Advanced Heart Failure Stages and Current Therapies

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Objective

- Participant will be able to identify the progression of advanced heart failure stages and current therapies.
Heart Failure

- Heart failure is when the hearts pumping ability is insufficient in maintaining blood flow to meet the body’s needs.
Cardiac Abnormalities

- **Restrictive Myopathy** - heart muscle is rigid and lack flexibility to expand normally. (good example is amyloidosis).

- **Hypertrophic Myopathy** - thick myocardium (small ventricular cavity).
Cardiac Abnormalities

• Congenital heart disease- birth defect of the heart and/or vessels. (Example tetralogy of Fallot)

• Dilated Myopathy-weakened and enlarged ventricle, poor muscle tone.
Cardiac Abnormalities

- Valvular heart disease- poor functioning valve causing poor movement of blood in or out of the chambers.
Heart Failure (HF)

• The leading cause of HF is coronary artery disease, high blood pressure and diabetes.
• 2.4% of the adult population are affected with HF.
  – Greater Des Moines population is ~599,789. This would mean ~ 14,394 of adults in the Des Moines area may have heart failure.
Systolic vs. Diastolic HF

• Normally the heart ejects 50-75% of the blood from the left ventricle.

• Diastolic Heart Failure- Left ventricle is not able to fill properly during the diastolic (filing) phase. Less blood is ejected from the heart than what should be.
  – HFpEF (preserved ejection fraction >50%).

• Systolic Heart Failure- Left ventricle is not able to squeeze hard enough to push blood out to the rest of the body during systole. (heart damage from MI, thin/narrow muscle lining).
  – HFrEF (reduced ejection fraction <50%).
Therapy Options

- Diet
- Exercise
- Diabetes management
- Blood pressure control
- Options for structural issues (parachute, TAVR, Mitra Clip, surgery)
- Coronary intervention (stenting, balloon angio plasty and/or coronary artery bypass graft (CABG))
- Pacemaker/ resynchronization therapy/ ICD
- Mechanical circulatory support/ Cardiac transplant

Education (self care)
Patients with **Advanced** Heart Failure

- Repeated hospitalizations (greater or equal to 2 within the year)
- Progressive deterioration in renal function (rise in BUN and Cr)
- Weight loss without other cause (cardiac cachexia)
- Intolerance to ACE inhibitors or b-blockers due to hypotension and/or worsening HF.
- Frequent systolic blood pressure <90mmHg
- Persistent dyspnea with daily activities (bathing and dressing)
- Inability to walk 1 block on the level ground due to dyspnea or fatigue
- Frequent ICD shocks (arrhythmias)
- Increase escalation of diuretics (example furosemide equivalent to >160 mg per day).
- Progressive decline in serum sodium (<133)
Heart Failure Classification

<table>
<thead>
<tr>
<th>ACC/AHA Heart Failure Stage</th>
<th>NYHA Functional Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. At risk for heart failure but without structural heart disease or symptoms</td>
<td>None</td>
</tr>
<tr>
<td>B. Structural heart disease but without heart failure</td>
<td>I. Asymptomatic HF: no symptoms</td>
</tr>
<tr>
<td>C. Structural heart disease with prior or current heart failure symptoms</td>
<td>II. Mild HF: symptomatic with moderate exertion</td>
</tr>
<tr>
<td>D. Refractory heart failure requiring specialized interventions</td>
<td>III. Moderate HF: symptomatic with minimal exertion</td>
</tr>
<tr>
<td></td>
<td>IV. Severe HF: symptomatic at rest</td>
</tr>
</tbody>
</table>

Optimal Timing for Advanced Therapies

Peura J et al. Circulation 2012;126:2648-2667
## INTERMACS PROFILES AND OTHER CLASSIFICATION SYSTEMS

