ACC.17
66th Annual Scientific Session & Expo

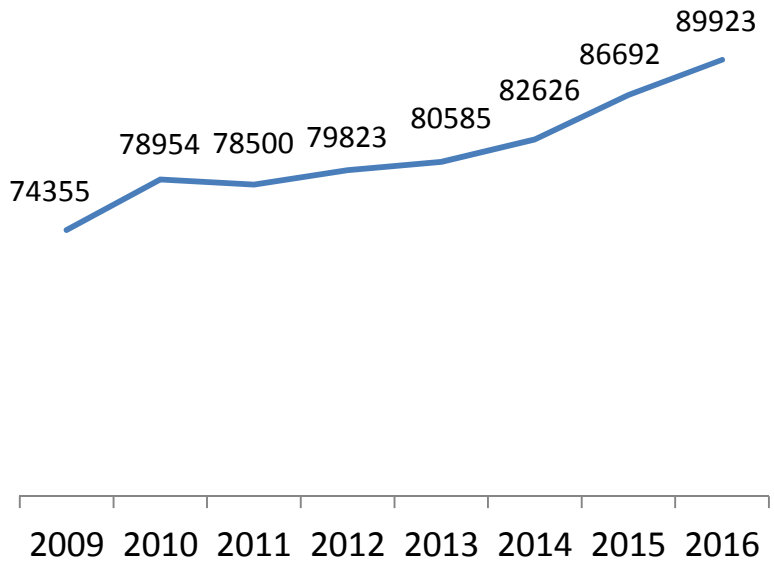
Outcomes for 15,259 US Patients With Acute MI Cardiogenic Shock (AMICS) Supported With Impella

William O'Neill, MD, FACC
Medical Director
Structural Heart Disease at Henry Ford Hospital, MI

WASHINGTON, DC
FRI • SAT • SUN
MARCH 17 – 19, 2017

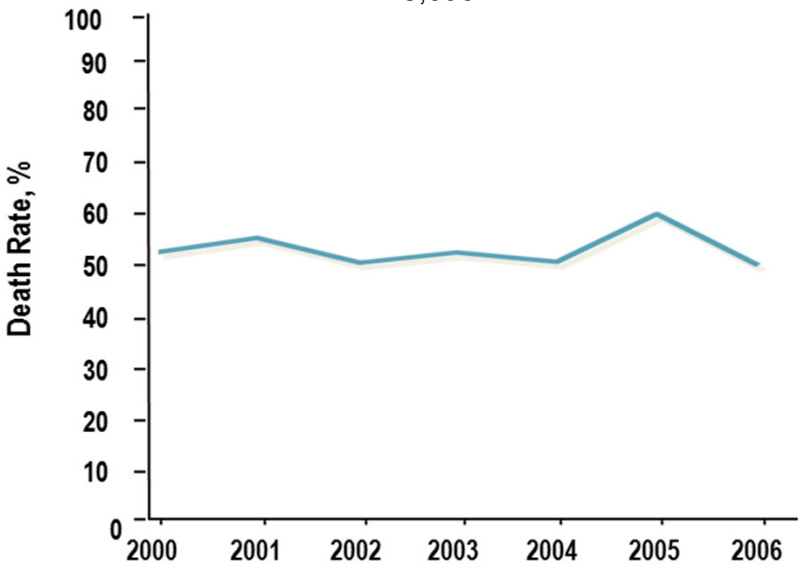
AMI Shock Mortality Unchanged in > 20 years

US AMI/CGS cases per year[1,2]



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*
3. *Jeger, et al. Ann Intern Med. 2008*

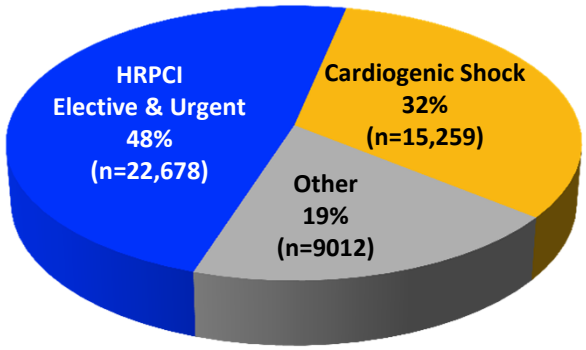
Impella Quality (IQ) Database Methods

- 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[1]

