Implantable Left Ventricular Assist Devices

Julie A. Shinn, MA, RN, CCRN, FAAN

The first bridge to transplant with a left ventricular assist device (LVAD) was performed over 20 years ago. Since that time, the devices have continued to evolve and now patients are being supported with devices as an alternative to transplantation. The primary indication of end-stage heart failure remains the same but increased knowledge about patient selection, the timing of implant, and patient management have contributed to improved outcomes with decreasing adverse events. Multiorgan failure, right ventricular failure, bleeding, infection, thromboembolism, and device malfunction continue to be the most serious threats to long-term survival in these patients. Despite that, patients who do well are now able to be discharged from the hospital and resume relatively normal lives with the devices. The article reviews 3 of the most widely used LVADs for bridge to transplant therapy: the Thoratec HeartMate vented electric; and the Novacor Left Ventricular Assist System. Indications, mechanism of operation, clinical problems, and out-of-hospital preparation are outlined.

KEY WORDS: alternative to transplantation, heart failure, ventricular assist devices

Considerable progress has been made in the last decade in treatment of congestive heart failure. Newer pharmacologic agents, biventricular pacing, and implantable defibrillators have enabled cardiologists with the ability to maintain patients in a compensated state with good quality of life for long periods of time. Surgical techniques of revascularization, valve repair, or replacement and surgical remodeling of the left ventricle also have extended the lives of many patients. Despite these advances, the 5-year mortality rate for heart failure continues to be about 70%.1 Approximately 5 million Americans have heart failure today and after the age of 65 years, it affects approximately 10 per 1000 of the population.1 Heart failure is the cause of approximately 250,000 deaths per year in the United States.2 As heart failure progresses and becomes more refractory to treatment, subsequent secondary organ dysfunction develops as a result of chronic poor organ perfusion. At this end stage of the clinical syndrome of heart failure, there is a 1-year mortality of more than 50%.3

Heart transplantation is a treatment option for many end-stage heart failure patients but with donor supply limited to approximately 2500 organs per year, it is clearly not an option for most patients.4 Younger patients without comorbidities are the most likely candidates for heart transplantation. They are also the best-suited candidates for left ventricular assist device (LVAD) implantation as a bridge to transplantation. The use of LVADs as bridges to transplantation has become a standard treatment option for advanced heart failure. Between January 2002 and May 2004, 312 patients in the International Society for Heart and Lung Transplantation’s (ISHLT’s) Mechanical Circulatory Support Database received bridge to transplant therapy in 48 centers submitting data2; 35 of those centers were in the United States. This number is actually an underestimate of all LVAD patients being bridged to transplant as the database is still relatively new and many centers have yet to enroll.

The goal of most companies that are developing LVAD devices is to develop products that can serve as permanent, definitive therapy. The HeartMate vented electric (VE) system (Thoratec, Pleasanton, Calif) was approved for this use by the Federal Food and Drug Administration (FDA) for destination therapy in
2003 and the Novacor Left Ventricular Assist System (LVAS) (World Heart, Oakland, Calif) is in the final stages of an evaluation study for premarket approval. It is estimated that 30,000 to 60,000 end-stage heart failure patients in the United States per year would be potential candidates for destination therapy.\(^8\)

The article reviews the clinical indications, clinical problems, and out-of-hospital preparation of the 3 most widely used LVADs as bridges to transplantation therapy: the Thoratec; HeartMate VE, XVE (a newer revision of the VE); and Novacor LVAS devices.

**Historical Perspective**

The first successful bridge to heart transplant with an implantable LVAD was done in 1984 with a Novacor LVAD.\(^7\) That patient lived more than 20 years after transplantation. Many lives have been saved by this technology but it has been difficult to determine who the best candidates are and who has the greatest chances of survival. Because of the relatively low volume of patients, no one center where LVAD implants are performed can amass enough data to answer that question well. For that reason, in 2001, a mechanical circulatory support device database was established by the ISHLT to collect and pool data from multiple institutions. The goal of this project is to accurately analyze data to help improve short- and long-term outcomes and to facilitate the selection of patients best suited for this therapy.\(^5\) The majority of the patients who have been entered in the database received LVADs capable of chronic support.

