An overview of approved and investigational left ventricular assist devices

Randy Marcel, MD, and Dan M. Meyer, MD

According to the American Heart Association, 4,600,000 people have congestive heart failure, and 550,000 new cases of congestive heart failure are diagnosed each year (1). Pharmacological intervention is the main therapy for most of these patients, but many become refractory to medical therapy. If these patients are suitable candidates, they are placed on the waiting list for heart transplantation. Those who are not candidates for transplant or for whom an organ is not available in a timely fashion may require mechanical support for their failing hearts with a left ventricular assist device (LVAD). This device may be used as a "bridge to recovery" or, in patients where no recovery is expected, as a "bridge to transplant" (2, 3).

The first experimental bridging devices were used at the Texas Heart Institute in 1968, 1978, and 1981 (4). However, all of the patients receiving the devices died while awaiting a donor heart for transplantation. The first successful bridge to transplant occurred in 1985 at the Texas Heart Institute (5). More recently, data from the REMATCH trial (for which Baylor University Medical Center was one of 20 US sites) indicated that LVAD treatment is a plausible alternative to medical therapy for patients who are not candidates for heart transplantation (6). This group of patients is beginning to receive LVADs as "destination therapy," with no intention of transplantation or removal of the device. LVAD destination therapy has now been approved by the US Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (6).

The cost of LVAD implantation is considerable but less than the cost of maintaining a status I candidate for heart transplant for 42 days, the median waiting time in 2001 (1). About 90% of patients fitted with an LVAD can be discharged from the hospital, and about 75% survive to undergo transplantation (7). Many studies suggest that patients with LVADs do better at transplant than those without such devices. The contention is that patients with LVADs demonstrate physiologic improvements that lead to better survival (8).

After reviewing the 3 FDA-approved LVADs, this article highlights 2 experimental devices and discusses anesthetic and technical considerations in their use.

APPROVED DEVICES

The 3 LVADs currently approved by the FDA for "bridge to transplant" are the HeartMate Left Ventricular Assist System (implantable pneumatic [IP] and vented electric [XVE] models) (Thoratec Corporation, Pleasanton, CA) *(Figure 1)*, the Novacor Wearable Left Ventricular Assist System (World Heart Corporation, Ottawa, Canada) *(Figure 2)*, and the Thoratec Ventricular Assist System (Thoratec Corporation, Pleasanton, CA) *(Figure 3)*. The goal of all 3 devices is to assume the function of the failing left ventricle. Each device drains blood from the left ventricle into a pump that ejects blood into the ascending thoracic aorta via a conduit. The Thoratec device is unique in that it may also be used to support the right ventricle with a second pump interposed between the right ventricle and the pulmonary artery (9).

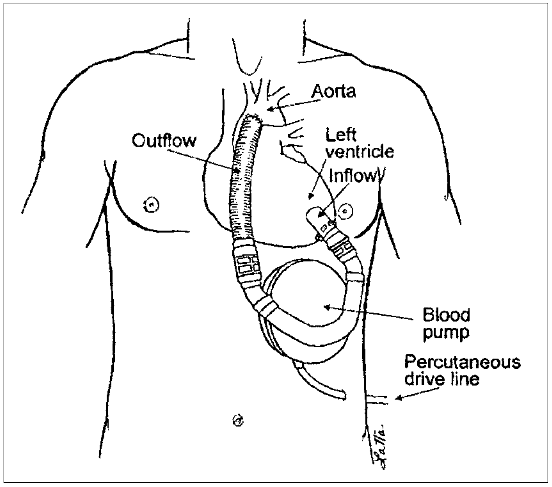

Figure 1. The HeartMate Implantable Pneumatic Left Ventricular Assist System. Reprinted with permission from reference 1.

These devices use unidirectional valves in the inflow and outflow conduits between the ventricle and aorta (1, 10). HeartMate and Novacor use porcine valves, while Thoratec uses mechanical valves (1). Regarding the need for long-term anticoagulation, HeartMate is unique with respect to the blood-contacting surfaces. It uses textured material to promote the formation of a pseudointimal lining, and thus only aspirin therapy is needed to prevent thrombosis (11). The Novacor and Thoratec devices have smooth surfaces and do not promote pseudointimal linings, and thus patients must be chronically anticoagulated with warfarin (10, 11).

From the Departments of Anesthesiology and Pain Management (Marcel) and Cardiothoracic Surgery (Meyer), Baylor University Medical Center, Dallas, Texas.

Corresponding author: Randy Marcel, MD, Department of Anesthesiology and Pain Management, Baylor University Medical Center, 3500 Gaston Avenue, Dallas, Texas 75246.

