The 2023 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support: a 10-year update

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GUIDELINE

The 2023 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: A 10- Year Update

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In 2013, the International Society for Heart and Lung Transplantation (ISHLT) published the first official guidelines for implantable mechanical circulatory support (MCS) as commissioned by its Board of Directory. Considering the substantial growth and technological advancement in the MCS field, much of the content of the 2013 report is no longer clinically relevant and new information is needed. In response to this and at the request of the Board of Directors to keep ISHLT guidelines appropriately updated, the MCS Council approved and commissioned the development of a focused update. The 2013 MCS guidelines were organized into individual Task Forces covering preoperative, intraoperative, and postoperative management of MCS patients. These guidelines exclusively pertain to patients treated with implantable left ventricular assist devices (LVADs). In addition to updating and augmenting this content, the 2023 Guidelines update includes 4 additional Task Forces resulting in the most comprehensive resource guiding the management of patients with durable mechanical circulatory support (DMCS). As the field of MCS has evolved, these guidelines now pertain to all configurations of DMCS including single and biventricular support.

During the development of this document some notable changes occurred that are relevant to the field. Most significantly, the HeartMate III was introduced into practice; and following a successful clinical trial, it was approved for use

in both the USA and Europe. As a result, the HeartMate II pump was rapidly phased out of clinical practice. More recently, Medtronic discontinued new implants of the HVAD. As there are a significant number of HVAD and HMII supported patients still in clinical practice, these guidelines remain pertinent and continue to guide the management of patients supported with these pumps. Eight years after the original guidelines were published, the Centers for Medicare and Medicaid Services redefined the categories for the approval of LVADs replacing the traditional bridge-to-transplant and Destination Therapy terminology. The traditional terminology remains widely used worldwide and as such continues to be used in these updated guidelines. Also, of note, these guidelines are intended to specifically guide the management of DMCS patients. Notably absent are utilization and management guidelines for temporary mechanical support, as these guidelines are forthcoming.

The terminology used in this guidelines-update is important and should be considered by the reader. As the new guidelines include additional implantable devices, we have substituted DMCS for implantable MCS and LVAD throughout the document. This term is used when a statement or recommendation is applicable broadly to all durable heart pumps and configurations. More specific terms such as LVAD, BIVAD, or TAH are used when a statement or recommendation is specific to a device or configuration. Writers were encouraged to use DMCS whenever possible.

Each Task Force was extensively reviewed by the Writing Committee, Co-Chairs, and by outside reviewers who were identified by the manuscripts leads. Every effort was made to avoid guideline recommendations which are not generally practiced in most medical centers or were otherwise controversial or unsettled in 2023.

The 2023 MCS Update is comprised of 9 individual Task Forces. These include:

Task Force 1: Selection of candidates for DMCS and risk management before implantation for fixed comorbidities.
Task Force 2: Patient optimization, consent, and appropriate timing for MCS: Modifiable risk management before implantation.
Task Force 3: Intraoperative and immediate postoperative management
Task Force 4: Inpatient management of patients with DMCS.
Task Force 5: Outpatient management of the mechanical circulatory support device recipient.
Task Force 6: VAD in adults with congenital heart disease.
Task Force 7: Evaluation for recovery.
Task Force 8: Section on biventricular assist devices and total artificial heart specifications.
Task Force 9: Section on center quality metrics, outcomes, volume, and staffing.

The contributing writers represent an international and multidisciplinary community, reflecting the membership of the International Society of Heart and Lung Transplantation and respecting its commitment to Gender, Geography and Generation. Task force leaders were chosen for their expertise and contributions to the MCS field, and the writing groups were selected to include junior and senior members from a range of specialties depending on the focus of the section.

Table 1

Class I	Strongly supported by evidence or consensus opinion. Such a treatment is strongly recommended
Class IIa	Evidence or consensus opinion mostly in favor. Such a treatment is reasonable to consider.
Class IIb	Evidence or consensus opinion conflicting or less well established. Such a treatment may be reasonable to consider.
Class III	Evidence or consensus opinion is against as the treatment is not effective or harmful. Such a treatment should be avoided.
Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or nonrandomized studies.
Level of evidence C	Consensus opinion or case reports. Clinical evidence lacking.

Task Force leaders were instructed to follow general guidelines conventions as outlined in Table 1. Following each task force is a table summarizing the 2013 recommendations on the left (not present with the new sections) and the 2023 updates on the right. While certain content was moved to better organize the material, the authors made every attempt to make the changes obvious, with side-by-side comparisons. Omitted recommendations from 2013 are simply not included in the 2023 updates. In this update, we have reviewed the prior recommendations and made the following determination:

Unchanged: Either reproduced verbatim or slightly modified if the change in wording did not alter clinical practice.

Modified: Used when a prior recommendation was substantially changed or altered in a way which could lead to a change in clinical practice. This could include expanding the scope of a prior recommendation, a change in the classification or the level of evidence supporting a recommendation.

New: Used when adding a recommendation which did not previously exists.

As with the original 2013 MCS guidelines, the authors have made every attempt to provide the best level of evidence, as a basis for these recommendations. Despite these efforts, a large portion of these recommendations continue to be based on consensus or expert opinion. While this document is comprehensive and designed to stand-alone, it references other ISHLT documents that are summarized and referenced within.

The 2023 MCD Guidelines Update represents a tremendous amount of work done over several years during

tumultuous and challenging times in our medical communities. The Task Force leaders were responsible for the comprehensiveness and quality of their section's content. During the editing phase, some of the content was moved between Task Forces to more sensibly organize the material. Due to the amount of time required to complete this document, additional updates were required to adjust for significant developments in the field. We applaud and congratulate the contributing writers and our reviewers for this momentous contribution to our MCS field.

Diyar Saeed, MD, PhD; David Feldman, MD; and David D'Alessandro, MD

Task Force 1

Selection of candidates for DMCS and risk management before implantation for fixed comorbidities

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Topic 1: Indications

Two major indications for durable mechanical circulatory support (DMCS) are accepted by regulatory bodies and payors both in the United States of America (USA) (1-4) and European countries (5, 6): bridge to cardiac transplantation (BTT) or permanent therapy for end-stage refractory heart failure, referred to as destination therapy (DT).

As of October 10, 2018, the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database has acquired data from 152 of 163 hospitals (93%) implanting durable Food and Drug Association (FDA)-approved devices in USA between 2006 and 2017 (1-4). According to the most recent North-American reports, more than 25,000 patients have received MCS therapy, of whom over 18,000 underwent continuous-flow (CF) LVAD device implantation (1-4).

The intention to treat at the time of implant category has evolved over time. Before the approval of continuous flow devices, approximately 200 implants per year were entered into the INTERMACS database. Only a small fraction of these implants were for DT. After approval of continuous flow devices for BTT, pulsatile technology was quickly supplanted by continuous flow pumps, and the volume of implants recorded in INTERMACS tripled. The volume of implants again grew dramatically after the approval of a continuous flow device for DT, and the DT indication accounted for roughly one-third of all new implants (1-6). Despite the majority of patients being implanted as BTT, only about half of these patients are actually listed for transplantation at the time of DMCS. While transplantation may be the ultimate intention for those not listed, these patients are often not initially eligible for transplantation for a variety of reasons. Implants under these circumstances are often colloquially referred to as "bridge to candidacy" (BTC), as in the United States the FDA does not recognize BTC as an approved indication similar to many European countries (1-6). In some patients, contraindications to transplant such as pulmonary hypertension, renal impairment, or obesity may improve after a period of DMCS such that transplant candidacy may be reconsidered. Conversely, these same contraindications may persist, or the patient may experience an adverse event during support that makes them ineligible for transplant. To illustrate this point, as many as 17% of DT recipients eventually undergo heart transplant, whereas many BTT patients, particularly those implanted as BTC, are no longer eligible for transplant after a period of support (1-6).

The frequency of CF LVAD implants for the DT indication increased with time (1-6). In patients who underwent centrifugal flow CF LVAD implant, the DT indication increased from 0% in 2012 to 27% in 2017, reflecting the impact of FDA approval of newer generation pumps for DT support. Between 2014 and 2020, the DT indication increased from 46% to 73% of patients in the United States who underwent axial flow CF LVAD support (7), whereas BTT frequencies declined (1-4). Over a mean support duration of 20 months, according to the most recent INTERMACS analysis (2008-2017), 1-year survival has reached 83%, and median survival has now surpassed 5 years with CF LVADs (1-4) (7) with similar results according to recent European data (5, 6).

Bridge to recovery may also be a goal of DMCS therapy in some patients (8-10). Clinical practice has demonstrated several examples of reverse myocardial remodeling in a variety of clinical conditions either occurring spontaneously

(e.g., nonischemic cardiomyopathy, myocarditis, treatable forms of inflammatory cardiomyopathies and recent onset disease) or facilitated through intervention (e.g., treatment of tachycardia-induced cardiomyopathy, pharmacological therapy, or cardiac resynchronization therapy) (1, 5, 8-10). LVADs provide significant volume and pressure unloading of the left ventricle and increased cardiac output, which allows reversal of the compensatory responses of the overloaded myocardium. As a result, some patients placed on long-term, DMCS demonstrate improvement of cardiac function, permitting weaning from the MCS device (Myocardial recovery with DMCS is focus of Task Force 7). Device explantation for myocardial recovery occurs in only 1% to 3% of all implants, though the proportion of patients achieving responder status, defined as a left ventricular internal diastolic diameter ≤6.0 cm and a left ventricular ejection fraction ≥40%, with mechanical unloading is 10% to 12% (8-12). In a recent prospective, multicenter nonrandomized study in patients with LVADs due to nonischemic cardiomyopathy (aged between 18 and 59 and with duration of heart failure less than or equal to 5 years) 40% achieved the primary end-point of alive free from mechanical support/heart transplantation 1-year post-LVAD explant (9).

Due to limited organ availability and changing prioritization schema for organ allocation, patients receiving DMCS are being supported for longer periods of time. In addition, the initial intent of DMCS implant may not be the ultimate therapy the patient receives. Listed patients become ineligible for transplant and initially ineligible patients becoming transplant candidates (13). In recognition of this, the field has evolved to use the terms short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) support. In the United States specifically, the Centers for Medicare and Medicaid Services (CMS) made a National Coverage Decision (NCD) to formally recognize the terms short-term and long-term (14). In addition, being listed for transplant is no longer a critical step in the decision-making framework in many regions across the globe and many regulatory bodies do not make the distinction between BTT and DT.

Indications for mechanical circulatory support

Class I

1. Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for durable mechanical circulatory (DMCS) support for short-term support as bridge to transplantation or bridge to candidacy.

Level of Evidence: A.

2. Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for DMCS for long-term support if transplant is unlikely to occur in the short-term, if a period of support will improve transplant candidacy, or as destination therapy for patients who are ineligible for transplant.

Level of Evidence: A.

Class IIA

1. Patients with dilated cardiomyopathy, particularly of recent onset and nonischemic etiology refractory to maximal medical therapy, should be considered for DMCS as bridge-to-recovery. Pharmacological treatment should be with maximally tolerated neurohormonal modulation, and surveillance for recovery of left ventricular function should be undertaken.

Level of Evidence: B

Selection of candidates for MCS device implantation

Role of the advanced heart failure cardiology team

The treatment of advanced heart failure has been furthered by the addition of new medications, monitoring devices, and interventions, all of which have resulted in improved outcomes in selected populations that may delay the individual need for DMCS. Despite these advances, heart failure with reduced ejection fraction (HFrEF) remains a progressive disease. Patients who develop symptoms of heart failure despite ongoing optimal management will experience deterioration in their quality of life and progressive risk for mortality. There is no single "best" prognostic marker or risk score that allows for early identification of patients who are in imminent need for DMCS or transplant therapy, which can result in referral for advanced therapies very late in the disease process, after the development of the sequela of long-term HF (sarcopenia, malnutrition, organ failure, fixed pulmonary vascular resistance) or frank cardiogenic shock that can reduce the probability of success with MCS.

Due to these complexities, patients with advanced HFrEF should be regularly assessed by a dedicated advanced heart failure team for optimization of therapy, regular comprehensive risk assessment, and early facilitation of shared decision making to define goals of care as well as education regarding therapeutic options, including MCS and transplant when appropriate. Another important role of the advanced HF team is to reduce the probability of patients under management deteriorating to the point of severe cardiogenic shock (INTERMACS profile 1 and 2) before consideration of MCS therapy.

Identification and treatment of reversible causes of cardiac disease

Before initiation of the evaluation for DMCS, reversible factors for HFrEF need to be evaluated and treated (e.g., valvular disease, coronary ischemia, arrhythmias, cardiotoxic agents). Guideline-directed medical and device therapy for HfrEF should be optimized including, but not limited to beta-blockers, angiotensin receptor/neprilysin

inhibitors, mineralicorticoid receptor antagonists, sodium-glucose cotransporter-2 (SGLT2) inhibitors, and cardiac resynchronization therapy.

Recommendations for the evaluation process of MCS candidates

Class I

1. All potential DMCS patients should be managed by an advanced heart failure team for optimization of therapies, risk assessment, and shared decision making.

Level of Evidence: C.

2. All patients should have any reversible causes of heart failure addressed before consideration for DMCS.

Level of Evidence: C.

3. All patients referred for DMCS should have their transplant candidacy assessed before implant.

Level of Evidence: C.

Clinical classification of advanced heart failure severity

New York Heart Association classification. Remain unchanged

INTERMACS Profiles are used to delineate HF severity and associated risk in patients with NYHA IIIB to IV symptoms being considered for DMCS (15-17). The ROADMAP study assessed outcomes in INTERMACS profile 4 to 7 patients compared to medical therapy, demonstrating higher survival with improved functional status, improved quality of life, and reduced depression despite a greater rate of major adverse events with LVAD in the first year of support (18). A further analysis of data from this trial suggested benefit was seen in INTERMACS profile 4, but not 5 to 7 patients (19), and there is insufficient evidence from recent clinical trials to support routine implantation in class 5 to 7 patients (13).

Clinical classification of MCS candidates

Class I

1. All patients being considered for DMCS should have their NYHA class assessed.

Level of Evidence: C.

2. All patients being assessed for DMCS should have their INTERMACS profile determined.

Level of Evidence: C.

Risk stratification for consideration of MCS

Class IIa

1. Long-term DMCS for patients who are in acute cardiogenic shock should be reserved for the following:

a. Patients whose ventricular function is either 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 DMCS, as 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 DMCS. 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 to advanced therapy including heart transplant, or DMCS (BTT or DT) as appropriate.

Level of Evidence: C.

Risk stratification to determine timing of MCS therapy

DMCS should be considered in patients whose ventricular function is unlikely to recover or who are too ill to maintain normal hemodynamics and vital organ function without MCS. Ideally, patients who develop markers of increasing risk for HF mortality should be managed in partnership with an advanced heart failure program, with the purpose of early referral being partnered management, regular risk assessment, patient education and ongoing evaluation of the need for advanced therapies. Several risk scores and tests are available for risk stratification of HFrEF patients and include the Seattle Heart Failure Model, the Heart Failure Survival Score, and cardiopulmonary stress testing. A tool that can be used to trigger referral of a HF patient to an advanced heart failure program includes the I NEED HELP acronym (20) (Table 1).

Seattle Heart Failure Model. *No change*

Heart Failure Survival Score (HFSS). *No change*

Table 1 Triggers for Referral of Heart Failure Patient for Advanced Therapies Evaluation

I	IV Inotropes
N	NYHA IIIB/IV or persistently elevated Natriuretic peptides
E	End-organ dysfunction
E	EF $\leq$ 35%
D	Defibrillator shocks
H	Hospitalizations >1
E	Edema despite escalating diuretics
L	Low blood pressure, high heart rate
P	Progressive intolerance or downtitration of GDMT

Role of cardiopulmonary stress testing. *No change*
Need for inotropes. *No change*
Prediction of survival post-MCS

While risk-stratification models (21-26) have demonstrated an ability to define groups of patients at elevated risk for adverse outcomes, they have had limited application in actual decision making due to their limited application to an individual patient and dependence on small data sets. Newer models of predicting outcomes after LVAD implantation based on Bayesian network (BN) algorithms are demonstrating promise by drawing on the >400 preimplant variables available in the INTERMACS data set and the advantages of Bayesian analytics which allows for dynamic incorporation of multiple variables (27). Risk scores and BN models do not take into account patient-specific characteristics, clinical management practices and pump-patient interactions after implant. Consistent variables predictive of mortality include older age, renal and hepatic function, previous cardiac operations, lower INTERMACS profile, preoperative ventilator dependence, ischemic etiology of heart disease, and frailty. Overall, prediction of mortality after DMCS implantation remains challenging on an individual basis and ongoing efforts to refine these models remains critical to aid MCS teams in guiding patients through what can be difficult decisions where the preexisting bias tends to be in favor of accepting risk given even modest chances of success.

Risk stratification to determine timing of MCS therapy based on intermacs classification

Class I

1. INTERMACS profile 1 to 3 patients benefit in terms of survival from implantation of a LVAD

Level of Evidence: A.

Class IIb

1. INTERMACS profile 4 may benefit in terms of survival from implantation of a LVAD.

Level of Evidence: B.

Patients with coronary artery disease

Class IIa

1. Patients being considered for DMCS who have a history of coronary artery bypass grafting should have appropriate imaging to assess the location and course of the bypass grafts to guide the surgical approach.

Level of Evidence: C.

Patients with acute myocardial infarction

Class IIb

1. If possible, permanent DMCS should be delayed in the setting of an acute infarct (at least 5 days).

Level of Evidence: C.

Evaluation of MCS candidate with congenital heart disease: *Topic moved to TF 6*

Valvular disease: *Topic moved to TF 3*

Infective endocarditis: *Topic moved to TF 3*

Intracardiac shunts: *Topic moved to TF 3*

Intracardiac thrombus: *Topic moved to TF 3*

Atrial arrhythmias

Class I

1. Atrial flutter or fibrillation is not a contraindication to DMCS.

Level of Evidence: C.

Class IIb

1. Patients with medically refractory atrial tachyarrhythmias may benefit from ablation of the arrhythmia or AV node (with subsequent ICD/pacemaker placement) before LVAD implantation.

Level of Evidence: C.

Arrhythmia therapy

Class IIa

1. Patients with treatment refractory recurrent sustained ventricular tachycardia or ventricular fibrillation in the presence of untreatable arrhythmogenic pathologic substrate (e.g., giant cell myocarditis, scar, sarcoidosis), a biventricular support or a TAH is preferred over isolated LV support.

Level of Evidence: C.

Peripheral vascular disease

Class IIa

1. All patients with known atherosclerotic vascular disease or significant risk factors for its development should be screened for peripheral vascular disease before DMCS.

Level of Evidence: C.

2. Imaging to assess intrathoracic atherosclerotic burden should be considered.

Level of Evidence: C.

Class IIb

1. DMCS may be reasonable in select patients with manageable peripheral vascular disease.

Level of Evidence: C.

Life-limiting comorbidities and multiorgan failure

Class III

1. Consideration of DMCS in the setting of irreversible multiorgan failure is not recommended.

Level of Evidence: C.

Renal dysfunction

Improvement in renal function after LVAD has been documented (28), however INTERMACS data have shown that preimplant renal dysfunction predicts higher mortality after LVAD implant. The progressive reduction in survival with higher grades of renal dysfunction supports consideration of LVAD implant before cardiorenal syndrome is advanced.

For patients with severe renal dysfunction and other major comorbidities, initial support with a temporary device while awaiting organ recovery before implanting a durable pump could be considered (29, 30).

Recommendations for renal dysfunction

Class IIb

1. For patients with severe renal dysfunction, initial support with a temporary device to assess for potential of renal recovery before implanting DMCS can be considered.

Level of Evidence: B.

Pulmonary hypertension

Class I

1. All patients being considered for DMCS should have an invasive hemodynamic assessment of pulmonary vascular resistance.

Level of Evidence: C.

Pulmonary assessment: *Modified from Task Force 2*

Chest Imaging—It is advisable to obtain a preoperative chest radiograph in patients with undergoing thoracic surgery, to allow for a baseline image for any postoperative comparisons (31). Characterization of cardiac and extracardiac structures with computed tomography (CT) or magnetic resonance imaging (MRI) allows for identification of previous grafts, chest irregularities, aortic anatomy, diaphragmatic abnormalities, etc. and hence aids in determining practical surgical feasibility (32, 33).

Assessment of oxygenation and hypercapnia—An arterial blood gas (ABG) analysis is rarely needed as part of preoperative assessment but might be useful in patients with resting SpO_2 <93%, an abnormal serum bicarbonate, and severe abnormalities on PFTs (e.g., FEV1 <1 L or <50% predicted) (34, 35). A significantly abnormal ABG should lead to a reassessment of the indication for the proposed procedure and aggressive preoperative preparation. Current data do not support the routine use of preoperative ABG analyses to stratify risk for postoperative pulmonary complications.

Pulmonary function testing (PFTs)—Few studies have compared the incremental value obtained by spirometry with the risk estimate based on clinical evaluation. The direct impact of spirometry finding on predicting rates of prolonged mechanical ventilation, postoperative pneumonia, prolonged intensive care unit stay or death is not well established (36). However, PFTs may be useful in patients with known or suspected respiratory disease (e.g., unexplained dyspnea out of proportion to underlying heart failure, cigarette smoking >20 years, COPD, interstitial lung disease) (37). In special circumstances like in planned off-pump LVAD implantations through a left lateral thoracotomy with the need of single lung ventilation, preoperative measurements of FEV1 and DLCO can help in planning the operative procedure. Of note, pulmonary diffusion capacity correlates positively with left ventricular filling pressure, driven by increased lung capillary volume in patients with pulmonary congestion (38). Hence accurate evaluation of pulmonary function can be challenging due to coexistence of advanced heart failure.

The 2006 American College of Physicians guideline recommends that clinicians not use preoperative spirometry routinely for predicting the risk of postoperative pulmonary complications, nor be used as the primary factor to deny surgery (39). The American College of Chest Physicians guidelines, recommend that if the percent predicted postoperative FEV 1 and percent predicted postoperative DLCO values are both >60%, the patient is considered at low risk of anatomic lung resection, and no further tests are indicated (40).

Pulmonary assessment in patients with venoarterial extracorporeal life support (ECLS)/ECMO: Highly critical patients who have been stabilized with venoarterial Extracorporeal Life Support (ECLS) can be considered for LVAD implantation. VA ECLS can lead to left ventricular distension and subsequent lung injury. Therefore, in patients considered for LVAD implantation during the time of ECLS support, pulmonary assessment should be a focus as unrecognized lung injury that can lead to respiratory failure post-LVAD implantation (41).

Recommendations for pulmonary assessment

Class I

1. Patients should have a chest X-ray before DMCS implantation.

Level of Evidence: C.

Class IIa

1. In patients with prior cardiothoracic surgery or suspected pulmonary disease, assessment of thoracic anatomy with CT or MRI before DMCS implantation is reasonable.

Level of Evidence: C.

2. An assessment of lung function and screening for signs of pulmonary edema/lung injury during venoarterial ECLS support should be performed before DMCS implantation.

Level of Evidence: C.

Class IIb

1. PFT spirometry may be beneficial for patients with suspected lung disease (e.g., COPD) for preoperative optimization and perioperative management.

Level of Evidence: B.

Neurologic function

Class I

1. A thorough neurologic examination should be performed on every patient being considered for DMCS. 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 DMCS should have carotid and vertebral Doppler examination as a screen for occult vascular disease.

Level of Evidence: C.

3. CT scan or magnetic resonance imaging (MRI) is warranted in patients with previous stroke to establish a preoperative baseline study.

Level of Evidence: C.

Class III

1. DMCS 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.

Coagulation and hematologic disorders: *Modified to include preimplant management of thienopyridine antiplatelet agents and direct oral anticoagulants.*

Class I

1. All patients evaluated for DMCS therapy should have a PT/INR, aPTT, and platelet count assessed preoperatively.

Level of Evidence: C.

2. Baseline abnormalities in coagulation parameters not due to pharmacologic therapy should prompt an evaluation to determine the etiology before implant.

Level of Evidence: C.

3. Patients with a history of thrombophilia should have a hypercoagulable assessment before DMCS.

Level of Evidence: C.

4. Thienopyridine antiplatelet agents and direct oral anticoagulants should be discontinued before LVAD implantation.

Level of Evidence C.

Class IIa

1. Patients with a clinical syndrome of heparin-induced thrombocytopenia (HIT) should have confirmatory testing performed with a serotonin release assay.

Level of Evidence: C.

Malignancies

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 DMCS 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. DMCS as BTT or DT is not recommended for patients with an active malignancy and a life expectancy of <2 years.

Level of Evidence: C.

Diabetes (DM)

Screening and optimization of diabetes is recommended before DMCS

Diabetes is common in heart failure patients and treatment is an important component of GDMT. Presence of diabetes has been associated with infection and late mortality in LVAD patients.(42-44) Additionally, patients admitted for advanced medical therapies with hyperglycemia irrespective of any previous history are associated with increased mortality. Optimization of blood glucoses prior, during, and after surgery will likely yield the best results.

As a screening tool, there is some conflicting data regarding the utility of a hemoglobin A1c (HbA1c) and its ability to predict DMSCS outcomes. Although, preoperative HbA1c has not been specifically associated with mortality or adverse events, it may be a practical laboratory test to assess overall glycemic control before surgery. This complicated subject should not be oversimplified by one piece of data, but only serve as part of a more comprehensive risk stratification of patients. It is noteworthy that many patients without a history of DM may also have hyperglycemia in the perioperative period, and that the results of all patients (irrespective of previous history) is best predicted by glycemic control and chronic history of DM.

Irrespective of a preoperative HbA1c, patients with the poorest glycemic control have the highest mortality with and without diabetes. Hence, a management strategy that produces tight glycemic control (endocrine expertise recommended) will benefit all patients after DMCS implantation. Screening for the presence and severity of diabetes is therefore warranted and when possible, DMCS should be delayed until diabetes management has been optimized.

Recommendations for diabetes

Class I

1. All patients should be screened for diabetes before DMCS with a hemoglobin A1c.

Level of Evidence: C.

2. All patients with established diabetes should be assessed 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 consultation with an endocrinologist before implantation of DMCS and have their diabetes management optimized before implant.

Level of Evidence: C.

Class IIb

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

Level of Evidence: C.

Pregnancy

Class I

1. Use of contraception in women of child bearing age after DMCS is recommended.

Level of Evidence: C.

Class III

1. DMCS in the setting of active pregnancy is not recommended.

Level of Evidence: C.

Advanced age: *This recommendation has been removed as it applies to patients of all ages under consideration for DMCS.*

Gastrointestinal disorders

The incidence of gastrointestinal bleeding with continuous-flow devices ranges from 15% to 30% (45, 46). It has been acknowledged that coagulopathy, lack of pulsatility, acquired vonWillebrand syndrome and/or other risk factors such as (low platelet count, advanced age and frailty, a previous history of GI bleed, uncontrolled high INR) are risk factors for bleeding (47, 48).

Recommendations of gastrointestinal screening

Class IIa

1. In patients with recent history of gastrointestinal bleeding, melena, unexplained iron deficiency anemia, or premalignant polyps, screening with upper and lower endoscopy is reasonable.

Level of Evidence: C.

Psychosocial evaluation of MCS candidates

All MCS candidates should undergo a comprehensive psychosocial evaluation,(49) a process as outlined in the 2018 ISHLT consensus document for patients being evaluated for cardiothoracic transplantation and long-term mechanical circulatory support.(50) The goals of the evaluation process outlined in that document were to [1] assess risk factors for poor postimplantation outcomes; [2] collect information on factors related to patients' knowledge, understanding, and capacity to engage in decision making about MCS; [3] collect information to characterize patients' personal, social, and environmental resources and circumstances, including factors that may mitigate the impact of any psychosocial risk factors on postimplantation outcomes; [4] evaluate patients' knowledge about and capacity to operate the device (51). A brief psychosocial evaluation may be required for patient in cardiogenic shock to exclude any major contraindications. Here are the specific guideline recommendations:

Assessment of psychosocial risk factors

Class I

1. All patients should have a screen for psychosocial risk factors before DMCS.

Level of Evidence: C.

2. The psychosocial evaluation should have a screen for poor outcomes after implantation and include screenings for:

a. Treatment adherence and health behaviors

b. Mental health history

c. Substance abuse history

Level of Evidence: B.

3. The psychosocial evaluation should screen for factors related to patients' knowledge, understanding, and capacity to engage in decision making

a. Cognitive status and capacity to give informed consent

b. Knowledge and understanding of current illness

c. Knowledge and understanding of current treatment options

Level of Evidence: B.

4. *The psychosocial evaluation should screen for factors specific to patients' personal, social, and environmental resources and circumstances, including:*

a. Coping with illness

b. Social support

c. Social history

Level of Evidence: B.

5. The psychosocial evaluation should screen for knowledge about and capacity to operate a DMCS device.

Level of Evidence: C.

Class IIb

1. In patients with a history of nonadherent behavior, lack of sufficient social support, and limited coping skills are relative contraindications to DMCS.

Level of Evidence: C.

Class III

1. Poor compliance with medical regimens is a risk factor for poor outcomes related to DMCS. Patients who demonstrate an inability to comply with medical recommendations on multiple occasions should not receive DMCS.

Level of Evidence: C.

2. With rare exception DMCS should not be performed in patients who are unable to physically operate the pump, respond to device alarms, or report signs and symptoms to the device coordinator, or who live in an unsafe environment.

Level of Evidence: C.

The home environment

Ensuring a safe home environment for the patient's when they are discharged from the hospital is critical. This includes grounded electric outlets, telephone access, free of clutter or unsafe surroundings, and access to emergency medical services.

Recommendations for screening the home environment

Class I

1. All patients undergoing DMCS should be questioned about their home environment to assure it meets minimum safety and power requirements established by the program.

Level of Evidence: C.

Class III

1. Patients who do not have a safe environment into which to be discharged or lack access to reliable power should not be considered for DMCS.

Level of Evidence: C.

Psychiatric risk factors

Patients with underlying untreated active psychiatric illness are at high-risk for nonadherence and poor outcomes after LVAD and should undergo a prompt psychiatric evaluation to optimize therapy (51-56).

Recommendations for psychiatric risk factors

Class I

1. Patients with a history of a significant psychiatric illness who are considered for DMCS should undergo a thorough psychiatric and psychological evaluation to identify and treat potential risk factors.

Level of Evidence: C.

Class III

1. DMCS 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.

Specific substances of abuse (also addressed in TF 2)

In addition to screening for substance abuse as described in the 2018 ISHLT psychosocial consensus statement that may impact outcomes from a psychosocial perspective, there may also be directly attributable morbidity and mortality associated with their use.

Tobacco use

Recommendations for tobacco use

Class I

1. Patients considered for DMCS 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.

Level of Evidence: C.

Marijuana and cannabinoid use

Marijuana. With the increasing prevalence of legalized marijuana for medicinal use, recreational use or both there are increasing disparities in program's approach to marijuana use before implantation (57). Concerns regarding compliance, addiction, infection, drug interactions and neuropsychiatric effects, among others have been raised in the setting of organ transplantation (58, 59).

In a recent international survey of heart transplant centers, almost two thirds supported the listing of patients who used legal (nonsmoked) medical marijuana, whereas just over a quarter supported listing for users of legal recreational marijuana (60). At times transplant centers listing criteria conflict with laws that prohibit the denial of transplant to those who use marijuana. These protocols should also apply to those implanted as a bridge to transplantation and as with tobacco should not preclude emergent pump implant, particularly in the setting of legal use. However, the risks of marijuana use are not as well studied in MCS populations and there may be lower risk of pulmonary infection with inhalational use given the lack of immunosuppression. Although legal, many programs also ask patients to abstain from tobacco use, smoked or otherwise, to be considered for MCS.

Cannabidiol. Cannabidiol (CBD) oil has also been legalized in many jurisdictions and is used by patients for a variety of maladies, although there is weak evidence of its effectiveness. CBD oil is typically thought of as nonintoxicating as it has little to no tetrahydrocannabinol (THC) but, depending on the manufacturer, there may be enough THC to result in a positive toxicology screen for THC. It is metabolized through CYP450 and can inhibit CYP2C19, CYP2D6, and CYP2C9 (61).

Recommendations for marijuana and cannabinoid use

Class I

1. All patients who have a history of marijuana abuse should receive counseling about cessation and should receive follow-up as recommended by a thorough psychosocial evaluation.

Level of Evidence: C.

Class IIa

1. In jurisdictions where medicinal marijuana or cannabinoids are legal, confirmation of legal providers and prescriptions should be obtained, and their continued use should only be allowed as part of a properly supervised therapeutic regimen.

Level of Evidence: C.

2. Previous marijuana/cannabinoid use should not preclude emergent pump implantation as a potential BTT.

Level of Evidence: C.

Class IIb

1. In jurisdictions where recreational marijuana is legal, individual programs can determine the dose, frequency, route, and ability to continue its use in determining eligibility for DMCS.

Level of Evidence: C.

Class III

1. Patients who are actively abusing marijuana and do not follow programmatic recommendations regarding cessation should not be implanted with DMCS.

Level of Evidence: C.

Alcohol and substance abuse

Recommendations for Alcohol and substance abuse

Class IIb

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

Level of Evidence: C.

Class III

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

Level of Evidence: C.

Caregiver burden

Caregiver burden in DMCS patients is high, especially in the setting of recipient adverse events or poor functional status (62). Smaller studies have also shown that caregivers who were a spouse and lived in the same home had the greatest likelihood to sustain a caregiver relationship (63-65). While introduction of formal decision aids for caregivers improve knowledge and improve concordance between caregivers treatment choice and their values, they led to higher initial decisional conflict (66). For these reasons, a substantial caregiver burden may occasionally become the reason to forgo LVAD surgery for the patient.

Caregiver burden recommendations

Class I

1. Caregiver burden should be assessed before DMCS 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 patient's DMCS implantation.

Level of Evidence: C.

Shared decision making

It has been increasingly recognized that communicating the risks and benefits of complex medical procedures in a way that can be fully grasped by patients and understood in the context of their preferences can be a difficult to achieve. A process of shared decision making can better align decisions regarding therapies with patient's values and goals. Studies of shared decision making have recently been assessed in the field of MCS with the multicenter Share Decision Support Intervention for Patients and their Caregivers Offered Destination Therapy for End-stage Heart Failure (DECIDE-LVAD) randomized trial.

When compared to standard patient education, the decision support group had improved knowledge and better concordance between patient values and patient-reported treatment choice, but not with the eventual treatment. Importantly, the intervention group was also less likely to choose MCS (67). Patients with major pre-implant comorbidities were also more likely to have decisional conflict and higher stress postimplant, but not decision regret, depression or quality of life (68).

Recommendation for shared decision making

Class IIa

1. Enhancing traditional educational material with more structured shared decision making materials may be useful preimplantation to better align patient choice of therapy with their preferences.

Level of Evidence: B.

Financial assessment

Recommendation for financial assessment

Class IIa

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

Level of Evidence: C.

Assessment of frailty

Frailty is a biological syndrome that reflects a state of decreased physiologic resilience, placing patients at a heightened vulnerability in the face of stress (69, 70). Although commonly associated with advanced age, it is not confined to the elderly, nor does advanced age equate to frailty (69). It is highly prevalent in patients with advanced HF, affecting almost 50% of patients with NYHA class IV symptoms (71). Although difficult to quantify, frailty is usually diagnosed by the presence of a combination of fatigue/ exhaustion, weakness, slow gait and exercise intolerance. Advanced HF itself leads to muscle wasting, depression, cognitive dysfunction and cachexia—resulting in overlapping symptomatology with frailty (72). Furthermore, comorbidities like diabetes mellitus, chronic kidney disease contribute to chronic inflammation and metabolic stress, which in turn contribute to frailty.

It is well recognized that frailty is highly predictive of death, disability, prolonged hospitalization and rehospitalizations in patients undergoing cardiac surgery (73, 74). Given its significant impact on postsurgical morbidity and mortality, assessment of frailty is gaining increasing attention patient's being considered for durable LVAD (75). Integration of frailty assessment in patient selection for

Table 2 Frailty and Sarcopenia Measures for Consideration in Evaluating MCS Candidates

Frailty measure	Criteria	Classification of frailty	Outcomes predicted
Fried criteria Ref. (69, 70, 72)	1. Unintentional weight loss (10 pound or ≥5% weight loss in prior year, 1 point) 2. Weak handgrip strength (repeated 3× and averaged with dominant hand, 1 point) 3. Self-reported exhaustion (by questions from CES-D scale, 1 point) 4. Slow gait speed (5-m gait speed/15 feet walk time, 1 point) 5. Low self-reported physical activity (by Minnesota Leisure Time Activities Questionnaire, 1 point)	Nonfrail 0 point Prefrail 1-2 points Frail 3-5 points	30-day postoperative complications Discharge to a facility Length of stay Risk of mortality
Handgrip strength (HGS) Ref. (77)	Maximal isometric contraction with each hand 3 consecutive times, each followed by a 5-sec rest period, averaged for each hand and normalized for body weight	Frail: HGS <25% of body weight	Risk of mortality (short and long term) Postoperative complications
Deficit Index Ref. (75)	Includes a list of 31 indices as Yes/ No 1-14: Ability to perform activities of daily living 15-31: Comorbidities such as diabetes, peripheral vascular disease, cerebrovascular disease, chronic obstructive pulmonary disease, renal or liver disease, malignancy, dementia, hypertension, depression etc.	Nonfrail—lowest tertile Intermediately frail—middle tertile Frail—highest tertile	Risk of mortality and re-hospitalization
Muscle quantification Ref. (78, 79)	1. Psoas muscle areas at L3-L4 as measured by CT scan 2. Pectoralis muscle mass indexed to body surface area and attenuation approximated by mean Hounsfield units	Lowest tertile psoas muscle area by gender Unit change in muscle mass	Inpatient length of stay Mortality

LVADs is limited by lack of clear understanding of the syndrome's pathophysiology and the absence of a validated, objective risk assessment measure. Hence, clinicians continue to use the "eyeball test" as an overall assessment of the patient from the doorway to intuitively qualify this vulnerability (69). There are a wide range of existing frailty measures for characterizing frailty in LVAD-eligible patients is summarized in Table 2. The Fried Frailty Phenotype assesses for weight loss, gait speed, grip strength, self-reported exhaustion and physical inactivity, and is highly predictive of adverse outcomes in a variety of settings (72, 76). The Deficit Index assesses multiple deficits measured by clinical symptoms, functional impairments, laboratory findings and comorbidities as a quantitative measure of the severity of frailty (75). Although multidimensional frailty measures address several domains, they are inherently more cumbersome and hence difficult to use. Handgrip strength has been used as a single frailty measure, making it time- and resource-efficient (77). Measurements of sarcopenia using various imaging modalities have been predictive of post-LVAD outcomes (78, 79). Although slow gait speed is a common marker of frailty, it was the inability to perform the test due to being too sick that predicted mortality in INTERMACS population rather than the speed itself (80).

Since frailty is partly attributed to underlying HF, it has been suggested that some of the frailty phenotype may be modifiable with implantation of an LVAD—the LVAD "responsive" patient (69, 81). Although there is no clear evidence to support the use of exercise and supervised physical rehabilitation, efforts to mitigate frailty via improvements in muscle mass are encouraged. Importantly, in the absence of validated risk assessment tools, a single measure of frailty should not be the sole criteria for refusing LVAD for a patient.

Recommendations for frailty

Class IIa

1. In patients undergoing evaluation for DMCS, it is reasonable to include an objective evaluation to assess the burden of frailty.

Level of Evidence: C.

Recommendation for palliative care

Class IIa

1. Palliative care consultation should be considered as a component of the treatment of end-stage heart failure during the evaluation phase for DMCS. In addition to symptom management, goals and preference for end of life should be discussed with patients receiving DMCS as long-term support.

Level of Evidence: C.

Nutritional assessment

A nutritional assessment is recommended for LVAD candidates with the goal of identifying nutritional deficiencies and begin the process of correcting nutritional deficiencies if indicated (82, 83). MCS however should not be delayed to institute these nutritional measures as delays in circulatory support may increase short-term risk for patients. Nutritional biomarkers such albumin are commonly incorporated into LVAD risk scores that prognosticate risk after CF-LVAD implant (26). Patients with advanced heart failure undergoing LVAD implantation have pervasive malnutrition as measured by nutritional biomarkers including albumin, total lymphocyte count, prealbumin, and total cholesterol (84-87).

Although, a single biomarker is not superior to others, it is reasonable to assess these markers to understand the severity of preoperative malnutrition, describe risk for postoperative complications, and outline strategies to restore normal nutrition in the recovery period (88).

Recommendations for nutrition assessment

Class I

1. All patients should have assessment of their nutritional status before DMCS implantation including measurement of albumin, prealbumin, total cholesterol and total lymphocyte count.

Level of Evidence: B.

2. Patients who have indices of malnutrition before DMCS implantation should have an evaluation by a nutritional consultation service.

Level of Evidence: C.

Class IIa

1. Patients who have evidence of malnutrition before DMCS implantation should be considered for nutritional interventions before implantation if the patient's clinical status allows.

Level of Evidence: C.

Class III

1. Patients who have evidence of severe malnutrition before MCSD implantation should not have implantation delayed to maximize their nutritional status.

Level of Evidence: C.

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	Indications for DMCS: Class I: 1. Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for durable mechanical circulatory (DMCS) support for short-term support as bridge to transplantation or bridge to candidacy. Level of Evidence: A. (New) 2. Patients with advanced heart failure symptoms (New York Heart Association functional class IIIB-IV) refractory to maximal medical management, inotrope dependent or on temporary circulatory support, should be considered for DMCS for long-term support if transplant is unlikely to occur in the short-term, if a period of support will improve transplant candidacy, or as destination therapy for patients who are ineligible for transplant. Level of Evidence: A. (New) Class IIa: 1. Patients with dilated cardiomyopathy, particularly of recent onset and non-ischemic etiology refractory to maximal medical therapy, should be considered for DMCS as bridge-to-recovery. Pharmacological treatment should be with maximally tolerated neurohormonal modulation, and surveillance for recovery of left ventricular function should be undertaken. Level of Evidence: B. (New) (See Task Force 7 for additional information)
Evaluation Process of DMCS Candidates: Class I:	**Evaluation Process of DMCS Candidates:** Class I: 1. All potential DMCS patients should be managed by an advanced heart failure team for optimization of therapies, risk assessment, and shared decision making. Level of Evidence: C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
1. All patients should have any reversible causes of heart failure addressed prior to consideration for DMCS. Level of Evidence: A. 2. All patients referred for DMCS should have their transplant candidacy assessed prior to implant. Level of Evidence: A.	2. All patients should have any reversible causes of heart failure addressed prior to consideration for DMCS. Level of Evidence: C. (*Modified*) 3. All patients referred for DMCS should have their transplant candidacy assessed prior to implant. Level of Evidence: C. (*Modified*)
Clinical Classification of DMCS Candidates Class I: 1. All patients being considered for DMCS should have their NYHA class assessed. Level of Evidence: C. 2. All patients being assessed for DMCS should have their INTERMACS profile determined. Level of Evidence: C.	**Clinical Classification of DMCS Candidates** *Continuing approval without change*
Risk Stratification for Consideration of MCS: Class IIa: 1. Long-term DMCS for patients who are in acute cardiogenic shock should be reserved for the following: a. Patients whose ventricular function is either 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 DMCS, as 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 DMCS. 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 one-year mortality using prognostic models should be referred to advanced therapy including heart transplant, or DMCS (BTT or DT) as appropriate. Level of Evidence: C.	**Risk Stratification for Consideration of DMCS:** *Continuing approval without change*
Risk Stratification to Determine Timing of DMCS Therapy based on INTERMACS Classification:	**Risk Stratification to Determine Timing of DMCS Therapy based on INTERMACS Classification:** Class I: 1. INTERMACS profile 1-3 patients benefit in terms of survival from implantation of a LVAD. Level of Evidence: A. (New) Class IIb: 1. INTERMACS profile 4 may benefit in terms of survival from implantation of a LVAD. Level of Evidence: B. (New)
Patients with Coronary Artery Disease: Class IIa: 1. Patients being considered for DMCS who have a history of coronary artery bypass grafting should have a chest CT scan to provide the location and course of the bypass grafts to guide the surgical approach. Level of Evidence: C.	**Patients with Coronary Artery Disease:** Class IIa: 1. Patients being considered for DMCS who have a history of coronary artery bypass grafting should have appropriate imaging to assess the location and course of the bypass grafts to guide the surgical approach. Level of Evidence: C. (*Modified*)

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Task Force 1 Summary:
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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Patients with Acute Myocardial Infarction: Class IIb: 1. If possible, permanent DMCS should be delayed in the setting of an acute infarct involving the LV apex. Level of Evidence: C.	**Patients with Acute Myocardial Infarction:** Class IIb: 1. If possible, permanent DMCS should be delayed in the setting of an acute infarct (at least 5 days). Level of Evidence: C. (*Modified*)
Evaluation of DMCS 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 TAH. Level of Evidence: C.	**Evaluation of DMCS Candidates with Congenital Heart Disease** This topic is moved to Task Force 6.
Evaluation of DMCS candidates with Valvular Disease	**Evaluation of DMCS candidates with Valvular Disease** This topic is moved to Task Force 3.
Infective Endocarditis:	**Infective Endocarditis:** This topic is moved to Task Force 3.
Intracardiac Shunts:	**Intracardiac Shunts:** This topic is moved to Task force 3.
Intracardiac Thrombus:	**Intracardiac Thrombus:** This topic is moved to Task force 3.
Atrial Arrhythmias: Class I: 1. Atrial flutter or fibrillation is not a contraindication to DMCS. Level of Evidence: C. Class IIa: 1. Patients with medically refractory atrial tachyarrhythmias may benefit from ablation of the arrhythmia or AV node (with subsequent ICD/pacemaker placement) prior to LVAD implantation. Level of Evidence: C.	**Atrial Arrhythmias:** Class 1: 1. *Continuing approval without change*. Class IIb: 1. Patients with medically refractory atrial tachyarrhythmias may benefit from ablation of the arrhythmia or AV node (with subsequent ICD/pacemaker placement) prior to LVAD implantation. Level of Evidence: C. (*Modified*)
Arrhythmia Therapy: Class IIa: 1. Patients with treatment refractory recurrent sustained ventricular tachycardia or ventricular fibrillation in the presence of untreatable arrhythmogenic pathologic substrate (e.g., giant cell myocarditis, scar, sarcoidosis), a biventricular support or a TAH is preferred over isolated LV support. Level of Evidence: C.	**Arrhythmia Therapy:** *Continuing approval without change*
Peripheral Vascular Disease: 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 DMCS. Level of Evidence: C. Class IIb: 1. Peripheral vascular disease may be a relative contraindication to MCS based on its extent and severity. Level of Evidence: C.	**Peripheral Vascular Disease:** Class IIa: 1. *Continuing approval without change* 2. Imaging to assess intrathoracic atherosclerotic burden should be considered. Level of Evidence: C. (New) Class IIb: 1. DMCS may be reasonable in select patients with manageable peripheral vascular disease. Level of Evidence: C. (*Modified*)
Life-Limiting Comorbidities and Multiorgan Failure: Class III: 1. Consideration of DMCS in the setting of irreversible multiorgan failure is not recommended. Level of Evidence: C.	**Life-Limiting Comorbidities and Multiorgan Failure:** *Continuing approval without change*

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Renal Dysfunction: *Not previously discussed*	**Renal Dysfunction:** Class IIb: 1. For patients with severe renal dysfunction, initial support with a temporary device to assess for potential of renal recovery before implanting DMCS can be considered. Level of Evidence: B. (New)
Pulmonary Hypertension Class I: 1. All patients being considered for DMCS should have an invasive hemodynamic assessment of pulmonary vascular resistance. Level of Evidence: C.	**Pulmonary Hypertension** *Continuing approval without change*
Pulmonary and Thoracic Assessment *Previously Task Force 2* Class I: 1. Patients should have a chest X-ray and an arterial blood gas assessment prior to DMCS 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.	**Pulmonary and Thoracic Assessment** Class I: 1. Patients should have a chest X-ray prior to DMCS implantation Level of Evidence: C. (*Modified*) Class IIa: 1. In patients with prior cardiothoracic surgery or suspected pulmonary disease, assessment of thoracic anatomy with CT or MRI prior to DMCS implantation is reasonable. Level of Evidence: C. (*Modified*) Class IIb: 1. PFT spirometry may be beneficial to screen for patients with suspected lung disease (e.g. COPD) for pre-operative optimization and peri-operative management. Level of Evidence: B. (New) 2. An Assessment of lung function and screening for signs of pulmonary edema /lung injury during veno-arterial ECLS support should be performed prior to DMCS implantation. Level of Evidence: C. (New)
Neurologic Function: Class I: 1. A thorough neurologic examination should be performed on every patient being considered for DMCS. 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 DMCS should have carotid and vertebral Doppler examination as a screen for occult vascular disease. Level of Evidence: C. 3. CT scan or magnetic resonance imaging (MRI) is warranted in patients with previous stroke to establish a pre-operative baseline study. Level of Evidence: C. Class III: 1. DMCS 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.	**Neurologic Function:** *Continuing approval without change*
Coagulation and Hematologic Disorders: Class I: 1. All patients evaluated for DMCS therapy should have a PT/INR, aPTT, and platelet count 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.	**Coagulation and Hematologic Disorders:** Class 1: 1. *Continuing approval without change* 2. C*ontinuing approval without change*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
3. Patients with a history of thrombophilia prior to DMCS should have a hypercoagulable assessment prior to implant. Level of Evidence: C.	3. Patients with a history of thrombophilia should have a hypercoagulable assessment prior to DMCS. Level of Evidence: C. (*Unchanged*) 4. Thienopyridine anti-platelet agents and direct oral anticoagulants should be discontinued prior to LVAD implantation. Level of Evidence C. (New)
Class IIa: 1. Patients with a clinical syndrome of HIT should have confirmatory testing performed. Level of Evidence: C.	Class IIa: 1. Patients with a clinical syndrome of heparin-induced thrombocytopenia (HIT) should have confirmatory testing performed with a serotonin release assay. Level of Evidence: C. (*Modified*)
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 DMCS 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. DMCS 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 Malignancy:** *Continuing approval without change*
Diabetes: Class I: 1. All patients should be screened for diabetes prior to DMCS with a fasting glucose. Level of Evidence: C. 2. All patients with an abnormal fasting glucose or established diabetes should have a hemoglobin A1c drawn and be assessed 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 consultation with an endocrinologist prior to implantation of DMCS. Level of Evidence: C. Class IIb: 1. DMCS 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.	**Diabetes:** Class I: 1. All patients should be screened for diabetes prior to DMCS with a hemoglobin A1c. Level of Evidence C. (*Modified*) 2. All patients with established diabetes should be assessed for the degree of end-organ damage (retinopathy, neuropathy, nephropathy, and vascular disease). Level of Evidence: C. (*Unchanged*) 3. Patients with poorly controlled diabetes should have consultation with an endocrinologist prior to implantation of DMCS and have their diabetes managment optomized prior to implant. Level of Evidence: C. (*Modified*) Class IIb: 1. *Continuing approval without change*
Pregnancy: Class I: 1. Use of contraception in women of child bearing age after DMCS is recommended. Level of Evidence: C. Class III: 1. DMCS in the setting of active pregnancy is not recommended. Level of Evidence: C.	**Pregnancy:** *Continuing approval without change*
Age: Class IIb: 1. Patients >60 years old should undergo thorough evaluation for the presence of other clinical risk factors that may decrease survival or quality of life after DMCS. Level of Evidence: C.	**Age:** *This recommendation has been removed as it applies to patients of all ages under consideration for DMCS.*

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Task Force 1 Summary:
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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Gastrointestinal Disorders: *Not previously discussed*	**Gastrointestinal Disorders:** Class IIa: 1. In patients with recent history of gastrointestinal bleeding, melena, unexplained iron deficiency anemia, or premalignant polyps, screening with upper & lower endoscopy is reasonable. Level of Evidence C. (New)
Psychosocial Evaluation of DMCS Candidates: Class I: 1. All patients should have a screen for psychosocial risk factors prior to DMCS. Level of Evidence: C. 2. All patients should have a screen for cognitive dysfunction prior to DMCS. Level of Evidence: C. 3. Family, social, and emotional support must be assessed prior to DMCS. Level of Evidence: C. 4. Patients with a history of a significant psychiatric illness who are considered for DMCS should undergo a thorough psychiatric and psychological 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 healthcare needs to the MCS team, or patients who live in an unsafe environment are all contraindications to implantation. Level of Evidence: C. 2. DMCS 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.	**Psychosocial Evaluation of DMCS Candidates**: *Replaced by the new and modified recommendations below* Class I: 1. All patients should have a screen for psychosocial risk factors prior to DMCS. Level of Evidence: C. (Unchanged) 2. The psychosocial evaluation should have a screen for poor outcomes after implantation and include screenings for: a. Treatment adherence and health behaviors b. Mental health history c. Substance abuse history Level of Evidence: B. (New) 3. The psychosocial evaluation should screen for factors related to patients' knowledge, understanding and capacity to engage in decision-making a. Cognitive status and capacity to give informed consent b. Knowledge and understanding of current illness c. Knowledge and understanding of current treatment options Level of Evidence: B (New) 4. The psychosocial evaluation should screen for factors specific to patients' personal, social, and environmental resources and circumstances, including: a. Coping with illness b. Social support c. Social history Level of Evidence: B. (New) 5. The psychosocial evaluation should screen for knowledge about and capacity to operate a DMCS device. Level of Evidence: C. (New) Class IIb: 1. In patients with a history of non-adherent behavior, lack of sufficient social support and limited coping skills are relative contraindications to DMCS. Level of Evidence: C. (New) Class III: 1. Poor compliance with medical regimens is a risk factor for poor outcomes related to DMCS. Patients who demonstrate an inability to comply with medical recommendations on multiple occasions should not receive DMCS. Level of Evidence: C. (New) 2. With rare exception DMCS should not be performed in patients who are unable to physically operate the pump, respond to device alarms, or report signs and symptoms to the device coordinator, or who live in an unsafe environment. Level of Evidence: C. (New)

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Adherence to Medical Therapy and Social Network: Class I: 1. Assessment of medical compliance, social support and coping skills should be performed in all candidates for DMCS device implantation. Level of Evidence: C. Class IIa: 1. Lack of sufficient social support and limited coping skills are relative contraindications to DMCS in patients with a history of nonadherent behavior. Level of Evidence: C. Class III: 1. Poor compliance with medical regimens is a risk factor for poor outcomes related to MCS and mortality after heart transplantation. Patients who demonstrate an inability to comply with medical recommendations on multiple occasions should not receive MCS. Level of Evidence: C.	**Adherence to Medical Therapy and Social Network:** *Replaced by the new and modified recommendations above*
Home Environment:	**Home Environment:** Class I: 1. All patients undergoing DMCS should be questioned about their home environment to assure it meets minimum safety and power requirements established by the program. Level of Evidence: C. *(New)* Class III: 1. Patients who do not have a safe environment into which to be discharged or lack access to reliable power should not be considered for DMCS. Level of Evidence: C. *(New)*
Psychiatric Risk Factors: *(previously addressed under heading 'Psychological and Psychiatric Evaluation')*	**Psychiatric risk factors:** Class I: 1. Patients with a history of a significant psychiatric illness who are considered for DMCS should undergo a thorough psychiatric and psychological evaluation to identify and treat potential risk factors. Level of Evidence: C. *(Unchanged)* Class III: 1. DMCS 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. *(Unchanged)*
Recommendations for Tobacco Use: Class I: 1. Patients considered for DMCS 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 Tobacco Use:** Class I: 1. *Continuing approval without change* Class IIa: 1. Previous tobacco use should not preclude emergent pump implantation as a potential BTT. Level of Evidence: C. (*Modified***)**

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Marijuana and Cannabinoid Use: *(not previously discussed specifically)*	**Marijuana and Cannabinoid Use:** Class I: 1. All patients who have a history of marijuana abuse should receive counselling about cessation and should receive follow-up as recommended by a thorough psychosocial evaluation. Level of Evidence: C. (New) Class IIa: 1. In jurisdictions where medicinal marijuana or cannabinoids are legal, confirmation of legal providers and prescriptions should be obtained and their continued use should only be allowed as part of a properly supervised therapeutic regimen. Level of Evidence: C. (New) 2. Previous marijuana/cannabinoid use should not preclude emergent pump implantation as a potential BTT. Level of Evidence: C. (New) Class IIb: 1. In jurisdictions where recreational marijuana is legal, individual programs can determine the dose, frequency, route and ability to continue its use in determining eligibility for DMCS. Level of Evidence: C. (New) Class III: 1. Patients who are actively abusing marijuana and do not follow programmatic recommendations regarding cessation should not be implanted with DMCS. Level of Evidence: C. (New)
Alcohol and substance abuse: 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 DMCS therapy. Level of Evidence: C. Class III: 1. Active substance abusers (including alcohol) should not receive DMCS therapy. Level of Evidence: C.	**Alcohol and substance abuse:** *Continuing approval without change*
Caregiver Burden: Class I: 1. Caregiver burden should be assessed prior to DMCS 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 patient's DMCS implantation. Level of Evidence: C.	**Caregiver Burden:** *Continuing approval without change*
Shared decision- making: *Not previously discussed*	**Shared decision- making** Class IIa: 1. Enhancing traditional educational material with more structured shared decision making materials may be useful pre-implantation to better align patient choice of therapy with their preferences. Level of Evidence: B. (New)
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, insurance agent or an individual's family. Level of Evidence: C.	**Financial situation and insurance coverage:** *Continuing approval without change*

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Frailty:	**Frailty:**
Not previously discussed	Class IIa 1. In patients undergoing evaluation for DMCS, it is reasonable to include an objective evaluation to assess the burden of frailty. Level of Evidence: C. (New)
Palliative Care	**Palliative Care**
Previously Task Force 2	
Class IIa:	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 preference for end of life should be discussed with patients receiving DMCS as DT.	1. Palliative care consultation should be considered as a component of the treatment of end-stage heart failure during the evaluation phase for DMCS. In addition to symptom management, goals and preference for end of life should be discussed with patients receiving DMCS as long-term support.
Level of evidence: C.	Level of evidence: C. (*Unchanged*)
Nutrition Assessment	**Nutrition Assessment**
Previously Task Force 2	
Class I:	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	1. All patients should have assessment of their nutritional status prior to DMCS implantation including measurement of albumin, pre-albumin, total cholesterol and total lymphocyte count.
Level of evidence: B.	Level of evidence: B. (*Modified*)
2. Patients who have indices of malnutrition prior to DMCS implantation should have an evaluation by a nutritional consultation service.	2. *Continuing approval without change*
Level of evidence: C.	
Class IIa:	Class IIa:
1. Patients who have evidence of malnutrition prior to DMCS implantation should be considered for nutritional interventions prior to implantation if the patient's clinical status allows.	1. *Continuing approval without change*
Level of evidence: C.	
Class IIb:	Class III:
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.	1. Patients who have evidence of severe malnutrition prior to DMCS implantation should not have implantation delayed to maximize their nutritional status.
Level of evidence: C.	Level of evidence: C. (*Modified*)

Task Force 2

Patient optimization, consent, and appropriate timing for DMCS: Modifiable risk management before implantation

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Introduction

Evaluation of a patient for long-term mechanical circulatory support is similar to the evaluation for cardiac transplantation. Emergent situations may exist, precluding the ability to perform a thorough or ideal evaluation. Nevertheless, a comprehensive assessment of the patient and preoperative optimization using a multisystems approach prepares the patient for the best chance of a successful outcome. Preoperative risk scoring systems have been used to prognosticate postoperative outcomes, but their guidance yields less help in preoperative organ optimization. Although the algorithms are helpful, they cannot circumvent experienced clinical judgment.

