Bon Secours Advanced Heart Failure Center

Advanced Heart Failure Therapies - 2013

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A New Pumping Device Brings Hope for Cheney

By LAWRENCE K. ALTMAN, M.D.

Former Vice President Dick Cheney is recuperating from surgery to implant the kind of mechanical pump now being given to a small but growing number of people with heart failure so severe that they would most likely die within a few months without it.
Systolic Heart Failure (HFrEF)

Normal LV EF (55%) by 2D Echo

Systolic HF with EF ~10 %
Systolic Heart Failure (HFrEF)

Normal LV EF by MRI

Systolic HF with EF ~ 10%
LV Hypertrophy with Diastolic HF

Normal Heart

Hypertrophy
CHF Impact in the U.S.

- Prevalence: 5,800,000
- Annual Incidence: 660,000
- Annual Mortality: 284,365
- Hospitalizations: 2.4 to 3.6 million/year\(^1\)
- Outpatient Visits: 12 to 15 million/year\(^1\)

\(^1\) Rosamond, W et.al. Circulation 2008; 117:e25-e146
Regional distribution of HF RSRRs by quintile of performance.


Copyright © American Heart Association
Lifetime Risk for CHF is 1 in every 5 people

Worldwide Heart Failure Expected to Become More Common as Population Ages

Heart Failure Epidemiology Forecasts to 2015. Datamonitor 2002
Growth in U.S. Heart Failure Population Projection 2012 to 2030

Forecasting the Impact of Heart Failure in the United States; Paul A. Heidenreich, MD, MS, FAHA, Chair - AHA Policy Statement in Circulation: Heart Failure - Published online before print April 24, 2013, doi: 10.1161/HHF.0b013e318291329a
Financial Impact of Heart Failure

• Between 2012 and 2030, real (in 2010 $) total direct medical costs of HF are projected to increase from $21 billion to $53 billion per year.

• Total annual costs, including indirect costs for HF, are estimated to increase from $31 billion in 2012 to $70 billion (in 2030).

Forecasting the Impact of Heart Failure in the United States; Paul A. Heidenreich, MD, MS, FAHA, Chair - AHA Policy Statement in Circulation: Heart Failure - Published online before print April 24, 2013, doi: 10.1161/HHF.0b013e318291329a
New York Heart Association (NYHA) Classification for Heart Failure (First proposed in 1928)

- **NYHA Class I**
  - **Exercise Tolerance** - *NO* limitation
  - **Symptoms** - No symptoms during usual activity

- **NYHA Class II**
  - **Exercise Tolerance** - *MILD* limitation
  - **Symptoms** - Comfortable with rest or with mild exertion

- **NYHA Class III**
  - **Exercise Tolerance** - *MODERATE* limitation
  - **Symptoms** - Comfortable only at rest

- **NYHA Class IV**
  - **Exercise Tolerance** - *SEVERE* limitation
  - **Symptoms** - *Any* physical activity brings on discomfort and symptoms occur at rest
Natural History of Heart Failure

**Class IV**
- Severe symptoms despite optimal medical therapy
- Sharp deterioration in survival
- Increase in hospitalizations
- Progressive Organ System Failure

Adapted from Bristow, MR Management of Heart Failure, Heart Disease: A Textbook of Cardiovascular Medicine, 6th edition, ed. Braunwald et al.
HF is deadly!

~50% 5-year mortality

1 in 9 death certificates list HF as contributing to death
Adjusted survival curve by left ventricular function: HFrEF versus HFpEF.

Chun S et al. Circ Heart Fail 2012;5:414-421
Treated Heart Failure Survival by Type

Overall, 10-year mortality is 98.8%

National Trends in Heart Failure Hospitalization after Acute Myocardial Infarction for Medicare Beneficiaries: 1998-2010

CIRCULATIONAHA.113.003668 Published online before print November 4, 2013, doi: 10.1161/

Jersey Chen  Angela Hsieh  Kumar Dharmarajan  Frederick A. Masoudi  Harlan M. Krumholz
Physical Assessment
Physical Findings Consistent with Reduced Cardiac Output

- Somnolence or loss of mental acuity
- Low body temperature
- Tachycardia
- Low systolic blood pressure with narrow pulse pressure
- Diminished volume or low amplitude central arterial (i.e. femoral or carotid) pulses
- Pulsus alternans
- Cool, mottled extremities
- Cheyne-Stokes breathing
JVP = 2 + 5
= 7 cm of water

Top of Jugular Vein

Vertical distance above angle of Louis

5 cm

Right Atrium

angle of Louis
Prognostic Importance of Elevated JVP and an S₃

Assessing Volume Status

1. The **most** reliable sign of volume overload is JVD.

2. Right sided pressures are increased in many patients with elevated left sided pressures.

3. Volume overloaded patients may have peripheral edema but presence of non-cardiac cause may limit the utility of this finding.

