



LEFT VENTRICULAR ASSIST DEVICES: BRIDGE TO TRANSPLANT OR TO A BETTER LIFE

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I would like to share with you some information concerning left ventricular assist devices (LVADs). I have prepared this article in the frequently asked questions format which I find more interesting.

1. Who could benefit from LVAD?

Patients who benefit from the LVAD are people who have advanced or severe cases of heart failure. Patients with advanced heart failure have a 15-25% annual mortality and patients with severe heart failure have a greater than 25% annual mortality. Basically, patients with persistent or severe symptoms of heart failure who often have prolonged or repeated hospitalizations could be candidates. It is estimated that anywhere from 30,000 to 100,000 patients could benefit from heart transplantation. However, there are only slightly greater than 2,200 transplants performed annually. In addition to this, the waiting list is in excess of 4,000 patients.

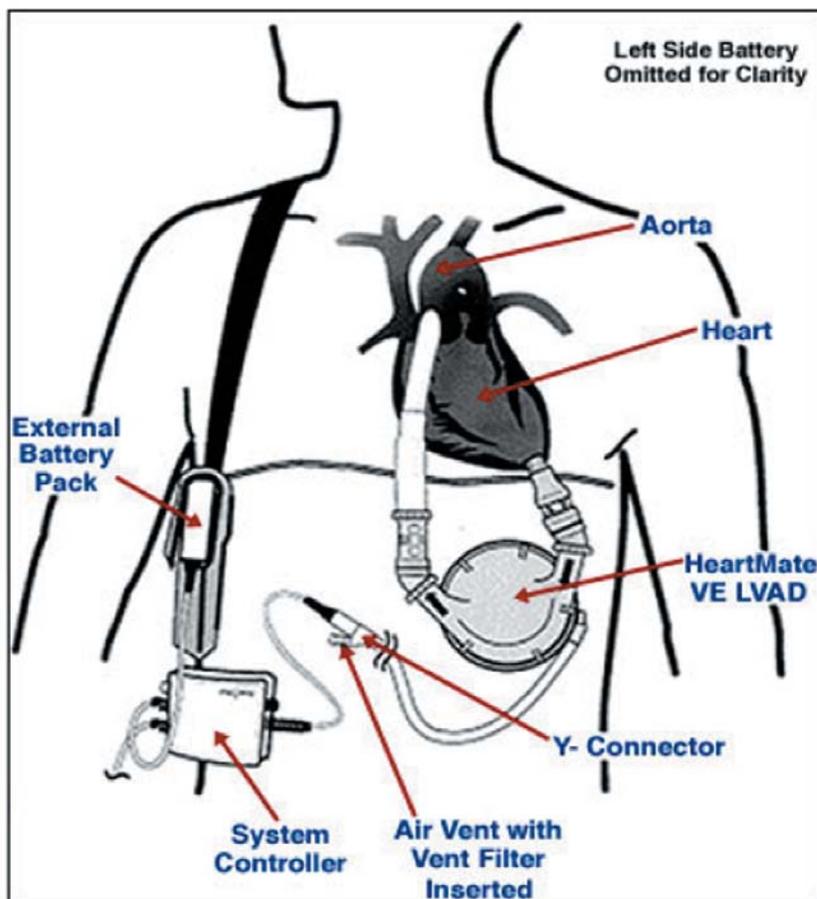
2. Is an LVAD an artificial heart?

The LVAD differs from an artificial heart. The LVAD allows the natural heart to remain in place where it can perform other critical biological functions. The LVAD blood pump can work with the biological control mechanisms of the patient's natural heart to increase the heart's pumping capability when required for activities such as climbing stairs. In addition, in case of mechanical failure, a total artificial heart would have no back up options. However, failure of a LVAD gives the patient at least some opportunity to get emergency help to survive the mechanical problem.

3. How does the LVAD work?

The LVAD is designed to assist the left ventricle, the main pumping chamber of the natural heart, which is responsible for pumping oxygen-rich blood from the lungs to the rest of the body. The LVAD supports the left ventricle which performs 80% of the heart's work. The key component of the

LVAD is the pump which is placed below the diaphragm and abdomen. It is attached to tip of the left ventricle and the aorta, which is the main artery that feeds blood flow to the entire body. The natural circulation is left in place and the LVAD provides all the energy necessary to propel blood through the body. The typical electric pump weighs approximately 2-1/2 pounds and is about 4



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inches in diameter and less than 2 inches in depth.

