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Community Based Management of Ventricular Assist Devices

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1. Introduction

Heart failure is a progressive disease associated with high mortality and poor quality of life. It is an increasingly common condition that affects over 5 million Americans with 670 000 new cases diagnosed each year (Lloyd-Jones et al., 2010). Patients with end stage heart failure have a grave prognosis even with maximal medical therapy. Hershberger and colleagues reported that the survival of inotrope dependent patients with end stage heart failure was 51 %, 26% and 6 % at 3, 6, 12 months respectively (Hershberger et al., 2003). Ventricular assist devices (VADs) have been in use for over two decades as a treatment option for patients with advanced heart failure. These mechanical pumps provide hemodynamic support to patients as bridges to cardiac transplantation or destination therapy for transplant ineligible patients. Development of VAD technology and improvements in medical management have allowed individuals with VADs to be discharged from hospitals to their communities. As the number of patients on VAD support continues to rise and more patients are discharged from hospital, outpatient management of VAD patients has become a critical component of mechanical circulatory support programs. This chapter will examine the literature on outpatient VAD support. The fundamental elements of a safe and effective discharge process will be summarized. VAD outpatient outcomes and community based management of device related complications will be discussed.

The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial was a landmark clinical trial that demonstrated that the use of left ventricular assist devices (LVADs) in patients with advanced heart failure resulted in a 48% reduction in the risk of death as compared to optimal medical management. The REMATCH trial randomized patients with end stage heart failure who were ineligible for cardiac transplantation to either LVAD therapy or optimal medical management. One year survival was 52% in the LVAD group and 25% in the medical therapy group and 2 year survival was 23 and 8 % respectively. The quality of life was significantly improved at one year in the device group. However, the frequency of serious adverse events in the device group was 2.35 times that in the medical therapy group (Rose et el., 2001). Despite substantial survival benefit and significant better quality of life, the study revealed that morbidity and mortality associated with the use of LVADs is considerable.

2. Device designs

A variety of long term VADs have been developed to benefit patients with end stage heart failure. Devices are classified based on a number of characteristics including device location and the method by which the device supports circulation. There are three generations of VADs currently available for use. First generation pumps use pulsatile action with volume displacement. Pulsatile VADs have multiple moving components that are vulnerable to failure over time. Second generation VADs are designed to address some of the problems seen with the first generation VADs. Developed over the past decade, second generation VADs are rotary pumps that provide continuous blood flow. Nonpulsatile flow allows for smaller and quieter devices with less mechanical parts. Continuous axial blood flow is generated by an impeller rotating at high speeds on mechanical bearings. The newest version, third generation VADs are continuous axial or centrifugal flow devices with bearingless impellers or rotors that are magnetically or hydrodynamically levitated (Visouli & Pitsis, 2008). There exist a number of different VADs and a complete review of all the devices is beyond the scope of this chapter. Table 1 briefly reviews some of the long term devices, their mode of action and current status.

Device	Manufacturer	Position	Type	Status
Novacor®	WorldHeart Corporation, Salt Lake City, UT, USA	Intracorporeal	Pulsatile	No longer in use since 2008
HeartMate® XVE	Thoratec Corporation, Pleasanton, Ca, USA	Intracorporeal	Pulsatile	CE mark approval 2003 FDA approval for BTT 2001 for DT 2003
HeartMate II®	Thoratec Corporation, Pleasanton, Ca, USA	Intracorporeal	Continuous Axial flow with blood-immersed bearings	CE mark approval 2005 FDA approval for BTT 2008 for DT 2010
Jarvik 2000	Jarvik Heart Inc. New York, NY, USA	Intracorporeal	Continuous Axial flow with blood-immersed bearings	CE mark approval 2005 USA trial BTT in progress
HeartWare® HVAD	HeartWare International Inc. Framingham, MA, USA	Intracorporeal	Centrifugal Continuous flow Hydromagnetic rotor suspension	CE mark approval 2009 USA BTT and DT trial in progress
DuraHeart®	Terumo Heart Inc. Ann Arbor, MI, USA	Intracorporeal	Centrifugal Continuous flow Magnetically levitated impeller	CE mark approval 2007 USA trial BTT in progress

BTT (Bridge to transplantation); DT (Destination therapy); FDA (Food and Drug Administration); CE (European Conformity)

Table 1. Long term implantable left ventricular assist devices

Many VAD centers use a variety of different types of LVADs in their mechanical circulatory support programs. Therefore, managing LVAD outpatients with different types of systems is not uncommon. Clinicians need to be familiar with the specifics of each device to minimize complications. While each device may have its own unique challenges, many of the issues are universal to all devices.

