LV Assist in High Risk PCI and Cardiogenic Shock: Is it Worth the Effort?

Vincent J. Pompili, MD, FACC, FSCAI
Professor of Internal Medicine
Director of Interventional Cardiovascular Medicine and Cardiac Catheterization Laboratories

What's This?
What's This?

[Image of a classroom]

What's This?

[Image of a medical treatment room]
Today’s Cardiac Cath Lab…

Treatment Space
  – Where we do PCI/Structural and Peripheral Interventions but also Resuscitation and Critical Care

• Hemodynamic Laboratory
  – Right and left heart catheterizations – under utilized but critical to patient management

• Learning Space to Improve Future Patient Care

Hemodynamics are Key to Patient Management

<table>
<thead>
<tr>
<th>Parameter and Patient</th>
<th>Patient 1 mLAD 90% pRCA 80%</th>
<th>Patient 2 mLAD 90% pRCA 80%</th>
<th>Patient 3 mLAD 90% pRCA 80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure (mmHg)</td>
<td>106/74</td>
<td>110/72</td>
<td>96/78</td>
</tr>
<tr>
<td>RA Pressure (mean)</td>
<td>14</td>
<td>8</td>
<td>18</td>
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<td>65/23 (37)</td>
<td>26/12 (17)</td>
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<td>PA Sat / Cardiac Output</td>
<td>58.8% 5.1(2.6)</td>
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<td>(Cardiac Index)</td>
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Hemodynamics are Key to Patient Management

• We make people ischemic during PCI!
  ▪ Catheters interfere with aorto-ostial flow,
    • LM lesions and large bore catheters
  ▪ Contrast does not contain hemoglobin and is a myocardial depressant
  ▪ Inflated microcatheters, inflated balloons, stents obstruct blood flow!

• Adverse hemodynamics can make what appears to be a controlled and stable situation **unstable** – cannot be ignored

Cardiogenic Shock Pathophysiology

• When a critical mass of LV is necrotic and fails to pump, stroke volume and CO falls
• Myocardial and coronary perfusion are compromised causing tachycardia and hypotension
• Increased LVEDP further decreases coronary perfusion
• Increase LV wall stress increases myocardial oxygen demand
• Lactic acidosis worsens myocardial performance
Frequency of CS Has Remained Steady Over Time

NRMI Registry¹

- Inclusion of 293,633 patients from Jan 1995-May 2004 with STEMI or new LBBB
- 775 US Hospitals with on-site PCI
- CS developed in 25,311 (8.6%) pts
- CS present on admission in 29%

Worcester Heart Attack Study²

- 1975-88 → 7.5%
- 1995 → 7.2%

In-hospital Mortality

USIK 1995, USIC 2000, FAST-MI France National Registry

<table>
<thead>
<tr>
<th>Year</th>
<th>Shock</th>
<th>No Shock</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>70 (62-77)</td>
<td>8.7 (7.5-10.0)</td>
</tr>
<tr>
<td>2000</td>
<td>63 (56-70)</td>
<td>4.2 (3.4-5.1)</td>
</tr>
<tr>
<td>2005</td>
<td>51 (44-59)</td>
<td>3.6 (3.0-4.4)</td>
</tr>
</tbody>
</table>

¹ Babaev et al JAMA 2005 294:448
² Goldberg RJ NEJM 1991; 325:1117
³ Holmes DR JACC 1995 26:668

Aissaoui et al. Eur Heart J 2012; 33:2535–2543
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

Adapted From Sanborn T. et al, JACC. 2000

The Shock Trial

The New England Journal of Medicine

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EARLY REVASCULARIZATION IN ACUTE MYOCARDIAL INFARCTION COMPLICATED BY CARDIOGENIC SHOCK