N=46,949

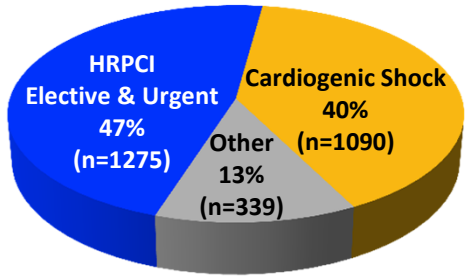


Observational IQ Database

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

cVAD Registry Data[2]

N=2,704



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

IQ Database[1]

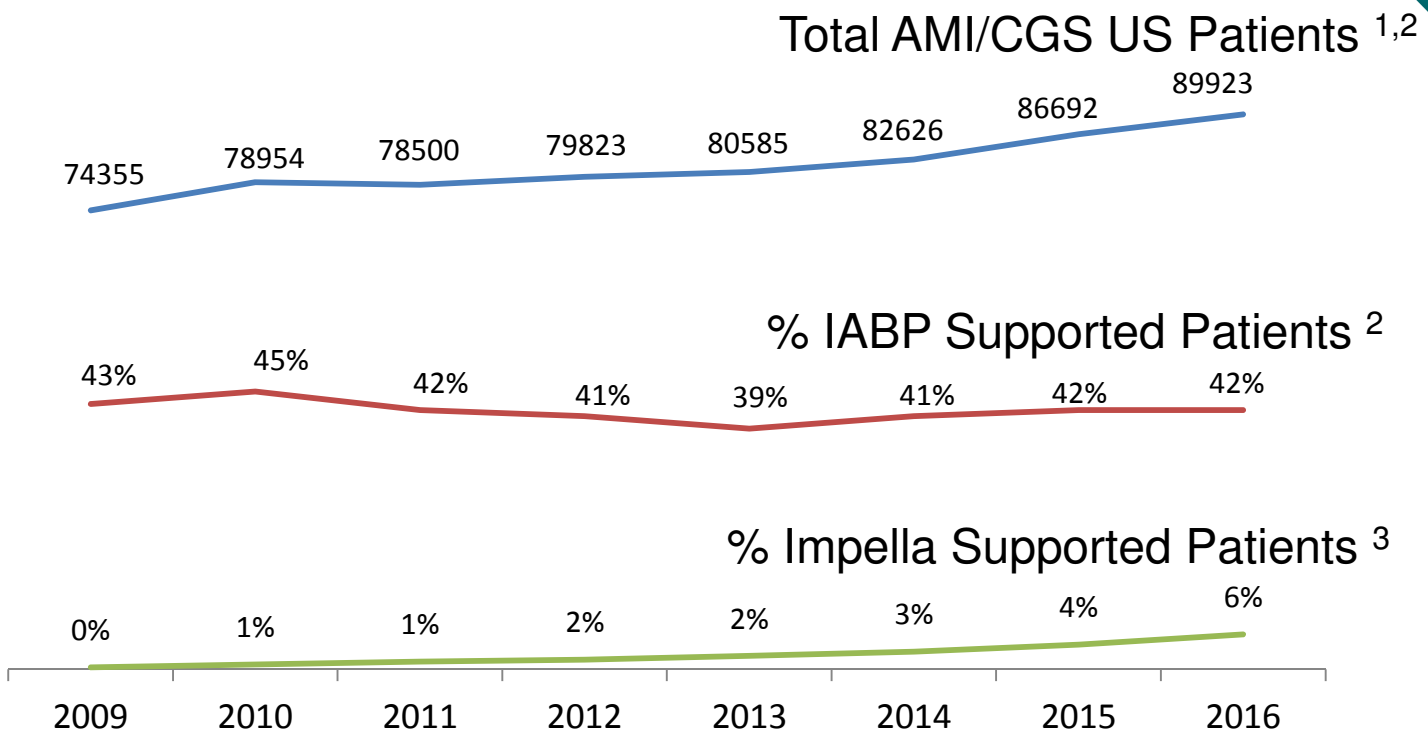
- **Age**
  - Mean: 63.6 y/o
  - Range: (19 – 99)
- **Gender**
  - 73% Male
- **Duration Of Support**
  - Mean: 3.78 Days
  - Median: 2.7 Days
  - Max: 94 Days
- **Survival to Explant**

cVAD Registry[2]

- **Age**
  - Mean: 66.3 y/o
  - Range: (19 – 95)
- **Gender**
  - 76% Male
- **Duration Of Support**
  - Mean: 1.63 Days
  - Median: 1.1 Days
  - Max: 10.6 Days
- **Survival to Explant, Discharge & 30 days**

