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ISHLT GUIDELINES

The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: Executive summary

Co-chairs: David Feldman, MD, PhD;* Salpy V. Pamboukian, MD, MSPH;*
Jeffrey J. Teuteberg, MD;*
Task Force Chairs (exclusive of co-authors): Emma Birks, MD; Katherine Lietz, MD;
Stephanie A. Moore, MD; Jeffrey A. Morgan, MD
Contributing Writers (exclusive of co-chairs or chairs): Francisco Arabia, MD; Mary E. Bauman, MScN, NP;
Hoger W. Buchholz, MD; Mario Deng, MD; Marc L. Dickstein, MD; Aly El-Banayosy, MD; Tonya Elliot, RN, MSN;
Daniel J. Goldstein, MD; Kathleen L. Grady, PhD, APN; Kylie Jones, RN; Katarzyna Hryniewicz, MD;
Ranjit John, MD; Annemarie Kaan, MCN, RN; Shimon Kusne, MD; Matthias Loebe, MD, PhD;
M. Patricia Massicotte, MHSc, MD; Nader Moazami, MD; Paul Mohacsi, MD; Martha Mooney, MD;
Thomas Nelson, MD; Francis Pagani, MD; William Perry, RN;
Evgenij V. Potapov, MD; J. Eduardo Rame, MD, MPhil; Stuart D. Russell, MD;
Erik N. Sorensen, PhD; Benjamin Sun, MD; and Martin Strueber, MD
Independent Reviewers: Abeel A. Mangi, MD; Michael G. Petty, PhD,RN; and Joseph Rogers, MD.

INSTITUTIONAL AFFILIATIONS
Co-chairs: Feldman D: Minneapolis Heart Institute, Minneapolis, Minnesota, Georgia Institute of Technology and Morehouse School of Medicine; Pamboukian SV: University of Alabama at Birmingham, Birmingham, Alabama; Teuteberg JJ: University of Pittsburgh, Pittsburgh, Pennsylvania
Task force chairs: Birks E: University of Louisville, Louisville, Kentucky; Lietz K: Loyola University, Chicago, Maywood, Illinois; Moore SA: Massachusetts General Hospital, Boston, Massachusetts; Morgan JA: Henry Ford Hospital, Detroit, Michigan
Contributing writers: Arabia F: Mayo Clinic Arizona, Phoenix, Arizona; Bauman ME: University of Alberta, Alberta, Canada; Buchholz HW: University of Alberta, Stollery Children's Hospital and Mazankowski Alberta Heart Institute, Edmonton, Alberta, Canada; Deng M: University of California at Los Angeles, Los Angeles, California; Dickstein ML: Columbia University, New York, New York; El-Banayosy A: Penn State Milton S. Hershey Medical Center, Hershey, Pennsylvania; Elliot T: Inova Fairfax, Falls Church, Virginia; Goldstein DJ: Montefiore Medical Center, New York, New York; Grady KL: Northwestern University, Chicago, Illinois; Jones K: Alfred Hospital, Melbourne, Australia; Hryniewicz K: Minneapolis Heart Institute, Minneapolis, Minnesota; John R: University of Minnesota, Minneapolis, Minnesota; Kaan A: St. Paul's Hospital, Vancouver, British Columbia, Canada; Kusne S: Mayo Clinic Arizona, Phoenix,

*Co-first authors contributed equally and are listed in alphabetical order.

Reprint requests: Amanda W. Rowe, International Society for Heart and Lung Transplantation, 14673 Midway Rd, Ste 200, Addison, TX 75001. Telephone: 804-873-2541; Fax: 817-912-1237.
E-mail address: amanda.rowe@ishlt.org

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Arizona; Loebe M: Methodist Hospital, Houston, Texas; Massicotte P: University of Alberta, Stollery Children's Hospital, Edmonton, Alberta, Canada; Moazami N: Minneapolis Heart Institute, Minneapolis, Minnesota; Mohacsi P: University Hospital, Bern, Switzerland; Mooney M: Sentara Norfolk, Virginia Beach, Virginia; Nelson T: Mayo Clinic Arizona, Phoenix, Arizona; Pagani F: University of Michigan, Ann Arbor, Michigan; Perry W: Integris Baptist Health Care, Oklahoma City, Oklahoma; Potapov EV: Deutsches Herzzentrum Berlin, Berlin, Germany; Rame JE: University of Pennsylvania, Philadelphia, Pennsylvania; Russell SD: Johns Hopkins, Baltimore, Maryland; Sorensen EN: University of Maryland, Baltimore, Maryland; Sun B: Minneapolis Heart Institute, Minneapolis, Minnesota; Strueber M: Hannover Medical School, Hanover, Germany

Independent reviewers: Mangi AA: Yale University School of Medicine, New Haven, Connecticut; Petty MG: University of Minnesota Medical Center, Fairview, Minneapolis, Minnesota; Rogers J: Duke University Medical Center, Durham, North Carolina

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The field of mechanical circulatory support (MSC) has made tremendous progress in the past 15 years. Thousands of patients worldwide have undergone implantation of long-term MSC devices (MCSDs). Currently, management of patients with MCSDs has been guided by individual clinicians and center-specific protocols. There have been few randomized studies to guide patient selection and care of the MCS patient. Short-term success with MCS therapy largely depends on patient selection, surgical technique, and post-operative management. Long-term success depends on physician and patient engagement in excellent care of their device and personal health. The International Society for Heart and Lung Transplantation (ISHLT) has made a commitment to convene an international and multidisciplinary panel of experts in MCS care.

The document results from the work of 5 Task Force Groups:

- Task Force 1 addresses the important issue of patient selection for permanent pump implantation. This section covers (1) the referral of patients for MCSD implantation, (2) evaluation of patients considered for MCSD implantation, which includes clinical assessment of heart failure, heart failure etiology, anatomic considerations, (3) medical and psychosocial evaluation, and (4) assessment of operative risk. Relative vs absolute contraindications are discussed as well as ethical dilemmas associated with this topic.
- Task Force 2 discusses the mechanisms that are important for patient optimization prior to device implantation. This section covers (1) management of cardiac and non-cardiac risk factors, (2) optimizing patients with relative contraindications and (3) informed consent and ethical issues as a continuum from Task Force 1. MCS patients once consented are members of their care team before implantation. Recommendations for multidisciplinary care, education, and psychosocial support are found in this Task Force.
- Task Force 3 discusses the intraoperative considerations and immediate post-operative care in the intensive care unit (ICU) setting. This section covers (1) anesthesia, (2) implantation techniques, (3) explantation techniques, (4) complex anatomic considerations, and (5) early post-operative management in the ICU.
- Task Force 4 addresses inpatient management during the post-operative phase, once the patient is out of the ICU through discharge, and during readmission to the hospital. This section covers (1) right ventricular (RV) and hemodynamic management, (2) anti-coagulation, (3) adjunct medical therapy, (4) driveline care, (5) psychosocial support and suitability for discharge to home, and (6) common reasons for hospital readmission and approaches to their management.
- Task Force 5 discusses the long-term outpatient care of the MCS patient using a multidisciplinary approach. This section covers (1) the outpatient management of device-related issues, (2) patient medical management and monitoring, (3) psychosocial long-term support, and (4) continued education of the patient and family.

It is important to note that every effort has been made to include as contributing writers cardiologists, cardiac surgeons, MCS coordinators, and other members of the multidisciplinary team. Because the guidelines are international, we also tried to balance perspective from different countries as best possible.

As the reader of these guidelines will observe, most of the recommendations are level of evidence C or consensus agreement. Gaps in evidence are highlighted where appropriate. Because MCS is an evolving field, device availability varies from center to center. We aim to address general issues of long-term use and not to focus on nuances of individual devices. Each manufacturer has recommendations for its specific device. There are also different indications for MCS, depending on patient urgency, and often, short-term MCS is emergently utilized. The focus of this document is long-term device therapy with the goal of patient discharge from the hospital. There is limited mention of short-term MCS support for acute shock patients in Task Force 1, 2, and 3. Lastly, we hope that these guidelines will

provide an impetus for organized dissemination of best practices from various centers with excellent outcomes into the literature to further the field of MCS.

Task Force 1: Selection of candidates for MCS and risk management prior to implantation for fixed comorbidities

Chair: Katherine Lietz, MD

Contributing Writers: Mario Deng, MD; David Feldman, MD, PhD; Annemarie Kaan, MCN, RN; Salpy V. Pamboukian, MD, MSPH; J. Eduardo Rame, MD, MPhil; Jeffrey J. Teuteberg, MD

Reviewers: Emma Birks, MD; Francis Pagani, MD; Michael G. Petty, PhD, RN; Abeel A. Mangi, MD

Topic 1: Patient selection

Recommendations for the evaluation process of MCS candidates:[1–7]

Class I:

1. All patients should have any reversible causes of heart failure addressed prior to consideration for MCS.
   Level of evidence: A.
2. All patients referred for MCS should have their transplant candidacy assessed prior to implant.
   Level of evidence: A.

