

Ventricular Assist Devices : Important Information for Patients and Families Michael M. Givertz

Circulation. 2011;124:e305-e311

doi: 10.1161/CIRCULATIONAHA.111.018226

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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Ventricular Assist Devices

Important Information for Patients and Families

Michael M. Givertz, MD

Heart failure is the final common pathway for many chronic heart diseases. With the aging of the population and advances in the treatment of cardiac disease, the number of patients with heart failure continues to increase. Although the majority of patients will remain stable for several years with standard medicines and surgery, a growing number will develop symptoms of advanced heart failure and may be referred for evaluation for heart transplant. For selected patients who are too ill to wait for a heart donor or who are not eligible for a heart transplant because of age or other medical problems, ventricular assist devices (VADs) offer life-saving therapy. Initially designed as temporary support to bridge patients to heart transplant, these devices are now available and increasingly being used as lifetime support or destination therapy. Improvements in device design, along with advances in surgical and medical management, have allowed VAD patients to return home, to work, and to their communities, with excellent quality of life. At the same time, however, unique challenges have been encountered. This *Cardiology Patient Page*

will discuss the fundamentals of VADs, including patient selection, pump design, surgical and medical treatment, expected benefits and long-term risks, and the team approach to care.

What is Advanced Heart Failure?

Heart failure is a common cardiac condition in which the heart is unable to pump blood at a sufficient rate to meet the demands of the body. There are 2 major types of heart failure: one is associated with abnormal heart filling (sometimes called diastolic heart failure or heart failure with preserved ejection fraction), and the other is associated with abnormal heart emptying (also called systolic heart failure or heart failure with reduced ejection fraction). Most patients who develop heart failure have had a prior injury or stress on the heart that caused the heart to weaken. Examples include a heart attack, high blood pressure, heart valve problems, and irregular heart rhythms. Exposure to toxins such as alcohol and chemotherapy can also cause heart failure. A smaller number of patients are born with a heart defect or a

genetic mutation that leads to heart failure in adulthood. Other common medical conditions, such as diabetes, obesity, and chronic lung or kidney disease, can worsen heart failure.

The major symptoms of heart failure include fatigue, shortness of breath, and fluid retention. In most patients, these symptoms can be relieved or stabilized with medications such as angiotensin-converting enzyme inhibitors, β -blockers, and diuretics (or fluid pills), along with changes in lifestyle and diet. Implantable heart devices, such as pacemakers and cardioverter-defibrillators, are also available to improve both the quality and duration of life. However, it is estimated that about 250 000 of the 7 million patients with heart failure living in the United States will develop symptoms of advanced heart failure (Table 1). For carefully selected patients, heart transplantation offers a life-saving therapy. However, given the shortage of organ donors (there are only \approx 2200 donor hearts available each year in the United States), the vast majority of patients with advanced heart failure will progress to end-stage disease. For some, mechanical circulatory support

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(*Circulation*. 2011;124:e305-e311.)

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Circulation is available at <http://circ.ahajournals.org>

DOI: 10.1161/CIRCULATIONAHA.111.018226

Table 1. Symptoms of Advanced Heart Failure

Fatigue

- Feeling tired or weak
- Unable to perform usual daily activities such as showering or dressing without stopping to rest

Shortness of breath

- Breathlessness with activities such as walking 1 block or up 1 flight of stairs
- Breathlessness at rest
- Waking up at night with cough or congestion, or having to sleep on pillows or in a reclining chair to breathe

Fluid retention

- Swelling in the legs (also called edema)
- Swelling in the abdomen with bloating, pain, and loss of appetite
- Chest congestion leading to cough and shortness of breath (see above)
- Weight gain

Other

- Palpitations
- Lightheadedness
- Depression, memory problems (especially in older patients)
- Weight loss due to poor appetite and increased body metabolism

or VADs are available to take over the function of the failing heart.

