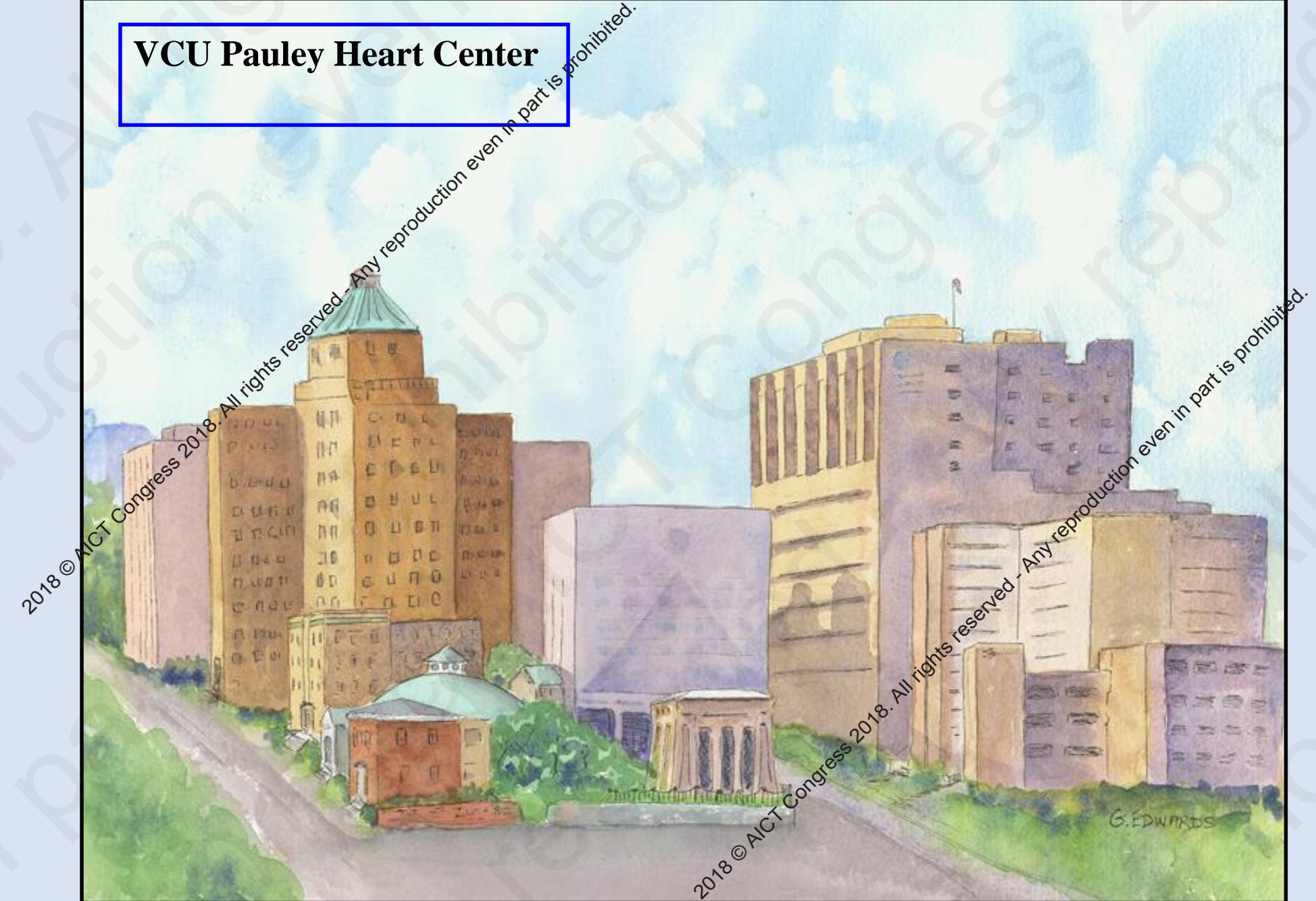


VCU Pauley Heart Center





AICT
ASIAN INTERVENTIONAL CARDIOVASCULAR THERAPEUTICS
THE OFFICIAL CONGRESS OF APSCIC

Current Strategies in Management of Cardiogenic Shock

George W. Vetrovec, MD, MACC, MSCAI
Professor Emeritus
Virginia Commonwealth University
Richmond, Virginia



Conflicts of Interest

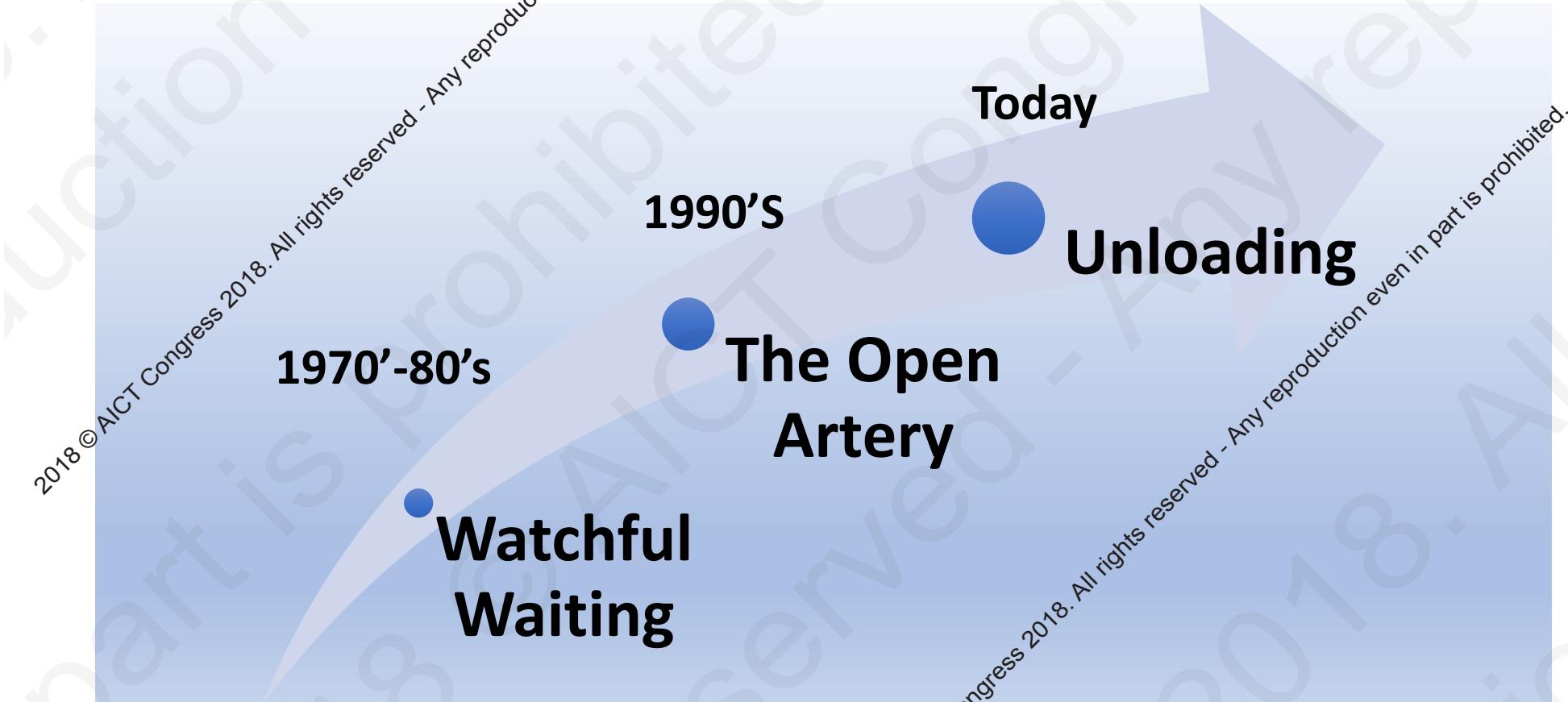
Speaker's name: George W. Vetrovec, MD, MACC, MSCAI

