Common Complications Associated With Left Ventricular Assist Device (LVAD) Implantation

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Overview

- Heart failure in the United States
- Mechanical circulatory support (MCS)
- Left ventricular assist devices (LVADs)
- Optimizing outcomes of LVAD implantation

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Heart Failure in the United States

- Affects about 6 million people
- More than 100,000 individuals with progressive heart failure:
  - Are refractory to available treatments
  - Have high rates of hospitalization and mortality
  - Have poor quality of life due to limited physical and social activities and psychological stress
- Heart transplantation is currently the preferred treatment for end-stage heart failure
  - However, donor hearts are in short supply and many patients do not meet the criteria for transplant

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CDC. *Heart Failure Fact Sheet*. 2012.

Mechanical Circulatory Support:
An Alternative to Transplantation

- Implantable mechanical pumps assist circulation of blood by one or both ventricles of the heart have evolved over several decades
- Potential candidates for ventricular assist devices (VADs) include patients who:
  - Are no longer responsive to conservative medical treatment
  - Are not candidates for a heart transplantation
  - Are awaiting a heart transplantation
  - Have acute heart failure and whose myocardial function is expected to return

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What Is An LVAD?

- A surgically implanted mechanical pump that is attached to the heart
  - Continuously takes blood from the left ventricle and moves it to the aorta, which then delivers oxygen-rich blood throughout the body
- Differs from an artificial heart, which replaces the failing heart completely
  - LVADs work with the heart to help it pump more blood with less work
- Can be extracorporeal, paracorporeal, implantable with percutaneous power support, or fully implantable
- May provide continuous or pulsatile flow

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Indications for LVAD Implantation

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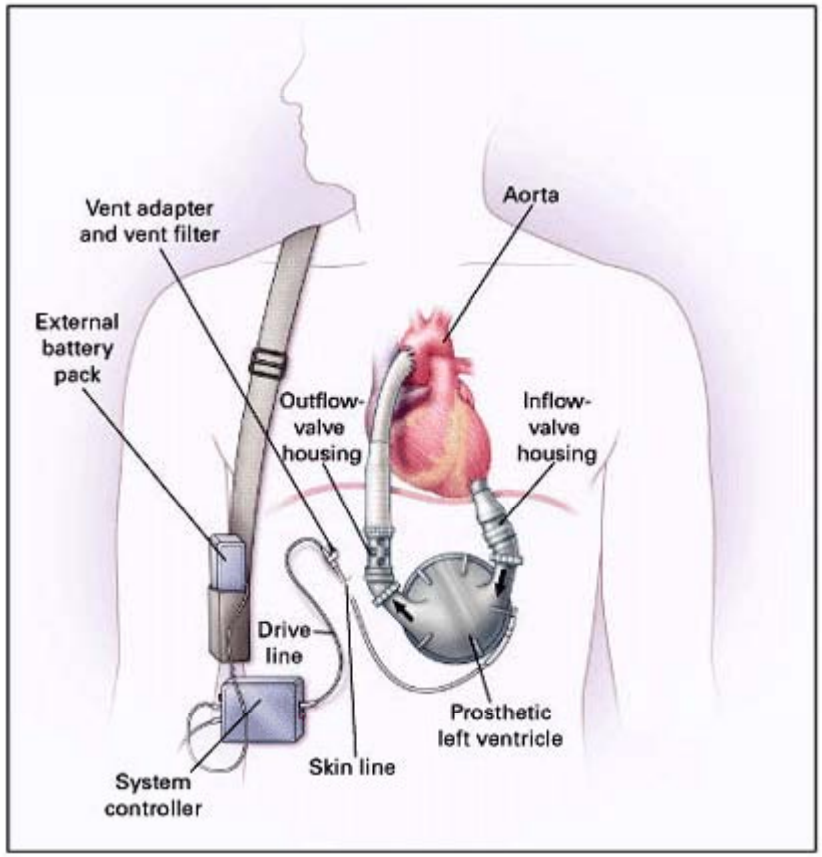
Bridge to Transplantation

- Patients who require heart transplantation but who have a poor predicted survival to transplant can undergo LVAD implantation
- At the time of transplant, the native heart and LVAD are removed and replaced by the donor organ



