AHA SCIENTIFIC STATEMENT

Recommendations for the Use of Mechanical Circulatory Support: Ambulatory and Community Patient Care

A Scientific Statement From the American Heart Association

Endorsed by the International Society for Heart and Lung Transplantation

Jennifer L. Cook, MD, FAHA, Chair
Monica Colvin, MD, FAHA, Co-Chair
Gary S. Francis, MD, FAHA
Kathleen L. Grady, PhD, RN, MS, FAHA
Timothy M. Hoffman, MD, FAHA
Mariell Jessup, MD, FAHA
Ranjit John, MD
Michael S. Kiernan, MD, FAHA
Judith E. Mitchell, MD, FAHA
Francis D. Pagani, MD, PhD, FAHA
Michael Petty, PhD, RN
Pasala Ravichandran, MD
Joseph G. Rogers, MD, FAHA
Marc J. Semigran, MD, FAHA
J. Matthew Toole, MD, FAHA
On behalf of the American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Cardiovascular Radiology and Intervention; and Council on Cardiovascular Surgery and Anesthesia

Key Words: AHA Scientific Statements ■ ambulatory care ■ congestive heart failure ■ emergency care ■ emergency first responders ■ ventricular assist device

CLINICAL STATEMENTS AND GUIDELINES

Mechanical circulatory support (MCS) offers a surgical option for advanced heart failure when optimal medical therapy is inadequate. MCS therapy improves prognosis, functional status, and quality of life.[1,2] The INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) tracks patient selection and outcomes for all implanted US Food and Drug Administration–approved MCS devices. From June 2006 until December 2014, >15 000 patients received MCS, and >2000 implantations are performed annually. One-year survival with current continuous-flow devices is reported to be 80%, and 2-year survival, 70%.[3] In patients awaiting heart transplantation, MCS provides a bridge to transplantation, and for others who are ineligible for heart transplantation, MCS provides permanent support or destination therapy. Indications and absolute and relative contraindications to durable MCS are listed in Table 1.

As of July 2014, 158 centers in the United States offer long-term MCS.[3] Patients often live a substantial distance from the implanting center, necessitating active involvement of local first responders (emergency medical technicians, police, and fire department personnel), emergency department staff, primary care, and referring cardiologists. Because patients with MCS are becoming increasingly mobile, basic knowledge of equipment is necessary for personnel in public areas such as schools, public transportation, and airplanes/airports. Ambulatory patients with MCS can span the entire age spectrum from pediatrics to geriatrics. The aim of this document is to provide guidance for nonexperts in MCS and to facilitate the informed assessment, stabilization, and transport of the patient with MCS back to the MCS center for definitive therapy. In addition, the principles herein provide a foundation for emergency management and a framework to address the management of known MCS-associated complications and expected comorbid medical problems.

EQUIPMENT OVERVIEW

Currently in the United States, the most frequently used durable devices are continuous-flow devices with axial (HeartMate II, St. Jude Corp, Minneapolis, MN) or centrifugal (HeartWare Ventricular Assist System, HeartWare Corp, Framingham, MA) flow (Figure 1A–1D). Excision of a round "core" from the left ventricular (LV) apex allows the device to be positioned within the LV. Anastomosis of the outflow cannula occurs at the ascending aorta. The pump is powered through the percutaneous lead (power cord) that exits through the abdominal wall. The percutaneous lead is attached to a controller that weighs between 1 and 1.5 lb, which operates the device and records data on operation. Typically, patients wear batteries during the day (lasting up to 12 hours) and plug into household power while their batteries charge at night. Practical field guides are available for further reference.[4]

All patients are issued a backup controller and spare batteries that they carry with them at all times. When transported to the emergency room, patients should

Table 1. Indications and Contraindications to Durable Mechanical Support

Indications: combination of the following:
Frequent hospitalizations for heart failure
NYHA class IIIb–IV functional limitations despite maximal therapy
Intolerance of neurohormonal antagonists
Increasing diuretic requirement
Symptomatic despite CRT
Inotrope dependence
Low peak Vo_2 (<14–16)
End-organ dysfunction attributable to low cardiac output
Contraindications
Absolute
Irreversible hepatic disease
Irreversible renal disease
Irreversible neurological disease
Medical nonadherence
Severe psychosocial limitations
Relative
Age >80 y for DT
Obesity or malnutrition
Musculoskeletal disease that impairs rehabilitation
Active systemic infection or prolonged intubation
Untreated malignancy
Severe PVD
Active substance abuse
Impaired cognitive function
Unmanaged psychiatric disorder
Lack of social support

CRT indicates cardiac resynchronization therapy; DT, destination therapy; NYHA, New York Heart Association; Vo_2, oxygen consumption; and PVD, peripheral vascular disease.

be instructed to bring this equipment and contact information for their MCS center. Ideally, if time and the patient's condition allow, peripheral equipment, including the battery charger and alternating-current power charger, should be brought to the emergency department, particularly if the responding emergency/urgent care center does not have this equipment available (Table 2).

Ambulatory patients will present on battery support. Care providers should evaluate the remaining battery life as displayed on the battery "fuel gauge." When emergency care is requested in patients' homes, responders may find the patient connected to household power. Before transport, patients will need to be connected to battery support. Failure to switch the power will lead to pump stoppage.

Controller Display Parameters

On the device controller, a display reports parameters that can be considered device "vital signs." These include the speed (revolutions per minute), power (Watts), and flow (liters per minute; Figure 2A and 2B and Table 3).

The device is adjusted by the implanting center to optimize LV unloading and to provide the best combined cardiac output (CO). The CO is contributed by both the MCS device and native heart flow. The speed remains fixed unless manually reprogrammed by the MCS center. The power required is measured and recorded. Typically, higher revolutions-per-minute speeds correlate with higher power. The flow is calculated with device-specific algorithms. The HeartMate II device displays an additional pulsatility index parameter, which reflects the change in device flow over the cardiac cycle.

COMANAGEMENT OF THE STABLE PATIENT

Longitudinal care of patients with MCS requires a multidisciplinary team to manage comorbid conditions. The implanting center typically maintains close follow-up; however, referring physicians and other specialty providers (often in outlying locations) participate in the coordinated plan of care. All participating practitioners benefit from an understanding of the unique challenges in this patient population.

Returning to Normalcy

Many signs and symptoms of heart failure (eg, shortness of breath, paroxysmal nocturnal dyspnea, and fluid weight gain) abate fairly soon after surgery. Other symptoms may resolve over a longer period of time (eg, fatigue, poor energy level, and decreased strength).[5] Thus, early mobilization and rehabilitation are important to a successful recovery. Aggressive physical and occupational therapy should begin as soon as possible after MCS surgery, and cardiac rehabilitation should continue beyond hospital discharge.[6]

A patient's return to a normal life after discharge includes incorporation of MCS self-care (eg, changing power sources) into his or her daily routines. Family caregiver support is an important component of self-care. Family caregivers who are also trained to assist with troubleshooting alarms typically change driveline exit dressings and address potential equipment malfunctions.