Abiomed – Consultant

Merck – Consultant

FDA - Consultant

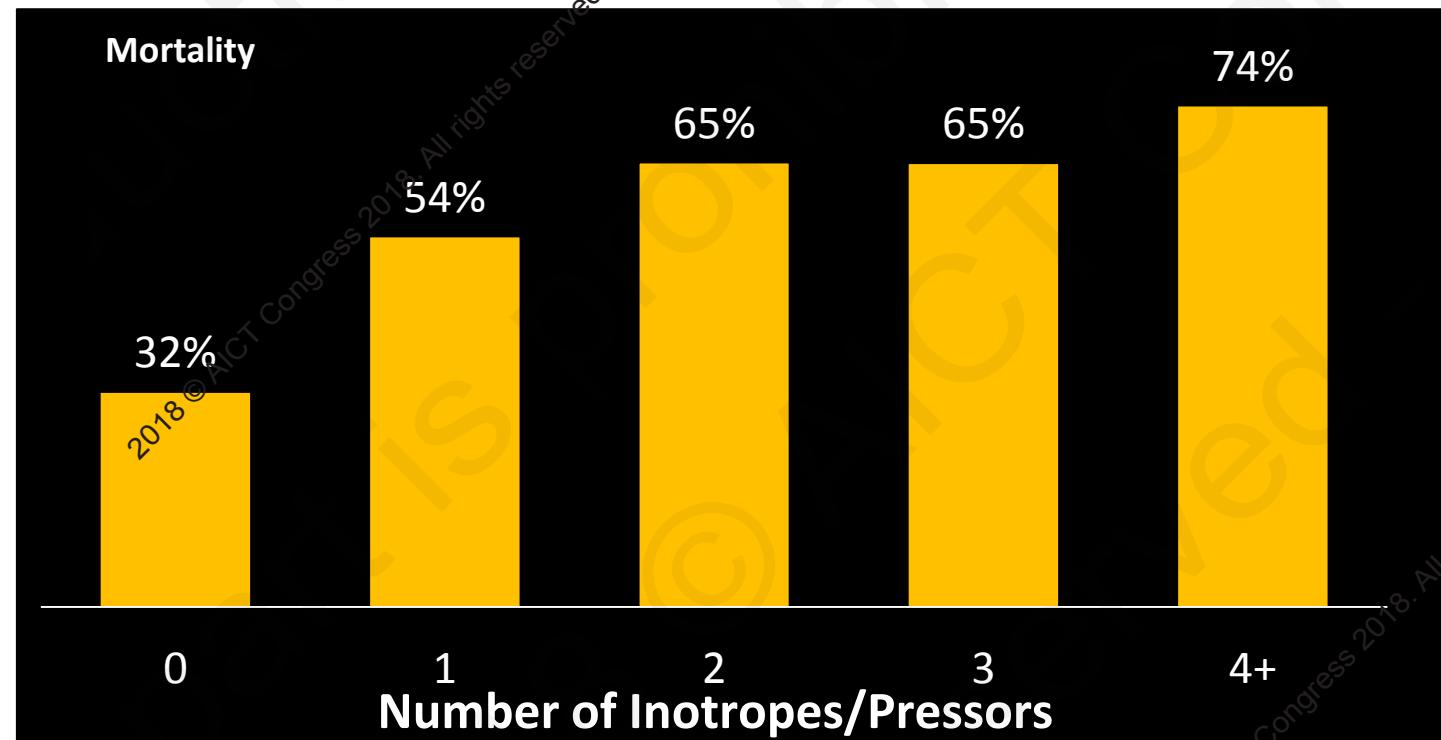
Management of Cardiogenic Shock



Increased Inotrope Exposure is associated with Mortality in AMI/CGS

Mortality and Number of Inotropes from cVAD Registry¹

P<0.001 (N=287)



1. Basir M, Schreiber T, Grines C, et al. Am. J. of Cardiology, 2016

Mortality Percent Based on Immediate Post-Operative Inotrope Requirements

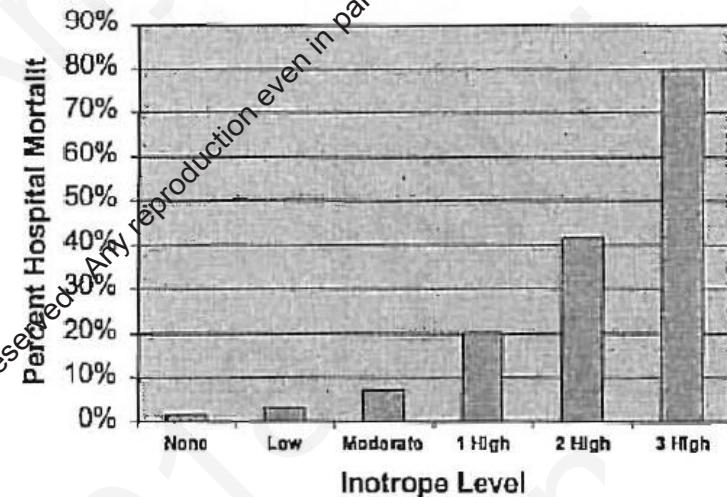


Figure 1. Mortality percent based on immediate post-operative inotrope requirements.

Samuels LE et al , J Card Surg. 1999

IABP-SHOCK

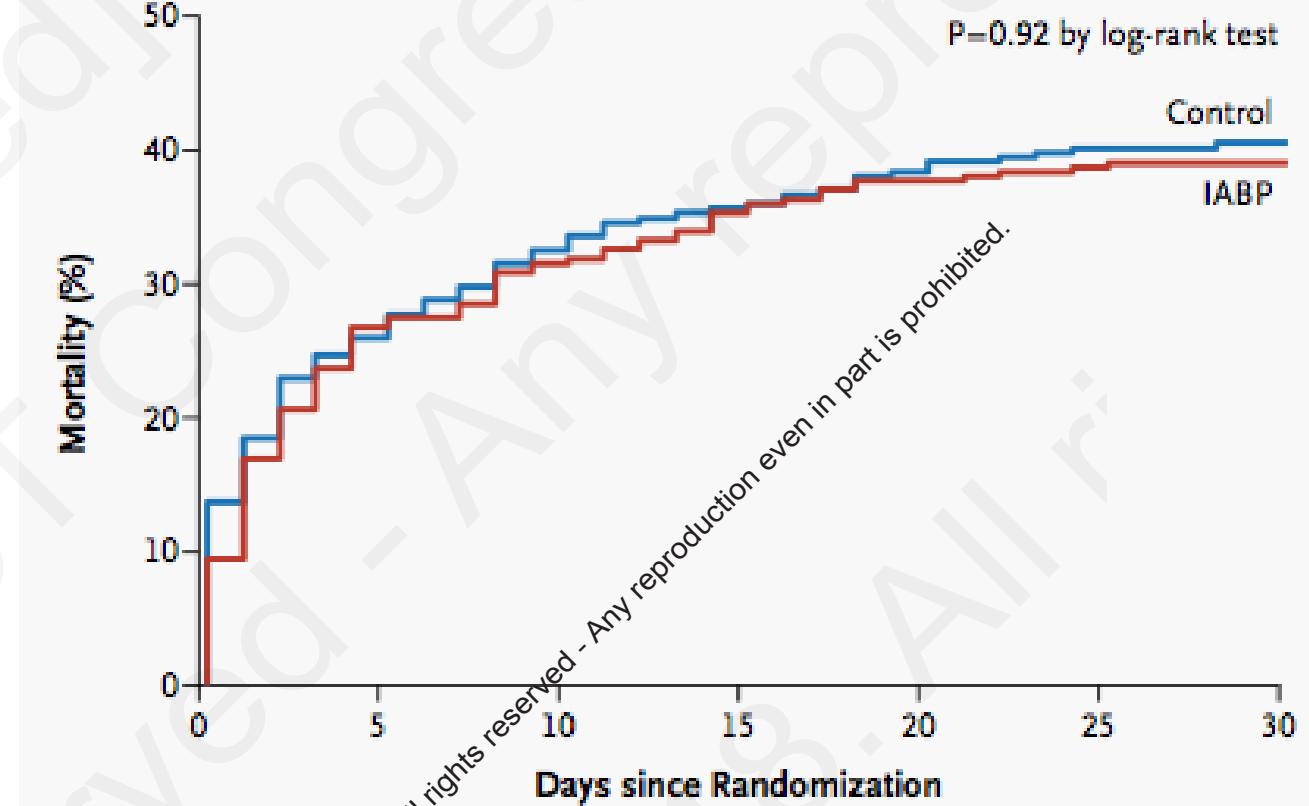
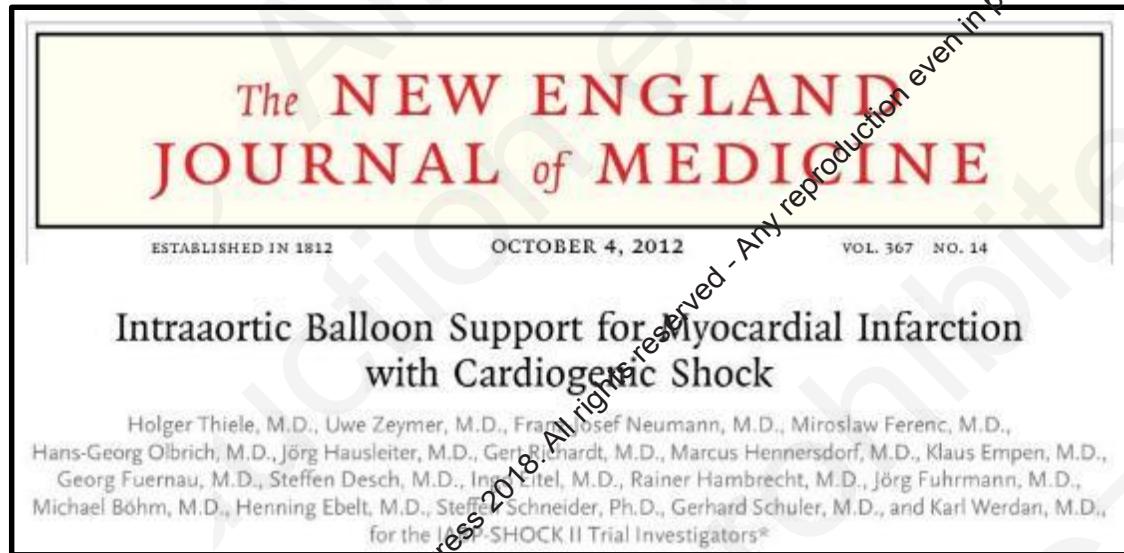


Figure 1. Time-to-Event Curves for the Primary End Point.

