Percutaneous Mechanical Hemodynamic Support

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COAST 2018
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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</thead>
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<tr>
<td>Speaker’s Bureau</td>
<td>None</td>
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<tr>
<td>Grant/Research Support</td>
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<tr>
<td>Consulting Fees/Honoraria</td>
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</table>
Outline

• Why and in Whom do we use Mechanical support? Back to Basics
• National Trends in Use of Mechanical Cardiac Support (MCS)
• IABP
• Impella
• Tandem Heart/ECMO (briefly)
• Summary
Outline

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• Impella

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• Summary
Hemodynamic and Metabolic Goals in Cardiogenic Shock

1. **Normalize hemodynamic profile**
   - CO, MAP
     - Lactate, pH
     - Decrease peri-procedural MI, arrhythmia, increasing coronary and end-organ perfusion, support complex procedures
   - Treat/prevent pulmonary edema (PCWP)
     - O$_2$ saturation
   - Treat/prevent excessive ↑ CVP

2. **LV Unloading**
   - Prevent/minimize remodeling
   - Minimize myocardial oxygen consumption
     - Determined by HR, Contractility, LV Mass, Pressure Volume Area (PVA)
High Risk Patients

1. **Substrate**
   - Elderly, low EF (<20-30%), CKD, DM, prior MI, frail

2. **Lesion**
   - Unprotected LM, high risk bifurcation, MV PCI, calcification, CTO, No re-flow, SVG, large territory vessels

3. **Presentation**
   - ADHF/Acute cardiogenic shock, STEMI/ACS, cardiac arrest, Recalcitrant ventricular arrhythmia
Who may benefit from percutaneous hemodynamic support?

• Guidelines:

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

5.6. Percutaneous Hemodynamic Support Devices: Recommendation

CLASS IIb
1. Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients. (Level of Evidence: C)

5.2.3. Cardiogenic Shock: Recommendations

CLASS I
1. PCI is recommended for patients with acute MI who develop cardiogenic shock and are suitable candidates. (Level of Evidence: B)
2. A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy. (Level of Evidence: B)
1. Percutaneous MCS (Impella and TandemHeart) > pharmacologic therapy. Should be reimbursed

2. **Cardiogenic shock** ↑↑ high mortality despite revascularization/meds. Early MCS *if* fail to rapidly improve

3. **High risk PCI**: MVD, LM, last patent conduit, inoperable, severely reduced EF, or elevated LVEDP

4. **Profound cardiogenic shock**: IABP < Impella CP, TandemHeart, ECMO

5. **ADHF**. Consider MCS > VAD if rapid recovery expected (e.g., fulminant myocarditis, peripartum CM, Takotsubo). Acute severe MR (post MI- ischemic vs papillary rupture)

6. If *oxygenation impaired*, add *oxygenator* to a TandemHeart circuit or use ECMO

7. **Insufficient data** to support or refute *routine use* of MCSs as adjunct to primary PCI in large AMI to ↓ reperfusion injury or infarct size

8. Failure to wean CPB, RHF s/p OHT, high-risk EP procedures w/ prolonged hypotension, valvular interventions

9. **Severe BiV failure**: Consider both RV and LV MCS or V-A ECMO. RV support for isolated RV failure

10. Registries and RCTs critically needed!

11. Early analyses *suggest cost-effectiveness* of MCS for *emergent* use > surgical ECMO or VAD support, and for *elective* use vs IABP. Further data are necessary.
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• Summary

- **Source: National Inpatient Sample**
  - Developed by AHRQ (Advanced Healthcare Research Quality)
  - Comprises 20% of all inpatient discharges from US hospitals.

- ICD9 codes used to identify PVAD vs IABP

- PVAD = Impella + Tandem Heart
• 30 fold increase in pVAD use in 6 yrs
• Increased PCI and Shock, decreased IABP volumes

- **Use of PVAD**
  - In 2007, 72 hospitals
  - In 2012, 477 hospitals

- **Annual volume of 10 or more PVADs/yr**
  - 0 in 2007
  - 102 in 2011

- **Propensity Matched Analysis**
  - PVADs in older, sicker, worse shock BUT after propensity matching, still ↑ mortality for PVAD vs IABP (OR 1.23, 1.06 – 1.43, p = 0.007)
• Registry Analysis

• Temporal trends in demographics, clinical characteristics, management strategies, and in-hospital outcomes

• Patient population: Patients with AMI complicated by cardiogenic shock undergoing PCI.

• N ~ 57,000 from 2005 – 2013.
Temporal Trends and Outcomes of Patients Undergoing Percutaneous Coronary Interventions for Cardiogenic Shock in the Setting of Acute Myocardial Infarction

A Report From the CathPCI Registry

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Catheterization Laboratory Characteristics in Cardiogenic Shock in the Setting of Acute Myocardial Infarction Patients Undergoing Percutaneous Coronary Intervention</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2005-2006 (n = 5,658)</th>
<th>2006-2008 (n = 10,337)</th>
<th>2009-2010 (n = 13,562)</th>
<th>2011-2013 (n = 26,940)</th>
<th>p Value</th>
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<tbody>
<tr>
<td>Symptom to presentation (STEMI only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>&lt;6 h</td>
<td>88.1</td>
<td>89.6</td>
<td>79.5</td>
<td>77.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6-12 h</td>
<td>7.7</td>
<td>6.6</td>
<td>9.2</td>
<td>9.3</td>
<td></td>
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<tr>
<td>&gt;12 h</td>
<td>4.2</td>
<td>3.8</td>
<td>11.3</td>
<td>13.5</td>
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<tr>
<td>Thrombolytics</td>
<td>4.0</td>
<td>2.0</td>
<td>1.7</td>
<td>1.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Radial access</td>
<td>0.4</td>
<td>0.6</td>
<td>1.1</td>
<td>4.2</td>
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</tr>
<tr>
<td>&gt;70% stenosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left main</td>
<td>7.1</td>
<td>7.7</td>
<td>8.4</td>
<td>8.9</td>
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<tr>
<td>LAD</td>
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<td>87.0</td>
<td>90.0</td>
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<td>LCX</td>
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<td>RCA</td>
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<td>63.6</td>
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<td>RI</td>
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<tr>
<td>Grafts</td>
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<td>10.9</td>
<td>10.6</td>
<td>10.0</td>
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<tr>
<td>Median fluoroscopy time (min)</td>
<td>14.0</td>
<td>13.0</td>
<td>13.0</td>
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<tr>
<td>Median contrast volume (ml)</td>
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<td>200.0</td>
<td>190.0</td>
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<td>High-risk lesion (type C)</td>
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<td>&gt;1 lesion treated</td>
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<td>IABP</td>
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<tr>
<td>Other LV support devices</td>
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<td>NA</td>
<td>5.5</td>
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<td>0.60</td>
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A Report From the CathPCI Registry

