Care & Complexities of Patients on Long-Term LVAD

Linda Ordway NP, CHFN
Clinical Care Manager
Cardiomyopathy Center
Cardiac Transplant and Ventricular Assist Device Program
Disclosures

• I will not discuss off label use or investigational use in my presentation

• I have no financial relationships to disclose
Who gets an LVAD?
The Course of Congestive Heart Failure

Phase 1
Initial symptoms of HF develop and HF treatment is initiated

Phase 2
Plateau of variable length reached with initial medical management, or following mechanical support or heart transplant

Phase 3
Functional status declines with variable slope; intermittent exacerbations of HF that respond to rescue efforts

Phase 4
Stage D HF, with refractory symptoms and limited function

Phase 5
End of life

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Sarah J. Goodlin Palliative Care in Congestive Heart Failure JACC 2009; 54:386-396
AHA/ACC Prognostic Classification

Stages of Heart Failure

Stage A
Patients with risk factors for development of structural heart disease. No symptoms

Stage B
Presence of structural heart disease (e.g., MI, LV dysfunction. No symptoms of heart failure

Stage C
Presence of structural heart disease with current or prior symptoms of heart failure amenable to therapy

Stage D
Heart failure symptoms refractory to conventional treatment requiring VAD, transplant or palliative care

NYHA Functional Classification

NYHA Class

Class I
Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea

Class II - Mild
Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.

Class III
Marked limitation of physical activity, but less than ordinary activity causes fatigue, palpitation, or dyspnea.

Class IV
Unable to carry out any physical activities without discomfort, symptoms of cardiac insufficiency at rest, and increased discomfort with any activity.

Athilingam et al International Journal of Nursing Science 2013 3(1): 22-32
Therapies for Stage D HF

Stage A
High risk with no symptoms

Stage B
Structural heart disease, previous or current symptoms

Stage C
Structural disease, previous or current symptoms

- Aldosterone antagonist,
- Consider multidisciplinary team
- Revascularization, mitral-valve surgery
- Cardiac resynchronization if bundle-branch block present
- Dietary sodium restriction, diuretics (and digoxin?)
- ACE inhibitors and beta-blockers in all patients

ACE inhibitors or ARBs in all patients; beta-blockers in selected patients

Treat hypertension, diabetes, dyslipidemia; ACE inhibitors or ARBs in some patients

Risk-factor reduction, patient and family education

Stage D
Refractory symptoms requiring special intervention

- VAD, transplantation
- Inotropes
- Hospice
Indications for LVAD therapy

• Bridge:
  – To transplant
  – To recovery
  – To decision

• Destination:
  – Permanent
Long Term Use of VADs

REMATCH
Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure

- Randomized clinical trial
  - Optimal medical therapy vs pulsatile flow LVAD
- Nontransplant candidates (n = 129)
  - EF ≤ 25%
  - Peak VO2 < 12 mL/kg/min
  - Or continuous infusion inotropes
- FDA approval for XVE as destination therapy

A Pulsatile-Flow LVAD

LVAD Destination Therapy (HMII Trial)
Medical Management (REMATCH, NEJM 2001)
Currently Approved LVADs

- HeartMate II
- HeartWare
- Centrifugal
LVAD Use is Increasing

- **Acute MI**
  - Increased survival
  - Increased # patients progress to advanced HF

- **Organ Donors**
  - Availability remains limited

- **VAD Technology**
  - Improvements in device developments
  - Smaller, lighter pumps, less moving parts break down and need replacement, implant techniques

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Adult Heart Transplants

% of Patients Bridged with Mechanical Circulatory Support*
(Transplants: January 2000 – December 2014)

- LVAD, RVAD, TAH, ECMO

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Limited Organ Availability

NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, the presented data may not mirror the changes in the number of heart transplants performed worldwide.
Evolution in LVAD Technology