Time-to-event curves are shown through 30 days after randomization for the primary end point of all-cause mortality. Event rates represent Kaplan-Meier estimates.



New Concept: Unloading

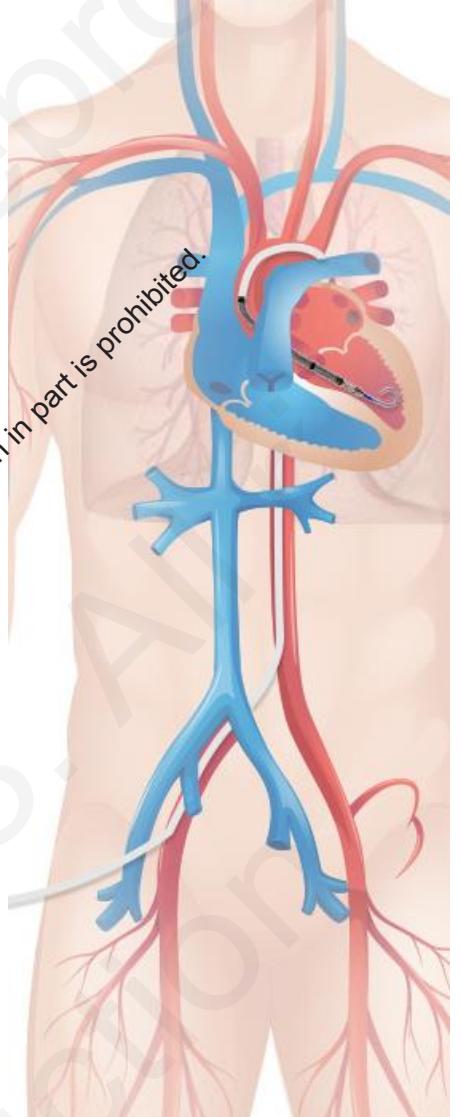
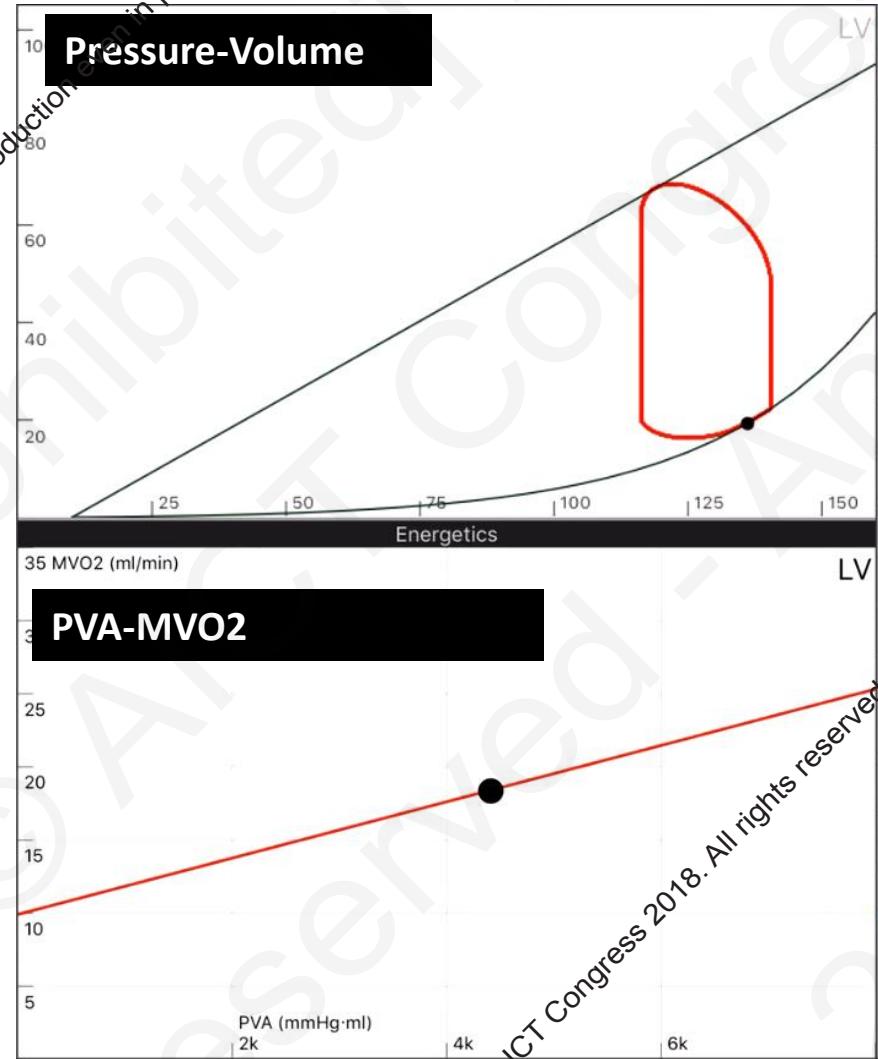
2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

Impact of MCS on Hemodynamics and Energetics

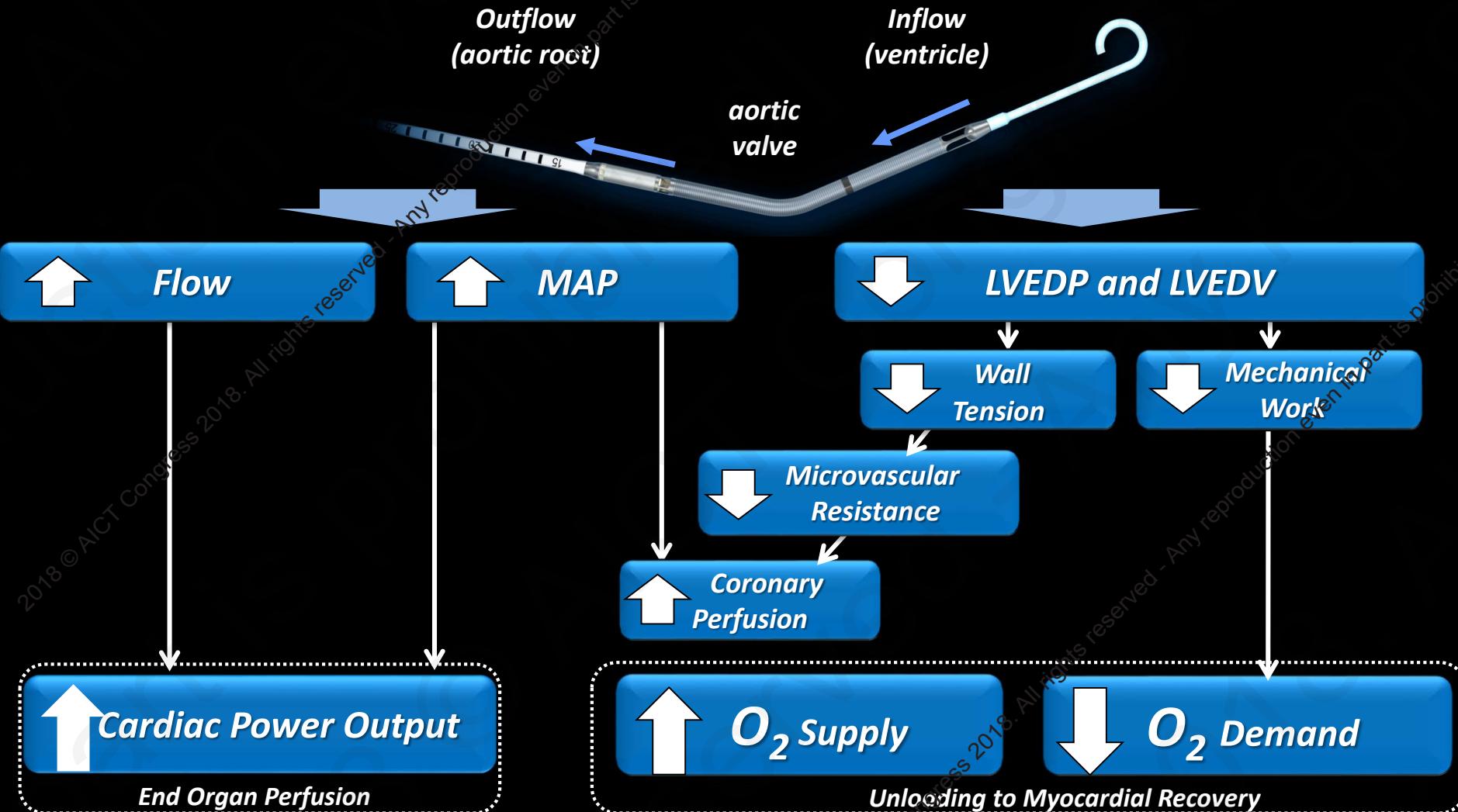
↓ Peak LVP
↓ Preload

↓ PVA
↓ MVO2



2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

Hemodynamic Effects of Impella Support



Fincke J, et al. Am Coll Cardiol 2004
den Uil CA, et al. Eur Heart J 2010
Mendoza DD, et al. AMJ 2007
Torgersen C, et al. Crit Care 2009
Torre-Amione G, et al. J Card Fail 2009

Suga H, et al. Am J Physiol 1979
Suga H, et al. Am J Physiol 1981
Burkhoff D, et al. Am J Physiol Heart Circ 2005
Burkhoff D, et al. Mechanical Properties Of The Heart And Its Interaction With The Vascular System. (White Paper) 2011