A significant study opened the door for the expanded use of implantable LVADs as an alternative to transplantation. The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) was a randomized, controlled trial of 129 patients in 20 institutions who were ineligible candidates for heart transplantation. Of those, 68 were randomized to receive the HeartMate VE LVAD and 61 patients served as controls, receiving optimal medical management.\(^8\) The importance of the study was the demonstration that LVAD implants were associated with a relative reduction in the risk of death of 48% during the entire follow-up period compared to the medical therapy group (\(P = .001\)).\(^8\) This study led to the FDA approval of the device for use as destination therapy in November 2002. Subsequent to that, the Centers for Medicare and Medicaid Services (CMS) approved national insurance coverage for destination therapy in October 2003.

**Indications for LVAD Therapy**

The primary indication for LVAD therapy is end-stage heart failure that is no longer responding to conventional medical management. If the implant is for bridge to transplant, the patient would be required to meet transplant criteria and to already be accepted as a transplant candidate. Patient selection is extremely important determinant of patient outcome following LVAD implant.\(^5,10\) Prior to implant, the majority of patients will be hospitalized on intravenous inotropic therapy. Many will require the support of intra-aortic balloon pump therapy, although some centers do ventricular assist device (VAD) implantation without a trial on intra-aortic balloon pump therapy. It is important to time surgery before renal and hepatic dysfunction deteriorate and before postoperative right ventricular failure will become a significant problem.\(^10\)

The best outcomes will be achieved in patients going for implant under elective conditions. Emergency implant is associated with higher mortality.\(^11\) Investigators at Columbia University have calculated a risk factor score that can be used to predict outcomes after device implant.\(^12\) They identified several risk factors that place patients at greater risk of mortality in a consecutive series of 130 patients. Each factor carries a weighted score and a total score of more than 5 corresponded to 47% mortality compared to 12% mortality in patients with scores of less than 5. Risk factors included mechanical ventilation, previous LVAD, or right ventricular assist device used as a bridge to a more long-term VAD, postcardiotomy shock, previous cardiac surgery, a central venous pressure more than 16 mm Hg as an indicator of the extent of right ventricular failure, a prothrombin time more than 16 seconds, acute myocardial infarction, and ischemic cardiomyopathy.\(^12\) The single most important risk factor for mortality after LVAD implant is the presence of preoperative mechanical ventilation.\(^12\) Table 1 summarizes the risk factors for mortality. At present, no universal criteria exist and patient selection remains a complex process.\(^13\)

**Overview of the Devices**

This review cannot possibly outline in detail all of the LVAD devices being used and evaluated today. Many have merits but are still in investigational stages requiring FDA approval for use in selected centers. This review will focus on 3 devices that are used widely and have FDA approval for bridge to transplantation.

**Thoratec LVAD**

The Thoratec LVAD is an external, paracorporeal, pulsatile pneumatic pump. Its placement is achieved via a median sternotomy on cardiopulmonary bypass. The inflow cannula is placed in the left ventricular
apex and tunneled subcostally to the external pump. Blood is returned via an outflow cannula, again, subcostally to the ascending aorta. The inflow cannula can also be placed in the left atrium but less optimal flows will be a disadvantage and that is not the usual approach if the patient is being bridged to transplant. Figure 1 illustrates the placement of this pump. The blood sac is a smooth, polyurethane material, which will necessitate that the patient be anticoagulated initially with heparin and later converted to warfarin sodium. A console or the driver of the pump is connected via a pneumatic hose that will deliver alternating pressure or vacuum inside the rigid shell housing the blood sac. With pressure, the blood sac collapses, causing ejection to occur. Application of vacuum creates a pressure gradient assisting filling from the left ventricle. Unidirectional flow is maintained by tilting disk valves in the blood pump. The maximum stroke volume of this pump is 65 millimeters. Its flow or output will depend on how quickly the pump fills. Pump flow rates range from 1.3 to 7.2 mm per minute.14

The cannula to and from the pump are covered with a Dacron material that allows for endothelial cell ingrowth, which effectively seals off the tract of the cannula into the mediastinum, preventing migration of bacteria from the skin into the mediastinum. This act of sealing also allows the patient considerable mobility after this process is complete. It usually takes up to 10 days for sealing to be completed.