Obesity

Obesity is common in the heart failure (HF) population. Severe obesity (body mass index (BMI) >35-40 kg/m^2) is considered a relative contraindication to transplantation (1), and is associated with a modest increase in mortality after transplantation (2). Therefore, many of these patients are ultimately implanted with durable left ventricular assist devices as a bridge to transplant or as destination therapy, because of institutional guidelines that support severe obesity as a relative contraindication to transplant.

Obesity thresholds for durable mechanical circulatory support (DMCS) are quite varied among institutions. Associations with preimplant obesity and postimplant mortality are mixed. Multiple single-center, retrospective analyses have shown similar survival outcomes across the spectrum of BMI, even with extreme obesity (3-7). A recent meta-analysis ($n = 26,842$ HF patients—9,509 obese and 17,333 nonobese) suggested lower 6-month mortality in obese individuals [RR = 0.79 [0.73, 0.86]; $p < .001$), although similar longer term mortality (8). In contrast, in the most recent IMACS report ($n = 16,286$), BMI (increase by 5 units) was associated with a modest increase in early (HR 1.11, $p = .0008$) and constant mortality risk (HR 1.05, =0.0053) in multivariate modeling (9). The associations with obesity and postoperative morbidity in DMCS are more apparent. Preimplant obesity increases the risk for device-related infections, pump thrombosis, right heart failure, and heart failure readmissions (7, 8, 10-13). This data set continues to evolve as limited data comparing a *less invasive* implant strategy, suggests similar outcomes between obese and nonobese individuals (14).

LVAD implantation as a bridge to transplant (BTT) in obese individuals is a common practice. In a 2016 analysis of the UNOS database, obese individuals supported as BTT had higher complication rates including infection and thromboembolism requiring waitlist status upgrades. Significant weight and body composition changes may also lead to cannula malposition, which is itself associated with adverse events (15, 16). Waitlist mortality was similar, though post-transplant outcomes were worse in obese patients. (16, 17)

Bariatric surgery, mainly laparoscopic sleeve gastrectomy, is increasingly being utilized as a weight loss strategy both during (18) and after LVAD implantation (19, 20). Acceptable safety profiles have been reported in case series. Although cardiac rehabilitation improves functional capacity and quality of life (QOL) in LVAD patients (21, 22), formal exercise training has not been well studied as a weight loss strategy. Weight loss reduction strategies in patients supported with LVAD therapy remains an area requiring further investigation.

Recommendations for obesity

Class 1. Obesity itself is not a contraindication to DMCS. However, obesity increases the risk of postoperative morbidities including infection, cannula malposition, right heart failure, and heart failure readmissions. Surgical risk and comorbidities must be carefully considered at the time of evaluation.

Level of Evidence: B.

Class IIb. Bariatric surgery has been utilized both before and after MCS implantation in small case series as a weight loss strategy. It may be considered in select cases and at expert centers. Weight loss should be encouraged for all patients with BMI >30.

Level of Evidence: C.

Nutrition

Malnutrition or cachexia is common in patients with advanced HF who are being considered for DMCS. The etiology of malnutrition is multifaceted but is due, in part, to increased inflammation, catabolic signaling, neurohormonal dysregulation, inadequate caloric consumption, and malabsorption. Poor nutritional status is associated with increased morbidity and mortality (23-25). Nutritional status as reflected in a low BMI has also been shown to be a risk factor for poor survival after MCS. Part of the evaluation for candidacy for DMCS should be a nutritional assessment and consultation with a nutritional support team. (26)

A variety of metrics are available to assess the nutritional state and routine laboratories should at least include albumin, prealbumin, and C-reactive protein. Prealbumin has been suggested as a useful marker, as it can be used to assess the impact of nutritional interventions over a reasonably short duration. (27) Prealbumin is not a precursor of albumin and is more properly known as transthyretin, a protein which binds thyroid hormone and retinol, whose concentration drops rapidly with a fall in its synthetic rate. Levels of prealbumin delineate nutritional risk with levels <5 mg/dL being critically low, 5 to 10 mg/dL high risk, 11 to 19 mg/dL mild risk, and at 20 to 40 mg/dL are normal. Improvements in albumin following DMCS placement have been associated with improved outcomes (28, 29), although the impact of aggressive nutritional interventions have not been proven. Early nutritional intervention in ICU patients is frequently recommended, however randomized intervention trials remain to be performed. The risks of the patient deteriorating, which is associated with worse outcomes after DMCS, must be weighed against the time needed to make a meaningful impact on the patient's nutritional status. Nutritional assessment may be most useful to risk stratify patients preoperatively and ensure timely

intervention postoperatively. However, if patients have poor nutritional status before DMCS and are not immediately candidates, intensive preoperative nutritional interventions may be reasonable. (23)

Recommendations for nutrition

Class I

All patients should have assessment of their nutritional status before MCS with at least a measurement of albumin and prealbumin (Level of evidence: C).

Patients who have indices of malnutrition prior MCS should have an evaluation by a nutritional consultation service (Level of evidence: C).

Class IIa

Patients who have evidence of malnutrition before MCS should receive nutritional interventions before MCS (Level of evidence: C).

Class IIb

Patients who have evidence of malnutrition before MCS should have their implantation delayed to maximize their nutritional states, if time allows after assessment of their hemodynamic status (Level of evidence: C).

Management of end organ dysfunction

Renal dysfunction

Renal dysfunction in the HF patient at the time of DMCS implantation is common, and multifactorial. Acute kidney injury (AKI) may result from acute worsening of heart function, or chronic kidney disease may exist as a result of intrinsic renal disease, renal venous hypertension, or neurohormonal imbalance associated with chronic heart failure. Pre-MCS chronic kidney disease (CKD) Stage IV and V are associated with increased morbidity and mortality in postoperative MCS patients.(30) The need for hemodialysis before MCS is associated with dismal outcomes (30-32). MCS patients undergoing hemodialysis require a team familiar with the nuances of managing acute volume shifts in a patient undergoing MCS.(33) Many dialysis centers will not accept a MCSD patient, which further limits options for MCS in the patient with CKD.(34) Recently, centers are carefully selecting patients with severe renal dysfunction (CKD Stage IV−V), and applying a comprehensive strategy to preoperatively maximize renal function (including temporary MCS) with acceptable postoperative outcomes (35-37).

Patients undergoing a simultaneous heart-kidney transplant (SHKT) in the modern era with pretransplant MCSD have equivalent survival to those undergoing SHKT without MCSD.(38, 39) However, the need for post-SHKT hemodialysis, a major risk factor for in-hospital and long-term mortality, was increased in patients requiring preoperative hemodialysis (39).

Recommendations for managing renal function

Class I

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

Level of Evidence: C.

2. Patients with decompensated congestive heart failure and renal dysfunction should have a period of hemodynamic optimization (with inotropic and/or temporary mechanical circulatory support if clinically indicated) with the goal of volume optimization.

Level of Evidence: C.

3. Assessment of serum creatinine (SCr), blood urea nitrogen (BUN), 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 IIa: Patients with CKD Stage IV and V should be carefully selected for MCSD.

Level of Evidence: C.

Class IIb: DMCS as a bridge to SHKT may be considered in carefully selected patients, with a plan for long-term hemodialysis in an experienced center.

Level of Evidence: C.

Class III: The anticipation of permanent dialysis should be a contraindication for destination therapy.

Level of Evidence: B.

Hepatic dysfunction

Hepatic dysfunction is common in patients with acute decompensated congestive heart failure and shock. Patients who present with acute decompensation and hepatic dysfunction should be aggressively treated with inotropes, diuresis, and if necessary, temporary MCS before implantation of DMCS.(40, 41) Implantation of DMCS in patients with severe hepatic dysfunction leads to improvement in hepatic function in patients who survive the procedure.(42, 43) Patients with cirrhosis or end stage liver disease are poor candidates for DMCS.(44, 45)

Hepatic dysfunction associated with advanced heart failure is often an occult process. Chronically elevated right atrial pressures, renal dysfunction, significant tricuspid valve regurgitation, and abnormal liver function tests may indicate increased risk for hepatic fibrosis.(44) Many such patients may have significant hepatic dysfunction with no or only modest abnormalities of alanine aminotransferase (ALT) or aspartate aminotransferase (AST) or total bilirubin. Providers should have a low threshold to seek further investigation. If hepatic dysfunction is present or suspected, screening for fibrosis or cirrhosis with ultrasonography or CT scan to assess should be performed. Ultrasound findings may overestimate the severity of liver disease.(46) If the diagnosis of cirrhosis is suspected, a hepatologist should be consulted and transhepatic wedge pressure measured at the time of pre-DMCS right heart catheterization and consideration of trans-jugular hepatic biopsy to confirm cirrhosis severity and portal hypertension. Fibrosis without significant portal hypertension may not be a barrier to implantation in the presence of normal hepatic synthetic capacity as evident with normal coagulation profile.

The degree of liver disease may be assessed through both the Childs-Pugh class and the Model for End Stage Liver

Disease (MELD) score. Both classification systems have been used to predict perioperative morbidity and mortality in patients with cirrhosis, although the MELD score is more often used in more recent literature. The MELD score has been shown to be an independent predictor of increased need for perioperative transfusion and both short-term and long-term morbidity and mortality. The United Network for Organ Sharing (UNOS) identifies a patient with a MELD >17 of having increased survival following a liver transplant.(47) A MELD score >13 to 17 is the inflection point for increased risk of poor outcome following MCS.(45, 48) Those patients that have confirmed cirrhosis or end stage liver disease are poor candidates for DMCS except in very rare circumstances. (44, 48).

Even in the absence of hepatic failure, patients with hepatic dysfunction before DMCS implantation are at increased risk of bleeding and may have substantial transfusion requirements. Such patients are at greater risk for allosensitization, lung injury with exacerbation of right ventricular (RV) dysfunction, and infection. To minimize the risk of bleeding, coagulation abnormalities should be corrected, and unnecessary antiplatelet agents should be discontinued before DMCS implantation, ideally 3 to 7 days before surgery.(37, 49, 50)

Recommendations for managing hepatic dysfunction

Class I

1. Patients with a history of liver disease, abnormalities of liver function tests, chronic right hear failure or Fontan physiology should have an ultrasound of their liver to screen for cirrhosis before DMCS implantation.

Level of Evidence: C.

2. Patients who have suspected cirrhosis should receive further radiologic and tissue confirmation in conjunction with a hepatology consult.

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 before DMCS 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 MELD score are poor candidates for DMCS therapy.

Level of Evidence: B.

Pulmonary dysfunction

These guidelines do not specifically cover pulmonary hypertension or congenital considerations and serve only to provide some direction regarding the optimization or identify avoidable pitfalls before DMCS surgery.

Assessment of intrathoracic anatomy is mandatory in the preoperative evaluation of the cardiac surgical patient. A patient who has never had thoracic surgery may be evaluated with a posteroanterior and lateral chest radiograph. Chest computed tomography (CT) or magnetic resonance imaging (MRI) have the advantage of further delineating intrathoracic anatomy and should be performed in the setting of prior cardiac or thoracic surgery, or suspected thoracic abnormalities.(51) In a patient with history of peripheral vascular disease, assessment of the thoracic aorta for calcification with CT is also an important consideration. CT or MRI may also be helpful in diagnosing the presence or severity of chronic lung disease.

The severity of chronic lung disease may be difficult to diagnose in the heart failure patient, particularly one who presents with acutely decompensated congestive heart failure. Often, patients have been treated for chronic lung disease with supplemental oxygen before the diagnosis of heart failure. An assessment of chronic lung disease should begin with a thorough history, including social, environmental, and presence of familial pulmonary disease. Controversy persists with regard to the prognostic utility of PFT's, (long a predictor of poor outcomes with conventional cardiac surgery) (52-54), as poor performance may be influenced by multiple factors both related and unrelated to the patient's congestive heart failure, and should not be used as the sole factor to exclude the patient from candidacy(40). However, all randomized, controlled device trials of continuous flow LVAD's excluded patients with severely reduced pulmonary function as defined by pulmonary function studies (FEV1/FVC < 0.7, and FEV1 <50% predicted) (55-57).

Preoperative pulmonary risk factors can be divided into patient-related and procedurally related risk categories.(58) The patient-related risk factors include age, chronic disease [e.g., chronic obstructive pulmonary disease (COPD), asthma, sleep apnea, pulmonary hypertension], tobacco history, obesity, general health status, functional dependence and any current respiratory infection or unresolved metabolic issues. Operative risk factors include the surgical incision site, the duration of surgery, anesthetic technique, and if the surgery is on an emergent basis.(59)

Subsequent to a chest radiography or CT scanning, an evaluation of lung function utilizing pulmonary function test (PFTs) will help delineate most COPD, restrictive and lung diffusion pathology. Although many patients may have a restrictive pattern on their PFTs, frequently this is the result of heart failure and an anatomical consequence of the patient's cardiomyopathy.(60) Treatment of the patient's anemia, heart failure, and reverse remodeling associated with DMCS placement may improve the patient's lung diffusion capacity and restrictive filling pattern. Less alterable restrictive filling related to obesity, spinal, or rib cage abnormalities may be less relevant after addressing all the other "reversible items." Conversely, patients with COPD have a 2.7 to 4.7-fold increased risk of postsurgical complications.(60, 61) Smoking cessation for 4 to 8 weeks or more before surgery (if electively

scheduled) will attenuate postoperative complications. Further risk stratification may be achieved by using the multifactorial risk index for postoperative respiratory failure or the Canet Risk Index.(62) Although there is a significant degree of variability, most pulmonologists and thoracic surgeons will agree that an FEV1 <70% predicted (severe disease <50% of predicted) (32), FVC <70%, or an FEV1/FVC <70%, is consistent with significant pulmonary disease. However, the numbers in themselves are not highly sensitive/specific for all patients and may under diagnose younger or taller patients and over diagnose older and shorter patients. Perhaps the most accurate of these measures is the FEV1/FVC ratio of 65% to 70% of predicted (63-65).

Recommendations for pulmonary and thoracic assessment

Class I

1. Patients should have a chest radiograph before DMCS implantation.

Level of Evidence: C.

2. Patients should have an assessment of thoracic anatomy before DMCS implantation in the setting of prior cardiothoracic surgery or suspected thoracic abnormalities. These may include a radiologic examination with either CT or MRI.

Level of Evidence: C.

3. Positive airway pressure, early ambulation, induced cough incentive spirometry and effective pain control subsequent to surgery may all decrease postoperative complications.

Level of Evidence: C.

Longitudinal assessment of right heart function before durable LVAD: Clinical, imaging, and hemodynamic integration

Right sided heart failure (RHF) remains a major clinical challenge and requires integration of clinical, imaging and hemodynamics to best determine what areas of the right heart unit can be addressed before, during, and after device implantation. RV dysfunction is common in the setting of advanced heart failure as a consequence of pulmonary venous hypertension from chronically elevated left ventricular filling pressures, valvular pathology, or a combination of these processes.(66) Noncardiac sources of elevated pulmonary artery pressures such as hypoxic lung disease, sleep apnea, or pulmonary thromboembolism may further exacerbate RV dysfunction. Adequate RV function is critical for a patient to do well with left ventricular (LV) support alone.

Despite advances in technology and processes of care, postoperative RHF remains the lead cause of premature morbidity and mortality after durable LVAD implantation (67-69). There is paucity regarding strategies to evaluate the vulnerable right heart before, during and after LVAD challenged by heterogeneous definitions and variable performance of derived-multivariate risk scores (70). Therefore, incorporating longitudinal outcomes with right heart-focused clinical, structural and hemodynamic transitions can best aid clinicians anticipate and mitigate risk of clinically significant events, particularly if on short-term MCS without immediate access to heart transplantation (71, 72).

Physiology of early and late RHF after LVAD

Early severe RHF after durable LVAD is associated with a rapid domino-effect of right ventricular−pulmonary artery (RV-PA) uncoupling that follows transient (i.e., volume and ischemia) and structural (i.e., septal shift and apical coring) changes that add to increased venous return provided after LVAD initiation (73). The combination of serial dynamic structural changes can lead to RV dilatation, tricuspid regurgitation (TR) and ventricular-interdependent effects associated with leftward septal shift that limit both LV filling and RV stroke volume (SV) (74, 75). Improvement in RV contractility associated with passive or reactive elevated pulmonary vascular resistance (mPAP) due to elevated left heart loading conditions (PCWP) can be improved after temporary or durable LVAD activation (76). In contrast, fixed pulmonary hypertension and chronic RV dysfunction are at risk of uncoupling the RV-PA circulation leading to early-severe RHF, particularly with associated transient and structural events occurring in the perioperative state (77). Late RHF after durable LVAD although less characterized, carries important longitudinal considerations and is often associated with atrial-ventricular asynchrony (arrhythmias) and specific LVAD flow-mediated changes (78).

Clinical profiling of right heart function in advanced heart failure

Identifiable risk factors associated with a higher incidence of early severe postoperative RHF (requiring biventricular support after LVAD) include etiology (chemotherapy-induced cardiomyopathy), severity (cardiogenic shock, high INTERMACS profile, and presence of temporary circulatory support in the form of V-A ECMO before durable LVAD) and preexisting therapies (preimplant phosphodiesterase inhibitors) (78). The physiological derangements of the vulnerable right heart before and after durable LVAD can be translated into clinical signs of hypoperfusion and predominantly right heart congestion, often without evidence of pulmonary congestion. Associated LVAD-related clinical signs of acute RHF include low device flow and suction events limiting speed optimization (73).

Right heart imaging

Echocardiographic evaluation has evolved beyond standard 2-D imaging limited by the complex geometry and retrosternal positioning of the RV in addition to the load and angle dependence of standard imaging quantitative parameters such as TAPSE, RVFAC and tricuspid annular systolic velocity by tissue Doppler (79). RV strain is an emerging tool angle that is potentially load independent, which may

be able to discriminate patients at risk of RHF subsequent to an LVAD (80). While cardiac MRI remains the gold-standard method for function, performance and volumetric assessment of RH function, limitations in patients with advanced heart failure include compatibility with device therapies, hence the emerging role of 3D echocardiography as another available tool for longitudinal RH evaluation in LVAD recipients (81). The impact of dyssynchrony and tricuspid valve organic and/or functional abnormalities can be also best established by the use of echocardiography and evolving 3-D imaging, which may aid with perioperative decision making (82, 83). The next era of video-based deep learning of raw transthoracic echocardiographic images outperforms any of the standard echocardiographic parameters and currently available risk scores and holds future promise. (84)

Invasive hemodynamic integration

Invasive hemodynamics provide real-time insight on right heart function and coupling with systemic and pulmonary vasculature being the ultimate perioperative blueprint for therapeutic responsiveness to longitudinal mechanical unloading (85). The measure of right atrium (RA) to pulmonary capillary wedge pressure (PCWP) ratio has been the landmark standard to predict RHF after LVAD implantation, however hemodynamic indices have evolved toward a better understanding of the interaction of the right heart unit (pump, valves, conduits) and additional contributions of dysfunction (86). Impaired RV stroke work is also best determined by invasive hemodynamics and requires estimation of cardiac output by the Fick method, as thermodilution might be underestimated in the context of tricuspid regurgitation (87). Several formulas to quantify RV afterload include pulmonary vascular resistance, transpulmonary gradient, diastolic pressure gradient, PA elastance, PA compliance, and PA impedance, however none of these values in isolation definitely identifies RH failure (88).

Hemodynamic indices such as pulmonary artery pulsatility index (PAPi), which is the ratio of PA pulse (estimate of RV pulsatile load and contractile strength) pressure divided by RA pressure (estimate of RV congestion) has been shown to be a reliable marker of acute RHF after LVAD implantation (89, 90) with PAPi $< 1.85 \pm 0.1$ being associated with increased risk (89, 90). Another strong hemodynamic predictor identified is coupling of RA pressure with pulmonary arterial elastance which is the ratio of systolic pulmonary artery pressure to stroke volume (91). Additional novel hemodynamic indices at the time of implantation have shown to be independent risk factors for RVF after LVAD include "RV distensibility index" which requires interpretation of the RA waveform, showing a dominant "Y" descent that was equal or deeper than the "X" descent (92, 93). The longitudinal evaluation of the imaging and hemodynamic representation of the right heart unit before DMCS remains a novel area of research calling for further integration (93, 94).

Recommendations to assess pre-VAD RV function

Class I: All patients should have invasive focused hemodynamic evaluation of the right heart unit before DMCS implantation. Low Pulmonary artery pulsatility index is a prognostic indicator for right ventricular failure after durable LVAD.

Level of Evidence: B.

Class I: All patients should have invasive hemodynamic evaluation before DMCS integrated with multimodality imaging with echocardiography and/or cardiac MRI focused quantitative parameters of right heart function and tricuspid valve integrity.

Level of Evidence: B.

RV optimization before LVAD

Patients who are scheduled urgently for LVAD implantation should undergo right heart catheterization to assess pulmonary artery pressures to determine degree of RV dysfunction and to provide information regarding need for preoperative diuresis, inotrope, or temporary MCS. Patients who are going to the operating room electively should have right heart catheterization performed within 1 to 2 weeks before surgery with consideration given to preoperative placement of a pulmonary artery catheter based on previous hemodynamic values and concern for RV dysfunction. Urgent/emergent cases should always have a pulmonary artery catheter preoperatively in the ICU with tailored therapy (95, 96).

The most common cause of RV dysfunction in patients in patients who are LVAD candidates is LV dysfunction as elevated PCWP leads to postcapillary pulmonary hypertension. RV dysfunction may also be a manifestation of reduced coronary perfusion or ventricular interdependence, and impaired RV filling due to pericardial constraints in the setting of LV dilation (97). Right heart catheterization will allow for determination of precapillary or postcapillary hypertension with the recognition that many patients with severe LV function will have reactive pulmonary hypertension which is the result of chronic elevation in left sided filling pressures. A goal central venous pressure (CVP) of less than or equal to 15 mm Hg should be achieved before LVAD implantation. Diuretics are the mainstay of therapy for preload management. Intravenous diuretics are often required due to the presence of intestinal edema which reduces absorption of oral diuretics. IV loop diuretics can be given as a continuous infusion or in bolus form. Thiazide diuretics may also be used as adjunctive therapy. Some patients will manifest diuretic resistance(98). If improvements in RV contractility are ineffective and preload remains elevated despite high doses of diuretics, hemodialysis (specifically ultrafiltration) may be considered to achieve the target CVP. There is little evidence of the efficacy of ultrafiltration in typical heart failure populations, but improvement in CVP and resultant improvement in hepatic and renal function may be particularly beneficial in the preoperative state(99). All potential medical therapies

(diuresis, inotropes, and temporary MCS) should be employed before dialysis or ultrafiltration.

Medications which dilate the pulmonary arterial system have long been used to manage pulmonary hypertension and have also been used in patients with right sided heart failure to reduce RV afterload. Inhaled nitric oxide, prostaglandin inhibitors and phosphodiesterase 5 inhibitors (PDE5i) such as sildenafil have been used for this purpose. In the pre-VAD implant setting, care must be taken to avoid excessive pulmonary artery dilation as this can lead to acute increases in left sided filling pressures. Preoperative sildenafil use was found to be associated with a higher incidence of post-LVAD implantation RV failure even when accounting for the variable reasons for why patients may be on PDEi. Preoperative sildenafil use has not been shown to reduce the risk of postoperative RHF(100). Inotropes can be used to augment RV contractility. Inotrope choice should be made based on safety and efficacy. The minimum effective dose should be chosen to avoid arrhythmias. Atrial and ventricular arrhythmias should be treated preoperatively (see section on Arrhythmias) due to the negative impact that these arrhythmias may have on the unsupported RV post-LVAD implant.

Although there is data for the use of a percutaneous right ventricular assist device (RPella TM Abiomed) for RHF post LVAD implantation (101-103), this strategy has not been studied preemptively. Although data shows that intra-aortic balloon pump (IABP) use has favorable results on RV hemodynamics, preemptive use has in HF patients before LVAD demonstrates mixed results(104, 105). There is a lack of randomized control studies in this area.

Patients with poor RV or refractory biventricular function despite maximal medical therapy before LVAD implant, may be considered for ECMO or planned/preemptive BiVAD implantation (106, 107). BiVADs can be performed with right paracorporeal VAD (RA-PA, RV-PA), venopulmonary arterial ECLS, or durable BiVAD implantation. Although survival for patients on BiVAD support is inferior to LVAD support alone(108), planned BiVAD implant (vs unplanned or delayed) may confer survival benefit. Preoperative hemodynamic and echocardiographic should be strongly considered when determining need for biventricular support. Alternatively, If the clinical response to intravenous inotropes and vasopressors is deemed inadequate, then temporary MCS may be utilized. Examples of clinical situations where clinicians may resort to temporary MCS devices to augment pharmacological management of CS include: (1) Escalating doses of inotropes due to a persistently low cardiac output (particularly when more than one inotrope is being used); (2) progressive end-organ damage that is attributed to hypoperfusion; (3) inability to improve pulmonary congestion despite diuretics and/or mechanical fluid removal; (4) rising lactate that is deemed to be due to cardiogenic shock; and (5) refractory hypotension due to low cardiac output.

Temporary VADs are, for the most part, percutaneous devices that are readily available, can be rapidly deployed, and do not need the extensive evaluation that is required before implantation of durable LVADs. (109, 110) It should be noted however, that assessment of right ventricular parameters, tricuspid valvular regurgitation and hemodynamics under ECMO or support are not diagnostic due to the pressure and volume unloading by the external support device.

Hemodynamic Considerations	RVSWI <0.30 mm Hg L/m^2
	RA $\geq$ 15 mm Hg
	RA/PCWP $\geq$ 0.63
	TPG $\geq$ to 12
Echocardiographic considerations	RV dilatation score $\geq$ 3
	RV impairment score $\geq$ 3
	Tricuspid regurgitation $\geq$ 3

Adapted from Shehab et al. (107)

Recommendations for preoperative RV optimization

Class 1. Preoperatively, patients with echo and hemodynamic evidence of RV dysfunction should undergo optimization with invasive hemodynamics data. Diuresis, dialysis, inotropes, IABP, or temporary percutaneous mechanical circulatory support should be considered. After optimization, if RV function remains suboptimal, consideration should be given to planned BIVAD support.

Level of Evidence: C.

The use of temporary mechanical circulatory support should be strongly considered in patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurological assessment before placement of a long-term device.

Level of Evidence: C.

Weaning of temporary mechanical circulatory support

Temporary mechanical circulatory support (T-MCS) is increasingly being utilized as rescue therapy in patients with cardiogenic shock, or as prophylactic therapy in patients at risk for cardiogenic shock or those undergoing high-risk coronary, valvular, or electrophysiologic interventional procedures.

T-MCS is usually intended for short-term support. Patients clinically stabilized on T-MCS who are not candidates for heart transplantation, and those who are not currently candidates for heart transplantation, may still qualify for DMCS as long-term therapy or as a bridge to decision, respectively. The type of durable MCS device to be used (LVAD, RVAD, bi-VAD, or TAH) is influenced by several clinical factors including the underlying etiology of the cardiogenic shock that necessitated T-MCS, the type of T-MCS being utilized (LVAD, RVAD, bi-VAD, ECMO), the hemodynamic profile while on the T-MCS and institutional preferences. In patients who are clinically stabilized with T-MCS and who qualify for heart transplantation, T-MCS may be left in place as a bridge until they undergo the transplant surgery.

Once clinically stabilized, patients should be assessed for readiness to wean off T-MCS. There are no established

guidelines for weaning protocols from these devices, or for the parameters and criteria to be used.(111) Most centers utilize a combination of clinical (e.g., end-organ function, oxygenation/ventilation, neurologic status), hemodynamic (e.g., blood pressure, right and left sided filling pressures, cardiac output/index, pulsatility, vasoactive medication requirements), metabolic (e.g., lactic acidosis), and imaging (e.g., echocardiographic assessment of LV/RV size and function, severity of valvular disease) factors to determine timing of initiation of the wean. The specific set of factors used for each patient is device-, institution-, and provider-specific, and it is usually personalized depending on the patient's presentation, reason for requiring T-MCS, response to therapy, and clinical course. These factors are usually monitored carefully during the weaning process to evaluate whether T-MCS can be successfully discontinued (e.g., removal of IABP or Impella device, decannulation of ECMO circuit), or de-escalated (e.g., transition from ECMO to Impella).

For patients who are clinically stabilized with T-MCS but deemed not to be candidates for weaning, and for those who fail the weaning trials, it is reasonable to consider a period of LV/RV rest, to re-attempt hemodynamic optimization, and to search for reversible factors when applicable. If weaning is still not achieved despite these efforts, then these patients are considered to be device-dependent and should be evaluated for their candidacy for heart transplantation and/or DMCS. For those deemed not candidates for these surgical therapies the multidisciplinary team should discuss end of life issues with patients and their caregivers, and prepare them for a transition to comfort measures, withdrawal of care, or hospice.

Recommendations for weaning from T-MCS

- Patients clinically stabilized on temporary MCS should be assessed for readiness to wean off temporary MCS.
- Class IIa; Level of evidence: C
- Patients clinically stabilized on temporary MCS who cannot be weaned from temporary MCS should be considered for heart transplantation, if eligible.
- Class IIa; Level of evidence: C
- Patients clinically stabilized on temporary MCS who cannot be weaned from temporary MCS and who are not eligible for heart transplantation should be considered for DMCS.
- Class IIa; Level of evidence: C
- Patients clinically stabilized on temporary MCS who cannot be weaned from temporary MCS and who are not eligible for heart transplantation or DMCS should be considered for end of life care. Class IIa; Level of evidence: C

Management of infection

Chronic HF results in a state of chronic immunosuppression and is associated with other chronic medical conditions that predispose and exacerbate the risk of infection (112, 113). Active identification and treatment of infections are a crucial part of the pre- and postoperative management of patients treated with DMCS.

Preoperative identification of colonization/infection

Many patients under consideration for DMCS have had prolonged hospitalizations or frequent hospital exposures increasing the risk of colonization; this may include indwelling urinary catheters, central venous catheters, ECLS cannula, endotracheal tubes, etc.

Colonization with multidrug resistant bacteria, including MRSA, is associated with an increased risk of infection and death and should be identified before DMCS implantation (114, 115).

Preimplantation fever is associated with device-related infections. A comprehensive history and examination should be performed to exclude preoperative infection including evaluation of lines/catheters (116). When there is suspicion, appropriate cultures should be obtained as well as imaging dictated by the clinical picture (117).

The oral cavity is a common source of bacteremia and periodontal disease is highly prevalent in chronic heart failure, as well as in patients with DMCS (118-120). However, a clear link between dental treatment and cardiac surgical outcomes has not been established with a need for more data and protocolization (121, 122). It is reasonable to seek preoperative dental assessment to exclude or treat dental/periodontal pathology that might predispose to bacteremia and infection.

Recommendations for preoperative identification of colonization/infection

Class I

All patients should undergo preoperative testing to exclude colonization.

Level of Evidence: A

All patients should undergo pre-DMCS evaluation to exclude infection.

Level of Evidence: C

Class: IIa

All patients should undergo pre-DMCS dental evaluation if time and clinical status permit.

Level of Evidence: C

Preoperative management of colonization and infection

Staphylococcal colonization is associated with an increased risk of infection. When identified on preoperative screening, topical treatment with intranasal mupirocin and chlorhexidine soap should be administered (115, 123).

Active infection identified before DMCS implant should be aggressively treated and eradicated due to the perioperative morbidity associated with infection and also the risk of device seeding/infection. Established principles for management of infection should be applied and, whenever possible, surgery should be postponed until the remote

infection is treated (115, 117). Staphylococcal infections and other gram positive organisms are frequently the cause of early device-related infections (124, 125). Infection of the device is a cause of recurrent admissions, is hard to eliminate despite suppressive antibiotics, and is associated with significant morbidity (including ischemic/hemorrhagic cerebrovascular events) and mortality (126-133). Device infection may necessitate consideration for device explant/exchange or heart transplant, which are in turn associated with recurrence of infection and worse transplant outcomes (134-139).

Due to the complexity of infections and underlying medical conditions in this patient population, as well as the implications of device infection, consultation with an Infectious Disease specialist is recommended for the management of all active infections in patients under consideration for DMCS device implantation.

To minimize the risk of perioperative infection, all unnecessary exposures should be eliminated before DMCS device implantation. Where possible outpatient evaluation and planning for DMCS should be entertained due to the established risk of surgical site infection associated with hospitalization and the excellent perioperative outcomes associated with DMCS device implantation in ambulatory heart failure patients (140-144).

Recommendations for the preoperative management of colonization, prevention, and active infection

Class I

All patients with colonization should receive appropriate preoperative treatment if time and clinical status permit. (Level of evidence: A)

All patients with an active infection should receive an appropriate course of antibiotics, and source control when applicable, before implantation of a DMCS device. (Level of evidence: C)

All patients with an active infection should be managed in consultation with an infectious disease specialist. (Level of evidence: C)

Class IIa

All patients, to the extent permitted by clinical status, should have unnecessary exposures eliminated before DMCS device implantation through limiting preoperative hospitalization, maintenance of ambulatory status, and removal of lines/catheters. (Level of evidence: C)

Recommendation for antibiotic prophylaxis

The selection of antimicrobial prophylaxis should ideally rely on prospective studies investigating the effects of different perioperative regimes on early and/or late DMCS-specific adverse events and/or related infections in randomized clinical trials. However, these studies are lacking, to date. Therefore, general considerations regarding antimicrobial prophylaxis in cardiothoracic surgery, the knowledge regarding DMCS-specific and/or related infections, as well as the current practice within DMCS studies and within the DMCS community should be taken into account. This is in line with the 2017 ISHLT consensus document for prevention and management strategies for DMCS (145).

Colonization and resulting treatments

As primary prophylaxis preoperative bathing or showering with either plain soap or antimicrobial soap is good clinical practice and should be recommended(146). Patients should have a nasal swab to screen for methicillin-resistant *Staphylococcus aureus* and receive topical treatment if positive before DMCS implantation. In proved cases of MRSA/MSSA colonized patients or in patients being at high risk for such a colonization antimicrobial prophylaxis should cover these species. This treatment could be constituted by decolonization with intranasal application of mupirocin 2% ointment with or without chlorhexidine gluconate body wash (123, 146).

Choice of antibiotic agent

In general, the antibiotic prophylaxis regime should target Staphylococcus species in all patients(145). Regarding the general use of Vancomycin or an additional antimicrobial agent in addition to Cefazolin there is one single center study showing no difference in VAD-related infections (147). New data on antibiotic prophylaxis in general cardiac surgery patients suggest the use of Vancomycin in high-risk patients (BMI <18 or >30, Reoperation, renal failure, diabetes mellitus, COPB or immunosuppressed patients) to be preventive for wound healing in this high-risk cohort. (148)

Furthermore, Vancomycin is recommended by surgical guidelines in environments with a high likelihood or documented MRSA colonization or allergy against beta-lactam agents (149). Routine broad-spectrum gram-negative prophylaxis is not recommended due to drug-drug interactions (149, 150). The routine use of antifungal prophylaxis in all patients undergoing VAD implantation is not recommended (151). In general, the local epidemiological experience of infectious disease specialists should be involved and discussed individually.

Timing and duration of antibiotic prophylaxis

The prophylactic antibiotics should be infused within 1 hour before the first skin incision (149). As recommended for antibiotic prophylaxis in general cardiac surgery the administration of vancomycin should be started within 2 hours before skin incision (150). If the operative time exceeds the duration of 2 half-time of the antibiotic agents, the application should be repeated (149). In case of significant blood loss of more than 1,500 mL re-dosing of antibiotic prophylaxis should be considered (149). The duration of prophylaxis should not extend 48 hours on a routine basis (149-151). The duration of antibiotic prophylaxis should not be extended due to presence of chest tubes.(152, 153)

Secondary prophylaxis

Secondary prophylaxis should be considered in all DMCS patients (e.g., dental procedures). While DMCS recipients are considered at an unknown risk group for infective endocarditis (154), the 2013 ISHLT MCS guidelines and the 2017 ISHLT consensus regarding prevention and management of infections in DMCS patients recommend the use of secondary prophylaxis in MCS patients (40, 145). Giving the devastating consequences of infections and positive blood cultures in VAD patients this recommendation is reinforced (155, 156).

Summary of recommendations for antibiotic prophylaxis

Class I

1. *Preoperative bathing or showering with either plain soap or antimicrobial soap is recommended (Level of evidence: C)*
2. *Preoperative nasal swab to screen for methicillin-resistant Staphylococcus aureus is recommended (Level of evidence: A)*
3. *In nasal carriers of S. aureus decolonization with intranasal application of mupirocin 2% ointment with or without chlorhexidine gluconate body wash is recommended (Level of evidence: A)*
4. *The antibiotic prophylaxis regime should cover Staphylococcus species in all patients (Level of evidence: C)*
5. *Vancomycin is recommended by surgical guidelines in environments with a high likelihood or documented MRSA colonization (149) (Level of evidence: B)*
6. *Antibiotic prophylaxis infusion within 1 hour before the first incision is recommended (Level of evidence: B)*
7. *Vancomycin infusion is recommended 2 hours before first incision to achieve therapeutic range (Level of evidence: B)*
8. *Additional intraoperative dose(s) are recommended if the operative procedure last longer than 2 half-lives of the AP agent(s) (Level of evidence: B)*
9. *Additional intraoperative dose(s) are recommended in case of significant blood loses of more than 1,500 mL (Level of evidence: B)*

Class II

1. *Vancomycin might be considered in high-risk patients (BMI <18, >30, Reoperation, renal failure, diabetes mellitus, COPB, or immunosuppressed patients) (Level of evidence: B)*
2. *The local epidemiological experience of infectious disease specialists should be recognized to guide the AP (Level of evidence: C)*
3. *Secondary prophylaxis should be considered in all DMCS patients (e.g., dental procedures) (Level of evidence: C)*
4. *An infectious disease consultation should be considered before extending AP beyond 48 hours (Level of evidence: C)*

Class III

1. *Application of broad-spectrum gram-negative prophylaxis is not recommended to avoid possible drug-drug interactions (Level of evidence: B)*
2. *Routine antifungal prophylaxis is not recommended (Level of evidence: C)*
3. *The duration of AP should not exceed 48 hours (Level of evidence: B)*
4. *The duration of antibiotic prophylaxis should not be extended due to the presence of open-chest situation or remaining chest drainages (Level of evidence: B)*

Substance abuse (alcohol, drugs, marijuana, tobacco)

Substance abuse has been shown to impact survival and morbidity in end stage heart failure (HF) that require advanced medical therapies. Tobacco and drug (including alcohol) abuse before device implantation/transplantation increases the risk for postsurgical complications and mortality, which is frequently mediated by relapse of the patient's drug-of-choice or a new addiction. Recidivism subsequent to implantation is associated with an increased rate of noncompliance. Longer durations of abstinence before implantation or transplantation may decrease the likelihood of relapse. Psychiatric disorders, substance abuse, noncompliance, a lack of caregiver support, or scarcity of financial resources should be identified and addressed before DMCS implantation (157). All of these noncardiovascular variables have been known to have a large impact on outcomes and patients' quality of life (158-160). An inability for these items to be resolved before transplant may be a contraindication to DMCS implantation (1, 161).

Tobacco: Smoking tobacco increases the risks for morbidities, including pump thrombosis and gastrointestinal bleeding in DMCS patients (162-164). Tobacco use also leads to an increase in mortality in DMCS and transplant recipients (159, 165-167). Active smoking is a relative contraindication for HTX (1, 161, 168, 169) and DMCS.

Vaping: Repeated exposure over a long time to e-cigarette vapor poses substantial potential risk for heart and lungs. Long-term data showing that vaping is a "healthier alternative" than cigarette smoking does not exist at this time point (170). There are no studies regarding side effects of vaping in transplant or DMCS patients. At this juncture, vaping should be considered a relative contraindication for DMCS, as there is no data to suggest this is any safer than traditional tobacco ingestion or inhalation routes. Further studies need to address the impact of short and long-term impact of vaping as no definitive studies exists at the time of this publication.

Alcohol and drug abuse: Driveline infections and hospital readmissions occur at an increased rate in DMCS recipients who abuse alcohol and drugs (158, 159, 167). Subsequent to DMCS, substance abuse is known to increase mortality in heart transplant patients (171). Additional

studies have examined the role of drug abuse on post-LVAD outcomes and found that patients with a history of drug abuse were more likely to be readmitted. This may be in part, due to a greater likelihood of driveline infection, thrombosis, stroke, and bleeding (167). Investigators found that patients with substance abuse had 3.2-fold increase in mortality compared with a matched cohort, and a 5.4-fold increased rate of chronic drive-line infection (159). Other investigators have found that, specifically illegal drug use predicted readmission rates in patients receiving an LVAD as destination therapy (DT). Some data suggest that increased hemolysis and observed driveline-related issues may leading to readmission rates may be related more to compliance with site care and anticoagulation management relative to other variables that may cause readmission (158).

Gray zone marijuana: bridge to transplant: Marijuana use, which is now legal for medical and/or recreational use in some countries and some portions of the United States remains a controversial issue regarding patient selection for advanced medical therapies. Although active substance abuse disorders have long been considered a contraindication to organ transplantation and DMCS, these guidelines will have to be revisited over the next several years. Changes to the guidelines or individual programs' policies should be based on an increasing body of evidence and not based on social norms. (172). Overall, decisions on whether to offer DMCS to patients with a substance abuse history have been difficult. Substance abuse should not necessarily be treated differently from potentially treatable medical comorbidities, and that an LVAD would offer an opportunity for medical stabilization and substance abuse rehabilitation.

Current data would suggest that utilization of marijuana use may impact patient care including adherence (173, 174), infection (174, 175),6,7 drug interactions (176) as well as patient survival. In a recent systematic review, cannabis use was shown to have cardiopulmonary implications by increasing heart rate and reducing blood pressure, but there has been insufficient evidence to implicate cannabis with new arrhythmias, worsening ischemia, or sudden death (177). With regard to the lungs, the potential for parenchymal infections from smoking cannabis is described in case reports of immunosuppressed patients, in part, related to the inhalation of fungal elements (174, 175, 178, 179). Other investigators have also linked marijuana use to psychosis, depression, anxiety, polysubstance abuse, and cognitive deficits, raising concerns regarding adherence after transplantation. (1, 164, 170, 171). This raises issues surrounding how marijuana policies are developed in the future.

General considerations

Current guidelines endorsed some variability and regional differences by allowing each center to develop its own specific criteria for adjudicating candidacy for DMCS and HTX for marijuana users (1). Before making a decision on any patient, a psychosocial evaluation pre-MCS should include a complete assessment/history of all drugs and amount, current status, any treatments received, periods of abstinence, and insight or willingness to receive treatment (161). Input from an experienced social worker, therapist and perhaps an addiction specialist may be indicated for some patients. This may include some degree of inpatient or outpatient therapy if the patient has been abstinent for a limited period of time. At the time of this publication, every active substance disorder is a contraindication to cardiothoracic transplantation at most centers worldwide. (1) Similar policies will likely evolve for opioids as well. Until evidence to the contrary emerges, the authors propose that smoking or vaping cannabis should be actively discouraged and should be consistent with the institutional policies regarding the utilization of alcohol and tobacco. We recommend 6 months abstinence from smoking, vaping, alcohol, marijuana and all nonprescribed/illicit drugs before DMCS implantation, but recreational or medicinal noninhalational cannabis or alcohol use is not an absolute contraindication for DMCS and should not preclude emergent pump implantation. Circumstances related to each patient and program will need to be considered on a case by case basis. The previous guidelines (TX and VAD) and this document propose that patients should not be listed for transplant until they are abstinent for 6 months of alcohol, tobacco, marijuana and all other substance of abuse.

Recommendations

Class I

The psychosocial evaluation should assess history of use of all substances, current status, any treatments received, periods of abstinence, and insight and willingness to receive treatment (Level of evidence: C).

Every patient with a history of substance abuse and/or active substance abuse should be discussed by a multidisciplinary team (psychologist, social, surgeon, cardiologist) for decision making and timing about DMCS implantation (Level of evidence: C).

Patients considered for DMCS implantation should receive education on the importance of alcohol, marijuana tobacco, and illicit drug cessation before device implantation and throughout the duration of device support (Level of evidence: C).

Alcohol, smoking/vaping and illicit drug cessation before DMCS implantation is recommended. If this cannot be accomplished before implantation due to patients' medical urgency, abstinence is required afterward, if patients are to be considered for transplantation. Abstinence for a least 6 months after implantation is ideal (Level of evidence: C).

Class IIa

The fifth edition of The Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria can be used to characterize whether patients have a dependency or use

disorder, which in turn can inform decisions around candidacy for implantation and transplantation.

Mild to moderate substance use should not preclude emergent pump implantation but will require further evaluation subsequent to device implantation. Patients should not be made active on the transplant waiting list until 6 months of alcohol/drug abstinence has been proven (Level of evidence: C).

Medical Marijuana use should not preclude from DMCS implantation, but the indication should be evaluated carefully for medical necessity (Level of evidence: C).

Class IIb

A structured rehabilitative program may be considered for patients with a recent (24-month) history of alcohol or drug abuse if implantation and/or transplantation is being considered (Level of evidence: C).

Heavy-active tobacco smoking is a relative contraindication to DMCS implantation. Active tobacco smoking at the time of DMCS implantation is a risk factor for poor outcomes after implantation and may impact pulmonary or heaptic function long-term (Level of evidence: C).

It is reasonable to consider active heavy/excessive and chronic alcohol, drug abuse (including marijuana) as contraindication to DMCS implantation (Level of evidence: C).

Class III

Patients who remain active substance abusers should not be listed as BTT (Level of evidence: C).

Active addiction to illicit drugs or alcohol without a patient life-long commitment to stop is a contraindication for DMCS implantation (Level of evidence: C).

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Timing of Surgery	**Timing of Surgery**
Management of obesity and patient expectations:	**Management of obesity and patient expectations:**
Class I: 1. Obesity (BMI 30-35 kg/m2), 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 (BMI $\geq$ 35 kg/m2). Level of Evidence: B.	Class I: Obesity itself is not a contraindication to DMCS. However, obesity increases the risk of post-operative morbidities including infection, cannula malposition, right heart failure and heart failure readmissions. Therefore, surgical risk and comorbidities must be carefully considered at the time of evaluation. Level of Evidence: B. (*Modified*)
	Class IIb: 2. Bariatric surgery has been utilized both before and after DMCS implantation in small case series as a weight loss strategy. It may be considered in select cases and at expert centers. Weight loss should be encouraged for all patients with BMI >30. Level of Evidence: C. (New)
Class I: 1. A detailed informed consent should discuss the salient aspects of the DMCS placement, common expectations, and possible complications in the peri- and post-operative period. Level of Evidence: C.	Class I: 1. *Continuing approval without change*
Class IIb: 1. Quality of life should be assessed prior to and following DMCS implantation to help guide patient decisions. Assessment tools including Minnesota Living with Heart Failure (MLWHF), Sickness Impact Profile, Euroqol and others should be considered to help guide patient care. Level of Evidence: C.	Class IIb: 1. *Continuing approval without change*
Nutrition:	**Nutrition:**
Class I: 1. All patients should have assessment of their nutritional status prior to DMCS with at least a measurement of albumin and prealbumin. Level of Evidence: B. 2. Patients who have indices of malnutrition prior DMCS should have an evaluation by a nutritional consultation service. Level of Evidence: C.	*Continuing approval without change*

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Class IIa: 1. Patients who have evidence of malnutrition prior to DMCS should receive nutritional interventions prior to DMCS Level of Evidence: C. Class IIb: 1. Patients who have evidence of malnutrition prior to DMCS should have their implantation delayed to maximize their nutritional states, if time allows after assessment of their hemodynamic status. Level of Evidence: C.	
Management of end organ dysfunction	**Management of end organ dysfunction**
Renal:	**Renal:**
Class I: 1. All patients should have their renal function monitored closely prior to DMCS implantation. Level if 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.	Class I: 1. All patients should have their renal function monitored closely prior to DMCS implantation. Level if Evidence: C. (*Unchanged*) 2. Patients with decompensated congestive heart failure and renal dysfunction should have a period of hemodynamic optimization (with inotropic and/or temporary mechanical circulatory support if clinically indicated) with the goal of volume optimization. Level of Evidence: C. (*Modified*)
3. Assessment of serum creatinine (SCr), blood urea nitrogen (BUN), 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 DMCS. Level of Evidence: C.	3. Assessment of serum creatinine (SCr), blood urea nitrogen (BUN), 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 DMCS. Level of Evidence: C. (*Unchanged*) Class IIa: 1. Patients with CKD Stage IV and V may be carefully selected for DMCS. Level of Evidence: C. (New) Class IIb: 1. DMCS as a bridge to SHKT may be considered in carefully selected patients, with a plan for long-term haemodialysis in an experienced center. Level of Evidence: C. (New)
Class III: 1. Permanent dialysis should be a contraindication for destination therapy. Level of Evidence: C.	Class III: 1. The anticipation of permanent dialysis should be a contraindication for destination therapy. Level of Evidence: B. (*Modified*)
Hepatic:	**Hepatic:**
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 of their liver to screen for cirrhosis prior to DMCS 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 IIa: 1. Patients with an elevated INR not due to warfarin therapy should be considered for treatment prior to DMCS 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 MELD score are poor candidates for DMCS therapy. Level of Evidence: B.	*Continuing approval without change*

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Pulmonary: Class I. 1. Patients should have a chest x-ray prior to DMCS implantation. Level of Evidence: C. 2. Patients should have some assessment of thoracic anatomy prior to DMCS implantation in the setting of prior cardiothoracic surgery or suspected thoracic abnormalities. These may include a radiologic examination with either CT or MRI. Level of Evidence: C. 3. Positive airway pressure, early ambulation, induced cough incentive spirometry and effective pain control subsequent to surgery may all decrease postoperative complications. Level of Evidence: C.	**Pulmonary:** *Continuing approval without change*
Assessment of RV function: Class I: 1. All patients should have an echocardiographic assessment of RV function prior to DMCS implantation. Level of Evidence: C. 2. All patients should have invasive assessment of intracardiac filling pressures prior to DMCS implantation, with a particular emphasis on RV hemodynamics. Level of Evidence: C.	**Assessment of RV function:** *Replaced by the new and modified recommendations below* Class I: 1. All patients should have invasive focused hemodynamic evaluation of the right heart unit prior to DMCS implantation. Low Pulmonary artery pulsatility index is a prognostic indicator for right ventricular failure after durable LVAD. Level of Evidence B (New) 2. All patients should have invasive hemodynamic evaluation prior to DMCS integrated with multimodality imaging with echocardiography and/or cardiac MRI focused quantitative parameters of right heart function and tricuspid valve integrity. Level of Evidence B. (New)
Preoperative RV optimization: Class I: 1. Preoperatively, patients with evidence of RV dysfunction should be admitted to the hospital for aggressive management, which may include diuresis, ultrafiltration, inotropes, IABP, or other short term mechanical support. Once optimized, RV function should be reassessed. Level of Evidence: C. 2. The use of temporary mechanical support should be strongly considered in patients with multi-organ failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurological assessment prior to placement of a long- term device. Level of Evidence: C.	**Preoperative RV optimization:** Class I: 1. Pre-operatively, patients with echo and hemodynamic evidence of RV dysfunction should undergo optimization with invasive hemodynamics data. Diuresis, dialysis, inotropes, IABP, or temporary percutanous support should be considered. After optimization, if RV remains sub-optimal consideration should be given to planned BIVAD support. Level of Evidence: C. (*Modified*) 2. *Continuing approval without change*
Management of 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 implantation of a DMCS. Level of Evidence: C. 2. All patients should have all unnecessary lines and catheters removed prior to DMCS implantation Level of Evidence: C. 3. All patients should have a dental assessment and any remedial treatment, if time and clinical status permits, prior to DMCS implantation. Level of Evidence: C.	**Management of infection:** *Replaced by the new and modified recommendations below* Class I: 1. All patients should undergo pre-operative testing to exclude colonization. Level of Evidence: A. (New) 2. All patients should undergo pre-operative evaluation to exclude infection. Level of Evidence: C. (New) 3. All patients with colonization should receive appropriate pre-operative treatment if time and clinical status permit. Level of Evidence: A. (New) 4. All patients with an active infection should receive an appropriate course of antibiotics, and source control when applicable, prior to implantation of a DMCS device. Level of Evidence: C. (New) 5. All patients with an active infection should be managed in consultation with an infectious disease specialist. Level of Evidence: C. (New) Class IIA: 1. All patients should undergo pre-operative dental evaluation if time and clinical status permit. Level of Evidence: C. (New) 2. All patients, to the extent permitted by clinical status, should have unnecessary exposures eliminated prior to DMCS device implantation through limiting pre-operative hospitalization, maintenance of ambulatory status, and removal of lines/catheters Level of Evidence: C. (New)

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

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Recommendation for antibiotic prophylaxis: Class I: 1. Patients should receive preoperative antibiotics with broad spectrum gram-positive and gram-negative coverage as appropriate prior to DMCS implantation. Level of Evidence: C. 2. Routine antibiotic prophylaxis should include at least one dose prior to surgery administered within 60 minutes of the first incision, remain in the therapeutic range throughout their duration, and not extend beyond 24-48 hours. Level of Evidence: C. 3. Patients should have a nasal swab to screen for MRSA and receive topical treatment if positive prior to MCSD implantation Level of Evidence: C.	**Recommendation for antibiotic prophylaxis:** *Replaced by the new and modified recommendations below* Class I: 1. In nasal carriers of S. aureus Decolonization with intranasal application of mupirocin 2% ointment with or without chlorhexidine gluconate body wash is recommended. Level of Evidence: A. (*Modified*) 2. The antibiotic prophylaxis regime should cover Staphylococcus species in all patients. Level of Evidence: C. (*Modified*) 3. Antibiotic prophylaxis infusion within one hour prior to the first incision is recommended. Level of Evidence: B. (*Modified*) 4. Additional intra-operative dose(s) are recommended if the operative procedure last longer than 2 half-lives of the AP agent(s). Level of Evidence: B. (*Modified*) 5. Preoperative bathing or showering with either plain soap or antimicrobial soap is recommended. Level of Evidence: C. (New) 6. Preoperative nasal swab to screen for methicillin-resistant Staphylococcus aureus is recommended. Level of Evidence: A. (New) 7. Vancomycin is recommended by surgical guidelines in environments with a high likelihood or documented MRSA colonization. Level of Evidence: B. (New) 8. Vancomycin infusion is recommended 2 hours prior to first incision to achieve therapeutic range. Level of Evidence: B. (New) 9. Additional intraoperative dose(s) are recommended in case of significant blood loses of more than 1500 ml. Level of Evidence: B. (New) Class II: 1. Vancomycin might be considered in high risk patients (BMI <18, > 30, Reoperation, renal failure, diabetes mellitus, COPB or immunosuppressed patients). Level of Evidence: B. (New) 2. The local epidemiological experience of infectious disease specialists should be recognized to guide the AP. Level of Evidence: C. (New) 3. Secondary prophylaxis should be considered in all MCS patients (e.g. dental procedures). Level of Evidence: C. (New) 4. An infectious disease consultation should be considered before extending AP beyond 48 hours. Level of Evidence: C. (New) Class III: 1. Application of broad-spectrum gram-negative prophylaxis is not recommended to avoid possible drug-drug interactions. Level of Evidence: B. (New) 2. Routine anti-fungal prophylaxis is not recommended. Level of Evidence: C. (New) 3. The duration of AP should not exceed 48 hours. Level of Evidence: B. (New) 4. The duration of antibiotic prophylaxis should not be extended due to the presence of open-chest situation or remaining chest drainages. Level of Evidence: B. (New)

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Task Force 2 Summary :
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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Substance abuse (alcohol, drugs, marijuana, tobacco):	**Substance abuse (alcohol, drugs, marijuana, tobacco):** *Replaced by the new and modified recommendations below*
Class I: 1. Patients considered for DMCS 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 I: 1. Every patient with a history of substance abuse and/or active substance abuse should be discussed by a multidisciplinary team (psychologist, social, surgeon, cardiologist) for decision making and timing about DMCS implantation: C (New) 2. The psychosocial evaluation should assess history of use of all substances, current status, any treatments received, periods of abstinence, and insight and willingness to receive treatment. Level of evidence: C. (New) 3. Patients considered for DMCS implantation should receive education on the importance of alcohol, marijuana tobacco and illicit drug cessation before device implantation and throughout the duration of device support. Level of evidence: C. (New) 4. Alcohol, smoking/vaping and illicit drug cessation before DMCS implantation is recommended. If this cannot be accomplished before implantation due to patients' medical urgency, abstinence is required afterward, if patients are to be considered for transplantation. Abstinence for a least 6 months after implantation is ideal. Level of evidence: C. (New)
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.	Class IIa: 1. The fifth edition of The Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria can be used to characterize whether patients have a dependency or use disorder, which in turn can inform decisions around candidacy for DMCS and transplantation. Level of evidence: C. (New) 2. Mild to moderate substance use should not preclude emergent pump implantation but will require further evaluation subsequent to device implantation. Patients should not be made active on the transplant waiting list until 6 months of alcohol/drug abstinence has been proven. Level of evidence: C. (New) 3. Medical Marijuana use should not preclude from DMCS implantation but the indication should be evaluated carefully for medical necessity. Level of evidence: C. (New)
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 DMCS therapy. Level of Evidence: C.	Class IIb: 1. A structured rehabilitative program may be considered for patients with a recent (24-month) history of alcohol or drug abuse if implantation and/or transplantation is being considered. Level of evidence: C. (New) 2. Heavy-active tobacco smoking is a relative contraindication to DMCS implantation. Active tobacco smoking at the time of DMCS implantation is a risk factor for poor outcomes after implantation and may impact pulmonary or hepatic function long-term. Level of evidence: C. (New) 3. It is reasonable to consider active heavy/excessive and chronic alcohol, drug abuse (including marijuana) as a strong relative contraindication to DMCS implantation. Level of evidence: C. (New)

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Class III: 1. Active substance abusers (including alcohol) should not receive DMCS therapy. Level of Evidence: C.	Class III: 1. Patients who remain active substance abusers should not be listed as BTT. Level of evidence: C. (New) 2. Active addiction to illicit drugs or alcohol without a patient life-long commitment to stop is a contraindication for DMCS implantation. Level of evidence: C. (New)

Task Force 3

Intraoperative and immediate postoperative management

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Introduction

Task Force 3 focuses on the implant technique, intraoperative considerations and the immediate postoperative management of patients undergoing durable LVAD. Implant techniques and perioperative management of patients undergoing planned durable BIVADs or TAH will be discussed in Task Force 8.

