Task Force 5: Outpatient Management of the Mechanical Circulatory Support Device Recipient

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Topic 1: Transitioning the MCSD Patient to the Home or Community Environment

Introduction

The first step in maximizing long-term survival after initial mechanical circulatory support device (MCSD) placement is ensuring a smooth transition from the hospital setting to the home environment. This time of transition can be fraught with fear and anxiety for the MCSD patient and their family. The MCSD program should mobilize a multidisciplinary team to maximize patients' rehabilitation, quality of life, and assimilation into the community while minimizing complications.

Evaluation for Safety of the Home Environment

MCS patients have unique requirements that mandate attention as they transition to home in order to provide an environment that is safe for device operation. A primary consideration is the need for continuous electrical supply. MCSDs are dependent on electricity. Therefore, to prevent unintentional power interruption that may result in pump stoppage, outlets must be grounded, extension cords should not be used to power the external components, and outlets used for the left ventricular assist device (LVAD) and its components should not be controlled by a switch.

The local electric provider should be notified that the customer has a MCSD and is dependent on electricity. Local companies may have online forms available to facilitate notifying the electric provider of the device's need for continuous electric supply. Additionally, the implanting center may need to write a letter to inform the company of the device’s electrical requirements. The notification must include the customer’s account number as a reference. Patients must also develop a plan for
managing their device if unanticipated electrical interruption to their home occurs for an extended period of time, such as during a natural disaster. Options may include staying with relatives who have electricity, going to a local EMS station temporarily, going to a hotel or hospital, or purchasing a generator.

Patients and families should consider the most appropriate placement for device equipment to minimize risk of falls, allow easy access to the bathroom and kitchen, and maximum opportunity to interact with family. Alarms should be easily audible to other household members throughout the home. The environment should be free of clutter and have adequate lighting to prevent falls. The bathroom should be safe for showering with placement of a shower chair. A seat lift should be installed on the toilet if recommended by physical therapy.

Patients must have a working telephone for emergency use and to facilitate communication with the implanting center. Patients should practice paging the on call MCS team when they arrive home to ensure they can reach the team quickly. This test should be done as soon as possible upon arriving home after discharge, so that patients have rehearsed the routine prior to needing to page if an actual emergency occurs. A discharge check list may be developed to facilitate communication regarding the specific home modifications that need to be made and to document progress in meeting these requirements prior to discharge.

**Recommendations for Evaluation of Safety of the Home Environment:**

*Class I:*

1. An uninterrupted supply of electricity to continuously power the MCSD must be ensured. Outlets must be grounded, and the use of electrical extension cords or outlets with a switch should be avoided. The local electrical company must be notified of the customer’s need for electricity to power life sustaining equipment in the home. Patients are advised to develop an emergency plan in the event electricity becomes unavailable in the home.

   **Level of Evidence: C.**
2. Patients should have a working telephone to allow outgoing calls in the event of an emergency and to allow the implanting center to contact the patient. The patient should familiarize themselves with paging the MCS team should an actual emergency arise.

   Level of Evidence: C.

Class IIa:
1. Equipment at home should be placed in a configuration that minimizes the risk of falls, allows easy access to living and sleeping areas, and allows family members to hear alarms. Lighting should be adequate. The bathroom should be safe for showering with a shower chair, toilet seat, or any other necessary physical aids.

   Level of Evidence: C.

2. A discharge check list may be developed to facilitate communication regarding the specific necessary home modifications and to document progress in meeting these requirements prior to discharge.

   Level of Evidence: C.

Community Outreach by MCS Team

The MCS team should notify local EMS responders of the patient’s home address and basic device design (i.e. non-pulsatile flow). A request should be made to make the patients’ home a “location of interest” that will alert EMS providers that a patient has a MCSD. Patients and families are encouraged to visit EMS first responder stations to notify the EMS responders in person of the home address and basic device design.

Quick reference materials (Figure 1) assist EMS providers in identifying patients with MCSDs. The field guides provide step-by-step instructions for maneuvers such as controller changes. The field guides can be given to emergency departments, local hospitals, dialysis centers, long term care facilities, or any location caring for MCSD patients.

The MCS team should notify the local hospital, including the emergency room and referring physician, that MCSD patients will be living in the area and of their unique
medical needs. The MCS team may offer to provide teaching materials, device manuals, or in-services based on the resources the implanting facility can commit to outreach efforts. Field guides could be a tool given to remote hospitals as part of the education package provided by the implanting center.

**Recommendations for Community Outreach by the MCS Team:**

*Class I:*

1. Community outreach should be performed by the implanting center's MCS team to inform the local health care providers including EMS personnel, emergency room staff, and referring physicians of the reintegration of the MCSD patient to his/her local environment. Education should be delivered so providers have knowledge of the concepts involving MCS and the associated physiologic changes.

   **Level of Evidence: C.**

*Class Ila:*

1. Appropriate emergency maneuvers should be reviewed with local health care providers. Consideration may be given to developing a field guide for EMS personnel to aid in emergency responses.

   **Level of Evidence: C.**

**Assessment of Social Network**

The MCS team designee must interview patients and family members regarding the strength and depth of their social support. Usually this interview is performed by a trained social worker or discharge planner. The social worker may involve family, friends, co-workers, and community organization members. The social support members must clearly state the nature of their involvement. They must commit to be trained in the proper daily and emergent management of the device. They must also commit to driving patients to follow up appointments. If it is determined that the social support network is weak or unreliable, the social worker may develop a “social contract” with specific duties that need to be performed in order to formalize the commitment. The social worker, along with other members of the team, must reassess the ability of
family and friends to provide support as caregiver fatigue may cause a disintegration of the discharge plan.

To ensure successful outcome after MCSD placement, the primary designated caregiver(s) should receive adequate training and demonstrate competence with respect to MCSD functions and the appropriate response to alarms. A checklist may be helpful in assessing the ability of the caregiver to perform maneuvers related to the MCSD and troubleshoot emergency situations.

The Joint Commission requires patients and families to give feedback to the implanting center regarding their experience at home after the discharge process has occurred. A survey tool may be useful in evaluating the overall program, staff education, and support. It is recommended that the survey results be presented at a multidisciplinary quality meeting on a regular basis as a stimulus for program improvements.

**Recommendations for Assessment of Social Network:**

*Class I:*

1. The primary designated caregiver should demonstrate competency in functioning of the MCSD and the appropriate response to alarms.
   
   **Level of Evidence: C.**

2. The MCS team designee must interview patients and family members regarding the strength and depth of their social support. The social worker or other MCS staff member may need to develop a formal “social contract” with the patient’s social network and/or caregiver(s) that outlines their commitment and responsibilities to ensure they are prepared to assist patients with device and/or driving needs until the patient is able.

   **Level of Evidence: C.**

3. A survey tool should be developed that allows patients to provide feedback to the MCS program on their preparedness for the transition to the home environment. Survey results should be reviewed by the multidisciplinary MCS team at regular intervals to help facilitate programmatic improvements.

   **Level of Evidence: C.**
Driving a Motor Vehicle

Whether patients are permitted to drive after MCSD implant is a center specific decision, in conjunction with local regulations. Basic criteria should be met if patients are allowed to drive. The patient’s sternum must be stable, which usually requires 6 - 8 weeks of post-operative recovery. Incisional pain must be managed without narcotics. Patients must reliably demonstrate their ability to manage MCSD emergencies independently as dictated by the implanting center. The local jurisdiction paperwork must be completed as required (e.g. department of motor vehicle forms).

Recommendations for Driving a Motor Vehicle:

*Class IIb:*

1. Clearance to drive a motor vehicle is a center specific decision and should be guided by local laws.

   **Level of Evidence:** C.

Topic 2: Follow-up Care

Introduction

After implantation of the MCSD and discharge from the index hospitalization, the clinician is faced with the challenge of caring for the MCSD patient in the outpatient setting. This phase of care may last years, particularly for DT patients. The clinical concerns faced by the patient and clinician may evolve considerably over time, and these changes must be reflected in the type of outpatient follow-up care delivered. For example, in the early post-MCSD implantation period, there may be an emphasis on rehabilitation efforts. Over the later phase, the clinician must address longer term complications of MCSD support such as acquired aortic insufficiency and right ventricular decline, as well as progression or development of other co-morbid illnesses. These patients should receive ongoing follow-up in specialized MCSD centers because of the nature of this developing field where recognition and description of longer term complications is evolving.
Multidisciplinary Approach to Follow-up Care

Successful mid- and long-term outcomes for patients with MCSD are dependent on a multidisciplinary team approach to outpatient management. This approach is achieved by combining the expertise of cardiovascular surgeons, advanced heart failure cardiologists, specialized MCS coordinators and other health care providers.

Role of the Cardiologist

The cardiologist oversees optimization of heart failure therapy in the postoperative period. Once the patient has resumed standard heart failure therapy, ongoing surveillance is necessary to address device and non-device related issues that may limit long term survival. These issues may include right ventricular failure, evidence of device related infection, progression of known co-morbidities, and development of new medical issues.

