Outcomes for 15,259 US Patients With Acute MI Cardiogenic Shock (AMICS) Supported With Impella

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High In-Hospital Mortality During AMI Cardiogenic Shock

2. Acute Cardiac Assist Report, Health Research International – August 2015
Impella Quality (IQ) Database Methods

• Abiomed clinical personnel collecting real world data from >98% of US cases since 2009; >50,000 patients
• >15,000 patients with AMI-CGS
• FDA Approval 2016, AMI/CGS therapy and heart recovery
• Audited by Abiomed Heart Team (Cardiologists and CV Surgeon)
• HIPAA compliant data collection, FDA Maude protocol compliant
• “Exempt” status by Henry Ford Hospital IRB
• Survival tracked to device explant
IQ Program Data Resources

Abiomed Impella Quality (IQ) Database
N=46,949

HRPCI Elective & Urgent 48% (n=22,678)
Cardiogenic Shock 32% (n=15,259)
Other 19% (n=9012)

Observational IQ Database

- IRB Exempt / HIPAA Compliant
- 1,010 US Impella Centers; 2009-2017
- Abiomed Heart Team Physicians Audited
- All Devices, All Indications

Abiomed Impella Quality (IQ) Database, Danvers MA

1. Abiomed Impella Quality (IQ) Database, Danvers MA
2. cVAD Registry Data of Patients Undergoing PCI for Acute Myocardial Infarction Complicated by Cardiogenic Shock as of September 2015

IRB Registry Data

- IRB approval at all institutions (65)
- Retrospective (‘09 to ‘15); Prospective (‘16)
- FDA protocols and CEC Events Adjudication
- All Devices, All Patients Enrolled
# AMI/CGS Impella Patient Demographics

<table>
<thead>
<tr>
<th>IQ Database(^1)</th>
<th>cVAD Registry(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong>&lt;br&gt;– Mean: 63.6 y/o&lt;br&gt;– Range: (19 – 99)</td>
<td><strong>Age</strong>&lt;br&gt;– Mean: 66.3 y/o&lt;br&gt;– Range: (19 – 95)</td>
</tr>
<tr>
<td><strong>Gender</strong>&lt;br&gt;– 73% Male</td>
<td><strong>Gender</strong>&lt;br&gt;– 76% Male</td>
</tr>
<tr>
<td><strong>Duration Of Support</strong>&lt;br&gt;– Mean: 3.78 Days&lt;br&gt;– Median: 2.7 Days&lt;br&gt;– Max: 94 Days</td>
<td><strong>Duration Of Support</strong>&lt;br&gt;– Mean: 1.63 Days&lt;br&gt;– Median: 1.1 Days&lt;br&gt;– Max: 10.6 Days</td>
</tr>
<tr>
<td><strong>Survival to Explant</strong></td>
<td><strong>Survival to Explant, Discharge &amp; 30 days</strong></td>
</tr>
</tbody>
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1. Abiomed Impella Quality (IQ) Database, Danvers MA
2. cVAD Registry Data of Patients Undergoing PCI for Acute Myocardial Infarction Complicated by Cardiogenic Shock as of September 2015
Impella Utilization in AMI Shock

Total AMI/CGS US Patients

% IABP Supported Patients

% Impella Supported Patients

1. Acute Cardiac Assist Report, Health Research International – August 2015
Variation in Impella AMI/CGS Outcomes

Distribution of Impella Site Outcomes

2. Top 20% performing sites have higher volume of Impella utilization
3. Greater than 90% of survivors were explanted with native heart recovery in 2016
4. Mean survival of 58% in 2016. Improvement of 14% (relative) since FDA approval
Impella Pre-PCI associated with Improved Survival in AMI/CGS

IQ Database¹

<table>
<thead>
<tr>
<th>IABP/Inotropes Pre-PCI</th>
<th>Impella Pre-PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>52%</td>
<td>59%</td>
</tr>
<tr>
<td>N=3121</td>
<td>N=2450</td>
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</tbody>
</table>

