Study Development and Design of the DECIDE-LVAD Trial

A Multicenter Trial of a Shared DECision Support Intervention for Patients and Their Caregivers Offered DEstination Therapy for End-Stage Heart Failure

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We will not discuss off label use or investigational use in this presentation.

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Jocelyn Thompson has no disclosures
Presentation Summary

• Part 1: DT LVADs for Heart Failure
• Part 2: Gaps in DT Decision Making
• Part 3: Developing a Decision Aid
• Part 4: Testing a Decision Aid (PCORI)
Part 1:
DT LVADs for Advanced Heart Failure
Transition to Advanced Heart Failure:
- Oral therapies failing
- A time for many major decisions

AHA Scientific Statement

Decision Making in Advanced Heart Failure

A Scientific Statement From the American Heart Association

Endorsed by Heart Failure Society of America and American Association of Heart Failure Nurses

Larry A. Allen, MD, MHS, Co-Chair; Lynne W. Stevenson, MD, Co-Chair;
Kathleen L. Grady, PhD, APN, FAHA, Co-Chair; Nathan E. Goldstein, MD;
Daniel D. Matlock, MD, MPH; Robert M. Arnold, MD; Nancy R. Cook, ScD;
G. Michael Felker, MD, MHS; Gary S. Francis, MD, FAHA; Paul J. Hauptman, MD;
Edward P. Havranek, MD; Harlan M. Krumholz, MD, SM, FAHA; Donna Mancini, MD;
Barbara Riegel, DNSc, RN, FAHA; John A. Spertus, MD, MPH, FAHA; on behalf of the American
Advanced HF: Tough Choices
“There are some things worse than death”

The Artificial Heart is Becoming Mainstream

Barney Clark
1982

Dick Cheney
2010
What is an LVAD?
What is an LVAD?

**Driveline**
A cord that connects the pump to the outside. This passes through the skin and holds important electrical wires.

**Batteries**
A power source for the pump. The pump must always be plugged into either batteries or an electrical wall outlet.

**Controller**
A computer that operates the pump. The controller displays messages and sounds alarms about the device.

**Pump**
A motor placed inside the chest. It pushes blood from the heart to the body.
What is Destination Therapy? (DT)

• LVADs initially became mainstream as a therapy to stabilize and “bridge” patients who were waiting for transplantation.

• As artificial heart technology has improved, LVADs expanded to people dying from heart failure who are not eligible for transplant = DT.
DT-Eligible = NOT Transplant Eligible

1) Advanced age, 2) Comorbidity, 3) Psychosocial

#1: HF epidemic

#2: Donor hearts limited

#3: Technology improving

DT growing … fast

Implants for Destination Therapy: June 2006 – December 2013, n = 3516

- Continuous Flow Intracorporeal Pump
- Pulsatile Flow Intracorporeal Pump

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<th>Puls Intra Pump</th>
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<td>2013</td>
<td>1052</td>
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</table>
“Magical”: NNT=2

**Figure 1.** Survival Rates in Two Trials of Left Ventricular Assist Devices (LVADs) as Destination Therapy.

The curves labeled 2009 are those reported by Slaughter and colleagues in this issue of the *Journal*; those labeled 2001 were reported for the REMATCH trial.¹
LVAD Complications Abound

Rehospitalized for Any Cause
- 55%

Major Bleeding†
- 0-1 month after LVAD (typically surgical)
  - 30%
- 1-12 months after LVAD
  - 20%

Stroke‡
- 10%

Serious Device-Related Infection§
- 20%

Device Malfunction Due to Clotting||
- 5%

Ongoing Heart Failure¶
- 18%

Part 2: Gaps in DT Decision Making

CHALLENGES
I Expected Times Like This- but Never Thought They'd Be So Bad, So Long, and So Frequent.
Informed consent” Is Broken

APPENDIX 1 – Universal Consent Form

XXX HOSPITALS & HEALTH CENTERS

Request and Consent to Evaluation and Expectations for Mechanical Circulatory Support Device (MCSD) Implantation Bridge to Transplantation-Destination Therapy (BTT or DT)

