Mechanical Circulatory Support: 

*Indications and Implications*

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• I have no disclosures
Overview

• Indications for Mechanical Circulatory Support

• Categories of available support

• Patient outcomes

• Special considerations when operating on patients with Mechanical Circulatory Support
History of Mechanical Circulatory Support

- **1953** Cardiopulmonary bypass
- **1962** Intra-aortic balloon pump
- **1964** NIH develops Artificial Heart Program
- **1965** DeBakey: Successfully used an assist device for post cardiotomy patient
- **1967** Barnard: First human heart transplant
- **1969** Cooley: Total artificial heart (TAH) as bridge to transplantation
History of Mechanical Circulatory Support

- **1980s** Cyclosporine introduced – Heart transplant becomes gold standard

- **1984** TAH implanted survival 112 days

- **1994 – 98** First generation LVADs approved for bridge to transplantation

Jarvik-7 artificial heart

Helman, DN. Prog. Cardiovasc Dis 2000
Sometime in July 2006..
2016 Indications/Options for Mechanical Circulatory Support

- Acute Heart Failure
- Acute Pulmonary Failure
- Chronic Heart Failure
Acute Heart Failure

- Venoarterial (VA) ECMO
  - Provides full cardiopulmonary support
  - Contraindicated in patients who can’t be anticoagulated
  - Complications include:
    - Bleeding
    - peripheral ischemia
    - hemolysis
    - vascular injury
    - stroke
Acute Heart Failure

Percutaneous extracorporeal circuit to bypass the left or right ventricle

Achieves flows up to 4-5 L/min
Acute Heart Failure

• CentriMag®

• Configured for left, right or biventricular support

• Used as a bridge to decision
Acute Pulmonary Failure

Veno-Venous (VV) ECMO
## UVA ECMO Program 2013-16

<table>
<thead>
<tr>
<th># of Pt's per Type</th>
<th>FY '16</th>
<th>FY '15</th>
<th>FY '14</th>
<th>FY '13</th>
</tr>
</thead>
<tbody>
<tr>
<td>VV</td>
<td>7</td>
<td>2</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>VA</td>
<td>14</td>
<td>11</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>ECPR</td>
<td>9</td>
<td>7</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total Pt. per yr.</strong></td>
<td><strong>30</strong></td>
<td><strong>20</strong></td>
<td><strong>20</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>
## Wean from ECMO Survival

<table>
<thead>
<tr>
<th>Support Type</th>
<th>FY '16</th>
<th>FY '15</th>
<th>FY '14</th>
<th>FY '13</th>
<th>ELSO</th>
</tr>
</thead>
<tbody>
<tr>
<td>VV</td>
<td>43%</td>
<td>100%</td>
<td>86%</td>
<td>60%</td>
<td>65%</td>
</tr>
<tr>
<td>VA</td>
<td>79%</td>
<td>67%</td>
<td>40%</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>ECPR</td>
<td>56%</td>
<td>67%</td>
<td>25%</td>
<td>50%</td>
<td>29%</td>
</tr>
</tbody>
</table>

## Survival to Discharge

<table>
<thead>
<tr>
<th>Discharge Survival</th>
<th>FY '16</th>
<th>FY '15</th>
<th>FY '14</th>
<th>FY '13</th>
<th>ELSO</th>
</tr>
</thead>
<tbody>
<tr>
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<td>43%</td>
<td>50%</td>
<td>86%</td>
<td>60%</td>
<td>56%</td>
</tr>
<tr>
<td>VA</td>
<td>57%</td>
<td>67%</td>
<td>0%</td>
<td>40%</td>
<td>40%</td>
</tr>
<tr>
<td>ECPR</td>
<td>33%</td>
<td>50%</td>
<td>13%</td>
<td>25%</td>
<td>29%</td>
</tr>
</tbody>
</table>
Indications for MCS

Chronic Heart Failure
Heart Failure is a Common Problem

• 2.6% of Americans carry a diagnosis of heart failure

• 7 million people

• 500,000 more are diagnosed each year

• High readmission rates
  – 20% at 1 month, 50% at 6 months

Casper JACC 2010; 55: 294
Miller Circulation 2011; 123: 1552
Heart Failure Hospitalization Rates

Figure 1. HF Hospitalization Rates Among Medicare Beneficiaries, Age ≥65 Years, 2000–2006: Total Population
Heart Failure Affects Younger Populations

Figure 1. Percent distribution of hospitalizations for congestive heart failure, by age in years: United States, 2000 and 2010

NOTES: Changes in the percentages for each age group shown were statistically significant at the 0.05 level using a weighted least squares regression method to measure linear trends over time. Data from all years were included in this test. Estimates may not add to 100% due to rounding.

