Cardiogenic Shock: The Role of Mechanical Support

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THE PERIPHERAL EVENT OF THE YEAR
Disclosures

Consultant:
• Abiomed
• Maquet
• St. Jude / Abbott

Food:
In the era of full disclosure, I do partake of food provided by just about any vendor to the Cath Lab
Addressing Heart Failure in 2017

WHIP THE HORSE

UNLOAD THE WAGON

SLOW THE HORSE

GET A NEW HORSE

GET A TRACTOR

HEAL THE HORSE
Clinical Goals in Emergent Patients

• Restore Stable Hemodynamics
  – *reversing decline of end-organ perfusion, reducing risk of end-organ failure, breaking cycle of cardiogenic shock*

• Minimize Infarct Size
  – *reducing myocardial ischemia, halting cell damage, maximizing residual cardiac function*

• Ease-of-Use & Safety
  – *consistent with critical treatment time scenarios and risk-benefit considerations of emergency care*
Clinical Goals in Complex Interventions

• Maintain Hemodynamics
  – *avoiding disruptions in cardiac output, clinical challenges to end-organ function and neurological instabilities*

• More Time for Balloon Inflation & Stent Placement
  – *by raising the patient’s ischemic threshold to minimize cell damage from balloon inflation or coronary dissection*

• Prophylactic Safety Profile & Ease-of-Use
  – *reduce complications such as bleeding or embolization to end organs such as stroke or limb ischemia*
Heart muscle can recover with support


**High Potential of heart muscle recovery, Gain in Ejection Fraction**

**Low Potential of heart muscle recovery, Loss in Ejection Fraction**

A  Ventricular remodeling after acute infarction

- **Initial infarct**
- **Expansion of infarct (hours to days)**
- **Global remodeling (days to months)**
INTERMACS SCORE
Interagency Registry for Mechanically Assisted Circulatory Support

Long-Term LVAD
Ideal candidates are INTERMACS classes 3-4

Short-Term LVAD
Candidates are INTERMACS classes 1-2

Not LVAD Candidate
INTERMACS 1 or those with multisystem organ failure

Lietz and Miller
Curr Opin Cardiol
2009, 24:246–251
Evolution of Cardiac Support in Cath lab

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

Timeline:
- **70's**
- **80's**
- **90's**
- **00's**

Einstein Healthcare Network 2017
Gibbon heart-lung machine Model II. Reprinted with permission from reference 5.

Cohn L H Circulation. 2003;107:2168-2170
Percutaneous assist devices in cardiogenic shock.

A. IABP
B. Impella
C. TandemHeart
D. ECMO

Werdan K et al. Eur Heart J 2014;35:156-167
IABP Support

PROs:
- Mature technology
- Increases modestly Cardiac Output
- Increases Coronary Perfusion
- Ease of Use
- Low Complication rate?

CONs:
- Does not unload the heart
- Require some cardiac power
- Require a stable rhythm
- No proven benefit on mortality
TandemHeart pLVAD

- TH Pro used for LV support;
- TH Duo used in RV failure
- Cannulas are inserted percutaneously through the femoral vein and advanced across the intraatrial septum into the left atrium
- The pump withdraws oxygenated blood from the left atrium and returns it to the femoral arteries via arterial cannulas
- Provides up to 5L/min of flow
- Can be used for up to 14 days
PRT TandemHeart vs. IABP

- University of Leipzig (2005)
- CS p AMI with intention for PCI
- PRT: TandemHeart (21) vs. IABP (20)
- Improved Hemodynamic parameters
  - Cardiac Power Index
    - TandemHeart 0.22 → 0.37
    - IABP 0.22 → 0.28
    - p<0.004
- Improved Metabolic Parameters
  - Serum Lactate (6 hours)
- Complications
  - Increased Complications in TH vs. IABP
- Mortality (30 day)
  - TandemHeart 45%
  - IABP 43%
  - (P=0.86)
TandemHeart vs. IABP

