

EDUCATION AND PRACTICE

PREHOSPITAL ASSESSMENT AND MANAGEMENT OF PATIENTS WITH VENTRICULAR-ASSIST DEVICES

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ABSTRACT

Advances in the management of heart failure have led to an increasing number of patients living outside the hospital with a variety of ventricular-assist devices (VADs). These implantable pumps may be placed temporarily as a bridge to cardiac transplantation or resolution of a reversible condition, or as destination therapy for the rest of the patient's life. Emergency medical services (EMS) providers may be called to care for such patients experiencing an emergency related to the device itself, the underlying cardiac condition, or a totally unrelated medical or traumatic issue. Providers should have a basic knowledge of how these devices work and what sort of complications VAD patients may experience. In addition, they should know how to troubleshoot the devices if they alarm or malfunction, what emergency interventions can and cannot be performed, and where to turn for guidance if needed. Challenges related to management of patients with VADs include their poor baseline medical status, limitations of traditional prehospital assessment techniques, the relative infrequency with which these patients are encountered, and the rapidity with which device technology is evolving. This article presents a brief history of VADs, with an emphasis on left ventricular-assist devices (LVADs), reviews the relevant anatomy and pathophysiology, and describes the types of devices currently in clinical use. It discusses patient-specific and device-specific complications that may be encountered and concludes

with an approach to prehospital patient assessment and care. **Key words:** heart-assist devices; heart failure; ventricular dysfunction, left; assisted circulation

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INTRODUCTION

A limited numbers of hospital beds, ongoing cost-containment efforts, and tightening insurance reimbursement for inpatient care have led to a push for more out-of-hospital management of patients with serious, chronic medical conditions. Much of this care is technology-dependent. Patients on home hemodialysis, portable ventilators, and a variety of infusion pumps are encountered with increasing frequency by emergency medical services (EMS) providers. Patients with congestive heart failure (CHF) and implantable cardioverter-defibrillators (ICDs) are also frequently encountered.

A growing number of heart failure patients are being discharged from the hospital with ventricular-assist devices (VADs). These are surgically implanted pumps that assist the pumping action of one or both ventricles. They are typically placed in patients with New York Heart Association Class IV or advanced Class III disease, meaning those who may be comfortable at rest but become symptomatic with even mild physical activity.¹ Ventricular-assist devices include left ventricular-assist devices (LVADs); right ventricular-assist devices (RVADs); and biventricular-assist devices (BiVADs), which involve two independent pumps. Left ventricular-assist devices are the most common of these. They typically have an inflow cannula placed in the apex of the left ventricle and an outflow cannula inserted into the ascending aorta. The devices assume some or all of the function of the ventricle, depending on the underlying cardiac pathology. Left ventricular-assist devices are used in a number of contexts. For most patients, they are a bridge to transplantation. However, they may also be used as a bridge to candidacy for transplantation; as

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a bridge to recovery from a reversible condition, such as myocarditis, cardiogenic shock, or postcardiotomy failure; or as destination therapy, meaning that patients will depend on them for the rest of their lives.

Management of patients with VADs presents unique challenges for EMS providers. First, because the flow through many of these devices is not pulsatile, the patient may not have a palpable pulse. The blood pressure, if measureable, may not be an accurate measure of perfusion. As a consequence, the patient's hemodynamic status must be determined by other means. Second, depending on the EMS system, encounters with VAD patients may be very infrequent, making it difficult for providers to become confident in caring for them. Third, the technology is rapidly evolving, with new devices entering the market on a routine basis. As a result, it is difficult for EMS providers to maintain an awareness of the multiple devices they may encounter. Service medical directors may also be unfamiliar with VADs, which means that very few EMS systems have protocols for managing VAD patients. Finally, interventions, such as cardiopulmonary resuscitation (CPR), which may be indicated for other patients with VADs. The intent of this paper is to address these issues. Specifically, it will present the history and evolution of VADs, review the relevant anatomy and physiology, and describe the different types of devices that EMS providers may encounter. Next, the unique challenges of patient assessment will be covered. Typical emergencies of VAD patients and the appropriate interventions will be described. Finally, available resources pertaining to emergency care of these patients will be presented. Because LVADs are most frequently encountered, they will be emphasized.

