Executive Summary

Left ventricular assist devices have become an established treatment for patients with advanced heart failure, as a bridge to transplantation or recovery, or as a long-term option for those who are not candidates for cardiac transplantation (destination therapy). Although studies have clearly shown that LVADs can significantly improve quality of life for patients, there are substantial risks associated with these devices. Careful patient selection for LVAD implantation may help to prevent significant potential risks and complications, as well as to improve the efficacy of these procedures.

Introduction

Heart failure affects about 6 million people in the United States, and more than 100,000 people in the United States with progressive heart failure are refractory to available treatments and have high rates of hospitalization and mortality and a 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. Unfortunately, the supply of donor hearts is far less than needed and many patients do not meet the criteria for heart transplantation, primarily due to old age and comorbidities such as diabetes with damage to vital organs, pulmonary hypertension, renal insufficiency, malignancies, and morbid obesity.

Implantable mechanical pumps that assist the circulation of blood by one or both ventricles of the heart have evolved over several decades. Throughout the 1990s, ventricular assist devices (VADs) underwent many modifications to improve reliability and reduce complications, as well as to improve utility and ease of use for patients living with these devices. Potential candidates for VADs include patients who: are no longer responsive to conservative medical treatment; are not candidates for a heart transplantation; are awaiting a heart transplantation; and have acute heart failure and whose myocardial function is expected to return. Although VADs improve the mortality and quality of life of patients with heart failure, the devices also carry risk of potentially life-threatening complications.

How LVADs Work

Ventricular assist devices function to reduce myocardial work by reducing ventricular preload while maintaining systemic circulation. The devices may be extracorporeal, paracorporeal, implantable with percutaneous power support, or fully implantable, and may provide continuous or pulsatile flow. Ventricular assist devices may provide left ventricular support (LVAD), right ventricular support (RVAD), or biventricular support (BiVAD).

An LVAD is a surgically implanted mechanical pump that is attached to the heart. An LVAD differs from an artificial heart because it works with the heart to help it pump more blood with less work, instead of replacing the failing heart completely. The LVAD continuously takes blood from the left ventricle and moves it to the aorta, which then delivers oxygen-rich blood throughout the body.

The LVAD has both internal and external components. The actual pump sits on or next to the heart’s left ventricle with a tube attached that routes the blood to the aorta. A cable called a driveline extends from the pump, out through the skin, and connects the pump to a controller and power sources worn outside the body. Batteries or electricity power the pump.

Currently, there are several different LVAD models available. Each has unique engineering characteristics and different external equipment, but they all serve the same function. Earlier LVAD models were larger, noisier, and less durable, with bulkier power sources.
Indications for LVAD Implantation

Left ventricular assist devices are used to treat patients with end-stage heart failure to improve survival and quality of life. Patients who require heart transplantation but who have a poor predicted survival to transplant can undergo LVAD implantation as a bridge to transplantation. At the time of transplant, the native heart and LVAD are removed and replaced by the donor organ.

An LVAD may also be placed in a patient with cardiogenic shock with the intent to remove it after the shock condition has resolved. This indication is known as bridge to recovery. Patients in either precardiotomy cardiogenic shock (e.g., fulminating myocarditis, acute myocardial infarction) or postcardiotomy shock (e.g., postcoronary artery bypass graft, postaortic valve replacement) may benefit from LVAD placement until the heart has recovered enough function that support is no longer required.

The most recently approved indication for LVADs is use as destination therapy 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 contraindicating transplant). These patients undergo permanent LVAD implantation.

Complications Associated with LVAD Placement & Contributing Risk Factors

Although LVADs improve clinical outcomes in patients with advanced heart failure, the devices are associated with potentially life-threatening complications such as thromboembolism, hemorrhage, right ventricular (RV) failure, and infection. Numerous studies have evaluated the impact of specific preoperative comorbid conditions on LVAD outcomes. Factors that contribute to poor outcome following LVAD implantation may include: age, sepsis, and advancing degrees of organ dysfunction, particularly renal and hepatic dysfunction. Thorough preoperative evaluation is necessary to determine whether significant comorbidities exist that pose perioperative risk. Family and psychosocial support and preoperative neurologic function may also affect LVAD outcomes. Patients considered for LVAD therapy should have no major irreversible cognitive defects that would limit their understanding of LVAD maintenance and ability to troubleshoot LVAD alarms.

Thromboembolism

Thromboembolism is one of the main concerns in patients with LVADs. The reported incidence of thromboembolic events ranges from 10% to 25%. The risk for the development of thromboembolism depends on factors such as presence of infection, the pump design, and the anticoagulation regimen used. Most thromboembolic events are cerebrovascular, but they are often accompanied by other events such as peripheral embolization of the spleen, kidneys, extremities, or visceral arteries. The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial reports that 24% of patients with LVADs experienced significant neurological events including stroke, transient ischemic attack, and toxic encephalopathy.

