USE OF THE HEARTWARE™ HVAD™ SYSTEM FOR A **PATIENT WITH A HIGH BODY MASS INDEX**

Case Study:
University of Maryland Medical Center
Baltimore, Maryland

Medtronic
Further, Together

CASE STUDY:
UNIVERSITY OF MARYLAND MEDICAL CENTER, BALTIMORE, MARYLAND

CASE AT-A-GLANCE

Age: 28 years old at time of implant
Gender: Male
Diagnoses: Non-ischemic cardiomyopathy, NYHA Class IV heart failure
Complicating Factors: BMI of 62, s/p gastric bypass surgery
Treating Facility: University of Maryland Medical Center
Device Selection Considerations: The patient was expected to lose significant weight following surgery, which required a VAD that would not shift position as his body habitus changed, as well as a device that would be durable for longer term support

CASE HISTORY

In 2008, a 25-year-old male was diagnosed with non-ischemic cardiomyopathy. The following year he went into ventricular fibrillation and was subsequently implanted with an implantable cardioverter-defibrillator. Despite escalation of medical management by heart failure cardiologists, his heart failure continued to progress. Although he attempted to lose weight, his body mass index (BMI) increased and his heart failure symptoms worsened, as evidenced by increased fluid retention, dyspnea and fatigue. Unfortunately, despite his NYHA classification IIIB, his immediate options were limited secondary to morbid obesity (BMI = 62).

Three years after his initial heart failure diagnosis, in an effort to reduce his BMI, the patient elected to undergo Roux-en-Y gastric bypass surgery. Following his surgery, his heart failure progressively worsened; he advanced to NYHA Classification IV and became inotrope-dependent. Two months after gastric bypass surgery, his heart failure had not improved, he was still inotrope-dependent, and his ejection fraction remained severely depressed (<20%). The decision was made to implant the patient with the HeartWare™ HVAD™ Pump.

TREATMENT APPROACH:

The decision to move forward with a VAD implant was not taken lightly. This patient was considered INTERMACS classification level 2 (progressive decline), but was not actively listed for transplant due to his morbid obesity; at our institution, a patient must have a BMI <=35 in order to be actively listed for cardiac transplantation. The team discussed various devices that might be best for this patient and finally decided to proceed with the HVAD System. The plan was to implant the VAD, allow the patient to recover from surgery, and then resume a diet and exercise plan that would lead to significant weight loss. Given the marked weight loss that was expected, the chosen device would need to be durable for longer term support, powerful enough to support his large frame, and, most importantly, maintain a stable position in the ventricle as his body shape and size changed.

The patient was implanted with a HeartWare HVAD Pump without complication as previously described[1]. Post-implant, the pump speed was adjusted to meet his hemodynamic requirements, which meant an initial speed of 3800 RPM. The higher speed was slowly lowered to the recommended upper limit of 3200 RPM by post-operative day 12 as the patient underwent diuresis. His only post-operative complication was prolonged right ventricular dysfunction, requiring inotropic support for three weeks, which fully resolved prior to discharge home.

DISCUSSION:

The transition from medical therapy to surgical therapy for the treatment of advanced heart failure often presents many challenges. When developing a treatment strategy and implanting a VAD, BMI and overall body habitus should be integral to the discussion. This is a growing problem; as of 2012, more than one-third of all Americans were clinically obese (BMI ≥ 30), with 14.5% classified as grade 2 obesity (BMI of 35-39) and 6.4% classified as grade 3 or extremely obese (BMI ≥40)[2].

Body shape, body size, and potential weight fluctuations need to be taken into account when implanting a VAD, as the VAD can shift as the patient loses weight and result in a maligned inflow cannula. Because the HVAD Pump is implanted in the pericardial space and not in an abdominal pocket, the inflow cannula position is maintained even as the body habitus changes[3], as shown in the figures below.

Some clinicians may be reticent to implant a VAD in a morbidly obese patient owing to concern over infections, prolonged time for wound healing, or other factors. However, our experience is that a VAD can be implanted in these patients with low morbidity and mortality risks. The patient did not experience any intra-operative complications or peri-operative infections, and there was no delay in wound healing. The patient did develop a driveline infection after more than 30 months of HVAD Pump support that was successfully treated with oral antibiotics and more aggressive exit site care.