Increase of all lesion types
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IABP ↓  
pVAD ↑
Mortality rates 27% → 30%
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• Summary
IABP

• Most Common

• Dual lumen (helium, pressure)

• Why do we use helium
  – Low viscosity – shuttles fast in/out of body
  – Absorbs rapidly and non-toxic

• When is the balloon supposed to inflate?
  – Onset of diastole
  – Electrocardiographic repolarization (or the middle of the T wave)

• When is the balloon supposed to deflate?
  – Onset of systole
  – Peak of R wave
Hemodynamic Effects of IABP

Flow → AOp → Flow → O₂ Supply → O₂ Demand → Limited Unloading → Microvascular Resistance → Wall Tension → Mechanical Work → EDV, EDP

Cardiac Power Output → Hemodynamic Protection
Patient’s must have some level of LV function and electrical stability for IABP to be effective.
Comparison of Hospital Mortality With Intra-Aortic Balloon Counterpulsation Insertion Before Versus After Primary Percutaneous Coronary Intervention for Cardiogenic Shock Complicating Acute Myocardial Infarction

- Retrospective
- N = 48
- AMI c/b CS
- Pre-PCI IABP
  - ↓ peak CK
  - ↓ in-hosp mortality
  - ↓ MACE

- First paper to suggest that Pre-PCI IABP is better than Post-PCI

(Am J Cardiol 2010;105:967–971)
Elective Intra-aortic Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention
A Randomized Controlled Trial

**Figure 1. Study Flow**

- **301 Patients randomized**
  - 151 Randomized to receive PCI with elective IABP insertion
  - 150 Randomized to receive PCI with no planned IABP insertion
  - 147 Received treatment as randomized
    - 3 No IABP insertion (vascular access difficulty)
    - 1 Underwent CABG surgery
  - 147 Received treatment as randomized
    - 2 Underwent IABP insertion before PCI
    - 1 Referred for CABG surgery (separate admission)
  - 151 Assessed for in-hospital/28-d MACCE
  - 150 Assessed for in-hospital/28-d MACCE
  - 149 Assessed for 6-mo mortality
    - 1 Data unavailable
  - 151 Included in primary analysis
  - 150 Included in primary analysis

**Graph:**
- Cumulative Mortality, %
- Log-rank P = .33
- No planned IABP
- Elective IABP
- Follow-up, mo
- No. at risk
  - No planned IABP: 150 147 144 141 140 140 0
  - Elective IABP: 151 146 146 146 145 144 0
Established that IABPs are generally safe and well tolerated
Single-center observational data suggested ↓ mortality and MACE with elective IABP during high risk PCI. (2003, 2006), BCIS-1 was the 1st RCT to investigate safety and efficacy of IABP during high-risk PCI.
Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

Figure 1. Time-to-Event Curves for the Primary End Point.
Time-to-event curves are shown through 30 days after randomization for the primary end point of all-cause mortality. Event rates represent Kaplan–Meier estimates.
• N=600 (1:1) in Germany, RCT.
  – 95% underwent primary PCI, 90% stent

• Bottom Line:
  – No difference in 30d mortality by ITT.

• No difference in “process of care” outcomes
  – ICU LOS, duration of catecholamines, time to stability
  – Adverse events the same

• Prior to this study, use of IABP for AMI with CS was Class I (B and C) recommendation
  – Change to 2B
**Controversies:**

- 96% of IABP group actually got IABP
  - So 4% died before IABP could be inserted
- 10% of control arm got IABP (protocol violation)
- *(Nearly)* more LVAD implantations in control arm
  - 3.7% vs 7.4% \( (p = 0.053) \)
- **Timing** of IABP not controlled
  - 87% if IABPs inserted post PCI
- Mortality rate 40%
  - Other registries at RCT (42 – 48%)
  - ? More mild and moderate CS
- High use of inotropes and low rate of patients with SBP < 90 pre randomization.
• 76464 patients w/ PCI + CS
• 2009-2013
• 54% No MCS
  39% IABP only
  3.5% other MCS (O-MCS)
  3.6% both IABP + O-MCS
• IABP use decreased without increase in MCS
• Majority of O-MCS was clustered in a few hospitals
Most Recent Guidelines

2013

ACCF/AHA Guideline

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction
A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines

Class IIa

1. The use of intra-aortic balloon pump (IABP) counterpulsation can be useful for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy.455–459 (Level of Evidence: B)

Class IIb

1. Alternative LV assist devices for circulatory support may be considered in patients with refractory cardiogenic shock. (Level of Evidence: C)

2017

2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC)

Recommendations for the management of cardiogenic shock in STElevation myocardial infarction

| Intra-aortic balloon pumping should be considered in patients with haemodynamic instability cardiogenic shock due to mechanical complications. | IIa | C |
| Short-term mechanical support can be considered in patients in refractory shock. | IIb | C |
| Routine intra-aortic balloon pumping is not indicated.177,437 | III | B |
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Impella

- **Non-pulsatile axial flow**

- **5 versions**
  - 12F – Impella 2.5 (2.5 L/min)
  - 14F – Impella CP (3-4.3 L/min)
  - 21F – Impella 5.0/LD (5L/min)
  - 22F – Impella RP (>4L/min)

- **Benefits**
  - Does not require timing/trigger
  - Stable during transient arrhythmias

- **Negatives**
  - Ventricular arrhythmias not well tolerated if RV dysfunction
  - Positioning outside cath lab
  - Hemolysis/thrombocytopenia
  - Large bore access
Hemodynamic Effects of Impella® Support