Thromboembolic complications occur as a result of the contact between the foreign surface of the device and the patient’s blood. The blood-foreign body interaction activates immune cells and coagulation pathways and attracts platelets and complement proteins, thus initiating the formation of a clot.

Adequate anticoagulation therapy is the single most effective measure to prevent formation of thrombi. Studies have shown that ineffective anticoagulation after implantation is the strongest risk factor for thromboembolic complications. Other interventions used to prevent thromboembolic complications include careful preoperative patient selection, limiting the device implantation in patients with significant neurological history, as well as revascularization of carotid arteries in patients with carotid stenosis.

Hemorrhage

Postoperative bleeding is a frequent occurrence in patients with VAD. It occurs in 60% of patients with VAD, and ap-
proximately 20% to 40% of patients undergo reoperation to treat hemorrhage. Factors that contribute to postoperative bleeding include need for anticoagulation, prolonged surgical procedure with cardiopulmonary bypass, and extensive surgical dissection. In addition, patients with heart failure are frequently prone to bleeding because they experience hepatic dysfunction due to hepatic congestion.

Postoperative hemorrhage may contribute to further complications such as 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.

**RV Failure**

Patients with LVADs are at risk for the development of right heart failure (RHF), which is associated with a significant rise in mortality and morbidity, higher rates of hemorrhage and kidney failure, and lower bridge to transplantation rates. It is estimated that RHF occurs in approximately 11% of patients after the insertion of the device.

Right heart failure may develop suddenly after LVAD insertion. Although some patients may have had some degree of RV dysfunction before the surgery, the RV failure does not become apparent until after surgery when there is an obvious imbalance between the newly supported left ventricle and the failing right ventricle. The mechanical emptying of the left ventricle causes the intraventricular septum to bulge away from the right ventricle into the left ventricle, thus reducing RV efficiency. Furthermore, the improved function of the left ventricle causes higher forward flow of blood into the systemic circulation. This increases venous return that may rise beyond the capability of the right ventricle. Other factors that contribute to decline of RV function after LVAD implantation include myocardial stunning, ischemia, arrhythmias, and increased pulmonary vascular resistance.

**Infection**

Infection is a frequent complication of LVAD implantation and may be manifested by pneumonia, mediastinitis, urinary tract infections, or line sepsis. However, patients may also experience device-related chronic infections such as driveline infections, pump pocket infections, endocarditis, or sepsis. The high rates of infections among patients with LVAD may be related to the fact that the patients are already malnourished and weakened preoperatively and, therefore, more susceptible to pathogens. Risk for infection may also increase with patient comorbidities, especially diabetes, obesity, and chronic obstructive pulmonary disease, as well as other factors such as length of the preoperative hospital stay, postoperative bleeding, blood transfusions, and the need for surgical re-exploration.

Patients are also vulnerable to device-related infections because the percutaneous drivelines are exposed to outside pathogens. In addition, the devices have many cavities and pockets that harbor microorganisms. They create a turbulent blood flow through the pumps which, contributes to the adherence of the pathogens to device surfaces. Device-related infections are associated with increased occurrence of thromboembolic events, strokes, and other complications, prolonging patient hospitalization and increasing healthcare costs.

**Optimizing Outcomes for LVAD Implantation**

The highest risk of death after LVAD implantation is before hospital discharge. Therefore, patient selection and the timing of implantation are two of the major determinants of success. Main selection criteria include assessment of the patient’s severity of illness and ability to successfully undergo the implant procedure. The selection of appropriate candidates with a potentially good outcome is of major importance in LVAD implantation.

**Assess Compliance with Evidence-Based Guidelines**

Insurance companies often base coverage decisions on evidence-based clinical practice guidelines developed by professional societies. In 2012, the American Heart Association published recommendations for the use of mechanical circulatory support (MCS). The statement includes general considerations for determining the appropriateness of MCS. The document discusses management strategies for the MCS patient, including selection criteria, and underscores
two principles that have evolved over the past decade: 1) some patients are too profoundly ill with multisystem organ failure to benefit from the best MCS and aggressive inotropic therapy; and 2) complex decisions about candidacy for transplantation or MCS are best made by an experienced multidisciplinary team.

