

# Characteristics, Frequency, and Disposition of Patients With a HeartMate II Left Ventricular Assist Device Presenting to the ED

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## Abstract

**Background:** Left ventricular assist devices (LVADs) are used to treat patients with end-stage heart failure, either as a bridge to heart transplantation or as destination therapy for patients not suitable for heart transplant. The number of patients with LVADs and the number of medical centers in the United States involved in implantation of these devices is increasing. Although the HeartWare Ventricular Assist Device (Medtronic) is currently the most common implant, based on previous popularity, there are still more HeartMate IIs (HMII) (Abbott Laboratories) currently in use. Given the high likelihood that a patient with an LVAD will seek ED care at some point, emergency physicians must be able to identify and manage the complications associated with these devices.

The purpose of this study was to identify the type, frequency, and disposition of patients with an HMII LVAD who presented to an urban tertiary care referral center ED.

**Methods:** This was a retrospective study of patients with an HMII LVAD who presented to an urban ED between April 1, 2009 and September 9, 2012. All patients with an HMII LVAD who presented to the ED were included in the study, and there were no exclusion criteria. Electronic medical records were reviewed by study investigators to identify all ED visits by HMII LVAD patients during the study period to identify the reason for presentation, the frequency of ED visits, and final patient disposition.

**Results:** A total of 98 patients in the catchment area had an HMII LVAD implanted during the study period. Sixty-seven (68%) of these presented to the ED, for a total of 248 ED visits. The average number of ED visits per patient was 3.7. The most common reasons for presentation included bleeding (14.9%); volume overload (14.9%), weakness/lightheadedness/dizziness/syncope (9.6%), device malfunction (8.1%), and infection (2.8%). Approximately 56% of the ED visits were directly LVAD-related. Fifty-seven percent of the patients required admission to the hospital.

**Conclusions:** Approximately two-thirds of patients with an HMII LVAD presented to the ED, many of whom presented multiple times. The most common complications observed were bleeding and volume overload. Fifty-seven percent of these patients required hospitalization.

### Introduction

Approximately 6.5 million adults in the United States have heart failure, accounting for nearly 1 million ED visits annually.<sup>1</sup> Advanced heart failure is particularly difficult to treat, and is associated with significant morbidity and mortality. While medical therapy is the initial treatment for patients with advanced heart failure, it has limited effectiveness; therefore, at the present time, heart transplant is the most effective treatment for heart failure refractory to medical management.

According to the 2013 Registry of the International Society for Heart and Lung Transplantation, 4,096 cardiac transplants were performed worldwide in 2011, approximately 2,000 of which were done in the United States.<sup>2</sup>

The average age of a heart transplant recipient in the United States is 55 years.<sup>2</sup> In 2017, there were nearly 4,000 patients on the United Network for Organ Sharing, the organization that manages the national transplant waiting list in the United States and matches donors to recipients.<sup>3</sup> Unfortunately, the number of patients requiring a heart transplant far exceeds the number of registered donors, and a large number of patients must wait years for transplantation. In addition to those awaiting a heart transplant, there are many patients with advanced heart failure who are not suitable candidates for transplant (usually due to age).

### Left Ventricular Assist Devices

As of December 31, 2016, a total of 22,866 US Food and Drug Administration (FDA)-approved devices were listed in the Interagency Registry for Mechanically Assisted Circulatory Support, 17,016 of which were continuous-flow (CF) left ventricular assist devices (LVADs), including the HeartMate II (HMII) (Abbott Laboratories) and the HeartWare Ventricular Assist Device (HVAD) (Medtronic).<sup>4</sup> Left ventricular assist devices, which have been in use for over 30 years, have evolved into smaller,

quieter, and more durable devices. The current generation of LVADs has a CF design (as opposed to the older pulsatile-flow [PF] design). More importantly, CF LVADs are associated with higher survival rates and increased quality of life than the earlier PF models.<sup>5</sup> For these reasons, CF LVADs are being used much more frequently today. As previously noted, LVADs serve as a temporizing measure for patients awaiting a heart transplant (ie, bridge-to-transplant therapy [BTT]) or as the primary treatment for patients who are not suitable candidates for transplant (ie, destination therapy [DT]).

