Ventricular Assist Device Technology in the Rehabilitation World

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Disclosures:

- Marcia – Speakers Bureau, Consultant, Thoratec – St. Jude Medical - Abbott
What does a Ventricular Assist Device (VAD) Rehabilitation Program Look Like?

The Rehab center needs to work as a team with the Mechanical Circulation Support Group for:

- Initial training of the staff
- Yearly competencies
- Emergent patient care issues
- Troubleshooting
- Patient education
- Patient discharge preparation and planning
Staff VAD Education

- Includes all units caring for LVAD’s: OR, ICU, PCU, Rehab, APC, PACU, ER, Home Health
- Initial Education 4 hour Class
- Yearly Competencies- “high risk, low use"
  - MCS Day bimonthly or part of Unit Yearly Competencies
  - Joint Commission is going to want to see process-
    - competency statements
    - tracking log
    - How to those making assignments know who is competent
- Initial 1 hour class for therapists, then Annual Ancillary Continuing Education Program
Therapy Assisted Patient Teaching

- **Physical Therapy**
  - Power changes, Transfers, Ambulation, protection of DLS with activities, Wii Fit

- **Occupational Therapy**
  - Equipment management (shoulder holster, bags etc.) hand strength for power connections

- **Speech Therapy** – Swallow, Memory and Equipment Training, Flashcards
What Patients are Considered for a VAD?

- Approved Cardiac Transplant Candidate (BTT), or "Destination Therapy" (DT), Possible Bridge to Recovery (BTR)
- As of Feb 2010 HM II was FDA approved for both BTT and DT
- EF <25%, MVO2 <14, NY Heart Class 4
- On inotropic support (meds that increase force of heart muscle contraction i.e.: digoxin)
- Possibly on IABC (intra-aortic balloon counter pulsation)
- Left Atrial pressure or PCW>20 with either:
  - Systolic <80 mmHg or
  - CI < 2.0 l/min/m²
- Early signs of other end organ failure r/t heart failure, i.e. increasing BUN, Creat, AST or ALT
- Contraindicated with BSA<1.3mm² (HM II) or signs of infection
Device Overview

- Pulsatile - initial pumps, first generation
  - TAH (initially Jarvik)
  - HeartMate I
- Continuous Flow – pulseless, second generation
  - Axial Flow
  - Centrifugal Flow
- Where to next? Fully Implantable
Internationally VAD Pumps Implanted

- **SynCardia TAH**
  - Implanted: 3,000
  - Countries: 15
  - FDA approved
  - BTT

- **HeartWare VAD**
  - Implanted: 13,000
  - Countries: 47
  - FDA approved
  - BTT

- **Heartmate 2**
  - Implanted: 25,000
  - Countries: 25
  - FDA approved

- **Heartmate 3**
  - Implanted: 1,500
  - Countries: 25
  - Clinical Trials
OVER 25,000 PATIENTS HAVE BEEN IMPLANTED WITH THE HeartMate II™ LVAD

Many patients have been supported for more than five years, and some for more than ten years.*

<table>
<thead>
<tr>
<th>Years of Support (Cumulative)</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥1</td>
<td>13,843</td>
</tr>
<tr>
<td>≥2</td>
<td>8,554</td>
</tr>
<tr>
<td>≥3</td>
<td>5,191</td>
</tr>
<tr>
<td>≥4</td>
<td>3,932</td>
</tr>
<tr>
<td>≥5</td>
<td>1,574</td>
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<tr>
<td>≥6</td>
<td>845</td>
</tr>
<tr>
<td>≥7</td>
<td>396</td>
</tr>
<tr>
<td>≥8</td>
<td>152</td>
</tr>
<tr>
<td>≥9</td>
<td>58</td>
</tr>
<tr>
<td>≥10</td>
<td>20</td>
</tr>
</tbody>
</table>

More than 9,000 patients receiving ongoing support*

The above numbers are cumulative. Patients with a duration of ≥ 2 years are included in the number of patients ≥ 1 year.