An obvious advantage of this pump is that it can be placed in smaller individuals such as women or adolescents. Its paracorporeal position does not require the larger body habitus needed for the totally implantable LVADs. This pump requires a body surface area of 1.3 m squared versus the totally implantable pumps, which require a body surface area of 1.5 meters squared. Another advantage of the system is that a second pump can easily be added to support the right ventricle when indicated.

Two modes of operation are commonly used with this pump. It can be run at a fixed rate determined by clinicians or in an automatic mode. The automatic mode operates by activation of a switch signaling a full blood sac. This switch initiates the filling of the pump housing with compressed air, which forces the blood out of the blood sac, and ejection commences. When ejection is complete, vacuum is applied and filling of the blood sac begins. Fill to empty is a term that is used to describe this method of operation. The preferred trigger for pump ejection is when the pump reaches full fill. It can be run at a fixed rate, but it is preferred to have the blood sac fully fill to prevent the possibility of thrombus formation within the blood sac. Any LVAD that operates in such a method will be asynchronous with the native heart rate and will increase or decrease its rate on the basis of the rate of filling. In this way, the pump rate can increase to accommodate the patient’s activity level and increased rate of venous return to the heart. Pump rates typically decrease when the patient is at rest. Any pump using a fill to empty mode will be totally dependent on the patient’s preload status for adequate pump output and support of systemic circulation.

Although the Thoratec pump is pneumatic, electrical power must be available at all times to run the compressors. A portable console that can run the pump on battery power is available. Each fully charged battery with the portable console can support a patient on an LVAD for up to 80 minutes. With a pneumatic system, ventricular assist can be maintained utilizing manual pumping to compress the blood sack in the event of a console malfunction. Patients being maintained on the portable system can be discharged from the hospital to wait for organ donation. The Thoratec VAD system was approved for use as a bridge to transplant device in 1995.14

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<th>TABLE 1</th>
<th>Risk Factors for Mortality After LVAD Implant*</th>
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<tr>
<td>Mechanical ventilation</td>
<td>Previous LVAD or RVAD used to bridge to a long-term VAD</td>
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<td>Postcardiotomy shock</td>
<td>Redo surgery</td>
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<tr>
<td>CVP &gt; 16 mm Hg</td>
<td>Prothrombin time &gt; 16 s</td>
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<td>Ischemic cardiomyopathy</td>
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*LVAD indicates left ventricular assist device; RVAD, right ventricular assist device; VAD, ventricular assist device, and CVP, central venous pressure.

**FIGURE 1.** Placement of the Thoratec left ventricular assist device is illustrated depicting the paracorporeal placement with the pump outside the body and with the inflow and outflow cannula traversing subcostally to the left ventricle and ascending aorta respectively. This is an example of biventricular support. Reprinted with permission from Thoratec Corp, Pleasanton, Calif.
A newer version of this pump is the Thoratec Internal Ventricular Assist Device (IVAD), which is a smaller version of the same pump, allowing it to be implantable. A wire for the electrical signal of “full fill” and the pneumatic hose remains external. The principles of pump operation are the same. The advantages are increased patient mobility, esthetics, and the reimbursement category for implanted pumps. Also, the esthetics of living outside the hospital with an implanted pump is more appealing. This particular pump was approved for use by the FDA in August 2004.

HeartMate VE and XVE Pump

The HeartMate VE or XVE is a totally implantable electrically driven pulsatile LVAD. The pump is most often positioned preperitonally in the left upper abdominal quadrant or alternatively intraabdominally. Implantation requires a median sternotomy that extends to the umbilicus and the use of cardiopulmonary bypass. This 2-compartment surgery increases the risk of infection, which is greater in this case than when the device is isolated to the chest cavity alone. The pump is made of medical grade titanium. The inflow cannula is positioned in the apex of the left ventricle, bringing blood into the pump. Blood is returned to the ascending aorta from the outflow cannula of the pump. Constructed porcine tissue valves maintain unidirectional flow. A percutaneous lead from the pump is tunneled subcutaneously to exit the body in the right upper quadrant just above waist level. The lead carries electrical energy to the pump and brings data from transducers located in the pump, alerting clinicians or the patient to changes in pump rate, stroke volume, or pump output. This pump has a flow rate capability in excess of 10 liters per minute.15