P<0.001

CVAD Registry²

<table>
<thead>
<tr>
<th>IABP/Inotropes Pre-PCI</th>
<th>Impella Pre-PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>62%</td>
<td>67%</td>
</tr>
<tr>
<td>N=164</td>
<td>N=121</td>
</tr>
</tbody>
</table>

P<0.001

Hemodynamic Monitoring associated with Improved Survival in AMI/CGS

IQ Database\(^1\)

<table>
<thead>
<tr>
<th>No Hemodynamic Monitoring</th>
<th>Hemodynamic Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>49%</td>
<td>63%</td>
</tr>
<tr>
<td>N=8767</td>
<td>N=5217</td>
</tr>
</tbody>
</table>

P<0.0001

CVAD Registry\(^2\)

<table>
<thead>
<tr>
<th>No Hemodynamic Monitoring</th>
<th>Hemodynamic Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>68%</td>
<td>76%</td>
</tr>
<tr>
<td>N=634</td>
<td>N=516</td>
</tr>
</tbody>
</table>

P=0.002

2. CVAD survival to explant 2009-2016
Increased Inotrope Exposure is associated with Mortality in AMI/CGS

Mortality and Number of Inotropes from cVAD Registry

P<0.001 (N=287)


Samuels LE et al., J Card Surg. 1999
Detroit Cardiogenic Shock Initiative
Detroit CSI AMI/CGS Pilot Study

- July 2016 to February 2017
  - all sites performed >10 AMICS cases w/ Impella within last calendar year
- Enrolled 37 patients
  - Age 63 +/- 13 years (36-87)
- Rapid Door to Unloading times (average 82 minutes)
- 62% supported w/ Impella Pre-PCI
- RHC use 84%
- 86% of patients established TIMI III flow
- Decrease Inotropic/Vasopressor use in 80% of cases

Cardiac Power Output
(CPO = MAP x CO)

- 0.56 Watts (N=21)
- 0.96 Watts (N=27)
  - 58% increase
  - P <0.001

100% Native Heart Recovery in Survivors

Outcomes

- Survival to Explant
  - Metro Detroit Before Study: 51%
  - Detroit CSI: 89%
- Survival to Discharge
  - Detroit CSI: 84%

100% Native Heart Recovery
In surviving Patients (31/31)

1. Abiomed Impella Quality (IQ) Database, Jan 2015 to July 2016 for Aggregate DTW Metro Hospitals AMI/CGS Survival to Explant
Conclusions

- AMI CGS mortality remains unchanged despite major advances in cardiac care in past 20 years
- Despite FDA PMA approval, Impella is used in ~5% of US AMI Shock Cases
- There is a wide institutional variation in AMI CGS outcomes with Impella use
- Key Observations Associated with Improved Outcomes:
  - Increased institutional use of Impella
  - Impella use prior to PCI
  - Reduced exposure to high dose inotropes
  - Protocol using hemodynamic monitoring to guide escalation and weaning
- Prospective, systematic adoption of best practices (DCSI) markedly improves survival and native heart recovery
Thank You
**Early Identification**

**AECC (Early Cardiogenic Shock) Protocol**

**DETOURCSI Treatment Algorithm**

**Inclusion Criteria**
- Shortness of breath
- Septic shock
- Myocardial infarction

**Exclusion Criteria**
- Severe aortic stenosis
- Severe mitral regurgitation
- Severe right ventricular dysfunction
- Severe pulmonary hypertension

**ACTIVATE CATH LAB**

**QUALITY MEASURES**
- **Hemodynamic Monitoring**
  - CPO > 0.6
  - PAPi > 1.85
  - Improve survival to hospital discharge to >80%

**Unload Prior to PCI (DTU)**

**Hemodynamic Calculations**
1. Cardiac Power Output (CPO) = MAP x CO
2. Pulmonary Artery Pulsatility Index (PAPI) = dPAP / dPRA

**Escalation**

**DETOURCSI Shock Initiative**

**Access**
- Obtain femoral arterial access (via direct visualization with use of ultrasound)
- Obtain venous access (Femoral or Internal jugular)
- Obtain other risk calculated cardiac index or LVEDP

IF LVEDP > 15 or Cardiac Index < 2.2 AMI anatomy suitable, place IMPELLA