After discharge, patients with MCS adjust to performing activities of daily living (eg, bathing, dressing, sleeping, home management, and work) and engaging in leisure activities. Most patients identify bathing as a key component of normalcy. Submersion in a bathtub

Circulation. 2017;135:e1145–e1158. DOI: 10.1161/CIR.0000000000000507

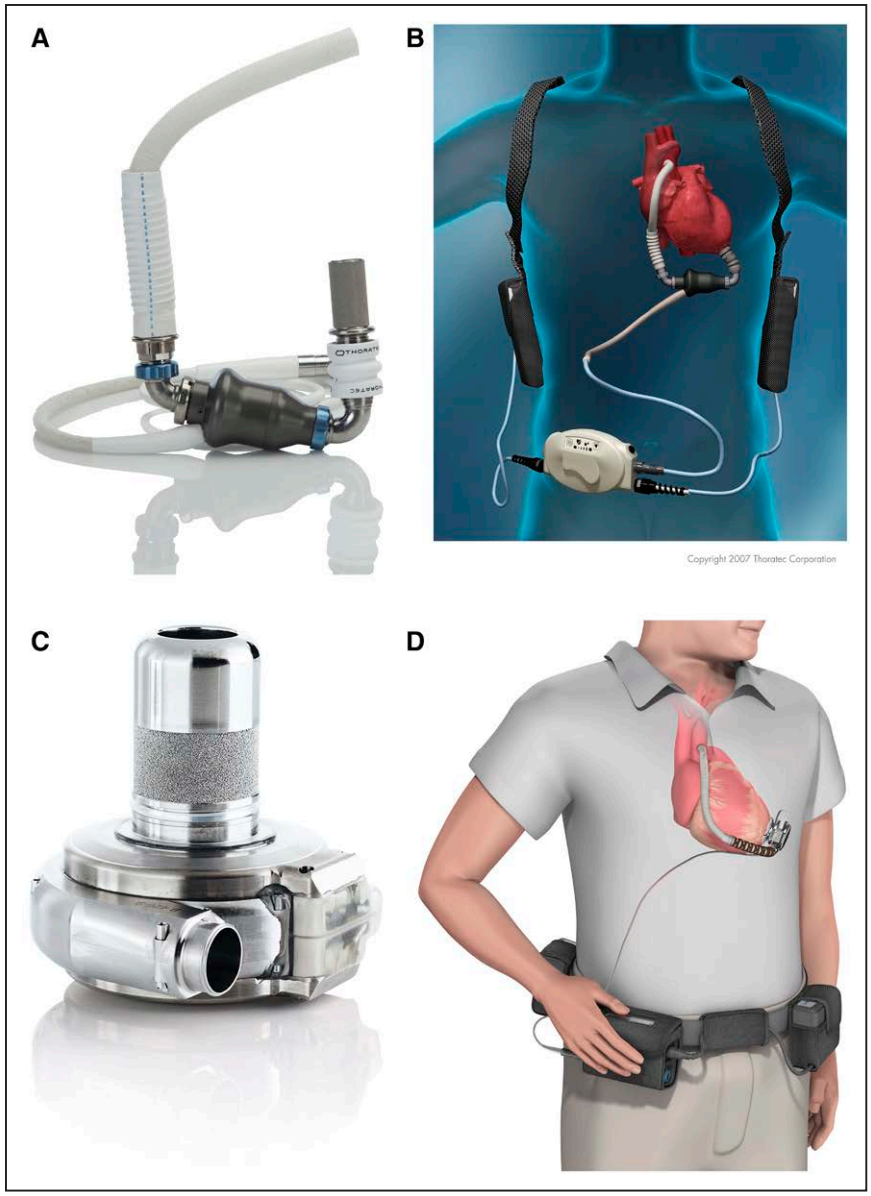

Figure 1. A through D, US Food and Drug Administration–approved devices.
A and **B**, HeartMate II ventricular assist system. HeartMate II, HeartMate 3, and St. Jude Medical are trademarks of St. Jude Medical Inc or its related companies. Reproduced with permission of St. Jude Medical. Copyright © 2017. All rights reserved. **C** and **D**, HeartWare ventricular assist system. Reproduced with permission from HeartWare.

and swimming are prohibited with these electrically powered devices; however, the manufacturers have developed accessories that allow patients to shower once the driveline site has healed adequately. Sleeping requires planning so that equipment is set up in the bedroom and allows nighttime trips to the bathroom. Patients adapt to sleeping with the controller and finding comfortable positions for sleep, given the presence of the pump and drive line. In addition, resumption of work, more strenuous activities (including leisure activities), and sexual intimacy may be challenging.[5,7]

Driving is also an important activity for many patients who undergo device implantation because it promotes independence, reduces caregiver burden, and facilitates social interaction. Patients cite the ability to drive as a major contributor to improved quality of life.[8] Eligibility for driving should be determined by the individual center, taking into consideration the patient's recovery from debility and local laws. Factors to be considered are the potential impact of the sudden deployment of a supplemental restraint system (airbag) against a passenger or driver with an implanted device[9] and the presence of an implantable cardiac defibrillator (ICD). Furthermore, the potential for sudden pump malfunction, change in level

Table 2. Equipment to Be Transported With Patient

Implanting center information
Backup controller
Backup batteries
AC power source
Battery charger

AC indicates alternating current.

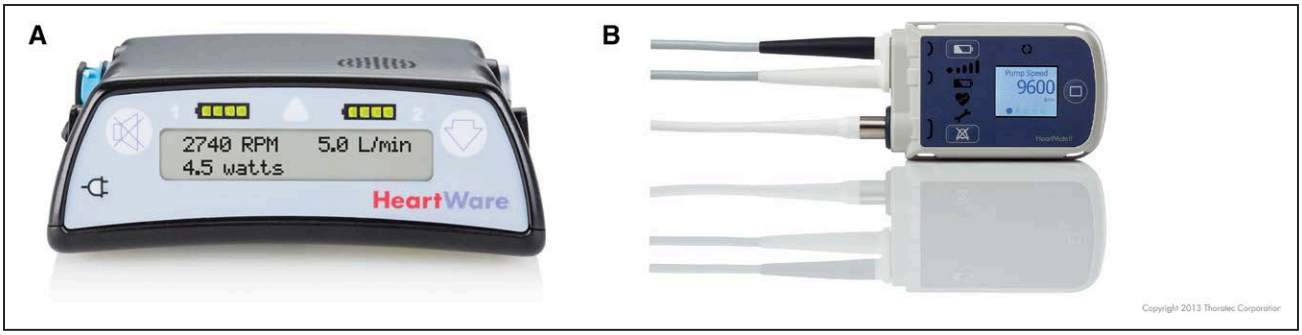

Figure 2. A and B, Display monitors.
A, HeartWare Controller. Reproduced with permission from HeartWare. **B**, HeartMate II controller. HeartMate II, HeartMate 3, and St. Jude Medical are trademarks of St. Jude Medical Inc or its related companies. Reproduced with permission of St. Jude Medical. Copyright © 2017. All rights reserved.

of consciousness, and driver distraction by alarms may pose a risk to the patient who is driving, passengers in the vehicle, and others on the road.

Anticoagulation

Anticoagulation with warfarin is required for all continuous-flow devices; however, the level of anticoagulation may vary by center, practice, and device type.[10,11] Antiplatelet therapy with aspirin and often a second antiplatelet agent is necessary because of the threat of stasis, thrombosis, shear-induced platelet dysfunction, and hemolysis. Upregulation of platelet function is described with MCS and may contribute to long-term risk of thromboembolic events.[12,13] In the case of subtherapeutic international normalized ratio, the necessity of bridging is patient specific and should be guided by the implanting center.

Hypertension and Hypotension

Titration of medical therapy to maintain a mean arterial blood pressure in the normal range is imperative to optimize forward flow and to prevent adverse events.[6,8,14] Hypertension after ventricular assist device (VAD) implantation is common, and an increase in diastolic pressure with a continuous-flow device may exacerbate or lead to hypertension.[15] Increased afterload decreases pump flow and increases the risk of neurological events and end-organ damage.[6,8,14] Neurohormone-modifying agents such as angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, β-blockers, and mineralocorticoid receptor antagonists are used to decrease afterload, to improve pump function, and to potentially contribute to ventricular recovery. Diuretics are frequently prescribed to manage symptoms of right ventricular (RV) failure and fluid retention. Hydralazine/nitrates and phosphodiesterase type 5 inhibitors such as sildenafil and tadalafil may also be used for RV failure and pulmonary hypertension.[16]

Renal Failure

Renal insufficiency is common in end-stage heart failure. After MCS implantation, 67% of patients have been reported to experience improved renal function.[17] Hemodialysis is complicated yet occasionally possible with special consideration of hemodynamics, anticoagulation, and volume assessment. Continuous veno-venous hemodialysis and inpatient intermittent hemodialysis are relatively common in the early postoperative recovery period. Similar outcomes in bridge-to-transplantation patients with a left VAD requiring hemodialysis and those not needing renal replacement therapy have been reported.[18] The availability of outpatient hemodialysis centers with the capacity of offering outpatient therapy is essential for the patient with MCS to achieve hospital discharge after surgery, and renal failure requiring dialysis is often an impediment to hospital discharge. Successful peritoneal dialysis is reported but at this time is not routine practice.[19]

Diabetes Mellitus

Close serum glucose control is essential to reduce postoperative infection and progressive diabetes mellitus-related end-organ dysfunction. Insulin requirements may change significantly when the patient develops increased functional capacity, appetite, and nutrient absorption. Poor glucose control influences a patient's transplantation candidacy.[20]

Table 3. Normal Parameters

	RPM	Power, W	Flow, L/min	Pulsatility
HeartMate II	8000–10 000	5.0–8.0	4.0–7.0	5.0–8.0
HeartWare Ventricular Assist Device	2400–3200	3.0–7.0	3.5–7.0	

RPM indicates revolutions per minute.

