2014
Need to Know Intermediate
Heart Failure & Ventricular Assist Devices

Jackson HEALTH SYSTEM
Heart Failure Prevalence

• Heart failure affects over 5.3M patients in the United States. ¹

• 300,000-800,000 Americans have advanced heart failure.

• Over 250,000 patients die of heart failure each year. ¹


Etiologies of Cardiac Failure

• Coronary artery disease
• Idiopathic cardiomyopathy
• Peripartum cardiomyopathy
• Dilated cardiomyopathy
• Ischemic cardiomyopathy
• Acute valvular disease
• Arrhythmia (supraventricular or ventricular)
• Myocarditis
• Congenital heart disease
• Drug induced
• Diabetes mellitus
• Hypertension
Heart Failure

- In a healthy person, the left ventricle of the heart pumps oxygenated blood into the aorta. The blood is circulated through the body until it returns through the venous system to the right side of the heart. The blood is then pumped into the lungs where it is re-oxygenated.

- If the left ventricle is not working properly, the oxygenated blood is not fully cleared from the lungs and the blood is not circulated effectively. In order to compensate, the left ventricular muscle tends to work harder in an effort to supply adequate blood flow.

- Unfortunately, the result is not increased flow but rather dilation of the ventricle because of the increased effort. This dilation then makes it harder for the heart to contract effectively which results in even lower flow, increased effort and further dilation of the ventricle.

- This degenerative process continues until the patient becomes debilitated and eventually may die from inadequate clearing of the lungs and inadequate flow of oxygenated blood to the organs. The inadequate lung clearance or congestion is why the advanced stages of heart failure are called Congestive Heart Failure or "CHF".
Pharmacological Management

- Pharmacologic management of CHF focuses primarily on increasing the force of heart contractions.

- A drug regimen of beta-blockers, diuretics, digitalis and angiotensin-converting enzymes (ACE inhibitors) aim to improve the effectiveness of the heart's contractions and slow CHF progression.

- Although drug therapy for heart failure can improve the quality of life and also modestly prolong survival, the currently available approaches do not halt the progression of this disease.
United States — Heart Disease Death Rates

Age-adjusted Average (Annual) Deaths per 100,000

- 195 - 382
- 383 - 430
- 431 - 473
- 474 - 522
- 523 - 747
- Insufficient Data

Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Heart Failure Classification
What is the NYHA?

- The New York Heart Association (NYHA) classification is primarily used to describe the functional limitations of patients with heart failure.
- This system relates symptoms to everyday activities and the patient’s quality of life.
- This classification allows patients to move from one class to another based on symptoms.
- A patient with Class IV heart failure could move to Class III with diuretic therapy.
- It does not address the evolution and progressive nature of heart failure.
## New York Heart Association Classification of Heart Failure

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>- No limitation of physical activity&lt;br&gt;- No undue fatigue, palpitation or dyspnea</td>
</tr>
<tr>
<td>Mild</td>
<td>- Slight limitation of physical activity&lt;br&gt;- Comfortable at rest&lt;br&gt;- Less than ordinary activity results in fatigue, palpitation, or dyspnea</td>
</tr>
<tr>
<td>Moderate</td>
<td>- Marked limitation of physical activity&lt;br&gt;- Comfortable at rest&lt;br&gt;- Less than ordinary activity results in fatigue, palpitation, or dyspnea</td>
</tr>
<tr>
<td>Severe</td>
<td>- Unable to carry out any physical activity without discomfort&lt;br&gt;- Symptoms of cardiac insufficiency at rest&lt;br&gt;- Physical activity causes increased discomfort</td>
</tr>
</tbody>
</table>

Criteria Committee of the New York Heart Association, 1964.
How Many Hearts are Donated Each Year?
Approximately 2200 hearts are donated each year and it is on the decline.

NOW LET’S COMPARE:

240,000 Class IV Heart Failure Patients
vs.
2,200 Heart Donations
When Should the MCS Discussion Begin?

This slide highlights the fact that VAD has for some time been considered therapy of last resort, but as technology improves and studies and guidelines support the therapy, it needs to be considered and discussed with patients earlier. **WE NEED TO BE IN STAGE C, BUT THE PERCEPTION STILL EXISTS THAT VAD THERAPY FITS IN STAGE D.**
What is a VAD?
Milestones

• 1991 First patient with an LVAD (portable Heartmate XVE) was allowed to leave the hospital to await transplantation at home.