4. **Most** patients with chronic heart failure do not have rales (even with markedly elevated pressures)

5. Changes in body weight are helpful in detecting short-term in fluid status but are less reliable during long periods of follow-up.

Alternatives to Medical Therapy:

1) Bi-ventricular Pacing/ICDs

2) Cardiac Transplantation

3) Left Ventricular Assist Devices
Advanced/End Stage Systolic HF Demographics

300 Million Population

CHF=2.5 % of Pop.*
or

6.5-7 Million Total

45-50 % Preserved Systolic Function 3.0-3.5 Million

50-55 % Systolic HF
3.0-3.5 Million

Class IV = 100-150,000

30% Class I
35% Class II
25% Class III
5-10 % Class IV

Theoretical Candidates for Transplantation or Destination LVAD Therapy

Class IV < 75 years old
75-100,000 Patients per year

*AHA 2006
Heart Transplantation Survival

Current Era Survival

All comparisons significant at \( p < 0.0001 \)

Copyright © 2000 International Society for Heart and Lung Transplantation
Source: United Network for Organ Sharing (UNOS), scientific registry data.
HEART TRANSPLANTATION


- Half-life = 10.0 years
- Conditional Half-life = 13.0 years

N=78,050

N at risk at 22 years: 145

Survival (%)

Years

2009
Current Left Ventricular Assist Device Uses

- Bridge To Transplant
- Bridge To Recovery
- Bridge to Bridge
- Destination Therapy
Referral Guidelines for Left Ventricular Assist Devices

- NYHA Class IIIB or Class IV and ≤ 75 years of age
- Inability to walk one block without shortness of breath
- One or more CHF related admissions in the past 6 months
- Documentation of poor cardiac function by echo and cath
- Escalating Diuretic dose
- At the first consideration of intravenous HF drug therapy
- Intolerant or Refractory to Standard Heart Failure Drugs
- Progressive Kidney Failure
Time for LVAD evaluation?

Left Ventricular Assist Device

Consider referral if Ejection fraction (EF) < 25%

Potential supporting criteria:

- One heart failure admission in the past year (mortality becomes 50%/yr)
- Decreasing tolerance of β-blocker and/or ACEI/ARB therapy
- Heart failure symptoms despite resynchronization therapy
- Increasing diuretic dose
- Inability to walk one block without dyspnea (shortness of breath)
- Worsening renal function

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VAD Pager (804) 351-0553
Possible Contraindications

- Inability to tolerate anticoagulation
- Inadequate Social support
- Irreversible end organ failure
- Lack acceptance of blood products
- Pregnancy
- Cancer or Active Infection
- No data on BSA < 1.3 m², use medical judgment
Left Ventricular Assist Devices

A Pulsatile-Flow LVAD
- External battery pack
- Skin entry site
- Left ventricle
- Aorta
- Percutaneous lead
- Pulsatile-flow LVAD

B Continuous-Flow LVAD
- Continuous-flow LVAD
- Outlet stator and diffuser
- Motor
- Pump housing
- Inlet stator and blood-flow straightener

Pulsatile Flow
- One-way outflow valve (closed)
- Blood-pumping chamber
- Motor
- Pulsatile flow

Continuous Flow
- One-way inflow valve (open)
- Flexible diaphragm
- Blood flow
- Pusher plate
- Actuator bearing
Schematic of Pulsatile LVADs
Thoratec VAD Chamber

Right or left ventricular support
Extracorporeal position
External air compression
Stroke volume of 65 ml up to 7 l/min
HeartMate I (XVE) vs. HeartMate II
Continuous Flow LVADs

Thoratec HeartMate II

The HeartMate® II Left Ventricular Assist System
Intra-operative TEE – New VAD Implantation

08/24/2010 10:48:43

FR 35Hz
17cm

2D
68%
C 50
P Off
Gen

PAT T: 37.0°C
TEE T: 39.4°C

*** bpm
HeartMate II Freedom from Major Device Failure or Replacement

Remaining at risk
281 131 72 52

6 mo: 96±1%
12 mo: 93±2%
18 mo: 92±3%

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

4/21/2010
Evolving Technology

Centrifugal Magnetically Levitated Pumps
Heartware LVADs

HVAD

MVAD

“D” Cell Battery
Thoratec® HeartMate III
HeartMate III*

Ultra-Compact, Fully Mag-Lev VAD
(Finalizing Design)