- PRT Multi-Center (2006)
- Cardiogenic Shock (70% AMI)
- TandemHeart ($n=19$) vs. IABP ($n=14$); “roll-in” ($n=9$)

A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock

Daniel Burkehoff, MD, PhD, Howard Cohen, MD, Corinna Brunschweig, MD, and William W. O'Neill, MD, for the TandemHeart Investigators Group® Orangeburg and New York City, NY; Zurich, Switzerland; and Royal Oak, MI

Background and Aim Despite major advances in the treatment of heart failure, cardiogenic shock (CGS) remains associated with substantial mortality. Recent data suggest that the TandemHeart percutaneous ventricular assist device (pVAD) may be useful in the management of CGS. The aim of this prospective randomized study was to test the hypothesis that pVAD provides superior hemodynamic support compared with intraaortic balloon pumping (IABP).

Methods Forty-two patients from 12 centers presenting within 24 hours of developing CGS were included in the study and treated in an initial roll-in phase ($n=9$) or randomized to treatment with IABP ($n=14$) or TandemHeart pVAD ($n=19$). Thirty patients ($71\%$) had persistent CGS despite having an IABP in place at the time of study enrollment.

Results Cardiogenic shock was due to myocardial infarction in 70% of the patients and decompensated heart failure in most of the remaining patients. The mean duration of support was 2.5 days. Compared with IABP, the TandemHeart pVAD achieved significantly greater increases in cardiac index and mean arterial blood pressure and significantly greater decreases in pulmonary capillary wedge pressure. Overall 30-day survival and severe adverse events were not significantly different between the 2 groups.

Conclusion In patients presenting within 24 hours of the development of CGS, TandemHeart significantly improves hemodynamic parameters, even in patients failing IABP. Larger studies are required to assess the influence of improved hemodynamics on survival. [Am Heart J 2006;152:469-477]

Despite major advances in the treatment of heart failure, for patients with mild, moderate, or severe symptoms, cardiogenic shock (CGS) is an area of relative progress. Cardiogenic shock occurs in a variety of settings such as myocardial infarction, postcardiomyomy, decompensated chronic heart failure, acute valvular failure, and myocarditis. Depending on the clinical circumstances, inhospital mortality rates are reported in the range between 40% and 80%. No study has yet shown a strategy to improve short-term (30 day) survival, although emergency revascularization enhances survival at 6 and 12 months compared with conservative medical treatment. Insertion of an intraaortic balloon is considered to be standard of care in patients with medically refractory CGS despite the fact that there are no randomized studies proving its efficacy.

Accordingly, there have been multiple efforts to develop devices to provide more effective hemodynamic support while maintaining the clinically acceptable degree of invasiveness of the intraaortic balloon pumping (IABP). One such device, the TandemHeart percutaneous ventricular assist device (pVAD), has recently been studied in the setting of CGS and was shown to improve all hemodynamic parameters and reduce serum lactate, indicating improved tissue oxygenation and reversal of the CGS state.

The purpose of this study was to test the hypothesis that the TandemHeart pVAD would provide superior hemodynamic support compared with IABP. Correlation...
Impella LP 2.5, CP, and 5.0

- Utilized for LV support only; not appropriate to use with RV failure
- Impella LP 2.5 and CP can be inserted through the femoral artery during a standard catheterization procedure; provides up to 2.5L or 3.5L of flow
- Impella 5.0 inserted via femoral or axillary artery cut down; provides up to 5.0L of flow
- The catheter is advanced through the ascending aorta into the left ventricle
- Pulls blood from an inlet near the tip of the catheter and expels blood into the ascending aorta
- FDA approved for support of up to 6 hours
Pulse pressure prior to stent deployment

Depressed systolic arterial pressure during stent deployment. Patient supported with Impella maintaining diastolic arterial pressure ~90mmHg
Pulse pressure prior to stent deployment

Depressed systolic arterial pressure during stent deployment. Patient supported with Impella maintaining diastolic arterial pressure ~90mmHg

