Estimating Benefit in Ambulatory Heart Failure Patients

MedaMACS Progress Report 2014

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Disclosures

• Consulting for Thoratec Corporation
Enrollment Progress
through 5/1/2014

11 Centers

n=83

Entered  Remaining

72%  28%
## Baseline Demographics & Clinical Features

n=74

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean(SD) or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>58 (11)</td>
</tr>
<tr>
<td>Female</td>
<td>34</td>
</tr>
<tr>
<td>White</td>
<td>66</td>
</tr>
<tr>
<td>Hispanic</td>
<td>9</td>
</tr>
<tr>
<td>Working</td>
<td>19</td>
</tr>
<tr>
<td>Disability</td>
<td>52</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean(SD) or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERMACS Profile</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td>5</td>
<td>34</td>
</tr>
<tr>
<td>6</td>
<td>41</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Ejection Fraction, %</td>
<td>21 (7)</td>
</tr>
</tbody>
</table>
Clinical Enrollment Data
n=74

<table>
<thead>
<tr>
<th>Variable</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient status</td>
<td>63</td>
</tr>
<tr>
<td>Followed &gt;1 yr by center</td>
<td>62</td>
</tr>
<tr>
<td>Cardiac Hosp prior 12mos</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>33</td>
</tr>
<tr>
<td>2</td>
<td>34</td>
</tr>
<tr>
<td>≥3</td>
<td>33</td>
</tr>
<tr>
<td>Prior Transplant eval</td>
<td>26</td>
</tr>
<tr>
<td>Prior DT VAD eval</td>
<td>12</td>
</tr>
<tr>
<td>Ischemic Etiology</td>
<td>31</td>
</tr>
<tr>
<td>Prior Cardiac Surgery</td>
<td>24</td>
</tr>
</tbody>
</table>

Data through 4/1/2014
## Burden of Comorbid Conditions

**n=74**

<table>
<thead>
<tr>
<th>Variable</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>41</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>37</td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td>34</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>28</td>
</tr>
<tr>
<td>Morbid obesity</td>
<td>34</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>8</td>
</tr>
<tr>
<td>History of cancer</td>
<td>11</td>
</tr>
<tr>
<td>Limited social support</td>
<td>18</td>
</tr>
<tr>
<td>Repeated non-compliance</td>
<td>19</td>
</tr>
<tr>
<td>History of smoking</td>
<td>37</td>
</tr>
</tbody>
</table>
MedaMACS Study Encounters

1 Month Re-Look Baseline

Inpt or outpt A B

Time Zero

outpt

One month

6 mos Phone Interview

1 Yr

18m Phone Interview

2 Yrs

End

Consent

6MW

gait speed

Euroqol+KCCQ

VAD Survey

Risk Scores

Baseline A

1mo.

6MW

gait speed

Euroqol+KCCQ

VAD Survey

Events

Treatments

Baseline B

12mos

6MW

gait speed

Euroqol+KCCQ

VAD Survey

Events

Risk Scores

Treatments

1-Yr Visit C

24mos

6MW

gait speed

Euroqol+KCCQ

VAD Survey

Events

Risk Scores

Treatments

2-Yr Visit D

Face-to-face encounters

Telephone Contact

Study Site Phone Calls 6 and 18 mos

Events (hosp, stroke, transplant, vad, inotropes, death)

Meds, Euroqol, NYHA/INTERMACS profile
Early Reassessment Uncovers Divergent Patient Trajectories

**Functional Capacity**

Δ30 m in Six Minute Walk

- Worsened: 20%
- No change: 30%
- Improved: 50%

n=37

**Quality of Life**

Δ5 points in EuroQOL VAS

- Worsened: 10%
- No change: 20%
- Improved: 70%

n=53
Patient Feelings About Receiving a VAD

Toward VAD: 32%
No Change: 49%
Away from VAD: 19%

Change From A → B

* Definitely Yes
  - Baseline A: 20%
  - Baseline B: 10%
  - Total: 30%

* Probably Yes
  - Baseline A: 15%
  - Baseline B: 25%
  - Total: 40%

* Don’t know
  - Baseline A: 30%
  - Baseline B: 20%
  - Total: 50%

* Probably Not
  - Baseline A: 25%
  - Baseline B: 15%
  - Total: 40%

* Definitely Not
  - Baseline A: 20%
  - Baseline B: 10%
  - Total: 30%

n=53 with paired data
Physician Estimates of Need for Stage D Intervention in Next Year

Change From A → B
- More likely: 20%
- No Change: 51%
- Less likely: 29%

n=53 with paired data
## Patient Centered Outcomes Beyond Survival

<table>
<thead>
<tr>
<th></th>
<th>MedaMACS</th>
<th>INTERMACS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events/Hospitalizations</td>
<td>Stroke, GI bleeding, infection, transplant, worsening heart failure</td>
<td></td>
</tr>
<tr>
<td>Metabolic Profile</td>
<td>Nutrition, renal function, BMI</td>
<td></td>
</tr>
<tr>
<td>Functional Capacity</td>
<td>6 minute walk</td>
<td></td>
</tr>
<tr>
<td>Frailty</td>
<td>Gait speed</td>
<td></td>
</tr>
<tr>
<td>Quality of Life</td>
<td>EuroQOL-5D, KCCQ, Stress/Coping/Satisfaction Survey</td>
<td></td>
</tr>
</tbody>
</table>
Early Outcomes and Events

- 52 hospitalizations
- 7 deaths
- 1 transplant
- 3 VADs
- 1 consent withdrawn

Story of the Three VADs…
All men, 2 working full time at enrollment, all three obese, two with pulmonary hypertension, ALL in INTERMACS profiles 6/7 at Baseline A
Linking MedaMACS to INTERMACS

Survival over Months since Enrollment

- INTERMACS 6/7: 88%
- INTERMACS 5: 84%
- INTERMACS 4: 60%

Mechanical Support

- Medical Therapy

Flow Type and D
- Continuous - LVAD
- Continuous - BiVAD
- Pulsatile - LVAD
- Pulsatile - BiVAD
- Pulsatile - TAH

At Risk:

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
<th>12</th>
<th>15</th>
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<td>239</td>
<td>58</td>
<td>19</td>
<td>9</td>
<td>6</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>318</td>
<td>65</td>
<td>26</td>
<td>14</td>
<td>10</td>
<td>9</td>
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<tr>
<td>612</td>
<td>290</td>
<td>183</td>
<td>109</td>
<td>82</td>
<td>69</td>
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<tr>
<td>248</td>
<td>115</td>
<td>88</td>
<td>66</td>
<td>49</td>
<td>41</td>
<td>31</td>
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<tr>
<td>9112</td>
<td>6080</td>
<td>3963</td>
<td>2687</td>
<td>1792</td>
<td>1167</td>
<td>685</td>
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</tbody>
</table>

Medamacs
MedaMACS: The Road Ahead

• Patient-centered outcomes beyond survival are required in the “less sick”

• Map journey in parallel and in series with MCS

• Explore triage points for MCS
  – Frailty, patient willingness, QOL

• Forum for hypothesis-driven research in ambulatory advanced HF population

• Inform the conversation with our HF patients
Acknowledgements

- MedaMACS investigators and coordinators
- UAB team at the DCC
- Ryan Cantor