

Continuous-Flow LVAD Therapy *continued from front*

LVAD as “destination therapy” for patients with end-stage heart failure who were ineligible for transplantation was investigated in the REMATCH trial, a prospective, randomized study of LVADs versus medical therapy.⁵ In this landmark study, the two-year survival rate was significantly better for patients receiving an LVAD compared to those receiving medical therapy alone (24 percent vs. 8 percent). Based on these results, in 2003, the HeartMate XVE[®] pulsatile LVAD (Thoratec Corporation, Pleasanton, Calif., U.S.) became the first device to be approved by the U.S. Food and Drug Administration (FDA) for destination therapy in end-stage heart failure.⁶

Emory’s VAD program implanted our first device as destination therapy in 2006 in a patient who was inotrope-dependent but who was not a candidate for heart transplantation.

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The Chamber

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Continuous-Flow LVAD Therapy: A Successful Alternative for End-Stage Heart Failure

By Sonjoy Laskar, MD, Assistant Professor of Medicine; Center for Heart Failure Therapy, and J. David Vega, MD, Associate Professor of Surgery; Director, Heart Transplant and VAD Programs, Emory University Hospital

Despite advances in the treatment of congestive heart failure, the survival of patients with end-stage disease remains quite dismal. Patients who are unable to be weaned from inotropic support by definition have a very poor survival rate; patients receiving continuous palliative inotropes have a six-month mortality rate between 60 percent and 75 percent.¹ Additional negative prognostic risk factors include repeated hospitalizations for volume overload, repeated episodes of ventricular tachycardia and worsening renal insufficiency due to cardiac causes. However, no definitive clinical risk score has been developed to identify end-stage heart failure. This is an active area of clinical investigation at Emory under the direction of Javed Butler, MD.

While transplantation is definitive therapy for end-stage heart failure,² the number of cardiac transplants performed in the U.S. each year is limited to approximately 2,200 due to donor availability.³ Left ventricular assist devices (LVADs) are a type of mechanical circulatory support device that have been in use for more than 25 years primarily in patients with refractory heart failure who are awaiting transplantation.⁴ Emory University Hospital has been at the forefront of VAD therapy, implanting our first device in 1988 and more than 65 devices since then.

continued inside



Continuous Flow: The Next Evolution in LVAD Therapy

A study published in *The New England Journal of Medicine* in December 2009 demonstrated that continuous-flow LVADs significantly improved the probability of stroke-free survival and decreased the probability of device failure at two years compared with a pulsatile-flow LVAD in patients with end-stage heart failure who were ineligible for transplantation.⁷ In addition, patients who received the continuous-flow device had an actuarial survival rate at two years of 58 percent versus 24 percent for patients who received the pulsatile-flow device (*Figure 1*).

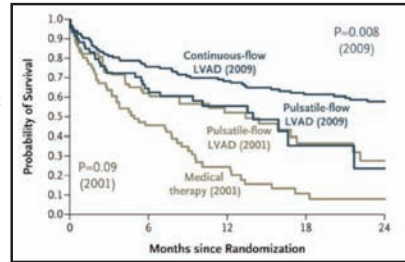


Figure 1: Survival rates in two trials of LVADs as destination therapy. The curves labeled 2009 are those reported by Slaughter and colleagues in the December 2009 issue of *The New England Journal of Medicine*,⁷ and those labeled 2001 were reported for the REMATCH trial.⁵

The HeartMate II® (Thoratec Corporation, Pleasanton, Calif., U.S.), a smaller, continuous-flow LVAD, received FDA approval in January 2010 as destination therapy for patients with end-stage heart failure who are ineligible for transplantation (*Figure 2*).⁸ The HeartMate II uses an internal motor to pump blood continuously into the ascending aorta, providing up to 10 liters of cardiac output per minute. Due to its smaller size, the device has a larger potential patient population than previous-generation LVADs. In addition, the HeartMate II is designed to provide greater mechanical reliability than previously available devices because it contains only one moving part – the internal rotor.⁹

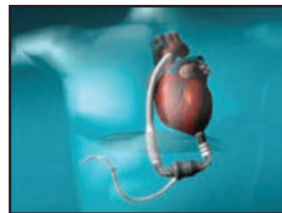


Figure 2: HeartMate II® LVAD; reprinted with permission from Thoratec Corporation.

More recently, HeartWare International (Framingham, MA) introduced the HeartWare LVAD system, which uses a continuous centrifugal pump to provide up to 10 liters of cardiac output per minute (*Figure 3*). Because the device is implanted above the diaphragm, directly adjacent to the heart, both surgery and recovery times are minimized.¹⁰



Figure 3: HeartWare® LVAD; reprinted with permission from HeartWare International.

Like the HeartMate II, the HeartWare LVAD contains only one moving part – the internal impeller. In addition, it has no mechanical bearings or points of contact between the impeller and the pump housing in order to lower the risk of device failure and is designed to help minimize the risk of device-induced hemolysis and thrombus.¹⁰

Already approved in Europe as a bridge to cardiac transplantation, the safety and efficacy of the HeartWare LVAD are currently under investigation in the U.S. in the ADVANCE trial, a crucial step toward securing FDA approval for the bridge-to-transplant indication.¹¹ Emory University Hospital is one of approximately 30 registered ADVANCE trial sites and has implanted one device to date.

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The Emory VAD Team

Led by world-renowned cardiothoracic surgeon David Vega, MD, the VAD team has many years of experience using a VAD as a form of destination therapy for individuals who are not eligible for or are unwilling to undergo a heart transplantation.

CARDIOLOGISTS

- Andrew L. Smith, MD
- S. Raja Laskar, MD

CARDIOTHORACIC SURGEONS

- J. David Vega, MD
- Duc Nguyen, MD

To refer a patient or to speak to one of the VAD program physicians, please call **404-778-5273**.

Why Choose Emory?

Emory University Hospital’s Cardiac VAD destination therapy program has earned the “Gold Seal of Approval” from The Joint Commission. The program has achieved this status because of the experience of our multidisciplinary team and our compliance with performance standards that positively impact clinical outcomes. Emory has the only certified program of its kind in Georgia and is one of 80 such centers in the country.

Emory implanted its first VAD in 1988. Since then we have implanted more than 65 VADs, including 26 HeartMate II devices and one HeartWare device.

Learn more about Emory University Hospital’s Cardiac VAD destination therapy program at www.emoryhealthcare.org/lvad.

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