Effectiveness of a Shared Decision Making Intervention for Patients Offered a Destination Therapy Left Ventricular Assist Device for End-Stage Heart Failure: The DECIDE-LVAD Trial

Larry A. Allen, MD, MHS
on behalf of the investigators, clinicians, patients, families, and funders
DT LVADs Involve Complex Tradeoffs

Benefits

Risks/Burdens
DT LVADs Involve Complex Tradeoffs

Benefits

Risks/Burdens

Graph showing survival rates over months since randomization with different LVAD types and medical therapy.
DT LVADs Involve Complex Tradeoffs

Benefits

- Continuous-flow LVAD (2009)
- Pulsatile-flow LVAD (2009)
- Medical therapy (2001)

Risks/Burdens

1 in 10 have a disabling stroke

- 10%

2 in 10 have a serious bleed that requires medical attention

- 20%

Driveline care, power source management
DT LVADs Involve Complex Tradeoffs

Benefits

Continous-flow LVAD (2009)

Risks/Burdens

1 in 10 have a disabling stroke

10%

Preference-Sensitive Decision

Driveline care, power source management
Decision Aids Standardize the Process

“A meeting between two experts”
In 2014, identified 77 LVAD educational materials…

- 97% discussed benefits
- 53% mentioned any risks
- 36% mentioned lifestyle considerations
- 1% mentioned palliative care or hospice as an option
- 0% met majority International Patient Decision Aid Standards
DECIDE-LVAD Trial

Test the **effectiveness** of a shared decision support intervention for patients considering DT LVAD consisting of:

1. Site-based training
2. Implementation of patient decision aids
Design: 6-Site, Stepped Wedge Trial

- **Enrollment:** June 2015 – Jan 2017

<table>
<thead>
<tr>
<th>Site</th>
<th>Pre 4 months</th>
<th>Phase 1 4 months</th>
<th>Phase 2 4 months</th>
<th>Phase 3 4 months</th>
<th>Phase 4 4 months</th>
<th>Post 4 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinating Site</td>
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<tr>
<td>2 Random Sites</td>
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<td>2 Random Sites</td>
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<tr>
<td>1 Random Site</td>
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**Legend:**
- Control Period
- Roll-Out
- Intervention Period
Patients and Data Collection

Initiation of formal DT LVAD evaluation

Enrollment, Baseline 1 Survey

Formal DT LVAD education

Baseline 2 Survey

1-Month Follow-Up Survey

6-Month Follow-Up Survey

INTERVENTION: Incorporate Patient Decision Aids
Primary Outcome: DECISION QUALITY

“The extent to which medical decision making reflects the considered preferences of a well-informed patient.”

Values-Choice Concordance

Knowledge

Higher-Quality LVAD Decision

Option chosen optimizes values, goals, and preferences

Lower-Quality LVAD Decision

An informed patient
Values-Choice Concordance

Values
- Do everything I can to live longer, even if that means having major surgery and being dependent on a machine.
- Live with whatever time I have left, without going through major surgery or being dependent on a machine.

Choice
- LVAD
- No LVAD

Concordant
Values-Choice Concordance

Values

Do everything I can to live longer, even if that means having major surgery and being dependent on a machine.

Live with whatever time I have left, without going through major surgery or being dependent on a machine.

Choice

LVAD

No LVAD

Discordant
Analysis

• Knowledge: linear mixed model
  • Adjusted for trends over time and significant differences at baseline

• Values-choice concordance: Kendall’s tau correlation coefficient
## Participants

### 248 patients enrolled (from n=385 eligible; power/planned n=168)
- Enrolled patients more likely to be white non-Hispanic than non-enrolled (75% vs. 64%)

<table>
<thead>
<tr>
<th></th>
<th>Control (n=135)</th>
<th>Intervention (n=113)</th>
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<tbody>
<tr>
<td>Age, mean years (SD)</td>
<td>63.5 (9.7)</td>
<td>63.2 (10.2)</td>
</tr>
<tr>
<td>Male</td>
<td>82.2%</td>
<td>86.7%</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>79.1%</td>
<td>82.7%</td>
</tr>
<tr>
<td>Some college or more</td>
<td>56.4%</td>
<td>69.2%</td>
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<tr>
<td>On Disability</td>
<td>27.6%</td>
<td>32.0%</td>
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<tr>
<td>Married</td>
<td>72.5%</td>
<td>65.4%</td>
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<tr>
<td>Diagnosed &lt; 2 years</td>
<td>11.9%</td>
<td>12.4%</td>
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<tr>
<td>Enrolled in ICU</td>
<td>21.5%</td>
<td>26.5%</td>
</tr>
<tr>
<td>INTERMACS 4-7 (p&lt;0.01)</td>
<td>18.3%</td>
<td>44.6%</td>
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Intervention Delivery

• Training
  • All sites participated: 31-72 staff per site

• Patient decision aid exposure
  • 88% received pamphlet decision aid
  • 92% received video decision aid

• “Educational materials” felt to be biased in favor of LVAD
  • 54% of control patients
  • 43% of intervention patients (p=0.13)
Knowledge

- Control: 59.5% → 64.9%
- Intervention: 59.1% → 70.0%
- Adjusted difference of difference: 5.5%

Knowledge Improvement

Higher-Quality LVAD Decision

Kendall's Tau Correlation (at 1 month)

Values-Choice Concordance

P = 0.030

Control

Intervention

Staff Education and Patient Decision Aid

Lower-Quality LVAD Decision

Usual Care

Knowledge Improvement

Percent difference, mean (baseline 1 to baseline 2)
Values-Choice Concordance

- Control: 0.17 correlation coefficient
- Intervention: 0.48 correlation coefficient
- Adjusted difference of difference: 0.28
Secondary Outcomes: 6-month implant

Adjusted for Site and Time Period

P=0.008

26% decrease in patient going on to LVAD
Secondary Outcomes

- No significant differences in:
  - Concordance stated value at 1-month to actual treatment received by 6-month
  - Decision conflict
  - Decision regret
  - Control preferences
  - Illness acceptance
  - Stress
  - Depression
  - Quality of life
Considerations

Strengths

• Real-world look through a hybrid effectiveness-implementation design
• Rare upstream capture of patients *considering* for DT LVAD (not just LVAD recipients)

Limitations

• Stepped-wedge is a quasi-experimental design
• Missing data due to death and withdrawal of patients not implanted
Conclusion

Formal integration of a shared decision support intervention for DT LVAD was associated with:

1. Improved decision quality
2. Reduction in implantation
Thank You!

- Trial sites
- Funder: pcori
- Patients and caregivers

Decision aids available for free at: http://patientdecisionaid.org/LVAD/