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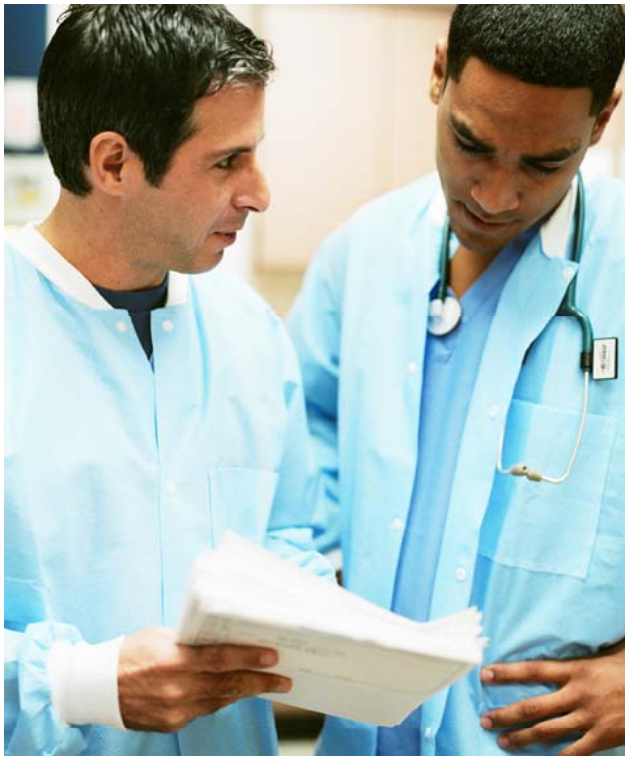
Bridge to Recovery



- LVAD may be placed in a patient with cardiogenic shock with the intent to remove it after the shock condition has resolved
- Patients in either precardiotomy cardiogenic shock or postcardiotomy shock may benefit from LVAD placement until the heart has recovered enough function that support is no longer required

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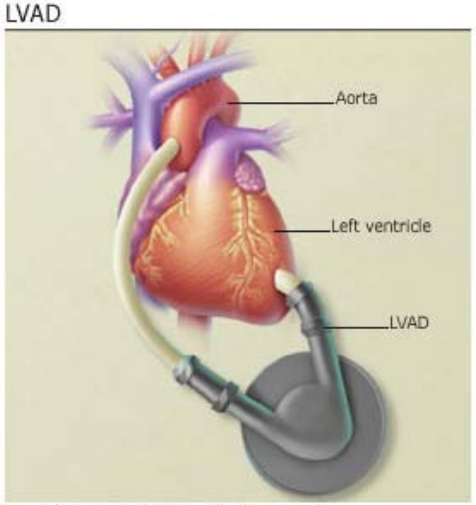
Destination Therapy: The Most Recently Approved Indication

- LVAD implantation may be used for patients:
  - With end-stage heart failure and poor predictive survival in their current medical state
  - Who are not eligible for transplantation (usually due to advanced age, significant comorbidities, or psychosocial issues)
- Patients undergo permanent LVAD implantation



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Complications Associated With LVAD Placement and Contributing Risk Factors

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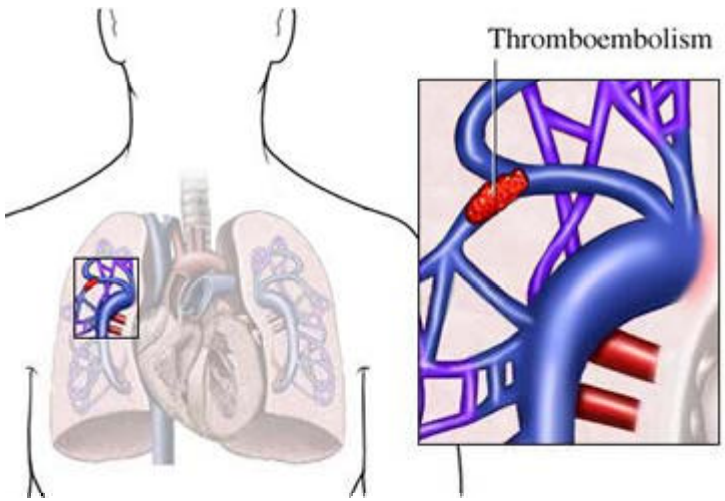
Thromboembolism



- Clot formation may result from contact between foreign surface of the device and patient's blood
- Most events are cerebrovascular, but often accompanied by other events (e.g., peripheral embolization of the kidneys, extremities, or visceral arteries)
- The reported incidence of thromboembolic events ranges from 10% to 25%

Limathe et al. *Transplant Proc*. 2004;36:3123-3128.