3. Preparing for hospital discharge

A review of the literature reveals that most mechanical circulatory support programs have similar criteria for discharging patients from hospital on LVAD support. See Table 2 for general criteria for discharging LVAD patients home.

1. Stable vital signs, LVAD hemodynamics and pump function
2. Stable hemoglobin and end organ function
3. Native heart able to support patient in the case of serious VAD malfunction.
4. Adequate wound healing
5. Patient is ambulatory-approved for discharge by physiotherapist
6. Patient able to perform activities of daily living (ADLs) with minimal assistance-approved for discharge by occupational therapist
7. Patient and caregiver complete LVAD training and demonstrate proficiency in LVAD management
8. Patient and caregiver have completed out of hospital excursions
9. Notification of emergency medical services, local emergency room staff and electric company
10. List of emergency contacts given to LVAD patient
11. Outpatient appointment scheduled

Table 2. Criteria for discharging left ventricular assist device patients home

The LVAD patient's medical condition must be determined to be stable before discharge. This includes patient's volume status, LVAD function, medication regime and laboratory results. The LVAD patient must be physically capable of managing his or her self care. Self care activities include monitoring daily weights, administration of medication, device management and exit site care. Completion of a physical and occupational therapy program permits LVAD patients to be independent and perform their activities of daily living (ADLs) with minimal assistance. Maintaining a stable international normalized ratio (INR) in the therapeutic range ensures the risk of bleeding or thromboembolism after discharge is minimized.

Although patient's medical readiness for discharge is critical, patient and caregiver must be knowledgeable on all aspects of the care and operation of the LVAD prior to discharge. Patient and caregiver must complete a comprehensive LVAD educational program that encompasses routine care to trouble shooting device problems. Both patient and caregiver must be able to respond appropriately to LVAD system alarms and emergency situations. Proficiency with changing LVAD batteries and power sources must be demonstrated by patient and caregiver. Following extensive training, competency evaluation and skill demonstration must be performed by patient and caregiver before discharge. Since meticulous care of the LVAD exit site is critical, education emphasizing proper exit site care

is essential. Patient or caregiver must be able to perform independent LVAD exit site dressing changes using aseptic technique. Patient and caregiver must be able to monitor the device for proper function, identify alarm conditions and know when to contact the VAD team for support and assistance. Once the patient and caregiver demonstrate competence with their device, it is important for the LVAD patient and caregiver to go on out of hospital excursions to foster independence and promote confidence prior to formal discharge.

4. Community support

Discharge preparation involves notification of the LVAD patient's community resources. Methods of informing local care providers include providing written material, a training CD or LVAD education presentations. VAD coordinators play an important role in coordinating the care between local care providers and the VAD team. As LVAD patients may present to their local emergency room with urgent LVAD related problems such as arrhythmias, device malfunction or stroke, communication between local care providers and the VAD team is vital. Instructing local Emergency Medical Services (EMS) personnel and emergency room (ER) staff on LVAD emergency measures may be considered. However, ensuring the training of all EMS and ER personnel may be difficult. Therefore training the patient and their family to direct the actions of EMS and ER personnel in collaboration with the personnel at the VAD center may be at better approach (Holman et al., 2001). LVAD patients that live a considerable distance from the VAD center may require routine follow up with their local cardiologist and primary care physician. Therefore, it is important that local physicians are familiar with the device and have access to the VAD team at any time. Emergency contact numbers for the patient's VAD center should be with the LVAD patient at all times. Also, community dentists must be informed that VAD patients should receive bacterial endocarditis prophylaxis prior to dental procedures. The electric company should be notified of the LVAD patient's dependence on electrical power and need for priority status for power restoration should a power failure occur. And lastly, local cardiac rehabilitation centers must be given information to safely exercise the VAD patient. Patient and community education and support are key elements of a successful outpatient program.