- Full magnetic levitation optimized for efficiency
  - Low power consumption - Longer battery runtime
  - Designed to generate a near physiologic pulse which may have meaningful clinical benefits$^1$
  - Easily adaptable to Fully Implantable LVAS

- Enhanced hemocompatibility / minimal thrombogenicity
  - Large blood path passages (10X greater than hydrodynamic devices) with centrifugal flow and Full Magnetic Levitation (FML)
  - Proven HeartMate textured blood contacting surfaces – low/no anticoagulation therapy
  - Facilitates low speed operation without an increased risk of thrombus formation$^1$

- Less invasive Implantation
  - Intra-thoracic placement
  - Designed to reduce tunneling path size (20% reduction)

- Ultra-long life
  - Non-contacting FML rotor
  - Modular percutaneous lead (driveline)

* In development and not available for clinical use
1 To be determined in clinical trial
“It appears to be some kind of wireless technology.”
HeartMate Wireless Architecture*

**Both SM and PM are required for in-clinic programming and monitoring**

Project Objectives

- In-clinic LVAS programming and monitoring platform aimed at reducing cost while improving practice efficiency and usability.
- Integrate wireless hardware into the System Controller
- Utilize current System Monitor software & improve
  - Graphic interface (organization, layout)
  - Incorporate Trending (PI, Flow, Speed, Power)
- Combines TLC II® and HeartMate monitoring and programming platforms
Remote Monitoring*

Home or Office

Alert Notifications

Patient Information via web page

Home

LVAD Patient

Wireless Controller

Data

Internet

Project Objectives

• Improve patient outcomes
• Improve practice efficiency and/or reduce practice costs
• Establish reimbursement and business model structures that allows for patient access

*In development and not available for clinical use
Fully-Implantable LVAS (FILVAS)*

**Fully Implantable System**
(Finalizing Design)

- No percutaneous lead
- Potential for improved quality of life
  - No daily dressings
  - Ability to swim and shower
  - Less limitations on movement
- Advanced battery technology
  - Custom cell technology tailored for implantable LVAD application
  - Targeting “untethered” run times of ~3 hours initially and ~2 hours at 3-year mark
- Reduced size Implanted components with highly reliable electronics

*In development and not available for clinical use*
EMS Response Overview
Key Principles

- Peripheral pulses may not be palpable.
- Assess the patient for signs of good circulation to determine if perfusion is adequate.
- Standard measures to obtain blood pressure & pulse oximetry may produce unreliable & inaccurate readings.
Key Principles

- Pump flow is dependent on preload & afterload.
- HeartMate II LVAD does not have valves and retrograde flow back into the left ventricle can occur if the pump stops.
- Patients are at risk of bleeding due to anticoagulation and antiplatelet therapy.
System Overview

- Implantated pump
- System Controller
- Batteries and Clips
- Power Module
- Display Module
- Emergency Power Pack
Typical Components

- HeartMate battery worn externally in holster
- Power lead
- Percutaneous lead exiting body
- HeartMate II LVAS or "heart pump"
- System Controller
- Aorta
- Heart
System Controller

- The “Brains”
- Connects pump to power source
- Controls pump speed and power
- Redundant mother boards
- Provides visual and audio alarms
- Records events
System Controller Indicators

- Test Select Button
- Battery Fuel Gauge
- Battery Symbol (Yellow & Red)
- Silence Alarm Button
- Power Symbol
- Cell Module Symbol
- Red Heart Symbol
Patient Assessment Protocol

- Contact VAD team (Pager (804) 351-0553)
- Follow routine procedures
- Follow BLS/ACLS Guidelines (except chest compressions)
  - Reliability of the EKG is not effected by VAD
- Family will be able to assist with alarms
- Assess LVAD function
- Assess peripheral perfusion
Inadequate Perfusion

- Check that the percutaneous lead is connected to the system controller.
- Check that both system controller power leads are connected to power.
- Check the battery fuel gauge.
- Check the system controller for active alarms.
- Connect the EKG monitor to the patient.
If Defibrillation Is Indicated:

- Avoid placing pads over VAD (located in upper left abdomen)

- Do not disconnect the percutaneous or power leads.
Use the SILENCE ALARM button to silence alarms: do not unplug the controller or power cables to silence alarms.

Remember that the patient may not have a palpable pulse. Assess the patient for signs of adequate perfusion.