HeartMate II

HeartWare
Timing of LVAD Placement

**INTERMACS SCORE**

Interagency Registry for Mechanically Assisted Circulatory Support

- **1-year survival**
  - 100%
  - 50%
  - 25%
  - 10%
  - 0%

- **Classes**
  - Class IIIB: Walking wounded
  - Housebound
  - Frequent flyer
  - Stable dependent
  - Sliding fast
  - Crash & burn
  - Dying/MOF

- **Survival**
  - % 1-year survival
  - Intermacs level: 5-7, 3-4, 1-2, MOF
  - Survival: Months to years, Weeks to months, Hours to weeks, Hours to days

- **VAD benefit**
  - Not established
  - Yes
  - Bridge to decision in selected cases

**Long-Term LVAD**
Ideal candidates are INTERMACS classes 3-4

**Short-Term LVAD**
Candidates are INTERMACS classes 1-2

**Not a LVAD Candidate**
INTERMACS 1 or those with multisystem organ failure

Lietz and Miller
Curr Opin Cardiol
2009, 24:246–251
Preparing VAD Patients for DC

- Post Discharge follow up Care and Monitoring
- Community Services Coordinated
- Completion of all VAD hands on competencies, identification and troubleshooting VAD alarms
- Physically able to complete basic ADL’s “safely”
- Must be Medically Stable
Setting up Community Care: Discharge

• **Electricity**
  – up to code, outlets grounded

• **Contact electric company notify patient living on heart pump**
  – Patient should be on a “priority restore power list”
  – Intervene when patient has financial issues so that power is not shut off

• **Contact local EMS & Emergency Department**
  – education, training & contact information for VAD team

• **Community/Home services**
  – Review dressing change protocol/ VS monitoring with VNA/PT/OT in the home
  – Cardiac Rehab to give guidelines on monitoring during exercise
Do’s & Don’ts
Daily care at home:
Self Care Management Expectations

- **System operation**
  - Device function
  - Identify components, how & when to change out

- **Equipment Cleaning and Maintenance**

- **Troubleshooting**

- **Emergency Response**
  - Who to call, how to call, when to call

- **Percutaneous Lead Management**
  - Dressing changes
  - Identification of infection

Both the patient and “Caregiver” need to demonstrate competency

Slaughter, Mark S, et al. JHLT Vol 29, No 4S, April 2010
HM II LVAD Instructions for Use, Thoratec Corporation
HVAD Instructions for Use, Heartware Corporation
Competencies to Master

Challenges to Attaining Competency:

- Cognitive issues
- Motor issues
- Language issues
- Literacy issues
Education Strategies

- Didactic teaching and testing
  - Written information from patient manuals
  - One on one “show & tell”
  - Video/DVD
- Demonstration & return demonstration
  - Hands on with patient’s own equipment
  - Extra equipment: test loops
- Practice and Re-inforcement
  - Especially important for dexterity issues
Teaching Begins at Evaluation... When Does it End?

IT NEVER ENDS!!!!
Challenges in clinical care

• BP monitoring??
• ICD-yes or no?
• Biv pacing?
• How/what to monitor in cardiac rehab?
• Chest compressions??
What is it like to live on an LVAD??
QOL Measures After LVAD

6 min walk distance

Mean distance walked in 6 min, m

BTT (N): 38 146 120 97
DT (N): 129 207 232 199

Percentage of patients

NYHA functional class

MLWHF Questionnaire

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QOL: Driving with an LVAD

Your Health and Driving Safely

Could Your Medical Condition Cause a Collision?

Did you know that Massachusetts is a self reporting state? That means it is your responsibility to report to the Registry of Motor Vehicles any medical condition that may affect your ability to drive. The purpose of this brochure is to help drivers identify some medical conditions that can lead to impaired driving. The RMV consulted with medical experts before developing regulations about minimum physical abilities necessary for driving, and these regulations apply to all licensed drivers and new applicants. Other standards may apply to commercial drivers.