Topic 1: Anesthesia-related issues

Durable mechanical circulatory support (DMCS) is deployed in patients with a wide range of hemodynamic profiles and etiologies. The anesthetic management for patients undergoing DMCS implantation must take into consideration the general principles of anesthesia in patients with advanced cardiac disease, the specific pathophysiology based on the underlying etiology, the hemodynamic profile, and the unique physiological challenges associated with left ventricular assist devices.

Patient preparation

A large-bore intravenous line and indwelling intra-arterial line for continuous blood pressure monitoring should be placed before the induction of anesthesia. The intra-arterial cannula allows continuous arterial blood pressure monitoring and serial sampling for blood gas analyses. Specific placement of the arterial cannula in the right radial or brachial artery should be considered, in anticipation of potential venoarterial extracorporeal oxygenation support in the event of right heart failure and severe hemodynamic instability. Central venous cannulation is also essential for monitoring of central venous pressure (CVP), sampling for blood gas analyses, and administration of vasoactive medications. Ultrasound-guided insertion is preferred(1).

A pulmonary artery catheter (PAC) can be helpful for monitoring of cardiac output, assessment of oxygen delivery (mixed venous oxygen saturation) and pulmonary arterial pressure and vascular resistance, which may guide intra- and postoperative management. Central venous access for PAC should be established but the catheter (balloon floatation) may be inserted after DMCS implantation and separation from cardiopulmonary bypass.

Near infrared spectroscopy (NIRS) can be used to continuously monitor cerebral oxygen saturation as a surrogate for cerebral perfusion. A drop in cerebral oxygen saturation may indicate compromised oxygen delivery and should prompt further investigation and intervention.

Implantable cardioverter-defibrillators should be de-activated before surgery. The use of external defibrillator pads are recommended during the surgery. In patients with pacemakers (including cardiac resynchronization therapy) who have an underlying rhythm, pacing function can be reprogrammed to a "back-up" pacing mode (such as VVI at 40 bpm). In pacemaker-dependent patients with no underlying rhythm, the pacemaker should be reprogrammed to asynchronous mode (e.g., DOO or VOO at 100 bpm). Asynchronous pacing can occasionally be arrhythmogenic in the presence of an intrinsic rhythm due to delivery of ventricular pacing on the vulnerable period on the T wave (R on T phenomenon). Pacemaker function such as rate responsive mode should be deactivated. Continuous electrocardiographic monitoring is mandatory and intraoperative arrhythmias should be managed conventionally. The cardiac rhythm device should be checked postoperatively. Pacemaker and ICD therapy should be re-activated postoperatively.

Recommendations

- *Patients undergoing DMCS implantation should have preoperative insertion of large bore cannula, central venous catheter, PAC, and indwelling arterial line for continuous monitoring and intravenous access (Class I, Level of evidence C).*
- *Cardiac rhythm device should be reprogrammed preoperatively, taking into consideration the type of device and the underlying rhythm (Class I, Level of evidence B).*

Induction and maintenance of general anesthesia

Induction and maintenance of anesthesia is usually achieved with a combination of intravenous and inhalational anesthetic agents. Inhalational agents (e.g., fluorinated ethers such as sevoflurane, desflurane, and isoflurane) have putative cardio-protective effects, but a recent randomized trial comparing inhalational and total intravenous agents in patients undergoing coronary artery bypass surgery failed to demonstrate any difference in clinical outcomes(2). The anesthetic strategy for DMCS implantation typically includes intravenous hypnotics (e.g., etomidate (0.2−0.3 mg/kg) and midazolam) and opioids (e.g., sufentanil or fentanyl) at induction, and propofol, opioids and/or inhalational agents for maintenance of anesthesia. Propofol should be used with caution for induction of anesthesia due to its systemic vasodilatation effects, particularly in patients with combined pre- and postcapillary pulmonary hypertension.

Hypotension may be more common on induction of anesthesia in patients with advanced heart failure for a number of reasons: (i) preexisting use of vasodilators (such as angiotensin converting enzyme (ACE)-inhibitors or the more recent angiotensin receptor-neprilysin inhibitor(3)) and beta-blockers, which are now the mainstay of heart failure therapy; (ii) decreased myocardial reserve related to the underlying cardiomyopathy; (iii) the cardiodepressive and vasodilatory effects of anesthetic agents, and (iv) positive pressure ventilation which decreases venous return and an increase in right ventricular (RV) afterload. Fluid administration may not correct hypotension and risks worsening pulmonary and/or systemic congestion, particularly as most candidates for DMCS implantation will have severe left ventricular (LV) impairment and elevated filling pressures. Hypotension on induction may require a combination of vasopressors and inotropes.

The preservation of right heart function is an important consideration during DMCS implantation. Pulmonary hypertension due to left heart disease is common in patients with advanced heart failure. Most intravenous and inhalational anesthetic agents have minimal effects on pulmonary vascular resistance (PVR) and oxygenation, but may depress RV contractility, which can adversely affect ventriculo-arterial (RV-pulmonary circulation) coupling. Histamine-releasing relaxants (atracurium) have been reported to increase PVR and worsen right heart function. Low tidal volume ventilation (4-6 mL/kg predicted body weight) during cardiopulmonary bypass may reduce the risk of lung injury (4) and should be considered, as it does not usually compromise the surgical field for DMCS implant. The maintenance of pulmonary perfusion during cardiopulmonary bypass is not commonly practiced with as yet unproven benefit.

In critically ill patients, additional considerations include abnormal hepatic and renal function, altered levels of plasma proteins (decreased albumin concentration), and altered volume of distribution due to vasodilation, capillary leak, and resuscitation, which will alter circulating drug levels due to pharmacokinetic changes in distribution, metabolism, and clearance. These changes are exacerbated by the use of venoarterial extracorporeal membrane oxygenation (VA ECMO) due to increased volume of distribution. Intravenous anesthetic agents are favored in patients on VA ECMO, as inhalational anesthetic agents may not be reliably delivered in patients with reduced pulmonary blood flow.

Recommendations

- *Cardiac anesthesia should be performed by practitioners familiar with the clinical issues associated with DMCS placement, including considerations at the time of induction, during surgery, during separation from cardiopulmonary bypass, and initiation of the DMCS (Class I, Level of evidence B).*

Transesophageal echocardiography

Echocardiography is necessary in the preoperative assessment of patients before DMCS implantation. Nonetheless, intra-/perioperative TEE is essential and is considered standard of care for baseline precardiopulmonary bypass (CPB) assessment of structural and valvular abnormalities, to guide cannulation and concomitant surgical intervention and postimplant management during the transitioning from CPB to DMCS support(5). Perioperative TEE should be performed by appropriately trained practitioners.

Baseline assessment before initiation of CPB should include: (i) the aortic valve (regurgitation will cause pump recirculation), (ii) LV (impact on cannulation technique) and left atrial (guide anticoagulation) thrombi, (iii) possible patent foramen ovale or any other intracardiac shunt (a left-to-right shunt may be reversed and the shunt fraction increased with LV unloading), (iv) baseline RV size and function, and (v) the cause (e.g., annular dilatation or implantable cardioverter defibrillator (ICD) /pacemaker lead-related) and severity of tricuspid insufficiency (determine the potential need for intervention on the tricuspid valve). In some cases, the mitral valve should be examined for stenosis (e.g., the presence of Mitraclip) and the aorta for atheroma.

TEE can be helpful in positioning of the LV cannula. Indentation of the LV by the surgeon can be easily visualized to confirm the position of the LV apex. The position of the cannula can also be confirmed and optimally directed toward the mitral valve. The results of concomitant surgical interventions can also be assessed. Before attempting to separate from CPB and during de-airing, TEE should be used to detect residual intracardiac air. It may be possible to visualize air embolism into the right coronary artery, which may exacerbate right ventricular dysfunction. During weaning from CPB and initiation of DMCS, TEE should be used continuously to assess the degree of LV unloading, RV size and septal position. The TEE findings can be used to supplement hemodynamic monitoring to guide inotropic and vasopressor support, fluid administration during separation from CPB. In the immediate post-CPB period, the TEE should be used to assess RV size and function, detect septal dysfunction, LV over-decompression (adjustment of pump speed) and RV failure. The severity of aortic regurgitation and intracardiac shunting should be re-assessed on DMCS support after separation from CPB. The technical success of any additional concomitant surgical procedures (e.g., aortic valve replacement) should also be assessed. Chest closure and administration of protamine may result in hemodynamic instability in some cases. TEE assessment of the cannula position and RV function can aid in differentiating the possible diagnoses in the event of hemodynamic deterioration.

Separation from cardiopulmonary bypass

Standard criteria before weaning from CPB should apply in DMCS implant including rewarming the patient, de-airing the heart, stable cardiac electrical activity (with temporary synchronous pacing preferably), and satisfactory ventilator (lung) mechanics, hematocrit, metabolic and blood gas parameters. The process of separation from CPB include concurrent: (i) (gradual) reduction in the CPB pump flow; (ii) transfusion of blood volume from the reservoir to the patient; (iii) initiation and (gradual) up-titration of LVAD flow; and (iv) support of right heart to maintain LVAD flow and cardiac output. Continuous flow LVADs do not have valves built in and would allow reversal of blood flow along a pressure gradient. Thus, continuous flow LVADs must be initiated (at low pump speeds) to avoid retrograde blood flow during weaning from CPB. The LVAD pump speed is then slowly increased in parallel with reduction in CPB flow. Typically, the patient is almost completely separated from cardiopulmonary bypass before full LVAD flow is achieved to preserve septal orientation and RV function.

The right heart should be optimized before and during separation from CPB: (a) RV preload must be managed judiciously with transfusion of blood volume from CPB reservoir, cell salvage or blood products (if correction of hematocrit or coagulopathy is indicated); (b) Inotropes such as milrinone or dobutamine should be initiated in all patients while on bypass and continued beyond separation from CPB to maintain contractility; (c) Vasopressors such as norepinephrine and vasopressin should be considered to maintain perfusion pressure for the RV; (d) Atrio-ventricular synchrony and heart rate should be maintained with temporary pacing if indicated; (e) RV afterload can be minimized with the use of pulmonary vasodilators and avoiding excessive tidal volumes with mechanical ventilation. Pulmonary vasodilator therapy (such as nitric oxide and inhaled prostaglandins) should be considered in patients with combined pre- and postcapillary pulmonary vasculature before separation from bypass to reduce RV afterload. Inhaled pulmonary vasodilators have less systemic vasodilatory effects and improve V/Q matching. Inhaled nitric oxide failed to reduce the incidence of RV failure in a multicenter randomized trial (6). Nonetheless, the use of inhaled pulmonary vasodilators remains widely accepted (7). Meanwhile, the ventilator is adjusted to maintain normal arterial pH value with pCO_2 <40 mm Hg (ideally >35 mm Hg).

Protamine is often administered after separation from CPB to reverse the anticoagulant effects of heparin. Protamine dosing varies between centers. In the absence of randomized trials, a protamine-to-heparin ratio of 0.6 to 1.0 based on initial heparin dosing (usually 400 IU/kg to achieve activated clotting time of >400 sec), not exceeding a ratio of 1.0 (1 mg of protamine to 100 IU of heparin) has been suggested (8). Pulmonary hypertension and hemodynamic deterioration are well-recognized adverse effects of protamine.

Pulmonary arterial catheters should be inserted (floated) to monitor cardiac output and mixed-venous oxygen saturation, monitor changes in PVR and assessment of right heart function after separation from CPB. Some surgeons may consider the implantation of a direct left atrial pressure line to monitor the left atrial pressure. However, careful handling of these pressure lines are mandatory to avoid accidental air embolism. The hemodynamic data from the PAC should be interpreted in conjunction with TEE study of RV function, LV unloading and septal position. Increase in CVP, changes in CVP waveform (emergence of new v-waves), falling pulmonary artery systolic or pulse pressure and cardiac output and rising mean pulmonary artery to systemic arterial blood pressure ratio (MPAP: MAP) may indicate right heart failure. A complete TEE examination should be performed following separation from CPB.

Recommendations

- *Intraoperative transesophageal echocardiography should be performed by physicians with advanced training in the intraoperative assessment of cardiac structure and function (Class I, Level of evidence B).*
- *Pulmonary artery catheter should be used to guide hemodynamic management after separation from CPB (Class IIa, Level of evidence C).*
- *A left atrial pressure line may be considered in selected patients after DMCS implantation (Class IIb, Level of evidence: C).*
- *Inhaled nitric oxide and prostaglandins, and phosphodiesterase-3 inhibitors (*e.g., *milrinone) should be considered for the management of RV dysfunction (Class IIa, Level of evidence C).*
- *The ventilator is adjusted to maintain normal arterial pH value with pCO_2 <40 mm Hg (ideally >35 mm Hg) (Class IIa, Level of evidence C).*

Topic 2: Implantation techniques

Implantation technique for mechanical circulatory support device (DMCS)

Since the 2013 guideline, continuous-flow left ventricular assist devices (CF-LVAD) have enjoyed further technological advancements and have become an integral part of the management of patients with end-stage heart failure, while other durable DMCSs remain very limited with specific roles. Acknowledging the present status, as well as, different, specific techniques, and procedural nuances required for each DMCS, the general principle of the implantation technique for implantable CF-LVAD through a midline sternotomy is described here.

The surgical knowledge of the CF-LVAD implant procedure has been more widely shared among heart failure surgeons. As a result, newer generations of LVADs require less complex implantation surgery. Although the technique for CF-LVAD implantation still varies depending on the institution and individual surgeon, certain common steps are followed.

The surgical team consists of the lead surgeon, an experienced assistant, a scrub nurse, a circulator, and a scrubbed person to assemble the CF-LVAD pump [either a physician's assistant, perfusionist, ventricular assist device (VAD) coordinator, or scrub nurse]. Advanced hemodynamic management, especially for the right ventricle, requires an experienced cardiac anesthesia team. A perfusion team is in the room with the cardiopulmonary bypass machine primed. Evaluation with intraoperative transesophageal echocardiogram is an essential part of patient and device management. Preexisting indwelling catheters, such as PICC line and Swan-Ganz catheter, are removed or replaced. Appropriate broad-spectrum antibiotics are administered for prophylaxis.

A vertical midline incision is made, beginning just below the sternal notch with variable extension below the xyphoid depending on the type of device being implanted and the corresponding required pocket size, if any. A midline sternotomy is made. Pump pocket is only necessary if an axial flow pump is implanted. If the device requires a device pocket, it is developed posterior to the posterior rectus sheath in the preperitoneal space. A model of the pump can be used to confirm appropriate sizing of the pocket, which extends as laterally as possible to allow optimal positioning of the inflow cannula. No pump pocket is required for intrapericardial pumps. Pericardium is opened as necessary at the time of implantation of centrifugal pumps. For intrapericardial pumps, some surgeons prefer to enter the left pleural space to create extra space for pump placement. It is critically important to cease any bleeding at this point, even if minor. For reoperations, bleeding due to adhesions should be meticulously addressed before heparinization.

Recommendations

- *LVAD implantation requires a multidisciplinary team with experience in device implantation (Class I, Level of evidence C).*
- *Appropriate broad-spectrum antibiotics are administered for prophylaxis (Class I, Level of evidence B).*
- *Standard cardiovascular surgical procedures should be followed including use of clippers for chest hair and alcohol-based agents for skin preparation (unless contra-indicated) as recommended by national guidelines and the MCS Academic Research Consortium. (Class I, Level of evidence A).*
- *Standard LVAD implantation technique is performed through a median sternotomy (Class IIa, Level of evidence C).*
- *If pump pocket is necessary, a pump pocket is created by dividing attachments of the left hemidiaphragm to the costal cartilage. A model of the pump can be used to confirm appropriate sizing of the pocket (Class IIa, Level of evidence C).*

Tunneling of the driveline

Before systemic heparinization if possible, a tunnel is developed using the provided tunneler. Care is taken not to violate the peritoneum and injure abdominal content. The tunneler is passed through the posterior rectus sheath and the rectus muscle. The exit point is generally halfway between the umbilicus and the costal margin. The driveline is pulled though the exit site. All of the velour is kept in the subcutaneous space so that only silicone is in contact with skin at the exit site. The exit site may be closed with a subcuticular suture, and the driveline is secured with sutures. Notably, at the time of preoperative education of the patient, the exact side of driveline exit site (left or right) may be discussed and patient's preference is followed.

Driveline implantation technique

Surgical techniques for driveline tunneling and exit site creation have evolved with device progression to

accommodate changes in pump pocket formation, intrapericardial and thoracic placement as well as emerging smaller and increased flexibility in the percutaneous driveline with each successive device iteration.

The specific surgical techniques used may vary but all techniques aim to accomplish the transition from the pump body in the thoracic cavity to the cutaneous exit site, traditionally through avascular planes such as the rectus sheath to the abdominal wall, although alternate exit sites have been employed (9-12).

Consensus exists on (a) surgical tunneling technique to keep the entire (DL) velour portion of the driveline below or contained within the subcutaneous tunnel, resulting in a silicone-skin interface (SSI) at the exit site and (b) meticulous hemostasis in the driveline tunnel and exit site (11, 12).

Consideration is given to the anchoring the driveline close to the exit site, to mitigate potential trauma and prevent micro bleeding, which may progress to driveline infection. Anchoring can be accomplished by suture or surgical appliance application to stabilize and transfer weight and tension with movement and trauma.

Extended tunneling to prevent driveline infection has been described and several centers advocate for variations of a double tunnel technique. The double tunnel driveline technique includes placement of the driveline in the sheath of the rectus muscle in the umbilical direction and then subcutaneously to the left upper quadrant. This technique has been reported by several centers reporting low incidence of driveline infection and improved mortality (13, 14).

Alternative exit sites have been utilized in LVAD implantation include the postauricular position for the Jarvik 2000 LVAD, and chest wall exit site placement used by select implanting centers (10, 13, 14). These site selections capitalize on the improved blood supply of these regions, as well as possibly improved stabilization, and anatomic locations that may afford expanded lifestyle tolerances, and achieve better initial healing and lower driveline infection rates (13, 14).

Recommendations

- *The driveline should be implanted: a) within the rectus sheath with an exit site on the abdominal wall determined by a preoperative assessment of body habitus and anticipated clothing; b) with the entire velour portion of the driveline positioned below/contained within the subcutaneous tunnel, resulting in a silicone-skin interface (SSI) at the exit site (Class I, Level of evidence C).*
- *Extended tunneling may be useful using a double tunnel driveline technique that places the driveline within the sheath of the rectus muscle in the umbilical direction and then subcutaneously to the left upper quadrant (Class IIb, Level of evidence C).*
- *External fixation during the initial healing period may decrease traumatic bleeding and prevent future driveline infection (Class I, Level of evidence C).*

Cannulation

The patient is fully heparinized. The distal ascending aorta is cannulated, preserving enough space for the later placement of a partial occluding clamp for an outflow graft anastomosis. The RA is then cannulated, unless a tricuspid valve repair or closure of an atrial septal defect/patent foramen ovale is planned through bicaval cannulation. Carbon dioxide is also brought onto the field. The patient is then placed on cardiopulmonary bypass and kept at normothermia or mild hypothermia. Hemofiltration may be used to remove excess intravascular volume. A left ventricular vent via right superior pulmonary vein is usually not necessary, as this will make the de-airing process more complicated. Any concomitant procedure should precede the implantation of the inflow and outflow cannula of the LVAD, as the implantation will obstruct the visualization of the intracardiac structures. Coring of the left ventricular apex, however, might be considered before concomitant procedures to decompress the left ventricle.

Recommendations

- *A standard cannulation technique is used to allow safe implantation and adequate heart decompression, and concomitant valve interventions as needed (Class I, Level of evidence C).*
- *Carbon dioxide may be used throughout the procedure (Class IIb, Level of evidence C).*

Coring procedure

The left ventricle is elevated to expose the apex by placing several sponges into the pericardial cavity, or by placing posterior pericardial sutures. The left ventricular apex is identified by palpating the dimple and marked as an inflow site. Alternatively, an inflow site located slightly anterior to the left apical dimple of the left ventricle is favored by other surgeons. Appropriate positioning of the inflow cannula guided by the mitral valve alignment needs to be confirmed using transesophageal echocardiogram regardless of the pump type. The apical ventriculotomy, which is created using a manufacture-provided coring knife, can precede ("core-then-sew") or follow ("sew-then-core") the placement of the inflow sewing ring. The left ventricular cavity is then inspected for trabeculations through the ventriculotomy. Prominent trabeculations are excised, and any thrombus is removed. When mobile left ventricular thrombi exist, especially fresh thrombi, it may be prudent to carefully open the apical area using a surgical knife and excise the myocardium of an approximate size in a circular fashion for the inflow instead of coring with a coring knife. Aortic cross clamp and induction of cardioplegic myocardial arrest may be considered as well. The coring knife might not work, either, in special circumstances, such as an existing left ventricular patch or extensive endocardial calcification. Finally, alternative LVAD inflow sites, such as the left ventricular inferior wall (diaphragmatic surface), have been reported without widespread use.

For the placement of an inflow sewing ring, twelve 2-0 Tevdek pledgetted sutures are placed in a horizontal mattress fashion deep in the myocardium. These sutures are passed through the sewing ring and tied snugly, paying attention to avoid fracturing the myocardium. When the "core-then-sew" sequence is chosen, each needle of these Tevdek sutures should be placed as follows: first, take a deep, full-thickness bite approximately 2cm away from the edge of the ventriculotomy; next, take the needle out through the ventriculotomy, and then, place the needle inside-out taking a small partial thickness epicardial bite at the edge of the ventriculotomy.

Alternatively, with the "sew-then-core" technique, a running suture technique may be used. Large prolene pledgetted sutures are placed at 4 corners and run along the circumference of the sewing ring, placing each bite deep into the myocardium.

The inflow of the pump is then inserted into the inflow ring and secured using the device-specific system. It is important to orient the pump so that the outflow graft runs toward the right side of the heart. The outflow graft and bend relief may be connected to the pump for intrapericardial pumps before inflow insertion. While they can be connected to the pump after the outflow graft anastomosis, meticulous attention needs to be paid to the orientation of the graft, which otherwise may twist and become obstructed.

The heart is placed back in its normal position with the pump. For patients with limited pericardial space, the pump might be placed in the left pleural space as described above.

Recommendations

- *The surgeons technique should be guided by the implant instructions in the manufacturer's INFORMATION FOR USE (IFU) documents provided specific to each device. (Class I, Level of evidence C).*
- *Standard inflow coring and implantation is carried at the left ventricular apex or in an anterior-lateral fashion (Class I, Level of evidence C).*
- *Careful inspection of the LV apex is recommended if feasible to remove obstructive trabeculae or left ventricular thrombus (Class IIa, Level of evidence C).*

Outflow graft anastomosis

The outflow graft is beveled at an appropriate length to be anastomosed to the proximal ascending aorta. This measurement should be such that the graft eventually lies lateral to the right atrium, thus precluding undue pressure on these structures following sternal closure. Moreover, lateral placement protects the outflow from injury during sternal reentry. A partial occlusion side biting clamp is then applied to the proximal ascending aorta. An aortotomy is made with a blade and then extended with scissors or an aortotomy punch. The graft is then anastomosed to the proximal ascending aorta using 4-0 Prolene sutures in running or interrupted fashion, with or without buttressing Teflon pledgets or bovine pericardium. The keys to a hemostatic anastomosis may include the following: selection of the aortic site with good tissue integrity, creation of an aortotomy with clean edges, avoidance of size mismatch between the aortotomy and the beveled graft, proper and atraumatic suture technique. The use of hemostatic agents may be considered but may cause severe adhesions at the time of transplantation. The anastomosis should be performed at the lateral aspect of the greater curvature of the ascending aorta, if possible, to maximize rheology of flow to systemic circulation.

The graft is then de-aired and clamped, and the anastomosis is meticulously inspected for bleeding. Even mild bleeding can lead to a need for mediastinal re-exploration and should be aggressively repaired with proper surgical technique, such as placement of repair sutures and/or application of hemostatic agents with manual pressure. Some surgeons wrap the outflow graft with an additional layer of coverage, such as Dacron graft, GoreTex pericardial membrane (Gore Medical Products, Flagstaff, Arizona.), or bovine pericardium, to enhance hemostasis and to reduce the chance of outflow graft injury during sternal reentry. However, there are concerns regarding outflow graft compression from these materials. Therefore, many manufacturers discourage from complete wrapping of the outflow graft particularly when GoreTex membrane is used.

Recommendations

- *The outflow graft is beveled to appropriate length (optimally with a 45-60 degree) to be anastomosed to lateral aspect of the greater curvature of the proximal ascending aorta. The graft eventually should be placed lateral to the right atrium in a matter which prevents compression following sternal closure (Class I, Level of evidence C).*
- *Careful and meticulous deairing should be performed before initiation of LVAD (Class I, Level of evidence C).*
- *Liberal application of hemostatic agents is not recommended to avoid adhesions at the time of reoperation (Class III, Level of evidence C).*
- *Complete wrapping of the outflow graft particularly with GoreTex membrane is not recommended. (Class III, Level of evidence C).*

De-airing

Following completion of the implant, venting needle holes are created in the outflow graft using an 18G needle with a clamp on the outflow graft, while the patient is placed in deep Trendelenburg position. The patient is slowly weaned from cardiopulmonary bypass. The heart is allowed to fill with volume as the anesthesiologist gives large breaths to evacuate air that may be entrapped in the pulmonary veins. It is recommended to perform the deairing procedure before the outflow graft anastomose and afterward through a needle inserted into the outflow graft and ascending aorta. Under transesophageal guidance, the left ventricular and left atrial appendage are shaken by the surgeon to further encourage displacement of trapped bubbles. Dilated, poorly contracting left ventricles can harbor air bubbles within the

trabeculae that can be difficult to clear and may require extensive shaking of the ventricle and patient to fully evacuate. The device driveline is connected to the controller, and the LVAD is actuated at a low speed with the clamp on the outflow graft for further deairing of the pump. Embolization of air into the RCA may be suspected by visualization of remaining air in the left ventricle and aortic root, or even within the small acute marginal branches, as well as, by the appearance of inferior wall ST segment elevations. Right ventricular dysfunction with chamber dilatation, elevation of central venous pressure, development of significant tricuspid regurgitation, and/or poor LVAD filling may occur. These may mandate reinstitution of full cardiopulmonary bypass support, maintenance of high perfusion pressures to push the air through the right coronary system, and further de-airing maneuvers. Even in the most dramatic instances, air-induced right heart failure can be reversed, and right ventricular assist device support averted.

Recommendations

- *Careful and meticulous deairing should be performed before initiation of LVAD (Class I, Level of evidence C).*

Weaning off cardiopulmonary bypass and actuating DMCS

Once all of the air is evacuated, as determined by transesophageal echocardiogram monitoring, the patient is separated from cardiopulmonary bypass. Inotropic support (e.g., dobutamine, milrinone, and/or epinephrine), as well as, inhaled nitric oxide are started at this point to optimize right ventricular function. Additionally, vasopressors (norepinephrine and vasopressin) are started to maintain a mean arterial pressure of 75 to 90 mm Hg. The outflow graft is unclamped, and the pump speed is gradually increased and optimized under transesophageal echocardiogram guidance according to specific device recommendations. Adequate aortic perfusion pressure should be maintained to avoid excess unloading of the left ventricle by the continuous-flow pump, which will lead to interventricular septal shift, right ventricular failure, and hemodynamic collapse. Throughout this process, the de-airing hole in the outflow graft is kept open to allow for additional de-airing.

Excessive pump speeds aimed at improving LVAD output may induce septal shift or lead to increased venous return and overwhelm the dysfunctional right ventricle. Thus, it is suggested that LVAD speeds be maintained at a level sufficient in attaining satisfactory hemodynamic support with optimal left ventricular decompression (intermittent aortic valve opening and absence of significant mitral regurgitation), and without leftward intraventricular septal shift. Frequent assessment with transesophageal echocardiogram is crucial to constantly evaluate the degree of left ventricular decompression, degree of valvular regurgitation, inflow cannula positioning, flow across the inflow and outflow cannulae, and right ventricular function. All these variables are susceptible to dynamic and significant changes at any point following LVAD implantation. It is noteworthy that the management of right ventricular function is essential immediately after LVAD implantation. Relevant parameters are constantly monitored and assessed, and necessary adjustment in pharmacologic support or LVAD speed is implemented by the LVAD team without delay. Before separation from cardiopulmonary bypass and thereafter, it is essential that optimal oxygenation is maintained, and acidosis and hypercarbia be avoided. Hypoxia, hypercarbia, and acidosis can lead to pulmonary vasoconstriction resulting in increased afterload to the right ventricle. Preload management is vigilantly monitored with the central venous pressure, transesophageal echocardiogram and visual inspection of the right ventricular and right atrial free walls. In general, a central venous pressure of $\leq$14 mm Hg is desirable. Rapid administration of large amounts of intravenous fluids or blood products should be avoided. If the blood products are necessary, they should be administered in combination with diuretics.

Afterload management can be achieved by the use of nonselective (milrinone) and selective (inhaled nitric oxide or inhaled prostaglandin) pulmonary vasodilators. As outlined previously, efforts to lower pulmonary vascular resistance by judicious use of the ventilator to optimize oxygenation and maintain normo- or mild hypocarbia are essential.

Right ventricular contractility can be enhanced by the use of ß2-agonists like dobutamine, isoproterenol, or epinephrine, as well as PDE inhibitors.

Atrioventricular pacing may be attempted for bradyarrhythmia to enhance right ventricular function.

Again, constant assessment of the right ventricular function is warranted, and identification of any hint of right ventricular failure should prompt aggressive treatment by combining all of the above. In the event of persistent and refractory right ventricular failure, mechanical right ventricular support should be instituted without delay.

Recommendations

- *Selective inotropic therapy, pulmonary vasodilator therapy, systemic oxygenation, and heart rate with atrioventricular pacing, if necessary, should be optimized to prevent or manage right heart failure (Class I, Level of evidence C).*
- *Continuous TEE guidance should be used to assess right ventricular function and degree of LV unloading during initiation of LVAD pump (Class I, Level of evidence C).*
- *Pump speed should be increased and adjusted to maintain adequate aortic perfusion pressure, systemic perfusion and avoid excess unloading of the left ventricle (Class I, Level of evidence C).*

Achieving hemostasis

Bleeding remains the most common complication following LVAD implantation(15). Several factors contribute to the unequivocal propensity for perioperative bleeding during and immediately following LVAD surgery. Most

frequently discussed and important in CF-LVAD surgery-related bleeding is the development of acquired Von Willebrand syndrome, which occurs immediately following LVAD surgery (16). Additional contributing factors include poor nutritional status, preoperative use of anticoagulants, antiplatelet agents, and herbal medicines known to affect platelet function, hepatic dysfunction, hypothermia, dilutional thrombocytopenia, acquired von Willebrand disease associated with CF pump, and the interaction between blood and blood-contacting surfaces of the device.

Bleeding is often accompanied by the need for transfusions, which is associated with important clinical implications. First, previous cardiac surgery studies suggest that blood transfusion induces an immunosuppressive state that can contribute to the development of nosocomial infections (17, 18). Second, blood transfusions have been associated with pulmonary insufficiency (19). Transfusion associated lung injury (TRALI), is thought to be induced by passive transfusion of complement activating antibodies. Of particular concern to DMCS recipients awaiting transplantation is the risk of allosensitization. This may result in elevated panel reactive antibodies that can complicate or even preclude transplantation. Thus, focused efforts must be placed on minimizing perioperative bleeding and the need for transfusion.

Hematological consideration

If possible, removal of 1 to 2 units of whole blood before heparinization and institution of cardiopulmonary bypass allows for the return of platelet- and factor-rich autologous blood to the patient after protamine reversal. Following cannulation, retrograde autologous priming should be undertaken to further reduce hemodilution. Minimizing total cardiopulmonary bypass time may reduce the unfavorable extracorporeal-induced trauma of blood elements.

Antifibrinolytics, such as aminocaproic acid and tranexamic acid, are routinely used, and complete heparin reversal with protamine to achieve a normal ACT is applied.

Since all patients who receive CF-LVAD immediately develop acquired Von Willebrand syndrome, as above, treating this condition early with administration of Desmopressin (20) or vWF concentrate replacement with Haemate-P (21), as well as, cryoprecipitate transfusion may be considered. Recent data suggest that the less disruption of Von Willebrand is observed in patients supported with HeartMate III (22). Prompt and judicious use of blood products should be entertained if coagulopathy is encountered after full protamine reversal. In patients with renal insufficiency, the use of desmopressin should be considered(23). Thromboelastography and rotational thromboelastometry as point-of-care tests during surgery and the early postoperative period might be useful, while convincing evidence remains absent(24). Recent data suggest that using the Quantra system (HemoSonics, LLC, Charlottesville, VA) may provide useful data for guiding transfusion management (25). However, experience in DMCS patients remains limited and precludes sufficient recommendation at this stage.

Surgical consideration

As above, DMCS creates a unique challenge to the surgeons in hemostasis, and therefore, hemostasis is an art of heart failure surgeons. Experienced surgeons have many tips and tricks to eventually achieve a "dry" surgical field. As outlined in the previous sections, obtaining hemostasis as the procedure progresses prevents later bleeding problems.

Surgeons should be aware of the importance of meticulous hemostasis in all surgical areas, such as the sternal edges, the pleural fat pads, the device pocket, the sternal wire holes, and, in reoperative cases, torn adhesions between the epicardium, pericardium, and exposed lung surfaces, in addition to inflow and outflow attachment sites for the DMCS. "Oozing" from these instrumented raw surfaces, which become easily hemostatic in routine cardiac procedures, may continue to bleed due to unique hematological abnormalities associated with DMCSs. Surgeons should become familiar with adjunctive instruments, compounds and sealants for hemostasis.

In the event of persistent bleeding tendency, packing the mediastinum and returning to the operating room within 24 to 48 hours for unpacking and sternal closure is warranted. The advantages of this approach are that it reduces the need for reopening the sternum (and, hence, additional sternal trauma from rewiring). It also allows for the removal of residual clots, thus removing potential nidi for future infection. This practice often leads to successful correction of coagulopathy and patient rewarming without an increase in infectious sternal wound complications.

Closing sternotomy

Preparation for future sternal reentry is warranted. The pericardium may be reapproximated in the superior pericardium. A GoreTex pericardial membrane or similar barrier may be sutured to the pericardial edges to reconstruct the rest of the pericardium. The sternum and soft tissue are closed in the standard fashion.

Recommendations

- *Careful and compulsive surgical technique is warranted to achieve hemostasis (Class I, Level of evidence C)*
- *Meticulous and protocol-directed blood transfusion should be utilized to correct coagulation anomalies (Class I, Level of evidence C).*
- *Selective utilization of sealants may be considered to achieve hemostasis (Class IIb, Level of evidence C).*
- *In selected patients, pericardial closure using a biologic or synthetic patch to shield the pump outflow graft and the right ventricle is recommended to avoid injuries from re-entry (Class IIa, Level of evidence C).*

Concomitant procedures along with implantation of CF-LVAD

When a concomitant procedure(s) is planned, it should generally precede the implantation of the inflow and outflow of the LVAD, which obscure the visualization of the

intracardiac structure and interfere with mobilization of the heart. Cardioplegic myocardial arrest is generally required only for the aortic valve-related procedure or for presence of mobile left ventricular thrombus.

Intracardiac shunts

The patent foramen ovale is closed primarily with running sutures with bicaval cannulation. This procedure can be performed without aortic cross clamp and is best performed before the creation of the outflow graft anastomosis, as the outflow can preclude easy access to the right atrium once it is secured in place. Proper filling of the left ventricle is required in the contemporary management of CF-LVAD, and therefore, the left atrial pressure is almost always higher than the RA pressure, avoiding postoperative right-to-left shunting and systemic hypoxemia. To avoid bicaval cannulation and atriotomy, particularly in patients undergoing less invasive LVAD implantation, some surgeons leave small patent foramen ovale and consider closure only if flow reversal and/or desaturation is observed after coming off cardiopulmonary bypass. No sufficient data exist regarding the long-term impact of this approach. Another option is to consider intervential closure, if necessary. However, closure remains required when: the atrial shunt is large; the right atrium is opened (for tricuspid repair); and biventricular support is planned.

Recommendations

- *Preoperative assessment of the presence of interatrial communication should be performed using TEE (Class I, Level of evidence C).*
- *Closure of a significant interatrial shunt should be performed (Class I, Level of evidence C).*
- *-An LVAD alone in the setting of an unrepairable ventricular septal defect or free wall rupture is not recommended. (Class III, Level of evidence C).*

Management of coexisting valvular disease

Aortic regurgitation

Unlike other valvular diseases, aortic regurgitation has a significant and proven impact on the clinical course of LVAD patients. It leads to auto-circulation of the blood; in which blood form the outflow flows retrograde back into the left ventricle. Overcoming the aortic regurgitation by increasing the LVAD speed, which allows appropriate decompression of the left ventricle, may work only to a certain point, beyond which left ventricular volume overload through significant aortic regurgitation will lead to left heart failure. Importantly, aortic regurgitation appears to be induced by LVAD-related hemodynamics, which worsens over time (26-28). In this juncture, addressing the aortic regurgitation at LVAD surgery is rather aggressively considered, especially when prolonged support is anticipated. While preoperative and intraoperative echocardiographic assessment guides the indication for the intervention, significance of aortic regurgitation may manifest as overwhelming back bleed through the left ventricular apical core during the LVAD inflow placement on on-pump beating heart, and this observation may warrant repairing the aortic regurgitation.

The most commonly performed procedure for aortic regurgitation is a central aortic valve cusp approximation ("Park stitch")(29). After aortic cross-clamping and cardioplegic myocardial arrest, a transverse aortotomy, separate from and proximal to the longitudinal aortotomy for the outflow graft anastomosis, is made to approach the aortic valve. The repair is performed by approximating the center of the leaflets with a 4-0 pledgetted polypropylene suture. After completion of the repair and aortotomy closure, the aortic cross clamp is removed. The rest of the procedure was conducted in the usual fashion with a beating heart. The mid-term results of this procedure appear promising (30, 31).

Suture closure technique of native aortic valve closure with felt strips is also reported. This technique involves horizontal mattress suture placement to approximate the leaflet edges with a second layer of over-and-over stitch anchored to the aortic wall (32). Other groups have reported the use of a circular patch of glutaraldehyde-treated bovine pericardium, sewn circumferentially to the AV annulus with a running 3-0 polypropylene suture, permanently closing the left ventricular outflow tract(33). AV closure is efficient and is associated with a low rate of AI recurrence. This approach, however, leaves the patient completely dependent on the pump, and adverse events such as pump thrombosis or malfunction could be devastating. This technique should not be used when myocardial function recovery is possible or expected. Using the data of the Heartmate II Pivotal Trials for BTT and DT indications, John et al. found that patients with concomitant AV procedures ($n = 80$ patients, divided into AV repair [$n = 18$], closure [$n = 32$], and replacement [$n = 30$]) were sicker and had higher early mortality and RVF rates.(34) In that study, 30-day mortality was lowest for AV closure (6.3%), followed by AV replacement (13%) and AV repair (18%). Survival rates at 1 and 2 years were also lower after AV closure than after AV repair or replacement (84.1% vs 70.9%, 75% vs 57%, and 64% vs 43%, respectively; $p < .001$). In an INTERMACS database analysis ($n = 305$ patients, divided into AV repair [$n = 125$], closure [$n = 95$], and replacement [$n = 85$]), Robertson et al. reported increased mortality associated with complete oversewing of the valve, with most deaths occurring early after the procedure.(35, 36)

Lastly, aortic valve replacement with a biological valve might be considered with the understanding that it requires longer cardiopulmonary bypass and myocardial ischemic times(37). There are no data supporting the ideal biological valve selection in LVAD patients. However, some surgeons prefer porcine valves over pericardial valves assuming better durability of porcine valves.

Recommendations

- *More than mild aortic regurgitation should be addressed at the time of LVAD implant. Aortic valve replacement using a biologic valve should be performed, if necessary (Class I, Level of evidence: C).*

- *Aortic valve closure techniques may be considered to address more than mild aortic regurgitation in selected patients (Class IIb, Level of evidence: C)*

Aortic stenosis

Aortic valve stenosis is well tolerated during LVAD support and, thus, does not typically require concomitant intervention. Even when left ventricular recovery is anticipated, aortic valve replacement with a biological valve might not be advisable, unless fast recovery is expected, since a biological valve may suffer from thrombosis or early degeneration with fusion of the cusps.

Recommendations

- *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 (Class I, Level of evidence: C).*
- *-In patients with severe aortic stenosis and potential for recovery, aortic valve replacement may be considered, regardless of the degree of concomitant aortic insufficiency (Class IIb, Level of evidence: C).*

Aortic root disease

Recommendations

- *Patients with a history of vascular disease and/or coronary artery disease should have a preoperative assessment of their ascending aorta for aneurysmal dilation and atherosclerotic burden with a CT scan before implant (Class IIa, Level of evidence: C).*
- *The indications and cut-offs to replace aortic root and/or ascending aorta is similar to the recommendations followed in routine cardiac surgical procedures (Class I, Level of evidence: C).*

Mitral regurgitation

Functional mitral regurgitation commonly accompanies end-stage cardiomyopathies. While unloading of the left ventricle with LVAD is frequently observed, leading to a decrease in left ventricular size and improving the functional mitral regurgitation, residual mitral regurgitation may be observed in up to 30% of LVAD patients (38-40). Acknowledging less evidence is available than aortic or tricuspid repair, some experts recommend intervening on mitral regurgitation at LVAD surgery, and case series suggest it does not add substantial early risk to the LVAD surgery (41-43). The visualization of the mitral valve can be obtained through a standard right-sided left atriotomy on the beating decompressed heart, and a restrictive mitral annuloplasty is performed using a commercially available annuloplasty ring. In selected cases, edge-to-edge repair (Alfieri stitch) may be chosen, and this can be performed through the standard left atriotomy, the left ventricular apical core, or the aortotomy with an aortic valve procedure (31). Alternatively, mitral valve replacement can be considered.

Recommendations

- *Concomitant mitral valve interventions may be considered during LVAD implantation. Mitral valve repair or mitral valve replacement using a bioprosthetic valve can be performed on the beating decompressed heart (Class IIb, Level of evidence: C).*

Mitral stenosis

Mitral stenosis is infrequently encountered in patients with advanced left ventricular dysfunction. Significant mitral valve stenosis may be encountered in patients with history of multiple MitraClip deployments. Significant mitral stenosis must be corrected at the time of surgery because it limits LVAD filling and maintains left atrial and pulmonary hypertension. Significant mitral stenosis often requires a valve replacement, while milder forms of rheumatic stenosis might be successfully treated with commissurotomy. Use of a mechanical valve is not recommended due to the risk of thromboembolic complications.

Recommendations

- *Significant mitral stenosis needs to be addressed during LVAD implant. Commissurotomy or mitral valve replacement using a bioprosthetic valve can be performed on the beating decompressed heart (Class I, Level of evidence: C).*

Tricuspid regurgitation

Patients who need LVAD implantation often have biventricular dysfunction. Tricuspid annular dilatation and leaflet tethering associated with right ventricular dysfunction causes significant tricuspid regurgitation in combination with leaflet restriction caused by an existing lead(s) belonging to a pacemaker and/or defibrillator. Significant preoperative tricuspid regurgitation (moderate to severe) is a predictor of worse outcomes after LVAD implantation(44). While contradictory reports continued to be published regarding the clinical impact of tricuspid repair (45-48), many experts continue to argue for repairing significant tricuspid regurgitation at the time of LVAD implantation. A restrictive ring annuloplasty, in which a tricuspid ring of 28 to 32 mm is implanted, generally suffices. Significant destruction of the leaflets, usually the septal leaflet, by the lead(s) might require a valve replacement or modified tricuspid valve repair (bicuspidization). Use of a mechanical valve should be discouraged. This procedure should precede the outflow graft anastomosis, which interferes with the visualization of the tricuspid valve. A standard tricuspid ring annuloplasty is then performed on the beating heart. Secure closure of the right atriotomy is warranted to prevent bleeding from the suture line, which is exposed to high pressure. In recent years, many studies have been published with special focus on the concomitant TV repair at the time of LVAD implantation (45, 47-49). The majority of recent publications failed to show any advantage of adding additional tricuspid valve procedures at the time of VAD implantation (45, 47-50). Extracting data from the Society of Thoracic Surgeons database, Robertson et al. analyzed the records of 2,196 patients with moderate-to-severe preoperative TR who underwent CF-LVAD implantation, of

whom 27% (588 patients) underwent a concomitant TV procedure.(47) After adjustments for between-group differences, the authors concluded that performing a concomitant TV procedure did not reduce the rate of early death or RVAD requirement and was associated with worse early postoperative outcomes (postoperative renal failure, greater transfusion requirement, reoperation, prolonged ventilation, prolonged intensive care unit stay, and prolonged hospital stay). The same findings were reported by Song et al. in an analysis of 2,527 CF-LVAD patients from the INTERMACS database. Although significant TR was associated with a lower survival rate, TV repair did not confer improved survival.(46) Veen et al reported the results of a meta-analysis of 8 retrospective studies including 562 patients undergoing isolated CF-LVAD implantation and 303 CF-LVAD patients with concomitant TV procedures. (48) Patients with both TV procedures and LVAD implantation had a more severe clinical condition than patients who had isolated CF-LVAD. The authors observed no significant difference in early mortality, RVF, acute kidney injury, hospital stay, or RVAD implantation between groups. Late mortality and RVF were also similar. Based on the recent evidence, it seems that concomitant tricuspid valve repair may be omitted at the time of VAD implantation. Duke University Medical Center launched a randomized trial that aims to definitively address the necessity of TV repair at the time of LVAD implantation.

Recommendations

- *Concomitant tricuspid valve interventions may be considered during LVAD implantation in patients with greater than moderate tricuspid regurgitation. Tricuspid valve repair or replacement using a bioprosthetic valve can be performed (Class IIb, Level of evidence: B).*

Preexisting prosthetic valves

A biological valve, whether in the aortic or mitral position, is well tolerated during LVAD support, while the presence of mechanical prosthetic valves (usually mitral or aortic) may complicate management of the DMCS recipient. It has been suggested that a mechanical aortic prosthesis be addressed with a patch sewn to the annulus, thus rendering the valve nonfunctional(51). Mechanical valves may be partially or fully immobile because the left ventricle is unable to contract sufficiently to open the valve. This immobility may create an area of subvalvular stasis and poor washing that can lead to thrombus formation with subsequent risk of embolization. Replacement of a preexisting mechanical valve with a biological valve requires longer myocardial ischemia and explantation of a well-incorporated mechanical valve, which may be technically difficult.

Because of the need to maintain a functional valve (i.e., mechanical mitral valve cannot simply be oversewn or removed) and greater technical complexity required to exchange a mechanical mitral valve, most surgeons recommend leaving these prostheses in place. Small case series reported safety of this approach(52). Higher maintenance international normalized ratio (INR) may be warranted.

Recommendation

- *Functioning bioprosthetic prostheses do not require removal or replacement at the time of implant (Class I, Level of evidence: C).*
- *Aortic mechanical prosthesis should be replaced with a bioprosthetic valve during LVAD implantation (Class I, Level of evidence: B).*
- *When a mechanical aortic valve is present, patch closure may be considered when no other options are feasible (Class IIb, Level of evidence: C).*
- *Routine replacement of properly functioning mechanical mitral valve is not recommended (Class III, Level of evidence: C).*

Left atrial appendage occlusion

Ischemic stroke is one of the most devastating complications associated with LVAD support. Although the sources of LVAD-associated strokes are multifocal, left atrial appendage might play an important role given the high incidence of atrial fibrillation in this population. A recent, small case series suggested that concomitant left atrial appendage occlusion may reduce thromboembolic events; however, the data are quite preliminary(53). Of importance, left atrial appendage occlusion with a device covered with woven polyester fabric may induce significant adhesion to the surrounding tissue and might complicate subsequent heart transplantation.

Recommendations

- *Left atrial appendage closure may be considered during LVAD implantation (Class IIb, Level of evidence: C).*

Miscellaneous procedures
Recommendations

- *Intracardiac thrombus should be removed at the time of DMCS implantation (Class I, Level of evidence: C).*
- *In the presence of a massive intracardiac thrombus, total artificial heart implantation may be considered (Class IIb, Level of evidence: C).*
- *Surgical ablation may be considered for selected patients with recurrent arrhythmias at the time of DMCS implantation (Class IIb, Level of evidence C).*

Device exchange

With extended follow-up with continuous flow pumps, an increase in pump thrombosis rates led to processes and algorithms to detect early pump failure and algorithms to determine the need for pump exchange (54, 55). Screening laboratory surveillance for device malfunction, laboratory of lactate dehydrogenase and plasma free hemoglobin levels during patient follow-up should routinely be performed for detection of new hemolysis. Additional events such as LVAD alarms, change in pump parameters, and clinical thrombotic events should prompt evaluation of pump thrombosis. (56) (57, 58) The diagnostic evaluation of an LVAD with potential thrombus or suspected obstruction is

out of focus of this task force but may include static echocardiography and dynamic ramp testing of the LVAD under altered hemodynamic conditions. CT imaging, with or without IV contrasts, to evaluate pump position, external compression, potential outflow graft problems, and gross inflow alignment, extent of infection as well as aid in operative planning.(58) (59)

Pump exchange may be accomplished by full sternotomy or via minimal incisions (subcostal, thoracotomy) depending on the component(s) to be exchanged and extent of infection, and/or thrombus. Full LVAD system exchange in the presence of pump thrombosis and outflow graft thrombus can be best accomplished through a median sternotomy and the use of cardiopulmonary bypass. During exchange for idiopathic pump thrombosis, the LV inflow site should be examined, with consideration made for excising/debriding an obstructive scar in the LVAD inflow space. Limited exchange (pump only) may be considered in select patients and can be accomplished through minimal incisions (subcostal, small left thoracotomy) with or without the use of cardiopulmonary bypass(58, 60). Limited incision approaches should not compromise the ability to replace the entire LVAD system when indicated. Pump only exchanges may be associated with an increase in recurrent pump thrombosis(55). Early LVAD exchange should be consider in lower surgical risk patients to avoid the risk of pump stoppage, cerebral infarction, and to decrease the risk of renal failure due to pigmented nephropathy. (61, 62)

Recommendations

- *Pump exchange may be accomplished by minimal incisions (subcostal, thoracotomy), or full sternotomy depending on the component(s) to be exchanged and extent of infection, and/or thrombus (Class IIa, Level of evidence: C).*
- *Early LVAD exchange should be considered in patients with pump thrombosis who progress despite initial management (Class IIa, Level of evidence: C).*

Special situations and considerations

LVAD exchange for infection should be performed with distinct operative filed/planes to avoid contamination of the new pump. Alternative positioning of LVAD inflow and body may be considered to avoid re-contamination. An alternative LVAD may be considered when recurrent thrombosis occurs, or specific patient factors are incompatible with the current device. (63, 64) Thrombolytic and catheter-based therapy for pump thrombosis has limited, but reported successes in pump thrombosis and may be considered in patients who are high-risk surgical candidates or decline LVAD exchange. [6, 7] (65)

Recommendations

- *An alternative LVAD may be considered when recurrent thrombosis occurs, or specific patient factors are incompatible with the current device or contribute to recurrent events (Class IIb, Level of evidence: C).*
- *LVAD exchange for infection may be performed with distinct operative field/planes to avoid contamination of the new pump (Class IIb, Level of evidence: C).*

Topic 3: Special consideration for VAD implantation

Repeat sternotomy

The number of patients who have had at least one prior sternotomy before LVAD implantation is dramatically increasing. Previous studies have demonstrated an ambiguous relationship between repeat sternotomy and clinical outcomes (66-69). As third generation, smaller profile centrifugal devices are now predominantly implanted in end-stage heart failure patients, less invasive surgical approaches are now increasingly favored over repeat median sternotomy to decrease surgical complexity (70). Nevertheless, several studies have demonstrated that previous bypass surgery, valve or congenital heart surgery are not associated with worse outcomes in patients receiving LVADs (2).

Extensive preoperative assessment should be performed to allow proper surgical planning. For those with prior bypass surgery, the exact location and patency of grafts should be identified by CT scan or other thoracic imaging. Patients with congenital heart disease after corrective or palliative surgeries in medical history should have recent detailed imaging (71). CT scan is mandatory to identify anatomy of the heart, great vessels and relationship of enlarged right or systemic ventricle to posterior sternum. Individual morphology is often determining proper pump placement and cannulation sites. For precise assessment of aortic root, ascending aorta and groin vessels we can use 3-dimensional (3D) vascular planning software.

Before standard repeat median sternotomy is performed, ultrasound-guided vascular insertion of guide wires into the femoral artery and vein with subsequent placement of 5 or 6 F sheaths should be performed to facilitate emergent initiation of cardiopulmonary bypass in presence of a hostile sternal re-entry. Some surgeons prefer to expose the common vessels with a surgical cut-down. Alternatively, the right subclavian/axillary artery can be dissected out, and an 8 mm vascular graft anastomosed which can serve as an arterial perfusion site. This may be especially helpful in cases where the femoral arteries are heavily diseased or otherwise inadequate.

Surgery is then performed under general anesthesia through the original skin incision. An oscillating saw is used to open the sternum. Careful dissection of the heart structures is carried out. After systemic heparinization, cardiopulmonary bypass is instituted in standard fashion via the ascending aorta and the right atrium. Alternatively, to avoid excessive dissection of the right atrium, a dual-stage venous cannula can be inserted through femoral vein (using already 5/6 F sheath on site) under echo guidance. The same cannula can be used later as an inflow cannula for temporary right ventricle support if fulminant right ventricular failure is encountered. (72). Alternative approaches to arterial cannulation in case of complex aortic disease were described earlier. The

remainder of the surgical procedure is performed in standard fashion. In case of excessive bleeding at the end of the procedure, a planned second look operation should be considered.

Recommendations

- *Full repeat sternotomy in patients undergoing LVAD implantation should be considered if there is need for concomitant valvular procedure such as aortic valve repair/replacement or aortic aneurysm repair (Class IIa, Level of evidence: C).*
- *In patients with congenital heart disease, the collaboration between pediatric and adult centers is critically important (Class I, Level of evidence: C).*
- *A less invasive LVAD implantation may be beneficial in selected patients with repeat sternotomy to minimize the operative trauma (Class IIb, Level of evidence: C).*
- *A decision to perform repeat sternotomy or less invasive approach should be driven by multidisciplinary heart team to lower perioperative and postoperative complications (Class IIa, Level of evidence: C).*

Minimally invasive approach

Since the introduction of the minimally invasive techniques for ventricle assist device (MI-VAD) implantation (73, 74), their application has constantly increased worldwide covering up to 70% of all left-ventricle assist device (LVAD) operations in specialized centers(75). The safety of the thoracotomy approach has been demonstrated by several single center experiences (75-86) and multicenter studies such as the LATERAL trial which showed a 6-month-mortality rate of 7.6% (87). Favorable outcomes have been demonstrated also in INTERMACS level 1 high-risk patients with a significant higher survival rate at 30-day and 1-year follow-up compared to conventional sternotomy (76). One of the main advantages of MI-VAD is represented by reduced blood product transfusions both during and after the surgical operation (78, 79) and a low rate of re-operations for bleeding ranging from 0 to 13.6 (75, 76, 80, 87, 88). The protective role of MI-VAD is confirmed also by the low incidence of postoperative right ventricle (RV) failure and reduced need for RV assist devices(75, 81, 87, 89) required in 0.7-6.1% of cases according to literature (75, 76, 87, 90-92). In a recently published multicenter trial, Saeed et al. were able to show significantly lower RV failure in patients supported with less invasive VAD implantation compared to sterotomy approach.(93) The pericardial geometry supporting the RV function remains intact with the MI-VAD approach and any excessive manipulation or luxation of the heart is avoided allowing more physiological RV conditions(73). Further advantages of the MI-VAD approach are represented by the shorter operation and cardiopulmonary bypass time (75, 76, 78, 87) as well as a more intuitive assessment of pump positioning (90). All these aspects lead to a short hospital stay which varies on average between 6 and 23 days (76, 78, 79, 82, 83, 87, 90) depending on the preoperative condition of the patient. Moreover, the avoidance of a full sternotomy and reduced retrosternal adhesions at the time of heart transplant make the MI-VAD approach particularly suitable for bridge-to-transplant patients (79).

While almost every patient may potentially benefit from a MI-VAD approach, this technique may be also considered for requiring LVAD implantation with aortic valve surgery (84, 87, 90) and patients with lower INTERMACS profiles (76). On the other side, insufficient evidence is available regarding patients requiring concomitant surgery for tricuspid or pulmonary valve disease, multiple vessel coronary artery disease, hemodynamically significant patent foramen ovale or left atrial clot removal (76, 78, 80, 84, 85, 87). Furthermore, MI-VAD is not recommended in patients requiring long-term biventricular assist device, long-term right ventricle assist device or total artificial heart implantation due to the dimensions of the devices and the surgical steps required for their implantation.

The recommended approach is an 8 to 10 cm left lateral thoracotomy (73) to be performed at the level of the apex of the left ventricle (87). A preoperative transthoracic echocardiography might help identifying the precise position of the left ventricle apex, avoiding suboptimal exposure of the heart during surgery (87). In case of previous cardiac operations or planned right anterior mini-thoracotomy, a preoperative computed tomography scan is also advised to identify the position of the ascending aorta and retrosternal adhesions (78, 87, 90). While the left thoracotomy is universally applied for pump positioning, the outflow graft anastomosis can be performed through an upper hemisternotomy (73) or a right anterior mini-thoracotomy in the 2nd-3rd intercostal space (74). No robust evidence is available in favor of one of these 2 approaches (86) and, therefore, their application should be based on the local expertise of the implanting center. Alternative minimally invasive approaches for outflow graft anastomosis are possible in case of calcified ascending aorta or significant risk of damage to cardiac structures with an upper hemisternotomy or a right anterior mini-thoracotomy. The left or right subclavian artery can be exposed through a local incision while the descending aorta can be accessed through an extended left thoracotomy (94). The MI-VAD approach should also be considered in case of LVAD exchange where the access to the pump can be gained through a lateral thoracotomy and, if necessary, a partial rib resection (95). In case of MI-VAD device exchange, survival at 6 months is up to 75.6%(95), in line with the 79.7% (range: 32.3−97.0%) survival rate after pump exchange described in recent literature (96).

A special mention should be reserved to the training process for MI-VAD surgery. Most clinical studies report data from highly specialized centers with specific MI-VAD programs. Within the LATERAL trial, a previous experience with a minimum of 10 cases of LVAD implantation through sternotomy was advised before starting the MI-VAD program (87). Moreover, didactic surgical training, hands-on courses and 1:1 physician proctorship led by an experienced MI-VAD surgeon should be considered when starting a minimally invasive program for LVAD implantation (87).

