Management of Acute Shock and Right Ventricular Failure

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Department of Thoracic and Cardiovascular Surgery and Biomedical Engineering, Cleveland Clinic
Disclosures

• NONE
CARDIOGENIC SHOCK
Scope of the Problem

Diverse etiology

- 7-10% Acute MI
- Cardiac Arrest
- Post-cardiotomy 0.2-0.5%
- Decompensated CHF
- Acute fulminant myocarditis
- Acute Cardiac Allograft Rejection
CARDIOGENIC SHOCK
Definition

- **Arterial hypotension** (systolic arterial blood pressure below 90 mmHg or mean arterial blood pressure below 70 mmHg for 30 minutes or longer with or without therapy);
- **PCWP >18 mmHg** (in patients with a pulmonary artery catheter) *or* an acute decrease of the left ventricular ejection fraction below 40%.
- Need for a continuous infusion of inotropic drugs
- **IABP**

## Incidence and mortality cardiogenic shock with AMI

<table>
<thead>
<tr>
<th>Study</th>
<th>N pts</th>
<th>yr</th>
<th>AMI (%)</th>
<th>% shock on all AMI</th>
<th>% shock at admission on all shock</th>
<th>Mortality pts in shock (%)</th>
</tr>
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<tbody>
<tr>
<td>NRMI-2</td>
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<td>12,084</td>
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<th>Year</th>
<th>Total</th>
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<tr>
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<td>434 (60.3)</td>
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<td>160 (69.9)</td>
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*Abbreviation: NRMI, National Registry of Myocardial Infarction.
*The Mantel-Haenszel $\chi^2$ probability for the 2-sided alternative hypothesis that a linear association exists is presented.
†Through May.
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P value: <.001 for <.001 for <.001

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*The Mantel-Haenszel $\chi^2$ statistic was used to test the hypothesis that a linear association exists between year and mortality. **P value for the 2-sided alternative hypothesis that a linear association exists is presented. †Through May.
Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

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

ABSTRACT

BACKGROUND

In current international guidelines, intraaortic balloon counterpulsation is considered to be a class I treatment for cardiogenic shock complicating acute myocardial infarction. However, evidence is based mainly on registry data, and there is a paucity of randomized clinical trials.

METHODS

In this randomized, prospective, open-label, multicenter trial, we randomly assigned 600 patients with cardiogenic shock complicating acute myocardial infarction to intraaortic balloon counterpulsation (IABP group, 301 patients) or no intraaortic balloon counterpulsation (control group, 299 patients). All patients were expected to undergo early revascularization (by means of percutaneous coronary intervention or bypass surgery) and to receive the best available medical therapy. The primary efficacy end point was 30-day all-cause mortality. Safety assessments included major bleeding, peripheral ischemic complications, sepsis, and stroke.

RESULTS

A total of 300 patients in the IABP group and 298 in the control group were included in the analysis of the primary end point. At 30 days, 119 patients in the IABP group (39.7%) and 123 patients in the control group (41.3%) had died (relative risk with IABP, 0.96; 95% confidence interval, 0.79 to 1.17; P=0.69). There were no significant differences in secondary end points or in process-of-care measures, including the time to hemodynamic stabilization, the length of stay in the intensive care unit, serum lactate levels, the dose and duration of catecholamine therapy, and renal function. The IABP group and the control group did not differ significantly with respect to the rates of major bleeding (3.3% and 4.4%, respectively; P=0.51), peripheral ischemic complications (4.3% and 3.4%, P=0.53), sepsis (15.7% and 20.5%, P=0.15), and stroke (0.7% and 1.7%, P=0.28).

CONCLUSIONS

The use of intraaortic balloon counterpulsation did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction for whom an early revascularization strategy was planned. (Funded by the German Research Foundation and others; IABP-SHOCK II ClinicalTrials.gov number, NCT00491036.)
SHOCK II Trial

P = 0.92 by log-rank test

Mortality (%) vs Days since Randomization

Control vs IABP
Limitations of Conventional Therapy

- IABP decreases LV workload and increase C.O. by 10-15%  
- Need for high dose inotropic support increases myocardial oxygen demand  
- Mortality for cardiogenic shock remains >50%

Could more powerful mechanical support improve outcomes?
Emerging Role of Early Mechanical Circulatory Support

- Hemodynamic stabilization
- Normalization of end organ perfusion
- Potential for Cardiac recovery and weaning
- **Time for evaluation of other options**
  - Transplant
  - Long-term Mechanical Therapy (Destination Therapy)
Timing is Critical

Early intervention increases the probability of survival:

In Acute Settings, Cardiac Function is RECOVERABLE
LV “Recovery” Goals

- To decompress the ventricle(s).
- Wean toxic levels of inotropes.
- Allow ATP stores to return.
- Allow cytokines to be metabolized.
- Preserve end organ function.
Potential reduction in infarct size
LAD occlusion model

Massive Myocardial damage

Impella study – Flameng et al 2000

Up to 5-times Reduction in infarct size over base line
Increasing Use of ECMO

Why ECMO?