**Flow**
- *Outflow* (aortic root)
- *Inflow* (ventricle)

**MAP**
- *LVEDP and LVEDV*
  - *Wall Tension*
  - *Mechanical Work*
  - *Microvascular Resistance*

**Coronary Perfusion**

**Cardiac Power Output**
- *End Organ Perfusion*

**O₂ Supply**

**O₂ Demand**
- *Unloading to Myocardial Recovery*

**References**
- Mendoza DD, et al. AMJ 2007
• Hemodynamic effects
  – Unload LV – ↑ forward flow
  – ↓ myocardial oxygen demand
  – ↑ MAP
  – ↓ PCWP

• Contraindications?
  – Mechanical AV
  – LV thrombus
  – ? AS and AI (Relative contraindications)
  – PAD
  – Systemic anticoagulation intolerance (ACT goals)

• Complications:
  – Vascular Injury
  – Hemolysis
    • 5-10% in first 24h. Reposition.
  – Thrombocytopenia
A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

**ISAR-SHOCK**

- Feasible
- Safe
- Impella > IABP for cardiac output
- Both had 54% Mortality

Impella 2.5, Prospective, Randomized, n = 25
CI increased at 30 minutes, but overall mortality was the same.
Real-World Use of the Impella 2.5 Circulatory Support System in Complex High-Risk Percutaneous Coronary Intervention: The USpella Registry

TABLE I. Baseline Demographics and Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD (range) or %</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>70 ± 10 (43–91)</td>
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<tr>
<td>Male</td>
<td>74</td>
</tr>
<tr>
<td>Multivessel disease</td>
<td>89</td>
</tr>
<tr>
<td>Unprotected left main</td>
<td>51</td>
</tr>
<tr>
<td>Last remaining patent conduit</td>
<td>10</td>
</tr>
<tr>
<td>Prior MI</td>
<td>56</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>48</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>28</td>
</tr>
<tr>
<td>Diabetes</td>
<td>47</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>22</td>
</tr>
<tr>
<td>Chronic renal insufficiency</td>
<td>33</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>30</td>
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<tr>
<td>New York Heart Association</td>
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<tr>
<td>Class III</td>
<td>35</td>
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<tr>
<td>Class IV</td>
<td>31</td>
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<tr>
<td>LVEF</td>
<td>31 ± 17 (5–76)</td>
</tr>
<tr>
<td>LVEF &lt; 35%</td>
<td>69</td>
</tr>
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- n = 175
- Syntax Scores 37-39
- Procedural Success was 90%
- 30d MACE = 8%
- 1 year survival 88%

Safe for high risk PCI with high survival rates

Catheterization and Cardiovascular Interventions 80:717-725 (2012)
A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention

The PROTECT II Study

Randomized Intent-to-Treat N=448

Intent-To-Treat (ITT) population (N=448)

IABP (N=223)
30day, N=222
90day F/U, N=219

(IABP (N=223)
30day, N=222
90day F/U, N=219

(Impella 2.5 (N=225)
30day, N=225
90day F/U, N=224

Per Protocol (PP) population (N=427)

IABP
30day, N=211
90day F/U, N=210

Impella 2.5
30day, N=216
90day F/U, N=215

2 Withdraw consent post PCI (alive)
3 EF>=35%
3 Not 3VD or ULM
1 Active MI
1 Severe PVD
1 Platelets<70000
1 Lost to F/U post discharge (day3)

1 EF>=35%
1 Not 3VD or ULM
2 Active MI
2 Severe PVD or AS
1 Platelets<70000
1 Creatinine>4
1 PCI performed after study stopped

*ABIOMED Funded

(Circulation. 2012;126:1717-1727.)
A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention
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<tr>
<td>Age, y</td>
<td>67±11</td>
<td>68±11</td>
<td>0.488</td>
</tr>
<tr>
<td>Sex, male, %</td>
<td>81.2</td>
<td>80.0</td>
<td>0.668</td>
</tr>
<tr>
<td>History of CHF, %</td>
<td>83.4</td>
<td>91.1</td>
<td>0.014</td>
</tr>
<tr>
<td>Current NYHA (class III/IV), %</td>
<td>64.6</td>
<td>67.0</td>
<td>0.632</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>50.7</td>
<td>52.0</td>
<td>0.779</td>
</tr>
<tr>
<td>Renal insufficiency, %</td>
<td>30.2</td>
<td>23.1</td>
<td>0.091</td>
</tr>
<tr>
<td>Peripheral vascular disease, %</td>
<td>26.5</td>
<td>25.7</td>
<td>0.851</td>
</tr>
<tr>
<td>Implantable cardiac defibrillator, %</td>
<td>31.1</td>
<td>34.7</td>
<td>0.420</td>
</tr>
<tr>
<td>Previous CABG, %</td>
<td>28.7</td>
<td>28.2</td>
<td>0.032</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>24.1±6.3</td>
<td>23.4±6.3</td>
<td>0.244</td>
</tr>
<tr>
<td>STS mortality score, %</td>
<td>6±7</td>
<td>6±6</td>
<td>0.809</td>
</tr>
<tr>
<td>SYNTAX score</td>
<td>29.3±13.5</td>
<td>30.3±13.1</td>
<td>0.514</td>
</tr>
<tr>
<td>Mayo PCI score, %</td>
<td>8.4±3.6</td>
<td>8.8±3.4</td>
<td>0.154</td>
</tr>
<tr>
<td>New York PCI score, %</td>
<td>10.8±3.4</td>
<td>11.2±3.3</td>
<td>0.207</td>
</tr>
<tr>
<td>Not surgical candidate, %</td>
<td>64.6</td>
<td>63.6</td>
<td>0.822</td>
</tr>
</tbody>
</table>

(Circulation. 2012;126:1717-1727.)
A Prospective, Randomized Clinical Trial of Hemodynamic Support With Impella 2.5 Versus Intra-Aortic Balloon Pump in Patients Undergoing High-Risk Percutaneous Coronary Intervention
The PROTECT II Study

Intention to Treat

Per Protocol

(Circulation. 2012;126:1717-1727.)
The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

(J Interven Cardiol 2014;27:1–11)
The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

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The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

(J Interven Cardiol 2014;27:1–11)