BACKGROUND

Ventricular-assist devices were first developed in the 1960s. The first clinical application was in 1963, when a VAD was implanted into a patient who had undergone an aortic valve replacement but subsequently went into cardiogenic shock. Because of the VAD, the patient's pulmonary edema resolved, but he died when the pump was turned off. In 1966, Liotta and DeBakey placed a VAD in a patient who had undergone a double valve replacement but could not be weaned from cardiopulmonary bypass. The patient's cardiac function recovered after 10 days, and the pump was removed.^{2,3} An extension of VAD technology, the first artificial heart was implanted in 1969 in a patient who was severely disabled by coronary artery disease but had refused heart transplantation.⁴

During the 1970s and 1980s, the National Heart, Lung, and Blood Institute heavily funded development of VADs that were implantable, were electrically powered, and would allow patients to be mo-

bile. Resulting devices included the Novacor LVAD, the Pierce-Donachy VAD system, and the HeartMate 1000 and HeartMate VAD.^{5,6} In 1991, patients with vented electric HeartMate LVADs were first able to live outside the hospital.⁷ In 1994, the pneumatically driven HeartMate IP (i.e., implantable pneumatic) received Food and Drug Administration (FDA) approval as a bridge to transplantation. In 1998, the FDA approved the electrically powered HeartMate VE (i.e., vented electric) and the Novacor LVAS (i.e., left ventricular assist system) for use as a bridge to transplantation, permitting hospital discharge.⁸ Since that time, the number of VADs, and the number of EMS encounters with VAD patients, has increased.

LEFT VENTRICULAR-ASSIST DEVICE DESIGN

Over the past two decades, LVAD design has dramatically changed, with a movement from pneumatic to electrical power, and from pulsatile to continuous flow. Four distinct generations of VADs have been described, based on this evolving technology (Table 1).

First-generation devices include the HeartMate XVE and the Thoratec PVAD (i.e., paracorporeal ventricular-assist device). They mimic the left ventricle's natural pumping action through the use of diaphragms or pusher plates, which cause blood to be sucked into the left ventricle and then expelled into the aorta. The result is pulsatile blood flow, which means the patient will have a detectable pulse and measureable blood pressure.⁹ First-generation LVADs consist of inflow and outflow cannulas, unidirectional valves, a pumping chamber, an electrical-line power source, a battery pack for when the patient is mobile, and a system controller. As with most LVADs, they are

TABLE 1. Generations of Left Ventricular-Assist Devices

First Generation
Berlin Heart EXCOR (Berlin Heart AG)
HeartMate XVE (Thoratec)
Novacor LVAS (World Heart Corp.)
Thoratec PVAD (Thoratec)
Second Generation
HeartMate II (Thoratec)
Jarvik 2000 (Jarvik Heart)
MicroMed DeBakey VAD (MicroMed Cardiovascular)
Third Generation
Berlin Heart INCOR (Berlin Heart AG)
CentriMag (Levitronix)
CorAide (Cleveland Clinic Foundation)
DuraHeart LVAS (Terumo Somerset, USA)
HeartMate III (Thoratec)
HeartQuest (WorldHeart)
HVAD Pump (HeartWare)
Levacor (World Heart Corp.)
VentrAssist (formerly Ventracor)
Fourth Generation
MAGNEVAD (Gold Medical Technologies)
HeartAssist 5 (MicroMed Cardiovascular)

usually placed in the intra-abdominal or preperitoneal space. They are driven electrically or pneumatically. Electrical pumps use an electromagnetic pusher plate to drive the blood. Pneumatic devices, on the other hand, cyclically generate fixed amounts of air pressure to drive out the stroke volume. In case of pump failure, a backup hand pump may be used to generate the needed air pressure. First-generation LVADs have been shown to produce a 48% reduction in risk of death compared with management with medical therapy alone. The downsides of these devices are their large size and weight and the technical challenges of implantation, especially in smaller patients.¹⁰