Role of the Surgeon

The surgeon monitors the patient for appropriate post-surgical recovery including sternotomy and driveline healing. Driveline and pump pocket infections or device malfunctions may require surgical intervention in addition to antimicrobial therapy.

Role of the MCS Coordinator

The MCS coordinator has the critically important role of transitioning the patient back to their community and serving as the primary communication link between the patient and the MCS team over the patient’s lifetime. The coordinator works with the team in troubleshooting device related problems including alarms and changes in device parameters.

Role of Other Disciplines

Patients with MCSDs may develop complications requiring the expertise of other specialties, such as infectious disease, gastroenterology, psychiatry, or others. The MCS team should strive to establish collaborative relationships with health care
providers from other specialties, who over time will become familiar with the unique issues affecting this patient population.

*Role of the Referring Physician*

The referring physician is encouraged to re-establish care with the MCSD patient. Although most referring physicians will likely defer the bulk of patient management decisions to the MCS team, it is useful to have a provider available in the patient’s community to help facilitate assessment of the patient and transfer to the MCS center in case of emergency. In addition, transitioning the patient back to their referring physician helps increase awareness in the referring community of the potential benefits of MCSD therapy, which is often underutilized in the treatment of advanced heart failure patients.

**Recommendations for the Multidisciplinary Approach to Follow-up Care:**

*Class I:*

1. Management of the patient with a MCSD should be performed by a multidisciplinary team including cardiovascular surgeons, advanced heart failure cardiologists, and specialized MCS coordinators. Other health care providers may collaborate with the primary MCS team when additional expertise is required.

   **Level of Evidence:** C.

**Frequency of MCS Center Follow-up**

In the early postoperative period, frequent outpatient visits ensure that patients appropriately convalesce, and it allows the medical team to continually assess the patient’s and caregivers’ competency with device management. During the early outpatient timeframe, it may be advisable for patients to stay within close travelling distance of the MCS center, to allow for rapid transfer to the hospital should emergencies arise. This may be especially relevant at centers that encompass a large geographic referral area. One disease management model suggests that patients stay within 30 minutes driving distance for two weeks post hospital discharge, with a tapering schedule of clinic visits from twice per week down to a minimum of once monthly for the
duration of time the patient is maintained on MCSD support. These clinic visits should be coupled with a schedule of routine surveillance testing for patient and device related factors that may have unfavorable effects on MCS device function and patient survival, and to look for evidence of myocardial recovery. A disease management model may include monitoring phone calls placed from the MCS coordinator to the patient or caregiver to proactively identify issues that may have adverse effects on patient outcomes.

**Recommendations for Frequency of Visits:**

*Class I:*

1. MCS patients should be seen in clinic regularly with increased frequency during the early post-operative period, which can be tapered based on clinical stability.
   
   **Level of Evidence: B.**

2. MCS patients should have a routine schedule of testing to look for evidence of myocardial recovery and to survey for patient or device related issues that may adversely affect outcomes.
   
   **Level of Evidence: B.**

*Class IIa:*

1. Between routinely scheduled visits, monitoring phone calls from the MCS coordinator to the patient or caregiver may help proactively identify issues that may adversely affect patient outcomes.
   
   **Level of Evidence: B.**

**Routine Testing Post MCSD Placement**

*Role of Echocardiography*

Transthoracic echocardiography is an important component of the pre and post-evaluation of MCSD. Prior to implantation, patients with mild left ventricular dilatation (characterized as end diastolic dimension <60mm) have a higher incidence of recovery than those with moderate or severe dilatation. Parameters that indicate improved myocardial function post implantation include increase in LVEF to 40-45%,
normalization of fractional shortening, consistent aortic valve opening, and normalization of left ventricular dimensions.\textsuperscript{10-12} Dobutamine stress echocardiography may be helpful in identifying patients with enough myocardial reserve to allow device explant.\textsuperscript{13} All MCSD patients should be screened for evidence of myocardial recovery, particularly when there is a potentially reversible underlying etiology, such as myocarditis, there is a short duration of history of heart failure, or the patient is of a young age (<45 years).

Echocardiography is helpful in the assessment of complications that may impact survival. Low MCSD flow rates may be due to obstruction secondary to malposition of the cannula, intracardiac thrombus, or impingement by cardiac structures. The ventricle may appear distended with shift of the septum towards the unsupported ventricle.\textsuperscript{14} In the presence of kinking, there may be loss of Doppler flow signal within the VAD cannula. Obstruction may be diagnosed by high spectral Doppler velocities (>2.3 m/s inflow and >2.1 m/s outflow for pulsatile pumps, and >2 m/s for axial flow pumps) obtained by continuous wave Doppler and color Doppler aliasing at the cannula orifice.\textsuperscript{15,16} Echocardiography may show underfilling resulting from dehydration, sepsis, or hemorrhage, which can result in obstruction of the inflow cannula by the septum or other cardiac structures.\textsuperscript{14} Bacteremia may lead to endocarditis of the native heart structures, prosthetic valves, or VAD components, which can be detected by echocardiography.\textsuperscript{17}

Particular attention must be focused on the native aortic valve while on device support. Echocardiography is used to visualize the aortic valve opening, which is important to prevent thrombus formation in the aortic root and for optimal device function with some VAD types. Over time, hemodynamically significant aortic regurgitation may develop as a consequence of aortic root dilation.\textsuperscript{18,19} Commissural fusion and valve thickening have been noted as well, which may contribute to the development of aortic regurgitation.\textsuperscript{20,21}
Recommendations for the Use of Echocardiography:

Class I:

1. Echocardiography should be performed as part of the pre-operative assessment and routinely at regular intervals postoperatively to evaluate for signs of myocardial recovery and optimal MCSD function. Echocardiography can be utilized for setting optimal pump parameters.

   Level of evidence: B.

2. In addition to routine studies, echocardiography should be performed as part of the evaluation of suboptimal MCSD function or in the presence of clinical signs of circulatory dysfunction including congestive or low output symptoms.

   Level of Evidence B.

Role of Right Heart Catheterization

Assessment of Persistent HF Symptoms. Patients experiencing symptoms of recurrent heart failure after MCSD placement require further assessment to elucidate the cause. Cardiac catheterization can be used to define causes of MCSD malfunction, as well as native heart causes of persistent heart failure. Hemodynamic measurement obtained by placement of a PA catheter is crucial in determining if there is inadequate LV unloading, manifested by elevated pulmonary capillary wedge pressure. Elevated left sided filling pressure may be due to low VAD pump speed, cannula malposition, obstruction or kinking. Native heart factors may include valvular heart disease. In particular, aortic regurgitation may develop post VAD placement and result in increased VAD flow rates, discrepancy between measured cardiac output by PA catheterization and displayed VAD flow, and elevated filling pressures.

Assessment of Right Ventricular Dysfunction. After MCSD placement, right ventricular function may deteriorate over time with hemodynamic sequelae including drops in VAD flow and cardiac output, loss of pulsatility, and manifestations of right heart failure/cor pulmonale. Elevated central venous pressure (CVP) and low measured cardiac output in the absence of elevated left sided filling pressures as measured by PA catheterization may necessitate a trial of inotropic therapy for RV support, or other enhancement of medical therapy to help optimize RV function.
Assessment of Pulmonary Hypertension. Patients being bridged to cardiac transplantation with MCSD therapy often have pulmonary hypertension that precludes immediate transplantation. After device placement, PA catheterization should be used at regular intervals to evaluate for improvement in pulmonary artery pressure, transpulmonary gradient (mean pulmonary artery pressure minus pulmonary artery wedge pressure), and/or pulmonary vascular resistance to values that would allow progression to cardiac transplantation.

Assessment of Myocardial Recovery. Right heart catheterization with hemodynamic measurement may be utilized to corroborate other evidence of myocardial recovery. A pulmonary artery catheter may be placed with step-wise lowering of pump speed to document acceptable hemodynamics with decreasing pump support and aid in the decision making for pump explantation.

Recommendations for the Use of Right Heart Catheterization:

Class I:
1. Right heart catheterization is useful in the assessment of persistent or recurrent heart failure symptoms after MCSD placement and to evaluate for evidence of RV failure or device malfunction.

   Level of Evidence: B.

2. Right heart catheterization should be performed at regular intervals in patients being evaluated or listed for heart transplant to document pulmonary artery pressures, as irreversible pulmonary hypertension is associated with early allograft dysfunction/failure post heart transplantation.

   Level of Evidence: A.

Class IIa:

1. Right heart catheterization should be performed to help corroborate evidence of myocardial recovery. The pulmonary artery catheter may be left in place with serial lowering of pump speed to confirm acceptable hemodynamics with decreasing VAD support prior to pump explantation.

