Hospice & Palliative Care Consultant’s Guide to Ventricular Assist Devices (VADs)

Originally created by: Ellin Gafford MD, The Ohio State University and Keith Swetz MD, The Mayo Clinic

**CMS Criteria for VAD Placement**

**INDICATIONS FOR COVERAGE**

1. **Preauthorization** by the Plan is required;
2. **Post-cardiotomy:** (acute bridge to recovery)
   - a. Used for support of blood circulation in the period following open heart surgery
   - b. Used according to the Food and Drug Administration (FDA) - approved labeling instructions;
3. **Bridge-to-Transplant: (BTT)**
   - a. The member is approved by the Plan and listed as a candidate for heart transplantation
   - b. Used according to the FDA - approved labeling instructions;
4. **Destination Therapy: (DT)** intended for members who require permanent mechanical cardiac support:
   - a. The member has chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) for at least 90 days with a life expectancy of less than 2 years; **AND**
   - b. The member is not a candidate for heart transplantation; **AND**
   - c. The member meets all the following criteria:
     1. Heart failure symptoms have failed to respond to medical management (including dietary salt restriction, diuretics, digitalis, beta-blockers, and ACE inhibitors) for at least 45 of the last 60 days; or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; **and**
     2. Documented left ventricular ejection fraction (EF) <25%; **and**
     3. Demonstrated functional limitation with a peak oxygen consumption of<14 ml/kg/min per stress test; or the member has continued need for intravenous inotropic therapy.

**Types of Therapy with VAD Implants**

1. **BTT** – Bridge to Transplant - when pt is transplant candidate, but unlikely to survive long enough to receive a heart
2. **DT** – Destination Therapy – pt is not a transplant candidate, but would benefit from prolonged VAD placement
3. **Bridge to recovery** – The rare occasion that the native heart recovers adequate function to allow explants, this is the application for post-cardiotomy (This could initially be either a BTT or DT patient)

**Survival Statistics**

**BTT vs DT vs Medical Management (MM)**

<table>
<thead>
<tr>
<th>Therapy</th>
<th>1 year</th>
<th>2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTT – 6 mos</td>
<td>91%</td>
<td>85%</td>
</tr>
<tr>
<td>BTT – 1 year</td>
<td>83%</td>
<td>75%</td>
</tr>
<tr>
<td>DT – 1 year</td>
<td>68%</td>
<td>58%</td>
</tr>
<tr>
<td>MM – 1 year</td>
<td>27%</td>
<td>8%</td>
</tr>
</tbody>
</table>

1 Starling et al; Coll Cardiol 2011; 57:1890-8.
2 Goldstein et al; Circ Heart Fail. 2011; 4:519-527.
NYHA Functional Classification for Heart Failure

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Cardiac Disease. No physical limitation or symptoms with exertion.</td>
</tr>
<tr>
<td>II</td>
<td>Symptom-free at rest. Significant limitation of activity due to fatigue, angina. Dyspnea which resolves with rest.</td>
</tr>
<tr>
<td>III</td>
<td>Symptom-free at rest. Significant limitation of activity due to fatigue, angina. Dyspnea.</td>
</tr>
<tr>
<td>IV</td>
<td>Unable to perform any activity without discomfort. Symptoms of angina, Dyspnea, and fatigue may be present at rest.</td>
</tr>
</tbody>
</table>

NYHA, New York Heart Association

Common Differences Between Traditional Advance Directives and Preparedness Plans in Patients Receiving LVAD as Destination Therapy

<table>
<thead>
<tr>
<th>Measure to be considered</th>
<th>Advance directive</th>
<th>Preparedness plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics. long-term role</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Artificial nutrition</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Blood transfusions</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Goals and expectations</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Hydration</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Intracranial hemorrhage</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>LVAD failure</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>LVAD infection</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>Organ donation</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Postoperative plans for rehabilitation</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>Power of attorney appointed</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Psychosocial assessment</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>Review of perioperative morbidity and mortality</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>Social dynamics reviewed</td>
<td>−</td>
<td>++</td>
</tr>
<tr>
<td>Spiritual and/or religious preferences</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Stroke</td>
<td>−</td>
<td>++</td>
</tr>
</tbody>
</table>

= not generally found in document; + = may be found in document; ++ = often found in document. LVAD = left ventricular assist device.