The percentage of patients receiving an LVAD as a DT has increased from around 15% between 2006 to 2007 to nearly 46% in 2014.<sup>6</sup> Recently, several reports following LVAD patients demonstrated a reverse remodeling of the heart and recovery of native cardiac function that was sufficient enough in some patients as to permit LVAD removal (ie, bridge to recovery).<sup>7</sup> In the United States, the number of patients undergoing LVAD removal due to recovery remains fewer than 3%.<sup>6</sup>

With the increase in the number of patients receiving LVADs, there is an increased likelihood of LVAD patients presenting to an ED due to device-related complications. Recognized complications associated with LVADs include thrombosis, infection, bleeding, and issues with volume status.<sup>5,7</sup> However, the frequency of LVAD-associated complications and the final disposition of these patients is less well known.

### HeartMate II Patient ED Presentation Study

#### Purpose

The purpose of our study was to identify the reasons for LVAD patient presentation to the ED, the frequency of these presentations, and the final disposition of these patients. Our institution, Sentara Norfolk General Hospital (SNGH), is a level I trauma and a tertiary care referral center, and

it is the only hospital in a large area of Virginia to perform LVAD implantation.

Our study involved only patients implanted with the HMII LVAD.

## Methods

### Patients and Study Design

This was a retrospective study of patients with an HMII LVAD who presented to the SNGH ED between April 1, 2009 and September 9, 2012. All patients implanted with an HMII LVAD during the study period were assigned a study number linking the patient to their medical record number and social security number. Study numbers were assigned at the time of LVAD implantation by one of the investigators. This document was kept in a secure and locked location in the department of emergency medicine and was not accessible to anyone other than study investigators.

The electronic medical records were retrospectively reviewed to identify any HMII LVAD patient presenting to the SNGH ED during the study period. Information abstracted from the ED medical records included patient age, sex, initial complaint, final diagnosis, and disposition. Only the patient's assigned study number was used on the data collection form, and no personal identifying information was present.

This study was granted approval for human subject research by the Eastern Virginia Medical School Institutional Review Board. Eligible patients included all patients with an HMII LVAD implanted during the study period. Study patients who presented to the SNGH ED between April 1, 2009 and September 9, 2012 were identified by a retrospective chart review. These patients were instructed to specifically seek care at the SNGH ED in the event of an emergency. There were no exclusion criteria.

Data were collected and reported in real numbers and percentages. No formal statistical analysis was used in evaluating the results.

## Results

Between April 1, 2009 and September 9, 2012, there were a total of 98 patients with an HMII LVAD that had been implanted during the study period at SNGH. The average patient age was 53.6 years, with a range from age 20 years to 78 years. Sixty-seven (68%) of the patients enrolled in the study required at least one ED visit. The HMII LVAD patients who presented to the ED ranged in age from 20 years to 78 years, with an average age of 53.1 years. The average number of ED visits by these 67 patients was 3.7, with a range of 1 to 12. Approximately 56% of the ED visits were directly LVAD-related. In all, 67 patients were responsible for a total of 248 ED visits.

The two most common reasons for presentation to the ED involved bleeding and volume overload. A total of 37 ED visits (14.9%), were related to bleeding, which included gastrointestinal (GI) bleeding (18/37 or 49%), epistaxis, hematuria, gingival bleeding, and postoperative bleeding following tooth extraction.

Volume overload accounted for 37 ED visits (14.9%), and the most common presenting symptom in these patients was shortness of breath. Other reasons patients presented to the ED were weakness/light-headedness/dizziness/syncope (24/9.6%), device malfunction (20/8.1%), infection (7/2.8%), and transient ischemic attack/cerebrovascular accident (6/2.4%). For infection-related ED visits, two presentations (2.9%) involved a driveline infection. Common causes for ED visits related to device malfunction included battery failure and device-alarm activation. Overall, 142 of the 248 total ED visits (57.3%) resulted in hospital admission. One patient in the study presented in cardiac arrest and could not be resuscitated.

The remaining 108 LVAD patient ED visits (44%), did not appear to be related to the presence of the LVAD, but rather represented common reasons for presentation to an ED. These other non-LVAD-related

reasons for presentation to the ED were due to motor vehicle incidents (3); assault (2); dental pain (3); mechanical fall (5); and upper respiratory tract infection (4), and represented small groupings of patient reasons for an ED visit.