   Level of Evidence: C.
Role of Computed Tomography Angiography

Computed tomography angiography (CTA) may be a helpful tool for assessing persistent or recurrent heart failure symptoms in patients with MCSD. This technique allows visualization of inflow and outflow VAD cannulas including placement, angulation, kinking, or obstruction when other imaging modalities have not been revealing. The inflow cannula should be directed to the center of the left ventricular cavity with a neutral septum and without thrombus formation. The outflow cannula should be free of kinking with a patent aortic anastomosis. Caution should be used in administering intravenous contrast in patient with renal insufficiency.

Recommendations for Use of Computed Tomography Angiography:

Class I:

1. CT angiography allows visualization of the native heart and MCSD components and may be valuable when other imaging modalities have not been revealing, especially in the face of persistent or recurrent heart failure symptoms post MCSD implant.

   Level of Evidence: B

Role of Functional Capacity Assessments

Routine assessment of exercise capacity is required for patients with mechanical circulatory support as part of the Joint Commission Certification for centers offering DT in the United States. In addition, objective measure of functional status is useful in prescribing activity in the early post-operative rehabilitation period, and it allows the clinician to follow the patient’s progress over time.

Maximal oxygen consumption (peak VO$_2$) during cardiopulmonary stress testing (CPX) is the most objective and well-validated measure of exercise capacity in heart failure. Post MCSD placement, there are limited data on improvements in peak VO$_2$, particularly in DT patients, due to attrition of subjects over time and survivorship effect. Modest increases in peak VO$_2$ may be observed, usually within the first weeks to months after device placement.

Six minute walk testing (6MWT) is easily performed in any clinic setting. It does not require specialized equipment, and it simply measures the distance covered by
encouraged walking on a level hallway within 6 minutes. Unlike a maximal CPX, it does not provide specific information on the function of each of the different organs and systems involved in exercise or the mechanism of exercise limitation. However, correlation of the 6MWT to peak VO$_2$ is moderate to good, with 6MWT being between 83% and 91% accurate in predicting peak VO$_2$ in chronic heart failure patients if distance walked is less than 450 to 490 meters, respectively.\textsuperscript{31-33} Data are lacking that examine outcomes in patients with mechanical circulatory support limited 6MWT distances. However, this submaximal exercise test may be helpful in assessing patients’ capacity to perform activities of daily living.

**Recommendations for Functional Capacity Testing:**

*Class I:*

1. Measurement of exercise capacity should be undertaken post MCSD placement to allow for appropriate exercise prescription, which may be part of a formal cardiac rehabilitation program.

   **Level of Evidence:** B.

*Class IIa:*

1. Cardiopulmonary stress testing and/or six minute walk testing performed at regular intervals is helpful in objectively assessing functional capacity in patients with MCSD. Suggested intervals are 3 months, 6 months, and then at 6 month intervals through 2 years after implant, then yearly thereafter.

   **Level of Evidence:** C.

**Quality of Life Assessments**

One of the primary goals of MCSD therapy is to improve quality of life for patients with advanced heart failure. Therefore, it is important to measure health related quality of life (HRQOL) both at baseline (prior to implantation) and at regular intervals post operatively. Selection of reliable and valid HRQOL instrument(s) should be based on an understanding of the strengths and weaknesses of generic and disease-specific questionnaires, as well as the potential burden imposed on patients. In addition to
overall HRQOL information, domains measured should include physical and occupational function, psychological state, social interaction, and somatic sensation (i.e., symptoms).\textsuperscript{34} Meaningful assessments may include quality-adjusted survival that evaluates patient preferences for trade-offs between QOL and survival outcomes, or calculating quality-adjusted life years to conduct a cost-utility analysis. It is also important to determine reasons for non-completion of functional and HRQOL assessments across time. Collection of data regarding caregiver burden and QOL might be considered. Table 1 summarizes available tools for measuring generic and heart failure specific HRQOL.

**Recommendations for Health Related Quality of Life Assessments:**

**Class I:**

1. HRQOL should be measured prior to MCSD implantation and at regular intervals longitudinally for the duration of MCSD support. Both generic and heart-failure specific measures can be utilized. Suggested intervals are 3 months, 6 months, and then at 6 month intervals through 2 years after implant, then yearly thereafter.

   **Level of Evidence:** \textit{B}.

**Laboratory Studies**

Serial laboratory studies should be obtained over the duration of MCSD follow up. These should include general studies related to end-organ function, studies related to the device itself, and studies to diagnose or monitor the status of co-morbid conditions.

**Assessment of End-Organ Function.** Lab studies should be obtained on an ongoing basis to monitor end-organ function. These include, but are not limited to, creatinine and blood urea nitrogen to assess renal function and liver enzymes to assess liver integrity.

**Assessment of MCSD Related Issues.** Continuous flow devices requiring anticoagulation and/or antiplatelet therapy require monitoring of therapy. Patients on warfarin should have regular international normalized ratio (INR) obtained, with the target range determined by the device manufacturer’s recommendation and clinical
status of the patient. Effectiveness of antiplatelet therapy may be monitored using platelet aggregation studies or thromboelastography (TEG). In order to monitor for evidence of hemolysis, complete blood count, lactate dehydrogenase and plasma free hemoglobin may be measured.

**Diagnosis and Monitoring of Co-morbid Conditions.** Blood work to diagnose new co-morbid conditions or to monitor the status of existing conditions should be obtained. Examples include lipid profile for patients with dyslipidemia, fasting glucose and hemoglobin A1C in patients with diabetes, and thyroid panel in patients taking amiodarone.

**Recommendations for Laboratory Studies:**

**Class I:**

1. Laboratory studies should be obtained at regular intervals to assess end-organ function, monitor device specific issues, and diagnose or follow the status of co-morbid conditions.

   **Level of Evidence:** C.

**Assessment of the MCSD**

**Driveline/Lead/Component Assessment.** The driveline should be assessed at each patient visit to look for evidence of appropriate appearance and to exclude the presence of driveline infection. Ideally, there should be robust ingrowth of tissue into the driveline with good adherence. The driveline should be examined to exclude any breeches or defects in the casing as well as evidence of appropriate immobilization to minimize chances of tissue trauma at the exit site due to pulling. All connections should be examined to ensure they are intact. The console should be examined if present. Alarms should be reviewed and downloads performed at regular intervals. Battery status should be assessed, and the patient should be asked if they are carrying their backup equipment including extra batteries and controller. The appearance of the driveline, and other components should be noted in the medical record as part of the physical examination of the patient. A photographic record of the driveline exit site may also be helpful in assessing its appearance over time.
Adjustment of Pump Parameters for Optimal Device Function. The patient should bring a log of pump parameters to each clinic visit for review by the MCS team. Over time, adjustments in pump parameters may be needed which should be done according to the recommendations of the manufacturer. These changes may be guided by echocardiography and right heart catheterization.

Showering. The patient should be trained in the appropriate technique for showering once it is determined that satisfactory wound healing has taken place. Depending on when the patient is discharged relative to their implant, this education may be done in the outpatient setting.

Dressing Changes at the Driveline Site. The patient and caregiver should be trained in appropriate technique for dressing changes at the driveline site prior to hospital discharge, and independence in this skill should be demonstrated to the bedside nurse or VAD coordinator prior to discharge. Dressing protocols tend to be center specific. Ongoing reinforcement of proper technique should be provided at subsequent outpatient visits. Re-education may be necessary and especially important in the presence of driveline related infections or when surgical debridement has been performed.

Recommendations for Assessment of the MCSD:
Class I:
1. The driveline, exit site, and MCSD components should be examined at each clinic visit to ensure their integrity. Alarm history and downloads should be obtained at regular intervals. Pump parameters should be reviewed regularly and adjusted accordingly to optimize pump functioning for the duration of time the patient is on support.
   Level of Evidence: C.
2. The patient should be trained in proper self-care including showering technique and dressing changes prior to hospital discharge. These skills may need reinforcement over the patient’s lifetime, depending on the clinical course.
   Level of Evidence: C.
Health Maintenance

Patients with MCSDs are advised to follow general health maintenance guidelines according to their age and gender. Vaccines should be administered according to CDC recommendations. Appropriate dental care should be continued.

Recommendation for Health Maintenance:

Class I:

1. Patients with MCSD therapy should continue to follow a general health maintenance schedule, including gender-related and age-specific recommendations, routine vaccinations, and dental care.

   Level of Evidence: A.

Topic 3: Cardiac Rehabilitation and Exercise Guidelines

Cardiac rehabilitation has been demonstrated to reduce mortality in patients with coronary artery disease by 20 - 25%\(^{35,36}\). Additionally, it has been shown to improve blood pressure and reduce recurrent myocardial infarctions and strokes, and improve quality of life\(^ {37}\). Despite the improvements shown in patients with coronary artery disease, there were significant concerns about the risks and benefits of cardiac rehabilitation in heart failure patients until the publication of the Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) trial\(^ {38}\). In this trial, 2331 patients with NYHA Class II-IV heart failure symptoms were randomized to either exercise training or usual care. The patients who underwent exercise training had 36 supervised exercise session of aerobic activity followed by home based training. There was no difference in the primary endpoint of all-cause mortality or hospitalization between the two groups. However, after adjusting for prespecified high-risk covariates (exercise duration, LVEF, Beck Depression Inventory II score, and history of atrial fibrillation or flutter); patients who underwent exercise training had an 11% reduction in the primary endpoint (HR 0.89, 95% CI 0.81-0.99, P=0.03)\(^ {38}\).

