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

• No disclosures
Outline

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

Causes of Cardiogenic Shock

- Predominant LV Failure: 74.5%
- Acute Severe MR: 8.3%
- VSD: 4.6%
- Isolated RV Shock: 3.4%
- Tamponade/rupture: 1.7%
- Other: 7.5%
- AMI Shock
- Acute on Chronic HF
- Fulminant myocarditis
- Peripartum CM
- Chemotherapy induced CM
- Primary graft failure

Adapted From Sanborn T. et al, JACC. 2000
## Cardiogenic shock - definition

<table>
<thead>
<tr>
<th>Clinical / laboratory</th>
<th>Based on Hemodynamics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Altered mentation</td>
<td>• Persistent hypotension</td>
</tr>
<tr>
<td>• SOB</td>
<td>• Systolic BP &lt; 80-90 mmHg or</td>
</tr>
<tr>
<td>• Abdominal pain/V</td>
<td>• MAP &lt; 60mmHg or 30 mmHg below</td>
</tr>
<tr>
<td>• Cool periphery</td>
<td>baseline in pts with HTN</td>
</tr>
<tr>
<td>• Pulmonary congestion</td>
<td>• Cardiac Index</td>
</tr>
<tr>
<td>• Low urine output</td>
<td>&lt; 2.2 without support or &lt; 2.0L/min/m²</td>
</tr>
<tr>
<td>• Lactic acidosis and</td>
<td>with moderate/maximal support</td>
</tr>
<tr>
<td>[HCO₃⁻]</td>
<td>• Elevated Filling Pressures</td>
</tr>
<tr>
<td></td>
<td>• LVEDP &gt; 18 mmHg</td>
</tr>
<tr>
<td></td>
<td>• RVEDP &gt; 10-15 mmHg</td>
</tr>
</tbody>
</table>

### Cardiogenic shock is not all created equal

- Clinical / laboratory: Altered mentation, SOB, Abdominal pain/V, Cool periphery, Pulmonary congestion, Low urine output, Lactic acidosis and [HCO₃⁻]
- 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/m² with moderate/maximal support, Elevated Filling Pressures, LVEDP > 18 mmHg, RVEDP > 10-15 mmHg
Cardiogenic Shock is a Spectrum

Pre-Shock | Shock | Profound Shock
--- | --- | ---
No Hemodynamic Support | Needs Partial Hemodynamic Support | Needs Full Hemodynamic Support

Mortality

- No inotrope: 2%
- Low dose: 3%
- Moderate dose: 7.5%
- One high dose: 21%
- Two high dose: 42%
- Three high dose: 80%

Mortality Risk with Inotrope Dosing


SCAI Classification of cardiogenic shock

SCAI
Society for Cardiovascular Angiography & Interventions
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


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

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 (inotropes, 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


For more information, please visit: www.scai.org/shockdefinition
SCAI Classification to Predicts Mortality in the CICU

- Retrospective analysis of Mayo Clinic CICU patients admitted with CS between 2007 and 2015.
- 10,044 patients
  - 43.1% had ACS, 46.1% had heart failure, and 12.1% had CA.
  - The proportion of patients in SCAI CS stages A through E 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),
  - Each higher SCAI shock stage was associated with increased hospital mortality compared with SCAI shock stage A

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

SCAI Classification after Cardiac Arrest

- The SCAI shock grade was applied to an observational registry of OOHCA patients between 2012 and 2017.
- 393 patients (median age 64.3 years, 24.9% females)
- Stage A 107 patients (27.2%)
- Stage B 94 (23.9%)
- Stage C 66 (16.8%)
- Stage D 91 (23.2%)
- Stage E 35 (8.9%)
- There was a step-wise significant increase in 30-day mortality with increasing shock grade:
  - Stage A 28.9%
  - Stage B 33.0%
  - Stage C 54.5%
  - Stage D 59.3%
  - Stage E 82.9%
- Need for RRT
- Multiorgan failure

Old Formulas New Applications

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.


PAPI

The pulmonary artery pulsatility index identifies severe right ventricular dysfunction in acute infarction.

Shock Team and Predictors of Outcome

HUP Shock Team

- Overall Goals of the Shock Team
  - Pathway development, with continual knowledge of the literature
  - Rapid patient identification
  - Mechanism of action
  - Transfer center
  - Expedited decision-making by the shock team: go or no-go

  "Go or no-go"

  Improving outcomes

  - "Go": patient has a potentially treatable insult and/or has an Exit plan (durable or without an exit plan but not a durable VAD candidate)
  - Once it is a “go” immediate mobilization of the appropriate team members and deployment of support
National Cardiogenic Shock Registry

- 35 sites, 171 consecutive patients in CS, mean age 63, 77% male
- 49% had a history of cardiac arrest, 10% ECPR
- All centers agreed to treat patients with AMI-CS using a standard protocol emphasizing invasive hemodynamic monitoring and rapid initiation of MCS.
- Average door to support times of 85 ± 63 min
- Average door to balloon times of 87 ± 58 min.
- 74% of patients had MCS implanted prior to PCI.