Examples of singular reasons for presentation to the ED included one patient who presented with suicidal ideation, and another patient who presented for evaluation of symptoms suspicious for a sexually transmitted infection.

### Discussion

As the number of patients with advanced heart failure continues to increase, the number of those with an LVAD also increases. Between 2006 and June 2013, nearly 9,000 adult patients in the United States received a durable LVAD.<sup>6</sup> In the early years of LVAD implantation, patients were restricted to remain in proximity of geographical areas surrounding academic health care centers. An increased comfort level by both physicians and patients now allows LVAD patients to reside in more distant communities. This increase in LVAD implantation, coupled with the widening patient distribution, make it important for every emergency physician (EP) to have a working knowledge of the device and its associated complications. To date, the characteristics and frequency of LVAD patient presentations to the ED have not been well characterized.

Left ventricular assist devices are considered in patients who have significant symptoms associated with poor LV function or who cannot maintain normal hemodynamics and vital organ function. Continuous-flow LVADs account for almost all devices currently implanted. During our data-collection period, there were two FDA-approved implantable LVADs—the HMII, approved for BTT in 2008 and for DT in 2010; and the HVAD approved for BTT in 2012. In August 2017, HeartMate III (Abbott Laboratories) was approved by the FDA. All patients

enrolled in our study were recipients of the HMII device, as this was the only type of LVAD implant performed at our hospital. Current survival with the HMII LVAD is 80% at 1 year and 69% at 2 years, and there has not been shown to be a significant difference when stratified by era of implant.<sup>6</sup>

### Device Designs and Structures

The pump of the HMII is inserted into the abdominal cavity, whereas the HVAD is implanted in the chest cavity, with the inflow cannula in the apex of the LV and the outflow cannula connecting to the proximal aorta. Blood is continuously pumped through the system.<sup>8,9</sup> The pump is connected to a driveline that exits the body and connects to a controller. Continuous-flow devices have either an axial or centrifugal blood pump. Axial devices have an impeller that is connected to ball-and-cup bearings that accelerate blood along its axis. Newer axial flow pumps incorporate magnetic levitation of the rotor and do not require the use of bearings. Centrifugal devices accelerate blood circumferentially with a rotor that is suspended within in the blood pool by electromagnetic or hydrodynamic forces.<sup>10</sup> The controller is powered by two external batteries or connected to a power base unit where the pump can be interrogated. The controller is usually housed in a garment worn by the patient, one that also includes the batteries. The controller can also be powered by a base unit that can be plugged into an electrical outlet.<sup>11</sup>

There are, and continue to be, advances in both LVAD design and function. Since the time period of our study, changes have been made in the outflow bend relief (the tube at the junction of the outflow cannula and the pump housing designed to prevent kinking of the outflow cannula) and the LVAD controller. Older controllers have been replaced with newer models, but many of the LVAD pumps in this article remain in service.

### Anticoagulation Therapy

Patients who have a CF LVAD require anticoagulation therapy with warfarin to a target international normalized ratio (INR) of 2 to 3, in addition to aspirin therapy of 325 mg daily.<sup>8,9</sup> Newer oral anticoagulant drugs are not routinely given to patients who have a CF LVAD.

### Cardiopulmonary Evaluation

With CF LVADs, blood is pumped continuously, and a constant, machine-like murmur can be heard on auscultation rather than the typical heart sounds. Patients who have an LVAD may not have palpable arterial pulses. Doppler evaluation of the brachial artery and a manual blood pressure (BP) cuff are used to listen for the start of Korotkoff sounds as the cuff is released. The pressure at which the first sound is heard is used to estimate the patient's mean arterial pressure (MAP) at the time when there is no pulse; and the systolic BP (SBP) is heard at the time when there is pulse. Patients with a CF LVAD with nonpulsatile flow should have a MAP between 70 mm Hg and 90 mm Hg (HMII), or 70 mm Hg and 80 mm Hg (HVAD). Patients who have a CF LVAD with a palpable pulse should have an SBP less than 120 mm Hg (HMII) or 105 mm Hg (HVAD). Readings outside of these ranges require an adjustment in the patient's antihypertensive therapy, since high BP increases the risk of stroke and can impair the cardiac support provided by the LVAD.<sup>8</sup> Low BP may be the result of inadequate pump speed, dehydration, inflow cannula obstruction, or pump thrombus.