Recommendations

- *A training/observation in a specialized center should be considered before launching less invasive LVAD implantation program (Class IIa, Level of evidence: C).*
- *Less invasive LVAD implantation is recommended in selected patients if the procedure is performed in specialized centers with expertise and corresponding patient volume (Class IIa, Level of evidence: B).*
- *Patients undergoing isolated LVAD implantation or LVAD implantation combined with aortic valve surgery may be considered for minimal invasive approach in experienced centers (Class IIb, Level of evidence: C).*
- *For minimally invasive LVAD implantation, a limited left lateral thoracotomy performed over the apex of the left ventricle is the incision of choice for pump positioning. The anastomosis to the ascending aorta can be performed both through an upper hemisternotomy or a right anterior thoracotomy according to each center experience with minimally invasive approaches for aortic valve surgery (Class IIa, Level of evidence: C).*
- *The thoracotomy approach may be considered in selected patients requiring pump exchanges based on its less invasiveness (Class IIb, Level of evidence: C)*

Off-pump VAD implantation

Implanting and exchanging long-term DMCS devices without the use of cardiopulmonary bypass (CPB) has been selectively employed. Techniques can vary due to specific device configurations. Sternotomy and nonsternotomy approaches have both been utilized (82, 85, 97-100). Limitations to more widespread adoption includes absence of technique-specific surgical tools and surgical reluctance.

Implantation of virtually every LVAD system has been selectively performed without the use of cardiopulmonary bypass (99). Controlling blood loss from the left ventricular apex during coring and device insertion are the steps that differ from using CPB. Rapid pacing, ventricular fibrillation, and finger control are techniques that can be utilized to minimize ventricular apical bleeding after coring.

Left ventricular thrombus, intracardiac shunts, and valvular issues that require intervention are relative contraindications. Avoiding the CPB circuit reduces inflammation, platelet activation, and coagulation factor consumption (62). This in theory could reduce perioperative vasoplegia, bleeding, and right heart dysfunction. Though perioperative transfusion requirements seem to be reduced (85, 97), direct evidence for reduction of vasoplegia or right heart dysfunction has not yet been shown. Other perioperative issues of stroke, infection, length of stay, and overall survival appear equivalent to on pump implantation, likely reflecting the patient's preoperative status and overall small sample size of off pump experience.

Off-pump implantation or exchange of implantable of ventricular assist devices differs from on pump implantation in the technique of left ventricular apex control. The apex can be accessed via sternotomy or left thoracotomy. Once access to the left ventricular apex is established, marking of the cuff site with methylene blue or a marking pen will facilitate accurate placement of the sutures and seating of the sewing cuff. Attachment of the sewing cuff can often be performed before heparinization. Once the sewing cuff is secured to the heart, heparinization can be instituted to an activated clotting time (ACT) of 300 sec.

Coring the LV apex and placing the inlet cannula into the sewing cuff is the critical step in off-pump implantation. This can be broken into 5 steps:

1. *Hemostasis*
   Blood loss during left ventricular apical coring can be minimized by rapid pacing, active fibrillation, and hand control of the apex. Active ventricular fibrillation appears most effective. The defibrillator should be charged before initiating either rapid pacing or active fibrillation.
2. *Hemodynamic management*
   Peripheral vasoconstriction should be judiciously utilized before apical coring. Anticipatory use of vasoconstrictors before active fibrillation or rapid pacing will help return hemodynamics to baseline when the active arrhythmias are terminated. (i.e., 20 mcg norepinephrine bolus). The defibrillator should be charged before initiating the apical coring sequence.
3. *Control of the apical plug*
   Depending on the coring knife used, a suture may need to be placed on the apex to control the plug when it is removed. Two of the coring devices will sequester the apical plug. A Foley catheter inserted into the ventricle with 7 mL of saline can also control the plug when a traditional coring knife is used. Rapid coring is important in minimizing blood loss.
4. *Insertion of the VAD*
   Once the core is removed and confirmed to be intact, the prepared LVAD can be slid into the sewing cuff and secured.
5. *Deairing*
   There is rarely any air that will be seen in the LV. Inversion of the VAD pump may allow air to become entrained. After attaching the LVAD to the heart, briefly unclamp the outflow graft to allow any entrained air to be expelled.

Procedural steps

Once the sewing cuff is attached, heparinization is instituted to maintain an ACT of 300 sec or greater. The coring knife is then positioned onto the LV apex. A low dose vasoconstrictor is then given to raise the blood pressure. The defibrillator is then charged, and its charge is maintained. Rapid pacing or active fibrillation is then initiated. The LV apex is then cored, and an intact specimen is confirmed. The LVAD is then inserted into the sewing cuff and secured. Rapid pacing or active fibrillation is then terminated. Cardioversion is performed if necessary. The outflow graft of the LVAD is then released for a few beats to allow deairing. The heart is then placed in situ.

The outflow graft may then be attached to the aorta using a side biting clamp. The remainder of the implant does not differ from any standard approach.

Recommendations

- *Implantation and exchange of implantable LVADs may be safely performed without CPB either though sternotomy or thoracotomy (Class IIb, Level of evidence: C).*
- *Off-pump DMCS implantation should not be considered in the presence on intracardiac thrombus (Class III, Level of evidence: C).*

Topic 4: Explantation techniques: explantation of LVADS for heart transplantation

Preoperative considerations

In preparation for heart transplantation, bridge-to-transplant (BTT) LVAD patients represent a special challenge for everyone in the transplant team involved. So far, no randomized study exists to cover this special situation leading to a high level of evidence. However, based on surgical experience and center expertise, recommendations and strategies can be defined for patient on permanent continuous-flow (cf) or pulsatile (p) LVADs. In the current era, more less-invasive surgical cf-LVAD implantation technique or the biventricular configuration of 2 independent cf-LVAD's are used, therefore those techniques have to be known to define the surgical strategy for device preparation and explantation.

The tremendous development in the field of left ventricular assist devices has resulted in increased usage of cf-LVADs as a bridge to transplant strategy and accumulating number of patients with LVAD waiting for donor heart. In parallel, increased incidence of device-related complications (thromb-embolic event, device infection, device malfunction, malign arrhythmia, and others) in BTT candidates poses a technical challenge for LVAD preparation and removal during heart transplantation. Despite this development, the overall outcome postheart transplantation in cf-LVAD patients is not significantly inferior compared to those patients without a cf-LVAD, this is observed in centers performing lager numbers of complex cardiac procedures. However, it is noted that the LVAD explant and heart transplantation is a longer and more technical complex procedure that leads to increased amount of transfusion, more vasoplegia, and longer intubation and intensive care time. Certain VAD associated complications render patients high risk for cardiac transplantation. Especially patients with chronic right heart failure and device infections are at high risk for perioperative vasoplegia, excessive bleeding, postoperative multiorgan failure and infections and should therefore be well selected. Patients with hemocompatibility-related adverse events remain good transplant candidates with the exception of disabling strokes.

In general, a dedicated team is the key element to achieve a successful heart transplantation. Surgically, cf-LVAD preparation and heart transplantation is a longer and more technical complex procedure that's necessitates redo-sternotomy, and careful outflow-graft, drive line (DL) and pump excision. Today, huge pump pockets or abdominal pump placement is no longer observed, making situs preparation less dangerous and more predictable. However, cf-VAD pumps are associated with significant adhesions at the left ventrocular apex site, particularly if the pump is not well covered at the time of primary implant. Notably, the growing adaption of less invasive implant techniques (bilateral thoracotomy, upper hemisternotomy/thoracotomy) may significantly reduce the complexity of subsequent heart transplantation. Centers that routinely perform less invasive VAD implantations report reduced surgical complexity and bleeding and blood product used during heart transplantation (91-93, 101). However, in some patients, special attention has to be taken to avoid prematurely severing a pump component, and injuring right ventricular or lung structures, especially in cases where the pericardium was left open at the time of the primary procedure.

Mediastinal exposure, cannulation, and cardiopulmonary bypass

Heart transplantation is usually carried out with a median sternotomy. A preoperative CT should be available in all patients before heart transplantation. A CT scan of the entire aorta is recommended. The CT scan aids in planning re-sternotomy and vascular access and reveals potential hazards including proximity of the outflow graft or driveline to the sternum as well as calcifications in the ascending aorta and alternative vascular access routes. Depending on the preoperative CT-scan and surgeon's preference, the re-sternotomy can be performed with or without previous institution of cardiopulmonary bypass. In patients with a properly placed outflow graft and driveline away from the sternum, sternotomy can be performed without cardiopulmonary bypass. However, securing femoral or subclavian vascular access in advance is advisable (see previous recommendation for repeat sternotomy). If there is a risk to damage the driveline or outflow graft upon re-sternotomy it is advisable to institute cardiopulmonary bypass before re-sternotomy. Access for peripheral bypass can be achieved via the femoral vessels or the subclavian artery. The subclavian artery is preferable in patients with significant descending aortic arteriosclerosis and peripheral vascular disease. If arterial cannulation is performed via the femoral artery, peripheral perfusion should be monitored.

After sternotomy, the most severe adhesions are anticipated at the anterior surface of the heart and surrounding all internal device components. In some patients, pericardial membranes were placed during DMCS implantation to allow easier entry at this point. Care must be taken to avoid injury to the outflow graft and to the right ventricle. Maintenance of hemostasis is required at this point, especially when CPB is not in use. Unexpected severe bleeding should lead to immediate institution of CPB. The outflow graft itself represents an excellent option for arterial cannulation of CPB in case of emergency.

Device explantation

We continue to follow the 2013 guidelines which describes in detail the method of device explantation. In

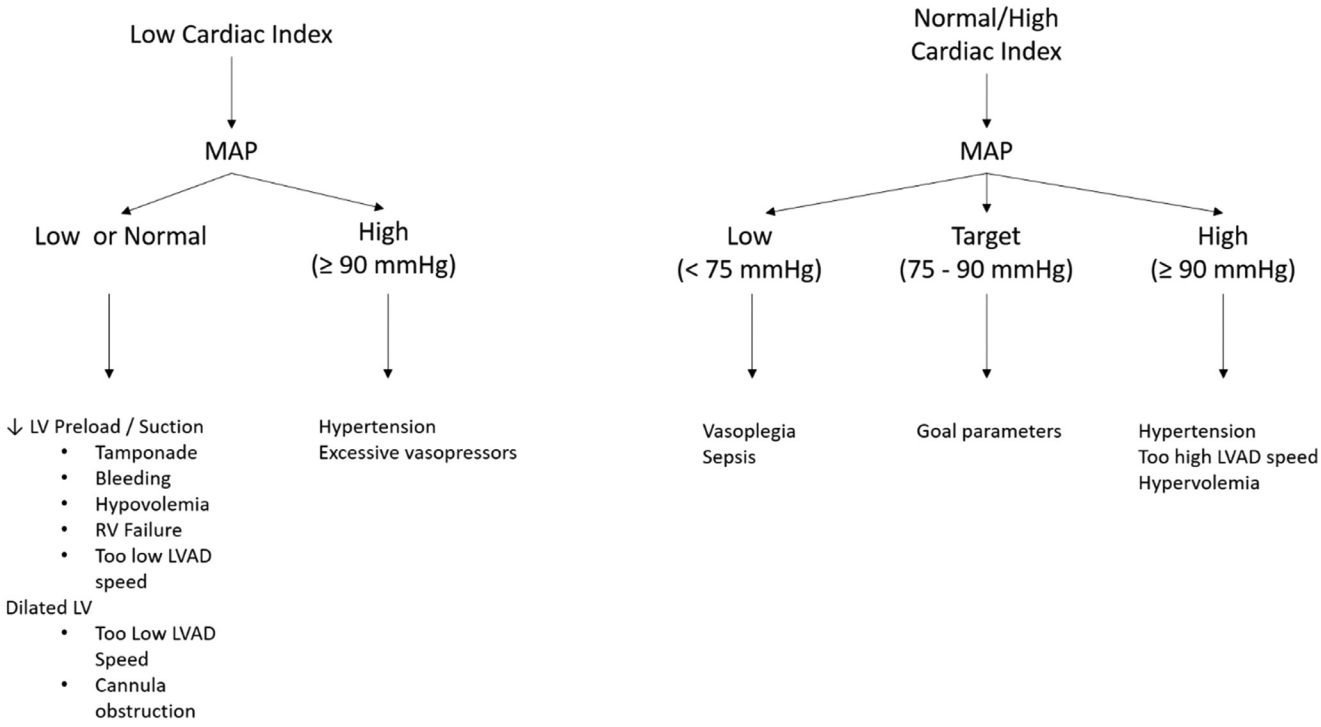

Figure 1 Early postoperative hemodynamic monitoring.

more recent years, centrifugal pumps have been the dominant type of device implanted. Differences and pitfalls in device explantation of centrifugal pumps is already described in details. Further, the possible advantage of device explantation in the patients who underwent less invasive VAD implantation is covered earlier. It is important to consider pericardial closure and well coverage of the pump at the time of primary surgery regardless of the implantation approach to minimize the adhesions at the time of heart transplantation.

Topic 5: Early postoperative management

Monitoring

Postoperative monitoring is largely unchanged from the initial 2013 guidelines. Specific recommendations with levels of evidence were not included for this section initially and are now defined. The table and figure in the original document have been updated into 2 figures based on recommendations in this and other sections of the guideline update.

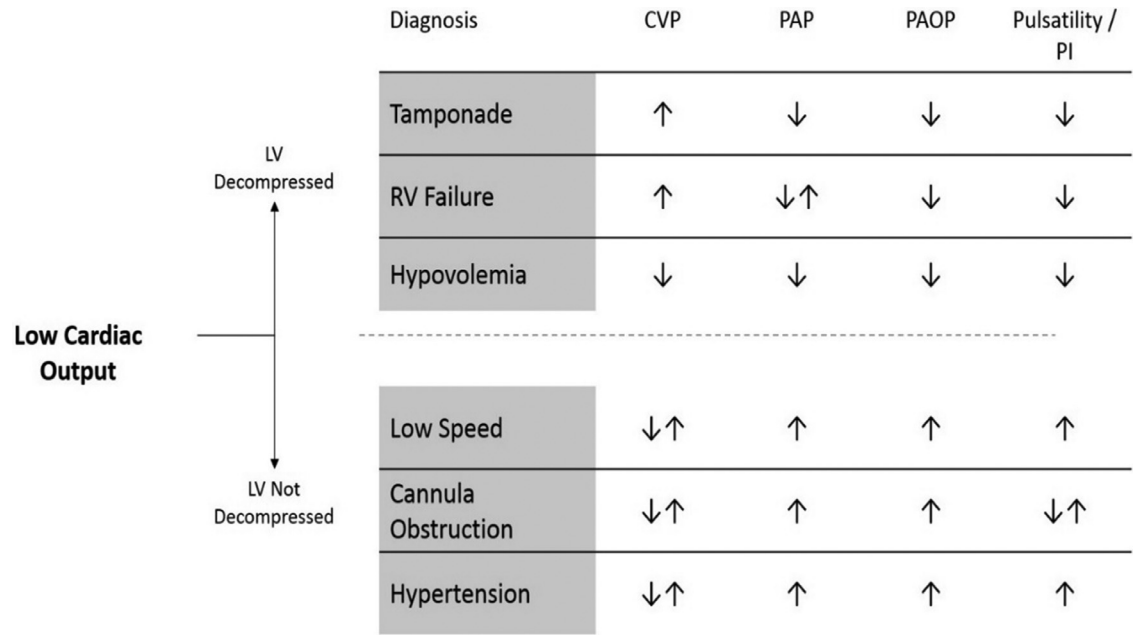

Figure 2 Hemodynamic and echocardiographic clues for diagnosing the cause for decreased cardiac index after DMCS Implantation.

Early postoperative hemodynamic monitoring and intervention strategies have not been studied comparatively and all recommendations are based on expert opinion. The original guidelines presented clinical scenarios in a table format to offer expert guidance for typical clinical scenarios. The information from the original table has been reformatted into Figure 1 and recommendations for specific drugs have been removed and replaced with possible etiologies for the hemodynamic parameters. The new figure also de-emphasizes AV opening as a treatment target in the early postoperative period to avoid distracting away from the primary clinical targets blood pressure and cardiac output optimization.

The original figure 1 titled "Low Pump Output Algorithm," has been reformatted into a new Figure 2 which provides an overview of using invasive hemodynamics, LVAD pulsatility and LV cavity diameter-related assessments to diagnose the cause of low cardiac output after DMCS implantation. The treatment recommendations have been removed from the figure and included in appropriate sections in this document.

Continuous hemodynamic monitoring with transesophageal echocardiography in the intensive care unit may be helpful in guiding therapy, adjusting LVAD speed and diagnosing complications.(102, 103) The utility of routine use of this evolving technology after LVAD implantation has not been established.

Recommendations

- *Continuous invasive hemodynamic monitoring of cardiac and pulmonary filling pressures, arterial pressure and cardiac output help optimize organ perfusion and identify complications after DMCS implantation (Class I, Level of evidence: C).*
- *The implantation of Swan Ganz catheter should be considered for continuous monitoring of the cardiac output, assessment of oxygen delivery (mixed venous oxygen saturation) and pulmonary arterial pressure and vascular resistance (Class I, Level of evidence: C).*
- *Vasoactive agents and inotropes should be used to maintain a cardiac index of >2.2 L/min/m^2 and a mean arterial pressure between 75 and 90 mm Hg (Class I, Level of evidence: C).*
- *A low cardiac index early after DMCS implantation should prompt an urgent evaluation of intravascular volume, cardiac tamponade, and right ventricular dysfunction (Class I, Level of evidence: C).*
- *Adjunctive data from the LVAD monitor or controller including flow, waveform morphology and LVAD flow pulsatility may further help optimize flow and identify complications, however should not supplant hemodynamic data and clinical assessment (Class IIa, Level of evidence: C).*
- *Hemodynamic monitoring with echocardiography may be considered in select cases where additional imaging information may alter therapy and the invasive hemodynamics and clinical assessment are nondiagnostic or incongruent (Class IIa, Level of evidence: C).*

Early postoperative period

Hemostasis, hemodynamic stability, and gas exchange are key priorities in the early postoperative period. The patient's clinical presentation, etiology, and presenting hemodynamic profile (and INTERMACS profile) should be considered in anticipating early postoperative complications. LVAD implantation in patients with critical cardiogenic shock is associated with higher morbidity and mortality (104), with greater risk of coagulopathy (particularly in patients with pre-existing antiplatelet or antithrombotic therapy), higher vasopressor and transfusion requirements and risk of RV failure.

Coagulopathy should be corrected in the early postoperative period after separation from CPB, based on hemostatic intervention algorithms that incorporate predefined triggers and targets derived from thromboelastometry and thromboelastography monitoring. Thromboelastometry and thromboelastography-guided hemostatic interventions lower re-exploration rate and incidence of postoperative acute kidney injury (105).

Minor DMCS adjustments may be made in the early postoperative period but major changes are rarely needed, and indeed may adversely affect the RV. Significant reductions in pulsatility and flow, and the occurrence of suction events in the absence of pump speed changes are usually the result of changes in LV preload from volume loss (bleeding), tamponade or RV dysfunction. A higher systemic blood pressure (with the use of vasopressors) may be required to maintain RV perfusion and function, particularly if the CVP is significantly elevated. Diuresis and continuous venovenous hemofiltration (CVVH), if diuresis is inadequate should be considered early to prevent significant elevations in filling pressures and consequent RV dilation and failure. Inotropes should be titrated based on monitoring of cardiac output and organ perfusion and should be maintained throughout the early postoperative period.

Recommendations

- *Coagulopathy should be corrected in the early postoperative period (Class IIa, Level of evidence: C).*

Respiratory management

Respiratory management is largely unchanged from the 2013 guidelines. Specific recommendations with levels of evidence were not included for this section initially and are now defined. Additional recommendation-based risk stratification from recent publications has been included.

Efforts to reduce duration of mechanical ventilation after DMCS failure may improve clinical outcomes. There are limited data on risk factors and outcomes for respiratory failure after LVAD implantations. A single center study that evaluated 139 patients after implantation of a CF-LVAD found that prolonged mechanical ventilation was associated decreased survival at 180 days (62% vs 10%, $p < .001$).(106) Patients with need for prolonged mechanical ventilation were characterized as more severely ill at the time of device implantation and independent predictors of

respiratory failure included poorer renal function, lower platelet count and prior sternotomy.

Mechanical ventilation is associated with pulmonary complications and adverse effects on RV function. The practice of limiting tidal volumes (tidal volume 6-8 mL/kg predicted body weight) should be adopted to minimize pulmonary complications (107). Over-inflation of the lungs also exacerbates elevation in PVR and should be avoided. Excessive tidal volumes, driving pressures and positive end-expiratory pressures can exacerbate RV dysfunction. Typically, patients remain sedated and mechanically ventilated for at least several hours postoperatively. Fast- (and ultra-fast)-track anesthesia has gained acceptance in cardiac surgery, and has been reported in DMCS implantation to minimize ventilator-associated complications and resource use (108). Fast-track anesthesia may be considered in selected uncomplicated patients with INTERMACS 3 and 4 heart failure profiles. The conventional criteria of hemodynamic stability, normothermia, hemostasis, respiratory drive, oxygenation, and responsiveness are prerequisites for extubation. Inhaled pulmonary vasodilator such as nitric oxide should be weaned off before extubation.

Recommendations

- *The duration of mechanical ventilation should be minimized to avoid infectious complications and hemodynamic consequences (Class I, Level of evidence: B).*
- *After DMCS implant, implement mechanical ventilation strategies to prevent hypoxia and hypercapnia. Hypoxia and hypercapnia both can promote pulmonary vasculature vasoconstriction and thus impair RV function (Class I, Level of evidence: C).*
- *After DMCS implant, mechanical ventilation strategies should be implemented to reduce RV afterload including avoiding high PEEP, high plateau pressures and extremes of tidal volumes (target: 6-8 mL/kg predicted body weight) (Class I, Level of evidence: C).*
- *Optimizing intrinsic pulmonary function before LVAD implantation including treating pulmonary edema, infections and avoiding blood product transfusion may reduce duration of prolonged mechanical ventilation and possibly improve survival postoperatively (Class I, Level of evidence: C).*
- *Fast-track anesthesia may be considered in selected uncomplicated patients with INTERMACS 3 and 4 heart failure profiles (Class IIb, Level of evidence: C).*

Bleeding

Liberal vs restrictive transfusion strategy

Anemia is common in patients with chronic disease. Effort should be directed in the preoperative period to optimize red blood cell mass (109). Patients receiving DMCS therapy have increased risk of intra and postoperative bleeding due to hemodilution, blood loss and acquired von Willebrand factor (VWF) defect due to high shear stress forces in continuous−flow devices (110).

There are no studies on hemoglobin (Hb) transfusion threshold for DMCS patients: all the conclusions are drawn upon data existing in critically ill medical / surgical patients (111-119). In one of the largest and most recent trials, the Transfusion Requirements in Cardiac Surgery III trial (113, 114), postsurgical coronary and valve patients, with 30-day mortality risk of at least 4% defined by Euroscore of 6, were randomly assigned to a restrictive (blood transfusion threshold when the hemoglobin level is less than 7.5 g/dL to maintain a range between 7.5 g/dL and 9 g/dL) vs a liberal (blood transfusion threshold when the hemoglobin is less than 9 per dL in the operating room or intensive care unit or less than 8.5 per dL on the floor) blood transfusion strategy. A restrictive strategy was noninferior to a liberal strategy with regard to death from any cause and major morbidity (new onset of renal failure with dialysis, stroke, and myocardial infarction) at discharge from the hospital or 28 days (114) and at 6 months follow-up (113). These results are in contrast to the randomized Transfusion Indication Threshold Reduction (TITRe2) trial (115) of 2003 patients undergoing cardiac surgery utilizing same trigger value for transfusions: all cause of mortality at 90 days was significantly worse for the restrictive group (4.2% vs 2.6%; OR of 1.6, 95% confidence interval 1.00-2.67; $p = .045$). Of note, 3% of patients had symptoms of heart failure with class NYHA IV, thus, the results may not be generalized to heart failure patients requiring DMCS therapy. In subgroup analyses, the TRICS investigator have shown that the restrictive strategy in patients with poor left ventricular ejection fraction and preoperative anemia (Hb < 12 g/dL) led to same outcomes as the liberal transfusion strategy (114). While there is no consensus regarding the optimal threshold for blood transfusions in cardiac surgery patients, even less so in DMCS patients, the threshold of Hb < 7.5 to 8 g/dL to maintain a range of 7 to 9 g/dL seems safe and applicable to most cardiac patients and those critically ill and normovolemic (117). Furthermore, data suggest that the increased risk of 30-day mortality in perioperative patients is intensified if adopting a higher threshold for transfusion at lower Hgb level (7−7.5 g/dL studies vs 8 g/dL) (116). Therefore, patients undergoing DMCS therapy who have limited cardiovascular reserve, may benefit from higher hemoglobin levels to increase organ perfusion. Thus, blood cell transfusions should be triggered by evidence of end-organ ischemia, or hypovolemia, and to ensure adequate organ perfusion (mixed venous) not isolated to a single hemoglobin level value. In conclusion, a minimum of hemoglobin level of 8 g/dL seems to be a reasonable level for most DMCS patients in the postoperative period.

Transfusion of blood products

Blood products are often used in the perioperative period to reverse coagulopathy associated with DMCS implant. Point of care testing should be used to reduce transfusions requirements (109) and follow the same algorithm used for any cardiac surgery procedure. Care should

be taken to limit transfusions of blood products and packed red blood cells to avoid increase in central venous pressure and pulmonary vascular resistance predisposing to right ventricular dysfunction. Both, Thromboelastography and Thromboelastometry have been successfully used in cardiac surgery (105, 120) to help gauge transfusion requirements. In a large meta-analysis of 5,233 patients, the major benefit was seen in reduction of percentage of transfused fresh frozen plasma and platelets, followed by packed red blood cells. In conclusion, evidence from meta-analysis in cardiac surgery patients suggests that use of point of care testing is beneficial in reducing the amount of blood products transfused.

Recommendations

- *A transfusion threshold of minimum of 8 g/dL in the early postoperative period is advisable for most patients undergoing DMCS implantation. The hemoglobin value should be considered along with clinical and hemodynamic status and end-organ perfusion to maintain sufficient oxygen delivery. Higher hemoglobin levels may be indicated in hypovolemic, critically ill patients with poor end−organ perfusion or end-organ ischemia/injury (Class IIa, Level of evidence: B).*

Antithrombotic regimen

Bleeding and thrombosis are still the 2 most commons complications in DMCS patients, with bleeding being more frequent in the early postoperative period. While target range for anticoagulation with warfarin for each device is specified by the manufacturer, there is still uncertainty regarding timing/dosage of unfractionated heparin and antiplatelet regimen. As a result of this uncertainty, there is significant variability in practice patterns, and individual centers have instituted their own set of practice guidelines specific to antithrombotic therapy (121).

Robust evidence is lacking for anticoagulation management postoperatively in DMCS patients; data are gathered from clinical device trials and recommendations based on consensus opinion. In general, within 24 hours of the surgery, heparin bridge should be started if hemostasis is achieved and chest tube output is less than 50 mL for several hours (at least 8 hours after surgery) to achieve aPTT goals of 40 to 60 sec aiming to higher end of aPTT goals after the first couple of days of therapy. Notably, normal aPTT ranges may vary between instruments and reagents. Further, patients in acute phase and on device may develop lupus anticoagulant which prolongs baseline aPTT. Warfarin is usually started on postoperative day 2 to 3 once the patient has demonstrated adequate enteral absorption. For centrifugal pumps such as the HeartMate 3 (HM3, Abbott, Pleasanton, CA) and HVAD (Medtronic, Minneapolis, MN) and axial flow pump Heartmate 2 (Abbott, Pleasanton, CA); warfarin is started on postoperative day 2 with target INR between 2 and 3. Aspirin is the most common antiplatelet agent used unless the patient has an allergy or contraindication to it. Aspirin is started between postoperative day 1 to 3 at dosage between 81 and 325 mg according to individual center's practice (121). Aspirin dosage can be titrated according to level of antiplatelet inhibition; however, this practice has not been shown to reduce thrombotic events (122). Data from the PREVENtion of HeartMate II Pump Thrombosis trial (123) showed significant reduction in risk of pump thrombosis at 3 months (2.9% vs the anticipated 4%) and at 6 months (1.9% vs 8.9%; $p < .01$) if strict adherence to surgical and anticoagulation protocol was followed. The MagLev technology left ventricular assist device system (HM3, Abbott, Pleasanton, CA) has shown reduced rates of pump thrombosis compared to axial flow pumps (124) and studies are underway to further optimize and standardize the anticoagulation and antiplatelet regimens.

Recommendations

- *Anticoagulation and antiplatelet therapy should be initiated in the postoperative period in the ICU with the aim of achieving prespecified programmatic goals for aPTT, INR and desired antiplatelet effects (Class I, Level of evidence: C).*

Early right heart failure

Right heart failure is a major cause of morbidity and mortality after DMCS implantation. Right heart failure can manifest as a failure to wean from CPB, or low or falling cardiac output and systemic blood pressure in association with high or increasing CVP and inotrope and vasopressor therapy, in the absence of other causes (e.g., pericardial tamponade). In clinical trials, right heart failure has been defined as the requirement for RV support (right ventricular assist device or venoarterial ECMO) or prolonged inotropic support (>1 or 2 weeks) (125).

Specific hemodynamic definition of right heart failure is lacking, but a combination of criteria including cardiac index <2.0 L/min/m^2, mean arterial blood pressure ≤55mm Hg and CVP >15mm Hg, mixed venous saturation ≤55% and high inotrope requirements (>10 mcg/kg/min of dobutamine or equivalent) has been used. More recently, the pulmonary artery pulsatility index (PAPI = (pulmonary artery systolic − pulmonary artery diastolic pressure)/right atrial pressure) has been used to assess right heart failure during LVAD support. This index has multiple determinants and will reflect changes in any of the components of the right heart system-systemic venous system, RV function and the pulmonary circulation. As such, PAPI will vary significantly in different patient populations based on the underlying pathophysiology, which would render the application of a single PAPI threshold across different patient groups invalid. Studies have shown mean PAPI values of 1.3 to 1.8 in patients with severe right heart failure post-LVAD implant(126).

Right heart failure may be managed medically in some cases, but the insertion of RVAD is indicated if hemodynamic indices fail to improve with medical therapy, before end-organ malperfusion develops or progresses. There are

no clinical trials on timing or modality of mechanical circulatory support for right heart failure. Some centers report better outcomes if RVAD is inserted at the time of LVAD implantation compared to late RVAD support when more severe hemodynamic compromise and end-organ dysfunction had developed(127, 128). However, outcomes appear to be comparable if RVAD support is deployed before the development of severe hemodynamic indices and end-organ dysfunction (after LVAD implant)(129). Hence, hemodynamic indices, LVAD parameters and end-organ function should be monitored continuously in the early postoperative period. Both VA ECMO and RVAD have been used successfully in right heart failure post-LVAD implant.

Management of early right ventricular dysfunction

The recommendations for treating right ventricular dysfunction in the perioperative were not included in the 2013 guidelines.

Right ventricular failure after LVAD implantation is associated with prolonged hospitalizations and poorer survival.(130) Supporting the RV early after surgery ensures the LVAD has adequate preload to provide systemic perfusion. Right ventricular dysfunction after LVAD implantation may be related to a number of clinical factors including intrinsic preoperative RV dysfunction, elevated pulmonary vascular resistance, injury from cardiopulmonary bypass, loss of pericardial restraint, over decompression of the left ventricle sternal compression of the RV and reduced LV contractility and twist. (131)

Conservative measures to improve RV function

Continuous invasive hemodynamic monitoring can help diagnose and tailor treatment of RV failure after surgery. Early liberal utilization of intravenous inotropes (i.e., dobutamine, low dose dopamine) or inodilators (milrinone) is preferred, while vasopressors with inotropic properties should be considered in the setting of systemic hypotension (see section titled *Monitoring*).

Perioperative surveillance of the central venous pressure must ensure that patients do not develop profound hypovolemia, to avoid under-filling of the myopathic right ventricle. Furthermore, excessive venous pressure and volume leading to RV distension may further impair contractile function.(132) Efforts to reduce the CVP/PAOP ratio to less than one after cardiac surgery are associated with improved cardiac index after cardiopulmonary bypass. (133)

Reducing pulmonary vascular resistance and excess afterload can further augment stroke volume and promote RV-PA coupling. Adequate LV unloading with LVAD-related decompression and volume removal lead to reductions in pulmonary pressures early after surgery. (134) Further reduction in pulmonary resistance may be achieved with inhaled or intravenous pulmonary vasodilators. Inhaled nitric oxide, inhaled and intravenous prostacylines and inhaled milrinone have been studied after LVAD implantation, while several studies have shown acute changes that augment cardiac output or LVAD flow, Potapov et al. study hampered by cross over did not detect a clinical beneficial effect of inhaled nitric oxide (6, 135-137). Vigilant monitoring of mechanical ventilation settings and acid-base balance can also help reduce pulmonary vascular resistance (see section Respiratory Management).

The predominant myocardial contributor to RV contraction is the longitudinal shortening of the intraventricular septum, and the LV contributes to a considerable portion of RV function through these shared muscle fibers. (138, 139) Over-decompression of the LV through reduced afterload or excessive LVAD speed, may result in a decrease LV contractile force (low preload/Frank-Starling mechanism and Anrep effect) and thus further impaired RV function.(138, 140, 141) Although clinical data are sparse to translate these physiological observation to postoperative LVAD care, it is reasonable to avoid over decompression of the LV and strive for septal balance if it does not compromise systemic perfusion.

Sternal compression

Closure of the sternum after cardiac surgery is associated with decreased cardiac output related to compression of thoracic organs and vessels. (142) While routine delayed sternal closure has not been proven to be beneficial after LVAD implantation, it is a reasonable consideration in the setting of excessive bleeding, thoracic edema or excessive RV distension to avoid tamponade or sternal compression of the RV (143-145).

Recommendations

- *Evaluate for tamponade from bleeding or sternal compression as a cause of early RV failure (Class I, Level of evidence: C).*

Right ventricular assist devices

Patients may have persistent RV failure even after efforts to optimize RV preload, augment RV contractility, reduce pulmonary vascular resistance and relieve tamponade/sternal compression. In this situation, it is appropriate to consider a right ventricular assist device, ECMO, or total artificial heart.

Although prospective, comparative studies to guide timing of RVAD insertion are lacking, delayed, or unplanned device insertion appears to be associated with poor outcomes. Takeda et al. described poor outcomes in patient with *unplanned* RVAD with 50% in hospital mortality. (146) Fitzpatrick et al. observed improved survival to hospital discharge with early (at the time of surgery) vs delayed (median 2 days) implantation of an RVAD. (147) Observational data with contemporary device designs and less invasive cannulation techniques to suggest that early/perioperative implantation are effective.

Lazar et al. observed an 88.2% survival to discharge for patients with planned RVAD implantation utilizing cannulation techniques that allow device removal without redo-sternotomy. (148)

Newer percutaneous RVAD devices provide hemodynamic unloading comparable to surgical devices with less morbidity and may be appropriate for selected patients (149-151). Complications and risks for extended support for LVAD patients with these devices have not been defined adequately powered studies with extended durations of support.

Utilization of intracorporeal VADs for biventricular support has been reported, although early reports suggest significant morbidity, device failure and poor survival. (152) Implantation of a total artificial heart is also an effective therapy for persistent shock, especially in the setting of device failure, thrombotic complications and malignant arrhythmias after LVAD or BI-VAD placement. (153)

Recommendations

- *Early implantation for surgically implanted or percutaneous mechanical support with an RVAD should be considered in patients with refractory RV failure (Class I, Level of evidence: C).*
- *Patient with high-risk preoperative features for RV failure may be considered for planned RVAD implantation before worsening of cardiogenic shock (Class IIb, Level of evidence: C).*

Discontinuation of invasive lines and drains

The 2013 recommendations for removal of invasive lines and drains remain unchanged (154). A special consideration should be reserved for tunneled lines present before surgery used for long-term IV medications blood draws. Ideally those lines should be removed before surgery and if not able then as soon as possible following surgery. Moreover, in patients requiring inotropic support in the postoperative period, a peripheral IV or a peripherally inserted central catheter (PICC) may reduce the risk of infection as opposed to an indwelling central IV line. Depending on where the distal port of the PICC is situated, it may still be useful for monitoring central venous pressure.

Other considerations

Once patient is extubated, early mobilization and feeding follows the same principles for postoperative cardiac patients (154). If a patient cannot be extubated, early placement postgastric feeding tube and enteral nutrition is advised to improve nutritional status. For sicker patients or those who have been intubated a longer time in the ICU, postextubation, a speech and swallow assessment performed at the bedside is necessary to avoid aspiration. A formal video swallow may need to be performed in case of failed bedside evaluation.

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Topic 1: Anesthesia Related Issues	**Topic 1: Anesthesia Related Issues** *Continuing approval with more detailed description of the role of TEE and other perioperative management strategies*
Class I:	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.	1. Patients undergoing DMCS implantation should have pre-operative insertion of large bore cannula, central venous catheter, PAC, and indwelling arterial line for continuous monitoring and intravenous access Level of evidence B. *(Unchanged)*
	2. Cardiac rhythm device should be reprogrammed pre-operatively, taking into consideration the type of device and the underlying rhythm. Level of evidence B. (New)
3. 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. *Continuing approval without change*
4. Intraoperative transesophageal echocardiography should be performed by physicians with advanced training in the intraoperative assessment of cardiac structure and function. Level of evidence B.	4. Continuing approval without change.
	Class IIa: 1. Pulmonary artery catheter should be used to guide hemodynamic management after separation from CPB. Level of evidence C. (New) 2. Inhaled nitric oxide and prostaglandins, and phosphodiesterase-3 inhibitors (eg: milrinone) should be considered for the management of RV dysfunction. Level of evidence C. (New) 3. The ventilator is adjusted to maintain normal arterial pH value with pCO2 <40 mmHg (ideally >35 mm Hg). Level of evidence C. (New)
	Class IIb: 1. A left atrial pressure line may be considered in selected patients after DMCS implantation. Level of Evidence: C (New)
Topic 2: Implantation Techniques Implant techniques vary with pump type; readers are referred to the online document for a full discussion of these issues.	**Topic 2: Implantation Techniques** *(Modified)* *Continuing approval for implantation techniques. However, recommendation classifications are now included.* Class I: 1. LVAD implantation requires a multidisciplinary team with experience in device implantation. Level of evidence C. (New) 2. Appropriate broad-spectrum antibiotics are administered for prophylaxis. Level of evidence B. (New) 3. Standard cardiovascular surgical procedures should be followed including use of clippers for chest hair and alcohol-based agents for skin preparation (unless contra-indicated) as recommended by national guidelines and the MCS Academic Research Consortium. Level of evidence A. (New) 4. A standard cannulation technique is used to allow safe implantation and adequate heart decompression, and concomitant valve interventions as needed. Level of evidence C. *(Unchanged)* 5. The driveline should be implanted: a) within the rectus sheath with an exit site on the abdominal wall determined by a preoperative assessment of body habitus and anticipated clothing; b) with the entire velour portion of the driveline positioned below/contained within the subcutaneous tunnel, resulting in a silicone-skin interface (SSI) at the exit site. Level of Evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	6. External fixation during the initial healing period may decrease traumatic bleeding and prevent future driveline infection. Level of Evidence C. *(New)* 7. The surgeon's technique should be guided by the implant instructions in the manufacturer's INFORMATION FOR USE (IFU) documents provided specific to each device. Level of evidence C. *(New)* 8. Standard inflow coring and implantation is carried at the left ventricular apex or in an anterior-lateral fashion. Level of evidence C. *(New)* 9. The outflow graft is beveled (optimally with a 45-60 degree) to appropriate length to be anastomosed to lateral aspect of the greater curvature of the proximal ascending aorta. The graft eventually should be placed lateral to the right atrium in a matter which prevents compression following sternal closure. Level of evidence C. *(New)* 10. Careful and meticulous deairing should be performed before initiation of LVAD. Level of evidence C. *(New)* 11. Selective inotropic therapy, pulmonary vasodilator therapy, systemic oxygenation, and heart rate with atrio-ventricular pacing if necessary, should be optimized to prevent or manage right heart failure. Level of evidence C. *(New)* 12. Continuous TEE guidance should be used to assess right ventricular function and degree of LV unloading during initiation of LVAD pump. Level of evidence C. *(New)* 13. Pump speed should be increased and adjusted to maintain adequate aortic perfusion pressure, systemic perfusion and avoid excess unloading of the left ventricle. Level of Evidence *(New)* 14. Careful and compulsive surgical technique is warranted to achieve hemostasis. Level of evidence C. *(New)* 15. Meticulous and protocol-directed blood transfusion should be utilized to correct coagulation anomalies. Level of evidence C. *(New)* Class IIa: 1.Standard LVAD implantation technique is performed through a median sternotomy. Level of evidence C. (New) 2. If pump pocket is necessary, a pump pocket is created by dividing attachments of the left hemidiaphragm to the costal cartilage. A model of the pump can be used to confirm appropriate sizing of the pocket. Level of evidence C. *(Unchanged*) 3. Careful inspection of the LV apex is recommended if feasible to remove obstructive trabeculae or left ventricular thrombus. Level of evidence C. *(New)* 4. In selected patients, pericardial closure using a biologic or synthetic patch to shield the pump outflow graft and the right ventricle is recommended to avoid injuries from re-entry. Level of evidence C. (New) Class IIb: 1. Carbon dioxide may be used throughout the procedure. Level of evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	2. Extended tunneling may be useful using a double tunnel driveline technique that places the driveline within the sheath of the rectus muscle in the umbilical direction and then subcutaneously to the left upper quadrant .Level of Evidence C. *(New)* 3. Selective utilization of sealants may be considered to achieve hemostasis. Level of evidence C. *(New)* Class III: 1. Liberal application of hemostatic agents is not recommended to avoid adhesions at the time of reoperation. Level of evidence C. *(New)* 2. Complete wrapping of the outflow graft particularly with GoreTex membrane is not recommended. Level of evidence C. *(New)*
Concomitant Procedures Along with Implantation of CF-LVAD (MODIFIED)	***Concomitant Procedures Along with Implantation of CF-LVAD (MODIFIED)*** Moved from TF 1
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.	*Intracardiac Shunts:* Class I: 1. Preoperative Assessment of the presence of interatrial communication should be performed using TEE. Level of evidence C. *(Unchanged)* 2. Closure of a significant interatrial shunt should be performed. Level of evidence C. (Modified) Class III: 1. *Continuing approval without change*
Aortic Valve Disease: Class I: 1. More than mild aortic insufficiency should prompt consideration for surgical intervention during device implantation. Level of evidence C.	*Aortic Valve Disease:* Class I: 1. More than mild aortic regurgitation should be addressed at the time of LVAD implant. Aortic valve replacement using a biologic valve should be performed, if necessary. Level of evidence C. *(Modified)* Class IIb: 1. Aortic valve closure techniques may be considered to address more than mild aortic regurgitation in selected patients. Level of evidence C. *(Modified)*
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. 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.	*Aortic Stenosis:* Class I: 1. *Continuing approval without change* Class IIb: 1. In patients with severe aortic stenosis and potential for recovery, aortic valve replacement may be considered, regardless of the degree of concomitant aortic insufficiency. Level of evidence C. *(Modified)*
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.	*Aortic Root Disease:* Class IIa: 1. *Continuing approval without change* 2. The indications and cut-offs to replace aortic root and/or ascending aorta is similar to the recommendations followed in routine cardiac surgical procedures. Level of evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Mitral Valve Regurgitation: 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 MR is not recommended. Level of evidence C.	*Mitral Valve Regurgitation:* Class IIb: 1. Concomitant mitral valve interventions may be considered during LVAD implantation. Mitral valve repair or mitral valve replacement using a bioprosthetic valve can be performed on the beating decompressed heart. Level of evidence C. *(Modified)* *Removed*
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 LVAD implantation. Level of evidence C.	*Mitral Valve Stenosis:* Class I: 1. Significant mitral stenosis needs to be addressed during LVAD implant. Commissurotomy or mitral valve replacement using a bioprosthetic valve can be performed on the beating decompressed heart. Level of evidence C. *(Modified)*
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.	*Tricuspid Valve Regurgitation:* Class IIb: 1. Concomitant tricuspid valve interventions may be considered during LVAD implantation in patients with greater than moderate tricuspid regurgitation. Tricuspid valve repair or replacement using a bioprosthetic valve can be performed. Level of evidence B. *(Modified)*
Preexisting Prosthetic Valves Class I: 1. Functioning bioprosthetic prostheses 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.	*Preexisting Prosthetic Valves* Class I: 1. *Continuing approval without change* 2. Aortic mechanical prosthesis should be replaced with a bioprosthetic valve during LVAD implantation. Level of evidence B. *(Modified)* Class IIb: 1. When a mechanical aortic valve is present, patch closure may be considered when no other options are feasible. Level of evidence C. *(Modified)*
Mechanical Mitral Valves: Class III: 1. Routine replacement of properly functioning mechanical mitral valve is not recommended. Level of evidence C.	*Mechanical Mitral Valves:* Class III: 1. *Continuing approval without change*
	Miscellaneous Procedures: Class I: 1. Intracardiac thrombus should be removed at the time of DMCS implantation. Level of evidence C. *(New)* Class IIb: 1. Left atrial appendage closure may be considered during LVAD implantation. Level of evidence C. *(New)* 2. In the presence of a massive intracardiac thrombus, total artificial heart implantation may be considered. Level of evidence C. *(New)* 3. Surgical ablation may be considered for selected patients with recurrent arrhythmias at the time of DMCS implantation. Level of evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	DEVICE EXCHANGE (New) Class IIa: 1. Pump exchange may be accomplished by minimal incisions (subcostal, thoracotomy), or full sternotomy depending on the component(s) to be exchanged and extent of infection, and/or thrombus. Level of evidence C. *(New)* 2. Early LVAD exchange should be considered in patients with pump thrombosis who progress despite initial management. Level of evidence C. *(New)* Class IIb: 1. An alternative LVAD may be considered when recurrent thrombosis occurs, or specific patient factors are incompatible with the current device or contribute to recurrent events. Level of evidence C. *(New)* 2. LVAD exchange for infection may be performed with distinct operative field/planes to avoid contamination of the new pump. Level of evidence C. *(New)*
TOPIC 3: SPECIAL CONSIDERATION 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	**TOPIC 3: SPECIAL CONSIDERATION FOR VAD IMPLANTATION** *Replaced by the new and modified recommendations below* Class I: 1. In patients with congenital heart disease, the collaboration between pediatric and adult centers is critically important. Level of Evidence: C. *(New)* Class IIa: 1. Full repeat sternotomy in patients undergoing LVAD implantation should be considered if there is need for concomitant valvular procedure such as aortic valve repair/replacement or aortic aneurysm repair. Level of Evidence C. *(New)* 2. A decision to perform repeat sternotomy or less invasive approach should be driven by multidisciplinary heart team to lower perioperative and postoperative complications. Level of Evidence: C. *(New)* 3. A training/observation in a specialzed center should be considered before launching less invasive LVAD implantation program. Level of evidence C. (New) 4. Less invasive LVAD implantation is recommended in selected patients if the procedure is performed in specialized centers with expertise and corresponding patient volume. Level of Evidence B. *(New)* 5. For minimally invasive LVAD implantation, a limited left lateral thoracotomy performed over the apex of the left ventricle is the incision of choice for pump positioning. The anastomosis to the ascending aorta can be performed both through an upper hemisternotomy or a right anterior thoracotomy according to each center experience with minimally invasive approaches for aortic valve surgery. Level of Evidence C. *(New)* Class IIb: 1. A less invasive LVAD implantation may be beneficial in selected patients with repeat sternotomy to minimize the operative trauma. Level of Evidence C. *(New)* 2. Patients undergoing isolated LVAD implantation or LVAD implantation combined with aortic valve surgery may be considered for minimal invasive approach in experienced centers. Level of Evidence C. *(New)*

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Task Force 3 Summary:
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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	3. The thoracotomy approach may be considered in selected patients requiring pump exchanges based on its less invasiveness. Level of Evidence C. *(New)* 4. Implantation and exchange of implantable LVADs may be safely performed without CPB either though sternotomy or thoracotomy. Level of Evidence C. *(New)* Class III: 1. Off-Pump DMCS implantation should not be considered in the presence on intracardiac thrombus. Level of Evidence C. *(New)*
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 4: EXPLANTATION TECHNIQUES: EXPLANTATION OF LVADS FOR HEART TRANSPLANTATION** *Continuing approval without change*
TOPIC 5: EARLY POST-OPERATIVE MANAGEMENT	**TOPIC 5: EARLY POST-OPERATIVE MANAGEMENT *(New)*** Class I: 1. Continuous invasive hemodynamic monitoring of cardiac and pulmonary filling pressures, arterial pressure and cardiac output help optimize organ perfusion and identify complications after DMCS implantation. Level of Evidence C. *(New)* 2. The implantation of Swan Ganz Catheter should be considered for continuous monitoring of the cardiac output, assessment of oxygen delivery (mixed venous oxygen saturation) and pulmonary arterial pressure and vascular resistance. Level of Evidence C. *(New)* 3. Vasoactive agents and inotropes should be used to maintain a cardiac index of > 2.2 L/min/m2 and a mean arterial pressure between 75 and 90 mmHg. Level of Evidence C. *(New)* 4. A low cardiac index early after DMCS implantation should prompt an urgent evaluation of intravascular volume, cardiac tamponade, and right ventricular dysfunction. Level of Evidence: C. *(New)* Class IIa: 1. Adjunctive data from the LVAD monitor or controller including flow, waveform morphology and LVAD flow pulsatility may further help optimize flow and identify complications, however should not supplant hemodynamic data and clinical assessment. Level of Evidence: C. *(New)* 2. Hemodynamic monitoring with echocardiography may be considered in select cases where additional imaging information may alter therapy and the invasive hemodynamics and clinical assessment are non-diagnostic or incongruent. Level of Evidence: C. *(New)* 3. Coagulopathy should be corrected in the early post-operative period. Level of Evidence C. *(New)* *Respiratory Management* Class I: 1. The duration of mechanical ventilation should be minimized to avoid infectious complications and hemodynamic consequences. Level of Evidence B. *(New)*

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Task Force 3 Summary: Intraoperative and Immediate Postoperative Management	
2013 Guidelines Recommendations	**New and Modified in 2023 Updated Guidelines**
	2. After DMCS implant, implement mechanical ventilation strategies to prevent hypoxia and hypercapnia. Hypoxia and hypercapnia both can promote pulmonary vasculature vasoconstriction and thus impair RV function. Level of Evidence C. *(New)* 3. After DMCS implant, mechanical ventilation strategies should be implemented to reduce RV afterload including avoiding high PEEP, high plateau pressures and extremes of tidal volumes (target: 6-8 ml/kg predicted body weight). Level of Evidence C. *(New)* 4. Optimizing intrinsic pulmonary function prior to LVAD implantation including treating pulmonary edema, infections and avoiding blood product transfusion may reduce duration of prolonged mechanical ventilation and possibly improve survival post-operatively. Level of Evidence C. *(New)* Class IIb: 1. Fast-track anesthesia may be considered in selected uncomplicated patients with INTERMACS 3 and 4 heart failure profiles. Level of Evidence C. *(New)* *Bleeding* Class I: 1. Anticoagulation and antiplatelet therapy should be initiated in the postoperative period in the ICU with the aim of achieving prespecified programmatic goals for aPTT, INR and desired antiplatelet effects. Level of Evidence C. *(New)* Class IIa: 1. A transfusion threshold of minimum of 8 g/dL in the early postoperative period is advisable for most patients undergoing DMCS implantation. The hemoglobin value should be considered along with clinical and hemodynamic status and end-organ perfusion to maintain sufficient oxygen delivery. Higher hemoglobin levels may be indicated in hypovolemic, critically ill patients with poor end–organ perfusion or end-organ ischemia/injury. Level of Evidence B. *(New)* *Management of Early Right Ventricular Dysfunction (New)* Class I: 1. Evaluate for tamponade from bleeding or sternal compression as a cause of early RV failure. Level of Evidence C. *(New)* 2. Early implantation for surgically implanted or percutaneous mechanical support with an RVAD should be considered in patients with refractory RV failure. Level of Evidence C. *(New)* Class IIb: 1. Patient with high risk pre-operative features for RV failure may be considered for planned RVAD implantation prior to worsening of cardiogenic shock. Level of Evidence C. *(New)*

Task Force 4

Inpatient management of patients with durable mechanical circulatory support devices

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Introduction

Task Force 4 addresses inpatient management in postoperative patients who have transitioned out of the intensive care unit and/or during readmission to the hospital. This section covers inopressor management, neurohormonal pharmacotherapy, anticoagulation and antiplatelet therapy, best practices for driveline management, assessment of patient and caregiver device-related education and suitability for discharge to home, and maintenance of health care provider competency. In addition, Task Force 4 summarizes recommendations for the evaluation and management of complications common to patients on DMCSs and in the event of cardiopulmonary arrest.

Postoperative inopressor management for the non-ICU DMCS patient

Treatment of new or progressive right heart dysfunction in the non-ICU postoperative period

Following LVAD implant, patients may display new or progressive right ventricular (RV) dysfunction. The academic research consortium has defined early right heart failure after LVAD implant as "early acute" (need or RVAD implant concomitant with LVAD) and "early postimplant RV failure" (need for temporary or durable RVAD or ECMO within 30 days of LVAD implant, failure to wean inotropes or inhaled pulmonary vasodilators within 14 days, or death due to RV failure).(1) Right ventricular failure occurring after 30 days is defined as late right heart failure. The definitions of RV failure require clinical signs of right heart dysfunction to be evident, including physical exam findings (elevated jugular venous pressure, ascites, peripheral edema), decreased LVAD flows (or low LVAD waveform pulsatility in continuous-flow MCSDs), and/or laboratory abnormalities suggestive of cardiorenal syndrome or hepatic congestion. Inopressor support may facilitate stabilization of end-organ function and improvement of hypervolemia. Embryologically, structurally, and functionally, the RV is different from the LV, potentially yielding different responses between the RV and LV to inopressor support, as well as ventricular preload and afterload. (2) Animal studies of the failing RV demonstrate downregulation of β-adrenergic receptors and upregulation of α-receptors, potentially yielding greater responsiveness to alpha-adrenergic or other non-β-adrenergic support interventions. (3, 4) RV mechanics can also be improved by reducing RV wall stress (wall stress $\sim$ (Pressure x Radius)/thickness, where pressure is the pulmonary pressure, radius and thickness are that of the RV) through either diuresis or a reduction in RV afterload via pulmonary vasodilators.

Once euvolemic, inotrope wean should be done cautiously, with ongoing examination for recurrent signs and symptoms of RV dysfunction. Right heart catheterization and/or echocardiography may be useful in patients failing inotrope wean, allowing for evaluation of RV filling pressures, stroke work, ejection fraction, septal position, and the adequacy of LVAD support. (5) Carefully selected LVAD patients with refractory RV failure may be considered for temporary or durable RV support. (6, 7)

Recommendations for management of new or progressive RV dysfunction

Class I

1. The academic research consortium definition of right heart failure should be used to characterize right ventricular failure after LVAD implant as early acute, early postimplant, or late right heart failure.

Level of Evidence: C.

2. Inotropic support may need to be continued into the remote postoperative period (>2 weeks) when there is evidence for right heart dysfunction such as elevated jugular venous pressure, signs of venous congestion, decreased LVAD 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.

3. In patients with elevated right sided filling pressures, decongestion is critical to reduce RV wall stress. Intravenous diuretics should be used in nonanuric patients to achieve decongestion. In those with significant renal impairment or oliguria, renal replacement therapy and/or ultrafiltration should be employed as needed to maintain optimal volume status.

Level of Evidence: C.

Class IIa

1. Inotropes and vasopressors such as dobutamine and epinephrine may assist with RV inotropy (3, 4, 8) while inotropes with pulmonary vasodilatory properties, like milrinone and levosimendan, may be useful for reducing RV wall stress and increasing RV contractility. (9)

Level of Evidence: B.

2. Temporary or Durable RV mechanical support can be useful in carefully selected LVAD patients with evidence of severe RV dysfunction.

Level of Evidence: B.

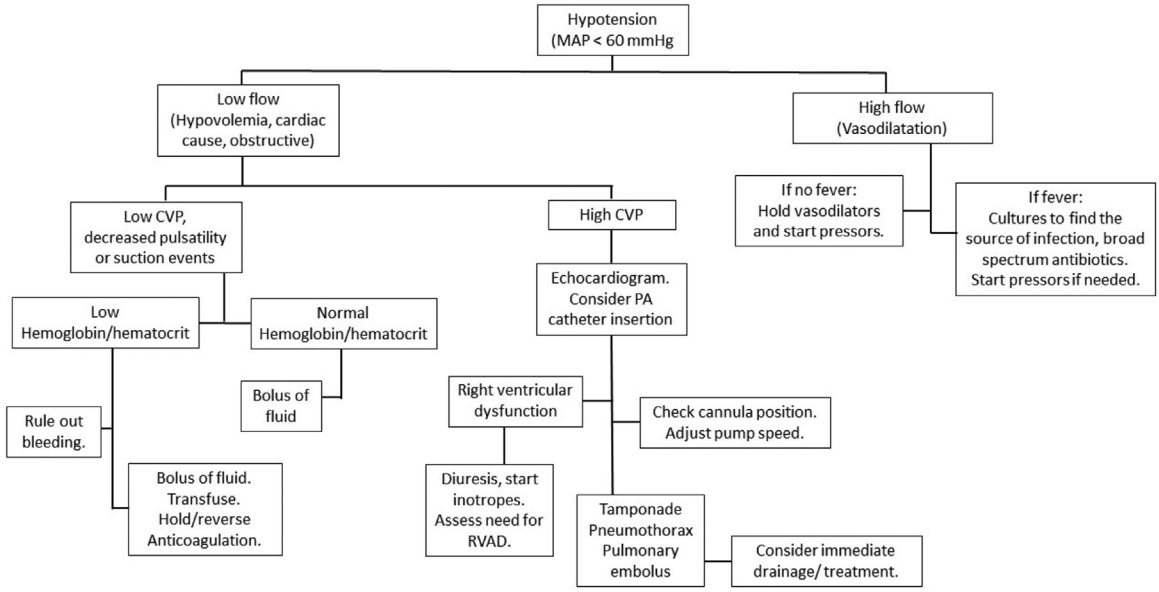

Figure 1 Systematic approach to hypotension. CVP, central venous pressure; MAP, mean arterial pressure; RVAD, right ventricular assist device.

3. Sequential nephron blockade (e.g., intravenous chlorothiazide or oral metolazone) or use of ultrafiltration can be considered in LVAD patients with elevated right-sided filling pressures who are poorly responsive to high dose intravenous loop diuretics.

Level of Evidence: C.

Class IIb

1. Cardiac glycosides, such as digoxin, have not been well studied in patients with RV dysfunction but may be a reasonable adjunct to therapy. (8)

Level of Evidence: C.

2. For patients with persistent pulmonary hypertension who exhibit signs of RV dysfunction, pulmonary hypertension-specific therapies, such as phospodiesterase-5 inhibitors, might be considered for acute therapy but their effectiveness remains uncertain. (10)

Level of Evidence: C.

3. Pacemaker therapy to promote a low grade tachycardia may be useful if the heart rate is not optimal to support hemodynamics. (9)

Level of Evidence: C.