Thromboembolism: Risk Factors & Interventions

- Risk depends on factors such as:
  - Presence of infection
  - Pump design
  - Anticoagulation regimen used
- Interventions to prevent:
  - Adequate anticoagulation therapy
  - Careful preoperative patient selection
  - Limiting device implantation in patients with significant neurological history
  - Revascularization of carotid arteries in patients with carotid stenosis

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Limathe et al. *Transplant Proc*. 2004;36:3123-3128.
Pae et al. *J Heart Lung Transplant*. 2007;26:1-7.

Hemorrhage

- Postoperative bleeding occurs in 60% of patients with VADs; 20% to 40% of patients undergo reoperation
- May contribute to further complications
  - Hypoperfusion, multiorgan failure, or intracranial bleeding
  - If a patient requires massive blood transfusion, there is further risk for respiratory failure that can lead to adult respiratory distress syndrome

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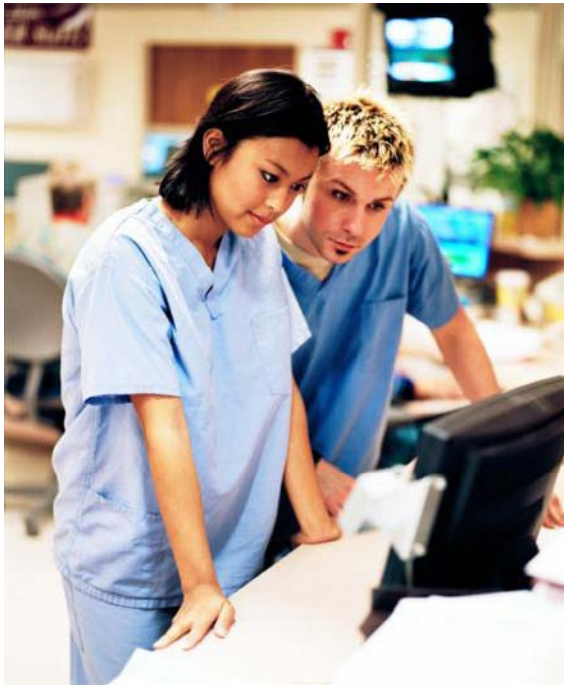
Amir et al. *Tex Heart J*. 2005;32:399-401.
Hampton et al. *Artif Organs*. 2002;26:902-908.

Risk Factors for Hemorrhage

- Need for anticoagulation
- Prolonged surgical procedure with cardiopulmonary bypass
- Extensive surgical dissection
- Hepatic dysfunction



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Shinn. *J Cardiovasc Nurs*. 2005;20:S22-S30.

Right Ventricular (RV) Failure

- Occure in about 11% of patients following LVAD insertion
  - Significantly increases mortality and morbidity
  - Higher rates of hemorrhage and kidney failure
  - Lower bridge to transplantation rates
- RHF may develop suddenly after LVAD insertion
- Some degree of RV dysfunction may have existed before surgery, but the RV failure does not become apparent until after surgery
  - There is an obvious imbalance between the newly supported left ventricle and the failing right ventricle

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Deng et al. *J Heart Lung Transplant*. 2005;24:1182-1187.

What Causes RV Failure?

- LVAD insertion reduces RV efficiency
  - Mechanical emptying of the left ventricle causes intraventricular septum to bulge away from right ventricle into the left
  - Improved function of the left ventricle causes higher forward flow of blood into the systemic circulation, increasing venous return that may rise beyond the capability of the right ventricle
- Other factors that contribute
  - Myocardial stunning, ischemia, arrhythmias, increased pulmonary vascular resistance

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Dang et al. *J Heart Lung Transplant*. 2006;25:1-5.
Kavarana et al. *Ann Thorac Surg*. 2002;73:745-750.

Infection

- May be manifested by:
  - Pneumonia
  - Mediastinitis
  - Urinary tract infections
  - Line sepsis
- Device-related chronic infections:
  - Driveline infections
  - Pump pocket infections
  - Endocarditis
  - Sepsis

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Shinn. *J Cardiovasc Nurs*. 2005;20:S22-S30.