### Bleeding

In our study, bleeding and volume overload were the two most common reasons LVAD patients presented to the ED. Interestingly, in a systematic review of clinical outcomes following CF LVAD implantation, bleeding was the most commonly recorded adverse event.<sup>12</sup> In fact, the majority of patients in all of the studies reviewed experienced at least one bleeding event.

In one study of 139 HMII LVAD patients, the risk of bleeding was greatest within the first two weeks, and early bleeding was associated with increased mortality.<sup>13</sup> The most common source of bleeding complications in patients with a CF LVAD are GI, similar to our study.<sup>14</sup>

In a review and meta-analysis by Draper et al,<sup>15</sup> of GI bleeding in 1,697 patients with CF LVADs, the pooled prevalence was 23%. Subgroup analysis demonstrated an increased risk of bleeding in older patients and in those who had an elevated serum creatinine level.<sup>15</sup> Upper GI bleeding occurred in 48% of patients, lower GI bleeding in 22%, small-bowel bleeding in 15%, and bleeding at an unknown site in 19%. The most common cause of the bleeding was from arteriovenous malformations (AVMs).<sup>15</sup> In their review, Draper et al<sup>15</sup> found a 9.3% prevalence of recurrent GI bleeding and a pooled event rate for an all-cause mortality rate of 23%.

They also noted that the increased risk of GI bleeding in CF LVAD patients is multifactorial. For example, there was decreased activity of type 2 von Willebrand factor multimers in patients with CF LVADs, leading to an acquired von Willebrand syndrome.<sup>15</sup>

Another finding seen in this review was that CF devices lead to a low pulse-pressure system, which is thought to cause some degree of intestinal hypoperfusion, potentially leading to vascular dilation and AVM formation.<sup>15</sup> Based on findings, a neurovascular etiology involving increased sympathetic tone resulting in smooth muscle relaxation and AVM formation has been proposed. Lastly, the anticoagulation required with the CF LVADs to prevent pump thrombosis also increases the risk of GI bleeding, especially when combined with aspirin or other antiplatelet agents which are routinely prescribed.<sup>15</sup>

### Volume Overload

Interestingly, in our study, volume overload as a cause for ED presentation was



the same as for bleeding complications. In the systematic review of clinical outcomes in CF LVAD patients, volume overload or ongoing heart failure occurred in 18% of patients 1 year after device implantation.<sup>12</sup>

The clinical presentation of patients experiencing volume overload is typically dyspnea and fatigue; on physical examination they will frequently demonstrate evidence of fluid retention, such as dependent edema and pulmonary congestion.<sup>16</sup> Causes of volume overload in the LVAD patient includes medication noncompliance, inadequate pump speed, device malfunction, right ventricular failure, impaired renal function, and cardiac tamponade.<sup>16</sup> These patients will frequently have MAPs greater than 90 mm Hg, and may require treatment with diuretics, calcium channel blockers, beta-blockers, or angiotensin-converting enzyme inhibitors.<sup>8</sup>

### **Weakness, Lightheadedness, Dizziness, Syncope**

In our study, some combination of weakness, lightheadedness, dizziness, and syncope accounted for the third most common cause of ED presentation (9.6%). In the majority of cases, this was due to dehydration. Usually, these patients will have a MAP less than 60 mm Hg. Unfortunately, patients with pump thrombosis, sepsis, or cannula malposition can also present with a low MAP. It is important to differentiate the cause, as the management is quite different, depending on the etiology. Bedside ultrasound can play an important role in evaluating the volume status and cannula position.<sup>8</sup> In addition, emergent consult with the patients ventricular assist device (VAD) treatment team is critical.<sup>8</sup> Pump thrombus is a medical emergency and is usually associated with hematuria without red blood cells in the urine, acute kidney injury, and marked elevations in lactate dehydrogenase and serum free hemoglobin.<sup>8</sup> If not treated promptly, renal failure and death may result. If dehydration is the cause, gentle rehydration with intravenous

normal saline and electrolyte replacement may be all that is required.