Recommendations for the clinical classification of MCS candidates:[7]

Class I:

1. All patients being considered for MCS should have their New York Heart Association functional class assessed.
   Level of evidence: C.
2. All patients being assessed for MCS should have their Interagency Registry for Mechanically Assisted Support (INTERMACS) profile determined.
   Level of evidence: C.

Recommendations for risk stratification for consideration of MCS:[8–30]

Class IIa:

1. Long-term MCS for patients who are in acute cardiogenic shock should be reserved for the following:
   a. Patients whose ventricular function is deemed unrecoverable or unlikely to recover without long-term device support.
   b. Patients who are deemed too ill to maintain normal hemodynamics and vital organ function with temporary MCSDs, or who cannot be weaned from temporary MCSDs or inotropic support.
   c. Patients with the capacity for meaningful recovery of end-organ function and quality of life.
   d. Patients without irreversible end-organ damage.
   Level of evidence: C.
2. Patients who are inotrope-dependent should be considered for MCS because they represent a group with high mortality with ongoing medical management.
   Level of evidence: B.
3. Patients with end-stage systolic heart failure who do not fall into recommendations 1 and 2 above should undergo routine risk stratification at regular intervals to determine the need for and optimal timing of MCS. This determination may be aided by risk assessment calculators and cardiopulmonary stress testing.
   Level of evidence: C.
4. Heart failure patients who are at high-risk for 1-year mortality using prognostic models should be referred for advanced therapy including heart transplant, or MCS (bridge to transplantation [BTT] or destination therapy [DT]) as appropriate.
   Level of evidence: C.

Topic 2: Risk management of comorbidities

Recommendations for patients with coronary artery disease:[31,32]

Class IIa:

1. Patients being considered for MCS who have a history of coronary artery bypass grafting should have a chest computed tomography (CT) scan to provide the location and course of the bypass grafts to guide the surgical approach.
   Level of evidence: C.

Recommendations for patients with acute myocardial infarction:

Class IIb:

1. If possible, permanent MCS should be delayed in the setting of an acute infarct involving the left ventricular (LV) apex.
   Level of evidence: C.

Recommendations for the evaluation of MCS candidates with congenital heart disease:

Class I:

1. All patients with congenital heart disease should have recent imaging to fully document cardiac morphology, assess for the presence of shunts or collateral vessels, and the location and course of their great vessels.
   Level of evidence: C.

Class IIa:

1. Patients with complex congenital heart disease, atypical situs, or residual intraventricular shunts who are not candidates for LV support should be considered for a total artificial heart.
   Level of evidence: C.

Recommendations for aortic valve disease:

Class I:

1. Functioning bioprosthetic valves do not require removal or replacement at the time of implant.
   Level of evidence: C.

2. Replacement of a pre-existing aortic mechanical valve with a bioprosthetic valve or oversewing the aortic valve at the time of implantation is recommended.
   Level of evidence: C.

Recommendations for aortic regurgitation:
Class I:

1. More than mild aortic insufficiency should prompt consideration for surgical intervention during device implantation.
   Level of evidence: C

Recommendations for aortic stenosis:
Class I:

1. Patients with aortic stenosis of any degree that is accompanied by more than mild aortic insufficiency should prompt consideration for a bioprosthetic aortic valve replacement during MCS implant (see Section 3).
   Level of evidence: C.

Class IIb:

1. Patients with severe aortic stenosis may be considered for aortic valve replacement, regardless of the degree of concomitant aortic insufficiency.
   Level of evidence: C.

Recommendations for aortic root disease:
Class IIa:

1. Patients with a history of vascular disease and/or coronary artery disease should have a pre-operative assessment of their ascending aorta for aneurysmal dilation and atherosclerotic burden with a CT scan prior to implant.
   Level of evidence: C.

Recommendations for mitral valve:
Class IIb:

1. Severe mitral insufficiency is not a contraindication to MCS and does not routinely require surgical repair or valve replacement, unless there is expectation of ventricular recovery.
   Level of evidence: C.

Class III:

1. Routine mitral valve repair or replacement for severe mitral regurgitation is not recommended.
   Level of evidence: C.

Recommendations for mitral valve stenosis:
Class I:

1. Valve replacement with a tissue valve should be considered if there is moderate or worse mitral valve stenosis at the time of left ventricular assist device (LVAD) implantation.
   Level of evidence: C

Recommendations for mechanical mitral valves:
Class III:

1. Routine replacement of properly functioning mechanical mitral valve is not recommended.
   Level of evidence: C.

Recommendations for tricuspid valve regurgitation:
Class IIa:

1. Moderate or greater tricuspid regurgitation should prompt consideration of surgical repair at the time of implant.
   Level of evidence: C.

Recommendations for infective endocarditis:
Class I:

1. Device implantation in patients who have been bacteremic should have documented clearance of the bacteremia for at least 5 days on appropriate anti-microbial therapy. This anti-microbial therapy should include a total duration of at least 7 total days prior to MCSD implantation.
   Level of evidence: C.

Class III:

1. Acute valvular infectious endocarditis with active bacteremia is an absolute contraindication to MCS implantation.
   Level of evidence: C.
2. Active infection of an implantable cardioverter defibrillator (ICD) or pacemaker with bacteremia is an absolute contraindication to MCS implantation.
   Level of evidence: C.

Recommendations for intracardiac shunts:
Class I:

1. Atrial septal defects and patent foramen ovale should be closed at the time of MCS implantation.
   Level of evidence: C.

Class III:

1. An LVAD alone in the setting of an unrepairable ventricular septal defect or free wall rupture is not recommended.
   Level of evidence: C.

Recommendations for intracardiac thrombus:
Class IIa:

1. Echocardiography or CT, with contrast when necessary, should be used pre-operatively to screen for intracardiac thrombus.
   Level of evidence: C.

Recommendations for atrial arrhythmias:

Class I:

1. Atrial flutter or fibrillation is not a contraindication to MCS.
   Level of evidence: C.

Class IIa:

1. Patients with medically refractory atrial tachyarrhythmias may benefit from ablation of the arrhythmia or atrioventricular node (with subsequent ICD/pacemaker placement) prior to LVAD implantation.
   Level of evidence: C.

Recommendations for arrhythmia therapy:

Class IIa:

1. Patients with treatment-refractory recurrent sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) in the presence of untreatable arrhythmogenic pathologic substrate (eg, giant cell myocarditis, scar, sarcoidosis), should not be considered for LV support alone, but rather biventricular support or a total artificial heart.
   Level of evidence: C.

Recommendations for peripheral vascular disease:[33–35]

Class IIa:

1. All patients with known atherosclerotic vascular disease or significant risk factors for its development should be screened for peripheral vascular disease prior to MCS.
   Level of evidence: C.

Class IIb:

1. Peripheral vascular disease may be a relative contra-indication to MCS based on its extent and severity.
   Level of evidence: C.

Recommendations for life-limiting comorbidities and multiorgan failure:[4]

Class III:

1. Consideration of MCS in the setting of irreversible multiorgan failure is not recommended.
   Level of evidence: C.

Recommendations for pulmonary hypertension[36–38]

Class I:

1. All patients being considered for MCS should have an invasive hemodynamic assessment of pulmonary vascular resistance.
   Level of evidence: C.

Recommendations for neurologic function:[39]

Class I:

1. A thorough neurologic examination should be performed on every patient being considered for MCS. Neurologic consultation should be obtained for patients with significant neurologic disease or dementia, or significant atherosclerotic vascular disease of their carotid or vertebral systems.
   Level of evidence: C.
2. All patients being considered for MCS should have a carotid and vertebral Doppler examination as a screen for occult vascular disease.
   Level of evidence: C.
3. CT scan or magnetic resonance imaging is warranted in patients with previous stroke to establish a pre-operative baseline study.
   Level of evidence: C.

Class III:

1. MCS is not recommended in patients with neuromuscular disease that severely compromises their ability to use and care for external system components or to ambulate and exercise.
   Level of evidence: C.

Recommendations for coagulation and hematologic disorders:[40–44]

Class I:

1. All patients evaluated for MCS therapy should have a prothrombin time/international normalized ratio (INR), partial thromboplastin time, and platelet assessed pre-operatively.
   Level of evidence: C.
2. Baseline abnormalities in coagulation parameters not due to pharmacologic therapy should prompt an evaluation to determine the etiology prior to implant.
   Level of evidence: C.
3. Patients with a history of thrombophilia prior to MCS should have a hypercoagulable assessment before implant.
   Level of evidence: C.

