Percutaneous Mechanical Circulatory Support

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Relevant Financial Relationship(s)
None

Off Label Usage
Yes
Learning Objectives

- Know indications for mechanical circulatory support (MCS)
- Understand hemodynamic effects of MCS
- Appreciate benefits, risks, and outcomes of MCS
55-Year-Old Female With Decompensated Heart Failure

**History**

- CAD s/p multiple PCIs
- Biventricular failure (LVEF 15%, s/p ICD 2/2015)
- HTN IDDM
- Acute-on-chronic renal insufficiency
- Congestive hepatopathy with intermittent encephalopathy
- Fall with subdural bleed

**Meds**

- Aspirin 81 mg, Effient 10 mg daily
- Milrinone 0.5 mcg/kg/min
- Bumex 1 mg two times a day
- Metolazone 2.5 mg one time daily
- Carvedilol 25 mg two times a day
- Imdur 30 daily/ hydralazine 25 mg TID
- Novolog 10 units daily, Levemir 10-14 units SC bid
NT-ProBNP 10260
Nitroprusside challenge, 4.5 mcg/kg/min
What To Do?

Mechanical Support

Heart Transplant

Palliative Care
TandemHeart Placement
TandemHeart Placement
With MCS

**TandemHeart**

**Creatinine**

- **Creatinine** levels with MCS over time, showing peak at the 21st day.
VAD implantation 5 days later

- Explantation of TandemHeart
- HeartMate II as destination therapy
- Tricuspid valve repair with a 26-mm CarboMedics ring
- Prolonged hospital stay but rehabilitating well
EXPERT CONSENSUS DOCUMENT: EXECUTIVE SUMMARY

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care

Endorsed by the American Heart Association, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencionista; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d’intervention

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LV Assist Devices

A

IABP

Impella
Fundamental Hemodynamic Principles

External Stroke Work (SW)

Pressure-volume (PV) loop

LV pressure (mm Hg)

LV vol (mL)

Aortic valve opens

Mitral valve opens

Aortic valve closes

Mitral valve closes
Pressure vs Flow
Cardiac Power Output (CPO)

Cardiac Power Output (CPO)
= 1 watt = 1 J/sec = 100 cJ/sec
= Cardiac Output (CO) * Mean Arterial Pressure (MAP)
= 5.0 L/min flow * 90 mm Hg pressure = 100 cJ/sec work

JACC 44:340–349, 2004
**Pressure vs Flow**

**Cardiac Power Output (CPO)**

Cardiac power output = \( \frac{\text{Mean arterial pressure} \times \text{cardiac output}}{451} \)

Estimated in-hospital mortality (%)

Cardiac power output

Pressure (mm Hg)

Volume (mL)

CPO = SW x HR

JACC 44:340–349, 2004
Cardiogenic Shock

- ↓ Contractility
- ↓ BP
- ↓ SV
- ↑ Baroreflex
- ↑ HR
- ↑ Preload
- ↑ Afterload
IABP

- Universally available
- Limited support
- Pressure waveform
- Not flow based
## Available Evidence on IABP

<table>
<thead>
<tr>
<th>Study</th>
<th>Randomized</th>
<th>IABP</th>
<th>Control</th>
<th>Primary or clinical outcome</th>
<th>IABP vs control</th>
<th>P</th>
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<tbody>
<tr>
<td>NRMI-2&lt;sup&gt;1&lt;/sup&gt;</td>
<td>No</td>
<td>7,268</td>
<td>15,912</td>
<td>In-hospital mortality</td>
<td>67 vs 49</td>
<td>47 vs 45</td>
</tr>
<tr>
<td>GUSTO-I&lt;sup&gt;2&lt;/sup&gt;</td>
<td>No/Post-hoc</td>
<td>62</td>
<td>248</td>
<td>All-cause mortality at 30 days</td>
<td>47 vs 60</td>
<td>(60 vs 67)</td>
</tr>
<tr>
<td>CRISP-AMI&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Yes</td>
<td>161</td>
<td>176</td>
<td>All-cause death at 6 mo</td>
<td>1.9 vs 5.2%</td>
<td></td>
</tr>
<tr>
<td>BCIS-I&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Yes</td>
<td>151</td>
<td>150</td>
<td>MACCE at 28 days</td>
<td>15.2 vs 16%</td>
<td></td>
</tr>
<tr>
<td>IABP-SHOCK II&lt;sup&gt;5&lt;/sup&gt;</td>
<td>Yes</td>
<td>301</td>
<td>299</td>
<td>All-cause death at 30 days</td>
<td>39.3 vs 41.7%</td>
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Hemodynamic Effects of LA→AO