Loss of Consciousness

Many medical conditions can cause a person to lose consciousness or “pass out” without warning. Heart conditions, breathing problems, diabetes, seizure disorders and sleep disturbances can affect mental alertness. If you’ve suffered a loss of consciousness or an episode of altered consciousness (such as low blood sugar, lightheadedness, or disorientation) you MUST turn in your driver’s license for at least six (6) months. The RMV will provide you with a free Mass I.D. to use during that time. If, after six (6) months, your doctor certifies that you have been episode free, you can regain your driving privileges. The RMV will provide you with a new license free of charge.

http://www.massrmv.com/rmv/medical/Med_Af...
Sex and Intimacy Among Patients With Implantable Left-Ventricular Assist Devices

Linda Marcuccilli, MS, RN; Jesus (Jessie) Casida, PhD, APN-C; Rosalind M. Peters, PhD, RN; Susan Wright, MS, RN

- Sexual and intimate relationships improved as the left-ventricular assist device improved overall health.
- Participants experience an increased sense of connectedness and intimacy even in the absence of sexual intercourse.
- Satisfying and fulfilling sexual and intimate relationships promoted a sense of normalcy.
Common complications of LVADs

- Bleeding
- Thrombosis
- Hemolysis
- Right heart failure
- Infection
- Aortic Regurgitation

Technical problems and device failure

- Neurologic complications
- Abdominal complications
- Ventricular Arrhythmias

2013 ISHLT Guidelines for Mechanical Circulatory Support
Potapov et al. Curr Opin Cardiol 2011: 26:237
Management to prevent complications

- Comprehensive Pre-VAD evaluation
- Early Postoperative Care
- Continuing Medical Care
- Patient Family Education & Training
- Transitions in Care & Community Resources
Bleeding Post LVAD

Sites of Bleeding
Mucosal surfaces
• GI, nasopharynx
• Intracranial vessels
Leaky connection at the pump
Inadequate pre-clotting (sealing) of polyester grafts in the conduits

Causes of Bleeding
Need for anticoagulation
• Heparin Warfarin ASA

Early post op period
• CPB coagulopathies
• Impaired coagulation due to hepatic congestion

> 1 week post implant
• Acquired Von Willebrand Deficiency (aVWD)
Angiodysplasia of GI Tract
• AVMs, gastritis

Anticoagulation

Acquired Von Willebrand Deficiency

Angiodysplasia

DeMirozu ZT et al. J Heart Lung Transplant 2011; 30:849
Slaughter MS et al. J Heart Lung Transplant 2010; 29:S1
2013 ISHLT Guidelines for Mechanical Circulatory Support
Development of aVWD with LVADs

Occurs in all patients and all CF devices

Pathophysiology: 2 parallel processes

- **Mechanical Demolition** - Shear stress physically breaks down large active vWF multimers into smaller multimers
- **Enzymatic Cleavage** - vWF degradation occurs through ADAMTS-13 cleavage of large active vWF multimers into small non-active multimers

Bartoli et al J Thoracic and Cardiovascular Surgery 2014; 149:1:281-289
Sadler J Evan NEJM 2003; 349:323-325
2013 ISHLT Guidelines for Mechanical Circulatory Support
Angiodysplasia

Angioectasia

arteriovenous malformation

telangectesis

dilated, thin walled vascular channels that appear macroscopically as a cluster of cherry spots, can be located throughout the GI tract

Incidence

• Older patients with GI Bleeding
• End stage renal disease (ESRD)
• VWD
• Aortic Stenosis

Evaluation

• Endoscopy
• Capsule endoscopy
• Tagged RBC scan or Angiography to localize site

Intervention

• Clipping/Mechanical Coagulation
• Adjust anticoagulation, reverse or DC
• Use of octreotide, thalidomide, estrogen

Impact on QOL

• Anemia
• Frequent admissions
• Frequent procedures
• Frequent transfusions

2013 ISHLT Guidelines for Mechanical Circulatory Support
Hemolysis, Thrombosis, Embolism

Thrombosis is suggested by the development of hemolysis and changes in pump performance.