Circulation. 2017;135:e1145–e1158. DOI: 10.1161/CIR.0000000000000507

Psychosocial, Behavioral, and Cognitive Problems

Patients may be evaluated for MCS implantation as an outpatient or while hospitalized. Evaluation includes a rigorous clinical and psychosocial/behavioral assessment. Patients also learn more about their diagnosis and prognosis, MCS risks (eg, adverse events) and benefits (eg, lengthening life and improving quality of life), and reasonable alternatives and their associated risks and benefits. Patients, in turn, share their preferences for care, goals in life, and what they hope to gain from MCS therapy with their families and clinicians. The intention of informed consent is to document shared decision making.

Debilitating psychiatric morbidity may be a contraindication to MCS. Patients with psychosocial, behavioral, cognitive, or other mental disorders who undergo MCS implantation may require referral for psychiatric medication management, counseling, or cognitive behavioral therapy.[21]

Whether patients with MCS have psychosocial or behavioral comorbidities, they experience psychosocial challenges related to MCS self-care and returning home.[7] Modifications to activities of daily living are required. Patients and caregivers can experience significant stress.[22,23] Early after implantation, patients are often grateful for the device, but they may experience anxiety related to learning and implementing self-care and adapting to lifestyle changes after discharge.[5] Over time, patients and caregivers gain confidence in their ability to perform MCS self-care and to incorporate lifestyle modifications into daily living.[5] However, frustration and depression may occur, related to discomfort with carrying equipment, body image issues, loss of independence, and symptoms (eg, ongoing right-sided heart failure or new MCS-related symptoms). Caregivers may also feel burdened by the time and effort needed to assist patients with MCS with device-related care on a daily basis. A multidisciplinary plan involving medical and psychosocial care, including psychopharmacology and counseling, may contribute to positive outcomes for both patients and caregivers.

Cardiac-related cognitive dysfunction often resolves after MCS, which may significantly improve the quality of life for the patient and family. In elderly destination therapy patients, dementia can become an issue, and follow-up cognitive assessment and treatment may be needed.[24] If post-MCS cognitive dysfunction increases, patients may be at risk for dementia-related adverse events and poor outcomes, and caregivers may incur significant personal and financial burden (eg, placement of the elderly patient with MCS in a memory care unit).[25]

MANAGEMENT OF CHRONIC COMPLICATIONS

RV Failure

During the investigation of decompensated MCS, RV failure must be in the differential because it remains the Achilles heel of LV mechanical support. The relationships of LV and RV geometry and LV-to-RV transit are important concepts in the MCS physiological system. RV failure may follow a variety of physiological conditions.

First, elevated preload from volume overload or blood resuscitation, for example, increases wall stress and can lead to RV dilation and functional tricuspid regurgitation. Second, high device speeds can lead to high CO, which may cause increased venous return to the failing RV. Third, an underfilled LV may allow shifting or suction of the interventricular septum. In this case, the loss of septal contribution to RV contractility can lead to RV failure. Finally, increased RV afterload attributable to pulmonary hypertension and elevated transpulmonary gradient is a common cause of RV failure.[25a]

Progressive RV failure is associated with tricuspid regurgitation, hepatic congestion, and peripheral edema. Transthoracic echocardiography may demonstrate RV dilation, hypocontractility, and septal shifting toward the LV. Inotropes to support RV function, pulmonary vasodilators to decrease transpulmonary gradient, or diuresis can be used in the short term to help the impaired and failing RV. If increased LV filling pressures are suspected (findings of hypertension or pulmonary edema), afterload reduction may improve RV function by augmenting forward flow. Phosphodiesterase type 5 inhibitors can be used in this setting to reduce pulmonary hypertension and to support the RV.[26] In general, consultation with an MCS center is crucial in the assessment and treatment of RV failure in the patient with MCS.

Aortic Insufficiency

Aortic insufficiency is known to complicate ≈25% of patients with nonpulsatile MCS.[27,28] The understanding of aortic insufficiency after MCS is evolving; however, continuous closure of the aortic valve is thought to be a central factor. Careful attention to outflow cannula orientation to prevent direct flow toward the aortic valve can minimize stress on the valve. For patients requiring long duration of support, aortic insufficiency may become a serious morbidity. Management of hypertension and intravascular volume optimization is important. If aortic insufficiency persists when these factors are controlled, further evaluation by the MCS center is necessary.

Bleeding

With continuous-flow devices, bleeding complications appear to be associated with additional factors beyond the level of anticoagulation.[29–31] Factors contributing to bleeding include platelet dysfunction,[32] acquired von Willebrand syndrome,[33] and gastrointestinal bleeding related to arteriovenous malformations.[30] Events most commonly seen are gastrointestinal bleeds and epistaxis.

Anemia

Anemia, regardless of the cause, is associated with significant morbidity and mortality in patients with MCS.[34] Transfusion of red blood cells can be detrimental for the bridge-to-transplantation patient, increasing anti-HLA antibodies and complicating eventual donor matching. Transfusion should be targeted to symptomatic patients only. Iron replacement can be done safely when indicated. Caution is suggested with the use of erythropoietin-stimulating agents because of their potential to promote thrombosis.

Hemolysis

A baseline level of hemolysis occurs in patients with MCS and may be monitored by periodic laboratory studies (eg, urinalysis, plasma free hemoglobin, haptoglobin, and lactate dehydrogenase analysis).[35] Baseline and serial measurements are helpful after changes in clinical status when obstruction or thrombosis is considered. Elevation of lactate dehydrogenase above the patient's baseline or 2.5 times the upper level of normal requires evaluation at an MCS center.[36]

Pump Thrombosis

Thrombosis is a relatively frequent adverse event,[37] with a reported incidence of 5.5% to 12.2% in patients with MCS.[38–40] Thrombosis is associated with significant morbidity because device exchange is typically necessary. INTERMACS data indicate that 2-year survival after pump exchange or no history of thrombus is 56% and 69%, respectively.[39] Factors that may contribute to thrombus formation are subtherapeutic anticoagulation, low pump speed, and elevated blood pressure.[40] Elevation of lactate dehydrogenase can occur up to 3 months before clinically significant pump thrombosis. It is helpful to obtain a lactate dehydrogenase level during the evaluation of patient with MCS.[38] When thrombus is suspected, management should always be coordinated with the MCS center.

Neurological Events

Stroke is a relatively frequent adverse event of MCS. Among all devices, an incidence of 11% is observed at 1 year and of 17% at 2 years.[3] Risk factors for stroke in patients on left VAD support remain poorly defined. Because hypertension is a known major risk factor for ischemic and hemorrhagic stroke, postimplantation hypertension should be avoided (Table 4).

Table 4. Stroke in Patients With a VAD

Evaluation of Stroke	
Assessment	**Purpose**
PT/PTT, INR	Guide management of anticoagulation
Head CT scan	Assess severity and type of stroke (hemorrhagic vs ischemic)
Doppler blood pressure	Manage hypertension
CTA of the neck and/or carotid Doppler (if not completed before LVAD insertion)	Assess for alternative causes of stroke
CT of the chest and CXR	Assess device positioning (look for kinking of cannula or device obstruction)
Neurology and/or neurosurgical consultation	Make recommendations for stroke management (BP guidelines, surgical intervention if hemorrhagic, etc)

BP indicates blood pressure; CT, computed tomography; CTA, computed tomography angiography; CXR, chest x-ray; INR, international normalized ratio; LVAD, left ventricular assist device; PT, prothrombin time; PTT, partial thromboplastin time; and VAD, ventricular assist device.