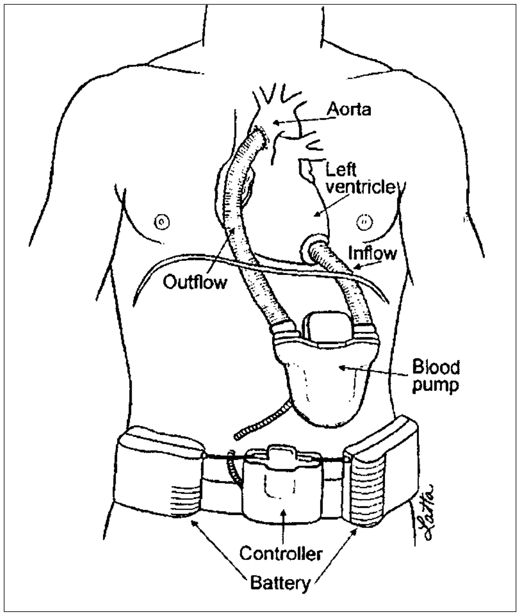

Figure 2. The Novacor Wearable Left Ventricular Assist System. Reprinted with permission from reference 1.

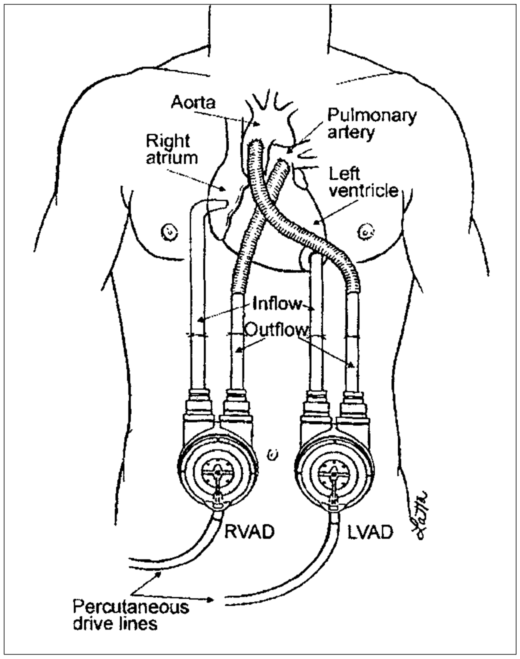

Figure 3. The Thoratec Ventricular Assist System in the biventricular support configuration. RVAD indicates right ventricular assist device; LVAD, left ventricular assist device. Reprinted with permission from reference 1.

Both HeartMate and Novacor are fully implanted in the body. The pumps are placed in the left upper quadrant of the abdomen, and only the driveline, which connects the pump to the control unit, transverses the skin (10, 11). The Thoratec device, in contrast, is positioned in a "paracorporeal" location, which allows some flexibility in using this pump in smaller patients (12). The conduits transverse the skin to connect with the pump, which is external to the skin on the upper abdomen.

All 3 devices provide pulsatile flow with a stroke volume that is determined by the preejection chamber volume and the outflow resistance. The heart continues to beat in its own rhythm, but since the left ventricle is volume unloaded throughout the cardiac cycle, it contributes very little to the aortic flow. The right ventricle continues to function as a pump for pulmonary circulation except when the right-sided portion of the Thoratec pump is in use. All 3 pumps work in a fill-and-empty mode, with the contents of the pump being delivered with each cycle of the pump. Thus, preload of the pump is very important in determining the stroke volume delivered. HeartMate and Novacor can deliver 10 L/min, and Thoratec can deliver >7 L/min (1).

All pumps connect by a driveline to a controller unit that is worn on a belt. The HeartMate and Novacor devices have a battery pack to power the unit, but the Thoratec device although portable is not wearable (1). These pumps, either pneumatically or electrically, pressurize air supplied by the driver to move the internal compliance chambers inside the pumps. Blood is moved along the one-way valves connecting the left ventricle to the aorta.

COMPLICATIONS

The most frequent complications of ventricular assist devices are bleeding, infection, thromboembolism, renal failure, hemolysis, and neurological dysfunction (13, 14). Bleeding and infection are the most prevalent and immediate complications (13, 14). Bleeding is due to the coagulopathy of hepatic dysfunction secondary to right heart failure and is the result of the extensive surgical procedure required. Cardiopulmonary bypass and blood-pump rheology also cause platelet dysfunction. Infection rates are about 30% to 40% and contribute to significant morbidity (15). Infection usually occurs because the driveline acts as a conduit from the outside environment; moreover, the large surgical pocket created to house the LVAD can collect undrained blood and serve as a potential culture medium.

LATEST DEVICES

The MicroMed DeBakey VAD *(Figure 4)* and the Jarvik 2000 are new LVADs currently under clinical investigation in heart transplant patients (2). Both provide continuous nonpulsatile flow by a rotating vaned propeller. Baylor University Medical Center was one of the first 4 centers in the USA selected for the initial FDA trial of the DeBakey VAD and remains in a select group of major heart transplant centers approved to use the device. To date, over 260 DeBakey VADs have been placed worldwide, with results similar to those of other LVADs.