Exercise training was felt to be safe, a finding that is of perhaps more importance when considering cardiac rehabilitation in patients with a MCSD. During the exercise training period, 37 patients were hospitalized due to an event that occurred during or
within 3 hours after exercise. A similar number of events was reported among patients in the usual care group. Based on the results of this trial, it is now generally accepted that exercise training in heart failure patients does not improve survival, but it is safe and is associated with an improvement in quality of life. The effects of cardiac rehabilitation in patients with a MCSD have not been well studied. It is clear that with both pulsatile and continuous flow LVADs, exercise is safe and exercise tolerance improves.\(^{39-41}\)

The two primary areas of focus for patient rehabilitation after MCSD implant include early strength training to reduce short-term post operative morbidity and post-discharge training to improve exercise capacity. Preoperatively, MCSD patients are often functionally limited due to both their heart failure and the need for chronic bed rest in patients with balloon pumps and right heart catheters. The resultant muscle wasting and weakness leads to a very debilitated patient who is at risk for prolonged ventilation, falls, fractures, and an increased risk of infection. Early mobilization of patients after surgery has been retrospectively associated with an improved ability to wean from the ventilator and shorter postoperative stays.\(^{42,43}\) These interventions included muscle strengthening and breathing exercises, bed mobility activities, transfers from bed to chair or commode, and gait training,\(^{43}\) which are quite similar to the usual physical therapy activities for patients that have undergone cardiac surgery.

There are few data demonstrating the effects of cardiac rehabilitation in patients with MCSDs.\(^{44}\) Exercise training is considered safe, and it is associated with a reduction in norepinephrine and epinephrine levels.\(^{44,45}\) The data evaluating exercise in patients with a MCSD are limited, but extrapolating from the safety of cardiac rehabilitation in patients with heart failure or after cardiac surgery, it appears that cardiac rehabilitation in patients after MCSD implant is safe and improves exercise tolerance. A program similar to that studied in the HF-ACTION trial should be used for patients with MCSD since it was shown to be safe in the chronic heart failure population. In HF-ACTION, patients exercised on either a treadmill or stationary cycle for 15 to 30 minutes at a workload corresponding to 60% of their heart rate reserve.\(^{38}\) For patients with continuous flow devices, exercising to a Borg Rating of Perceived Exertion level of 12-14 could be used instead of the target heart rate, since it is difficult
to obtain a pulse in those patients. Additionally, patients should participate in the other components of typical cardiac rehabilitation programs, including education about risk factors and psychosocial counseling.\textsuperscript{46,47} A few special considerations are warranted for MCSD patients undergoing cardiac rehabilitation. The facility and staff should receive basic training about MCSDs, and the meanings of the various alarms. Patients should be instructed to discuss the alarms with their trainers. Additionally, patients should be educated to stay well hydrated and to stop exercising if they experience dizziness, diaphoresis, severe dyspnea, or significant chest pain.\textsuperscript{43} Finally, patients should stop exercising if their pump starts to alarm, and they should be advised against silencing the alarm and continuing to exercise.

**Recommendation for Exercise and Cardiac Rehabilitation:**

*Class I:*

1. All patients who are able should be enrolled in cardiac rehabilitation after surgical placement of a MCSD.

   **Level of Evidence:** C.

**Topic 4: Medical Management of the MCSD Patient**

**Introduction**

Patients are required to adhere to an often complex pharmacologic regimen including drugs specific to the functioning of the device (such as anticoagulation and antiplatelet agents), drugs specific to the underlying heart disease, and drugs to treat comorbid conditions. In addition to pharmacologic therapy, optimizing nutritional status and addressing substance use issues are important considerations in MCSD patients, especially in those bridging to cardiac transplantation.

**Anti-Coagulation**

Most devices, with the exception of the Heartmate XVE, require chronic anticoagulation with warfarin. Patients typically have achieved their goal INR prior to being discharged from their implant hospitalization. The goal INR ranges for FDA approved devices are shown in Table 2. It is critical that a reliable system is in place to
track the INR in all patients on MCS, to maintain a record of their goal level of anticoagulation, to assure routine INR measurements, and to communicate any necessary changes in warfarin doses so that patients are maintained in their therapeutic range. Given the complexity of patients who receive MCS, the variety of potential devices, and patients’ concomitant medical conditions, the MCS team should generally be responsible for anticoagulation management rather than utilizing an anticoagulation clinic or outside physicians. Although alternatives to warfarin have now been approved by the FDA (dabigatran, rivaroxaban), they have not been adequately studied in the MCSD population and are not recommended.

Goal INR ranges attempt to strike a balance between the potential risks of thromboembolism or pump thrombosis and bleeding risks. Pulsatile devices with mechanical valves such as the Thoratec PVAD require warfarin with an INR range similar to mechanical heart valves. In contrast to most devices, the HeartMate XVE does not have mechanical valves. It has a textured volume displacement chamber that becomes endothelized and therefore does not require warfarin, only aspirin. However with smaller and more durable pumps available for BTT and DT, utilization of the HeartMate XVE has declined substantially. In the HeartMate II BTT trial, the goal INR was 2–3, and the rate of bleeding beyond 30 days which required ≥2 units of blood was 0.69 events per patient year. The rates of hemorrhagic and ischemic strokes were <0.1 per patient-year, and the pump thrombosis rate was 0.02 per patient-year. However, a review of 331 patients enrolled in the HeartMate II BTT trial that were supported for at least one month revealed that thrombotic event rates increased with an INR <1.5, and hemorrhagic event rates increased with an INR >2.5. Hemorrhagic and thrombotic events occurred at similar rates with an INR range of 1.5 – 2 versus 2 – 2.5 as seen in Figure 2. Thus, many centers have decreased their INR goals for the HeartMate II from 2.0-3.0 to 1.5–2.0. However, caution must be exercised in loosely applying these lower INR ranges, as isolated cases of pump and outflow graft thrombosis have been reported. The effects of more recent device design changes on thrombosis rates may mean INR targets derived from data utilizing previous pump designs may not reflect current thrombosis risk. Since recommendations regarding goal INR ranges are evolving, maintaining INRs at or above 2 may be most prudent.
There is no consensus on how frequently the INR should be monitored once the patient is discharged with a therapeutic INR. Monitoring of the INR may be weekly or even more frequent until a dose that achieves a stable INR is determined. Thereafter, the INR may be assessed monthly in the setting of clinical stability. The availability of home INR monitoring has not been established in a population on MCS, but it may allow for more frequent monitoring and more rigorous maintenance of INR in the therapeutic range. As in the setting of mechanical valves or atrial fibrillation, warfarin can be held for supratherapeutic INR values in the absence of bleeding. Acute reversal of anticoagulation in the absence of clinically significant bleeding has a high potential for harm, and there is no associated benefit to offset this risk. For devices with mechanical valves, an INR between 2-2.5 may only require a simple dose adjustment of warfarin. Alternatively, patients with an INR substantially below the goal range could be treated with home administration of low molecular weight heparin, if feasible, or be hospitalized for heparin bridging. Patients frequently require invasive procedures for which they cannot be therapeutically anticoagulated with warfarin. Most patients are hospitalized and bridged with heparin, especially those with devices requiring the most intense anticoagulation. Patients with continuous flow devices that require a lower therapeutic INR range, such as the HeartMate II, may be able to have many invasive procedures at the lower end of their therapeutic INR.

In the setting of clinically significant blood loss, warfarin may be held or even reversed, with caution, if needed. Antiplatelet therapy can be continued in many cases, but it may also need to be discontinued. Devices requiring higher INR ranges and those with mechanical valves are likely at the highest risk in these circumstances. Patients with extracorporeal pumps can have their pump housing inspected for clot if anticoagulation needs to be held, but clot may still be present that is not evident from visual inspection alone. The risk of bleeding must be balanced with the risk of thromboembolism or pump thrombosis for each patient, pump, and clinical setting.

Other concomitant medical conditions that may require anticoagulation at or above the level required for the MCSD must be considered, such as atrial fibrillation, pulmonary embolism, or a mechanical valve. While some of these indications may be
time limited, others may persist throughout the duration of MCS. Persistently low flows may also be another situation where anticoagulation may need to be intensified due to the risk of thrombus formation from stasis.

**Recommendations for Anticoagulation:**

*Class I:*

1. Patients with MCSD should receive anticoagulation with warfarin to maintain an INR within a range as specified by each device manufacturer.

   **Level of Evidence: B.**

**Antiplatlet Therapy**

Many devices recommend aspirin 81 or 325 mg daily in addition to the warfarin anticoagulation. However, the necessity of antiplatelet therapy, the particular antiplatelet drug or drugs, dosage, and frequency has not been established. Newer agents such as ticagrelor and prasugrel have not been studied in MCS patients and cannot be recommended.