Your heart failure is defined as a condition in which your heart is unable to pump enough blood to support the basic needs of your body. This can make you feel tired, have abnormal rhythms, and shortness of breathe, in addition to causing your other organs to fail (e.g. liver or kidneys). You are being offered this treatment option because you have a marked increase risk of irreversible end-organ damage or death over the [time period]. For this reason, you are being considered for placement of a Mechanical Circulatory Support Device (MCSD) at [XXX Hospital & Health System]. The heart pump is designed to take over the pumping action of your heart but before you undergo this procedure, it is important that you and your family understand the options, benefits, risks, and expectations associated with having a MCSD. It is required that you and your proposed caregiver(s) understand and agree with the treatment plan and are willing to participate in the guidelines outlined in the following pages.

At this time, you are being considered for a MCSD or more commonly called a Ventricular Assist Device (VAD) for Bridge to Transplantation. Bridge to transplant (BTT) is when a VAD is used to help extend the life of someone waiting for a heart transplant. This is subject to change pending the results from your evaluation and your Physician’s decision. This consent pertains only to VAD therapy; you will receive information regarding heart transplantation allocation, procedures, and risks from the transplant program at a different time. Although you are being considered for MCSD implantation for Bridge to Transplantation, it is possible that you will not be a transplant candidate after you receive the MCSD if your medical condition worsens.
Marketing Will Be Marketing
77 VAD Patient Education Materials (%)
- 41(53) Contained risks
- 75(97) Contained benefits
- 28(36) Contained lifestyle considerations
- 8(10) Contained caregiver information
- 25(32) Contained details on surgical procedure
- 1(1) Mentioned hospice or palliative care

14 Records that recognized a medical decision and/or presented other options (%)
- 0(0) Met IPDAS criteria for decision aid
- 2(14) With readability below 8th grade level
- 13(93) Biased towards accepting LVAD
- 7(50) Contained outdated statistics
Part 3: Developing a Decision Aid

Left Ventricular Assist Device (LVAD) for Destination Therapy
Pilot work: Needs assessments

- Semi-structured interviews:
  - Patients: 15 acceptors; 7 decliners
  - Caregivers: 16 of acceptors; 1 of decliner (7 bereaved)
  - MCS Coordinators: 16 RN, 1 NP, 1 MBA
Patient Perspectives

REFLECTIVE
Utilitarian
“I thought about it an awful lot”

AUTOMATIC
Self-preservation
“There was no choice”
## Reflective

“...it was a hard choice. It wasn't an easy choice for me to make. If I get the LVAD I live, if I don't get it I die. Do I choose to live? Or do I choose to die?...so I fumbled with that for a little while before I made the decision to do it.”

ACCEPTER #03; <1 month since implant

## Automatic

I: “Did you weigh the pros and cons of the decision at all?”

R: “No. No. Didn't even think twice about it. When they told me that I couldn’t have a transplant...this was the only option I had. That or push up daisies...so I automatically took this.”

ACCEPTER #09; >1 month since implant
International Patient Decision Aid Standards (IPDAS)

1. Provide information about options
2. Present probabilities (unbiased and understandable)
3. Provide methods for clarifying values
4. Structured guidance for deliberation and communication
Iterative DA Design

- Interviewed: 13 PT; 7 CG, 23 clinicians, 2 groups
- 18x DA versions!!
Recognize Emotion

You are being considered for an LVAD. This booklet is designed to help you understand what an LVAD is and to help you, your family, and your doctors think about what is best for you. Your values and goals are the most important factors in making a decision.

What are your current feelings about being considered for an LVAD?

Think about…

- how you want to live the rest of your life
- your hopes and fears
- your biggest questions

Now that you’ve thought about your first impressions, let’s talk through the details of this decision.

You are in a tough spot.

You have severe heart failure. Your current medicines are no longer working. Without a major heart surgery, you may die soon - but you are not eligible for a transplant. Therefore, you are being considered for an LVAD (partial artificial heart).

Many patients like you have found this scary or confusing. Some patients have felt pressured to make a decision.

These emotions are normal.
Basic Concepts

Parts of an LVAD

**Driveline**
A cord that connects the pump to the outside. This passes through the skin and holds important electrical wires.