Survival to discharge was 72%.

Predictors of mortality:
- Creatinine ≥ 2,
- lactate > 4,
- (CPO) < 0.6
- age ≥ 70.

IABP-SHOCK II Predictors

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

Clinical Parameter

<table>
<thead>
<tr>
<th>Clinical Parameter</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;73</td>
<td>1</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>2</td>
</tr>
<tr>
<td>Glucose &gt;191</td>
<td>1</td>
</tr>
<tr>
<td>Creatinine &gt;1.5</td>
<td>1</td>
</tr>
<tr>
<td>TIMI &lt;3 after PCI</td>
<td>2</td>
</tr>
<tr>
<td>Lactate (a) &gt;5</td>
<td>2</td>
</tr>
</tbody>
</table>

Poss J et al, JACC 2017

Predictors of Survival after VA ECMO

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

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

Mina Karami¹, Corstiaan A den Uijl²,³, Dagmar M Ouweneel¹, Niels TB Scholte², Annemarie E Engström²,³, Sakir Akin⁴, Wim K Lagrand⁴, Alexander PJ Vlaar⁴, Lucia S Jewballi²,³ and José PS Henriques¹
A retrospective, two-centre study

The primary outcome

- 30-day mortality.

Secondary outcome

- The occurrence of device-related complications (limb ischemia, access site-related bleeding, access site-related infection).


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)

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
Case

- Readmitted with worsening SOB at rest, dizziness, hypotension, MAP 58-62
- Creatinine up to 2.3, lactate 1.9, AST/ALT 95/110
- RHC with RA 17 PA 64/34 PCWP 36 Fick CO/CI 4.4/2.1
- CPO 0.6 (Normal > 0.6)
- Started on dobutamine gtt with initial improvement in hemodynamics
Case

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

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
Case

- More tachycardic/borderline hypotensive
- Lactate trending up again
- RA 16, PAP 50/27, CI 1.7 despite dobutamine at 5, milrinone at 0.5. Lasix gtt at 40 mg/h, IABP 1:1
- CPO 0.4  PAPi 1.4
- Awake, but “struggling"

Case

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

MAP < 60, HR > 100, CI < 2.2, lactate nl/mildly up
Volume/inotropes/SNP

STEMI/NSTEMI/Acute HF
MAP > 60, CI > 2.2, CVP < 10, NL lactate

Be aware! Volume/inotropes/MCS?
Thank you!
VA ECMO
THE BIG GUN, OR IS IT?

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

Ivan J. Chavez MD, FSCAI, FACC
Minneapolis Heart Institute
Abbott Northwestern Hospital
Disclosures

- None

The Problem

Cardiogenic shock continues to be associated with poor survival
Cardiogenic Shock: The Gunfight

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
SCAI Stages of Cardiogenic Shock

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For more information, please visit www.scai.org/shockdefiniton
History of MCS

- ECMO
- IABP
- CPS
- Hemopump
- TandemHeart
- Impella

---

Mechanical Support Devices in the Cath Lab

![Diagram](image)

**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.15
Cardiogenic Shock: IABP

IABP: SHOCK II Trial Outcomes

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

Cardiogenic Shock: Impella

[Diagram showing the mechanisms of cardiac dysfunction and shock with related cytokines and hemodynamic changes.]

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

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

Eur Heart J (2014) 35 (3): 156-167
Percutaneous Assist Devices in CS: A Meta-analysis (n=3)

<table>
<thead>
<tr>
<th></th>
<th>LVAD n</th>
<th>IABP n</th>
<th>30-day mortality relative risk</th>
<th>P(heterogeneity)</th>
<th>I²</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiele et al.</td>
<td>9/21</td>
<td>9/20</td>
<td>0.95 (0.48 – 1.90)</td>
<td>0.63</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Burkhoff et al.</td>
<td>9/19</td>
<td>5/14</td>
<td>1.33 (0.57 – 3.10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seyfarth et al.</td>
<td>6/13</td>
<td>6/13</td>
<td>1.00 (0.44 – 2.29)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pooled</td>
<td>24/53</td>
<td>20/47</td>
<td>1.06 (0.88 – 1.66)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Favours LVAD Favours IABP


IMPRESS Trial: IABP vs Impella CP

Dagmar M. Oweneel et al. JACC 2017;69:278-287
“….Brings a knife to a gunfight”