Class IIa:

1. Patients with a clinical syndrome of heparin-induced thrombocytopenia should have confirmatory testing performed.
   Level of evidence: C.
2. Thienopyridine anti-platelet agents should be stopped at least 5 days prior to surgery unless there is a compelling indication for continued use.
   Level of evidence: C.

Recommendations for malignancy:

Class I:

1. Patients with a history of a treated cancer who are in long-term remission or who are considered free of

disease may be candidates for MCS as BTT, with the involvement of an oncologist to determine risk of recurrence or progression.
Level of evidence: C.

Class IIa:

1. Patients with a history of recently treated or active cancer who have a reasonable life-expectancy (>2 years) may be candidates for DT if evaluated in conjunction with an oncologist to determine risk.
Level of evidence: C.

Class III:

1. MCS as BTT or DT is not recommended for patients with an active malignancy and a life expectancy of <2 years.
Level of evidence: C.

Recommendations for diabetes:[45–47]

Class I:

1. All patients should be screened for diabetes with a fasting glucose prior to MCS.
Level of evidence: C.
2. All patients with an abnormal fasting glucose or established diabetes should have a hemoglobin A_{1c} assessed and be evaluated for the degree of end-organ damage (retinopathy, neuropathy, nephropathy, and vascular disease).
Level of evidence: C.
3. Patients with poorly controlled diabetes should have a consultation with an endocrinologist prior to implantation.
Level of evidence: C.

Class IIb:

1. MCS is relatively contraindicated in the setting of diabetes-related proliferative retinopathy, very poor glycemic control, or severe nephropathy, vasculopathy, or peripheral neuropathy.
Level of evidence: C.

Recommendations for pregnancy:[48–51]

Class I:

1. Use of contraception in women of childbearing age after MCS is recommended.
Level of evidence: C.

Class III:

1. MCS in the setting of active pregnancy is not recommended.
Level of evidence: C.

Recommendations for age:[52,53]

Class IIb:

1. Patients aged > 60 years should undergo thorough evaluation for the presence of other clinical risk factors that may decrease survival or quality of life after MCS.
Level of evidence: C.

Recommendations for psychologic and psychiatric evaluation:[54–61]

Class I:

1. All patients should have a screen for psychosocial risk factors prior to MCS.
Level of evidence: C.
2. All patients should have a screen for cognitive dysfunction prior to MCS.
Level of evidence: C.
3. Family, social, and emotional support must be assessed prior to MCS.
Level of evidence: C.
4. Patients with a history of a significant psychiatric illness who are considered for MCS should undergo a thorough psychiatric and psychologic evaluation to identify potential risk factors.
Level of evidence: C.

Class III:

1. MCS should not be performed in patients who are unable to physically operate their pump or respond to device alarms. In addition, an inability to report signs and symptoms of device malfunction or other health care needs to the MCS team, or patients who live in an unsafe environment are all contraindications to implantation.
Level of evidence: C.
2. MCS is not recommended in patients with active psychiatric illness that requires long-term institutionalization or who have the inability to care for or maintain their device.
Level of evidence: C.

Recommendations for adherence to medical therapy and social network:[59–63]

Class I:

1. Assessment of medical compliance, social support, and coping skills should be performed in all candidates for MCS device implantation.
Level of evidence: C.

Class IIa:

1. Lack of sufficient social support and limited coping skills are relative contraindications to MCS in patients with a history of non-adherent behavior.
Level of evidence: C.

Class III:

1. Poor compliance with medical regimens is a risk factor for poor outcomes related to MCS and death after heart

transplantation. Patients who demonstrate an inability to comply with medical recommendations on multiple occasions should not receive MCS.

Level of evidence: C.

Recommendations for tobacco use:

Class I:

1. Patients considered for MCS implantation should receive education on the importance of tobacco cessation and reduction in environmental and second-hand exposure before device implantation and throughout the duration of device support.

   Level of evidence: C.

Class IIa:

1. Previous tobacco use should not preclude emergent pump implantation as a potential BTT. However, patients should not be made active on the transplant waiting list until 6 months of nicotine abstinence has been proven.

   Level of evidence: C.

Recommendations for alcohol and substance abuse:[64]

Class IIb:

1. The patient should be abstinent for a period of time as determined a priori by the program in order to be considered for MCS therapy.

   Level of evidence: C.

Class III:

1. Active substance abusers (including alcohol) should not receive MCS therapy.

   Level of evidence: C.

Recommendations for caregiver burden:[65–68]

Class I:

1. Caregiver burden should be assessed prior to MCS implantation to assure that support will be available. Agreement on behalf of the patient is not sufficient.

   Level of evidence: C.

Class IIb:

1. Significant caregiver burden or lack of any caregiver is a relative contraindication to the patient's MCS implantation.

   Level of evidence: C.

Recommendation for the evaluation of patient's financial situation and insurance coverage:

Class IIa:

1. A mechanism must be in place to provide financial aid or support for post-operative care for those who have limitations to medical coverage. Depending on the country, this may be provided by the government, an insurance agent, or an individual's family.

   Level of evidence: C.

Task Force 2: Patient optimization, consent, and appropriate timing for MCS: Modifiable risk management prior to implantation

Co-chairs: Emma Birks, MD; David Feldman, MD, PhD

Contributing Writers: Katarzyna Hryniewicz, MD; Nader Moazami, MD; William Perry, RN; J. Eduardo Rame, MD; Benjamin Sun, MD; Jeffrey J. Teuteberg, MD

Independent Reviewer: Francis Pagani, MD

Recommendations for obesity:[2,69–73]

Class I:

1. Obesity (body mass index 30–35 kg/m^2), in and of itself, is not a contraindication to MCS, but surgical risk and attendant comorbidities must be carefully considered prior to MCS in the morbidly obese patient (body mass index $\geq$ 35 kg/m^2).

   Level of evidence: B.

Recommendations for managing patient expectations:[2,74,75]

Class I:

1. A detailed informed consent should discuss the salient aspects of the MCSD placement, common expectations, and possible complications in the peri-operative and post-operative period.

   Level of evidence: C.

Class IIb:

1. Quality of life should be assessed before and after MCSD implantation to help guide patient decisions. Assessment tools, including Minnesota Living with Heart Failure questionnaire, Sickness Impact Profile, EuroQol, and others should be considered to help guide patient care.

   Level of evidence: C.

Recommendations for palliative care:[76,77]

Class IIa:

1. Palliative care consultation should be a component of the treatment of end-stage heart failure during the evaluation phase for MCS. In addition to symptom management, goals and preferences for end of life should be discussed with patients receiving MCS as DT.

   Level of evidence: C.

Recommendations for managing renal function:[78–88]

Class I:

1. All patients should have their renal function monitored closely prior to MCSD implantation.

   Level of evidence: C.

2. Patients with volume overload and/or poor output in the setting of renal dysfunction should have a period of hemodynamic optimization (with inotropic support if clinically indicated) combined with aggressive diuresis or mechanical volume removal.
   Level of evidence: C.
3. Assessment of serum creatinine, blood urea nitrogen, and a 24-hour urine collection for creatinine clearance and proteinuria after patients are hemodynamically optimized should be performed in all patients being considered for MCS.
   Level of evidence: C.

Class III:

1. Permanent dialysis should be a contraindication for destination therapy.
   Level of evidence: C.

Recommendations for nutrition assessment:[89,90]

Class I:

1. All patients should have assessment of their nutritional status prior to MCSD implantation with at least a measurement of albumin and pre-albumin.
   Level of evidence: B.
2. Patients who have indices of malnutrition prior to MCSD implantation should have an evaluation by a nutritional consultation service.
   Level of evidence: C.

Class IIa:

1. Patients who have evidence of malnutrition prior to MCSD implantation should be considered for nutritional interventions prior to implantation if the patient's clinical status allows.
   Level of evidence: C.

Class IIb:

1. Patients who have evidence of severe malnutrition prior to MCSD implantation should consider having implantation delayed to maximize their nutritional status, if the patient's clinical status allows.
   Level of evidence: C.

Recommendations for managing infection risk:[91–94]

Class I:

1. All patients should have all unnecessary lines and catheters removed prior to MCSD implantation.
   Level of evidence: C.
2. All patients should have a dental assessment and any remedial treatment, if time and clinical status permits, prior to MCSD implantation.
   Level of evidence: C.

Recommendations for managing active infection:

Class I:

1. Patients with active infections should receive an appropriate course of antibiotic therapy, as directed by an infectious disease specialist, prior to MCSD implantation.
   Level of evidence: C.