Heart Failure is Deadly

- Following a HF admission
  - 30 day mortality 10%
  - 1 year mortality 22%
  - 5 year mortality 42%

Hunt Circulation 2009; 119: e391
Roger Circulation 2011; 123: e18
Setoguchi Am Heart J 2007; 154: 260
Medical Management Works... For a While

In a patient with an LVEF<35% and NYHA class II-III symptoms:

- Mortality rate is ~20%/year, median survival ~2.5 years
- Mortality rate of ~15%/year, median survival ~3.3 years
- Mortality rate of ~10%/year, median survival ~5 years
- Mortality rate of ~7.5%/year, median survival ~6.7 years
- Mortality rate of ~5.8%/year, median survival of ~9 years
- ACE-I + beta-blocker
- ACE-I + BB + aldo-I
- ACE-I + BB + aldo-I + ICD

Garg JAMA 1995;273:1450
Flather Lancet 2000;355:1575
CIBIS-II Lancet 1999;353:9
Pitt NEJM 1999;341:709
Pitt NEJM 2003;348:1309
SCD-HeFT NEJM 2005;352:225
Medically Refractory Heart Failure

- Frequent hospitalizations despite compliance

- Evidence of end-organ damage
  - Worsening renal/hepatic function
  - Pulmonary hypertension

- Inability to tolerate evidence-based medications
  - Worsening renal function
  - Hypotension
Consideration of Advanced Therapies

• Transplantation
  – Gold standard with 60% expected survival at 10 years
  – Limited by availability of donors
  – Not everyone is a candidate

• Mechanical Circulatory Support
  – Fully implanted left ventricular support (LVAD)
  – Total artificial heart (TAH)
Mechanical Support Strategies

• Bridge to transplant
  – Listed but unable to keep medically stable while waiting

• Destination
  – Bridge to candidacy – need to resolve some issue(s) prior to being a transplant candidate
  – True destination – no expectation of listing
  – Bridge to recovery – myocarditis, peripartum, acute MI
HeartMate XVE

- Pulsatile device
- 83 ml x 120 bpm = 10 L/min

Slaughter NEJM 2009; 361: 2241

Rose NEJM 2001; 345: 1435
Limitations of Pulsatile LVADs

• Size of the device
  – Extensive dissection for implantation
  – Not suitable for smaller adults
• Durability
• Air displacement – large driveline
Continuous Flow LVADs

- Smaller device, smaller driveline
- Fewer moving parts – more durable
- No valves
- No pulse!
HeartMate II

- Speed 6000-15000 rpm
- Flow 3-10 L/min
- Axial pump

Miller NEJM 2007; 357: 885
HeartMate II – DT Trial

- 200 patients randomized to HMII or XVE
- Primary endpoint – survival free from disabling stroke or pump exchange at 2 yrs.
  - HMII 46%
  - XVE 11%

Slaughter NEJM 2009; 361: 2241
HeartMate II
HeartMate II
HeartMate II
HeartWare HVAD
Approved for BTT in 2012

1800-4000 rpm, 10 L/min
Centrifugal/ Hydrodynamic Bearing
HeartWare HVAD
Technical Considerations

- Aortic insufficiency
- ASD/VSD
- Mitral stenosis
- Small LV cavity (HCM)
- Calcified aorta or apex
- RV function and tricuspid regurgitation
Syncardia Total Artificial Heart

- Pneumatic driver (pulsatile flow)
- 130 patient BTT trial
- 79% survival to transplant, average 79 days of support

