Are we ready to implant LVAD’s in the less sick?

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The Landscape is Changing

www.STEMmom.org
Do we have equipoise?

- Smaller pumps, less intrusive
- Less invasive surgery
- Better survival with continuous flow pumps
- Improves HRQoL
- Known poor HRQoL in most NYHA Class III-IV
- Poor functional capacity
- We have been able to identify the Profiles and we have seen the difference in survival
- Drop in stroke rate? Gender differences
- Drop in infection rates
Do we have equipoise?

- Pumps are smaller
  - Surgery less invasive
- Continuous flow pumps—better survival
  - Pumps more durable
- Improvements in HRQoL
Figure 4 Comparisons for mechanical circulatory support patients with complete data on the EQ-5D according to Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profiles: (A) visual analog scale; (B) mobility, any problems; (C) ...
Improvements in Functional Capacity

Rogers J et al. JACC Vol. 55, No. 17, 2010
# Improvements in line infection

<table>
<thead>
<tr>
<th>Primary Cause of Death</th>
<th>Implant Date Period</th>
<th>Total</th>
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<tbody>
<tr>
<td></td>
<td>&lt; 2010</td>
<td>2010 - 2011</td>
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<tr>
<td>Circulatory: Arterial Non-CNS Thromboembolism</td>
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<td>15</td>
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<tr>
<td>Circulatory: CHF</td>
<td>38</td>
<td>37</td>
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<tr>
<td>Circulatory: Cardiac Arrhythmia</td>
<td>22</td>
<td>39</td>
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<tr>
<td>Circulatory: End Stage Cardiomyopathy</td>
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<td>17</td>
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<td>Circulatory: Heart Disease</td>
<td>8</td>
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<td>Circulatory: Hemolysis</td>
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<td>Circulatory: Ischemic Cardiomyopathy</td>
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<td>Circulatory: Major Bleeding</td>
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<td>Circulatory: Myocardial Infarction</td>
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<td>Circulatory: Myocardial Rupture</td>
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<td>Circulatory: Other, Specify</td>
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<td>37</td>
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<td>Circulatory: Pericardial Fluid Collection</td>
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<td>Circulatory: Right Heart Failure</td>
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<td>66</td>
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<tr>
<td>Circulatory: Ruptured Aortic Aneurysm</td>
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<tr>
<td>Digestive: Renal Dysfunction</td>
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<td>Major Infection</td>
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<tr>
<td>Multisystem Organ Failure (MSOF)</td>
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<tr>
<td>Nervous System: Neurological Dysfunction</td>
<td>140</td>
<td>205</td>
</tr>
</tbody>
</table>
Do we have equipoise?

- Profiles are truly descriptive and discriminatory

Barge-Caballero E et al. Circ Heart Fail. 2013;6:763-772
Grp 1= Profile 1  
Grp 2= Profile 2,3,  
Grp 3= Profile 4-7

Figure 4 Actuarial survival post-LVAD.

Andrew J. Boyle, Deborah D. Ascheim, Mark J. Russo, Robert L. Kormos, Ranjit John, Yoshifumi Naka, Annetine ...

Clinical outcomes for continuous-flow left ventricular assist device patients stratified by pre-operative INTERMACS classification

Who are we implanting MCS?
We are already implanting on the less sick
BUT

Who are the patients?

Age?

When to intervene?

NYHA Imprecise Nature and the “eye of the beholder”
A depiction of the clinical course of heart failure with associated types and intensities of available therapies.

Transition to Advanced Heart Failure:
- Oral therapies failing
- A time for many major decisions
- Consider MCS and/or transplantation, if eligible
- Consider inversion of care plan to one dominated by a palliative approach, which may involve formal hospice

All-Cause Mortality (NYHA Class II-III)

HR 0.93 (95% CI 0.84, 1.02), $P = 0.13$

HR 0.96 (95% CI: 0.79, 1.17), $P = 0.70$

Excellent medical/device therapy
Figure 2: 90-Day In-Hospital Mortality by Risk Categories of DTRS

Teuteberg JJ. J Am Coll Cardiol 2012;60:44–51)
161 Patients with INTERMACS 4-7 Heart Failure Have Reduced Quality of Life

Figure 2 Physical function/activities of daily living dimensions on the EQ-5D according to Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profiles: (A) mobility problems; (B) unusual activities problems; and (C) self-care problems.
Adult Primary Continuous Flow LVAD/BiVADs, n=6732
By Age Groups


% Survival

Grp 1: < 50 yrs, n= 1758
Deaths= 293

Grp 2: 50–64 yrs, n= 3054
Deaths= 648

Grp 3: 65-69 yrs, n= 1030
Deaths= 275

Grp 4: 70+ yrs, n= 889
Deaths= 268

Overall p < .0001

Event: Death (censored at transplant and recovery)

Months post implant

Figure 3
Figure 21 Freedom from adverse events listed in Figure 19, stratified by Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) level. Error bars indicate ±1 standard error. BIVAD, biventricular assist device.

James K. Kirklin, David C. Naftel, Robert L. Kormos, Lynne W. Stevenson, Francis D. Pagani, Marissa A. Miller...

Fifth INTERMACS annual report: Risk factor analysis from more than 6,000 mechanical circulatory support patients

The Journal of Heart and Lung Transplantation, Volume 32, Issue 2, 2013, 141 - 156

http://dx.doi.org/10.1016/j.healun.2012.12.004
Unacceptable risks for the less sick?

Figure 1 Time of cumulative hospital participation and patients entered into the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database.

Kirklin et al. The Journal of Heart and Lung Transplantation, Volume 32, Issue 2, 2013, 141 - 156

Boyle AJ et al. JACC, Volume 63, Issue 9, 2014, 880 - 888
THANK YOU!
Preoperative INTERMACS Profiles Determine Postoperative Outcomes in Critically Ill Patients Undergoing Emergency Heart Transplantation Clinical Perspective


Circ Heart Fail
Volume 6(4):763-772
July 16, 2013
Causes of death pertaining to preoperative Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profiles.

Barge-Caballero E et al. Circ Heart Fail. 2013;6:763-772
Distribution of patients during the study period.

Barge-Caballero E et al. Circ Heart Fail. 2013;6:763-772
Figure 1 EQ-5D visual analog scale (VAS) results according to Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profiles. The range bars indicate the standard error.

Kathleen L. Grady, David Naftel, Lynne Stevenson, Mary Amanda Dew, Gerdi Weidner, Francis D. Pagani, James K...

INTERMACS profile
1 -- 12 (5) NA
2-- 104 (42)
3-- 71 (29)
4--7 60 (24)

Jorde UP et al. (J Am Coll Cardiol 2014;63:1751–7)
In-hospital postoperative outcomes after emergency heart transplantation.

Barge-Caballero E et al. Circ Heart Fail. 2013;6:763-772
Long-term survival after heart transplantation.

Barge-Caballero E et al. Circ Heart Fail. 2013;6:763-772