5. Outpatient follow up

Follow up in the clinic is an essential component of the care and management of outpatient LVADs. See Table 3 for routine outpatient follow up care. The frequency of clinic visits

- Weekly clinic visits that include a physical exam, interrogation of the device, laboratory testing, optimization of medical therapy and discussion of patient concerns.
- All LVAD patients are re-started on heart failure medications. Up titration of ace inhibitor and beta blocker is assessed during clinic visits.
- Routine echocardiograms every month or when clinically indicated to evaluate left and right ventricular function, valvular function and estimation of right ventricular systolic pressure (RVSP). Echo based adjustments to VAD speed may be required.
- Clinic visits are decreased to bi-weekly or monthly when LVAD patients are on optimal medical therapy and there are no active issues.

Table 3. Outpatient LVAD follow up care

depends on the patient's condition, medical issues or concerns with device function. Once discharged from hospital, LVAD patients usually return to the outpatient clinic weekly until the VAD team determines less frequent visits are warranted. However, an outpatient should be assessed whenever there is a significant change in the patient's medical status, LVAD pump readings or any alarm condition occurs. It is critical that the outpatient has access to the VAD team at all times for any emergencies or for technical support. Emergency procedures should be reviewed in clinic with patient and caregiver on a regular basis.

6. Discharge rates

Although LVADs have been in use for nearly two decades, the Food and Drug Administration (FDA) only allowed LVAD bridge to transplantation patients to be discharged to their home environment as of 1996 (Park et al., 2005). In 2001, a review of outpatient VAD programs revealed that only 40-60% of patients with LVADs awaiting cardiac transplantation were discharged (Holman et al., 2001). However as mechanical circulatory support programs become more comfortable with discharging patients on LVAD support, the number of patients discharged from hospital is increasing. Lietz and colleagues reported 71% of destination therapy LVAD patients were discharged home or to a nursing facility (Lietz et al., 2007). In a study with bridge to transplantation LVAD patients, 75 % of patients with HeartMate II (Thoratec, Pleasanton, CA, USA) continuous flow LVAD were discharged from hospital. The median hospital stay after surgery was 25 days. 54% of discharged patients required rehospitalization for complications (Miller et al., 2007). Similar results were reported by Pagani and associates. In this study with bridge to transplantation patients, 78% of patients with HeartMate II LVAD were discharged from hospital with a medium hospital stay after surgery of 25 days. 68% of discharged patients required rehospitalization (Pagani et al., 2009). In a recent clinical trial of patients who were ineligible for cardiac transplantation, 86% of patients with a continuous flow LVAD and 76% of patients with a pulsatile LVAD were discharged from hospital. The median length of stay after surgery was 27 days with continuous flow device and 28 days with pulsatile device (Slaughter et al., 2009). MacIver and colleagues reported that 71% of LVAD patients were discharged home and that complications occurring in the community were low. This study found that patients supported for more than 3 months spent 70% of their support time at home and this increased to 94 % for patients supported for more than 1 year (MacIver et al., 2009). As demonstrated in the literature, an increasing number of patients on VAD support are discharged from hospitals and outpatient management is crucial to successful LVAD outcomes.

7. Results of long term VAD support

Management of LVAD patients requires a thorough understanding of the risks and potential complications associated with LVAD therapy. Reviewing the literature on mechanical circulatory support allows clinicians to identify and manage common LVAD issues and adverse events in order to improve patient outcomes and survival. HeartMate VE and XVE (Thoratec, Pleasanton, CA, USA) and Novacor (World Heart, Oakland, CA, USA) have been the most widely used and studied long term implantable LVADs. The HeartMate VE LVAD was the device used in the REMATCH trial. The 1 and 2 year survival rates of LVAD patients in the REMATCH trial was 52% and 23 % respectively. The most common causes of