Sauren LDC, et al. Artif Organs 2007
Meyns B, et al. J Am Coll Cardiol 2003
Remmelink M, et al. Catheter Cardiovasc Interv 2007
Aqel RA, et al. J Nucl Cardiol 2009
Lam K, et al. Clin Res Cardiol 2009

Reesink KD, et al. Chest 2004
Valgimigli M, et al. Catheter Cardiovasc Interv 2005
Remmelink M, et al. Catheter Cardiovasc Interv 2010
Naidu S, et al. Novel Circulation.2011
Weber DM, et al. Cardiac Interventions Today Supplement Aug/Sep 2009



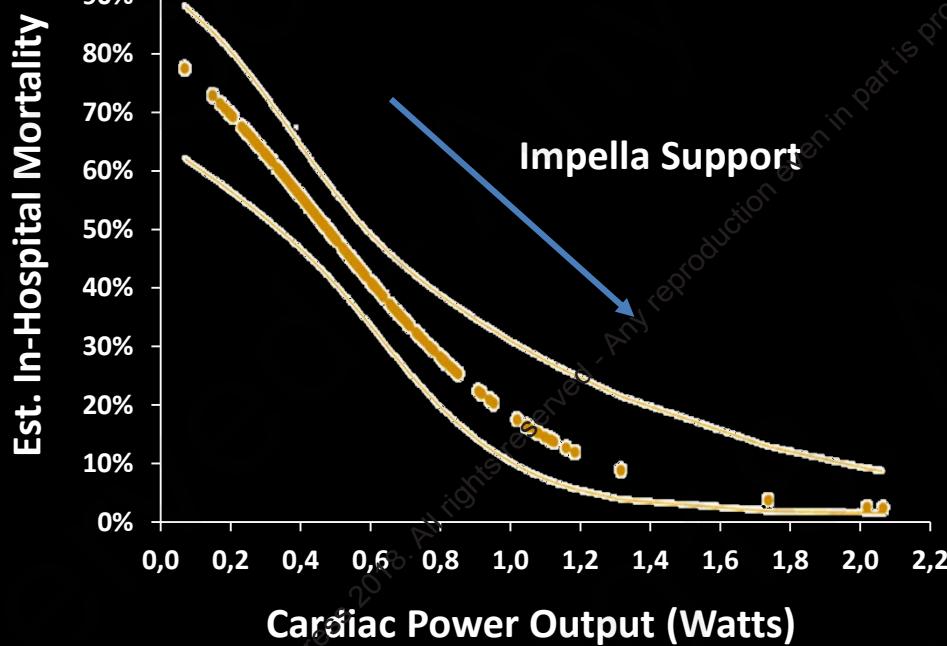
USA Impella Acceptance

- Only FDA PMA approved MCS Device for Temporary Hemodynamic Support
 - Cardiogenic Shock (AMI/PCCS) [cVAD Registry]
 - High Risk PCI [PROTECT II Study]
 - Cardiomyopathy/Peripartum/Myocarditis [cVAD Registry]
- Guideline Recommended
 - Multiple PCI, Shock, Heart Failure Guidelines

Cardiac Power Output

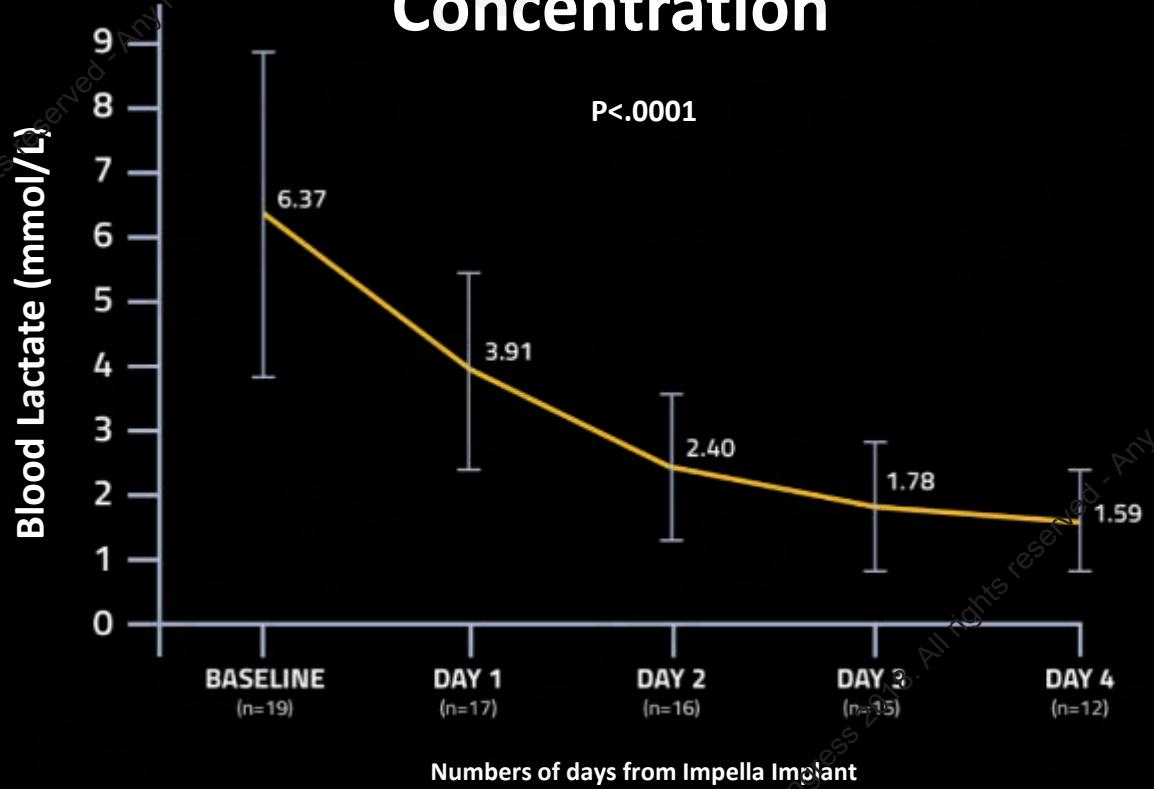


$$\text{MAP} \times \text{Cardiac Output} \times .0022 = \text{Cardiac Power Output}$$



Improved End Organ Perfusion With Impella

Reduction of Blood Lactate Concentration



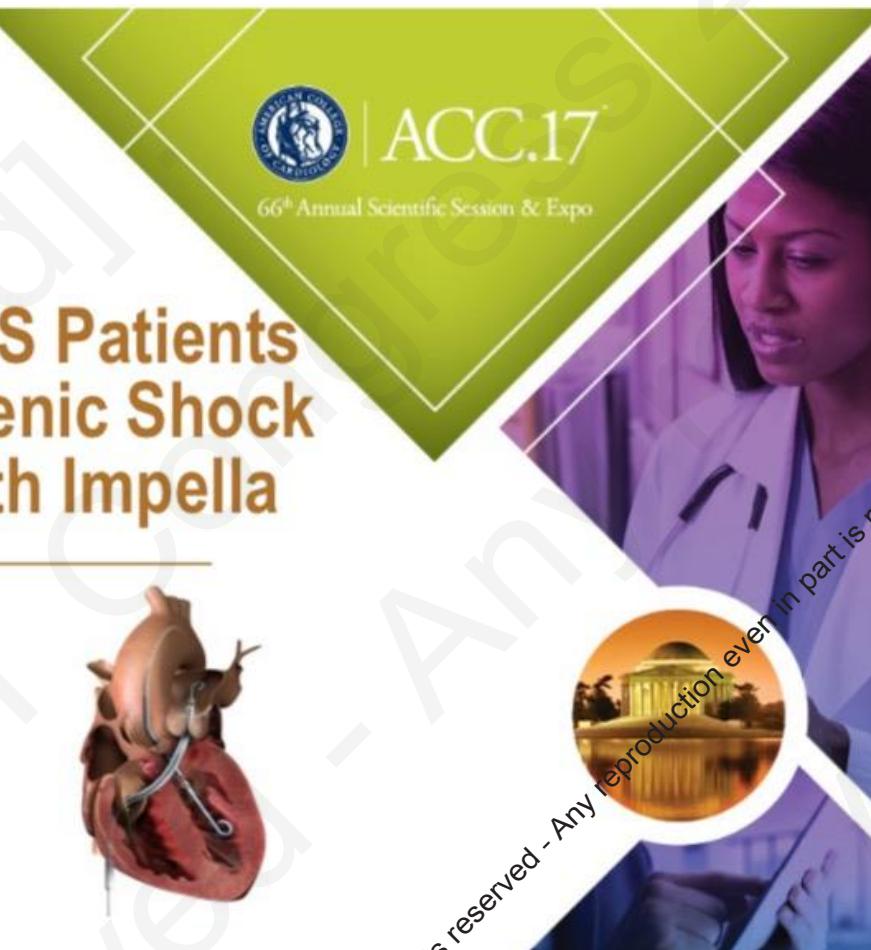
2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

