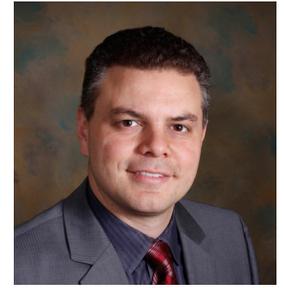


Use of the HVAD® System for a Patient with a Small Body Surface Area



By Liviu Klein, MD, MS

Assistant Professor of Medicine
Division of Cardiology, University of California San Francisco
Director, Mechanical Circulatory Support & Heart Failure Device Program

Case At-A-Glance:

Age: 42 years old

Gender: Female

Diagnoses: Cardiomyopathy, NYHA Class IV heart failure

Complicating Factors: Small BSA (1.5), refractory ventricular tachycardia

Treatment Approach: LVAD for BTT

Treating Facility: University of California, San Francisco

Device Selection Considerations: The patient's small frame required a device appropriate for her body

Case History:

A 42-year-old woman was diagnosed in 2010 with non-ischemic cardiomyopathy and then developed refractory ventricular tachycardia (VT). She was taking three medications to treat the recurrent VT and had previously received an implantable cardioverter-defibrillator (ICD). After an ablation procedure in June, she went into cardiogenic shock and was referred to UCSF. At the time of referral, her left ventricular ejection fraction was 10% and the patient was classified as INTERMACS 1. The patient was placed on extracorporeal membrane oxygenation (ECMO) support for approximately 15 days to stabilize her prior to implantation of a left ventricular assist device (LVAD).

Treatment Approach:

The patient's body surface area (BSA) and poor bi-ventricular function informed our VAD selection and treatment strategy. At 5'1" and 115 pounds, her small body frame would not be optimal for an LVAD placed in the abdominal cavity. Further, we were initially concerned that she would also require long term right ventricular (RV) support, which led us to select a VAD that was smaller and more versatile.

Durability was another consideration for our treatment decision. The patient's panel reactive antibody (PRA) titer was 90% for Class I and 98% for Class II. While the patient was listed with UNOS for a heart transplant, her high PRA score may make it significantly more difficult to find a suitable donor heart. As a result, we wanted a smaller-profile ventricular assist device that had proven length of support. For these reasons, we selected the HVAD® System from HeartWare.

The patient was supported by ECMO throughout the surgical procedure. Upon evaluation at the time of implant, only left ventricular (LV) support was needed, and the HVAD® Pump was implanted as previously described¹ with no complications. The pump speed was initially set at ~2400 RPM and was later increased to ~2600 RPM to provide adequate hemodynamic support given the extent of her LV dysfunction. The patient was monitored in the ICU for roughly seven days and then transferred to the telemetry unit before being discharged home. She remains on the transplant list and has returned to a near normal life while living with the HVAD System.

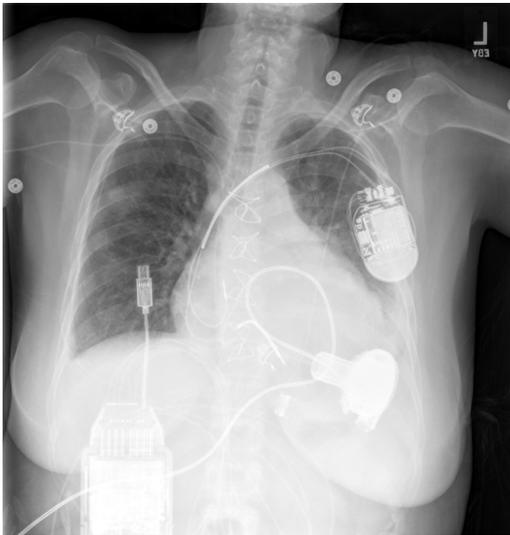
¹Slaughter MS. Implantation of the HeartWare Left Ventricular Assist Device. *Semin Thorac Cardiovasc Surg.* 2011; 23(3):245-7.

Discussion:

Body habitus is an important consideration when devising a treatment strategy for advanced heart failure. Women can be particularly difficult to treat because of their small BSA and relatively shallow abdominal cavity. These factors may have contributed to the historical under-treatment of women with advanced heart failure using mechanical circulatory support. Even with the availability of newer devices, women continue to represent only about 21% of all VAD patients.

At UCSF, by taking advantage of the versatility offered by the HVAD System we have been able to increase significantly the proportion of women receiving a VAD. Its smaller size and pericardial placement eliminates the need for a pump pocket and fits smaller body types. As we treat a large Asian-American population, this is especially important and we are able to accommodate the needs of more patients with the HVAD Pump.

The patient's post-implant stay was lengthened by her poor state of health upon referral, requiring extensive physical therapy, but she was eventually discharged home. Now, living at home, the patient is able to participate in activities that she could not do before implant. Prior to implantation, she received ICD shocks on an almost daily basis, which significantly limited her activity. However, with the HVAD System she is able to participate in life again, including playing with her children, shopping, cooking, and enjoying her church community.



X-ray showing the position of the HVAD in the patient's relatively small frame

VAD Team:

Georg Wieselthaler, MD
Ghannam Al Dossari, MD
Teresa De Marco, MD
Munir Janmahomed, MD
Van Selby, MD
Kelly McClure
Sonia Sharma
Kim Eleuteri
Christy Feigbutz

² Joyce DL, Conte JV, Russell SD, et al. Disparities in access to left ventricular assist device therapy. J Surg Res. 2009; 152:111-7.

³ INTERMACS, Quarterly Statistical Report. 2014 1st Quarter.

©2015 HeartWare, Inc. GL1118 Rev01 01/15

HEARTWARE, HVAD and the HEARTWARE logo are registered trademarks of HeartWare, Inc.

WARNING: Serious and life-threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.

For full prescribing information please see the Instructions for Use (IFU). The IFU can be found at www.heartware.com/clinicians/instructions-use.

In the USA the HVAD system is intended for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Refer to the "Instructions for Use" for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events and Instructions prior to using this device.