As the pump fills, air must be displaced from the pump housing to the outside and must reenter as air space is created during pump ejection. The air vent that facilitates these maneuvers can also be attached to a hand pump for emergency manual pumping if the electrical mechanism fails. If the situation is unrepairable, these pumps can be converted to pneumatically driven systems requiring that discharged patients be readmitted to the hospital. Figure 2 illustrates the design and positioning of the HeartMate VE LVAD. Figure 3 is a picture of both the Thoratec and HeartMate Pumps.

HeartMate’s percutaneous lead is covered with a Dacron material that will allow for tissue ingrowth that, when intact, will protect the patient from infection. The lead is connected to a system controller, which runs and monitors the pump for alarm conditions. The controller is attached to a source of AC power or 2 portable lead acid batteries that are capable of 4 to 6 hours of untethered support. Controllers can be clipped to a belt and batteries can be carried in a shoulder holster or waist pack. External components are relatively light weight, which allows the patient a broader range of activities than the Thoratec pump.
As with the Thoratec, the HeartMate can either be operated at a fixed rate or in the automatic mode in which ejection occurs when the pump is fully filled. Pump rates in the automatic mode are determined by how quickly the blood pump is filled by the left ventricle. A unique characteristic of the HeartMate is the textured interior surface of the blood pump that encourages endothelial cells to cover the surface creating a biologic lining. As a result of this smooth biologic lining interfacing with the blood, patients do not need to be maintained on warfarin for anticoagulation as do all other with LVAD devices. Antiplatelet therapy is all that is required.16

**Novacor LVAS**

Like the HeartMate, the Novacor pump is an implantable, electrically driven, pulsatile LVAD. It is one of the most reliable systems of circulatory support.17 In fact, it comes with a 3-year warranty and it is the only pump to offer such a warranty. Long-term support capability has been demonstrated. By Kaplan-Meier analysis, excluding percutaneous lead damage, more than 86% of pumps are in service at 3 years.18 With long-term use, eventual wearing of mechanical parts and the porcine tissue valves can occur, requiring elective replacement. In 10 patients who have lived longer than 3 years on pump support, 3 patients required pump replacement.18 The Novacor is still in the process of acquiring FDA approval for destination therapy use in the United States. The positioning of the pump in the left upper quadrant of the abdomen is similar to the technique of the HeartMate VE placement with the same connections to the left ventricle and aorta. A percutaneous lead is also used to bring electrical power to the pump, to send hemodynamic information from the pump to the system monitor and to provide a route for airflow in and out of the pump housing. Figure 4 illustrates the Novacor pump placement. Pump flow rates of 10 liters per minute are achievable with this LVAD.

Modes of operation are similar to the HeartMate as well. It can either be programmed to run in a fixed rate mode or in a fill to empty mode. The rate of blood filling the pump determines when ejection occurs in the later mode. When it is set to trigger when filling decreases by 100%, it runs in fill to empty mode. That percentage can be decreased to allow for synchronization with the native heart systole. In a bridge to transplant patient or eventually a destination therapy patient, that feature is not necessary. It might be used in a patient who might potentially be weaned from the pump. Explantation of LVADs following myocardial recovery after LVAD support has been reported in small numbers of patients.19–21

The Novacor pump is currently being evaluated as a destination therapy device under an FDA controlled trial. The trial, Investigation of Non-Transplant Eligible Patients who are Inotrope Dependent or INTrEPID, is completed but the results are yet to be released.

Unlike HeartMate, the Novacor requires anticoagulation with heparin initially followed by conversion to warfarin sodium. In addition, antiplatelet agents are required to prevent thrombotic events and transient ischemic phenomena. These events are most likely to occur in the first 30 days postimplant.17 Initially, stroke was a greater problem in the Novacor LVAS but modifications in the outflow graft have been made. As a result, the incidence of these adverse events is similar in both pumps.17

Like the HeartMate pump, the batteries and controller can be carried or worn by the patient. Patients can be untethered from AC power for up to 5 hours per battery. Battery support duration is only limited by the number of charged batteries a patient has in his or her possession.