Causes of Death After LVAD Implantation as DT

<table>
<thead>
<tr>
<th>Cause</th>
<th>Total Deaths (n=155)</th>
<th>In-Hospital Deaths (n=76)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sepsis</td>
<td>46 (29.5)</td>
<td>25 (32.9)</td>
</tr>
<tr>
<td>Multiorgan failure</td>
<td>20 (12.8)</td>
<td>15 (19.7)</td>
</tr>
<tr>
<td>Stroke</td>
<td>14 (9.0)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Right heart failure</td>
<td>12 (8.4)</td>
<td>11 (14.5)</td>
</tr>
<tr>
<td>LVAD failure</td>
<td>10 (6.4)</td>
<td>4 (5.2)</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>7 (4.5)</td>
<td>5 (6.6)</td>
</tr>
<tr>
<td>Technical</td>
<td>5 (3.2)</td>
<td>4 (5.3)</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>5 (3.2)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Cancer</td>
<td>4 (2.6)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>4 (2.6)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Accident</td>
<td>3 (1.9)</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>2 (1.3)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Sudden death</td>
<td>2 (1.3)</td>
<td>0</td>
</tr>
<tr>
<td>Left ventricular failure</td>
<td>2 (1.3)</td>
<td>0</td>
</tr>
<tr>
<td>Other causes</td>
<td>12 (7.7)</td>
<td>4 (5.2)</td>
</tr>
<tr>
<td>Not reported</td>
<td>7 (4.5)</td>
<td>1 (1.3)</td>
</tr>
</tbody>
</table>

Values are expressed as n (%).


ACC/AHA Staging System for Heart Failure

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>High risk for heart failure, no structural defect. Example, diabetes, hypertension</td>
</tr>
<tr>
<td>B</td>
<td>Structural defect causing asymptomatic ventricular dysfunction. Patient has never had clinical heart failure. Example, left ventricular hypertrophy, previous MI</td>
</tr>
<tr>
<td>C</td>
<td>Current or past symptoms of HF associated with structural abnormalities. Most HF patients fit in this group.</td>
</tr>
<tr>
<td>D</td>
<td>Refractory end-stage heart failure. These patients are candidates for heart transplant, specialized interventions or hospice.</td>
</tr>
</tbody>
</table>

ACC, American College of Cardiology; AHA, American Heart Association; MI myocardial infarction; HF heart failure

Device Deactivation

- Determine if ICD present/active-deactivate
- Determine if aorta is oversewn-if so, circulation stops abruptly with VAD deactivation
- Symptom management medications must circulate to effect prior to deactivation
- Discuss sedation, as indicated by circumstances, with patient and/or family/surrogates
- Establish availability of mechanical circulatory support (MCS) team (in person or by phone)
- Discuss plan with patient, family, medical team-include discussion of discontinuation of other life support (if present) simultaneous with VAD deactivation
- Have a “Time Out” to discuss plan and roles/responsibilities in detail with bedside RN, RT, perfusionist, clergy, SSW, and other staff
- Typical medications are used (Midazolam or Lorazepam; Morphine, Hydromorphone or Fentanyl) Ensure drugs are in the room in adequate quantity
- Silence all alarms (e.g. telemetry); darken monitors
  - HeartMateII®: Unscrew small controller battery→Silence alarm→Remove device battery/power source→Silence alarm→Remove device battery/power source→Device should be silent→Detach controller from patient
  - HeartWare®: Uncap blue port→Remove and hold red stopper from back of device→Remove power source #1→Put red alarm stopper in blue port→Remove 2nd power source→Device should be silent→Detach controller from patient
- Have “quiet container” if alarm will not silence – (eg large hazard box with foam or pillows)
- Once deactivated, and silent, device can be left in place for visitation – removed when body is prepared
- If other critical care life supports are present, many families prefer to discontinue all others forms of support first, and deactivate the VAD last.
Mechanical Circulatory Support
What does it mean to patients and where does Palliative Care fit in?