Recommendations for antibiotic prophylaxis:[95–97]

Class I:

1. Patients should receive pre-operative antibiotics with broad-spectrum gram-positive and gram-negative coverage, as appropriate, prior to MCSD implantation.
   Level of evidence: C.
2. Routine antibiotic prophylaxis should include at least 1 dose prior to surgery administered within 60 minutes of the first incision, remain in the therapeutic range throughout the duration of their use, and not extend beyond 24 to 48 hours.
   Level of evidence: C.
3. Patients should have a nasal swab to screen for methicillin-resistant *Staphylococcus aureus* and receive topical treatment if positive prior to MCSD implantation.
   Level of evidence: C.

Recommendations for hepatic dysfunction:[3,40,85,86,98–102]

Class I:

1. Patients with a history of liver disease, abnormalities of liver function tests, chronic right heart failure, or Fontan physiology should have an ultrasound assessment of their liver to screen for cirrhosis prior to MCSD implantation.
   Level of evidence: C.
2. Patients who have suspected cirrhosis should receive further radiologic and tissue confirmation in conjunction with a hepatology consultation.
   Level of evidence: C.
3. Patients with abnormal liver function and decompensated hemodynamics should receive aggressive therapy aimed at the restoration of hepatic blood flow and reduction of hepatic congestion.
   Level of evidence: C.

Class II:

1. Patients with an elevated INR not due to warfarin therapy should be considered for treatment prior to MCSD implantation, and efforts should be made to optimize nutrition and right-sided intracardiac filling pressures.
   Level of evidence: C.

Class III:

1. Patients with confirmed cirrhosis or an increased Model for End Stage Liver Disease (MELD) score are poor candidates for MCSD therapy.
   Level of evidence: B.

Recommendations for pulmonary and thoracic assessment:[103–117]

Class I:

1. Patients should have a chest X-ray and an arterial blood gas assessment prior to MCSD implantation.
   Level of evidence: C.
2. Patients should have some assessment of thoracic anatomy prior to MCSD implantation or in the setting of prior surgery or suspected thoracic abnormalities. These may include a radiologic examination with CT or magnetic resonance imaging.
   Level of evidence: C.
3. Positive airway pressure, early ambulation, induced cough, incentive spirometry, and effective pain control subsequent to surgery may all decrease post-operative complications.
   Level of evidence: C.

Recommendations for management of patients with decompensated heart failure:[1,118–120]

Class I:

1. Short-term mechanical support, including extracorporeal membrane oxygenation, should be used in acutely decompensated patients who are failing maximal medical therapy.
   Level of evidence: C.

Recommendations for temporary mechanical support:[119,121–129]

Class I:

1. The use of temporary mechanical support should be strongly considered in patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurologic assessment prior to placement of a long-term MCSD.
   Level of evidence: C.

Recommendations for assessing RV function:[102,130–139]

Class I:

1. All patients should have an echocardiographic assessment of RV function prior to MCSD implantation.
   Level of evidence: C.
2. All patients should have invasive assessment of intracardiac filling pressures prior to MCSD implantation, with a particular emphasis on RV hemodynamics.
   Level of evidence: C.

Recommendations for management of RV dysfunction: [3,4,31,79,134,135,139–142]

Class I:

1. Pre-operatively, patients with evidence of RV dysfunction should be admitted to the hospital for aggressive management, which may include diuresis, ultrafiltration, inotropes, intra-aortic balloon pump, or other short-term mechanical support. Once optimized, RV function should be reassessed.
   Level of evidence: C.
2. RV dysfunction post-MCS should be managed with diuresis, inotropes, and pulmonary vasodilators, including nitric oxide or inhaled prostacyclin. RV dysfunction refractory to medical management may require placement of a short-term or long-term mechanical RV support device.
   Level of evidence: C.

Class IIb:

1. Phosphodiesterase 5 inhibitors may be considered for management of RV dysfunction in the setting of pulmonary hypertension after MCS.
   Level of evidence: C.

Task Force 3: Intraoperative and immediate post-operative management

Chair: Jeffrey A. Morgan, MD

Contributing Writers: Marc L. Dickstein, MD; Aly El-Banayosy, MD; Daniel J. Goldstein, MD; Matthias Loebe, MD, PhD; Erik N. Sorensen, PhD; Martin Strueber, MD

Independent Reviewer: Francis Pagani, MD

Topic 1: Anesthesia-related issues

Recommendations for managing anesthesia issues:[143–157]

Class I:

1. Patients undergoing MCSD placement should have insertion of a large-bore intravenous line, arterial line, and pulmonary artery catheter to allow for continuous monitoring and intravascular access.
   Level of evidence: B
2. Cardiac anesthesia should be performed by those familiar with the clinical issues associated with MCSD placement, including considerations at the time of induction, during surgery, during separation from cardiopulmonary bypass, and at the time the MCSD is actuated.
   Level of evidence: B
3. Intraoperative transesophageal echocardiography should be performed by physicians with advanced training in the intraoperative assessment of cardiac structure and function.
   Level of evidence: B

Topic 2: Implantation techniques

Implant techniques vary with pump type; readers are referred to the on-line document for a full discussion of these issues (available on the JHLTonline.org Web site).

Topic 3: Special considerations for VAD implantation

These considerations may vary with pump type; readers are referred to the on-line document for a full discussion of these issues (available on the JHLTonline.org Web site).

Topic 4: Explantation techniques: Explantation of LVADs for heart transplantation

Explant techniques vary with pump type; readers are referred to the on-line document for a full discussion of these issues (available on the JHLTonline.org Web site).

Topic 5: Early post-operative management: Hemodynamic management

Recommendations for early post-operative hemodynamic management are presented in Table 1.[88,158,159] Figure 1 provides recommendations for low pump output treatment. Early post-operative anti-coagulation management recommendations are presented in Tables 2, 3, and 4.[43,87,160–167] Table 5 provides guidelines for removal of invasive lines and drains in a stable post-operative MCS patient. Ventilation parameters for the early post-operative period are outlined in Table 6.[159,168–170] Table 7 outlines suggested guidelines for feeding, mobility issues, and discharge preparation.

Task Force 4: Inpatient management of patients with MCSDs

Co-chairs: Stephanie A. Moore, MD; Salpy V. Pamboukian MD, MSPH; Jeffrey J. Teuteberg, MD

Contributing writers: Francisco Arabia, MD; Mary E. Bauman, MScN, NP; Hoger W. Buchholz, MD; Ranjit John, MD; David Feldman, MD, PhD; Kathleen L. Grady, PhD, APN; Kylie Jones, RN; Shimon Kusne, MD; M. Patricia Massicotte, MHSc, MD; Martha Mooney, MD; Thomas Nelson, MD; Francis Pagani, MD

Recommendations for the treatment of right heart dysfunction in the non-ICU post-operative period:[172,173]

Class I:

1. Inotropic support may need to be continued into the remote post-operative period (> 2 weeks) when there is evidence for right heart dysfunction such as elevated jugular venous pressure, signs of venous congestion, decreased VAD flows (or low pulsatility in continuous-flow MCSD), or end-organ dysfunction. Once euvolemic, inotrope wean should be done cautiously, with ongoing examination for recurrent signs and symptoms of RV dysfunction.
   Level of evidence: C.
2. Diuretics and renal replacement therapy, such as continuous venovenous hemofiltration, should be used early and continued as needed to maintain optimal volume status.
   Level of evidence: C.

Class IIb

1. Cardiac glycosides may be used to support RV function.
   Level of evidence: C.
2. For patients with persistent pulmonary hypertension who exhibit signs of RV dysfunction, pulmonary hypertension-specific therapies, such as phosphodiesterase-5 inhibitors, should be considered.
   Level of evidence: C.
3. Pacemaker therapy can be used if the heart rate is not optimal to support hemodynamics.
   Level of evidence: C.

Table 1 Treatment Recommendations for Early Post-operative Hemodynamic Management

Cardiac index (liters/min/m^2)	MAP (mm Hg)	LV ejection	Primary recommendation	Alternative
< 2.2	< 65	No	Epinephrine Vasopressin Norepinephrine	Dopamine
		Yes	Increase pump speed	Volume for low CVP
	> 65	No	Dobutamine	Milrinone
		Yes	Increase pump speed	
	> 90	No	Milrinone	Sodium nitroprusside
		Yes	Sodium nitroprusside Nitroglycerin Hydralazine	Milrinone Nicardipine
> 2.2	< 65	No	Norepinephrine	Vasopressin
		Yes	Norepinephrine	Vasopressin
	> 65 and < 90	No	No intervention	
		Yes	No intervention	
	> 90	No	Sodium nitroprusside Nitroglycerin Hydralazine	Milrinone Nicardipine
		Yes	Sodium nitroprusside	Nicardipine

CVP, central venous pressure; LV, left ventricular; MAP, mean arterial pressure.