• 1994 Heartmate gets FDA approval.
A VAD is a mechanical circulatory device that is used to partially or completely replace the function of a failing heart.

Goal of device: to direct blood away from the failing ventricle (Left and/or Right) and provide flow to the circulation (Systemic and/or Pulmonary).
VAD System: Basic Features

- Pump (VAD)
  - Internal or external placement
- Wearable or portable control system
- Power source
  - AC power or battery power that is outside of the body
- The pump can vary in method of operation, size and placement
Two Types of Pumps: Pulsatile & Continuous Flow

- Pulsatile pumps mimic the natural pulsing action of the heart
  - These pumps are also known as volume displacement pumps

- Continuous flow pumps use either centrifugal pumps or axial flow pumps
  - Both types have a central rotor containing permanent magnets. Controlled electric currents apply forces to the magnets, which in turn cause the rotors to rotate
Types of VADs
Total Artificial Heart

First FDA approved total artificial heart 2004
Short Term Device Options

Bridge to recovery
Bridge to decision

- ECMO
- IABP
- AbioMed 5000
- Tandem Heart
- Centrimag
- Impella

Circulation 112 (3): 438
Intra-aortic Balloon Pump (IABP)

- Developed in late 1960s
- Counterpulsation is synchronized to the EKG or arterial waveforms
- Increase coronary perfusion
- Decrease left ventricular stroke work and myocardial oxygen requirements
- Most widely used form of mechanical circulatory support
- Indications for its use include:
  - Failure to wean from cardiopulmonary bypass
  - Cardiogenic shock after MI
  - Heart failure
  - Refractory ventricular arrhythmias with ongoing ischemia
Bridge to Bridge: ECMO

- Immediately stabilize circulation
- Improve end organ perfusion
- Overall survival comparable between ECMO + LVAD versus LVAD alone
- Clinical indicators of poor outcome after ECMO: consider VAD implantation carefully
  - Elevated blood lactate levels
  - Elevated LFTs

Centrifugal Pumps

- Acute hemodynamic support
- Continuous flow
- Extracorporeal
- LV, RV or biventricular support
- Wide availability
- Ease of use
- Relatively low cost
- Limited duration of support
- Bridge to recovery
- Bridge to decision

Tandem Hearts

- Acute hemodynamic support
- Centrifugal pump
- Percutaneous placement
- LV support via trans-septal cannula
- Used in high risk cardiac catheterization procedures
- Risk of vascular injuries due to cannula size
Levitronix Centrimag

- Newer generation
- Centifugal pump
- Continuous flow
- Extracorporeal
- Impeller within the pump rotates in contact-free manner
- Increased durability
- Minimal thrombus formation and hemolysis of RBCs

![Levitronix Centrimag Image](image_url)
Impella

- Axial flow pumps
- Acute hemodynamic support
- Miniaturized impeller pump in catheter
- Helical catheter tip placed across aortic valve and left ventricle
- Percutaneous or direct placement
- Flow up to 5 L/min
- Bridge to recovery
Types of VADs

- There are two main types of VADS in use at Jackson Memorial Hospital.

- The type of device used is decided by the VAD team and is based on individual patient condition and indication for the VAD.
Long Term Device Options

- Bridge to Transplant
- Destination Therapy
- HeartMate II & HeartMate II PC
- HeartWare
Heartmate II

- Axial flow
- LV support
- Flows 10L/min
- Long term durability
- Bridge to transplant
- Approved January 2010 for destination therapy
- Over 4000 devices implanted to date
Anatomical Placement
HeartMate II Power Sources

Power Module

14 volt Lithium Ion batteries & clips
HeartMate II Pocket Controller

- Lightweight, pocket-sized LVAD controller that safely and smartly enables an active lifestyle for HeartMate II Patients.
- Backup battery provides at least 15 minutes of full power in an emergency situation.
- Prioritized visual alarms with clear, actionable instructions.
- Driveline diagnostic capabilities for added security that the driveline wires are intact and functional.
- Programmed for use in 37 languages.
- Designed for an active lifestyle. Lightweight and compact with single-side cable design slides easily into a front pocket without extra bulk or heavy weight.
- Durable, shock-resistant outer case, cables, and electronics are ideal for active patients.
HeartWare

• The pump is designed to draw blood from the left ventricle and propel it through an outflow graft connected to the patient's ascending aorta.

• The device is capable of generating up to 10 liters of blood flow per minute. Has only one moving part, the impeller, which spins at rates between 2,400 and 3,200 revolutions per minute.