KellyAnn Light-McGroary, MD
University of Iowa Hospitals and Clinics
HPCAI Annual Meeting
November 1, 2012

Objectives
- Identify candidates for LVAD therapy
- List benefits and burdens of LVAD therapy
- Discuss ethical and practical considerations of LVAD deactivation
- Discuss “preparedness planning” for LVAD candidates
- Consider optimal timing for palliative care consultations
### Candidates for MCS therapy

#### ACC/AHA Staging System

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<thead>
<tr>
<th>Stage</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>High risk for HF, No Structural heart disease (e.g. HTN, DM)</td>
</tr>
<tr>
<td>B</td>
<td>Structural Cardiac Defect; Asymptomatic Ventricular dysfunction (LVF, prior MI); No prior HF</td>
</tr>
<tr>
<td>C</td>
<td>Structural Cardiac Defect; Current or past HF symptoms</td>
</tr>
<tr>
<td>D</td>
<td>Refractory End Stage HF (Candidates for HT, Hospice, or specialized interventions)</td>
</tr>
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#### NYHA Functional Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>NYHA Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>I</td>
<td>No physical symptoms</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>Symptom free at rest, slight exertional limitation, resolves w/rest</td>
</tr>
<tr>
<td></td>
<td>III</td>
<td>Symptom free at Rest; Significant limitation of activity due to Symptoms (CP, DOE)</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>Symptoms at rest (CP, SOB) Unable to do any activity without discomfort</td>
</tr>
</tbody>
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### ACC/AHA Staging System

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</table>
Heart Failure by NYHA Class

- NYHA IV: 5%
- NYHA III: 25%
- NYHA II: 35%
- NYHA I: 35%

5-15% of all HF patients have severe persistent symptoms = Stage D

MCS Candidate Pool

- 250,000-500,000 ESHF pts in terminal phase of disease (ACC Stage D = refractory to MM)
- Mean survival 3.4 months
- **Inotrope dependent = up to 94% 1 yr mortality**
- 80,000-150,000 pts/yr could benefit from HT
- HT performed approximately 2,200/yr
- LVAD as DT is available alternate

Prognostic challenges

- “Too Early” vs. “Too Late”
- Sick enough to recognize the benefit
- Well enough to minimize risks/burdens

Selection Guidelines

- ACC/AHA
  - Annual Mortality > 50%
- CMS
  - Survival < 2 years
  - Neither comes with a tool for measuring mortality
SHFM in Risk Stratification

- Accurate for MM and DT when includes
  - IABP
  - Inotropes
  - Ventilator

- Accurate for both MM and LVAD 1 year survival

<table>
<thead>
<tr>
<th></th>
<th>Predicted</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Manage</td>
<td>30%</td>
<td>28%</td>
</tr>
<tr>
<td>VAD</td>
<td>49%</td>
<td>52%</td>
</tr>
</tbody>
</table>


SMHF Calculator

Copyright 2004-2007 Wayne Levy and David Limber
INTERMACS Profile Descriptions

<table>
<thead>
<tr>
<th>Profile #</th>
<th>Clinical Description</th>
<th>Vivid Descriptors</th>
<th>Prognostic terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Critical cardiogenic shock</td>
<td>Crash and Burn</td>
<td>Minutes to Hours</td>
</tr>
<tr>
<td>2</td>
<td>Progressive decline</td>
<td>Sliding on inotrope</td>
<td>Hours to Days</td>
</tr>
<tr>
<td>3</td>
<td>Stable, inotrope Dependant</td>
<td>Dependent stability</td>
<td>Days to weeks</td>
</tr>
<tr>
<td>4</td>
<td>Resting symptoms</td>
<td>Pre-inotrope vs. ?pre-VAD</td>
<td>Weeks to Weeks/Month</td>
</tr>
<tr>
<td>5</td>
<td>Exertion Intolerant</td>
<td>Cachexia, ADL’s failing</td>
<td>Month to Days (no typo)</td>
</tr>
<tr>
<td>6</td>
<td>Exertion Limited</td>
<td>Walking Wounded</td>
<td>Weeks to Months</td>
</tr>
<tr>
<td>7</td>
<td>Advanced NYHA III</td>
<td>TBD</td>
<td>Today to Tomorrow</td>
</tr>
</tbody>
</table>