The variety of antiplatelet strategies used in the HeartMate II BTT trial is illustrated in Figure 3. The prevalence of aspirin resistance varies widely in the literature from 5.5-60%, and it may be as high as 55% in a heart failure population.\(^{51,52}\) In a small study of Thoratec LVADs, aspirin resistance was observed in 26% of patients and persisted weeks after the surgery in some patients.\(^{53}\) Studies have also demonstrated that markers of persistent platelet activation remain elevated for weeks after the implant surgery.\(^{54}\) In small studies of patients with continuous flow devices, prolonged elevation of inflammatory markers and impaired platelet function has also been observed.\(^{55,56}\)

Higher rates of significant gastrointestinal bleeding have been reported in patients with axial continuous flow pumps as compared to patients with pulsatile pumps.\(^{57}\) The high sheer stress of such pumps has been postulated to result in destruction of large multimers of von Willebrand factor (vWF), leading to decreased platelet aggregation and acquired von Willebrand disease.\(^{56,58,59}\). This process may be similar to the high sheer stress and resultant high rates of bleeding associated with
aortic stenosis. While many cases of gastrointestinal bleeding are associated with arteriovenous malformations (AVMs), it is unclear whether the decrease in platelet aggregation is responsible for more bleeding from occult AVMs, or if the lack of pulsatility itself may lead to the formation of AVMs. It is also unknown if patients with centrifugal continuous flow pumps develop a similar deficiency of vWF. Regardless, platelet aggregation and vWF activity normalize after cardiac transplantation. The occurrence of impaired platelet function and the development of an acquired von Willebrand syndrome has led some experts to question the utility of routine antiplatelet therapy in patients with axial flow pumps.

Consensus is lacking with regard to appropriate dosing strategies for antiplatelet agents. Fixed dose antiplatelet therapy may be used, or the dose may be selected based on platelet function. For the latter, the optimal method of assessing platelet function is not known. Physicians must also consider co-existing medical conditions that may require antiplatelet therapy, including as drug-eluting stents, prior stroke, or peripheral vascular disease. These requirements may be either time limited or permanent, and the required duration of antiplatelet therapy should be noted if different from the routine device specific therapies.

**Recommendations for Antiplatelet Therapy:**

**Class IIa:**

1. Chronic antiplatelet therapy with aspirin 81-325 mg daily may be used in addition to warfarin in patients with MCSD.
   
   **Level of Evidence: C.**

2. Antiplatelet therapy beyond aspirin 81-325 mg daily may be added to warfarin as per the recommendations of specific device manufacturers.
   
   **Level of Evidence: C.**

**Class IIb:**

1. Assessment of platelet function may be used to direct the dosing and number of antiplatelet drugs.
   
   **Level of Evidence: C.**
Heart Failure Therapy

In patients who receive MCSD as a possible bridge to recovery, many clinicians may add evidence-based heart failure therapy in an attempt to maximize the chance of recovery. However, there is limited evidence to support the efficacy of this strategy. Myocardial recovery has been observed in some patients with nonischemic cardiomyopathy who were administered an aggressive heart failure based regimen (lisinopril, carvedilol, spironolactone, and losartan) and the beta_2_ agonist clenbuterol.\(^6^4\) However, clenbuterol is not commercially available outside of research protocols. In the setting of BTT and DT, there is no evidence that single or combination heart failure pharmacotherapy provides benefit in terms clinical outcomes or myocardial recovery.

MCS results in acute improvement to the heart failure state,\(^6^5\) but volume overload typically persists until after discharge. It may become chronic if not aggressively treated in certain cases. Numerous conditions may contribute to venous congestion, including right ventricular dysfunction, renal insufficiency, hypoalbuminemia, or inadequate unloading of the left ventricle due to suboptimal VAD settings or mechanical obstruction to inflow or outflow. Most patients require diuretics at the time of discharge from their implant hospitalization. However, once euvolemia is achieved, the diuretic use may be decreased or even discontinued.

After the patient’s heart failure status improves, hypertension present prior to the onset of advanced heart failure generally returns. In addition to typical adverse consequences of hypertension, increased afterload from hypertension can impact VAD performance and longevity. MCSD pumps tend to produce less flow and provide less ventricular unloading in the setting of hypertension. Hypertension increases stress on the pneumatic or mechanical drivers in pulsatile pumps which, in turn, can increase mechanical wear. Flow in nonpulsatile pumps is afterload dependent, such that at a constant speed, there will be less forward flow with higher blood pressures. If the blood pressure becomes chronically elevated, the inadequate unloading of the left ventricle will be persistent due to the reduction in forward flow. ACE-inhibitors or ARBs reduce afterload and are the first line drugs for post-MCS hypertension. In addition, there is widespread evidence that these agents are beneficial in patients with diabetes and vascular disease, which are common comorbidities in those undergoing MCS. ACE
inhibitors are usually favored over ARBs in such circumstances primarily because of cost considerations. Renal insufficiency or hyperkalemia may limit the use or dosage of ACE-inhibitors and ARBs, especially in the early post-operative period prior to full renal recovery. Beta blockers, calcium channel blockers, and alpha blockers may be utilized to achieve additional blood pressure control as needed.

Beta-blockers are useful adjuncts to ACE-inhibitors or ARBs for blood pressure control, but caution should be exercised when initiating beta blockade in the setting of marginal RV function, especially in the face of persistent volume overload. Beta-blockade is also useful for rate control in the setting of atrial and ventricular tachyarrhythmias. There is no evidence base for the routine addition of aldosterone blockade after MCSD implantation, and it is typically rarely used other than as a means to limit the need for potassium supplementation. Many patients post-MCSD still have some degree of renal insufficiency,\(^6^6\) which increases the risk of hyperkalemia with aldosterone receptor antagonists. Nitrates and hydralazine are useful for afterload reduction in patients who cannot tolerate an ACE-inhibitor or ARB due to renal insufficiency or hyperkalemia.

**Recommendations for Heart Failure Therapy:**

**Class I:**

1. Diuretics are useful for the management of volume overload during MCS.

   **Level of Evidence:** C.

**Class IIa:**

1. An ACE-inhibitor or ARB may be used for hypertension, or for risk reduction in patients with vascular disease and diabetes.

   **Level of Evidence:** C.

2. Beta-blockers may be used for hypertension or for rate control in patients with tachyarrhythmias.

   **Level of Evidence:** C
Class IIb:

1. Mineralocorticoid receptor antagonists (MRAs, or aldosterone antagonists) may be used to limit the need for potassium repletion in patients with adequate renal function.
   
   **Level of Evidence: C.**

2. Digoxin may be useful in the setting of atrial fibrillation with rapid ventricular response.
   
   **Level of Evidence: C.**

Risk Factor Modification

**Hypertension**

Although blood pressure (BP) control is important as previously described, clinical trial evidence that identifies optimal target blood pressure is lacking in patients with MCSD. The INTERMACS definition of a hypertension adverse event is new onset SBP >140 mmHg or DBP >90 mmHg for pulsatile pumps and mean BP >110 mmHg for continuous flow pumps. The American Diabetes Association (ADA) blood pressure recommendations (SBP <130 mmHg and DBP <80 mmHg) are reasonable goals given the prevalence of vascular disease and diabetes in this population, as well as the mechanical consequences of persistently elevated blood pressure on pulsatile devices. As noted above, blood pressure control for patients with continuous flow pumps is essential to maximize pump output and ensure adequate decompression of the left ventricle. Outpatient assessment of blood pressure, especially at home, is difficult because patients may have very little pulsatility; thus, the BP can be very difficult to auscultate. Clinics that provide care for patients with continuous flow devices must be equipped with a Doppler probe to properly assess blood pressure. There is no evidence base for blood pressure targets with continuous flow pumps, but a mean blood pressure of ≤80 mmHg is a reasonable goal.
**Recommendations for Hypertension Management:**

*Class IIb:*

1. Patients with pulsatile MCSDs should have a blood pressure goal of SBP <130 and DBP <85 mmHg.
   
   **Level of Evidence: C.**

2. Patients with nonpulsatile MCSDs should have a mean blood pressure goal of ≤80 mmHg.
   
   **Level of evidence: C.**

**Diabetes**

Patients should be screened for diabetes, and those with pre-implant diabetes should resume therapy post-operatively and continue their diabetes follow up after discharge. Patients should also reestablish or initiate follow up with their local primary care physicians and/or endocrinologists to assist in diabetes management. The MCSD clinic should also assure patients with diabetes are obtaining routine screening by ophthalmology, nephrology, and podiatry as necessary.

