ECMO as a bridge to durable LVAD therapy

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Systolic Heart Failure

- Prevalence 4.8 million U.S.
- 287,000 deaths per year
- $39 billion spent on CHF
- Survival outlook <5 years
- 550,000 new cases per year
- Aging population
- Rise in incidence of diabetes and obesity
Ventricular Assist Devices

Primary Continuous Flow Pumps by implant year era

P(overall) = .005
P(Era 1 vs Era 2) = .01
P(Era 1 vs Era 3) = .01
P(Era 2 vs Era 3) = .17

% Survival

-------------|-----------|-----------|-----------|
| n=6906, deaths=2826 | n=5326, deaths=1652 | n=5400, deaths=920 |
3 months | 91% | 89% | 90% |
6 months | 81% | 87% | 87% |
12 months | 80% | 81% | 82% |
24 months | 68% | 70% | 73% |
36 months | 57% | 60% | --- |

Event: Death (censored at transplant and device cessation)

Months post implant
Ventricular Assist Devices

- Standard of care as bridge to transplant
- Increasingly utilized as destination therapy
## INTERMACS Level

<table>
<thead>
<tr>
<th>Level 1: Critical cardiogenic shock- “Crash and Burn”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2: Progressive decline despite inotopic support- “Sliding on Inotropes”</td>
</tr>
<tr>
<td>Level 3: Stable but inotrope dependent- “Dependent Stability”</td>
</tr>
<tr>
<td>Level 4: Resting symptoms</td>
</tr>
<tr>
<td>Level 5: Exertion intolerant</td>
</tr>
<tr>
<td>Level 6: Exertion limited- “Walking wounded”</td>
</tr>
<tr>
<td>Level 7: Advanced NYHA III</td>
</tr>
</tbody>
</table>
Importance of Intermacs Level

Survival by Intermacs Profiles*

<table>
<thead>
<tr>
<th>Intermacs Profiles</th>
<th>n</th>
<th>deaths</th>
<th>6 mths</th>
<th>12 mths</th>
<th>36 mths</th>
<th>48 mths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profile 1</td>
<td>1629</td>
<td>477</td>
<td>79%</td>
<td>74%</td>
<td>52%</td>
<td>51%</td>
</tr>
<tr>
<td>Profiles 2 &amp; 3</td>
<td>7437</td>
<td>1716</td>
<td>88%</td>
<td>82%</td>
<td>61%</td>
<td>53%</td>
</tr>
<tr>
<td>Profiles 4-7</td>
<td>1651</td>
<td>376</td>
<td>89%</td>
<td>84%</td>
<td>67%</td>
<td>57%</td>
</tr>
</tbody>
</table>

Event: Death = censored at transplant, recovery and device exchange

*P(overall) < .0001
p(Profile 1 vs. Profiles 2 & 3) < .0001
p(Profile 1 vs. Profiles 4-7) < .0001
p(Profiles 2&3 vs. Profiles 4-7) = .02
Predicting Survival in Patients Receiving Continuous Flow Left Ventricular Assist Devices

The HeartMate II Risk Score

Jennifer Cowger, MD, MS,* Kartik Sundareswaran, PrfD,† Joseph G. Rogers, MD,‡
Soon J. Park, MD,§ Francis D. Pagani, MD, PrfD,* Geetha Bhat, MD, PrfD,‖ Brian Jaski, MD,¶
David J. Farrar, PrfD,† Mark S. Slaughter, MD#

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate</th>
<th>SE</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per 10 yrs)</td>
<td>0.274</td>
<td>0.12</td>
<td>1.32 (1.05–1.65)</td>
<td>0.018</td>
</tr>
<tr>
<td>Albumin (per g/dl)</td>
<td>−0.723</td>
<td>0.23</td>
<td>0.49 (0.31–0.76)</td>
<td>0.002</td>
</tr>
<tr>
<td>Creatinine (per mg/dl)</td>
<td>0.740</td>
<td>0.22</td>
<td>2.10 (1.37–3.21)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>INR (per unit)</td>
<td>1.136</td>
<td>0.32</td>
<td>3.11 (1.66–5.84)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Center volume &lt;15</td>
<td>0.807</td>
<td>0.34</td>
<td>2.24 (1.15–4.37)</td>
<td>0.018</td>
</tr>
</tbody>
</table>
Possible to Downgrade INTERMACS Levels?