**Controller**
A computer that operates the pump. The controller displays messages and sounds alarms about the device.

**Batteries**
A power source for the pump. The pump must always be plugged into either batteries or an electrical wall outlet.

**Pump**
A motor placed inside the chest. It pushes blood from the heart to the body.
**Contrasting Summary of Options**

**Life with an LVAD**

**How long might I live?**
Patients usually live longer with an LVAD. After 1 year, about 8 out of 10 patients who got an LVAD are still alive.\(^1\)

80% | Alive | Dead
---|---|---

**How might I feel?**
Of those patients who get through surgery, many feel big improvements in heart failure symptoms—less shortness of breath, less swelling, and more energy.\(^1\) Most survivors they can do more.

**What complications might occur?**
1 year after surgery, about:\(^1\)
- 5 to 6 patients out of 10 are readmitted to the hospital.
- 1 in 10 patients have a disabling stroke.
- 10% develop a device-related infection.
- 2 in 10 have a serious bleed that requires medical attention.
- Nearly 1 in 10 need surgery again to replace the LVAD pump.

**Life without an LVAD**

**How long might I live?**
Patients usually do not live as long without an LVAD. After 1 year, almost 2 out of 10 patients who did not get an LVAD are still alive.

17% | Alive | Dead
---|---|---

**How might I feel?**
Nearly all patients without an LVAD continue

**What might occur if I don’t get an LVAD?**
Most likely, patients will not be alive at 1 year.
- Patients will not have to be dependent on a machine to live.
- Patients can often leave the hospital earlier and spend their remaining time at home.
- Patients often decide to only take medicine to help with pain and other symptoms.
- Palliative care and hospice are available, but without an LVAD, patients might need these services sooner (see description on next page).
If I get an LVAD, how will my life change?

There are many life-changing aspects of the LVAD that you should consider.

**Power Source:** You must be plugged into a power source at all times – loss of electrical power to the pump can result in death. When you are sleeping you will plug into an electrical outlet. During the day you can switch over to batteries, which last about 6-12 hours.

**Carrying Equipment:** Along with batteries, you will have to carry the controller. Equipment can be carried in a vest or on a belt. Battery packs weigh about 7 pounds. Carrying extra battery packs and an extra controller is also important, in case they need to be changed.

**Driveline Care:** The driveline site (where the electrical cord exits the skin) must be managed carefully. Bandages must be changed and the site should be cleaned several times a week. Lack of care could cause a deadly infection.

**Medicine:** With an LVAD, you will have to take blood thinners for the rest of your life. You may need to continue some medicine to help with your heart, but most patients take their medication at night and can return to their normal routine during the day.
Palliative Care

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

What is palliative care?
Palliative care is medical care for people with serious illnesses. It helps provide relief from symptoms, pain and stress. It also provides emotional and spiritual support. The goal of palliative care is to improve quality of life for patients and their caregivers.

What is hospice?
Hospice care is given by health professionals for patients near the end of their lives. This care includes medical, emotional, and spiritual support, and helps to provide comfort and peace for patients. Hospice care usually occurs at a patient's home. It can also occur in other settings, such as a nursing home.

Patient Perspectives:

Patients who got an LVAD

“It wasn't an easy choice for me to make. But then I started focusing on my life. On myself.”

“I was willing to do anything they told me I had to do to feel better.”

Patients who chose not to get an LVAD

“I don't know if the pump would keep me alive. And even if it does, I'm not sure it would be worth living. Because I'm not going to claw and hold on to the wall to stay alive.”
Inclusion of Family

An LVAD is a major decision for caregivers, too.

Caring for a patient with severe heart failure often requires lifestyle changes. When a patient gets an LVAD, the caregiver’s lifestyle can change further. The caregiver’s responsibilities are different for every patient and change over time.

Most LVAD caregivers express happiness in being able to help their loved one. However, some caregivers feel stressed with responsibilities, finances, or the health of the patient.

Caregivers of patients who choose not to get the LVAD may also experience similar responsibilities and feelings.