**Complications**

There are several postoperative complications to be vigilant for and are seen in all of the previously
described LVAD populations. The causes of death following device implant are primarily multiorgan failure, renal failure, right ventricular failure, and infection.\textsuperscript{10} Bleeding and thrombembolism are 2 other important complications causing postoperative morbidity. Patient selection and timing of the device implantation appear to be critical factors that determine successful outcome.\textsuperscript{10} As data on complications and patient characteristics accumulate, risk factors for these complications will be better understood and outcomes should improve over time.

**Multiorgan Failure**

Patients with end-stage heart failure have many preoperative conditions that may contribute to the development of multiorgan failure postoperatively. Preoperative low perfusion may be evident and may persist postoperatively after the insult of cardiopulmonary bypass and the surgery itself. Preoperatively, patients may be supported with mechanical ventilation and may already have some degree of pulmonary dysfunction. Often, creatinine, blood urea nitrogen, and bilirubin levels are elevated, suggesting renal and hepatic dysfunction. Nutrition is often inadequate and is very likely an underestimated risk factor in mechanical support.\textsuperscript{10} The more severe the level of secondary organ dysfunction is preoperatively, the greater the risk of postoperative multiorgan failure. Multiorgan failure accounted for 27% of deaths reported to the ISHLT circulatory support database.\textsuperscript{5}

**Right Ventricular Failure**

Right ventricular failure is a concern in any patient who has elevated pulmonary and central venous pressures in the preoperative setting. The hallmark of right ventricular failure in the postoperative period will be elevated central venous pressures, an empty left ventricle, and a decrease in device outputs.\textsuperscript{15} These patients will require right ventricular unloading with vasodilators and/or nitric oxide and prolonged inotropic support of the right ventricle. Given time, the right ventricle usually recovers as left sided unloading remains constant with the assist of the LVAD. An occasional patient may require temporary assist from a short-term right ventricular assist device. Continual biventricular support might be employed in a bridge to transplant patient with either the implanted or paracorporeal Thoratec but this would not be a suitable option for a destination therapy patient. That type of patient would need to utilize a temporary support device.

**Bleeding**

Postoperative bleeding is common and there are many factors that contribute. Prolonged cardiopulmonary bypass time, anticoagulation, and extensive surgical dissection, especially with the Heartmate VE and Novacor, will contribute to increased risk of bleeding. Preoperative hepatic dysfunction will also add to the risk of coagulopathy. Patients who have had previous cardiac surgical interventions will be more prone to bleeding because of excessive scarring in the mediastinum and the need for more surgical dissection. Excessive bleeding has been as frequent as 20% and 50% with the Thoratec, HeartMate, and Novacor devices but has decreased with greater device experience.\textsuperscript{15} The ISHLT database reports a 27.8% incidence of postoperative bleeding.\textsuperscript{5}

**Infection**

Infection is a serious complication that occurs frequently. Patients are vulnerable to the usual postoperative infections seen in any postsurgical patient such as line sepsis, pneumonias, and urinary tract infections.\textsuperscript{15} These infections may have been present preoperatively because of the debilitated nature of the patients’ conditions. Device-related infections can occur in the percutaneous driveline, the pump pocket, from the pump in the form of endocarditis, or in the blood stream. Percutaneous driveline infections are the most common. The most common pathogens are staphylococcus, pseudomonas, enterococcus, and candida.\textsuperscript{22} Pocket infection rates range from 11% to 24% for the HeartMate and Novacor LVADs, with even greater rates of driveline infections, which range from 18% to 30%.\textsuperscript{23} The ISHLT circulatory support database reports a 32.5% incidence of infection and that infection is responsible for 7% of deaths for all devices in the database.\textsuperscript{5} Infection does not present an obstacle to successful transplantation as long as it is identified and appropriately treated. In the REMATCH trial, the probability of infection of the LVAD device was 28% within 3 months of implant and was the leading cause of death.\textsuperscript{8} Once device infection occurs, it can usually be controlled for some period of time but often reoccurs, causing late mortality and morbidity.\textsuperscript{22} As we enter the era of destination LVAD therapy, device-related infection is a major concern. In permanent implants, chronic infection will decrease quality of life, increase the cost of care, and may require replacement of the device.\textsuperscript{24} Along with the usual practices to prevent infection, steps to prevent inoculation of the pumps and components in the operating room include limiting room traffic, avoiding opening the LVAD sterile packaging prematurely, assembling the pump in a low traffic area, using dummy pumps to size and fashion the abdominal pockets, using antibiotic-soaked sponges to cover components prior to implant, using antibiotic.
irrigations prior to closure immobilizing the percutaneous lead with a secure dressing, and abdominal binder prior to leaving the operating room. Immobilizing the percutaneous lead, power cables, or drivelines will be crucial to the healing of the site. Tissue ingrowth into the velour covering of the leads or drivelines will take about 10 to 14 days to be complete. If the sealing of the track is disrupted by movement or tension on the lead or driveline during this time, it may never heal completely. Incomplete healing will allow microorganisms to be able to track up the tunneled lead to the pump pocket or the mediastinum. Meticulous dressing changes need to be performed daily and their importance emphasized to patients and caregivers as they begin to assume their own care.