Table 2. Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Impella Pre-PCI</th>
<th>Impella Post-PCI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 154 (mean ± SD, median [IQR], or %)</td>
<td>N = 63 (mean ± SD, median [IQR], or %)</td>
<td>N = 91 (mean ± SD, median [IQR], or %)</td>
<td></td>
</tr>
<tr>
<td>Duration of Impella support, hours</td>
<td>23.7 [3.5 62.7]</td>
<td>22.8 [1.6 52.8]</td>
<td>24.2 [4.2 69.2]</td>
<td>0.39</td>
</tr>
<tr>
<td>Median door-to-balloon time, min</td>
<td>63.5 [40.3 113.5]</td>
<td>112 [79 112]</td>
<td>52 [34 81]</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Suspected infarct related artery territory

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Impella Pre-PCI</th>
<th>Impella Post-PCI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left main</td>
<td>16.1%</td>
<td>23.8%</td>
<td>9.5%</td>
<td>0.02</td>
</tr>
<tr>
<td>Left anterior descending</td>
<td>52.6%</td>
<td>53.9%</td>
<td>51.4%</td>
<td>0.76</td>
</tr>
<tr>
<td>Left circumflex</td>
<td>10.9%</td>
<td>4.8%</td>
<td>16.2%</td>
<td>0.03</td>
</tr>
<tr>
<td>Right coronary</td>
<td>16.8%</td>
<td>12.7%</td>
<td>20.3%</td>
<td>0.24</td>
</tr>
<tr>
<td>Graft</td>
<td>3.7%</td>
<td>4.8%</td>
<td>2.7%</td>
<td>0.52</td>
</tr>
<tr>
<td>Number of diseased vessels</td>
<td>1.8±0.76</td>
<td>1.94±0.72</td>
<td>1.70±0.79</td>
<td>0.07</td>
</tr>
<tr>
<td>Number of significant lesions (≥70%)</td>
<td>2.57±1.39</td>
<td>2.74±1.49</td>
<td>2.42±1.28</td>
<td>0.19</td>
</tr>
<tr>
<td>Number of vessel treated</td>
<td>1.42±0.63</td>
<td>1.57±0.67</td>
<td>1.30±0.57</td>
<td>0.01</td>
</tr>
<tr>
<td>Number of lesions treated</td>
<td>2.02±1.24</td>
<td>2.33±1.40</td>
<td>1.77±1.02</td>
<td>0.006</td>
</tr>
<tr>
<td>Number of stents</td>
<td>1.68±1.02</td>
<td>1.94±1.15</td>
<td>1.47±0.85</td>
<td>0.007</td>
</tr>
<tr>
<td>TIMI flow [0–1] prior to PCI</td>
<td>80.2%</td>
<td>71.9%</td>
<td>84.8%</td>
<td>0.14</td>
</tr>
<tr>
<td>TIMI flow [0–1] post-PCI</td>
<td>8.7%</td>
<td>4.6%</td>
<td>11.9%</td>
<td>0.19</td>
</tr>
</tbody>
</table>
The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

(J Interven Cardiol 2014;27:1–11)
The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

(J Interven Cardiol 2014;27:1–11)

### Table 4. Multivariate Analysis for Predictors of In-Hospital Mortality

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation of Impella support prior to PCI</td>
<td>0.37</td>
<td>0.17–0.79</td>
<td>0.01</td>
</tr>
<tr>
<td>Age</td>
<td>1.05</td>
<td>1.02–1.08</td>
<td>0.003</td>
</tr>
<tr>
<td>Number of inotropes</td>
<td>1.56</td>
<td>1.11–2.18</td>
<td>0.01</td>
</tr>
<tr>
<td>Cardiogenic shock onset prior to admission</td>
<td>2.42</td>
<td>1.12–5.24</td>
<td>0.03</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>4.59</td>
<td>2.02–10.42</td>
<td>0.0003</td>
</tr>
</tbody>
</table>

*For each predictor, increases are marked with an arrow.*
The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

(J Interven Cardiol 2014;27:1–11)

Earlier MCS is BETTER!
• Jan 2009-Dec 2016

• 15,259 identified as having acute MI with cardiogenic shock

• 51% survived to explantations of pVAD

• Hospital volume predicted survival: Lowest volume (quintile) had 30% survival vs 76% in the top quintile (p < 0.001)

• 59% survival as first line treatment vs 52% in salvage cases
High Risk PCI Expanded FDA Indication:
(Now includes mild and mod reduced LVEF)

The Impella 2.5 and Impella CP are indicated for providing temporary (< 6 hours) ventricular support during elective or urgent high risk percutaneous coronary interventions (PCI) performed in hemodynamically stable patients with severe coronary artery disease, [and depressed left ventricular ejection fraction] when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option.

Use of the Impella 2.5 and the Impella CP in these patients may prevent hemodynamic instability which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

The Impella® platform is the only percutaneous temporary ventricular support devices that are FDA-approved for High Risk PCI.
Data Supporting Protected PCI Indication

<table>
<thead>
<tr>
<th>Scientific Evidence to Support PMA Applications*</th>
<th>Total Number of Patients in the Cohort</th>
<th>Number of Impella Protected PCI Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Severe Reduced LVEF ≤35%</td>
<td></td>
</tr>
<tr>
<td>Protect I</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Protect II</td>
<td>452</td>
<td>225</td>
</tr>
<tr>
<td>U.S. Impella Registry</td>
<td>1,322</td>
<td>709</td>
</tr>
<tr>
<td>Literature review</td>
<td>2,537</td>
<td>756</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong> 5,024</td>
<td><strong>2,403</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild, Moderately Reduced LVEF &gt;35%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cVAD Registry Study</td>
<td>693</td>
<td>464 / 229</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LVEF ≤35%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LVEF &gt;35%</td>
</tr>
<tr>
<td>Total</td>
<td>5,024</td>
<td>2,403</td>
</tr>
</tbody>
</table>

* Patient data may be provided in multiple PMA applications
Accepted Manuscript

Title: The Role of Mechanical Circulatory Support during Percutaneous Coronary Intervention in Patients Without Severely Depressed Left Ventricular Function

Author: Khaldoon Alaswad, Mir Babar Basir, Akshay Khandelwal, Theodore Schreiber, William Lombardi, William O'Neill

PII: S0002-9149(17)31923-9
DOI: https://doi.org/10.1016/j.amjcard.2017.11.045
Reference: AJC 23036