### **Device Malfunction**

Device malfunction was the next most common reason for ED presentation in our study, at 8.1%. This category included a number of different events, including battery failure, driveline fracture, and pump thrombosis. According to McIlvennan et al,<sup>12</sup> causes of device malfunction include thrombus formation with hemolysis, mechanical failure of the impeller, and driveline lead fractures with electrical failure. Again, the VAD team should be consulted immediately, and the EP should plug the LVAD into a hospital power base, if available, to conserve battery life. If power is interrupted, the pump will stop working. The EP should examine all of the connections from the percutaneous lead to the controller and from the controller to the batteries to ensure they are intact. The exit site for the percutaneous lead should be examined for evidence of trauma or signs of infection. The patient should also be asked about recent trauma to the driveline.

### **Neurological Events**

Interestingly, in other reviews, neurological events, including ischemic stroke, hemorrhagic stroke, and transient ischemic attack occur with higher frequency than was the case in the study, and are relatively common complications that can result in severe morbidity and mortality.<sup>12</sup> In the Interagency Registry for Mechanically Assisted Circulatory Support report, there was a 3% risk of stroke at 1 month, 5% at 3 months, 7% at 6 months, 11% at 12 months, 17% at 24 months, and 19% at 36 months post-implant.<sup>6,12</sup> Similarly, the HMII DT Trial demonstrated rates of ischemic and hemorrhagic stroke as high as 8% and 11% respectively, within the first 2 years following LVAD placement.<sup>5,6</sup> In our study, neurological events accounted for only six (2.4%) of ED visits. It is unclear why our numbers were less than those reported by others.

### Cardiac Events and Management

During the study period, one LVAD patient presented to the ED in cardiac arrest. Patients who have an LVAD and are in cardiac arrest have unique considerations that deserve discussion. If the LVAD pump has stopped functioning, connections between the system controller and the pump and power source must be checked, as loose connections need to be refitted and the pump restarted. It is important to note that when an LVAD ceases operation, blood becomes stagnant in the pump and conduits. Delays of even several minutes pose a significant risk for pump thrombosis, stroke, and thromboembolism when the device is restarted. If the pump does not restart and the patient is connected to batteries, the batteries should be replaced with a new, fully charged pair, or the device should be connected to a base unit.<sup>17</sup>

Due to the location of the outflow graft on the aorta and the inflow conduit in the LV apex, external chest compressions pose a risk of dislodging the device and causing fatal hemorrhage. Clinical judgment should be used when deciding to perform external chest compressions. A recent American Heart Association scientific statement concluded that withholding chest compression in a patient with an LVAD who is truly in circulatory failure that is not attributable to a device failure would cause more harm to the patient than the potential to dislodge the device.<sup>18</sup>

Direct cardiac massage, performed by a skilled surgeon may be effective in patients that have had recent device implantation, especially if prior to mediastinal healing.<sup>16</sup> If external defibrillation/cardioversion is required, the percutaneous lead should not be disconnected from the system controller and the pump should not be stopped prior to the delivery of a shock.<sup>17</sup>

### Study Limitations

This was a retrospective study and has the limitations common to all such studies. It is possible that some of the patients

in our study sought care at a hospital ED outside of our system, and therefore were not included in our study. This, however, is exceedingly unlikely as the cardiologists and care team continually emphasized and instructed all patients in our study only to present to the study hospital ED for any complaint. Similarly, the various emergency medical services agencies for our region were also instructed to bring all LVAD patients to the study hospital.

Another limitation of our study is the relatively small total number of patients (98) and that our findings may not apply to other patient populations. This limitation, however, would be true for any hospital system that limits the type of LVAD implant procedure to one manufacturer (HMII in this instance).

### Conclusion

Emergency physicians must be prepared to evaluate the LVAD patient presenting to the ED. A little over 55% of the time, the visit will be directly related to the LVAD; in the remainder of cases, patient presentation will be due to a non-LVAD-related cause. At initial presentation, however, the EP should assume that the ED visit is related to the LVAD, until a thorough history and physical examination can exclude otherwise.

Because of the high incidence of GI bleeding in LVAD patients, a rectal examination for blood in the stool should be performed for any complaint that may be related, such as generalized weakness, syncope, or shortness of breath. In the majority of cases, a complete blood count; complete metabolic profile, including lactic acid dehydrogenase; and coagulation studies, including prothrombin time and INRs, are indicated. Most patients with an LVAD will require a member of the VAD team (typically the perfusionist or biomedical engineer) to interrogate the controller if there is any concern about its function, including alarm sounding or lights flashing.

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