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

William O’Neill, MD, FACC
Medical Director
Structural Heart Disease at Henry Ford Hospital, MI
AMI Shock Mortality Unchanged in > 20 years

US AMI/CGS cases per year\(^1,2\)


74355 78954 78500 79823 80585 82626 86692 89923

High In-Hospital Mortality During AMI Cardiogenic Shock\(^3\)

N = 23,696

\(^1\) Sandhu A, McCoy I, Negi S, et al. Use of Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention; Insights from the National Cardiovascular Data Registry. Circulation, 2015;132:1243-1251

\(^2\) 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) Database¹
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

CvAD Registry Data²
N=2,704

- HRPCI Elective & Urgent 47% (n=1275)
- Cardiogenic Shock 40% (n=1090)
- Other 13% (n=339)

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

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
### 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></td>
<td><strong>Age</strong></td>
</tr>
<tr>
<td>– Mean: 63.6 y/o</td>
<td>– Mean: 66.3 y/o</td>
</tr>
<tr>
<td>– Range: (19 – 99)</td>
<td>– Range: (19 – 95)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>– 73% Male</td>
<td>– 76% Male</td>
</tr>
<tr>
<td><strong>Duration Of Support</strong></td>
<td><strong>Duration Of Support</strong></td>
</tr>
<tr>
<td>– Mean: 3.78 Days</td>
<td>– Mean: 1.63 Days</td>
</tr>
<tr>
<td></td>
<td>– Median: 2.7 Days</td>
</tr>
<tr>
<td></td>
<td>– Max: 94 Days</td>
</tr>
<tr>
<td></td>
<td>– Median: 1.1 Days</td>
</tr>
<tr>
<td></td>
<td>– 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>
</table>

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

1. Top 20% of sites have mean survival of 76%
2. Bottom 20% of sites have mean survival of 30%

Survival to Explant

# of Sites

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

IABP/Inotropes Pre-PCI: 52% (N=3121)
Impella Pre-PCI: 59% (N=2450)

P<0.001

cVAD Registry²

IABP/Inotropes Pre-PCI: 62% (N=164)
Impella Pre-PCI: 67% (N=121)

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>N=8767</td>
<td>N=5217</td>
</tr>
<tr>
<td>49%</td>
<td>63%</td>
</tr>
</tbody>
</table>

\(P < 0.0001\)

\\survival to explant 2009-2016

\survival to explant 2009-2016

\(N=634\)

\(N=516\)

\(P=0.002\)

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

Mortality and Number of Inotropes from cVAD Registry¹

P<0.001 (N=287)

Number of Inotropes/Pressors

<table>
<thead>
<tr>
<th>Number of Inotropes/Pressors</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>32%</td>
</tr>
<tr>
<td>1</td>
<td>54%</td>
</tr>
<tr>
<td>2</td>
<td>65%</td>
</tr>
<tr>
<td>3</td>
<td>65%</td>
</tr>
<tr>
<td>4+</td>
<td>74%</td>
</tr>
</tbody>
</table>


Figure 1. Mortality percent based on immediate post-operative inotrope requirements.

Samuels LE et al, J Card Surg. 1999
Detroit Cardiogenic Shock Initiative

DETROIT CSI
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

<table>
<thead>
<tr>
<th></th>
<th>CPO Pre-Impella</th>
<th>CPO On Impella</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>21</td>
<td>27</td>
</tr>
<tr>
<td>Cardiac Power Output $^1$ ( (CPO = MAP \times CO) )</td>
<td>0.56 Watts</td>
<td>0.96 Watts</td>
</tr>
</tbody>
</table>

58% increase
\( P < 0.001 \)

100% Native Heart Recovery in Survivors

Outcomes

Survival to Explant¹
Metro Detroit Before Study
51%

Survival to Explant²
Detroit CSI
89%

Survival to Discharge²
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

**Inclusion Criteria**
- Symptomatic chest pain or dyspnea lasting for >30 minutes in duration
- EKG evidence of ischemic changes (including STEMI or NSTEMI)
- Hypotension (<90/60)
- Need for vasopressors or inotropes to maintain systolic blood pressure >90

**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 LVEF

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

**Protocol Driven Treatment**

**Emergency Cath Lab Activation**
- **Activate Cath Lab**

**Hemodynamic Monitoring**

- **UNLOAD PRIOR TO PCI (DTU)**
- **Hemodynamic Calculations**
  1. Cardiac Power Output (CPO) = MAP x CO / 4.51
  2. Pulmonary Artery Pulsatility Index (PAPI) = sPAP – dPAP / RA

**Quality Measures**
- **Shock Onset to Device < 90 minutes**
- **Establish TIMI III Flow**
- **Complete Revascularization**
- **Maintain CPO >0.6**
- **Maintain PAPi > 1.85**
- **Improve survival to hospital discharge to >80%**

**Escalation**
- If CPO remains <0.6 operators should consider the two listed possibilities:
  - PAPi >1.85 provide right sided hemodynamic support.
  - PAPI >1.85 consideration should be made to provide additional hemodynamic support.
  - Local practice patterns should dictate the next steps, which may include:
    - Placement of a more robust hemodynamic support device
    - Transfer to LVAD/Transplant center
- If CPO >0.6 and PAPI >1.85 operators should consider providing right sided hemodynamic support.
- If CPO >0.6 and PAPI <1.85 operators should determine if MCS should be weaned and removed in the cath lab or left in with transfer to ICU.

**WEARING**
- MCS device should only be considered for explanation once the following criteria are met:
  - MCS device on
  - In patients who do not meet the above criteria MCS should remain for 2-5 days with strong consideration for transfer to LVAD/Transplant centers.