Arrhythmia and Heart Rhythm Management

Ventricular Arrhythmias

Ventricular arrhythmias occur in up to one third of patients with MCS.[41,42] Although ventricular arrhythmias are generally well tolerated, prolonged ventricular tachycardia can contribute to low flow and ultimately end-organ dysfunction with increased mortality.[41] The majority of patients with MCS have ICDs at the time of implantation, and appropriate ICD intervention occurs in up to 34% of supported patients.[43,44] In this population, arrhythmias may be precipitated by ventricular collapse related to "suction events." After ICD discharge, assessment for a correctable problem (eg, hypovolemia, excess pump speed, electrolyte abnormality) can reduce the risk of recurrent shocks. Antiarrhythmic agents may be useful in decreasing arrhythmias and subsequent ICD firings, which have a significant impact on quality of life.[45] Catheter ablation of unstable ventricular tachycardia has been successfully performed in patients on MCS.[46]

Device Interrogation

Device (ICD and cardiac resynchronization therapy) function should be assessed postoperatively because displacement of the generator and leads during the surgery has been described.[47,48] Electromagnetic interference is reported with some ICDs and implantable pacemakers, and telemetry function may be lost; however, the device continues to function normally.[48] Most defibrillators and pacemakers do not interact and are safe to use after MCS. It is generally recommended that patients who have incompatible devices undergo implantation with an alternative compatible device.[8,44] Successful ICD programming with an incompatible device has been described by shielding the ICD programmer or extension cable with aluminum or steel and by using a programming wand during interrogation.[49] Because of the risk of ventricular arrhythmias after MCS therapy and the unique circumstances of the patient on MCS, multidisciplinary management including electrophysiology is important.

Circulation. 2017;135:e1145–e1158. DOI: 10.1161/CIR.0000000000000507

Infection

Infection remains one of the most common causes of morbidity and mortality during VAD support. Currently, the incidence of device infection is roughly 30% at 3 years.[3] The percutaneous lead exit site through the skin poses risk for infection; trauma is the leading cause because a break in the healing seal formed at the driveline exit site provides a portal for infection. Patients and their families are trained in the immobilization of the percutaneous lead, meticulous exit-site care, and the prevention of pulling or dropping the external device components to minimize device infections.[8,50] Abdominal binders, additional gauze and tape, stoma-adhesive transparent dressings,[8] and other securing devices are essential to reduce traction and infection of the driveline exit site. Exit-site dressing protocol and frequency vary from center to center.

EMERGENCY PATIENT ASSESSMENT

When a patients on MCS is unstable, the MCS center should be contacted immediately. Patients are issued center contact information and basic emergency protocols to assist first responders in rapid assessment and stabilization. Because family caregivers are knowledgeable about device function and emergency protocols, they should assist in emergency management until communication is established with the MCS center. The initial survey of an unstable patient should ignore the presence of MCS and begin with consideration of conditions such as arrhythmias, infection, or hypovolemia (Table 5).[2] In addition, bleeding or thromboembolic complications need to be considered because patients with MCS are typically on anticoagulation.

Initial Assessment

Despite fixed revolutions per minute, the nature of the blood flow may be pulsatile or nonpulsatile, depending on the contractile reserve of the heart. Individual patients have a variable contribution to CO from the native heart and the device. This may change as a natural response to dynamic physiological conditions such as heart rate, circulatory volume, or vasodilation. If the device provides the majority of the CO, the aortic valve may open intermittently or not at all. No aortic valve opening is seen with severe LV dysfunction or high pump speed. In this circumstance, the arterial pulse pressure will be low, and the patient may not have a palpable pulse. Alternatively, with substantial native heart function or lower pump speeds, LV ejection will occur through the aortic valve. In this scenario, regular aortic valve opening and higher arterial pulse pressures are seen.

Table 5. Recommended Diagnostics for Assessment of Patients on Mechanical Circulatory Support

Chemistries
CBC
Urine analysis
LDH
PT/INR
ECG
Chest x-ray
Consider pacemaker interrogation

CBC indicated complete blood count; INR, international normalized ratio; LDH, lactate dehydrogenase; and PT, prothrombin time.

A unique approach is necessary when a clinical assessment is performed. Because patients may not have a palpable pulse, standard assessment of vital signs such as blood pressure, heart rate, and pulse oximetry may be unreliable. Initially, an attempt should be made to measure the blood pressure with an automated sphygmomanometer. This will be possible ≈50% of the time[51] because Korotkoff sounds may not be detectable because of low pulse pressure. Manual assessment with a Doppler ultrasound sphygmomanometer may be necessary to determine the pressure at which brachial artery blood flow resumes. Using Doppler requires special expertise and produces a single measurement that may represent the systolic blood pressure or mean arterial pressure (in situations when the pulse pressure is low). Current guidelines recommend maintenance of a mean systemic BP of <80 mm Hg (Class IIb, Level of Evidence C).[52] For more acutely ill patients, telemetry and invasive hemodynamic monitoring with an arterial line or pulmonary artery catheter may be necessary.[11] Patients with MCS who have any acute illness will respond physiologically to maintain adequate perfusion, similar to patients not on MCS. A knowledgeable clinician in consultation with the implanting center can safely stabilize patients.

Confirm Power

Power is delivered through 2 power sources (batteries or alternating-current power source) at all times via the controller to a percutaneous lead that exits the abdominal wall. Damage to this percutaneous lead can compromise the power supply, and this situation can be rectified only by a percutaneous lead repair or pump exchange, which requires transfer to a MCS center. When only one of the power cables is disconnected from the controller, the pump will function properly, but an alarm will sound to request a second power source. If both power supplies are disconnected at the same time, the pump will stop until at least one power source is restored. If there is concern for power failure, all connections should be checked and the power confirmed. If battery power is low, either the batteries should be replaced or the configuration should be changed to alternating-current power. When the power source is confirmed but there is no pump function (by

auscultation or persistent red heart alarm), the controller should be exchanged for the backup controller. Should a controller exchange be required, the caregiver or the patient if conscious may be able to perform this exchange because they have received training. A website has field guides that provide useful information for troubleshooting problems with currently available devices.[4]

Pump Stoppage

Cessation of pump function is rare with continuous-flow MCS devices because of improved mechanical reliability and long-term durability compared with earlier-generation pulsatile MCS.[1,2,53] Power failure is the most common cause of pump stoppage. Pump stoppage can result in stagnant blood flow and possible thrombus formation. Inadequate circulation may lead to altered mental status, cyanosis, and signs of heart failure. Restarting the pump after prolonged stoppage can result in stroke or other systemic thromboembolic complications. In the setting of pump failure, it is imperative that care be managed in collaboration with the MCS center. Patients who are comfortable, awake, oriented, and without evidence of heart failure are unlikely to have a severe device malfunction or pump stoppage. To confirm that the device is running, a stethoscope can be placed over the pump in the left upper abdomen, and a constant mechanical hum will be audible. Because under normal operation the patient may not have a peripheral pulse, sufficient arterial flow may need to be confirmed by clinical examination or Doppler. If the device alarm is not sounding, the problem is not likely to be device malfunction. Cardiogenic shock may be a consequence of pump stoppage and should be evaluated for and treated the same as shock in a patients not on MCS.

Transport

Patients with evidence of controller or pump malfunction require immediate evaluation at the nearest center with MCS experience; however, the unstable patient with MCS should be transported to the nearest hospital for stabilization. During transport, care must be taken to avoid excessive tension on the percutaneous lead, which can result in device malfunction or exit-site trauma. Furthermore, care should be used to avoid kinking or cutting the percutaneous lead if clothing needs to be removed. Peripheral equipment (backup batteries, backup controller, universal battery charger, and alternating-current power charger) should be transported with the patient.