The continuous flow technology of the new devices eliminates the need for valves, compliance chambers, and an externalized vent, thus minimizing thrombus formation in the device. The small size of each device allows its use in smaller patients, and the entire device is placed in the thoracic cavity, thus eliminating the need for access to the abdominal cavity and potentially lowering infection rates (2). Moreover, in some situations, such as in patients with multiple prior sternotomies, the small size of the device allows placement via a lateral thoracotomy. Another potential advantage of the axial flow pumps is that they can also act as true LVADs. The output of the device can be adjusted and thus allow for ventricular recovery. Other LVADs are true left ventricular replacement devices.

The anesthetic and surgical management of the DeBakey VAD and Jarvik 2000 differs from that of other LVADs and thus deserves comment.

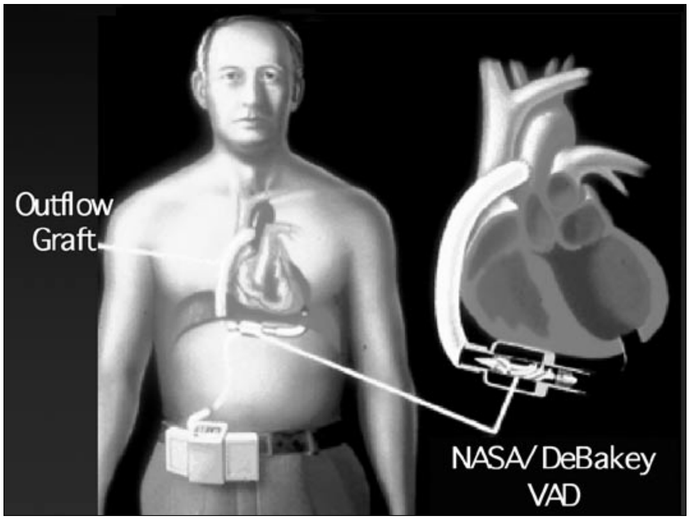

Figure 4. The DeBakey Left Ventricular Assist Device. Reprinted with permission from MicroMed.

Anesthetic management

Preoperative assessment should focus on any neurological deficits, cardiac function, hepatic function, and coagulation status. Preoperative drug therapies should be continued into the operative period. Preoperative prophylactic antibiotics are imperative since LVAD patients have a high incidence of infection.

Standard cardiac hemodynamic monitoring is used. A mixed venous pulmonary artery catheter is usually placed before induction of anesthesia, and a transpulmonary pressure gradient (mean pulmonary artery pressure minus pulmonary capillary wedge pressure) is calculated. This gradient is helpful in distinguishing the degree of pulmonary hypertension resulting from left ventricular failure from that resulting from increased pulmonary vascular resistance.

Transesophageal echocardiography (TEE) is now considered standard in LVAD cases. Anesthesiologists should be skilled at TEE since each phase of the LVAD implant requires ongoing evaluation of the left ventricle and the cardiologists cannot be expected to stay in the operating room for that purpose. A complete TEE assessment should be performed before cardiopulmonary bypass is started. Left and right ventricular function should be evaluated with particular attention to any thrombus at the apex of the left ventricle since this is the insertion site of the LVAD. Aortic valve insufficiency of moderate grade or greater will cause blood to leak back into the left ventricle when the device is activated (2). The atrial septum needs to be carefully inspected for any defects since activation of the device will result in decreased left atrial pressures and thus a right-to-left shunt via a patent foramen ovale. This will decrease systemic oxygenation and can be detrimental in an already compromised patient. The thoracic aorta should be inspected for plaque or defect as this is where the outflow graft of the LVAD device is connected. Careful alignment of the DeBakey VAD's inlet between the apex of the left ventricle and mitral valve is important to ensure proper function and flow of the device. TEE is also used to ensure deairing of the heart before weaning from cardiopulmonary bypass and activation of the device.

As the DeBakey VAD can pump 8 L/min from the left ventricle, the main problem during weaning from bypass is maintaining inflow from the right heart.

Right ventricular failure usually occurs to varying degrees in most of the patients presenting for LVAD; thus, maintaining pulmonary vasodilation and supporting right ventricular function is imperative. Epinephrine, amrinone, or milrinone is often used for this purpose. Norepinephrine is used to maintain systemic vascular resistance, and vasopressin can be added if necessary. If pulmonary vascular resistance remains high after these measures, then inhaled nitric oxide can be added. Prostaglandin E_1 infusions and sildenafil have also been used to treat pulmonary hypertension in LVAD patients.

