Can Comparative Effectiveness Study Tell Us What Is The Best Therapy For Class IV Heart Failure? Beta blockers or LVADs?
LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE

ERIC A. ROSE, M.D., ANNETINE C. GELUNS, PH.D., ALAN J. MOSKOWITZ, M.D., DANIEL F. HEITJAN, PH.D., LYNNE W. STEVENSON, M.D., WALTER DEMBITSKY, M.D., JAMES W. LONG, M.D., PH.D., DEBORAH D. ASCHEIM, M.D., ANITA R. TIERNEY, M.P.H., RONALD G. LEVITAN, M.Sc., JOHN T. WATSON, PH.D., AND PAUL MEIER, PH.D., FOR THE RANDOMIZED EVALUATION OF MECHANICAL ASSISTANCE FOR THE TREATMENT OF CONGESTIVE HEART FAILURE (REMATCH) STUDY GROUP*

EFFECT OF CARVEDILOL ON SURVIVAL IN SEVERE CHRONIC HEART FAILURE

MILTON PACKER, M.D., ANDREW J.S. COATS, M.D., MICHAEL B. FOWLER, M.D., HUGO A. KATUS, M.D., HENRY KRAM, M.B., B.S., PH.D., PAUL MOHACSI, M.D., JEAN L. ROULEAU, M.D., MICHAL TENDEA, M.D., ALAIN CASTAIGNE, M.D., ELLEN B. ROECKER, PH.D., MELISSA K. SCHULTZ, M.S., AND DAVID L. DEMETS, PH.D., FOR THE CARVEDILOL PROSPECTIVE RANDOMIZED CUMULATIVE SURVIVAL STUDY GROUP*
Triage Guided
By INTERMACS Profiles

- Importance of comparing a fruit to a fruit
- Shifting away from Profile 1 over time
- Device before Transplant vs Direct Transplant without Device vs Device Only
- Evolution of INTERMACS Profiles
- INTERMACS patients compared to MedaMACS
  - Line up by disease severity
  - Line up by intent
    - Transplant eligibility
    - Likelihood of RV failure?
    - Patient preferences?
REMATCH “Class IV”

- 19 unstable on $\geq 2$ inotropic agents
- 8 patients on 2 agents, couldn’t wean first agent
- 3 patients unsuccessful switch of one agent for another
- 34 unsuccessful wean due to hypotension or increased dyspnea

- 27 met VO2 $\leq 12$ criterion on inotropic therapy and did not attempt wean

- 38 patients oral therapy only met PkVO2 criteria
## INTERMACS Profiles and VAD Survival

**All VADS 2006-2007**

*Pagani at al ISHLT 2008*

<table>
<thead>
<tr>
<th>Profile</th>
<th>% Pts</th>
<th>6 Mo Surv Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crash and burn</td>
<td>46%</td>
<td>0.71</td>
</tr>
<tr>
<td>Sliding fast</td>
<td>40%</td>
<td>0.74</td>
</tr>
<tr>
<td>Stable on inotropes</td>
<td>8%</td>
<td>0.88</td>
</tr>
<tr>
<td>Resting symptoms home on oral therapy</td>
<td>6%</td>
<td>0.77</td>
</tr>
</tbody>
</table>
Changing Profiles of Severity

2006-2010

2011-2013
Continuous Flow LVAD/BiVAD Implants: 2008 – 2013, n=9372

- Level 1: n=1391, Deaths=381
- Level 2: n=3601, Deaths=942
- Level 3: n=2591, Deaths=544
- Levels 4-7, n=1789, Deaths=405

P < .0001

Event: Death (censored at transplant and recovery)

Months post implant
We do need a mechanical option before transplantation For INTERMACS 1 and 2

AVERAGE WAIT TIME FOR URGENT PATIENTS = 5 days!
Patients need support to survive and thrive for transplant.

How many surgeries do Profile 3-4 pts really need?

When and what intervention is for housebound or walking wounded?

<table>
<thead>
<tr>
<th>PROFILE-LEVEL</th>
<th>Official Shorthand</th>
<th>% Profiles In Bridge</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERMACS LEVEL 1</td>
<td>“Crash and burn”</td>
<td>18%</td>
</tr>
<tr>
<td>INTERMACS LEVEL 2</td>
<td>“Sliding fast” on ino</td>
<td>42%</td>
</tr>
<tr>
<td>INTERMACS LEVEL 3</td>
<td>Stable but Ino-Dependent Can be hosp or home</td>
<td>23%</td>
</tr>
<tr>
<td>INTERMACS LEVEL 4</td>
<td>Resting symptoms on oral therapy at home.</td>
<td>12%</td>
</tr>
<tr>
<td>INTERMACS LEVEL 5</td>
<td>“Housebound”, Comfortable at rest, symptoms with minimum activity ADL</td>
<td>3%</td>
</tr>
<tr>
<td>INTERMACS LEVEL 6</td>
<td>“Walking wounded”-ADL possible but meaningful activity limited</td>
<td>2%</td>
</tr>
<tr>
<td>INTERMACS LEVEL 7</td>
<td>Advanced Class III</td>
<td></td>
</tr>
</tbody>
</table>
Figure 6
Decreasing eligibility for listed pts after VAD
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Intermacs Profile Levels Evolve
Cardiac Filling Pressures Over Time

No change in
Cardiac Index:
Every level Both eras
Mean 2.1

PA Systolic Pressure
Every level Both eras
Mean about 50 mm

Slight change in PCW
Both eras:
Level 1 = 26, Level 2 = 25
Level 3-4 = 24 previous
= 23, 22 mm now
Intermacs and MedaMACS
Cardiac Filling Pressures Over Time

Central Venous Pressure

Level 1
Level 3
MedaMACS

2006-10
2011-13
Intermacs and MedaMACS
Systolic Blood Pressure at Implant

![Graph showing systolic blood pressure levels for Level 1, Level 3, and MedaMACS for the years 2006-10 and 2011-13. The graph compares the blood pressure levels across different levels and time periods.]
Intermacs and MedaMACS
Serum Creatinine Levels

Level 1
Level 2
Level 3
Level 4
MedaMACS

2006-10
2011-13

Levels 1 to 4 show a comparison of serum creatinine levels between 2006-10 and 2011-13.
Intermacs and MedaMACS Natriuretic Peptide Levels

BNP Levels (Similar for NT Pro BNP)

Level 1  Level 3  MedaMACS

2006-10  2011-13
Intermacs and MedaMACS
Albumin Levels
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What Is Likelihood that MedaMACS Patient Would Need BiVAD if VAD?
What Is Likelihood that MedaMACS Patient Would Be Transplant-Eligible?
Profiles for Comparison
Limits of Adjustment
EQ-5D Visual Analog Scale (VAS) across time (± SE)

Figure 14

**EQ5D VAS across time:**
- **Best**
- **Worst**

**Implant Eras:**
- **2008 – 2010**
- **2011 - 2013**

**P values**
- Pre-Implant: < .0001
- 3 month: .05
- 6 month: .07
- 12 month: .12
- 18 month: .48
- 24 month: .65
INTERMACS and MedaMACS Are Not Two Arms of a Study

That requires REMATCH REVIVE IT
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• Triage for transplant and devices
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• We cannot ever say what would have happened with different therapy:
  – Our answers will be in the form of
    “These patients had these outcomes”