death in the LVAD group were sepsis (41%), failure of the device (17%) and ischemic stroke (10%) (Rose et al., 2001). Extended follow-up of the REMATCH trial patients confirmed survival rates at 1 year and 2 year for patients receiving LVADs was 52% and 29% respectively (Park et al., 2005). Outcomes of LVAD destination therapy in the post REMATCH era described by Leitz and associates showed relatively no change in the overall survival after HeartMate XVE LVAD implantation. Survival was 56 % and 30.9% at 1 year and 2 years respectively. The leading causes of overall mortality included sepsis (29.5%), multiorgan failure (12.8%) and right heart failure (8.4%). LVAD failure accounted for 6% of deaths (Lietz et al., 2007). However, a more recent study of patients undergoing destination therapy with HeartMate XVE demonstrated that long term LVAD destination therapy can be improved. Long and his colleagues reported a 2 year survival of 77 % for the LVAD destination therapy group as compared with the REMATCH trial rate of 23%. This study also had a 38% reduction of adverse events as compared with the REMATCH trial results. Causes of death long term were related to LVAD failure (8.7%), infection (8.7%) and malignancy (4.3%). Therefore, relative to the REMATCH trial results, the rate of death after discharge was decreased by a factor of 2.5 (Long et al., 2008). Although the study was a single center experience and not a randomized controlled trial, the results suggest that patient selection and advances in LVAD patient management have the potential for improving destination therapy outcomes.

The prospective, non randomized Investigation of Nontransplant-Eligible Patients Who Are Inotrope Dependent (INTrEPID) trial compared the outcomes of patients supported on the Novacor LVAD with patients treated with optimal medical therapy. The study demonstrated that patients with a Novacor LVAD had superior survival rates at 1 year as compared to the medical therapy group (27 % vs. 11%). This trial found that stroke (34%) and infection (24%) accounted for the majority of deaths in the LVAD group. While 62 % of the LVAD patients experienced a stroke or transient ischemic attack during the study, there was no mortality attributable to LVAD malfunction (Rogers et al., 2007). Although the REMATCH and the INTrEPID trials demonstrated that patients treated with LVAD destination therapy had significant improvement in survival compared with optimal medical therapy, morbidity due to sepsis, stroke and device failure is common with the first generation pulsatile devices.

Over the past 2 years a rapid growth in the use of continuous flow LVADs and a decline in pulsatile LVADs have been observed (Kirklin et al., 2010). In a prospective study, Miller and associates reported the survival rate of LVAD patients implanted with HeartMate II LVAD as a bridge to cardiac transplantation was 75% at 6 months and 68% at 12 months. The use of a continuous flow pump was not without complications. At 6 months, 19% of patients had died while on device support, 4 % had medical complications that precluded transplantation and 2 % had their devices replaced. Causes of death included sepsis (4%), ischemic stroke (4%) multisystem organ failure (3%) hemorrhagic stroke (2%) anoxic brain injury (1.5%), and right heart failure (1.5%). This study also reported that percutaneous lead infection occurred in 14% of patients but no pump pocket infection was observed (Miller et al., 2007).

A retrospective European study of LVAD patients who had received a HeartMate II LVAD reported a 1 year survival of 69% in the destination therapy group and 63% in the bridge to transplant group. Main causes of death were multiple organ failure, in most instances due to septic complications, and cerebrovascular accidents (CVA). One third of adverse events occurred within the first week post LVAD implant and only one cerebrovascular accident occurred after the first 9 days after surgery. There was no mechanical failure of the device. Sepsis remained the leading cause of death overall (Strűber et al., 2008).

In a recent prospective study by Pagani and associates, the overall survival for patients with a HeartMate II LVAD as bridge to transplant was 73% at 1 year and 72% at 18 months. The primary causes of death were sepsis (4%), stroke (4% ischemic and 2% hemorrhagic), right heart failure (3%) and device related deaths (3%). Only 4.6 % of deaths occurred after 6 months of device support and included sepsis, LVAD power loss and withdrawal of support. Although LVAD replacement occurred in 4% of patients due to device thrombosis (1.4%), percutaneous lead wire damage (1.4%) or for device infection (0.3%), there were no failures of the mechanical pumping mechanism. Also reported were significant improvements in LVAD patients' functional status, 6-minute walk test and quality of life (Pagani et al., 2009).

