**Approaches to Cardiogenic Shock**

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**Disclosures**

- Sunshine Heart, Inc. Consultant

**Heart Failure is a major driver of morbidity and mortality in the US**

- ~6.0 million adults (2.8%) in the US have heart failure  
- 670,000 new cases each year  
- #1 reason for hospitalization in people >65  
- After 4 hospitalizations, median survival is <6 months  
- More costly than all forms of cancer combined
1. Current estimates of adult patients with advanced heart failure (HF) in the United States, with projected left ventricular assist device (LVAD) candidates. U.S. population estimate is derived from U.S. Census data. Estimate of HF prevalence is derived from latest American Heart Association (AHA) statistics.

2. UNOS Website: http://optn.transplant.hrsa.gov


Indications for Acute Support

- Bridge to Recovery/Decision (mostly salvage cases)
- Cardiogenic shock due to refractory heart failure
  - Bridge to Transplant (BTT)
  - Bridge to Durable Device
- ECMO
  - Veno-venous (VV) – pre-/post lung transplant, ARDS
  - Veno-arterial (VA) – prolonged shock, post-cardiotomy
- Post-cardiotomy failure

Bridge to Recovery/Decision

- Bridge to Recovery
- Bridge to Another Device
- Bridge to Transplant
- Withdrawal of Support
Timing – earlier referral is best

- Identify candidates who will benefit from MCS
- Avoid end-organ damage
- Improve quality of life
- More rapid post-operative recovery if referred before co-morbidities begin to appear, i.e. renal dysfunction
- If referred earlier, they can be kept on the radar and receive timely intervention, rather than no intervention due to “too late” referral

- Avoid patients who are “too sick” to benefit

Types of Assist Devices

- Short term support
  - Percutaneous (Impella, Tandem Heart)
  - Surgical (CentriMag, Impella LD and 5.0)
  - ECMO (V-V / V-A)

Why not implant long term VAD support in cardiogenic shock?

- Unclear neurologic status
- Respiratory failure
- Acute renal and liver dysfunction
- Antithrombotic burden (antiplatelets, IIb/IIIa inhibitors)
- Uncertain potential for cardiac recovery
- Unknown psycho-social status
Patients in refractory cardiogenic shock with relative contraindications for permanent VAD can be:

1. Supported safely with temporary MCS devices.
2. Be bridged to a permanent VAD once contraindications for permanent VAD no longer exist.
3. Suitability for bridge to transplant ascertained while on initial temporary support.

*Short term devices provide an opportunity to “act” first and “ask” later*

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**Cardiogenic shock MCS network**

- Hospitals in area contacted to establish open channel of communication
- Consider early transfer to hub facility (transplant/VAD)
- Potential for spoke centers to gain experience with implant
  - Implant and transfer model

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*Figure 1: Schematic drawing of the Abiomed BVS 5000 ventricle assist device*
ABIOMED AB5000 System

- Bi-ventricular support (both sides of heart)
- Off-pump, easy cannula placement at all Heart Centers
- No coring of the heart, lower bleeding vs. BTT VADs

CENTRIMAG MAGLEV PUMP

- Elimination of seals and bearings
- Elimination of friction and heat generation in the blood path reducing the risk for thrombus formation and hemolysis
- Uniform washing of the rotor surface minimizes areas of blood stagnation and turbulence in the pump
**Bearingless Pump & Motor**

- No bearing and seals
- Disposable pump head
- 31 cc priming volume
- Max. pump speed: 5500 RPM
- Max. flow: 9.9 LM
- Rotor has magnetic core

**ECMO CIRCUIT**

**Percutaneous Cannulation (for ECMO)**

Generally Femoral vein to Femoral artery

In adults 19-21 Fr venous drainage cannula and 19-21 Fr arterial return cannula
Bilateral Support