To appear in: The American Journal of Cardiology
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>LVEF &lt;=35% (N=661 Patients)</th>
<th>LVEF &gt;35% (N=230 Patients)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Mean ±SD(N)</td>
<td>68.68±11.01</td>
<td>72.12±11.70</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Gender - Male</td>
<td>78%</td>
<td>67%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>88%</td>
<td>94%</td>
<td>0.017</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>53%</td>
<td>45%</td>
<td>0.042</td>
</tr>
<tr>
<td>Angina</td>
<td>41%</td>
<td>42%</td>
<td>0.696</td>
</tr>
<tr>
<td>Prior Stroke</td>
<td>7%</td>
<td>6%</td>
<td>0.879</td>
</tr>
<tr>
<td>Renal Insufficiency</td>
<td>34%</td>
<td>25%</td>
<td>0.010</td>
</tr>
<tr>
<td>Dialysis</td>
<td>24%</td>
<td>30%</td>
<td>0.378</td>
</tr>
<tr>
<td>CHF</td>
<td>65%</td>
<td>34%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Prior MI</td>
<td>53%</td>
<td>38%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>50%</td>
<td>42%</td>
<td>0.059</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>30%</td>
<td>29%</td>
<td>0.848</td>
</tr>
<tr>
<td>LVEF %</td>
<td>21.18±7.84</td>
<td>51.94±9.31</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>STS Mortality Score</td>
<td>6.37±7.11</td>
<td>4.87±5.84</td>
<td>0.007</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>1.58±1.26</td>
<td>1.35±1.02</td>
<td>0.015</td>
</tr>
</tbody>
</table>

Patient cohort >35% was older, more often female, had more hypertension

# Procedural Characteristics

<table>
<thead>
<tr>
<th>Procedural Characteristics</th>
<th>LVEF &lt;=35% (N=661 Patients)</th>
<th>LVEF &gt;35% (N=230 Patients)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of diseased vessels</td>
<td>1.73±0.79 (649)</td>
<td>1.90±0.71 (220)</td>
<td>0.005</td>
</tr>
<tr>
<td>Number of vessels treated</td>
<td>1.55±0.73 (649)</td>
<td>1.81±0.60 (216)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Use of rotational atherectomy (RA)</td>
<td>14.90% (649)</td>
<td>21.21% (216)</td>
<td>0.046</td>
</tr>
<tr>
<td>Average number of passes per lesion</td>
<td>2.51±1.63</td>
<td>3.33±2.09</td>
<td>0.017</td>
</tr>
<tr>
<td>Number of lesions treated</td>
<td>1.67±0.76 (604)</td>
<td>1.87±0.80 (212)</td>
<td>0.001</td>
</tr>
<tr>
<td>Coronary vessel involved:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left anterior descending artery</td>
<td>35.50% (662/1865)</td>
<td>33.84% (245/724)</td>
<td>0.428</td>
</tr>
<tr>
<td>Left Main:</td>
<td>13.08% (244/1865)</td>
<td>23.62% (171/724)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Distal LM and proximal LAD</td>
<td>8.02% (53/661)</td>
<td>18.70% (43/230)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Distal LM and proximal LCx</td>
<td>7.11% (47/661)</td>
<td>18.70% (43/230)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>LCx</td>
<td>28.36% (529/1865)</td>
<td>26.93% (195/724)</td>
<td>0.467</td>
</tr>
<tr>
<td>RCA</td>
<td>18.34% (342/1865)</td>
<td>11.74% (85/724)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Graft</td>
<td>4.72% (88/1865)</td>
<td>3.87% (28/724)</td>
<td>0.347</td>
</tr>
<tr>
<td>SVG</td>
<td>4.29% (80/1865)</td>
<td>3.31% (24/724)</td>
<td>0.257</td>
</tr>
</tbody>
</table>

Patient cohort >35% had more diseased vessels, more RA, more lesions treated, more Left Main

### Favorable MACCE in Both Cohorts

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>LVEF &lt;=35% (N=661 Patients)</th>
<th>LVEF &gt;35% (N=230 Patients)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACCE</td>
<td>4.54%</td>
<td>3.48%</td>
<td>0.574</td>
</tr>
<tr>
<td>Death</td>
<td>3.78%</td>
<td>1.74%</td>
<td>0.193</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0.30%</td>
<td>1.30%</td>
<td>0.112</td>
</tr>
<tr>
<td>CVA/Stroke</td>
<td>0.00%</td>
<td>0.00%</td>
<td>--</td>
</tr>
<tr>
<td>Revascularization</td>
<td>0.61%</td>
<td>1.30%</td>
<td>0.383</td>
</tr>
<tr>
<td>Acute Renal Dysfunction</td>
<td>6.05%</td>
<td>2.61%</td>
<td>0.055</td>
</tr>
<tr>
<td>Bleeding requiring Surgery</td>
<td>0.76%</td>
<td>0.43%</td>
<td>1.000</td>
</tr>
<tr>
<td>Vascular Complication requiring Surgery</td>
<td>1.06%</td>
<td>2.17%</td>
<td>0.201</td>
</tr>
<tr>
<td>Device Malfunction</td>
<td>0.15%</td>
<td>0.00%</td>
<td>1.000</td>
</tr>
<tr>
<td>Failure to Achieve Angiographic Success</td>
<td>0.30%</td>
<td>0.87%</td>
<td>0.275</td>
</tr>
<tr>
<td>(Residual Stenosis &lt;30% after stent implant)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MACCE and adverse event rates favorable and consistent between two patient cohorts**

Favorable MACCE in Both Cohorts

MACCE and adverse event rates favorable and consistent between two patient cohorts

Conclusions

Patients with LVEF >35% when compared to patients with LVEF ≤35% were:

1. Older age (72 vs 69 years, p<0.001)

2. More extensive CAD, more diseased vessels (1.9 vs 1.7; p=0.005)

3. More LM (13% vs 24% <.0001) and more MVD intervention

4. More use of rotational atherectomy (21% vs 15% p=0.046)

5. Prevalence of high-risk clinical features; renal failure (25%) and DM (45%)

Despite high-risk features, MACCE favorable overall – No differences between groups (3.48% vs 4.54%; p = 0.574).