Cardiogenic Shock

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

Cardiogenic Shock: VA ECMO

[Image of cardiac shock diagram with labels: IL-6, IL-7, IL-8, IL-10, IF, G-CSF, MCP-1, MIP-1, Systemic inflammation, Inflammatory cytokines, iNOS, Peroxynitrite, Systemic perfusion, Hypotension, Coronary perfusion, Pulmonary congestion, Hypoxaemia, Progressive myocardial dysfunction, Death, Myocardial infarction, Myocardial dysfunction, Systolic, Diastolic, LVESP, Compensatory vasoconstriction, Vasodilation, SVR, Eur Heart J (2014) 35 (3): 156-167]
TABLE 2

<table>
<thead>
<tr>
<th>Options for short-term circulatory support</th>
<th>IABP</th>
<th>TandemHeart</th>
<th>Impella 2.5</th>
<th>Impella CP, 5.0</th>
<th>ECMO</th>
<th>CentriMag</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circulatory support</td>
<td>15%</td>
<td>30%–60%</td>
<td>30%–60%</td>
<td>75%–100%</td>
<td>75%–100%</td>
<td>75%–100%</td>
</tr>
<tr>
<td>Insertion</td>
<td>Percutaneous</td>
<td>Percutaneous, septal puncture</td>
<td>Percutaneous</td>
<td>Arterial access</td>
<td>Percutaneous</td>
<td>Sternotomy</td>
</tr>
</tbody>
</table>

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


---

**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
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

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)
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
Devices for MCS: V-A ECMO

- Contraindications
  - Aortic insufficiency
  - Severe peripheral vascular disease

- Complications
  - Bleeding
  - Thrombosis
  - Embolic events/CVA
  - Vascular complications

VA ECMO in Refractory Shock and Cardiac Arrest
VA ECMO

VA ECMO Challenges

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

Coronary Tissue Perfusion

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

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
VA ECMO Complications: LV overload

Cardiogenic shock: Physiology
VA ECMO Limitations: LV Overload

VA ECMO Complications: LV overload
VA ECMO Complications: Pulmonary Edema


VA ECMO Limitation: LV Overload

VA ECMO Complications: LV thrombosis
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)

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%)
Cardiogenic Shock: MCS Devices

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Comparison of devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>IABP</td>
<td>ECMO</td>
</tr>
<tr>
<td>Pump mechanism</td>
<td>Pneumatic</td>
</tr>
<tr>
<td>Cannula size</td>
<td>7.9 Fr</td>
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<tr>
<td>Insertion technique</td>
<td>Descending aorta via the femoral artery</td>
</tr>
<tr>
<td>Haemodynamic support</td>
<td>0.5 – 5.0 L min⁻¹</td>
</tr>
<tr>
<td>Implantation time</td>
<td>+</td>
</tr>
<tr>
<td>Risk of limb ischaemia</td>
<td>+</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>+</td>
</tr>
<tr>
<td>Haemolysis</td>
<td>+</td>
</tr>
<tr>
<td>Post-implantation management complexity</td>
<td>+</td>
</tr>
<tr>
<td>Optional active cooling in post-cardiopulmonary resuscitation patients</td>
<td>No</td>
</tr>
</tbody>
</table>

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 Guenewalt and Hannan.¹⁰
Vascular Ultrasound

Effects of MCS Devices

A

Pressure

Ea2  Ea1

Emax

Volume

IABP

B

Pressure

Ea1

Emax

Volume

pLVAD

C

Pressure

Ea1  Ea2

Emax

Volume

ECMO
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

Longitudinal Plane Cannula Placement

[Image of cannula placement]
Percutaneous Cannulation: Reperfusion Sheath
VA ECMO Challenges: Lower Limb Ischemia Strategies

- Distal Perfusion
- Arterial Return Cannula
- Venous Drainage Cannula
- NIRs
Alternative Cannulation Strategies

Right Axillary Access
Central Cannulation
Trans-Caval Access

VA ECMO Challenges: Differential Hypoxemia

A
B
C
VA ECMO Challenges: Differential Hypoxemia

- Potential Strategies
  - Right axillary arterial return cannula
  - Central cannulation
  - Hybrid configuration
  - VA-V ECMO
Differential Hypoxemia Management Strategies: Hybrid VA-V ECMO

Bilateral VA ECMO Cannulation
“….Brings a knife to a gunfight”

Definition?