Second-generation LVADs include the Jarvik 2000 and the HeartMate II (Fig. 1). These devices have a continuous-flow rotary pump. As a consequence, the patient may or may not have a pulse, depending on whether the device fully replaces the ventricle's function or simply boosts it. These devices are smaller than first-generation LVADs, are easier to implant, and are more durable. They have just one moving part, the impeller, which drives blood flow. Second-generation LVADs may be divided into those with axial pumps and those with centrifugal, or radial, pumps. Axial pumps are designed after Archimedes' screw, which used a corkscrew shape to raise water against gravity.

The inflow and outflow are in line with the impeller, which allows the pumps to be smaller. In centrifugal pumps, the inflow and outflow cannulas are at right angles to flow. The advantage to this design is that less suction is generated, decreasing the risk of collapse of the ventricle around the inflow cannula or distortion of the interventricular septum, which can in turn lead to right ventricular failure.¹¹ A recent trial comparing survival in patients with continuous-flow and pulsatile-flow LVADs demonstrated a 58% two-year survival rate with the continuous-flow devices and a 24% survival rate with the pulsatile devices. Compared with pulsatile-flow devices,^{12,13} continuous-flow devices are associated with lower rates of infection, right heart failure, respiratory failure, renal failure, and arrhythmias. A potential disadvantage of continuous-flow LVADs is that, because they are valveless, there is the potential for regurgitant blood flow back from the aorta if the pump stops.

Third-generation LVADs improve on the second-generation design. Examples are the HeartMate III and the DuraHeart LVAS. They employ continuous-flow, axial-flow, or centrifugal pumps. The impeller is suspended by magnets (magnetic levitation), monitored by position sensors, and driven by electromagnets. There is no mechanical contact between the impeller and the pump casing. As a result, the risk of hemolysis or clot formation is lower, the devices are quieter, and they can function for years.^{14,15}

What can be considered fourth-generation LVADs or beyond are in various stages of development and clinical testing. Features include smaller size, reduced thrombogenicity, wireless design to enable remote monitoring of the device, and a return to pulsatile blood flow, which is believed to improve organ perfusion. Another improvement being investigated is elimination of the driveline, meaning no cable would run through the skin to connect the LVAD to an external power source. Because driveline infections are a major risk for LVAD patients, this should greatly reduce patient morbidity.¹⁶

