Course Objectives:
- Describe novel heart replacement technologies used to treat heart failure.
- Review the most common complications associated with these devices.
- Explain how to troubleshoot the devices in the ED to improve patient safety and quality of care.

Ventricular Assist Device (VAD)

I. Background
   A. Epidemiology
      - Heart failure affects 6-10% of all people over the age of 65
      - 2 million patients worldwide have end-stage heart failure
      - 5 million CHF patients in the U.S.
      - 550,000 new cases annually in the U.S.
      - 250,000 deaths annually due to CHF
      - Primary diagnosis in >900,000 hospitalizations per year in U.S.
      - Direct and indirect costs of CHF total $30 billion
      - Cardiac transplant is the definitive treatment for advanced CHF, with 2800 cases done annually in the U.S.

   B. Goals of the VAD
      1. Bridge to transplantation (BTT)
         a. Severe CHF
         b. Pulmonary hypertension
         c. Refractory ventricular tachycardia
         d. Ischemic cardiomyopathy
      2. Destination therapy (DT)
         a. Severe CHF in patients who are not transplant candidates
      3. Bridge to recovery (BTR) - shortest-term use
         a. Post myocardial infarction
         b. Post-cardiotomy shock
         c. Dilated cardiomyopathy

   C. Types of VADs
      1. Right ventricular (RVAD)
      2. Left ventricular (LVAD)
3. Biventricular (BiVAD)

D. Operational mode
- Fixed rate
- Automatic – more closely resembles normal physiologic conditions; pump ejects when 90% full or when it senses a decreased rate of filling

E. Cost of VAD
- >$60,000 per device
- >$200,000 for implant and hospitalization

II. Biomechanics

Generally, VADs consist internally of:
- Inflow catheter or conduit
- Outflow catheter or conduit
- Chamber with pump or rotor

Externally:
- Percutaneous driveline: connects the internal VAD to the external power source
- Power/control source
- Rechargeable Lithium batteries – single charge lasts up to 10hrs

VAD pump
1. Continuous flow
   - Significantly smaller in size and weight compared with pulsatile pumps
     a. Thoratec Heartmate II – LVAD with axial-flow pump; BTT, DT

2. Pulsatile flow
   a. Thoratec Percutaneous Ventricular Assist Device (PVAD) – Bi- or Uni-VAD with pneumatic sac-type pump; BTR, BTT
   b. Thoratec Implantable Ventricular Assist Device (IVAD) – Bi- or Uni-VAD with pneumatic sac-type pump; BTR, BTT
   c. Thoratec Heartmate XVE – LVAD with electric, pusher-plate pump, BTT, DT

<table>
<thead>
<tr>
<th>Device</th>
<th>Inflow catheter</th>
<th>Outflow catheter</th>
<th>Pump</th>
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<tbody>
<tr>
<td>LVAD</td>
<td>Left atrium or ventricle</td>
<td>Aorta</td>
<td>Pre-peritoneal or intra-abdominal</td>
</tr>
<tr>
<td>RVAD</td>
<td>Right atrium or ventricle</td>
<td>Pulmonary artery</td>
<td>Pre-peritoneal or intra-abdominal</td>
</tr>
<tr>
<td>BiVAD</td>
<td>Right atrium or ventricle, Left atrium or ventricle</td>
<td>Pulmonary artery, Aorta</td>
<td>Pre-peritoneal or intra-abdominal</td>
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III. Clinical trials:
A. Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH)
   - **LANDMARK STUDY**
   - 1998-2001
   - Multicenter study conducted at 20 cardiac transplant centers in the U.S.
   - Compared optimal medical management vs. LVAD in CHF patients who were not candidates for transplant
   - Results: 129 patients enrolled. Patients with LVAD had 48% risk reduction in all-cause mortality, 52% 1-year survival (25% in medical group), 29% 2-year survival (13% in medical group)
   - Led to FDA-approval of VAD as a destination therapy

B. Investigation of NonTransplant-Eligible Patients who are Inotrope Dependent (INTrEPID)
   - 2000-2003
   - Prospective, non-randomized
   - Results: 55 patients enrolled: 37 received LVAD and 18 received optimal medical therapy (OMT). LVAD group had 46% 6-month survival (22% OMT), 27% 1-year survival (11% OMT). 5 LVAD patient improved sufficiently to become cardiac transplant candidate (1 OMT)
   - Conclusion: LVAD is superior to medical therapy in a very sick patient population requiring chronic inotropic support.

IV. Complications
Interagency for Mechanically Assisted Circulatory Support (INTERMACS) tracks adverse events related to mechanical circulatory support devices that are FDA-approved in use in the U.S.