Risk Factors:
- Pump design
- Malposition of cannulae
- Disconnection of bend relief of outflow graft
- Pump thrombosis
- HIT

Thrombosis
Can occur early or late
Associated with high mortality
Incidence: 0.01-0.11/patient year

Risk Factors:
- Inadequate anticoagulation
- Atrial Fibrillation
- Hypercoagulable states
- Infection-> Inflammatory State

Mehra MR et al J Heart Lung Transplant 2014; 33:1
Uriel N et al J Heart Lung Transplant 2014; 33:51
2013 ISHLT Guidelines for Mechanical Circulatory Support
Thrombosis evaluation & management

**Evaluation**

- Hemolysis
  - ↑LDH 2-3x baseline
  - ↑plasma free hemoglobin
  - ↓Haptoglobin
  - UA with + blood, *no RBCs*, reddish brown or “cola” colored
- Echo: look for AoV opening
- ↑power/flows = thrombus
- CTA to evaluate for visible angulation, kinking or thrombus in outflow

**Treatment of LVAD pump thrombosis**

- *LVAD pump exchange*
- Heart transplant (if candidate)
- IV anticoagulation w/heparin or DTI (bivalirudin)
- Thrombolysis with TPA* **Not recommended**
  - Has been used cautiously with patients who are *not surgical candidates for exchange*

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Al-Quthami. Circ Heart Fail. 2012 Jul 1;5(4):e68-70
Uriel N et al J Am Coll Cardiol 2012; 105:1030
Neurologic complications of LVAD

Stroke
- ischemic or hemorrhagic
- occur peri-operative or late after LVAD
- Greater frequency in right hemisphere, suggest cardioembolic vs. atherogenic source
- Leading cause of long term mortality
  - ischemic stroke 0.05-0.1/patient-year
  - hemorrhagic stroke 0.01-0.08/patient-year

Etiology
- Partial inflow cannula obstruction
- Deformation blood pathway in pump
- Twisting or kinking of outflow graft
- Inadequate anticoagulation

Stroke Prevention: maintain therapeutic anticoagulation and aggressive BP management (BP <90-MAP or doppler)

- Cardioembolic stroke, eval for intracardiac/VAD thrombosis
  - TTE or TEE, CTA
  - Systemic TPA contraindicated

2013 ISHLT Guidelines for Mechanical Circulatory Support
Multiple Factors Contributing to Development of RVF post LVAD

- Chronic RHF
- Intraop ischemia
- PRBC Transfusions
- Tricuspid Regurg
- Congestion (hepatic/renal)

• ↑RAP

• ↑PVR

- Pulmonary hypertension
- Cardiopulmonary Bypass
- Transfusions
- Hypoxia
- Acidosis

Normal LV
LV Suction

- High LVAD Speed/Flow
- ↑speed -> ↑LV unloading
- IVS shift ->LV
- Change in RV geometry
- ↑ RV loading

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Evaluation & management of RHF

Evaluation

Pre-VAD

Physical exam: ↑JVP, hepatomegaly, edema

VAD

Low Flow, low pulsatility

Echo

Evaluate Baseline RV function
  – Optimize VAD speed

Right heart catherization

Evaluate for pulmonary hypertension

RA & PCWP (+ratio)
  – Cardiac output/index

Labs: LFTs, BNP

Post-VAD

Risk Prediction Score(s)
  – RVSWI (<250), RAP>15
  – Severe RV dysfunction TAPSE<0.75cm on echo
  – Renal insufficiency, hepatic dysfunction

Management

Early & Late RV Failure

• Adjust VAD speed with echo guidance to keep IVS midline

• Inotropes to support RV function
  – Milrinone, dobutamine, dopamine, Digoxin

• Other medications
  – Diuretics to manage fluids
    • IV lasix, po torsemide, thiazides
  – High dose Aldosterone antagonists
  – Sildenafil

• Impact on QOL-> acute HF

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Infection
Can occur in the pump, pump pocket &/or driveline
Are classified as pump specific, related or non pump related