Recommendations for managing hypotension in the non-ICU postoperative period

Systemic hypotension in the postoperative period can confer great morbidity and mortality for DMCS patients. Presently, data suggest increased risks of stroke and pump thrombosis in patients on second generation LVADs with a mean arterial pressure >90 mm Hg. (11) But, sufficient data to define hypotension and guide intervention in DMCS patients are lacking. In an analysis of Intermacs data, patients on second generation continuous flow LVADs with a MAP <75 mm Hg had increased mortality and frequencies of renal failure. (12) Thus, management should include both proactive and reactive approaches to mitigate hypotension.

In the preoperative setting, medications (beta-blockers, ACE-inhibitors, ARBs, ARNIs) that inhibit the sympathetic response to surgical stress and bleeding should be discontinued, especially those agents with long half-lives. Additionally, it is advisable to stop SGLT-2 inhibitors, given their association with diabetic ketoacidosis during periods of stress. Medications strongly associated with the development of serotonin syndrome should be identified and a discussion on the risks and benefits of continuing in the perioperative setting is warranted.

In the postoperative period, patients with hypotension should have a thorough work-up to determine the underlying cause(s). The initial step is to confirm that the patient is indeed hypotensive, as the lack of a pulse can prove problematic for some automated blood pressure monitors. A Doppler opening pressure or arterial line assessment may be required.(13) The physical exam is key to evaluating for signs of hypovolemia. If present, chest tube output and stools should be checked to assess for bleeding. Central venous pressure should be checked to assess the patient volume status and for signs of RV dysfunction which may impede LVAD filling and flows. Telemetry or EKG should be reviewed to evaluate for new onset arrhythmias that may contribute to RVF. Finally, a TTE may be useful to evaluate for the presence of tamponade physiology and to assess right ventricular and LVAD function. The LVAD should be interrogated, looking for alarms or readings that may signify RVF or LVAD dysfunction. If no correctable cause for hypotension is found, vasopressors such as norepinephrine might be useful (14-17). Primary vasoplegia after LVAD implant occurs in 33% to 48% of patients, remains poorly understood, and is associated with inferior outcomes (18, 19).

Class I

1. A systematic approach to hypotension should be used, as shown in Figure 1.

Level of Evidence: C.

Neurohormonal blockade and treatment of hypertension post-MCS implant

Medical therapy is a critical component of the care of LVAD patients, and neurohormonal blockade should be started following vasopressor wean during the postoperative period. The primary goals of medical therapy during this phase of care include volume management, treatment of systemic hypertension and optimization of RV function. Early initiation of neurohormonal blockade may also provide long-term benefits for ventricular reverse remodeling and myocardial recovery during LVAD support (20-22).

Hypertension increases pump afterload and impairs LVAD function. Due to the association of hypertension with hemorrhagic stroke in LVAD patients (23), blood pressure management should be initiated to maintain a mean arterial pressure 75 to 90 mm Hg for patients on continuous flow LVAD support. (11, 24) Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) are well established vasodilator therapies in heart failure patients, and their use is recommended in LVAD patients as well. Observational data support a role for ACE inhibitors and ARBs in the reduction of gastrointestinal bleeding due to arteriovenous malformation (25-27). In particular, one study showed marked reductions in subsequent gastrointestinal bleeding when ACE inhibitors or ARBs were started within the first 30 postoperative days.(25) If additional afterload reduction is required, or if ACE inhibitor / ARB use is limited or contraindicated, hydralazine and nitrates can be introduced. Nitrates should not be given if the patient is already being treated by a phosphodiesterase-5 inhibitor. (28) There are presently no large studies available to support the use of angiotensin receptor neprilysin inhibitors in LVAD patients, but they may be considered in carefully selected patients who well tolerate moderate doses of ACE inhibitor/ARB therapy. It is important to monitor for medication side-effects, including headaches (nitrates and milrinone), nausea (hydralazine and milrinone), and cough or angioedema (ACE inhibitors and ARNIs).

While neurohormonal blockade therapy in LVAD patients has not been studied in a randomized trial, observational data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) showed improved 4-year survival and quality of life in patients taking neurohormonal blockade therapy.(29) Importantly, outcomes were most favorable in patients who were taking all 3 classes of neurohormonal blockade therapy as compared to those taking medications from only one or 2 classes. Furthermore, another INTERMACS analysis found significantly higher rates of use of all neurohormonal blocking agents in patients who achieved complete recovery permitting device explantation.(20) Beta-blockers and mineralocorticoid receptor antagonists should also be started during the postoperative period due to their known beneficial effects on reverse remodeling and heart failure outcomes. Beta-blockers can be initiated once patients are stable off inotropes, although caution and slow titration should be employed in patients with poor right ventricular function. Mineralocorticoid receptor antagonists can be started once renal function has stabilized postoperatively. The use of mineralocorticoid receptor antagonists in patients with advanced CKD and/or hyperkalemia is not recommended.

Recommendations for neurohormonal blockade and the treatment of hypertension after LVAD implantation

Class 1

1. Pharmacotherapy with neurohormonal blocking agents (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, angiotensin receptor blocker-neprilysin inhibitors, beta-blocker, mineralocorticoid receptor antagonist) is preferred for blood pressure management in durable LVAD patients.

Level of Evidence: B.

2. Early neurohormonal blockade should be started in all stable durable LVAD patients to promote ventricular reverse remodeling and myocardial recovery during LVAD support.

Level of Evidence: B.

Class IIb

1. Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control. Data in LVAD patients are lacking and utilization can be extrapolated from studies in other heart failure populations and those with secondary pulmonary hypertension. These medications are limited by data and need for frequent administration due to short half-lives.

Level of Evidence: C.

2. Dihydropyridine calcium channel blockers, centrally acting alpha-2 receptors agonists (clonidine), and peripheral alpha-1 antagonists are third line agents in the management of hypertension in patients on MCS support. These agents should be used when first and second line agents are contraindicated or as supplemental therapy in individuals with resistant hypertension.

Level of Evidence: C.

Pulmonary vasodilators reduce RV afterload and are often used perioperatively. In patients with persistent RV failure, phosphodiesterase-5 inhibitors or nitrates may be used as a transition from inhaled or intravenous pulmonary vasodilators such as inhaled nitric oxide or epoprostenol. Long-term use of phosphodiesterase-5 inhibitors has been associated with reduced pulmonary vascular resistance in LVAD patients who are being evaluated for heart transplantation, although it is unclear whether the benefits observed could have been achieved with LVAD therapy alone.(30) Presently, individual and meta-analyses showing definitive benefit for phosphodiesterase-5 inhibitor use after LVAD are lacking. Following extubation, careful monitoring of blood gases and patient mentation is necessary to avoid hypoventilation and hypoxia, which can trigger reactive pulmonary hypertension and RV dysfunction. In patients

Table 1 Echocardiography Defined Postimplant Continuous Flow LVAD Complications

Pericardial effusion
With or without cardiac tamponade including RV compression. *Tamponade*: respirophasic flow changes; poor RVOT SV.
LV failure secondary to partial LV unloading
(by serial exam comparison) a. 2D/3D: increasing LV size by linear or volume measurements; increased AV opening duration, increased left atrial volume. b. Doppler: increased mitral inflow peak E-wave diastolic velocity, increased E/A and E/e′ ratio, decreased deceleration time of mitral E velocity, worsening functional MR, and elevated pulmonary artery systolic pressure.
RV failure
a. 2D: increased RV size, decreased RV systolic function, high RAP (dilated IVC/leftward atrial septal shift), leftward deviation of ventricular septum. b. Doppler: increased TR severity, reduced RVOT SV, reduced LVAD inflow cannula and/or outflow-graft velocities (ie, <0.5 m/sec with severe failure); inflow-cannula high velocities if associated with a suction event. Note: a "too-high" LVAD pump speed may contribute to RV failure by increasing TR (septal shift) and/or by increasing RV preload.
Inadequate LV filling or excessive LV unloading
Small LV dimensions (typically <3 cm and/or marked deviation of interventricular septum towards LV). Note: May be due to RV failure and/or pump speed too high for loading conditions.
LVAD suction with induced ventricular ectopy
Underfilled LV and mechanical impact of inflow cannula with LV endocardium, typically septum, resolves with speed turndown.
LVAD-related continuous aortic insufficiency
Clinically significant—at least moderate and possibly severe—characterized by an AR proximal jet-to-LVOT height ratio >46%, or AR vena contracta ≥3 mm; increased LV size and relatively decreased RVOT SV despite normal/increased inflow cannula and/or outflow graft flows.
LVAD-related mitral regurgitation
a. Primary: inflow cannula interference with mitral apparatus. b. Secondary: MR-functional, related to partial LV unloading/persistent heart failure. Note: Elements of both *a* and *b* may be present.
Intracardiac thrombus
Including right and left atrial, LV apical, and aortic root thrombus
Inflow-cannula abnormality
a. *2D/3D*: small or crowded inflow zone with or without evidence of localized obstructive muscle trabeculation, adjacent MV apparatus or thrombus; malpositioned inflow cannula. b. *High-velocity* color or spectral Doppler at inflow orifice. Results from malposition, suction event/other inflow obstruction: aliased color-flow Doppler, CW Doppler velocity >1.5 m/s. c. *Low-velocity* inflow (markedly reduced peak systolic and nadir diastolic velocities) may indicate internal inflow-cannula thrombosis or more distal obstruction within the system. Doppler flow velocity profile may appear relatively "continuous" (decreased phasic /pulsatile pattern).
Outflow-graft abnormality
Typically due to obstruction/pump cessation. a. 2D/3D imaging: visible kink or thrombus (infrequently seen). b. Doppler: peak outflow-graft velocity ≥2 m/s* if near obstruction site; however, diminshed or absent spectral Doppler signal if sample volume is remote from obstruction location, combined with lack of RVOT SV change and/or expected LV-dimension change with pump-speed changes.
Hypertensive emergency
New reduced/minimal AV opening relative to baseline exam at normal BP, especially if associated with new/worsened LV dilatation and worsening MR. Note: hypertension may follow an increase in pump speed.
Pump malfunction/pump arrest:
a. Reduced inflow-cannula or outflow-graft flow velocities on color and spectral Doppler or, with pump arrest, shows diastolic flow reversal. b. Signs of worsening HF: including dilated LV, worsening MR, worsened TR, and/or increased TR velocity; attenuated speed-change responses: decrease or absence of expected changes in LV linear dimension, AV opening duration, and RVOT SV with increased or decreased pump speeds; for HVAD, loss of inflow-cannula Doppler artifact.

AV, aortic valve; AR, aortic regurgitation; CW, continuous wave; IVC, inferior vena cava; LV, left ventricle/left ventricular; LVOT, left ventricular outflow tract; MR, mitral regurgitation; RAP, right atrial pressure; RV, right ventricle/ventricular; RVOT, right ventricular outflow tract; SV, stroke volume; TR, tricuspid regurgitation.

with obstructive sleep apnea, therapy should be continued during their postoperative stay.

Recommendation for the management of pulmonary hypertension early after LVAD implantation

Class I

1. Following extubation, blood gases and patient mentation should be carefully monitored to avoid hypoventilation and/or hypoxia, which can trigger RV failure.

Level of Evidence: C.

Class IIb

1. Pulmonary vasodilator therapies, such as inhaled nitric oxide, oral or intravenous nitrates, epoprostenol or oral phosphodiesterase-5 inhibitors may be considered for acute management of pulmonary hypertension in postoperative patients with elevated pulmonary pressures with close monitoring for the development of increased left sided filling pressures.

Level of Evidence: C.

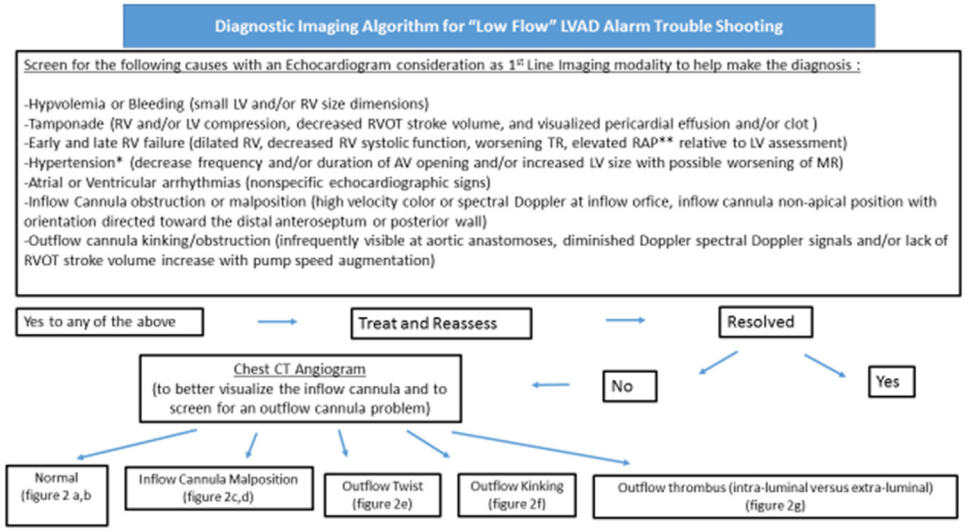

Figure 2 Diagnostic imaging algorithm for "Low Flow" LVAD alarm trouble shooting. AV, aortic valve; CT, computed tomography; LV, left ventricle; MR, mitral regurgitation; RAP, right atrial pressure; RV, right ventricle; RVOT, right ventricular outflow tract; TR, tricuspid regurgitation.

Cardiac imaging in the postoperative period

Cardiac imaging is integral in the management of LVAD patients including device speed optimization, trouble-shooting device complications (Table 1 and Figure 2), and screening for myocardial recovery (31-38). A multidisciplinary evaluation of imaging, inclusive of the imaging specialist, advanced heart failure cardiologist, and/or cardiac surgeon may be beneficial for achieving timely and accurate diagnoses in the setting of presumed device dysfunction. The examination of LVAD patients using transthoracic or transesophageal echocardiography has expanded over the past several years to include detailed interrogation of the outflow cannula in addition to the inflow cannula and novel assessments for identifying device malfunction.(31, 32, 35) Investigators have demonstrated the accuracy of echocardiography to estimate intracardiac hemodynamics and have shown inferior outcome in those with elevated estimated LV filling pressure while on LVAD support.(33, 34) Although echocardiography is the first line imaging technique to monitor patients on LVAD support, it is limited to evaluating cardiac and central system components. Multimodality imaging including Chest Computed Tomography (CT) and nuclear imaging tests (like multiple-gated acquisition equilibrium radionuclide angiography and18-fluorodeoxyglucose (FDG) PET/CT) have become important diagnostic tools to guide management in this patient population (35, 39-48). Chest CT, in particular, permits a very comprehensive evaluation of the DMCS system and has become an important diagnostic tool in patients with device dysfunction, including outflow cannula obstruction (Figure 3) (35, 39-42). However, anastomosis stenosis may not be recognized by this technique, and it may be difficult to distinguish between outflow graft intraluminal obstruction and extra-luminal or external compression. In select patients with outflow cannula obstruction, ventriculography, select angiography, and pressure gradient assessment may be useful for the diagnosis and management of this particular LVAD complication (49-52).

Recommendation for transthoracic and transesophageal echocardiography in the postoperative period

Class I

1. Echocardiography is an integral part of determining optimal continuous-flow LVAD pump speed. Common goals include adequate LV unloading with minimization of mitral regurgitation, while simultaneously maintaining the LV septum in the midline.(31)

Level of Evidence: C.

2. Echocardiography should be used to detect and define causes of partial LV unloading, LVAD complications, and to screen for myocardial recovery (31-35).

Level of Evidence: B.

Class IIa

1. Contrast echocardiography should be used to overcome challenges in assessing ventricular size and function, better visualize the inflow cannula inlet, and to screen for intracardiac and/or aortic root thrombus in select patients. (36, 37)

Level of Evidence: B.

Class IIb

1. postoperatively, the revolutions per minute of continuous-flow pumps may be set low enough to allow for intermittent aortic valve opening, but not at the expense of inadequate LV unloading and end-organ hypoperfusion. It is not known if these observed benefits apply to patients supported by a centrifugal-flow fully magnetically levitated device with an artificial pulse.(31)

Level of Evidence: B.

2. Long-term, maintaining intermittent aortic valve opening may reduce the risk of aortic valve fusion and the risk of late aortic valve insufficiency. This should not be

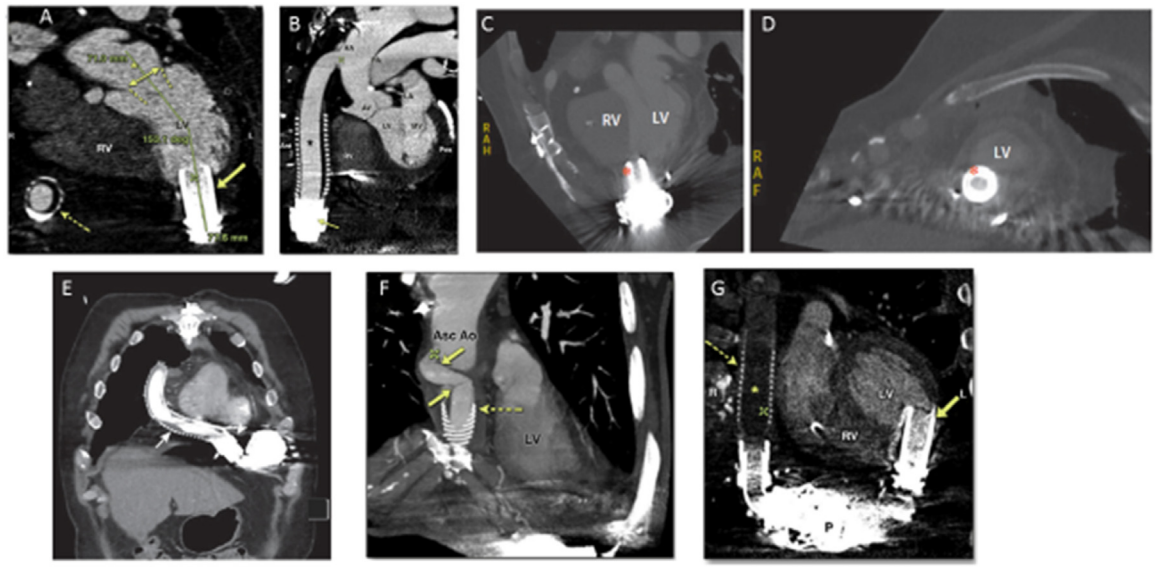

Figure 3 (A) Two-dimensional multiplanar reformatted multidetector cardiac computed tomography (MDCT) image shows a HeartMate II left ventricular assist device (LVAD) (Abbott, Abbott Parkway, IL) inflow cannula (block arrow) normally positioned at the left ventricular (LV) apex and directed toward the mitral annulus (asterisk). Cross section of the outflow graft (broken arrow). Adapted with permission from Vivo et al. (40) (B) Multiplanar reformatted image (quasi-sagittal view) shows a normally positioned outflow cannula (arrow) with graft (asterisk) anastomosed to the ascending aorta (X). Adapted with permission from Vivo et al.(40) (C) Five-chamber illustration of the HVAD inflow cannula (red asterisk) placed in the inferior apical segment and oriented immediately adjacent to the apical septal segment. Adapted with permission from Almarzooq et al. (35) (D) Short-axis view confirming the inferior apical segment orientation. Although there was no obvious visual evidence of inflow obstruction or thrombus, there was inward septal motion of the mid to distal inferoapical segment. This limited systolic flow toward the inflow cannula accounted for recurring low-flow alarms without another cause, consistent with inflow cannula mal-position as opposed to a normal inflow cannula directed parallel to the LV outflow tract/mitral valve. LV, left ventricular. Adapted with permission from Almarzooq et al. (35) (E) CT chest with contrast, coronal reconstruction. Outflow graft metallic swivel joint (arrowhead) secured to the pump allows free rotation of the outflow graft after implantation to allow adjustment by the surgeon. However, this design feature can result in sporadic and insidious twisting due to pump movement late after implantation, resulting in a "candy wrapper" twist (arrow). Adapted with permission from Almarzooq et al.(35) (F) Marked kinking of outflow cannula in a 68-year-old man with device alarms indicating low-flow and high power spikes. Two-dimensional coronal view showed marked kinking at 2 points (solid arrows) of the outflow graft (broken arrow). Adapted with permission from Vivo et al. (40) (G) Coronal oblique view revealed absence of contrast (asterisk) within the outflow cannula/graft (broken arrow). Not shown, very low CT attenuating number suggestive of thrombus. Block arrow (C) indicates IC with suboptimal contrast enhancement similar to LV. Adapted with permission from Vivo et al. (40)

undertaken, however, at the expense of organ perfusion. (31)

Level of Evidence: B.

Recommendations for the use of chest computed tomography

Class I

1. Computed tomography (CT) is useful for detailed visualization of multiple components of the DMCS device, including device inflow cannula, the outflow graft, and the driveline (35, 39-42).

Level of Evidence: B.

2. When indicated, CT should be used to identify DMCS complications including inflow cannula malposition, outflow-graft kinking or obstruction, cardiac compression, and/or infection (35, 39-42).

Level of Evidence: B.

3. CT is recommended before device exchange to ensure patency of the outflow cannula and, if a sternal entry is planned, to assess approximation of DMCS components to the sternum.

Level of Evidence: C.

Recommendation for the use of selective angiography in the hospitalized DMCS patient

Class IIa

1. Ventriculography with injection of radiopaque contrast into the LV and select outflow cannula graft angiography with pressure gradient assessment can be useful to visualize and guide treatment (e.g., endovascular stenting) of outflow graft obstruction in select patients with suspected outflow cannula thrombosis or kinking (49-52).

Level of Evidence: B.

2. Selective coronary angiography can be useful to detect and guide treatment of aortic root and coronary clot and/or severe coronary occlusion in select patients with evidence of acute myocardial injury while on LVAD support.

Level of Evidence: C.

Recommendations for nuclear imaging

Class IIb

1. Nuclear imaging techniques (including technetium-99m (99mTc)-sestamibi single photon emission computed tomography (SPECT), and nuclear 123I-meta-iodobenzylguanidine (MIBG)) may be considered as an imaging alternative to screen for myocardial recovery in the setting of a nondiagnostic echocardiogram.

Level of Evidence B.

2. Radiolabeled white blood cell scintigraphy (e.g., WBC SPECT/CT) may be used to evaluate patients with a suspected LVAD infection. This technique is limited by images with relatively poor counts and is a less sensitive technique compared to FDG PET/CT to detect device-related infections.(35, 53, 54)

Level of Evidence: B.

Recommendations for the use of FDG positron emission tomography/CT

Class IIb

1. An 18-fluorodeoxyglucose (FDG) PET/CT may be considered to help identify LVAD-related infection sites (e.g., pump/pump pocket vs isolated driveline vs outflow cannula) and to guide treatment and prognosis (45-48).

Level of Evidence: B.

Anticoagulation and antiplatelet therapy post-DMCS

In the early postoperative period, careful attention to anticoagulation and antiplatelet therapies and patient clinical status is imperative to reduce the risks of thrombotic and bleeding complications. In patients without evidence of bleeding, intravenous heparin therapy is usually started postoperative day 1 to 2. Transition from parenteral to oral anticoagulation therapy should be started as soon as patients are hemodynamically stable and without concerns for active bleeding or plans for imminent invasive interventions. In general, this is around days 2 to 3 postoperative. A multidisciplinary approach to antiplatelet and anticoagulation therapies, inclusive of members of the critical care, surgical, cardiology, nursing, and pharmacy teams, may help reduce the risks of complications from therapy complications that may arise from drug-drug interactions or changes in patient clinical or nutritional statuses. Parental heparin therapies should be monitored according to institutional protocols using either activated partial thrombin time (aPTT) or anti-Xa monitoring. Device-specific instructions for use should guide goal INR values and antiplatelet therapy dose. Patients with a sudden rise in INR should be examined for clinical evidence of right heart failure and a chart review should be undertaken to identify any possible changes in other pharmaceutical therapies that could impact warfarin metabolism. Patients with a sudden drop in INR may have poor drug absorption or may have an interaction with another drug or nutritional therapy.

Recommendations for anticoagulation and antiplatelet therapy post-DMCS

Class I

1. Anticoagulation and antiplatelet therapy initiated postoperatively in the ICU setting should be continued with the aim of achieving device-specific recommended INR for warfarin and desired antiplatelet effects.

Level of Evidence: B.

2. Bleeding in the early postoperative period during the index hospitalization should be urgently evaluated with lowering, discontinuation, and/or reversal of anticoagulation and antiplatelet medications.

Level of Evidence: C.

Infection prevention post-DMCS therapy

Morbidity and mortality in the early postoperative period is high in patients with infectious complications, in particular bacteremia. (55) Non-DMCS infections within the first 3 months following implant are much more common than DMCS-specific or MCS-related infections and are an important source of morbidity and mortality early after DMCS implant. (55, 56) Meticulous infection control practices are necessary to reduce nosocomial infections, such as catheter-related bacteremia, catheter-associated urinary tract infections, ventilator-associated as well as aspiration pneumonia and *Clostridioides difficile* infection. Local hospital guidelines should be followed with input from infection control colleagues. (57) Intraoperative techniques and recommendations to minimize infectious complications is covered in Task Force 3.

Recommendations for infection prevention

Class I

1. Development of a standardized postoperative DL management strategy for health care providers and patients/caregivers is recommended to reduce the risk of DL infection. Management strategies should include application of an antimicrobial cleaning solution with sterile or clean technique; application of an occlusive dressing appropriate for the level of DL incorporation; and careful DL fixation.(58, 59)

Level of Evidence: C.

2. It is recommended that DL dressing changes are initially performed daily. Once the DL is incorporated/healed, frequency can be reduced to 1 to 3 times weekly. Local chlorhexidine-based cleansing agent is recommended as first-line agent for cleansing the DL exit site. (57, 60)

Level of Evidence: C.

3. DL stabilization is essential to reduce DL mobility and to aid in tissue healing.(61) It is recommended that DL stabilization be achieved using an abdominal wall DL anchor or fabric binder.

Level of Evidence: C.

Class IIa

1. Documentation of the DL appearance with photography and a written description of the driveline to include the presence or absence of erythema, induration, tenderness, drainage or blood as well as the presence or absence of skin incorporation is likely beneficial for longitudinal and interdisciplinary driveline assessment.

Level of evidence: C.

2. Chlorhexidine has been associated with a sensitivity dermatitis. In those with a chlorhexidine sensitivity, it is reasonable to use betadine as an alternative although betadine is associated with greater risk of infection.(60, 62)

Level of evidence: C.

Class IIb

1. The addition of a silver or chlorhexidine impregnated patch/gauze to the DL exit site may be beneficial.(58, 60, 62) Direct comparisons between silver impregnated vs chlorhexidine impregnated dressings are lacking.

Level of Evidence: C.

Class III

1. Antibiotic prophylaxis for greater than 48 hours is not associated with a reduction in SSI and is not recommended. (57)

Level of Evidence: B.

2. Routine antifungal prophylaxis is not recommended due to low rates of fungal infections with contemporary devices as well as lack of efficacy in previous retrospectives series.(63)

Level of Evidence: B.

3. Presence of various drains, catheters, or open chest is not an indication to prolong antibiotic prophylaxis.(57)

Level of Evidence: C.

Recommendations for optimization of nutritional status

Class I

1. Consultation with nutritional services should be obtained at the time of implantation with ongoing follow-up postoperatively to ensure nutrition goals are being met.

Level of Evidence: C.

2. Postoperatively 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.

Class IIb

1. It is reasonable to monitor prealbumin and albumin levels for assessment of nutrition risk.

Level of Evidence: C.

Education and assessment of DMCS patient and caregiver readiness for discharge

After surgery, the patient and caregivers should learn about device management, initially at a basic level, and then with increasing complexity. Before hospital discharge, patients and family should be able to demonstrate a clear understanding of the requirements for safe DMCS care.(64-66) During the postoperative admission, the DMCS care knowledge and skills of the patient and caregivers should be ensured through education and training, competency validation, and provision of educational materials.(67) Successful long-term DMCS support includes a high degree of self-care by the patient and their caregiver(s). All 3 components of self-care deserve special attention: 1) self-care maintenance, including activities related to the device (e.g., system maintenance) and lifestyle (e.g., hygiene and personal care) 2) self-care monitoring (e.g., monitoring for complications such as infections or bleeding) and 3) self-care management (e.g., handling of the alarms and medication adjustments). To perform optimal self-care once DMCS patients are discharged, they need optimal education by a multidisciplinary team.(68)

Patient and caregiver education include skills necessary for safe daily DMCS management (e.g., maintenance of batteries and other DMCS equipment), recognition and management of DMCS alarms, anticoagulation monitoring, wound care and dressing procedures,(69, 70) and recognition of signs and symptoms of complications including infection, pump thrombosis and neurological dysfunction. Patients also need to understand important lifestyle restrictions after DMCS implant.(71) Discussion of limitations may need to be individualized for the patient, based on the hobbies he or she enjoyed preoperatively.

The patient and caregivers should be provided with a device-specific education manual so that they can continue to learn and reinforce what has been taught on their own time. To promote safe DMCS patient discharge, both the patient and caregivers should complete a written competency test or at least an exit interview with demonstration of skills (e.g., dressing change procedures, changing of batteries) to ensure competent learning before discharge.(64)

Bedside nurses trained on center-specific DMCS care and patient education models are integral to the patient and family education process. Nurses should be encouraged to reinforce education already provided by DMCS coordinators and / or provide education to the patient as part of their routine daily care. Education should be repetitive, consistent, and reinforced regularly to promote patient and caregiver competence and confidence. (72) Education tools can assist DMCS clinicians in the education of DMCS patients and facilitate consistency among the nursing staff in the safe management of the device. These tools also serve as a useful way of monitoring patient progress.(64) Lastly, it is important to note that education needs to be

individualized with assessment of the DMCS patient's learning ability, educational level, and possible barriers to learning.(64, 67) Shorter, more frequent sessions may also facilitate learning and retention of information. Educating DMCS patients and their caregivers may contribute to increased understanding of DMCS, prevention and better management of symptoms, fewer adverse events, and decreased hospital readmissions. Education should not cease upon hospital discharge and protocols for patient and family re-education during long-term support should be in place at each center.

Patient and caregiver education on device parameters and alarms. Device-specific DMCS parameters should be charted in the patient's medical records, similar to documentation of other hemodynamic parameters. Ranges of acceptable values and triggers for physician notification should be established. Patients and caregivers should receive similar education on parameter documentation and call parameters for the outpatient setting should be taught before discharge.

Recommendations for Patient and Caregiver Education

Class I

1. Patient and caregiver education should be initiated shortly after surgery and reinforced by the multidisciplinary DMCS team.

Level of Evidence: C.

2. Educational strategies should employ written, verbal and hands-on methods.

Level of Evidence: C.

3. Patients and caregivers should receive education while inpatient on daily DMCS management and normal device parameters (including speed, power, and flows) and should be advised on all parameters for abnormal values or alarms.

Level of Evidence: C.

4. Patients and caregivers should receive education while inpatient about signs and symptoms of common complications (e.g., stroke, gastrointestinal bleeding, driveline infection) during device support.

Level of Evidence: C.

5. DMCS equipment should be labeled with the DMCS center's emergency contact number and patients and caregivers should demonstrate knowledge on who contact should DMCS urgencies arise in the outpatient setting.

Level of Evidence: C.

6. Patients and designated caregivers should demonstrate safe driveline management, including driveline cleansing, fixation, and monitoring according to institutional protocol.

Level of Evidence: C.

7. It is recommended that patients and key caregivers receive annual re-education in the outpatient setting on device and driveline management and signs and symptoms of key complications.

Level of Evidence: C.

Class IIb

1. It may be beneficial to initiate device-specific education before surgery with patients and/or care givers.

Level of Evidence: C.

Assessment of MCS parameters during normal and aberrant device function

DMCS devices have unique physiology leading to need for individualized settings for each patient. DMCS screens display information critical for identifying proper or aberrant device function. Therefore, it is imperative that information provided by the device is evaluated and documented in a uniform manner on a regular basis while patients are hospitalized.

After implantation of DMCS, normal values specific to each patient should be established. The team should have triggers to notify physicians or DMCS coordinators if parameters are changing. Commonly displayed parameters on continuous flow devices include speed (revolutions of the impeller per minute or RPM), flow (liters/minute), power (Watts) and pulsatility. Pulsatility is the size of the flow pulse generated by pre- and afterload changes over the cardiac cycle. It is displayed either numerically (e.g., Pulsatility Index in HeartMate II or HeartMate 3) or visually (e.g., HVAD wave form). Table 2 summarizes causes of deviation from "normal" device conditions. Alarms are device specific, and the user's manual should be referenced for explanation of these. During the index hospitalization, the patient and caregivers should begin garnering experience with monitoring DMCS parameters.

To assess parameter changes, the DMCS clinicians must not only analyze pump parameters and log files but also put device readings in the context of clinical changes, laboratory results and therapeutic images. Common etiologies for reduced LVAD flows include bleeding, dehydration, pericardial tamponade, RV dysfunction, inflow or outflow occlusion, and suction. During suction events, the ipsilateral ventricular cavity is collapsing around VAD inflow cannula. The most common reasons for suction include volume depletion (73), tamponade, or inflow cannula malposition. During malposition, the inflow cannula may abut the ventricular wall or septum, leading to intermittent inflow occlusion. Suction or over support of the ventricle can induce ventricular arrhythmias through cannula stimulation of the myocardium. (74) Pulsatility markers might be low (PI < 2.0) or extremely high (PI > 6.0) in combination with low flow alarms.

Power is a measure of both current and voltage applied to the MCS motor. Power is directly related to device speed and device flow. Higher VAD speeds will draw more energy than lower speeds and higher device flows (e.g., aortic insufficiency) may yield higher power readings. Blood flow may be disturbed at different levels of the LVAD device (see Table 2) with varying impact on pump power readings (52, 75-79). LVAD inflow

Table 2 Causes of Deviation From Normal Device Conditions

Condition	Flow	Pulsatility	Power	CVP	PI events/suction *	Management
Hypovolemia (73)	↓	↓ or ↑	↓	↓	↑↑	Volume challenge, consider bleeding, consider sepsis
Right heart failure	↓	↓	↓	↑	↑↑	Echo, optimize volume, pulmonary vasodilators, optimize pump speed
Tamponade (73)	↓	↓	↓	↑	↑	Echo, surgery
Aortic regurgitation (73)	↑	↓	↑	↔ or ↑	↓	Echo, correct blood pressure, RPM changes, surgery
Hypertension (73)	↓	↑	↓	↔ or ↑	↑ (PI events) ↓ (suction)	Treat hypertension
Vasodilation	↑	↓	↑	↓	Variable	sepsis, pressors if hypotensive
anemia	↓	↓	↓	↔	↓	Adjust HCT setting; consider transfusion if bleeding or low mixed venous sat.
Arrhythmias (73, 74)	↓	↓	↓	↔ or ↑	↑	Treat arrhythmias, reduce pump speed if suction induced
Rotor/impellar thrombosis (52, 76-79)	↑	Variable	↑ or ↑↑	Variable	↔	Follow pump thrombosis protocol incl. Log file analysis: Add additional antiplatelet and anticoagulants. Consider thrombolytic therapy (device dependent) or emergent pump exchange if needed (52)
Outflow graft obstruction/thrombosis (52, 78, 214)	↓↓	↓	↓↓	↔ or ↑	↔ or ↓	Echo (ramp (32, 140)), CT chest, log file analysis; stenting of outflow graft might be considered (78, 214)
Outflow graft twist (215)	↓↓	↓	↓↓	↔ or ↑	↔ or ↓	Echo (ramp (32, 140)), CT chest, log file analysis; Surgical correction with untwisting of the graft or pump exchange
Inflow cannula obstruction/occlusion (52, 76, 78)	↓↓	↓	↓↓	↔ or ↑	↔ or ↓	Echo (ramp (32, 140)), CT chest, log file analysis
Recovery	Variable	↑	Variable	↓	Variable	Nothing acute

*Note: PI events (e.g., HeartMate 3) are not necessarily triggered by suction, also arrhythmias or hypertension might cause PI events.

obstruction (thrombus, suction, myocardial ingestion) can occur at the level of the inflow cannula (prepump thrombosis), leading to a drop in VAD flow and pump power. Alternatively, thrombus formation may occur between the impeller and the pump housing (intrapump thrombosis) leading to an increase in the energy required to maintain pump set speed. This leads to a concomitant rise in pump power despite a simultaneous reduction in actual pump flow. In this situation, MCS devices that estimate flow from pump power utilization may provide inaccurately high flow readings. Finally, outflow graft obstruction may occur due to stenosis, thrombosis or twist, and may lead to gradual reductions in power and flow (postpump thrombosis).(14) To this end, enhanced analysis of log files may be beneficial to detect changes in pump power, flow and overall function (80-82).

Recommendations for documentation of DMCS parameters and device monitoring

Documentation of device parameters

Class I

1. DMCS parameters (flow, power, pump speed) should be recorded in the medical record at regular intervals with established parameters which require physician notification.

Level of Evidence: C.

Device monitoring

1. Changes in parameters outside of normal ranges should be thoroughly evaluated and treated appropriately.

Level of Evidence: B.

2. It is critical that advanced heart failure specialists, DMCS coordinators, and cardiac surgeons and advanced practitioners involved in regular DMCS patient care understand device-specific readings, response to device alarms, and maintain competency in DMCS device interrogations.

Level of Evidence: C.

Psychological and psychosocial considerations for patients with durable MCSD

Anxiety and depression. Post-DMCS patients have described a variety of emotions. The 2 most commonly noted psychological disorders include depression and anxiety,(83) prompting assessments for these in overall health-related quality of life after DMCS. Variance in scores for subjective health status over time may be primarily related

to depression and anxiety rather than clinical factors.(84) Feelings of exhaustion, uncertainty (i.e., about receiving a heart transplant), impatience, frustration, and fear of dying may contribute to anxiety and depression, and avoidant coping scores have been significantly correlated with both depression and anxiety.(85) Among DMCS and cardiac transplant patients, depression is associated with lack of adherence to medical treatment, less effective coping strategies, and higher risk for complications such as infections (86-89). Improvements have been noted in depression and anxiety from baseline to 6 to 12 months post-LVAD.(90) However, pretransplant depression is a strong predictor of posttransplant depression,(86) so interventions should begin pre-DMCS.

There are a number of reasons for adjustment issues post-DMCS and issues may differ between patients suffering an acute, catastrophic cardiac event vs those with more chronic forms of heart failure. Patients may have stress from being hospitalized and away from home or loved ones and cognitive changes from delirium or stroke may impact psychosocial adjustment post-LVAD.(91) The type of DMCS (TAH vs LVAD) and/or implant strategy may also have an impact on psychosocial adjustment post-DMCS (e.g., consistency of relying on DMCS for the rest of one's life vs the unpredictability of awaiting a transplant).

Interventions. Pharmacologic and psychotherapeutic strategies can be used to treat psychosocial disorders before and after DMCS.(83) Patients prefer discussing MCS implantation earlier on in the disease trajectory, and prefer empathetic rather than authoritarian communication styles.(85) Hearing from other MCS patients can be an important mechanism for patients and/or caregivers share fears, ask questions, and glean practical coping strategies.(85) After DMCS implant, referral to physical rehabilitation along with ongoing support from social work, psychology/psychiatry, palliative care, and/or spiritual care are important interventions to support patient emotional and physical recovery.(92, 93) Ultimately, each patient's adjustment (physical, emotional, cognitive, social) will be affected by their varied background, including their own psychological characteristics, personality, family, support, beliefs, age, prior experiences, and expectations,(85, 94) thus underscoring more holistic, interprofessional psychosocial assessment at baseline to better understand how to support the patient.

Suicidal ideation. While it is normal for a patient with a chronic life-threatening condition to discuss death,(95) signs of hopelessness, apathy, and passive medical nonadherence may warrant screening to ascertain whether the patient is suicidal.(96) Some measures for depression have a designated item that screens for suicidal thoughts. Staff should have a clear protocol for communicating potential concerns to the appropriate MCS team members and be ready to provide context for psychology and/or psychiatry when making a referral.(96, 97)

Caregivers. Informal caregivers often have under-recognized psychosocial challenges and quality of life changes associated with DMCS implantation,(98) describing emotional distress, isolation, limited freedom, anxiety, and uncertainty for the future.(99) Even for caregivers who feel adequately prepared for their role, unexpected changes can occur and adaptations are often needed for the home environment. It is not uncommon for caregivers to neglect their own health care needs. Posttraumatic stress disorder among caregivers has also been reported.(99, 100) Options for resources for psychosocial support should be made available to the patient's informal caregiver and family, because these individuals are part of the recovery trajectory both inpatient and outpatient. Loss of caregiver support is associated with increased 30-day readmission rates.(101)

Recommendations for psychosocial support post-DMCS implantation

Class I

1. *Routine psychosocial support for both patients (83-87, 92, 93, 102) and designated caregivers (84, 95, 98, 100, 101) should be available from social workers, psychologist, nurses, and other members of the team, with further resources available (i.e., palliative care, spiritual care) during adjustment to life changes after DMCS.*

   Level of Evidence: B.

2. *Routine surveillance for psychiatric symptoms (i.e., depressive symptoms, anxiety) should be performed with referral to specialists (i.e., social work, psychology, and/or psychiatry) for further assessment, interventions, and follow-up as needed (83-89, 92, 93, 102, 103).*

   Level of evidence: B.

Class IIa

1. Hearing from other DMCS patients can be useful and allows DMCS candidates and caregivers the opportunity to share fears, ask questions, and to glean practical coping strategies.

Level of Evidence: C.

Inpatient MCS care using an interdisciplinary team approach

Patients on DMCSs often have several active medical issues coincident with heart failure and DMCS needs. In addition to integrating care recommendations from consultants addressing new or worsening noncardiac medical issues, coordination of care recommendations from DMCS team members in physical rehabilitation, nutrition, pharmacology, palliative medicine, critical care, and psychology needs to be undertaken. A team-based care approach is one means of engaging multiple providers into a DMCS patient's care. A multidisciplinary approach to patient care engages knowledge and recommendations from multiple disciplines but each discipline team member stays within their boundaries. An interdisciplinary team approach to patient care synthesizes and harmonizes the expertise of the various team members into one integrated plan. An interdisciplinary care approach allows for care unification and

efficiency, addressing competing or divergent care team recommendations to achieve the best care plan for the individual patient. While data on the benefits of multidisciplinary/interdisciplinary care approach are minimal in DMCSs (104), the approach has shown benefit in non-DMCSs patients with advanced heart failure (105, 106) and patients undergoing cardiac transplant (107, 108), reducing lengths of stay, improving utilization of guideline directed therapy, and improving outcomes.

Recommendations for inpatient DMCS care by the multidisciplinary team

Class I

1. An interdisciplinary team led cooperatively by cardiac surgery and advanced heart failure cardiology and composed of subspecialty services integral to DMCS care (e.g., palliative care, psychiatry, critical care intensivists, social work, occupational and physical therapy, pharmacy) and DMCS coordinators is requisite during the inpatient management of MCS patients. (104, 105)

Level of Evidence: C.

Class IIa

1. The regular use of interdisciplinary rounds may be beneficial for improving interteam communication between specialties, developing a patient centric care plan, and organizing patient education and discharge needs.

Level of Evidence: B.

Management of inpatient complications during MCS support

Management of anticoagulation and antiplatelet therapy for patients who present with gastrointestinal bleeding

Patients on DMCSs require anticoagulation and antiplatelet therapies to reduce thromboembolic complications. Presently, anticoagulation with the vitamin K antagonist warfarin is standard of care. Data from well-designed trials to support use of novel oral anticoagulants (NOACs), including direct thrombin inhibitors, are lacking. Intravenous anticoagulation, most commonly with unfractionated heparin, is started when surgical hemostasis is achieved, usually within 24 hours of surgery. Parenteral therapy is then transitioned to oral warfarin and aspirin therapy when invasive procedures are no longer anticipated; large bore vascular cannulas have been removed; vasopressor support has been weaned; and hemoglobin levels are stabilized. Initial doses of aspirin therapy and INR goals should conform to device-specific instructions for use (IFU).

The requirement for anticoagulation and antiplatelet therapy predisposes patients to bleeding complications, and some complications occur at frequencies higher than that of the general population on similar levels of anticoagulation. In particular, DMCS patients are highly susceptible to spontaneous bleeding, most commonly from mucocutaneous sites such as the gastrointestinal, vaginal, and/or oral-nasopharyngeal (109-111). The incidence of gastrointestinal bleeding (GIB) in patients on continuous flow devices has been shown to range from 18% to 26% and rebleeding is common during prolonged support (110-112). Gastrointestinal bleeding (GIB) in patients on continuous flow LVAD support is most commonly the result of arteriovenous malformations (AVM) that develop in the gastrointestinal tract. Clinical studies have shown that AVMs occur in higher frequency in patients on continuous flow vs pulsatile flow support, a finding that is likely multifactorial in etiology, being related to acquired aberrancies in vascular signaling (e.g., vascular endothelial growth factor (VEGF), angiopoetin) and platelet receptor function; reduced concentrations of high molecular weight von Willebrand factor; reduced arterial pulse pressure with distal vascular bed ischemia; and mucocutaneous tissue congestion and the increased vasodilatory state associated with right heart failure.(112-116)

For patients who present with mucocutaneous bleeding, warfarin may be held or even reversed, depending on the severity of the bleeding and the INR. Antiplatelet therapy is often discontinued as well. Anticoagulation and antiplatelet therapy typically continue to be withheld until the source of the bleeding has been addressed or, if a source has not been identified, until the bleeding subsides. (117) Data are presently lacking to guide adjustments in INR goals and antiplatelet dosing or withdrawal in patients with bleeding events, and patient-specific and device-specific factors should weigh into treatment decisions.

Recommendations for management of anticoagulation and antiplatelet therapy for patients who present with mucocutaneous bleeding

Class I

1. Anticoagulation and antiplatelet therapy should be held in the setting of clinically significant bleeding.

Level of Evidence: C.

2. Anticoagulation should be reversed in the setting of an elevated INR and life-threatening bleeding.

Level of Evidence: C.

3. Anticoagulation and antiplatelet 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 laboratory markers of hemolysis should be carefully monitored while anticoagulation and antiplatelet therapy are being withheld or dose reduced.

Level of Evidence: C.

Class IIa

1. Individuals with acute anemia who are clinically stable and without deficit may be monitored with cessation of anticoagulation without need for urgent INR reversal.

Level of Evidence: C.

An interdisciplinary approach to patients with acute anemia is critical for rapid and safe DMCS patient care. Stool should be evaluated for signs of upper (melena) or lower (hemetechezia) bleeding and occult stool testing should be undertaken when bleeding is not obvious. A careful examination of the nasopharynx and oral cavity is recommended to uncover signs of upper cavity blood loss that could contribute to melena or stool occult positivity. Spontaneous hematomas have been reported in DMCS patients, especially those treated with low molecular weight heparin agents, and a careful examination of the torso is recommended. Select patients may benefit from CT scanning to look for evidence of spontaneous retroperitoneal bleeding.

Consultation with the gastrointestinal specialty clinical team is essential for those patients with concerns for gastrointestinal bleeding so that colonoscopy and/or upper GI endoscopy can be undertaken. If results are inconclusive, double balloon technique enteroscopy and/or capsule endoscopy may be considered.(118, 119) In select patients with active bleeding, a tagged red blood cell scan or angiography may be useful. In 20% to 30% of patients, a definitive source of gastrointestinal bleeding may not be found. Following testing/treatment, anticoagulation and antiplatelet therapy can be restarted with close observation of patient stool and hemoglobin.

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

Class 1

1. Patients presenting with unexplained anemia and/or concerns for mucocutaneous bleeding after DMCS should have an examination of the nasopharynx and stool should be assessed for signs of visible or occult blood.

Level of Evidence: C.

2. Patients with concerns for a gastrointestinal source of blood loss should be managed in consultation with the Gastroenterology team and a colonoscopy and/or upper endoscopic evaluation should be undertaken in those experiencing their first gastrointestinal bleeding event.

Level of Evidence: C.

3. Once the initial mucocutaneous bleeding has resolved, anticoagulation and antiplatelet therapy should be reintroduced with careful monitoring of patient hemoglobin and stool.

Level of Evidence: C.

Class IIa

1. If colonoscopy and/or upper endoscopic evaluations are negative, evaluation of the small bowel with enteroscopy should be considered

Level of Evidence: C.

2. In the setting of persistent bleeding and a negative endoscopic evaluation, it I reasonable to obtain a tagged red blood cell scan, capsule endoscopy, or angiography.

Level of Evidence: C.

In patients who suffer an initial mucocutaneous bleeding event, recurrence can be encountered in 30% to 40% of patients on LVAD support. The initial physical and laboratory evaluation of those with recurrent anemia is similar to an individual with an incident event, but the utilization of invasive testing may be altered based on the results of prior evaluations. If the source of bleeding remains unidentified or is not amenable to endoscopic or surgical interventions, then alterations in anticoagulation or antiplatelet therapy should be considered. The risks and benefits of altering anticoagulant and antiplatelet therapy should be weighed against the risks of pump thrombosis or thromboembolism for each patient, pump type, and clinical scenario. There are presently no robust data to support the safety or efficacy of changes in pump speed to promote pulsatility. (120, 121)

Pharmaceutical therapy to prevent incident or recurrent mucocutaneous bleeding

Angiotensin-converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) therapies have been correlated with a reduced risk of all-cause GIB and AVM-associated GIB in patients with LVADs. ACE inhibitor/ARB therapy is associated with a protective effect of developing GIBs in CF-LVAD patients, with a dose threshold of >5 mg of daily lisinopril equivalence, possibly due to prevention of AVM formation.(25, 26, 122)

In patients with incident GIBs, limited data exists regarding the benefit of octreotide, hormonal therapy, thalidomide, or replacement of vWF in patients with a history of GIB.(123-129) In a nonrandomized study utilizing historic controls, patients with continuous-flow LVADs receiving secondary prophylaxis with octreotide had a significantly lower GIB recurrence. (123) Octreotide can be administered in subcutaneous (100-200 mcg 2-3 times daily) and depot (20 g IM monthly) formulation and data are lacking to support a specific formulation and duration of therapy. Therapy costs with marginal data and drug side effects (including diarrhea, gastric upset, injection-site pain, flatulence, and abdominal pain) have limited widespread use of octreotide in patients with gastrointestinal bleeding on continuous-flow LVAD support. The efficacy of other therapies such as digoxin, thalidomide, and omega-3 therapy in the prevention of gastrointestinal bleeding in LVAD patients has not been shown in well designed and well powered studies.(130-133) Thalidomide is has been associated with increased thrombotic tendency in other patient populations and drug handling requires strict precautions due to teratogenicity, leading to limited prescription privileges in many countries.

Coincident risks in patients with bleeding events

Patients with GIB events have been found to be at significantly increased risk for subsequent thromboembolic events. Although the exact cause of this relationship is unknown, it suggests that a reduction in anticoagulation and antiplatelet management in response to GIB may contribute to this risk. (117) It is likely that device hemocompatibility profile also plays a role in subsequent thrombosis risk. Thus, LVAD patients who have interruption of anticoagulation and/or antiplatelet therapies during management of bleeding events should be closely monitored for signs of thrombotic complications, inclusive of laboratory monitoring (LDH and/or serum free hemoglobin) and device parameters (power, flow).

Recommendations for the evaluation and management of patients with recurrent episodes of mucocutaneous bleeding

Class 1

1. The patient, the device and markers of hemolysis should be carefully monitored when anticoagulation and antiplatelet therapy have been reduced or discontinued due to recurrent mucocutaneous bleeding.

Level of Evidence: C.

Class IIb

1. Repeated endoscopic evaluation may be reasonable in DMCS patients with recurrent gastrointestinal bleeding episodes, especially if prior therapeutic targets were identified. However, in patients with recurrent negative endoscopic evaluations, the utility and benefit of repeated endoscopy and/or angiography is likely low.

Level of Evidence: C.

2. In the setting of recurrent mucocutaneous bleeding with no identified source or a source that is not amenable to therapy, it may be reasonable to lower warfarin anticoagulation goals or amend antiplatelet therapy. Adjustments should be reevaluated in the context of bleeding severity, pump type, and complication history to derive an individualized patient risk:benefit ratio.

Level of Evidence: C.

3. Angiotensin converting enzyme inhibitors and angiotensin receptor blockers may be beneficial in reducing the incidence or recurrence of GIB.

Level of Evidence: B.

4. The use of subcutaneous or depot octreotide may be considered in patients with recurrent GI bleeds.

Level of Evidence: B.

5. In patients with recurrent mucocutaneous bleeding, the usefulness of digoxin, thalidomide and/or fish oil pharmacotherapy has not been established.

Level of Evidence: C.

Class III

1. While low pulse pressure during LVAD support is associated with AVM development, bowel wall ischemia, and mucocutaneous bleeding, the effectiveness of pump speed reduction in patients on continuous flow pumps in reducing bleeding has not been well established and may be harmful.

Level of Evidence: C.

Diagnosis and management of device thrombosis

The narrative of device thrombosis during LVAD support has followed a complete arc in less than a decade. This complication was not included in the original 2013 MCS guidelines, reflecting an early ignorance of this complication. Since then, device thrombosis came to the forefront of DMCS management, and most recently, new device designs have minimized this complication.

Device thrombosis refers to the ingestion or de novo development of a clot within the pump's flow path, including the inflow cannula, the mechanical rotor, or the outflow graft. As has been previously conceptualized, a host of the pump-, patient-, and management-related factors can contribute to the development of pump thrombosis.(134) It is also important to note that the risk, diagnosis, and management of pump thrombosis is specific to each device and is heavily influenced by patient comorbidities and candidacy and feasibility for heart transplantation. While thrombosis of the HeartMate II (Abbott, Abbott Park, IL) axial flow device and the HVAD (Medtronic, Minneapolis, MN) centrifugal flow pump were rare in clinical trials (occurring in 5-6% at 1-2 years), subsequent studies and registry analyses revealed rates as high as 7% to 12% at 1 year.(135) The newest generation centrifugal flow device, the HeartMate 3 (Abbott, Abbott Park, IL), was explicitly designed to mitigate device thrombosis, and the early experience has shown this complication to be rare in patients on HeartMate 3 support.(136)

Diagnosis of device thrombosis

A comprehensive diagnostic algorithm for device thrombosis encompasses clinical assessment, laboratory analyses, standard and advanced imaging modalities, and device parameter interrogation. Patients with pump thrombosis may exhibit marked variability in clinical stability, hemodynamics, and recorded pump parameters with variability driven by patient characteristics (e.g., degree of residual cardiac function) and local and degree of pump impairment (e.g., partial vs complete inflow occlusion). Pump flow and/or power aberrations are often noted, and such changes may be acute or can be insidious and progressive over time. In patients on LVAD support, insufficient left ventricular unloading may impart enhanced peripheral pulsatility manifested as the recurrences of previously undetectable palpable radial pulse. Circulatory deterioration may progress to clinical manifestations of a low-flow heart failure syndrome, arrhythmia, and, in the extreme form, to signs of cardiogenic shock. A detailed evaluation for signs of neurologic and/or peripheral embolism (e.g., digital infarction), volume overload, and malperfusion should be undertaken.

Laboratory measures of end-organ function and intravascular hemolysis are integral in the diagnostic algorithm. (134) Intravascular hemolysis related to pump thrombosis is signified by an elevation of serum lactate dehydrogenase (LDH) increase and plasma free hemoglobin (pfHg).(137, 138) The discrimination of LDH for detecting pump thrombosis in HeartMate II and HVAD patients has been shown to be superior to that of pfHg.(137, 138) In addition, pump model must be taken into account. Studies show that baseline levels of LDH during normal pump function run higher for HMII than HVAD and HM3 devices, leaving many to consider 2.5 times the upper limit of a laboratory LDH normal as significant hemolysis for HMII patients and lower thresholds for those on centrifugal flow technologies.(136-138)

Echocardiography represents the first-line imaging modality.(134) A decrease in inflow and outflow cannula peak continuous wave Doppler velocities combined with an increased aortic valve opening frequency, mitral valve regurgitation progression, and left ventricular dimensions increment can be suggestive of pump-related blood-flow impediment.(139) Ramp testing represents an advanced echocardiographic procedure by the staged incremental increase of the pump rotational speed to ascertain dynamic unloading performance in patients on Heartmate II and HVAD support. (32, 140) Echocardiography, however, cannot rule out pump thrombosis and should be coupled with invasive hemodynamic measurement in patients where PT is suspected despite normal or inconclusive echocardiogram. Additionally, computerized tomography with contrast and angiography is instrumental for examining the outflow cannula for patency and/or evidence of kink or torsion; the location and course of the outflow for surgical re-entry; and the position of the inflow cannula within the ventricle. (39, 141)

The final obligatory component of evaluating a patient with concern for pump thrombosis is an interrogation of pump log-files.(52, 76, 134) Log files should be sent for manufacturer retrospective analysis so that longitudinal trends in device flow and power can be reported graphically and interpretation of data can be shared and discussed. In general, an acute or slow rise in device power consumption may reflect friction on the rotor, which can be suggestive of acute or chronic intrapump thrombosis, respectively. In contrast, an acute or slow decrease in pump power from baseline may be indicative of a pre- (inflow occlusion) or postpump (e.g., outflow kink) obstruction.(142) Twisting of the outflow graft can occur early or later after surgical implant. Additionally, proteinaceous buildup between the bend relief and outflow tract has mimicked device thrombosis in the HeartMate 3 and extrinsic compression of the outflow graft from hematoma or other substances has been rarely noted.(142) Importantly, LDH levels should not be markedly elevated in cases of outflow occlusion, unless the flow reduction/stasis has triggered a secondary thrombosis of the device. Please refer to the section on "Assessment of MCS Parameters During Normal and Aberrant Device Function" for details on pump parameters.

Therapy

The basic principle in the management of device thrombosis is that each device and patient is unique. Nonetheless, some general tenets can be made. First, patients with suspected or confirmed device thrombosis should be admitted to the hospital for intravenous heparin to achieve therapeutic anticoagulation. It is also reasonable to choose an intravenous direct thrombin inhibitor such as bivalirudin or argatroban in lieu of heparin.(143-145) Mechanistically, direct thrombin inhibitors provide the additional benefit of antiplatelet properties, as well as activity on the clot-bound thrombin.(146, 147) If signs and symptoms of device thrombosis resolve with intravenous antithrombotic therapy, patients may be transitioned back to warfarin, often with a higher target INR than initially prescribed.(134) There is not enough evidence to recommend the addition of adjuvant oral antiplatelet therapy such as clopidogrel or dipyridamole.(148) Regardless, many programs do add these agents to aspirin or increase aspirin dose in this scenario.

In patients who do not respond to initial antithrombotic therapy or are hemodynamically unstable on presentation, treatment escalation is device-dependent.(134) The existing data suggest that the HeartMate II (Abbott, Abbott Park, IL) is unlikely to respond to further pharmacologic therapy, and device exchange or transplant should be pursued in those who are candidates.(149, 150) In contrast, some carefully selected patients supported with the HVAD (Medtronic, Minneapolis, MN) have demonstrated clinical improvement following administration of thrombolytic therapy.(52, 77) Analysis of log files may help differentiate clot accumulation pattern (progressive vs abrupt) such that chronic, denatured clot is likely less response to lytic therapy.(76, 151) The risks of bleeding and secondary neurologic complications, as well as the impact on immediate surgical candidacy if lytic therapy fails, should be considered in making treatment decisions. Reports of device thrombosis with the HeartMate 3 are rare, and as such, there is not enough evidence to guide a decision of device exchange vs thrombolytics. Glycoprotein IIb/IIIa inhibitors have been used either alone or combined with other antithrombotic therapy to treat device thrombosis.(77) This experience has largely been unsuccessful with poor resolution of the clot and high rates of bleeding.(152)

Patients for whom device exchange is deemed necessary should also be considered for urgent transplantation if they are hemodynamically stable and without embolic phenomenon, especially if the expected wait time is short. Finally, it should be noted that recurrent device thrombus rates after device exchange are higher than standard.(153, 154) In this regard, the initial experience with device exchange from HeartMate II or HVAD to a HeartMate 3 has been promising, with lower recurrent device thrombosis rates.(155) This decision should be individualized based on patient factors and surgical expertise.

Recommendations for the diagnosis of device thrombosis

Class I

1. In patients with suspected device thrombosis, hospital admission for expedited assessment is recommended.

Level of Evidence: C.

2. Prompt patient evaluation and serial examinations are imperative for detecting and managing patient hypoperfusion related to pump dysfunction.

Level of Evidence: C.

3. The initial evaluation of suspected device thrombosis should include device interrogation with manufacturer log file analysis to assess pump parameters changes over time.

Level of Evidence: B.

4. The initial evaluation of suspected device thrombosis should include laboratory tests (lactate dehydrogenase, hemoglobin, and plasma free hemoglobin) to assist in the diagnosis of intravascular hemolysis and hemoglobinuria (urinalysis) and to detect end-organ dysfunction.

Level of Evidence: B.

5. The initial evaluation of suspected device thrombosis should include an echocardiogram to assess for LV unloading with and without speed adjustment (i.e., RAMP study).

Level of Evidence: B.

6. In patients with a high suspicion of device thrombosis, CT angiogram to evaluate the outflow graft is recommended.

Level of Evidence: C.

Class IIa

1. In patients with clinical signs of heart failure, right heart catheterization with or without pump speed adjustment to assess LV and RV unloading should be considered to evaluate suspected device thrombosis and to assist in the management of heart failure.

Level of Evidence: C.

Class IIb

1. Left heart catheterization for assessment of patency of the outflow graft can be considered in suspected device thrombosis.

Level of Evidence: C.

Recommendations for the management of device thrombosis

Class I

1. Initial management of patients with confirmed device thrombosis should include intravenous systemic anticoagulation with heparin.

Level of Evidence: C.

2. In patients with confirmed device thrombosis who are candidates for surgery, pump exchange is the definitive therapy.

Level of Evidence: B.

Class IIa

1. In patients with confirmed device thrombosis who are hemodynamically stable and expected wait time for heart transplant is short, it may be reasonable to defer the pump exchange for urgent transplantation.

Level of Evidence: C.

2. In carefully selected patients supported by a hydrodynamic centrifugal pump with confirmed device thrombosis, systemic or intraventricular thrombolytic therapy can be considered as an initial management strategy over device exchange.

Level of Evidence: C.

Class IIb

1. It might be reasonable to choose bivalirudin over heparin as an initial agent for intravenous systemic anticoagulation.

Level of Evidence: C.

2. In the heightened thrombotic proclivity of patients with recurrent pump thrombosis, exchange to HeartMate 3 from prior device may be reasonable.

Level of Evidence: C.

3. In patients with confirmed device thrombosis, the safety and efficacy of glycoprotein IIb/IIIa inhibitors alone or in conjunction with other anticoagulation has not been established.

Level of Evidence: B.

Acute management of patients who present with a new neurologic event

Ischemic and hemorrhagic strokes are a common serious adverse event following durable mechanical circulatory support (DMCS) and can contribute to significant patient morbidity and mortality.(156) Neurologic events may also be transient or even covert, where diagnosis is made by imaging alone. Patients with acute ischemic stroke are also at risk for transformation to a hemorrhagic stroke. Clinical trials presently use varying definitions to capture neurologic events, which can complicate comparisons of clinical events across trials. In 2020, the STS Intermacs definitions of neurological dysfunction were revised, and these definitions should be used going forward.(1) Definitions include a description of stroke type (Table 3); a classification as patient-, device- or management-related; and a characterization of stroke severity, disability, and recovery (Table 4).

Incidence

Reports from clinical trials, institutional retrospective reviews and large registries illustrate progress in the field of DMCS. Landmark clinical trials for the HeartMate II LVAD report a rate of neurologic complications ranging from 0.03 to 0.09 events per patient year (EPPY). Early reports of the HVAD hydrodynamic flow centrifugal device suggested comparable event rates to HeartMate II axial flow device.(157) However, the ENDURANCE destination therapy trial reported a considerably increased stroke incidence in the HVAD cohort.(158) Incident ischemic stroke occurred in 17.6% of patients supported with an HVAD as compared to 8.1% of patients supported with a HeartMate II, while incident hemorrhagic stroke occurred in 14.9% (HVAD) and 4.0% (HeartMate II) at 2 years of follow-up. Following alteration of HVAD pump design (to include inflow sintering) and anticoagulation, antiplatelet and blood

Table 3 MCS-ARC Neurologic Dysfunction Adverse Event

Type 1	Overt CNS injury: acutely symptomatic brain or spinal cord injury	
Type 1a	**Ischemic stroke**	Sudden onset of neurologic signs or symptoms fitting a focal or multifocal vascular territory within the brain, spinal cord, or retina, that: 1) persist for ≥ 24 hours or until death, with pathology or neuroimaging evidence that demonstrates either: a) CNS infarction in the corresponding vascular territory (with or without hemorrhage); or b) absence of other apparent causes (including hemorrhage), even if no evidence of acute ischemia in the corresponding vascular territory is detected. or 2) Symptoms lasting < 24 hours with pathology or neuroimaging confirmation of CNS infarction in the corresponding vascular territory. Note: when CNS infarction location does not match the transient symptoms, the event would be classified as covert CNS infarction (Type 2a) and a TIA (Type 3a), but not an ischemic stroke. Signs and symptoms consistent with stroke typically include an acute onset of one of the following: focal weakness and/or numbness, impaired language production or comprehension, homonymous hemianopia or quadrantanopia, diplopia, altitudinal monocular blindness, hemispatial neglect, dysarthria, vertigo, or ataxia.For pediatric patients, generalized symptoms such as seizure, irritability, or altered wakefulness may be accepted as confirmation of acute stroke if imaging or pathology demonstrates previously undocumented CNS infarction.
Sub-type 1aH	**Ischemic stroke with hemorrhagic conversion**	Ischemic stroke includes hemorrhagic conversions. These should be sub-classified as Class A or B when an ischemic stroke is the primary mechanism and pathology, or neuroimaging confirms a hemorrhagic conversion. Class A **Petechial (non−space-occupying) hemorrhage:** Petechiae or confluent petechiae within the infarction or its margins, but without a space-occupying effect. Class B **Confluent (space-occupying) hemorrhage:** Confluent hemorrhage or hematoma originating from within the infarcted area with space-occupying effect.
Type 1b	**Symptomatic intracerebral hemorrhage**	Rapidly developing neurologic signs or symptoms (focal or global) caused by an intraparenchymal, intraventricular, spinal cord, or retinal collection of blood, not caused by trauma.
Type 1c	**Symptomatic sub-arachnoid hemorrhage**	Rapidly developing neurologic signs or symptoms (focal or global) and/or headache caused by bleeding into the sub-arachnoid space, not caused by trauma.
Type 1d	**Stroke, not otherwise specified**	An episode of acute focal neurologic signs or symptoms and/or headache presumed to be caused by CNS ischemia or CNS hemorrhage, persisting ≥ 24 hours or until death, but without sufficient evidence to be classified as one of the above (i.e., no neuroimaging performed).
Type 1e	**Symptomatic hypoxic-ischemic injury**	Non-focal (global) neurologic signs or symptoms due to diffuse brain, spinal cord, or retinal cell death (confirmed by pathology or neuroimaging) in a non-vascular distribution, attributable to hypotension and/or hypoxia.
Type 1f	**Symptomatic sub-dural hemorrhage**	An episode of acute focal neurologic signs or symptoms and/or headache accompanied by evidence of bleeding into the sub-dural space.
Type 2	**Covert CNS injury: Acutely asymptomatic brain or spinal cord injury detected by neuroimaging**	
Type 2a	**Covert CNS infarction**	Brain, spinal cord, or retinal cell death attributable to focal or multifocal ischemia on the basis of neuroimaging or pathologic evidence of CNS infarction, without a history of acute neurologic symptoms consistent with the lesion location.
Sub-type 2aH	**Covert CNS infarction with hemorrhagic conversion**	Covert CNS infarction includes hemorrhagic conversions. These should be sub-classified as Class A or B when CNS infarction is the primary mechanism and neuroimaging, or pathology confirms a hemorrhagic conversion. Class A **Petechial (non−space-occupying) hemorrhage** Petechiae or confluent petechiae within the infarction or its margins, but without a space-occupying effect Class B **Confluent (space-occupying) hemorrhage:** Confluent hemorrhage originating from within the infarcted area with space-occupying effect
Type 2b	**Covert CNS hemorrhage**	Neuroimaging or pathologic evidence of CNS hemorrhage within the brain parenchyma, sub-arachnoid space, sub-dural space, ventricular system, spinal cord or retina on neuroimaging that is not caused by trauma, without a history of acute neurologic symptoms consistent with the bleeding location.
Type 3	**Neurologic dysfunction (acutely symptomatic) without CNS injury**	
Type 3a	**TIA**	Transient focal neurologic signs or symptoms (lasting < 24 hours) presumed to be owing to the focal brain, spinal cord, or retinal ischemia, but without evidence of acute infarction by neuroimaging or pathology (or in the absence of imaging)
Type 3b	**Delirium without CNS injury**	Transient non-focal (global) neurologic signs or symptoms (variable duration) without evidence of cell death by neuroimaging or pathology

The association of the neurologic event should be classified as:

- **Patient-related:** (e.g., documentation of previous carotid or cerebrovascular disease, coagulopathy unrelated to surgical technique such as non-adherence with anti-coagulation medication resulting in an inappropriately high level of anti-coagulation, related to illicit drug use, non-adherence with other medications, trauma, associated with sepsis)
- **Management-related:** (e.g., over anti-coagulation or associated with the use of accessory assist device, hypotension or hypertension-related to surgical procedure)
- **Device-related:** (e.g. secondary to pump thrombosis or device malfunction)

Table 4 Classification of Acute Severity, Recovery, and Long-Term Disability

Acute Severity	1. **Mild neurologic dysfunction:** NIHSS 0-5 2. **Moderate neurologic dysfunction:** NIHSS 6-14 3. **Severe neurologic dysfunction:** NIHSS ≥15 **NOTE:** Severity assessment should be performed at the time of diagnosis of any overt CNS injury (Types 1) to ensure accurate classification
Stroke Recovery	**Stroke with complete recovery:** A modified Rankin Score (MRS) at 30-90 days of 0 OR a return to the patient's pre-stroke baseline MRS, in the absence of any ongoing new symptoms due to the stroke.
Stroke Disability	• **Fatal Stroke:** Death resulting from a stroke where the cause of death is attributable to the stroke. • **Disabling stroke:** An MRS ≥2 at 30-90 days with an increase of at least 1 point compared to the pre-stroke baseline. • **Non-disabling stroke:** An MRS <2 at 30-90 days, or ≥2 without an increase of at least 1 compared to the pre-stroke baseline. **NOTE:** Disability assessment applies **only** to subjects with overt CNS injury (Type 1) and should be performed at 90± 14 days after the stroke event.

Abbreviations: CNS, central nervous system; MRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale
(For Pediatric Patients the pediatric NIH SS will be used.)

pressure management, a later report from the ADVANCE cohort including continued access protocol patients reported a reduced ischemic stroke prevalence of 6.8% and a hemorrhagic stroke prevalence 8.4% at 180 days after device implant.(23) From Intermacs ($n = 18,380$ patients), 6-month freedom from first stroke or TIA was 91% in patients on axial flow support vs 86% in patients on HVAD support. By 48 months, the magnitude of difference was less (69% axial flow and 66% HVAD).(159) In the HeartMate3 trial, no difference was found in 6-month stroke rates between HeartMate II and HeartMate3 devices.(136) However, after 180 days, the incidence of stroke was 3.3 times lower in patients on HeartMate 3 support vs HeartMate II.(136) A comparative, single center cohort study was undertaken of patients on HeartMate 3 ($n = 84$) vs HVAD ($n = 163$) support. Stroke free survival at 1 year was 77% for HVAD patients and 84% for HeartMate 3 patients.(160) In a separate analysis of 105 patients on continuous flow LVAD support for 18 months, patients supported with a HeartMate 3 LVAD had a lower incidence of stroke (0%)

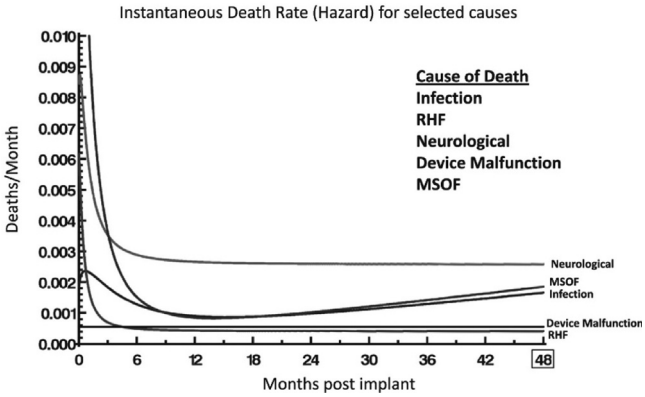

Figure 4 Hazard function curves indicating instantaneous risk of death over time for the major causes/modes of death. LVAD, left ventricular assist device; BiVAD, biventricular assist device; RHF, right heart failure; MSOF, multiple system organ failure. Reproduced with permission from Kirklin et al. (165)

compared with patients support with HeartMate II (26%) and HVAD (40%) devices ($p < .001$).(161) Unadjusted differences were also noted in the 2020 Intermacs annual report.(162) Within the sample of patients on HeartMate 3 and HVAD support, freedom from stroke at 12 months was 93% and 84%, respectively.(162) These data along with comparative, matched survival analyses of HVAD vs HeartMate 3 led to the removal of HVAD from the market in 2021.(162)

Timing of stroke after LVAD implant

Stroke is one of the most common complications during short- and long-term durable LVAD support. While the cumulative hazard for stroke continues to increase after device implant, the instantaneous hazard for stroke markedly varies by time from LVAD operation. In a single institutional retrospective analysis of patients on HeartMate II and HVAD support, the timing of stroke was bimodal with the highest risks immediately postoperatively and increasing again 9 to 12 months later. Of the early strokes, 96% occurred in the first 30 days and 75% in the first 2 weeks.(163) In the 24-month HVAD Endurance study, over 50% of strokes occurred within 180 days of implant.(158)

Mortality and stroke

Stroke is one of the leading causes of death in LVAD patients.(164) The instantaneous risk of stroke-related mortality tends to follow a J-shaped curve, with high initial mortality risk within 1 to 3 months of implant, decreasing thereafter. (165) Cumulatively, stroke is the greatest cause of mortality following LVAD implant.(165) (Figure 4) Strokes of any type (ischemic and hemorrhagic) and strokes of any severity (disabling and nondisabling strokes) are associated with inferior survival compared to patients without stroke.(165, 166)

Risk factors

A number of modifiable and nonmodifiable risk factors are correlated with neurologic complications following LVAD implant. Three risk factors—sex, infection, and hypertension—are emerging as the most important.

Female sex

In a report from INTERMACS, female sex correlated with increased risk of stroke (hazard ratio of 1.52, $p <$ .001). In a separate multivariate analysis, female sex independently predicted of both ischemic and hemorrhagic stroke.(166) Although sex is not a modifiable risk factor, there may be unidentified physiological factors specific to women.

Infection

A series of single center retrospective reports identified the correlation between infection and stroke, especially hemorrhagic stroke.(167-170) In a recent cohort study of LVAD patients with documented infection, 13% developed a stroke, a median of 4 days from the documented infection.(171) The largest studied cohort to date includes 16,597 IMACS patients where infection occurred in 42%. Infected patients had a greater prevalence of stroke (18% vs 11%, $p < .001$), with hemorrhagic stroke being more common. The rate of stroke was numerically highest in patients with VAD-related infections (0.17 events per patient year, EPPY) as compared to those with non-VAD infections (0.15 EPPY) or VAD-specific infections (0.11 EPPY).(172)

Hypertension

Hypertension is associated with increased rates of stroke in the general population and within the subpopulation of patients on LVAD support. In addition to cerebral vascular changes, systemic hypertension increases pump head differential pressure, which can lead to a reduction in flow through the pump and the potential for intrapump or intraventricular thrombus formation. In patients on HVAD support, hypertension (defined as a MAP >85-90 mm Hg) was associated with an increased risk for stroke and pump thrombosis.(158) This correlation led to the development of the Endurance supplemental trial, which demonstrated that patients with targeted BP control to a consensus MAP <85 mm Hg by automated cuff or <90 mm Hg by Doppler experienced fewer neurologic events than that of patients in prior HVAD clinical trials.(23) In a study of stroke patients largely on HeartMate II support, there is also evidence to support targeting for a systolic blood pressure less than 100 mm Hg to reduce stroke risk.(173) Presently, precise targets for BP control specific to each device flow profile have not been identified. BP dichotomization threshold for HVAD patients in the Endurance trial was based largely on expert consensus statements (dichotomized at the 2013 MCS guideline MAP recommendation) and not data distribution, and study data for optimal BP control in patients on HM3 support is presently lacking. A recent analysis of INTERMACS data identified hypotension (MAP ≤75 and SBP <90 mm Hg) as a stronger correlate for increased overall mortality in outpatients on either HeartMate II or HVAD support, but elevated average mean arterial pressures above the sample median MAP (90 mm Hg) and/or SBP (>108 mm Hg) were also associated with increased

mortality and stroke.(12) Thus, in the early postoperative period when arterial lines are often present, it seems reasonable to aim for a measured MAP 75 to 90 mm Hg. Correlation between simultaneous mean arterial pressure obtained from the arterial line, automated cuff, and the Doppler opening pressure may help with interpretation of Doppler values following discharge from the intensive care unit.(174) If automated cuff measurements are used, the mean arterial pressure, rather than systolic or diastolic pressures, should be followed.

Recommendations for BP control and monitoring in the early postoperative period

Class I

1. Arterial line monitoring is recommended early after LVAD implant to allow for accurate BP monitoring.

Level of Evidence: C.

Class IIa

1. To reduce the risk of stroke in hospitalized patients, it is reasonable to target a mean arterial pressure 75 to 90 mm Hg.(12, 23, 173)

Level of evidence: B.

Class III

1. There are no data to support aggressive afterload reduction after LVAD implant. Excessive pharmacologic hypotension (MAP <75 mm Hg) should be avoided.(12)

Level of Evidence: C

Management of neurology events in patients on LVAD support

All patients who develop a new neurologic deficit or sudden severe headache should be quickly assessed by the DMCS team in conjunction with neurologists or the acute stroke team. Neurologic events after DMCS implant include ischemic strokes or transient ischemic attacks, hemorrhagic intracerebral bleeds, subdural and/or subarachnoid bleeds, and seizures. There are no specific recommendations for management of neurologic complications in DMCS patients, but the type and location of the neurologic event and the clinical status of the patient often dictate management. Institutions have adapted internal protocols due to the reality that standard stroke guidelines are based on data where DMCS patients were excluded. Additionally, DMCS patients have unique aberrations in thrombosis and fibrinolysis that must be taken into account. Management of antiplatelet agents and warfarin following a neurologic event is challenging. Again, no data exist for best practice.

For patients who present with acute ischemic stroke, neurovascular intervention is reported to be effective and safe (175) and in one report nearly one-quarter of patients with acute ischemic stroke had a large vessel occlusion amenable to clot retrieval.(163) Unlike the general patient population, use of intravenous t-PA in DMCS patients with acute stroke has been less widely applied due to concerns about increased risk of intracerebral hemorrhage and concomitant use of anticoagulation therapy.(176) Interdisciplinary care with Neurology is advised as permissive hypertension is usually recommended in patients with ischemic stroke to promote cerebral collateral perfusion. Once the acute neurological event has been stabilized, the timing of hypertension control to meet MAP goals of 75 to 90 mm Hg in DMCS patients should be discussed.

Recommendations for the acute management of patients who present with a new neurological deficit

Class I

1. Rapid evaluation of patients with new onset severe headache or new neurologic signs or symptoms is required. This could include a brief history and baseline examination, CT angiography of the head and neck, assessment of coagulation parameters and platelet count, and prompt neurological consultation. Level of evidence: C.

2. In the setting of hemorrhagic stroke, discontinuation or reversal of anticoagulation and discontinuation of antiplatelet therapy is generally recommended unless otherwise advised by the neurological consultant.

Level of Evidence: C.

3. Pump log files should be interrogated for signs of device thrombosis, malfunction, or patient-related power interruption.

Level of Evidence: C.

4. In patients with thrombotic cerebrovascular occlusion, cerebral angiography with intervention should be considered.(163, 175)

Level of Evidence: B.

Class IIa

1. Assessing for a source of thrombus in the setting of an embolic stroke is reasonable. This may include trending of patient INRs, chart review for cessation of anticoagulation, carotid ultrasound, transesophageal echocardiography, or defibrillator interrogation as clinically indicated.

Level of Evidence: C.

2. In patients with cerebrovascular event, placement of an arterial line for continuous blood pressure measurement and management is reasonable.

Level of Evidence: C

Class IIb

1. Selective use of thrombolytics in the setting of thrombotic stroke without hemorrhage on imaging may be considered.

Level of Evidence: B.

Class III

1. Routine use of an interventional radiologic approach to managing thrombotic strokes is not recommended.(163, 175)

Level of Evidence: B.

2. The routine administration of thrombolytic therapy is not recommended without appropriate imaging documenting absence of intracerebral hemorrhage and a discussion of risks and benefits of thrombolytic therapy with neurology consultants.

Level of Evidence: C.

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

Class 1

1. Formal stroke rehabilitation in consultation with a neurologist is recommended.

Level of Evidence: B.

2. Close monitoring of anticoagulation in patients with a recent embolic or hemorrhagic stroke is recommended.

Level of Evidence: C.

3. Long-term control of blood pressure is recommended once patients have recovered from the acute neurologic event.

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 anticoagulation in patients with hemorrhagic stroke should be done in consultation with a neurologist or neurosurgeon.

Level of Evidence C.

Class IIa

1. To prevent recurrent stroke in DMCS patients, it is reasonable to target a mean arterial pressure 75 to 90 mm Hg, with avoidance of excessive pharmacology hypotension (MAP <75 mm Hg). Collaboration with Neurology consultative services is recommended before escalation of antihypertensive therapies.(12)

Level of Evidence: C.

Class IIb

2. In patients with embolic strokes, data are insufficient to support or refute adjustment in antiplatelet therapy dosing or regimens. It may be reasonable to consider escalation of antiplatelet therapy in patients who have thrombotic events with documented compliance to warfarin and aspirin therapies.

Level of Evidence C.

The association of the neurological event should be classified as:

- **Patient related**: (e.g., documentation of previous carotid or cerebrovascular disease, coagulopathy unrelated to surgical technique such as noncompliance with anticoagulation medication resulting in inappropriately high level of anticoagulation, related to illicit drug use, noncompliance with other medications, trauma, associated with sepsis).
- **Management related**: (e.g., overanticoagulation or associated with use of accessory assist device, hypotension or hypertension related to surgical procedure).
- **Device related**: (e.g., secondary to pump thrombosis or device malfunction).

Evaluation and treatment of MCS-related infections

Infection is an important contributor to morbidity and mortality after DMCS implant. In the 2020 Intermacs annual update, 30% of patients undergoing LVAD support had a major infection by 1 year of implant.(177) Infections after LVAD should be categorized per the recommendations of the ISHLT consensus document and the MCS Academic Research Consortium: MCSD-specific, MCSD-related, and non-MCSD infections.(1, 57) MCSD-specific infections involve the pump and/or cannula, pump pocket, or the driveline, while MCSD-related infections occur in patients without MCSD but may be more common in those with an LVAD. MCSD-related infections include infective endocarditis, bloodstream infections, and mediastinitis. Non-MCSD infections are all other infections occurring after LVAD implant (e.g., urinary tract infections, pneumonia). The occurrence of infection after LVAD implant is correlated with increased frequencies of stroke and may increase a patient's risk of pump thrombosis. In a study of 16,597 patients on continuous flow LVAD support, patients who developed an infection had a prevalence of stroke of 18% compared with those without a history of infection. One-year survival in those with MCSD-specific vs MCSD-related vs non-MCSD infections was 87%, 71%, and 72%, respectively ($p < .001$).(172) The most common causes of infections in DMCS patients are *Staphylococcus aureus* and *Pseudomonas aeruginosa*. Prompt recognition and treatment of infection is critical for ensuring optimal outcomes after MCS.

Recommendations for the work-up of suspected infection

Class I

1. Basic laboratory testing, including a complete blood count with differential, serum creatinine, C-reactive protein, lactate dehydrogenase, INR, and urinalysis, is recommended in patients with a suspected DMCS infection.

Level of Evidence: C.

2. At least 3 sets of blood cultures over 24 hours should be obtained in patients with a suspected DMCS infection, even when afebrile.

Level of Evidence: C.

3. For those with a suspected driveline infection, obtaining a sample for Gram stain and bacterial culture is recommended. Fungal cultures should be obtained in those with

evidence of recurrent or persistent signs of infection and negative bacterial cultures.

Level of Evidence: B.

4. When clinically indicated, aspirate from other potential sources, as dictated by presenting symptoms and examination, is recommended.

Level of Evidence: A.

5. In those with concern for MCS-specific infection, CT imaging of the chest, abdomen, and pelvis should be performed to characterize the extent of infection.

Level of Evidence: C.

6. In those with concern for DMCS-specific infection, transesophageal echocardiogram to examine valves and other intracardiac devices is recommended.

Level of Evidence: C.

Class IIa

1. Erythrocyte sedimentation rate or serial C-reactive protein should be considered.

Level of evidence: C.

2. In those with infection isolated to the driveline, ultrasound of the exit site may be useful for characterizing depth and loculation of infection. However, patients with concern for deep infections should have the full extent of the driveline and the pump examined with CT.

Level of Evidence: C.

Class III

1. In patients with driveline cellulitis or dermatitis and no clinical, laboratory or microbial evidence of deeper infection, routine CT of the chest, abdomen, and pelvis or transesophageal echocardiogram are not recommended.

Level of Evidence: C.

Classifying infections in patients on DMCS

Class I

1. The ISHLT consensus document for MCS infection nomenclature should be used to classify infections as MCS-specific, MCS-related, or non-MCS infections.(57)

Recommendations for management of MCSD-specific/related infection

Class I

1. Once an infection is suspected, empiric antimicrobial therapy against Staphylococcus sp. and Pseudomonas aeruginosa (most common etiologies of MCS-related and -specific infections) should be started promptly while microbiological data are pending.(178, 179)

Level of Evidence: B.

2. Patients with DL infection limited to the superficial fascia without systemic signs of sepsis, should be treated with pathogen-specific antibiotic course for 2 weeks.(57)

Level of Evidence C.

3. Patients with deep DL infection (infection deeper to subcutaneous fascia) or pocket/pump/cannula infection should be hospitalized for systemic antibiotics and consideration for surgical drainage (with or without vacuum-assisted closure, VAC).(57, 180, 181) Systemic pathogen-specific antibiotic therapy should be continued for 6 to 8 weeks followed by long-term antibiotic suppression (detailed recommendations in 2017 ISHLT consensus).(57) Definitive cure consists of device explant with consideration for heart transplant, if appropriate.(182-184)

Level of Evidence: C.

4. Patients with recalcitrant infection should be considered for transplant listing (as applicable) or device exchange. It is important to consider removal of all hardware (including defibrillators or pacemakers) at the time of device exchange or transplant.

Level of Evidence: C.

Recommendations for inpatient treatment of arrhythmias

This section of the guidelines will be divided into management of arrhythmias that occur in the immediate postoperative period and those that occur later during DMCS. Clinical trials to inform arrhythmia management in the DMCS population are scarce. The outlined recommendations are formulated largely from observational data and expert consensus.

Management of postoperative ventricular arrhythmias in the LVAD patient

Ventricular arrhythmias (VAs) occur in 20% to 50% of LVAD recipients.(185, 186) The risk for VAs is highest in the early postoperative period, decreasing over time.(185, 187) While VADs provide variable degrees of hemodynamic support during arrhythmia events, VA should be promptly treated to reduce the risk of patient decompensation.(188) A history of VA before LVAD is highly correlated with the development of post-LVAD VAs.(185, 189, 190) A number of factors likely contribute to the increased frequency of arrhythmias the immediate postoperative period, including preexisting substrates for VAs, a high postoperative adrenergic state, electrolyte shifts, myocardial disruption from surgical cannula placement, and use of intravenous inopressor support.(191, 192) Prolongation of QTc and altered refractoriness have also been implicated.(193)

Interventions to reduce the risk of arrhythmia development in the early postoperative period should be undertaken. Interventions include maintenance of electrolyte levels, de-escalation of inopressor support as quickly as safely feasible, reduction of wall stress through diuresis, pain control, treatment of hypoxia, and/or increasing or decreasing LVAD speed to optimize ventricular filling while simultaneously avoiding suction. LVAD interrogation and echocardiography also should be undertaken to assess for the occurrence of suction events and to visualize LV inflow cannula position, respectively.(192) In patients who are suctioning in the setting of hypovolemia and/bleeding, prompt fluid resuscitation is warranted. A reduction in the LVAD speed, while transiently beneficial, may be poorly tolerated in the long-term. Invasive hemodynamic and echo-guided LVAD speed optimization may be helpful in such circumstances. For patients on chronic amiodarone therapy or previously treated with amiodarone, assessing

thyroid function is important for ensuring absence of amiodarone-related thyroid toxicity.(194)

Ventricular arrhythmias of short duration are often tolerated in patients on LVAD support.(188, 195) In general, if cardiac index or indexed device flows remains above 2 L/min/m^2, mean arterial pressure is >65 to 70 mm Hg, and end organ function is preserved, urgent cardioversion may be delayed in favor of less aggressive interventions. In hemodynamically stable patients, an ECG should be obtained to collect data on VA morphology. Patient optimization in conjunction with an intravenous antiarrhythmic (such as amiodarone) often leads to chemical cardioversion and/or may improve the chances of success of antitachycardia pacing or cardioversion. Patients with signs of hemodynamic instability or those with prolonged VAs should undergo electrical cardioversion to avoid end organ compromise or LVAD thrombosis. Repeated cardioversions have been associated with acute reduction in right ventricular function (196) but LVAD dysfunction directly attributed to electrical cardioversion has not been reported.

In patients with refractory or malignant (defined as >3 bouts of sustained (30 sec) VT in 24 hours) ventricular tachycardia after LVAD, re-intubation and sedation may assist in reducing adrenergic arrhythmia drive. A higher threshold for electrical cardioversion in those with an ICD in place can be considered to prevent draining of the ICD battery and to reduce patient physical and mental discomfort from repetitive shocks. Patients with refractory, hemodynamically unstable ventricular tachycardia may require catheter ablation or transplant list upgrading, as applicable. (197, 198) Limited data may support a role for neuraxial modulation with thoracic epidural anesthesia or a stellate ganglion block in patients who fail the other therapeutic trials above.(199-201)

Recommendations for the management of ventricular arrhythmias in LVAD inpatients

Class I

1. Patients with new ventricular arrhythmias after LVAD implantation should be promptly evaluated for hemodynamic stability using available hemodynamic monitoring.

Level of Evidence: C.

2. In LVAD patients with hemodynamic instability (as evidenced by acute kidney injury, low MCS flows, signs of new or worsening RV failure, symptomatic hypotension or hypoxia) due to new onset ventricular arrhythmia, urgent cardioversion/defibrillation and/or antitachycardia pacing is recommended.

Level of Evidence: C.

3. Patients with new ventricular arrhythmias post-LVAD implantation should undergo LVAD interrogation and echocardiography to assess for the possibility of suction events.

Level of Evidence C.

Class IIa

1. In patients who are hemodynamically stable in a new ventricular arrhythmia post-LVAD, it is reasonable to try electrolyte optimization and intravenous antiarrhythmic therapy before electrical cardioversion. An ECG should be obtained to capture VT morphology. Prolonged (>30 minutes) VT/VF in patients on isolated LVAD support should generally be avoided regardless of hemodynamic stability.

Level of Evidence: C.

2. Patients with refractory, hemodynamically unstable ventricular tachycardia may require catheter ablation. Catheter ablation should be performed by an electrophysiologist with experience treating DMCS patients.

Level of Evidence: C.

Management of postoperative atrial arrhythmias in the LVAD patient

Atrial fibrillation (AF) is common comorbidity in LVAD recipients. In the MOMENTUM 3 clinical trial, 42% of patients had a preoperative history of atrial fibrillation. (136) New atrial arrhythmias after LVAD implant are also frequent, with AF being the most common.(202) If hemodynamic instability is present, cardioversion can be performed. For patients who are hemodynamically stable, cardioversion can often be delayed until further hemodynamic optimization is achieved as discussed above for ventricular arrhythmias. Intravenous amiodarone can provide some degree of rate control and can lead to chemical cardioversion. If amiodarone is used for the indication of AF only, this can often be discontinued after 6 to 12 weeks if remission of AF is achieved. A similar approach can be implemented for atrial tachycardia and atrial flutter in the immediate postoperative period.

Recommendations for the management of atrial arrhythmias in LVAD inpatients

Class I

1. In DMCS patients who develop sudden hemodynamic instability due to new atrial arrhythmias, synchronized cardioversion should be performed.

Level of Evidence: C.

Class IIa

1. In patients who are hemodynamically stable in a new atrial arrhythmia post-LVAD, it is reasonable to attempt volume optimization and medication adjustments before a trial of chemical or electrical cardioversion.

Level of evidence: C.

Outflow graft obstruction

Outflow graft obstruction is an increasingly recognized device-related complication and can occur early or late after implantation.(203-205) Patients frequently present with right heart failure and with a gradual or abrupt reduction in LVAD flows. Outflow obstruction can be secondary to technical issues such as graft kinking or twisting or can result from graft thrombosis or external

compression. This latter complication has been shown to be the most common cause and can be precipitated by externally wrapping the outflow graft which allows blood and proteinaceous debris to accumulate. (203) With respect to the HeartMate III LVAD, the original pump design allowed the outflow graft to swill freely at the attachment to the pump housing. This resulted in a small percentage of patient who developed an obstruction caused by twisting.(206) A design modification has been made which now locks the outflow graft into the desired orientation and outflow graft twisting is no longer being reported. Imaging is critical to identify potential causes and corrective options (See TF4 Cardiac Imaging in the Postoperative Period).

While surgical correction of outflow obstruction is the definitive treatment, surgical morbidity can be high, especially in elderly patients. Accumulating reports have demonstrated the feasibility of percutaneous approaches to alleviate select patients who present with obstruction. (203, 204, 207)

Recommendations for management of outflow graft obstruction

Class I

1. Surgical intervention is indicated in patients with documented, hemodynamically significant outflow graft obstruction.

Level of Evidence: C

Class IIb

1. Percutaneous treatment approaches are reasonable to consider in select patients with documented, hemodynamically significant outflow graft obstruction.

Level of Evidence: B

Management of device failure and malfunction due to nonthrombotic complications

While clinical trial definitions of device malfunction can vary, a device malfunction is generally considered present when any component of the DMCS fails to operate as specified in the manufacturer Instructions for Use. (208) Device malfunction can be categorized as major or minor in occurrence. Minor device malfunction may occur when external device components (e.g., controller, batteries) fail to exhibit normal function, often requiring repair or replacement. While minor device dysfunction by definition does not lead to death or need for surgical replacement and are often omitted from clinical trial and Registry reports, they can negatively impact quality of life through alarms, patient anxiety, and need for unscheduled visits. In a multicenter study of 213 patients on Heartmate II and HVAD support, device dysfunction during LVAD support occurred in 51% and 36% of patients, respectively, while 11% and 3.8% has more than 4 events during support.(209) Of the 30% were due to controller issues and 19% were due to battery dysfunction.(209) Major device dysfunction occurs when one or more components of the LVAD leads to inadequate cardiac support, leading to death or prompting urgent transplant, pump exchange, or driveline repair.(208) Pump thrombosis is a common cause of major device dysfunction and the treatment and management is discussed above. Power failure, most commonly due to driveline fracture, is another form of major device dysfunction that constitutes an emergency with the potential for pump stoppage.

Education of patients, caregivers, and medical staff about device alarms is important for achieving a quick diagnosis and intervention. Until widespread technology is available to monitor device parameters remotely, triaging LVAD alarms requires a clinical history and review of controller/device data. While some causes for minor device dysfunction can be handled over the phone or at clinic follow-up, major device alarms require in person evaluation by trained LVAD staff. As such, patients should be directed to their local emergency room to ensure stability and then transported back to the implanting center for evaluation and treatment.

After ensuring patient clinical stability, all external components of the device should be examined. The controller should be interrogated for alarms frequency, alarm type, and duration. If an interruption to power supply is noted, a careful inspection of device connections for signs of corrosion, debris, or damage should be undertaken, and security of connections should be noted. The driveline should be followed from abdominal exit to controller insertion and the external sheathing should be inspected for compromise. Batteries should demonstrate maintenance of charge and devices with battery clips should demonstrate secure fixation of the batteries and battery contacts should be clean. If a driveline fault is suspected, the driveline should be imaged with X-ray in its entirety. Urgent notification of the manufacturer is recommended for guidance on diagnosis and to allow tracking of equipment malfunction. While external driveline fractures may be repaired by the manufacturer, the definitive therapy for other major causes of major device dysfunction is pump exchange or cardiac transplant in eligible patients. Patients who are not candidates for reoperation may benefit from palliative care consultation with or without inotrope support.

Recommendations for management of device failure and malfunction

Class I

1. Pump stoppage of a continuous-flow MCSD constitutes a medical emergency, and the patient should be assessed for circulatory stability and then rapidly transported back to the implanting center or another expert DMCS center for treatment.

Level of Evidence: C.

2. Definitive therapy for major device dysfunction that cannot be resolved with external driveline repair is surgical pump exchange or transplant as clinical stability allows.

*Level of evidence: **C.***

3. Patients with a functioning pump, but with alarms or changes in parameters that suggest the pump is at risk for electrical or mechanical failure should also be transferred

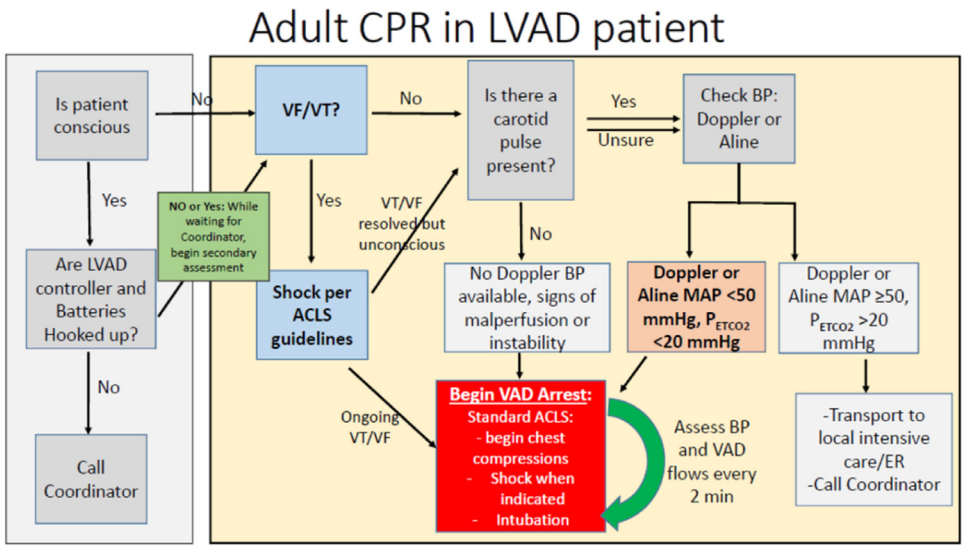

Figure 5 Adult CPR in LVAD patients. ACLS, advanced cardiovascular life support; BP, blood pressure; ER, emergency room; MAP, mean arterial pressure; VF, ventricular fibrillation; VT, ventricular tachycardia.

urgently to the implanting center for evaluation and management.

Level of Evidence: C.
Class IIa
1. In patients with a malfunctioning MCS device and evidence of malperfusion, it is reasonable to use inopressor or ECMO support until a definitive plan is established.

Level of Evidence: C.
Class IIb
1. For patients who are unable to undergo surgery, percutaneous occlusion of the outflow cannula might be considered to halt the backflow of blood through the valveless outflow cannula as a stabilizing maneuver.

Level of Evidence: C.
2. For patients who are unable or unwilling to undergo surgery, inotrope support might be considered for palliation.
Level of Evidence: C.

Recommendations for management of the MCS patient during noncardiac procedures: Moved to Task Force 5

Managing MCS patients with cardiopulmonary arrest

In-hospital cardiopulmonary arrests are not uncommon in the DMCS patient population. In a single center study of 111 LVAD patients, cardiopulmonary arrest occurred in 14%, accounting for 4% of all hospital arrests during the period of study.(210) LVAD patients are more likely to experience delays in initiation of cardiopulmonary resuscitation (CPR) and LVAD patients with delayed CPR suffer higher mortality.(210) Common causes for delayed or insufficient cardiopulmonary resuscitation in LVAD patients include difficulty assessing blood pressure and/or heart rate, difficulty assessing oxygenation, unfamiliarity with a resuscitation algorithm for MCS patients, and concerns that chest compressions may dislodge or damage device components. In patients on total artificial heart support who have evidence of hypoperfusion, chest compressions will provide no benefit and are more likely to inflict harm. Adequate data on the clinical benefit and safety of performing chest compressions during cardiopulmonary resuscitation (CPR) of patients on LVAD support are lacking. In patients on isolated LVAD support in cardiac arrest with evidence of malperfusion, the benefit of chest compressions likely outweighs the risks of device and bleeding complications inflicted during CPR.(211-213) Given the complexity of assessing DMCS patients in extremis, development of hospital resuscitation protocols and education of hospital first responders is critical for DMCS centers.

Figure 5 depicts the critical elements of evaluation and management of the unstable DMCS patient. The first step is assessing for adequacy of oxygenation and perfusion. Assessing perfusion and oxygenation in the unstable DMCS patient is multifaceted and is best and most rapidly achieved using more than one DMCS trained first responder. Patient mentation, skin color, and capillary refill are important in assessing adequacy of systemic perfusion in DMCS patients. Even in hemodynamically stable patients, first responders should be aware that many patients on continuous flow LVAD and biventricular support do not have a palpable radial or femoral pulse and pulse oximetry readings can be erroneous. Total artificial heart (TAH) patients should have a palpable radial or femoral pulse and pulse oximetry is usually accurate. Next, evidence of DMCS function should be assessed by listening for mechanical sounds (an LVAD hum or TAH pulsation) over the chest. Absence of flow on auscultation or on the device controller/monitor should prompt assessment of the DMCS device and device power connections.

An accurate assessment of blood pressure is important for managing the unstable DMCS patient. In most patients

with or without DMCS support, adequate end organ perfusion is usually achieved with a MAP ≥70 mm Hg. The absence of a palpable pulse or blood pressure measured by automatic cuff and/or via manual sphygmomanometer in patients on continuous flow LVAD support are not reliable indicators of patient malperfusion. Unstable LVAD patients without arterial line pressure availability should have rapid blood pressure assessment by Doppler. To this end, it is vital to have Dopplers readily available for first responder teams managing hospitalized DMCS patients. Given the complexities with assessing LVAD patients in distress, waveform capnography may also be a useful surrogate measure of systemic perfusion. Individuals with adequate cardiac output and ventilation should have a P_{ETCO2} of 35 to 40 mm Hg on capnography. A P_{ETCO2} <20 mm Hg in an unresponsive, pulseless, LVAD patient with correct intubation signifies a markedly reduced perfusion state (<1.5 L/min in animal models).(212) To this end, an LVAD patient with a P_{ETCO2} <20 mm Hg and/or Doppler opening pressure <50 mm Hg would likely benefit from cardiopulmonary resuscitation and chest compressions (Figure 5).(211, 212) Data are lacking on the use of mechanical CPR devices.

In unstable LVAD patients who are in arrhythmias, defibrillation may be safely performed. Transvenous or epicardial pacing can also be applied in the setting of hemodynamically significant bradyarrythmias or nodal arrest. Electrical cardiac activity is absent in all patients on TAH support. There is no role for defibrillation and/or pacing in the TAH patient population.

Pulmonary resuscitation is performed according to usual guidelines.(212) Due to limited accuracy and precision of pulse oximetry in LVAD and biventricular support patients, arterial blood gas monitoring is recommended in unstable patients.

Recommendations for managing MCS patients with cardiopulmonary arrest

Class I

1. Due to delays identified in initiation of cardiopulmonary resuscitation in DMCS patients, institutional DMCS resuscitation guidelines should be developed for hospitals who directly care for DMCS patients.

Level of Evidence: C.

2. In patients with a continuous flow LVAD, a mean arterial pressure ≥75 mm Hg usually provides adequate tissue perfusion. In patients without an arterial line, use of a Doppler for blood pressure assessment may be required due to the limited accuracy and precision of current automatic blood pressure devices.(211, 212)

Level of Evidence: C.

3. Defibrillation may be safely performed in patients on LVAD support who are in unstable arrhythmias.(210-213)

Level of Evidence: B.

4. Measurement of the partial pressure of end-tidal carbon dioxide (P_{ETCO2}) via waveform capnography can assist in confirming advanced airway placement and in assessing and tracking perfusion in DMCS patients who are mechanically ventilated. A normal P_{ETCO2} is 35 to 40 mm Hg, with lower values suggestive of systemic malperfusion.(211, 212).

Level of Evidence: C.

Class IIa

1. Unless advanced directives state otherwise, cardiopulmonary resuscitation (CPR) with chest compressions is generally advised in unconscious patients on isolated LVAD support without evidence of adequate cardiac perfusion (including a mean arterial pressure <50 mm Hg). There are no data regarding the safety or benefit of chest compressions in LVAD patients with concomitant RVAD support.(210-213)

Level of Evidence: B.

Class IIb

1. It might be reasonable to consider hypothermic protocols in appropriately selected LVAD patients with a GCS <8 who sustain cardiac arrest with return of spontaneous circulation.(211)

Level of Evidence: C.

Class III

1. CPR, defibrillation, and/or pacing are not beneficial in patients on TAH support.(211, 212)

Level of Evidence: C.

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CNS, central nervous system; MRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale.

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Task Force 4:
Inpatient management of patients with MCSDs Summary

2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
Early Postoperative Management	
Postoperative inopressor management for the non-ICU MCS patient	
Treatment of right heart dysfunction in the non-ICU post-operative period: 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.	**Treatment of right heart dysfunction in the non-ICU post-operative period:** Class I: 1. The academic research consortium definition of right heart failure should be used to characterize right ventricular failure after LVAD implant as early acute, early post-implant, or late right heart failure. Level of Evidence C. *(New)* 2. *Continuing approval without change*

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Task Force 4:
Inpatient management of patients with MCSDs Summary

2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
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.	3. In patients with elevated right-sided filling pressures, decongestion is critical to reduce RV wall stress. Intravenous diuretics should be used in non-anuric patients to achieve decongestion. In those with significant renal impairment or oliguria, renal replacement therapy and/or ultrafiltration should be employed as needed to maintain optimal volume status. Level of Evidence C. (*Modified*)
	Class IIa: 1. Inotropes and vasopressors such as dobutamine and epinephrine may assist with RV inotropy while inotropes with pulmonary vasodilatory properties, like milrinone and levosimendan, may be useful for reducing RV wall stress and increasing RV contractility. Level of Evidence B. *(New)* 2. Temporary or Durable RV mechanical support can be useful in carefully selected LVAD patients with evidence of severe RV dysfunction. Level of Evidence B. *(New)* 3. Sequential nephron blockade (e.g. intravenous chlorothiazide or oral metolazone) or use of ultrafiltration can be considered in LVAD patients with elevated right sided filling pressures who are poorly responsive to high dose intravenous loop diuretics. Level of Evidence C. *(New)*
Class IIb: 1. Cardiac glycosides may be used to support RV function. Level of Evidence C.	Class IIb: 1. Cardiac glycosides, such as digoxin, have not been well studied in patients with RV dysfunction but may be a reasonable adjunct to therapy. Level of Evidence C. (*Modified*)
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.	2. For patients with persistent pulmonary hypertension who exhibit signs of RV dysfunction, pulmonary hypertension-specific therapies, such as phosphodiesterase-5 inhibitors, might be considered for acute therapy but their effectiveness remains uncertain. Level of Evidence C. (*Modified*)
3. Pacemaker therapy can be used if the heart rate is not optimal to support hemodynamics. Level of Evidence C.	3. Pacemaker therapy to promote a low-grade tachycardia may be useful if the heart rate is not optimal to support hemodynamics. Level of Evidence C. (*Unchanged*)
Managing hypotension in the non-ICU post-operative period: Class I: 1. A systematic approach to hypotension should be used, as shown in Figure 1. Level of Evidence C.	**Managing hypotension in the non-ICU post-operative period:** Class I: 1. *Continuing approval without change*
Neurohormonal blockade and treatment of hypertension post-MCS implant	
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, b-blocker, hydralazine, nitrates) is preferred for blood pressure management. Level of Evidence C	**Neurohormonal blockade and the treatment of hypertension post-MCS implant:** Class I: 1. Pharmacotherapy with neurohormonal blocking agents (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, angiotensin receptor blocker neprilysin inhibitors, beta-blocker, mineralocorticoid receptor antagonist) is preferred for blood pressure management in durable LVAD patients. Level of Evidence B. (*Modified*) 2. Early neurohormonal blockade should be started in all stable durable LVAD patients to promote ventricular reverse remodeling and myocardial recovery during LVAD support. Level of Evidence B. *(New)* Class IIb: 1. Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control. Data in LVAD patients are lacking and utilization can be extrapolated from studies in other heart failure populations and those with secondary pulmonary hypertension. These medications are limited by data and need for frequent administration due to short half-lives. Level of Evidence C. *(New)*

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
	2. Dihydropyridine calcium channel blockers, centrally acting alpha-2 receptors agonists (clonidine), and peripheral alpha-1 antagonists are third line agents in the management of hypertension in patients on DMCS support. These agents may be considered when first and second line agents are contraindicated or as supplemental therapy in individuals with resistant hypertension. Level of Evidence C. *(New)* **Recommendation for the Management of Pulmonary Hypertension Early after LVAD Implantation *(New)*** Class I: 1. Following extubation, blood gases and patient mentation should be carefully monitored to avoid hypoventilation and/or hypoxia, which can trigger RV failure. Level of Evidence C. *(New)* Class IIb: 1. Pulmonary vasodilator therapies, such as inhaled nitric oxide, oral or intravenous nitrates, epoprostenol or oral phosphodiesterase-5 inhibitors may be considered for acute management of pulmonary hypertension in postoperative patients with elevated pulmonary pressures with close monitoring of left sided filling pressures. Level of Evidence C. *(New)*
Cardiac imaging in the post-operative period	
Echocardiography in the non- ICU post-operative period: 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.	**Echocardiography in the post-operative period:** Class I: 1. Echocardiography is an integral part of determining optimal continuous-flow LVAD pump speed. Common goals include adequate LV unloading with minimization of mitral regurgitation, while simultaneously maintaining the LV septum in the midline. Level of Evidence C. (*Unchanged*) 2. Echocardiography should be used to detect and define causes of partial LV unloading, LVAD complications, and to screen for myocardial recovery. Level of Evidence B. *(New)* Class IIa: 1. Contrast echocardiography should be used to overcome challenges in assessing ventricular size and function, better visualize the inflow cannula inlet, and to screen for intra-cardiac and/or aortic root thrombus in select patients. Level of Evidence B. *(New)*
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.	Class IIb: 1. Post-operatively, the revolutions per minute of continuous-flow pumps may be set low enough to allow for intermittent aortic valve opening, but not at the expense of inadequate LV unloading or end-organ hypoperfusion. It is not known if these observed benefits apply to patients supported by a centrifugal-flow fully magnetically levitated device with an artificial pulse. Level of Evidence B. (*Modified*)
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.	2. Long-term, maintaining intermittent aortic valve opening may reduce the risk of aortic valve fusion and the risk of late aortic valve insufficiency**.** This should not be undertaken, however, at the expense of organ perfusion. Level of Evidence B. (*Modified*)

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
	The use of Computed Tomography in the post-operative period *(New)*
	Class I:
	1. Computed tomography (CT) is useful for detailed visualization of multiple components of the DMCS device, including device inflow cannula, the outflow graft and the driveline.
	Level of Evidence B. *(New)*
	2. When indicated, CT should be used to identify DMCS complications including inflow cannula malposition, outflow-graft kinking or obstruction, cardiac compression, and/or infection.
	Level of Evidence B. *(New)*
	3. CT is recommended prior to device exchange to ensure patency of the outflow cannula and, if a sternal entry is planned, to assess approximation of DMCS components to the sternum.
	Level of Evidence C. *(New)*
	The use of selective angiography in the hospitalized DMCS patient *(New)*
	Class IIa:
	1. Ventriculography with injection of radiopaque contrast into the LV and/or select outflow cannula graft angiography with pressure gradient assessment can be useful to visualize and guide treatment (e.g. endovascular stenting) of outflow graft obstruction in select patients with suspected outflow cannula thrombosis or kinking.
	Level of Evidence B. *(New)*
	2. Selective coronary angiography can be useful to detect and guide treatment of aortic root and coronary clot and/or severe coronary occlusion in select patients with evidence of acute myocardial injury while on LVAD support.
	Level of Evidence C. *(New)*
	The use of Nuclear Imaging in the post-operative period *(New)*
	Class IIb:
	1. Nuclear imaging techniques (including technetium-99m (99mTc)-sestamibi single photon emission computed tomography (SPECT), and nuclear 123I-meta-iodobenzylguanidine (MIBG)) may be considered as an imaging alternative to screen for myocardial recovery in the setting of a non-diagnostic echocardiogram.
	Level of Evidence B. *(New)*
	2. Radiolabeled white blood cell scintigraphy (e.g. WBC SPECT/CT) may be used to evaluate patients with a suspected LVAD infection.
	Level of Evidence B. *(New)*
	The use of FDG Positron Emission Tomography/CT (*New*)
	Class IIb:
	1. 18-fluorodeoxyglucose (FDG) PET/CT may be considered to help identify LVAD-related infection sites (e.g. pump/pump pocket versus isolated driveline versus outflow graft) and to guide treatment and prognosis.
	Level of Evidence B. *(New)*

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
Anticoagulation after DMCS	
Anti-coagulation and anti- platelet therapy post-DMCS: 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.	**Anti-coagulation and anti- platelet therapy post-DMCS:** Class I: *Continuing approval without change.*
Infection prevention post-DMCS therapy:	
Infection prevention post-DMCS therapy: 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.	**Infection prevention post-DMCS therapy:** *Replaced by the new and modified recommendations below* Class I: 1. Development of a standardized post-operative DL management strategy for health care providers and patients/caregivers is recommended to reduce the risk of DL infection. Management strategies should include application of an antimicrobial cleaning solution with sterile or clean technique; application of an occlusive dressing appropriate for the level of DL incorporation; and careful DL fixation. Level of Evidence C. (*Modified*) 2. It is recommended that DL dressing changes are initially performed daily. Once the DL is incorporated/healed, frequency can be reduced to 1-3 times weekly. Local chlorhexidine-based cleansing agent is recommended as first-line agent for cleansing the DL exit site. Level of Evidence C. *(New)* 3. DL stabilization is essential to reduce DL mobility and to aid in tissue healing. It is recommended that DL stabilization be achieved using an abdominal wall DL anchor or fabric binder. Level of Evidence C. (*Modified*) Class IIa: 1. Documentation of the DL appearance with photography and a written description of the driveline to include the presence or absence of erythema, induration, tenderness, drainage or blood as well as the presence or absence of skin incorporation is likely beneficial for longitudinal and interdisciplinary driveline assessment. Level of Evidence C. *(New)* 2. Chlorhexidine has been associated with a sensitivity dermatitis. In those with a chlorhexidine sensitivity, it is reasonable to use betadine as an alternative although betadine is associated with greater risk of infection. Level of Evidence C. *(New)* Class IIb: 1. The addition of a silver or chlorhexidine impregnated patch/gauze to the DL exit site may be beneficial. Direct comparisons between silver impregnated vs. chlorhexidine impregnated dressings are lacking. Level of Evidence C. *(New)* Class III: 1. Antibiotic prophylaxis for greater than 48 hours is not associated with a reduction in SSI. Level of Evidence B (*New*)

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
	2. Routine use of antifungal prophylaxis is not recommended due to low rates of fungal infections with contemporary devices as well as lack of efficacy in previous retrospective series. Level of Evidence B. *(New)* 2. Presence of various drains, catheters, or open chest is not an indication to prolong antibiotic prophylaxis. Level of Evidence C. *(New)*
Optimization of nutritional status: 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.	**Optimization of nutritional status:** Class I: 1. *Continuing approval without change*
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.	2. *Continuing approval without change.*
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.	Class IIb: 1. It is reasonable to monitor pre-albumin and albumin levels for assessment of nutrition risk. Level of Evidence C. (*Modified*)
Education and Assessment of MCS patient and caregiver readiness for discharge	
Health care provider and patient education: Class I: 1. Health care providers should be trained in DMCS therapy with opportunity to attend refresher classes and ongoing assessment of competency. Level of Evidence C.	**Health care provider and patient education:** *In the 2023 updated Guidelines, separate sections on patient education and health care provider education were included. Due to extensive changes, new guidelines are provided for both patient/caregiver education (see below) and health provider education (refer to Task Forces 5 and 9).*
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 successfully discharging a MCS patient: 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 DMCS patient is recommended. Level of Evidence C.	**Patient and caregiver education:** *Replaced by the new and modified recommendations below* Class I: 1. Patient and caregiver education should be initiated shortly after surgery and reinforced by the multi-disciplinary DMCS team. Level of Evidence C. (*Modified*) 2. Educational strategies should employ written, verbal and hands-on methods. Level of Evidence C. (*Modified*) 3. Patients and caregivers should receive education while inpatient on daily DMCS management and normal device parameters (ie speed, power, and flows) and should be advised on all parameters for abnormal values or alarms. Level of Evidence C. (*Modified*) 4. Patients and caregivers should receive education while inpatient about signs and symptoms of common complications (e.g. stroke, gastrointestinal bleeding, driveline infection) during device support. Level of Evidence C. *(New)* 5. DMCS equipment should be labelled with the DMCS center's emergency contact number and patients and caregivers should demonstrate knowledge on who contact should DMCS urgencies arise in the outpatient setting. Level of Evidence C. *(New)*

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
	6. Patients and designated caregivers should demonstrate safe driveline management, including driveline cleansing, fixation, and monitoring according to institutional protocol. Level of Evidence C. *(New)* 7. It is recommended that patients and key caregivers receive annual re-education in the outpatient setting on device and driveline management and signs and symptoms of key complications. Level of Evidence C. *(New)* Class IIb 1. It may be beneficial to initiate device-specific education prior to surgery with patients and/or care givers. Level of Evidence C. *(New)*
Health care-provider and medical support service education:	**Health care-provider and medical support service education:** *Moved to Task Force 9: Section on center quality metrics, outcomes, volume and staffing*
Documentation of DMCS Parameters:	
Documentation of device parameters: Class I: 1. DMCS parameters should be recorded in the medical chart at regular intervals with established criteria for ranges outside of which physician should be notified Level of Evidence C.	**Documentation of device parameters:** Class I: 1. DMCS parameters (ie flow, power, pump speed) should be recorded in the medical record at regular intervals with established parameters which require physician notification. Level of Evidence C. *(Unchanged)*
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. 3. Changes in parameters outside of normal ranges should be thoroughly evaluated and treated appropriately. Level of Evidence C.	**Device monitoring:** *Replaced by the new and modified recommendations below* Class I: 1. Changes in parameters outside of normal ranges should be thoroughly evaluated and treated appropriately. Level of Evidence B. (*Modified*) 2. It is critical that advanced heart failure specialists, DMCS coordinators, and cardiac surgeons and advanced practitioners involved in regular DMCS patient care understand device specific readings, response to device alarms, and maintain competency in DMCS device interrogations. Level of Evidence C. (*Modified*)
Psychological and psychosocial considerations for patients with durable MCSD	
Psychosocial support while hospitalized post-MCSD implantation: Class I: 1. Routine support should be available from social workers, psychologists, or psychiatrists as patients and families adjust to life changes after DMCS. 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.	**Psychosocial support while hospitalized post-MCSD implantation:** *Replaced by the new and modified recommendations below* Class I: 1. Routine psychosocial support for both patients and designated caregivers should be available from social workers, nurses, and other members of the team, with further resources available (i.e. palliative care, spiritual care) during adjustment to life changes after DMCS. Level of Evidence B. (*Modified*) 2. Routine surveillance for psychiatric symptoms (i.e. depressive symptoms, anxiety) should be performed with referral to specialists (i.e. social work, psychology, and/or psychiatry) for further assessment, interventions, and follow-up as needed. Level of Evidence B. (U*nchanged*) Class IIa: 1. Hearing from other DMCS patients can be useful and allows DMCS candidates and caregivers the opportunity to share fears, ask questions, and to glean practical coping strategies. Level of Evidence C. *(New)*

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
Inpatient DMCS care by the multidisciplinary team:	
Inpatient DMCS care by a multidisciplinary team: Class I: 1. A multidisciplinary team led cooperatively by cardiac surgeons and cardiologists and composed of sub- specialists (ie, palliative care, psychiatry, and others as needed), DMCS coordinators, and other ancillary special- ties (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.	**Inpatient DMCS care by a multidisciplinary team:** Class I: 1. An interdisciplinary team led cooperatively by cardiac surgery and advanced heart failure cardiology and composed of subspecialty services integral to DMCS care (e.g. palliative care, psychiatry, critical care intensivists, social work, occupational and physical therapy, pharmacy) and DMCS coordinators is requisite during the inpatient management of DMCS patients. Level of Evidence C. (*Unchanged*) Class IIa 1. The regular use of interdisciplinary rounds can be beneficial for improving inter-team communication between specialties, developing a patient-centric care plan, and organizing patient education and discharge needs. Level of Evidence B. *(New)*
MANAGEMENT OF INPATIENT COMPLICATIONS DURING MCS SUPPORT	
Management of anti-coagulation and anti-platelet therapy for patients who present with evidence of bleeding:	
Management of anti- coagulation and anti-platelet therapy for patients who present with gastrointestinal bleeding: 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 anticoagulation and anti-platelet therapy is being withheld or the dose reduced. Level of Evidence C.	**Management of anti- coagulation and anti-platelet therapy for patients who present with evidence of bleeding:** Class I: 1. *Continuing approval without change*. 2. Anticoagulation should be reversed in the setting of an elevated INR and life-threatening bleeding. Level of Evidence C. (*Modified*) 3. *Continuing approval without change*. 4. The patient, device parameters, and laboratory markers of hemolysis should be carefully monitored while anticoagulation and antiplatelet therapy are being withheld or dose reduced. Level of Evidence C. (*Modified*) Class IIa: 1. Individuals with acute anemia who are clinically stable and without deficit may be monitored with cessation of anticoagulation without need for urgent INR reversal. Level of Evidence C. *(New)*
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 colonoscopy and/ or upper endoscopy evaluation are 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, anticoagulation and anti-platelet therapy can be reintroduced with careful monitoring. Level of Evidence C.	**Evaluation and management of patients who present with a first episode of mucocutaneous bleeding:** *Replaced by the new and modified recommendations below* Class I: 1. Patients presenting with unexplained anemia and/or concerns for mucocutaneous bleeding after DMCS should have an examination of the nasopharynx and stool should be assessed for signs of visible or occult blood Level of Evidence C. *(New)* 2. Patients with concerns for a gastrointestinal source of blood loss should be managed in consultation with the Gastroenterology team and a colonoscopy and/or upper endoscopic evaluation should be undertaken in those experiencing their first gastrointestinal bleeding event. Level of Evidence C. (*Modified*) 3. Once the initial mucocutaneous bleeding has resolved, anticoagulation and anti-platelet therapy should be reintroduced with careful monitoring of patient hemoglobin and stool. Level of Evidence C. (*Modified*) Class IIa: 1. If colonoscopy and/ or upper endoscopy evaluation are negative, evaluation of the small bowel with enteroscopy should be considered. Level of Evidence C. *(New)* 2. In the setting of persistent bleeding and a negative endoscopic evaluation, it is reasonable to obtain a tagged red blood cell scan, capsule endoscopy, or angiography. Level of Evidence C. (*Modified*)

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
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.	**Evaluation and management of patients who present with recurrent episodes of gastrointestinal bleeding:** *Replaced by the new and modified recommendations below* Class I: 1. The patient, the device and markers of hemolysis should be carefully monitored when anticoagulation and antiplatelet therapy have been reduced or discontinued due to recurrent mucocutaneous bleeding. Level of Evidence C. (*Modified*) Class IIb: 1. Repeated endoscopic evaluation may be reasonable in DMCS patients with recurrent gastrointestinal bleeding episodes, especially if prior therapeutic targets were identified. However, in patients with recurrent negative endoscopic evaluations, the utility and benefit of repeated endoscopy and/or angiography is likley low. Level of Evidence C. *(New)* 2. In the setting of recurrent mucocutaneous bleeding with no identified source or a source that is not amenable to therapy, it may be reasonable to lower warfarin anticoagulation goals or amend antiplatelet therapy. Adjustments should be reevaluated in the context of bleeding severity, pump type, and complication history to derive an individualized patient risk:benefit ratio. Level of Evidence C. *(New)* 3. Angiotensin converting enzyme inhibitors and angiotensin receptor blockers may be beneficial in reducing the incidence or recurrence of GIB. Level of Evidence B. *(New)* 4. The use of depot octreotide may be considered in patients with recurrent GI bleeds. Level of Evidence B. *(New)* 5. In patients with recurrent mucocutaneous bleeding, the usefulness of digoxin, thalidomide and/or fish oil pharmacotherapy has not been established. Level of Evidence C. *(New)* Class III: 1. While low pulse pressure during DMCS support is associated with AVM development, bowel wall ischemia, and mucocutaneous bleeding, the effectiveness of pump speed reduction in patients on continuous flow pumps in reducing bleeding has not been well established and may be harmful. Level of Evidence C. (*Modified*)

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
Diagnosis and Management of Device Thrombosis	
Recommendations for the diagnosis of device thrombosis: *(Not addressed in 2013)*	**Recommendations for the diagnosis of device thrombosis:** Class I: 1. In patients with suspected device thrombosis, hospital admission for expedited assessment is recommended. Level of Evidence C. *(New)* 2. Prompt patient evaluation and serial examinations are imperative for detecting and managing patient hypoperfusion related to pump dysfunction. Level of Evidence C. *(New)* 3. The initial evaluation of suspected device thrombosis should include device interrogation with manufacturer log file analysis to assess pump parameters changes over time. Level of Evidence B. *(New)* 4. The initial evaluation of suspected device thrombosis should include laboratory tests (lactate dehydrogenase, hemoglobin, and plasma free hemoglobin) to assist in the diagnosis of intravascular hemolysis and hemoglobinuria (urinalysis) and to detect end-organ dysfunction. Level of Evidence B. *(New)* 5. The initial evaluation of suspected device thrombosis should include an echocardiogram to assess for LV unloading with and without speed adjustment (i.e., RAMP study). Level of Evidence B. *(New)* 6. In patients with a high suspicion of device thrombosis, CT angiogram to evaluate the outflow graft is recommended. Level of Evidence C. *(New)* Class IIa: 1. In patients with clinical signs of heart failure, right heart catheterization with or without pump speed adjustment to assess LV and RV unloading should be considered to evaluate suspected device thrombosis and to assist in the management of heart failure. Level of Evidence C. *(New)* Class IIb: 1. Left heart catheterization for assessment of patency of the outflow graft can be considered in suspected device thrombosis. Level of Evidence C. *(New)*
Recommendations for the management of device thrombosis: (Not addressed in 2013)	**Recommendations for the management of device thrombosis:** Class I: 1. Initial management of patients with confirmed device thrombosis should include intravenous systemic anticoagulation with heparin. Level of Evidence C. *(New)* 2. In patients with confirmed device thrombosis who are candidates for surgery, pump exchange is the definitive therapy. Level of Evidence B. *(New)* Class IIa: 1. In patients with confirmed device thrombosis who are hemodynamically stable and expected wait time for heart transplant is short, it may be reasonable to defer the pump exchange for urgent transplantation. Level of Evidence C. *(New)* 2. In carefully selected patients supported by a hydrodynamic centrifugal pump with confirmed device thrombosis, systemic or intraventricular thrombolytic therapy can be considered as an initial management strategy over device exchange. Level of Evidence C. *(New)*

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
	Class IIb: 1. It might be reasonable to choose bivalirudin over heparin as an initial agent for intravenous systemic anticoagulation. Level of Evidence C. *(New)* 2. In the heightened thrombotic proclivity of patients with recurrent pump thrombosis, exchange to HeartMate 3 from prior device may be reasonable. Level of Evidence C. *(New)* 3. In patients with confirmed device thrombosis, the safety and efficacy of glycoprotein IIb/IIIa inhibitors alone or in conjunction with other anticoagulation has not been established. Level of Evidence B. *(New)*
Blood pressure monitoring for stroke mitigation	
Recommendations for BP control and monitoring in the early postoperative period: (Not addressed in 2013)	**Recommendations for BP control and monitoring in the early postoperative period:** Class I: 1. Arterial line monitoring is recommended early after LVAD implant to allow for accurate BP monitoring. Level of Evidence C. *(New)* Class IIa: 1. To reduce the risk of stroke in hospitalized patients, it is reasonable to target a mean arterial pressure 75-90 mmHg. Level of Evidence B. *(New)* Class III: 1. There are no data to support aggressive afterload reduction after LVAD implant. Excessive pharmacologic hypotension (MAP <75 mmHg) should be avoided. Level of Evidence C. *(New)*
Acute management of patients who present with a new neurologic event:	
Acute management of patients who present with a new neurologic deficit: 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.	**Acute management of patients who present with a new neurologic deficit:** *Replaced by the new and modified recommendations below* Class I: 1. Rapid evaluation of patients with new onset severe headache or new neurologic signs or symptoms is required. This should include a brief history and baseline examination, CT angiography of the head and neck, assessment of coagulation parameters and platelet count, and prompt neurological consultation. Level of Evidence C. *(New)* 2. In the setting of hemorrhagic stroke, discontinuation or reversal of anticoagulation and discontinuation of anti-platelet therapy is generally recommended unless otherwise advised by the neurological consultant. Level of Evidence C. *(New)* 3. Pump logfiles should be interrogated for signs of device thrombosis, malfunction, or patient related power interruption. Level of Evidence C. *(New)* 4. In patients with thrombotic cerebrovascular occlusion, cerebral angiography with intervention should be considered. Level of Evidence B. *(New)* Class IIa: 1. Assessing for a source of thrombus in the setting of an embolic stroke is reasonable. This may include trending of patient INRs, chart review for cessation of anticoagulation, carotid ultrasound, transesophageal echocardiography, or defibrillator interrogation as clinically indicated. Level of Evidence C. (*Modified*) 2. In patients with cerebrovascular event, placement of an arterial line for continuous blood pressure measurement and management is reasonable. Level of Evidence C. *(New)* Class IIb: 1. Selective use of thrombolytics in the setting of thrombotic stroke without hemorrhage on imaging may be considered. Level of Evidence B. (*Unchanged*)

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2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
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.	Class III: 1. Routine use of an interventional radiologic approach to managing thrombotic strokes is not recommended. Level of Evidence B. (*Modified*) 2. The routine administration of thrombolytic therapy is not recommended without appropriate imaging documenting absence of intracerebral hemorrhage and a discussion of risks and benefits of thrombolytic therapy with Neurology consultants Level of Evidence C. *(Unchanged)*
Chronic management of patients after presentation with a new neurologic deficit:	**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.	Class I: 1. *Continuing approval without change*
2. Close monitoring of anticoagulation in the setting of an embolic event to assure adequate levels of anticoagulation is recommended. Level of Evidence C.	2. Close monitoring of anticoagulation in patients with a recent embolic or hemorrhagic stroke is recommended. Level of Evidence C. (*Unchanged*)
3. Long-term control of blood pressure is recommended. Level of Evidence B.	3. Long-term control of blood pressure is recommended once patients have recovered from the acute neurologic event. Level of Evidence B. (*Unchanged)*
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.	4. *Continuing approval without change*.
5. Resumption of anti-coagulation in consultation with neurology or neurosurgery in the setting of hemorrhagic stroke is recommended. Level of Evidence C.	5. Resumption of anti-coagulation in patients with hemorrhagic stroke should be done in consultation with a neurologist or neurosurgeon. Level of Evidence C. (*Unchanged*)
	Class IIa: 1. To prevent recurrent stroke in DMCS patients, it is reasonable to target a mean arterial pressure 75-90 mmHg, with avoidance of excessive pharmacology hypotension (MAP <75 mmHg). Collaboration with Neurology consultative services is recommended prior to escalation of antihypertensive therapies Level of Evidence C. *(New)*
	Class IIb: 1. In patients with embolic strokes, data are insufficient to support or refute adjustment in antiplatelet therapy dosing or regimens. It may be reasonable to consider escalation of antiplatelet therapy in patients who have thrombotic events with documented compliance to warfarin and aspirin therapies. Level of Evidence C. *(New)*
Assessment of neurocognitive deficits:	**Assessment of neurocognitive deficits:**
Class I: 1. Routine neurocognitive assessment at 3, 6, 12, and 18 months after implant is recommended. Level of Evidence C.	Class IIa: 1. Routine neurocognitive assessment at 3, 6, 12, and 18 months after implant is reasonable. Level of Evidence C. *(Modified)*

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Task Force 4:
Inpatient management of patients with MCSDs Summary

2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
Evaluation and treatment of MCS-related infections	
Evaluation of DMCS patients with a suspected infection:	**Evaluation of DMCS patients with a suspected infection:** *Replaced by the new and modified recommendations below*
Class I: 1. In all patients, a complete blood count, chest radiographic imaging, and blood cultures is recommended. Level of Evidence A.	Class I: 1. Basic laboratory testing, including a complete blood count with differential, basic metabolic profile, lactate dehydrogenase, INR, and urinalysis, is recommended in patients with a suspected DMCS infection. Level of Evidence C**.** (*Modified*)
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.	2. At least 3 sets of blood cultures over 24 hours should be obtained in patients with a suspected DMCS infection, even when afebrile. Level of Evidence C. (*Modified*)
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.	3. For those with a suspected driveline infection, obtaining a sample for Gram stain and bacterial culture is recommended. Fungal cultures should be obtained in those with evidence of recurrent or persistent signs of infection and negative bacterial cultures. Level of Evidence B. (*Modified*)
4. When clinically indicated, aspirate from other potential sources, as dictated by presenting symptoms and examination, 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 C. (*Modified*)
5. Directed radiographic studies based on presenting symptoms and examination are recommended. Level of Evidence A.	5. In those with concern for DMCS-specific infection, CT imaging of the chest, abdomen, and pelvis should be performed to characterize the extent of infection. Level of Evidence C. (*Unchanged*)
	6. In those with concern for DMCS-specific infection, transesophageal echocardiogram to examine valves and other intracardiac devices is recommended. Level of Evidence C. (New)
Class IIa: 1. Erythrocyte sedimentation rate or serial C-reactive protein should be considered. Level of Evidence C.	Class IIa. 1. Erythrocyte sedimentation rate or serial C-reactive protein should be considered. Level of Evidence C. *(Unchanged)*
	2. In those with infection isolated to the driveline, ultrasound of the exit site may be useful for characterizing depth and loculation of infection. However, patients with concern for deep infections should have the full extent of the driveline and the pump examined with CT. Level of Evidence C. *(New)*
Class III: 1. Routine CT of the chest, abdomen, and pelvis is not recommended. Level of Evidence C.	Class III: 1. In patients with driveline cellulitis or dermatitis and no clinical, laboratory or microbial evidence of deeper infection, routine CT of the chest, abdomen, and pelvis or transesophageal echocardiogram are not recommended. Level of Evidence C. (*Modified*)
Determination of an MCSD- specific infection: 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.	**Classifying infections in patients on DMCS** Class I: 1. The ISHLT consensus document for DMCS infection nomenclature should be used to classify infections as MCS-specific, MCS-related, or non-MCS infections. Level of Evidence C. *(New)*
2. A probable MCSD-specific infection is defined as 1 major and 3 minor criteria or 4 minor criteria. Level of Evidence B.	2. *Removed from guidelines*
3. A possible MCSD-specific infection is defined as 1 major and 1 minor or 3 minor criteria. Level of Evidence B.	3. *Removed from guidelines*

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Inpatient management of patients with MCSDs Summary

2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
Determination of an MCSD pocket infection: Class I: 1. A proven DMCS 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 DMCS pocket infection is defined as 1 major and 3 minor or 4 minor criteria. Level of Evidence B. 3. A possible DMCS pocket infection is defined as 1 major and 1 minor or 3 minor criteria. Level of Evidence B	**Determination of an MCSD pocket infection:** *Removed from guidelines*
Management of DMCS specific/related infection: (Not addressed in 2013)	**Management of DMCS specific/related infection:** ***(New)*** Class I: 1. Once an infection is suspected, empiric antimicrobial therapy against *Staphylococcus* sp. and *Pseudomonas aeruginosa* (most common etiologies of DMCS-related and -specific infections) should be started promptly while microbiological data is pending. Level of Evidence B. *(New)* 2. Patients with DL infection limited to the superficial fascia without systemic signs of sepsis, should be treated with pathogen-specific antibiotic course for two weeks. Level of Evidence C. *(New)* 3. Patients with evidence of a deep DL infection (infection deeper to subcutaneous fascia) or pocket/ pump/ cannula infection should be hospitalized for systemic antibiotics and consideration for surgical drainage (with or without vacuum-assisted closure (VAC). Systemic pathogen-specific antibiotic therapy should be continued for 6-8 weeks followed by long-term antibiotic suppression (detailed recommendations in 2017 ISHLT consensus). Definitive cure consists of device explant with consideration for heart transplant, if appropriate. Level of Evidence C. *(New)* 4. Patients with recalcitrant infection should be considered for transplant listing (as applicable) or device exchange. It is important to consider removal of all hardware (including defibrillators or pacemakers) at the time of device exchange or transplant. Level of Evidence C. *(New)*

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Task Force 4:
Inpatient management of patients with MCSDs Summary

2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
Recommendations for inpatient treatment of arrhythmias:	
Inpatient treatment of ventricular arrhythmias: Class I: 1. LVAD patients with incessant ventricular arrhythmias require prompt admission for further management because hemodynamic compromise may occur. Level of Evidence C. 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 DMCS. Level of Evidence C.	**Inpatient treatment of ventricular arrhythmias:** *Replaced by the new and modified recommendations below* Class I: 1. Patients with new ventricular arrhythmias after LVAD implantation should be promptly evaluated for hemodynamic stability using available hemodynamic monitoring. Level of Evidence C. (*Unchanged*) 2. In patients with hemodynamic instability (as evidenced by acute kidney injury, low MCS flows, signs of new or worsening RV failure, symptomatic hypotension or hypoxia) due to new onset ventricular arrhythmia, urgent cardioversion/defibrillation and/or anti-tachycardia pacing is recommended. Level of Evidence C. *(New)* 3. Patients with new ventricular arrhythmias post LVAD implantation should undergo LVAD interrogation and echocardiography to assess for the possibility of suction events. Level of Evidence C. *(New)* Class IIa: 1. In patients who are hemodynamically stable in a new ventricular arrhythmia post LVAD, it is reasonable to try electrolyte optimization and intravenous antiarrhythmic therapy prior to electrical cardioversion. An ECG should be obtained to capture VT morphology. Prolonged (> 30 minutes) VT/VF in patients on isolated LVAD support should generally be avoided regardless of hemodynamic stability. Level of Evidence C. *(New)* 2. Patients with refractory, hemodynamically unstable ventricular tachycardia may require catheter ablation. Catheter ablation should be performed by an electrophysiologist with experience treating DMCS patients. Level of Evidence C. (*Modified*)
Management of atrial arrhythmias in LVAD inpatients: (Not addressed in 2013)	**Management of atrial arrhythmias in LVAD inpatients: (New)** Class I: 1. In DMCS patients who develop sudden hemodynamic instability due to new atrial arrhythmias, synchronized cardioversion should be performed. Level of Evidence C. *(New)* Class IIa: 1. In patients who are hemodynamically stable in a new atrial arrhythmia post LVAD, it is reasonable to attempt volume optimization and medication adjustments prior to a trial of chemical or electrical cardioversion. Level of Evidence C. *(New)*
Management of the MCS patient during non-cardiac procedures: Class I: 1. The DMCS team should be made aware when a DMCS patient is undergoing a non-cardiac procedure so that collaboration between the MCS and surgical teams can take place. Level of Evidence C.	**Management of the MCS patient during non-cardiac procedures:** *Continuing approval without change*

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Task Force 4:
Inpatient management of patients with MCSDs Summary

2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
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 Doppl 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, DMCS parameters should be continuously monitored by expert personnel such as DMCS 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 DMCS. Level of Evidence C. Class II: 1. Whenever possible, the surgeon performing the non-cardiac procedure should have experience in operating on patients with DMCS. Level of Evidence C.	
Recommendations for the management of device failure and malfunction due to non-thrombotic complications:	
Recommendations for management of outflow graft obstruction.	**Recommendations for management of outflow graft obstruction: (New)** Class I 1. Surgical intervention is indicated in patients with documented, hemodynamically significant outflow graft obstruction. Level of Evidence C. *(New)* Class IIb: 1. Percutaneous treatment approaches are reasonable to consider in select patients with documented, hemodynamically significant outflow graft obstruction. Level of Evidence B. *(New)*
Device failure and malfunction: Class I: 1. Pump stoppage of a continuous-flow DMCS 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.	**Device failure and malfunction:** Class I: 1. Pump stoppage of a continuous-flow DMCS constitutes a medical emergency, and the patient should be assessed for circulatory stability and then rapidly transported back to the implanting center or another expert DMCS center for treatment. Level of Evidence C. (*Unchanged*)

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Task Force 4:
Inpatient management of patients with MCSDs Summary

2013 Guidelines recommendations	New and modified in 2023 Updated Guidelines
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.	2. Definitive therapy for major device dysfunction that cannot be resolved with external driveline repair is surgical pump exchange or transplant as clinical stability allows. Level of Evidence C. (*Modified*) 3. Patients with a functioning pump, but with alarms or changes in parameters that suggest the pump is at risk for electrical or mechanical failure should also be transferred urgently to the implanting center for evaluation and management. Level of Evidence C. (*Unchanged*) Class IIa: 1. In patients with a malfunctioning DMCS device and evidence of malperfusion, it is reasonable to use inopressor or ECMO support until a definitive plan is established. Level of Evidence C. *(New)* Class IIb: 1. For patients who are unable to undergo surgery, percutaneous occlusion of the outflow cannula might be considered to halt the backflow of blood through the valveless outflow cannula as a stabilizing maneuver. Level of Evidence C. (*Unchanged*) 2. For patients who are unable or unwilling to undergo surgery, inotrope support might be considered for palliation. Level of Evidence C. *(New)*
Managing MCS Patients with Cardiopulmonary Arrest:	
Not addressed in 2013	**Managing Cardiac Arrest**: ***(New)*** Class I: 1. Due to delays identified in initiation of cardiopulmonary resuscitation in DMCS patients, institutional DMCS resuscitation guidelines should be developed for hospitals who directly care for DMCS patients. Level of Evidence C. *(New)* 2. In patients with a continuous flow LVAD, a mean arterial pressure ≥75 mmHg usually provides adequate tissue perfusion. In patients without an arterial line, use of a Doppler for blood pressure assessment may be required due to the limited accuracy and precision of current automatic blood pressure devices. Level of Evidence C. *(New)* 3. Defibrillation may be safely performed in patients on LVAD support who are in an unstable arrhythmiaa. Level of Evidence B. *(New)* 4. Measurement of the partial pressure of end-tidal carbon dioxide (P_{ETCO2}) via waveform capnography can assist in confirming advanced airway placement and in assessing and tracking perfusion in DMCS patients who are mechanically ventilated. A normal P_{ETCO2} is 35 to 40 mm Hg, with lower values suggestive of systemic malperfusion Level of Evidence C. *(New)* Class IIa: 1. Unless advanced directives state otherwise, cardiopulmonary resuscitation (CPR) with chest compressions is generally advised in unconscious patients on isolated LVAD support without evidence of adequate cardiac perfusion (including a mean arterial pressure <50 mmHg). There are no data regarding the safety or benefit of chest compressions in LVAD patients with concomitant RVAD support. Level of Evidence B. *(New)* Class IIb: 1. It might be reasonable to consider hypothermic protocols in appropriately selected LVAD patients with a GCS <8 who sustain cardiac arrest with return of spontaneous circulation. Level of Evidence C. *(New)* Class III 1. CPR, defibrillation, and/or pacing are not beneficial in patients on total artificial heart support. Level of Evidence C. *(New)*

Task Force 5

Outpatient management of the durable mechanical circulatory system recipient

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

The first step in maximizing long-term survival after initial DMCS placement is ensuring a smooth transition from the hospital setting to the home environment. This time of transition can be a vulnerable period for DMCS patients and their caregivers. The DMCS program should mobilize a multidisciplinary team to maximize patients' rehabilitation, quality of life, and assimilation into the community while minimizing complications.

1.1 Recommendations for evaluation of safety of the home environment: (1-5)

Class I

1. *An uninterrupted supply of electricity to continuously power the DMCS must be ensured. Outlets must be grounded, and the use of electrical extension cords or outlets powered by 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 maintaining contact with 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, sleeping and restroom 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 before discharge. Level of evidence: C.*

Community outreach by the MCS team

Education of the community surrounding DMCS therapy is crucial to successful outpatient management. Community education should be provided, at a minimum, at patient discharge and reviewed at regular intervals. Targeting of community education should include referring providers, primary care and community health providers, emergency services, and local hospital providers. Additionally, education of an extended patient support system when possible is beneficial. Notification of utilities providers should be completed by the patient or family. Utility notification does not guarantee uninterrupted service but places the patient's address on a "priority" status in case of utility outage. Community education is key for management of non−DMCS-related patient issues as well as identification and care of DMCS-related emergencies.

Community education should include basic device purpose and function, patient physiological changes, and assessment techniques with device-specific findings. Education should also include the essential information necessary to help the community provider differentiate between DMCS-related vs non−DMCS-related issues. Finally, DMCS emergency intervention should be covered including how to access emergency device management guidance tools and resources as well as how to locate the nearest DMCS capable hospital location (Table 1).

In the case of pediatric patients, school health providers, administrators, and teaching staff should also be included.

The DMCS implanting center is encouraged to provide face to face education to the appropriate community providers when feasible. Involvement of the patient and family should be encouraged so that community providers have a

Table 1 Suggested Basic Components of an MCSD Community Education Program

DMCS purpose	• General purpose of DMCS • Indications for use • DMCS components • Brief DMCS anatomy and implant procedure • Normal vs DMCS assisted cardiovascular physiology
DMCS function	• Overview and demonstration of basic operation of DMCS ○ Overview and demonstration of DMCS function under normal operation ○ Overview, explanation, and demonstration of DMCS function in each different alarm state • Recognition of audible alarm • How to find the visual cues on the DMCS controller • Recognition of alarm states that require intervention ○ Demonstration of DMCS field appropriate alarm interventions • How to change power sources • How to change controller • How to silence audible alarm
DMCS patient assessment	• Overview of most frequent DMCS complications • Differentiating DMCS vs Non-DMCS issues • Assessment of device operation • Determining the model of DMCS device ○ Look for Color Coded EMS Field Guide Tags ○ Locate controller—Manufacturer Name • CPR recommendations • Modified ACLS Protocols ○ Arrhythmia recognition and intervention measures • Nonpulsatile blood pressure measurement - https://www.mylvad.com/patients-caregivers/lvad-lifestyle/video-library/how-measure-blood-pressure-person-continuous-flow • Transport of DMCS patient should include support equipment (bag and chargers if available).
DMCS emergency resources	• HFSA/SAEM/ISHLT clinical expert consensus document on the emergency management of patients with ventricular assist devices. https://www.jhltonline.org/article/S1053-2498(19)31499-8/pdf • ICCAC DMCS Field Guides - https://www.mylvad.com/medical-professionals/resource-library/ems-field-guides • Manufacturer emergency device guides • Manufacturer video training resources • How to find the closest DMCS support center — https://www.mylvad.com/patients-caregivers/locate-hospital/hospital-map
Institutional-specific instructions	• Emergency contact information and procedures • Other relevant information and instructions

"baseline" view of patient condition as well as to review device emergency procedures for the patient. When face to face education cannot be performed, community providers should be notified and provided with a self-directed educational program. Links to online resources should be utilized when possible, to provide a consistent method of accessing the latest updates to emergency protocols and procedures.

Recommendations for community outreach by the MCS team: (1, 6-13)

Class I

1. *Community education should be provided by the DMCS implanting center at patient discharge. Level of Evidence: C.*
2. *Recommendations for essential community education components include DMCS purpose, function, patient assessment, emergency resources, and institutional-specific information (Table 1). Level of Evidence: C.*
3. *Community education programs should be targeted for referring providers, primary care and community health providers, emergency services, and local hospital providers. In the case of pediatric patients, school health providers, administrators, and teaching staff should also be included. Inclusion of patient extended support lay providers is beneficial. Level of Evidence: C.*
4. *Utilities companies should be notified of patient reliance on electrical power. Level of Evidence: C.*

Class IIa

1. *Community education should occur in a face to face manner when feasible. Level of Evidence: C.*
2. *Patient involvement in community education is beneficial. Level of Evidence: C.*
3. *Provision of accessible resources (online training, emergency procedure guides, hospital location resources) is beneficial for community provider reference. Level of Evidence: C.*

Recommendations for assessment of the social network: (1)

Class I

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

Driving a motor vehicle

With improvement in DMCS technology and overall survival with DMCS, as well as increasing use of MCS as destination therapy, patients are often able to return to their normal life with only a few limitations. This makes the question of whether or not patients with DMCS should be allowed to drive in a private or commercial capacity much more relevant. Driving carries risks not only to the driver, but also any passengers and persons outside of the vehicle, making it a public health concern. The risks pertaining to driving in patients with DMCS center around the risk of sudden loss of consciousness or loss of control over the vehicle which could result from device malfunction, loss of power, arrhythmias requiring ICD therapy or stroke.

Whether patients are permitted to drive after DMCS implant has typically been 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 6−9 weeks of postoperative recovery. Incisional pain must be managed without narcotics. Patients must reliably demonstrate their ability to manage DMCS emergencies independently as dictated by the implanting center. The local jurisdiction paperwork must be completed as required (e.g., department of motor vehicle forms).

According to recent literature*(14-20)* most of the stable DMCS patients with NYHA functional class I-III qualify for private driving. Commercial driving, as defined by local laws such as driving for a living or driving passenger carrying vehicles, should be avoided due to the public health risks posed by any possible complications that might occur while on DMCS. Every country/region has its own regulations with regards to driving with medical conditions, but especially for commercial driving and those must be followed. A recent study reported that 72% of patients are still driving and 28% did not continue driving after DMCS implantation, but the frequency of driving dropped from 80% driving daily to 52% (20).

Recommendations for driving a motor vehicle: (1, 14-21)

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.*
2. *Patients in whom functional capacity has been restored with an LVAD should pose a similar risk to self and others while driving a personal motor vehicle for non-commercial purpose as heart failure patients with an implantable cardiac defibrillator. Level of evidence: C*

Class III

1. *Commercial driving is not recommended in patients with DMCS. Level of evidence: C*

Flying with the commercial airlines

Multiple factors can affect cardiovascular health during air travel, including decreased atmospheric pressure, decreased humidity, gas expansion, prolonged immobility, and increased physical and emotional stress and DMCS patients may be more vulnerable to these factors.

Most commercial flights cruise at the altitude between 7,000 and 13,000 m above sea level and pressurization of the cabin is essential to keep the passengers alive. Compressed air is routed to the cabin and prevents the excessive fall in atmospheric pressure and decrease in partial pressure of inspired oxygen, which decreases not more than 30. As a consequence, this should keep arterial blood oxygen saturation >90% in healthy individuals. Atmospheric air used to pressurize the cabin has low humidity (<1%) which might increase insensible water loss. Gas expansion (a gas trapped in a closed space will expand by approximately 35% when going from sea level to cabin altitude) and immobilization as a source of deep venous thromboembolism are less relevant problems for DMCS patients traveling by plane.

Individual reports of patients with DMCS who traveled by commercial plane are available(22, 23) and air travel for stable DMCS patients is usually considered to be safe (24). Not all airline companies allow DMCS patients on board and patients are advised to check with airline beforehand regarding the possibility of travel with DMCS. International Air Transport Association (IATA) regularly releases their updated recommendations on its website (25). Patients should fill out a medical clearance form issued by the International Air Transport Association (MEDIF, FREMEC forms by IATA) before traveling to provide airlines with relevant information about their DMCS device/batteries and any special assistance they might require during the flight. The patients should also notify the security personnel

that they have a DMCS and need to take it on board. No interferences between security gate and DMCS equipment has been reported (22). Most MCS programs (up to 100%) support airplane travel on commercial airlines domestically, but only a small percentage of them support international travel (26).

DMCS patients should be aware that spare (LVAD lithium ion) batteries must only be packed in carry-on baggage and that lithium ion batteries carried by passengers remain a safety concern for airlines. DMCS patients may carry devices powered by lithium batteries and might be therefore subject to certain conditions.(27) Important back-up externals should be available anytime, especially during long-distance flights. According to the IATA website, portable electronic devices are more prone to failure when in use and/or when charging. DMCS patients should be aware of this and regularly monitor any (especially MCS) devices in the cabin.

During flight insensible fluid loss due to low humidity can result in minor hemodynamic alteration (22, 23, 28), because MCS are sensitive to preload changes. Additional fully charged batteries should be available on board (28), as well as medical documentation and DMCS card. DMCS patients should locate and contact the MCS center at travel destination for those traveling long distance, as well as their health insurance, whether they would cover treatment costs abroad.

Recommendations to fly with the commercial airlines (22-24, 26, 28, 29)

Class I

1. *Clinically stable patients with normally functioning DMCS can travel on commercial flights under the condition to have enough batteries available and/or there is a possibility to recharge batteries on board. Level of evidence: C*

Class III

1. *Flying is not recommended in unstable patients, with DMCS dysfunction and life threatening comorbidities as well as in those not stabilized after recent hospitalization. Level of evidence: C*

Topic 2: Follow-up care

Multidisciplinary approach to follow-up care

DMCS patient care in the hospital and clinic settings requires collaborative efforts by a multidisciplinary team to ensure successful short- and long-term outcomes and reduce morbidity and mortality. This approach is achieved by combining the expertise of cardiovascular surgeons, advanced heart failure cardiologists, specialized DMCS coordinators, dedicated social workers, palliative care teams, other health care providers, and referring physicians.

Role of the cardiologist

The advanced heart failure cardiologist is one of the most important (NOT only "a") member of a multidisciplinary team that reviews potential DMCS candidates and aids in discussion of salient information regarding potential for DMCS candidacy. Once candidacy has been determined, the cardiologist may work to optimize the patient before durable device implantation or while a patient is supported with temporary mechanical circulatory support. Following DMCS implant, the cardiologist will supervise heart failure therapy management and hemodynamic optimization in the postoperative period. Once a patient has been reinitiated on optimized heart failure therapy following DMCS implant, ensuring regular ongoing cardiology surveillance will aid in managing and addressing device- and nondevice-related issues that may impact long-term survival. These issues may include cardiac-related concerns including right ventricular failure, the function of the aortic valve, adjustments of the device speed and arrhythmias or other comorbidities such as gastrointestinal bleeding and device-related infection or development of new medical issues. The cardiologist may also serve a role in managing care of the readmitted DMCS patient during their hospitalization.

Role of the surgeon

The surgeon is responsible for initial pump placement and is also involved as one of the leading decision makers with multidisciplinary discussions regarding DMCS candidacy before implantation. Postoperatively, surgical monitoring of the patient ensures appropriate postsurgical recovery including thoracotomy or sternotomy incisional site healing and driveline healing. Driveline and pump pocket infections, device thrombosis, or device malfunctions may also require surgical intervention. When patients require surgical intervention for other noncardiac concerns such as gastric bypass surgery, general surgery teams may request the presence of the cardiothoracic surgeon during cases to avoid disruption of the driveline or interfering with device configurations. MCS surgeons may also function in dual roles as a cardiac transplant surgeon. For patients implanted as bridge to transplant, the DMCS surgeon may perform cardiac transplantation when an organ becomes available.

Role of the DMCS (or VAD) coordinator

The DMCS coordinator is involved in all aspects of DMCS patient care. As a member of a multidisciplinary team, the DMCS coordinator is involved with reviewing and contributing to discussion regarding patient candidacy and aids in assessment of the patients as well as DMCS education. Once deemed a candidate, the DMCS coordinator will help ensure appropriate testing and hemodynamic optimization transpires before implant and in some cases, may be present for and aid in pump preparation in surgery. Postoperatively, the DMCS coordinator will work with the multidisciplinary team to ensure that VAD optimization occurs and may

participate in medical and hemodynamic optimization of the patient. Educating patients, their caregivers, and the patient's community and local providers generally falls under DMCS coordinator core responsibilities. Some DMCS coordinators are also responsible for data collection, quality metrics, equipment management, dressing supply distribution, and additional VAD-specific roles such as staffing a VAD support group for patients and caregivers. The DMCS coordinator ensures a successful transition of the patient to their home community through completion of these activities and serves an important communication role between patients, the DMCS team, and the local medical teams. Most DMCS coordinators have on-call responsibilities where they assist in device alarms, parameter changes, patient or provider concerns, and other troubleshooting and device-related problems. This role continues to evolve globally and encompasses a range of medical providers from registered nurses, advanced practice providers, engineers, perfusionists, and physicians, to medical providers of other training qualifications.

Role of social work (this role may be different in other countries and might be covered by the nursing staff, MCS-coordinators, psychocardiologists or others depending on local systems)

The social worker plays a critical role in the evaluation of potential DMCS candidates by reviewing psychosocial factors including compliance, caregiver support availability, drug and alcohol use, home environment assessment, learning abilities, and review of insurance and financial resources available to the patient when applicable. Social work contributions are also invaluable during hospitalization to ensure that patients have established networks in their home environment and to ensure access to resources in their community to aid in success. In addition, the social worker may help to coordinate dialysis centers, skilled care facility placement, antibiotics and infusion therapy support at home, wound vac therapy at home, and other complex medical needs required for successful hospital discharge and transition to support at home. Social workers are also involved in readmissions of DMCS patients and aid in connecting patients with resources to best meet their complex medical needs.

Role of other disciplines

Adverse events frequently necessitate hospitalization of the DMCS patient and require specialty consultative services such as infectious disease, gastroenterology, neurology, psychiatry, and others. The DMCS team should strive to establish collaborative relationships with health care providers from other specialties. Unique challenges affecting this patient population including lack of palpable pulse and blood pressure challenges should be generally understood by consulting specialists who provide care for the DMCS patient. Collaborative management is necessary to provide optimal patient care and improve outcomes from adverse events.

Role of the referring physician

The referring physician often provides the initial referral of heart failure patients who may be candidates for advanced therapy with a DMCS device. Once a patient is implanted and discharged from the implanting center, both the referring physician and MCS team should continue to foster a relationship to help re-establish care for the DMCS patient and to enhance continuity and patient-centered care. Frequently, the majority of DMCS-specific management falls under the jurisdiction of the MCS team and non-MCS issues and concerns such as diabetes or gout remain under the management of the referring physician. It is important for the referring physician to be aware of general DMCS patient features and DMCS resources as they frequently aid in local assessment of the patient and transfer to the MCS center in case of emergency. The referring physician is also an important partner in helping to educate the patient's community about DMCS therapy and can enhance local awareness.

Recommendations for the multidisciplinary approach to follow-up care: (1)

Class I

1. *Management of the patient with an DMCS should be performed by a multidisciplinary team that includes cardiovascular surgeons, advanced heart failure cardiologists, and specialized DMCS coordinators. Other health care providers may collaborate with the primary MCS team when additional expertise is required. Level of evidence: C.*

Recommendations for scheduled follow up/ frequency of visits: (1, 30)

Class I

1. *DMCS patients should be seen in clinic regularly with the frequency dictated by clinical need. Level of evidence: B.*
2. *DMCS patients should have routine monitoring of blood work, blood pressure, driveline, and device diagnostics at each visit to proactively identify issues that may affect patient outcomes. Level of evidence: B.*

Class IIa

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

Use of echocardiography in patients with DMCS device

Echocardiography is essential for the optimal care of DMCS patients. (31-33) Serial imaging provides an

understanding of the complex hemodynamics produced by the pump-patient interface that results in an unloaded LV and fully loaded RV. Device speed optimization, defined as the speed at which the LV is adequately unloaded with a midline interventricular septum with minimal MR and intermittent AV opening, can vary dramatically from patient to patient, and change over time.(33) Mean arterial pressure, volume status, intrinsic myocardial contractility, neurohormonal blockade and vasoactive medications can further influence cardiac output and pump function. Serial performance of standardized, speed-varying echocardiographic ramp tests is useful for both speed optimization and detection of device malfunction.(34)

While the ideal frequency for performing ambulatory echocardiography has not been established, consensus opinion recommends at least annual screening. Others have recommended a more frequent schedule of every 3 or 6 to 12 months in asymptomatic patients to screen for aortic insufficiency.(35, 36) Periodic echocardiography allows for the detection and quantification of myocardial recovery. (37) Protocolized echocardiograms with device speed turndowns may not only identify potential candidates for device removal, but also provide meaningful risk stratification and prognostic information.(38, 39) Chronic RV failure, presenting weeks or months following LVAD support, may result in altered drug metabolism, worsening nutrition, diuretic resistance and poor quality of life.(40, 41) Optimal speed programming that avoids excessive LV unloading and venous return while positioning the interventricular septum in a midline position should be performed with the use of echocardiographic guidance.

Recommendations for use of echocardiography with MCSD: (31-41)

Class I

1. *Echocardiography should be performed routinely at regular intervals to evaluate for signs of myocardial recovery, right ventricular function, aortic insufficiency and optimal LVAD 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 suboptimal DMCS function or in the presence of clinical signs of circulatory dysfunction, including congestive or low output symptoms. Level of evidence: B.*

Class IIa

1. *The frequency of routine echocardiography can be determined by individual programs but should be performed no less than annually. Level of evidence: C.*

Use of right heart catheterization in patients with DMCS (34, 42-49)

Recommendations for use of right heart catheterization in patients with DMCS

Class I

1. *Right heart catheterization is useful in the assessment of persistent or recurrent heart failure symptoms after LVAD placement and to evaluate RV failure, device malfunction or evidence of inadequate left ventricle unloading as assessed by echocardiography. 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 prove reversibility of the pulmonary artery pressures. Irreversible pulmonary hypertension is associated with early allograft dysfunction/ failure after heart transplantation. Level of evidence: B.*

Class IIa

1) *Right heart catheterization should be performed at the discretion of the clinician to optimize LVAD speed and medical therapy to balance adequate left ventricular unloading, pulmonary artery hemodynamics, cardiac output and right ventricular function in all LVAD patients to reduce heart failure hospitalization and hemocompatibility-related adverse events. Level of evidence: B.*
2) *Right heart catheterization should be performed to assess myocardial recovery. Assessment of hemodynamics can be performed in the catheterization laboratory with serial lowering of the pump speed or the pulmonary artery catheter may be left in place with continuous lowering of the pump speed overtime to confirm acceptable hemodynamics with decreasing LVAD support before pump explanation. Level of evidence: C.*

Use of CT angiography in patients with DMCS (1, 50-53)

Recommendations for use of CT angiography in patients with DMCS

Class I

1. *CT angiography allows visualization of the native heart and DMCS components and may be valuable when other imaging modalities have not been revealing. Level of evidence: B.*
2. *CT angiography is recommended if an LVAD outflow graft obstruction is suspected. CT angiography with 3D reconstruction can help identify causes of outflow graft obstruction such as graft thrombosis, external*

compression, outflow graft twisting or kinking. Level of evidence: C.

Recommendations for functional capacity testing: (1)

Class I

1. Measurement of exercise capacity should be undertaken after DMCS 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 DMCS. 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 assessment of health-related quality of life (HRQOL) in patients with DMCS: (54-87)

Rationale for HRQOL assessment: There are 2 main reasons why a patient chooses to undergo DMCS implant: to improve survival or improve HRQOL. Patients may prioritize one choice over the over.(54) Baseline and routine longitudinal measurement of HRQOL are recommended to: (a) provide data for shared-decision making, (55, 56) (b) identify risk factors,(57) (c) evaluate outcomes of device implant and management,(58) and (d) test interventions to improve post-DMCS HRQOL.(59, 60) Additionally, routine HRQOL assessment is important for policy decisions, allocation of resources, and provides data for institutions to meet regulatory requirements (e.g., for continual evaluation, revision, and implementation of a plan of care to meet ongoing needs of the patient).(61, 62)

Baseline data collection for HRQOL ideally occurs outpatient before DMCS implant, but often patients are evaluated for DMCS candidacy while hospitalized. Assessment of HRQOL for inpatients immediately post-DMCS may yield scores potentially inflated by the relief of being alive after a grueling surgery; yet patients have been untested with challenges of independence upon discharge to home (63). Therefore, for hospitalized patients immediately post-implant, it is reasonable to target only specific aspects of a HRQOL domain (e.g., the emotional, to identify anxiety and depression)(62, 64) or spiritual distress.(65) Patients are hospitalized for a variety of reasons post-MCS (66) and frequent hospitalizations may be a nidus for patients and the clinical team to re-evaluate how the patient's expectations, adherence, support, and health status are congruent with the patient's wishes and perception of HRQOL.(55, 64, 67, 68) A major decrease in HRQOL should be a trigger for further evaluation and a plan should be in place for more comprehensive HRQOL assessment after the patient is discharged.

HRQOL as data for decision making. Studies have primarily focused on HRQOL pre- to post-LVAD (56, 66) but findings are mixed from past studies attempting to identify who is at highest preoperative risk for lower postoperative HRQOL (in part due to small sample sizes, varying measures, missing baseline and/or follow-up data that include complications or death, and perhaps even cultural differences).(69) Using a combined mortality and HRQOL endpoint to define LVAD success, about one-third of LVAD patients suffer a poor outcome (primarily related to death rate of 22.4%).(70) Poor outcomes were more likely among those with higher body mass indices, lower hemoglobin, greater comorbidity, and poorer baseline HRQOL assessment.(70) Further study may clarify potential interactions (e.g., age, gender, social support, caregiver burden) and other psychosocial variables that may contribute to decision-making aids for patients considering MCSD, of which there are currently at least 2 available for patients considering MCSD.(67, 71) The Kansas City Cardiomyopathy Questionnaire (KCCQ) at 3 months post-LVAD has been significantly associated with long-term mortality. (57) Thus, measurement of post-LVAD HRQOL has potential to help identify patients who need targeted interventions and may help guide timing of treatment options (transplant or palliative care).

Clarifying measurement. Among patients with heart failure, functional capacity (FC) may have only a modest correlation with patient reported outcomes measures (PROMs).(72) While FC is routinely calculated by objective measures, HRQOL is by definition subjective and currently has no established instrument specifically designed for patients with MCS. Therefore, it is important that the MCS team clarify the precise patient perceptions which they wish to measure, including terms and instruments.

QOL measurement typically includes several domains (i.e., physical, emotional, cognitive, social, and spiritual/meaning) as compared to the more narrow term HRQOL which is often used to delineate factors more likely to be influenced by a health condition, such as physical and emotional status after major cardiovascular surgery.(73, 74) Both terms are patient-perceived and dynamic. Typically, more than one instrument is used in attempt to achieve comprehensiveness. Two heart failure-specific instruments have the most established psychometric properties within the heart failure and MCS population: (75) the Minnesota Living with Heart Failure (MLHF)(76) Questionnaire and the KCCQ.(77) Typically, a generic instrument is also used to allow for comparisons across patient populations (e.g., the EuroQol (EQ-5D) with visual analog scale (VAS).(78, 79)

After the first year post-LVAD, only about 18% of surviving patients have heart failure symptoms, so repeated use of heart failure measures has limitations.(66) Existing measures do not capture the many concerns unique to most patients with a MCS (i.e., a drive-line exiting from one's

body, continual reliance on batteries). Moreover, it is unclear how well the impact of common complications (bleeding, device infection, stroke, pump thrombosis) is perceived by patients with MCS. This was demonstrated by finding that although patients with HM3 devices had significantly less incidence of pump thrombosis and bleeding in HM3 compared to HMII, no significant differences were found in HRQOL as measured by KCCQ and EuroQoL, highlighting the need for more precise HRQOL measures that are specific and comprehensive for MCS patients.(69) Qualitative studies have elicited patient concerns that are not captured on heart failure-specific measures, including the weight of device, stress of keeping batteries charged, changes in social and work interaction, self-image, and sleep.(74, 80) Sexual activity post-MCS has been described as both improved (due to better health status)(74, 81) and diminished due to batteries and driveline, with these patients having independently associated higher rates of depression as well as partners reporting of their own respective decreased mental quality of life.(82) Although there is no disease-specific instrument established for HRQOL in MCS, at least 2 MCSD-specific instruments are in the process of development: the Mechanical Circulatory Support Measures of Adjustment and Quality of Life (MCS A-QOL)(83) and the Quality of Life with a Left-Ventricular Assist Device (QOLVAD).(74) Both new instruments are undergoing psychometric testing.

Practical considerations. Before 2014, the INTERMACS registry had provided large samples of HRQOL, albeit with up to 40% missing data.(84) Institutions should have an ongoing, active, audited registry and scheduled follow-up clinic visits that allow a time and place to complete assessments and support staff time for data entry. Reasons for missing data should be documented.(64) Further, identifying reasons for noncompletion of both FC and HRQOL would enhance interpretability. For example, for a 6-minute walk distance of 0, more data should be provided to clarify if this represents a patient who refuses to walk; a patient who is unable due to medical/cardiac condition (i.e., patient on ventilator); or a patient unable to walk due to other condition (i.e., due to hip pain). HRQOL assessment can serve as a catalyst for the clinician to discuss with an outpatient how perceptions compare to an objective measure, allowing for mutual reassessment of goals, expectations, and resources.(55)

Clinical meaningfulness. Clinical application with recognition of minimally important differences in scores for PROs are commonly under-utilized by most MCSD teams and deserve more attention.(85) In clinic, real-time review of scores could be helpful to identify those who need referral based on concerns. Clinically important changes in scores have been established.(86) Expert clinicians in MCSD care have suggested certain scores (e.g., MLHFQ >60(87); KCCQ <40(87) or <45(69)) as practical makers for comparing group differences or prompting discussions with the patient about whether additional issues may be impacting HRQOL beyond those most commonly associated with MCSD, allowing for referrals to appropriate resources (e.g., counseling, chronic pain management).

Recommendations for assessing HRQOL in patients on DMCS

Class I

1. A comprehensive assessment of HRQOL (physical, emotional, social) and functional capacity using reliable and valid instruments should be undertaken before MCS implant (if patient is capable) and following discharge. Level of evidence B.

Class IIa

1. HRQOL and functional capacity data should be collected at regular follow-up intervals (including baseline, 3 months, 6 months, and at 6-month intervals through 2 years after implant and yearly thereafter) to allow for an assessment of patient trajectory and identification of areas for intervention. Level of evidence B.
2. HRQOL assessment should include a disease-specific instrument previously validated in the DMCS population. Level of evidence B.
3. HRQOL assessment in DMCS patients should include a generic instrument (e.g., the EQ-5D with VAS) to enable comparison of findings across healthy and chronically ill populations and enable time trade-off and cost-utility analyses. Level of evidence C.
4. When assessing functional capacity and HRQOL, reasons for missing data should be included (e.g., unable to complete due to cardiac limitation, unable to complete due to other limitation, unwilling to complete) to avoid bias. Level of evidence C.
5. MCS teams should consider when additional PROMs may benefit some patients (e.g., sexual, social, or spiritual wellbeing) and work toward using PROMs in the clinical setting. Level of evidence B.

Class IIb

1. *Assessment of HRQOL while hospitalized post-DMCS implantation may be reasonable by targeting select HRQOL domains (e.g., depressive symptoms, anxiety). Class IIb, Level of evidence C.*
2. *For patients still hospitalized after 1 month postoperatively and for those re-hospitalized post-DMCS, inpatient assessment of select measures of HRQOL (e.g., spiritual or social wellbeing) may be appropriate, given that these may be affected by prolonged or frequent hospitalization and complications. Class IIb, Level of evidence C.*

Recommendations for laboratory studies in patients with DMCS: (1)

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 DMCS: (1)

Class I

1. *The driveline, exit site, and DMCS 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, before 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 in patients with DMCS: *(1)*

Class I

1. Patients with DMCS 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 (CR) is a behavior modification program targeting cardiovascular risk factors. The multidisciplinary approach includes exercise and strength training, smoking cessation strategies, and nutritional and dietary modifications for primary and secondary prevention of cardiac disease (88) . CR has been shown to improve blood pressure and reduce recurrent myocardial infarctions and strokes, and improve quality of life (89). Despite the improvements shown in patients with coronary artery disease, the risks and benefits of CR in heart failure patients was unknown until the publication of the Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) trial (90). The trial included 2,331 patients with New York Heart Association (NYHA) Class II-IV heart failure symptoms who were randomized to either exercise training or usual care. Results from the trial showed that exercise training in heart failure patients is safe and associated with improvement in quality of life without a significant impact on overall survival. A meta-analysis of cardiac rehabilitation protocols for DMCS patients yielded 6 papers demonstrating improved outcomes related to functional and health status. A total of 183 patients in these 6 trials were included in the meta-analysis. Entry into formal CR exercise programs varied from only days after implant to 10 months but other demographics were similar, mean age was 51 and the combined cohort was 83% male. Although the participant size in each study was small, the quantitative analysis allowed for a bigger cohort to be analyzed and demonstrated a significant improvement in functional status. Another important finding from this analysis is that there were no reported serious safety events during DMCS patient exercise sessions. (91).

CR interventions occur in 3 phases. Exercise during the index hospitalization focuses on early strength training to reduce short-term postoperative morbidity. The goal of CR in the postdischarge phase is to improve exercise capacity. Finally, patients may choose to continue in exercise maintenance programs to sustain the benefits of exercise and lifestyle changes. Preoperatively, DMCS patients are often functionally limited due to ravaging effects of heart failure and deconditioning related to immobility. The resultant muscle wasting and weakness is a risk for prolonged ventilation, falls, fractures, and an increased risk of infection. Early interventions including muscle strengthening and breathing exercises, bed mobility activities, transfers from bed to chair or commode, and gait training result in improved functional capacity at discharge (92-94) . Special considerations for exercise in the early postoperative period include sternal precautions, balance challenges due to peripheral equipment and bags containing back up controller and batteries, securement of drive line, and protocolizing alternative methods for measuring exercise tolerance (94) . 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.(94)

Outpatient CR for DMCS patient has been shown to be effective in improving exercise capacity, health status, reducing readmission and mortality (92, 95, 96). Special considerations are warranted for DMCS patients participating cardiac rehabilitation programs. The facility and staff should receive basic training about continuous flow physiology, monitoring patients, and DMCS alarm response. All patients must have charged batteries and back up equipment with them at all times during exercise sessions. If patients arrive without back up equipment, the session must be delayed until patients secure equipment. The drive line exit site must be stabilized and protected from inadvertent trauma. LVAD parameters and mean arterial pressure measurements should be taken before and after exercise and must be within normal limits as prescribed by the implanting center (97). If these parameters are out of range, the CR team must inform the implanting center and seek recommendations. Patients are independent in managing their equipment before discharge so patients can attend to nuisance alarms such as low voltage requiring battery exchange. If patients experience a low flow alarm, halt exercise and remove patients from equipment to seated position. The CR staff needs to page the implanting center for recommendations. Additionally, patients should be instructed to stop exercising if they experience dizziness, diaphoresis, severe dyspnea, or significant chest pain. Emergency services (911) are called when patients have signs of stroke, ICD activation and/or monitored arrhythmias are detected, or alarms indicating equipment failure occur. Chest compressions may be initiated when the LVAD is not effectively perfusing and the patient is unconscious (9).

Recommendations for exercise and cardiac rehabilitation: (9, 88-97)

Class I

1. All patients who are able should be enrolled in cardiac rehabilitation after surgical placement of an DMCS. Level of evidence: C.