Copeland NEJM 2004; 351: 859
SynCardia TAH

- Up to 9.5 L/min
- FDA approved BTT, humanitarian use for DT
- Longest duration of support 3.75 yrs.
- 1,200 implants
- Freedom Driver allowing discharge home
Trends in Mechanical Circulatory Support

![Graph showing implant trends from June 2006 to December 2014, n=13286.](image)
Pedimacs Enrollment

pediMACS Implants: 9/19/2012 - 05/01/2015
Cumulative Hospital, Patient, and Device Enrollment Counts

Kirklin J Heart Lung Transplant. 2015; 1495: 1504
## Complications associated with LVADs

<table>
<thead>
<tr>
<th>Early</th>
<th>Late</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Bleeding/Hypovolemia</td>
<td>• Aortic insufficiency</td>
</tr>
<tr>
<td>• Tamponade</td>
<td>• Ventricular arrhythmias</td>
</tr>
<tr>
<td>• RV failure</td>
<td>• Pump thrombosis</td>
</tr>
<tr>
<td>• Ventricular arrhythmias</td>
<td>• Intracranial hemorrhage</td>
</tr>
<tr>
<td>• Pulmonary Embolism</td>
<td>• GI bleeding</td>
</tr>
</tbody>
</table>

- Driveline infections
- Cannula migration
- Preformed antibodies (for transplant candidates)
Complications associated with LVADs
Survival


LVAD

LVAD Centrifugal: n=1301, Deaths=172
LVAD Axial: N=3966, deaths=703

BiVAD

BiVAD Centrifugal: n=63, deaths=25
BiVAD Axial: n=99, Deaths=37

P(overall) < .0001
LVAD Centrifugal vs. Axial: p=.04
BiVAD Centrifugal vs. Axial: p=.56

Event: Death (censored at transplant and recovery)
Living with an LVAD
Living with an LVAD

• Always connected to power source
  – battery or wall power
  – Battery life about 10 hours

• Daily anticoagulation
  – Aspirin 325 mg daily and warfarin goal INR 2-2.5 (or 3)

• Avoid strong magnets
  – MRI

• No swimming
Improved Quality of Life

EQ5D Dimension: Self Care

By Era
2008-2011
2012-2014

% with Problems

Pre-Implant < .0001
3 mths < .0001
6 mths .009
12 mths .33
18 mths .76
24 mths .80

Kirklin J Heart Lung Transplant. 2015; 1495: 1504
University of Virginia
Mechanical Circulatory Support Program
UVA
Mechanical Circulatory Support Program

- **1989**: Heart transplant program begins
- **1990**: UVa participates in research trial to evaluate long-term VAD
- **1996**: First implant of a FDA approved pulsatile VAD
- **2004**: First continuous flow VAD implant
- **2013**: UVa implants 150\textsuperscript{th} continuous flow device
- **2014**: First pediatric LVAD implant
- **2015**: UVa participates in LVAD + stem cell trial
- **2016**: UVa implants first TAH, 1\textsuperscript{st} ‘mini’ VAD implant
UVA Durable LVAD Implants

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Privileged Under Virginia Code Section 8.01-581.17
Where Our Patients Live
Lower Rehospitalization Rates

Rehospitalization within first 90 days (episodes per 100 pt months)

Rehospitalization after first 90 days

UVA

INTERMAC
Improved NYHA Functional Capacity

- **Pre-Implant**
- **3 Months Post**
- **6 Months Post**
- **12 Months Post**

Class 4
Class 3
Class 2
Class 1
Non-Cardiac surgery in the MCS population
Non-Cardiac surgery in the MCS population

- Cholecystectomy
- Feeding gastrostomy
- Colectomy
- Bariatric Surgery
- Orthopedic surgery
- Neurosurgery
- ...

Images of medical equipment and medical staff.
Non-Cardiac surgery in the LVAD population

• Involve a heart-failure cardiologist

• Prepare the operating room
  – Anesthesia, perfusion

• Be cognizant of anticoagulation
Non-Cardiac surgery in the LVAD population

- Involve cardiac surgery if operating in/around driveline
- Minimize cephalad retraction
Summary

• Mechanical circulatory support is still a relatively young technology
• Significant increase in survival among patients with end stage heart disease
• Quality of life is improved with long term implantable devices
• Many opportunities for further development
Thank You