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<th>Change</th>
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<tbody>
<tr>
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<td>CPO</td>
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<tr>
<td>PVA</td>
<td>→/↓</td>
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</table>
Lossy compression - not intended for diagnosis
Percutaneous Left Ventricular Assist Device With TandemHeart for High-Risk Percutaneous Coronary Intervention: The Mayo Clinic Experience

Oluseun O. Alli,1 MD, Inder M. Singh,1 MD, David R. Holmes, Jr.,1 MD, FACC, Juan N. Pulido,2 MD, Soon J. Park,3 MD, and Charanjit S. Rihal,1* MD, FACC

Background: In patients with poor left ventricular function and severe left main or multivessel coronary disease, coronary artery bypass grafting (CABG) surgery has been the preferred therapy. However, a number of these patients are either inoperable or poor surgical candidates due to comorbid conditions and previous cardiac surgical procedures. These patients are generally poor candidates for standard percutaneous coronary intervention (PCI) techniques. A hybrid PCI approach with hemodynamic support may be a viable strategy for these patients. We report our experience using the TandemHeart percutaneous left ventricular assist device during high-risk PCI. Methods: Retrospective cross-sectional analysis of prospectively collected data in 54 patients undergoing high-risk PCI using the TandemHeart device for support. Hemodynamic and clinical data were collected and analyzed. Results: Baseline clinical characteristics were as follows: mean age 72 ± 1.7 years, males 78%, median ejection fraction 20%, mean serum creatinine 1.8 ± 0.3 mg/dL, recent myocardial infarction 52%, COPD 33%, previous CABG 50%, diabetes mellitus 41%, and hypertension 83%. The median SYNTAX score was 33, and the median Jeopardy score was 10. The predicted surgical revascularization mortality was 13% by the Society for Thoracic Surgery risk score and 33% by Euroscore. There was a significant decrease in right and left heart pressures (P < 0.05) with a concomitant increase in the cardiac output from 4.7 to 5.7 L/min (P = 0.03) during TandemHeart support. Left main and multivessel PCI was performed in 62% of patients, and rotational was used in 48%. Procedural success rate was 97%, whereas 30-day and 6 month survival were 90% and 87%, respectively. Major vascular complications occurred in 13% of cases. None of our patients developed contrast induced nephropathy or needed dialysis. Conclusions: High-risk PCI with percutaneous left ventricular support using TandemHeart is a viable therapeutic strategy for a select subset of patients at very high risk with standard percutaneous revascularization techniques. © 2012 Wiley Periodicals Inc.

Key words: percutaneous coronary interventions; left ventricular assist device; cardiogenic shock; multivessel disease; coronary artery bypass graft
Right Heart Pressures

<table>
<thead>
<tr>
<th>T1</th>
<th>T2</th>
<th>T3</th>
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<tbody>
<tr>
<td>RAP</td>
<td>16.5</td>
<td>10.7</td>
</tr>
<tr>
<td>PAWP</td>
<td>24.7</td>
<td>17.5</td>
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<tr>
<td>PASP</td>
<td>44.6</td>
<td>36.3</td>
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</tbody>
</table>

P<0.001
P=0.02
P=0.04
Cardiac Output

CO

L/min

T1

T2

T3

4.7

5.8

5.7

↑23%

P=0.03

0 1 2 3 4 5 6 7

5.7
Survival
TandemHeart Assisted PCI

In-hospital: 87.2%
30-day: 87.2%
180-day: 80.6%
## Complications

<table>
<thead>
<tr>
<th>Variable (%):</th>
<th>Mean</th>
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<td>Major vascular complication*</td>
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<tr>
<td>Stroke</td>
<td>1</td>
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<tr>
<td>Worsening renal function</td>
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</tr>
<tr>
<td>Thrombocytopenia</td>
<td>10</td>
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</tbody>
</table>

*Includes elective repair
The Percutaneous Ventricular Assist Device in Severe Refractory Cardiogenic Shock

Biswajit Kar, MD,*† Igor D. Gregoric, MD,* Sukhdeep S. Basra, MD,‡ Gary M. Idelchik, MD,* Pranav Loyalka, MD*

Houston, Texas

Objectives
We evaluated the efficacy and safety of the percutaneous ventricular assist device (pVAD) in patients in severe refractory cardiogenic shock (SRCS) despite intra-aortic balloon pump (IABP) and/or high-dose vasopressor support.

Background
SRCS is associated with substantial mortality despite IABP counterpulsation. Until recently, there was no rapid, minimally invasive means of providing increased hemodynamic support in SRCS.