More recently, the International Society for Heart and Lung Transplantation published the first comprehensive guidelines for all phases of evaluating, implanting, and managing patients who receive LVADs or related equipment. The guidelines address:

- Patient selection, including assessments of operative risk and discussion of ethical dilemmas
- Preparing patients for implantation, including risk-factor management, informed consent, and recommendations for multidisciplinary care
- Intraoperative and immediate postoperative care, covering a selection of operative technique, anatomic considerations, and intensive care unit management
- Inpatient and intermediate-term postoperative care, which includes hemodynamic management, anticoagulation, other medical management, care of the driveline and other hardware issues, and psychosocial support
- Long-term outpatient care, including multidisciplinary care, monitoring, long-term psychosocial support, and patient and family education

**Ensure Proper Documentation**

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

Individuals are usually required to have documented:

- Acute cardiogenic shock, acute myocarditis, or unsuccessful weaning from cardiopulmonary bypass following cardiac surgery (bridge to recovery)
- Risk of imminent death from left ventricular heart failure (bridge to transplantation in cardiac transplant patients)

When used as destination therapy for individuals who are not candidates for heart transplantation, many plans require documentation of all of the following criteria:

- New York Heart Association (NYHA) Class IV end-stage left ventricular heart failure
- Left ventricular ejection fraction (LVEF) <25%
- Demonstrated functional limitations, with a peak oxygen consumption of <14 milliliters per kilogram of body weight per minute
- Failure of optimal medical therapy according to device-specific parameters

**Identify Physicians’ Knowledge, Attitudes and Competencies: Credentialing and Privileging**

Credentialing physicians is an important step toward protecting patients from harm, while privileging physicians ensures that organizations have the most qualified and competent physicians on their medical staffs. Credentialing verifies that a physician meets standards as determined by an organization, by reviewing information regarding the individual’s license, experience, certification, education, training, malpractice and adverse clinical occurrences, clinical judgment, and character by investigation and observation; the process should also include conflict of interest questions in order to identify any potential financial incentives for performing more surgeries or using a particular device. Privileging defines a physician’s scope of practice and the clinical services he or she may provide. Privileging is based on demonstrated competence and is a data-driven process.

Physician privileging involves gathering information with which to decide the types of care, treatment, and services or
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procedures that a practitioner will be authorized to perform in a specific setting (e.g., hospital), taking into consideration setting-specific characteristics, such as adequacy of the facilities, equipment, and number and type of qualified support personnel and resources. Other criteria that determine the practitioner’s qualifications include the physician’s education, training (residency and/or fellowship), and clinical experience (number of procedures performed with satisfactory outcomes).

Credentialing and privileging require qualified and objective physician-controlled peer review, utilizing criteria that have been established through common legal, professional, and administrative practices, endorsed by a formal consensus process, and that are publicly available. These criteria must be directly related to quality of patient care, and documented physician performance should be measured against these criteria. Peer review decisions must be fair and without conflicts of interest and have dated detailed documentation, and should be confidential and protected.

Hospitals with a history or pattern of retaining or contracting with incompetent and low-quality providers may be subject to potential legal liability for any injuries to patients, exclusion from federal and state health benefit program participation, loss of commercial contracts, and loss of accreditation by healthcare standards organizations.

Anesthesia Complications

The efficacy and safety of LVAD implantation can be evaluated by looking at not only mortality rates, but also postoperative morbidity. Identifying appropriate patients before the onset of significant organ dysfunction can improve survival and reduce the degree of morbidity.

Role of External Peer Review in Ensuring Quality of Patient Care & Safety

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 not only in-depth evaluation of sentinel events but also (re)credentialing, (re)privileging, proctoring, and ongoing measurement and monitoring of physician performance.

Peer review committees that are composed primarily of in-house personnel often lack the resources to help the hospital achieve their performance improvement goals, and social and professional relationships can 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. It may also be an effective solution for hospitals that lack adequate physician resources to conduct timely performance analyses.

When properly executed, external peer review can reduce medical errors through objective evaluations performed in a non-punitive, educational context that supports a healthy culture of continuous improvement. This results from physicians knowing that their work will be objectively evaluated at regular intervals by board-certified specialists with the same credentials and from similar practice settings, thereby leading to improved quality of care and patient safety. Ongoing evaluation of physicians can also uncover problematic practice patterns, as well as physician- and hospital-level issues that need to be addressed.

External peer review can also play a key role in reducing or eliminating the risks associated with increased malpractice claims. In addition, it can directly lower the cost of delivering quality care, with the greatest impact on high-risk procedures such as LVAD implantation. Unlike internal peer review, which only looks at sentinel events, external peer review can help hospitals to discover, highlight, and deal with physician performance issues quickly and efficiently before they turn into claims.

Conclusions

Mechanical circulatory support has evolved considerably in recent years, with LVADs emerging as the standard of care for
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advanced heart failure patients requiring long-term mechanical circulatory support. Although studies have shown that LVADs improve patient outcomes and quality of life, complications persist during LVAD support due to pre-existing effects of advanced heart failure, the requirement for extensive surgery to implant the device, and the effects of the device in compromised patients. 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.

Bibliography


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