The LVAD caregiver helps with:
- Driveline site bandage changes and checking for infection
- Battery care
- Equipment care and alarm response
- Managing medicines
- Assisting with follow-up care

Caregiver Perspectives:

Caregivers of patients with an LVAD

“I am so thankful for the LVAD. You learn to deal with those little things.”
Values Clarification

Take some time to consider what you have learned about LVADs and think about how you want to live the rest of your life.

On a Scale...
How do you want to live out the rest of your life (check one box)?

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.

Reflection...

<table>
<thead>
<tr>
<th>With an LVAD?</th>
<th>Without an LVAD?</th>
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<tbody>
<tr>
<td>What do you hope for with or without an LVAD?</td>
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</table>
Controlled Patient/Caregiver Testimonials

Cliff

Don
Part: 4
Testing a Decision Aid – Implementation

A Multicenter Trial of a Shared Decision Support Intervention for Patients and their Caregivers Offered Destination Therapy for End-Stage Heart Failure

Principal Investigator:
Larry A. Allen, MD, MS

Organization
University of Colorado Denver

Funding Announcement
Communication and Dissemination Research
Figure 4. Summary of completed work, current proposal, and future plans for our DT LVAD shared decision support intervention.

**Decision Needs Assessment**
- Evidence Summary
  - Patient Educational Materials (Review)
  - Patient Outcomes (Systematic Review)
  - Caregiver Outcomes (Meta-synthesis)

**Decision Support Development**
- Intervention
  1. Decision Aid
     - Pamphlet
     - Video
  2. Decision Training

**Decision Quality Testing**
- 6-Site Step Wedge Trial
  - Reach
  - Effectiveness
    - Decision Quality
  - Adoption
  - Implementation
  - Maintenance

**Dissemination**
- DT LVAD Shared Decision Support
  - Certification
    - Joint Commission
  - Education
    - CardioSmart (ACC)
    - MYLVAD.com
- Diffusion to Other New Technologies
  - Model for Decision Support in Advanced Illness

**Stakeholders**
- Direct Perspectives
  - Patient Interviews
  - Caregiver Interviews
  - Coordinator Interviews
- Iterative Revision
  - Patients Input
  - Caregiver Input
  - Site-PI Input
- Advisory Panel
  - Patients + Caregivers + Clinicians
  - Policy Stakeholders
    - Joint Commission + ACC

**Completed!**

**Completed!**

**Current PCORI Proposal**

**Future**
DECIDE-LVAD Trial

• 3-year RCT
• 6 sites: CU, Duke, Brigham, Mayo, Barnes, St Vincent’s

**Objective**: We propose to understand the effectiveness and implementation of a shared decision support intervention for advanced heart failure patients considering DT LVAD.
# Stepped-Wedge Design

## Figure 5. Stepped wedge randomization scheme.

<table>
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<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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<td>1 Random Site</td>
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- **Control Period**
- **Roll-Out**
- **Intervention Period**
Stepped-Wedge Design

• Why not something else?
  – Classic patient-level randomization not possible due to diffusion; intervention is largely program-based
  – Cluster randomization (3 sites DA, 3 sites none)

• Advantages:
  – Still random
  – Phased implementation over time = iterative formative evaluation

• Disadvantages:
  – Diffusion between sites
  – Other changes in LVAD care over the intervention period
RE-AIM

- **Reach**, **Effectiveness**, **Adoption**, **Implementation**, **Maintenance**
  - Dr. Russ Glasgow
  - Assesses an intervention’s potential for dissemination and public health impact using the five criteria

Evaluate: (1) LVAD program’s current decision support process (control); (2) our decision support intervention (intervention).
• Proportion of target population who receives intervention

1. What educational materials did the patient receive to help them make a decision? **Check all that apply**
   - DECIDE-LVAD decision aid pamphlet
   - DECIDE-LVAD decision aid video
   - Thoratec pamphlet
   - Thoratec “VAD: A Treatment Choice for Heart Failure” video
   - ISHLT consent form
   - Local hospital/program consent form
   - Other video: ________________
   - Other pamphlet: ________________
   - Other: ______________________

5. Was the primary caregiver present when the patient first viewed the materials?
   - Yes
   - No

8. Who else (other than the primary caregiver) was present when the patient first viewed the materials? **Check all that apply**
   - None
   - Spouse
   - Child
   - Parent
   - Relative
   - Friend
   - Other: ______________________
Effectiveness