SURGICAL CANNULATION
Tandem Extremity Protection
• 117 patients with severe refractory cardiogenic shock
• 58 patients (48%) were undergoing active CPR at time of insertion
• 80 patients with ischemic and 37 patients with non-ischemic cardiomyopathy
• 60% 30-day survival and 55% 6-month survival

Tandem Heart
Texas Heart Experience

• Cardiac index increased from 0.5 to 3.0
• SBP increased from 75 to 100
• Mixed venous O2 saturation increased from 49% to 69%
• Urine output increased from 70 cc/day to 1,200 cc/day


Abiomed Impella 5.0
Impella® is the only percutaneous heart pump proven safe and effective for hemodynamic stabilization to enable *Heart Recovery*. 
Indications now include Protected PCI and Cardiogenic Shock in the setting of AMI and Postcardiotomy.

*Heart Recovery is an improvement in heart muscle function that enables a patient to sustain quality of life at home with their native heart*
FDA Indication

The Impella 2.5™, Impella CP®, Impella 5.0® and Impella LD™ catheters, in conjunction with the Automated Impella Controller console, are intended for short-term use (<4 days for the Impella 2.5 and Impella CP and <6 days for the Impella 5.0 and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction (AMI) or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures with or without an intra-aortic balloon pump.

The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

* Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without IABP.

Data Supporting FDA Indications

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<th>Scientific Evidence</th>
<th>Total # of Patients</th>
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<td>Recover I FDA Study</td>
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(4,000 Patients from FDA medical device reporting (MDR) database)

Hemodynamic Stabilization with Impella

Unloads Left Venticle & Coronary Perfusion

End Organ Perfusion

Right Side Support

Right Side Impella RP

Left Side Impella LD/LCP

Escalation & Ambulation

Seyfarth et al., JACC, 2008

Remmelink M et al., Cath Card Interv. 2007

Lima B. et al., Am J Cardiol 2016

Anderson MB. et al., J Ht Lg Transplant. 2015

Lam K. et al,. Clin Res Cardiol, 2009

Casassus et a., JOIC, 2015
Incidence of Cardiogenic Shock Growing

Cardiogenic Shock in STEMI Increasing

STEMI Cardiogenic Shock in Medicare Age Increasing

Cardiogenic Shock Remains Leading Cause of Mortality in Acute Myocardial Infarction

High In-Hospital Mortality During AMI Cardiogenic Shock

... and Ongoing Hazard Post Discharge after AMI Cardiogenic Shock

Mortality in PCI with Cardiogenic Shock Remains a Clinical Challenge

In-Hospital Mortality AMI Cardiogenic Shock with PCI

AJC Cardiogenic Shock PCI only Omit mortality 50%
IABP in AMI Cardiogenic Shock: No Hemodynamic or Survival Benefit

2. Thiele H et al. NEJM 2012 - Clinicaltrial.gov # NCT00491036

IABP-SHOCK II
Randomized Controlled Trial
N = 600

IABP SHOCK I
Randomized Controlled Trial
N = 40

IABP Increased hazard risk of stroke, downgraded to Class IIb (benefit), Level of Evidence A, ESC STEMI Guidelines 2014

IABP (n=19) Medical Therapy  (n=21)

log-rank, p=0.92

41.3%
39.7%

CPO = MAP x Cardiac Output x 0.0022

Impella® Heart Pump: How It Works

Placement in Left Ventricle

Improvement in Cardiac Index
IABP SHOCK Randomized Controlled Trial

Impella 2.5

Augmented CI

Impella 2.5

Ventricular Unloading

Pre-Support On Impella

1.71±0.45

2.20±0.64

P=0.02

1.73±0.59

1.84±0.71

Impella 2.5

Native CI

Pre-Support

On Impella

Impella 2.5

N=26

Impella 2.5

N=6

Augmented CI

Ventricular Unloading

Pre-Support On Impella

Hemodynamic Stability & LV Unloading with Impella®
**Improved Myocardial Perfusion with Impella**