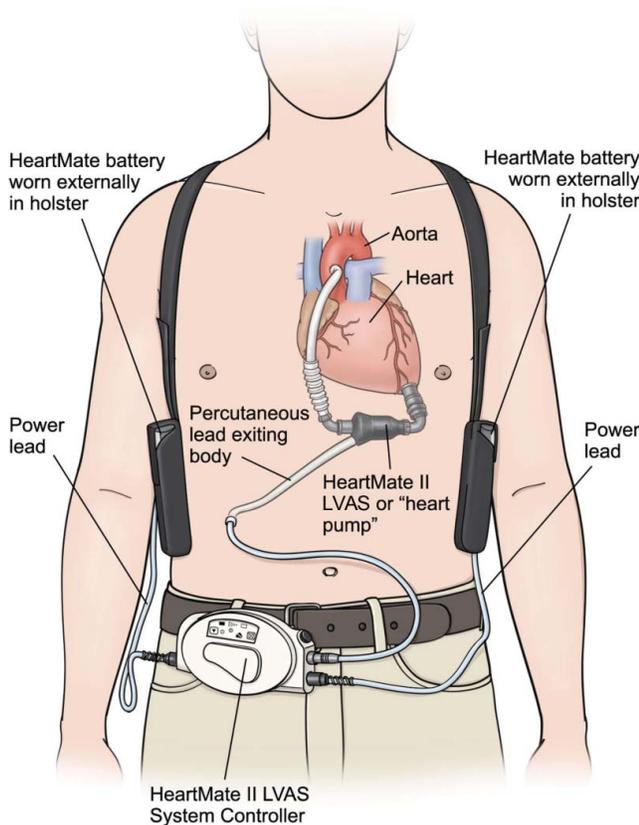


FIGURE 1. HeartMate II left ventricular-assist device (LVAD). Reprinted with the permission of Thoratec Corporation. LVAS = left ventricular-assist system.

THE LEFT VENTRICULAR-ASSIST DEVICE PATIENT

Prior to receiving an LVAD, patients undergo careful screening. A number of indications, relative contraindications, and contraindications have been established. In addition to specific physiologic criteria, psychosocial considerations are heavily emphasized. Patients must not have serious underlying psychiatric illnesses that could impair their ability to maintain the device. In addition, they need to have a strong support system of family or friends who are willing to assume the responsibility of caregiver and to undergo the necessary training to respond appropriately in case of emergency.

A number of preparatory steps are taken prior to hospital discharge of patients with newly implanted VADs. Patients and their family members or other caregivers undergo training, which includes how to change power sources, batteries, and the device's system controller; and how to stabilize the driveline and change the driveline dressing. They are provided spare batteries and a backup system controller. Other topics include response to device alarms and what to do in the event of an emergency.¹⁷ Also prior to discharge, the patient's care team generally contacts local EMS agencies to notify them that the patient will be in the community. This gives EMS the opportunity to become familiar with the type of LVAD they may encounter. In addition, their dispatch center can place on the patient's address a premise history briefly advising emergency responders of indicated and contraindicated interventions. Finally, prior to discharge advance directives are often addressed, so that the patient's wishes are respected in case of pump failure, and caregivers know how to respond in accordance with those wishes.¹⁸

In addition to being supported by trained family members or other caregivers, all LVAD patients are followed by a multidisciplinary medical team until the device is no longer needed. An LVAD coordinator is available around the clock and can be a valuable source of information and advice for the patient, family, and EMS providers.¹⁹ The team also provides patients with written instructions for EMS providers detailing the type of device, emergency interventions, contact information for their LVAD coordinator, and their preferred destination hospital.

COMPLICATIONS

Complications encountered in LVAD patients may be classified as those related to the patient and those pertaining to the device. Only some of these are amenable to prehospital intervention. The most common complications related to the patient include neurologic events, hemorrhage, and arrhythmias. Neurologic complications, including transient ischemic attack (TIA) and stroke, both thrombotic and hemorrhagic, are a relatively common cause of morbidity and mortality among LVAD patients. The incidence of stroke ranges from 8% to 25%. Patients at increased risk are those with a history of a previous stroke and those with a postoperative infection following device implantation.²⁰

Epistaxis, gastrointestinal bleeding, and hematoma formation are the most commonly encountered types of hemorrhage in LVAD patients. Bleeding may result from the direct effects of the device, from acquired von Willebrand disease, or from therapeutic anticoagulation.²¹ Because thromboembolic events are a significant risk following LVAD implantation, ad-

ministration of antiplatelet drugs as well as anticoagulation with warfarin are common postoperative practices. The target international normalized ratio (INR) has traditionally been in the 1.5 to 2.5 range. There is a trend toward tolerating lower INRs to minimize the risk of iatrogenic hemorrhage.¹⁰ However, hemorrhage continues to be a significant concern.

