Rationale for Prophylactic Support During Percutaneous Coronary Intervention

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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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Euroscore</td>
</tr>
<tr>
<td>2</td>
<td>STS Score</td>
</tr>
<tr>
<td>3</td>
<td>Mass-Dac CABG</td>
</tr>
<tr>
<td>4</td>
<td>Hannan-CABG</td>
</tr>
<tr>
<td>5</td>
<td>Euroscore/Parsonnet</td>
</tr>
<tr>
<td>6</td>
<td>CCMRP</td>
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</tbody>
</table>

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

Existing risk calculators do not account for deranged hemodynamic conditions.

### Coronary Risk Calculators

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Mayo Clinic</td>
</tr>
<tr>
<td>2</td>
<td>Wu-PCI</td>
</tr>
<tr>
<td>3</td>
<td>Mass-Dac PCI</td>
</tr>
<tr>
<td>4</td>
<td>SYNTAX Score</td>
</tr>
</tbody>
</table>
When is Circulatory Support Rational?

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

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Physiology of High Risk PCI

Arterial and Venous Features Govern Myocardial Perfusion

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

1. LV pressure overload
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
   - Comprehensive evaluation (Neuro, Surgical, or Adv HF)
How is Circulatory Support Supposed to Work?

- LV EDV
- LV ESP
- LV Work
- LV EDP

Reduced Myocardial O₂ Demand
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?

Unassisted Systolic Pressure: 98 mmHg
Unassisted Diastolic Pressure: 58 mmHg

Augmented Diastolic Pressure: 122 mmHg
Assisted Systolic Pressure: 75 mmHg
Hemodynamics of Counterpulsation: A Lost Art

Non-Augmented Diastolic Pressure (A)
Non-Augmented Systolic Pressure (B)
Dicrotic Notch Pressure (C)
Augmented Diastolic Pressure (D)
Reduced Aortic End-Diastolic Pressure (E)
Augmented Reduced Systolic Pressure (F)
Systolic Unloading (B-F)
Diastolic Augmentation (D-A)
Diastolic unloading (A-E)
Deflation Pressure (D-E)
Slope of Deflation Pressure (mmHg/sec)
How effectively are we using IABP therapy?

Kapur NK et al. J Inv Card 2014
How does Rotodynamic Support Work?

Baseline

Tandem 6500 rpm

6500 rpm + LAD PTCA

Systemic and coronary perfusion maintained.

- LV EDV
- LV ESP
- LV Work
- LV EDP

Reduced Myocardial \( O_2 \) Demand
Mechanical Unloading: Targeting the LV or the LA

**A**
- **Impella CP: 3.1 LPM**
  - LV Pressure (mmHg) vs. LV Volume (mL)
  - ON and OFF states depicted

**B**
- **TandemHeart: 3.1 LPM**
  - LV Pressure (mmHg) vs. LV Volume (mL)
  - ON and OFF states depicted

**C**
- **TandemHeart: 4.4 LPM**
  - LV Pressure (mmHg) vs. LV Volume (mL)
  - ON and OFF states depicted

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**LV Stroke Work**
- Baseline, Infarct, CP (3.1 LPM), TH (3.1 LPM), TH (4.4 LPM)
- Bars with asterisks indicating significant differences

**LV Stroke Volume**
- Baseline, Infarct, CP (3.1 LPM), TH (3.1 LPM), TH (4.4 LPM)
- Bars with asterisks indicating significant differences

Kapur et al ASAIO 2014
What’s the differential diagnosis for this patient with heart failure undergoing a procedure?

LV Pressure Overload due to VA-ECMO
Why I don’t use VA-ECMO to support high-risk PCI?

1) Increased Ea
2) Increased Wall Stress (Afterload)
Rationale for Venting the LV with VA-ECMO

1) Unchanged $E_a$
2) Reduced Wall Stress (Afterload)
LV Venting: ECPELLA
LV Venting: ECPELLA

EC-PELLA: VA-ECMO + Impella CP

VA-ECMO without CP
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>Intraprocedural events (%)</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>Inhospital MACCEs (%)</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.

Am J Cardiol 2006;98:608-12
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.

No. at risk
- No planned IABP:
  - 150 at 6 months
- Elective IABP:
  - 151 at 6 months

Follow-up, mo
Cumulative Mortality, %

Log-rank $P = .33$
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
Does Circulatory Support Work in Elective HR-PCI?

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th></th>
<th>90 Days</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IABP (n=222)</td>
<td>Impella 2.5 (n=225)</td>
<td>P</td>
<td>IABP (n=219)</td>
</tr>
<tr>
<td>Composite of major adverse events</td>
<td>40.1</td>
<td>35.1</td>
<td>0.277</td>
<td>49.3</td>
</tr>
<tr>
<td>Death</td>
<td>5.9</td>
<td>7.6</td>
<td>0.473</td>
<td>8.7</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>1.8</td>
<td>0.0</td>
<td>0.043</td>
<td>2.7</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>10.4</td>
<td>13.8</td>
<td>0.268</td>
<td>14.2</td>
</tr>
<tr>
<td>Repeat revascularization</td>
<td>4.1</td>
<td>1.3</td>
<td>0.075</td>
<td>7.8</td>
</tr>
</tbody>
</table>

No clear difference between IABP and Impella 2.5 LP in 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 be beneficial
Does Circulatory Support Work in Acute MI?

**CRISP-AMI:**
Pre-reperfusion IABP in Anterior MI

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**Table 3. Cardiac Magnetic Resonance Imaging (MRI) Findings**

<table>
<thead>
<tr>
<th>Time from symptom onset to MRI, median (IQR), d</th>
<th>Total (N = 337)</th>
<th>IABC Plus PCI (n = 161)</th>
<th>PCI Alone (n = 176)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4.0 (3.0-5.0)</td>
<td>4.0 (3.0-5.0)</td>
<td>4.0 (3.0-4.0)</td>
<td>.20</td>
</tr>
</tbody>
</table>

**Primary End Point**

<table>
<thead>
<tr>
<th>Infarct size, % of left ventricular mass</th>
<th>Total (N = 337)</th>
<th>IABC Plus PCI (n = 161)</th>
<th>PCI Alone (n = 176)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per-protocol analysis, No. (%)</td>
<td>275 (81.6)</td>
<td>133 (82.6)</td>
<td>142 (80.7)</td>
<td>.06</td>
</tr>
<tr>
<td>Mean (95% CI)</td>
<td>39.8 (37.4-42.1)</td>
<td>42.1 (38.7-45.6)</td>
<td>37.5 (34.3-40.8)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>38.8 (26.0-52.2)</td>
<td>42.8 (27.2-54.7)</td>
<td>36.2 (25.9-49.4)</td>
<td></td>
</tr>
</tbody>
</table>
Why the disconnect between hemodynamic effect and clinical outcomes?

1. Patient selection
   - No hemodynamic criteria used to characterize patients.

2. Device selection/timing
   - No hemodynamic evaluation of device effect.
   - Pre-PCI vs Bailout support impacts outcomes.

3. No exit strategy in cardiogenic shock.
   - Salvaging the unsalvegeable?

4. Incomplete support with a uni-ventricular strategy?
   - No assessment of RV function in shock.
**High Risk PCI**

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

**Treatment of Cardiogenic Shock**

The use of intra-aortic balloon pump counterpulsation can be useful for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological.

Alternative LV assist devices for circulatory support may be considered in patients with refractory cardiogenic shock.
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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