JUDITH S. HOCMAN, M.D., LYNN A. SLEEPER, Sc.D., JOHN G. WEBB, M.D., TIMOTHY A. SANBORN, M.D., HARVEY D. WHITE, D.Sc., J. DAVID TALLEY, M.D., CHRISTOPHER E. BULLER, M.D., ALICE K. JACOBS, M.D., JAMES N. SLATER, M.D., JACQUES COL, M.D., SOLIA M. MCKINLAY, PH.D., AND THIERRY H. LEJEMTEL, M.D., FOR THE SHOCK INVESTIGATORS.
Shock Trial: 30 day Mortality (1\textsuperscript{st} Endpoint)

Revascularization (n = 152)
Medical therapy (n = 150)

Days after Randomization

The SHOCK Trial: All Patients (6 Yrs)

Log-Rank $P = .03$

Early Revascularization
Initial Medical Stabilization

No. at Risk
ERV 152 56 42 33 18 3
IMS 150 38 29 18 9 2
Cardiac Power as a Correlate of Mortality

Cardiac Power = (Mean Arterial Pressure x Cardiac Output)

The Rationale for Hemodynamic Support
Ventricular Assist in Shock

**Hypotheses:**

- Blood pressure stabilization with end-organ oxygen delivery will prevent multi-organ ischemia
- Decreased wall tension will improve myocardial blood flow and reduce workload
- Reduced metabolic requirements to beating, non-working heart can enhance cellular repair / salvage
- LV pressure and volume unloading will enhance remodeling capability
There are no randomized, controlled studies on the efficacy of parachutes.

Umbrellas protect from rain – randomized studies not useful

adapted from H. Thiele

The Limitations of Evidence-Based Medicine…

Short Term MCS – Choices?

Left Sided Support
- IABP
- Impella (2.5/CP/5.0)
- Tandem Heart
- St. Jude PHP
- ECMO

Right Sided
- Impella RP
- ProtekDuo
Intra-Aortic Balloon Pump

**PROs:**
- Well known technology
- Increases coronary perfusion
- Mild increase in cardiac output
- Ease of use
- Cost

**CONs:**
- Requires a minimum of cardiac function
- Requires a stable rhythm
- Modest unloading
- IT DOESN'T SEEM TO WORK ALL THAT WELL
Bail-out IABP in 18 cases (12%) in control group

Procedural Complications:
- Prolonged hypotension
- VT/VF req. defib
- CPR req. ventilation

Hazard ratio 0.66 (95% CI 0.44 to 0.98)

BCIS-1: All Cause Mortality

Hazard ratio 0.66 (95% CI 0.44 to 0.98)
IABP SHOCK II: 1 year Mortality

- 30-day mortality: 41.3% IABP, 39.7% Control
- 6-month mortality: 48.7% IABP, 49.2% Control
- 12-month mortality: 51.8% IABP, 51.4% Control