**Thromboembolism**

Death from stroke accounts for 10% of all deaths in the ISHLT database. Neurologic dysfunction occurred in 14% of patients. All of these devices have a blood-device interface that harbors the potential for thrombus formation. With the exception of the HeartMate, all of the described devices require anticoagulation with warfarin and antiplatelet agents. The HeartMate’s biologic lining, described earlier, precludes the need for anything other than antiplatelet therapy. The Novacor device has previously been associated with higher rates of stroke than the other devices. However, modifications in the outflow graft have lead to a thromboembolic rate similar to the HeartMate device. A recent study reported the incidence of thromboembolic events before modifications at 23% compared to an incidence of 6% after modifications. In a large multicenter trial of 280 patients supported with the HeartMate VE, thromboembolic events occurred in 12% of patients; 6% were deemed device related. Neurologic impairment following thromboembolic events range from transient central nervous system or neuromuscular disorders to permanent disability.

**Device Malfunction**

It is not unexpected that some degree of device failure or malfunction occurs over time with mechanical devices. Moving mechanical parts incur wear. Motor failure, wear on bearings, wear on valves, and breaking of external components because of wear and tear by patients have all contributed to device failure and malfunction. The probability of device failure by 24 months in the REMATCH trial was 35% requiring replacement of the device in 10 patients. In the bridge to transplant population at Columbia University, device malfunction that was considered clinically significant only occurred in 5.7% of the single lead HeartMate VE patients (N = 174), with a mean support duration of 65.3 days. In a report of 277 patients (137 HeartMate VEs, 81 pneumatic HeartMates and 57 Novacors), there were 21 device failures only one of which was a Novacor. The Novacor has demonstrated a very high degree of reliability and durability and impending wearing out of the pump can be diagnosed at least 2 months before anticipated potential failure. This wear on pumps will become a problem that will need to be further addressed in the destination therapy patients.

**Discharging Patients From the Hospital**

Following transfer from the intensive care unit, patients and caregivers begin training for eventual discharge from the hospital. Outpatient care requires reliable compliance by the patient and caregiver, continued education with constant reinforcement, and adequate anticoagulation monitoring. Table 2 outlines teaching topics unique to LVADs that patients must understand and be competent in before discharge can occur. These issues are crucial because a lack of understanding or an inability to demonstrate proper device management could lead to morbidity and possibly endanger a patient’s life. It is recommended that a teaching documentation tool with specific competencies be used to track patient and caregiver progress. Patients receive written information in the form of patient handbooks from the various companies. Teaching the patient to become independent occurs on a daily basis with instruction by LVAD coordinators and continual reinforcement by the unit staff nurses. To reinforce the importance of

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<th>TABLE 2</th>
<th>Preparation for Discharge: Patient Training and Education Topics Unique to LVAD Therapy*</th>
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<td>■ Components of the LVAD system and their functions</td>
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<td>■ Care and maintenance of the equipment</td>
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<td>■ Contact with emergency medical services</td>
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*LVAD indicates left ventricular assist device.
what is being taught, some centers use signed consents or contracts to emphasize to the patients and caregivers the importance of following the protocols or instructions.29,30