**Recommendations for Diabetes Management:**

*Class Ila:*

1. Patients with diabetes should have continued therapy and close follow-up for their diabetes while on MCS.
   
   **Level of Evidence: C.**

**Renal Disease**

Renal insufficiency is common prior to MCS from a combination of low output, high right atrial pressures, and an adverse neurohormonal milieu.\(^{67,68}\) Recovery of renal function is common after MCSD implantation, and the majority of benefit from MCS on renal function is usually seen in the first 1-2 months.\(^{66}\) Recovery of renal function can be maximized by assuring appropriate device output by adequate settings and aggressively treating hypertension, especially in those with continuous flow pumps. Renal function should also be monitored closely while treating residual volume overload.
with diuretics. Renal insufficiency in the setting of diabetes should prompt treatment
with an ACE inhibitor or ARB, particularly in the setting of proteinuria. Recovery of renal
function may also necessitate dose-adjusting renally cleared medications.

**Recommendations for Treatment of Renal Disease:**

*Class IIb:*

1. Renal function should be monitored on an ongoing basis after MCSD placement.
   
   **Level of Evidence: C.**

2. Persistent renal insufficiency after MCS should prompt further evaluation and
   management.

   **Level of Evidence: C.**

**Hemolysis**

Clinically significant hemolysis in patients with MCSD is rare. It is potentially
more common with continuous flow pumps, but the rate is still <5%. Review of device
parameters during clinic visits and examining longitudinal trends may help detect
excessive pump speeds or other situations that may increase the risk for hemolysis. In
the HeartMate II BTT trial, hemolysis was defined as two measurements of a plasma
free hemoglobin >40 mg/dL or an LDH >1000 mg/dL within 24 hours. INTERMACS
defines hemolysis as a plasma free hemoglobin >40 mg/dL in association with clinical
signs of hemolysis beyond 72 hours post implantation. Hemolysis not related to the
device, e.g. from transfusions or liver disease, should also be considered in the
differential. Screening for hemolysis with LDH and plasma free hemoglobin should
occur at least monthly in addition to assessment of the hematocrit and hemoglobin.

**Recommendations for Evaluation and Management of Hemolysis:**

*Class Ila:*

1. Screening for hemolysis should occur in the setting of an unexpected drop in the
   hemoglobin or hematocrit or with other clinical signs of hemolysis; e.g.,
   hemoglobinuria.

   **Level of Evidence: C.**
Class IIb:

1. Routine screening for hemolysis with LDH and plasma free hemoglobin in addition to hemoglobin or hematocrit should occur periodically throughout the duration of MCS.

   Level of Evidence: C.

Dietary Considerations: Obesity and Malnutrition

Malnutrition is a marker for poor outcomes post MCSD implantation, with malnutrition defined as a pre-implant BMI <18.5 kg/m². In the outpatient setting, patients should have serial assessment of their weight and their adherence to the nutritional guidelines established as an inpatient. Nutritional recovery is best followed with pre-albumin rather than albumin because lack of improvement in pre-albumin has been linked to poor outcomes post-MCS. Patients should be referred to a nutritionist as needed to assure nutritional goals are being met.

There are overlapping epidemics of obesity and heart failure. Although the impact of obesity on outcomes and adverse events has not been definitively established, patients who are obese (BMI >30) or morbidly obese (BMI >40) may not be transplant eligible and certainly do not realize the same improvement in functional capacity as the non-obese. Furthermore the obese are at risk for numerous other comorbidities including diabetes, hypertension, and persistent sleep apnea. Many patients may receive MCS as a bridge to weight loss, but there has been no evidence to demonstrate that such a strategy results in substantial weight loss. Weight gain can become more prevalent over time as cachexia resolves and patients revert to their prior poor eating habits. As with all obese patients, there is unlikely to be significant progress in the absence of patient motivation and a formal strategy to address weight loss. Exercise is an important component to weight loss in particular, and referral to cardiac rehabilitation is recommended and is addressed in Topic 3. Lastly, the combination of obesity surgery, either at the time of or after MCSD implantation, has not been performed in sufficient numbers to determine the efficacy and safety of this strategy.
Recommendations for Dietary Management:

Class Ila:
1. Weight loss should be encouraged for all patients with a BMI >30.
   
   Level of Evidence: C.

Smoking and Substance Abuse

Some patients may still be smoking at the time of implantation. Smoking cessation should be addressed during the immediate post-implantation hospitalization and should continue to be emphasized post-implantation at each follow up. Some patient’s transplant candidacy may hinge on their cessation, but smoking cessation should be encouraged even in the absence of transplant eligibility. Both pharmacologic and psychiatric/psychological help may be offered. Routine screening for those whose transplant candidacy is dependent on their abstinence can be done in clinic with urine cotinine measurements.

Alcohol and substance abuse should be addressed in conjunction with social workers, psychiatrists, psychologists, and substance abuse specialists and programs. Often patients with a history of substance abuse enter into a contract with the implanting center which outlines the center’s expectations in regards to a patient’s particular goals and involves periodic screening for compliance with counseling and other outpatient support efforts.

Recommendations for Smoking and Substance Abuse:

Class I:
1. Smoking cessation should be encouraged in all patients on MCS who continue to use tobacco.
   
   Level of Evidence: C.

Class Ila:
1. Alcohol and drug treatment programs should be required for patients with a history of substance abuse.
   
   Level of Evidence: C.
Topic 5: ICD and Arrhythmia Issues

Introduction

Patients with MCSD still have substrate that places them at increased risk for development of arrhythmias. Those with an LVAD alone may be significantly adversely affected by the development of arrhythmias. In contrast, patients with biventricular support tolerate severe arrhythmias, including ventricular tachycardia (VT) or ventricular fibrillation (VF), often with little or no sequela. In the DT population, patients are likely to be impacted by arrhythmias over the duration of their life with device; therefore, the clinician must have familiarity with these issues.

ICD and Pacemakers

Most patients who receive MCSD in the current era will also have an ICD alone or in combination with cardiac resynchronization therapy (CRT). In the recent HeartMate II BTT trial, 76% of patients had an ICD and in the HeartMate II DT trial 82% had an ICD. In the absence of persistent ventricular dysrhythmias, the defibrillator function of an ICD should be turned back on post-operatively and this should be confirmed prior to discharge from the implant hospitalization. Permanent inactivation of the ICD should routinely be considered in patients who have biventricular support and are in persistent VT or VF. Pacemaker or ICD functions such as back-up pacing for bradycardia, biventricular pacing, anti-tachycardiac pacing, and defibrillation will not adversely affect most current generation pumps or their controlling systems. Rarely, some ICDs and pacemakers may need programming changes due to electromagnetic interference from the assist device or repositioning of the RV lead. Device manufacturers often have a list of such pump-ICD interactions on their websites.

Patients who do not have an ICD prior to MCS are typically those who receive MCS after presenting with acute myopathies or post-cardiotomy failure. ICD placement is warranted prior to discharge as appropriate shocks occur in 21% of MCS patients and ICD is associated with improved survival in MCS-supported heart failure patients.

After discharge, patients should re-establish contact with their electrophysiologist and/or resume home monitoring of their ICD or pacemakers. Often these clinic visits are scheduled to coincide with outpatient visits to the mechanical support clinic.
Routine interrogation of devices allows for assessment of ventricular dysrhythmias as well as the occurrence or recurrence of atrial fibrillation.

**Recommendations for ICD Placement:**

*Class I:*
1. For patients who have an ICD prior to MCS, the ICD should be reactivated in the post-operative setting.
   
   **Level of Evidence: A.**

*Class IIa:*
1. Routine placement of an ICD should be considered for patients who did not have an ICD prior to MCS.
   
   **Level of Evidence: B.**
2. Inactivation of the ICD should be considered in patients with BiVADs who are in persistent VT/VF or who have frequent sustained runs of VT despite optimal antiarrhythmic therapy.
   
   **Level of Evidence: C.**

**Atrial Fibrillation or Atrial Flutter**

Both atrial fibrillation (AF) and atrial flutter are common pre-implantation, often persist post-implantation, and may even occur peri-operatively. Rate control and adequate anticoagulation are the primary goals of therapy. Atrial dysrhythmias may be more likely to occur or recur post-operatively in the setting of volume overload, inadequate decompression of the left and/or right ventricles, or in the setting of RV failure. Poor rate control may cause RV failure in the setting of marginal RV function and thus poor LVAD filling. For patients with long-standing AF prior to implantation, relief of the heart failure state may decrease atrial stretch enough to warrant an attempt at restoration of sinus rhythm. However, many of these patients have substantial adverse atrial remodeling, and they are unlikely to maintain sinus rhythm even with normalization of their hemodynamics. Once patients are rate controlled, the major
impact of paroxysmal or persistent atrial arrhythmias is to increase the goal INR to 2-3 for devices that have target INRs <2.

For patients with new onset AF, it is reasonable to attempt cardioversion, either electrically or pharmaceutically once inotropic support is discontinued and volume status has normalized. For patients who have been cardioverted with an antiarrhythmic drug, it is reasonable to continue the antiarrhythmic with appropriate follow up, especially in the case of amiodarone. There is no known long-term advantage to an aggressive pursuit of sinus rhythm in patients with controlled ventricular rates, except to minimize anticoagulation requirements. However, in the setting of atrial dysrhythmias with poorly controlled ventricular rates, antiarrhythmics, cardioversion and even AV nodal ablation with permanent pacing (if an ICD or pacemaker is already in place) are all potential options.73

**Recommendations for Management of Atrial Fibrillation and Flutter:**

*Class I:*

1. Cardioversion of atrial fibrillation is recommended in patients with rapid ventricular rates that compromise device performance.