Slaughter and colleagues reported their results of a randomized controlled trial comparing outcomes in patients with advanced heart failure who were ineligible for transplantation and received either a pulsatile flow HeartMate XVE LVAD or a continuous flow HeartMate II LVAD. Estimates of the 1 and 2 year survival rates were 68% and 58 % respectively with the continuous flow device and 55% and 24 % with the pulsatile device. The leading causes of death in patients with continuous flow device were hemorrhagic stroke (9%), right heart failure (5%), sepsis (4%) and external power interruption (4%) while the leading cause of death in patients with a pulsatile device were hemorrhagic stroke (10%), right heart failure (8%), multiorgan failure (7%) and ischemic stroke (5%). Continuous flow LVAD significantly improved the probability of survival free from stroke and reoperation for device repair or replacement at 2 years (Slaughter et al., 2009). While both devices significantly improved patients' quality of life and functional capacity, the 2 year survival rate with the continuous flow device was more than twice the rate with pulsatile device.

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database first annual report found that cardiovascular causes (including right ventricular failure and fatal arrhythmias) and multiorgan failure predominated as early causes of death whereas central nervous system events and infection were the most common causes of death after the first month of LVAD implantation. Bleeding and infection were the most common adverse events both early and later (Kirklin et al., 2008). While pulsatile VADS were the only available devices in the first INTERMACS report, the second INTERMACS report included data on continuous flow devices. The report demonstrated that continuous flow devices have become the preferred choice for bridge to transplantation therapy as 85% of LVADs implanted between July 2008 and January 2009 were continuous flow VADS. In general, adverse events were reduced in patients with continuous flow devices for device malfunction, infection, hepatic dysfunction and neurologic events (Kirklin et al., 2010). A review of the studies with HeartMate II LVAD, a second generation device, provides evidence of improved outcomes and reduced morbidity with continuous flow pumps as compared with pulsatile pumps. Overall there was significant reduction of adverse events including percutaneous lead infection and neurological events with the non pulsatile device.

8. Outpatient LVAD outcomes

A review of the literature reveals that there is limited research on outpatient outcomes. The literature consists mostly of single center reports that are based on small numbers of outpatients. Also, the majority of studies describe outpatient outcomes while on pulsatile VAD support with very few studies that include non pulsatile VADs. See Table 3 for a review of the literature on LVAD outpatient outcomes.

Authors	Study period	Number of discharged patients	Device	Results
Myers et al., 1996	Unknown	21	HeartMate VE	15 readmissions to the hospital: 9 for medical reasons and 6 for device related problems. No deaths occurred outside of the hospital. Two patients returned to full-time employment
Schmid et al., 1999	1995-1998	16	HeartMate VE, Novacor	Reasons for readmission included systemic or driveline infections, suspected or true thromboembolic events, suspected malfunction of LVAD, 1 death due to cerebral bleed, 1 death due to ventricular fibrillation
Morales et al., 2000	1993-1998	44	HeartMate VE	None of the outpatients died. No strokes occurred. 46% minor device malfunctions and 6.8 % major device malfunctions occurred. 18% device related infections
El-Banayosy et al., 2001	1994-2000	66	HeartMate VE, Novacor	29 patients were not readmitted. Primary reasons for readmission were neurologic disorders and infection complications. 24% died on LVAD support (15% multiorgan failure and/or sepsis, 4.5% cerebral infarction, 3% cerebral bleed, 1.5% brain death)
Richenbacher & Seemuth, 2001	1999-2001	13	HeartMate VE	1 death due to fungal sepsis with embolic event. 62% required readmission (2 patients with device related infections, 2 patients with neurologic events, 1 device malfunction requiring pump replacement, 3 non VAD related admissions)