*Based on clinical trial and device tracking data as of February 28, 2017. Zinc report #SJM-HM-101-6-0032(1).
## Differences in Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HeartMate 2</th>
<th>HeartMate 3</th>
<th>HeartWare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Method of Blood Flow</strong></td>
<td>Axial flow</td>
<td>Centrifugal flow with pulse feature @ speeds &gt;4,000rpm</td>
<td>Centrifugal flow</td>
</tr>
<tr>
<td><strong>Speed</strong></td>
<td>Range 6,000-15,000, generally 9-10 thousand, Fixed based on LV diameter</td>
<td>Range 3,000-9,000, generally 5,000-6,000, Fixed based on LV diameter</td>
<td>Range 1,800-4,000 Range 2,000-3,000 Fixed based on LV diameter</td>
</tr>
<tr>
<td><strong>Flow - Calculated based on Speed and Power. Both pumps dependent on Speed, as well as preload and afterload</strong></td>
<td>Range 2-10 l/min, usually 3-7 l/min</td>
<td>Range 2-10 l/min. Also takes Hct into account when calculating – to be more accurate</td>
<td>Range 2-10 l/min. Also takes Hct into account when calculating – to be more accurate</td>
</tr>
<tr>
<td><strong>Pulsatility Index (PI)</strong></td>
<td>Theoretical range: 0-20, &lt;3 getting close to PI events &amp; not enough fluid in LV</td>
<td>Theoretical range: 0-10, &lt;3 getting close to PI events &amp; not enough fluid in LV</td>
<td>N/A – Waveform on system monitor</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>Should be &lt;10, if &gt;10 Consult MCS Department</td>
<td>Should be &lt;10, if &gt;10 Consult MCS Department</td>
<td>Should be &lt;10, if &gt;10 Consult MCS Department</td>
</tr>
<tr>
<td><strong>Controller - Not Interchangeable</strong></td>
<td>Older EPC or Pocket Controller - light grey in color</td>
<td>Pocket Controller – dark grey in color</td>
<td></td>
</tr>
<tr>
<td><strong>Other External Equipment</strong></td>
<td>Li-Ion Batteries, Battery clips, Power module with patientt Cable, Battery charger, System Monitor, Mobile Power Unit</td>
<td>Same, with addition of &quot;Mobile Power Unit&quot; for use at home</td>
<td>Li-Ion Batteries, AC Cable, DC cable, Battery charger, System Monitor</td>
</tr>
</tbody>
</table>
HEARTMATE II LVAD

- FDA Approved for BTT or DT
- Axial flow - they may not have a pulse and you may need a doppler to get BP (MAP)
- Speed 9-10,000 rpm’s (typically seen)
- PI 3-8, Power 4-6
- External controller and power source
FLOW TECHNOLOGY

Advanced Continuous Flow Technology
Pocket System Controller

Alarm Indicators

- Black Power Lead Symbol
- White Power Lead Symbol
- Driveline Symbol
- Yellow Wrench Advisory Symbol
- Red Heart Symbol
- Hazard Battery Symbol
- Low Battery Advisory Symbol
HeartMate III LVAS

- In Clinical Trials–60 selected centers
- FDA Approved BTT/recovery 8/2017
- Centrifugal flow—
  - Magnetically Levitated
  - Large Gaps
  - Has a pulsing mode q 2seconds
- Speed 5-6,000 rpm’s (typically seen)
- PI 3-8, Power 3-5
- External controller and power source
HM III System Controller User Interface

- Cable Disconnect Symbols
- Battery Button
- Pump Running Symbol
- Display Button
- User Interface Screen
- Status Symbols
- Silence Alarm Button
HeartMate Peripherals

Power sources
- Power Module (PM)
- Batteries - Li-ion with Clips and separate Battery charger
- Mobile Power unit

System Monitor
HeartWare – HVAD

- FDA Approved for BTT not approved for DT yet
- Centrifugal flow - they may not have a pulse
- Speed 2-3,000 rpm’s (typically seen)
- No PI, Power 3-6
- External controller and power source
HeartWare™ Controller Display

- Alarm Indicator
- Battery Indicator 1
- Battery Indicator 2
- Power Source 1
- Power Source 2
- Alarm Mute Button
- AC/DC Indicator
- Controller Display
- Scroll Button