   **Level of Evidence: C.**

*Class IIa:*

1. When atrial fibrillation is present and does not interfere with device functioning, management following the most recent ACC/AHA atrial fibrillation guidelines (2006)73 is reasonable.

   **Level of Evidence: C.**

**Ventricular Arrhythmias**

In the immediate post-operative period, ventricular dysrhythmias are also reasonably common. These either persist from the pre-implantation period, or they are exacerbated by the post-operative state. In the Heart Mate II BTT trial, 56% of patients had a history of ventricular arrhythmia. Post-operatively, 42% had a ventricular arrhythmia, most of which occurred in the first 30 days.49 Beyond the first month post-
implant, sustained ventricular dysrhythmias are much less common. Occurrence of sustained VT or VF in the outpatient setting can be discovered as the result of palpitations, light headedness, an appropriate ICD shock, or upon routine interrogation of the device. The effect of persistent ventricular arrhythmias on LVAD function is primarily the result of the tachycardia on right ventricular function. The more marginal the right ventricular function and the faster the ventricular rhythm, the more likely patients will experience RV dysfunction. The RV dysfunction usually results in underfilling of the left ventricle and thus the LVAD. Patients may experience hypotension and low flow alarms or, in those with continuous flow pumps, an increased likelihood of suction event. Lastly, in contrast to LVADs, patients who have BiVADs can usually hemodynamically tolerate persistent VT or even VF. However, such patients may still have compromised RVAD filling, have a slightly higher long-term risk of thromboembolism, and have no back up native heart function if support becomes interrupted through device failure or user error.

The approach to the occurrence of sustained ventricular arrhythmias is much the same as in those without MCS. Searches for reversible causes such as electrolyte abnormalities, drugs which may prolong the QT interval, or more uncommonly, ischemia are reasonable first steps. There are causes of ventricular arrhythmias specific to MCS that should be recognized. With the widespread adoption of continuous flow devices, clinicians have to be aware of the possibility of a suction event, or over decompression of the left ventricle, as a source for ventricular arrhythmias. Many of the ventricular arrhythmias that occur with a suction event are recurrent episodes of premature ventricular contractions (PVCs) or short runs of VT, but the arrhythmias may become prolonged or even potentially sustained. A suction event can occur in a number of settings: after increasing the speed of the device; with volume loss in the setting of over diuresis, bleeding, tamponade, or dehydration from emesis, diarrhea, or insensible losses; or sudden decreases in afterload such as with aggressive treatment of hypertension. In the setting of a suction event, patient and device parameters should be reviewed. Lastly, patients may experience new onset VT as a result of reentry around the apical ventricular cannula.
Treatments for VT not caused by a suction event are similar to those recommended for patients without MCSD, including beta-blockade, antiarrhythmics, and/or cardioversion. Reprogramming of the ICD may sometimes be necessary to avoid unnecessary or inappropriate shocks. Patients may even require mapping and ablation if the rhythms are difficult to control pharmacologically.

**Recommendations for Management of Ventricular Arrhythmias:**

**Class I:**
1. Cardioversion is recommended for VT that results in poor device flows and/or hemodynamic compromise.
   
   **Level of Evidence: C.**
2. The occurrence of VT on MCS should prompt a search for reversible causes, such as electrolyte abnormalities or drug toxicities.
   
   **Level of Evidence: C.**

**Class IIa:**
1. Amiodarone is a reasonable chronic outpatient treatment to prevent recurrence of VT in patients with MCS.
   
   **Level of Evidence: C.**
2. Beta-blockade may be a useful adjunct to antiarrhythmics in the setting of recurrent VT.
   
   **Level of Evidence: C.**
3. Recurrent VT in the setting of a continuous flow pump should prompt consideration of a suction event.
   
   **Level of Evidence: C.**

**Class IIb:**
1. In patients with biventricular support with VF who are refractory to therapy, but have stable flows, the patient may be left in VF with the defibrillator function of the ICD turned off.
   
   **Level of Evidence: C.**
**Topic 6: Psychological and Psychiatric Issues**

Compared to palliative treatment strategies,\textsuperscript{75,76} MCS is an alternative, but costly treatment option for advanced heart disease. The presence of premorbid psychiatric disorders, the use of psychotropic drugs, and previous neurologic events must be taken into account during MCS evaluation as psychiatric burden influences compliance and overall outcome.\textsuperscript{77,78} After discharge, caregivers of a MCS patient are additionally placed under significant pressure which changes over the span of the MCS experience. Different coping mechanisms are used to deal with the initial shock and significant burden.\textsuperscript{79} For patients undergoing heart transplant, partner support seems to be one of the most significant psychosocial variables that can influence clinical success.\textsuperscript{80} Similarly, the following psychosocial predictors of clinical success from one study of heart transplant patients might also be applicable to MCS candidates: empathy, partner support (affective involvement), few demands for emotional communication (affective expression), self-control, stress resistance, emotional stability, high frustration tolerance, low aggression level, and younger age.\textsuperscript{80}

**Bridge-to-Transplant (BTT)**

Even as implantation of MCS as DT receives more and more ubiquitous acceptance, the major indication still remains BTT. A European study prospectively comparing health related quality of life between MCS and heart transplant patients showed HRQoL improved significantly in heart transplant patients in the SF-36 physical (\(P = 0.02\)), but not in the psychosocial (\(P = 0.27\)) component score during follow-up. In the MCS group, HRQoL showed improvements for both the SF-36 physical and psychosocial component scores (both \(P = 0.04\)).\textsuperscript{81} Interestingly, the BTT strategy does not lead to post-traumatic stress disorder (PTSD) in patients, but it may result in this condition in their spouses over the long term.\textsuperscript{82,83}

**Destination Therapy (DT)**

For patients with advanced heart failure and contraindications to cardiac transplantation, MCS have evolved as a permanent alternative, or DT.\textsuperscript{84} Moreover, as technology progresses in the context of limited organ donor supplies, MCSDs may
replace cardiac transplantation in the future. Success with MCS depends on adherence to a complicated mechanical regimen combined with anticoagulation and care for the driveline.\textsuperscript{85} Even with successful outcomes, life is still far from normal. During the duration of support, which may be years, psychiatric and psychosocial issues may either progress or newly emerge. This highlights the importance of ongoing surveillance by the MCSD team for these types of issues.

**Adherence**

Adherent behavior is not only a prerequisite for a successful BTT strategy,\textsuperscript{86} but also for transplantation. A large number of studies have shown that preoperative factors exist which may predict post-transplant compliance,\textsuperscript{87} and these may also be relevant to the MCS patient. These include: demographic variables, psychological variables, psychiatric disorders, poor social support, pretransplant non-adherence, obesity, and substance abuse.

**Evaluation of Mental State**

A rising proportion of cardiac transplant candidates are equipped with MCSD. This patient cohort is burdened with characteristic psychiatric and psychosocial problems (Figure 4).\textsuperscript{88} To illustrate this issue, one small study showed six (out of the notably small cohort of fourteen) heart transplant candidates with an MCS had more than one DSM-IV diagnosis.\textsuperscript{88} The drugs used in nine patients included antipsychotics, antidepressants and anti-anxiety drugs. Only five (36\%) candidates remained without psychiatric interventions. Patients identified with psychiatric issues should be formally evaluated by a psychiatrist, ideally one familiar with mental illness in the context of chronic medical illness. Appropriate pharmacologic treatment and psychological therapy should be initiated. Counseling may need to be extended to family members as well.

**Suicide after MCS Implantation**

Depression and anxiety are well documented in patients with end-stage heart failure. This state correlates with a higher risk of suicide. Cases of suicide in MCS patients by disconnecting at the driveline or batteries have been reported.\textsuperscript{89} Pre-implant
psychological screening and long-term psychological support should be provided to this vulnerable patient population.

Neurocognitive Assessment during Follow-Up

Although physical rehabilitation and emotional adjustment to heart transplant is similar in MCS-and non-MCS-bridged patients, MCS patients retain greater levels of cognitive impairment and return to correspondingly lower levels of social functioning post-transplant. In a single-arm, non-randomized prospective study, the cognitive performance of advanced heart failure patients remained stable or showed slight improvements from month “one” to month “six” under continuous-blood-flow support with the HeartMate II.

Age Related Considerations

As the incidence of advanced heart failure affecting the elderly increases, new elements for psychosocial assessment needs to be considered. Screening for pre-senile dementia and Alzheimer disease must be included in the evaluation, as these conditions may limit the patient's long term survival.

Recommendations for Psychological and Psychiatric Issues:

Class I:
1. Patients being considered for MCSD should have a detailed psychosocial evaluation.
   
   Level of Evidence: C.