Authors	Study period	Number of discharged patients	Device	Results
Holman et al., 2002	1997-2001	20	Thoratec VAD (Thoratec Corp., Pleasanton, CA), HeartMate VE	5 deaths after hospital readmission (1 sepsis, 1 conduit tear, 3 neurologic events) 4 device infections, 3 device malfunctions that required pump replacement
Drews et al., 2003	1996-2001	38	Novacor, Berlin Heart (Berlin Heart GmbH, Germany)	Total mortality 16%. 2 deaths due to cerebral embolism, 1 death due to cerebral hemorrhage, 2 deaths due to systemic infection, 1 death due to multiorgan failure. 84 % patients required readmission for cerebral embolism (9%), bleeding (1%), wound infection (24%), coagulation disorder (14%), non VAD related (46%)
Frazier et al., 2007	2003-2007	35	HeartMate II	No device malfunctions in outpatient setting. 1 device removed due to pump pocket infection. 1 death due to hemorrhagic stroke. 2 patients had sudden death at home.
Potapov et al., 2008	1996-2006	114	Berlin Heart, Novacor, MicroMed DeBakey (MicroMed Cardiovascular Inc. Houston, Tx, USA), HeartMate VE, DuraHeart, Incor (Berlin Heart, Germany) LionHeart (Arrow International, Inc. Reading, PA, USA)	Outpatients spent 67% time at home. 56% readmission unrelated to VAD, 20.9% wound infection, 10.9% coagulation disorders, 7.7% cerebral embolism

Authors	Study period	Number of discharged patients	Device	Results
MacIver et al., 2009	2001-2006	17	HeartMate XVE, Novacor, HeartMate II	88% outpatients survived until transplant or explant. 1 death due to cerebral vascular accident. 1 subarachnoid hemorrhage (patient survived to transplant). 29% incidence of driveline or pocket infection. 29% had device malfunction. 1 patient remained on support at end of study period

Table 3. Literature on LVAD outpatient outcomes

Allen and associates published a retrospective review of patients supported more than 1 year on a Heartmate I or HeartMate II LVAD from 2000 to 2009 which revealed that although LVAD support is not without complications, LVAD patients spend the majority of time (87%) out of hospital enjoying a good quality of life. Causes of readmission included infection (43.2%), anticoagulation complications (11.5%), gastrointestinal bleeding (8.8%), LVAD malfunction (8.1%), neurologic (7.4%). There were 10% of patients that were never readmitted while on LVAD support with HeartMate II LVAD. However, 26.7% of patients required LVAD exchange for mechanical failure, electrical failure and thrombosis. While there was a trend toward higher exchange rates and shorter exchange times with HeartMate I, the differences were not statistically significant. While 77% of LVAD patients required additional operations, 57% were related to percutaneous lead or LVAD pocket infections (Allen et al., 2010). This study found that device related infections are common no matter which generation of device and that they are detrimental to the LVAD patient's quality of life.

9. Quality of life

An important aspect to consider for outpatient support is the impact of LVAD therapy on quality of life. A majority of patients with advanced heart failure express a strong desire for improvements in quality of life and functionality even at the expense of longevity (Rogers et al., 2010). The REMATCH trial provided evidence that LVADs improved the quality of life for end stage heart failure patients ineligible for transplantation (Rose et al., 2001). A review of the literature reveals there is strong evidence that demonstrates the positive effect of long term mechanical support on functional capacity. In a study with patients who received a Heartmate VE LVAD, 30% of outpatients were able to return to work or school, 33 % to sexual activity and 44% to driving (Morales et al., 2000). Data from advanced heart failure patients enrolled in the HeartMate II LVAD trials were analyzed by Rogers and colleagues