Display:
3000 RPM 5.0 L/min
4.8 Watts
HeartWare® System Components

- HVAD™ Pump
- HeartWare™ Controller
- HeartWare™ Monitor
- HeartWare™ Batteries & Battery Charger
- HeartWare™ Controller AC Adapter
- HeartWare™ Controller DC Adapter
Patient Considerations During the Rehab Stay

- Patient Assessment
- BP management
- Anticoagulation
- Nutrition
- Strengthening and Conditioning
- Education reinforcement
Patient Assessment

- **Neuro** – TIA’s and Strokes need to be evaluated immediately “Stroke Code”, flashcards for training
- **Cardiac** – BP goals, Flow goals, HR, Arrhythmias – K+, Mg++, Preload – fluid, weight, Afterload – HTN, Thrombus
- **Pulmonary** – PE, pulmonary edema, pneumonia
- **GI** – Bleeding
- **GU** – tea colored urine
- **Infection** – foreign body, driveline site/ stabilization
- **Nutrition** – Diet instruction, including Low NA, Diabetes, wound healing, Micronutrients, supplements i.e. Core Power
- **Mobility** – Strengthening and Conditioning
Taking a BP….Hemodynamic Management

- Use manual BP cuff with Doppler to determine BP.
- You can try using automatic BP, but may not get a reading. Must correlate with Doppler.
Yellow Wrench – Advisory Alarms

- Power Cable Disconnect
- Low voltage advisory
- System Controller Fault
- System Controller Back Up Battery Fault
- Driveline Fault
- CALL MCS for instructions, not critical
- RED BATTERY-Critical 5 min warning
Red Heart Advisory Alarm

Call 911, Call MCS Coordinator
Is the Pump pumping?
Green Light on with Red Heart
Patient Problem
Green Light OFF with Red Heart
Check Power, Change controller under
direction of MCS Coordinator
Hypovolemia

Low BP
Low PI (pulsatility index)
Low flow or “---”

Interventions: Volume,
Decrease diuretics
Low volume and low flow may lead to ventricular collapse:
VAD is preload dependent

This is indicative of speed drops greater than 200 RPMs and low PI’s, low BP

May cause arrhythmias or right sided failure
Arrhythmias

May have:
- Low Pls
- Low flows or “---”
- Low power
- “Pl Events” indicated by speed drops of 200 or more

Patients may tolerate, feel flu like
K+ > 4.5, Mg++ > 2.1
AICDs will be on
Hypervolemia

High MAP/ BP
High PI
High Flow

Interventions: Diuretics changes, watch for unresponsiveness
Hypertension

High PI
Low flow or “---”

Interventions: Bring down the MAP, this will lower the pressure differential and increase the flow
Right Sided Failure

- High BP
- Low PI even though speed optimized
- Low Flow or “---”
- Increased congestion, SOB, weight gain

Interventions: Report early, may need an Echo.
Pump Thrombus

Increase in power, over 10 Watts
Unexplained changes in flow
Thrombus may come from two sources:
  Clot formed on blades or other surfaces inside the VAD
  Clot originated from somewhere else and entered the pump, Afib, PE, etc.
Case Studies
Patient Scenario 1

- Your patient feels dizzy and lightheaded when sitting on the side of the bed.
- You take vital signs and are unable to use the automatic cuff
  - What would you do?
- Your patient has the following numbers:
  - Flow: 3.5 (Had been 5.4)
  - Speed: 9000
  - PI: 2.2
  - Power: 4.1 W
- What should you do next?
Your patient feels SOB when sitting on the side of the bed.
You take vital signs using the automatic cuff, you get 140/90, pulsatile.
What would you do?
Your patient has the following numbers:
- Flow: 7.5 (Had been 5.5)
- Speed: 9600
- PI: 8.0
- Power: 6.8 W
What should you do next?
Patient Scenario 3

Patient calls you to his room. He states that he thinks his AICD might have fired. His speed is usually at 9200, but he notices that it dips down to 8200.

