Ventricular Assist Devices:
What you and your EMS providers need to know!

National Association of EMS Physicians Annual Meeting

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DISCLOSURE

I have no relevant financial relationships with any commercial interests.
OBJECTIVES

- Explain how to evaluate a patient with an LVAD.

- List the ACLS treatments that are acceptable to perform in a patient with an LVAD.

- Explain how to appropriately transport a patient with an LVAD.

Congestive Heart Failure

- An extremely complex condition

- A condition in which the heart can no longer effectively pump enough blood to the rest of the body

- Typically heart failure is a chronic, long-term condition

Congestive Heart Failure

- Systolic heart failure
  - The heart cannot pump, or eject, the blood out of the heart very well

- Diastolic heart failure
  - The heart muscles are stiff and do not fill up with blood easily
Congestive Heart Failure

- Most commonly caused by ischemic heart disease
  - 70% of HF cases in the US

Causes of Heart Failure

- Conditions that damage the heart muscle or limit its ability to function normally:
  - Coronary artery disease (most common)
  - Hypertension
  - Cardiomyopathies
  - Drugs – B-blockers, CC-blockers, cytotoxic drugs
  - Toxins – EtOH, cocaine, mercury, cobalt, arsenic
  - Endocrine conditions – DM, hyper/hypo-thyroid
  - Infiltrative conditions – sarcoidosis, amyloidosis
  - Chagas’ disease
  - HIV
  - End-stage renal disease

- Conditions that reduce cardiac output:
  - Increased vascular resistance with hypertension
  - Abnormal heart rhythm: a-fib, v-tach
  - Pericardial disease
  - Obstructive sleep apnea
  - Aortic stenosis
Causes of Heart Failure

- Conditions that result in a high cardiac output:
  - Anemia
  - Thyrotoxicosis
  - Septicemia
  - Liver failure
  - AV shunts
  - Pegat’s disease
  - Thiamine deficiency

Classification of HF

- New York Heart Association
  - Classifies HF into classes based on functional limitations and severity
    - Class I (Normal): Few observable symptoms, no limitations in ordinary physical activity.
    - Class II (Mild): Mild observable symptoms and slight limitation during ordinary activity. Comfortable at rest.
    - Class III (Moderate): Marked limitation in physical activity due to symptoms even during less-than-ordinary activity. Comfortable only at rest.
    - Class IV (Severe): End-stage HF. Severe limitations. Experience symptoms even while at rest.

Classification of HF

- ACC/AHA Classification of HF
  - Classification from risk for developing disease to severe disability with disease.
    - Stage A (High risk for developing HF): HTN, DM, CAD, family history
    - Stage B (Asymptomatic HF): Previous MI, valvular disorders, LV dysfunction
    - Stage C (Symptomatic HF): Structural heart disease, fatigue, low tolerance for physical activity
    - Stage D (Refractory end-stage HF): Severe limitations. Experience symptoms even while at rest.
Epidemiology

- HF effects 6–10% of all people over the age of 65
- 2 million patients worldwide have end-stage HF
- 5.7 million Americans have HF

Epidemiology

- HF is responsible for more hospitalizations than all cancers combined
- Rehospitalization rates during the 6 months following discharge are 50%

Epidemiology

- 550,000 new cases of HF diagnosed every year
- 300,000 deaths from HF each year
Prognosis

- Pts with NYHA class IV, ACC/AHA stage D HF have more than 50% mortality at 1 year
- HF associated with acute MI has an inpatient mortality rate of 20–40%
  - Mortality approaches 80% in pts who are also hypotensive (cardiogenic shock)

Treatment

- Correction of systemic factors
- Lifestyle modifications
- Removal of “bad” drugs
- Vaccinations
- Treatment of the cause of the HF
- Medications to treat symptoms
- Medications to improve patient survival
- Devices
- Mechanical
- Heart Transplant

Medications to improve patient survival
Beneficial effects of mechanical support

- Improvement in myocardial contractile performance
- Reversal of downregulation of beta receptors seen in HF, with restoration in the ability of the heart to respond to the inotropic effects of sympathetic stimulation
- Normalization of chamber geometry, reduction of myocardial fibrosis, hypertrophy, and disruption in cytoskeletal proteins

The structural reverse remodeling is generally complete by about 40 days, with evidence of clinical benefit and an improvement in quality of life

In one study of 15 men, exercise capacity and peak VO2 at 12 weeks after LVAD implantation were comparable to that seen at 12 weeks and one year after heart transplantation
Feasibility trials were conducted for different device therapies over the last 15 years.

For patients with refractory heart failure, LVAD destination therapy (DT) has been shown to have better survival than optimized medical therapy (OMT).