Types of VADs

Many different mechanical devices have been developed to support the failing heart, ranging from total artificial hearts to VADs. The main purpose of a VAD is to unload the failing heart and help maintain blood flow to vital organs. VADs were originally developed to serve as a temporary bridge to heart recovery, and then as a bridge to transplant. Over the past 10 years, however, VADs have been approved by the US Food and Drug Administration to provide permanent or lifetime support for patients with end-stage heart failure. Temporary VADs are also available and can be placed by cardiologists in the heart catheterization laboratory or by surgeons in the operating room. These devices provide short-term support while other medical problems (eg, infection, kidney fail-

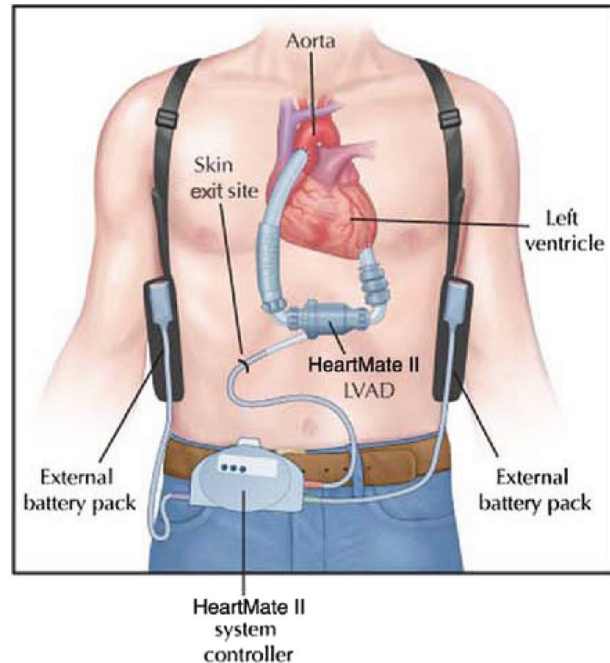


Figure 1. Components of a typical VAD. A continuous-flow left ventricular assist device consists of a pump connected to the heart and aorta via an inflow and outflow cannula, a driveline that exits the skin on the right, and a system controller that is typically worn on a belt. Power to the controller and pump is provided by external batteries or a power-based unit. VAD indicates ventricular assist device. Adapted from Wilson et al,¹ with permission of the publisher. Copyright © 2009, Elsevier.

ure) can be treated, and the prognosis of the patient better defined.

Bridge to transplant or destination therapy VADs are typically placed through a chest incision after the patient has been placed on a heart-lung bypass machine. There are 3 major components of the VAD (Figure 1): the inflow cannula, the outflow cannula, and the pump itself. The inflow cannula is a large tube that drains blood from the heart into the pump; the outflow cannula returns blood to either the aorta (in a left ventricular assist device or LVAD) or pulmonary artery (in a right ventricular assist device). A minority of patients with failing left and right ventricles need biventricular assist devices or a total artificial heart to bridge them to transplant.

First-generation pumps were pulsatile, contained artificial heart valves, and ejected blood at rates typically between 80 and 100 times per minute with the use of either forced air or electricity. Second-generation pumps circulate blood in a continuous fashion

by use of an internal rotor that spins up to 15 000 times per minute (typical range, 8000–10 000 rpm). The major advantages of continuous-flow pumps are that they are smaller, quieter, easier to implant, and last longer than the older, pulsatile pumps. Currently approved VADs are implanted just below the diaphragm in the abdomen, or can sit outside of the body on top of the abdomen. Smaller pumps that can be implanted adjacent to the heart in the chest cavity or provide only partial heart support are under development. A driveline that contains the power wires exits the skin, usually on the right side of the abdomen, and connects to a controller that is worn on a belt. This controller is then connected to either a power-based unit that plugs into the wall or large batteries that can be worn in a holster or vest for portable use. The controller is the brain of the pump, and provides important information to the patient, caregivers, and medical team about VAD function and battery life. Less commonly used

Table 2. Reasons for VAD Implantation

- Bridge to recovery
- Bridge to transplant
- Lifetime or destination therapy
- Bridge to candidacy

VAD indicates ventricular assist device.

pumps that sit outside of the body connect directly to a portable driver on wheels that can be pulled like a small suitcase.

Why Are VADs Implanted?

VADs are typically used for one of 3 reasons: as a bridge to recovery, bridge to transplantation, or destination therapy (Table 2). Bridge to recovery is for patients who need only temporary support (eg, days to weeks), during which time the heart recovers from an acute injury and the VAD is then removed. Examples include patients with a large heart attack or severe inflammation of the heart following a viral illness. In national databases, these patients make up <5% of the total VAD population. Bridge to transplant is the largest group to receive VADs. These patients are eligible for a heart transplant, but are too sick to wait for a donor heart to become available. Last, destination therapy patients are not eligible for heart transplant because of older age (eg, >70 years) or other chronic medical problems, and receive a permanent VAD to treat end-stage heart failure. Another term that is sometimes used is bridge to candidacy for patients who might be eligible for transplant, but need a period of VAD support to see whether vital organ function, nutrition, and strength can improve to allow successful heart transplant. In rare cases of patients with longstanding heart disease, VAD support may result in complete reversal of heart failure and allow the pump to be removed.