Alarm Assessment

There are 2 levels of alarms: advisory and critical (Table 6). Critical alarms are constant, are associated with red warning lights, and can be silenced for only short periods. All critical alarms require immediate

Table 6. Causes of VAD Alarms

Potential Causes	Advisory (Noncritical)	Critical
Power	Power source disconnect Low battery power System controller internal battery depleted	Driveline disconnect Depleted batteries Power module disconnect (if not connected to batteries)
Hardware	System controller dysfunction Lead fracture	Pump stoppage (failure) System controller malfunction
Low flow	Low flow and/or suction event Speed too high or low Hypovolemia RV dysfunction Tamponade Inflow cannula obstruction Hypertension Inflow/outflow obstruction Arrhythmia	Extremely low flow Speed too high or low Hypovolemia RV dysfunction Tamponade Inflow cannula obstruction Hypertension Inflow/outflow obstruction Arrhythmia RV dysfunction
High power	Increased power Thrombus Hypertension Electric fault	
Evaluation	Call primary LVAD team Assess urgently within 24 h Auscultate over the device Doppler blood pressure PT/PTT, INR LDH ECG CT/CXR to assess cannula/device positioning Inspect power cable connections	Call primary LVAD team Immediate evaluation Auscultate over the device Doppler blood pressure PT/PTT, INR LDH ECG Inspect driveline and power cable connections (broken pins) Pulmonary artery catheterization
Management options	Replace batteries or connect to power module Intravenous fluids Inotropes Exchange system controller Hypertension control Anticoagulation/ thrombolysis	Replace batteries or connect to power module Exchange system controller ACLS (when appropriate) Treat for cardiogenic shock

ACLS indicates advanced cardiac life support; CT, computed tomography; CXR, chest x-ray; INR, international normalized ratio; LDH, lactate dehydrogenase; LVAD, left ventricular assist device; PT, prothrombin time; PTT, partial thromboplastin time; RV, right ventricular; and VAD, ventricular assist device.

Circulation. 2017;135:e1145–e1158. DOI: 10.1161/CIR.0000000000000507

assessment and action because they indicate an impending loss of hemodynamic support.[54,55] The first response to a critical alarm is to identify adequate power supply and intact cable connections. If the alarm persists, exchange of the controller to the backup controller should be considered according to MCS center recommendations.

Advisory alarms are intermittent audible alarms that are associated with yellow warning lights.[54,55] They can be silenced for prolonged periods and indicate a minor problem with the patient or the device. Although they require immediate attention, advisory alarms can be addressed in a nonemergent fashion because events that trigger advisory alarms have little effect on hemodynamics and are unlikely to be associated with clinical deterioration. The asymptomatic patient who does not have a change in pump parameters can have device function evaluated at the next routine appointment if cleared by the MCS implanting center. Frequently, advisory alarms can be assessed by telephone without the need for transport to the implanting center or local hospital emergency department. The most common advisory alarm occurs with either a disconnected power cable or low battery life. An advisory alarm accompanied by clinical symptoms or changes in pump parameters should be treated as a critical alarm.

Approach to Advanced Cardiac Life Support

Because of the mechanical circulatory circuit, patients with MCS may remain hemodynamically stable even during malignant ventricular arrhythmias. Standard chest compressions as part of resuscitation efforts must be reserved as a last resort because they can lead to MCS cannula dislodgement or cardiac injury.

If the pump is running normally, the unconscious patient may have adequate circulation despite arrhythmia or pulselessness. Confirmation of circulation should be assessed by Doppler assessment of mean arterial pressure immediately. Standard cardiac life support procedures should be initiated with adaptations based on the presence of artificial circulation.[54,55] When indicated per advanced cardiac life support protocols, pacing, defibrillation, and pharmacological interventions, including fluid resuscitation, should be performed before external chest compressions. Positioning of defibrillation pads directly over the implanted pump should be avoided.[9] Patients with continuous-flow MCS should not be disconnected from their power source before defibrillation. If perfusion is absent or inadequate, external chest compressions may be warranted.

END-OF-LIFE DECISION MAKING

Palliative Care and Hospice

Whether patients with advanced heart failure choose medical management or MCS implantation, referral to palliative care is an important "actionable" step at the time of informed consent. Referral to palliative care should be viewed as an adjunctive service, not as an alternative service, especially for patients considering destination therapy. Not to be confused with hospice or withdrawal of care, the focus of palliative care is to improve quality of life through the prevention and relief of suffering.[56] Involvement of palliative care services in the multidisciplinary team leads to increased patient satisfaction with the quality of care.[57] During the patient selection process, the palliative care team can mobilize important services such as symptom management and psychological or spiritual support.

Because of the unique circumstances that occur at the end of life in patients with MCS, specific advance directives should be completed before device implantation, with emphasis on what the patient would desire in the case of serious complication.[58–60] Over the course of treatment after MCS, the palliative care team is valuable to support patients and caregivers, especially if a catastrophic complication occurs after implantation (eg, debilitating stroke or overwhelming infection).[61,62] After a serious adverse event or in the setting of profoundly impaired quality of life, the palliative care team can recommend hospice.

Withdrawal of Long-Term MCS

MCS is life-sustaining therapy, and elective withdrawal of support may be appropriate when quality of life is no longer improved and continued support would in effect prolong suffering.[62,63] In this scenario, withdrawal of life support, allowing patients to simply succumb to their underlying condition, is morally, legally, and ethically acceptable on the basis of a determination of benefits and burdens of the treatment.[58,62,64] Patients with MCS may request that the device be turned off, and physicians are obliged to respect a competent patient's (or surrogate decision maker's) request. A comprehensive end-of-life plan of care focused on the conditions that a patient would expect might lead to withdrawal of life-sustaining therapy should be defined before implantation[65] and should be revisited over the course of patient care.[60,62] The device can be deactivated in the hospital or at home, according to patient preference. Patient comfort is a high priority. Administration of anesthetics, analgesics, and anxiolytics at appropriate doses can relieve symptoms and reduce suffering. A successful approach is to include team members who are capable of deactivating the device and alarms and providing comfort care to the patient and psychological support to the family and care team.[62,66]

COMMUNITY OF CARE PROVIDERS

From the time of referral for advanced heart failure therapy to the initiation of formal evaluation to the patient's

return to the comforts of home, a community of providers is necessary. In this unique patient population, specialized implantation centers must coordinate care with local first responders (emergency medical technicians, police, and fire department personnel), emergency department staff, and primary care and referring cardiologists. As these patients return to a robust lifestyle, they also return to work and school, as well as travel on public transportation, cruise ships, and commercial airlines. A coordinated effort allows competent and supportive care to a group of patients for whom both quality of life and longevity are highly valued.

CLINICAL SUMMARY

Patient Evaluation

1. The primary MCS team should be contacted for any patient-related emergencies.
2. In non–life-threatening situations, care providers inexperienced with the management of MCS should defer device management to patients and their family caregivers until contact can be established with the MCS center or device company technical support.
3. Whenever possible, emergency medical service providers who will be transporting a patients on MCS should also transport the patient's backup and peripheral equipment.
4. A Doppler probe and a manual cuff can be used to obtain blood pressure in a patient supported by continuous-flow MCS because the automated measurement of heart rate, pulse oximetry, and blood pressure may be unreliable in this setting.
5. Once pump function is established, assessment of the unstable patient on MCS should begin with a general evaluation of the patient for the inciting condition (eg, arrhythmia, hypovolemic or distributive shock, and acute blood loss).
6. Outpatients who present with MCS device stoppage should not have the device restarted without the guidance of the primary MCS center.

Pump Evaluation

1. Device parameters such as power, speed, flow, and pulsatility should be recorded throughout the patient's course.
2. If battery power is low, either the batteries should be replaced or the configuration should be changed to wall power.
3. When power source is confirmed but there is a persistent device alarm, the controller should be exchanged for the backup controller.
4. If thrombus is suspected, assessment for hemolysis, including lactate dehydrogenase, is recommended.

Chronic Medical Management

1. The percutaneous lead should be secured to reduce traction and infection because driveline trauma is the primary cause of driveline infections.
2. A strict aseptic protocol should be followed when dressing is changed.
3. Patients should receive physical and occupational therapy while hospitalized and referral for cardiac rehabilitation at hospital discharge.
4. Treatment with evidence-based heart failure medical therapies could be beneficial in patients on MCS.
5. Evidence-based management of comorbid conditions (eg, hypertension, hyperlipidemia, and diabetes mellitus) is recommended.

Well-Being and End of Life

1. If psychiatric disability is present after MCS, referral to mental health providers for care, including medication management, counseling, or cognitive behavioral therapy, is recommended.
2. Palliative care involvement is indicated during MCS evaluation and for patients with MCS, especially when receiving destination therapy.
3. When the prognosis is poor for patients with MCS and their suffering and burden outweigh the benefits, deactivation of the MCS device should be discussed with the patient and family caregivers.