As weaning from the bypass occurs, the DeBakey VAD speed is increased by 1000-rpm increments (2). As flow rate of the pump increases, sufficient blood is shunted through the pump to prevent the aortic valve from opening. This can cause stasis of blood in the aortic root and decreased coronary blood flow. By using TEE, the pump flow is adjusted to allow the aortic valve to open. The dynamic relation between left ventricular inflow, right ventricular function, preload, afterload, aortic valve movement, and pump speed is carefully adjusted using TEE and the pulmonary artery catheter.

Patients are usually transported to the intensive care unit while sedated with propofol. Ongoing adjustments of vasopressors, pulmonary vasodilators, and preload are individualized to each patient. When hemodynamically stable, patients can be extubated and administered analgesics as necessary.

Technical management

The technical aspects of implantation of these newer devices are similar to the techniques used with the more conventional LVADs. The advantages of the newer, axial flow devices are related to their smaller size, eliminating the need to construct a preperitoneal pocket and therefore limiting the operative time significantly. More emphasis is placed on positioning the inflow conduit in the ventricle, which accents the importance of the anesthesiologist's expertise with TEE.

The shorter operative time, the more limited surgical procedure, and therefore the smaller area for potential bleeding may decrease the need for many of the blood products that are often necessary when implanting LVADs. However, the underlying coagulopathy related to the hepatic congestion, as discussed above, usually mandates the need for some component therapy.

---

1. Hunt SA, Frazier OH. Mechanical circulatory support and cardiac transplantation. *Circulation* 1998;97:2079–2090.
2. Nussmeier NA, Probert CB, Hirsch D, Cooper JR Jr, Gregoric ID, Myers TJ, Frazier OH. Anesthetic management for implantation of the Jarvik 2000 left ventricular assist system. *Anesth Analg* 2003;97:964–971.
3. Mets B. Anesthesia for left ventricular assist device placement. *J Cardiothorac Vasc Anesth* 2000;14:316–326.
4. Nicolosi AC, Pagel PS. Perioperative considerations in the patient with a left ventricular assist device. *Anesthesiology* 2003;98:565–570.
5. Goldsmith M. First implant of portable heart-assist device. *JAMA* 1991;265: 2930, 2933.
6. Rose EA, Moskowitz AJ, Packer M, Sollano JA, Williams DL, Tierney AR, Heitjan DF, Meier P, Ascheim DD, Levitan RG, Weinberg AD, Stevenson LW, Shapiro PA, Lazar RM, Watson JT, Goldstein DJ, Gelijns AC. The REMATCH trial: rationale, design, and end points. Randomized Evaluation

of Mechanical Assistance for the Treatment of Congestive Heart Failure. *Ann Thorac Surg* 1999;67:723–730.

7. Rose EA, Levin HR, Oz MC, Frazier OH, Macmanus Q, Burton NA, Lefrak EA. Artificial circulatory support with textured interior surfaces. A counterintuitive approach to minimizing thromboembolism. *Circulation* 1994;90: II87–II91.
8. Frazier OH, Rose EA, McCarthy P, Burton NA, Tector A, Levin H, Kayne HL, Poirier VL, Dasse KA. Improved mortality and rehabilitation of transplant candidates treated with a long-term implantable left ventricular assist system. *Ann Surg* 1995;222:327–336; discussion 336–338.
9. Farrar DJ, Hill JD. Univentricular and biventricular Thoratec VAD support as a bridge to transplantation. *Ann Thorac Surg* 1993;55:276–282.
10. Ley SJ, Hill JD. Thoratec ventricular assist device. In Qual SJ, ed. *Cardiac Mechanical Assistance Beyond Balloon Pumping*. St. Louis, MO: CV Mosby, 1993:67.
11. Shinn JA, Oyer PE. Novacor ventricular assist system. In Qual SJ, ed. *Cardiac Mechanical Assistance Beyond Balloon Pumping*. St. Louis, MO: CV Mosby, 1993:99.
12. Reedy JE, Swartz MT, Lohmann DP, Moroney DA, Vaca KJ, McBride LR, Pennington DG. The importance of patient mobility with ventricular assist device support. *ASAIO J* 1992;38:M151–M153.
13. Quaini E, Pavie A, Chieco S, Mambrito B. The Concerted Action "Heart" European registry on clinical application of mechanical circulatory support systems: bridge to transplant. The Registry Scientific Committee. *Eur J Cardiothorac Surg* 1997;11:182–188.
14. Mehta SM, Aufierio TX, Pae WE Jr, Miller CA, Pierce WS. Combined Registry for Clinical Use of Mechanical Ventricular Assist Pumps and the Total Artificial Heart in conjunction with heart transplantation: sixth official report–1994. *J Heart Lung Transplant* 1995;14:585–593.
15. Moroney DA, Vaca KJ. Infectious complications associated with ventricular assist devices. *Am J Crit Care* 1995;4:204–209.