Patient Evaluation

Candidates for implantation of a VAD undergo an extensive medical and psychosocial evaluation before a final decision about treatment. Typically, this evaluation occurs during a heart failure

hospitalization, and includes cardiovascular testing such as an echocardiogram (heart ultrasound), stress test, and heart catheterization, and tests of other vital organ function, as well, including kidney, lung, and liver function. A general medical evaluation, including an update of routine health maintenance screens (for example, mammogram, prostate examination, and cholesterol blood test) and infectious disease screening (such as hepatitis, HIV, and tuberculosis) are also performed. Appropriate vaccines are administered. In addition, patients are routinely evaluated by a VAD nutritionist, physical therapist, and pharmacist, and they undergo a dental examination.

A major focus of the evaluation is determining the potential for VAD therapy to improve quality of life while educating patients and families about the benefits and risks of VADs. Extensive teaching occurs during this process. Candidates must understand the VAD regimen before the implantation of the VAD, and they must show that they have adequate support and identify caregivers to be trained in the use of the device. These supports must be available to the VAD patient until they are able to independently care for the VAD. A VAD social worker and psychiatrist play key roles in this evaluation, and all patients must sign an informed consent form agreeing to the process. In addition, patients are asked to participate in a national database of VAD patients that is required for all Medicare-approved programs in the United States. Data are collected at the baseline evaluation, throughout the surgical admission, and on a regular basis during outpatient follow-up.

Recovery From Surgery, Preparing for Hospital Discharge, and Return Home

The VAD operation takes between 6 and 10 hours. After surgery, patients spend on average 4 to 6 days in the cardiac surgery intensive care unit be-

fore being transferred to the step-down unit. This early period is focused on optimizing pump flow and monitoring for recovery of kidney, liver, and lung function. Intravenous diuretics are often used to get rid of extra fluid that may have accumulated from heart failure or was given during the operation to support blood pressure. After the patient wakes up and is able to breathe on his/her own, ventilator support is removed. Surgical lines and drainage tubes are removed, and the patient is allowed to begin eating and taking oral medications. The keys to surgical success are early mobilization, good nutrition and physical therapy, and meticulous wound care, as well. For most patients with VADs, the blood must be carefully thinned with intravenous and then oral medications to avoid blood clot formation.

Preparing the patient and caregivers for discharge home is the primary responsibility of the VAD coordinator. The coordinator is typically a nurse practitioner or physician assistant who specializes in the care of patients with VADs. These individuals are extremely knowledgeable about all aspects of VAD care, including surgical and medical treatment and pump technology and support. They assist in obtaining the necessary equipment and supplies, and work closely with other VAD team members to ensure a successful outcome (Figure 2). Central to their role is proper training of the patient, family, and community to allow a smooth transition home. If education and training are successful (Table 3), quality of life on the VAD will be maximized. The following components are critical to this process:

Physical Exercise

Once patients have recovered from surgery, it is expected that they will work on regaining strength and increasing exercise tolerance. In the hospital, this process is coordinated by a physical therapist. Following discharge, some patients may feel comfortable initiating an exercise program

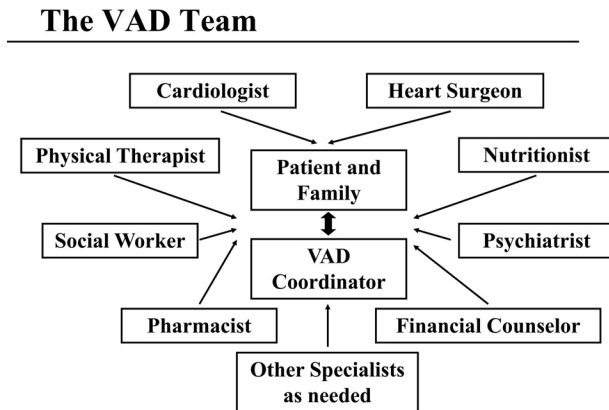


Figure 2. The VAD team. To optimize quality of life, patients and families must learn to work closely with many members of the VAD team. The VAD coordinator plays a central role in this multidisciplinary process. VAD indicates ventricular assist device.

at home. For others, enrollment in an outpatient cardiac rehabilitation program (often affiliated with a community hospital) provides support and helps to build confidence. The long-term goal is 30 minutes of submaximal aerobic exercise, such as walking or biking, daily.