Clinical Trials for DT
- REMATCH
- INTePIDs
- CUBS
- INTERMACS Registry
REMATCH

- The landmark trial for DT
- 900 pts screened
- Randomized 129 patients with end stage heart failure ineligible for heart transplant to either implantation of Heartmate XVE or OMT
- All patients had to have:
  - OMT for at least 60 of the last 90 days
  - Thought to have a life expectancy of < 2 years at time of enrollment

REMATCH

- NYHA IV
- EF < 25%
- Peak O2 consumption < 12 ml/kg/min or dependence on IV inotropes

REMATCH

- Improved NYHA functional class from IV to II
- 1 and 2 year survival on LVAD 52% and 23%
- 1 and 2 year survival on OMT 25% and 8% (p = 0.009)
- Median survival 408 days in LVAD group and 150 days in OMT group
- At the time of final analysis there were 41 deaths out of 68 and the main cause was sepsis (41%) and device failure (17%)
REMATCH
- Apart from the primary outcomes, most others were disappointing
  - Only 50% survived for 1 year
  - Quality of life was not greatly improved
  - 10 of 68 LVADs replaced, 2 patients had a 3rd LVAD

This trial was >10 years ago and the technology was different (used pulsatile flow)

INTTrEPI
- Novacor LVAD for patients who were considered inotrope dependent in prospective NONrandomized study
  - 55 patients at 13 centers (US and Canada)
  - Included adults with inotrope dependent Stage D heart failure, EF < 25%, NYHA IV for the 3 months before enrollment, non-transplant candidates
Treatment – VAD

- **INTrEPID**
  - Both groups had end-organ hypoperfusion
  - Survival at 6 months: LVAD 46%, OMT 22%
  - Survival at 12 months: LVAD 27%, OMT 11%
  - Majority cause of death in LVAD group
    - Stroke 34%
    - 62% of patients in LVAD group developed a stroke (especially in the 1st month of transplant)
    - Infection 24%

- **INTrEPID**
  - The survival rate was less than in REMATCH
  - Device failure was lower than in REMATCH

- **intermacs**
Indications for assist device
- Patients who face imminent death
- Unable to come off cardiopulmonary bypass after surgery
- Massive acute MI
- Acute myocarditis with severe decompensation
- Severe rejection to previous heart transplant
- Refractory HF as a “bridge to transplantation”
- Chronic HF with a very poor long-term prognosis and are not transplant candidates (age, malignancy, COPD, non-compliance, etc)
Treatment – VAD

Criteria for left ventricular assist device implantation

- Active heart transplant candidate
- On maximal inotropic support, with or without intraaortic balloon pump
- Systolic blood pressure < 90 mmHg OR
- Cardiac index < 2.5 L/min/m² OR
- Pulmonary capillary wedge pressure > 20 mmHg

Mechanics

- Continuous flow
  - Significantly smaller size and weight
  - Improved outcomes
- Pulsatile flow
  - More physiologic
  - Larger in size and weight
  - Worse outcomes

Components

- Pump
- System controller
- Drive/Power line
- Batteries and battery clips
- Power base unit
- Power base unit cable
- Display module

***ALWAYS TRANSPORT ALL COMPONENTS OF THE DEVICE WITH THE PATIENT***
Components

- Pump
  - Can be paracorporeal
    - Pump is located outside the body
  - Can be implanted internally below the diaphragm
    - Intraperitoneal
    - Properitoneal
Treatment – VAD

- Pump
  - Can be implanted internally below the diaphragm
    - Intraperitoneal
    - Properitoneal

System controller
- A small computer that serves as the "brain" of the VAD
- Connected to the pump and to the power supply
- Warning system for pump operations
Treatment – VAD

- System controller

![System controller image]

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Treatment – VAD

- BatteryFuelGage
- BatterySymbol
- PowerSymbol (green)
- ControllerCellSymbol (yellow)
- RedHeartSymbol
- SilenceAlarmsButton

![VAD control panel image]

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Treatment – VAD

1. Make sure System Controller is connected to the pump.
2. Make sure System Controller is connected to a power source (batteries, AC, or DC).
3. If alarm continues, immediately call for emergency help (911 if available), then call your hospital contact person.

![Warning icon]
Patient Assessment

How do you assess a patient with a VAD?
- May be pulseless
- May not be able to obtain pulse oximetry

- May not be able to obtain NIBP (via conventional methods)
- SPEAK TO THE PATIENT!!!
- End tidal CO2
- Manual BP via Doppler and sphygmomanometer or arterial line

Imaging

Anastomosis of outflow graft to ascending aorta

Outflow graft with surrounding vessel rela. Contrast fills entire graph with no evidence of kinking

Vet portion of the inflow cannula at LV apex
What are the potential complications associated with a VAD?