Logrank p = 0.94
RR 1.02
95% CI 0.88-1.19

No. at risk
IABP 301
Control 299

Days after randomization

IABP SHOCK II: Treatment / Processes of Care

<table>
<thead>
<tr>
<th>Variable</th>
<th>IABP (n=301)</th>
<th>Control (n=299)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary PCI; n/total (%)</td>
<td>287/301 (95.3)</td>
<td>288/299 (96.3)</td>
</tr>
<tr>
<td>Stent implanted; n/total (%)</td>
<td>273/301 (90.7)</td>
<td>266/299 (89.0)</td>
</tr>
<tr>
<td>Drug-eluting stent; n/total (%)</td>
<td>126/301 (41.9)</td>
<td>123/299 (41.1)</td>
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<tr>
<td>Immediate PCI of non-culprit lesions; n/total (%)</td>
<td>90/301 (29.9)</td>
<td>81/299 (27.1)</td>
</tr>
<tr>
<td>Immediate bypass surgery; n/total (%)</td>
<td>8/301 (2.7)</td>
<td>10/299 (3.3)</td>
</tr>
<tr>
<td>Staged bypass surgery; n/total (%)</td>
<td>3/301 (1.0)</td>
<td>4/299 (1.3)</td>
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<tr>
<td>Active left ventricular assist device; n/total (%)</td>
<td>11/301 (3.7)</td>
<td>22/299 (7.4)</td>
</tr>
<tr>
<td>Mild hypothermia; n/total (%)</td>
<td>106/301 (35.2)</td>
<td>120/299 (40.1)</td>
</tr>
<tr>
<td>Mechanical ventilation; n/total (%)</td>
<td>240/301 (79.7)</td>
<td>252/299 (84.3)</td>
</tr>
<tr>
<td>Mechanical ventilation duration (days); median (IQR)</td>
<td>3.0 (1.0-8.0)</td>
<td>3.0 (1.0-8.0)</td>
</tr>
<tr>
<td>ICU treatment (days); median (IQR)</td>
<td>6.0 (3.0-12.0)</td>
<td>6.0 (3.0-13.0)</td>
</tr>
<tr>
<td>Renal replacement therapy; n/total (%)</td>
<td>62/301 (20.6)</td>
<td>47/299 (15.7)</td>
</tr>
<tr>
<td>Catecholamines (µg/kg per minute); median (IQR)</td>
<td>4.1 (2.9-7.7)</td>
<td>4.2 (3.6-8.3)</td>
</tr>
<tr>
<td>Dopamine</td>
<td>0.3 (0.1-1.2)</td>
<td>0.4 (0.1-1.1)</td>
</tr>
<tr>
<td>Norepinephrine</td>
<td>0.3 (0.1-1.3)</td>
<td>0.3 (0.2-1.4)</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>10.2 (4.9-20.6)</td>
<td>9.0 (4.8-17.6)</td>
</tr>
<tr>
<td>Dobutamine</td>
<td>3.0 (1.0-5.0)</td>
<td>3.0 (1.0-6.0)</td>
</tr>
</tbody>
</table>

Median BP ~90/55 mmHg, HR ~92 bpm

IABP placed after PCI in 87% of pts

10% up to IABP
Dynamic System + Dynamic Disease = Dynamic Caregiver

52 year old male with High-Risk NSTEMI – EF 15%

Treatment Plan?
52 year old male with High-Risk NSTEMI – EF 15%

Do you Really Want to go Commando Here?

Treatment Plan?

Hemodynamic Effects of Impella Support

Flow  MAP  LVEDP and LVEDV

Cardiac Power Output  MAP  Mechanical Work

O2 Supply  O2 Demand

Flow  MAP  LVEDP and LVEDV

Wall Tension  Microvascular Resistance  Coronary Perfusion

Cardiac Power Output  MAP  Mechanical Work

O2 Supply  O2 Demand

References:
- Mendoza DD, et al. AMJ 2007
- Burkhoff D. et al. Mechanical Properties Of The Heart And Its Interaction With The Vascular System. (White Paper) 2011
**Impella Improves Immediately the Hemodynamics in AMI Shock**

- **Cardiac Index**
  - Pre Impella*: 1.9±0.6
  - On Impella: 2.7±0.9
  - p=0.002

- **Mean Arterial Pressure**
  - Pre Impella: 62±17
  - On Impella: 92±21
  - p<0.0001

- **SVR**
  - Pre Impella*: 2.2±0.8
  - On Impella: 1.5±0.4
  - p=0.04

- **Wedge Pressure**
  - Pre Impella*: 28±9
  - On Impella: 21±12
  - p=0.04

*Pre-Impella measurements were recorded under clinical conditions (i.e., with inotropes + IABP).

