Utilization and Outcomes of Impella vs IABP Among Patients with AMI Complicated by Cardiogenic Shock Undergoing PCI

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Background

- Cardiogenic shock occurs in about 10% of patients with acute MI and is associated with substantial morbidity and mortality.
- In addition to timely reperfusion and medical therapy, mechanical circulatory support (MCS) devices may be used to provide hemodynamic support, but guideline recommendations are limited.
- Impella® devices provide greater hemodynamic support than IABP.¹
- Impella® has been marketed in the U.S. since 2008, but with limited randomized clinical trial evidence in cardiogenic shock.
  - Only 2 RCTs enrolling 74 total patients have compared Impella® vs IABP.
  - No difference in 30-day mortality, but higher bleeding with Impella® use.¹,²

Study Aims

1) Assess MCS device utilization over time among patients with AMI complicated by cardiogenic shock (AMI-CS) undergoing PCI.

2) Apply propensity score matching to examine clinical outcomes among patients receiving Impella® or IABP
   A. Primary effectiveness outcome: in-hospital death
   B. Primary safety outcome: in-hospital major bleeding
Methods: Data Source

• Identified patients with AMI-CS undergoing PCI between 10/1/2015 and 12/31/2017.
  ▪ Linked cohort of the NCDR® CathPCI Registry® (>1500 US hospitals) and Chest Pain - MI Registry™ (>1000 US hospitals).
  ▪ Standardized data elements: demographics, history, labs, procedural data
  ▪ Robust data quality standards, including auditing.

• Cardiogenic shock: SBP < 90 mm Hg and/or cardiac index <2.2 L/min/m² for ≥ 30 minutes secondary to ventricular dysfunction, and/or requirement for inotropic, vasopressor, or MCS device therapy.
Methods: Cohort Construction

NCDR® CathPCI Registry®
- n=1,600,032

NCDR Chest Pain - MI Registry™
- n=455,212

Patients in Linked Registries with AMI Undergoing PCI
- n=269,303

Matched Patients With AMI-CS Undergoing PCI
- n=28,304

- Impella® Only
  - n=1,768 (6.2%)

- IABP Only
  - n=8,471 (29.9%)

- Medical Therapy Only
  - n=16,227 (57.3%)

- Other MCS Devices or Multiple Devices
  - n=1,838 (6.5%)
Characteristics of Patients with AMI-CS Undergoing PCI

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Impella® Only (n=1,768)</th>
<th>IABP Only (n=8,471)</th>
<th>Medical Therapy Only (n=16,227)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) years</td>
<td>64.2 (12.0)</td>
<td>65.2 (12.4)</td>
<td>65.3 (12.8)</td>
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<tr>
<td>Male sex, %</td>
<td>71.3</td>
<td>69.2</td>
<td>64.8</td>
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<tr>
<td>Transferred from outside facility, %</td>
<td>27.3</td>
<td>23.8</td>
<td>24.8</td>
</tr>
<tr>
<td>Prior MI, %</td>
<td>22.3</td>
<td>20.7</td>
<td>22.0</td>
</tr>
<tr>
<td>Cerebrovascular disease, %</td>
<td>10.8</td>
<td>10.4</td>
<td>11.7</td>
</tr>
<tr>
<td>Peripheral artery disease, %</td>
<td>9.7</td>
<td>7.6</td>
<td>10.0</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>36.5</td>
<td>33.7</td>
<td>31.5</td>
</tr>
<tr>
<td>Cardiac arrest at first medical contact, %</td>
<td>25.4</td>
<td>24.3</td>
<td>23.4</td>
</tr>
<tr>
<td>STEMI, %</td>
<td>78.2</td>
<td>84.4</td>
<td>79.7</td>
</tr>
<tr>
<td>Anterior infarction, %</td>
<td>50.6</td>
<td>47.4</td>
<td>32.1</td>
</tr>
<tr>
<td>Left main and/or proximal LAD disease, %</td>
<td>62.6</td>
<td>54.7</td>
<td>33.5</td>
</tr>
<tr>
<td>Multivessel disease, %</td>
<td>66.2</td>
<td>63.5</td>
<td>48.6</td>
</tr>
</tbody>
</table>
MCS Device Utilization Over Time