In preparation for eventual discharge, patients are gradually introduced to experiences outside the hospital. Initially, they are accompanied outside the hospital for various excursions by professional staff. As they become more confident and competent, they are encouraged to make out-of-hospital excursions independently. Some institutions encourage an overnight stay out of hospital prior to discharge. With dedicated, daily teaching and reinforcement, patients who do well from a medical point of view and have adequate caregiver support can be discharged as early as 14 days postimplant.28 Many institutions require that patients reside within a limited radius of the hospital, which is usually a 2-hour drive, while other institutions will allow patients to go home even if that distance exceeds a 2-hour limit. In this case, the patient and caregiver must reside locally, demonstrate competence, and have no outstanding medical issues before being allowed to live outside a close radius to the medical center. It is important that the medical center personnel advise the patient’s local physician and emergency medical personnel of an LVAD patient’s presence in the community. Training and education of these individuals is recommended in the event of emergencies in the community.28 These individuals include staff in the local emergency department, the fire department, and paramedics and emergency medical technicians who are likely to respond to an emergency in the home.

As we enter the era of destination therapy, we will see more older patients receiving LVAD implants because transplantation is not an option for them. Older age has some potential impacts on patient teaching and discharge planning. Older patients may need modification in the discharge teaching plan because of cognitive impairment, physical limitations such as arthritis, and an inherent discomfort with technology.28 These patients may need a 24-hour companion where younger patients do not. This requirement will put more strain on the family or caregivers and plans will need to be in place to address this issue.29

Reimbursement

The CMS have recently made significant changes in the reimbursement for implantable LVADs and for the approved external LVADs. These figures are contained in the Medicare Hospital Inpatient Prospective Payment System Final Rule for fiscal year 2005 (www.cms.hhs.gov/providers/hipps/frnotices.asp).

Basically, the new rule, effective October 1, 2004, improves payment for destination therapy and bridge to transplant. CMS has reclassified implants of implantable pulsatile LVADs from diagnosis related group (DRG) 525 to DRG 103. This is significant because DRG 525 previously reimbursed substantially less than DRG 103, which is the category for heart transplantation. The LVAD implant surgery and subsequent recovery is often more complex and associated with a longer length of stay, both in the intensive care unit and the hospital in general. Now, patients who are discharged longer than 30 days after LVAD implant and readmitted for a later heart transplant are able to be classified as DRG 103 a second time, allowing for a second payment for the transplant surgery and hospitalization. The base reimbursement rates for DRG 525 are $56,500 and $97,200 for DRG 103.

Examples of how reimbursement would occur with different types of LVADs can be illustrated using the Thoratec extracorporeal device versus an implantable device. A Thoratec extracorporeal LVAD would fall into category 525 but if the heart transplant occurs during the same hospital admission, reimbursement would be based on the transplant DRG 103. If the Thoratec patient is discharged for more than 30 days and readmitted for transplant, the reimbursement rate for the first admission would be based on DRG 525 and on DRG 103 for the second admission. A patient who receives an implanted LVAD would be classified under DRG 103. If the heart transplant occurs during the same admission, reimbursement for both surgeries is based on that one DRG. If the same patient is discharged with the implanted LVAD for greater than 30 days and readmitted for a later heart transplant, the institution will be reimbursed based on 2 DRG 103s. These changes will likely open the door for wider use of LVAD therapy by more institutions.

Conclusion

Although an attempt has been made to present an objective overview of the devices described in the article, the current methods of recording, analyzing, and publicizing information regarding adverse events and outcomes are often not standardized sufficiently to allow for meaningful comparisons of the devices. Pooling of these data in an international database where standardized definitions are employed should help with future, more accurate comparisons.

We are on the verge of seeing a variety of end-stage heart failure patients being supported on long-term assist device therapy. Many pumps have now or will shortly be proven to be effective and reliable for long-term support of these patients with an acceptable complication rate. Because of changes in reimbursement rates, the use of these devices will become more widely accepted. We still have a lot to
learn about appropriate candidate selection and when we do, the therapy will become more cost-effective. This patient population represents an opportunity for advanced practice nursing to step in and provide direction for this new population of individuals who will need chronic care and support.

REFERENCES