Pulsatile versus continuous flow LV-support devices for high-risk PCI

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Interventional Cardiologist

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HSC meeting Athens, Greece
Potential conflicts of interest

Speaker's name: Joost Daemen

☑️ I have the following potential conflicts of interest to report:

Institutional grant/research support:
ABBOTT VASCULAR, BOSTON SCIENTIFIC, Acist medical, Medtronic, PulseCath.

Consultancy and speaker fees:
Pythagoras Medical, Acist medical, Medtronic, PulseCath, ReCor medical
MCS may complement PCIs in elective high-risk interventions and in cardiogenic shock

Decision based on anatomical, clinical and hemodynamic criteria:
- disease extension
- complex coronary lesions including left main stem disease, heavy calcification, bifurcations and chronic total occlusions amenable to PCI.
- Age
- co-morbidities
- low contractile reserve
The struggle for evidence

Elective Intra-aortic Balloon Counterpulsation During High-Risk Percutaneous Coronary Intervention

Interventional Cardiology

Intra-aortic Balloon Counterpulsation and Infarct Size in Patients With Acute Anterior Myocardial Infarction Without Shock

The CRISP AMI Randomized Trial

JAMA 2010
“Elective IABP insertion did not reduce the incidence of MACCE following PCI. These results do not support a strategy of routine IABP placement before PCI in all patients with severe left ventricular dysfunction and extensive coronary disease.”

CIRCULATION 2012
“The 30-day incidence of major adverse events was not different for patients with IABP or Impella 2.5 hemodynamic support.”

JAMA 2011
“Among patients with acute anterior STEMI without shock, IABC plus primary PCI compared with PCI alone did not result in reduced infarct size.”
Longer-term outcome favor MCS
IABP and Impella 2.5

Long-term data of BCIS-I trial
Perera et al. Circulation 2013

Per protocol analysis of PROTECT-II
O’Neill et al. Circulation 2012
High Risk PCI in Erasmus MC

198 elective cases

* The primary end-point was a composite of procedure related adverse events including death (up to 24 hours), cardiac arrest requiring resuscitation, hypotension with need for vasopressor support, need for rescue MCS, limb ischemia with need for surgery and need for endotracheal intubation.
IABP

Since 1968

- Decreases afterload
- Decreases LVEDV, Wall Stress and stroke work
- Increases stroke volume and MAP
- Increase in mean coronary pressure to lower intra-myocardial pressure
- Reduces myocardial microvascular Resistance
- Decreases MVO2
- Improves coronary blood flow, myocardial perfusion, and oxygen supply improve
- Limited increase in CO (<0.5L)

## Multiple options for MCS

<table>
<thead>
<tr>
<th></th>
<th>IABP</th>
<th>iVAC2L*</th>
<th>Impella</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size (F)</td>
<td>7-8</td>
<td>17</td>
<td>13 (2.5), 14 (CP), 21 (5.0)</td>
</tr>
<tr>
<td>Pump</td>
<td>Pneumatic</td>
<td>Pneumatic</td>
<td>Axial flow</td>
</tr>
<tr>
<td>Support</td>
<td>Counterpulsation</td>
<td>LV to aorta</td>
<td>LV to aorta</td>
</tr>
<tr>
<td>Max. flow (L/min)</td>
<td>0.3-1.0</td>
<td>2.0</td>
<td>2.5, 3.7, 5.0</td>
</tr>
<tr>
<td>Insertion site</td>
<td>Femoral artery</td>
<td>Femoral artery</td>
<td>Femoral artery</td>
</tr>
<tr>
<td>CE mark</td>
<td>Weeks</td>
<td>24h</td>
<td>10 days</td>
</tr>
<tr>
<td>FDA</td>
<td>Weeks</td>
<td>No</td>
<td>7 days</td>
</tr>
<tr>
<td>Requires stable rhythm</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Implantation time (min)</td>
<td>10</td>
<td>16</td>
<td>11-25</td>
</tr>
<tr>
<td>Afterload</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>MAP</td>
<td>↓</td>
<td>↑</td>
<td>↑↑</td>
</tr>
<tr>
<td>Cardiac output</td>
<td>↑</td>
<td>↑↑</td>
<td>↑↑↑</td>
</tr>
<tr>
<td>Cardiac power output</td>
<td>↑</td>
<td>↑</td>
<td>↑↑</td>
</tr>
<tr>
<td>EDP</td>
<td>↓</td>
<td>↓</td>
<td>↓↓</td>
</tr>
<tr>
<td>PCWP</td>
<td>↓</td>
<td>↔</td>
<td>↓</td>
</tr>
<tr>
<td>Preload</td>
<td>↔</td>
<td>unknown</td>
<td>↓↓</td>
</tr>
<tr>
<td>Coronary perfusion</td>
<td>↑</td>
<td>unknown</td>
<td>↑</td>
</tr>
<tr>
<td>MVO₂</td>
<td>↓</td>
<td>↓↓</td>
<td>↓↓</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>0</td>
<td>0</td>
<td>++++</td>
</tr>
</tbody>
</table>
Hemodynamic effects