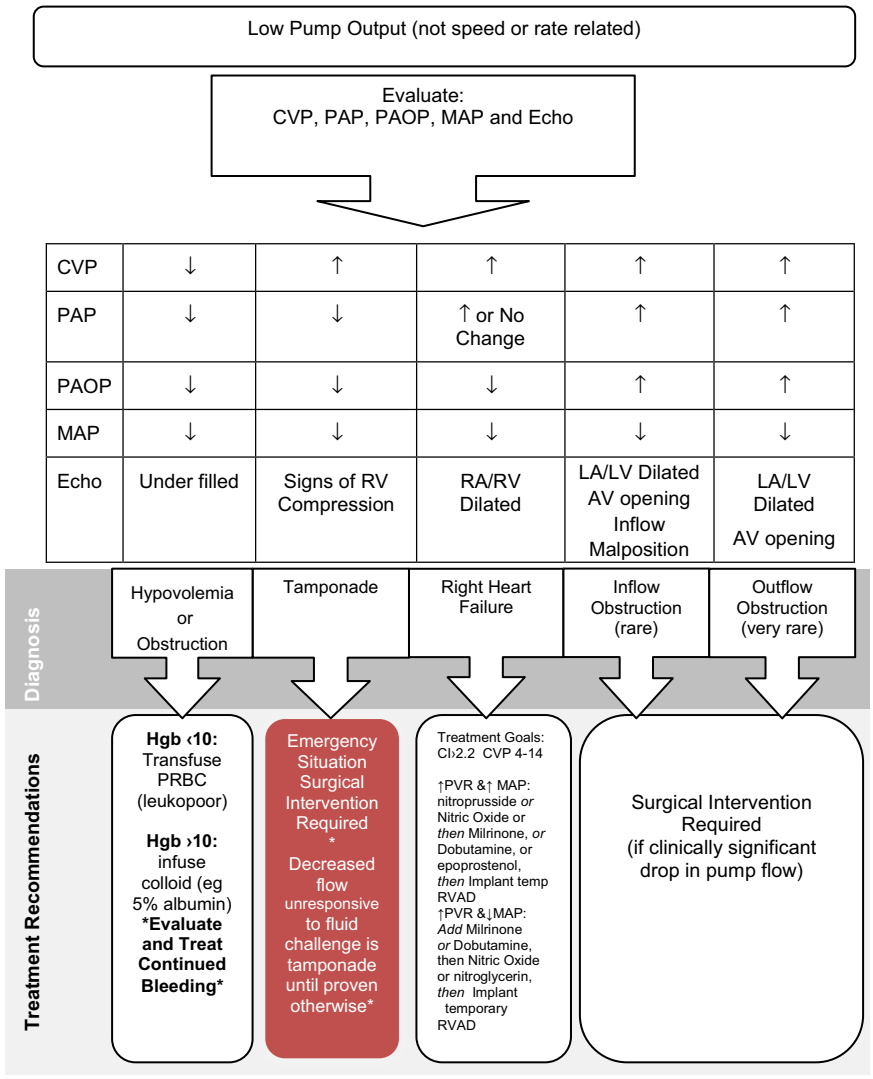

Figure 1 Treatment algorithm for low pump output. AV, arteriovenous; CI, cardiac index; CVP, central venous pressure; Hgb, hemoglobin; LA, left atrium; LV, left ventricle; MAP, mean arterial pressure; PAOP, pulmonary artery occlusion pressure; PAP, pulmonary artery pressure; PRBC, packed red blood cells; PVR, peripheral vascular resistance; RA, right atrium; RV, right ventricular; RVAD, right ventricular assist device.

Recommendations for managing hypotension in the non-ICU post-operative period:

Class I:

1. A systematic approach to hypotension should be used, as shown in Figure 2.
   Level of evidence: C.

Recommendations for neurohormonal blockade and the treatment of hypertension post-MCS implant:

Class I:

1. Pharmacotherapy with heart failure medications (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, β-blocker, hydralazine, nitrates) is preferred for blood pressure management.
   Level of evidence: C

Recommendations for echocardiography in the non-ICU post-operative period:[174–176]

Class I:

1. Echocardiography is an integral part of determining the revolutions per minute of continuous-flow pumps. Common goals include adequate LV unloading while maintaining the LV septum in the midline and minimizing mitral regurgitation.
   Level of evidence: C.

Class IIb:

1. Post-operatively, the revolutions per minute of continuous-flow pumps should be set low enough to allow for intermittent aortic valve opening.
   Level of evidence: B.

Table 2 Early Post-operative Anti-coagulation Management of HeartMate II[a] Patients Using Heparin

Timing	Action	Target
After CBP—leaving operating room	Complete reversal of heparin	Not applicable
ICU admission—24 hours	No action required, consider acetylsalicylic acid	Not applicable
Post-operative Day 1–2	IV heparin or alternative anti-coagulation, if no evidence of bleeding	PTT (40–60 seconds)
Post-operative Day 2–3	Continue heparin	PTT (60–80 seconds)
	Start warfarin and aspirin (81–325 mg daily) after removal of chest tubes	INR (2.0–3.0)

CPB, cardiopulmonary bypass; ICU, intensive care unit; INR, international normalized ratio; IV, intravenous; PTT, partial thromboplastin time.
[a]Thoratec, Pleasanton, California.

Table 3 Post-operative Anti-coagulation Management for Implantable Centrifugal Pumps

Timing	Action	Target
After CBP—leaving operating room	Complete reversal of heparin	Not applicable
ICU admission—24 hours	No action required, consider acetylsalicylic acid	Not applicable
Post-operative Day 1–2	IV heparin or alternative anti-coagulation, if no evidence bleeding	PTT (40–60 seconds)
Post-operative Day 2–3	Continue heparin	PTT (60–80 seconds)
	Start warfarin and aspirin (81-325 mg daily) after removal of chest tubes	INR (2.0–3.0)

CPB, cardiopulmonary bypass; ICU, intensive care unit; INR, international normalized ratio; IV, intravenous; PTT, partial thromboplastin time.

Table 4 Post-operative Anti-coagulation Management for Pulsatile Mechanical Circulatory Support Devices

Timing	Action	Target
After CBP—leaving operating room	Complete reversal of heparin	Not applicable
ICU admission—24 hours	No action	Not applicable
Post-operative Day 2	Start IV heparin if no evidence bleeding	PTT (40–60 seconds)
Post-operative Day 3	Continue heparin	PTT (60–80 seconds)
	Start warfarin and aspirin (81-325 mg daily) after removal of chest tubes	INR (2.5–3.5)

CPB, cardiopulmonary bypass; ICU, intensive care unit; INR, international normalized ratio; IV, intravenous; PTT, partial thromboplastin time.

Table 5 Guidelines for Removal of Invasive Lines and Drains in the Non-complicated Post-operative Mechanical Circulatory Support Patient

Type of line/drain	Time to discontinuation	Notes
PA catheter	24–48 hours	Must remain in place for severe right heart failure requiring high doses of inotropes
Arterial line	48–72 hours	Must remain in place until all vasoactive medications are weaned
Central venous line	Until no longer needed	Must remain in place until all vasoactive medications are weaned
Chest tubes	48 hours or when drainage is $<$ 100 ml in the previous 6 hours	Preferably after patient has sat up to assure that drainage is not positional
Pocket drain	72 hours or when drainage is $<$ 100 ml for the previous 8 hours	May be removed sooner if pocket communicates with left pleural space and if the left sided chest tube remains in place

PA, pulmonary artery.

Table 6 Parameters for Post-operative Mechanical Circulatory Support Patient Ventilation[171]

Mode	Assist/Control
Rate	10–12 breaths/min
Tidal volume	6–8 ml/kg
Positive end expiratory pressure	5 cm H_2O

2. Long-term, maintaining intermittent aortic valve opening may reduce the risk of aortic valve fusion and the risk of late aortic valve insufficiency.
   Level of evidence: B.

Recommendations for anti-coagulation and anti-platelet therapy post-MCS:[163]

Class I:

1. Anti-coagulation and anti-platelet therapy initiated post-operatively in the ICU setting should be continued with the aim of achieving device-specific recommended INR for warfarin and desired anti-platelet effects.
   Level of evidence: B.
2. Bleeding in the early post-operative period during the index hospitalization should be urgently evaluated with lowering, discontinuation, and/or reversal of anti-coagulation and anti-platelet medications.
   Level of evidence: C.

Recommendations for infection prevention post-MCS therapy:[96,177–203]

Class I:

1. The driveline should be stabilized immediately after the device is placed and throughout the duration of support.
   Level of evidence: C.
2. A dressing change protocol should be immediately initiated post-operatively.
   Level of evidence: C.
3. Secondary antibiotic prophylaxis for prevention of endocarditis has not been studied in the MCS population but would be considered reasonable due to the risk of bacteremia in this group.
   Level of evidence: C.