Hemodynamic Support

In HR PCI ... PROTECT I
PROTECT II MAE Outcome

**Intent to Treat (N=447)**

- 30 day MAE: 40.4% (N=223), 35.7% (N=224), p=0.312

- 90 day MAE: 49.5% (N=220), 41.4% (N=222), p=0.087

**Per Protocol (N=426)**

- 30 day MAE: 42.7% (N=211), 34.9% (N=215), p=0.160

- 90 day MAE: 51.4% (N=210), 40.8% (N=213), p=0.029

*MAE = Major Adverse Event Rate
Per Protocol = Patients that met all incl./excl. criteria.*
Procedural Characteristics (N=324)

Significant Imbalance Between Two Arms

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Impella (Mean ± SD or %)</th>
<th>IABP (Mean ± SD or %)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of SVG lesions</td>
<td>16.1%</td>
<td>8.7%</td>
<td>0.04</td>
</tr>
<tr>
<td>Rotational Atherectomy</td>
<td>15.3%</td>
<td>8.1%</td>
<td>0.04</td>
</tr>
<tr>
<td>Total Contrast Media (cc)</td>
<td>265±149</td>
<td>231±107</td>
<td>0.02</td>
</tr>
<tr>
<td>Total PCI time (hour)</td>
<td>1.1±0.7</td>
<td>1.0±0.7</td>
<td>0.16</td>
</tr>
<tr>
<td>Total Support Time (hour)</td>
<td>1.8±2.7</td>
<td>8.7±24.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Discharge from Cathlab on device support</td>
<td>5.7%</td>
<td>31.8%</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
ECMO (VA)

- Used for patients with a combination of acute cardiac and respiratory failure
- A cannula takes deoxygenated blood from a central vein or the right atrium, pumps it past the oxygenator, and then returns the oxygenated blood, under pressure, to the arterial side of the circulation
- Can be used for days to weeks
First Successful ECMO Patient
### Table 2: Comparison of devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Pump mechanism</th>
<th>Cannula size</th>
<th>Insertion technique</th>
<th>Haemodynamic support</th>
<th>Implantation time</th>
<th>Risk of limb ischaemia</th>
<th>Anticoagulation</th>
<th>Haemolysis</th>
<th>Post-implantation management complexity</th>
<th>Optimal active cooling in post-cardiopulmonary resuscitation patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>IABP</td>
<td>Pneumatic</td>
<td>7.9 Fr</td>
<td>Descending aorta via the femoral artery</td>
<td>0.5 – 1.0 L min⁻¹</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+++</td>
<td>No</td>
</tr>
<tr>
<td>ECMO</td>
<td>Centrifugal</td>
<td>18–21 Fr inflow; 15–22 Fr outflow</td>
<td>Inflow cannula into the right atrium via the femoral vein, outflow cannula into the descending aorta via the femoral artery</td>
<td>&gt;4.5 L min⁻¹</td>
<td>++</td>
<td>++</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>Yes</td>
</tr>
<tr>
<td>TandemHeart</td>
<td>Centrifugal</td>
<td>21 Fr inflow; 15–17 Fr outflow</td>
<td>21 Fr inflow cannula into left atrium via femoral vein and transseptal puncture and 15–17 Fr outflow cannula into the femoral artery</td>
<td>4 L min⁻¹</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>(Yes)</td>
</tr>
<tr>
<td>Impella 2.5</td>
<td>Axial flow</td>
<td>13 Fr</td>
<td>12 Fr catheter placed retrogradely across the aortic valve via the femoral artery</td>
<td>2.5 L min⁻¹</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>No</td>
</tr>
<tr>
<td>Impella 5.0</td>
<td>Axial flow</td>
<td>22 Fr</td>
<td>21 Fr catheter placed retrogradely across the aortic valve via a surgical cutdown of the femoral artery</td>
<td>5.0 L min⁻¹</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
<td>+++</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 Ouweneel and Henriques.32
“However beautiful the strategy, you should occasionally look at the results.”

-Winston Churchill
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