PCI with elective MCS was feasible and safe

Revascularization Strategy by Risk Category

### Surgical Risk

- **Low**
  - PCI
- **Medium**
  - CABG or PCI
  - PCI or CABG
- **High**
  - CABG
  - CABG or PCI
  - Support & PCI

### Anatomic Risk

- **Low**
  - PCI
- **Medium**
  - CABG or PCI
- **High**
  - CABG

### SYNTAX Study

- Often inoperable

---

Patients Most Appropriate for Revascularization

Coronary Revascularization Appropriateness Guidelines
ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT

<table>
<thead>
<tr>
<th>Heart Failure</th>
<th>Angina</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Risk Findings on Noninvasive Study</strong></td>
<td><strong>CCS Class III or IV Angina</strong></td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td><strong>Stress Test Med. Rx</strong></td>
</tr>
<tr>
<td><strong>Med. Rx</strong></td>
<td><strong>CTO of 1 vz.; no other disease</strong></td>
</tr>
<tr>
<td>Class III or IV</td>
<td>High Risk Max Rx</td>
</tr>
<tr>
<td>Class I or II</td>
<td>High Risk No/min Rx</td>
</tr>
<tr>
<td>Asymptomatic Max Rx</td>
<td>Int. Risk Max Rx</td>
</tr>
<tr>
<td>Class III or IV No/min Rx</td>
<td>Int. Risk No/min Rx</td>
</tr>
<tr>
<td>Class I or II No/min Rx</td>
<td>Low Risk Max Rx</td>
</tr>
<tr>
<td>Asymptomatic No/min Rx</td>
<td>Low Risk No/min Rx</td>
</tr>
<tr>
<td></td>
<td>Coronary Anatomy</td>
</tr>
<tr>
<td></td>
<td>CTO of 1 vz.; no other disease</td>
</tr>
<tr>
<td></td>
<td>1-2 vz. disease; no Prox. LAD</td>
</tr>
<tr>
<td></td>
<td>1 vz. disease of Prox. LAD</td>
</tr>
<tr>
<td></td>
<td>2 vz. disease with Prox. LAD</td>
</tr>
<tr>
<td></td>
<td>3 vz. disease; no Left Main</td>
</tr>
</tbody>
</table>

Protected PCI Patients
More Heart Failure
More Angina
More Complex
More likely to be appropriate

A = Appropriate, U = Uncertain, I= Inappropriate

1. Patel MR, et al, J AM Coll Cardiol. 2012;59(9); 857-881
Outline

• Why and in Whom do we use Mechanical support? Back to Basics
• National Trends in Use of Mechanical Cardiac Support (MCS)
• IABP
• Impella
• Tandem Heart/ECMO (briefly)
• Summary
Tandem Heart
Tandem Heart

- **Four components**
  - 21 F transseptal cannula
  - Centrifugal pump
  - Femoral arterial cannula
    - 15F – 19F (3.5 - 5L/min)
  - Control Console

- Both LV and pump contribute flow to aorta in “tandem” (CO is additive)
  - ↓ blood from LA to LV
  - ↓ LV preload, workload, filling pressures, wall stress and MvO2
  - Severity of LV dysfunction determines dependency on tandem heart—flat line for some patients

- Do not tolerate VT/VF very well
  - Still need RV function

- **Contraindications**
  - Severe RV dysfunction
  - VSD vs severe AI?
  - Intolerance to anticoagulation (ACT > 300 required)

- **Complications**
  - Coagulopathies (DIC, HITT), Hemolysis
  - Vascular
ECMO
Hemodynamic Effects of ECMO

Flow → Cardiac Power Output
AOP → EDV, EDP
EDV, EDP → Wall Tension, Mechanical Work
Wall Tension, Mechanical Work → Microvascular Resistance
Microvascular Resistance → Coronary Flow
Coronary Flow → Oxygen Supply
Oxygen Supply → Oxygen Demand
Oxygen Demand → Loads the Heart

Hemodynamic Protection

Burkhoff D. et al. J Am Coll Cardiol. 2015 Dec
## Differences

<table>
<thead>
<tr>
<th></th>
<th>ECMO/CPS</th>
<th>TandemHeart</th>
<th>IABP</th>
<th>Impella 2.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular surgery required</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Vascular access points</td>
<td>Multiple</td>
<td>Multiple</td>
<td>Single</td>
<td>Single</td>
</tr>
<tr>
<td>Catheter/cannula size</td>
<td>20–28 F</td>
<td>17–21 F</td>
<td>7–8 F</td>
<td>9 F</td>
</tr>
<tr>
<td>Cardiac wall puncture</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Inotropic drug dependency</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Physiologic timing</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### Continuous Flow Pumps

- **Pulsatile**
  - IABP
  - Impella CP
- **Axial-Flow**
  - PHP *
- **Centrifugal Flow**
  - TandemHeart
  - VA-ECMO

*Investigational*
**Hemodynamic Support (CPO)**

- **Inotropes**
  - Low
  - High

- **IAB + Inotropes**
  - Low
  - High

- **ECMO**
  - Retrograde flow

**Myocardial Protection (PVA)**

- **High**
- **Low**
- **Positive**
- **Negative**

- **Impella 2.5®**
  - Forward flow

- **Impella CP®**
  - Forward flow

- **Impella 5.0®**
  - Forward flow

**Therapy / Device Summary**
Outline

• Why and in Whom do we use Mechanical support? Back to Basics

• National Trends in Use of Mechanical Cardiac Support (MCS)

• IABP

• Impella

• Tandem Heart/ECMO (briefly)

• Summary
Summary

- MCS intended to improve hemodynamic profile, improve coronary and end organ perfusion, support complex procedures

- Trends: IABP on the decline, pVADs on the rise

- IABP: Quick, easy. Mild support. Cheap. Decent data

- Impella: More support, more expensive. Slightly more robust data, though this is industry driven

- For high risk patients, earlier MCS is better than later
<table>
<thead>
<tr>
<th>Which To Use:</th>
<th>What To Use:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Substrate</strong></td>
<td>• How much support needed?</td>
</tr>
<tr>
<td>• Elderly</td>
<td></td>
</tr>
<tr>
<td>• Low EF</td>
<td></td>
</tr>
<tr>
<td>• Renal failure</td>
<td></td>
</tr>
<tr>
<td>• Vasculature adequate</td>
<td></td>
</tr>
<tr>
<td>• Frail</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Lesion +/- Low EF</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Unprotected LM</td>
<td></td>
</tr>
<tr>
<td>• Multivessel PCI</td>
<td></td>
</tr>
<tr>
<td>• Prolonged ischemia expected (rotational atherectomy, diffuse disease)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Presentation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Shock</td>
<td></td>
</tr>
<tr>
<td>• Large STEMI</td>
<td></td>
</tr>
<tr>
<td>• CHF</td>
<td></td>
</tr>
</tbody>
</table>
Thank You

Questions?