Table 7 Mobility and Feeding Guidelines

Activity	Goal
Out of bed to chair	Post-op Day 1
Feeding	Post-op Day 1
Discharge from intensive care unit	Post-op Day 3–5

Recommendations for optimization of nutritional status:[89,204–208]

Class I:

1. Consultation with nutritional services should be obtained at the time of implantation with ongoing follow-up post-operatively to ensure nutrition goals are being met.
   Level of evidence: C.
2. Post-operatively for those unable to meet nutritional goals orally, feeding should be started early and preferably through an enteral feeding tube. Parenteral nutrition should only be started if enteral nutrition is not possible and under the guidance of nutritional consultation.
   Level of evidence: C.
3. Pre-albumin and C-reactive protein levels can be monitored weekly to track the nutritional status of the post-operative patient. As nutrition improves, pre-albumin should rise and C-reactive protein should decrease.
   Level of evidence: C.

Recommendations for health care provider and patient education:[209–217]

Class I:

1. Health care providers should be trained in MCSD therapy with opportunity to attend refresher classes and ongoing assessment of competency.
   Level of evidence: C.
2. Patient and caregiver education should be initiated shortly after surgery and reinforced by the nursing staff. Educational strategies should use written, verbal, and practical methods.
   Level of evidence: C.

Recommendations for documentation of device parameters:

Class I:

1. MCS parameters should be recorded in the medical record at regular intervals with established criteria for parameters which require physician notification.
   Level of evidence: C.

Recommendations for device monitoring:

Class I:

1. Normal values for device parameters should be established and recorded in the medical record with triggers for physician notification.
   Level of evidence: C.
2. The patient and family members should be taught to track their device parameters and alert staff when changes are observed.
   Level of evidence: C.

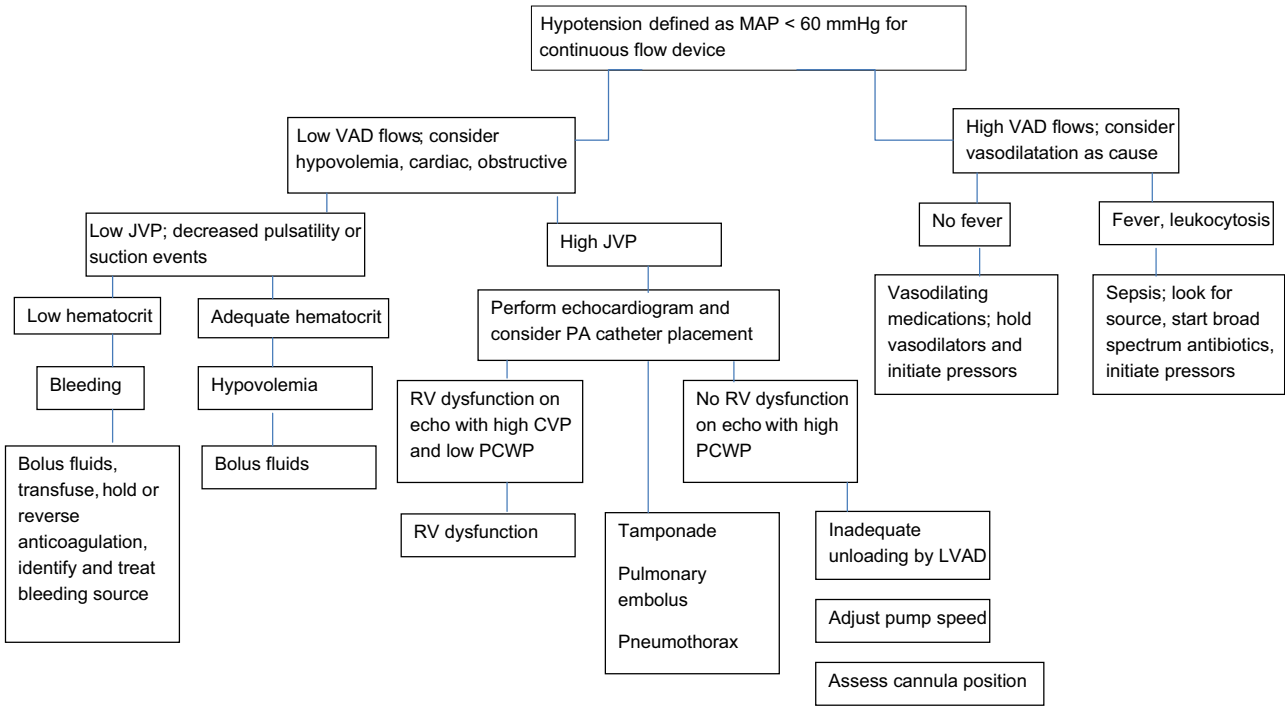

Figure 2 Algorithm for assessment of hypotension after implant. CVP, central venous pressure; JVP, jugular venous pressure; LVAD, left ventricular assist device; MAP, mean arterial pressure; PA, pulmonary artery; PCWP, pulmonary capillary wedge pressure; RV, right ventricular; VAD, left ventricular assist device.

3. Changes in parameters outside of normal ranges should be thoroughly evaluated and treated appropriately.
   Level of evidence: C.

Recommendations for psychosocial support while hospitalized post-MCSD implantation:[55,218–221]

Class I:

1. Routine support should be available from social workers, psychologists, or psychiatrists as patients and families adjust to life changes after MCS.
   Level of evidence: B
2. Routine surveillance for psychiatric symptoms should be performed. If symptoms develop, consultation with specialists (including social work, psychology, and/or psychiatry) for diagnosis, treatment, and follow-up is recommended.
   Level of evidence: B.

Recommendations for inpatient MCS care by a multidisciplinary team:[76,222–231]

Class I:

1. A multidisciplinary team led cooperatively by cardiac surgeons and cardiologists and composed of subspecialists (ie, palliative care, psychiatry, and others as needed), MCS coordinators, and other ancillary specialties (ie, social worker, psychologist, pharmacist, dietitian, physical therapist, occupational therapist, and rehabilitation services) is indicated for the in-hospital management of MCS patients.
   Level of evidence: C.

Recommendations for routine assessment of health-related quality of life while hospitalized post-MCSD implantation:[219–221,232]

Class IIb:

1. Routine assessment of health-related quality of life (HRQOL) while hospitalized after MCS implantation may be reasonable. Hospitalized patients are beginning to adjust to living with MCS and thus require MCS team support as they recover from surgery and rehabilitate. Assessment of specific problems that are related to domains of HRQOL (eg, depression, anxiety, or pain) based on symptoms should help guide an action plan for these patients.
   Level of evidence: B.

Recommendations for successfully discharging a MCS patient:[214,233]

Class I:

1. Caregiver and community provider education with written discharge instructions and preemptive home preparation regarding the safe management of the device and the MCS patient is recommended.
   Level of evidence: C.

Recommendations for management of anti-coagulation and anti-platelet therapy for patients who present with gastrointestinal bleeding: [233–240]

Class I:

1. Anti-coagulation and anti-platelet therapy should be held in the setting of clinically significant bleeding.
   Level of evidence: C.
2. Anti-coagulation should be reversed in the setting of an elevated INR and clinically significant bleeding.
   Level of evidence: C.
3. Anti-coagulation and anti-platelet therapy should continue to be held until clinically significant bleeding resolves in the absence of evidence of pump dysfunction.
   Level of evidence: C.
4. The patient, device parameters, and the pump housing (if applicable) should be carefully monitored while anti-coagulation and anti-platelet therapy is being withheld or the dose reduced.
   Level of evidence: C.

Recommendations for the evaluation and management of patients who present with a first episode of gastrointestinal bleeding:

Class I:

1. Patients should be managed in consultation with gastroenterology.
   Level of evidence: C.
2. Patients should at least have a colonoscopy and/or upper endoscopic evaluation.
   Level of evidence: C.
3. If the result of the colonoscopy and/or upper endoscopic evaluation is negative, evaluation of the small bowel, particularly in those with continuous-flow devices, should be considered.
   Level of evidence: C.
4. In the setting of persistent bleeding and a negative endoscopic evaluation, a tagged red blood scan or angiography should be considered.
   Level of evidence: C.
5. Once the gastrointestinal bleeding has resolved, anti-coagulation and anti-platelet therapy can be reintroduced with careful monitoring.
   Level of evidence: C.

Recommendations for the evaluation and management of patients who present with recurrent episodes of gastrointestinal bleeding:

Class I:

1. Repeated endoscopic evaluation should take place in conjunction with gastroenterology consultation.
   Level of evidence: C.
2. In the setting of recurrent gastrointestinal bleeding with no source or a source that is not amenable to therapy, the type and intensity or even the use of anti-platelet therapy should be reevaluated in the context of the bleeding severity and pump type.
   Level of evidence: C.
3. In the setting of recurrent gastrointestinal bleeding with no source or a source that is not amenable to therapy, the goal INR or even the continued use of warfarin should be reevaluated in the context of the bleeding severity and pump type.
   Level of evidence: C.
4. The patient and device parameters should be carefully monitored when anti-coagulation and anti-platelet therapy have been reduced or discontinued due to recurrent gastrointestinal bleeding.
   Level of evidence: C.