• Is designed to be implanted in the pericardial space, directly adjacent to the heart.

• Implantation above the diaphragm is expected to lead to relatively short surgery time and quick recovery.
Pericardial Placement

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to the “Instructions For Use” for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events and Instructions prior to using this device.
HeartWare® System

Small pump attaches directly to the heart

Thin, flexible driveline cable exits skin

A small controller & batteries run the pump

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to the Instructions For Use® for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events and Instructions prior to using this device.
HeartWare Patient Peripheral Components

- HeartWare® Controller: Controls and manages VAD operation
- HeartWare® Power Sources: Power the controller and pump
  - Batteries
  - AC adapter (plugs into wall outlet)
  - DC adapter (plugs into car outlet)
- Patient Pack: Holds a controller & 2 batteries; may be worn around waist or over the shoulder
  - HeartWare® Shower Bag: Holds a controller & 2 batteries while showering
- HeartWare® Battery Charger: Can simultaneously charge up to 4 batteries

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to the "Instructions For Use" for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events and Instructions prior to using this device.
So who gets a VAD?

And ...

Which one do they get?
Bridge to Transplant

- Bridge to Transplant is used in patients to:
  - Maintain circulation until a donor heart is available
  - Non-reversible left heart failure
  - Patients who may wait longer for a donor heart
  - Improve post-transplant outcomes
  - Non-reversible left heart failure
  - Imminent risk of death
  - Candidate for cardiac transplantation
  - For in-patient and out-patient use
Destination Therapy

• Not a transplant candidate due to age, malignancy or co-morbidities, based on current status.

• FDA criteria:
  – NYHA Class IV Heart Failure
  – Optimum medical therapy for 60 of last 90 days
  – Survival < 2 years
  – Not a transplant candidate

• Additional CMS criteria
  – VO2 Max < 12
Common Device Issues/Complications

- Bleeding
- Thrombosis
- Infection
- Right ventricle dysfunction
- Suckdown (non-pulsatile devices only)
- Device failure/malfunction
- Hemolysis
- Arrhythmias
- Hyper/hypotension
Common Device Issues /Complications

• Device failure/ Malfunction
  – Determine if the device is on
  – Listen for alarms
  – Assess for signs of hypoperfusion
  – Assess for hypotension

• Hemolysis
  – Dark Urine
  – Increasing VAD power
  – Hypotension
  – Irregular VAD sounds
Commonly used medication for patients with LVAD

- **Coumadin ® (warfarin)**
- Beta Blockers — These drugs help the heart beat more slowly and with less force, which helps reduce blood pressure. Beta blockers also help blood vessels open up, to improve circulation.
- Ace Inhibitors/ARBs — to reduce your blood pressure.
- Calcium Channel Blockers — These drugs can help reduce blood pressure by relaxing the heart muscle and blood vessels.
- Diuretics.
- PDE5 Inhibitors (Revatio ® or Tadalafil®) — These types of medication are sometimes used to help prevent abnormally high blood pressure in the arteries of the lungs, which can cause the right side of the heart to have to work harder.
- Aspirin – Depends on the device and patient: ASA 325mg po daily or ASA 81mg po daily
- Milrinone ®—inotropes, which help the heart contract, allowing it to pump blood more effectively. It also helps lower unusually high blood pressure in the arteries of the lungs, which can cause the right side of the heart to have to work hard.
Additional Resources

- Thoratec.com
- ThoratecU.com
- HeartWare.com
- MyLVAD.com
- HeartHope.com
Contact Information

• Mechanical/Device Issues
  – Biomedical Engineer  305- 277- 5939

• Inpatient Clinical Issues
  – Days (7A-3:30P)  305-208-0558
  – After Hours/weekends  JMH: 0538

• Out-Patient Clinical Issues
  – Days (7A-3:30P)  305-855-0093
  – After Hours/weekends  305-585-5400

Page operator- Ask for VAD/Heart transplant Coordinator on call

*This information will be posted in your area.
Contact Information

• Company Support Lines
  – Thoratec HeartLine 1-800-456-1477
  – HeartWare Hotline 1-888-494-6365

• New VAD Referrals
  – Pre/VAD Referrals 305-837-5059

*This information will be posted in your area*
For More Information

- Check your unit area for device specific resource manuals.
- Also, Specific VAD devices, manuals and related policies can be found on JMH Net Portal.