Risk Factors for Infection

- Increased patient susceptibility to pathogens when malnourished and weakened preoperatively
- Comorbidities
  - Diabetes, obesity, and chronic obstructive pulmonary disease
- Other factors
  - Length of preoperative hospital stay, postoperative bleeding, blood transfusions, and the need for surgical re-exploration
- Device design
  - Percutaneous drivelines are exposed to outside pathogens
  - Devices have many cavities and pockets that harbor microorganisms
  - Turbulent blood flow through the pumps contributes to adherence of pathogens to device surfaces

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Mekontso-Dessap et al. *Clin Infect Dis*. 2002;35:1308-1313.
Raman et al. *Cardiology*. 2004;101:104-110.

Optimizing Outcomes

- The highest risk of death after LVAD implantation is before hospital discharge
- Major determinants of successful implantation
  - Patient selection
  - Timing of implantation
- Main criteria for selecting appropriate candidates with a potentially good outcome
  - Assessment of the patient's severity of illness
  - Patient's ability to successfully undergo the implant procedure

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Assess Compliance With Evidence-Based Guidelines

- Evidence-based clinical practice guidelines developed by professional societies
  - American Heart Association (AHA)
  - International Society of Heart and Lung Transplantation (ISHLT)

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AHA 2012 Recommendations for MCS

- Includes general considerations for determining appropriateness of MCS
- Discusses management strategies for the MCS patient, including selection criteria
- Underscores two principles that have evolved over the past decade
  - Some patients are too profoundly ill with multisystem organ failure to benefit from the best MCS and aggressive inotropic therapy
  - Complex decisions about candidacy for transplantation or MCS are best made by an experienced multidisciplinary team

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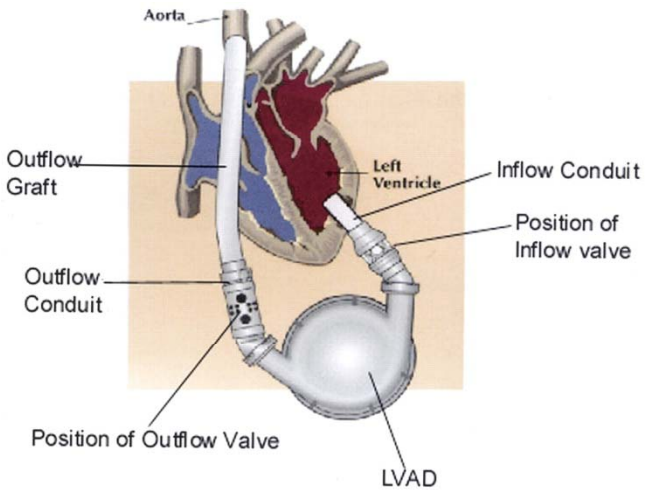
Peura et al. *Circulation*. 2012 Oct 29. [Epub ahead of print.]

ISHLT 2013 Guidelines for MCS



- Addresses all phases of evaluating, implanting, and managing patients who receive LVADs or related equipment
  - Patient selection
  - Preparing patients for implantation
  - Intraoperative and immediate postoperative care
  - Inpatient and intermediate-term postoperative care
  - Long-term outpatient care

Feldman et al. *J Heart Lung Transplant*. 2013;32:157-187.

Ensure Proper Documentation

- Thorough physician documentation is critical for reimbursement of LVAD implantation
- Most insurance companies cover LVADs approved by the FDA as medically necessary when used in accordance with device-specific, FDA-approved indications and contraindications

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General Documentation Requirements for LVADs

- Bridge to recovery
  - Acute cardiogenic shock, acute myocarditis, or unsuccessful weaning from cardiopulmonary bypass following cardiac surgery
- Bridge to transplantation
  - Risk of imminent death from left ventricular heart failure
- Destination therapy
  - NYHA Class IV end-stage left ventricular heart failure
  - LVEF <25%
  - Demonstrated functional limitations, with peak oxygen consumption ≤14 mL/kg/min
  - Failure of optimal medical therapy according to device-specific parameters

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Identify Physicians' Knowledge, Attitudes, and Competencies

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Physician Privileging

- Recognizes physician qualifications and competency
- Defines a physician's scope of practice and the clinical services he or she may provide
- Based on demonstrated competence
- A data-driven process

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Determining Physician Qualifications

- Involves gathering information to decide the types of care, treatment, and services or procedures that a practitioner will be authorized to perform in a specific setting
- Factors to consider
  - Setting-specific characteristics
  - Physician's education, training, and clinical experience