to assess the impact of continuous flow LVADs on functional capacity and heart failure–related quality of life. The study found that LVAD patients demonstrated early and sustained improvement in functional status and quality of life. Following implantation with HeartMate II LVAD, 82% bridge to transplantation and 80% destination therapy patients at 6 months and 79 % destination therapy patients at 24 months improved to New York Heart Association (NYHA) functional class I or II. Mean 6 minute walk distance in destination therapy patients was 204 meters in patients able to ambulate at baseline, which improved to 350 and 360 meters at 6 and 24 months. There were significant and sustained improvements from baseline in both bridge to transplantation and destination therapy patients in median Minnesota Living With Heart Failure and Kansas City Cardiomyopathy Questionnaires overall summary scores (Rogers et al., 2010). Pagani and his colleagues reported similar findings with patients who underwent HeartMate II LVAD implantation as bridge to transplantation. At 6 months, there were significant improvements in functional status and 6-minute walk test (from 0% to 83 % of patients in New York Heart Association functional class I or II and from 13% to 89% of patients completing a 6 -minute walk test) and in quality of life (mean value improved 41% with Minnesota Living With Heart Failure and 75% with Kansas City Cardiomyopathy Questionnaires) (Pagani et al., 2009). While the literature shows there is substantial survival benefit and significant improvement in quality of life, clinicians must manage and reduce the complications associated with LVAD therapy.

10. Outpatient medical management

The literature reveals that device related infection is a major cause of morbidity and mortality in LVAD patients. Infection prevention and management is an important aspect of LVAD outpatient care. The percutaneous driveline exit site remains the major source of device related infections in LVAD patients. It is vital to treat percutaneous driveline infections in order to prevent pump pocket infections. The usual organisms cultured are Staphylococcus and other biofilm forming organisms such as Pseudomonas, Enterococcus and Candida (Holman et al., 2003). Patients must be taught strict adherence to aseptic technique for LVAD exit site care. Another critical component of infection prevention is immobilization of the percutaneous driveline to promote tissue ingrowth and reduce infection risk. Patients must monitor for signs and symptoms of infections such as fever, chills, erythema or tenderness at exit site or along driveline or purulent drainage from exit site and notify the VAD team immediately should signs of infection develop. If infection is suspected, the clinician should initiate broad spectrum antibiotics once a culture of exit site has been obtained. After the organism is identified the patient should be started on the most appropriate antibiotic therapy as per culture and sensitivity results. Consultation with Infectious Diseases Service may be necessary to optimize antibiotic therapy.

Advanced practice guidelines for HeartMate destination therapy is an excellent resource for clinicians and contains care guidelines for infection prevention, management and treatment that can be applied to all devices. General recommendations include performing an ultrasound or computed tomography (CT) scan to detect presence of fluid accumulation or infection (Chinn et al., 2004). If LVAD patient experiences systemic symptoms such as fever, chills, leukocytosis, blood cultures should be obtained to exclude bacteremia. Bacteremia must be treated aggressively as it may lead to endocarditis of the pump. If LVAD pocket

infection is suspected, incision and drainage may be necessary to obtain cultures. Increasing the LVAD patient's status on the transplant list may be indicated if patient develops LVAD exit site infection. Fungal infections have been associated with vegetative growth on LVADs and persistent systemic fungal infection may require LVAD replacement (Thoratec Corporation, 2008). While it is possible to treat some patients on an outpatient basis, many LVAD patients require rehospitalization for intravenous antibiotic administration for driveline exit site infections. MacIver and colleagues reported that 75% of driveline infections in outpatient LVADs were managed in the outpatient clinic with a single course of oral antibiotics (MacIver et al., 2009).

Research demonstrates that LVAD patients may experience a neurological event during LVAD support. LVAD patients are routinely placed on anticoagulation and antiplatelet therapy to decrease the risk of thromboembolic complications during LVAD support. Antiplatelet therapy for LVAD patients usually consists of enteric coated aspirin 81 to 325 mg daily. Some VAD centers add dipyridamole to the antiplatelet regime. For patients who have an allergy to aspirin, clopidogrel may be used in its place. Thromboelastography can be performed to assess antiplatelet effect. The HeartMate II clinical trial found that pump thrombosis was rare with 4% occurring in destination therapy patients and 1.4% in bridge to transplantation patients (Slaughter et al., 2010). However, as there is a potential for a neurologic event to occur while on LVAD support, it is prudent for clinicians to order a computed tomography (CT) scan for any change in the mental status of a LVAD patient to assess for subdural hematoma, thromboembolism or intracerebral hemorrhage. It is important to maintain adequate pump flows to avoid transient ischemic attacks (TIA) or ischemic strokes. Likewise it is critical not to be too aggressive with anticoagulation in order to avoid hemorrhagic strokes. A recent study by Boyle and associates found that while thrombotic event rates in patients discharged with HeartMate II was 3.3%, hemorrhagic event rates were 22%. The gastrointestinal system was identified as the most frequent site of bleeding in outpatients. In Boyle's analysis of outpatient anticoagulation, 9.4% of patients discharged from hospital on HeartMate II support required blood transfusions due to gastrointestinal bleeding (Boyle et al., 2009). Outpatient LVAD management must include regular testing of anticoagulation and complete blood counts. Anticoagulation and antiplatelet therapy must be carefully monitored to avoid adverse events and may need to be adjusted to minimize risks of thromboembolism or hemorrhage.