<table>
<thead>
<tr>
<th>Profile #</th>
<th>Description</th>
<th>NYHA Class</th>
<th>Time to MCS therapy</th>
<th>AHA/ACC Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERMACS 1</td>
<td>Crashing and burning</td>
<td>IV</td>
<td>Within hours</td>
<td>D</td>
</tr>
<tr>
<td>INTERMACS 2</td>
<td>Progressive decline on inotropic support</td>
<td>IV</td>
<td>Within a few days</td>
<td>D</td>
</tr>
<tr>
<td>INTERMACS 3</td>
<td>Stable but inotrope dependent</td>
<td>IV</td>
<td>Within a few weeks</td>
<td>D</td>
</tr>
<tr>
<td>INTERMACS 4</td>
<td>Recurrent advanced heart failure; resting symptoms at home on oral therapy</td>
<td>Ambulatory IV</td>
<td>Within weeks to months</td>
<td>D</td>
</tr>
<tr>
<td>INTERMACS 5</td>
<td>Exertion intolerant</td>
<td>Ambulatory IV</td>
<td>Variable</td>
<td>D</td>
</tr>
<tr>
<td>INTERMACS 6</td>
<td>Exertion limited or walking wounded</td>
<td>Ambulatory IV</td>
<td>Variable</td>
<td>C-D</td>
</tr>
<tr>
<td>INTERMACS 7</td>
<td>Advanced NYHA III</td>
<td>IIIIB</td>
<td>Variable</td>
<td>C</td>
</tr>
</tbody>
</table>

A depiction of the clinical course of heart failure with associated types and intensities of available therapies.

Transition to Advanced Heart Failure:
- Oral therapies failing
- A time for many major decisions
- Consider MCS and/or transplantation, if eligible
- Consider inversion of care plan to one dominated by a palliative approach, which may involve formal hospice

Triggers

Triggers below help the healthcare provider evaluate the patients decline in heart function therefore prompt collaboration with heart failure cardiologist.

- Hospitalization for heart failure
- First ICD shock
- Upgrade to CRT-D device with no improvement in heart failure symptoms
- Development of cardiorenal syndrome
- Withdrawal of ACE
Timing

- Heart failure is a progressive disease. The art of caring for advance heart failure patients is helping them make decisions on next best treatment options and educating them on self care and symptom management.
- Five year survival, 50%.
- Best time to talk about options is in the ambulatory setting.
- Hospital admission should be a time to review and possibly update care options rather than introduce advanced therapy care decision options.
- Advanced therapies is about improving quality of life.

Lesny, P. et al. (2013). Journal of Heart and Lung Transplant
Advanced Heart Failure Team

- Physicians/ARNP
- Heart Failure Case Managers
- VAD Coordinator
- VAD Social Worker
- Palliative Care Coordinator
- Transplant partners at UIHC
What does a VAD do?

• The VAD assists the heart by helping pump more blood to the rest of the body, from the left ventricle up to the aorta.

• Ventricular Assist Device can be called other names:
  – LVAS (Left Ventricular Assist System)
  – MCS (Mechanical Circulatory Support)

• HeartMate II is the only long term mechanical assist device approved by the FDA (patient lives with the device at home).

Picture above is the VAD pump attached to the heart (internally).
## ROADMAP Patient Population

<table>
<thead>
<tr>
<th>NYHA Class III</th>
<th>Class IIIB</th>
<th>Class IV (Ambulatory)</th>
<th>Class IV (On Inotropes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERMACS Profiles</td>
<td>1.0%</td>
<td>1.4%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

**Percent of current implants in INTERMACS**:
- Class IIIB: 1.0%
- Class IIIB: 1.4%
- Class IV (Ambulatory): 3.0%
- Class IV (On Inotropes): 14.6%

**FDA Approval: Class IIIB/IV**
- Currently Not Approved
- Limited Adoption
- Growing Acceptance

### REVIVE-IT
- ROADMAP Non-inotrope dependent

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2. GL-HM2-04150215
3. Jerry D. Estep, MD – Presented on April 17
FDA Approval

• Bridge to Transplant
  – Non-reversible left heart failure
  – Imminent risk of death
  – Candidate for cardiac transplantation

• Destination Therapy
  – Not a candidate for transplant
  – All other treatment options have been exhausted.
  – Goal is to improve quality of life and decrease HF symptoms.
Criteria for Destination Therapy

End-Stage heart failure (New York Hear Association Class IV) who are not candidates for heart transplantation, and meet all of the following conditions:

• Have failed to respond to optimal medical management (Including 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

• Have a left ventricular ejection fraction (LVEF) <25%; and

• Have demonstrated functional limitation with a peak oxygen consumption of <14 ml/kg/min unless balloon pump or inotrope dependent or physically unable to perform the test (cardiopulmonary treadmill- CPX).
Evaluation Phase