Nutrition

Because of chronic illness and recurrent hospitalization, many patients with heart failure are malnourished at the time of VAD implantation. Poor nutrition can delay wound healing and increase the risk of infection; therefore, assessment by a nutritionist is critical to regaining strength and energy. During the hospitalization and sometimes after discharge, the nutritionist keeps a record of daily intake

Table 3. Components of VAD Education and Successful Discharge Home

- Exercise and physical therapy
- Nutrition
- VAD self-care
 - Driveline site dressing changes
 - System controller checks
 - VAD log book
- Activity restrictions
- Responsibility of primary physicians, VAD coordinator, and visiting nurses
- Role of EMTs and local emergency rooms
- Electric company and home power supply

VAD indicates ventricular assist device; EMT, emergency medical technician.

and makes recommendations for calorie and vitamin supplementation. Routine blood tests help track progress as well.

VAD Self-Care

In the hospital, nursing and medical staff are responsible for VAD care and proper function. Once at home, patients and caregivers must take over this job, which includes cleaning and checking equipment, changing the driveline dressing by the use of sterile technique, monitoring for infection, recording vital signs and VAD data, and making sure that batteries are working properly. Showers are allowed with proper equipment covering, but bathing and swimming are not possible with current VADs. Visiting nurses may assist in VAD care during the first 1 to 2 weeks after discharge, with a particular focus on dressing changes, medication adjustments, and laboratory draws.

Restriction on Activities

VAD patients should avoid situations or environments that may increase the risk of infection, such as sick contacts or daycare centers, but they are not restricted from public gatherings. Good hygiene and regular hand-washing are keys for anyone touching the VAD equipment or driveline dressing. Although exercise is encouraged, strenuous activities or contact sports that could inadvertently lead to device

damage or trauma to the driveline site are discouraged. Prolonged exposure to cold or heat should also be avoided. Restrictions on driving are specific to individual VAD programs and may be subject to state laws; patients are encouraged to speak with their VAD team about the safety and timing of resuming driving.

Constant and Safe Power Source

Before discharge, the electric supply at home must be confirmed and undergo a safety check to ensure proper grounding for battery charging. In addition, the electric company is notified to place the VAD patient on a list for priority power restoration in the event of an electric outage. Planned power outages are avoided, and the company is requested not to turn off electricity in the event of a late or nonpayment. A VAD financial counselor is available to help resolve billing issues if they occur.

Follow-Up in the VAD Clinic

Following uncomplicated surgery, patients will typically be discharged home to follow-up in the VAD clinic in 1 to 2 weeks, and monthly thereafter. The first several visits will involve a history and physical examination by the VAD physician, and review of medications and device function (eg, alarms, battery life) by the VAD coordinator. The driveline dressing may be changed allowing for examination of the driveline site, especially if there is concern for infection (see below). In some cases, the VAD surgeon may need to re-evaluate the patient if there are unresolved surgical issues, such as instability of the chest wound, or remaining tubes to be pulled. Diet and exercise are reviewed with particular attention to heart-healthy foods and gradual increase in aerobic activities such as walking or biking. Emergency contact numbers and reasons to seek emergency care are reviewed.

Patients are asked to check their blood pressure (if possible), weight, and temperature daily, and to record values in a VAD log book. Specific device readings, such as pump speed and flow, are also recorded by hand. Diabetic patients are asked to keep a record of their blood sugars, because unusual fluctuations or high readings can be an early sign of infection. Out-patient consultation with a nutritionist or social worker is arranged as needed. Patients are encouraged to follow up with their primary care physicians and cardiologists within 1 month of discharge. In the event of an emergency department visit, patients and caregivers are taught to bring with them their VAD equipment, up-to-date medication list, VAD doctors' names and numbers, emergency contact and healthcare proxy information, and living will, if available.

Medical Care on a VAD

Medical care of VAD patients requires close attention to several issues, including treatment of high blood pressure, anticoagulation, and heart rhythm disturbances. The majority of patients develop high blood pressure after VAD implantation, and this can have an impact on the durability of pump function and increase the risk of stroke. The first-generation pulsatile VADs were more likely to fail from bearing or internal valve wear if the blood pressure was not well controlled. With the second-generation continuous-flow pumps, blood pressure has a more direct impact on pump speed and flow. However, because of the nature of continuous blood flow, patients typically lack a pulse and the usual sounds heard with a stethoscope or picked up by an automatic blood pressure machine. Instead, average blood pressure must be measured by the use of a small ultrasound machine (or Doppler probe). When present, high blood pressure should be treated aggressively and may require more than 2 or 3 medications, such as angiotensin-converting enzyme inhibitors, β -blockers, and di-

uretics, to control. Reducing salt in the diet can also help.

