Cath Lab Essentials: LV Assist Devices for Hemodynamic Support (IABP, Impella, Tandem Heart)

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Goals

■ To compare and contrast mechanical LV assistance and percutaneous support devices in terms of their designs and ideal applications
■ Review current indications for commonly used devices
■ Describe the factors that should be considered when choosing the most appropriate devices
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%

Shock Registry
JACC 2000 35:1063
Physiology of Cardiogenic Shock: A Downward Spiral

Myocardial Infarction

Blood pressure [↓ BP]

Damaged heart muscle

Inflammatory activation

Myocardial perfusion (blush ↓)

Myocardial ischemia

Coronary artery perfusion

Hemodynamic support

Vasodilation [SVR ↓]

Cardiac output

Reperfusion of IRA : PCI or CABG

Death

Reducing inflammatory response: ?
Emergency revascularisation - SHOCK Trial

85% of survivors NYHA Class I/II at 12 months after early revascularization or initial medical stabilization

Hochman JAMA 2000;285:190
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)

Cardiac Support in Cath lab
Hemodynamic Principles

ECMO  IABP  CPS  Hemopump  TandemHeart  Impella

70’ s  80’ s  90’ s  00’ s
Intra-Aortic Balloon Pump

- Introduced in 1968 (Kantrowitz)
- First “true percutaneous” support device
- Cheapest, commonest (20% of all cardiogenic shock cases), CO 0.5L/min
- Stabilize pt, but not full support
- No outcome benefit

Hemodynamic Effects:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Effect</th>
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<tbody>
<tr>
<td>Diastolic pressure</td>
<td>↑↑</td>
</tr>
<tr>
<td>CO</td>
<td>↑</td>
</tr>
<tr>
<td>MAP</td>
<td>↑</td>
</tr>
<tr>
<td>LV Wall Tension</td>
<td>↓↓</td>
</tr>
<tr>
<td>PCWP</td>
<td>↓↓</td>
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<tr>
<td>Oxygen Demand</td>
<td>↓</td>
</tr>
<tr>
<td>LV Volume</td>
<td>↓</td>
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<tr>
<td>Coronary Blood Flow</td>
<td>⇔</td>
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IABP improves myocardial Oxygen supply

STTI represents oxygen demand, and the diastolic pressure time index (DPTI) represents oxygen supply. IABP counterpulsation increases DPTI during IABP inflation and decreases STTI on the beat following IABP deflation. Intra-aortic balloon counterpulsation improves the ratio of myocardial oxygen supply and demand, reducing the risk of further ischemia or reductions in contractility.
Onset systole
deflate

Adjust timing

Onset systole deflate
Figure 5. Marked diastolic augmentation of aortic pressures observed with intra-aortic balloon pump use.

Nair et al Journal of Invasive Cardiology 2011
Figure 4. Pulmonary capillary wedge pressure (left) and pulmonary artery pressure (right) before (top) and after (bottom) insertion of the intra-aortic balloon pump.
Early Trials and Registry Data for IABP

- Shock Registry (n=292): TT only 63%, TT + IABP 47%
- NRMI Registry (n=23,180): TT only 69%, TT + IABP 49%
- TACTICS: TT only 43%, TT + IABP 34%
- GUSTO I & III: TT only 59%, TT + IABP 45%
- Kovack (n=46): TT only 68%, TT + IABP 23%
IABP in Cardiogenic Shock Primary PCI

Retrospective analysis of 23,180 patients from NRMI database

7268 treated by IABP  (trend towards improved mortality)
• High risk patients (age > 70, EF < 45%, etc) in PPCI in AMI
• Randomized to 26-48 hrs IABP (n=211) or conventional Rx after PCI (n=226)
• No benefit in mortality or LV function, at discharge or 6 weeks
IABP-Shock II Trial: Results Primary Study Endpoint:
30-day Mortality
(IABP in Cardiogenic Shock and Primary PCI)

Mortality (%)

P=0.92 by log-rank test
Relative risk 0.96; 95% CI 0.79-1.17; P=0.69 by Chi²-Test