Manu Uberoi
Abhimanyu.Uberoi@kp.org
(971) 278 - 8259
70 yo with inferior STEMI
70 yo with inferior STEMI
70 yo with inferior STEMI
70 yo with inferior STEMI

- On HD 3, RNs call noting blood in the gas line

Despite 30 minutes of manual pressure, continued bleeding from access site.

The patient is transferred urgently to the cath lab.

in retracting IABP
70 yo with inferior STEMI
75 yo, DM, CRI, EF 20%, high risk NSTEMI
75 yo, DM, CRI, EF 20%, high risk NSTEMI
75 yo, DM, CRI, EF 20%, high risk NSTEMI
75 yo, DM, CRI, EF 20%, high risk NSTEMI
60 yo, DM, ESRD, s/p CABG, high risk NSTEMI
60 yo, DM, ESRD, s/p CABG, high risk NSTEMI
60 yo, DM, ESRD, s/p CABG, high risk NSTEMI
60 yo, DM, ESRD, s/p CABG, high risk NSTEMI
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

Extreme angulation
Severe AI
EF 35%
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

Short LM
Severe LM disease
Severe prox-mid LAD disease
Severe diagonal disease
Significant Calcium
L dominant
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

Severe kyphoscoliosis
Severe iliofem tortuosity
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

After PreClose Attempt
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

R Femoral Angio
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

Decision Time

1. Stop everything, let groins heal
2. Send for surgery?
3. Proceed with PCI? Without support?
4. If with support, how would you do it?
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

What We Did

1. Upsized R sheath to 14Fr Impella Sheath
2. Used L CFA access for 7 Fr Guide
3. Insert Impella
4. Roto PCI of LM/LAD/Diag
5. Remove Impella
6. Endovascular Repair of L CFA
7. Manual pull of R CFA Sheath in ICU
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.
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75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.
75 yo male, severe scoliosis, Parkinson’s, Osteogenesis Imperfecta, wheelchair dependent, admitted with NSTEMI.

What happened to R groin?

ACT 144. Pulling sheath in a minute.

ok. thanks. how does the other side look?

Looks fine.

He thrombosed his right leg while we were holding pressure. Garrett is here. We are calling vascular.
85 yo, angina, HTN, MVD, hybernating myocardium
85 yo, angina, HTN, MVD, hybernating myocardium
85 yo, angina, HTN, MVD, hybernating myocardium
85 yo, angina, HTN, MVD, hybernating myocardium
85 yo, angina, HTN, MVD, hibernating myocardium
When I think Mechanical Support is needed?

• For HR PCI
  – Hemodynamic condition of patient at time of PCI
  – Anticipated risk of hemodynamic compromise during procedure
  – Need for support after revascularization

• In Acute MI, STEMI and high risk NSTEMI
  – Myocardial Ischemia
    • LV systolic and diastolic dysfunction
    • Elevated intracardiac pressures
  – Potential for thrombotic microembolization
    • Infarct extension
  – Hemodynamic decompensation
  – Procedural Complication
THANK YOU
IABP

• STEMI and high risk NSTEMI
• Myocardial Ischemia
  – LV systolic and diastolic dysfunction
  – Elevated intracardiac pressures
• Potential for thrombotic microembolization
  – Infarct extension
  – Hemodynamic decompensation
• Procedural Complication

• MCS may:
  – Reduces myocardial oxygen consumption
  – Improve coronary perfusion
Cases

- Torress, MRN 2215483 IABP for RCA
  - IVUS guided re-entry for RCA
  - Inferior STEMI
- Richard Vincent
- Sammy Donahoe
- Lan Thi
- Michael Hall
- Wanda Simpson
- Albert Fischer
- Khanhnhay
- Robb
Although introduction of IABP counterpulsation was hailed as a major advance, there was no mortality benefit at 30-day or 12-month follow-up in a major randomized controlled trial of IABP versus medical therapy in 600 subjects eligible for revascularization (IABP in Cardiogenic Shock II [IABP-SHOCK II]) (6, 8). The IABP-SHOCK II trial has been criticized because of a high crossover rate, relatively smaller sample size, timing of IABP insertion, and lower mortality (40%) than reported earlier. Notably, there were positive trends in certain subsets that some hypothesize could benefit from IABP support (9). Nevertheless, the recommendation for IABP use has been downgraded from class I to IIa in the United States (US) and European guidelines. Percutaneous mechanical circulatory support.

Currently in development, the i-cor system (Xenios AG, Heilbronn, Germany) is similar to an ECMO circuit and provides up to 8L/min of blood flow. Novel to the i-cor device, continuous flow or diastolic augmentation with electrocardiogram-triggered pulsatile flow can be provided. The HeartMate PHP (Percutaneous Heart Pump, St. Jude, St. Paul, MN) is an axialflow circulatory device, which expands when across the aortic valve and provides up to 5L/min of blood flow. It is currently being compared with the Impella 2.5 in high-risk PCI patients. The Reitan Catheter Pump (CardioBridge GmbH, Hechingen, Germany), placed in the descending thoracic aorta distal to the subclavian artery, creates a pressure gradient similar to the IABP counterpulsation resulting in decreased afterload and increased perfusion distally. Also positioned in the descending aorta, the Aortix device (Procyrion, Houston, TX) has expanding anchors and a transcutaneous charger allowing for sheath removal and potentially provides durable support (36).


