Regional Differences in Utilization and Outcomes of Left Ventricular Assist Devices: Insights from the INTERMACS Registry

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Disclosures

- Dr. Ventura is a consultant to Thoratec and Otsuka.
- Dr. Naftel is a consultant to Thoratec and Heartware.
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Background

- With a limited number of heart donors, left ventricular assist devices (LVADS) are increasingly used in patients with advanced heart failure.

- Current data from UNOS suggest regional disparities in waiting times for patients awaiting heart transplantation in the United States.

- Although this may theoretically impact the utilization of LVAD particularly as BTT strategy, no studies have been performed to carefully evaluate this issue.
Hypothesis

- Important geographic differences in baseline demographics, INTERMACS risk profiles, LVAD use and Outcomes may exist among patients enrolled in the INTERMACS database
Study Aims

- Describe demographic and clinical characteristics among LVAD patients enrolled in the INTERMACS registry from four distinct geographic regions: Northeast, Midwest, South and West.

- Compare device strategy (BTT vs. DT) among regions.

- Explore regional differences in outcomes among patient receiving continuous flow (CF)-LVAD.
INTERMACS: June 2006 – March 2013

All Primary Pts implanted
As of 3/31/2013

8609

Adults: N=8531

Pediatric Patients:
(patients < 19 yrs of age
at time of implant)
N=78

Pulsatile Flow: N=1127

BiVAD: n=309
TAH: n=190
LVAD: n=628

Continuous Flow: N=7404

BiVAD: n=192
LVAD: n=7212

Patients < 19 yrs of age at time of implant
**INTERMACS: June 2006 – March 2013**

**Adult Primary Continuous Flow Implants, n=7404**

<table>
<thead>
<tr>
<th>Region</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>2605</td>
</tr>
<tr>
<td>Midwest</td>
<td>2210</td>
</tr>
<tr>
<td>South</td>
<td>1616</td>
</tr>
<tr>
<td>West</td>
<td>973</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>7404</td>
</tr>
</tbody>
</table>

**Geographic Regions**

- Northeast: 35%
- Midwest: 30.0%
- South: 22.0%
- West: 13.0%
Baseline Characteristics

- No significant regional differences with regard to patients’ age, gender or body mass index (BMI).
- Northeast had more diabetic patients.
- Patients from the Northeast and South were more likely to have INTERMACS risk profiles 1 and 2.
- South had more black patients while West had more Hispanics.
- BTT strategy was more common in the Northeast.
- DT was more likely in the South.
- Patients in the Northeast were more likely to receive BIVAD or ECMO.
Survival after implant by Geographic Region

P(overall) = 0.01
NE vs. MW = 0.90
NE vs. So = 0.004
NE vs. West = 0.81
MW vs. So = 0.004
MW vs. West = 0.68
So vs. West = 0.05

<table>
<thead>
<tr>
<th>Region</th>
<th>n</th>
<th>Events</th>
<th>% Survival at 1 yr post implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>2605</td>
<td>560</td>
<td>80.6%</td>
</tr>
<tr>
<td>Midwest</td>
<td>2210</td>
<td>483</td>
<td>82.0%</td>
</tr>
<tr>
<td>South</td>
<td>1616</td>
<td>407</td>
<td>77.5%</td>
</tr>
<tr>
<td>West</td>
<td>973</td>
<td>203</td>
<td>81.3%</td>
</tr>
<tr>
<td>Totals</td>
<td>7404</td>
<td>1653</td>
<td></td>
</tr>
</tbody>
</table>

Event: Death with a device in place (censored at transplant or recovery)
Overall Survival By Device Strategy

<table>
<thead>
<tr>
<th>Strategy</th>
<th>n</th>
<th>Events</th>
<th>1 yr post implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTT Listed</td>
<td>2004</td>
<td>337</td>
<td>85.5%</td>
</tr>
<tr>
<td>BTC</td>
<td>2775</td>
<td>590</td>
<td>81.7%</td>
</tr>
<tr>
<td>DT</td>
<td>2527</td>
<td>704</td>
<td>75.3%</td>
</tr>
</tbody>
</table>

Event: Death with a device in place (censored at transplant or recovery)

P(overall) < .0001
DT vs. BTT p < .0001
DT vs. BTC p < .0001
BTT vs. BTC p = .0003
Overall Regional Survival By Device Strategy

**Northeast Region**
- 1 yr post implant: BTT Listed 87.4%, BTC 80.6%, DT 74.4%
- Survival rates:
  - BTT Listed
  - BTC
  - DT
- P(overall) < .0001
- DT vs. BTT p < .0001
- DT vs. BTC p = .0005
- BTT vs. BTC p = .0004

