Rationale for Left Ventricular Support During Percutaneous Coronary Intervention

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Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high risk patients.
Defining Risk during PCI

Risk: an exposure to the possibility of loss or injury caused by an action or inaction.

To mitigate risk in PCI, ask three questions in advance:

1) Can I achieve angiographic success?
2) Can I do this without causing a complication?
3) Will successful PCI clinically benefit my patient?
Defining Risk during PCI

Patient
- Advanced Age
- Female
- Diabetics
- Prior MI
- Multivessel disease
- Renal dysfunction
- Periph. Vasc. disease
- Depressed LV function

Technical
- ACC/AHA Classification
- SCAI Classification
- Large myocardium at risk (Jeopardy Score)
- Sole-remaining vessel
- Unprotected LM
- Bifurcation lesions
- Chronic total occlusions
- Saphenous vein graft

Clinical
- Any ACS (Active Ischemia)
- Cardiogenic Shock
## Defining Risk during PCI

### CABG Risk Calculators

1. Euroscore
2. STS Score
3. Mass-Dac CABG
4. Hannan-CABG
5. Euroscore/Parsonnet
6. CCMRP

### Coronary Risk Calculators

1. Mayo Clinic
2. Wu-PCI
3. Mass-Dac PCI
4. SYNTAX Score

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Risk calculators for the use of circulatory support during PCI do not exist.

Existing risk calculators do not account for deranged hemodynamic conditions.
Physiology of High Risk PCI

Arterial and Venous Features Govern Myocardial Perfusion

1. Mean arterial pressure
2. Complex coronary anatomy
3. Microvascular obstruction

Arterial pressure
Slope as measure of resistance
Waterfall pressure
Venous pressures
Location or length

1. Increased LV-EDP
2. Systemic venous congestion
3. Coronary sinus congestion

What is the hemodynamic condition of your patient?
Goals of Circulatory Support during PCI


2. Reduce myocardial oxygen demand by limiting LV wall stress.

3. Augment coronary perfusion.

4. Create a ‘window in time’ for complete revascularization.
   - Multi-vessel PCI
   - Atherectomy/Thrombectomy
   - Bifurcation PCI
When is Circulatory Support Rational?

**Patient**
- Advanced Age
- Female
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## When is Circulatory Support Rational?

### Revascularization Strategy by Risk Category

<table>
<thead>
<tr>
<th>Anatomic Risk</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>PCI</td>
<td>PCI</td>
<td>PCI</td>
</tr>
<tr>
<td>Medium</td>
<td>CABG or PCI</td>
<td>PCI or CABG</td>
<td>Support* &amp; PCI</td>
</tr>
<tr>
<td>High</td>
<td>CABG</td>
<td>CABG or PCI</td>
<td>Support* &amp; PCI</td>
</tr>
</tbody>
</table>

* Hemodynamic Instability

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How is Circulatory Support Supposed to Work?

- Maintain Systemic Perfusion
- Reduced Myocardial $O_2$ Demand

LV EDV
LV ESP
LV Work
LV EDP

Pressure
Volume

MAP
Left-sided Circulatory Support Options are Expanding

Continuous Flow Pumps

<table>
<thead>
<tr>
<th>Pulsatile</th>
<th>Axial-Flow</th>
<th>Centrifugal Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>IABP</td>
<td>Impella CP</td>
<td>TandemHeart</td>
</tr>
<tr>
<td>Intracorporeal</td>
<td>PHP *</td>
<td>VA-ECCMO</td>
</tr>
</tbody>
</table>

* Investigational

Kapur and Esposito. HF Clinic Rev 2014
Augmented Diastolic Pressure: 122 mmHg
Assisted Systolic Pressure: 75 mmHg

MEGA-IABP Hemodynamic Effect:
Systolic Unloading: 98 → 75 mmHg
Diastolic Augmentation: 58 → 122 mmHg

How does IABP Support Work?
1. Reduces Systolic Pressure
2. Maintains MAP by Augmenting Diastolic Pressure
Recent IABP Trials Fail to Show Clinical Benefit

- No assessment of hemodynamic IABP effect
- No trials incorporating larger capacity IABPs

Red = Non-Responder
Failed to Unload Systolic Pressure by > 10mmHg

Arjun Majithia (PGY3) and Kapur et al J Inv Card 2014
Is this tracing reassuring to you?

IABP Supported LM PCI

Not Reassuring

1. Minimal diastolic augmentation prior to LM balloon inflation
2. MAP drops by 25mmHg (115 to 90)
3. Supported MAP driven by Augmented Pressures in Diastole Only
How does Rotodynamic Support Work?

pLVAD (Tandem) Supported LAD PCI

- Baseline: 93/57, 69
- Tandem 6500 rpm: 97/75, 81
- 6500 rpm + LAD PTCA: 73/67, 69

Systemic and coronary perfusion maintained + Reduced Myocardial \( O_2 \) Demand

- LV EDV
- LV ESP
- LV Work
- LV EDP
TandemHeart (LA-FA Bypass)

pLA-FA Bypass
Impella Axial-Flow Catheters

Percutaneous: Impella CP (14Fr)

LV → Asc Ao
A Primary Goal of Circulatory Support is to Reduce LV Pressure and Volume

Impella CP Reduces LV Pressure & Volume

TandemHeart Primarily Reduces LV Volume

James Nilson (PGY8), Michele Esposito (PGY3), and Kapur et al ASAIO 2015
Is this tracing reassuring to you?

