



Clinical

Comment

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CARDIAC SURGERY

The CardioVAD: Help for Patients Dying of Heart Failure

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Congestive heart failure (CHF) is one of the leading causes of death in the United States and is increasing in magnitude with the aging population. CHF currently affects more than 2 million patients and 400,000 new patients receive this diagnosis annually. Advances in medical therapy and transplantation have improved patient survival and quality of life. However, a large number of patients remain who have failed maximal medical therapy and are not transplant candidates. This situation occurs either owing to age (>70 years), advanced diabetes, malignancy, and/or renal, liver, or pulmonary dysfunction. In the past, there was nothing else to offer these patients except palliation with chronic inotropic therapy, which has a 6-month survival rate of less than 50 percent.

However, there is potential hope for these desperately ill patients. The National Institutes of Health have invested a significant amount of money in the development of circulatory support systems. Several devices have been developed, ranging from the total artificial heart used in Barney Clark

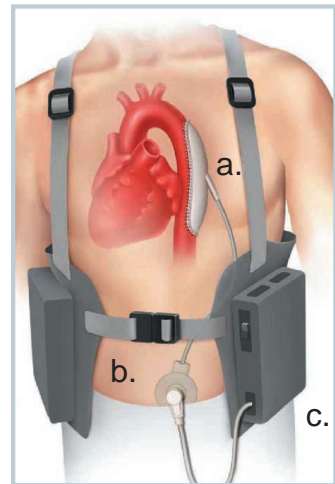


FIGURE 1. The CardioVAD after implantation. The CardioVAD is sewn to the descending aorta (a). The patient wears the percutaneous access device (b). The battery and drive console each weigh 2.5 lb (c).

IN THIS ISSUE...

INTERVENTIONAL CARDIOLOGY

- 4** Advances in
Interventional Cardiology

PEDIATRIC CARDIAC SURGERY

- 7** Optimizing Outcomes in
Neonatal Cardiac Surgery

PEDIATRIC CARDIOLOGY

- 11** Nonsurgical Closure of
the Persistent Patent
Ductus Arteriosus

EMERGENCY MEDICINE

- 13** The Public Access
Defibrillation Trial
and the Emergency
Resuscitation Center

ANNOUNCEMENTS

- 15** The Advanced Center for
Refractory Chest Pain
- 16** New Medical ICU Offers
Expanded Capacity

to ventricular assist devices (VADs), which now are used routinely.

VADs take blood out of the ventricle and pump it back to the rest of the body. This is accomplished either by pusher plate, rotary pump, or bladder compression technology. The ventricle essentially becomes a passive conduit but can function as an emergency backup if the VAD fails. Currently available VADs are approved only as a bridge to transplantation; that means that transplantation remains the destination of therapy. For the nontransplant patient in severe CHF (which is a much larger population than those who can benefit from transplant), there has been no permanent device for circulatory support.

The current VADs provide temporary lifesaving support but have limitations for permanent use. The devices are bulky, can cause bleeding, are prone to infections, and can cause thromboembolic events. Furthermore, the valved conduits that are required to keep blood flow unidirectional can deteriorate rapidly, and interruption of VAD function for greater than 1 minute can cause stasis and thrombosis of the device. Since the surgery to implant these devices is a major undertaking, it is those who have the most to gain from this technology — the debilitated and cardiac-cachectic patients — who can experience the most complications. Many new devices are under development that are designed to be smaller, more reliable, and totally implanted to decrease the incidence of infection; however, none are yet available.

One exciting novel device that has been under development over the last 30 years now is available at the University of Chicago for these desperately ill patients. The CardioVAD (LVAD Technologies, Detroit, Mich.) is unlike all other assist devices in that it uses the aorta to indirectly support the circulation (Figure 1, p.1). It can be best considered a permanent, larger, and more efficient version of the commonly used intraaortic balloon pump. The CardioVAD essentially is a polyurethane

FIGURE 2A. CardioVAD mechanism of action. During heart diastole, the CardioVAD inflates, pushing blood out of the aorta.

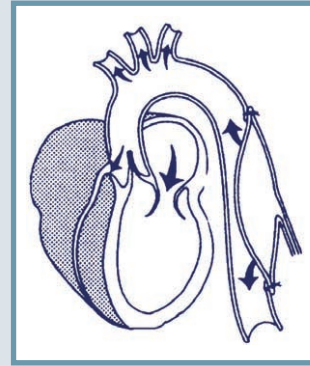
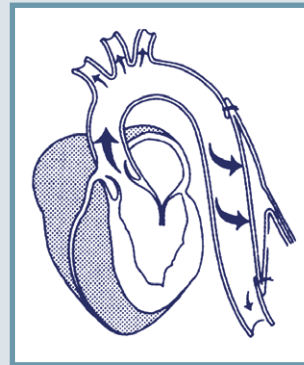


FIGURE 2B. Just before cardiac systole, the CardioVAD deflates, causing an area of lower pressure, drawing blood from the heart, and decreasing the workload of the heart.



diaphragm attached to a rigid housing that replaces the lateral portion of the descending aorta. Compressed air, supplied by the external drive unit, is used to inflate the device.