OUTCOMES:

Prior to implantation, the patient was NYHA Class IV. As such, his quality of life had significantly declined and he was not able to participate in normal activities for someone in his twenties. Within one month of being discharged, he had already lost a noticeable amount of weight and reported a significantly improved quality of life. Now at 31 years old, his BMI is approximately 35 and he leads a far more active lifestyle, including full-time employment. After more than three years with the HVAD System, the patient is NYHA Classification I, but has not recovered any LV systolic function. The patient is currently being evaluated for heart transplant eligibility.

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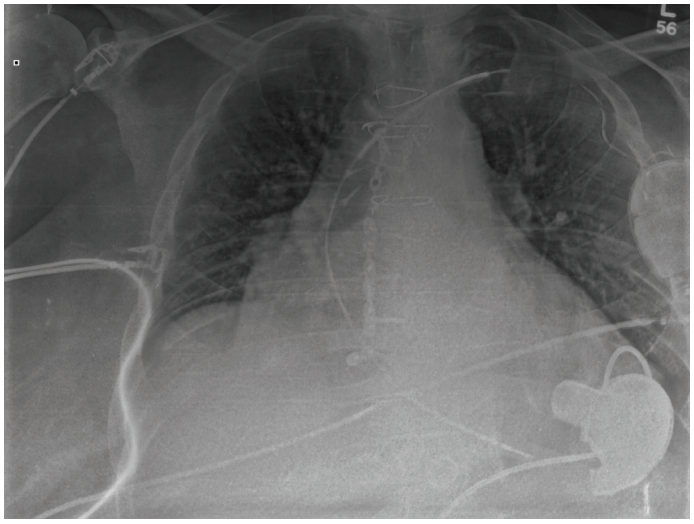
X-rays showing the position of the HeartWare HVAD Pump as the patient's body habitus changed over time



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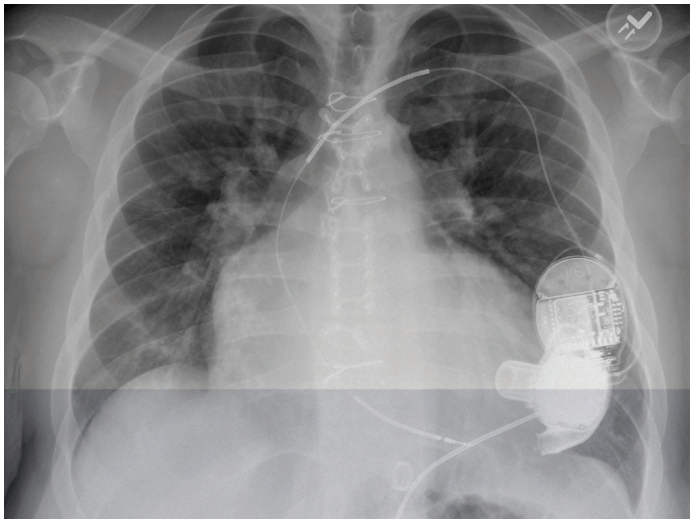

May 18, 2014

References

[1]Romano, M, Pagani, F. HeartWare: Principles and techniques for safe and effective implantation. Operative Techniques in Thoracic and Cardiovasculary Surgery. http://dx.doi.org/10.1053/j.optechstcvs.2013.11.003.

[2]Ogden, C. et al. JAMA. 2014;311(8):806-814. doi:10.1001/jama.2014.732.

[3]Sorensen EN, et al. Computed tomography correlates of inflow cannula malposition in a continuous-flow ventricular-assist-device. J Heart Lung Transpl 2013; 32 (6):654-657.

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Brief Statement: HeartWare™ HVAD™ System

Indications
The HeartWare™ Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

Contraindications
The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

Warnings/Precautions
Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

Potential Complications
Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, infection, hemolysis and sepsis.

Refer to the "Instructions for Use" for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at www.heartware.com/clinicians/instructions-use.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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