**Gain on Hemodynamics When Switching from IABP to Impella in AMI Shock**

Patient serves as his/her own control (N=20)

- **Systolic Blood Pressure**
  - On IABP: 82±19
  - Switched to Impella: 113±30
  - p<0.0001

- **Diastolic Blood Pressure**
  - On IABP: 59±15
  - Switched to Impella: 66±16
  - p=0.0002

- **Mean Arterial Pressure**
  - On IABP: 62±17
  - Switched to Impella: 83±17
  - p<0.0001
Outcome By Support Strategy

Support Strategy (N=154)

No support Pre-PCI (N=38)
  PCI
  Impella Post PCI

IABP Pre-PCI (N=53)
  PCI
  Impella Post PCI

Impella Pre-PCI (N=63)
  PCI
  Continue Impella

Survival to discharge

PCI LAD/Cx/RCA – Final Results

O’Neill et al, J Interven Cardiol 2013:9999:1-11

No Drama, No Hassle, Near Complete Revascularization
Thoratec (St. Jude) Percutaneous Heart Pump

- **Catheter-based axial flow pump**
  - Low profile percutaneous placement
  - Collapsible elastomeric impeller and nitinol cannula; expands to ~24F
  - Designed to deliver over 4L of flow under normal physiologic conditions

CardiacAssist TandemHeart

- Access to LA via standard transseptal technique
- Catheter exchanges made with Valvuloplasty guidewire or Amplatz soft tip wire
- Dilate septum with 2-stage (14/21 Fr.) dilator
- Place cannula in LA
How the System Works: TandemHeart Centrifugal Pump

Centrifugal pump provides up to 5 liters per minute of forward flow in a percutaneous configuration. Provides uniform flow and full pressure support.

Hemodynamic Effects of TandemHeart in Patients with Cardiogenic Shock

Cardiac Index

PCWP

Randomized Trial of TandemHeart vs IABP
n=41

Case 2: 59 M in CGS post NSTEMI, Intubated on FiO2 100%, 2 Inotropes

Urgent Angiogram

AoP: 108/88, HR 90. SpO2 87%
RHC: RA 14, RV 63/33, PAP 60/35/46, PCWP 32
What’s Your Choice?

You choose to institute hemodynamic support (MCS)

a) ECMO  
 b) Impella 2.5  
 c) Impella CP  
 d) Impella 5.0  
 e) IABP  
 f) Consultation for surgical BiVad

ECMO Circuits

VA-ECMO  
VV-ECMO
Adult Cardiac ECMO Use

300% Growth in Annual Procedures in Last 2 years

CPR with ECLS vs. Conventional CPR: In-Hospital Cardiac Arrest
Survival to Discharge Based Upon Duration of CPR
ECMO – Not A Free Lunch!

- Possibility of centrally deoxygenated blood
  - Brain Perfusion
- Limb Ischemia
- Bleeding
- Need for Transfusion
- Inflammatory Response
- Increased Afterload

Final Result

Overall Procedure:
- ECMO insertion
- IABP removed and re-insertion post PCI
- Treatment of occlusive ISR of PI branch with PCI
- PCI Cx
- PCI pLAD
- PCI LM
- Patient returned to CCU on V-A ECMO, off vasopressin, NE down from 16 to 8 mcg/min
Don’t Forget The RV

Right Heart Failure Always Worsens Mortality

<table>
<thead>
<tr>
<th>STUDY</th>
<th>RVEF &gt; 35, PVR &lt; 650</th>
<th>RVEF &lt; 35, PVR &gt; 650</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berger, 1993</td>
<td>5/58</td>
<td>20/1052</td>
</tr>
<tr>
<td>Zehender, 1993</td>
<td>27/107</td>
<td>4/93</td>
</tr>
<tr>
<td>Bueno, 1998</td>
<td>44/286</td>
<td>17/502</td>
</tr>
<tr>
<td>Mehta, 2001</td>
<td>35/491</td>
<td>35/638</td>
</tr>
<tr>
<td>TOTAL</td>
<td>143/1198</td>
<td>90/2747</td>
</tr>
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</table>

Odds Ratio 95% CI

- 1.0
- 2.2
- 3.3
- 4.3
- 5.0
- 6.0
- 7.0

% Survival

High PAP and Low RVEF

RV Failure and Left Heart Failure

RV Failure and Pulmonary HTN

Z=7.99  \( P<0.00001 \)
**RV Recovery**

![Graph showing Cardiac Survival % over years with lines for RV Infarction, LV Pump Failure, and p=0.002.]