Impella® Use Increased from 3.5% to 8.7% (p<0.001)
Methods: Propensity Matching

- **NCDR® CathPCI Registry®**
  - n=1,600,032
- **NCDR Chest Pain - MI Registry™**
  - n=455,212

Patients in Linked Registries with AMI Undergoing PCI
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- Impella® Only
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- Medical Therapy Only
  - n=16,227 (57.3%)
- Other MCS Devices or Multiple Devices
  - n=1,838 (6.5%)

Propensity Matched Patients Receiving Impella® vs IABP
  - n=1,680 pairs (total n=3,360)

95% of Impella® patients successfully matched
Characteristics of Propensity-Matched Cohort

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Impella® Only (n=1680)</th>
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<tr>
<td>Age, mean (SD) years</td>
<td>64.3 (11.9)</td>
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<td>Male sex, %</td>
<td>71.1</td>
<td>71.3</td>
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<td>Transferred from outside facility, %</td>
<td>27.4</td>
<td>26.8</td>
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<tr>
<td>Medical History, %</td>
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<td></td>
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<tr>
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<td>Clinical Characteristics, %</td>
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<td>66.1</td>
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Standardized mean difference was <0.10 for all 75 variables used for propensity score matching: demographics, clinical history and presentation, infarct location, coronary anatomy, and clinical laboratory data.
In-Hospital Clinical Outcomes

Death

- IABP: 34.1%
- Impella®: 45.0%

Absolute Risk Difference = 10.9 percentage points (95% CI, 7.6 to 14.2)

Major Bleeding

- IABP: 16.0%
- Impella®: 31.3%

Absolute Risk Difference = 15.4 percentage points (95% CI, 12.5 to 18.2)
In-Hospital Outcomes, Stratified by Timing of Device Placement

MCS Placement Prior to or During PCI
n=573 matched pairs

- **Death**: Impella® 45.6%, IABP 36.8%
- **Major Bleeding**: Impella® 27.4%, IABP 16.6%

Absolute Risk Difference: 8.7 percentage points (95% CI 3.1 to 14.4)

MCS Placement Post-PCI
n=662 matched pairs

- **Death**: Impella® 44.0%, IABP 32.2%
- **Major Bleeding**: Impella® 34.4%, IABP 15.7%

Absolute Risk Difference: 11.8 percentage points (95% CI 6.6 to 17.0)

(95% CI 6.1 to 15.6)

(95% CI 6.6 to 17.0)

(95% CI 14.2 to 23.3)
• Residual confounding
  ▪ Robust propensity match: standardized difference <0.10 for all 75 variables.
  ▪ 95% of patients treated with Impella®-only were successfully matched.
  ▪ Results consistent across multiple sensitivity analyses (timing of device placement; hospitals using both IABP and Impella®; excluding transfers)
• Clinical severity of AMI-CS patients in NCDR®
  ▪ Registry definition similar to trials.
  ▪ High event rate consistent with contemporary clinical trials and registries.
• Inability to distinguish different types of Impella® devices.
  ▪ Results primarily pertain to Impella® 2.5 and CP because 5.0 requires surgical cutdown, and patients receiving multiple devices were excluded.
Conclusions

This large, national, real-world study of patients with AMI-CS undergoing PCI demonstrates:

– A significant 2.5-fold increase in the utilization of Impella® devices.
– Impella® was associated with significantly higher rates of in-hospital death and major bleeding compared to IABP.

• These data provide important insights into the performance of MCS devices in routine clinical practice, and outcomes in RCT settings may differ.
• Better evidence and guidance are needed regarding the optimal management of patients with AMI-CS as well as the role of MCS devices in general, and Impella® in particular.