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

N = 23,696

2. Acute Cardiac Assist Report, Health Research International – August 2015

AMI Shock Mortality Unchanged in > 20 years
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) Database²
N=46,949

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

cVAD Registry Data
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 Database¹</th>
<th>cVAD Registry²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
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</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>
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</tr>
<tr>
<td>– 73% Male</td>
<td>– 76% Male</td>
</tr>
<tr>
<td><strong>Duration Of Support</strong></td>
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</tr>
<tr>
<td>– Mean: 3.78 Days</td>
<td>– Mean: 1.63 Days</td>
</tr>
<tr>
<td>– Median: 2.7 Days</td>
<td>– Median: 1.1 Days</td>
</tr>
<tr>
<td>– Max: 94 Days</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>

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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

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

Distribution of Impella Site Outcomes

# of Sites

Bottom 20% of sites have mean survival of 30%

Top 20% of sites have mean survival of 76%

Survival to Explant

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\(^1\)

- No Hemodynamic Monitoring: 49% (N=8767)
- Hemodynamic Monitoring: 63% (N=5217)

- \(P<0.0001\)

CvAD Registry\(^2\)

- No Hemodynamic Monitoring: 68% (N=634)
- Hemodynamic Monitoring: 76% (N=516)

- \(P=0.002\)

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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\textsuperscript{1}

P<0.001 (N=287)

Mortality

\begin{tabular}{|c|c|c|c|}
\hline
Number of Inotropes/Pressors & 0 & 1 & 2 & 3 & 4+ \\
\hline
Mortality & 32\% & 54\% & 65\% & 65\% & 74\% \\
\hline
\end{tabular}


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

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Hemodynamic Improvement On Support

**Cardiac Power Output**

(CPO = MAP $\times$ CO)

- 0.56 Watts
- 0.96 Watts

58% increase

$P < 0.001$

N=21

N=27

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100% Native Heart Recovery in Survivors

Outcomes

<table>
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<tr>
<th>Survival to Explant</th>
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<th>Survival to Discharge</th>
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<tr>
<td>Metro Detroit Before Study</td>
<td>Detroit CSI</td>
<td>Detroit CSI</td>
</tr>
<tr>
<td>51%</td>
<td>89%</td>
<td>84%</td>
</tr>
</tbody>
</table>

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
DETROIT CSI Treatment Algorithm

**Inclusion Criteria**
- Ischemic symptoms lasting for >30 minutes in duration
- EKG/STEMI evidence of ischemia (STEMI or NSTEMI)
- Hypotension (<90/60) or the need for vasopressor or inotropes to maintain systolic blood pressure >90
- Evidence of hypoperfusion (cool, clammy, oliguria, lactic acidosis)

**Exclusion Criteria**
- Septic, anaphylactic, hemorrhagic, and neurologic causes of shock
- Non ischemic causes of shock (hypotension (Pulmonary Embolism, Pneumothorax, Mucocutaneous, etc))
- Active bleeding
- Recent major surgery
- Mechanical complications of AMI
- Known left ventricular thrombus
- Mechanical aortic valve

**ACTIVATE CATH LAB**

**QUALITY MEASURES**
- Shock Onset to Device <90 mins
- Establish TIMI III Flow
- Maintain CPO >0.6
- Wean off Pressors & Inotropes
- Improve survival to hospital discharge to >80%

**ACCES**
- Obtain femoral arterial access (via direct visualization with use of ultrasound & fluoroscopy)
- Obtain venous access (Femoral or internal jugular)

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

**Hemodynamic Calculations**
1. Cardiac Power Output (CPO) = MAP x CO
2. Pulmonary Artery Pulsatility Index (PAPi) = aPAP - dPAP / RA

**If CPO remains <0.6 operators should consider the two listed possibilities:**
- PAPi <0.6 consider right sided hemodynamic support
- PAPi <0.5 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 is <0.6 and PAPi <0.5 consider providing right sided hemodynamic support
- If CPO is <0.6 and PAPi <0.9 operators should determine if MCS can be weaned and removed to the cath lab or remain implanted with transfer to ICU.

**WEANING**
- If Impella will remain in, perform a formal neuromonitoring exam (Doppler/Angiogram)
- Consider antegrade thoracic for distal perfusion as needed
- MCS device should only be considered for explanation once the following criteria are met:
  - Weaning off all inotropes and vasopressors
  - CO >0.6
  - PAP > 0.9
- In patients who do not meet the above criteria MCS should remain for 2-5 days with strong consideration for transfer to LVAD/Transplant center.