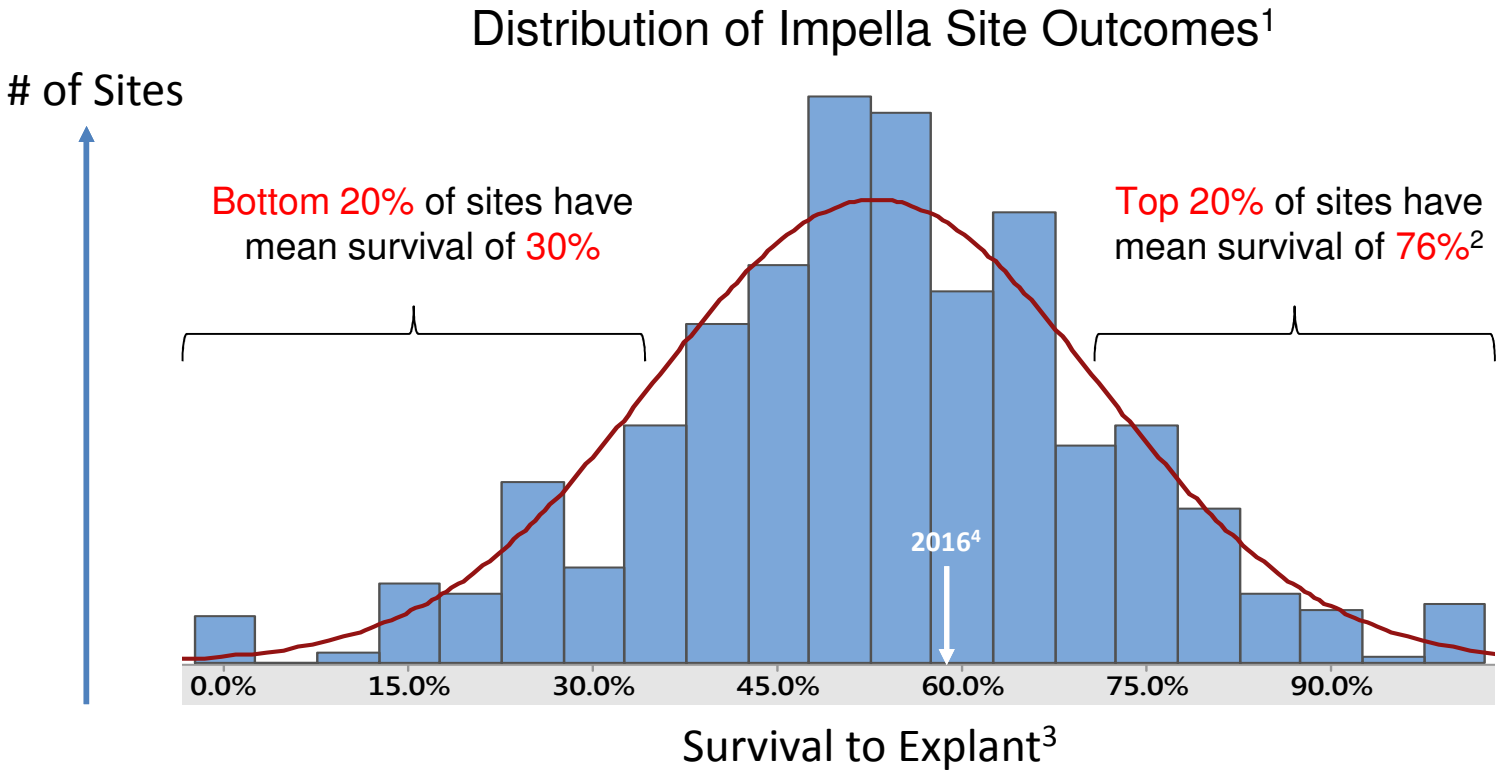
1. *Abiomed Impella Quality (IQ) Database, Danvers MA*
2. *cVAD Registry Data of Patients Undergoing PCI for Acute Myocardial Infarction Complicated by Cardiogenic Shock as of September 2015*