The current generation of mechanical pumps requires thinning of the blood (or anticoagulation) to prevent the formation of blood clots. These clots can cause dysfunction of the pump itself, or more typically, can embolize into the circulation and cause a transient ischemic attack, stroke, or lack of blood flow to a limb or vital organ. The typical blood-thinning regimen for continuous-flow pumps includes the use of warfarin (which blocks the formation of clotting proteins by the liver) and a baby aspirin (which inactivates platelets). The level of anticoagulation is monitored regularly by checking a blood test called the international normalized ratio and adjusting the dose of warfarin. This is usually performed by a nurse specialist or pharmacist in a hospital- or office-based anticoagulation service. In the event of bleeding or clotting (see below), the target international normalized ratio may need to be decreased or increased. Use of higher-dose aspirin or an additional antiplatelet agent, such as clopidogrel, is based on the patient's medical history (eg, prior transient ischemic attack or coronary artery stent).

Patients with advanced heart failure often have a history of arrhythmias (heart rhythm disturbances) arising from the upper and/or lower chambers, and may have undergone placement of a pacemaker or cardioverter-defibrillator before VAD surgery. Some may also be receiving antiarrhythmic therapy. Therefore, it is critical for these patients to maintain follow-up with their device/heart rhythm specialists. Although the majority of pacemakers/cardioverter-defibrillators are compatible with VADs, the internal settings may need to be adjusted after surgery to prevent unnecessary pacing or shocks. In some cases, a change in or addition of antiarrhythmic therapy may be necessary. Importantly, one sign of too much speed with a continuous-flow pump is the new occurrence of ventricular arrhythmias due to heart suction. In this

situation, an echocardiogram can be used to optimize heart filling while adjusting pump speed.

Complications of VADs


VADs offer life-saving therapy and improve quality of life of patients with end-stage heart failure, but they are not free of complications. In the most recent studies, 80% to 90% of patients are alive at 1 year, and 60% to 70% are living at 2 years. Others have undergone successful heart transplant, been weaned off the VAD (bridge to recovery), or died while living on a VAD. Early problems after surgery include bleeding from the chest and right heart failure. Later problems include other sources of bleeding, infection, stroke, or device malfunction.

Bleeding

Most cardiac surgery, including VAD implantation, requires high levels of anticoagulation while the patient is on the heart-lung machine. This fact, along with the need for both chest and abdominal incisions and the poor nutritional status of many patients, increases the risk of early bleeding. Most patients can be managed with reversal of anticoagulation and transfusion of blood products, but some may need to return urgently to the operating room for bleeding control. After hospital discharge, patients are at increased risk of bleeding from the gastrointestinal tract and nose bleeds. There are several contributing factors, including anticoagulation and antiplatelet therapy (discussed above), nonpulsatile blood flow leading to blood vessel malformation in the gut, and pump-related changes in blood-clotting factors. Many patients take iron supplementation, whereas a minority requires weekly injections to stimulate red blood cell production from the bone marrow. For recurrent or life-threatening bleeding, anticoagulation may be discontinued completely.

Right Heart Failure

Although most patients with advanced heart failure have severe weakness of the left ventricle and undergo LVAD



placement alone, a subgroup will also have weakness of the right ventricle that puts them at risk for developing right heart failure after LVAD surgery. Signs of right heart failure include swelling of the legs and abdomen, distention of neck veins, and collection of fluid under the lungs. Inadequate filling of the LVAD and reduced blood flow can lead to weakness, poor appetite, and organ dysfunction (eg, kidney failure). Most cases of right heart failure can be managed with short-term support with intravenously administered medications and diuretics. More severe cases will require placement of a right ventricular assist device to bridge to transplant. Risk scores have been developed to help doctors predict which patients are likely to develop right heart failure and would benefit from initial placement of biventricular assist devices or a total artificial heart.