- IMPRESS Trial
  - SBP < 90 for 30 minutes
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  - Signs of hypoperfusion
  - All patients intubated
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Impella in Cardiac Arrest: IMPRESS Trial

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

Outcome Trends in Pre-PCI Subgroups of Other CGS Studies

Thiele, et al. NEJM 2017
Ouweneel, et al. JACC 2018
**NATIONAL CSI ALGORITHM**

RAPID Identification of Cardiogenic Shock

- Cath Lab Activation
- Femoral Access
- AMI/CS Confirmed

**IMPELLA**

Door To Support Time

Target < 90 minutes

---

**IMPELLA**

PCI

CPO < 0.6

- Calculate PAPI
- PAPI < 0.9
- Possible RV Failure
- Consider RV Support

CPO ≥ 0.6 and PAPI > 0.9

- Right Heart Cath
- RV Normal
- Consider LV Support

Continue to Titrate
- Pressors/Inotropes

---

**CARDIAC POWER OUTPUT (CPO)**

CPO = MAP x CO / 451

**PULMONARY ARTERY PULSATILITY INDEX (PAPI)**

PAPI = dPA – dPVR / RA

---

As needed to confirm diagnosis
Improving Survival

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

National Cardiogenic Shock Initiative

Improving Survival

Sustained Improvement in CS Survival

Cardiogenic Shock Patient Survival

- 2017: 60%
- 2018: 75%
- 2019: 80%

Jan-Jun 2017: 35.0%
Jul-Dec 2017: 62.5%
Jan-Jun 2018: 76.5%
Jul-Dec 2018: 78.0%
Jan-Jun 2019: 80.0%
ECMO vs. IMPELLA

SCAI Stages of Cardiogenic Shock

- **AT RISK**: A patient with risk factors for cardiogenic shock who is not currently experiencing signs or symptoms. For example: large acute myocardial infarction, poor infarction, acute or chronic heart failure.
- **BEGINNING**: A patient who has clinical evidence of relative hypotension or tachycardia without hypotension.
- **CLASSIC**: A patient presenting with hyperperfusion requiring intervention beyond volume resuscitation (inotropes, pressor, or mechanical support including ECMO). These patients typically present with relative hypotension.
- **DETERIORATING**: A patient who fails to respond to initial interventions. Similar to stage C and getting worse.
- **EXTREMIS**: A patient being supported by multiple interventions who may be experiencing cardiac arrest with ongoing CPR and/or ECMO.
Devices for MCS: VA ECMO Outcomes

30 day survival 65%
1 year survival 57%
Discharged survival 85%
ECPR survival 86%

Cardiogenic Shock: Device Selection

Optimal timing
(early, late, futility)

MODS prevention/therapy

Optimal support

Optimal prevention/management of potential device-complications
(e.g. device malfunction, limb ischemia, hemolysis, infection/inflammation)

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

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
VA ECMO

VA ECMO Complications
Avoiding and Managing Complications of Mechanical Circulatory Support

MHIF CV Grand Rounds
2 November 2020

Yale L Wang, MD FACC FSCAI
Interventional Cardiology

No Disclosures
GUN CONTROL
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.
**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***
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.

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
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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
Meticulous Access Technique

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

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
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

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Specific Device Related Complications

- IABP
  - Device migration
  - Kinking
  - Rupture

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

Specific Device Related Complications

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

Low Flow State
Utilize Imaging Whenever Available

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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 increase. B. Aortic pressure (MAP) 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 afferent boiue of the arterial resistance and end-diastolic pressure increased. There is a concomitant decrease in aortic volume (determined by the width of the pressure-volume loop) and an increase in LV volume (LV-enddiastolic) 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

Understanding the Hemodynamics

Multi-factorial consideration

Understanding the Hemodynamics
LV venting options

III. LV Distention/Venting Strategy

- ESV rises LV dP/dt resulting in
- LV distention &
- Venting

Options for LV Venting:
- Myocardial hamy
- Eject, PEEP
- LV vent through PTCA
- LV vent through CABG

LV Volume (mL)
LV Pressure (mmHg)

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

LV Thrombosis

Figure 1: Hemodynamics effect of different venting strategies on LV distention during venting management. 3D-LGE imaging was used to assess regional LV function and LV thrombus burden. AU: LV area; B: LV basal area; C: LV circumferential length; CHF: chronic heart failure; D: LV diastolic area; E: LV end-diastolic area; F: LV end-systolic area; G: LV systolic area; H: LV thrombus burden; I: LV venting strategy; J: LV volume; K: LV venting time; L: LV venting duration; M: LV venting pressure; N: LV venting rate; O: LV venting time; P: LV venting volume; Q: LV venting velocity; R: LV venting volume; S: LV venting time; T: LV venting duration; U: LV venting rate; V: LV venting volume; W: LV venting time; X: LV venting duration; Y: LV venting rate; Z: LV venting volume
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Harlequin Syndrome
(North-South, Watershed)

Lotz, Circulation. 2014;130:1095-1104

Rao et al, Circ Heart Fail 2014;7:11-e004066
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Banfi et al., J Thorac Dis 2016;8(12):3762-73
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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