Thiele H et al. NEJM 2012;367:1287.
Indications for IABP

- High Risk PCI
- Cardiogenic Shock
- Refractory Ischemia
  - Left Main
  - 3 Vessel CAD
  - VT/VFib
- MR or VSD after MI
- Severe CHF--? Bridge to Transplant
- Pre-operative stabilization
- Weaning therapy after CABG
Contraindication to IABP

- Peripheral vascular disease
- Aortic regurgitation
- Aortic Dissection
- PDA
- HOCM
- Heparin intolerance
- Bleeding Diathesis
- Sepsis
Complications of IABP

- Vascular Access bleeding/complications
- Limb Ischemia
- Infection
- Thrombocytopenia
- Migration and aortic arch trauma
- Other non-vascular (CVA, embolization of cholesterol, balloon rupture)
- Air embolism risk (reduced by using helium gas)
### Hemodynamic Advantage of pVAD vs. IABP

<table>
<thead>
<tr>
<th>Advantage</th>
<th>pVAD</th>
<th>IABP</th>
</tr>
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<tbody>
<tr>
<td>Directly unload the left ventricle</td>
<td>+++</td>
<td>-</td>
</tr>
<tr>
<td>Reduce myocardial workload and oxygen consumption</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Increase cardiac output and coronary and end-organ perfusion</td>
<td>+++</td>
<td>+</td>
</tr>
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Tandem Heart

- Left atrial-to-femoral arterial LVAD
- 21F venous transeptal cannula
- 17F arterial cannula
- Maximum flow 4-5L/min

Hemodynamic Effects

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Transseptal puncture

21 F cannula in LA
Tandem Heart and cannulae

Venous cannula

arterial return cannula
TandemHeart Shock study: Randomized Comparison of IABP with PTVA (VAD) Device in Patients with Cardiogenic Shock

Kaplan–Meier Survival Estimates for 30 Day Survival

PTVA-VAD:
- Cardiac Power Index (CO x MBP)
- Hemodynamic parameters
- Metabolic parameters
- Vascular complications

Thiele et al, Eur Heart J 2005;26:1276
TandemHeart Shock Study

Cardiac Index

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
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<tbody>
<tr>
<td>IABP</td>
<td>1.5</td>
<td>1.7</td>
</tr>
<tr>
<td>PerVAD</td>
<td>1.7</td>
<td>2.3</td>
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*p=0.4*  
*p=0.005*  

30-day Mortality

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<th>Pre</th>
<th>Post</th>
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<tbody>
<tr>
<td>IABP</td>
<td>45%</td>
<td>9/20</td>
</tr>
<tr>
<td>PerVAD</td>
<td>43%</td>
<td>9/21</td>
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*p=0.8*  

Transfusion

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<th>Pre</th>
<th>Post</th>
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<tbody>
<tr>
<td>IABP</td>
<td>40%</td>
<td>8/20</td>
</tr>
<tr>
<td>PerVAD</td>
<td>90%</td>
<td>19/21</td>
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</tbody>
</table>

*p=0.002*  

Limb Ischemia

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<th>Post</th>
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</thead>
<tbody>
<tr>
<td>IABP</td>
<td>0%</td>
<td>0/20</td>
</tr>
<tr>
<td>PerVAD</td>
<td>33%</td>
<td>7/21</td>
</tr>
</tbody>
</table>

*p=0.009*  

Impella

- Axial flow pump
- Much simpler to use
- Increases cardiac output & unloads LV
- LP 2.5 – CO 2.5 L/min
- CP
  - 14 F percutaneous approach; Maximum 4 L flow
- LP 5.0
  - 21 F surgical cutdown; Maximum 5L flow
The Impella CP is built on the same foundation as the Impella 2.5, but provides more than a 50% increase in pumped blood volume (approx. 4L/min).
Principles of Impella Design