FOOTNOTES

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on November 10, 2016, and the American Heart Association Executive Committee on January 10, 2017. A copy of the document is available at http://professional.heart.org/statements by using either "Search for Guidelines & Statements" or the "Browse by Topic" area. To purchase additional reprints, call 843-216-2533 or e-mail kelle.ramsay@wolterskluwer.com.

The American Heart Association requests that this document be cited as follows: Cook JL, Colvin M, Francis GS, Grady KL, Hoffman TM, Jessup M, John R, Kiernan MS, Mitchell JE, Pagani FD, Petty M, Ravichandran P, Rogers JG, Semigran MJ, Toole JM; on behalf of the American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Cardiovascular Radiology and Intervention; and Council on Cardiovascular Surgery and Anesthesia. Recommendations for the use of mechanical circulatory support: ambulatory and

community patient care: a scientific statement from the American Heart Association. *Circulation.* 2017;135:e1145–e1158. doi: 10.1161/CIR.0000000000000507.

Expert peer review of AHA Scientific Statements is conducted by the AHA Office of Science Operations. For more on AHA statements and guidelines development, visit http://professional.heart.org/statements. Select the "Guidelines & Statements" drop-down menu, then click "Publication Development."

Circulation is available at http://circ.ahajournals.org.

DISCLOSURES

Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
Jennifer L. Cook	Banner University Medical Center Sarver Heart Center	None	None	None	None	None	None	None
Monica Colvin	University of Michigan	Care Dx*	None	None	None	None	None	None
Gary S. Francis	University of Minnesota	None	None	None	None	None	Amgen*; Novartis*; Merck*; Capricor*	None
Kathleen L. Grady	Northwestern University Cardiac Surgery	NIH (NIA, NHLBI, and NINR)†	None	None	Representing defense of an academic medical center in case on heart transplantation†	None	None	None
Timothy M. Hoffman	University of North Carolina Children's Hospital	None	None	None	None	None	None	None
Mariell Jessup	Leducq Corp	None	None	None	None	None	None	None
Ranjit John	University of Minnesota	HeartWare*; St. Jude*	None	None	None	None	St. Jude*	None
Michael S. Kiernan	Tufts Medical Center	None	None	None	Defense*	None	HeartWare, Inc*; Thoratec Corp*	None
Judith E. Mitchell	SUNY Downstate Medical Center	None	None	None	None	None	None	None
Francis D. Pagani	University of Michigan	None	None	None	None	None	None	None
Michael Petty	University of Minnesota Health Nursing	None	None	None	None	None	Thoratec Corp*; HeartWare Inc*	None
Pasala Ravichandran	Legacy Emanuel Medical Center	None	None	None	None	None	None	None
Joseph G. Rogers	Duke University	HeartWare*	None	None	None	None	None	None
Marc J. Semigran	MyoKardia, Inc	None	None	None	None	None	None	None
J. Matthew Toole	Roper Hospital Cardiothoracic Surgery	None	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
Bernice L. Coleman	Cedars Sinai Medical Center	None	None	None	None	None	None	None
Sudhir S. Kushwaha	Mayo Clinic	None	None	None	None	None	None	None
Randall C. Starling	Cleveland Clinic	Thoratec*; HeartWare (coinvestigator-sponsored research, co-PI clinical trial)*	None	None	None		Thoratec*; HeartWare*	

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

REFERENCES

1. Slaughter MS, Rogers JG, Milano CA, Russell SD, Conte JV, Feldman D, Sun B, Tatooles AJ, Delgado RM 3rd, Long JW, Wozniak TC, Ghumman W, Farrar DJ, Frazier OH; HeartMate II Investigators. Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med*. 2009;361:2241–2251. doi: 10.1056/NEJMoa0909938.
2. Pagani FD, Miller LW, Russell SD, Aaronson KD, John R, Boyle AJ, Conte JV, Bogaev RC, MacGillivray TE, Naka Y, Mancini D, Massey HT, Chen L, Klodell CT, Aranda JM, Moazami N, Ewald GA, Farrar DJ, Frazier OH; HeartMate II Investigators. Extended mechanical circulatory support with a continuous-flow rotary left ventricular assist device. *J Am Coll Cardiol*. 2009;54:312–321. doi: 10.1016/j.jacc.2009.03.055.
3. Kirklin JK, Naftel DC, Pagani FD, Kormos RL, Stevenson LW, Blume ED, Myers SL, Miller MA, Baldwin JT, Young JB. Seventh INTERMACS annual report: 15,000 patients and counting. *J Heart Lung Transplant*. 2015;34:1495–504. doi: 10.1016/j.healun.2015.10.003.
4. My LVAD website. https://www.mylvad.com/medical-professionals/ems. Accessed May 11, 2017..
5. Grady KL, Magasi S, Hahn EA, Buono S, McGee EC Jr, Yancy C. Health-related quality of life in mechanical circulatory support: development of a new conceptual model and items for self-administration. *J Heart Lung Transplant*. 2015;34:1292–1304. doi: 10.1016/j.healun.2015.04.003.
6. Slaughter MS. Long-term continuous flow left ventricular assist device support and end-organ function: prospects for destination therapy. *J Card Surg*. 2010;25:490–494. doi: 10.1111/j.1540-8191.2010.01075.x.
7. Casida JM, Marcuccilli L, Peters RM, Wright S. Lifestyle adjustments of adults with long-term implantable left ventricular assist devices: a phenomenologic inquiry. *Heart Lung*. 2011;40:511–520. doi: 10.1016/j.hrtlng.2011.05.002.
8. Wilson SR, Givertz MM, Stewart GC, Mudge GH Jr. Ventricular assist devices the challenges of outpatient management. *J Am Coll Cardiol*. 2009;54:1647–1659. doi: 10.1016/j.jacc.2009.06.035.
9. *HeartMate II Left Ventricular Assist System Community Living Manual*. Minneapolis, MN: St. Jude Medical; 2009.
10. Reilly MP, Wiegers SE, Cucchiara AJ, O'Hara ML, Plappert TJ, Loh E, Acker MA, St John Sutton M. Frequency, risk factors, and clinical outcomes of left ventricular assist device-associated ventricular thrombus. *Am J Cardiol*. 2000;86:1156–1159, A10.
11. Slaughter MS, Pagani FD, Rogers JG, Miller LW, Sun B, Russell SD, Starling RC, Chen L, Boyle AJ, Chillcott S, Adamson RM, Blood MS, Camacho MT, Idrissi KA, Petty M, Sobieski M, Wright S, Myers TJ, Farrar DJ; HeartMate II Clinical Investigators. Clinical management of continuous-flow left ventricular assist devices in advanced heart failure. *J Heart Lung Transplant*. 2010;29(suppl):S1–39. doi: 10.1016/j.healun.2010.01.011.
12. Koster A, Loebe M, Sodian R, Potapov EV, Hansen R, Müller J, Mertzlufft F, Crystal GJ, Kuppe H, Hetzer R. Heparin antibodies and thromboembolism in heparin-coated and noncoated ventricular assist devices. *J Thorac Cardiovasc Surg*. 2001;121:331–335. doi: 10.1067/mtc.2001.111655.
13. Matsubayashi H, Fastenau DR, McIntyre JA. Changes in platelet activation associated with left ventricular assist system placement. *J Heart Lung Transplant*. 2000;19:462–468.
14. Mountis MM, Starling RC. Management of left ventricular assist devices after surgery: bridge, destination, and recovery. *Curr Opin Cardiol*. 2009;24:252–256. doi: 10.1097/HCO.0b013e32832c7c09.
15. Myers TJ, Bolmers M, Gregoric ID, Kar B, Frazier OH. Assessment of arterial blood pressure during support with an axial flow left ventricular assist device. *J Heart Lung Transplant*. 2009;28:423–427. doi: 10.1016/j.healun.2009.01.013.
16. Jennings DL, Jones MC, Lanfear DE. Assessment of the heart failure pharmacotherapy of patients with continuous flow left-ventricular assist devices. *Int J Artif Organs*. 2012;35:177–179. doi: 10.5301/ijao.5000068.
17. Hasin T, Topilsky Y, Schirger JA, Li Z, Zhao Y, Boilson BA, Clavell AL, Rodeheffer RJ, Frantz RP, Edwards BS, Pereira NL, Joyce L, Daly R, Park SJ, Kushwaha SS. Changes in renal function after implantation of continuous-flow left ventricular assist devices. *J Am Coll Cardiol*. 2012;59:26–36. doi: 10.1016/j.jacc.2011.09.038.
18. Levin A, Garan RA, Topkarar VK, Takdea K, Takayama H, Mancini DM, Naka Y, Colombo PC, Yuzefpolskaya M. Favorable outcomes in dialysis dependent patients on LVAD BTT support. *J Heart Lung Transplant*. 2015;35:S68–S69. doi: http://dx.doi.org/10.1016/j.healun.2015.01.175.
19. Guglielmi AA, Guglielmi KE, Bhat G, Siemeck R, Tatooles AJ. Peritoneal dialysis after left ventricular assist device placement. *ASAIO J*. 2014;60:127–128. doi: 10.1097/MAT.0000000000000020.
20. Mehra MR, Kobashigawa J, Starling R, Russell S, Uber PA, Parameshwar J, Mohacsi P, Augustine S, Aaronson K, Barr M. Listing criteria for heart transplantation: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates–2006. *J Heart Lung Transplant*. 2006;25:1024–1042.