A: iVAC2L

B: IMPELLA CP

C: PHP / IMPELLA 5.0

D: IMPELLA RP

E: ECMO

F: ECMO + IMPELLA

G: TANDEMHEART

H: IABP
The Impella (CP)

- Axial flow pump (13Fr (2.5L); 14Fr (CP); 21Fr (5L))
- LV unloading, reduces LVEDV and LVESP, diminishing MVO2
- Increases coronary pressure, coronary flow reserve, and decreased MR, with improvements in coronary blood flow
- Hemolysis, Glc metabolism dysregulation, movement of pump

• 17F catheter across aortic valve is connected to an extracorporeal membrane pump

• iVAC2L actively aspirates blood from the left ventricle in systole and ejects this blood into the ascending aorta during diastole

• Pump is compatible with standard IABP console as a driver
iVAC2L Procedural overview
iVAC2L Aortic Pressure

HEART-PULSE
PULSE DUE TO iVAC2L™ FLOW

IABP HELIUM FLOW
Hemodynamics with PulseCath

- Counterpulsation
- Diastolic Pressure increases
- MAP increases
- C.O. varies*
Rotterdam PulseCath Feasibility Study

- Prospective observational Study
- N = 14 patients
- High-risk PCI
- Angiographic success 100%
- 1 major vascular complication
Patient selection

Inclusion

- Indicated for high-risk PCI and/or MCS support
- Expected MCS support up to 24 hr
- Patient is older than 18 years
- Signed Informed Consent

Exclusion

- Significant ascending aorta disease
- Significant degenerative AV disease or AoV prosthesis
- LV thrombus
- Severe peripheral arterial disease
- Bleeding disorders
- Recent stroke (< 6 months) and/or residual mRS > 2
## Baseline characteristics

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage or Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AGE, Y</strong></td>
<td>74 [56-84]</td>
</tr>
<tr>
<td><strong>GENDER, M</strong></td>
<td>64%</td>
</tr>
<tr>
<td><strong>MYOCARDIAL INFARCTION &lt;30 DAYS</strong></td>
<td>57%</td>
</tr>
<tr>
<td><strong>CONGESTIVE HEART FAILURE</strong></td>
<td>79%</td>
</tr>
<tr>
<td><strong>CURRENT NYHA CLASS III/IV</strong></td>
<td>64%</td>
</tr>
<tr>
<td><strong>DIABETES MELLITUS</strong></td>
<td>21%</td>
</tr>
<tr>
<td><strong>RENAL INSUFFICIENCY</strong></td>
<td>36%</td>
</tr>
<tr>
<td><strong>PERIPHERAL ARTERIAL DISEASE</strong></td>
<td>21%</td>
</tr>
<tr>
<td><strong>IMPLANTABLE CARDIAC DEFIBRILLATOR</strong></td>
<td>7%</td>
</tr>
<tr>
<td><strong>PREVIOUS CABG</strong></td>
<td>7%</td>
</tr>
<tr>
<td><strong>LVEF, %</strong></td>
<td>30 [16-35]</td>
</tr>
<tr>
<td><strong>STS MORTALITY SCORE, %</strong></td>
<td>5 [1-11]</td>
</tr>
<tr>
<td><strong>SYNTAX SCORE</strong></td>
<td>28.3 [16.5-58.5]</td>
</tr>
<tr>
<td><strong>NOT SURGICAL CANDIDATE</strong></td>
<td>57%</td>
</tr>
</tbody>
</table>
## Procedural characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO. OF LESIONS ATTEMPTED</td>
<td>3 [2-5]</td>
</tr>
<tr>
<td>LEFT MAIN STEM PCI</td>
<td>69%</td>
</tr>
<tr>
<td>USE OF HEPARIN, %</td>
<td>100%</td>
</tr>
<tr>
<td>TOTAL CONTRAST MEDIA, ML</td>
<td>200 [60-300]</td>
</tr>
<tr>
<td>ROTATIONAL AHERECTOMY, %</td>
<td>8%</td>
</tr>
<tr>
<td>TOTAL SUPPORT TIME, MIN</td>
<td>67 [23-149]</td>
</tr>
</tbody>
</table>
## Biochemical characteristics