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

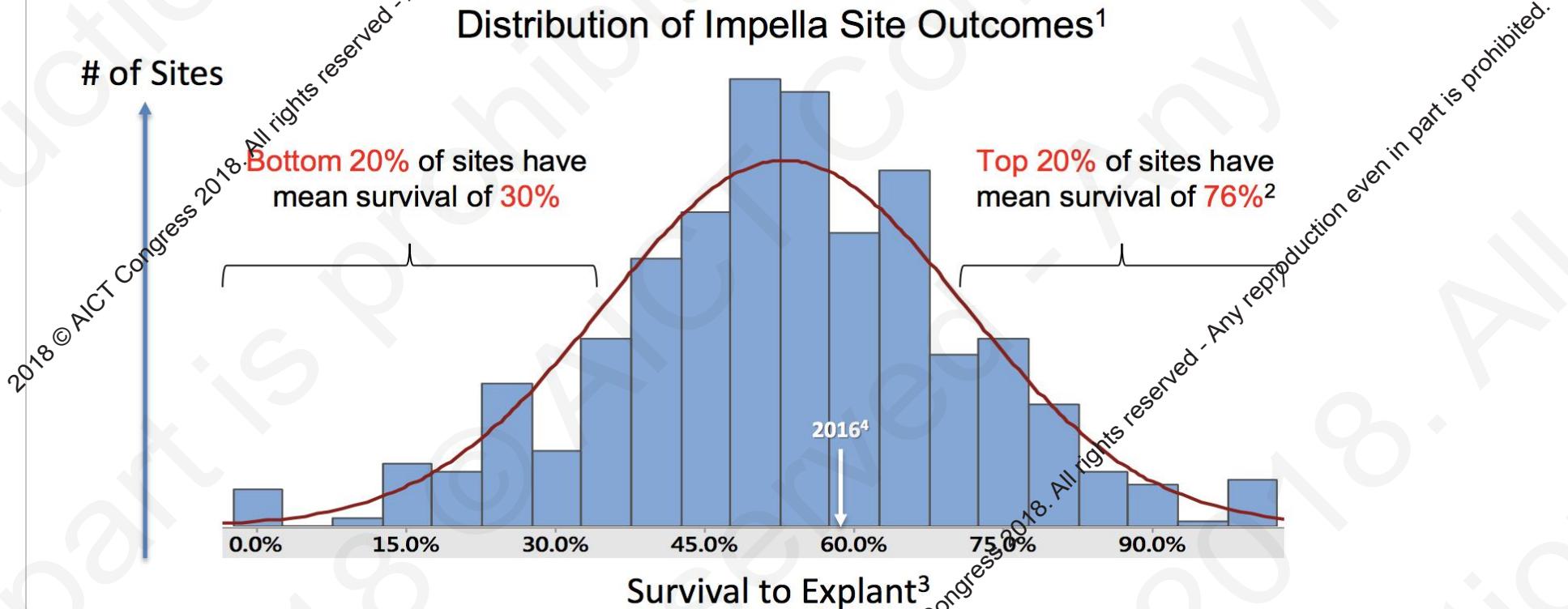
ACC.17
66th Annual Scientific Session & Expo



2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

IQ Database Demonstrates Major Variation in MI/Shock Outcomes

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

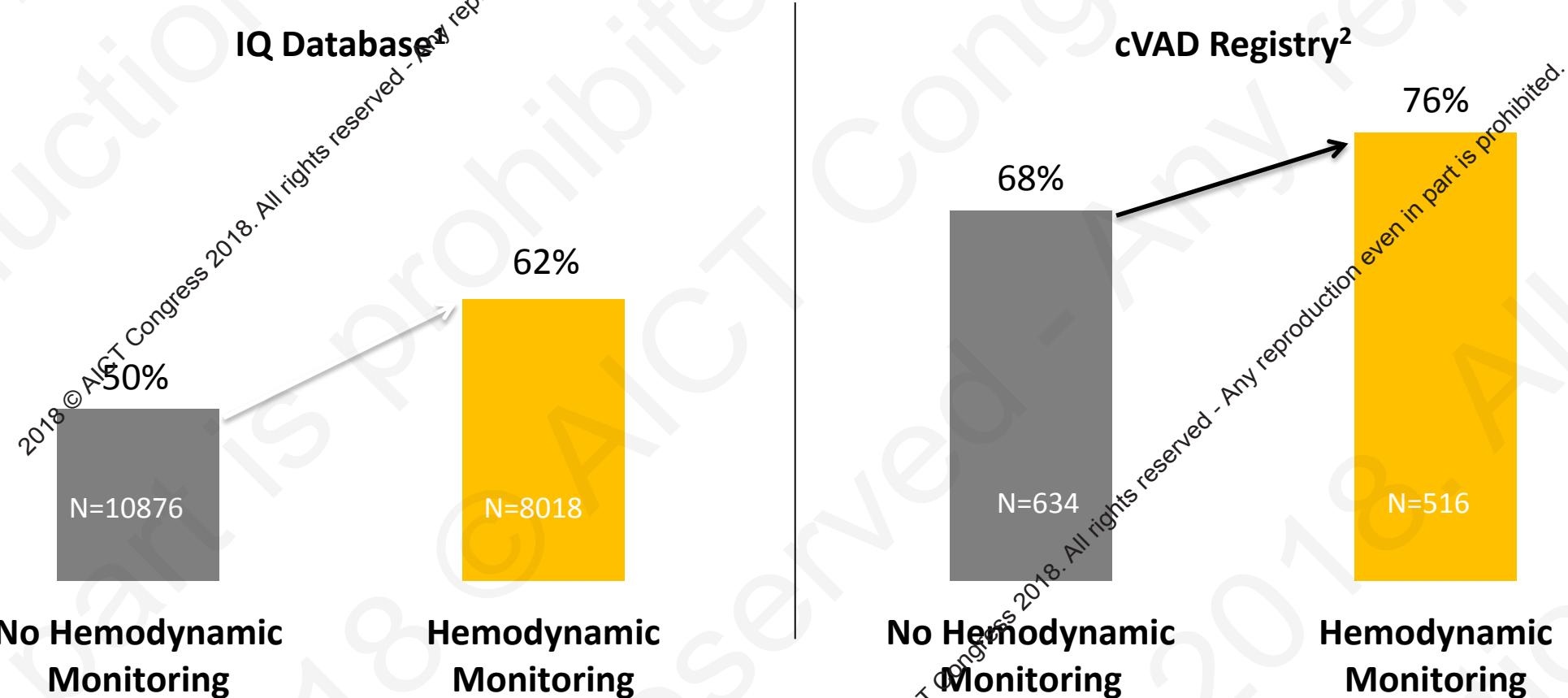
3. Greater than 90% of survivors were explanted with native heart recovery in 2016

4. Mean survival of 58% in 2016. Improvement of 14% (relative) since FDA approval

Factors Associated Better Outcomes

- Fewer Inotropes
- Use of Right Heart Catheterization
- Impella Insertion before PCI

Hemodynamic Monitoring associated with Improved Survival in AMI/CGS



1. *Abiomed Impella Quality (IQ) Database, US AMI/CGS Apr 2009– Oct 2017. Survival to Explant.* Danvers, MA: Abiomed.