Testing for cardiac transplant and LVAD

- Labs
- Left heart cath (angiogram) to eval coronaries
- Right heart cath- to evaluate increased filling pressures/back up of fluid on the right side.
- CT of chest if previous sternotomy
- CPX- Cardiopulmonary exercise stress test- VO2 less than 14
- Echocardiogram- Bubble study needed if may get LVAD
- 6 min walk test
- Ultrasounds- Carotid and Abdominal
- ABI- to rule out PVD
- Colonoscopy
- Mammogram, Pap, prostate eval (per sex)
- Palliative RN (evaluates POA/Will, 5 wishes and coping with disease process)
- Social Worker (evaluates social support at home and insurance coverage)
Heart Mate II

Registry Information to date (from Thoratec)

• Patients implanted: 20,000+ worldwide
• 100+ patients on support for over 5 years, with multiple patients over 8 years
• Longest supported patient on a single device (8+ years)
• Age range: 10 - 91 years
Optimal orientation of the LVAD cannulas
Patient Equipment

- Patient must have backup equipment with them at all times!
- All VAD patients have a primary caregiver who is fully trained to troubleshoot the equipment.
- Bag will contain emergency call number and alarm troubleshooting guide.
Blood Pressure Monitoring

• Less pulsatility of native pressure due to continuous-flow nature of the HeartMate II
• Blood pressure measurement
  – Doppler ultrasound once A-line removed
  – Automatic cuffs are inaccurate
• Targeting MAP with a goal of:
  – Mean ≈ 70-90 mmHg
• Hypertension
  – Effects on pump support
    • May decrease forward flow
    • Decrease in pump flow and power
  – In anti-coagulated patients, may increase risk of hemorrhagic stroke
Titrating Anticoagulation

- Warfarin dose for INR target of 2.0 ± 0.5
- Aspirin 81 to 325 mg/day
- Consider increasing anticoagulation during low flow states
  - LVAD Flow < 3.0 L/minute
- Gastrointestinal bleeding
  - von Willebrand disease
  - Reduced pulsatility
- Typically high INR’s will not require reversal agent, patient may be admitted for monitoring while trending down.
Emergencies

• In the occurrence that the patient becomes unresponsive, **DO NOT** perform chest compressions as this may dislodge the device.

• All other measures to resuscitate the patient (medications and airway) should be performed (check code status).

• Most patients have a pacer/ICD. If shock advised and current ICD is not shocking the patient, external defibrillation can be performed **without** disconnecting the VAD.

• If the device has any alarms, seek a VAD competent or VAD trained person right away.

• A heart failure physician is on call 24/7. All pump related emergencies should be directed to VAD coordinator on call. They are directed to call 515-633-3770, IHC heart failure line.
Risks

- **Bleeding**
  - Due to non pulsatility, patients are at risk for AVM’s
  - GI bleeding is most common

- **Stroke**
  - Patients must be anti-coagulated.
  - Typical INR goal is 2.0-3.0

- **Power disconnect**
  - Never disconnect both sources of power at the same time (i.e. both batteries).

- **Infection**
  - Must maintain sterile dressing to driveline site
  - Assess for infection

- **Suction events**
  - When inflow cannula contacts ventricular wall can cause ectopic beats.
  - Evaluate patient for dehydration or arrhythmias
Success Story

- July 2007 acute pulmonary edema PTCA/stents to RCA and OM1 and ramus. A few hours later coded and required a stent to the RCA again.
- June 2012 seen by Dr. Frazier, began verbalizing depressive conversations. NYHA III.
- September 21, 2012 Jerry was referred to Dr. Wickemeyer for an advanced HF consult
- May 3, 2013 LVAD implanted by Dr. Prabhakar with Dr. Bates at the University of Iowa.
- May 21, 2013 Mercy acute rehab for 2 weeks
- June 7, 2013 first visit to the IHC advanced heart failure clinic with new LVAD.
- July 25, 2013 first road trip to Kansas City.
Support Group

VAD support group brings other VAD patients and their caregivers from the community together to talk about living life with an LVAD.
**Functional Capacity after HMII LVAD**

*NYHA functional class was determined by an independent clinician at the time points shown. Improvements were statistically significant in both trials (p<0.001). Rogers JG, Aaronson KD, Boyle AJ et al, JACC, 2010;55:1826–34.*
Reference