Device malfunction is a potential complication that can occur in the outpatient setting. Diagnosing device malfunctions can be accomplished by interrogating the device on a routine basis. LVAD malfunctions can include controller failure, LVAD motor issues or percutaneous lead problems. LVAD patients must notify the VAD team whenever an alarm condition occurs. Teaching the LVAD patient to monitor for changes in pump readings enables patients to notify the VAD team whenever there are significant changes. Technical support from VAD manufacturers is available to assist clinicians and waveforms can be down loaded and sent for analysis. It is important for clinicians to accurately diagnose and manage LVAD malfunctions to prevent serious adverse events. Patients must be trained to recognize and respond to device problems.

Arrhythmias may occur in patients on LVAD support. Ambardeker and associates reported that 24% of LVAD patients in their study received an appropriate implantable cardioverter-

defibrillator (ICD) shock for a ventricular arrhythmia (Ambardeker et al., 2010). In order to avoid potential arrhythmias, it is important for clinicians to closely monitor and correct electrolyte imbalances. LVAD patients should be considered for placement of an ICD as prophylactic treatment for ventricular arrhythmias. Anti-arrhythmics or beta blockers may also be used to suppress ventricular arrhythmias. For patients supported on a continuous flow device, it is important to avoid setting the pump speed too high as this may result in a suction induced arrhythmia.

11. Conclusion

LVAD support has become an accepted standard of care for patients with advanced heart failure. The literature demonstrates that LVAD patients can be safely and effectively managed as outpatients in the community. Minor LVAD complications can be managed in an outpatient LVAD clinic and most LVAD outpatients spend the majority of their time out of hospital. However, serious adverse events may require LVAD outpatients to be readmitted to hospital for care. In general, driveline infection is the most common complication reported in the outpatient setting with both pulsatile and continuous flow devices. The literature reveals that due to the limited durability of pulsatile VADs, there has been an increase in the number of patients implanted with continuous flow LVADs. A review of recent clinical studies demonstrates that there are fewer device related complications with continuous flow LVADs. However, the development of continuous flow LVADs has resulted in the creation of new clinical problems. Frazier and colleagues found that continuous flow introduces physiologic phenomena such as arteriovenous malformation leading to gastrointestinal bleeding, septal shift with resultant right heart failure, thrombosis of the aortic valve non coronary sinus, aortic valve fusion and aortic valve insufficiency (Frazier et al., 2007). Further research is required to determine the durability and potential long term problems that may arise with long term use of continuous flow LVADs. Longer duration follow up of destination therapy patients on continuous flow LVAD support may reveal new issues with non pulsatile devices.

12. References

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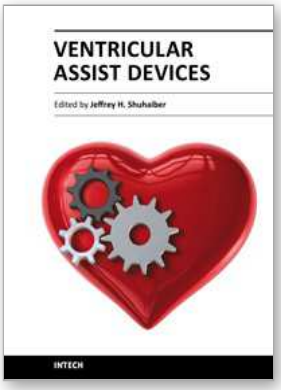

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The assist devices will continue adding a large number of years of life to humans globally and empower the medical society to optimize heart failure therapy. While expensive and cumbersome task, the foundation provided in this book reflects a contemporary product of original research from a multitude of different experts in the field. We hope this cumulative international effort provides the necessary tools for both the novice as well as the active practitioner aiming to change the outcome of these complex patients.

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