4. How long have LVADs been used?

LVADs actually date back to 1964 when the Natural Heart, Lung, and Blood Institute sponsored development of a mechanical device for support of both short and long term circulatory support. The initial devices were bulky and development of this originally gave way to development of the total artificial heart. However, artificial hearts took a back seat in the early 1990s due to high rates of infection and thromboembolic events coupled with low survival rates. A thromboembolic event occurs when a blood clot travels to the brain or other organs. In 1994, an air-driven LVAD was approved as a bridge to transplant. In 1998, self-contained vented electric devices were approved for the same purpose. An eight year clinical trial initiated in 1990 demonstrated that a LVAD made by HeartMate was both safe and efficacious for both hospitalized and discharged patients. The HeartMate vented electrical LVAD received FDA commercial approval in 1998. The vented electric LVAD with an extended lead was approved as a bridge to transplant in 2002. In April of 2003, the HeartMate XVE LVAD was approved by the FDA for destination therapy patients which will be discussed later.

5. How is the LVAD hooked up to the heart?

The HeartMate is implanted in the abdomen and is attached parallel to the patient's cardiovascular system. Blood is channeled into the LVAD by inflow conduit that attach to the tip of the patient's left ventricle. Once the blood comes from the natural heart by emptying into the pump, an external control system triggers the pump. A pusher plate forces a flexible polyurethane diaphragm upward pressurizing the blood chamber. This motion propels the blood through the outflow conduit and the graft attached to the aorta which is the main artery supplying the blood, with oxygen-rich blood. Valves located on each side of the device pumping chamber keeps blood flowing in only one direction.

6. How will a patient benefit from an LVAD?

The patient can return to many of his activities of daily living. Since patients are frequently discharged from the hospital on the device, they can return to their families, work, and school activities. Patients with LVAD can enjoy many every day activities. Because their physical and psychological well-being improves on the LVAD, these patients become more independent, and ultimately they are surgical candidates if they are selected to go on to heart transplant.

7. What's the risk of an LVAD?

There is an upfront surgical risk at the time of implant. The LVAD is still a machine and therefore, like any other machine, can have mechanical failures. However, there is back-up manual pumping for a vented electric HeartMate device. For example, the major risk has been thromboembolic complications and stroke. The HeartMate device is coated with proprietary textured blood contacting surfaces which includes sintered titanium microspheres which line the titanium side of the blood chamber and custom molded polyurethane which provides a similar irregular surface to the diaphragm. These surfaces decrease the risk of thromboembolic complications.

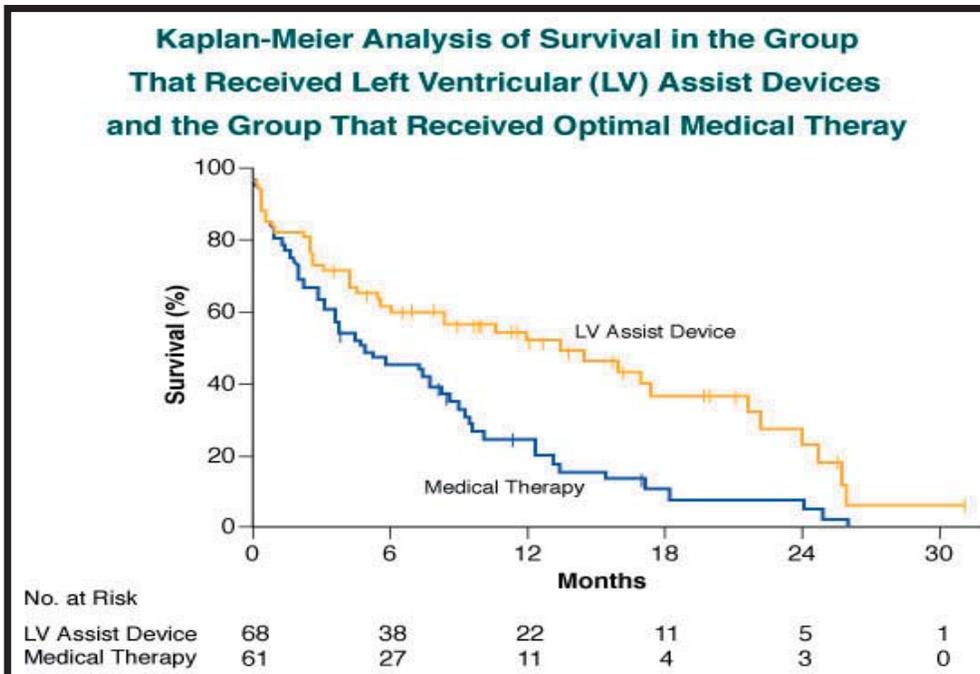
8. Can the LVAD help me prior to transplant?