*Mimic Heart’s Natural Function*

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

**EDV, EDP**

**AOP**

**Flow**

**O₂ Demand**

**O₂ Supply**

**Cardiac Power Output**

**Myocardial Protection**

**Systemic Hemodynamic Support**

Naidu S S Circulation 2011;123:533-543
IMPELLA Unloads Actively the Ventricle, Reduces Work Loads and Increases Cardiac Output

**End-Diastolic LV Pressure**

- Pump Off: 18 mmHg
- Pump On: 11 mmHg

**End-Diastolic Stroke Volume**

- Pump Off: 94 mL
- Pump On: 76 mL

**Total Cardiac Output**

- Pump Off: 6.0 L/min
- Pump On: 7.4 L/min

*M. Valgimigli et al., Catheterization & Cardiovascular Interventions 65:263–267 (2005)*
ISAR-SHOCK RANDOMIZED TRIAL:
IMPELLA 2.5 Provides Better Hemodynamic Support Than IABP in AMI Cardiogenic Shock*

Primary Endpoint:
Increase in Cardiac Index From Baseline
(measured after 30 min of support)

*p<0.01

*Seyfarth et al, J Am Coll Cardiol. 2008 Nov 4;52(19):1584-8
Overall 30 day mortality was 46% in both groups
PROTECT II 90-day Outcome (PP)

Hemodynamic support during high-risk, non-emergent PCI, N=654 Unprotected LM or last patent conduit & EF ≤35% or 3VD & EF ≥30%.

Per Protocol (PP)= Patients that met all incl./ excl. criteria.

The Impella device provided a higher level of support with an equal or lower adverse cardiac event rate.

* Designates statistically significant difference (p<0.05).
All other differences are non-significant.

O’Neill et al, Circulation. 2012;126:1717
Impella demonstrates EF improvements

**MACH II Trial**

- Study-Impella support post MI

1. **MACH II (N=20)**
   - Impella arm sicker at Baseline
   - Impella arm increased EF by 23 points
   - Control arm increased EF by 7
   - Impella arm had better QOL/activity at 3 years

2. **USpella Registry 9/2009**
   - Patients increased EF 7-9 points
   - 68% failing on IAB in cardiogenic shock
   - Age at 64 ± 16

1. MACH II Trial – Academic Medical Center, Netherlands, Mechanical Assistance for Acute Congestive Heart Failure, published in Journal of American College of Cardiology, March 11, 2008; 51: 1044-1046., 3-Year follow-up presented at TCT 2009

2. USpella, N=25 subjects have LVEF measurements
   * Longest available follow-up from PCI
Approach to cardiogenic shock

- Systolic BP > 70-85 mm Hg and good mentation: consider IABP to help prevent shock.

- Consider IABP in:
  - Bridge to surgery
  - Severe HF
  - Cardiogenic shock (mild to severe)

- BP < 70, or on inotropes and vasopressors: consider Impella (2.5-5L CO) or Tandem heart (4-5L)

- Complete Cardiogenic arrest: Extracorporeal membrane oxygenation and complete bypass
LV Support during High-Risk PCI: LVEF + Lesion Complexity

1. **LVEF >35%**
   - Simple PCI
   - **No support**

2. **LVEF 20-35%**
   - Complex PCI
   - IABP
   - SBP 75-80 mm Hg or mild Cardiogenic shock

3. **LVEF <20%**
   - Simple PCI
   - **IABP**
   - SBP 75-80 mm Hg or mild Cardiogenic shock

   - Complex PCI:
     - High Syntax score >32
     - STS >5
     - Extensive revasc.

   - Complex PCI:
     - SBP 40-70 mm Hg, more severe CS or multiple vasopressor/inotropic agents

   - Simple or Complex: Inoperable cases
     - **Impella/Tandem**
     - SBP 40-70 mm Hg, more severe CS or multiple vasopressor/inotropic agents
Questions

What are the complications of IABP?

A. vascular complications
B. CVA
C. embolization of cholesterol
D. balloon rupture
E. All of the above
Questions

- The following statement is true/false
- An IABP achieve its action through a counter pulsation:  Deflates during systole
  Inflates during Diastole
- What is used to inflate and deflate the balloon?