Stroke

VAD patients are at risk of stroke, which can be caused by blood clots leaving the pump, high blood pressure, or bleeding into the brain. The rates of stroke appear to have declined somewhat with the newer continuous-flow pumps, but the need for anticoagulation and ongoing risk of infection (which seems to increase the body's tendency to form clots) have not eliminated this complication. In older patients receiving VADs as destination therapy, underlying cerebrovascular disease may also increase the risk of stroke. Close monitoring of anticoagulation, optimal blood pressure control, and meticulous wound care are important strategies for minimizing stroke risk. Lowering blood cholesterol with a healthy diet and cholesterol-lowering medications such as statins can also lower this risk.

Infection

Device infection can occur at any time during VAD support, but most frequently develops in the first few weeks or months after implant. Common bacteria that live on the skin such as staphylococcus can gain access to the driveline and pump from the skin exit

site (see Figure 1). Alternatively, bacteria from the gut or urinary system can enter the bloodstream and secondarily infect the VAD. Patients who are immunosuppressed or have diabetes mellitus may be at increased risk for infections from uncommon organisms such as yeast. Depending on their severity and duration, driveline infections are treated with oral or intravenous antibiotics and daily wound care. Although most driveline or cannula infections cannot be cured, they can usually be suppressed until the time of transplant and hardware removal. For a small number of patients, overwhelming infection and death may occur. As with most infections, the key is prevention. This includes meticulous care of the driveline exit site with the use of a mask and sterile gloves during dressing changes, stabilization of the driveline and avoiding activities that could lead to local trauma, and education of patients and caregivers about the early signs of infection, and the importance of prompt notification of the VAD team.

Device Failure

With the first-generation pulsatile-flow pumps, device malfunction was a major cause of hospitalization and even death in VAD patients. These devices were designed for relatively short- or medium-term support to bridge patients to transplant. With the approval of pumps for destination therapy and increased waiting time for patients bridging to transplant, prolonged support (ie, >1–2 years) was required. However, up to two-thirds or more of pumps failed during this period. Fortunately, the newer continuous-flow pumps with fewer parts and a simpler operation have demonstrated improved durability. Malfunction of wires, controllers, and batteries still occurs, but these problems are relatively minor, indicated by alarms, and generally easy to repair. In rare instances, the entire VAD must be surgically replaced.

Quality of Life on a VAD: What to Expect?

Despite the possibility of complications with device therapy, most patients describe a marked improvement in their quality of life following VAD implantation. With normal blood flow to the body, symptoms of advanced heart failure resolve completely or are reduced to only a mild level. Patients are once again able to perform enjoyable activities such as exercise, travel, and sex. For younger patients, return to work or school is possible, and older patients enjoy hobbies and outdoor activities such as golf, hiking, and fishing. In patient surveys, the ability to drive is mentioned as one of the biggest advantages to VAD treatment. Compared with medications or pacemakers, VADs improve quality of life to a far greater degree.

Focus of Current Research

Until very recently, the heart was thought to be an organ that could not repair itself after suffering an injury such as a heart attack or developing end-stage cardiomyopathy (primary heart muscle disease). Recent research, however, suggests that the heart can indeed repair itself with rest and new therapies. A group at the University of London showed that patients with long-standing cardiomyopathy, supported on an LVAD and treated with high-dose ACE inhibitors, β -blockers, and a medicine to stimulate new muscle growth, could recover heart function, allowing the LVAD to be safely removed. Others are working to harness the power of stem cell therapy to reverse heart failure on a VAD. While physicians and VAD coordinators wait for these and other major breakthroughs to occur, device companies continue to make progress in reducing pump size and improving battery life with the goal of designing a fully implantable pump.

Further Information

For further information, see the following:



- American Heart Association, Conditions, Heart Failure, Prevention & Treatment. http://www.heart.org/HEARTORG/Conditions/HeartFailure/PreventionTreatmentofHeartFailure/Implantable-Medical-Devices-for-Heart-Failure_UCM_306354_Article.jsp.
- National Heart Lung and Blood Institute, Diseases and Conditions Index, Heart Failure, Treatments. <http://>

www.nhlbi.nih.gov/health/dci/Diseases/vad/vad_what.html.

- Heart Failure Society of America, HF Education Modules. http://www.hfsa.org/heart_failure_education_modules.asp.

Acknowledgments

The author would like to acknowledge Dr Sean Wilson, Dr Garrick Stewart, and Dr Gilbert H. Mudge, Jr, who contributed

significantly to prior clinical reviews on VAD patient selection and outpatient care from which this article benefited greatly.

Disclosures

None.

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1. Wilson SR, Givertz MM, Stewart GC, Mudge GH Jr. Ventricular assist devices: the challenges of outpatient management. *J Am Coll Cardiol*. 2009;54:1647–1659.