### Table 2. Randomized Controlled Trials of Percutaneous Ventricular Assist Devices Compared With Intra-Aortic Balloon Counterpulsation for Cardiogenic Shock

<table>
<thead>
<tr>
<th>Study</th>
<th>Date</th>
<th>Condition</th>
<th>Device</th>
<th>Control</th>
<th>Total Sample Size</th>
<th>Primary Outcome</th>
<th>Mortality at 30 d, IABP Vs Percutaneous Ventricular Assist Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oweneel et al (17)</td>
<td>2017</td>
<td>Cardiogenic shock</td>
<td>Impella CP, n = 24</td>
<td>IABP, n = 24</td>
<td>48</td>
<td>30-d mortality</td>
<td>50% vs 46%&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Oweneel et al (23)</td>
<td>2016</td>
<td>Cardiogenic shock</td>
<td>Impella 2.5, n = 12</td>
<td>IABP, n = 9</td>
<td>21</td>
<td>Left ventricular ejection fraction at 4 mo</td>
<td>11% vs 25%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Seyfarth et al (22)</td>
<td>2008</td>
<td>Cardiogenic shock</td>
<td>Impella 2.5, n = 12</td>
<td>IABP, n = 13</td>
<td>26</td>
<td>Cardiac index</td>
<td>46% vs 46%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Thiele et al (32)</td>
<td>2005</td>
<td>Cardiogenic shock</td>
<td>TandemHeart, n = 21</td>
<td>IABP, n = 20</td>
<td>41</td>
<td>CP index</td>
<td>45% vs 43%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Burkhoff et al (33)</td>
<td>2006</td>
<td>Cardiogenic shock</td>
<td>TandemHeart, n = 19</td>
<td>IABP, n = 14</td>
<td>33</td>
<td>Hemodynamic improvement</td>
<td>64% vs 53%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
recent CathPCI registry analysis of 56,497 patients with acute myocardial infarction (AMI) complicated with cardiogenic shock (CS) revealed increased in-hospital mortality from 27.6% in 2005 to 2006, to 30.6% in 2011 to 2013 ($P<0.01$), possibly indicating the increased complexity of patients presenting with AMI and CS. Of the 1,249,547 PCI procedures performed between July 2009 and June 2011 in the United States, 17% were emergent cases. The American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) guidelines support the use of these devices in various settings, including hemodynamic support during high-risk PCI, patients presenting with cardiogenic shock as a bridge to recovery, or during revascularization. Despite widespread use and availability of these devices, there is a paucity of randomized, controlled trials data demonstrating unequivocal superiority of these devices in the aforementioned settings. A contemporary review by the Interventional Scientific Council of the ACC outlines an elegant algorithm providing various scenarios where use of mechanical circulatory support may be appropriate and helpful in patients undergoing high-risk PCI with CS.
Novel devices

Mechanical circulatory support in cardiogenic shock

Karl Werdan, Stephan Gielen, Henning Ebelt, and Judith S. Hochman

Department of Internal Medicine III, Heart Center, Martin-Luther-University Halle-Wittenberg; University Hospital Halle/Saale, Ernst-Grube-Str. 40, Halle/Saale 06120, Germany; and Cardiovascular Clinical Research Center (CCRC), New York University Langone Medical Center, New York, NY, USA

Received 19 October 2012; revised 7 March 2013; accepted 10 June 2013; online publish-ahead-of-print 7 September 2013

Table 5: Meta-analysis of RCTs: effects of left ventricular assist devices—TandemHeart and Impella PL2.5 pump—in comparison with the effects of IABP on haemodynamics; 30-day-mortality and adverse events in patients with cardiogenic shock, mainly due to myocardial infarction

<table>
<thead>
<tr>
<th></th>
<th>Thiele et al.</th>
<th>Burkhoff et al.</th>
<th>Seyfarth et al.</th>
<th>Pooled (fixed effect model)</th>
<th>Pooled (random effects model)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LVAD (n = 21)</td>
<td>IABP (n = 20)</td>
<td>LVAD (n = 19)</td>
<td>IABP (n = 14)</td>
<td>LVAD (n = 13)</td>
</tr>
<tr>
<td>Haemodynamics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CI ± SD (L min⁻¹ m⁻³)</td>
<td>2.3 ± 0.6</td>
<td>1.8 ± 0.4</td>
<td>2.2 ± 0.6</td>
<td>2.1 ± 0.2</td>
<td>2.2 ± 0.6</td>
</tr>
<tr>
<td>MAP ± SD (mmHg)</td>
<td>76 ± 10</td>
<td>70 ± 16</td>
<td>91 ± 16</td>
<td>72 ± 12</td>
<td>87 ± 18</td>
</tr>
<tr>
<td>PCWP ± SD (mmHg)</td>
<td>16 ± 5</td>
<td>22 ± 7</td>
<td>16 ± 4</td>
<td>25 ± 3</td>
<td>19 ± 5</td>
</tr>
<tr>
<td>Clinical outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30-day mortality, n (%)</td>
<td>9 (43)</td>
<td>9 (45)</td>
<td>9 (47)</td>
<td>5 (36)</td>
<td>6 (46)</td>
</tr>
<tr>
<td>Reported adverse events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leg ischaemia, n (%)</td>
<td>7 (33)</td>
<td>0 (0)</td>
<td>4 (21)</td>
<td>2 (14)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Bleeding, n (%)</td>
<td>19 (90)</td>
<td>8 (40)</td>
<td>8 (42)</td>
<td>2 (14)</td>
<td>2.35 (1.40; 3.93)</td>
</tr>
<tr>
<td>Fever of sepsis, n (%)</td>
<td>17 (81)</td>
<td>10 (50)</td>
<td>4 (21)</td>
<td>5 (36)</td>
<td>1.38 (0.88; 2.15)</td>
</tr>
</tbody>
</table>

CI, cardiac index; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MAP, mean arterial pressure; PCWP, pulmonary capillary wedge pressure. From Cheng et al. For details on the statistical analysis please refer to the original paper.
The major IABP trials, meanwhile, have been disappointing. In the 37-center, randomized IABP-SHOCK II trial of patients with acute myocardial infarction (AMI) complicated by cardiogenic shock, IABPs failed to show a benefit over standard care in terms of all-cause mortality. In the randomized BCIS-1 trial, planned IABP use failed to improve short-term survival or MACCE rates over no planned use of the device in patients with multivessel coronary disease and severe left ventricular dysfunction (LVEF ≤ 30%) undergoing PCI, although longer-term survival was inexplicably improved.
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• Tandem Heart/ECMO (briefly)

• Summary