Yes. As mentioned previously, the LVAD was first approved as a bridge to transplant. In the initial study of the HeartMate vented electrical LVAD, the mean duration of the LVAD averaged 112 days, although 54 patients used the device from more than 180 days. In this study, 71% of LVAD treated patients survived and all but 10 of these patients eventually received a transplant. The survival of the LVAD treated at one year was significantly better than those of the controls with the survival at one year being 84% in the LVAD patients and 63% in the non-LVAD treated patients.

treated patients.

9. What if I am not a candidate for heart transplant?

Patients with heart failure are sometimes not considered candidates for heart transplantation if they are typically greater than 65 years of age, have significant pulmonary vascular disease, other co-existing diseases such as significant damage to liver, kidneys, or other systemic problems of cancer or chronic autoimmune diseases. In this case, the LVAD can be used to improve the patient's quality of life and prolong life. The Rematch trial was the key trial to compare medical therapy versus LVAD treatment. An elderly group experienced a 48% reduction in risk of death from any cause when compared to the medically treated arm. Based



Kaplan-Meier Analysis of Survival in the Group that Received Left Ventricular (LV) Assist Devices and the Group Test Received Optimal Medical Therapy

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on the results of the Rematch trial, in November of 2002 the Food and Drug Administration approved the HeartMate LVAD for destination therapy in patients who were not eligible for transplant.

10. Can the LVAD ever be removed?

Rarely. There are some patients that can use the LVAD as a bridge to recovery where the heart becomes strong enough to allow the heart to not need the support of the LVAD. The native heart always looks better when we study the heart using ultrasound after implant. The left ventricle tends to become much smaller and assume a more normal shape with the use of the LVAD. In addition, any degree of mitral regurgitation tends to improve significantly. The left ventricular contraction pattern appears to be much better with use of LVAD. However, due to the fact that the LVAD is doing most of the work, the improved contractility of the left ventricle may be artificial. In addition, it is felt that having the mechanical pump do most of the work of the heart, the heart muscle intrinsically could become weaker similar to weakness of an arm muscle if not used.

11. Will my insurance company pay for LVAD?

The United States Healthcare Financing Administration has authorized Medicare coverage for the HeartMate system. Therefore, this will be paid for by Medicare and most insurance companies will follow Medicare's lead. The HeartMate LVAD system is a cost effective alternative to conventional medical therapy for patients. Because the HeartMate system allows late stage heart failure patients to be rehabilitated, the ICU stays are often less than a week. Of note, the average wait for a donor heart is over 6 months and often longer depending on blood type. In addition, significant recovery at the point of transplant created healthier patients and more prudent use of donor resources.

12. How many LVADs have been implanted and where can this be done?

The Thoratec Corporation, which owns the HeartMate technology now reports that they have implanted greater than 4,100 patients worldwide. LVADs have been used in patients ranging from age 11 to age 78. The HeartMate systems are available to qualified hospitals that perform open heart surgery. This technology is currently available at the Baptist Memorial Hospital which is the only heart transplant center in this area. The cardiothoracic surgeons that are able to place these devices are Dr. Ed Garrett and Dr. Russ Carter of Cardiovascular Surgery Clinic.

13. What are the current investigational future directions of the LVAD?

Currently, we are involved in a randomized vital study trial of the HeartMate II pump which is a high speed rotary pump which was primarily designed to be used in small adults and children due to its smaller size. However, this system also is more durable since it has only 2 moving parts and has been felt to last for 5 years. Currently, the vented electric LVAD is believed to last approximately 2 years. In the future, the Heart Mate III, which features a miniature centrifugal pump and a magnetically levitated impeller promises the first lifetime design since it eliminates parts subject to wear completely.



About The Author

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