What is happening? How would you treat this
Patient Scenario 4

- Your patient has the following numbers:
  - Speed: 9000
  - Flow: 8.9 (Had been 6.0)
  - PI: 4.2
  - Power: 10.3 W

- What additional information would you need?
- What would you do for this patient?
Patient Education

- Everyone needs to be part of the education process.
- Repetition is critical for patients, especially the older ones.
Patient Education Post Op

- Teaching starts once awake – ICU
  - System Check, Power Changes
- Focus on: Learning Equipment
  - Caregivers, other significant people
- Dressing Changes
- Medications
- Community Training – Home Health, EMS
- Emergencies – Keep it Simple
- Two page summary of what they must know
- Competency check completed prior to rehab stay
Patient and family education is the responsibility of the entire staff.

- Focused training sessions occur with VAD Coordinator
- Create an education schedule with the patient and family.
- The entire staff should be aware that their time with the patient and family are opportunities to reinforce training.
- Charting what is completed.

**Discharge Planning**

- Patient and Caregiver competencies.
- Day Passes
Daily Checklist
Add Daily Goals

- Get up and sit on side of bed until stable
- Drink water (throughout day) 1___ 2___ 3___ 4___
- System Check
  - Write numbers from PC Display on sheet
- Change to Batteries
- AM Care teeth, wash up, shave
- Get dressed
- Breakfast
- AM Medications
- Posture Training
- Rest
- Dressing Change Monday/Friday (may be done at night)
- Walk 15 min exercise
- Check Battery Gauge (check throughout day)
- Rest

- ACTIVITY: ___________________
- Lunch / Medications
- Set Daily Goal for next Days Improvement
- Stretching Exercises
- ACTIVITY: ___________________
- Rest
- Walk 15 min exercise
- Check Battery Gauge
- ACTIVITY: ___________________
- Dinner / Meds
- May take short walk
- Review Equipment
- Rest
- Bedtime Meds
- Hook Up to Mobile Power Unit
HeartMate II Patient Data Collection at Home

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Speed Call &lt;8000</th>
<th>Flow Call &lt;3.5</th>
<th>P.I. Call &lt;5</th>
<th>Power Call &gt;10w</th>
<th>Backup Battery Charged</th>
<th>BP</th>
<th>Temp</th>
<th>Daily Weight</th>
<th>DL Site Change Mon / Fri</th>
<th>INR / Coumadin</th>
<th>Daily System Check Controller</th>
<th>Blood Sugars Other</th>
</tr>
</thead>
</table>

When to call and who to call:

A. Pump issues - any alarms, questions, unusual noises, speed slower than usual, driveline site issues - Call MCS 858-939-3863
B. Medical issues - fever, weakness, headache/dizziness, medications - Call NP 858-939-3831 or 858-939-3400 and ask for heart transplant nurse practitioner on call
Discharge

- Has MCS Team signed patient off for competency at home?
- Labs needed including INR
- Follow Up clinic appointments Cardiology, CV surgery, MCS
- Additional PT / OT or Speech needed at home?
- Home Health following?
- Reinforces Education with Patient and Family
- Identifies early problems and management strategies
- Reinforces dressing changes, equipment and alarms
- Transitions Patient to Home
Help Wanted

**Wanted:** Untrained family member or friend to act as advocate, researcher, care manager, emotional support for parent or spouse, sibling or friend, who has been diagnosed with serious illness.

**Duties:** Make medical decisions, negotiate w/ insurance or Medicare; pay bills; legal work; provide personal care and entertainment in the hospital or Rehab.
Help Wanted Continued

- **Aftercare at home:** Substitute for skilled nurse if injections, IV’s, O2, wound care (dressing changes) or tube feedings required.

- **Long Term Care:** RAPIDLY respond to alarms! Medication management, showering, toileting, lifting, transporting, etc.

- **Hours:** ON Demand

- **Salary and Benefits:** “0”  Personal satisfaction??
Your patient is not making progress and is unable to participate in PT / OT / Speech.

You have tried to do more frequent shorter periods with the therapies.

What should you do?

Can you discharge him home?

What other options are available?
Partnering with your community???

- What if there is no family or friends to assist the patient at home?
- What is their discharge plan?
- Identifying community resources.
Cardiac Rehab
Questions: