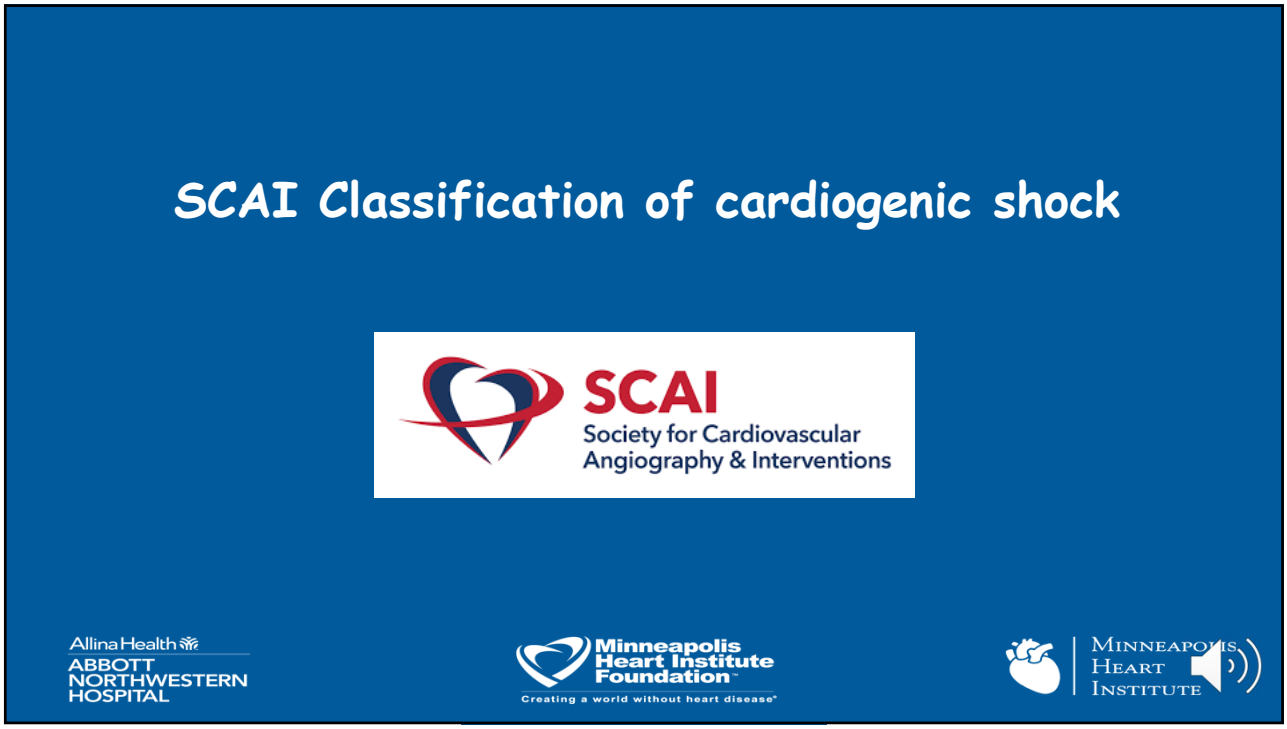
SCAI Classification of cardiogenic shock
SCAI
Society for Cardiovascular Angiography & Interventions
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SCAI clinical expert consensus statement on the classification of cardiogenic shock

This document was endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), the Society of Critical Care Medicine (SCCM), and the Society of Thoracic Surgeons (STS) in April 2019

David A. Baran MD, FSCAI (Co-Chair)[1] | Cindy L. Grines MD, FACC, FSCAI[2*] | Steven Bailey MD, MSCAI, FACC, FACP[3] | Daniel Burkhoff MD, PhD[4] | Shelley A. Hall MD, FACC, FHFSA, FAST[5] | Timothy D. Henry MD, MSCAI[6] | Steven M. Hollenberg MD[7‡] | Navin K. Kapur MD, FSCAI[8] | William O'Neill MD, MSCAI[9] | Joseph P. Ornato MD, FACP, FACC, FACEP[10] | Kelly Stelling RN[1] | Holger Thiele MD, FESC[11] | Sean van Diepen MD, MSc, FAHA[12†] | Srihari S. Naidu MD, FACC, FAHA, FSCAI (Chair)[13]

Baran DA et .Catheter Cardiovasc Interv. 2019 Jul 1;94(1):29-37.

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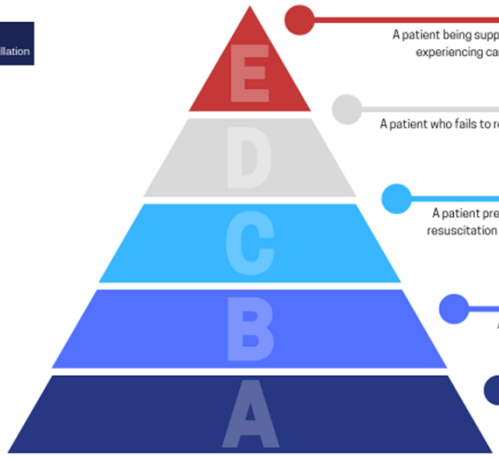
SCAI Society for Cardiovascular Angiography & Interventions

SCAI Stages of Cardiogenic Shock

Adapted from the SCAI Clinical Expert Consensus Statement on the Classification of Cardiogenic Shock
Endorsed by ACC, AHA, SCCM, and STS

Arrest (A) Modifier:
CPR, including defibrillation



EXTREMIS
A patient being supported by multiple interventions who may be experiencing cardiac arrest with ongoing CPR and/or ECMO.

DETERIORATING
A patient who fails to respond to initial interventions. Similar to stage C and getting worse.

CLASSIC
A patient presenting with hypoperfusion requiring intervention beyond volume resuscitation (inotrope, pressor, or mechanical support including ECMO). These patients typically present with relative hypotension.

BEGINNING
A patient who has clinical evidence of relative hypotension or tachycardia without hypoperfusion.

AT RISK
A patient with risk factors for cardiogenic shock who is not currently experiencing signs or symptoms. For example, large acute myocardial infarction, prior infarction, acute and/or acute on chronic heart failure.

Baran DA, Grines CL, Bailey S, et al. SCAI clinical expert consensus statement on the classification of cardiogenic shock. Catheter Cardiovasc Interv. 2019;1–9. https://doi.org/10.1002/ccd.28329
For more information, please visit: www.scai.org/shockdefinition

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SCAI Classification to Predicts Mortality in the CICU

- Retrospective analysis of Mayo Clinic CICU patients admitted with CS between 2007 and 2015.
-
- Each higher SCAI shock stage was associated with increased hospital mortality compared with SCAI shock stage A
-
- was 46.0%, 30.0%, 15.7%, 7.3%, and 1.0%
- Unadjusted hospital mortality in these stages was 3.0%, 7.1%, 12.4%, 40.4%, and 67.0% (p < 0.001),

Jentzer JC et al.JACC; Vol 74, Issue 17, Octber 2019

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SCAI cardiogenic shock classification after out of hospital cardiac arrest and association with outcome

Nilesh Pareek MA MBBS MRCP[1,2] | Rafal Dworakowski MA MBBS MRCP[1,2] | Ian Webb MA PhD FRCP[1,2] | Jemma Barash Bsc MBBS[1] | Gift Emezu MBBS[1] | Narbeh Melikian Bsc MD FRCP[1,2] | Jonathan Hill MA MBBS FRCP[1,2] | Ajay Shah MD FRCP[1,2] | Philip MacCarthy Bsc PhD FRCP[1,2] | Jonathan Byrne Bsc PhD FRCP[1,2]

Pareek N et al. Catheter Cardiovasc Interv. 2020;1-10.

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SCAI Classification after Cardiac Arrest

- The S… …y of OOHC…
- 393 p…
- Stage…
- Stage…
- Stage…
- Stage…
- Stage…

There was a step-wise significant increase in 30-day mortality with increasing shock grade:

A 28.9%
B 33.0%
C 54.5%
D 59.3%
E 82.9%

- Need for RRT
- Multiorgan failure

Pareek N, et al. Catheter Cardiovasc Interv. 2020.

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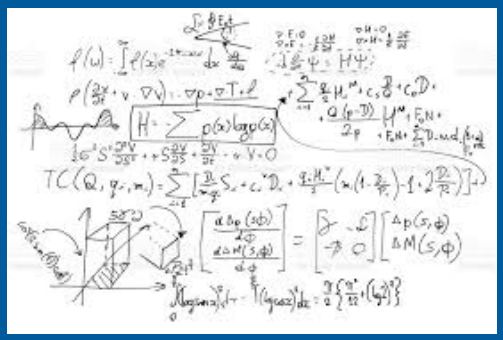
Old Formulas New Applications



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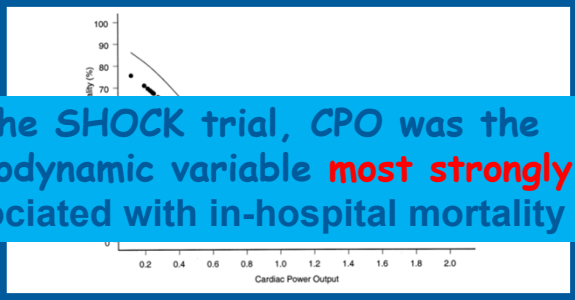
Cardiac Power Output

- CPO=MAP x CO/451.
- Normal > 0.6



In the SHOCK trial, CPO was the hemodynamic variable **most strongly** associated with in-hospital mortality

Fincke R et al. Cardiac power is the strongest hemodynamic correlate of mortality in cardiogenic shock: a report from the SHOCK trial registry. *J Am Coll Cardiol.* 2004;21;44(2):340-348.

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PAPI

The pulmonary artery pulsatility index identifies severe

myoca

Ravi Korabat
Prutkin, Nico

Guson

JOURNAL OF CARDIAC FAILURE

Log in

CLINICAL INVESTIGATION | VOLUME 24, ISSUE 7, P453-459, JULY 01, 2018

Prognostic Impact of Pulmonary Artery Pulsatility Index (PAPi) in Patients With Advanced Heart Failure: Insights From the ESCAPE Trial

Stephanie Meller Kochav, MD • Raul J. Flores, MD • Lauren K. Truby, MD • Veli K. Topkara, MD

Published: March 26, 2018 • DOI: https://doi.org/10.1016/j.cardfail.2018.03.008

Korabathina R et al. Catheter Cardiovasc Interv, 2012 Oct 1;80(4):593
Meller Kochav S et al. J Cardiac Failure; 2018 Jul;24(7):453-459.

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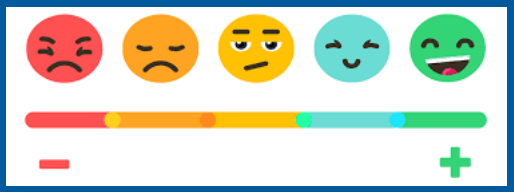
Shock Team and Predictors of Outcome



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HUP Shock Team

- Overall Goals of the Shock Team
  - Pathway development, with continual knowledge of the literature
  - Rapid patient identification
  - Mechanism of ac
    - Transfer cent
  - Expedited decisio
    - Bedside rounds as able, virtual rounds
      - "Go": patient has a potentially treatable insult and/or has an Exit plan (durable
      - of success or without an exit plan (ie: not a durable VAD candidate)
  - Once it is a "go" immediate mobilization of the appropriate team members and deployment of support

"Go or no-go"

Improving outcomes

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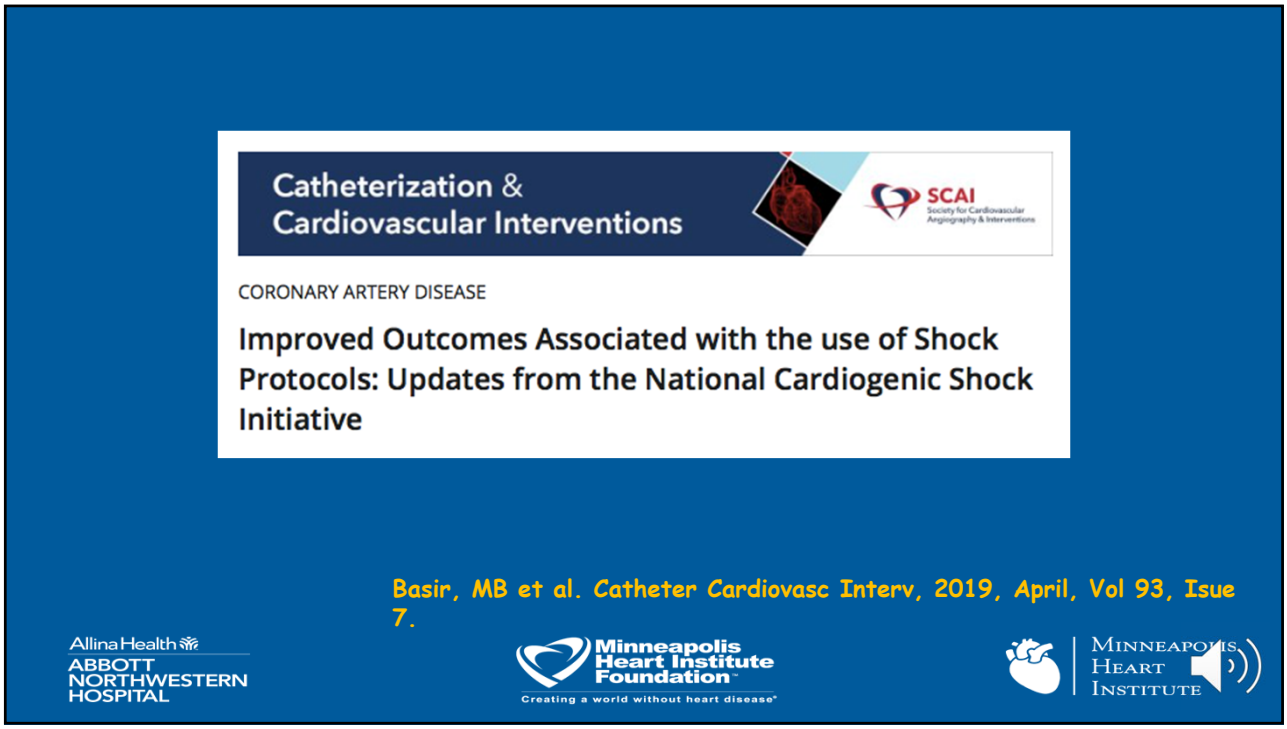
Catheterization &
Cardiovascular Interventions
SCAI
Society for Cardiovascular Angiography & Interventions
CORONARY ARTERY DISEASE
Improved Outcomes Associated with the use of Shock Protocols: Updates from the National Cardiogenic Shock Initiative
Basir, MB et al. Catheter Cardiovasc Interv, 2019, April, Vol 93, Isue 7.
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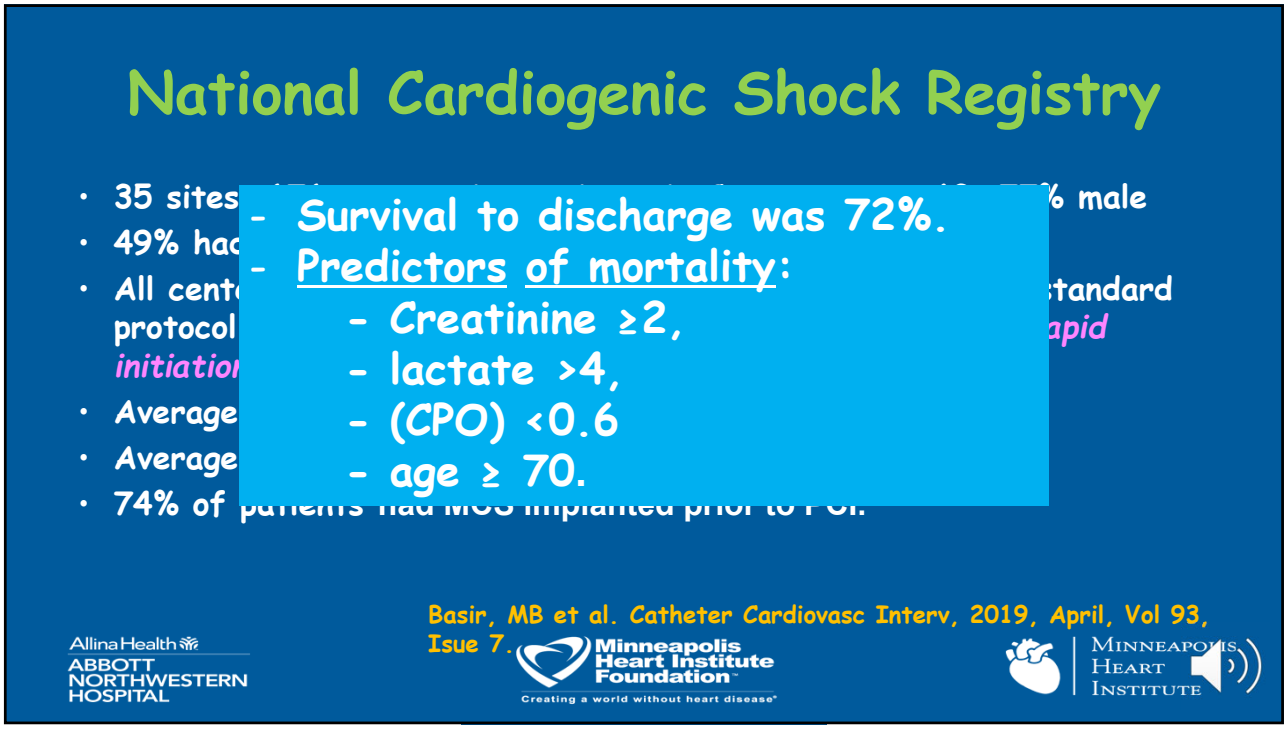
National Cardiogenic Shock Registry
- 35 sites
- 49% hac
- All cent
protocol
initiatio
- Average
- Average
- 74% of
% male
standard
apid
- Survival to discharge was 72%.
- Predictors of mortality:
- Creatinine ≥2,
- lactate >4,
- (CPO) <0.6
- age ≥ 70.
Basir, MB et al. Catheter Cardiovasc Interv, 2019, April, Vol 93, Isue 7.
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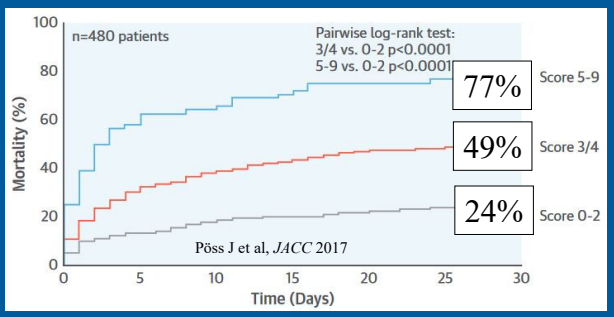
IABP-SHOCK II Predictors

- Identified 6 variables predictive of 30-day mortality
- Subsequently validated in external cohort

Clinical Parameter	
Age >73	1
Prior stroke	2
Glucose >191	1
Creatinine >1.5	1
TIMI <3 after PCI	2
Lactate (a) >5	2



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Poss J et al. JACC 2017;69:1913-20

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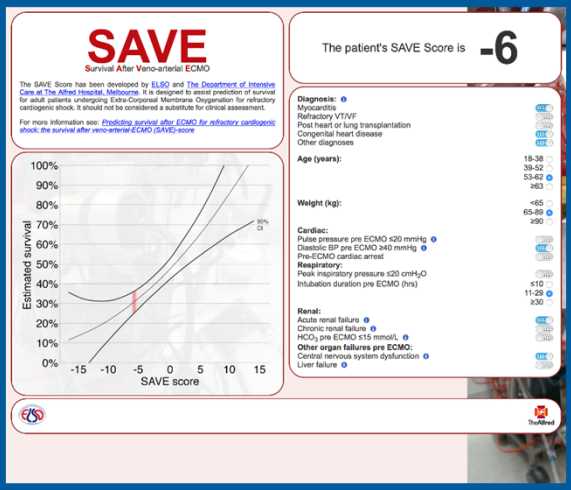
Predictors of Survival after VA ECMO



Schmidt M et al. Eur Heart J. 2015 Sep 1;36(33):2246-56.

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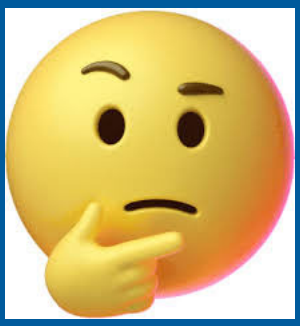
ECMO vs Impella



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European Heart Journal
Acute Cardiovascular Care

ESC European Society of Cardiology

Original scientific paper

Mechanical circulatory support in cardiogenic shock from acute myocardial infarction: Impella CP/5.0 versus ECMO

European Heart Journal: Acute Cardiovascular Care
2020, Vol. 9(2) 164–172

DOI: 10.1177/2048872619865891
journals.sagepub.com/home/acc
SAGE

Mina Karami[1], Corstiaan A den Uil[2,3], Dagmar M Ouweneel[1], Niels TB Scholte[2], Annemarie E Engström[2,3], Sakir Akin[4], Wim K Lagrand[5], Alexander PJ Vlaar[5], Lucia S Jewbali[2,3] and José PS Henriques[1]

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Impella CP/5.0 vs VA ECMO

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- 128 patients were included
- Impella, *N*=90, VA ECMO, *N*=38
- 30-day mortality 53% vs. 49%, (*P*=0.3),
- *Less* device related complications with Impella than VA ECMO (17% vs. 40%, *P* <0.01)

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ing,

Karami M et al. Eur Heart J Acute Cardiovasc Care 2020 Mar;9(2):164

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Case

- 56 years old male with end stage non – ischemic CM
- Evaluated for advanced HF therapies
- Discharged per his request with borderline but stable hemodynamics and scheduled for LVAD placement in 2 weeks

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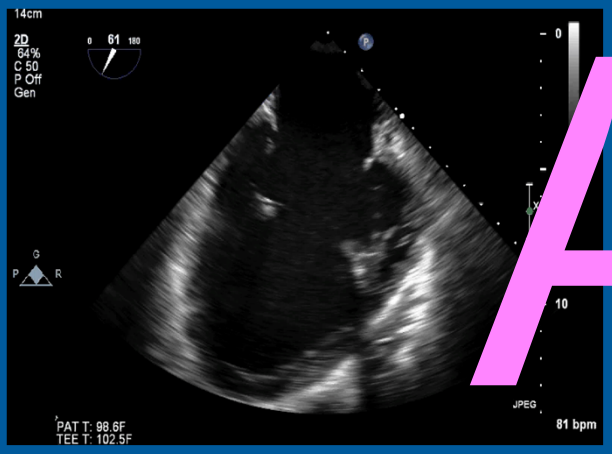
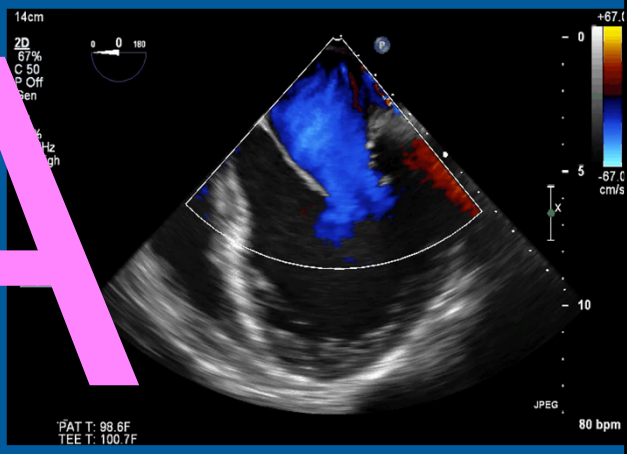
Echocardiogram





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Case

- Readmitted with worsening SOB at rest, dizziness, hypotension, MAP 58/52
- Creatinine up to 2.3, lactate 4.9, AST/ALT 95/110
- RHC with RA 17 PA [illegible] PCWP 36 Fick CO/CI 4.4/2.1
- CPO 0.6 (Normal > 0.6)
- Started on dobutamine gtt with initial improvement in hemodynamics

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Case

- Feeling poorly again, MAPs low 60s, CI 1.8 despite escalating doses of inotropes
- Creatinine up again, lactate 2.8
- CPO 0.5

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Case

- IABP placed
- Mild improvement in hemodynamics, CI 1.9-2.1
- Creatinine stabilized at 2.2, LFTs remain elevated Lactate initially down, but still 2-2.5

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Case

- More tachycardic/borderline hypotensive
- Lactate trending up a…
- RA 16, PAP 50/27, C… 1.7 desp…e dobutamine at 5, milrinone at 0.5. L…six gtt at …0 mg/h, IABP 1:1
- CPO 0.4 PAPi 1.4
- Awake, but "struggling

D

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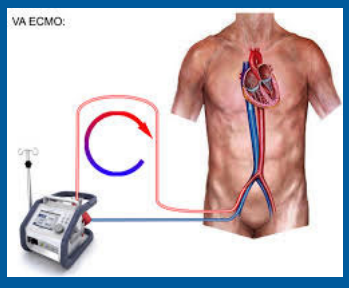
Case

- Decision to proceed with awake VA ECMO placement as bridge to durable LVAD.



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Improving Outcomes in INTERMACS 1 Category 1 Patients with Pre-LVAD, Awake Venous-Arterial Extracorporeal Membrane Oxygenation Support

Makoto Mori; Gerard McCloskey; Arnar Geirsson; Abeel A. Mangi; James J. Yun; Daniel Jacoby; Tariq Ahmad; Lavanya Bellumkonda; Forrester Lee; Michael E. Chen; Pramod Bonde

- 19/83 received aVA ECMO support before durable LVAD.
- Mean aVA ECMO support → 2.7 days.
- Survival of aVA ECMO patients was comparable with that of non-aVA ECMO INTERMACS 2 cohort (84.2% vs. 80.8%) at 1 year.

Mori M et al. ASAIO 2019

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SCAI Stages of Cardiogenic Shock

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Adapted from the SCAI Clinical Expert Consensus Statement on the Classification of Cardiogenic Shock
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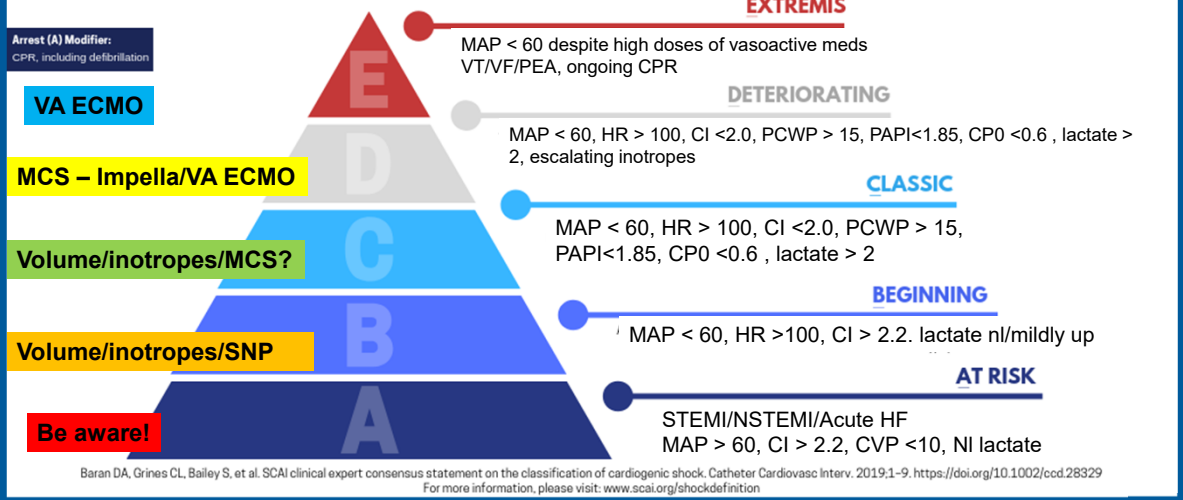

Baran DA, Grines CL, Bailey S, et al. SCAI clinical expert consensus statement on the classification of cardiogenic shock. Catheter Cardiovasc Interv. 2019;1–9. https://doi.org/10.1002/ccd.28329
For more information, please visit: www.scai.org/shockdefinition

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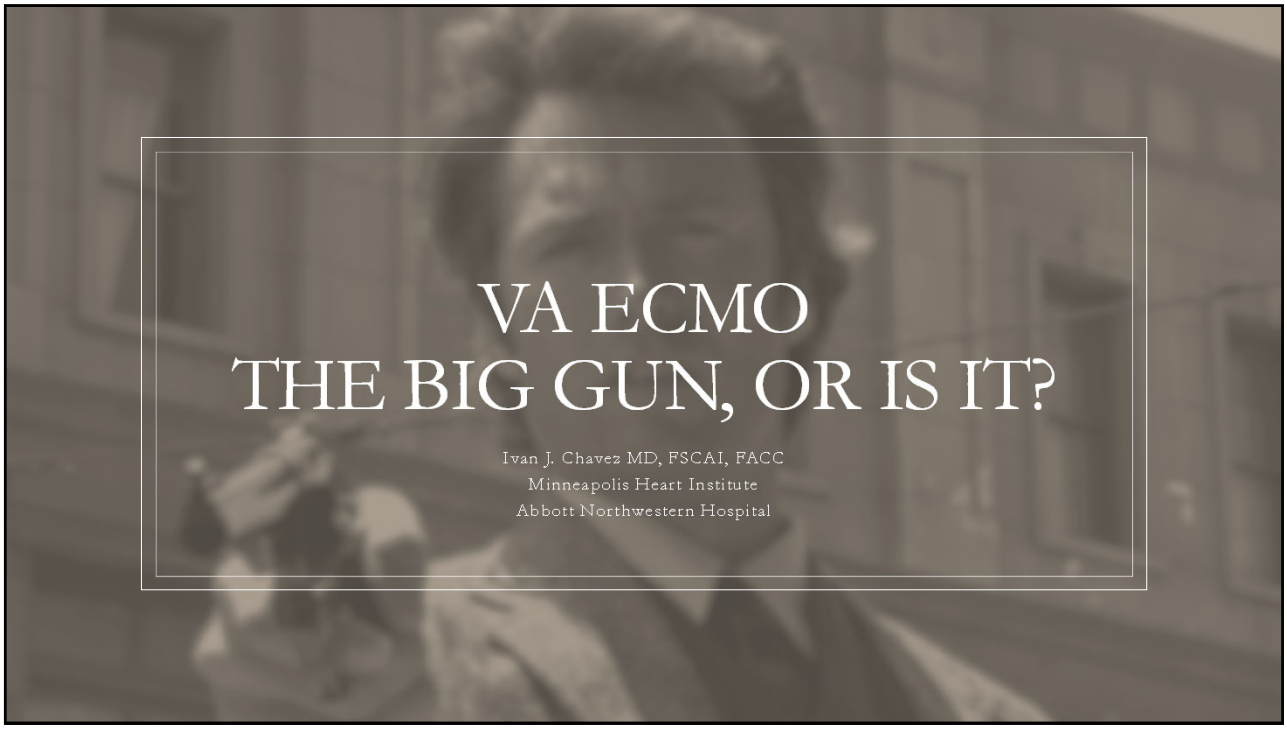
VA ECMO
THE BIG GUN, OR IS IT?
Ivan J. Chavez MD, FSCAI, FACC
Minneapolis Heart Institute
Abbott Northwestern Hospital

1


VA ECMO
THE BIG GUN, OR IS IT?
Ivan J. Chavez MD, FSCAI, FACC
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VA ECMO
THE BIG GUN, OR IS IT?
Ivan J. Chavez MD, FSCAI, FACC
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3


VA ECMO
THE BIG GUN, OR IS IT?
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Disclosures

- None

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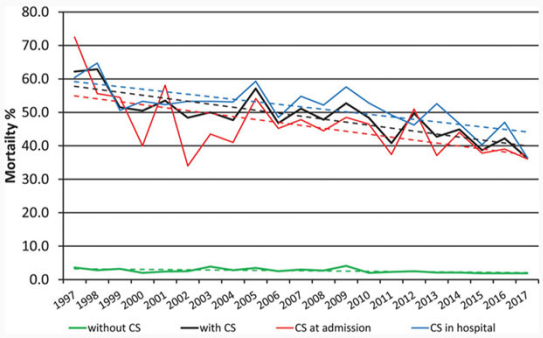
The Problem

Cardiogenic shock continues to be associated with poor survival



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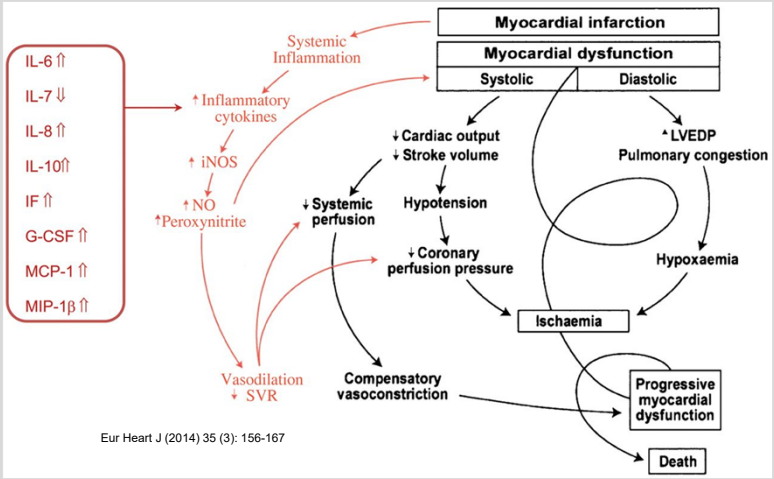
Cardiogenic Shock: The Gunfight



Eur Heart J (2014) 35 (3): 156-167

7

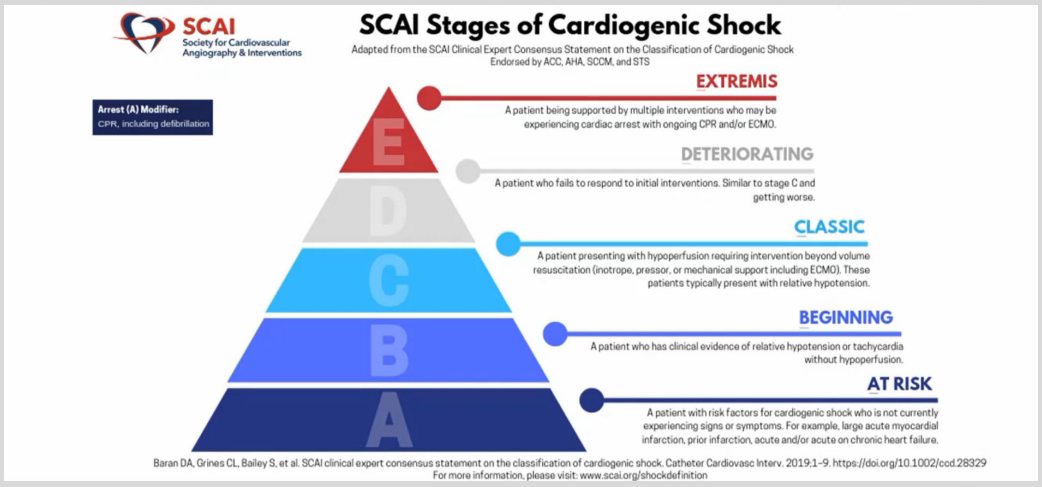
Definition?

- IMPRESS Trial
  - SBP < 90 for 30 minutes
  - Pressors for SBP > 90 min
  - Signs of hypoperfusion
  - All patients intubated
  - 90% cardiac arrest
  - 20 minutes to ROSC
  - 70-80% hypothermia
  - Lactate > 7.8, pH 7.1-7.2

- IABP SHOCK II Trial
  - SBP < 90 for 30 minutes
  - Pressors for SBP > 90 min
  - Signs of hypoperfusion
  - Pulmonary Congestion
  - Lactate > 2.0, altered mental status or UO<30cc/hr

8

SCAI Stages of Cardiogenic Shock



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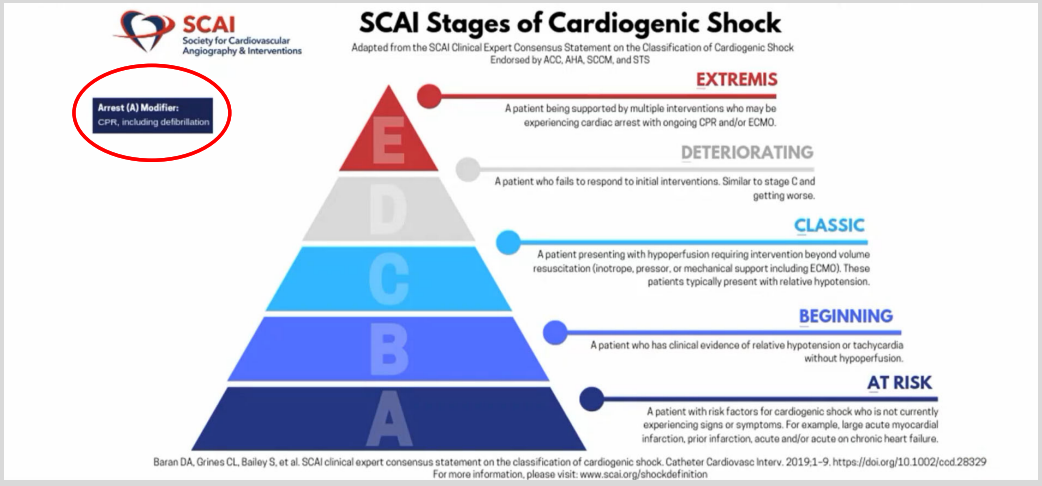
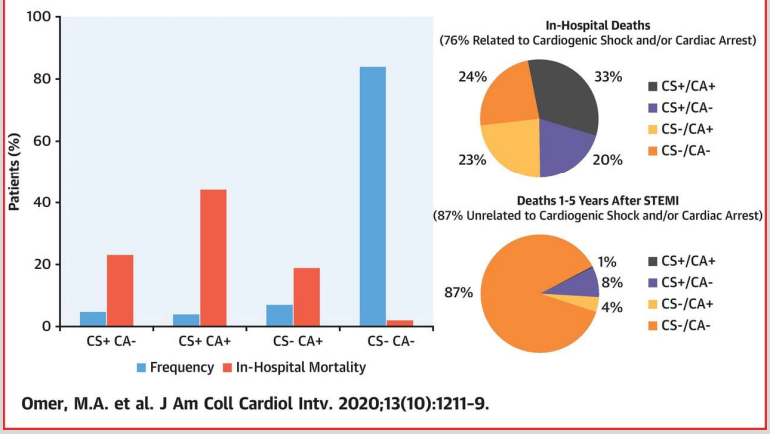
SCAI Stages of Cardiogenic Shock



10

CENTRAL ILLUSTRATION: Frequency, Short-Term Outcomes, and Long-Term Outcomes of CS and CA in Patients With STEMI Treated in a Regional Program



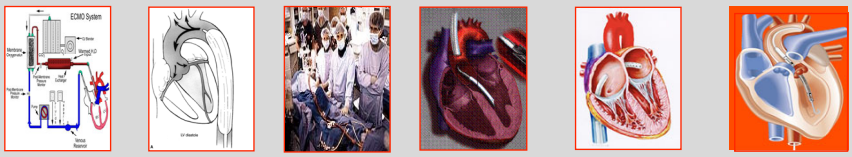
Omer, M.A. et al. J Am Coll Cardiol Intv. 2020;13(10):1211-9.

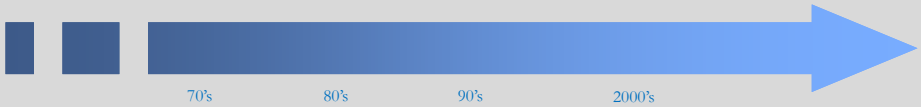
Mohamed A. Omer et al. J Am Coll Cardiol Intv
2020;13:1211-1219

JACC Cardiovascular Interventions

11

History of MCS





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Mechanical Support Devices in the Cath Lab

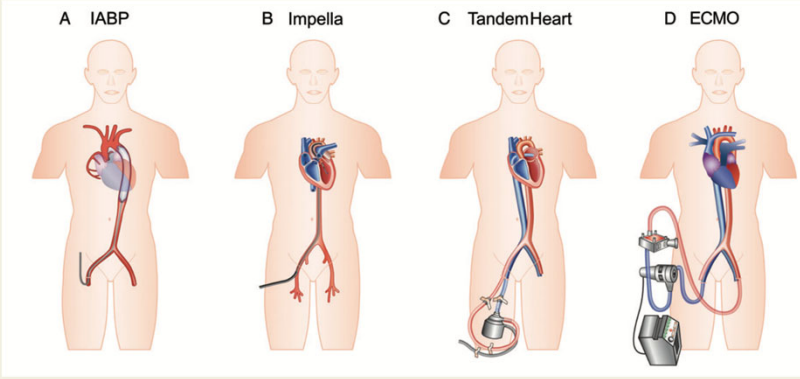
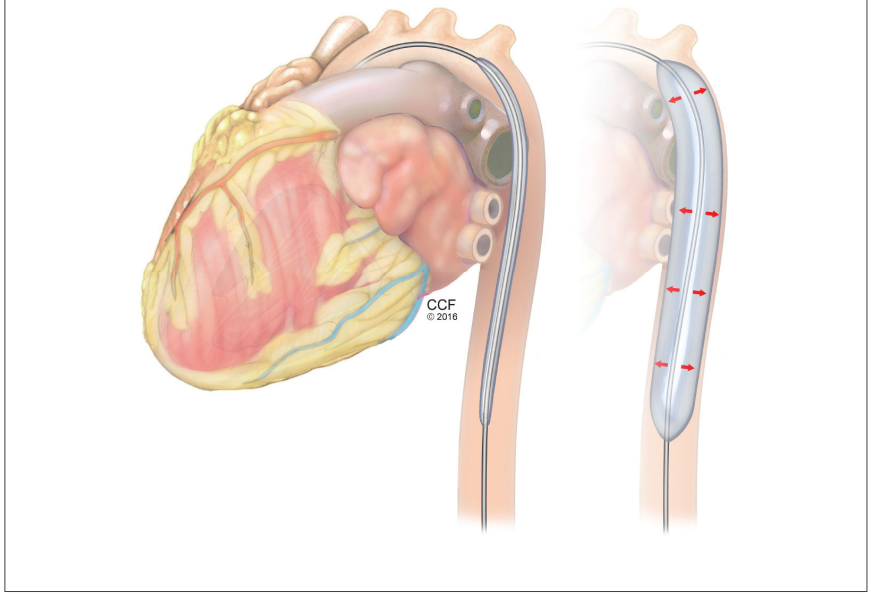


Figure 3 Percutaneous assist devices in cardiogenic shock. (*A*) Intra-aortic balloon counterpulsation; (*B*) Impella® pump; (*C*) TandemHeart™; (*D*) extracorporeal membrane oxygenation (ECMO). Modified from Thiele *et al.*[30]