2. *cVAD survival to explant 2009-2016*

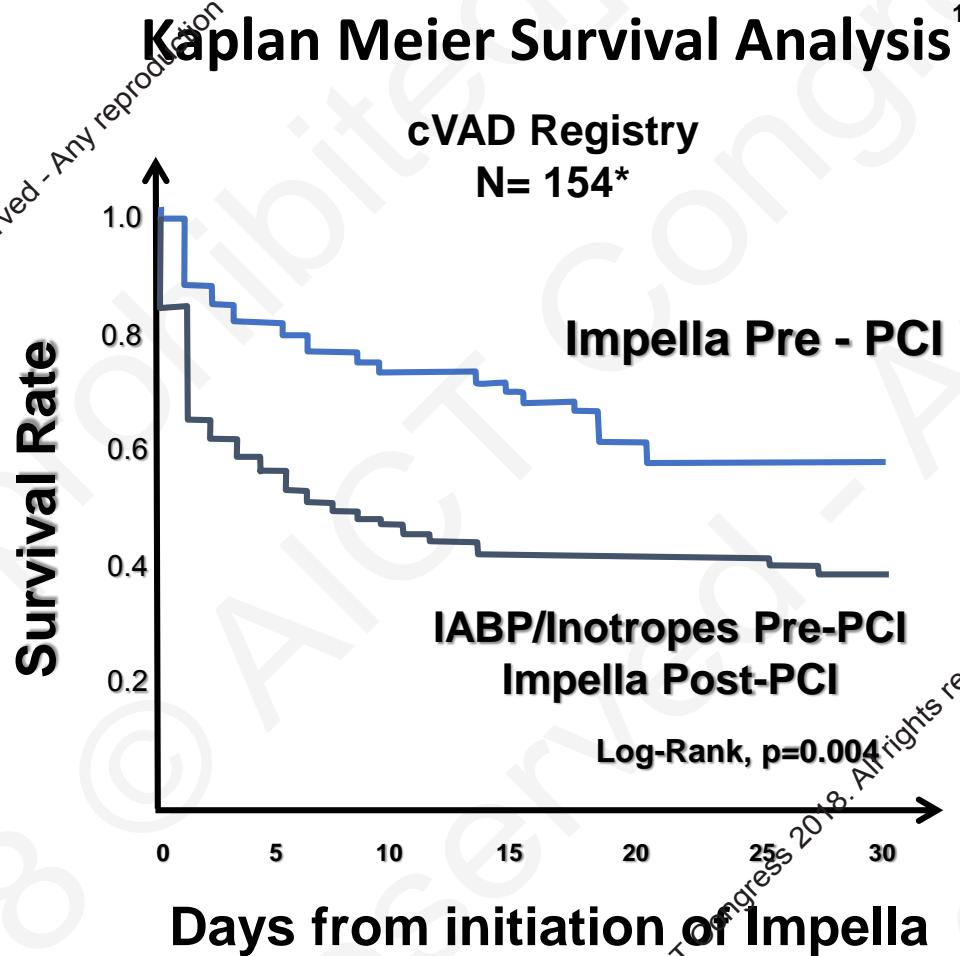


Unloading *before* Reperfusion

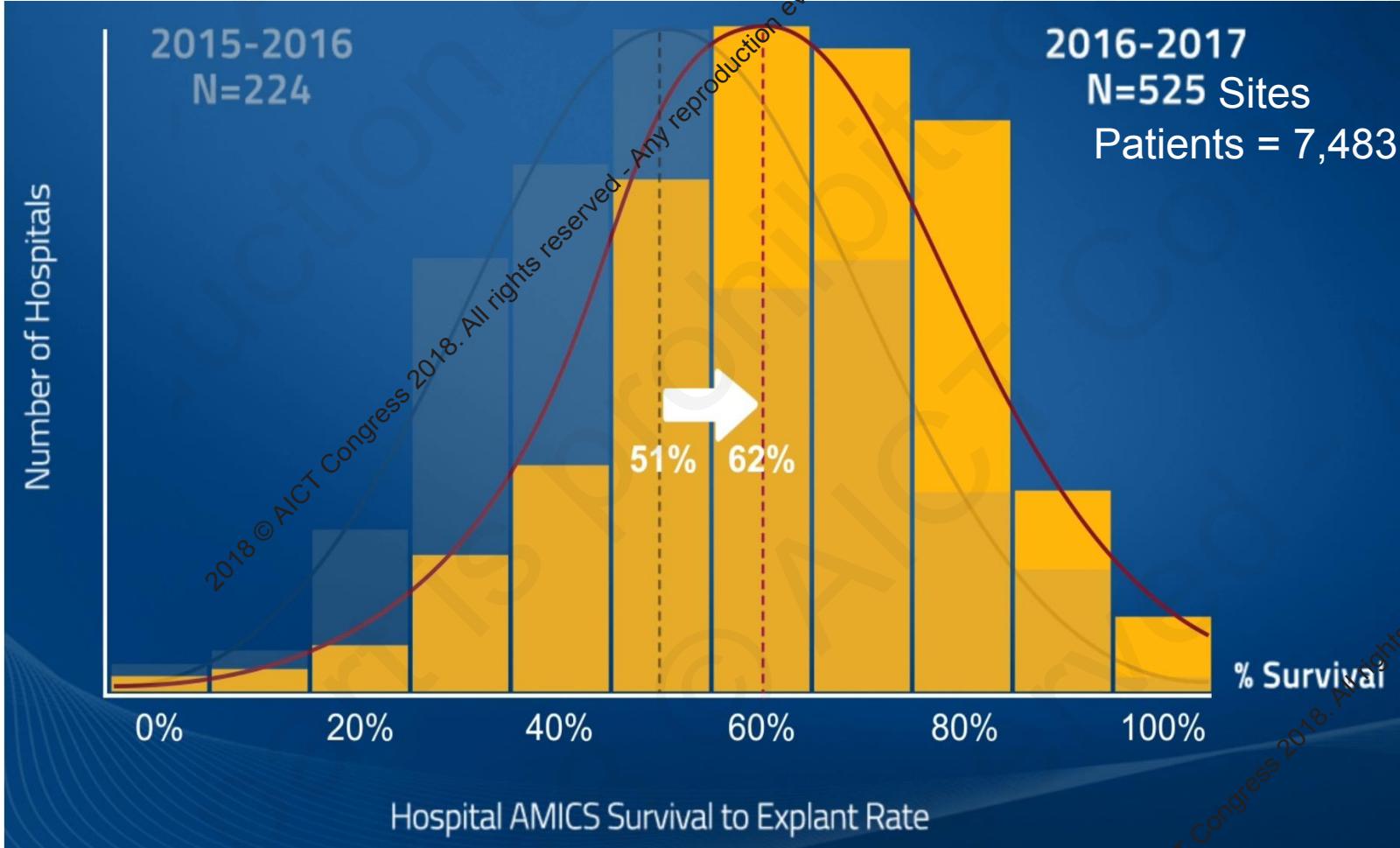
2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

Timing of Support in AMI CGS Impacts Outcomes: Early is Better



USA National Outcomes Improving



22% relative improvement in overall outcomes since FDA PMA in March, 2016 ($p<0.0001$)²

Data on file. Abiomed Impella Quality(IQ)Data AMI/CGS Apr 2016 – Sept 2017. Danvers, MA: Abiomed.

525 sites supporting >6 AMICS patients, 7,483 patients total since March 2016

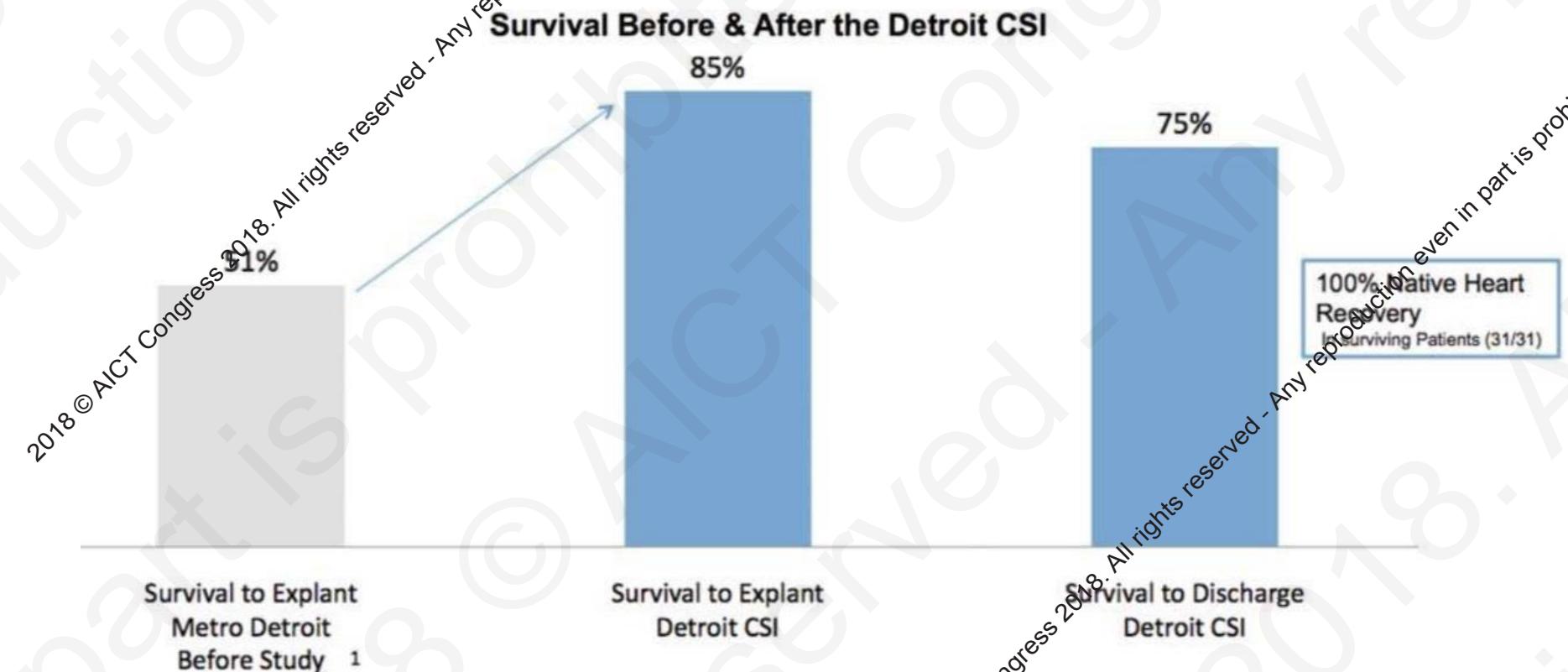


Detroit CSI

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

Baseline Survival vs. Detroit CSI



The National Cardiogenic Shock Initiative

88 Forms Completed

Excluded

65 AMICS w/ Early MCS Support

Out of Hospital Cardiac Arrest – 10/65 (15%)

In Hospital Cardiac Arrest – 17/65 (31%)

Pre-PCI Impella 48/65 (74%)

IP/Post Impella 17/65 (26%)