• Temporary mechanical circulatory support
  • Less expensive
  • Easier to implant
    • Peripheral insertion

• Restores circulatory stability and end organ perfusion
  • May allow end organ recovery
  • Permits time to better assess patients candidacy for durable LVAD
    • Medically
    • Psychologically
    • Socially
Temporary Mechanical Support Systems

• Peripheral VADs
  • Impella (Abiomed, Inc. Danvers, MA)
  • TandemHeart (Cardiac Assist, Pittsburgh, PA)

• Temporary surgical VADs
  • Abiomed BVS (Abiomed, Inc. Danvers, MA)
  • CentriMag (Thoratec, Inc. Pleasanton, CA)

• ECMO
Patient Populations

- Acute heart failure/cardiogenic shock
- Post-cardiotomy Support
- Chronic decompensated heart failure
When to Offer Temporary Mechanical Circulatory Support

Typically if you’re thinking about it you should probably do it

Delay in initiation leads to death
  Prolonged CPR
  Elevated lactate
When *not* to offer support

- Bridge to what?
  - Recovery
    - AMI, postcardiotomy, myocarditis
  - VAD/transplant
    - Chronic heart failure
Extracorporeal Membrane Oxygenation

• Modified cardiopulmonary bypass
• No blood:air interface
  • No venous reservoir
  • No cardiotomy suction
• Reduces inflammatory response
• Reduces requirements for anticoagulation
• VA ECMO
  • Cardiac support
• VV ECMO
  • Respiratory support
PROLONGED EXTRACORPOREAL OXYGENATION FOR ACUTE POST-TRAUMATIC RESPIRATORY FAILURE (SHOCK-LUNG SYNDROME)

Use of the Bramson Membrane Lung

What is in an ECMO Circuit?

Blood pump

Oxygenator
Blood Pumps

• Roller pumps
  • Hazard cavitation and circuit rupture

• Cone type centrifugal pumps
  • Thrombus around central bearing
  • Hemolysis

• Mendler design

Seal-less Centrifugal Blood Pump with Magnetically Suspended Rotor: Rot-a-Flot

Nikolaus Mendler, Franz Podechtl, Gerhard Feil, Peter Hiltmann, and Fritz Sebening

*Department of Cardiovascular Surgery, German Heart Center, Munich, Germany*

Artif Organs, Vol. 19, No. 7, 1995
Oxygenators

- Silicone rubber
  - High resistance
  - Blood cell activation
- Microporous hollow fibers
  - Plasma leakage
- Polymethyl Pentene (PMP)
  - Maquet Quadrox
  - Medos Hilite
Integrated Pump/Oxygenator

• More easily transportable
• User interface simplifies care
• Facilitated prime for rapid initiation

Cardiohelp (Maquet)
Extracorporeal Membrane Oxygenation Use Has Increased by 433% in Adults in the United States from 2006 to 2011

Christopher M. Sauer,* David D. Yuh,† and Pramod Bonde*†‡
Active ECLS Centers

Number of Centers vs. Number of Runs over the years 1990 to 2016.

- **Number of Centers**
  - Bars representing the number of centers from 1990 to 2016.
  - The number of centers increases gradually over the years.

- **Number of Runs**
  - Line graph showing the number of runs over the same period.
  - The number of runs also increases significantly from 1990 to 2016.

- **Legend**
  - **Centers** (blue bars)
  - **Cases** (black line)
Adult Respiratory Cases

Cumulative Runs

Annual Runs

ELSO Registry July 2016
Cumulative Survival in Cardiac Support

16 years old and over

ELSO Registry July 2016
Conduct of ECMO

- Cannulation
  - Peripheral
    - Percutaneous femoral
      - Expediency
      - No image guidance necessary
  - Surgical
    - Femoral
    - Axillary
- Central
  - Optimal flow
  - Time consuming
  - Bleeding
  - Infectious concerns
Conduct of ECMO

- Optimize flow to achieve hemodynamic goals
- Adjust sweep gas to normalize pCO2
  - Patient’s lungs work
- Moderate anticoagulation
  - ACT, aPTT, Xa, TEG
- Lung protective ventilation or extubation
- Diuresis or hemofiltration to achieve euvoolemia
- Minimize sedation
- Nutrition
- Ambulation?
Complications: Limb Ischemia

• Ubiquitous problem
• Large size cannula  
  • 15-19 Fr arterial
• Coexistent peripheral vascular disease
• Vasoconstrictors

• Difficult to assess limb for ischemia  
  • Both legs cold and underperfused  
  • No pulse to doppler
• Failure to recognize and treat will result in limb loss
Sensors placed on head and calf
Unilateral fall in rSO2 implies ischemia
6/17 patients with ischemia (35%)
Resolved with insertion of distal perfusion catheter or fasciotomy
No limbs lost
“Reperfusion Cannula”

- Additional arterial cannula into leg
  - Y in with arterial line through luer port in arterial line
  - “LEGMO”
- Estimated 100cc/min is adequate to maintain viability
- Variety of approaches to this strategy
  - Open cannulation of SFA (9 Fr wire wound sheath)
  - Percutaneous cannulation of SFA
    - Best if performed prior to insertion of antegrade cannula
  - Posterior tibial artery (6 or 8 Fr DLP)
Complications: Left Ventricular Distension

- ECMO is partial bypass
  - Residual RV output and bronchial flow
- LV must eject to avoid pulmonary edema

- Maintain aortic pulsatility
- Follow pulmonary artery pressures
- Liberal use of echo
  - LV size
  - Aortic valve opening
- Strategies to facilitate LV ejection
  - Inotropes (dobutamine, milrinone)
  - IABP
  - Control afterload
- Venting when necessary
Left Ventricular Venting

- Transthoracic LV vent
  - RSPV
  - LV apex
  - PA
- Percutaneous atrial septostomy
- TandemHeart drain
- Impella as LV vent
Complications: Harlequin Syndrome

- Femoral VA ECMO
- Dysfunctional lungs
- Left ventricular ejection

- Diagnose with right hand saturations
- Treatment:
  - Optimize ventilator
    - Avoid ventilator induced lung injury
  - Convert to VA-V ECMO
    - Usually occurs in the setting of cardiac recovery
Transition to Durable LVAD

Optimization of end organ function

Complications from TMCS
Evidence
Early transition from ECMO to durable support more effective than delayed

• Early = 4 days
Extracorporeal life support prior to left ventricular assist device implantation leads to improvement of the patients' INTERMACS levels and outcome.

David Schibilişky¹, Christoph Haller¹⁺, Bruno Lange¹, Barbara Schibilişky¹, Helene Haeberle², Peter Seizer³, Meinrad Gawaz³, Peter Rosenberger², Tobias Walker¹, Christian Schliensak¹

Table 1. Patient characteristics and etiology of heart failure.

<table>
<thead>
<tr>
<th>Patient #</th>
<th>Age (years)</th>
<th>Etiology of heart failure</th>
<th>INTERMACS (pre ECLS)</th>
<th>ECLS (out of center)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>61</td>
<td>DCM + Myocarditis</td>
<td>I</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>49</td>
<td>Myocardial Infarction</td>
<td>I</td>
<td>-</td>
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<tr>
<td>3</td>
<td>41</td>
<td>Cardiac Malignancy</td>
<td>I</td>
<td>-</td>
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<tr>
<td>4</td>
<td>20</td>
<td>Myocarditis</td>
<td>II</td>
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<td>I</td>
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<td>II</td>
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<td>9</td>
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<td>I</td>
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<td>DCM</td>
<td>I</td>
<td>-</td>
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<tr>
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<td>45</td>
<td>Myocardial Infarction</td>
<td>I</td>
<td>+</td>
</tr>
<tr>
<td>14</td>
<td>49</td>
<td>Myocardial Infarction</td>
<td>I</td>
<td>+</td>
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<td>54</td>
<td>Myocardial Infarction</td>
<td>I</td>
<td>+</td>
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Clinical Outcomes of Advanced Heart Failure Patients with Cardiogenic Shock Treated with Temporary Circulatory Support Before Durable LVAD Implant

PALAK SHAH, *SARA SMITH, † JONATHAN W. HAFT, ‡ SHASHANK S. DESAI, *NELSON A. BURTON, § MATTHEW A. ROMANO, ‡ KEITH D. AARONSON, ¶ FRANCIS D. PAGANI, ‡ AND JENNIFER A. COWGER

• TMCS were qualitatively different than those not on support
• INTERMACS 2-3 fared better than INTERMACS 1 or TMCS
• No significant differences in survival of TMCS and INTERMACS 1
Summary

• INTERMACS level 1 patients are at high perioperative risk
• Patients in shock can be supported with TMCS
  • ECMO utilization grown substantially
• Important limitations of ECMO must be recognized and mitigated
• Patients bridged to durable MCS with TMCS remain at elevated risk