AATS Cardiothoracic Critical Care Symposium

Postcardiotomy Circulatory Support

Francis D. Pagani MD PhD
Professor of Cardiac Surgery
University of Michigan
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HeartWare Inc: Contract Research; National Principal Investigator ENDURANCE TRIAL. (Contracts managed by the University of Michigan.)
Thresholds to initiate Mechanical Circulatory Support (MCS)

What defines the threshold to initiate mechanical circulatory support (MCS)?

- Inadequate hemodynamic support
- Hemodynamic criteria alone are not specific
  - Degree of medical intervention
  - Degree of vasopressor support
  - End-organ response to medical therapy
- Clinical scenario: Current and past medical history; Comorbidities
- Transplant status
- Institutional experience with MCS
Decisions and Assessments

● **Endpoint**: Transplant eligible?

● **Degree of support necessary**
  – Partial versus full support
  – Uni-ventricular versus biventricular failure
  – Significant hypoxia present? Need for ECMO?

● **Type of device**
  – What devices are available?
  – What is the local expertise? – Percutaneous options?

● **Institutional experience**

● **Timing of need**
  – Immediate (CPR) versus hours
Defining an Endpoint for MCS

- Part of an overall strategy
- Define the endpoint of therapy
  - **Recovery**
    - Goal for all support situations when feasible
  - **Bridge to durable MCSD (“Bridge to bridge”)**
    - Bridge to transplantation
    - Destination Therapy
    - Exercise caution
  - Transplant status
Thoratec HeartMate II
MicroMed DeBakey HeartAssist 5
MicroMed DeBakey Pediatric
Jarvik 2000
Berlin Heart Incor
HeartWare HVAD
Evaheart LVAD

Abiomed Impella LD
Levotronix CentriMag
Abiomed Impella 2.5
Abiomed Impella CP
Abiomed Impella 5.0
TandemHeart pVAD
ECMO

Abiomed AB 5000
IABP
Short
Long
Duration of Use

Surgical Implantation
Non-operative Implantation

Thoratec IVAD
Syncardia CardioWest TAH-t
Thoratec pVAD
Berlin Heart Excor
Berlin Heart Excor Pediatric

Pulsatile Volume Displacement Pump
Continuous-flow Pump
Temporary MCSD: Degree of Circulatory Support

- **IABP**
  - CI* ↑15%
  - Partial Support

- **TandemHeart pVAD Abiomed Impella 2.5 or CP**
  - CI ↑30-60%
  - Partial Support

- **Levitroneix CentriMag Abiomed AB 5000 Abiomed Impella LD or 5.0**
  - CI ↑75-100%
  - Full Support

- **ECMO**
  - CI ↑75-100%
  - Full Support

*CI – cardiac index*
Temporary MCSD: Ease of Insertion

- **Levitronix CentriMag**
- **Abiomed AB5000**
- **Impella LD or 5.0**
- **Impella 2.5 or CP**
- **TandemHeart pVAD**
- **IABP**

Degree of Hemodynamic Support
- Full Support
- Partial Support

Ease of Insertion, Availability
- **Surgical Experience**
- Surgical and Interventional Collaboration
- Interventional Experience (trans-septal approach)

- Sternotomy
- Femoral / Axillary Artery Cutdown
- Percutaneous
Characteristics of An Ideal Temporary MSCD

- Effective: provide a wide range of hemodynamic support: full to partial support flows
  - Maximize LV unloading
- Flexible with the ability to use in multiple clinical scenarios
  - Biventricular capability
- Ease of insertion / removal and operation
  - Avoiding the need for operation following recovery
- Ease of assessing LV recovery
- Minimal anticoagulation
- Permit patient mobility
- Biocompatible
  - Low thromboembolic risk
  - Low hemolysis
Which MCSD Do I Select?

- Emphasis on patient and clinical scenario
- Tailor the therapy / choice of device to the clinical situation
  - Postcardiotomy failure
    - Implantable system: Abiomed AB5000; CentriMag
  - Post MI cardiogenic shock
    - Percutaneous system: TandemHeart; Impella
  - Myocarditis
  - High risk Cath Lab interventions
    - Percutaneous system: Impella
  - High risk OPCAB support
- No one system is superior to all others for every clinical situation
  - No system has ever been demonstrated to improve survival over that of an IABP!
Percutaneous left ventricular assist devices vs. intra-aortic balloon pump counterpulsation for treatment of cardiogenic shock: a meta-analysis of controlled trials


CONCLUSIONS:
Although percutaneous LVAD provides superior hemodynamic support in patients with cardiogenic shock compared with IABP, the use of these more powerful devices did not improve early survival. These results do not yet support percutaneous LVAD as first-choice approach in the mechanical management of cardiogenic shock.
Conclusions:
The 30-day incidence of major adverse events was not different for patients with IABP or Impella 2.5 hemodynamic support. However, trends for improved outcomes were observed for Impella 2.5–supported patients at 90 days.
Conclusions:
The use of intraaortic balloon counterpulsation did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction for whom an early revascularization strategy was planned.
Time-to-Event Curves for the Primary End Point.