2. A formal consultation with a psychiatrist should be obtained for those with concerns for mental illness. Appropriate pharmacologic and psychological therapy should be initiated as needed. Counseling may need to be extended to include family members as well.
   
   Level of Evidence: C.
Topic 7: Emergency Procedures for Device Malfunction or Failure

Introduction

As MCSD technology has improved, the incidence of MCSD mechanical failure has rapidly decreased. However, the risk of device malfunction or frank device failure has not been totally eliminated. With continuous flow devices, it is impossible to manually actuate the device in the event of pump stoppage. Therefore, it is critically important to train patients and caregivers in emergency procedures and to establish an algorithm to transport the patient emergently to the implanting center where pump exchange can be performed.

Before Discharge Home

The training of patients, family, and other designated caregivers should be performed in the implanting hospital by the MCSD team. The training should include recognition of the different device alarms, the proper response to them, and appropriate means of resolving emergency situations. The training should be based on theoretical knowledge supported by a written manual provided by the company for the specific system and on practical exercises demonstrated by MCSD team. There should be a final test (oral, written or both) to show that the individual and caregivers have understood and retained the information.

After Discharge Home

Patients, relatives, and caregivers should receive regular refresher courses during outpatient visits in the skills needed to resolve emergency situations.

Establishing an On-Call Notification Tree

Each MCSD center should establish an on-call system that patients and their caregivers are familiar with and have practiced contacting. The “first-call” provider should be expert in trouble-shooting MCSD related malfunctions.
Establishing a Transport System

In the event a patient has a medical emergency including pump malfunction, a transport system should exist to expedite returning the patient to the implanting center. For centers that encompass a large geographic referral area, this may include transportation by medical jet. A critical care transport team familiar with management of MCSD patients should be dispatched for the transfer.

Recommendations for Emergency Procedures with Device Malfunction or Failures:

Class I:
1. The patient and their caregivers should be trained to recognize MCSD alarms and troubleshoot emergencies prior to hospital discharge. This training should be delivered using both written materials and visual demonstrations and emergency response skills should be tested prior to the patient and caregiver leaving the hospital.

   Level of Evidence: C.

2. Ongoing refreshers should be provided to patients and caregivers at outpatient visits to ensure they remain competent in emergency procedures.

   Level of Evidence: C.

3. An emergency on-call algorithm should be established that patients and caregivers are familiar with, so they may quickly contact the implanting center in the event of emergencies.

   Level of Evidence: C.

4. An emergency transport system should be established to expedite transfer back to the implanting center in the case of emergency.

   Level of Evidence: C.

Topic 8: End of Life Issues

General End of Life Issues

The mean age of patients reported to the INTERMACS registry for the (primary) implantation of a MCSD is approximately 52 years (range 4.5 to 79.9). Especially in an
older population ethical questions such as “should MCSDs be implanted in patients of advanced aged?” or “are there guidelines for turning-off the pump?” are becoming more and more important, especially in the context of limited societal financial resources. Patients being considered for MCSD therapy must be fully informed of the risks and benefits of therapy with autonomous decision making. Advanced care planning should be undertaken including designation of a surrogate decision maker and exploration of the patient’s values and treatment preferences in the event that they are unable to express their wishes. This can be facilitated by preparation of a living will. Collaboration with a palliative care team may help the primary MCSD team introduce these issues and concepts to patients being evaluated for MCS.

**Deactivating the MCSD**

Similar to the considerations faced when deactivating an ICD, there are many issues to weigh when considering turning off a MCSD. The patient’s wishes, either directly expressed or relayed through a living will or surrogate decision maker, are of paramount importance. A consensus by the treating medical team that the chance of meaningful recovery is negligible would further corroborate the futility of ongoing MCSD support. A hospital ethicist may aid in making decisions about deactivating the MCSD when consensus does not exist, especially when family members are at odds with the patient directly or with the medical team.

**Palliation and MCSDs**

Recently published data in metastatic cancer patients demonstrated that early referral to palliative care lead to improvements in both quality of life and mood, with less aggressive care at the end of life, but longer survival compared to a group assigned to standard care. In a small series of MCSD patients, consultation with palliative medicine was obtained around the time of device implantation. Of the 19 patients studied, 13 (68%) completed advanced directives. This proactive approach to involving palliative medicine may help optimize symptom management and facilitate referral to hospice at the juncture when survival on the MCSD is determined to be limited due to device or non-device related issues.
Recommendations for End-of Life Issues:

Class I:

1. Consultation with palliative medicine should be considered prior to MCSD implantation to facilitate discussion of end-of-life issues and establish an advance directive or living will.

   **Level of Evidence: C.**

2. In situations when there is no consensus about discontinuing MCSD support, consideration may be given to consulting with the hospital ethicist or ethics board.

   **Level of Evidence: C.**
Figure Legends

Figure 1. Sample Field Guide for the HeartMate II® Device, Manufactured by Thoratec

Figure 2. Hemorrhagic and Thrombotic Adverse Events through Six Months in the HeartMate II Bridge to Transplant Trial

Figure 3: Use of Antithrombotic Therapy over Time in the HeartMate II Bridge to Transplant Trial

Figure 4: Time Course of Heart Transplantation and Mental Problems


Table 1: Selected Generic and Heart Failure Related Measures of QOL

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Number of items</th>
<th>Domains</th>
<th>Range of scores</th>
<th>Administration</th>
<th>Time required</th>
</tr>
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<tbody>
<tr>
<td><strong>General</strong></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>SF-36</td>
<td>36</td>
<td>Physical function</td>
<td>0-100</td>
<td>Self</td>
<td>5-10 minutes</td>
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<tr>
<td></td>
<td></td>
<td>Role-physical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Social functioning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Role-emotional</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Mental health</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Vitality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>General Health</td>
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<tr>
<td>Sickness Impact Profile</td>
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<td>Physical</td>
<td>0-100%</td>
<td>Interview or self</td>
<td>20-30 minutes</td>
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<td></td>
<td></td>
<td>Psychosocial</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Independent</td>
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<tr>
<td>EuroQol</td>
<td>6</td>
<td>Mobility</td>
<td>1-3 for each question, can be converted into a weighted summary score + a visual analog scale</td>
<td>Self</td>
<td>90 seconds</td>
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<td></td>
<td></td>
<td>Self-care</td>
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<td>Usual activities</td>
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<td>Pain</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Depression</td>
<td></td>
<td></td>
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<tr>
<td><strong>Heart Failure Specific</strong></td>
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<td>Minnesota Living with Heart Failure Questionnaire</td>
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<td>Emotional</td>
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<td>Dyspnea</td>
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<td>Fatigue</td>
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<td></td>
<td>Emotional</td>
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<td>Items</td>
<td>Score Range</td>
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<tr>
<td>Quality of Life</td>
<td>Psychological activity, Physical activity, Life dissatisfaction, Somatic Symptoms</td>
<td>0-130</td>
<td>Best to worst</td>
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<td></td>
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<td></td>
<td>26</td>
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<tr>
<td>Kansas City Cardiomyopathy Questionnaire</td>
<td>Physical limitations, Symptoms, Self-efficacy, Social limitation, Quality of life</td>
<td>0-100</td>
<td>Worst to best</td>
<td></td>
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<tr>
<td></td>
<td>23</td>
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Table 2 - Anticoagulation and Antiplatelet Therapy for Approved Mechanical Circulatory Support Devices

<table>
<thead>
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<th>Device</th>
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<tbody>
<tr>
<td>AbioCor TAH</td>
<td>2.5 – 3.5</td>
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<tr>
<td>HeartMate XVE</td>
<td>No warfarin</td>
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<tr>
<td>HeartMate II</td>
<td>1.5-2.5</td>
</tr>
<tr>
<td>HeartWare HVAD</td>
<td>2.0-3.0</td>
</tr>
<tr>
<td>MicroMed DeBakey</td>
<td>2.5 – 3.5</td>
</tr>
<tr>
<td>Syncardia TAH</td>
<td>2.5 – 3.5</td>
</tr>
<tr>
<td>Thoratec IVAD</td>
<td>2.5 – 3.5</td>
</tr>
<tr>
<td>Thoratec PVAD</td>
<td>2.5 – 3.5</td>
</tr>
</tbody>
</table>
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Figure 2: Hemorrhagic and Thrombotic Adverse Events through Six Months in the HeartMate II Bridge to Transplant Trial

Figure 3: Use of Antithrombotic Therapy over Time in the HeartMate II Bridge to Transplant Trial

Anticoagulant - Labeling Cohort

Percentage of patients

0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1

Warfarin  ASA  Dipyrid  Trenal  Plavix  Other

Month 1  Month 2  Month 3  Month 4  Month 5  Month 6
Figure 4: Time Course of Heart Transplantation and Mental Problems

Fig. 4. The time course of heart transplantation and mental problems. In candidates who waited for several months or more in the hospital for transplantation, some emotional reactions occurred. The y-axis represents the instability of the patients' emotions, with instability increasing in the downward direction. Solid line, most candidates; dotted line, some candidates; LVAD, left ventricular assist device.