• Data collection from patients and caregivers
  – Inclusion criteria: Advanced heart failure patients being evaluated for DT LVAD and their primary caregiver

• Surveys at baseline, 1-month, and 6-months

• Outcomes:
  – Primary: Decision quality
    • Knowledge and value-treatment concordance
  – Secondary: Decision conflict, decision regret, control preferences, etc.
<table>
<thead>
<tr>
<th>Measure</th>
<th>PATIENT</th>
<th>CAREGIVER</th>
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<tr>
<td></td>
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<td>Cognitive Function: Short Portable Mental Status Questionnaire</td>
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<td>Decision Regret</td>
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<td>Anxiety/Depression: Hospital Anxiety and Depression Scale</td>
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<td>Quality of Life: EQ5D-3L and VAS</td>
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<td>Caregiver Preparedness: The Preparedness for Caregiving Scale</td>
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<td>Demographics</td>
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<td>Questionnaire – Role of the Family</td>
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<td>Caregiver Involvement in Decision Process: Family Satisfaction with Care Questionnaire</td>
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<td>Acceptability of Educational Materials: Acceptability Questionnaire</td>
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<td>Bereaved Caregiver Satisfaction with End-of-Life Care:</td>
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<td>CANHELP Bereavement Questionnaire [for bereaved caregivers only]</td>
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<tr>
<td>Bereaved Caregiver – DT LVAD Specific Questions [for bereaved caregivers only]</td>
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*BL1=Baseline 1 Survey; BL2=Baseline 2 Survey; 1m FU=1-Month Follow-Up Survey; 6m FU=6-Month Follow-Up Survey
Adoption, Implementation, Maintenance

1. Study Coordinator Checklist

- How educational materials are used

  2. Who provided the majority of the materials to the patient? **Check all that apply**
     - ☐ Mechanical Circulatory Support (MCS) Coordinator (RN, NP)
     - ☐ Surgeon (MD)
     - ☐ Heart Failure Specialist (MD, DO)
     - ☐ Other Clinician (MD, DO, PA)
     - ☐ Surgical House Staff (MD, DO)
     - ☐ Medical House Staff (MD, DO)
     - ☐ Floor/Unit Nursing
     - ☐ Palliative Care
     - ☐ Research assistant
     - ☐ Other: __________________________

  12. Did the patient watch the entire DECIDE-LVAD video?
     - ☐ Yes
     - ☐ No – patient watched part
     - ☐ No – patient did not watch video
     - ☐ I don’t know

  14. How did the patient watch the DECIDE-LVAD video?
     - ☐ On hospital room television with DVD
     - ☐ In-hospital on tablet device/computer
     - ☐ In-clinic on tablet device/computer
     - ☐ Took home DVD
     - ☐ Other:

  23. Did a clinician go through the DECIDE-LVAD pamphlet with the patient?
     - ☐ Yes
     - ☐ No
     - ☐ I don’t know

  22. Did the patient complete the written portion of the DECIDE-LVAD pamphlet?
     - ☐ Yes
     - ☐ No
     - ☐ I don’t know
Adoption, Implementation, Maintenance

2. Clinician qualitative interviews at each site
   • Range of staff type
   • Interviews pre- and post-intervention
     – **Baseline**: What is the current process?
     – **Follow-Up**: What is the process since intervention?
     – **Post-Study Follow-Up**: Maintenance plans?
Feasibility Pilot

- Funding: Heart Failure Society of America
- Refine trial study design and procedures
- At UCH only
- 8 patients; 7 caregivers enrolled so far
- Summary of feedback:
  - Survey instrument = less is more
  - Decision aid video = more is more
- Overlap with other studies common
• Pragmatic Approach: “Does this intervention work under usual conditions?”
Thanks!

• Core Team:
  – Larry Allen
  – Dan Matlock
  – Colleen McIlvennan
  – Jocelyn Thompson
  – Amy Jenkins
  – Mayo, Duke, BWH, Wash U, St. Vincent’s

• UCH Advanced HF Program

• Patients and Caregivers, like Cliff and Don