- Mechanical failure
- Power failure
- Thrombosis
- Infection
- Bleeding
- Dysrhythmia
What are the potential complications associated with a VAD?

- Mechanical failure
  - Should I do CPR?
    - With the majority of devices, the answer is NO!!!
    - There is a high risk of displacing the connections to the heart

- Power failure
  - Make sure the unit is connected to a power source
  - Never disconnect both batteries at the same time
  - Make sure the outlet the power unit is connected to is not controlled by a switch

  ***Batteries are temperature sensitive***
  ***The patient and the patient’s caregiver know the system best***

- Thrombosis
  - Blood is flowing over a non-biologic, non-native surface predisposes to thrombosis
  - 3–35% of patients with a VAD will experience thromboembolic disease
  - Most patients with VADs require continuous anticoagulation
What are the potential complications associated with a VAD?

- **Thrombosis**
  - CVA/TIA
    - REMATCH: 30/68 LVAD vs 4/61 OMT
    - INTrEPID: 62% LVAD vs 11% OMT
  - Pump thrombus
    - HeartMate II trial: 4% DT and 1.4% BTT
    - 2 required pump replacement, 2 died
    - Consider angiography, echo, or CT
    - Consider thrombolytic therapy in crashing patient

- **Infection**
  - Sites:
    - Surgical site, driveline (most common), device pocket, pump, systemic
  - Organisms:
    - Staph aureus, staph epidermis, enterococci, gram negative bacilli (pseudomonas, klebsiella, enterobacter), candida
What are the potential complications associated with a VAD?

- Bleeding
  - Hemorrhage is the most common complication of VAD placement
  - 30–50% of VAD implantations are complicated by bleeding
  - Causes:
    - Preoperative coagulopathy, poor nutritional status, thrombocytopenia, platelet dysfunction, extensive nature of surgery (median sternotomy and abdominal wall dissection), therapeutic anticoagulation
What are the potential complications associated with a VAD?

- Dysrhythmia
  - *Defibrillate, cardiovert, or give antiarrhythmics as indicated by ACLS***
  - NO CPR
  - Pump will continue to run but forward flow depends on blood initially reaching the atrium
  - *Patients with a continuous flow VAD pump may NOT have a pulse***

Complications

Patients are told to call EMS if they have a problem, BUT:

Community services. Community preparation varies greatly among users and should be individualized accordingly. Training of emergency medical services personnel on proper LVAS emergency measures should be considered. Specific written instructions or an emergency identification card with contact numbers to the VAD center for emergency notification should be with the patient at all times.

CASE CONFERENCES

SUSTAINED VENTRICULAR FIBRILLATION IN AN ALERT PATIENT: PRESERVED HEMODYNAMICS WITH A LEFT VENTRICULAR ASSIST DEVICE

Purnam Patel, MD, Jefferson C. Williams, MD, MPH, Jane H. Brice, MD, MPH

PREHOSPITAL EMERGENCY CARE 2011:335-336
Complications

Asymptomatic Sustained Ventricular Fibrillation in a Patient With Left Ventricular Assist Device

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Volume 21, no. 5—January 2011
Annals of Internal Medicine 21

Complications

The High-Tech Heart: LVAD emergencies in pre-transplant patients

Complications

Pumping Life Into Failing Hearts

What EMS providers should know about ventricular assist devices

Published: March 25th, 2011 10:14 PM EDT
SUMMARY

- Heart failure is complex
- Heart failure treatment is aimed at treating symptoms, decreasing mortality, and prevention of disease progression
- VADs are used as a bridge to further treatment or as destination therapy
- Most VADs are continuous flow and the patients will not have a pulse
- Most VADs result in CPR being contraindicated
- For dysrhythmias, follow ACLS guidelines

HeartMate II

- Support duration: Long-term
- Location: Abdominal implant
- Flow type: Centrifugal
- Defib/Cardioversion: OK
- Chest compressions: NO
- Back-up: Built in

HeartMate XVE

- Support duration: Long-term
- Location: Abdominal implant
- Flow type: Pulsatile
- Defib/Cardioversion: Only when hand-pumping
- Chest compressions: NO
- Back-up: Hand pump, pneumatic driver
HeartWare

- Support duration: Long-term
- Location: Pericardial implant
- Flow type: Axial
- Defib/Cardioversion: OK
- Chest compressions: NO
- Back-up: Built in

VentrAssist

- Support duration: Long-term
- Location: Abdominal implant
- Flow type: Centrifugal
- Defib/Cardioversion: OK after putting to battery
- Chest compressions: OK once in CPR mode
- Back-up: Built in

Thoratec VAD

- Support duration: Long-term
- Location: Paracorporeal implant
- Flow type: Pulsatile
- Defib/Cardioversion: OK
- Chest compressions: NO
- Back-up: Hand pump, second console