Arrhythmias can be problematic in LVAD patients. Atrial fibrillation is common and may result from the patient's underlying cardiac disease. While the LVAD will ensure adequate left-ventricular ejection, the loss of right atrial kick in the setting of atrial fibrillation may impair right ventricular function, especially in patients with underlying pulmonary hypertension.²² Ventricular arrhythmias, especially ventricular tachycardia, are also frequently encountered. These may result from the underlying cardiac condition, from mechanical irritation of the myocardium by the device, from increased left ventricular end-diastolic pressure, or from septal deviation or ventricular collapse resulting from excessive pump suction. Some patients may require an ICD to control recurrent episodes of ventricular tachycardia.^{19, 22-24} Table 2 presents a more complete list of patient-specific complications encountered in LVAD patients.

While the safety and reliability of LVADs are steadily improving, a number of device-specific complications may be encountered by EMS providers. These can involve the system controller, power source, battery pack, driveline, or the pump itself. Some of these events will trigger either visual or auditory alarms, which will need to be addressed.

Infection is the most common complication encountered in LVAD patients, with infection rates ranging from 18% to 59% of implantations. Despite engineering improvements, infection remains a significant cause of morbidity and mortality. It is second only to heart failure as a leading cause of death among LVAD patients. Infection can involve the surgical site, driveline, pump pocket, or the pump itself in the form of endocarditis.²⁵

TABLE 2. Complications Encountered in Left Ventricular-Assist Device Patients

Infection
Bleeding
Stroke/transient ischemic attack
Hemolysis
Arrhythmias
Volume overload
Dehydration
Hypertension
Hypotension
Cardiac tamponade
Recurrence of heart failure
New right ventricular failure
Aortic insufficiency

Mechanical failure of LVADs is fortunately rare. If the pump stops, this is more likely related to low battery voltage or a problem with the system controller than to actual device failure. More common problems involve the cables, including the driveline, which can become kinked, fractured, disconnected, or dislodged. While patients and their caregivers receive explicit instructions on securing the driveline and other cables, inadvertent damage or detachment can still occur, for example, by the patient's tripping on the driveline.^{26,27}

Other device-specific complications include suction events, device malposition, and thrombus formation. A suction event occurs when there is insufficient volume in the left ventricle for the set pump speed, resulting in collapse of the intake cannula. The device should automatically correct for this by reducing the pump speed, but ventricular arrhythmias may still be triggered.^{17,19} Devices that have been in place for months or years can also become malpositioned. Patients with LVADs tend to gain weight over time, which can change the position of the device, particularly the inflow cannula. This can lead to incomplete emptying of the left ventricle, resulting in right ventricular failure and arrhythmias.²⁸ Finally, LVAD implantation may induce a hypercoagulable state, which can result in life-threatening device-related thrombosis. A clot may form in the pump itself or migrate into the inflow cannula from elsewhere. Risk factors include subtherapeutic anticoagulation, atrial fibrillation, a preexisting hypercoagulable state, and bacteremia. Thrombosis should be suspected when there is a gradual or an acute increase in pump power use but a decrease in pump flow. Clinical manifestations can range from dyspnea and chest discomfort to cardiogenic shock. Treatment includes thrombolysis or pump replacement.^{28,29}

EMERGENCY ASSESSMENT AND MANAGEMENT

Emergency assessment of patients with LVADs involves checking for LVAD-related emergencies, exacerbations of underlying cardiac pathology, and unrelated medical conditions or trauma (Fig. 2). Non-LVAD-related emergencies should be managed in accordance with local protocols, with involvement of medical command physicians where indicated.

Evaluation of the LVAD involves determining what type of device it is and whether it has a pulsatile or continuous-flow pump. Patients with a pulsatile device, such as a HeartMate XVE or Thoratec PVAD, should have a pulse and measurable blood pressure. If a pulsatile pump fails, a hand pump must be used to maintain blood flow. Patients with continuous-flow LVADs, such as a HeartMate II, will have no detectable pulse. If the pump is functioning, auscultation over the apex of the heart should reveal a mechanical humming sound. In case of pump failure, use of a hand pump is