Impella Utilization in AMI Shock



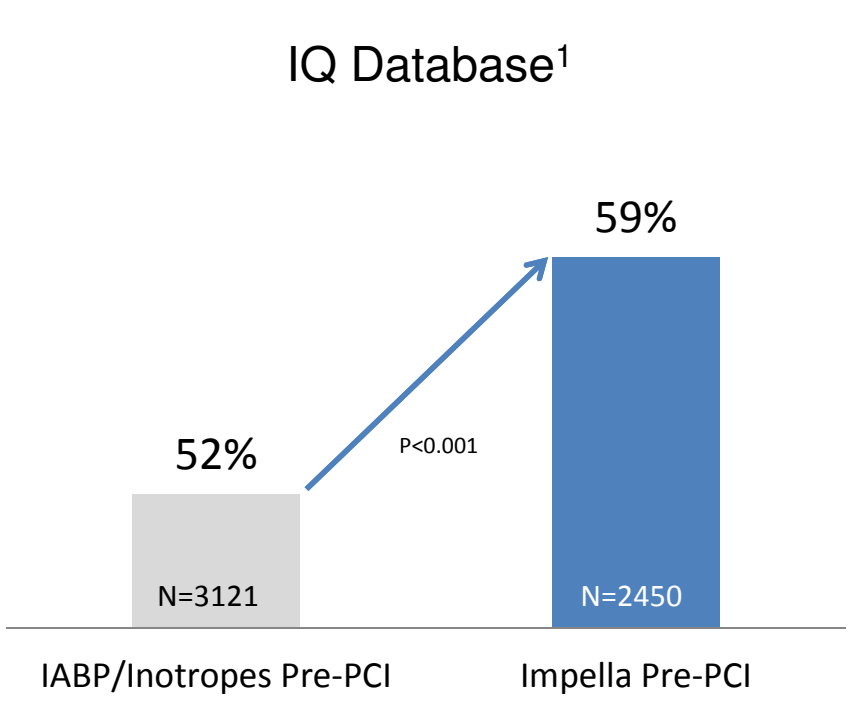
1. *Acute Cardiac Assist Report, Health Research International – August 2015*
2. *Sandhu A, McCoy I, Negi S, et al. Use of Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention; Insights from the National Cardiovascular Data Registry. Circulation, 2015;132:1243-1251*
3. *Data on file. Abiomed Impella Quality (IQ) Database, US AMI/CGS Jan 2009 – Dec 2016. Danvers, MA: Abiomed.*

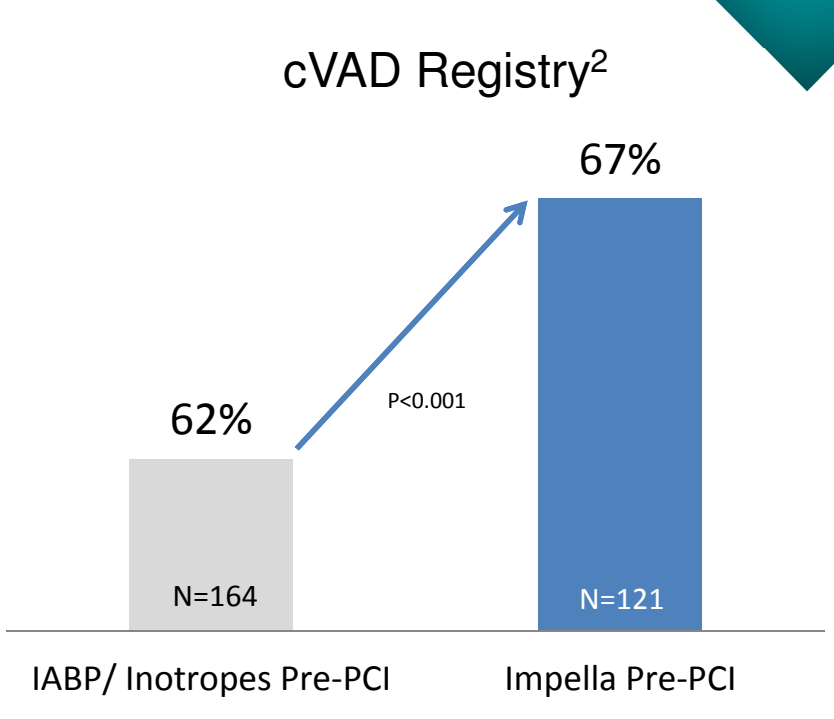
Variation in Impella AMI/CGS Outcomes



1. *791 sites supporting >4 AMICS patients, 15,529 patients total. Data on file. Abiomed Impella Quality(IQ)Data, AMI/CGS Jan 2009 – Dec 2016. Danvers, MA: Abiomed.*
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*