Red Flags-
Poor Prognosticators

Poor PPS
RV failure
Malnutrition
Thrombocytopenia
Active Infection
Types of Therapy with VAD Implants

- **BTT – Bridge to Transplant** - when pt is transplant candidate, but unlikely to survive long enough to receive a heart without life Support (LVAD)

- **DT – Destination Therapy** – pt is not a transplant candidate, but would benefit from prolonged LVAD placement

- **Bridge to recovery** – The rare occasion that the native heart recovers adequate function to allow explants, this is the application for post-cardiotomy (This could initially be either a BTT or DT patient)

MCS Options
Competing mechanical circulatory support (MCS) strategies

**Biventricular support (TAH)**
- Does not rely on native heart function
- Can reverse pathophysiology associated with RV failure
- Large BSA requirement

**Univentricular Support (LVAD or Bi-VAD)**
- More flexibility in pump size & geometry
- Leaves native heart intact (chance for recovery of function)
- Only supports LV function

Left Ventricular Assist Devices: 25 years of better, smaller, quieter

First goal: reduction of complications
Second goal: increased reliability
Third goal: reduced size
Next: Improved power supply
Implantable Ventricular Assist Device

http://www.nhlbi.nih.gov/health/health-topics/topics/vad/

HeartWare LVAD
A major limitation of LVADS: No RV support

Uncorrected RV failure can lead to ...

- Wasting/Poor nutritional status
- Coagulopathy
- Hepatic encephalopathy
- Edema and poor skin integrity
Options for patients with irreversible RV failure:

- LVAD + inotropes
- bi-VAD
- TAH

Total Artificial Heart

“Big Blue”
Syncardia homegoing portable driver trial: Freedom

CE approved for use in Europe

**Inclusion Criteria:**
- Eligible for transplant
- NYHA class IV, stage D
- BSA $\geq 1.7 \text{ m}^2$
- Pt. meets discharge criteria
- and stable antithrombotic regimen and normalization of end-organ function

**Exclusion Criteria:**
- Too sick to go home
Benefits and Burdens of MCS therapy

Long Term Survival DT

Adverse Events Post Continuous Flow LVAD

- Rehospitalization
- Resp Failure
- Arrhythmia
- Right HF
- Other neuro
- Bleeding
- Sepsis
- Local infxn
- VAD infxn
- Stroke
- Pump replacement

Practical Considerations for Deactivation

Deactivation

- Should have been planned prior to implantation
  - Planning should involve patient, surrogate, and team – everyone should be on the same page as the patient

- Ethically, withdrawing (deactivating) is equivalent to not having instituted the therapy
  - While this is true, be mindful of the emotional reality

Always:

Give medications at least **15 minutes BEFORE** LVAD is deactivated
Why are we seeing more VADs and what might one expect?

QOL and Care Trajectory after DT

Courses “A” and “B”
When things don’t go well or don’t get better after LVAD-DT implantation

Course “C”
The reason we do this…What to do with a “new lease on life”?
Implications of increasing DT prevalence

- DT prolongs life
- Numbers of patients treated with DT increasing
- Many patients experience early mortality and most experience symptoms, adverse events and psychosocial burdens
- It is inevitable clinicians will care for dying DT patients

DT as “Goal-directed therapy”

![Diagram showing Operative Risk vs. Futile Implants]

Worsening of nutritional state, end-organ and right ventricular function with progressive heart failure

Dudzinski, D; Ann Thorac Surg 2006;81:1185–8
Preparedness Planning For MCS Patients

Why engage palliative care before VAD implantation?

- Patients may decline or postpone DT
- Patients who choose DT need a "preparedness plan":
  - DT now with emphasis on palliation later
  - Palliative care in conjunction with DT
    - Treat symptoms including those associated with adverse events; pain
  - For all patients, establish criteria for withdrawing DT support (advance care planning)

What does palliative medicine specifically offer to DT patients?