21. Tylus-Earl N, Chillcott S. Mental health and medical challenges. Management of a depressed patient with a left ventricular assist system in an inpatient psychiatric setting. *J Psychosoc Nurs Ment Health Serv*. 2009;47:43–49; quiz 51. doi: 10.3928/02793695-20090902-02.
22. Usher BM, Cammarata K. Heart failure and family caregiver burden: an update. *Prog Cardiovasc Nurs*. 2009;24:113–114. doi: 10.1111/j.1751-7117.2009.00046.x.
23. Hooley PJ, Butler G, Howlett JG. The relationship of quality of life, depression, and caregiver burden in outpatients with congestive heart failure. *Congest Heart Fail*. 2005;11:303–310.
24. Petrucci RJ, Rogers JG, Blue L, Gallagher C, Russell SD, Dordunoo D, Jaski BE, Chillcott S, Sun B, Yanssens TL, Tatooles A, Koundakjian L, Farrar DJ, Slaughter MS. Neurocognitive function in destination therapy patients receiving continuous-flow vs pulsatile-flow left ventricular assist device support. *J Heart Lung Transplant*. 2012;31:27–36. doi: 10.1016/j.healun.2011.10.012.
25. Vitale CA, Chandekar R, Rodgers PE, Pagani FD, Malani PN. A call for guidance in the use of left ventricular assist devices in older adults. *J Am Geriatr Soc*. 2012;60:145–150. doi: 10.1111/j.1532-5415.2011.03740.x.

25a. Kormos RL, Teuteberg JJ, Pagani FD, Russell SD, John R, Miller LM, Massey T, Milano CA, Moazami N, Sundareswaran KS, Farrar DJ, for the HeartMate II Clinical Investigators. Right ventricular failure in patients with the HeartMate II continuous-flow left ventricular assist device: incidence, risk factors, and effect on outcomes. *J Thorac Cardiovasc Surg*. 2010;139:1316–1324. doi: 10.1016/j.jtcvs.2009.11.020.

26. MacGowan GA, Schueler S. Right heart failure after left ventricular assist device implantation: early and late. *Curr Opin Cardiol*. 2012;27:296–300. doi: 10.1097/HCO.0b013e3283511e60.
27. Pak SW, Uriel N, Takayama H, Cappleman S, Song R, Colombo PC, Charles S, Mancini D, Gillam L, Naka Y, Jorde UP. Prevalence of de novo aortic insufficiency during long-term support with left ventricular assist devices. *J Heart Lung Transplant*. 2010;29:1172–1176. doi: 10.1016/j.healun.2010.05.018.
28. Cowger J, Pagani FD, Haft JW, Romano MA, Aaronson KD, Kolias TJ. The development of aortic insufficiency in left ventricular assist device-supported patients. *Circ Heart Fail*. 2010;3:668–674. doi: 10.1161/CIRCHEARTFAILURE.109.917765.
29. Letsou GV, Shah N, Gregoric ID, Myers TJ, Delgado R, Frazier OH. Gastrointestinal bleeding from arteriovenous malformations in patients supported by the Jarvik 2000 axial-flow left ventricular assist device. *J Heart Lung Transplant*. 2005;24:105–109. doi: 10.1016/j.healun.2003.10.018.
30. Crow S, John R, Boyle A, Shumway S, Liao K, Colvin-Adams M, Toninato C, Missov E, Pritzker M, Martin C, Garry D, Thomas W, Joyce L. Gastrointestinal bleeding rates in recipients of nonpulsatile and pulsatile left ventricular assist devices. *J Thorac Cardiovasc Surg*. 2009;137:208–215. doi: 10.1016/j.jtcvs.2008.07.032.
31. John R, Kamdar F, Liao K, Colvin-Adams M, Miller L, Joyce L, Boyle A. Low thromboembolic risk for patients with the Heartmate II left ventricular assist device. *J Thorac Cardiovasc Surg*. 2008;136:1318–1323. doi: 10.1016/j.jtcvs.2007.12.077.
32. Steinlechner B, Dworschak M, Birkenberg B, Duris M, Zeidler P, Fischer H, Milosevic L, Wieselthaler G, Wolner E, Quehenberger P, Jilma B. Platelet dysfunction in outpatients with left ventricular assist devices. *Ann Thorac Surg*. 2009;87:131–137. doi: 10.1016/j.athoracsur.2008.10.027.
33. Geisen U, Heilmann C, Beyersdorf F, Benk C, Berchtold-Herz M, Schlensak C, Budde U, Zieger B. Non-surgical bleeding in patients with ventricular assist devices could be explained by acquired von Willebrand disease. *Eur J Cardiothorac Surg*. 2008;33:679–684. doi: 10.1016/j.ejcts.2007.12.047.
34. Vrtovec B, Radovancevic R, Delgado RM, Radovancevic B, Bracey AW, Gregoric ID, Frazier OH. Significance of anaemia in patients with advanced heart failure receiving long-term mechanical circulatory support. *Eur J Heart Fail*. 2009;11:1000–1004. doi: 10.1093/eurjhf/hfp110.
35. Slaughter MS. Hematologic effects of continuous flow left ventricular assist devices. *J Cardiovasc Transl Res*. 2010;3:618–624. doi: 10.1007/s12265-010-9222-6.
36. Cowger JA, Romano MA, Shah P, Shah N, Mehta V, Haft JW, Aaronson KD, Pagani FD. Hemolysis: a harbinger of adverse outcome after left ventricular assist device implant. *J Heart Lung Transplant*. 2014;33:35–43. doi: 10.1016/j.healun.2013.08.021.
37. Mehra MR, Stewart GC, Uber PA. The vexing problem of thrombosis in long-term mechanical circulatory support. *J Heart Lung Transplant*. 2014;33:1–11. doi: 10.1016/j.healun.2013.12.002.
38. Starling RC, Moazami N, Silvestry SC, Ewald G, Rogers JG, Milano CA, Rame JE, Acker MA, Blackstone EH, Ehrlinger J, Thuita L, Mountis MM, Soltesz EG, Lytle BW, Smedira NG. Unexpected abrupt increase in left ventricular assist device thrombosis. *N Engl J Med*. 2014;370:33–40. doi: 10.1056/NEJMoa1313385.
39. Kirklin JK, Naftel DC, Kormos RL, Pagani FD, Myers SL, Stevenson LW, Acker MA, Goldstein DL, Silvestry SC, Milano CA, Baldwin JT, Pinney S, Eduardo Rame J, Miller MA. Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) analysis of pump thrombosis in the HeartMate II left ventricular assist device [published correction appears in *J Heart Lung Transplant*. 2015;34:1356]. *J Heart Lung Transplant*. 2014;33:12–22. doi: 10.1016/j.healun.2013.11.001.
40. Najjar SS, Slaughter MS, Pagani FD, Starling RC, McGee EC, Eckman P, Tatooles AJ, Moazami N, Kormos RL, Hathaway DR, Najarian KB, Bhat G, Aaronson KD, Boyce SW; HVAD Bridge to Transplant ADVANCE Trial Investigators. An analysis of pump thrombus events in patients in the HeartWare ADVANCE bridge to transplant and continued access protocol trial. *J Heart Lung Transplant*. 2014;33:23–34. doi: 10.1016/j.healun.2013.12.001.
41. Bedi M, Kormos R, Winowich S, McNamara DM, Mathier MA, Murali S. Ventricular arrhythmias during left ventricular assist device support. *Am J Cardiol*. 2007;99:1151–1153. doi: 10.1016/j.amjcard.2006.11.051.
42. Jessup M, Abraham WT, Casey DE, Feldman AM, Francis GS, Ganiats TG, Konstam MA, Mancini DM, Rahko PS, Silver MA, Stevenson LW, Yancy CW. 2009 Focused update: ACCF/AHA guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2009;119:1977–2016. doi: 10.1161/CIRCULATIONAHA.109.192064.
43. Oswald H, Schultz-Wildelau C, Gardiwal A, Lüsebrink U, König T, Meyer A, Duncker D, Pichlmaier MA, Klein G, Strüber M. Implantable defibrillator therapy for ventricular tachyarrhythmia in left ventricular assist device patients. *Eur J Heart Fail*. 2010;12:593–599. doi: 10.1093/eurjhf/hfq048.
44. Oswald H, Klein G, Strüber M, Gardiwal A. Implantable defibrillator with left ventricular assist device compatibility. *Interact Cardiovasc Thorac Surg*. 2009;8:579–580. doi: 10.1510/icvts.2009.202077.
45. Raasch H, Jensen BC, Chang PP, Mounsey JP, Gehi AK, Chung EH, Sheridan BC, Bowen A, Katz JN. Epidemiology, management, and outcomes of sustained ventricular arrhythmias after continuous-flow left ventricular assist device implantation. *Am Heart J*. 2012;164:373–378. doi: 10.1016/j.ahj.2012.06.018.
46. Lü F, Eckman PM, Liao KK, Apostolidou I, John R, Chen T, Das GS, Francis GS, Lei H, Trohman RG, Benditt DG. Catheter ablation of hemodynamically unstable ventricular tachycardia with mechanical circulatory support. *Int J Cardiol*. 2013;168:3859–3865. doi: 10.1016/j.ijcard.2013.06.035.