Yes: Reassuring
Sustained MAP throughout the cardiac cycle
Next Generation Axial Flow Catheter:
Heartmate PHP (St. Jude)
14Fr Sheath → 24Fr Impeller

Actively Enrolling
SHIELD-II : High Risk PCI Trial in USA
Randomized 2:1 (HeartMate PHP vs. Impella 2.5)
Does Circulatory Support Work in Elective HR-PCI?

<table>
<thead>
<tr>
<th>(Prophylactic)</th>
<th>Group A (n = 61)</th>
<th>Group B (n = 72)</th>
<th>(Provisional)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intraprocedural events (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>0</td>
<td>11 (15)</td>
<td></td>
<td>.001</td>
</tr>
<tr>
<td>VF/VT</td>
<td>0</td>
<td>1 (2.0)</td>
<td></td>
<td>.48</td>
</tr>
<tr>
<td>CPA</td>
<td>0</td>
<td>1 (2.0)</td>
<td></td>
<td>.48</td>
</tr>
<tr>
<td>Hypotension/shock</td>
<td>0</td>
<td>11 (15)</td>
<td></td>
<td>.001</td>
</tr>
<tr>
<td><strong>Inhospital MACCEs (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>3 (5)</td>
<td>7 (10)</td>
<td></td>
<td>.29</td>
</tr>
<tr>
<td>Death</td>
<td>1 (2)</td>
<td>3 (4)</td>
<td></td>
<td>.23</td>
</tr>
<tr>
<td>AMI</td>
<td>2 (3.2)</td>
<td>4 (5.5)</td>
<td></td>
<td>.30</td>
</tr>
<tr>
<td>CABG</td>
<td>0</td>
<td>0</td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>0</td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td>Vascular complications*</td>
<td>0</td>
<td>2 (3)</td>
<td></td>
<td>.25</td>
</tr>
</tbody>
</table>

Prophylactic IABP reduces acute complications, but no change in mortality during PCI in patients with low LVEF.
## Does Circulatory Support Work in Elective HR-PCI?

<table>
<thead>
<tr>
<th>In-hospital and 30-day clinical outcomes</th>
<th>P-IABP (n = 69)</th>
<th>R-IABP (n = 46)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In-hospital outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>10 (22%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Q-wave myocardial infarction</td>
<td>0</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Non-Q-wave myocardial infarction</td>
<td>13 (20%)</td>
<td>26 (62%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Major complication</td>
<td>0</td>
<td>12 (26%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>30-Day outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>2 (4%)</td>
<td>11 (27%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Q-wave myocardial infarction</td>
<td>0</td>
<td>3 (9%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Death + Q-wave myocardial infarction</td>
<td>2 (4%)</td>
<td>13 (32%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Target lesion revascularization</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Target vessel revascularization*</td>
<td>0</td>
<td>2 (6%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Target lesion revascularization/major adverse cardiac events</td>
<td>2 (4%)</td>
<td>13 (32%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stent thrombosis†</td>
<td>1 (1%)</td>
<td>0</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Prophylactic, not rescue, IABP improves clinical outcomes during high risk PCI in patients with hemodynamic instability.
Does Circulatory Support Work in Elective HR-PCI?

BCIS-1 Study

HR-PCI Definition:
1. LVEF<30%
2. High Jeopardy Score

No 6-month mortality benefit to elective IABP insertion.

JAMA. 2010;304(8):867-874
Does Circulatory Support Work in Elective HR-PCI?

PROTECT II Trial Design

Patients Requiring Prophylactic Hemodynamic Support During Non-Emergent High Risk PCI on Unprotected LM/Last Patent Conduit and LVEF≤35% OR 3 Vessel Disease and LVEF≤30%

1:1

IABP + PCI

IMPELLA 2.5 + PCI

Primary Endpoint = 30-day Composite MAE* rate

Follow-up of the Composite MAE* rate at 90 days

*Major Adverse Events (MAE) : Death, MI (>3xULN CK-MB or Troponin), Stroke/TIA, Repeat Revasc, Cardiac or Vascular Operation of Vasc. Operation for limb ischemia, Acute Renal Dysfunction, Increase in Aortic insufficiency, Severe Hypotension, CPR/VT, Angio Failure
A trend towards benefit with Impella 2.5 over IABP among patients undergoing elective, HR-PCI.

Follow up analyses have been informative:
1. Trends towards benefit with ITT analysis favoring Impella
2. Rotational atherectomy is an extreme high risk substrate
3. Learning curve support devices improves outcomes
4. Multi-vessel revascularization may reduce MACCE

Circulation 2012
Why the disconnect between hemodynamic effect and clinical outcomes?

1. Patient selection
   - No hemodynamic criteria in HR-PCI trials.
   - Underestimating rotational atherectomy

2. Device selection/timing
   - Poor insight into the mechanics of LV support systems.
   - Pre-PCI vs Bailout support impacts outcomes.

3. Pursuing patients with extreme high risk.
   - Salvaging the unsalvageable?

4. Incomplete revascularization / reperfusion
Key Points:

- High risk PCI is a relative term that is being performed with increasing frequency.

- There is growing clinical data for the use of circulatory support during high risk PCI.

- Let the hemodynamics guide your approach:
  1. A careful assessment of **pre-procedural** hemodynamics
  2. Anticipated need for **intra-procedural** support
Thank you.
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