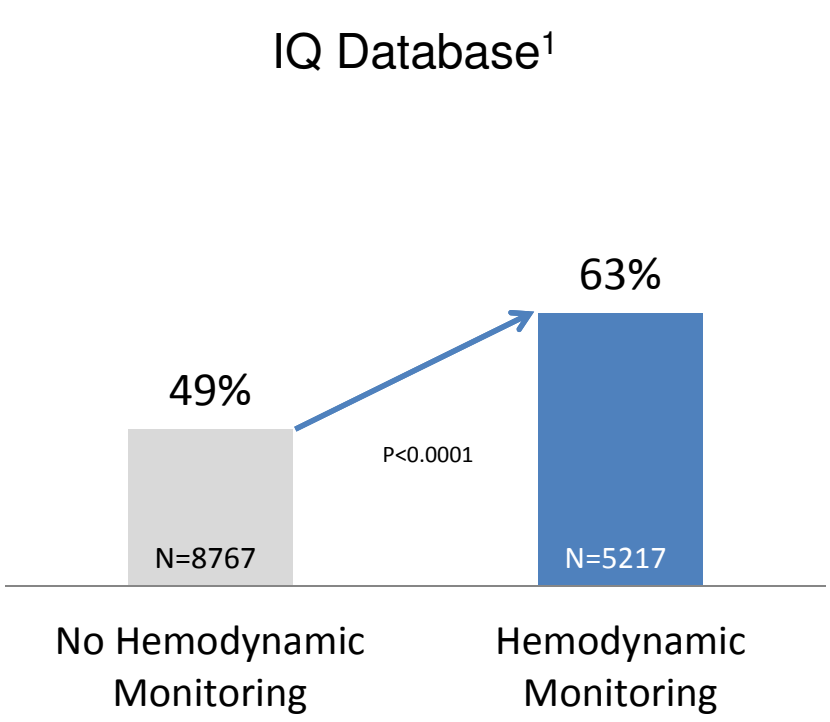
Impella Pre-PCI associated with Improved Survival in AMI/CGS

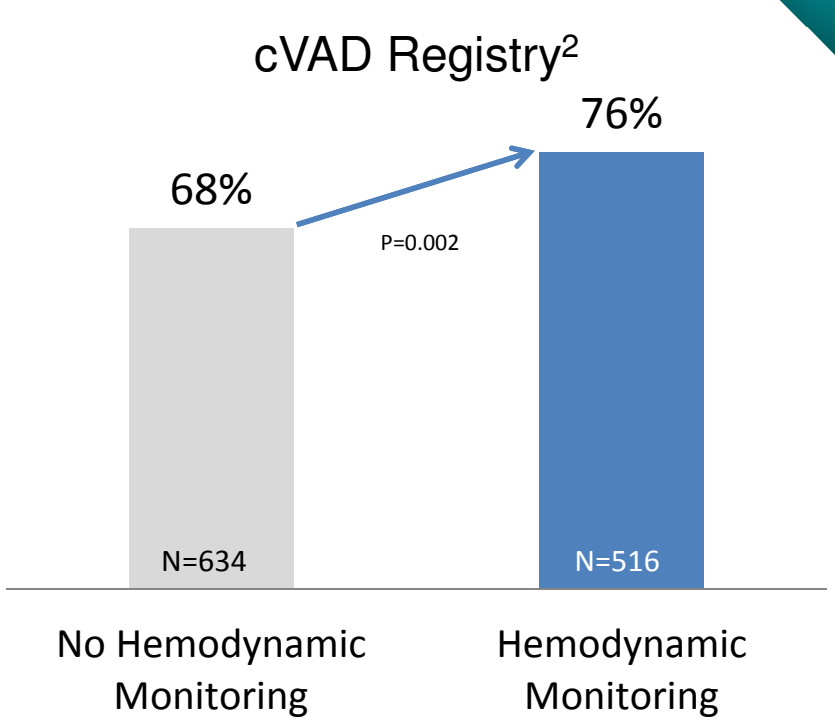




1. *Abiomed Impella Quality (IQ) Database, US AMI/CGS Apr 2009– Jan 2017. Survival to Explant. Danvers, MA: Abiomed.*
2. *Basir M, Schreiber T, Grines C, et al. Effect of Early Initiation of Mechanical Circulatory Support on Survival in Cardiogenic Shock. Am. J. of Cardiology, 2016*