Door to Balloon (STEMI) 98.3 min

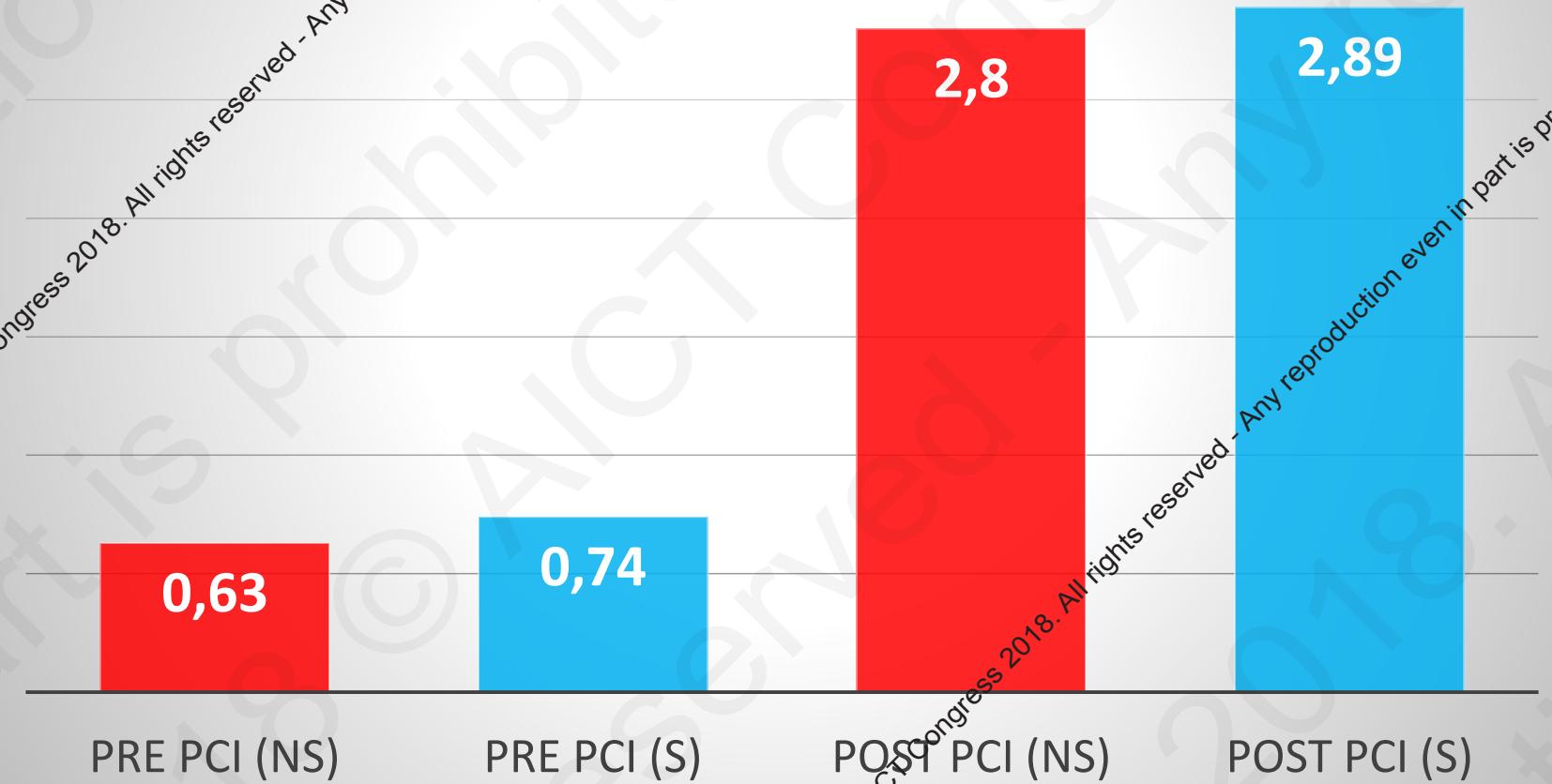
Door to Support 91.5 min

23 patients

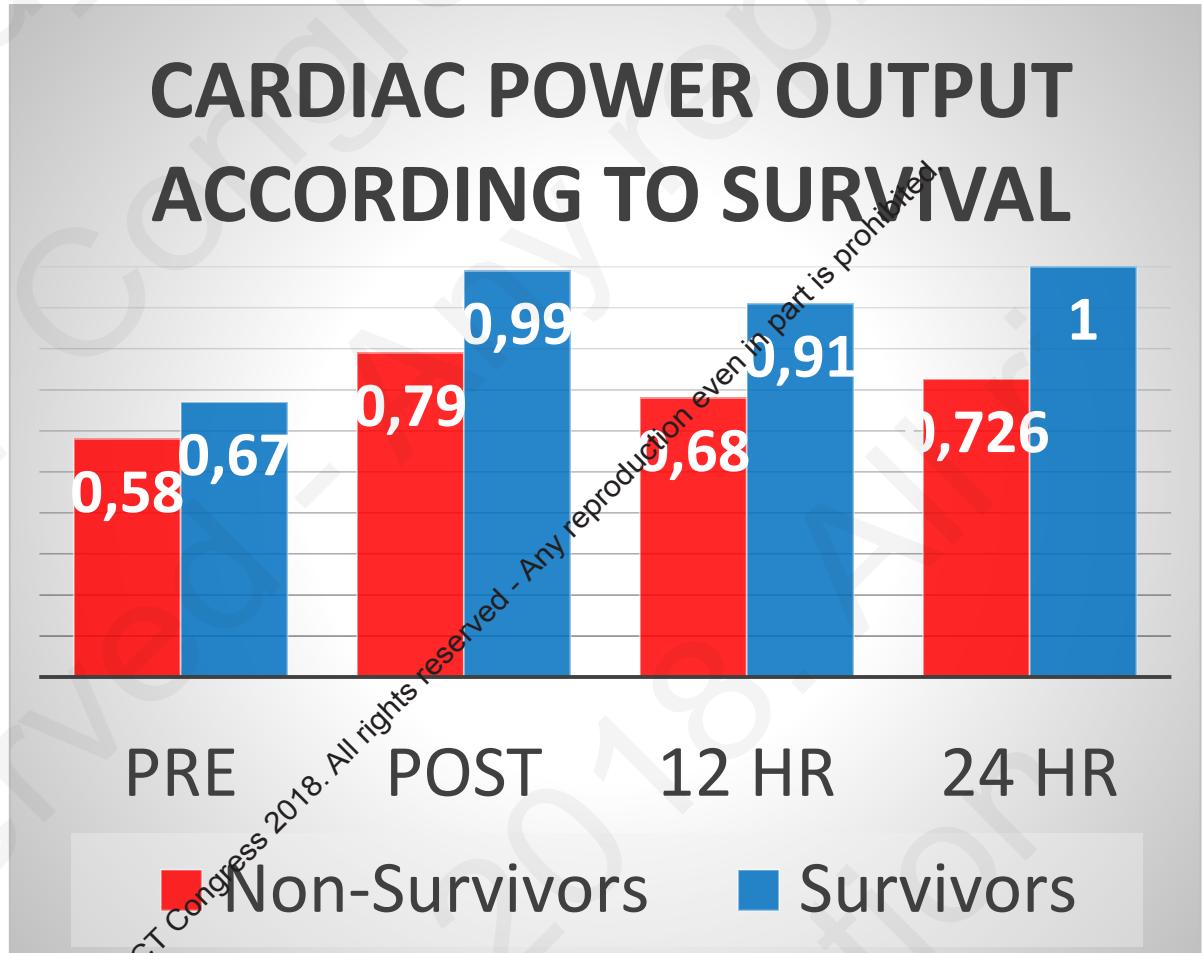
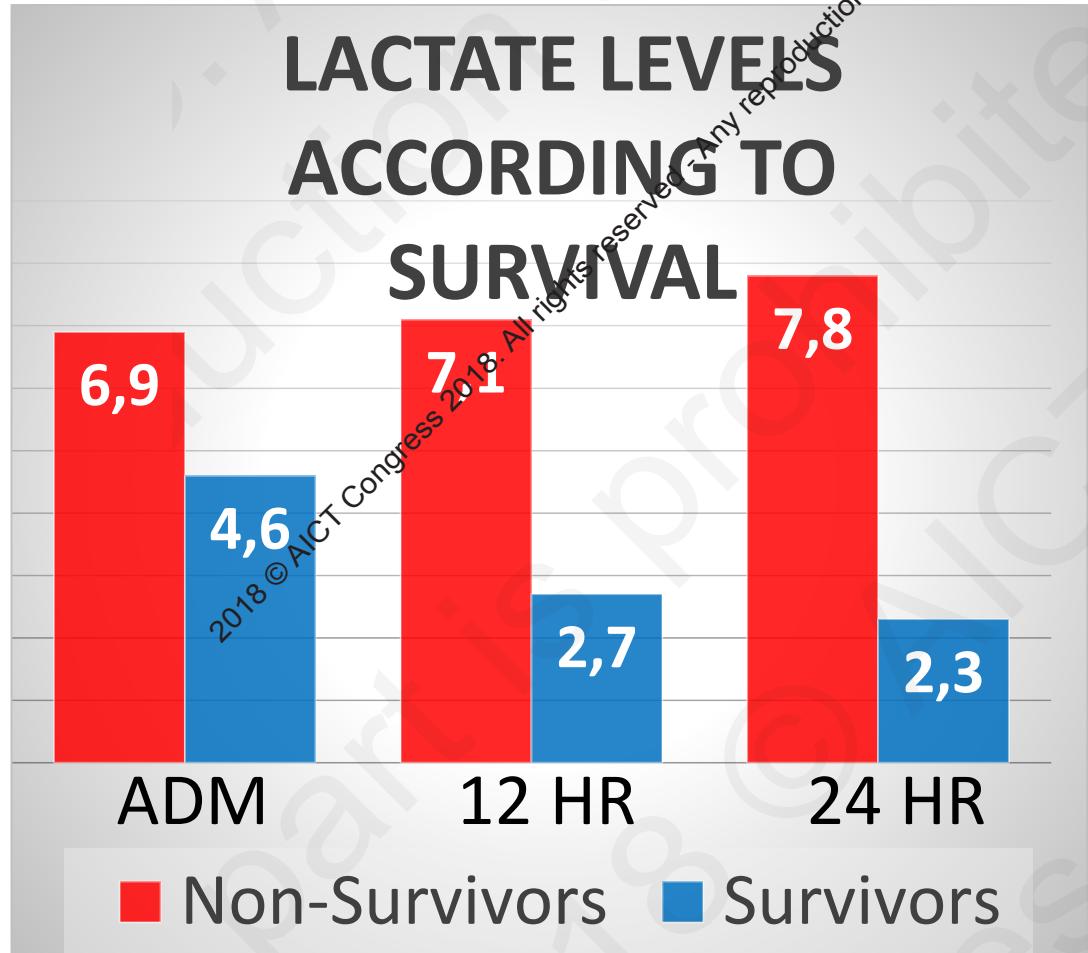
- **4 unwitnessed arrest w/ delay CPR**
- **2 Septic Shock**
- **1 Aortic Stenosis**
- **1 massive PE**
- **5 patients without evidence of shock**
 - **Procedural complication**
 - **Decompensated Heart Failure (2)**
 - **Hypertensive Emergency**
 - **9 patients with IABP prior to MCS**