Class IIb:

1. Reducing the pump speed for continuous-flow pumps in the setting of recurrent gastrointestinal bleeding due to arteriovenous malformations may be considered.
   Level of evidence: C.

Recommendations for the acute management of patients who present with a new neurologic deficit: [4,31,39,52,195,241–243]

Class I:

1. Assessment of current INR and review of recent INR is recommended.
   Level of evidence: B.
2. Prompt consultation with neurology is recommended.
   Level of evidence: B.
3. CT and angiography of the head and neck is recommended.
   Level of evidence: B.
4. Review of pump parameters for signs of device thrombosis or malfunction is recommended.
   Level of evidence: C.
5. Inspection of pump housing for clots in extracorporeal pumps is recommended.
   Level of evidence: C.
6. Discontinuation or reversal of anti-coagulation in the setting of hemorrhagic stroke is recommended.
   Level of evidence: B.

Class IIa:

1. Assessing for the source of thrombus in the setting of an embolic stroke should be considered.
   Level of evidence: B.

Class IIb:

1. Selective use of an interventional radiologic approach to thrombotic strokes may be considered.
   Level of evidence: C.
2. Selective use of thrombolytic agents in the setting of thrombotic stroke without CT scan evidence of hemorrhage may be considered.
   Level of evidence: C.

Class III:

1. Routine use of an interventional radiologic approach to thrombotic strokes is not recommended.
   Level of evidence: C.
2. Routine use of thrombolytics in the setting of thrombotic stroke without head CT scan evidence of hemorrhage is not recommended.
   Level of evidence: C.

Recommendations for the chronic management of patients after presentation with a new neurologic deficit:

Class I:

1. Formal stroke rehabilitation in consultation with neurology is recommended.
   Level of evidence: B.
2. Close monitoring of anti-coagulation in the setting of an embolic event to assure adequate levels of anti-coagulation is recommended.
   Level of evidence: C.
3. Long-term control of blood pressure is recommended.
   Level of evidence: B.
4. Administration of National Institutes of Health (NIH) stroke scale at 30 and 60 days after a neurologic event is recommended.
   Level of evidence: C.
5. Resumption of anti-coagulation in consultation with neurology or neurosurgery in the setting of hemorrhagic stroke is recommended.
   Level of evidence: C.

Recommendations for assessment of neurocognitive deficits:[32,244–246]

Class I:

1. Routine neurocognitive assessment at 3, 6, 12, and 18 months after implant is recommended.
   Level of evidence: C.

Recommendations for evaluation of MCS patients with a suspected infection:[247]

Class I:

1. In all patients, a complete blood count, chest radiographic imaging, and blood cultures is recommended.
   Level of evidence: A.
2. At least 3 sets of blood cultures over 24 hours should be drawn, with at least 1 culture from any indwelling central venous catheters.
   Level of evidence: A.
3. For those with a suspected cannula or driveline infection, obtaining a sample for Gram stain, KOH, and routine bacterial and fungal cultures is recommended.
   Level of evidence: A.
4. When clinically indicated, aspirate from other potential sources, as dictated by presenting symptoms and examination, is recommended.
   Level of evidence: A.
5. Directed radiographic studies based on presenting symptoms and examination are recommended.
   Level of evidence: A.

Class IIa:

1. Erythrocyte sedimentation rate or serial C-reactive protein should be considered.
   Level of evidence: C.

Class III:

1. Routine CT of the chest, abdomen, and pelvis is not recommended.
   Level of evidence: C.

Recommendations for determination of an MCSD-specific infection (Table 8):[247]

Class I:

1. A proven MCSD-specific infection is defined as definitive microbiologic, histologic confirmation at MCS explant or 2 major clinical criteria.
   Level of evidence: B.
2. A probable MCSD-specific infection is defined as 1 major and 3 minor criteria or 4 minor criteria.
   Level of evidence: B.
3. A possible MCSD-specific infection is defined as 1 major and 1 minor or 3 minor criteria.
   Level of evidence: B.

Recommendations for determination of an MCSD pocket infection:

Class I:

1. A proven MCSD pocket infection is defined as organisms cultured from fluid, abscess, or other infection seen during surgical exploration, or 2 major criteria.
   Level of evidence: B.
2. A probable MCSD pocket infection is defined as 1 major and 3 minor or 4 minor criteria.
   Level of evidence: B.
3. A possible MCSD pocket infection is defined as 1 major and 1 minor or 3 minor criteria.
   Level of evidence: B

Recommendations for inpatient treatment of ventricular arrhythmias:[248–252]

Class I:

1. MCS patients with incessant ventricular arrhythmias require prompt admission for further management because hemodynamic compromise may occur.
   Level of evidence: C.

Table 8 Determination of Mechanical Circulatory Support Device Infections

Infection	Determined by
MCSD-specific	
Proven	Definitive microbiology, or Histologic confirmation at explants, or 2 major clinical criteria
Probable	1 major and 3 minor criteria, or 4 minor criteria
Possible	1 major and 1 minor criteria, or 3 minor criteria
Unlikely	Presence of an alternative diagnosis, or Resolution after $\leq$4 days of antibiotics, or No pathologic evidence at surgery with antibiotics $\leq$4 days, or Not meeting established definitions
Pocket infections	
Proven	Organisms cultured from fluid, or Abscess, or Other infection seen during surgical exploration, or 2 major criteria
Probable	1 major and 3 minor criteria, or 4 minor criteria
Possible	1 major and 1 minor criteria, or 3 minor criteria
Unlikely	Definitive alternative diagnosis, or Resolution with $\leq$4 days of antibiotics, or No pathologic evidence at surgery after $\leq$4 days of antibiotics, or Negative cultures from fluid during surgery or aspiration

MCSD, mechanical circulatory support device.

2. Patients with ongoing VT refractory to medical therapy may require catheter ablation, which should be performed by an electrophysiologist with the requisite knowledge and expertise in treating patients with MCS.
   Level of evidence: C.

Recommendations for RV function:

Class I:

1. RV dysfunction after LVAD placement may occur as a late manifestation with symptoms and signs of right heart failure and changes in LVAD parameters, including a decrease in flows and pulsatility. Further evaluation should include an echocardiogram and right heart catheterization.
   Level of evidence: C.
2. When evidence of RV dysfunction exists, MCS patients may need to be admitted to the hospital for optimization, which may include initiation of inotropic support.
   Level of evidence: C.

Recommendations for device failure and malfunction:[3,31,195,253–257]

Class I:

1. Pump stoppage of a continuous-flow MCSD constitutes a medical emergency, and the patient should be rapidly transported back to the implanting center or another expert MCSD center for treatment.
   Level of evidence: C.
2. Definitive therapy for pump stoppage is surgical pump exchange if the patient is stable enough to undergo reoperation.
   Level of evidence: C.
3. Patients with a functioning pump, but with alarms or changes in parameters that cannot be resolved as an outpatient, may need to be admitted to the hospital for observation and close monitoring.
   Level of evidence: C.

Class IIb:

1. For patients who are unable to undergo surgery, the outflow cannula may be occluded percutaneously to halt the backflow of blood through the valveless outflow cannula as a stabilizing maneuver.
   Level of evidence: B.

Recommendations for management of the MCS patient during non-cardiac procedures:[258–265]

Class I:

1. The MCS team should be made aware when an MCS patient is undergoing a non-cardiac procedure so that collaboration between the MCS and surgical teams can take place.
   Level of evidence: C.
2. For non-emergency procedures, warfarin and anti-platelet therapy may be continued if the risk of bleeding associated with the procedure is low. If therapy needs to be stopped, warfarin and anti-platelet therapy should be held for an appropriate period of time as determined by the type of procedure being undertaken and risk of bleeding. Bridging with heparin or a heparin alternative while a patient is off warfarin may be considered.
   Level of evidence: C.
3. For emergency procedures, warfarin may need to be rapidly reversed with fresh frozen plasma or prothrombin protein concentrate. Vitamin K can be administered with caution, but has slower onset of action.
   Level of evidence: B.
4. Post-procedure, warfarin and anti-platelet therapy may be resumed when risk of surgical bleeding is deemed acceptable. Patients may be bridged with heparin or a heparin alternative while waiting for the INR to reach the target range.
   Level of evidence: B.
5. During minor procedures, blood pressure monitoring with Doppler is appropriate.
   Level of evidence: C.