Contact the VAD team. Pager (804) 351-0553

All BLS and ACLS protocols are valid for use with the patient with an LVAD (except chest compressions).
Alarms

- **Hazard Alarms**
  - RED and LOUD
  - Loss of hemodynamic support has occurred or is eminent

- **Advisory Alarms**
  - Green/Yellow and Intermittent
  - Minor malfunction or change of status
  - Need immediate attention but do not reflect hemodynamic compromise

- **System Controller Light**
  - Not an indication that the VAD is on or receiving power with the older controller.
  - Green circle on new Pocket Controller means pump is **ON**.
Red Heart Alarm

• Indicates:
  • Low flow (\(<\ 2.5\ \text{lpm})
  • Pump stopped
  • Percutaneous lead disconnection

• Troubleshooting:
  • Check the patient
  • Check the connections
  • Prepare to change out System Controller
Exchanging Power Sources

- **Never** disconnect both power leads at the same time.
- Carefully line up “half moon connections” and apply gentle pressure.
- Black to Black, White to White.
- Check battery level on system controller after exchanging batteries.
Patient Transport

- Keep the drive line in mind when placing immobilization devices:
  - Avoid kinking of line
  - Avoid pressure on VAD and drive line sites
- Keep the components accessible
- Bring with the patient:
  - Spare batteries
  - Backup System Controller
  - Power Module
  - Family
- All forms of ground and air transport are permitted.
HeartMate II Pocket System Controller

• **Safety by Design**
  - Backup battery
  - Prioritized visual alarms with clear, actionable instructions
  - Driveline diagnostic capability
  - Programmed for use in 37 languages

• **Designed for an active lifestyle**
  - Lightweight and compact with single-side cable design
  - Durable, shock-resistant outer case, cables, and electronics
  - Intuitive, discreet, and comfortable interface
System Controller User Interface
System Controller User Interface: Battery Button

Battery Button Functions

1. Operating battery fuel gauge
2. Starting a System Controller self test
3. Putting a running System Controller into Sleep Mode
System Controller Battery Gauge

- The battery gauge shows the approximate charge status of the power source connected to the controller: either the 14V Li-ION batteries or Power Module.
- Press and release the battery button to activate the battery gauge.

Important! The battery gauge does not show the status of the System Controller Back up Battery!
On 14 Volt Lithium-Ion battery power:

- **4 green bars** = 75–100% of battery power remains.
- **3 green bars** = 50–75% of battery power remains.
- **2 green bars** = 25–50% of battery power remains.
- **1 green bar** = less than 25% of battery power remains.
System Controller Battery Button: Self Test

- Perform a System Controller Self Test daily on the running System Controller
- Press and Hold the Battery Button for 5 seconds
- Release the button
- The screen will briefly turn white then black and then “Self Test” appears on the screen
- All audible/visible indicators should remain on for 15 seconds, then all audible indicators and lights stop, the screen goes black, and the self test is complete
Battery Button: Sleep Mode

System Controller Exchange:

1. To place a running System Controller into Sleep Mode disconnect the power source and driveline

2. Then press and hold the Battery Button for 5 seconds.

Back up System Controller

1. To place a Charging System Controller into Sleep Mode disconnect the power source.
System Controller User Interface: Alarm Button

Alarm Button Functions

1. Silencing active alarms
2. Displays last six relevant alarms when pressed simultaneously with the Display button
FURTHER INFO:
Thoratec eUniversity

- http://www.thoratec-eu.com
- Create User Name and Password
- Full EMS training component available 24/7
- Complete IFUs and learning materials available at thoratec.com
Summary

- Contact the VAD team – BSHSI Pager (804) 351-0553
- Avoid cutting the percutaneous lead or power leads.
- Keep the percutaneous lead close to the patient.
- Keep the system controller connections dry at all times.
- Contact the VAD team – BSHSI Pager (804) 351-0553
So, how do people respond to these devices?
Functional Status – 6 Minute Walk

Duration After LVAD Implantation

Baseline: 30 ± 88 meters
1 mo: 166 ± 168 meters
3 mo: 244 ± 218 meters
6 mo: 285 ± 235 meters

N = 271
98 percent of patients were NYHA Class IV at baseline.
Kansas City Cardiomyopathy Questionnaire

Overall Summary Scores

Duration After LVAD Implantation

Better QoL

Absolute Score

<table>
<thead>
<tr>
<th>Duration</th>
<th>Absolute Score</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>31 ± 26</td>
<td></td>
</tr>
<tr>
<td>1 mo</td>
<td>47 ± 23</td>
<td>+42%</td>
</tr>
<tr>
<td>3 mo</td>
<td>57 ± 21</td>
<td>+84%</td>
</tr>
<tr>
<td>6 mo</td>
<td>63 ± 22</td>
<td>+103%</td>
</tr>
</tbody>
</table>

% = improvement from baseline

N = 224
Before

3 Months post

6 months postop!!
Morning after Surgery

Two Days Later
Bon Secours Heart Failure and LVAD Program

Three Months Later
Thank You for Your Attention