P = 0.92 by log-rank test

Common Pitfalls in Initiating Temporary MCS

- Delayed initiation of MCS
- Underestimating the degree of support required: partial vs. full support device
- Not recognizing biventricular failure
- Not recognizing the severity of acute lung injury
- Not assessing risk of vascular injury / Prevention of limb ischemia
- Trying to do something with the device for which it was not intended to do:
  - bridge to transplant with a temporary MCSD (not recommended)
    - Suboptimal donor
    - Suboptimal patient status (nutrition, organ recovery)
## ADULT HEART TRANSPLANTS
### Risk Factors for 1 Year Mortality

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>N</th>
<th>Relative Risk</th>
<th>p-value</th>
<th>N</th>
<th>Relative Risk</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Temporary circulatory support*</td>
<td>35</td>
<td>2.22</td>
<td>.0034</td>
<td>110</td>
<td>2.76</td>
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<td>Diagnosis: Congenital heart disease</td>
<td>257</td>
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<td>220</td>
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<td>Dialysis</td>
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<td>209</td>
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<td>Female recipient</td>
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<td>.0394</td>
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<td>.0015</td>
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<td>Diagnosis: Valvular heart disease</td>
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<td>247</td>
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<td>.0352</td>
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<td>Donor cause of death: cerebrovascular/stroke</td>
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<td>1.09</td>
<td>.0077</td>
<td>2300</td>
<td>1.36</td>
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<td>Recipient cerebrovascular event prior to transplant</td>
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<td>.4053</td>
<td>421</td>
<td>1.31</td>
<td>.0278</td>
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<tr>
<td>Hospitalized at transplant (including ICU)</td>
<td>12352</td>
<td>1.01</td>
<td>.8082</td>
<td>5845</td>
<td>1.31</td>
<td>.0003</td>
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</table>

* Temporary circulatory support includes ECMO and Abiomed.

Note: All factors were significant at p < 0.05 in at least one of the eras.

2006
Common Pitfalls to Temporary MCS

Maximum MCS in terms of flow ≠ Maximum LV decompression:

- not optimizing LV decompression for LV recovery
- increasing the thromboembolic risk – LV thrombus from stasis

**Direct Unloading of the LV**
- Apical cannulation
  - Abiomed AB5000
  - Levitronix CentriMag
- RSPV with catheter placement across MV
  - Limits assessment of recovery
- Impella LD or 5.0
- Impella 2.5 or CP

**Indirect Unloading of the LV**
- ECMO
- TandemHeart
- IABP
Facilitating LV Apical Cannulation

Sewing the Teflon felt to the left ventricular apical myocardium with 2-0 Prolene suture using a horizontal mattress technique (1)

Placement of the left ventricular outflow cannula through the graft and secured with silk ties

Cannulation Options for Left Ventricular or Biventricular Support

A

Dome LA

LAA

Apex

B

RV

RSPV

Dome LA

Apex

LVAD

PA

RA

Ao

RVAD

LVAD


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Importance of Left Ventricular Unloading on Reducing Myocardial Injury

Improved Regional Myocardial Blood Flow, Left Ventricular Unloading, and Infarct Salvage Using an Axial-Flow, Transvalvular Left Ventricular Assist Device

A Comparison With Intra-Aortic Balloon Counterpulsation and Reperfusion Alone in a Canine Infarction Model

Richard W. Smalling, MD, PhD; David B. Cassidy, MD; Robert Barrett, MD; Bruce Lachterman, MD; Patty Felli, BS; and James Amirian, BS

<table>
<thead>
<tr>
<th>Table 5. Regional Myocardial Blood Flow Expressed as a Ratio of Ischemic Zone/Nonischemic Zone</th>
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<tbody>
<tr>
<td>Control state</td>
</tr>
<tr>
<td>Off</td>
</tr>
<tr>
<td>Control</td>
</tr>
<tr>
<td>IABP</td>
</tr>
<tr>
<td>Hemopump</td>
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</table>

Improved myocardial blood flow

Reduction in infarct size
Support with the Hemopump device alone improved the ratio of subendocardial to subepicardial blood flow, but endocardial underperfusion remained.

The association of IABP with the Hemopump device reduced the Hemopump output by 11% and increased myocardial blood flow to ischemic regions.

Perfusion to peripheral organs remained unaltered.

The transthoracic Hemopump device combined with an IABP is an ideal support system for the ischemic, failing heart.