6. During procedures with risk of hemodynamic instability, an arterial catheter should be placed for blood pressure monitoring.
   Level of evidence: C.
7. A central venous catheter may be placed for monitoring of central venous pressure and to administer drugs in the case of hemodynamic instability during surgical procedures of moderate or high risk.
   Level of evidence: B.
8. During non-cardiac procedures, MCSD parameters should be continuously monitored by expert personnel such as MCS nurses or perfusionists.
   Level of evidence: C.
9. A cardiovascular surgeon should be in the operating room or immediately available, especially in situations when the non-cardiac procedure is occurring close to the MCSD.
   Level of evidence: C.

Class II:

1. Whenever possible, the surgeon performing the non-cardiac procedure should have experience in operating on patients with MCSD.
   Level of evidence: C.

Task Force 5: Outpatient management of the MCSD recipient

Chair: Salpy V. Pamboukian, MD, MSPH

Contributing Writers: Tonya Elliot, RN, MSN; Paul Mogacsi, MD; Evgenij V. Potapov, MD; Stuart D. Russell, MD; Jeffrey J. Teuteberg, MD

Independent Reviewers: Joseph Rogers, MD; Francis Pagani, MD

Topic 1: Transitioning the MCSD patient to the home or community environment

Recommendations for evaluation of safety of the home environment:[87,216,266,267]

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 himself or herself 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, and have the appropriate toilet seat or any other necessary physical aids.
   Level of evidence: C.
2. A discharge checklist 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.

Recommendations for community outreach by the MCS team:[216,233,263–268]

Class I:

1. Community outreach should be performed by the implanting center's MCS team to inform the local health care providers, including emergency medical services personnel, emergency department staff, and referring physicians, of the reintegration of the MCSD patient to his or 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 IIa:

1. Appropriate emergency maneuvers should be reviewed with local health care providers. Consideration may be given to developing a field guide for emergency medical services personnel to aid in emergency responses.
   Level of evidence: C.

Recommendations for assessment of the social network:[267,269]

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.

Class IIb:

1. 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.

The multidisciplinary MCS team should review survey results at regular intervals to help facilitate programmatic improvements.

Level of evidence: C.

Recommendations for driving a motor vehicle:[267]

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

Recommendations for the multidisciplinary approach to follow-up care:

Class I:

1. Management of the patient with an MCSD should be performed by a multidisciplinary team that includes 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.

Recommendations for frequency of visits:[270]

Class I:

1. MCS patients should be seen in clinic regularly, the frequency of which is dictated by their clinical stability.

   Level of evidence: B.
2. MCS patients should have a routine schedule of testing to survey for patient-related 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.

Recommendations for the use of echocardiography:[176,271–282]

Class I:

1. Echocardiography should be performed as part of the pre-operative assessment and routinely at regular intervals post-operatively to evaluate for signs of myocardial recovery and optimal MCSD function. Echocardiography can be used 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 sub-optimal MCSD function or in the presence of clinical signs of circulatory dysfunction, including congestive or low output symptoms.

   Level of evidence B.

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 for or listed for heart transplant to document pulmonary artery pressures because irreversible pulmonary hypertension is associated with early allograft dysfunction/failure after 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 the pump speed to confirm acceptable hemodynamics with decreasing VAD support prior to pump explanation.

   Level of evidence: C.

Recommendations for use of CT angiography:[283–285]

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.

   Level of evidence: B

Recommendations for functional capacity testing:[286–294]

Class I:

1. Measurement of exercise capacity should be undertaken after 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 6-minute walk testing performed at regular intervals may be helpful in objectively assessing functional capacity in patients with MCSD. Suggested intervals are 3 months, 6 months, at

6-month intervals through 2 years after implant, and then yearly thereafter.

Level of evidence: C.

Recommendations for HRQOL:[295]

Class IIa:

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

   Level of evidence: B.

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 monitor the status of comorbid conditions.

   Level of evidence: C.

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 driveline should be assessed for proper position and use of binder or driveline immobilization at each clinic visit.

   Level of evidence: C.
3. 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.

Recommendations 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

Recommendations for exercise and cardiac rehabilitation:[296–308]

Class I:

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

   Level of evidence: C.

Topic 4: Medical management of the MCSD patient

Recommendations for anti-coagulation:[86,160,309]

Class I:

1. Patients with MCSD should receive anti-coagulation with warfarin to maintain an INR within a range as specified by each device manufacturer (Table 9).

   Level of evidence: B.

Recommendations for anti-platelet therapy:[237,238,310–320]

Class I:

1. Chronic anti-platelet therapy with aspirin (81–325 mg daily) may be used in addition to warfarin in patients with MCSD.

   Level of evidence: C.
2. Anti-platelet therapy beyond aspirin may be added to warfarin according to the recommendations of specific device manufacturers.

   Level of evidence: C.

Table 9 Anti-coagulation and Anti-platelet Therapy for Approved Mechanical Circulatory Support Devices

Device	INR range
AbioCor TAH[a]	2.5–3.5
HeartMate II[b,c]	2.0–3.0
HeartWare HVAD[d]	2.0–3.0
MicroMed DeBakey[e]	2.5–3.5
Syncardia TAH[f]	2.5–3.5
Thoratec IVAD[c]	2.5–3.5
Thoratec PVAD[c]	2.5–3.5

INR, international normalized ratio; IVAD, implantable ventricular assist device; PVAD, percutaneous ventricular assist device; TAH, total artificial heart.

[a]Abiomed, Danvers, Massachusetts.

[b]Goal from the clinical trials.

[c]Thoratec, Pleasanton, California.

[d]HeartWare International, Inc, Framingham, Massachusetts.

[e]MicroMed Technology, Houston, Texas.

[f]CardioWest SynCardia, Tucson, Arizona.

Class IIb:

1. Assessment of platelet function may be used to direct the dosing and number of anti-platelet drugs.
   Level of evidence: C.

Recommendations for heart failure therapy:[31,321–323]

Class I:

1. Diuretic agents are useful for the management of volume overload during MCS.
   Level of evidence: C.
2. An angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker may be used for hypertension or for risk reduction in patients with vascular disease and diabetes.
   Level of evidence: C.
3. β-Blockers may be used for hypertension or for rate control in patients with tachyarrhythmias.
   Level of evidence: C
4. Mineralocorticoid receptor antagonists may be used to limit the need for potassium repletion in patients with adequate renal function and for potential beneficial anti-fibrotic effects on the myocardium.
   Level of evidence: C.

Class II

1. Digoxin may be useful in the setting of atrial fibrillation with rapid ventricular response.
   Level of evidence: C.

Recommendations for hypertension management:

Class IIb:

1. Patients with pulsatile MCSDs should have a blood pressure goal of systolic blood pressure of < 130 mm Hg and a diastolic blood pressure of < 85 mm Hg.
   Level of evidence: C.
2. Patients with nonpulsatile MCSDs should have a mean blood pressure goal of ≤ 80 mm Hg
   Level of evidence: C.

Recommendations for diabetes management:[47]

Class IIa:

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

Recommendations for treatment of renal disease:[78,79,323]

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 in collaboration with nephrology.
   Level of evidence: C.

Recommendations for evaluation and management of hemolysis:[86,263,324–327]

Class I:

1. Screening for hemolysis should occur in the setting of an unexpected drop in the hemoglobin or hematocrit level or with other clinical signs of hemolysis (eg, hemoglobinuria).
   Level of evidence: C.
2. Hemolysis in the presence of altered pump function should prompt admission for optimization of anti-coagulation and anti-platelet management and possible pump exchange
   Level of evidence: B.

Class IIa:

1. Routine screening for hemolysis with lactate dehydrogenase and plasma-free hemoglobin assessment in addition to hemoglobin or hematocrit should occur periodically throughout the duration of MCS.
   Level of evidence: C.

Recommendations for dietary management:[328,329]

Class IIa:

1. Weight loss should be encouraged for all patients with a body mass index > 30 kg/m^2.
   Level of evidence: C.

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 IIa:

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

Recommendations for ICD placement:[3,31,330]

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 biventricular assist devices who are in persistent VT/VF or who have frequent sustained runs of VT despite optimal anti-arrhythmic therapy.
   Level of evidence: C.

Recommendations for management of atrial fibrillation and flutter:[331]

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 American College of Cardiology/American Heart Association atrial fibrillation guidelines (2011)[332] is recommended.
   Level of evidence: C.

Recommendations for management of ventricular arrhythmias:[86,333]

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. Therapy with β-blockade may be a useful 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: Psychologic and psychiatric issues

Recommendations for psychologic and psychiatric issues:[55,65,67,68,228,334–346]

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 psychiatric illness. Appropriate pharmacologic and psychologic 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

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 before the patient and caregiver leave 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 to the implanting center in the case of emergency.
   Level of evidence: C.

Topic 8: End of life issues

Recommendations for end of life issues:[4,58,347–350]

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, particularly when implanted as DT.
   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.

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Supplementary data

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