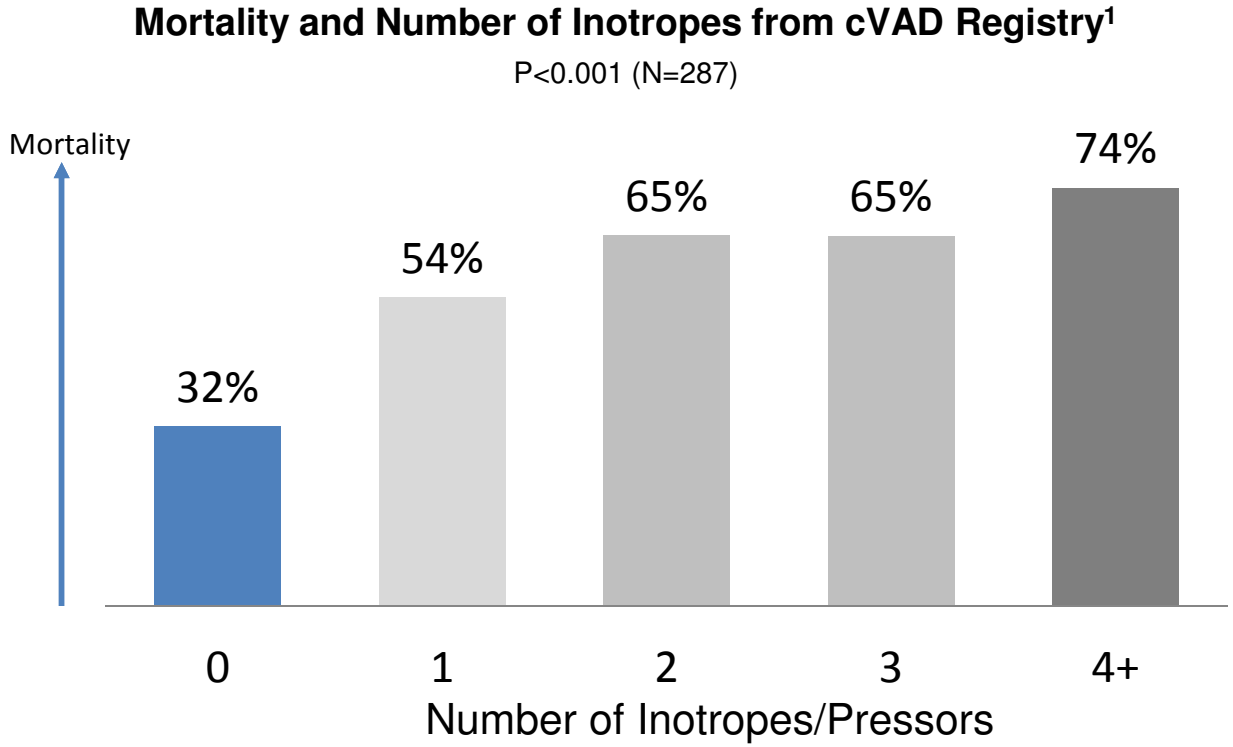
Hemodynamic Monitoring associated with Improved Survival in AMI/CGS





1. *Abiomed Impella Quality (IQ) Database, US AMI/CGS Apr 2009– Jan 2017. Survival to Explant. Danvers, MA: Abiomed.*
2. *cVAD survival to explant 2009-2016*

Increased Inotrope Exposure is associated with Mortality in AMI/CGS



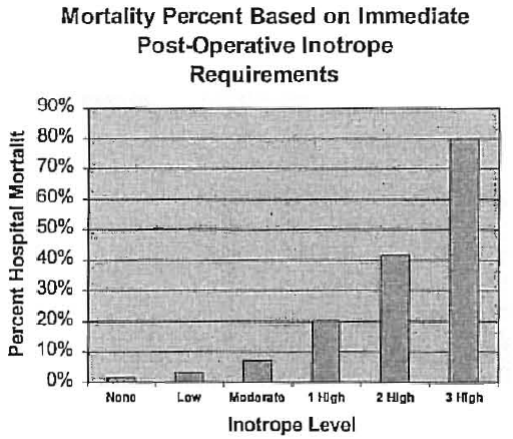
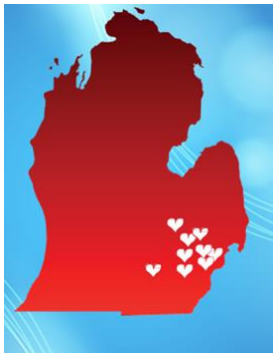


Figure 1. *Mortality percent based on immediate post-operative inotrope requirements.*

Samuels LE et al , J Card Surg. ***1999***

1. Basir M, Schreiber T, Grines C, et al. Effect of Early Initiation of Mechanical Circulatory Support on Survival in Cardiogenic Shock. Am. J. of Cardiology, 2016