Methods
A total of 117 patients with SRCS implanted with TandemHeart pVAD (CardiacAssist, Inc., Pittsburgh, Pennsylvania) were studied, of whom 56 patients (47.9%) underwent active cardiopulmonary resuscitation immediately before or at the time of implantation. Data was collected regarding clinical characteristics, hemodynamics, and laboratory values.

Results
Eighty patients had ischemic and 37 patients had nonischemic cardiomyopathy. The average duration of support was 5.8 ± 4.75 days. After implantation, the cardiac index improved from median 0.52 (interquartile range [IQR]: 0.8) l/(min-m²) to 3.0 (IQR: 0.9) l/(min-m²) (p < 0.001). The systolic blood pressure and mixed venous oxygen saturation increased from 75 (IQR: 15) mm Hg to 100 (IQR: 15) mm Hg (p < 0.001) and 49 (IQR: 11.5) to 69.3 (IQR: 10) (p < 0.001), respectively. The urine output increased from 70.7 (IQR: 70) ml/day to 1,200 (IQR: 1,620) ml/day (p < 0.001). The pulmonary capillary wedge pressure, lactic acid level, and creatinine level decreased, respectively, from 31.53 ± 10.2 mm Hg to 17.29 ± 10.82 mm Hg (p < 0.001), 24.5 (IQR: 74.25) mg/dl to 11 (IQR: 92) mg/dl (p < 0.001), and 1.5 (IQR: 0.95) mg/dl to 1.2 (IQR: 0.9) mg/dl (p = 0.009). The mortality rates at 30 days and 6 months were 40.2% and 45.3%, respectively.

Conclusions
The pVAD rapidly reversed the terminal hemodynamic compromise seen in patients with SRCS refractory to IABP and vasopressor support. (J Am Coll Cardiol 2011;57:688–96) © 2011 by the American College of Cardiology Foundation

(TandemHeart PVAD, N = 117)
Stratified Survival Analysis

- Bridge to transplant
- Bridge to LVAD
- Bridge to recovery

Days: 0 to 1,400
Cumulative survival: 0.0 to 1.0
Impella Platform

- 9 Fr Catheter diameter
- Flow rate up to 2.5 L/min
- 12 Fr pump motor
- Blood inlet area
- Outlet area

Received FDA 510(k) clearance June 2008
Hemodynamic Effects of Impella

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PROTECT II Trial

- Multicenter RCT for high-risk PCI patients
- Complex 3VD, UPLM, EF <35%

Randomized Intent-to-treat (N=448)

IABP (N=223)
30-day, N=222
90-day follow-up, N=219

Impella 2.5 (N=225)
30-day, N=225
90-day follow-up, N=224

- Stopped early for futility; no difference in primary endpoint (MACE) at discharge or 30 days
PROTECT-II Trial

Major adverse events rate (%)

- IABP
- Impella 2.5

Time post index procedure (days)

- P=0.147
- P=0.048
ECMO

### Parameter Change

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</table>
Overcoming Adverse Hemodynamic Effects of ECMO
Conclusion: Early extracorporeal membrane oxygenator-assisted primary percutaneous coronary intervention improved 30-day outcomes in patients with ST-segment elevation myocardial infarction with complicated with profound cardiac shock. (Crit Care Med 2010; 38:1810-1817)
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Indications for Percutaneous MCS (2015 Multi society Consensus Statement)

- Complications of AMI
- Severe HF in the setting of nonischemic CMP
- Acute cardiac allograft failure
- Post-transplant RV failure
- Patients slow to wean from CPB post-heart surgery
- Refractory arrhythmia
- High-risk coronary and structural cases
- High-risk VT ablation
Suggested Schema for Support Device in High-Risk PCI

<table>
<thead>
<tr>
<th>High Syntax Score</th>
<th>Noncomplex PCI</th>
<th>Complex PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal/ mildly reduced LVEF (&gt;35%)</td>
<td>None</td>
<td>IABP/Impella as back up</td>
</tr>
<tr>
<td>Severe LV dysfunction (LVEF&lt;35%) or recent decompensated heart failure</td>
<td>IABP/Impella as back up</td>
<td>Impella or TandemHeart</td>
</tr>
</tbody>
</table>
MCS Device Selection Considerations

- Pressure vs Flow
- Devices can be complementary
- Hemodynamics and oxygenation
- RV function
- Experience of the operator, cath lab staff and the institution
On the Horizon

Penn State PHP prototype circa 2008

Thoratec HeartMate PHP 2012

Thoratec HeartMate PHP, x-ray from first human experience March 2013