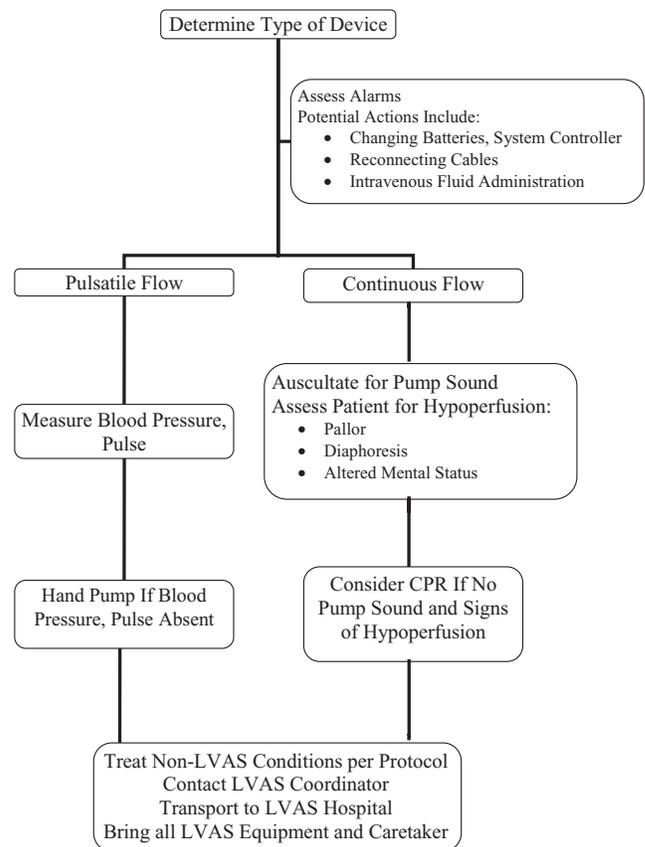


FIGURE 2. Emergency assessment of a patient with a left ventricular-assist device (LVAD). CPR = cardiopulmonary resuscitation.

not an option. Depending on the circumstances, other questions to address are whether the patient can be cardioverted or defibrillated if needed and whether chest compressions can be performed in case of pump failure. Patients, caregivers, and the patient's VAD coordinator should be able to answer these questions. Involvement of a medical command physician may be helpful. In addition, the patient or caregivers generally have written instructions, device manuals, and the VAD coordinator's contact information readily available for EMS providers.

When not functioning properly, LVADs will generate auditory and/or visual alarms on the system controller that will be manufacturer- or device-specific. Once again, the patient, caregivers, or VAD coordinator should be able to assist in their interpretation. Generally, LVADs will alarm for low power or loss of power, indicating that the batteries or controller may need to be changed, or that hand pumping should be initiated in the case of failure of a pulsatile device. Other alarms may indicate low pump flow, generally due to hypovolemia, in which case intravenous fluids should be administered. Alarms may also indicate that the driveline is not properly connected to the controller, or that a cable from the power source to the

controller has become disconnected, in which case all connections should be checked.^{9,30} Such troubleshooting should not delay patient transport.

Assessment of an LVAD patient's airway and breathing is for the most part no different from other patients. However, in patients with continuous-flow devices, pulse-oximetry readings may be unreliable because of the low pulse pressure generated by the pump.³¹ Assessment of the patient's circulatory status is more challenging. Because most LVADs in current use employ continuous-flow pumps, patients will be pulseless and their blood pressure undetectable by traditional means. Doppler devices are used in hospital to assess LVAD patients' hemodynamic status, but this is rarely an option in the prehospital setting. Therefore, EMS providers will need to assess patient perfusion by other means. Clinical findings of hypoperfusion may include pale, diaphoretic skin and altered mental status. The cardiac monitor tracing and 12-lead electrocardiogram should not be affected by the presence of an LVAD. Therefore, these can provide important information, as can the system controller, which may give a low-flow alarm. Assessment of the patient's neurologic status should include screening for an acute stroke. Patients with symptoms concerning for stroke should be managed like patients with native hearts, including ruling out stroke mimics such as hypoglycemia and transporting the patients to a stroke center, preferably one familiar with VADs. Finally, all LVAD patients should be carefully exposed, looking for signs of cable disconnection. However, the driveline skin site should only be visualized if absolutely necessary because of the importance of maintaining sterility. Extreme caution should be exercised so that cables are not inadvertently disconnected, cut with trauma shears, or dislodged, especially when moving or transporting the patient.