Evaluation of Suspected Infection

Infection Prevention: exterior lead immobilization and meticulous exit site care by clinicians, patient and caretakers

Echo to evaluate for vegetation

Evaluation & management of infection

Treatment of VAD infection
• IV antibiotics -broad spectrum coverage until C & S ID’d
• Local wound care
• Surgical debridement
• Continue chronic suppressive

2013 ISHLT Guidelines for MCS
Aortic insufficiency

- Development of de novo aortic regurgitation observed in up to 25% of patients on continuous flow devices
- Occurs more frequently in patients when the aortic valve remains closed (42% in one series) compared with those with frequent valve opening
- Significant AI should be treated with ↑pump speed & some will require valve surgery or TAVR
- Preventative strategies:
  - Replace, *stitch or over sew AV during initial VAD surgery if moderate to severe AI pre-op
  - Pump speed should be set to maintain intermittent AV opening under echo guidance

2013 ISHLT Guidelines for Mechanical Circulatory Support
Ventricular arrhythmias

Incidence
• Occurs in 22%-36% post VAD
• Majority in the first post-op month
• Early VT/VF predicts future events
• Non-use of/discontinuing beta blockers post-op may be associated with ↑arrhythmic events

Mechanisms of VT/VF in LVAD:
– Electrolyte abnormalities
– Use of QT prolonging agents
– Presence of suction events
– Inflow cannula contact w/septum
– Presence of arrhythmogenic substrate in cardiomyopathic heart or formation of new foci from surgical placement cannulae

Evaluation
• VT/VF may be well tolerated & resolve with ATP or defibrillation
• May cause HF due to RVD

Treatment includes:
• Antiarrhythmic agents
• VT catheter ablation

2013 ISHLT Guidelines for MCS
Technical problems & device failure

- Incidence of device failure is low, but catastrophic if pump stoppage occurs
- Most common reasons for pump stoppage
  - Thrombus formation in the rotor
  - Mechanical failure
- If pump stoppage occurs, risk of thrombus formation and embolization should the pump restart due to stagnant blood in pump
- For patients who are “pump dependent” (especially in those with over-sewn or closed AV) sudden stoppage may result in death
- When pump stops, there is backflow of blood thru valveless outflow cannula “free aortic insufficiency”

Treatment for Device Failure is VAD Exchange !!

Patient with residual function:
- Bolus with Heparin to prevent thrombus/embolization
- Utilize inotropes +/- IABP to stabilize prior to OR

2013 ISHLT Guidelines for Mechanical Circulatory Support
Onsite Support Groups Are Challenging:

- Most LVAD centers are located in cities
- Patients/families travel from rural communities
- Online Support Groups Available
Supported Patients & Families Give Back

Heartlink Programs
- Heart of Survival
- Angel Transport
- HeartBrothers Blog
- Team HeartBrothers
- Organ Donation Awareness

Who We Are

Four survivors helping others navigate Heart Failure, Ventricular Assist Devices, & Heart Transplants!
- **Heart of Survival** that provides gap assistance and tools to survive long-term hospitalization to patients and families

- **Angel Transport** to assist patients with medical ambulance transport costs that are not covered by medical insurance and other services

- **Support Blog** to link the heart failure community who share similar experiences

- **Team HeartBrothers** which is a volunteer team that provides face-to-face interaction with patients and families and assist in fundraising and organ donation awareness

- **Organ Donation Awareness** assists organ donation organizations in increasing awareness through our Team HeartBrothers volunteers
Summary

• The use of LVADs are increasing in frequency and longevity
• LVADs improve mortality for patients with Stage D HF
• Patients on VADs report an improved QOL
• There are many potential complications related to VAD therapy, affecting patient QOL and mortality
• Complications can be minimized through pre-op assessment, close medical management, patient education, training & follow up
• It is important to partner with community resources to assist with managing care of the LVAD patient
Thank You!

One's destination is never a place, but a new way of seeing things.

- Henry Miller