A. Device failure
   - Operating system, power source, or drive pump failure
   - 6% of patients experience device failure at 6 months, 64% at 2 years post-implantation
   - Second leading cause of death in REMATCH study
   - Only the Thoratec HeartMate XVE has a pneumatic hand pump backup system
   - Continuous flow LVADs have no valves so pump failure can result in retrograde flow
   - Device will alarm if pump has stopped working or is about to stop working, detects low-flow state, detects low battery state
   - Patient presenting with acute decompensated heart failure, increasing frequency in alarms, new or strange noises from the device, or new or strange sensations in the chest should prompt evaluation for VAD dysfunction:
• If the pump is running:
  1. Check all lead connections
  2. Reconnect any loose or disconnected leads

• If the pump is not running:
  1. Audible alarm will sound
     a. If due to complete power loss, system controller will not illuminate
     b. If the controller is still receiving power, controller will illuminate and indicate pump stop condition
  2. Make sure system controller is connected to a power source (battery or Power Base Unit)
  3. Make sure the driveline (or percutaneous lead) is connected to the system controller
  4. Make sure the percutaneous leads are not bent or kinked
  5. Press the “Test select” button or “Alarm reset” switch for 2 seconds. This may restart the pump
  6. Change power sources: if running on battery, switch to the Power Base Unit and vice versa (**change one battery at a time**)
  7. Switch to the back-up system controller
  8. Activate your cardiac catheterization laboratory
  9. Call VAD coordinator/manufacturer

• Was the device exposed to:
  • MRI
  • Static electricity: from television, vacuum, cell phone, etc
  • Water
  • Trauma to driveline, pocket, system controller

B. Thrombosis
  • Blood flowing over a non-biologic, non-native surface predisposes the patient to thrombosis
  • 3-35% of patients will experience thromboembolic disease
  • The Thoratec PVAD, IVAD, and Heartmate II require continuous anticoagulation. The Thoratec Heartmate XVE does NOT require anticoagulation.
  • Target INR = 1.5-2.5
  • CVA/TIA
    o REMATCH: 10 cerebral infarctions, 2 hemorrhagic strokes occurred in LVAD arm (16% occurrence rate). 42 strokes, TIAs, or metabolic encephalopathy occurred in 30/68 patients in LVAD group vs. 4 events in 4/61 OMT patients.
    o INTrEPID: 62% of LVAD patients experienced a stroke or TIA (20 patients had 30 strokes and 10 patients had 15 TIAs) versus 11% of OMT patients.
  • Pump thrombus
    o Should be suspected in presence of hemolysis, i.e. increased LDH, hemoglobinuria, or elevated plasma free HgB
HeartMate II clinical trial: 5/133 (4%) DT patients and 4/281 (1.4%) BTT patients experienced pump thrombus, requiring pump replacement and 2 died.

Consider angiography, echocardiography, or CT

Consider thrombolytic therapy in the crashing patient

C. Bleeding

- Hemorrhage is the most common complication associated with LVAD placement
- 30-50% of VAD implantations develop a bleeding complication
- May be due to:
  - Preoperative coagulopathy
  - Poor nutritional status
  - Cardiopulmonary bypass-induced thrombocytopenia
  - Platelet dysfunction
  - Extensive nature of surgery, including median sternotomy
  - Extensive abdominal wall dissection in creation of pump pocket

D. Infection

- VAD-related infections occur in 18-59% of VAD implantations
- Most common within first 3 months of VAD implantation
- Sepsis was leading cause of death in LVAD cohort in REMATCH and second leading cause of death in INTrEPID study
- Can occur at:
  - Surgical site
  - Driveline (most common) – infection can remain local or become systemic
  - Device pocket
  - Pump
  - Systemic: bacteremia, sepsis, endocarditis, mediastinitis, peritonitis, and pseudoaneurysm
- Infection usually involves multiple sites
- Common organisms
  - Staph aureus
  - Staph epidermis
  - Enterococci
  - Gram negative bacilli: Pseudomonas aeruginosa, Klebsiella, Enterobacter
  - Candida
- Decreased infection rates seen in continuous flow devices when compared with pulsatile flow
- Decreased infection rates seen in smaller devices when compared with larger VADs
- Totally implantable VADs should reduce risk of VAD-related infection
- Clinical presentation:
  - Fever
Leukocytosis
- Drainage, erythema, pain at or from driveline exit site
- Surgical site discharge, erythema, pain

**Work-up**
- Blood cultures
- Wound cultures
- Computed tomography – pocket infection/fluid collection
- Echocardiography – endocarditis
- Immunoscintigraphy – labeled WBC scan

**Treatment**
- Empiric broad-spectrum antibiotics, including fungal coverage
- Device infections require device removal
- Driveline infections may resolve with wound care and antibiotics but relapse is common
- Pump pocket infection require drainage and possible pump removal

**E. Right heart failure (RHF)**
- Known complication of LVAD
- 20-30% of LAVD implantations result in RHF
- Typically occurs in the immediate post-operative period
- Usually associated with perioperative hemorrhage and need for blood transfusion
- LV unloading via LVAD should decrease pulmonary artery pressures and, thereby, RV after-load. However, increased systemic venous return to a diseased RV that is unable to accommodate the increased volume results in RHF
- RHF compromises pump output due to subsequent reduced LVAD filling
- Pulmonary vasodilators and inotropic support should be initiated immediately
  - Sildenafil
  - Nitric oxide
  - Isoproterenol
  - Prostaglandins
  - ACE Inhibitors
  - Milrinone
- Consider transition to BiVAD

**F. Malignant cardiac dysrhythmia**
- Defibrillate, cardiovert, or give antiarrythmics as indicated by ACLS
- CPR can lead to trauma to the device and tissues in contact with the device
- Pump will continue to run but forward flow depends on blood initially reaching the atrium
- Remember that patients with continuous VAD pump will NOT have a pulse
• Thoratec Heartmate XVE: disconnect the driveline to the power supply/control console and hand-pump with a pneumatic device to avoid trauma from CPR

References