13

Intra-Aortic Balloon Pump

Cleveland Clinic Journal of Medicine. 2017 April;84(4):287-295



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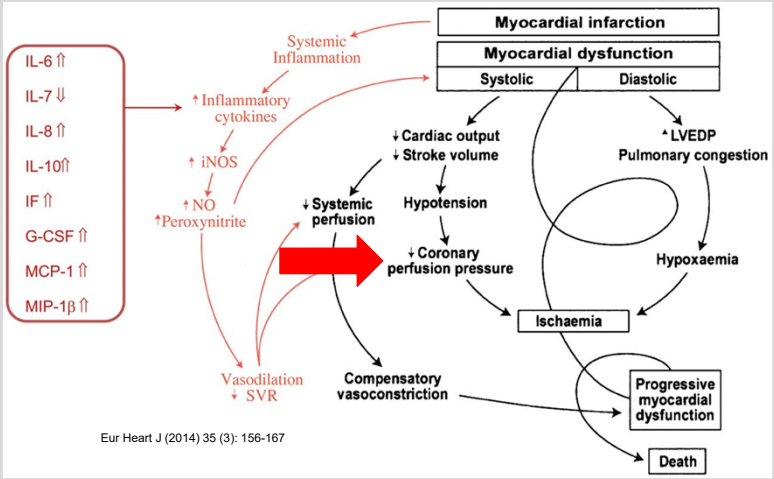
Cardiogenic Shock: IABP



Eur Heart J (2014) 35 (3): 156-167

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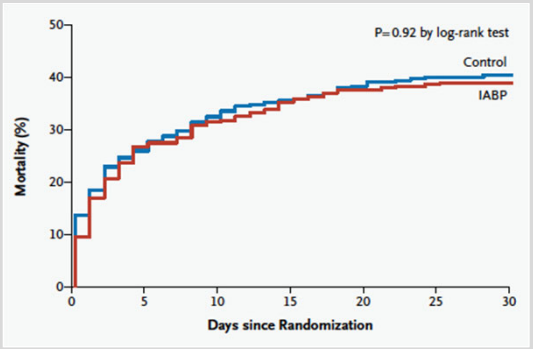
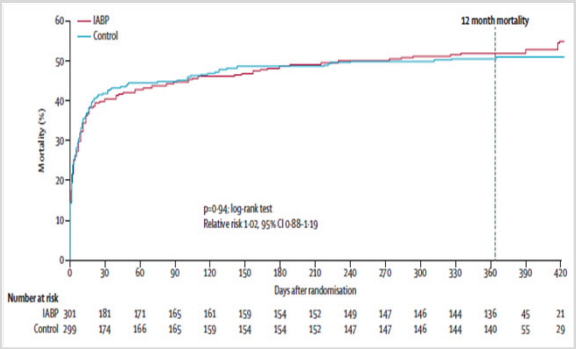
IABP: SHOCK II Trial Outcomes





Thiele et al. NEJM 2012;367:1287-96

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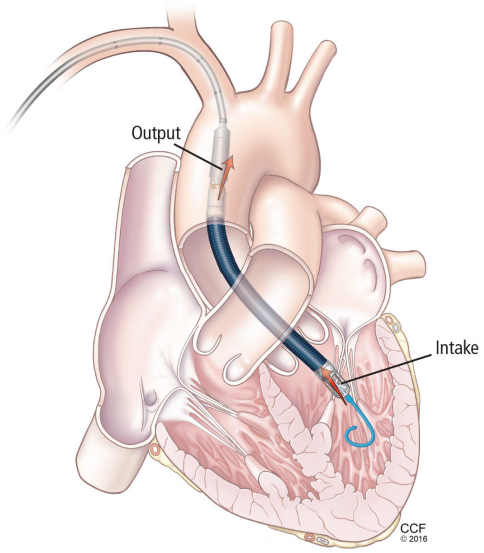

Impella

Cleveland Clinic Journal of Medicine. 2017 April;84(4):287-295

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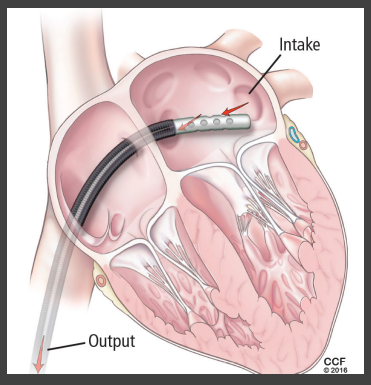

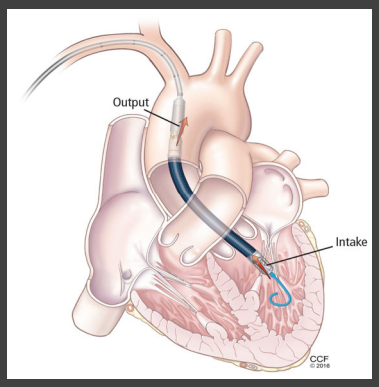

TANDEM HEART

IMPELLA

Cleveland Clinic Journal of Medicine. 2017 April;84(4):287-295

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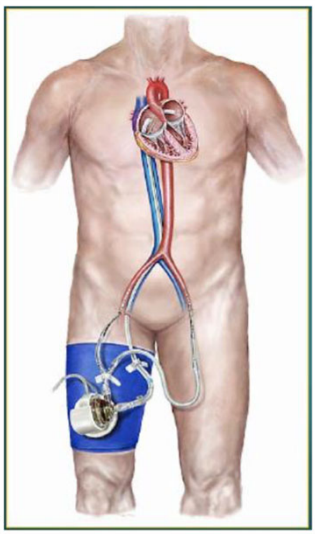
Devices for MCS: Tandem Heart

- Pumps blood extracorporeally from the left atrium (LA) to the iliofemoral arterial system via a trans septal placed left atrial cannula
- 21-F trans-septal cannula, a centrifugal pump, a femoral 19-F arterial cannula, and a control console.
- Reduces LV preload, LV workload, filling pressures, wall stress, and myocardial oxygen demand
- Requires transeptal expertise and additional procedure time



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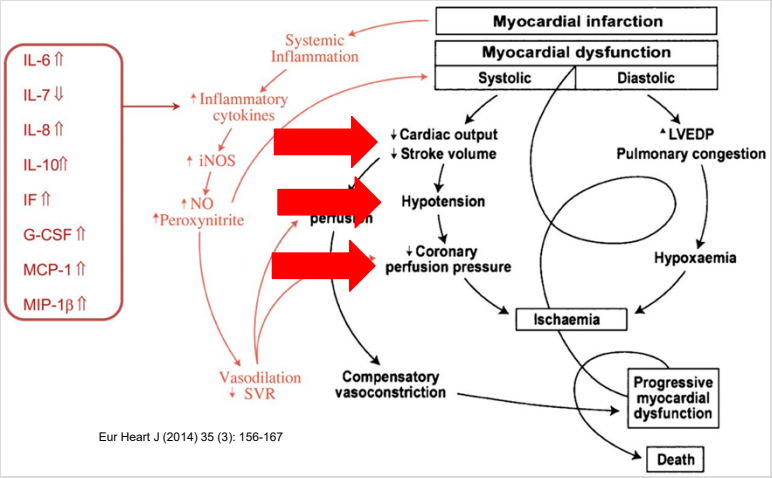
Cardiogenic Shock: Impella



Eur Heart J (2014) 35 (3): 156-167

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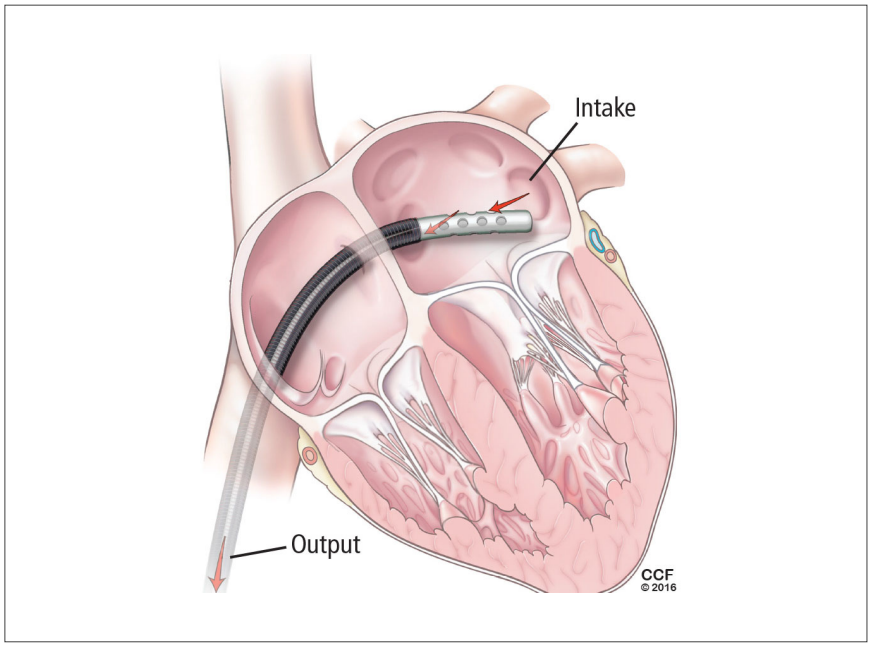
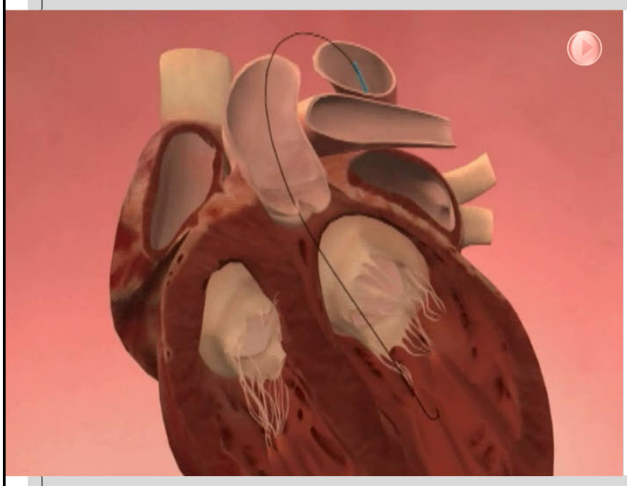
TANDEM HEART

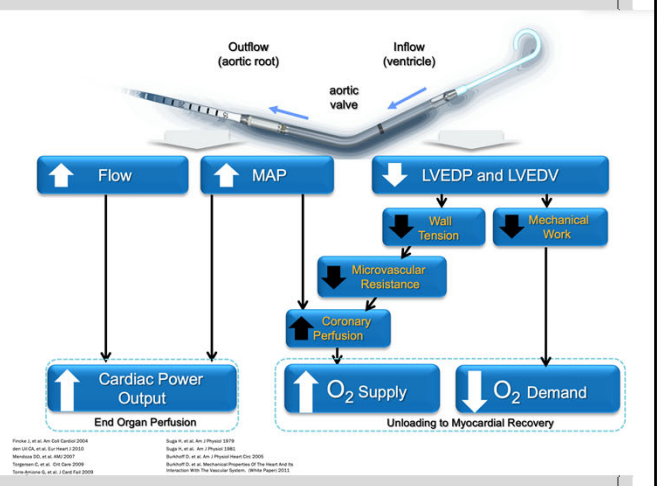
Cleveland Clinic Journal of Medicine. 2017 April;84(4):287-295



21

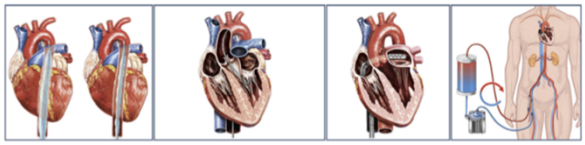
Devices for MCS: IMPELLA





22

FIGURE 1 Comparison of MCS Devices



	IABP	IMPELLA	TANDEMHEART	VA-ECMO
Cardiac Flow	0.3-0.5 L/ min	1-5L/ min (Impella 2.5, Impella CP, Impella 5)	2.5-5 L/ min	3-7 L-min
Mechanism	Aorta	LV → AO	LA → AO	RA → AO
Maximum implant days	Weeks	7 days	14 days	Weeks
Sheath size	7-8 Fr	13-14 Fr Impella 5.0 - 21 Fr	15-17 Fr Arterial 21 Fr Venous	14-16 Fr Arterial 18-21 Fr Venous
Femoral Artery Size	>4 mm	Impella 2.5 & CP - 5-5.5 mm Impella 5 - 8 mm	8 mm	8 mm
Cardiac synchrony or stable rhythm	Yes	No	No	No
Afterload	↓	↓	↑	↑↑↑
MAP	↑	↑↑	↑↑	↑↑
Cardiac Flow	↑	↑↑	↑↑	↑↑
Cardiac Power	↑	↑↑	↑↑	↑↑
LVEDP	↓	↓↓	↓↓	↔
PCWP	↓	↓↓	↓↓	↔
LV Preload	---	↓↓	↓↓	↓
Coronary Perfusion	↑	↑	---	---
Myocardial oxygen demand	↓	↓↓	↔↓	↔

A structured approach to determine the best adjunctive mechanical circulatory support (MCS) device required involves understanding the mechanisms, technical requirements, and hemodynamic responses of each device. AO = aorta; IABP = intra-aortic balloon pump; LA = left atrium; LV = left ventricle; LVEDP = left ventricular end diastolic pressure; MAP = mean arterial pressure; PCWP = pulmonary capillary wedge pressure; RA = right atrium; VA-ECMO = venoarterial extracorporeal membrane oxygenation.

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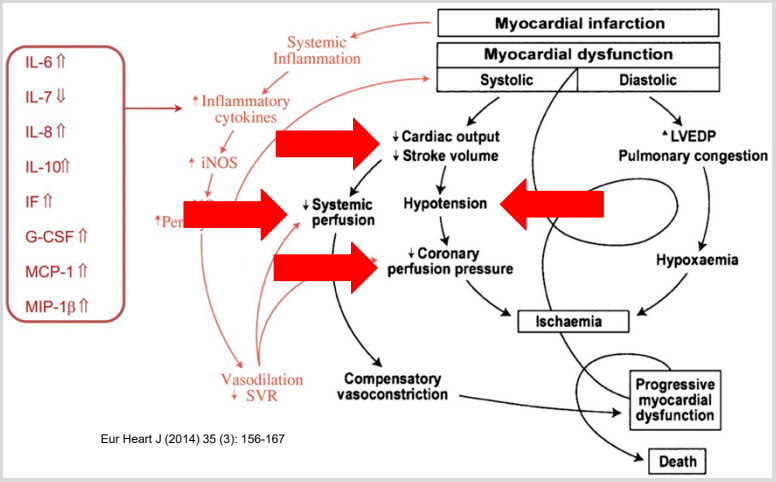
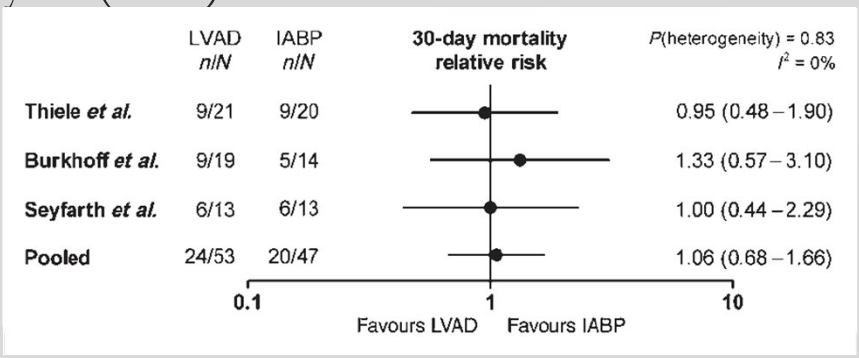
Cardiogenic Shock: pLVAD



Eur Heart J (2014) 35 (3): 156-167

24

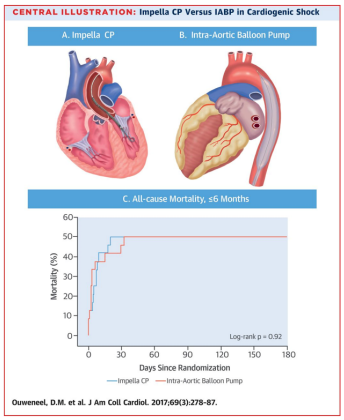
Percutaneous Assist Devices in CS: A Meta-analysis (n=3)



Cheng et al. European Heart Journal (2009) 30, 2102–2108

25

IMPRESS Trial: IABP vs Impella CP



Dagmar M. Ouweneel et al. JACC 2017;69:278-287

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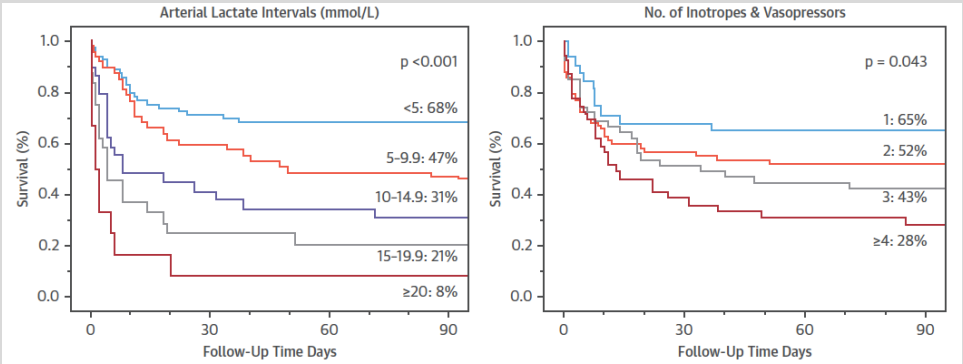
"….Brings a knife to a gunfight"

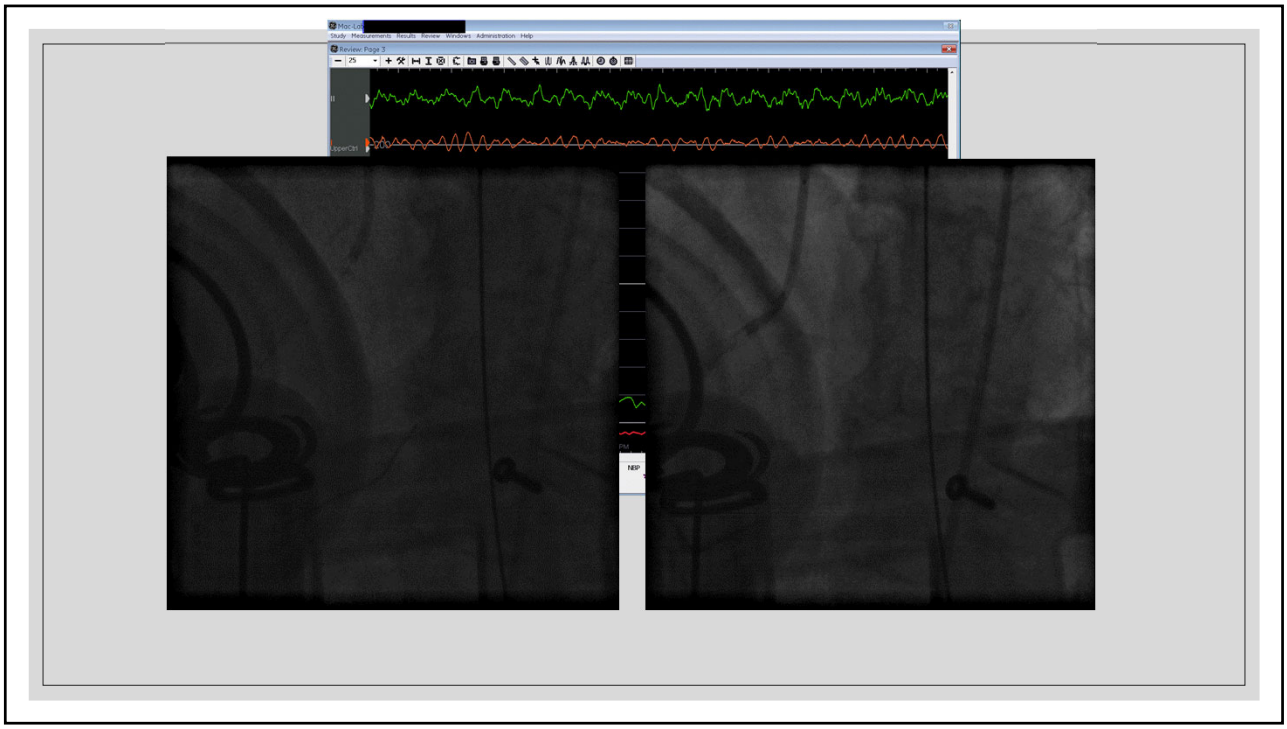
27

Cardiogenic Shock



Fux et al. J Am Coll Cardiol. 2017 Oct 17;70(16):2094-2096

28



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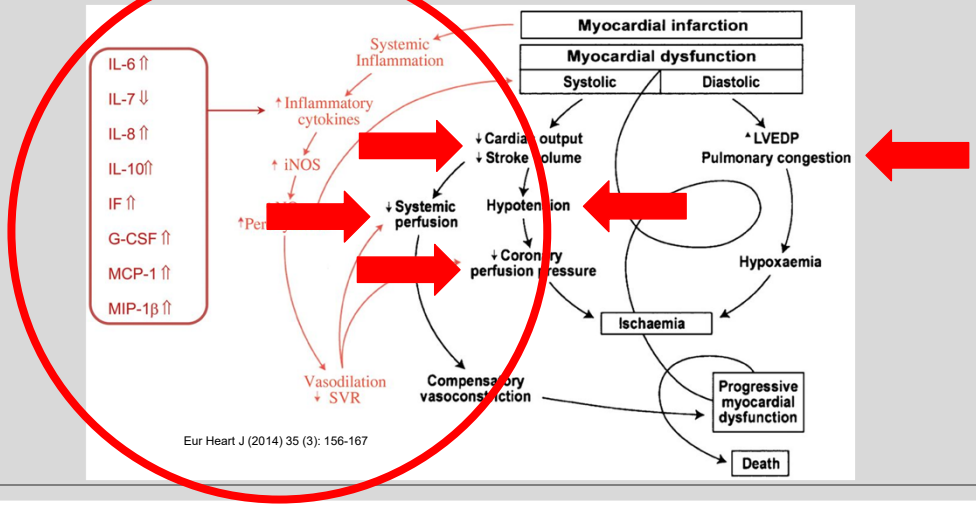
Cardiogenic Shock



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Cardiogenic Shock Dysfunction Syndrome (MODS)

Cardiogenic Shock

- NOT simply due to a decrease in cardiac contractile function
- A multiorgan system dysfunction syndrome (MODS)
  - Resulting from refractory peripheral tissue hypoperfusion and microcirculatory dysfunction
  - Systemic inflammatory response syndrome (SIRS)
  - Vasodilatory response
  - Sepsis syndrome
- Once MODS develops it is difficult to reverse
  - Increasing cardiac output is insufficient
  - Aggressive MCS devices placed in a timely fashion are needed

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Cardiogenic Shock: VA ECMO

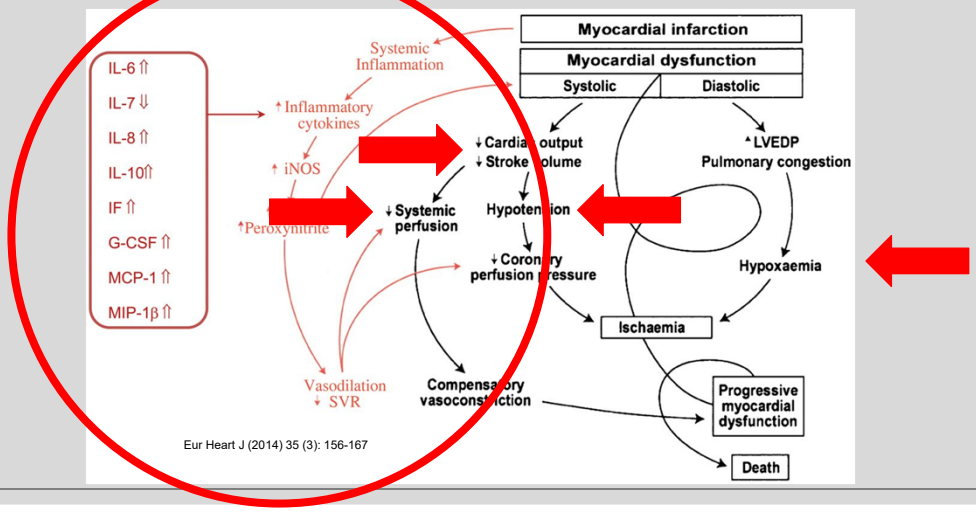

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TABLE 2

Options for short-term circulatory support

	IABP	TandemHeart	Impella 2.5	Impella CP, 5.0	ECMO	CentriMag
Circulatory support	15%	30%–60%	30%–60%	75%–100%	75%–100%	75%–100%
Insertion	Percutaneous	Percutaneous, septal puncture	Percutaneous	Arterial access	Percutaneous	Sternotomy

ECMO = extracorporeal membrane oxygenation; IABP = intra-aortic balloon pump

Cleveland Clinic Journal of Medicine. 2017 April;84(4):287-295

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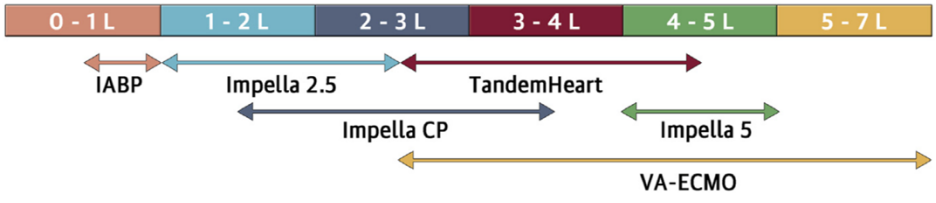
FIGURE 2 Comparison of MCS Devices and Their Impact on Cardiac Flow



Four main families of devices exist for percutaneous MCS, which includes IABP, Impella (Abiomed Inc., Danvers, Massachusetts), TandemHeart (CardiacAssist, Inc., Pittsburgh, Pennsylvania), and VA-ECMO. Each device provides a different level of cardiac flow and device selection should be tailored to the level of support needed. Abbreviations as in Figure 1.

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 9, NO. 9, 2016 MAY 9, 2016:871–83

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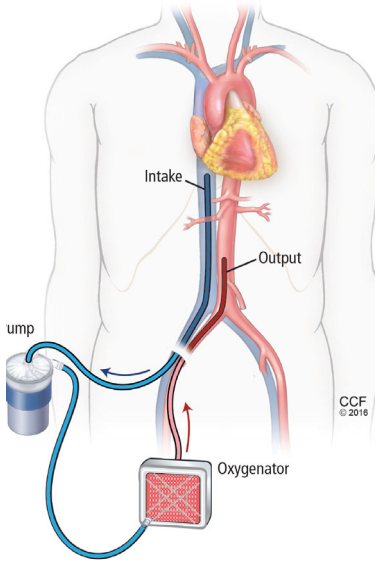

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V-A ECMO

- Centrifugal, nonpulsatile pump for blood propulsion
- Membrane oxygenator for gas exchange
- Venous cannula (25 F)drains deoxygenated blood into a membrane oxygenator for gas exchange
- Oxygenated blood is subsequently infused into the patient via an arterial cannula (15-17F)
- Systemic flows greater than 5L
- Best device in refractory shock

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V-A ECMO

- Hemodynamic effects
  - Systemic flows 5-6L depending on cannula size
  - Rapid correction of deleterious metabolic derangements related to cardiogenic shock
  - Likely the best MCS device for management of MODS
  - Increased myocardial oxygen demand on basis of increased volume and filling pressure
    - Unless LV unloaded (Impella or IABP) or vented (surgical vs. atrial septostomy)

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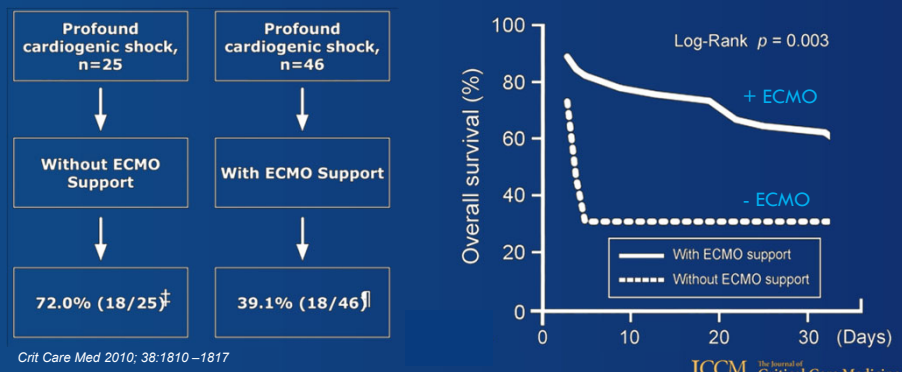
VA ECMO for AMI with Refractory Cardiogenic Shock

Profound Shock
SBP < 75 mmHg + IABP + Dopamine > 60 mcg/kg/min



Crit Care Med 2010; 38:1810 –1817

JCCM The Journal of Critical Care Medicine

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Cardiogenic Shock

- AMI etiologies
  - Acute LV/RV dysfunction and systolic pump failure
  - Acute structural complications
- Non AMI etiologies
  - End stage non-ischemic CM
  - Post-cardiotomy syndrome
  - Acute allograft failure
  - Acute myocarditis
  - End stage valvular and structural disease
  - Refractory arrhythmias
  - Massive pulmonary embolism
  - Drug overdose

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Devices for MCS: V-A ECMO

- Contraindications
  - Aortic insufficiency
  - Severe peripheral vascular disease
- Complications
  - Bleeding
  - Thrombosis
  - Embolic events/CVA
  - Vascular complications

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VA ECMO in Refractory Shock and Cardiac Arrest

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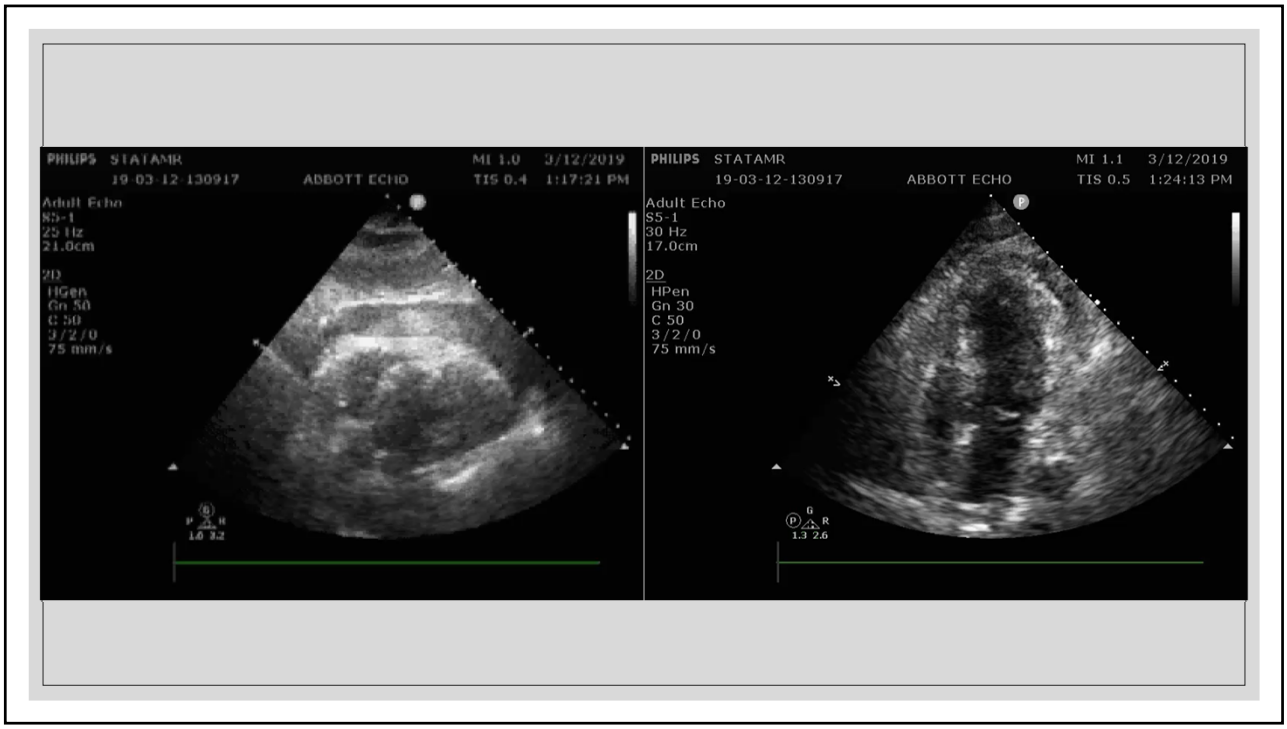
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TIS 0.4
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S5-1
25 Hz
21.0cm
2D
HGen
Gn 50
C 50
3/2/0
75 mm/s
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HPen
Gn 30
C 50
3/2/0
75 mm/s

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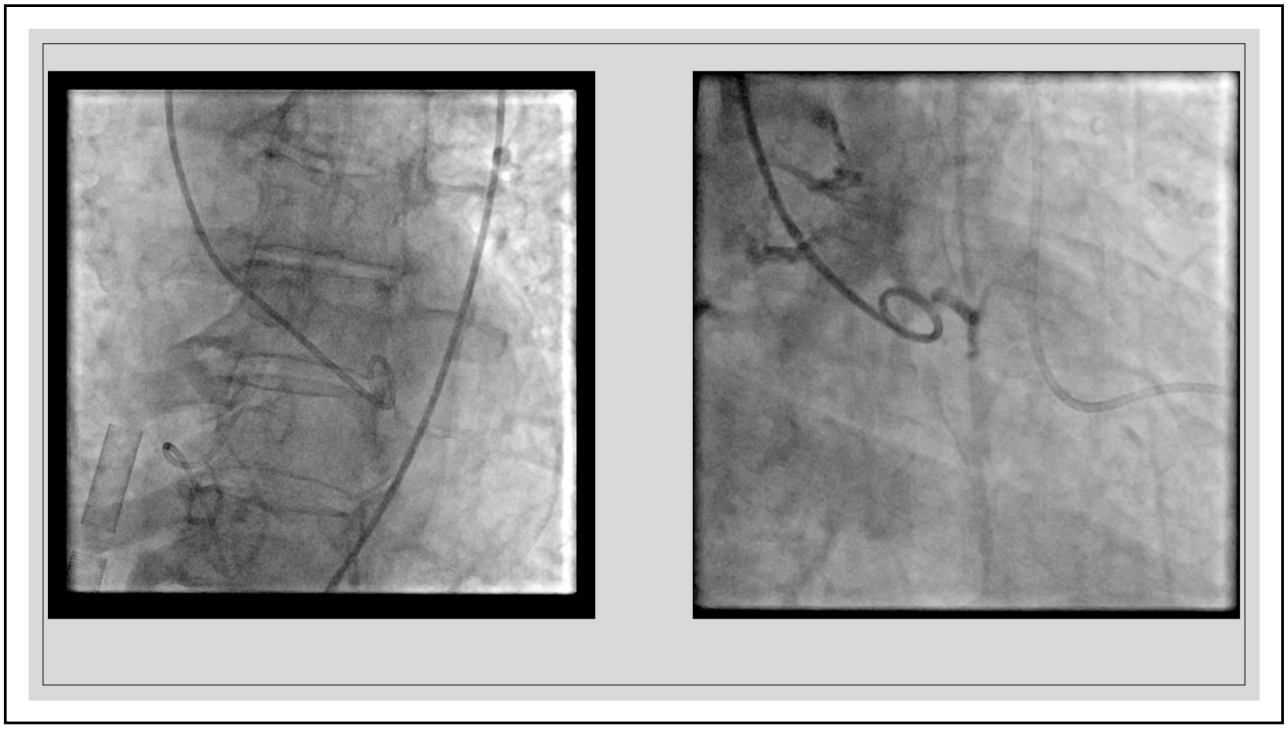

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VA ECMO

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VA ECMO Challenges

- Peripheral Vascular Disease
- Lower Limb Ischemia
- Left Ventricular (LV) Overload and Pulmonary Edema
- Differential Oxygenation (Harlequin Syndrome)

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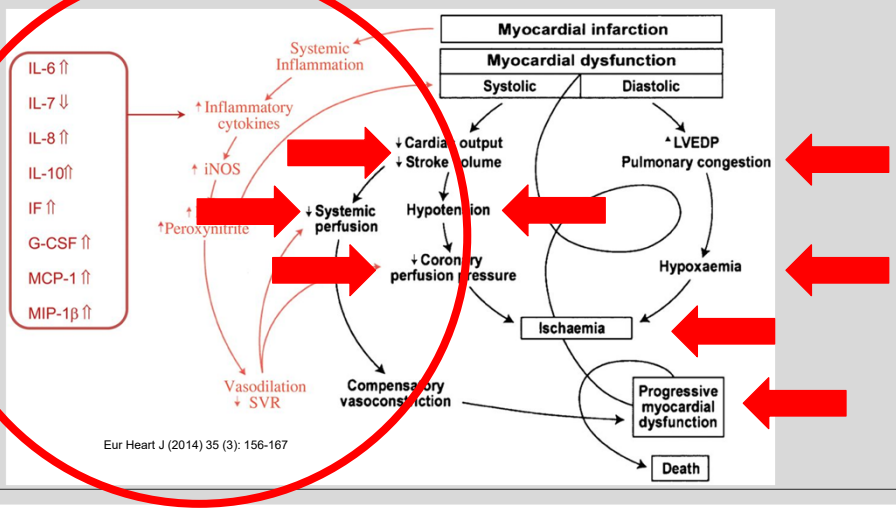
Cardiogenic Shock: VA ECMO



Eur Heart J (2014) 35 (3): 156-167

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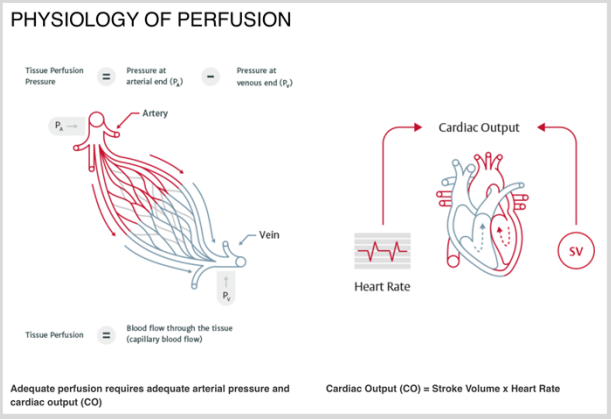
Coronary Tissue Perfusion

- Microvascular resistance
- Pressure gradient
  - Aortic pressure (MAP)
  - Coronary sinus (CS)/right atrial (RA) pressure
- Left ventricular end diastolic pressure (LVEDP)



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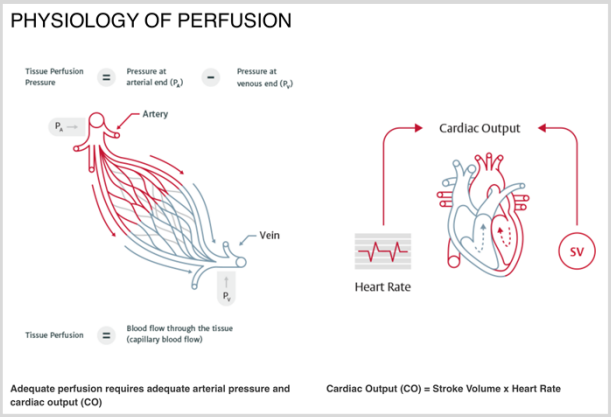
Coronary Tissue Perfusion

- Acute MI
  - Microvascular resistance is high
  - LVEDP is elevated
- Cardiogenic shock
  - Decrease aortic pressure
  - Increase RA pressure
  - Increase in LVEDP
  - Decrease in end organ perfusion pressure



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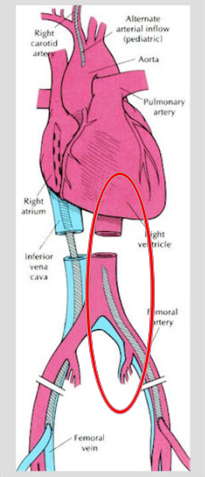
VA ECMO Limitations

- Significant LV mechanical overload
  - Increase myocardial ischemia
  - Increase myocardial oxygen demand
  - Impaired LV recovery
  - Adverse myocardial remodeling
  - Irreversible heart failure
  - LV dilation
  - Increase pulmonary capillary wedge pressure
  - Impaired gas exchange



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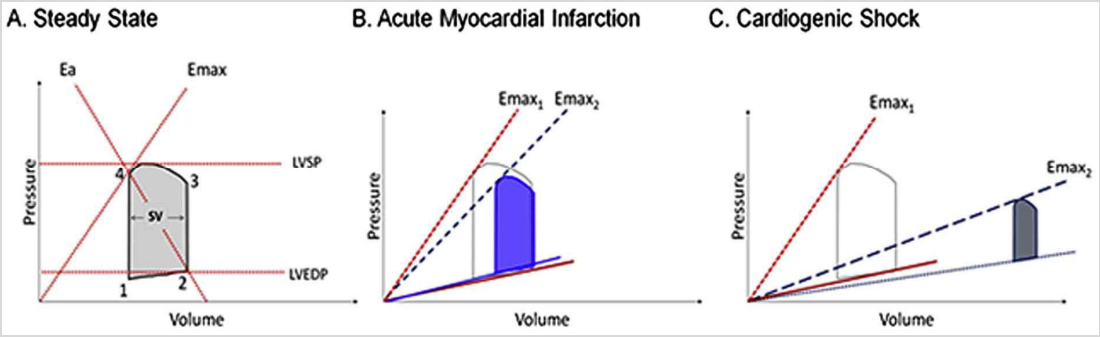
VA ECMO Complications: LV overload



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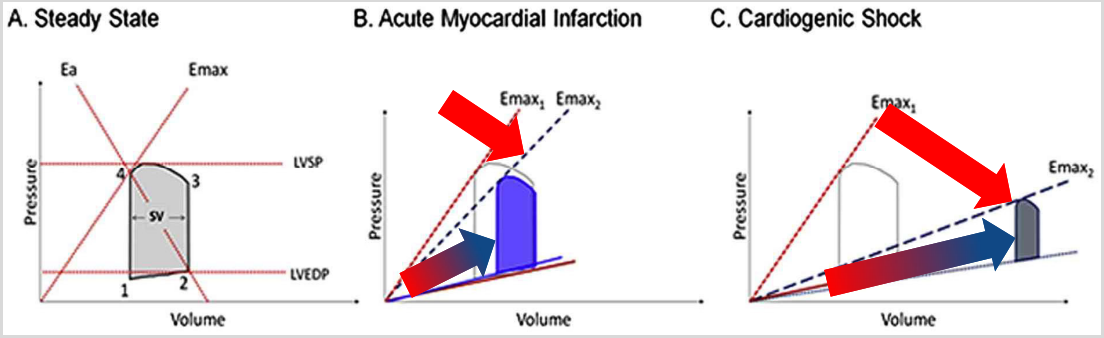
Cardiogenic shock: Physiology



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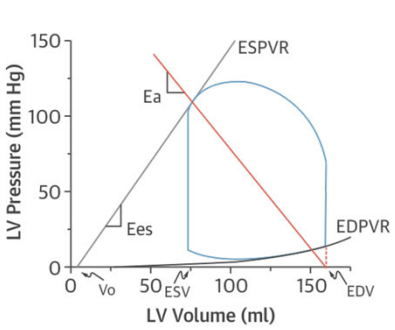
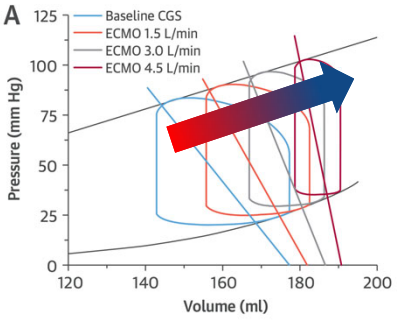
VA ECMO Limitations: LV Overload





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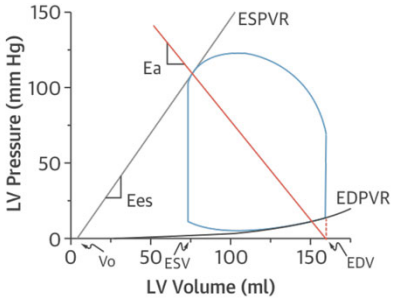
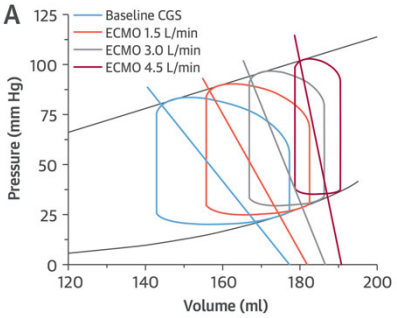
VA ECMO Complications: LV overload



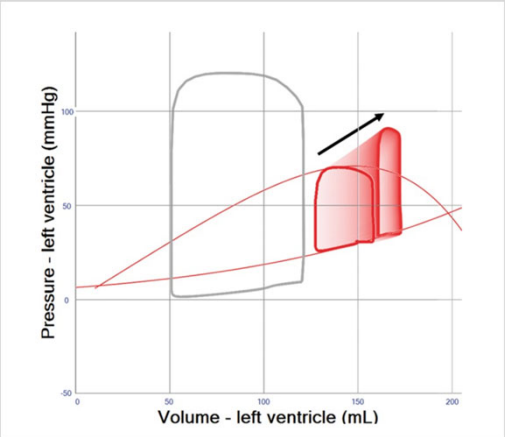


52

VA ECMO Complications: Pulmonary Edema

53

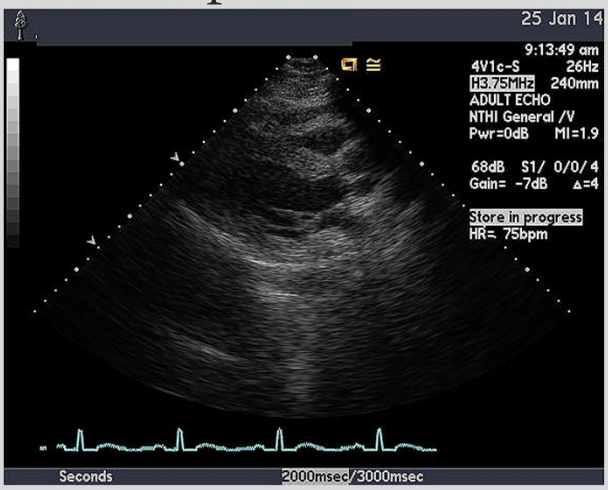
VA ECMO Limitation: LV Overload



D. Donker, D, Brodie, J. Henriques, M. Broomer ASAIO J. 2019 Jan; 65(1): 11–20.

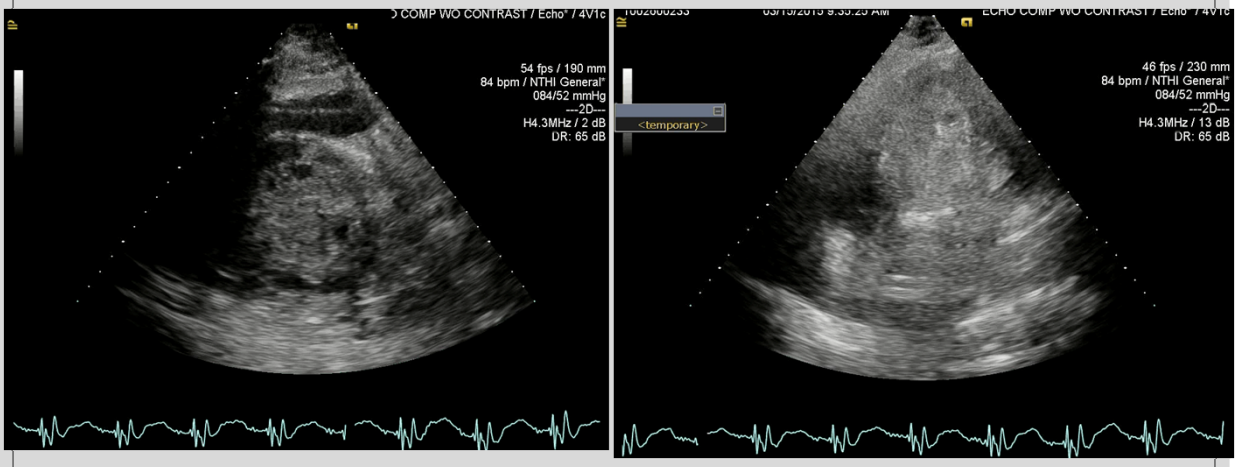
54

VA ECMO Complications:



55

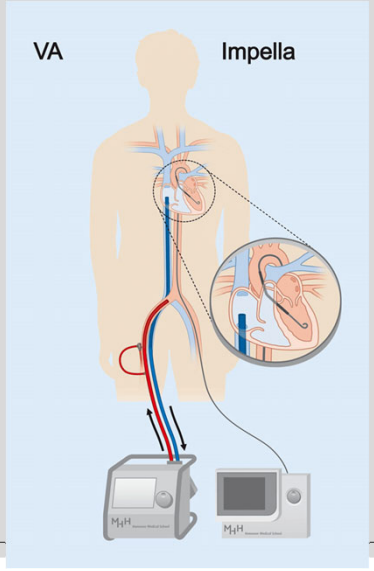
VA ECMO Complications: LV thrombosis



56

VA ECMO Complications: LV overload Strategies

- Decrease ECMO flow
- Improve LV ejection with inotropes
- Unload the LV with vasodilators
- Intra Aortic Balloon Pump
- Atrial Septostomy
- Surgical vent
- Add Impella (ECPELLA)



57

ECMO Cannulation: Avoiding Complication

- Complication rates historically high
  - Major bleeding (40.8%)
  - Lower extremity ischemia (16.9%)
  - Compartment syndrome (10.3%)
  - Amputation (4.7%)
  - Stroke (5.9%)
    - *Cheng, R. et.al.; Ann Thorac Surg* 2014;97:610–616.

58

Cardiogenic Shock: MCS Devices

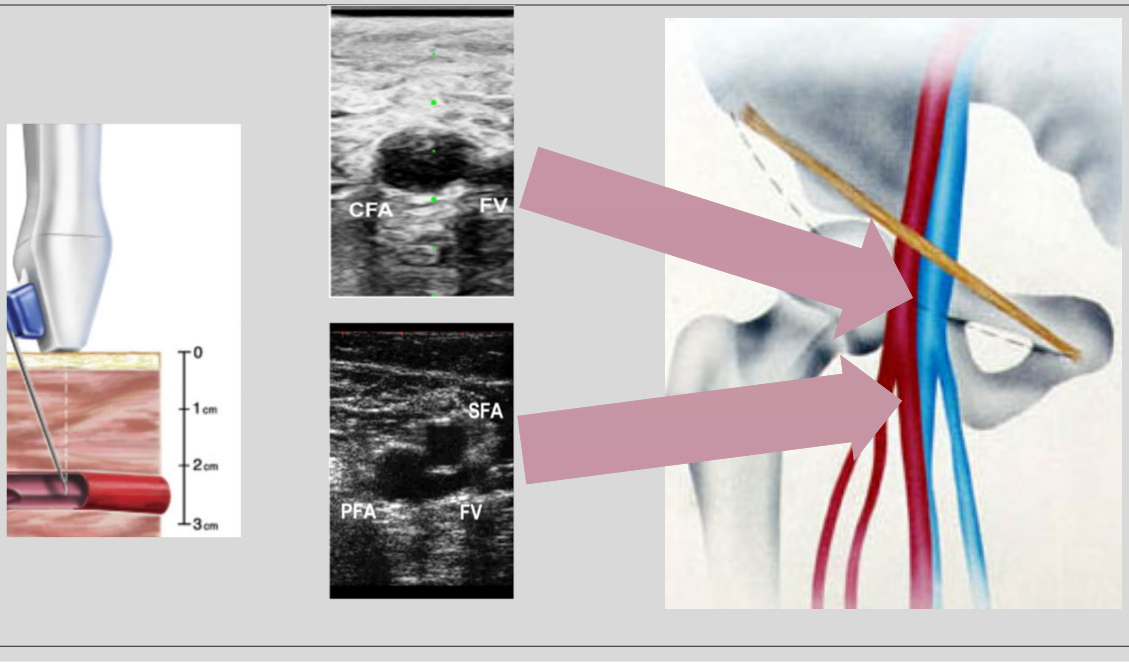
Table 2 Comparison of devices

	IABP	ECMO	TandemHeart	Impella 2.5	Impella 5.0
Pump mechanism	Pneumatic	Centrifugal	Centrifugal	Axial flow	Axial flow
Cannula size	7.9 Fr	18–21 Fr inflow;15–22 Fr outflow	21 Fr inflow; 15–17 Fr outflow	13 Fr	22 Fr
Insertion technique	Descending aorta via the femoral artery	Inflow cannula into the right atrium via the femoral vein, outflow cannula into the descending aorta via the femoral artery	21 Fr inflow cannula into left atrium via femoral vein and transseptal puncture and 15–17 Fr outflow cannula into the femoral artery	12 Fr catheter placed retrogradely across the aortic valve via the femoral artery	21 Fr catheter placed retrogradely across the aortic valve via a surgical cutdown of the femoral artery
Haemodynamic support	0.5 – 1.0 L min^{-1}	>4.5 L min^{-1}	4 L min^{-1}	2.5 L min^{-1}	5.0 L min^{-1}
Implantation time	+	++	+++	++	++++
Risk of limb ischaemia	+	+++	+++	++	++
Anticoagulation	+	+++	+++	+	+
Haemolysis	+	++	++	++	++
Post-implantation management complexity	+	+++	++++	++	++
Optional active cooling in post-cardiopulmonary resuscitation patients	No	Yes	(Yes)	No	No

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; +, ++, +++, ++++, relative qualitative grading concerning time ('implantation time'), risk ('risk of limb ischaemia'), intensity ('anticoagulation', 'post-implantation management complexity'), and severity ('haemolysis'). Modified from Ouweneel and Henriques.[32]

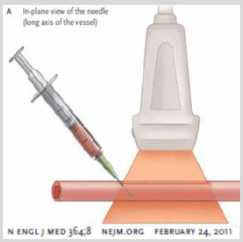
59

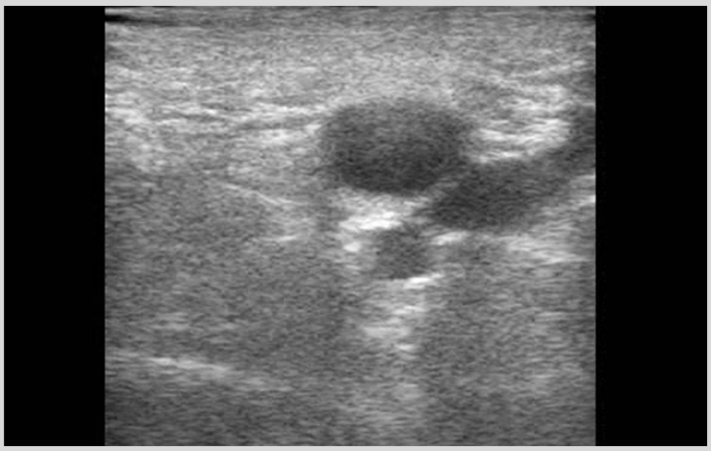
60



61

Vascular Ultrasound





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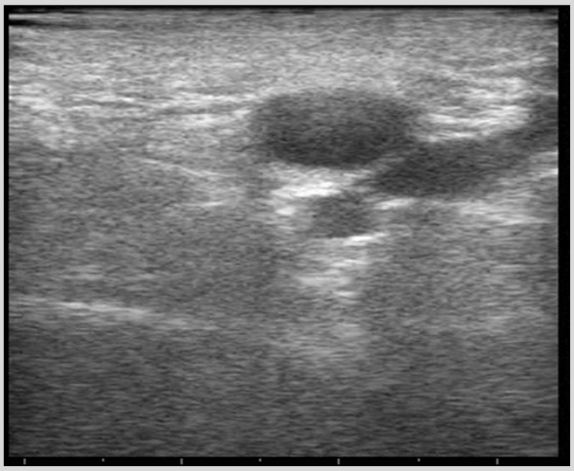
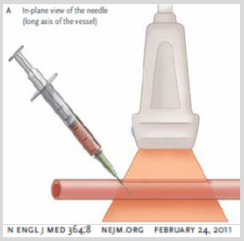
Vascular Ultrasound





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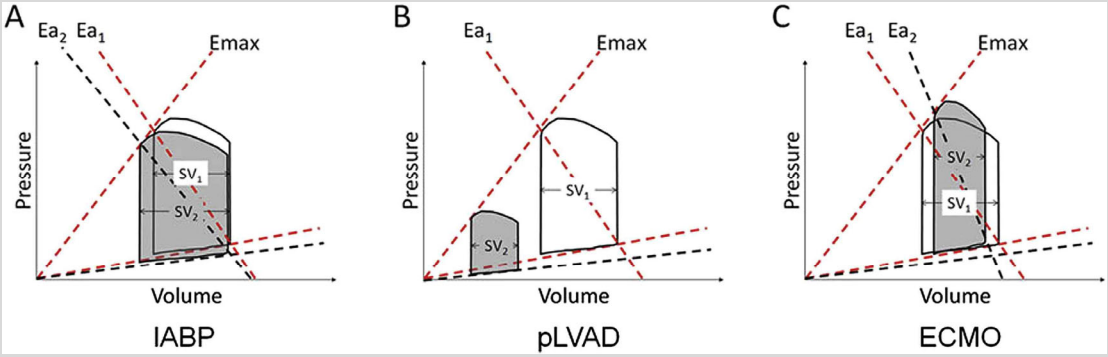
Effects of MCS Devices



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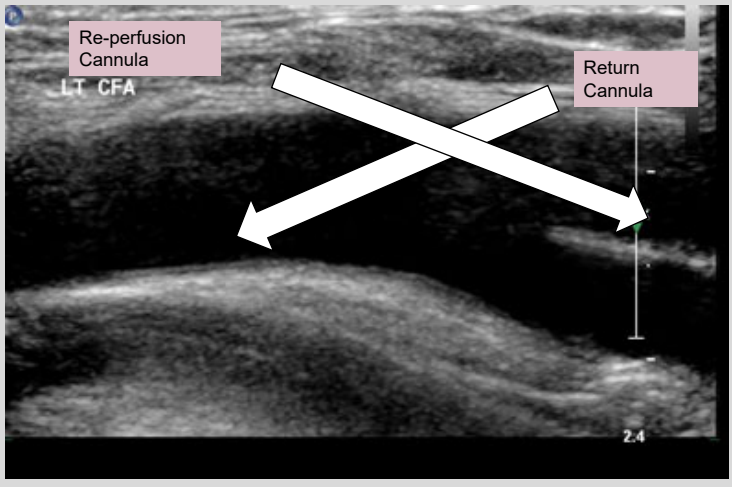
VA ECMO Challenges: Ischemic Lower Limb

- Limb preservation strategies
  - Vascular Surgery consultation
  - Continuous flow doppler of lower extremity
  - Near Infrared Spectroscopy (NIRS)
    - Lower than 40-50%
    - 20% differential compared to contralateral limb
  - Distal perfusion catheter
    - Placed by ultrasound guidance
    - 6 French short armored catheter.
  - Smaller arterial cannulas (No larger than 17 French)
  - Bilateral distribution of arterial and venous cannula

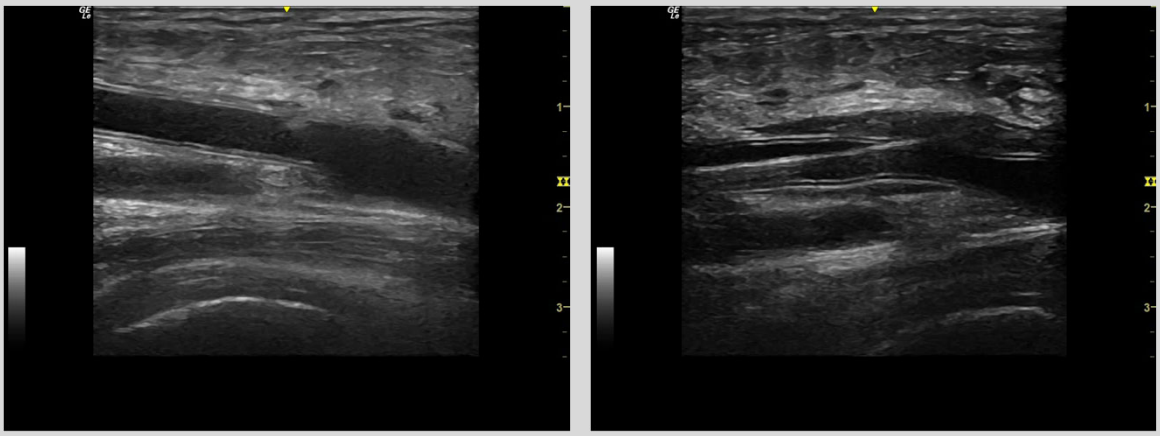
65

Longitudinal Plane Cannula Placement



66

Percutaneous Cannulation: Reperfusion Sheath



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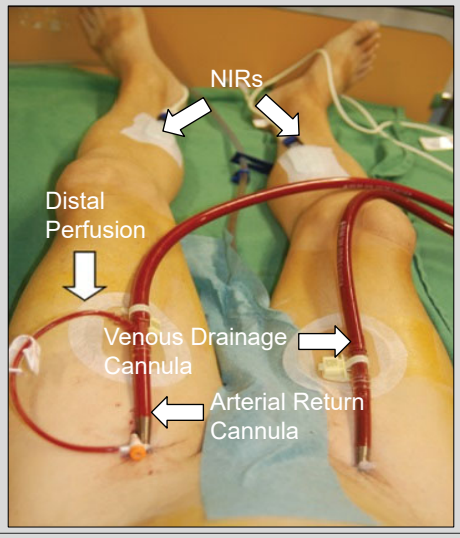
VA ECMO Challenges: Lower Limb Ischemia Strategies



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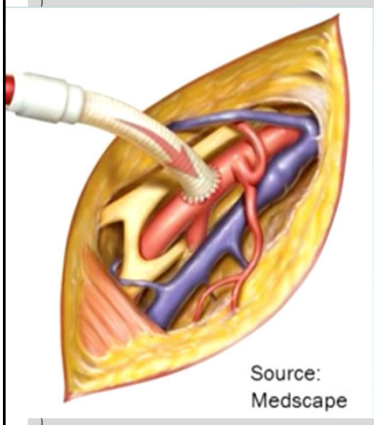
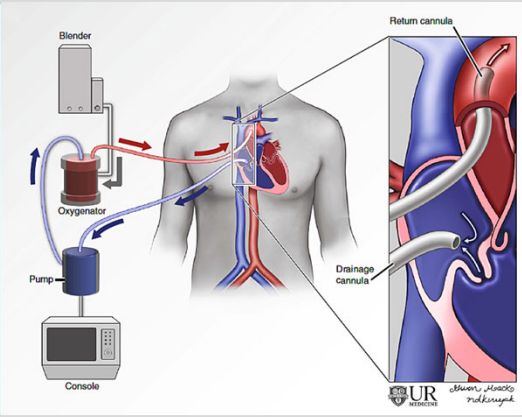
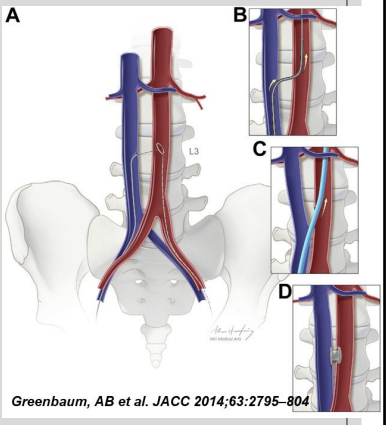
Alternative Cannulation Strategies



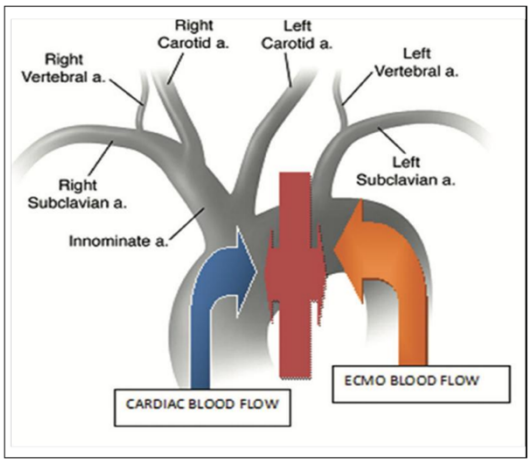


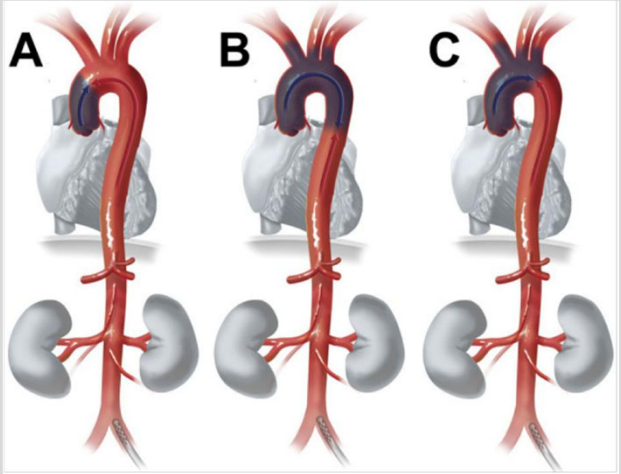


Right Axillary Access | Central Cannulation | Trans-Caval Access

71

VA ECMO Challenges: Differential Hypoxemia





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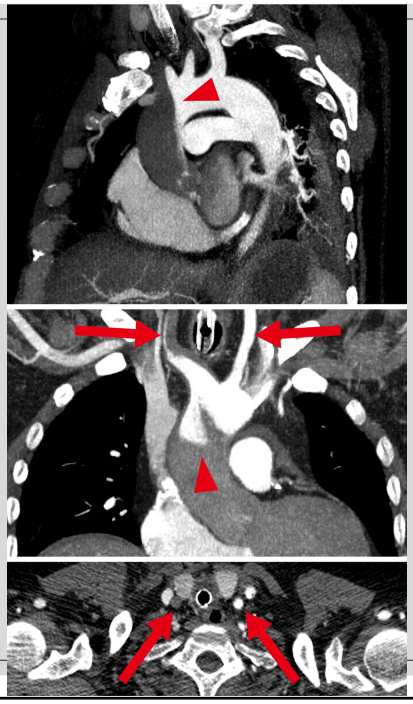

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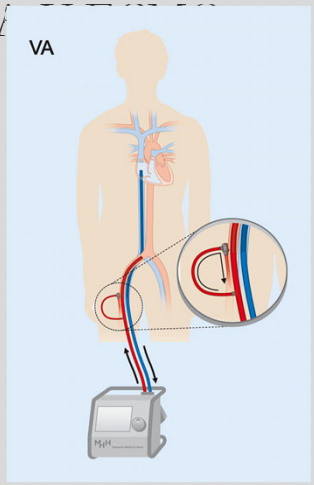
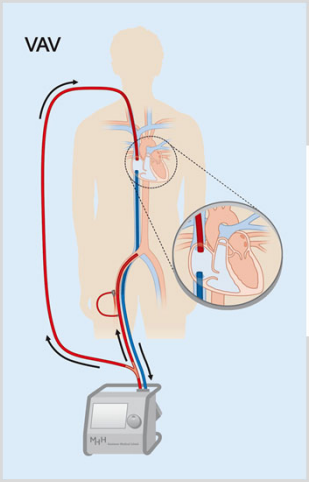
VA ECMO Challenges: Differential Hypoxemia

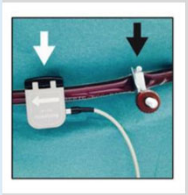
- Potential Strategies
  - Right axillary arterial return cannula
  - Central cannulation
  - Hybrid configuration
    - VA-V ECMO

74

Differential Hypoxemia Management Strategies: Hybrid VA

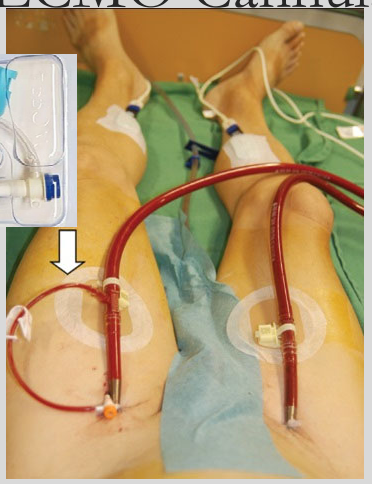






75

Bilateral VA ECMO Cannulation



76

"….Brings a knife to a gunfight"

77

Definition?

- IMPRESS Trial
  - SBP < 90 for 30 minutes
  - Pressors for SBP > 90 min
  - Signs of hypoperfusion
  - All patients intubated
  - 90% cardiac arrest
  - 20 minutes to ROSC
  - 70-80% hypothermia
  - Lactate > 7.8, pH 7.1-7.2
- IABP SHOCK II Trial
  - SBP < 90 for 30 minutes
  - Pressors for SBP > 90 min
  - Signs of hypoperfusion
  - Pulmonary Congestion
  - Lactate > 2.0, altered mental status or UO<30cc/hr

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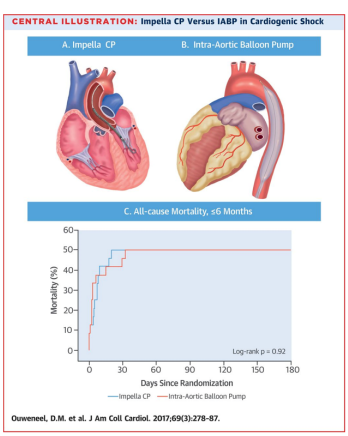
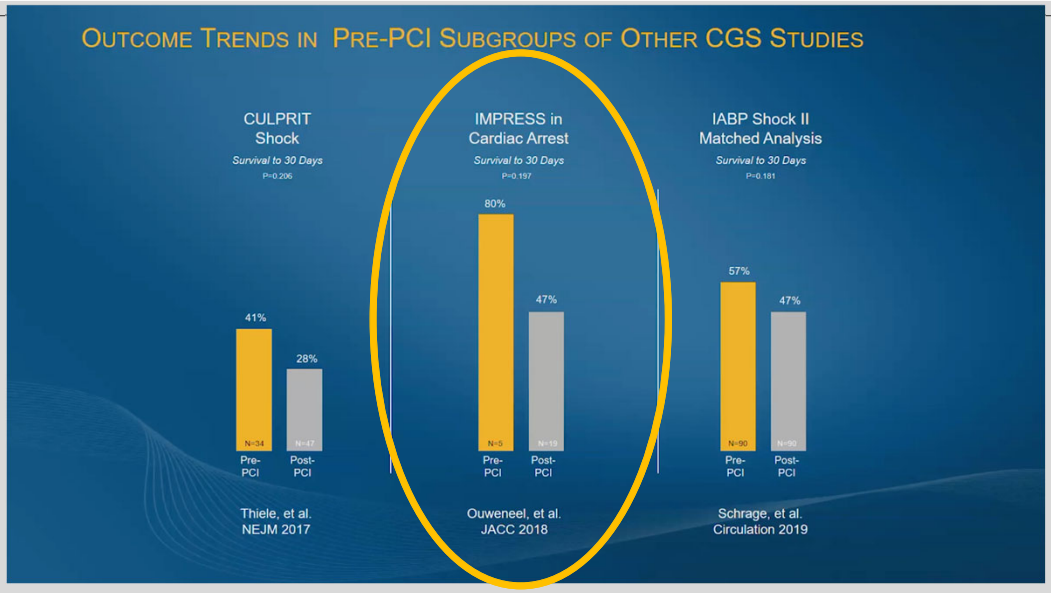
Impella in Cardiac Arrest: IMPRESS Trial



Dagmar M. Ouweneel et al. JACC 2017;69:278-287

79



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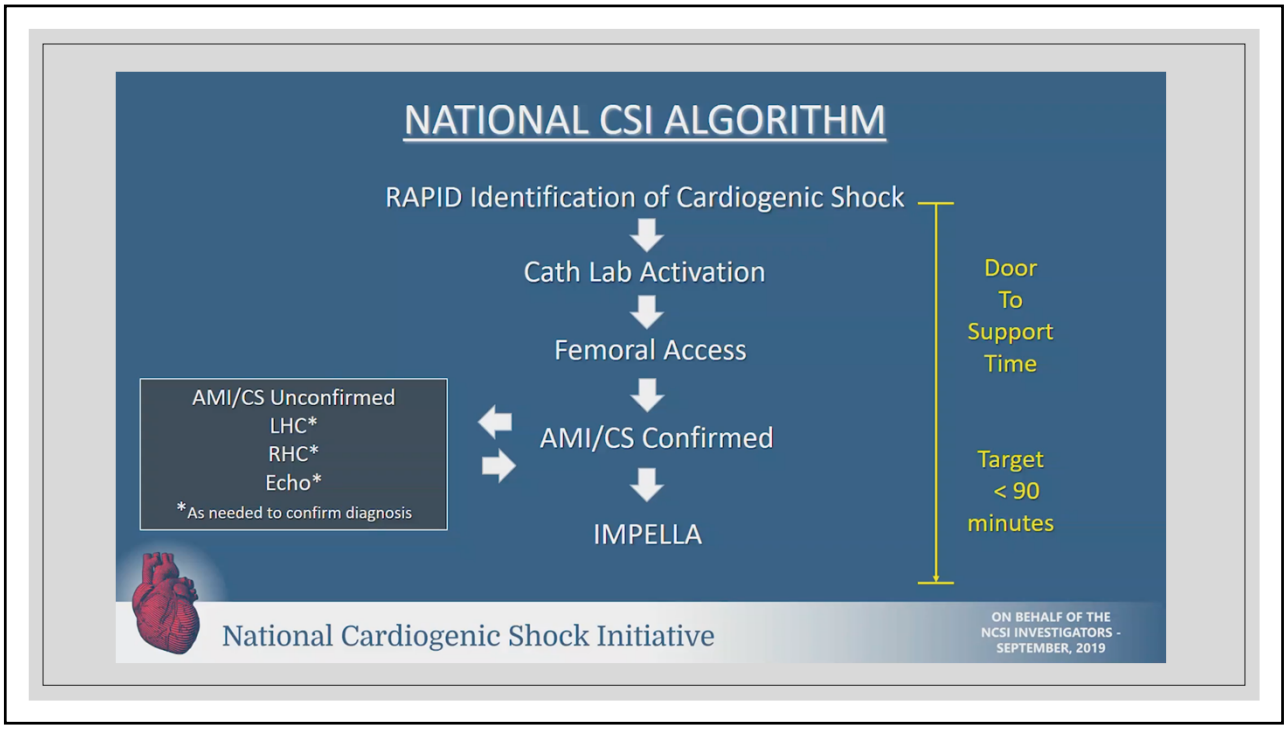
NATIONAL CSI ALGORITHM
RAPID Identification of Cardiogenic Shock
Cath Lab Activation
Femoral Access
AMI/CS Unconfirmed
LHC*
RHC*
Echo*
*As needed to confirm diagnosis
AMI/CS Confirmed
IMPELLA
Door To Support Time
Target < 90 minutes
National Cardiogenic Shock Initiative
ON BEHALF OF THE NCSI INVESTIGATORS - SEPTEMBER, 2019

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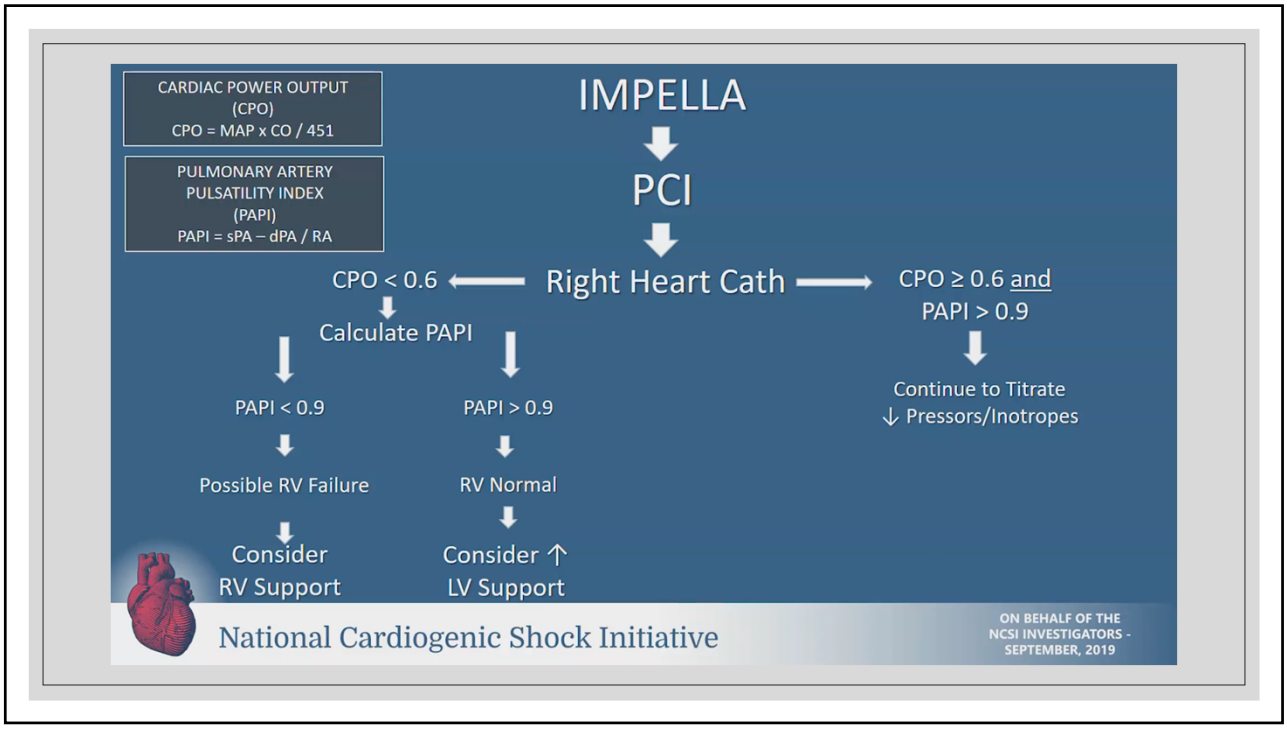
CARDIAC POWER OUTPUT (CPO)
CPO = MAP x CO / 451
PULMONARY ARTERY PULSATILITY INDEX (PAPI)
PAPI = sPA – dPA / RA
IMPELLA
PCI
Right Heart Cath
CPO < 0.6
Calculate PAPI
PAPI < 0.9
Possible RV Failure
Consider RV Support
PAPI > 0.9
RV Normal
Consider ↑ LV Support
CPO ≥ 0.6 and PAPI > 0.9
Continue to Titrate ↓ Pressors/Inotropes
National Cardiogenic Shock Initiative
ON BEHALF OF THE NCSI INVESTIGATORS - SEPTEMBER, 2019

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Variable	Sample Size	Age	Inotropes	Cardiac Arrest	HR	BP	Lactate	Lactate ≥ 2 mmol/l	Survival %
SHOCK	302	66	99	28	102	89/54	N/A	N/A	53
IABP SHOCK	600	70	90	45	92	90/55	4.1	74%	60
Culprit SHOCK	686	70	90	54	91	100/60	5.1	66%	49
DanGer	100	68	94	0	N/A	76/50	5.5	100%	N/A
NCSI	**250**	**63**	**83**	**40**	**90**	**78/51**	**5.3**	**74%**	**72**

National Cardiogenic Shock Initiative

ON BEHALF OF THE NCSI INVESTIGATORS - SEPTEMBER, 2019

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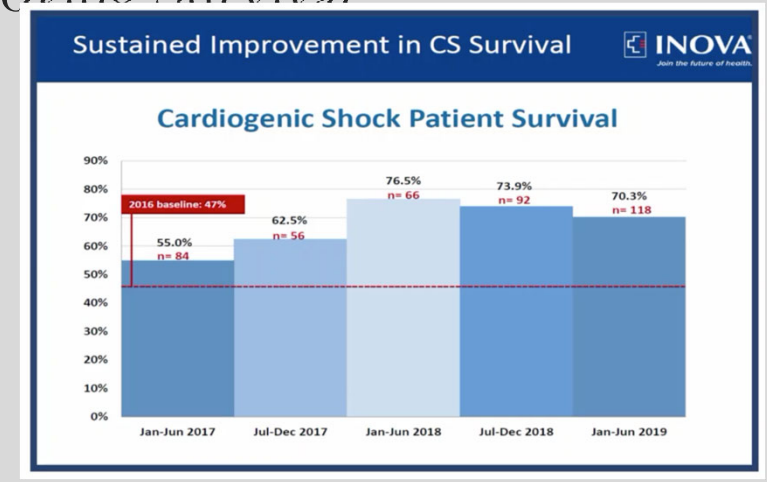
Improving Survival



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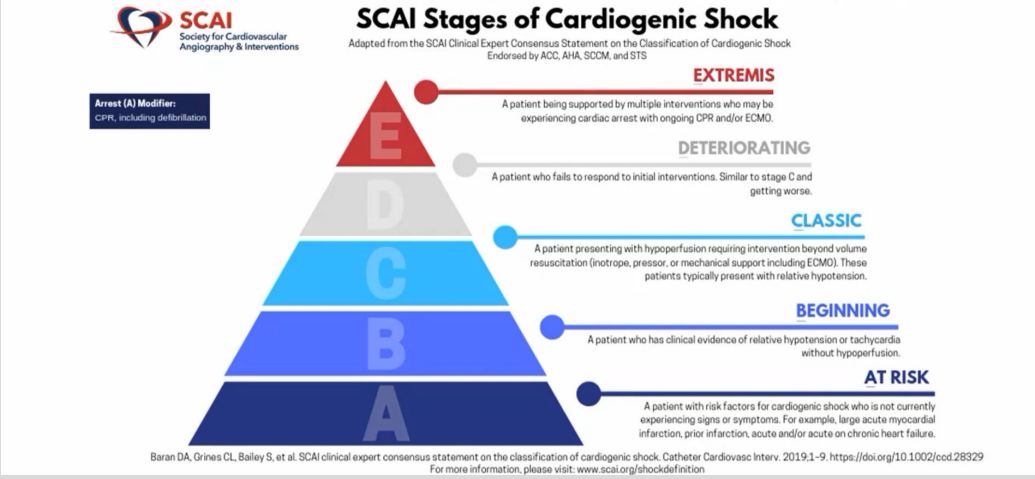
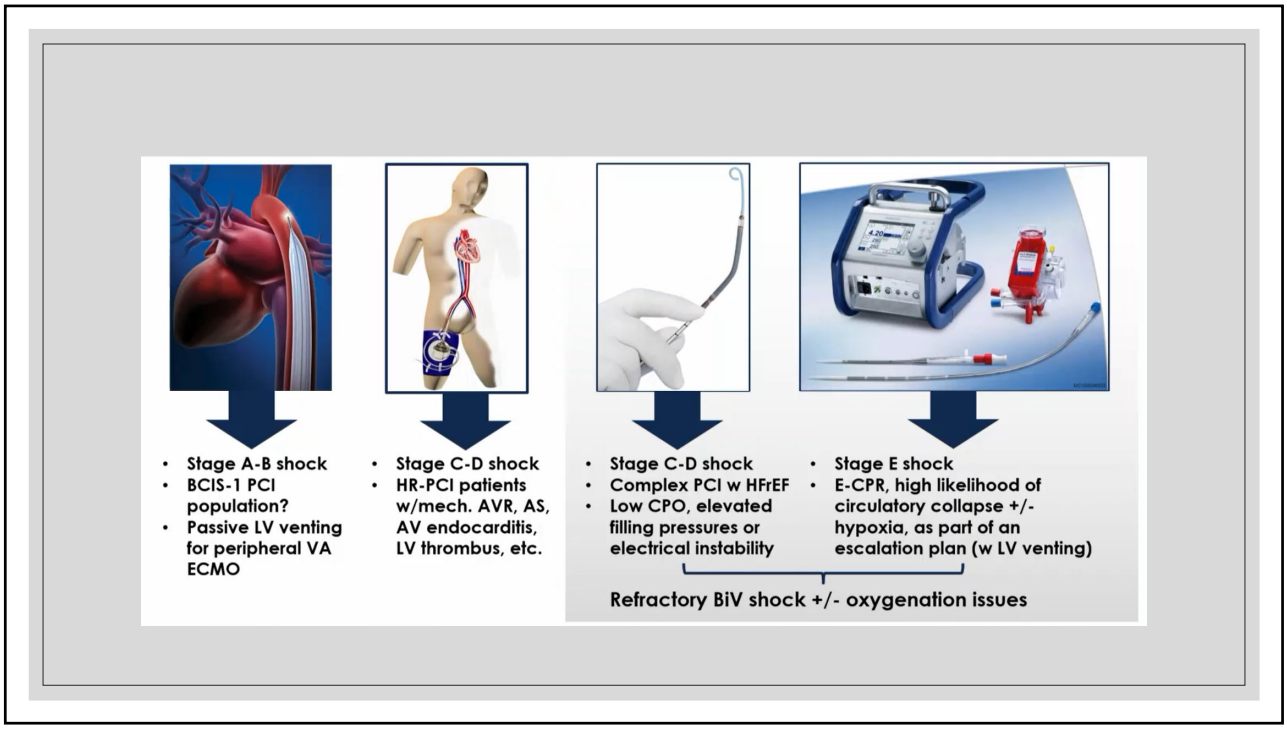
ECMO vs. IMPELLA

85

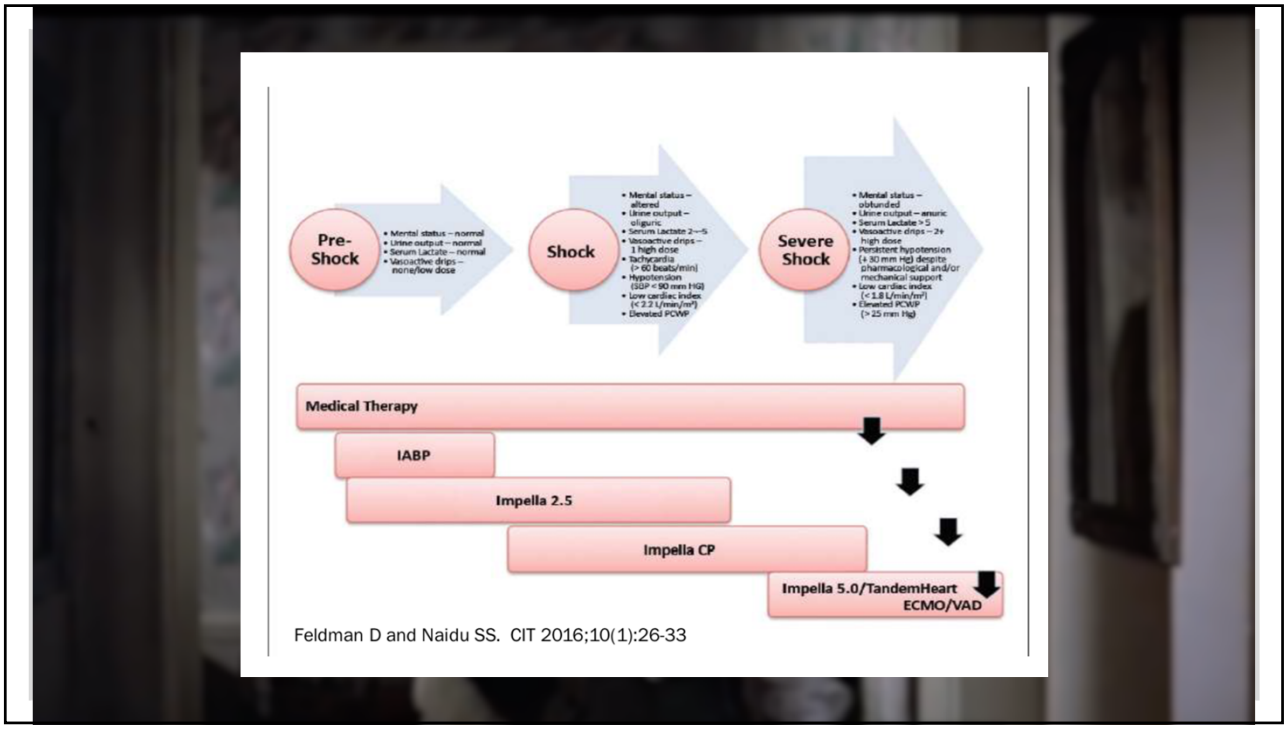
SCAI Stages of Cardiogenic Shock



86


• Stage A-B shock
• BCIS-1 PCI population?
• Passive LV venting for peripheral VA ECMO
• Stage C-D shock
• HR-PCI patients w/mech. AVR, AS, AV endocarditis, LV thrombus, etc.
• Stage C-D shock
• Complex PCI w HFrEF
• Low CPO, elevated filling pressures or electrical instability
• Stage E shock
• E-CPR, high likelihood of circulatory collapse +/- hypoxia, as part of an escalation plan (w LV venting)
Refractory BiV shock +/- oxygenation issues

87


Pre-Shock
Shock
Severe Shock
Medical Therapy
IABP
Impella 2.5
Impella CP
Impella 5.0/TandemHeart ECMO/VAD
Feldman D and Naidu SS. CIT 2016;10(1):26-33

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Devices for MCS: VA ECMO Outcomes

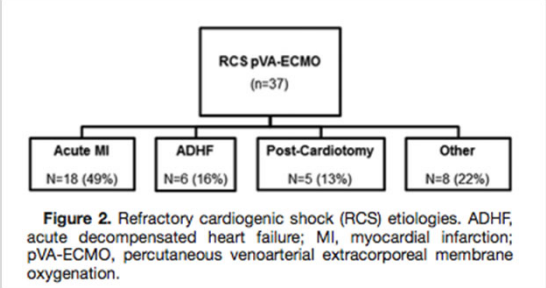

Figure 2. Refractory cardiogenic shock (RCS) etiologies. ADHF, acute decompensated heart failure; MI, myocardial infarction; pVA-ECMO, percutaneous venoarterial extracorporeal membrane oxygenation.

K. Hryniewicz,et.al. *ASAIO Journal* 2016; 62:397–402

30 day survival 65%

1 year survival 57%

Discharged survival 85%

ECPR survival 86%

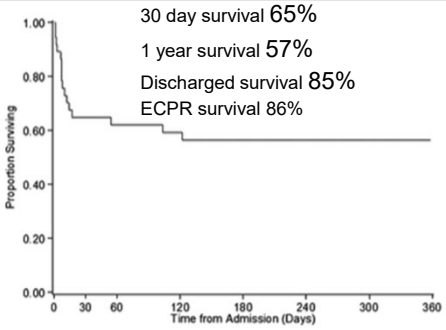

Figure 3. Kaplan–Meir survival curve of patients who underwent percutaneous venoarterial extracorporeal membrane oxygenation for refractory cardiogenic shock (n = 37). Thirty-day survival: 65%.

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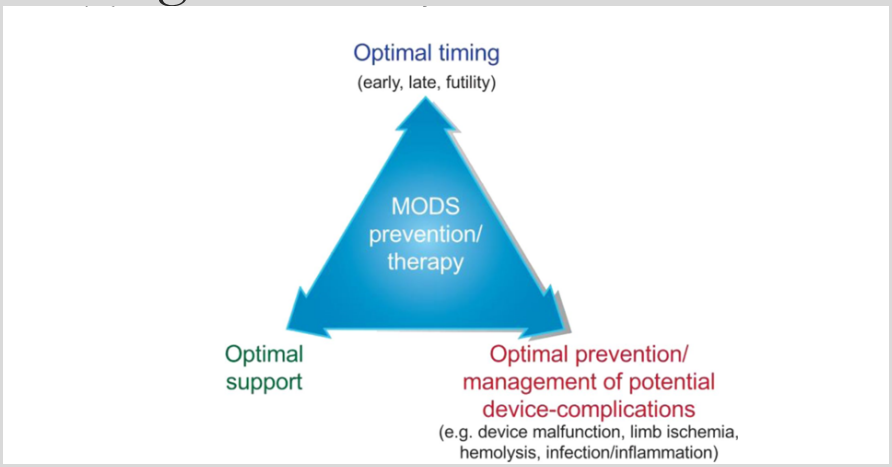
Cardiogenic Shock: Device Selection



Eur Heart J. 2015;36(20):1223-1230.

90

VA ECMO: The Big Gun?

- Provides the best hemodynamic support
- MCS device of choice for stage D and E shock
- Overloads the compromised LV
- Significant bleeding and vascular complications

91

VA ECMO: The Big Gun?

- Don't bring a knife to a gunfight
  - Early recognition using new SCAI definitions
- ECMO is not the only gun!
  - Optimal device selection
- Be careful how you shoot that gun!
  - Complication management

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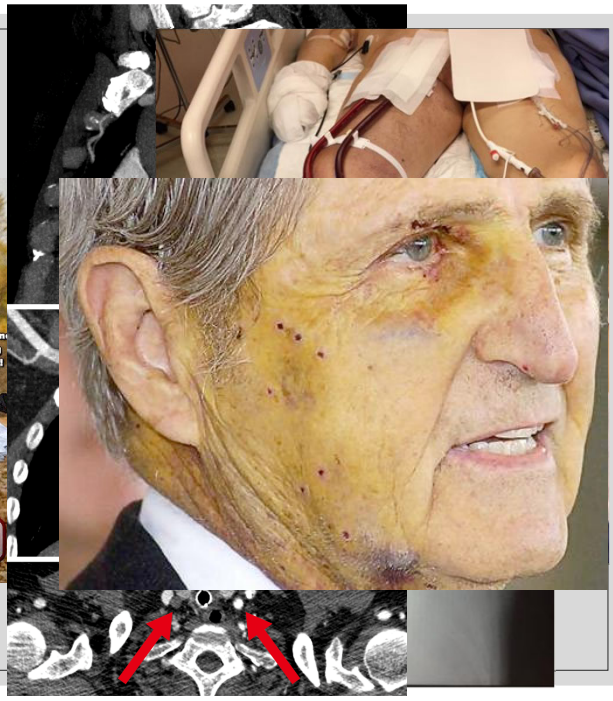
VA ECMO



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VA ECMO Complications

94

Avoiding and Managing Complications of Mechanical Circulatory Support

MHIF CV Grand Rounds
2 November 2020

Yale L Wang, MD FACC FSCAI
Interventional Cardiology

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1

No Disclosures

Minneapolis Heart Institute | Allina Health Abbott Northwestern Hospital | Minneapolis Heart Institute Foundation

2

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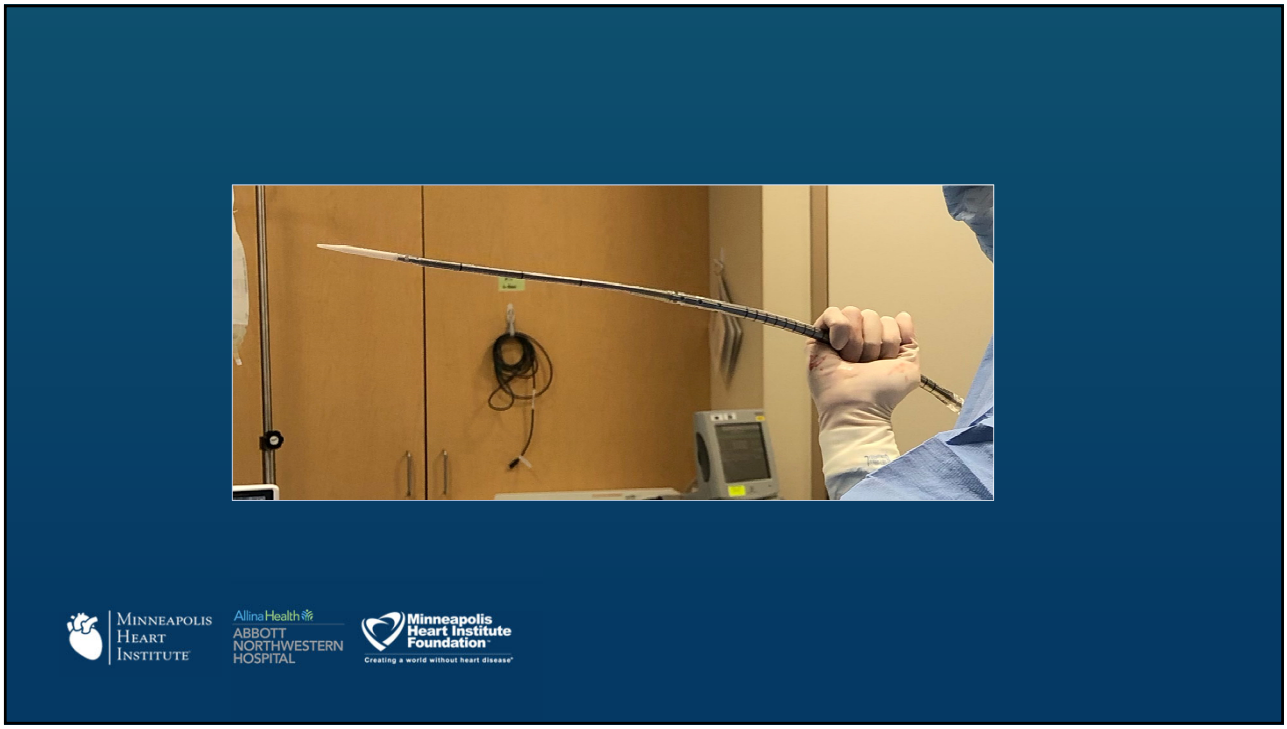
3

GUN CONTROL

4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Minneapolis Heart Institute Foundation
Creating a world without heart disease

5


Cannulas placed in 5 minutes, legs seem OK, crank the flow up to 4L, high five's all around, let's go home. Have a good night Kasia.

6

Greatest tool to minimize complications is a TEAM APPROACH

Advanced heart failure
Interventional Cardiology
Seasoned CV lab or OR team
Perfusion, IABP/Impella teams
CT surgery
Vascular surgery
ECMO Specialist Nurse
Intensivists, CICU nurses

To optimize long term outcome, an even larger team is required

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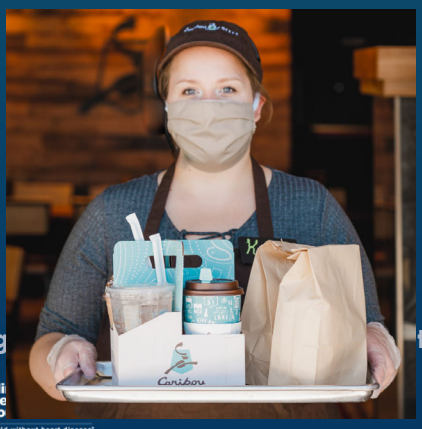
7

Greatest tool to minimize complications is a TEAM APPROACH



To optimize long team is required

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8

Impact of Vascular Complications on Survival

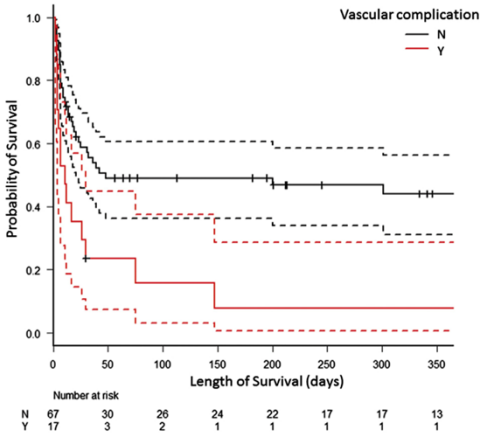
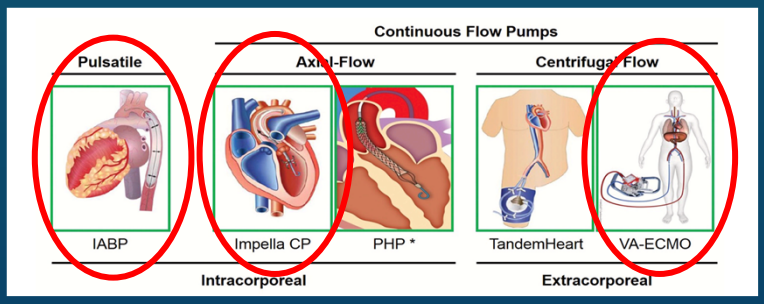


Fig 1. Kaplan-Meier survival curve of patients with (red lines) and without (black lines) vascular complication. Dashed lines show 95% confidence intervals.

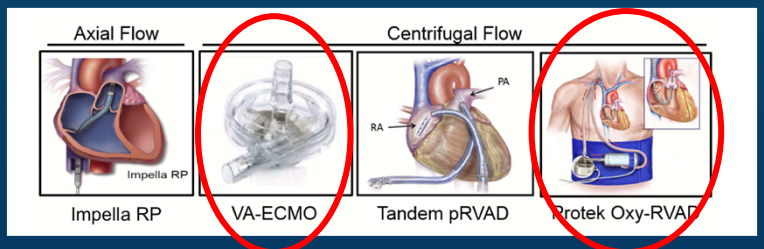
Tanaka et al, Ann Thorac Surg 2016;101:1729-34

9

LV

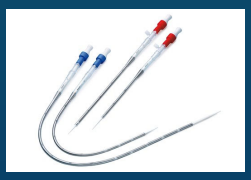


RV



Esposito ML, F1000Research 2017:6:737

10

IABP	Impella	ECMO	Protek Duo
			
7.5-8 Fr	14-22 Fr	Arterial 15-21 Fr Venous 25 Fr	Venous 29-31 Fr

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11

What Can Go Wrong?

Everything: hope for the best, expect (plan for) the worst

- Patient selection
- Vascular
  - Bleeding
  - Ischemia
- IABP, Impella specific complications
- ECMO
  - Mechanical
    - Related to circuit, cannulas
      - Poor flow, thrombosis, bleeding, air
      - Kinking, cannula positioning
  - Hemodynamics
    - LV distension, unloading
  - Harlequin syndrome
- Neurological

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Selection Process (High Risk PCI)

Brilakis, Manual of PCI 2020

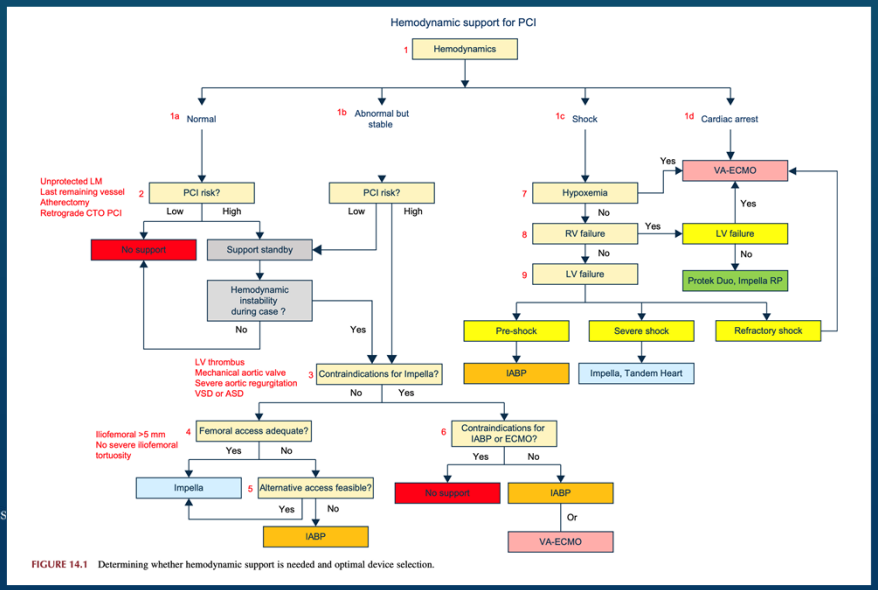

FIGURE 14.1 Determining whether hemodynamic support is needed and optimal device selection.