The CardioVAD is triggered by the electrical activity of the native heart (Figure 2) and is set to inflate during diastole. As the device inflates, it displaces 60 cc of blood from the arterial circulation. As the heart starts to contract during systole, the CardioVAD deflates and actually causes some suction. This vacuum, in addition to the blood already displaced by the CardioVAD, dramatically decreases the workload of the heart. In our human trials, patients' cardiac output has been shown to increase from 50 percent to 100 percent with the initiation of pumping, with a concomitant dramatic decrease in pulmonary artery pressures. The unit has no valves or conduits that can deteriorate over time. Simplicity is an important feature of the device; the only component placed into the thoracic cavity is the bladder, which has been life-tested for 15 years. All the



electronics reside outside the patient and can be readily maintained. The driveline is attached to the CardioVAD and is exteriorized through the skin. Percutaneous drivelines have been a major problem with all VADs, as they do not heal well owing to constant motion, and have a high risk of becoming infected. To obviate that problem, through proprietary cell-culture technology, the percutaneous access device is coated with the patient's own fibroblast, causing an in-growth of the skin and an antibacterial interface. A 2 cm round button placed in the right or left upper quadrant of the patient is the only thing visible from the device. The patient can simply snap on or off the driveline as clinically indicated. The batteries and console to drive the pump have been miniaturized into two 2.5 lb boxes that are the size of two paperback books and are carried in a vest.

The ease of implantation also makes the CardioVAD appealing for these nutritionally depleted patients. The heart is not touched during the implantation. Rather, through a limited posterior thoracotomy, the patient is placed on partial cardiopulmonary bypass and the lateral portion of the aorta is replaced by the CardioVAD. Since there is minimal dissection and good visibility of the anastomosis, bleeding has not been a problem. High thoracic epidurals are placed in these patients prior to implantation for improved cardiac performance and pain control. Patients usually are extubated within a day and can leave the intensive care unit within 3 days.

Inotropes such as dobutamine or milrinone are slowly weaned and the CardioVAD is allowed to pump continuously. The operation of the device is automatic. It senses electrical activity and deploys during diastole. It also senses pressure and deploys enough force to augment the patient's blood pressure from 20 to 30 mmHg. The patient's only control is an on/off switch. There is a correction algorithm for atrial fibrillation and maximum augmentation is obtained with heart rates of less than 130 bpm.

As part of a US Food and Drug Administration phase I trial, The University of Chicago is the only investigational site in the world that currently implants the CardioVAD (Figure 3). For inclusion in this trial, patients must: (1) be 18 to 80 years of age; (2) have a diagnosis of class III or higher heart failure that is refractory to maximal medical therapy; and (3) be ineligible for transplantation as determined by the physician or the patient's wishes. Exclusion criteria include: (1) left ventricular failure due to lesions amenable to conventional cardiac surgery; (2) uncontrolled sepsis; (3) uncontrolled hemodynamically compromising arrhythmias; (4) renal disease that requires permanent dialysis; (5) severe chronic obstructive pulmonary disease; or (6) recent cerebrovascular accident. Patients can go home as soon as they can ambulate and understand how to operate the device. Patients return for follow-up visits weekly for the first month and then in less frequent intervals.

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FIGURE 3. Adrian Kantrowitz, MD, inventor of the CardioVAD, meets with a patient during an outpatient clinic visit 4 weeks after implantation with the CardioVAD device.

Clinical results to date have been outstanding. Four patients have been implanted with the device. They were all men (average age, 74 years) with class IV+ heart failure. All were receiving maximal intravenous inotropes (cardiac index <1.6 L/min/M²), had a systemic blood pressure mean of less than 65 mmHg, and pulmonary artery diastolic pressures greater than 25 mmHg. The patients had lost an average of 25 lb due to heart failure. The average serum creatinine level was 2.5 mg/dL. Despite how sick the patients were, they all survived the surgery. One patient succumbed to pulmonary dysfunction, which was present preoperatively. The others weaned off inotropes, recovered renal function, and were fully ambulatory. One patient turns the device

on at night and is device-free for 8 hours during the day — giving him an almost normal quality of life.

CardioVAD technology is exciting and brings hope to patients with severe CHF. If you would like to refer a patient, please call Dr. Jeevanandam at (773) 702-2500.

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Interventional Cardiology

Advances in Interventional Cardiology

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It is now estimated that more than 700,000 cardiac interventional procedures are performed each year in the United States.¹ The success of these procedures is largely owing to significant improvements in technique and advancements in equipment, which allow percutaneous coronary interventions to be performed in 60 percent to 70 percent of patients who need coronary revascularization. However, these procedures still have a number of limitations.

Previously, acute complications, although infrequent, led to significant mortality and morbidity. The development and rapid growth of the use of stents has significantly reduced the number of acute complications of angioplasty procedures, so that the combined rates of death, myocardial infarction, and emergency bypass now are less than 5 percent, with an overall success rate of more than 95 percent, as recently reported by the National Heart, Lung, and Blood Institute PTCA (Percutaneous Transluminal Coronary Angioplasty) Dynamic Registry.²

Currently, more than 70 percent of coronary procedures involve the placement of a stent.² A large number of studies also have shown that stents combined with platelet glycoprotein IIb/IIIa antagonists, such as abciximab (ReoPro, Eli Lilly and Company, Indianapolis,