Detroit Cardiogenic Shock Initiative



ACC.17

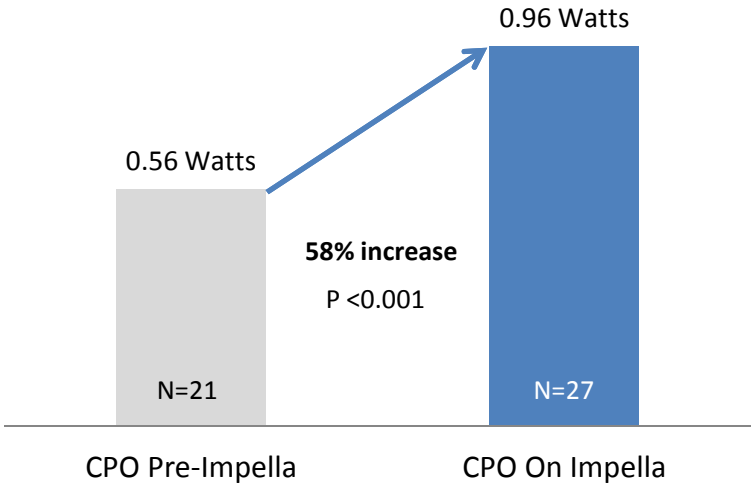
DETROIT CSI

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

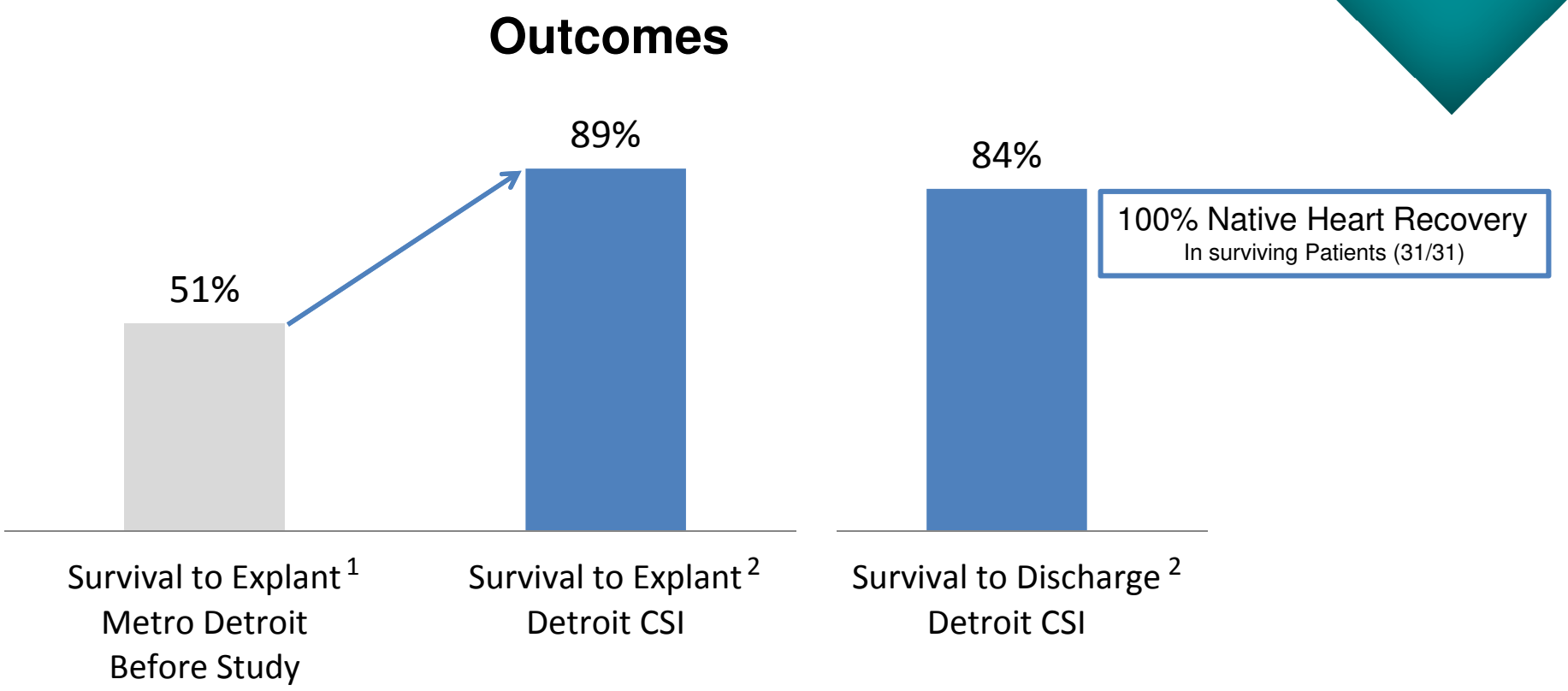
Hemodynamic Improvement On Support

Cardiac Power Output[1]
(CPO = MAP x CO)