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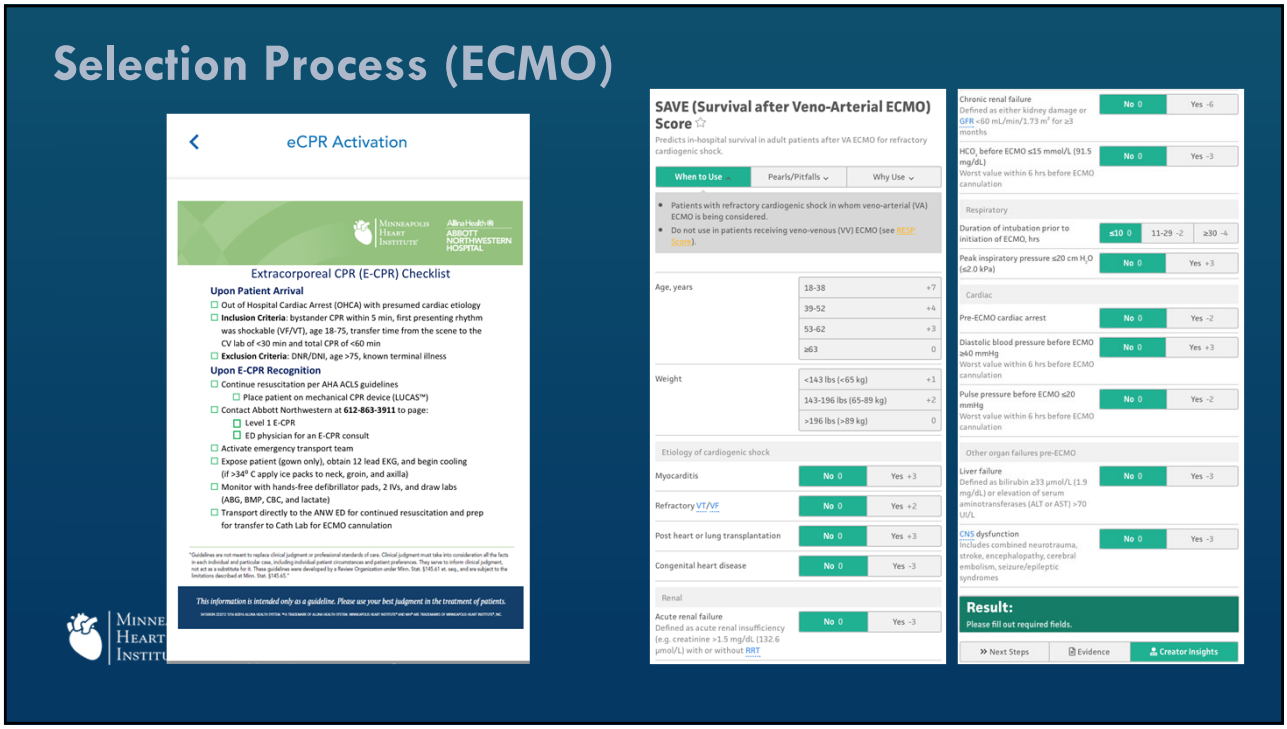
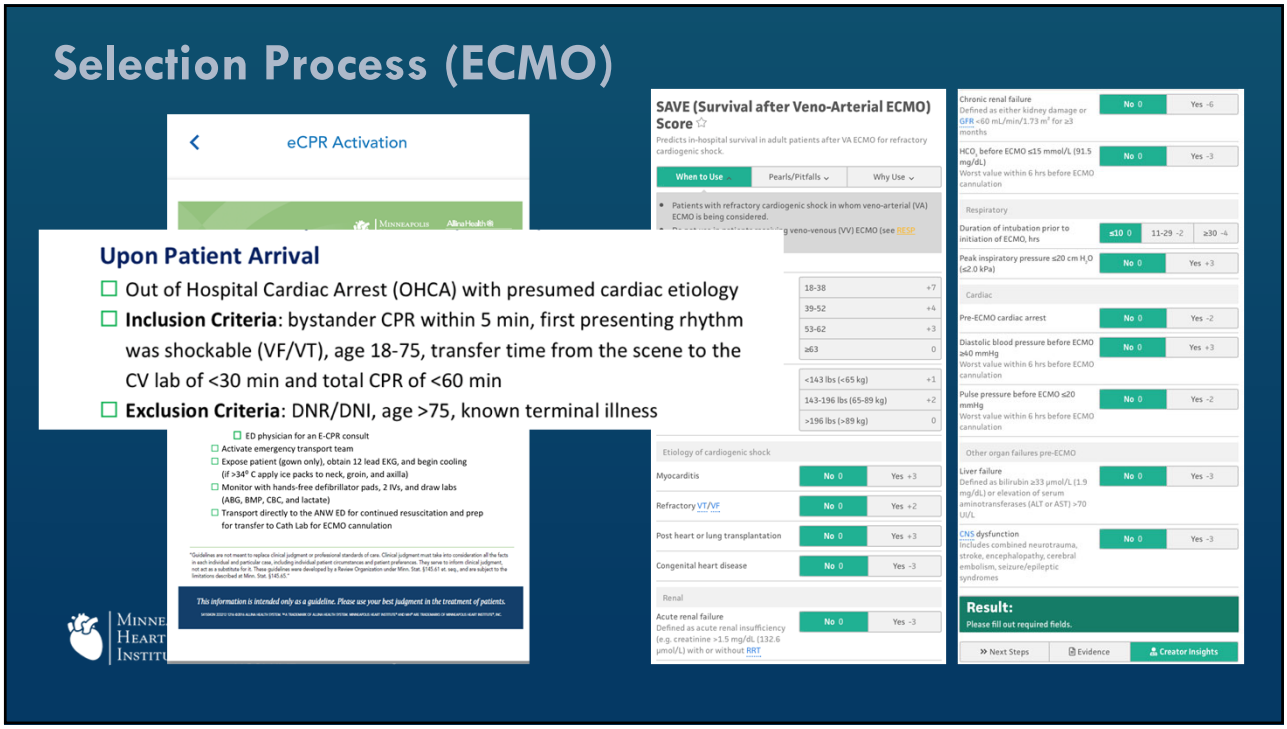
Selection Process (ECMO)



15

Selection Process (ECMO)



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Potential Complications

- **Arterial**
  - Dissection
  - Hematoma
  - Pseudoaneurysm
  - AV fistula
  - Retroperitoneal bleed
  - Embolization (thrombus, air)
  - Compartment syndrome
  - Limb ischemia/loss
  - Death
- **Venous**
  - Thrombosis
  - Hematoma
  - Retroperitoneal bleed
  - AV fistula
  - Death

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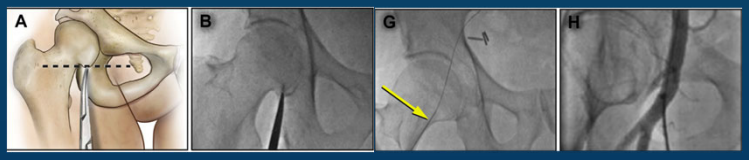
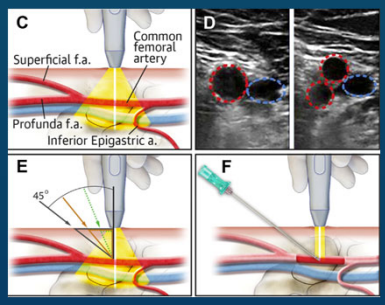
Meticulous Access Technique

- Utilizing
  - Fluoroscopy
  - Ultrasound guidance
  - Micro-puncture access
  - Angiography where indicated
  - Gradual escalation in wire support/stiffness
  - Attempted even in eCPR





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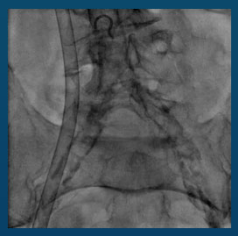
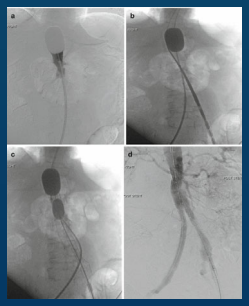
Sandoval et al, JACC Cardiovascular Interventions, 2017;10:12234-41

19

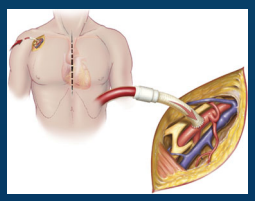
Bail Out for Vascular Catastrophe

- Size for patient, recognizing underlying PAD and vascular limitations
- Great working relationship with our vascular/cardiac surgeons
  - Every VA ECMO come with a vascular surgery consult
- Reasonable understanding of endovascular rescue techniques
  - Use of large balloons in aorta or iliac vessels
  - Coils for perforations
  - Covered stents
  - Thrombectomy
  - Retrieval and snare techniques
- Consider alternative access
  - Subclavian
  - Conversion to contralateral VA cannulation





Arthurs, Ruptured AAA 2017



Wong, Ann Thor Surg 2010

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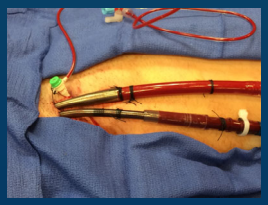
Limb Ischemia

- Place transcutaneous continuous near-infrared spectroscopy (NIRS) patches on both calves as soon as cannulas are in place to obtain regional oxygen saturations ($rStO_2$).
- Decision to place anterograde perfusion catheter is made prior to departure from CV lab.
- Usually maintain $rStO_2$>50-60%
- Consider if:
  - If >15-20% drop after cannulation, difference of >10% between limbs, or absolute $rStO_2$<50%
  - Can use anterograde CFA, SFA or retrograde PDA, PTA
  - Ultrasound and fluoroscopic guided access with angiographic confirmation
- Low bilateral $rStO_2$ will require systemic and hemodynamic evaluation

Keshavamurthy et al, Asian CV & Thor Annals 2015; 23(3):347-348



Pre-contralateral cannulation

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- **IABP, Impella specific complications**
- ECMO
  - Mechanical
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      - Poor flow, thrombosis, bleeding, air
      - Kinking, cannula positioning
  - Hemodynamics
    - LV distension, unloading
  - Harlequin syndrome
- Neurological

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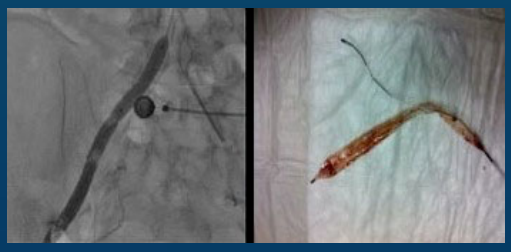
Specific Device Related Complications

- IABP
  - Device migration
  - Kinking
  - Rupture

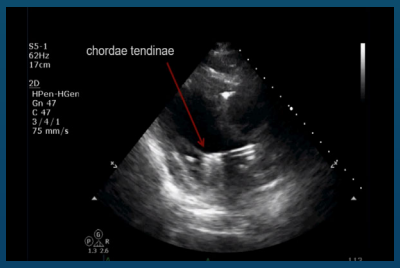


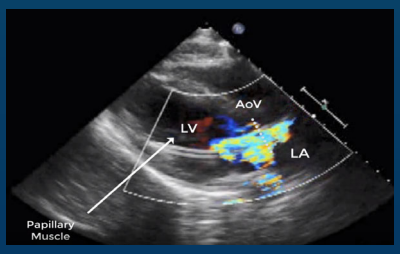
Chatzikyriakou, Eur Heart J(2013) 34 (Abstract Supplement), 1126

23

Specific Device Related Complications

- Impella
  - Improper positioning
    - mitral regurgitation
  - Kinking
  - Hemolysis
  - Arrhythmias





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Low Flow State

- **Prior to activating circuit**
  - Prime and inspect the system (perfusionist)
  - Appropriate anticoagulation before or as soon as cannulas are in place.
  - Back bleed and flush the system to ensure there is no thrombus or air
  - Appropriate positioning of the cannulas (occasionally VV instead of VA)
- **Low Flow**
  - Have perfusionist re-examine the circuit
  - Hypovolemia/bleeding
    - May see "chatter" and low pressure in drainage cannula.
    - May need to decrease drainage RPM
  - Use PA catheter, echo, arterial line, and colleagues to assist with decision making

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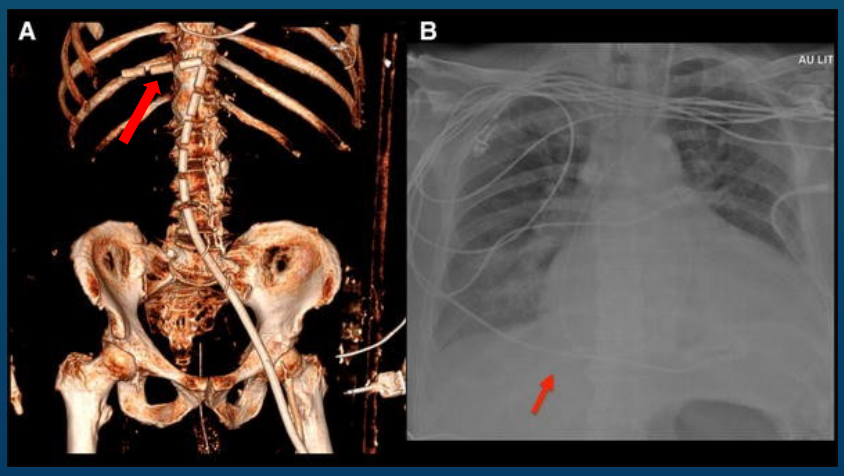
Utilize Imaging Whenever Available



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Serck et al, Intensive Care Medicine 2018;44: 1571-72

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Understanding the Hemodynamics
Is it all about flow and MAP?

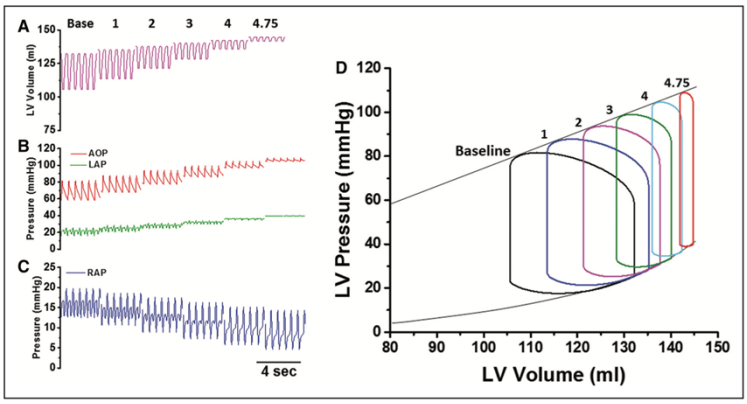

Figure 4. Hemodynamic changes that occur during acute cardiogenic shock and peripheral venoarterial extracorporeal membrane oxygenation (VA-ECMO) at increasing flow rates (1, 2, 3, 4, 4.75 L/min) with an unvented left ventricle (LV).
A, LV volume and pressure increases. **B**, Aortic pressure (AOP) and left atrial pressure (LAP) increase. **C**, Right atrial pressure (RAP) decreases. **D**, Pressure-volume loops generated during acute cardiogenic shock and VA-ECMO at increasing flow rates. With increasing ECMO flow rates, aortic pressure and afterload (slope of the arterial elastance and end-systolic pressure increase). There is a concomitant decrease in stroke volume (represented by the width of the pressure-volume loop) and an increase in LV volume (LV distention) and LAP. As stroke volume approaches zero, this would clinically correspond to the aortic valve remaining closed throughout the cardiac cycle.

Rao et al, Circ Heart Fail 2018;11:e004905

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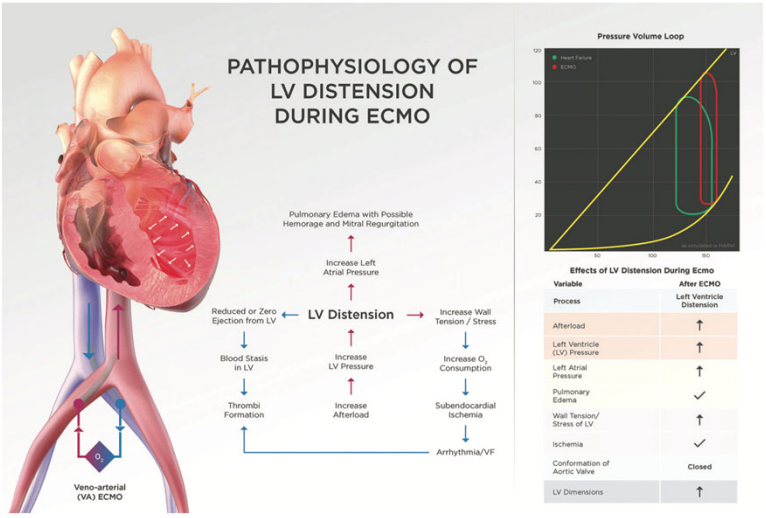
Understanding the Hemodynamics
Multi-factorial consideration



Amarelli et al, Advances in Extra-Corporeal Perfusion Therapies, Chapter 13.

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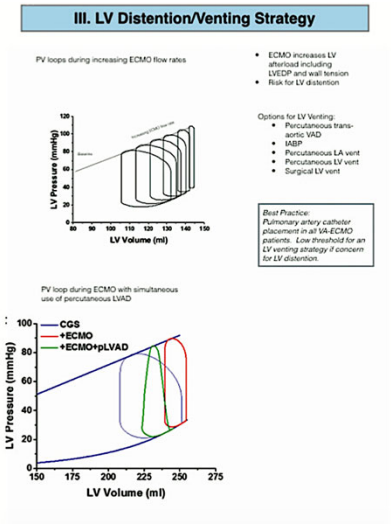
Understanding the Hemodynamics
LV venting options



Rao et al, Circ Heart Fail 2018;11:e004905

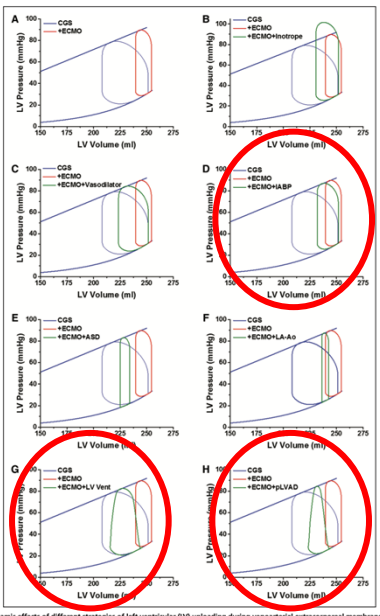


Figure 5. Hemodynamic effects of different strategies of left ventricular (LV) unloading during venoarterial extracorporeal membrane oxygenation (VA-ECMO).
Pressure-volume (PV) loops generated during acute cardiogenic shock (blue PV loops) and peripheral VA-ECMO with (**A**) no unloading strategy (red PV loops) and with the following venting strategies (green PV loops): (**B**) inotropic agent, (**C**) vasodilator agent, (**D**) intra-aortic balloon pump (IABP), (**E**) atrial septostomy, (**F**) left atrial (LA) venting via cannula connected to ECMO circuit, (**G**) direct LV venting via cannula connected to ECMO circuit, (**H**) percutaneous transaortic ventricular assist device.

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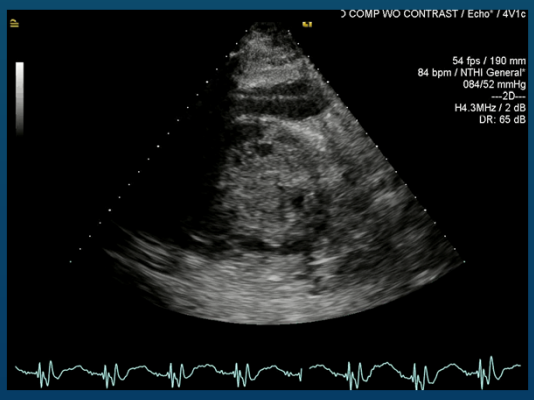
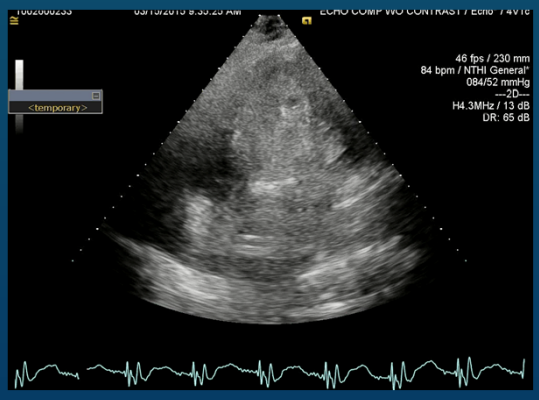
LV Thrombosis





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  - **Harlequin syndrome**
- Neurological

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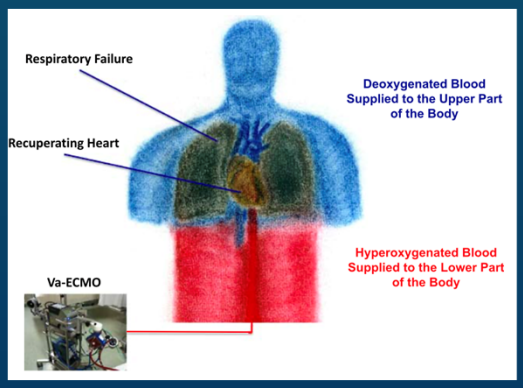
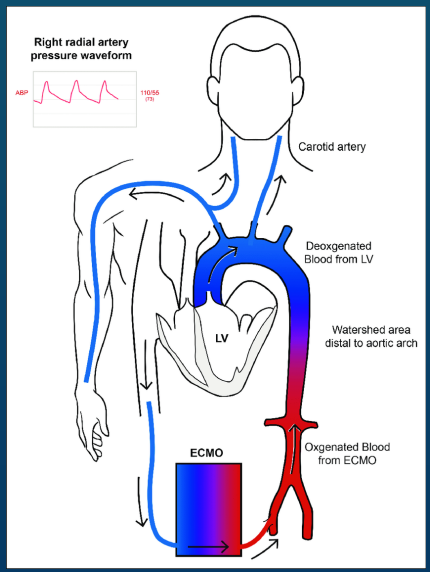
Harlequin Syndrome

(North-South, Watershed)



Lotz, Circulation. 2014;130:1095-1104



Rao et al, Circ Heart Fail 2018;11:e004905

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VAV ECMO
VV ECMO
Protek Duo

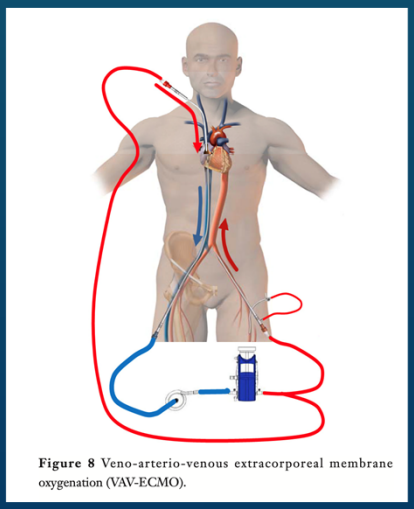
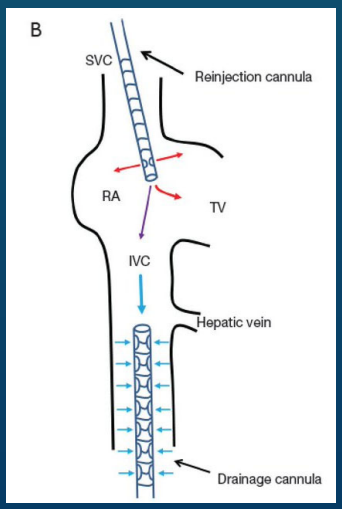


Figure 8 Veno-arterio-venous extracorporeal membrane oxygenation (VAV-ECMO).



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Banfi et al, , J Thorac Dis 2016;8(12):3762-73

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Neurological Complications

- Obviously very difficult to assess in the acute setting
- Embolic
- Hemorrhagic
- Seizures
- Monitoring
  - Low threshold for imaging if any trauma or obvious neurological abnormality
  - Cerebral near infrared spectroscopy (NIRS)
  - Transcranial doppler (TCD)
  - Electroencephalogram (EEG)

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Lo Coco et al, J Thorac Dis 2018;:10(12):6993-7004

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Greatest tool to minimize complications is a TEAM APPROACH

Advanced heart failure
Interventional Cardiology
Seasoned CV lab or OR team
Perfusion, IABP/Impella teams
CT surgery
Vascular surgery
ECMO Specialist Nurse
Intensivists, CICU nurses

****To optimize long term outcome, an even larger team is required****

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