Prehospital care of LVAD patients will be based on local patient care protocols. Airway and respiratory interventions will be the same as for other patients. All patients with evidence of hemodynamic compromise should have large-bore intravenous access. Because they are preload-dependent and also prone to dehydration, intravenous fluid administration can often readily reverse signs of hypoperfusion. Vasopressors should be given with caution, as the resultant increase in afterload may worsen pump flow.⁹

Only symptomatic arrhythmias should be treated. If the pump is functioning normally, patients may be able to tolerate ventricular tachycardia or even ventricular fibrillation. However, in the setting of concerning signs and symptoms, arrhythmias should be managed in accordance with standard protocols, including agents such as beta-blockers for rate control. There are no contraindications to the administration of the same antiarrhythmics used in patients with native hearts. Likewise, there are no contraindications to cardioversion

or defibrillation.²² However, efforts should be made to not place defibrillation pads immediately over the device. Depending on the device, prior to electrical intervention, cables to the system controller may need to be disconnected to minimize damage to the device's electronics. Providers should be cognizant that some LVAD patients will also have an ICD, which may discharge in response to certain arrhythmias.

Deciding when to initiate chest compressions on LVAD patients is perhaps the greatest challenge facing EMS providers and should only be made following a careful assessment of patient perfusion and device function. For patients with first-generation, pulsatile flow devices, if the pump has stopped, hand pumping, rather than chest compressions, should be started immediately. For later-generation models, a hand pump is not an option. Device manuals tend to be very cautious in their statements regarding chest compressions, recommending use of clinical judgment, or initiation only if necessary. The downside of chest compressions is the risk of dislodging the device, with the potential for exsanguination. However, if the pump has stopped, the heart will almost universally lack sufficient contractility to maintain perfusion, and the patient will have a very low probability of survival. In addition, if compressions are not initiated promptly, there is the risk of thrombosis within the pump, providing resistance to flow if the pump is restarted or if compressions are later begun. Thrombosis will also increase the risk of stroke if the patient survives. Given that they have severe to end-stage cardiac disease, some patients may not want to be resuscitated. Ideally, whether compressions should be initiated by EMS providers will be worked out in advance by discussion between patients, their caregivers, and their LVAD team, and that decision will be documented. However, given an unresponsive patient with clinical signs of hypoperfusion and no sound of pump function on auscultation, EMS providers will have to discuss the next step with caregivers on the scene and the LVAD coordinator by telephone. If the LVAD coordinator cannot be reached and the patient previously expressed a desire for resuscitative efforts, chest compressions should be initiated.

All LVAD patients should be transported to a hospital familiar with the management of LVADs, preferably to the hospital where the patient is being followed. Prehospital providers should bring with the patient all device equipment, including the hand pump for pulsatile LVADs, extra batteries, and primary and backup controllers, as well as family members or other caregivers.^{10,30}

CONCLUSION

Patients with LVADs are being cared for by EMS providers with increasing frequency. Such encounters can be stressful and challenging if providers are not

adequately prepared. While patients with LVADs may access EMS for injuries or for medical emergencies unrelated to their device or underlying cardiac condition, problems related to the device may require unique skill sets, rapid decision making, and consultation with family, other caregivers, and LVAD coordinators. It is therefore important that EMS systems develop protocols and training modules dealing with the care of these patients. Ongoing dialog should be initiated between EMS and area hospitals' LVAD staff. Finally, EMS providers should receive routine updates on LVAD patient assessment and management as the technology evolves.

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