1. *Fincke, et al., Cardiac Power Is the Strongest Hemodynamic Correlate of Mortality in Cardiogenic Shock: A Report From the SHOCK Trial Registry. JACC, Vol. 44, No. 2, 2004*

100% Native Heart Recovery in Survivors



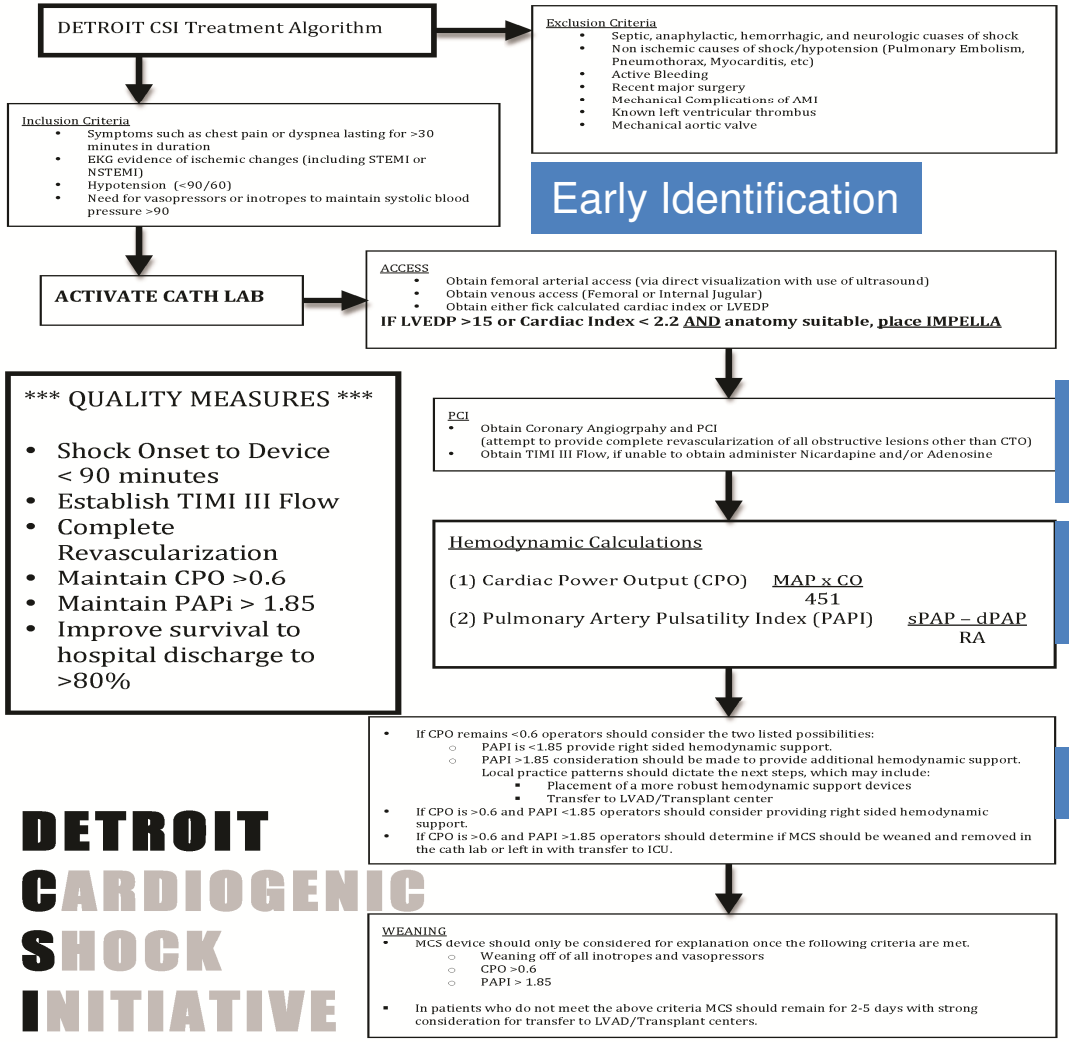
1. *Abiomed Impella Quality (IQ) Database , Jan 2015 to July 2016 for Aggregate DTW Metro Hospitals AMI/CGS Survival to Explant*
2. *Feasibility of Early Mechanical Support During Mechanical Reperfusion of Acute Myocardial Infarct Cardiogenic Shock; W. O'Neill, M. Basir, S. Dixon, K Patel, T Schreiber, S. Almany; In Press JACC Interventions*

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

Protocol Driven Treatment



Early Identification

Unload Prior to PCI (DTU)

Hemodynamic Monitoring

Escalation

ACC.17