74% Survival (N=48/65)

TIMI FLOW RATE



Strategic Outcomes



Predictors of Survival CPO & Lactate @ 12-24 Hrs

Lactate < 3 & CPO < 0.8

83% Survival

Lactate < 3 & CPO > 0.8

95% Survival

Lactate > 3 & CPO < 0.8

36% Survival

Lactate > 3 & CPO > 0.8

66% Survival

Basir, O'Neill et al (Unpublished, National CSI)

www.henryford.com/cardiohogenicshock



The Power of a Shock Team

Emphasis on TEAM



Protocols: A Guide to Consistent Practice

Encourages Door to Support

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

Impella® Best Practices in AMI Cardiogenic Shock

Identify¹⁻³

- SBP < 90 mmHg or on inotropes/pressors
- Cold, clammy, tachycardia
- Lactate elevated > 2 mmol/L

Stabilize Early

- Reduce Door to Unloading Time (DTU)
- Impella Support pre-PCI⁸⁻¹⁰
 - Reduce Inotropes/Pressors^{11,12}

Appropriate Revascularization

- Per Guidelines^{13,14}

Assess for Myocardial Recovery (Weaning and Transfer Protocols)

Myocardial Recovery^{15,16}

No Recovery Escalate (and Ambulate) or Transfer¹⁷

Cardiogenic etiology evaluation

- EKG (STEMI / NSTEMI)
- Echocardiography⁴
- If available, PA catheter, cardiac output, CPO, CI, PCWP, SvO₂⁵⁻⁷

- ↑ Cardiac Output
- ↑ Cardiac Power Output
- ↑ Urine Output
- ↓ Lactate
- ↓ Inotropes

- Ongoing Left Heart Failure
- Assess for Right Heart Failure

1. Reyentovich A, et al. *Nat Rev Cardiol.* 2016;13(8):481-492.
2. Hochman JS, et al. *N Engl J Med.* 1999;341(9):625-634.
3. Rihal CS, et al. *J Am Coll Cardiol.* 2015;65(19):e26-e26.
4. Picard MH, et al. *Circulation.* 2003;107(2):128-124.
5. Cohen MG, et al. *Am J Med.* 2005;118(5):482-488.

6. Kershaw R, et al. *Cardiol Clin.* 2011;29(2):281-288.
7. Chatterjee K. *Circulation.* 2009;119(1):147-152.
8. O'Neill WW, et al. *J Interv Cardiol.* 2014;27(1):1-11.
9. Joseph SM, et al. *J Interv Cardiol.* 2016 Jun;29(3):248-56.

10. Schroeter MR, et al. *J Invasive Cardiol.* 2016 Aug 15. [Epub ahead of print]
11. Samuels LE, et al. *J Card Surg.* 1999;14(4):288-293.
12. De Backer D, et al. *N Engl J Med.* 2010;362(9):779-789.
13. O'Gara PT, et al. *J Am Coll Cardiol.* 2013;61(4):e78-e140.

14. Steg PG, et al. *Eur Heart J.* 2012;33(20):2569-2619.
15. Casassus F, et al. *J Interv Cardiol.* 2015;28(1):41-50.
16. Lemire A, et al. *Ann Thorac Surg.* 2014;97(1):133-138.
17. Anderson MB, et al. *J Heart Lung Transplant.* 2015;34(12):1549-1560.



Strategic Points

Current Strategies in Management of Cardiogenic Shock

- Door to Unload First. TIME is MUSCLE!
- Reperfuse
- Hemodynamic Monitoring
 - Increase Cardiac Power
 - Reduce peripheral lactate
 - Improve Coronary Perfusion/Reduce myocardial work

This is a “First” Strategy - Not a Last Resort!

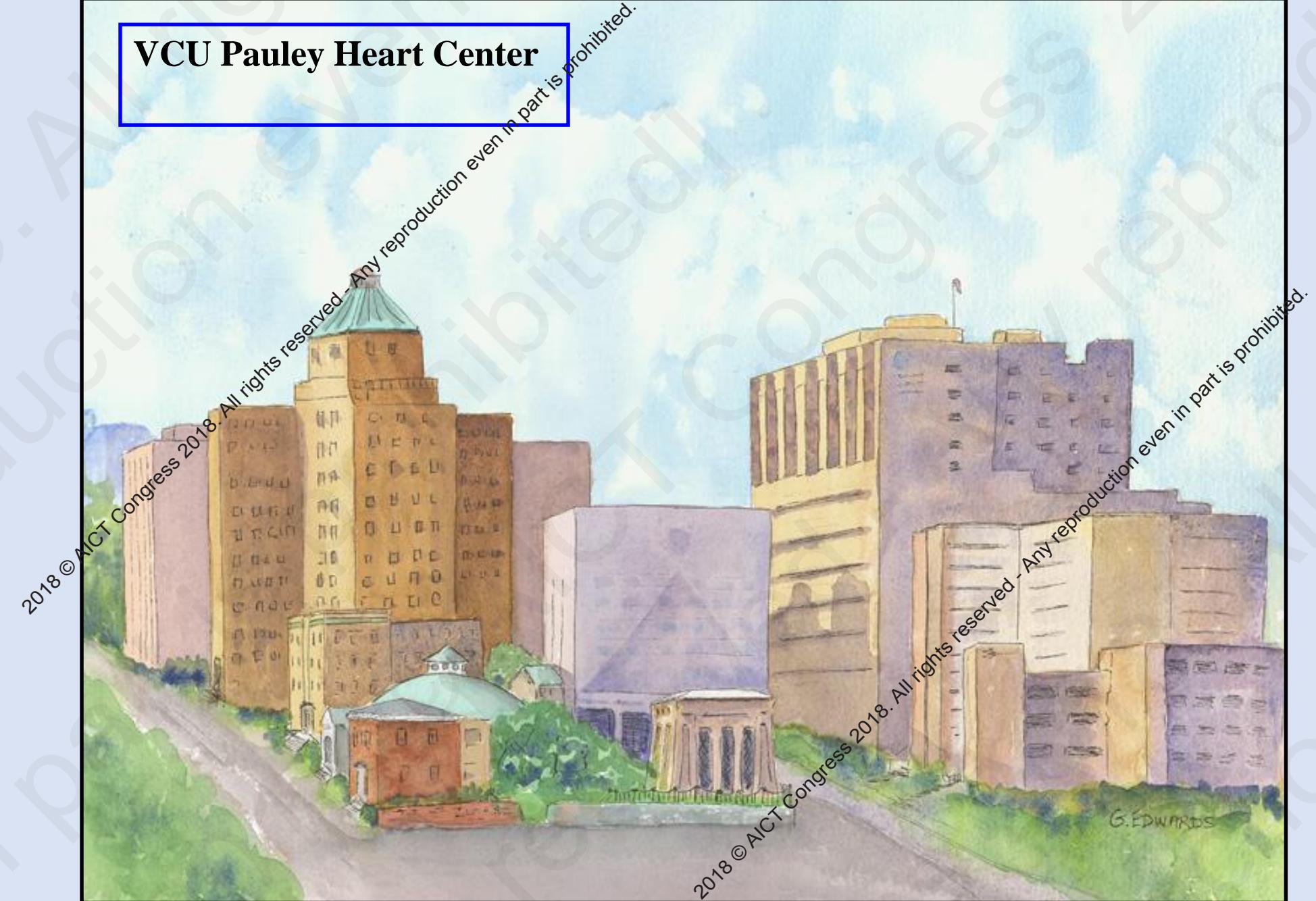


The Goal: Cardiac Recovery!

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

VCU Pauley Heart Center



14th



ASIAN INTERVENTIONAL CARDIOVASCULAR THERAPEUTICS
THE OFFICIAL CONGRESS OF APSIC



2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

7- 9th September 2018

Hong Kong
Convention and Exhibition Centre (HKCEC)

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.