<table>
<thead>
<tr>
<th>Test</th>
<th>Reference</th>
<th>Baseline</th>
<th>2 hours</th>
<th>24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HAEMOGLOBIN (MMOL/L)</strong></td>
<td>M: 8.6-10.5 mmol/L</td>
<td>7.2 [5.3-8.9]</td>
<td>6.5 [5.5-8.3]</td>
<td>6.3 [5.5-8.4]</td>
</tr>
<tr>
<td></td>
<td>F: 7.5-9.5 mmol/L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FREE HAEMOGLOBIN (MMOL/L)</strong></td>
<td>0-6 µmol/L</td>
<td>4 [1-10]</td>
<td>6 [1-10]</td>
<td>4 [3-8]</td>
</tr>
<tr>
<td><strong>HAPTOGLOBIN (G/L)</strong></td>
<td>&gt;0.27 g/L</td>
<td>2.0 [1.2-3.3]</td>
<td>1.5 [0.8-2.9]</td>
<td>2.3 [1.6-2.8]</td>
</tr>
<tr>
<td><strong>TOTAL BILIRUBIN (MMOL/L)</strong></td>
<td>&lt;17 µmol/L</td>
<td>7 [3-19]</td>
<td>8 [4-16]</td>
<td>7 [4-20]</td>
</tr>
<tr>
<td><strong>CREATININE (MMOL/L)</strong></td>
<td>65-115 µmol/L</td>
<td>95 [57-227]</td>
<td>97 [54-205]</td>
<td>99 [54-196]</td>
</tr>
</tbody>
</table>

### No haemolysis

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iVAC2L Hemodynamic Effects

Change in Mean Arterial Pressure

- Baseline
- During
- After

Change in Cardiac Output

- Baseline
- During
- After

Max iVAC2L support @ 78 bpm

iVAC2L as assessed by PV loop

1A

1B

1C

1D

1E

1F

1G iVAC2L activation and PVA

1H Cardiac Output during PCI with iVAC2L

Pulsatile vs. Continuous flow

Pulsatile Left Ventricular Assist Devices: What Is the Role in the Modern Era?

Pavan Atluri, MD, and Michael A. Acker, MD

With the widespread use of continuous-flow ventricular assist devices (VADs), the role of pulsatile VADs remain in question. In acute cardiogenic shock, pulsatile VADs maximize perfusion pressure, restore end organ perfusion, and maximally unload the pulmonary circulation and right heart. In addition, pulsatile left VADs allow for easy conversion to biventricular support using one platform, in the case of acute right ventricular failure. Pulsatile VADs still have a major role in the treatment of acute cardiogenic shock.

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Keywords: cardiogenic shock, LVADs, BVADS

- Difference in long-term support v.s. salvage intervention (shock)
- Pulsatile LV support results in superior LV unloading, higher systemic perfusion pressure, theoretically augmented coronary perfusion and more unloading of the right heart and pulmonary circulatory system (SynCardia Total Artificial Heart experience)

PULSE trial

- Prospective observational study
- 4 Centers
- N = 40 patients
- High-risk PCI
- iVAC2L (or Impella CP) & PV Loops with conductance catheter
- Assess hemodynamic unloading of LV
Conclusions

- Percutaneous MCS unloads the left ventricle
- MCS is feasible in high-risk PCI and *might* improve (long-term) patient outcomes
- Differences in performance and exact mechanisms of action between different forms of MCS
- iVAC2L is a promising new technology
  - From HD perspective more performant than IABP
  - PULSE TRIAL will further address LV unloading mechanism
- iVAC2L in shock requires further study
Thank You

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