Optimizing Management for Myocardial Recovery

- Identify potential candidates early
  - Echocardiography
- Optimize device position at implantation
  - LV apical drainage to maximize LV unloading
- Optimize hemodynamics and inotrope support
- Eliminate other causes to prevent recovery
  - Unsuspected tamponade / hypovolemic
  - Pulmonary injury / hypoxia
  - Uncorrected structural, valvular or coronary artery disease
Timing of “Bridge to Bridge” Strategy

- Myocardial recovery not likely or expected to take weeks or months

- **Bridge to bridge strategy**

- Two key organ systems to optimize function
  - Pulmonary
    - Pulmonary vascular resistance
  - Hepatic

- Temporary MCS not an independent risk factor – mortality/morbidity related to degree of organ injury
Timing of “Bridge to Bridge” Strategy

A

B

C

D

Pagani et. al. ATS 2000
Timing of “Bridge to Bridge” Strategy

![Graph showing survival to discharge and pulmonary compliance over time](image)
Indirect Unloading May Be Prone to Thromboembolic Risk In the Absence of Native Cardiac Output

- Stagnant areas of blood flow in the left ventricle
- Stagnant areas of blood flow in the aortic root
Importance of Residual Left Ventricular Output on Reducing Thromboembolic Risk

- Stagnant areas of blood flow in the aortic root
  - ECMO
  - TandemHeart

Importance of Residual Left Ventricular Output on Reducing Thromboembolic Risk

- ECMO
  - Maintain some degree of native cardiac output ≈ 20%
    - Need to maintain oxygenation of this residual output – upper body hypoxia – brain and cardiac ischemia
  - Prevent pulmonary artery thrombosis
  - Prevent stasis in the aortic root

- TandemHeart
  - Prevent stasis in the aortic root
ECMO

- Inadequate LV decompression
  - Left atrial septostomy
  - Retrograde LV decompression
  - Left atrial catheter
  - Left ventricular apex (mini-thorocotomy)
- Inadequate delivery of oxygenated blood in the ascending aorta
  - Monitoring arterial blood gas/arterial saturation from the right upper extremity
- Stasis of blood in the ascending aorta
- Risk of LV thrombus
- Need to maintain some degree of pulmonary blood flow (≈20-25%)
Other Considerations

● Valvular Pathology
  – Aortic insufficiency
    • Degree of AI can be significantly underestimated preimplant
    • Creates recirculation
  – Mechanical prosthesis in the aortic position
    • Risk of valve thrombosis
  – Tricuspid insufficiency
    • Contributes to RV dysfunction
    • May impair later weaning
    • May impair ability to support with LVAD alone
  – Mitral stenosis
  – Aortic stenosis
Summary

- Initiate support early when indicated.
- Select a device appropriate to the clinical scenario and institutional experience.
- Identify an endpoint and clarify transplant status early in the process.
- Always think recovery and maximize all variables to increase the likelihood of myocardial recovery.
- Understand the pitfalls and limitations relevant to each device and cannulation configuration.
Q61. Which of the following is not an FDA-approved indication for use of mechanical circulatory support:

a. Bridge to transplantation
b. Destination therapy (permanent device implantation)
c. Bridge to decision or candidacy
d. Bridge to recovery
Q62. Which of the following devices does not directly unload the left ventricle:

a. Impella

b. CentriMag with a cannula inserted into left apical drainage for pump inflow

c. ECMO

d. Abiomed AB5000 with a cannula inserted into the right superior pulmonary vein and positioned across the mitral valve
Temporary MCSD: IABP

- Most common form of MSC
- Greatest benefit in those with myocardial ischemia
Temporary MCSD: Levitronix CentriMag

- Extracorporeal CF rotary pump
- Centrifugal design
- Magnetically-levitated
- Left, Right, or Biventricular support – full support device
- Operative placement requiring sternotomy
- Bridge to recovery
Temporary MCSD: Abiomed AB5000

- Extracorporeal PF pump
- Pneumatic actuation
- Left, Right, or Biventricular support – full support device
- Operative placement requiring sternotomy
- Bridge to recovery
Temporary MCSD: TandemHeart

- Extracorporeal CF pump
- Centrifugal design - impellor supported with bearing
- Designed for left support – partial support device
- Percutaneous placement via atrial septostomy
- Bridge to recovery

Temporary MCSD: Impella

- CF pump with axial design
- Designed for left support – partial support device
- Percutaneous or surgical implantation
- Bridge to recovery
Percutaneous Heart Pump (PHP) System

Catheter-based axial flow pump

- Low-profile percutaneous device
- Collapsible elastomeric impeller and nitinol cannula; expands to ~24F
- Designed to deliver over 4L of flow under normal physiologic conditions

*In development. Not for clinical use

Program Status

- Demonstrated ability to deploy, generate desired blood flow, and withdraw device in bench and animal models
- 2011: enter preclinical testing and begin discussions with FDA
- Targeting first-in-man implant by end of 2012
Temporary MCSD: Paracorporeal Systems (BTT)

- Extracorporeal (paracorporeal) PF pump
- Pneumatic actuation
- Left, Right, or Biventricular support – full support device
- Surgical implantation
- Indications
  - Bridge to recovery
  - Bridge to transplantation
- Permits patient discharge to home but require tethering to portable drive console. Not “hands free”

Thoratec pVAD

Berlin Heart Excor