**RV Afterload is a Major Determinant of Cardiac Output**

![Graph showing Stroke Volume (% of Control Value) vs. P Vessel (mmHg) with lines for Right Ventricle and Left Ventricle.]

Greater impact of **acute** RV pressure overload on stroke volume.
Impella RP: Percutaneous Right Ventricular Assist Device (RVAD)

- Transfemoral venous insertion
- 3D shaped cannula
- 22 Fr motor housing
- Pump mounted on a 11Fr catheter
- Flow: 4 L/min @ 33,000 rpm
- Anticoagulation: ACT ~ 160-180 sec

Approved in US on HDE
CE Marked in Europe.

Recover Right – Hemodynamics

![Graphs showing Cardiac Index and Central Venous Pressure improvements with P<0.001 significance](image)
51 Year Old Female
Clinical Presentation – Presenting ECG:

- Diagnosed with acute inferoposterior STEMI complicated by cardiac arrest
- Cath lab activated and patient taken for emergency PCI

Diagnostic Cath (I)
Diagnostic Cath (II)

RHC Pre-PCI:

Cardiogenic Shock

PCI RCA – Final Results

Dottering following by direct stenting to mid and distal RCA
PCI Circumflex – Final Results

- Stent to OM 1 and main Circumflex
- Moderate distal LAD lesion for staging if required

**Hemodynamics**

<table>
<thead>
<tr>
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<td>10</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Dobutamine (mcg/kg/min)</td>
<td>-</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Levophed (mcg/min)</td>
<td>-</td>
<td>-</td>
<td>20</td>
</tr>
<tr>
<td>Vasopressin (units/min)</td>
<td>-</td>
<td>-</td>
<td>0.3</td>
</tr>
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</table>
Impella RP Insertion

- Device augmentation to 3.0L of flow
- Aneuric to 400cc urine before leaving cathlab
- Inotropes decreased

Hemodynamics

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<th>15 Minutes post RP Insertion</th>
<th>At RP Removal</th>
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<tr>
<td>Dobutamine (mcg/kg/min)</td>
<td>-</td>
<td>-</td>
<td>5</td>
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<td>15</td>
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</tr>
<tr>
<td>Vasopressin (units/min)</td>
<td>-</td>
<td>-</td>
<td>0.3</td>
<td>0.1</td>
<td>-</td>
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Paradigm Shift in Use of Short-term MCS

Patient with
Acute myocardial infarction (AMI),
Congestive heart failure (CHF), or
Coronary artery disease and other heart disease (CAD)

PRE-2007
MCS instituted after circulatory collapse (reactive)
Organ dysfunction has already occurred
Limited or no percutaneous MCS devices available
Most MCS implanted surgically (primarily by cardiac surgeons)
Longer hospital stay post-surgery
Higher mortality

POST-2007
Percutaneous MCS devices more readily available
MCS increasingly implemented without need for surgical consultation
Shorter hospital stay and higher rate of home discharges
Reduced hospital costs
Lower mortality

Avoidance of organ dysfunction

Shock Team Internal Communications Protocol

Ward/CCU Inpatient
Cath Lab Patient
Shock Patient Accepted for Transfer
Outside Call to HF Intensivist

SHOCK TEAM PAGER ACTIVATION

Shock Interventionalist
Shock Surgeon
Shock Fellow
Shock Intensivist

Shock Team Recommendation

Medical Management
Initiate MCS (Cath Lab/OR)
Conclusions

• The increased awareness of percutaneous options may improve outcomes in CGS
• In severe hemodynamic compromise IABP is clearly not the answer (though may be useful to increase coronary flow with no reflow or residual stenosis)
• pLVAD support makes most sense upfront in severe LV failure to allow intervention and bridging to recovery/decision or further supportive Rx
• ECMO is best for total “crash and burns”
• The availability of percutaneous RV support has further expanded our options for recovery and timing of destination therapies