47. Bakhtiary F, Therapidis P, Scherer M, Dzemali O, Moritz A, Kleine P. Electromagnetic interaction between an axial left ventricular assist device and an implantable cardioverter defibrillator. *J Thorac Cardiovasc Surg*. 2008;136:1380–1381. doi: 10.1016/j.jtcvs.2008.02.072.
48. Matthews JC, Betley D, Morady F, Pelosi F Jr. Adverse interaction between a left ventricular assist device and an implantable cardioverter defibrillator. *J Cardiovasc Electrophysiol*. 2007;18:1107–1108. doi: 10.1111/j.1540-8167.2007.00805.x.
49. Biviano A, Mancini D, Naka Y, Arellano J, Garan H. Overcoming electromagnetic interference by LVADs on ICD function by shielding the ICD programmer wand and extension cable. *Pacing Clin Electrophysiol*. 2009;32:945–948. doi: 10.1111/j.1540-8159.2009.02419.x.
50. Rogers JG, Aaronson KD, Boyle AJ, Russell SD, Milano CA, Pagani FD, Edwards BS, Park S, John R, Conte JV, Farrar DJ, Slaughter MS; HeartMate II Investigators. Continuous flow left ventricular assist device improves functional capacity and quality of life of advanced heart failure patients. *J Am Coll Cardiol*. 2010;55:1826–1834. doi: 10.1016/j.jacc.2009.12.052.
51. Wasson LT, Yuzefpolskaya M, Wakabayashi M, Takayama H, Naka Y, Uriel N, Jorde UP, Demmer RT, Colombo PC. Hypertension: an unstudied potential risk factor for adverse outcomes during continuous flow ventricular assist device support. *Heart Fail Rev*. 2015;20:317–322. doi: 10.1007/s10741-014-9458-3.
52. Feldman D, Pamboukian SV, Teuteberg JJ, Birks E, Lietz K, Moore SA, Morgan JA, Arabia F, Bauman ME, Buchholz HW, Deng M, Dickstein ML, El-Banayosy A, Elliot T, Goldstein DJ, Grady KL, Jones K, Hryniewicz K, John R, Kaan A, Kusne S, Loebe M, Massicotte MP, Moazami N, Mohacsi P, Mooney M, Nelson T, Pagani F, Perry W, Potapov EV, Eduardo Rame J, Russell SD, Sorensen EN, Sun B, Strueber M, Mangi AA, Petty MG, Rogers J; International Society for Heart and Lung Transplantation. The 2013 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support: executive summary. *J Heart Lung Transplant*. 2013;32:157–187. doi: 10.1016/j.healun.2012.09.013.
53. Pagani FD, Long JW, Dembitsky WP, Joyce LD, Miller LW. Improved mechanical reliability of the HeartMate XVE left ventricular assist system. *Ann Thorac Surg*. 2006;82:1413–1418. doi: 10.1016/j.athoracsur.2006.04.057.
54. *HeartMate II LVAS Clinical Operation & Patient Management*. Pleasanton, CA: Thoratec Corp; 2008.
55. *HeartWare Ventricular Assist System Instructions for Use*. Miami Lakes, FL: HeartWare Inc; 2009.
56. Rizzieri AG, Verheijde JL, Rady MY, McGregor JL. Ethical challenges with the left ventricular assist device as a destination therapy. *Philos Ethics Humanit Med*. 2008;3:20. doi: 10.1186/1747-5341-3-20.
57. Dy SM, Shugarman LR, Lorenz KA, Mularski RA, Lynn J; RAND-Southern California Evidence-Based Practice Center. A systematic review of satisfaction with care at the end of life. *J Am Geriatr Soc*. 2008;56:124–129. doi: 10.1111/j.1532-5415.2007.01507.x.
58. Bramstedt KA, Wenger NS. When withdrawal of life-sustaining care does more than allow death to take its course: the dilemma of left ventricular assist devices. *J Heart Lung Transplant*. 2001;20:544–548.
59. Bramstedt KA. Destination nowhere: a potential dilemma with ventricular assist devices. *ASAIO J*. 2008;54:1–2. doi: 10.1097/MAT.0b013e3181614f18.
60. Dudzinski DM. Ethics guidelines for destination therapy. *Ann Thorac Surg*. 2006;81:1185–1188. doi: 10.1016/j.athoracsur.2005.11.002.
61. Bramstedt KA, Nash PJ. When death is the outcome of informed refusal: dilemma of rejecting ventricular assist device therapy. *J Heart Lung Transplant*. 2005;24:229–230. doi: 10.1016/j.healun.2003.10.022.
62. Wiegand DL, Kalowes PG. Withdrawal of cardiac medications and devices. *AACN Adv Crit Care*. 2007;18:415–425. doi: 10.1097/01.AACN.0000298634.45653.81.
63. Prendergast TJ, Claessens MT, Luce JM. A national survey of end-of-life care for critically ill patients. *Am J Respir Crit Care Med*. 1998;158:1163–1167. doi: 10.1164/ajrccm.158.4.9801108.
64. Swetz KM, Ottenberg AL, Freeman MR, Mueller PS. Palliative care and end-of-life issues in patients treated with left ventricular assist devices as destination therapy. *Curr Heart Fail Rep*. 2011;8:212–218. doi: 10.1007/s11897-011-0060-x.
65. Allen LA, Stevenson LW, Grady KL, Goldstein NE, Matlock DD, Arnold RM, Cook NR, Felker GM, Francis GS, Hauptman PJ, Havranek EP, Krumholz HM, Mancini D, Riegel B, Spertus JA; on behalf of the American Heart Association Council on Quality of Care and Outcomes Research; Council on Cardiovascular Nursing; Council on Clinical Cardiology; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Surgery and Anesthesia. Decision making in advanced heart failure: a scientific statement from the American Heart Association. *Circulation*. 2012;125:1928–1952. doi: 10.1161/CIR.0b013e31824f2173.
66. MacIver J, Ross HJ. Withdrawal of ventricular assist device support. *J Palliat Care*. 2005;21:151–156.