• Advantages
  - Rapid insertion (Fem artery, Fem Vein)
  - Ease of insertion
  - Low cost
  - Low maintenance

• Disadvantages
  - Loads the failing LV
  - Immobility
  - Truly short term rescue device
Impella 2.5 Technology

Clinical Adoption in US

FDA Clearance in June’08
1000+ patients treated
300+ US Centers
2 Trials Open
USpella Registry
**Impella® 5.0**

Miniaturized Blood Pump Technology

- 21 Fr micro-axial pump (requires 22-24 Fr Sheath)

High-Flow Circulatory Support

- Delivers up to 5 L/min blood flow support

Directly Unloads Left Ventricle

- Actively unloads up to 5 L/min from LV

Peripheral Placement

- Single peripheral insertion point
- Femoral Artery Cut-down/ Axillary artery approach
## USpella AMI Population

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>No Shock</th>
<th>Shock</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD or %</td>
<td>Mean ± SD or %</td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>74 ± 10</td>
<td>64 ± 16</td>
<td>0.003</td>
</tr>
<tr>
<td>Gender (Male in %)</td>
<td>72 %</td>
<td>92 %</td>
<td>0.04</td>
</tr>
<tr>
<td>STEMI (NSTEMI)</td>
<td>3% (97%)</td>
<td>69% (31%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>33 ± 15</td>
<td>31 ± 14</td>
<td>0.6</td>
</tr>
<tr>
<td>Unprotected LM or LPC</td>
<td>50 %</td>
<td>50 %</td>
<td>0.9</td>
</tr>
<tr>
<td>Multivessel Disease</td>
<td>75 %</td>
<td>91 %</td>
<td>0.2</td>
</tr>
<tr>
<td>Revasc (PCI/CABG/None)</td>
<td>100% / 0 / 0</td>
<td>65% / 23% / 12%</td>
<td>0.002</td>
</tr>
<tr>
<td>Impella placement Pre-PCI</td>
<td>95%</td>
<td>14%</td>
<td>0.001</td>
</tr>
<tr>
<td>Pump Flow (L/min)</td>
<td>2.2 ± .3</td>
<td>2.2 ± .4</td>
<td>0.9</td>
</tr>
</tbody>
</table>
Impella Improves Hemodynamics in AMI Shock

**Cardiac Index**

- Pre Impella*: 1.9 ± 0.5
- On Impella: 2.5 ± 0.6

\( p = 0.02 \)

**Mean Arterial Pressure**

- Pre Impella*: 62 ± 19
- On Impella: 87 ± 16

\( p = 0.003 \)

**Systolic Vascular Resistance (SVR)**

- Pre Impella*: 1.8 ± 0.7
- On Impella: 1.3 ± 0.5

\( p = 0.01 \)

**Wedge Pressure**

- Pre Impella*: 28 ± 8
- On Impella: 20 ± 10

\( p = 0.001 \)

*Pre-Impella measurements were recorded with optimal medical management measures (inotropes + IABP)
Survival to Discharge By Indication

AMI with No Shock
- (n=36)
  - 89%

AMI with Shock
- (n=26)
  - 58%
Removes oxygenated blood from the LA via a transeptal cannula

Returns blood to the femoral artery

Continuous flow, centrifugal pump 4-5 LPM
TandemHeart® PTVA

Transseptal Cannulation
## Highlights of Texas Heart Institute Experience

### Refractory Cardiogenic Shock

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<th>Pre TandemHeart</th>
<th>Post TandemHeart</th>
<th>P value</th>
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<tr>
<td>CI (lpm)</td>
<td>0.7 +/- 0.5</td>
<td>2.79 +/- 0.97</td>
<td>&lt;0.0001</td>
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<tr>
<td>SVO2 (%)</td>
<td>39 +/- 10</td>
<td>66 +/- 8</td>
<td>&lt;0.0001</td>
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<tr>
<td>PCWP (mmHg)</td>
<td>29 +/- 9</td>
<td>14 +/- 5</td>
<td>&lt;0.0001</td>
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<tr>
<td>SBP (mmHg)</td>
<td>79 +/- 20</td>
<td>101 +/- 13</td>
<td>&lt;0.0001</td>
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<tr>
<td>Lactic acid (mg/dl)</td>
<td>64 +/- 54</td>
<td>27 +/- 30</td>
<td>&lt;0.03</td>
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<tr>
<td>Creatinine (mg/dl)</td>
<td>2.3 +/- 1.3</td>
<td>1.5 +/- 0.7</td>
<td>&lt;0.02</td>
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Cardiac Catheter Pump

- Low-profile percutaneous device delivered through 13F sheath
- Expands to 24F across aortic valve
- Designed to deliver over 4 lpm for up to 10 days

Target Applications

- Acute MI
- Cardiogenic Shock
- High-risk PCI
- Acutely decompensated heart failure
Treatment of RV Failure

- Pulmonary vasodilators (inhaled nitric oxide or prostacyclin)
- Inotropic drugs (milrinone, epinephrine)
- Avoidance of Hypoxia and Hypercarbia
- Adequate drainage of the pleural spaces
- Maintain MAP > 70 mmHg, CVP < 15 mmHg

- RVAD
  - Temporary (short- to mid-term)
Current Short-Term RVAD Devices
New Devices for Temporary RVAD support
Old Concepts New Designs

- Impella RP
- IDE Study ongoing for RV failure
  - Within 48 hours post LVAD
  - Within 48 hours post surgery or post MI.
IMPELLA RP
Conclusion

• Increasing Use of Mechanical Pumps for LV and RV support
• Majority will be percutaneously placed
• In addition to hemodynamic support ambulation will be possible
• The biggest driver for use will be cost
• Value-based medicine will mandate stricter selective use in patients