Coronary Flow Velocity

- Pre-Support: 61
- On Support: 72

CTO of LCX and RCA untreated

**Improved End Organ Perfusion With Impella**

Reduction of Blood Lactate Concentration

- Blood Lactate (mmol/L)
  - Numbers of days from Impella Implant

**Which patient for an acute device?**

- Cardiac arrest with ongoing CPR
- Cardiogenic shock, IABP-dependent on inotropes and pressors
- Intra-operative failure to wean from cardiopulmonary bypass
- Bridge to a decision: indeterminate neurologic status or other significant co-morbidity (i.e., possible incurable malignancy) with critical clinical deterioration

Barnabas Health
Device Choices for

**Cardiac arrest with ongoing CPR**

- CentriMag
- AB5000
- Alternate: Impella 5.0 or Tandem Heart

Device Choices for

**Cardiogenic shock, IABP-dependent on inotropes and pressors**

- CentriMag
- Impella 5.0
- Tandem Heart

Device Choices for

**Bridge to a decision: indeterminate neurologic status or other significant co-morbidity (i.e., possible incurable malignancy) with critical clinical deterioration**

- CentriMag
- Impella 5.0
- Tandem Heart
- AB5000
Device Choices for
Biventricular Bridge to Transplant (BTT)

- CentriMag or AB5000 (in-patient only)
- Tandem Heart or Impella (consider axillary approach, in-patient only)

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2008: 38 year old mother of three children with sudden, unexplained cardiogenic shock

- Was at a southern NJ hospital more than an hour away; EF 15%
- IABP placed for initial stabilization, allowed transfer to NBI
- Upon arrival, was on maximum pressors and inotropes with MAP 40-50, mixed venous O2 saturation 40%, extremities blue/grey, cold and clammy
- Intubated, following commands

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What to do next??

- Sternotomy and place short-term LVAD off-pump
- Insertion of femoral V-A ECMO
**She was brought to the operating room**

- CentriMag LVAD implanted off-pump
- Left IABP in overnight to augment BP
- IABP removed the next day: OOB on POD #2
- LVAD explanted 5 days later
- Discharged home after uneventful hospital recovery

2013: 41 y.o male s/p HeartMate II LVAD followed by heart transplant

- Seven months post-transplant, becomes non-compliant with immunosuppression meds
- Suffers 3B rejection with subsequent hemodynamic instability
- IABP placed, results in improved mixed venous O2 sats and hemodynamic improvement
- Few days later, likely due to ongoing myocardial necrosis due to rejection, suffers recurrent VT storms that become more frequent, EF 20%

**What to do next??**

- Re-do sternotomy and insertion of CentriMag short-term LVAD
  - Concern: he is only 6-8 months s/p two sternotomies – for HM II LVAD followed by heart transplant
- Insertion of femoral V-A ECMO
**He was brought to the operating room**

- Peripheral V-A ECMO established using cannulas surgically placed (open technique) in right femoral artery and right femoral vein
- Smaller re-perfusion catheter was placed in distal right femoral artery
- IABP left in place for BP augmentation
- ECMO removed 2 weeks later, EF 35%

**Case Presentations**

- 33 y.o. female, acute closure LAD, Impella placed at outside hospital but not functioning well, transferred in cardiogenic shock on high-dose pressors and inotropes

**Case Presentations**

- 54 y.o. male admitted with recurrent VT, stable during work-up, suffered Vfib arrest, refractory Vfib, with ongoing CPR to OR
Case Presentations

56 y.o. male awaiting heart transplant, Status 1A inpatient, EF 8%, decompensated CHF refractory to IABP and high-dose inotropes and pressors

Case Presentations: Failure to Wean from cardiopulmonary bypass

55 y.o. acute aortic dissection involving RCA, underwent Bentall, had RV failure despite additional SVG to RCA

Case Presentations: Failure to Wean from Cardiopulmonary Bypass

62 y.o. male suffered massive MI at outside hospital, had IABP, intubated, two episodes cardiac arrest, transferred in cardiogenic shock, underwent emergency CABG