- Medical decision-making
- Establish goals of care
- Coordinate care
- Manage symptoms
- Psychosocial and spiritual support
- Assure comfort, QOL and dignity
- Prognosis
- Ethics
- Technical assistance
- Active care of dying patients and loved ones
- Bereavement support

Major components of “preparedness planning” for DT patients

![Diagram of preparedness planning process]

- Event of device failure
- Inadequate quality of life after LVAD
- Preparedness plan
- Catastrophic complication(s) due to LVAD-associated factors
- Debilitative comorbidity condition(s)

Long term care and QOL considerations in DT patients

- Caregiver misperceptions
- Frequent clinic visits
- Insurance/financial
- Geographical limitations due to power source
- Limited local resources
  - Local medical community likely unprepared to care for DT patients
- Caregiver burnout
- EOL issues
  - Inevitable
  - Ethical aspects of withdrawing DT support
  - Palliative care

These considerations emphasize the need for a “preparedness plan.”

Ethical Considerations for Deactivation
Ethics of withdrawing VAD support

- Study period: 2003-2009
- Of 68 patients who underwent VAD implantation, 26 died
- Withdrawal of VAD support was requested for 14
- Median age 57 years
- All were receiving other life-sustaining treatments
- Twelve lacked decision-making capacity and were profoundly ill (e.g., multi-organ failure)
- Few had engaged in advance care planning (Swetz et al Hosp Pract 2011;39:78-84)
- Decision to withdraw VAD support was made at a multidisciplinary care conference for 11


Ethical analysis of withdrawing VAD support

- Withdrawal of VAD support is ethical and legal if consistent with patient’s values and goals
- Not akin to assisted suicide or euthanasia
  - Death is due to the underlying heart disease
- Dedicated team
  - Respect conscientious objection
- Basis for development of “preparedness planning” and call for involvement of palliative medicine

Criteria for withdrawing life-sustaining treatments

Balance of:
- Effectiveness in altering natural history of disease: province of the clinician
- Benefits: province of the patient
- Burdens: province of the patient

Pellegrino E, JAMA 2000;283:1065-7

Criteria applied to withdrawing DT support

- Effectiveness: maintains circulation, but may not reverse other pathologies
- Benefits: does patient or surrogate perceive benefit of prolonging life in its current state?
- Burdens: does patient or surrogate perceive prolongation of life as suffering, resource depletion, emotional burden or interference with a natural death—which are against the patient’s stated values or goals?
Resolving and preventing conflicts

Resolving conflicts:
- Multi-disciplinary care conferences
- Ethics consultation
- Courts

Preventing conflicts:
- “Preparedness plan”
  - Setting goals and timelines
  - Mutually defining futility
  - Multidisciplinary
  - Advance directives
- Palliative care consultation

Optimal Timing for Palliative Care Consult
VAD-DT patient
• Decreasing QOL
• Clinical decline

Multidisciplinary team

Patient and family

Determine goals of care

Is ongoing VAD support futile in supporting these goals?

No

Yes

Withdraw VAD support

• Treatment plan
• Ongoing communication among team members
• Focus: palliation

Initiate EOL process

Continue VAD support until death

• Treatment plan
• Ongoing communication among team members
• Focus: palliation

Initiate EOL process

Continue VAD support and medical management

Palliative care when withdrawing LVAD support (refer to handout)

- Survival: hours to days
- Similar to withdrawing mechanical ventilation
- Stop nonessential medical devices, monitors and infusions
- Treat symptoms
  - Pain, dyspnea and secretions
  - Opioids and sedatives
- Note safety alarms
  - Drive line and power
  - Withdraw simultaneously
- Withdraw simultaneously other life-sustaining treatments
- Assess of post-withdrawal symptoms
- Psychosocial and spiritual support
Conclusions

- Use of DT is increasing
- It is permissible to withdraw of DT support from patients who note its burdens outweigh its benefits
- DT patients should engage in palliative medicine-facilitated “preparedness planning”
- Palliative medicine providers will be called upon in an increasing fashion to assist with management of LVAD patients at the end-of-life