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
LVADs Involve Complex Tradeoffs

Benefits

Risks/Burdens
LVADs Involve Complex Tradeoffs

Benefits

Risks/Burdens

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

Probability of Survival

Months since Randomization

- 80% Alive
- 17% Alive

- 20% Dead
- 83% Dead
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

Risks/Burdens
1 in 10 have a disabling stroke
10%

Preference-Sensitive Decision

Driveline care, power source management
Decision Aids Standardize the Process

Patient

1. Knowledge Transfer
2. Patient Preferences
3. Deliberation/Consensus

Provider

“A meeting between two experts”
Deferred to Marketing

In 2014, identified 77 LVAD educational materials…

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

Iacovetto, Matlock, Thompson, McIvennan, Bradley, Larue, Allen. CircCQO. 2014;905.
Development and Alpha Testing
Iterative changes with patient, caregiver and clinician feedback

Emotion and Fear of Death

Decision Framing

Paper
8 pages

Palliative and Hospice Care

Video
26 minutes

Controlled Testimonials

Burdens Emphasized

Caregiver Integration

What might my life look like with each OPTION?

Life with an LVAD

Life without an LVAD

With or without an LVAD, there are services available to help with SYMPTOMS and suffering of advanced illness.

What is palliative care?

Patient Perspectives:

Ruth Wife

Dale Patient

Life with an LVAD

How long might I live?

Patients usually live longer with an LVAD. After 1 year, about 47% of patients who get an LVAD are alive. With hospice care, the average survival is slightly less. The goal of palliative care is to improve quality of life for patients and their caregivers.

Life without an LVAD

How long might I live?

Patients usually die within a year of not receiving an LVAD. After 1 year, about 17% of patients who don’t get an LVAD are alive.

With or without an LVAD, there are services available to help with SYMPTOMS and suffering of advanced illness.

What is hospice care?

Hospice care is given by health professionals for patients near the end of life.

Patient Perspectives:

Patient who got an LVAD

“Hard to find a word for me to express. How many times have I seen my life downstage?”

“Time willing to do anything they told me heart-related facts?”

Forrestine Patient

26 minutes

Burdens Emphasized

Caregiver Integration

What is hospice care?

Hospice care is given by health professionals for patients near the end of life.
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>
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</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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Patients and Data Collection

Initiation of formal DT LVAD evaluation

Formal DT LVAD education

Enrollment, Baseline 1 Survey

Baseline 2 Survey

1-Month Follow-Up Survey

6-Month Follow-Up Survey

Time 0

1 month

6 months
Primary Outcome: DECISION QUALITY

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

Higher-Quality LVAD Decision

Option chosen optimizes values, goals, and preferences

An informed patient

Knowledge

Lower-Quality LVAD Decision

Values-Choice Concordance
Values-Choice Concordance

Values

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

Choice

LVAD

No LVAD

Concordant

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

Values

<table>
<thead>
<tr>
<th>LVAD</th>
<th>No LVAD</th>
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<tr>
<td>Do everything I can to live longer, even if that means having major surgery and being dependent on a machine.</td>
<td>Live with whatever time I have left, without going through major surgery or being dependent on a machine.</td>
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</table>

Discordant
Analysis

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

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

• Sensitivity analysis:
  • Excluding sites
  • Among inpatient enrollments only
### 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%)

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

- Control: 0.17 correlation coefficient
- Intervention: 0.48 correlation coefficient
- Adjusted difference of difference: 0.28

Higher-Quality LVAD Decision

Knowledge Improvement

Percent difference, mean (baseline 1 to baseline 2)
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
Secondary Outcomes: 6-month implant

Adjusted for Site and Time Period

P=0.008

- Control: 80%
- Intervention: 54%

LVAD | No LVAD
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
- PCORI
- Patients and caregivers

Learn more at: patientdecisionaid.org/LVAD

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