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Optimizing the Process of Physician Privileging

- Requires qualified and objective physician-controlled peer review, with decisions that are:
  - Fair and without conflicts of interest
  - Based on dated, detailed documentation
  - Confidential and protected
- Documented physician performance should be measured against criteria that are:
  - Directly related to quality of patient care
  - Established through common legal, professional, and administrative practices
  - Endorsed by a formal consensus process
  - Publicly available

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The Cost of Retaining Incompetent and Low-Quality Providers

- Potential legal liability for any injuries to patients
- Exclusion from federal and state health benefit program participation
- Loss of commercial contracts
- Loss of accreditation by healthcare standards organizations

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Measure Patient Outcomes

- Evaluate the efficacy and safety of LVAD implantation
  - Mortality rates
  - Postoperative morbidity
- Identifying appropriate patients before the onset of significant organ dysfunction can improve survival and reduce the degree of morbidity

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External Peer Review Ensures Quality of Care

- Ongoing evaluation of hospital practitioners ensures excellence in physician performance and the highest standard of care for patients
- External peer review allows hospitals to perform:
  - In-depth evaluation of sentinel events
  - Credentialing and re-credentialing
  - Privileging and re-privileging
  - Proctoring
  - Ongoing measurement and monitoring of physician performance

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Internal vs. External Peer Review

- Internal peer review
  - Peer review committees composed primarily of in-house personnel often lack the resources to help the hospital achieve their performance improvement goals
  - Social and professional relationships lead to conflicts of interest
- External peer review
  - Avoids conflicts of interest that can arise from economic, professional, or social ties among physicians within a single institution
  - May be an effective solution for hospitals that lack adequate physician resources to conduct timely performance analyses

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Systematic External Peer Review As a Risk Reduction Strategy

- Reduces medical errors through objective evaluations performed in a nonpunitive, educational context that supports a culture of continuous improvement
- Improves quality of care and patient safety
  - Physicians know that their work will be objectively evaluated at regular intervals by board-certified specialists with the same credentials and from similar practice settings
- Uncovers problematic practice patterns and physician- and hospital-level issues that need to be addressed before they turn into claims

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Conclusions

- Mechanical circulatory support has evolved considerably in recent years
  - LVADs emerging as the standard of care for advanced heart failure patients requiring long-term MCS
- LVADs improve patient outcomes and quality of life, but complications persist due to:
  - Pre-existing effects of advanced heart failure
  - The requirement for extensive surgery to implant the device
  - The effects of the device in compromised patients

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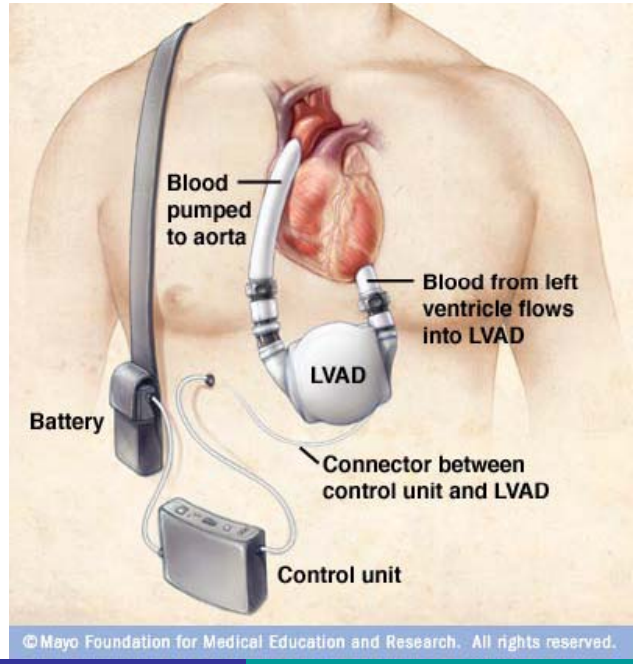
Conclusions (cont'd)

- Patient selection for LVAD therapy is the most important process in obtaining a successful outcome
- Evaluation requires assessing the appropriateness for device implantation based on need and risk of LVAD implant to the patient



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Questions & Answers

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Thank you for attending. All participants will receive a free copy of our latest publication via email:

"Common Complications Associated with Left Ventricular Assist Device (LVAD) Implantation"

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