**Midwest Region**
- 1 yr post implant: BTT Listed 85.0%, BTC 84.6%, DT 77.1%
- Survival rates:
  - BTT Listed
  - BTC
  - DT
- P(overall) = .003
- DT vs. BTT p = .008
- DT vs. BTC p = .003
- BTT vs. BTC p = .80

**Southern Region**
- 1 yr post implant: BTT Listed 81.5%, BTC 79.6%, DT 73.3%
- Survival rates:
  - BTT Listed
  - BTC
  - DT
- P(overall) = .001
- DT vs. BTT p = .0004
- DT vs. BTC p = .10
- BTT vs. BTC p = .03

**West Region**
- 1 yr post implant: BTT Listed 89.2%, BTC 80.9%, DT 77.6%
- Survival rates:
  - BTT Listed
  - BTC
  - DT
- P(overall) BTT p = .005
- DT vs. BTC p = .19
- BTT vs = .03
- DT vs.. BTC p = .08
Survival after implant by Geographical Region for BTT Listed

Event: Death with a device in place (censored at transplant or recovery)

### Region Survival at 1 yr post implant

<table>
<thead>
<tr>
<th>Region</th>
<th>n</th>
<th>Events</th>
<th>% Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>826</td>
<td>123</td>
<td>87.4%</td>
</tr>
<tr>
<td>Midwest</td>
<td>564</td>
<td>105</td>
<td>85.0%</td>
</tr>
<tr>
<td>South</td>
<td>434</td>
<td>87</td>
<td>81.5%</td>
</tr>
<tr>
<td>West</td>
<td>180</td>
<td>22</td>
<td>89.2%</td>
</tr>
<tr>
<td>Totals</td>
<td>2004</td>
<td>337</td>
<td></td>
</tr>
</tbody>
</table>

P(overall) .06
NE vs. MW .02
NE vs. So .03
NE vs. West .76
MW vs. So .97
MW vs. West .30
So vs. West .27
Survival after implant by Geographical Region for DT

Event: Death with a device in place (censored at transplant or recovery)

% Survival at Region n Events 1 yr post implant
Northeast 842 240 74.4%
Midwest 763 205 77.1%
South 656 190 73.3%
West 266 69 77.6%
Totals 2527 704

P(overall) .23
NE vs. MW .14
NE vs. So .65
NE vs. West .36
MW vs. So .08
MW vs. West .94
So vs. West .22
Survival after implant by Geographical Region for BTC

Event: Death with a device in place (censored at transplant or recovery)

% Survival

Region      n       Events     1 yr post implant
Northeast    899        288               81.0%
Midwest      858        167               84.6%
South        500        125               79.6%
West         518        110               81.0%
Totals  2775        590

P(overall)   .04
NE vs. MW    .25
NE vs. So    .07
NE vs. West  .75
MW vs. So    .004
MW vs. West  .15
So vs. West  .22
Competing Outcomes (Overall Cohort)

Outcome | % at 1 year
--- | ---
Alive (device in place) | 60%
Transplanted | 21%
Dead | 18%
Recovery | 1%

Proportion of Patients

Months after Implant

0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45 48
Competing Outcomes by Region

Northeast n=2605
Outcome % at 1 year
- Alive (device in place): 58%
- Transplanted: 23%
- Recovery: 1%
- Dead: 18%

Midwest n=2210
Outcome % at 1 year
- Alive (device in place): 60%
- Transplanted: 23%
- Recovery: 1%
- Dead: 16%

South n=1616
Outcome % at 1 year
- Alive (device in place): 60%
- Transplanted: 18%
- Recovery: 1%
- Dead: 21%

West n=973
Outcome % at 1 year
- Alive (device in place): 61%
- Transplanted: 21%
- Recovery: 1%
- Dead: 17%
Results Summary

- Significant differences in patient characteristics exists among regions where patients from the **Northeast** and **South** were more likely to have INTERMACS risk profiles 1 and 2 compared with those from the Midwest and West.

- While **BTT strategy** was more common in the **Northeast**, **DT** was more common in the **South**.

- Despite an overall **high survival** rate at **one year**, some significant differences in long-term mortality were observed by region, with the **South** having a significantly lower survival after LVAD implant.
Study Limitations

- Data were collected using a medical chart review.

- Residual unmeasured confounding variables may also explain some of these findings.

- Importantly, LVAD volume and experience of implanting centers were not adjusted for in this analysis.
Conclusions

- Regional differences in clinical profile and LVAD strategy exist in the US.

- Despite an overall high survival rate at 1 year, differences in mortality among regions were noted.

- The lower survival rate in the South may be attributed to patient characteristics and higher use of LVAD as DT.