Topic 4: Medical management of the DMCS patient

Recommendations for anticoagulation (1)

Class I

1. *Patients with DMCS should receive anticoagulation with warfarin to maintain an INR within a range as specified by each device manufacturer (Table 9). Level of evidence: B.*

Recommendations for antiplatelet therapy: (1)

Class I

1. *Chronic antiplatelet therapy with aspirin (81−325 mg daily) may be used in addition to warfarin in patients with DMCS. Level of evidence: C.*
2. *Antiplatelet therapy beyond aspirin may be added to warfarin according to 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 with DMCS

There are no prospective, randomized trials evaluating the use of evidence-based heart failure therapy in patients with DMCS. However, despite limited evidence many clinicians use these agents in an attempt to maximize the chance of recovery as well as to treat hypertension. Myocardial recovery has been observed in patients with nonischemic cardiomyopathy given an aggressive regimen of lisinopril, carvedilol, spironolactone, and losartan in addition to the beta-2 agonist clenbuterol with both pulsatile and continuous flow devices (98, 99). Clenbuterol is not available outside research protocols and this experience has not been replicated in a multicenter trial. Recently the RESTAGE −HF study evaluated the use of lisinopril 40 mg, spironolactone 25 mg, digoxin 0.125 mg, losartan 150 mg, and carvedilol 25 mg twice a day in 40 patients with nonischemic cardiomyopathy at 6 different centers(100). Of 36 patients evaluated, 18 were explanted. Fourteen of those patients were ongoing on medical therapy with 609 days follow-up. There is one study suggesting a possible mortality benefit from the use of these agents. A retrospective study evaluating 307 patients who underwent LVAD implantation at 2 institutions found that independent predictors of mortality included the use of angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB), age at the time of implant, postimplant length of stay, and INTERMACS profile 1 or 2 (101).

Despite the lack of evidence of benefit, heart failure therapy is reasonable to use for patients with LVAD. LVAD therapy is associated with reduction in LV end-diastolic volume and pressure, elimination of isovolumic contraction and relaxation periods, and reduction in the energetic requirements of the heart (102). Despite this improvement the neurohormonal up-regulation of heart failure does not completely revert to normal. LVAD therapy has been shown to reduce renin and aldosterone levels but is associated with an increase in angiotensin II and norepinephrine (103). The use of ACEI blocked the increase in norepinephrine although in that setting renin and aldosterone levels remained high. Similar to their use in heart failure patients, blocking the effects of this upregulation supports the theoretical benefit of ACEI/ARB and aldosterone antagonists in these patients.

Heart failure medical therapy is used as first-line therapy in most patients with LVADs. A study of 9,359 patients using data from the INTERMACS registry demonstrated that by 3 months after implant, 50% of patients were on ACEI/ARB, 60% on beta blockers, 33% on aldosterone antagonists, and 68% on loop diuretics (104). A similar study using 10,329 patients from the INTERMACS registry evaluating the use of antihypertensive medications demonstrated similar use of these medications increasing to about 3 months postimplant and then slowly rising to treat the increase in blood pressure that occurs over time(105).

The implantation of LVADs results in acute improvement in heart failure, but volume overload might persist for some time and requires careful medical management. The causes of volume overload include right ventricular dysfunction, renal insufficiency, hypoalbuminemia, or inadequate unloading of the left ventricle due to suboptimal LVAD settings or obstruction to inflow or outflow. Because of this, most patients require diuretics at the time of discharge from implant hospitalization. Some of these patients may be able to have their diuretics decreased and discontinued over time, but often, especially with continuous flow devices they will remain on them forever. Hypertension also becomes a significant problem for most patients and multiple studies have shown beneficial effects of controlling blood pressure with a reduction in neurologic events, aortic insufficiency and heart failure (106). The increase afterload from hypertension results in reduced flow through the LVAD and reduced left ventricular unloading and an increase in strokes. ACEI/ARB are therefore the first-line drugs for post-LVAD hypertension. ACEI/ARB have also been associated with a reduction in the incidence of gastrointestinal bleeding caused by arteriovenous malformations (107, 108). The use of ARNIs in the LVAD population has only been evaluated in small single center studies and has been shown to be safe and effective at blood pressure lowering.(109-111) ARNI use has been associated with reduction in brain natriuretic peptide levels and diuretic requirements even in patients with LVADs. (109, 112)

However, the role of these agents in the overall clinical trajectory of LVAD patients remains to be studied. ARNIs could be used as substitutes for ACEI/ARB for LVAD patients. ACEI/ARB/ARNI are also beneficial in patients with diabetes and vascular disease, comorbidities often present in patients requiring LVADs. When renal insufficiency or hyperkalemia limit the use of ACEI/ARB and beta blockers, nondihydropyridine calcium channel blockers and alpha blockers may be utilized if necessary for additional blood pressure control.

In addition to being used for the treatment of heart failure, beta blockers have also been shown to reduce arrhythmias(113).In patients with marginal RV function, especially in the setting of volume overload, caution should be used when initiating these agents. There is no evidence for the routine use of aldosterone antagonists independent of their use in combination with ACEI/ARB and beta blockers, but they may be used to limit the need for potassium supplementation and for antifibrotic effects. Nitrates and hydralazine are useful for afterload reduction in patients who cannot tolerate an ACEI/ARB due to renal insufficiency or hyperkalemia. There is little data about digoxin use with MCSD and it was not included in the INTERMACS reports(104, 105) . However, in addition to its rate control properties for atrial fibrillation there is one recent study reporting a reduction is gastrointestinal bleeding for LVAD patients on digoxin thought to be related to its inhibition of HIF-1a synthesis (114).

Recommendations for heart failure therapy with DMCS: (98-100, 104, 105, 109-114)

Class I

1. *Diuretics are useful for the management of volume overload with DMCS. Level of Evidence: C.*
2. *An ACE-inhibitor or ARB or ARNI should be used as tolerated and are warranted as disease/natural history-modifying agents, . Level of Evidence: B.*
3. *Beta-blockers should be used as tolerated and are warranted as disease/natural history-modifying agent and/or for rate control in patients with tachyarrhythmias. Level of Evidence: C*
4. *Betablockers have been associated with a reduced incidence of tachyarrhythmias. Level of evidence B (retrospective)*
5. *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.*

Class IIb

1. *Digoxin may be useful in the setting of atrial fibrillation with rapid ventricular recommendations for heart failure therapy. Level of Evidence: C*
2. *ARNI can be used instead of ACEI/ARB post-LVAD implant, as recommended for patients with heart failure with reduced ejection fraction without LVADs. Level of Evidence: C*
3. *Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control. Level of Evidence: C.*

Late right heart failure

Right heart failure occurring in patients on LVAD is associated with notable morbidity and mortality. To characterize right heart dysfunction occurring after the operative LVAD period, some have ascribed the term "late right heart failure" (L-RHF). Substantial variability exists in the timing ascribed to the definition of L-RHF, ranging from onset 14 to 90 days after LVAD.(115-119) To better characterize RHF in future study, the academic research consortium agreed on the definition of L-RHF as occurring >30 days after LVAD implantation, requiring clinical signs/symptoms of right heart dysfunction and either RVAD support or re-initiation of inotrope or vasopressor support or intravenous diuretic therapy for clinical RV dysfunction (120). This same definition was adopted by Intermacs in version 6 of their user manual (ref).

For most patients, delayed or late RHF is felt to result from worsening of preexisting pre- or postoperative right ventricular dysfunction, not uncommonly developing in the setting of complications that lead to volume loading (e.g., bleeding), hypoxia (e.g., pneumonia), or stimulation of the systemic inflammatory response system (e.g., infection) with concomitant hypotension and/or renal malperfusion. The frequency of de novo (RHF occurring in those with presumed normal preoperative right heart function) delayed or late RHF has not been well tallied but could be the result of pulmonary embolism, acute hypoxic respiratory failure with ARDS, or excessive LVAD speeds causing LV suction and septal shift.

Patients with delayed and/or late RHF have been shown to have increased hospitalizations, decreased survival, worse quality of life, increased risk of gastrointestinal bleeding and decreased posttransplant survival.(115-119) This complication is especially concerning in patients without an option for cardiac transplantation. While preoperative risk factors have been identified including hemodynamic or echocardiographic evidence of right ventricular dysfunction (117) and an enlarged tricuspid valve annulus (118), present risk models fail to adequately predict delayed and late RHF risks in the preoperative setting(119). While concern exists that intrapericardial pump placement or continuous flow design may impact septal longitudinal contraction and ventricular interdependence with resultant RV dysfunction, a clear association with pump design and configuration has yet to be established. A recent analysis of the HMII destination therapy trial involving 537 patients, documented the delayed and/or late RHF was evident in 8% of patients with a median time to development of 480 days(119). Nearly 60% of patients met criteria beyond 1 year after pump implant (119). The incidence of delayed and late RHF in the Momentum Registry has not been reported but a fully magnetically levitated design was not

protective of perioperative RHF so the risk of delayed and late RHF in these patients is likely similar(121).

The treatment for RHF was discussed earlier in the Task Force 4 and consideration of durable right ventricular support is covered in Task Force 8.

Recommendations for delayed right heart failure (115-121)

Class I

1. *Late right ventricular dysfunction after LVAD placement is defined as onset >30 days after LVAD implant with concomitant may occur as a delayed (14 days to <6 months) or late (≥6 months) manifestation with symptoms and signs of right heart dysfunction and requirement for mechanical right heart support or resumption of inotropes, vasopressors or intravenous diuretics.*
2. *RV failure results in changes in LVAD parameters including a decrease in flows and pulsatility. Further evaluation of patients with suspected late right heart failure should include device interrogation, an echocardiogram and/or right heart catheterization. Level of Evidence: C.*

Class IIa

1. *When evidence of right heart 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 hypertension management with DMCS: (1, 122)

Class I

1. *Pharmacotherapy with neurohormonal blocking agents (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, angiotensin receptor blocker-neprilysin inhibitors, beta-blocker, mineralocorticoid receptor antagonist) is preferred for blood pressure management in durable LVAD patients. Level of Evidence B.*

Class IIa

1. *Patients with continuous flow LVADs should have a mean arterial pressure goal of 75 to 90 mm Hg. Level of evidence: B.*

Class IIb

1. *Patients with pulsatile DMCS should have a blood pressure goal of mean arterial blood pressure of 75 to 90 mm Hg. Level of evidence: C.*
2. *Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control. Level of Evidence: C.*
3. *Dihydropyridine calcium channel blockers, centrally acting alpha-2 receptors agonists (clonidine), and peripheral alpha-1 antagonists are third line agents in the management of hypertension in patients on MCS support. These agents should be used when first and second line agents are contraindicated or as supplemental therapy in individuals with resistant hypertension. Level of Evidence: C.*

Recommendations for diabetes management: (1, 123)

Class IIa

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

Class IIb

1. *SGLT2 inhibitors may be considered in patients with DMCS based on benefits seen in patients with cardiovascular disease and diabetes. Level of evidence: C.*

Recommendations for treatment of renal disease: (1)

Class IIb

1. *Renal function should be monitored on an ongoing basis after DMCS placement. Level of evidence: C.*
2. *Persistent renal insufficiency after DMCS should prompt further evaluation and management in collaboration with nephrology. Level of evidence: C.*

Recommendations for evaluation and management of hemolysis: (1)

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 (e.g., hemoglobinuria). Level of evidence: C.*
2. *Hemolysis in the presence of altered pump function should prompt admission for optimization of anticoagulation and antiplatelet 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: (1, 124, 125)

Class IIa

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

Class IIb

1. *For patients unable to achieve necessary weight loss with diet and exercise, bariatric surgery may be considered. Level of evidence: C.*

Recommendations for management of smoking and substance abuse: (1)

Class I

1. *Smoking cessation should be encouraged in all patients on DMCS 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.*

Care of the driveline

Driveline exit site/driveline cable /driveline connection assessment

The driveline exit site should be assessed at each patient visit for evidence of appropriate appearance and to exclude the presence of driveline infection. Ideally, the skin is incorporated to the driveline with little or no redness or discharge. To limit cross-contamination, the driveline dressing should not be routinely opened at clinic, unless a concern by the patient is raised. Patients and caregivers should be educated on how to evaluate the appearance of the driveline exit site and how to identify presence of infection. Patient/caregiver assessment, driveline exit site assessment tools or photographic evidence may be utilized during patient visits to identify potential driveline exit site infection that require exposure and examination. A photographic record of the driveline exit site may also be helpful in assessing its appearance over time. The driveline should be assessed for appropriate positioning and immobilization with an adhesive anchoring device or binder to minimize the risk of repeated microskin trauma or trauma caused by line movement and/or pulling at exit site. The driveline should be examined to exclude any breeches or defects in the casing as well as for twisting or kinking requiring unraveling or straightening. All driveline connections should be examined to ensure they are intact.

Dressing procedure/showering. The patient and/or caregiver should be trained and be independent in a standardized institutional driveline dressing procedure before hospital discharge. To maximize compliance, 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. The patient should be trained in the appropriate technique for showering once it is determined that satisfactory wound healing has taken place.

Recommendations for care of the driveline: (126-133)

Class I

1. The driveline exit site should be assessed at each clinic visit for signs of infection, as reported by patients or carer. The driveline cable and driveline connections should be examined at each clinic visit to ensure their integrity. Level of Evidence: C.
2. The driveline should be assessed at each clinic visit for appropriate position and immobilization with an adhesive anchoring device or binder. Level of Evidence: C.
3. The patient should be trained in proper self-care including showering technique and driveline dressing procedure before hospital discharge. Ongoing reinforcement of proper technique should be provided over the patient's lifetime, depending on the clinical course. Level of Evidence: C.

Topic 5: Infection prevention and treatment with DMCS (131,134-145)

Infectious prophylaxis

Infection is clearly associated with worse prognosis in DMCS recipients: It is the first cause of readmission at 30 days (134) and it is associated with increased risk of stroke (both ischemic and hemorrhagic) (135-138) and death (135, 138-141), especially in patients who cannot be bridged to heart transplantation once the infection is controlled(140).

DMCS-specific infections may occur early or late after implant and the most common infection in the outpatient setting is a driveline infection that if untreated can progress to the pocket and/or pump (142). Patient education to avoid driveline exit site trauma is critical to avoid driveline infection, as well as careful driveline care and appropriate follow-up by the DMCS coordinator (131). For more details on driveline care see the dedicated chapter in these guidelines. Special attention on this matter must be taken in young patients (139) and patients with a history of substance abuse (143).

Secondary antibiotic prophylaxis for prevention of endocarditis in the context of procedures (dental, respiratory, genitourinary, gastrointestinal) have not been studied in DMCS recipients and has not been addressed in clinical guidelines (144). Since the burden of developing BSI is high in patients with DMCS, recommendations for secondary prophylaxis should be similar to highest-risk patients (145). This implies the use of antibiotic prophylaxis in dental procedures requiring manipulation of the gingival or periapical region of the teeth or perforation of the oral

mucosa. Antibiotic prophylaxis is not recommended for local anesthetic injections in noninfected tissues, treatment of superficial caries, removal of sutures, dental X-rays, placement or adjustment of removable prosthodontic or orthodontic appliances or braces or following the shedding of deciduous teeth or trauma to the lips and oral mucosa. Antibiotic prophylaxis is not recommended for respiratory tract, gastrointestinal and urogenital procedures (144).

Class IIa

1. *Secondary antibiotic prophylaxis for prevention of endocarditis has not been studied in DMCS recipients, but given the risks associated with blood stream infections in these patients it is considered reasonable in dental procedures requiring manipulation of the gingival or periapical region of the teeth or perforation of the oral mucosa and for an abscess requiring incision and drainage. Level of evidence: C.*

Class III

1. *Antibiotic prophylaxis is not recommended for local anesthetic injections in noninfected tissues, treatment of superficial caries, removal of sutures, dental X-rays, placement or adjustment of removable prosthodontic or orthodontic appliances or braces or following the shedding of deciduous teeth or trauma to the lips and oral mucosa. Level of evidence: C.*
2. *Antibiotic prophylaxis is not recommended for respiratory tract, gastrointestinal and urogenital procedures. Level of evidence: C.*

Topic 6: ICD, pacemakers and arrhythmias in patients with LVAD (146-172)

Implantable cardioverters and defibrillators

Because patients on LVAD support are less dependent of left ventricular filling for maintaining adequate cardiac output than patients not on mechanical circulatory support, they tolerate sustained ventricular tachycardia and ventricular fibrillation better than patients without LVAD. However, cardiac output is decreased during sustained ventricular arrhythmias, and patients are frequently symptomatic. The data on the need for ICD in such patients are conflicting.

While majority of studies, mostly observational, and meta-analyzes showed no survival benefit in LVAD patients with ICDs (146-152), some demonstrated survival advantage on ICD (153, 154). Therefore we suggest that in patients who already have ICD before LVAD implantation the device is reactivated in the postoperative period, and patients who did not have ICD before LVAD only receive them after the implantation if they have a history of sustained ventricular arrhythmias or are at a very high risk for ventricular arrhythmias with factors that affect how the arrhythmia might be hemodynamically tolerated such as elevated pulmonary vascular resistance.

Subcutaneous implantable cardioverter defibrillators

Subcutaneous implantable cardioverter defibrillators (S-ICD) can be used an alternative to transvenous implantable defibrillators in in patients who do not require pacing and are at risk for intravascular infections.(169) In patients with LVADs concomitant use of S-ICD raises concerns for electromagnetic interference that can lead to problems with sensing and increase the risk of inappropriate shocks. (170) There is limited data regarding the use of these devices in the LVAD population. In a recent multicenter study of 20 patients with LVADs and S-ICDs in the United States, the concomitant use of these devices was reported to be feasible, and only one S-ICD had to be disabled due to difficulties with sensing.(157) However, there are several reports of undersensing or oversensing by the S-ICD due to electromagnetic interference from the LVAD resulting in inappropriate shocks.(170, 171) S-ICDs also need to be reprogrammed after LVAD implantation to identify the most effective vector that can minimize the risk of inappropriate shocks while being able to effectively terminate spontaneous ventricular arrhythmias. Due to paucity of data we are unable to make a recommendation for or against the use of S-ICDs in patients with LVADs. For patients who have already have a S-ICD before LVAD implant, we recommend that the device be turned off during the LVAD implant surgery and following the implant the S-ICD should be reprogrammed to optimize its function. If the S-ICD function cannot be optimized, it may be reasonable to disable and/or explant the S-ICD to avoid inappropriate shocks. Whether the S-ICD needs to be replaced with a transvenous ICD would depend on prior history of spontaneous ventricular arrhythmias and individual infectious risk.

When ICD is in place, routine care, including regular interrogations and generator changes is appropriate. When more extensive interventions such as lead replacement/reposition is needed, careful consideration should be given to the risk/benefit ratio as LVAD patients are typically on chronic anticoagulation and have higher complication rate after invasive procedures than general population.(172)

Recommendations for ICD placement

Class I

1. *For patients who have an ICD before MCS, the ICD should be reactivated in the postoperative setting. Level of Evidence: B.*

Class IIa

1. *In patients with an LVAD and no prior history of ventricular arrhythmias, it is reasonable to defer ICD*

placement if for primary prevention. Level of evidence: B.
2. *In patients with LVAD and ICD, routine ICD management is appropriate (interrogation every 3 months with re-programming as needed). Level of evidence: C*
3. *In patients with LVAD and ICD, routine generator change should be considered if ICD is in place for secondary prevention. Level of evidence: C*
4. *ICD programming in patients with LVAD should be conservative with the goal of maximizing antitachycardia pacing and minimizing shocks. Level of evidence: B*

In patients with a subcutaneous ICD before LVAD implant, the device must be reprogrammed post-LVAD implant to allow appropriate sensing and avoid inappropriate shocks. Level of evidence: C

1. *Inactivation of the ICD should be considered in patients with biventricular assist devices (BiVADs) who are in persistent VT/VF or who have frequent sustained runs of VT despite optimal antiarrhythmic therapy. Level of evidence: C*
2. *Inactivation of ICD should be considered in LVAD patients with frequent shocks if they are asymptomatic or minimally symptomatic with sustained VT. Level of evidence: C*

Class III
1. *In patients who require an ICD implant for secondary prevention after LVAD implant, current generation subcutaneous ICDs are not recommended given concerns for electromagnetic interference and risk of inappropriate shocks. Level of evidence: C*

Cardiac resynchronization therapy(158-161)

Benefits of cardiac resynchronization therapy (CRT) in LVADs are even more controversial than ICD. Patients who respond favorably to CRT usually do not require an LVAD, and those who are so hemodynamically compromised that LVAD is indicated are clearly nonresponders. As of to date, there is no evidence of any survival or symptomatic benefits of CRT in patients on LVAD support (158-161). Therefore turning off the left ventricular lead may provide longer battery life without a compromise on morbidity or survival (161). Exceptions can be made for patients with nonischemic cardiomyopathy and complete bundle branch block who did not receive CRT before LVAD. Because they may have a chance to recovery on LVAD, CRT may be considered.

CRT in LVAD

Class IIb

1. In patients with LVAD and CRT, there is no clear benefit of continuation of biventricular pacing. To preserve the battery and minimize generator changes, turning off the left ventricular lead may be considered. Level of evidence: C

Arrhythmia management in LVADs

After the 2013 ISHLT Guidelines were published, the advancements were made in the areas of ablation for VT. Catheter ablation is considered a reasonable treatment strategy (162-165) and might be even associated with a better survival (164).

Antiarrhythmic drugs and beta-blockers are still used although not much evidence has been added. Because of full hemodynamic support, patients on LVADs can tolerate high doses of beta-blockers and other drugs with negative inotropic properties (166).

Atrial arrhythmias are prevalent in LVAD patients but are not found to be associated with increased mortality, thromboembolism, or stroke (167), and rhythm control measures were not associated with improved outcomes (168). Exercise tolerance at 6 months post-LVAD implant has been shown to be lower in patients with atrial fibrillation at the time of implant when compared with those without atrial fibrillation.(173) Management of atrial arrhythmias in patients with LVADs typically involves rate control with beta blockers and digoxin. There is no clinical trial data available to support the use of rhythm control with ablation treatment or antiarrhythmic drugs and left atrial appendage occlusion devices in this patient population.(156)

Recommendations for management of atrial arrhythmias

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 is recommended. Level of evidence: C.*

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 DMCS should prompt a search for reversible causes, such as electrolyte abnormalities, drug toxicities, or suction events. Level of Evidence: C.*

Class IIa

1. *Amiodarone is a reasonable chronic outpatient treatment to prevent recurrence of VT in patients with DMCS. Level of Evidence: C.*
2. *Beta-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.*
4. *Catheter ablation should be considered in recurrent symptomatic VT especially if it results in hemodynamic compromise. Level of Evidence: B.*

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 7: Psychologic and psychiatric issues (1)

Recommendations for management of psychologic and psychiatric issues

Class I

1. *Patients being considered for DMCS implantation 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 8: Emergency procedures for device malfunction or failure (174-178)

As DMCS technology has improved, the incidence of 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 device repair or 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 DMCS 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 DMCS 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 DMCS 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 DMCS-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 DMCS 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 DMCS alarms and troubleshoot emergencies before 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 9: End of life issues

Recommendations for end of life issues: (1)

Class I

1. *Consultation with palliative medicine, if available, should be considered before DMCS 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 DMCS support, consideration may be given to consulting with the hospital ethicist or ethics board, if available. Level of evidence: C.*

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Task Force 5 Summary:
Outpatient management of the DMCS recipient

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Topic 1 **Transitioning the DMCS patient to the home or community environment**	**Topic 1** **Transitioning the DMCS patient to the home or community environment**
1.1. Recommendations for evaluation of safety of the home environment: Class I: 1. An uninterrupted supply of electricity to continuously power the DMCS 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	**1.1. Recommendations for evaluation of safety of the home environment:** *Continuing approval without change*
1.2. 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 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.	**1.2. Recommendations for community outreach by the MCS team:** *Replaced by the new and modified recommendations below* Class I: 1. Community education should be provided by the DMCS implanting center at patient discharge. Level of Evidence C. *(Unchanged)* 2. Recommendations for essential community education components include DMCS purpose, function, patient assessment, emergency resources, and institutional specific information (Table 1 in text). Level of Evidence C. *(Modified)* 3. Community education programs should be targeted for referring providers, primary care and community health providers, emergency services, and local hospital providers. In the case of pediatric patients, school health providers, administrators, and teaching staff should also be included. Inclusion of patient extended support lay providers is beneficial. Level of Evidence C. *(Modified)*

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Task Force 5 Summary:
Outpatient management of the DMCS recipient

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	4. Utilities companies should be notified of patient reliance on electrical power. Level of Evidence C. *(New)*
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.	Class IIa: 1. Community education should occur in person or virtual manner when feasible. Level of Evidence C. *(New)* 2. Patient involvement in community education is beneficial. Level of Evidence C. *(New)* 3. Provision of accessible resources (online training, emergency procedure guides, hospital location resources) is beneficial for community provider reference. Level of Evidence C. *(New)*
1.3. Recommendations for assessment of the social network: Class I: 1. The primary designated caregiver should demonstrate competency in functioning of the DMCS and the appropriate response to alarms. Level of Evidence C. 2. The DMCS team designee must interview patients and family members regarding the strength and depth of their social support. The social worker or other DMCS 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 DMCS program on their preparedness for the transition to the home environment. The multidisciplinary DMCS team should review survey results at regular intervals to help facilitate programmatic improvements. Level of Evidence C.	**1.3. Recommendations for assessment of the social network:** *Continuing approval without change*
1.4. 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.	**1.4. Recommendations for driving a motor vehicle:** Class IIb: 1. Patients in whom functional capacity has been restored with an LVAD should pose a similar risk to self and others while driving a personal motor vehicle for noncommercial purpose as heart failure patients with an implantable cardiac defibrillator. Level of Evidence C. *(Modified)* Class III: 1. Commercial driving is not recommended in patients with DMCS. Level of Evidence C. *(New)*
	1.5. Recommendations for flying with a commercial airline: *(New)* Class I: 1. Clinically stable patients with normally functioning DMCS can travel on commercial flights under the condition that have enough batteries available and/or there is a possibility to recharge batteries on board. Level of Evidence C. *(New)* Class III: 1. Flying is not recommended in unstable patients, with DMCS dysfunction and life-threatening comorbidities as well as in those not stabilized after recent hospitalization. Level of Evidence C. *(New)*

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Task Force 5 Summary: Outpatient management of the DMCS recipient

2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Topic 2 **Follow up Care**	**Topic 2** **Follow up Care**
2.1. Recommendations for multidisciplinary approach to follow up care: Class I: 1. Management of the patient with an DMCS should be performed by a multidisciplinary team that includes cardiovascular surgeons, advanced heart failure cardiologists, and specialized DMCS coordinators. Other health care providers may collaborate with the primary DMCS team when additional expertise is required. Level of Evidence C.	**2.1. Recommendations for multidisciplinary approach to follow up care:** *Continuing approval without change*
2.2. Recommendations for frequency of visits: Class I: 1. DMCS patients should be seen in clinic regularly, the frequency of which is dictated by their clinical stability. Level of Evidence B. 2. DMCS 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 DMCS coordinator to the patient or caregiver may help proactively identify issues that may adversely affect patient outcomes. Level of Evidence B.	**2.2. Recommendations for scheduled follow up:** *Continuing approval without change*
2.3. Recommendations for use of echocardiography in patients with DMCS: 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 DMCS 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 suboptimal DMCS function or in the presence of clinical signs of circulatory dysfunction, including congestive or low output symptoms. Level of Evidence B.	**2.3. Recommendations for use of echocardiography with DMCS:** 1. *Continuing approval without change* 2. *Continuing approval without change* Class IIa: 1. The frequency of routine echocardiography can be determined by individual programs but should be performed no less than annually. Level of Evidence C. *(New)*
2.4. Recommendations for use of right heart catheterization in patients with DMCS: Class I: 1. Right heart catheterization is useful in the assessment of persistent or recurrent heart failure symptoms after LVAD 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.	**2.4. Recommendations for use of right heart catheterization with DMCS:** 1. *Continuing approval without change* 2. *Continuing approval without change*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
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 LVAD support prior to pump explanation. Level of Evidence C.	Class IIa: 1. Right heart catheterization should be performed at the discretion of the clinician to optimize LVAD speed and medical therapy to balance adequate left ventricular unloading, pulmonary artery hemodynamics, cardiac output, and right ventricular function in all LVAD patients in order to reduce heart failure hospitalization and hemocompatibility related adverse events. Level of Evidence B. *(Modified)*
2.5. Recommendations for use of CT angiography in patients with DMSC: Class I: 1. CT angiography allows visualization of the native heart and DMCS components and may be valuable when other imaging modalities have not been revealing. Level of Evidence B.	**2.5. Recommendations for use of CT angiography in patients with DMSC:** Class I: 1. *Continuing approval without change* 2. CT angiography is recommended if an outflow graft obstruction is suspected, and if renal function permits. CT angiography with 3D reconstruction can help identify causes of outflow graft obstruction such as graft thrombosis, external compression, outflow graft twisting or kinking. Level of Evidence C. *(New)*
2.6. Recommendations for functional capacity testing in patients with DMCS: Class I: 1. Measurement of exercise capacity should be undertaken after DMCS 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 DMCS. Suggested intervals are 3 months, 6 months, at 6-month intervals through 2 years after implant, and then yearly thereafter. Level of Evidence C.	**2.6. Recommendations for functional capacity testing in patients with DMCS:** *Continuing approval without change*
2.7. Recommendations for HRQOL: Class IIa: 1. HRQOL should be measured before DMCS implantation and at regular intervals longitudinally for the duration of DMCS 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.	**2.7. Recommendations for HRQOL:** Class I: 1. A comprehensive assessment of HRQOL (physical, emotional, social) and functional capacity using reliable and valid instruments should be undertaken following DMCS implant (if patient is capable) and following discharge. Level of Evidence B. *(Modified)* Class IIa: 1. HRQOL and functional capacity data should be collected at regular follow-up intervals (including baseline, 3 months, 6 months, and at 6-month intervals through 2 years after implant and yearly thereafter) to allow for an assessment of patient trajectory and identification of areas for intervention. Level of Evidence B. *(Unchanged)* 2. HRQOL assessment should include a disease-specific instrument previously validated in the DMCS population. Level of Evidence B. *(New)* 3. HRQOL assessment in DMCS patients should include a generic instrument (e.g. the EQ-5D with VAS) to enable comparison of findings across healthy and chronically ill populations and enable time trade-off and cost-utility analyses. Level of Evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	4. When assessing functional capacity and HRQOL, reasons for missing data should be included (e.g. unable to complete due to cardiac limitation, unable to complete due to other limitation, unwilling to complete) to avoid bias. Level of Evidence C. *(New)* 5. MCS teams should consider when additional PROMs may benefit some patients (e.g., sexual, social, or spiritual wellbeing) and work toward using PROMs in the clinical setting. Level of Evidence B. *(New)* ***Class IIb:*** 1. Assessment of HRQOL while hospitalized post-DMCS implantation may be reasonable by targeting select HRQOL domains (e.g., depressive symptoms, anxiety). Level of Evidence C. *(New)* 2. For patients still hospitalized after 1 month postoperatively and for those re-hospitalized post-DMCS, inpatient assessment of select measures of HRQOL (e.g., spiritual or social wellbeing) may be appropriate, given that these may be affected by prolonged or frequent hospitalization and complications. Level of Evidence C. *(New)*
2.8. Recommendations for laboratory studies in patients with DMCS: 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.	**2.8. Recommendations for laboratory studies in patients with DMCS:** *Continuing approval without change*
2.9. Recommendations for assessment of DMCS: Class I: 1. The driveline, exit site, and DMCS 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.	**2.9. Recommendations for assessment of DMCS:** *Continuing approval without change*
2.10. Recommendations for health maintenance: Class I: 1. Patients with DMCS 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.	**2.10. Recommendations for health maintenance:** *Continuing approval without change*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Topic 3 **Cardiac rehabilitation and exercise guidelines**	**Topic 3** **Cardiac rehabilitation and exercise guidelines**
3.1. Recommendations for exercise and cardiac rehabilitation: Class I: 1. All patients who are able should be enrolled in cardiac rehabilitation after surgical placement of DMCS. Level of Evidence C.	**3.1. Recommendations for exercise and cardiac rehabilitation:** *Continuing approval without change*
Topic 4 **Medical management of the DMCS patient**	**Topic 4** **Medical management of the DMCS patient**
4.1. Recommendations for anticoagulation: Class I: 1. Patients with DMCS should receive anti-coagulation with warfarin to maintain an INR within a range as specified by each device manufacturer. Level of Evidence B.	**4.1. Recommendations for anticoagulation:** *Continuing approval without change*
4.2. Recommendations for antiplatelet therapy: Class I: 1. Chronic anti-platelet therapy with aspirin (81–325 mg daily) may be used in addition to warfarin in patients with DMCS. 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. Class IIb: 1. Assessment of platelet function may be used to direct the dosing and number of anti-platelet drugs. Level of Evidence C.	**4.2. Recommendations for antiplatelet therapy:** *Continuing approval without change*
4.3. Recommendations for heart failure therapy: Class I: 1. Diuretics are useful for the management of volume overload during DMCS. Level of Evidence C. 2. 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. 3. ACE-inhibitors and ARB have been shown to reduce the incidence of gastrointestinal bleeding and mortality in patients with LVADs. Level of Evidence B. 4. Beta-blockers may be used for hypertension or for rate control in patients with tachyarrhythmias. Level of Evidence C. 5. 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. Class II: 1. Digoxin may be useful in the setting of atrial fibrillation with rapid ventricular response. Level of Evidence C	**4.3. Recommendations for heart failure therapy:** Class I: 1. *Continuing approval without change* 2. An ACE-inhibitor or ARB or ARNI should be used as tolerated and are warranted as disease/natural history-modifying agents. Level of Evidence B. *(Modified)* 3. Beta-blockers should be used as tolerated and are warranted as disease/natural history-modifying agent and/or for rate control in patients with tachyarrhythmias. Level of Evidence C *(Modified)* 4. *Continuing approval without change* 5. *Continuing approval without change* Class IIb: 1. *Continuing approval without change* 2. ARNI can be used instead of ACEI/ARB post LVAD implant, as recommended for patients with heart failure with reduced ejection fraction without LVAD. Level of Evidence C *(New)* *3.* Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control. Level of Evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
	4.4. Recommendations for delayed right heart failure: Class I: 1. Late right ventricular dysfunction after LVAD placement is defined as onset >30 days after LVAD implant. It may occur as a delayed (14 days to <6 months) or late (6 months) manifestation with symptoms and signs of right heart dysfunction and requirement for mechanical right heart support or resumption of inotropes, vasopressors or intravenous diuretics. Level of Evidence C. *(New)* 2. RV failure results in changes in LVAD parameters including a decrease in flows and pulsatility. Further evaluation of patients with suspected late right heart failure should include device interrogation, an echocardiogram and/or right heart catheterization. Level of Evidence C. *(Modified)* Class IIa: 1. When evidence of right heart 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. *(Modified)*
4.5. 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 DMCS should have a mean blood pressure goal of 80 mmHg. Level of Evidence C.	**4.5. Recommendations for hypertension management:** *Replaced by the new and modified recommendations below* Class I: 1. Pharmacotherapy with neurohormonal blocking agents (angiotensin-converting enzyme inhibitor, angiogtensin receptor blocker, angiotensin receptor blocker-neprilysin inhibitors, beta-blocker, mineralocorticoid receptor antagonist) is preferred for blood pressure management in durable LVAD patients. Level of Evidence B. *(New)* Class IIa: 1. Patients with continuous flow LVADs should have a mean arterial pressure goal of 75-90 mm Hg. Level of Evidence B. *(Modified)* Class IIb: 1. Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control. Level of Evidence C. *(New)* 2. Dihydropyridine calcium channel blockers, centrally acting alpha-2 receptors agonists (clonidine), and peripheral alpha-1 antagonists are third line agents in the management of hypertension in patients on DMCS support. These agents should be used when first and second line agents are contraindicated or as supplemental therapy in individuals with resistant hypertension. Level of Evidence C. *(New)*
4.6. Recommendations for diabetes management: Class IIa: 1. Patients with diabetes should have continued therapy and close follow-up for their diabetes while receiving DMCS. Level of Evidence C.	**4.6. Recommendations for diabetes management:** Class IIa: 1. *Continuing approval without change* 2. SGLT2 inhibitors should be considered in patients with DMCS based on benefits seen in patients with cardiovascular disease and diabetes. Level of Evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
4.7. Recommendations for treatment of renal disease: Class IIb: 1. Renal function should be monitored on an ongoing basis after DMCS placement. Level of Evidence C. 2. Persistent renal insufficiency after DMCS should prompt further evaluation and management in collaboration with nephrology. Level of Evidence C.	**4.7. Recommendations for treatment of renal disease:** *Continuing approval without change*
4.8. Recommendations for evaluation and management of hemolysis: 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 (e.g. hemoglobinuria). Level of Evidence C. 2. Hemolysis in the presence of altered pump function should prompt admission for optimization of anticoagulation and antiplatelet 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.	**4.8. Recommendations for evaluation and management of hemolysis:** *Continuing approval without change*
4.9. Recommendations for dietary management: Class IIa: 1. Weight loss should be encouraged for all patients with a body mass index of >30 kg/m2. Level of Evidence C.	**4.9. Recommendations for dietary management:** Class IIa: 1. *Continuing approval without change* Class IIb: 1. For patients unable to achieve necessary weight loss with diet and exercise, bariatric surgery may be considered. Level of Evidence C. *(New)*
4.10. 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.	**4.10. Recommendations for smoking and substance abuse:** *Continuing approval without change*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Topic 5 **Driveline Care, Infection Prevention and Treatment with DMCS**	**Topic 5** **Driveline Care, Infection Prevention and Treatment with DMCS**
	5.1. Recommendations for care of the driveline: *(New)* Class I: 1. The driveline exit site should be assessed at each clinic visit for signs of infection, as reported by patients or caregiver. The driveline cable and driveline connections should be examined at each clinic visit to ensure their integrity. Level of Evidence C. *(New)* 2. The driveline should be assessed at each clinic visit for appropriate position and immobilization with an adhesive anchoring device or binder. Level of Evidence C. *(New)* 3. The patient should be trained in proper self-care including showering technique and driveline dressing procedure prior to hospital discharge. Ongoing reinforcement of proper technique should be provided over the patient's lifetime, depending on the clinical course. Level of Evidence C. *(New)* **5.2. Recommendations for infectious prophylaxis after DMCS therapy: *(New)*** Class IIa: 1. Secondary antibiotic prophylaxis for prevention of endocarditis has not been studied in DMCS recipients, but given the risks associated with blood stream infections in these patients it is considered reasonable in dental procedures requiring manipulation of the gingival or periapical region of the teeth or perforation of the oral mucosa and for abscesses requiring incision and drainage. Level of Evidence C. *(New)* Class III: 1. Antibiotic prophylaxis is not recommended for local anesthetic injections in non-infected tissues, treatment of superficial caries, removal of sutures, dental X-rays, placement, or adjustment of removable prosthodontic or orthodontic appliances or braces or following the shedding of deciduous teeth or trauma to the lips and oral mucosa. Level of Evidence C. *(New)* 2. Antibiotic prophylaxis is not recommended for respiratory tract, gastrointestinal and urogenital procedures. Level of Evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Topic 6 **ICD and arrhythmias with DMCS**	**Topic 6** **ICD and arrhythmias with DMCS**
6.1. Recommendations for ICD placement:	**6.1. Recommendations for ICD management in patients with DMCS:**
Class I: 1. For patients who have an ICD prior to DMCS, the ICD should be reactivated in the post-operative setting. Level of Evidence A.	Class I: 1. *Continuing approval without change*
Class IIa: 1. Routine placement of an ICD should be considered for patients who did not have an ICD prior to DMCS. Level of Evidence B.	Class IIa 1. In patients with an LVAD and no prior history of ventricular arrhythmias, it is reasonable to defer ICD placement if for primary prevention. Level of Evidence B. *(Modified)*
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.	2. *Continuing approval without change* 3. In patients with LVAD and ICD, routine ICD management is appropriate (interrogation every 3 months with re-programming as needed). Level of Evidence C. *(New)* 4. In patients with LVAD and ICD, routine generator change should be considered only if ICD is in place for secondary prevention. Level of Evidence C. *(New)* 5. ICD programming in patients with LVAD should be conservative with the goal of maximizing anti-tachycardia pacing and minimizing shocks. Level of Evidence B. *(New)* 6. In patients with a subcutaneous ICD prior to LVAD implant, the device must be reprogrammed post LVAD implant to allow appropriate sensing and avoid inappropriate shocks. Level of Evidence C. *(New)* 7. Inactivation of ICD should be considered in LVAD patients with frequent shocks if they are asymptomatic or minimally symptomatic with sustained VT. Level of Evidence C. *(New)* Class III: 1. In patients who require an ICD implant for secondary prevention after LVAD implant, current generation subcutaneous ICDs are not recommended given concerns for electromagnetic interference and risk of inappropriate shocks. Level of Evidence C. *(New)* **6.2. Recommendations for CRT management in patients with DMCS: *(New)*** Class IIb: 1. In patients with LVAD and CRT, there is no clear benefit of continuation of biventricular pacing. In order to preserve the battery and minimize generator changes, turning off the left ventricular lead may be considered. Level of Evidence C. *(New)*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
6.3. 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 American College of Cardiology/American Heart Association atrial fibrillation guidelines is recommended. Level of Evidence C.	**6.3. Recommendations for management of atrial fibrillation and flutter:** *Continuing approval without change*
6.4. 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. Therapy with b-blockers 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.	**6.4. Recommendations for management of ventricular arrhythmias:** Class I: 1. *Continuing approval without change* 2. *Continuing approval without change* Class IIa: 1. *Continuing approval without change* 2. *Continuing approval without change* 3. *Continuing approval without change* 4. Catheter ablation should be considered in recurrent symptomatic VT especially if it results in hemodynamic compromise. Level of Evidence B. *(New)* Class IIb 1. *Continuing approval without change*
Topic 7 **Psychological and psychiatric issues**	**Topic 7** **Psychological and psychiatric issues**
7.1. Recommendations for psychological and psychiatric issues: **Class I:** 1. Patients being considered for DMCS implantation 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. Counselling may need to be extended to include family members as well. Level of Evidence C.	**7.1. Recommendations for psychological and psychiatric issues:** *Continuing approval without change*

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2013 Guidelines Recommendations	New and Modified in 2023 Updated Guidelines
Topic 8 **Emergency procedures for device malfunction or failure**	**Topic 8** **Emergency procedures for device malfunction or failure**
8.1. Recommendations for emergency procedures with device malfunction or failure: Class I: 1. The patient and their caregivers should be trained to recognize DMCS 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.	**8.1. Recommendations for emergency procedures with device malfunction or failure:** *Continuing approval without change*
Topic 9 **End of life issues**	**Topic 9** **End of life issues**
9.1. Recommendations for end of life issues: Class I: 1. Consultation with palliative medicine, if available, should be considered prior to DMCS 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 DMCS support, consideration may be given to consulting with the hospital ethicist or ethics board, if available. Level of Evidence C.	**9.1. Recommendations for end of life issues:** *Continuing approval without change*

Task Force 6

DMCS in adults with congenital heart disease

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Introduction

In adults with congenital heart disease (ACHD), heart failure remains the leading cause of morbidity and mortality, and accounts for 20% of hospital admissions (1). This

population has unique challenges when considering support with DMCS both as a bridge to transplant as well as durable VAD implantation for destination therapy. There is increasing experience with DMCS in young adults with CHD. Understanding the natural history of their heart failure, thorough work-up for comorbid issues, and complete assessment of surgical anatomy are critical for successful outcomes. Details of patient selection, device selection, and pre-VAD selection are critical to understand in this complex group. Although ACHD patients have a higher earlier mortality rate they have similar adverse event rates and improvement in quality of life when compared to non-ACHD patients (2).

Topic 1: Patient selection

Class I

1. *It is recommended to have recently obtained documentation of cardiac morphological and ventricular physiological data after last surgery, including the presence of shunts, collateral vessels and the location and course of great vessels in patients with CHD undergoing evaluation for mechanical circulatory support.*

Level of Evidence: B.(3-7)

1. *ACHD patients should have a preimplant evaluation including assessment of end organ function, surgical planning, and psychosocial and neurocognitive assessment.*

Level of Evidence: B. (8-10)

1. *Patients with ACHD, refractory to medical management should be evaluated for MCS early before progression of end-organ dysfunction.*

Level of Evidence: B. (2)

Class IIa

1. *ACHD patients that qualify for mechanical support demonstrate similar survival rates after durable DMCS implantation compared to non-ACHD patients. ACHD patients in heart failure should be actively evaluated for DMCS and heart transplantation.*

Level of Evidence: C.

Class III

1. Implantation of a device with patient-device size mismatch is not recommended.

Level of Evidence: C.

Topic 2: Biventricular CHD

Recommendations for patient selection and screening

Class I

1. *All patients being considered for DMCS should have their New York Heart Association functional class assessed and their Interagency Registry for Mechanically Assisted Support (INTERMACS) profile determined.*

Level of Evidence: C.(11-14).

Class IIa

1. *All patients with biventricular CHD, with either systemic morphological LV or RV dysfunction refractory to medical management should be evaluated for DMCS early before progression of subpulmonary ventricular failure and/or development of hepatic, renal and/or respiratory dysfunction, as outcomes for LVAD patients with biventricular CHD is comparable to non-ACHD patients.*

Level of Evidence: A.(7, 15)

1. *Evaluation of an adult CHD patient for DMCS may be done at a pediatric and/or adult cardiovascular center with clinical and surgical experience in CHD.*

Level of Evidence: C.(7, 16)

Recommendations for device selection

There is limited experience using VAD and/or TAH in ACHD patients as only 15% to 20% of all ACHD patients are provided with a VAD. Overall, <1% of all VADs are implanted in ACHD patients. That most common used VADs are or have been: HeartMate II (Thoratec Corporation, Pleasanton, CA), Heartware HVAD (Medtronic, Framingham, MA), HeartMate 3 (Abbott, Abbott Park, IL), Berlin Heart Excor (Berlin Heart AG, Berlin, Germany) and the Syncardia TAH (TAH-t; SynCardia Systems, Inc., Tucson, AZ). In June 2021 the distribution and sale of the HVAD System was stopped by the manufacture and is therefore no longer available for implantations. New technology and with it new devices are evolving like the combination Leviticus/Jarvik (2000) totally implantable system (FIVAD or Fully Implantable VAD),(17-19) the Evaheart (Sun Medical Technology Research Corporation, Nagano, Japan) unique pulsatile centrical pump (20) and NuPulse implantable truly minimally invasive partial support device (21). Notably for all devices, patients with history of multiple prior sternotomies are at a higher risk for mortality and morbidity (22).

Many factors play an important part in the decision-making process for device selection. These include but are not limited to access (sternotomy vs thoracotomy), unusual anatomy of certain congenital lesions (e.g., systemic right ventricles, single ventricles or small ventricles, etc.); the restriction of chest itself (from scoliosis, multiple thoracotomies, restrictive lung disease, etc.); the presentation of unusual physiology (high hematocrit associated with cyanosis, presence of significant ineffective circulation and volume overload from such anomalies as aortopulmonary or AP collaterals, etc.); and presence of residual lesions (e.g., aortic or neoaortic insufficiency, pulmonary insufficiency, presence of prior mechanical valves in different anatomic locations).

The HeartWare HVAD was the only FDA approved device for thoracotomy implantation (23) but there are other devices which been implanted using this approach off label.(24-26)

The HeartMate 3 was specifically engineered for improved hemocompatibility (27) and has been placed as in total artificial heart configuration (28). For pediatric patients, utilization of the Syncardia TAH is limited, but remains a valuable option in some ACHD patients (29). In recent years a 50 mL pump in

addition to the 70ml pump made by Syncardia may increase the potential utility of this pump in smaller patients (30). Overall implantation numbers of the Berlin Heart Excor are low. Still it has a prominent role in pediatrics but also in adults with or without CHD especially those with biventricular failure or single ventricle (see section below). It is important to recognize, however, that unlike the continuous flow devices, the Berlin Heart can function only within the constraints of its device and pump sizes. In patients with anticipated inefficient circulation (e.g., substantial aortopulmonary collateral requiring a high output), support provided by the pulsatile system will likely be inefficient and limited by the upper range of pulse rate these pulsatile devices can be programmed to perform. Finally, the Berlin cannulas can also be connected to continuous flow devices intended for temporary support, but would limit mobility and home discharge. Still, the Berlin Heart EXCORVR Pediatric VAD is currently the only VAD specifically designed and approved for the pediatric population in the USA, Europe, and Canada. In summary, it is impossible to cover all possible scenarios and give specific recommendations. Device selection has to be based on a case-by-case scenario and institutional and surgeon's preference in this complex patient population.

Special considerations

Operative considerations

Class I

1. *If a TAH placement is planned, a virtual fit/implantation is recommended (3-5, 31)*
   Level of Evidence: C.
2. *In patients with a systemic morphologic right ventricle undergoing systemic VAD placement, excision of muscular trabeculae including the moderator band from the inflow cannula site is recommended(32-39)*

Level of Evidence: C.

Class IIa

1. *It is likely beneficial to have a surgeon with experience in congenital heart surgery participate in DMCS implant in ACHD patients.*

Level of Evidence: C.

Class IIb

1. *In complex CHD patients with biventricular failure having adequate intrathoracic space, BIVADs or TAH may be considered as a bridge to transplant or as destination therapy.*
   Level of Evidence: C. (3, 7, 15, 40-43)
2. *In CHD patients with residual shunting, shunt closure at the time of DMCS implant may be of benefit*
   Level of Evidence: C. (44-46)
3. *In patients with a systemic morphologic right ventricle, undergoing systemic VAD placement, optimal inflow cannula location may be in the diaphragmatic wall of the right ventricle or right ventricular apex directed toward the tricuspid valve.*
   Level of Evidence: C. (18, 32, 35, 37-39, 45, 47-59)
4. *In patients with moderate or severe levels of anatomic complexity undergoing VAD implant, virtual fit to identify optimal inflow cannula and VAD orientation in the thorax using 3D printed models or virtual reality may be useful.*
   Level of Evidence: C. (60)

Management of associated conditions

Class I

1. *In patients with evidence of hepatic dysfunction, evaluation of the degree and etiology before DMCS implant is recommended.*
   Level of Evidence: C.
2. *In patients with congestive hepatopathy, identification of the mechanism underlying congestion before DMCS implant is recommended.*
   Level of Evidence: C.
3. *In patients with cardiorenal syndrome, ruling out venous obstruction before DMCS implant is recommended.*
   Level of Evidence: C.

Class IIa

1. *In patients with pulmonary hypertension, it is reasonable to use of VAD support to improve pulmonary hemodynamics as a bridge to decision.*
   Level of Evidence: C (54, 56, 59, 61-63).

Class IIb

1. *Earlier use of VAD therapy may help to decrease the early hazard associated with heart transplantation among ACHD patients by decreasing end-organ dysfunction and relieving pulmonary hypertension secondary to CHD.*
   Level of Evidence: C. (2, 64)

Topic 3: Single ventricle

Large, randomized trials investigating the use of DMCS in patients with single ventricle do not exist. The majority of data comes from small case series or single case reports revealing high mortality rates and a significant number of adverse event rates (7, 65-67). At adults, most of these patients with a single ventricle circulation will be in a Fontan circulation. An erosion of this Fontan circulation will occur at different stages, and tends to be multifactorial and yet remains only partly understood (68, 69). Still there are 2 major stages for Fontan failure: systemic ventricular failure or failure at the level of cardiopulmonary connection. In the single ventricle patient with Fontan circulation, current era mechanical circulatory support is best suited for patients with severe ventricular dysfunction. If ventricular function is preserved, ventricular assist device placement may result in worsening congestion of the right sided circulation (70, 71). Single ventricle patients typically have had multiple prior sternotomies with conduits or systemic-pulmonary shunts and collateral flow. These factors complicate sternal re-entry and dissection. Placement of

arterial and venous lines before surgery may be considered to allow initiation of emergent percutaneous cardiopulmonary bypass (71). These patients also have frequent associated comorbidities especially liver disease, protein losing enteropathy (PLE) as well as mental and cognitive dysfunction issues. Liver disease is common in single ventricle patients with Fontan circulation (72-74). This is not only because there is a higher prevalence of viral hepatitis in patients with congenital heart disease than in the general population. Chronically elevated filling pressures lead to hepatic congestion and ultimately hepatic fibrosis and cirrhosis. The presence of significant liver disease increases the risk of complications after VAD placement including major bleeding and infection and results in increased mortality. Intestinal protein loss and malabsorption in patients with PLE leads to hypoalbuminemia, lymphopenia, hypogammaglobulinemia, and failure to thrive (70). Caution should be taken in consideration of ventricular assist device placement in a patient with PLE given increased risk of infection, thromboembolism and the potential impact of associated frailty on rehabilitation. Though PLE typically resolves following heart transplantation, it is not known if PLE can be reliably improved with ventricular assist device implantation (75). Additionally, it is notable that psychosocial maladjustment, mood and anxiety disorders are common among patients with Fontan circulation (70, 76, 77).

Recommendations for patient selection and screening

Class IIb

1. *For patients with failing Fontan circulation, durable mechanical support might be viable option used for either cavopulmonary or ventricular support.*
   Level of Evidence: C. (78-83)
2. *For patients with failing Fontan circulation, TAH may be a viable option.*
   Level of Evidence: C. (30, 84)
3. *For patients with failing Fontan circulation, if ventricular function is preserved, VAD only for the ventricle may result in worsening congestion of the right sided circulation (70, 71).*
   Level of Evidence: C.
4. *When planning a VAD implantation in a patient with single ventricle, a virtual fit to identify optimal inflow cannula and VAD orientation in the thorax using 3D printed models or virtual reality may help optimize success.*
   Level of Evidence: C. (60, 85, 86)

Recommendations for device selection

Device selection in patients with single ventricle anatomy differs significantly from all other patients. As already mentioned most patients with a single ventricle physiology will be in a Fontan circulation meaning that there is no subpulmonary ventricle. While Fontan patients with failure of the systemic ventricle can be safely supported with every device on the market for LVAD implantation (17, 87, 88), this is not true for Fontan patients with failure at the level of cardiopulmonary connection. There remain 2 options: either VAD support for the cardiopulmonary connection or implanting a BVAD (89) or TAH (30, 42). While available VADs are not designed to support cardiopulmonary connection, they have been used for this indication (78-83).

Management of associated conditions

Class I

1. *In patients with evidence of hepatic dysfunction, evaluation of the degree and etiology before DMCS implant is recommended.*
   Level of Evidence: C.
2. *In patients with congestive hepatopathy, identification of the mechanism underlying congestion before DMCS implant is recommended.*
   Level of Evidence: C.
3. *In patients with cardiorenal syndrome, ruling out venous obstruction before DMCS implant is recommended.*
   Level of Evidence: C.

Class IIa

1. *All single ventricle patient should be screened for viral hepatitis before VAD implantation (90, 91)*
   Level of Evidence: C.
2. *For risk stratification, if VAD placement is planned in a single ventricle patient liver function tests, i.e., MELD and/or MELD eXcluding INR (MELD-XI) should be done. Likewise, hepatic imaging with computed tomography, magnetic resonance imaging, elastography or histopathologic assessment with hepatic biopsy should be considered. (92-95).*
   Level of Evidence: C.
3. *Careful psychosocial assessment and appropriate mental health care are required when considering VAD placement. Neurodevelopmental disabilities are common among patients with Fontan circulation and education should be tailored accordingly (8, 70, 96).*
   Level of Evidence: C.

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Task Force 6 Summary:
DMCS in Adults with Congenital Heart Disease *(New)*

Patient selection

Class I:

1. It is recommended to have recently obtained documentation of cardiac morphological and ventricular physiological data after last surgery, including the presence of shunts, collateral vessels and the location and course of great vessels in patients with congenital heart disease (CHD) undergoing evaluation for DMCS.

Level of Evidence B.

2. ACHD (adult –CHD) patients should have a pre-implant evaluation including assessment of end organ function, surgical planning, and psychosocial and neurocognitive assessment.

Level of Evidence B.

3. Patients with ACHD, refractory to medical management should be evaluated for MCS early before progression of end-organ dysfunction.

Level of Evidence B.

Class IIa:

1. ACHD patients that qualify for mechanical support demonstrate similar survival rates after durable DMCS implantation compared to non-ACHD patients. ACHD patients in heart failure should be actively evaluated for DMCS and heart transplantation.

Level of Evidence C.

Class III:

1. Implantation of a device with patient-device size mismatch is not recommended.

Level of Evidence C.

Biventricular CHD

Evaluation Process of DMCS Candidates

Class I:

1. All patients being considered for DMCS should have their New York Heart Association functional class assessed and their Interagency Registry for Mechanically Assisted Support (INTERMACS) profile determined.

Level of Evidence C.

Class IIa:

1. All patients with biventricular CHD, with either systemic morphological LV or RV dysfunction refractory to medical management should be evaluated for DMCS early before progression of sub pulmonary ventricular failure and/or development of hepatic, renal and/or respiratory dysfunction, as outcomes for LVAD patients with biventricular CHD is comparable to non-ACHD patients.

Level of Evidence A.

2. Evaluation of an adult CHD patient for DMCS may be done in at a pediatric and/or adult cardiovascular center with clinical and surgical experience in CHD.

Level of Evidence C.

Operative Considerations:

Class I:

1. If a TAH placement is planned, a virtual fit/implantation is recommended.

Level of Evidence C.

2. In patients with a systemic morphologic right ventricle undergoing systemic VAD placement, excision of muscular trabeculae including the moderator band from the inflow cannula site is recommended.

Level of Evidence C.

Class IIa:

1. It is likely beneficial to have a surgeon with experience in congenital heart surgery participate in DMCS implant in ACHD patients.

Level of Evidence C.

(*continued on next page*)

(*Continued*)

Task Force 6 Summary:
DMCS in Adults with Congenital Heart Disease *(New)*

Class IIb:
1. In complex CHD patients with biventricular failure having adequate intrathoracic space, BIVADs or TAH may be considered as a bridge to transplant or as destination therapy.
Level of Evidence C.
2. In CHD patients with residual shunting, shunt closure at the time of DMCS implant may be of benefit.
Level of Evidence C.
3. In patients with a systemic morphologic right ventricle, undergoing systemic VAD placement, optimal inflow cannula location may be in the diaphragmatic wall of the right ventricle or right ventricular apex directed toward the tricuspid valve.
Level of Evidence C.
4. In patients with moderate or severe levels of anatomic complexity undergoing VAD implant, virtual fit to identify optimal inflow cannula and VAD orientation in the thorax using 3D printed models or virtual reality may be useful.
Level of Evidence C.

Management of Asosciated Conditions:
Class I:
1. In patients with evidence of hepatic dysfunction, evaluation of the degree and etiology prior to DMCS implant is recommended.
Level of Evidence C.
2. In patients with congestive hepatopathy, identification of the mechanism underlying congestion prior to DMCS implant is recommended.
Level of Evidence C.
3. In patients with cardiorenal syndrome, ruling out venous obstruction prior to DMCS implant is recommended.
Level of Evidence C.
Class IIa:
1. In patients with pulmonary hypertension, it is reasonable to use of VAD support to improve pulmonary hemodynamics as a bridge to decision.
Level of Evidence C.
Class IIb:
1. Earlier use of VAD therapy may help to decrease the early hazard associated with heart transplantation among ACHD patients by decreasing end-organ dysfunction and relieving pulmonary hypertension secondary to CHD.
Level of Evidence C.

Single Ventricle CHD

Recommendation for Patient Selection and Screeing:
Class IIb:
1. For patients with failing Fontan circulation, durable mechanical support might be viable option used for either cavopulmonary or ventricular support.
Level of Evidence C.
2. For patients with failing Fontan circulation, TAH may be a viable option.
Level of Evidence C.
3. For patients with failing Fontan circulation, if ventricular function is preserved, VAD only for the ventricle may result in worsening congestion of the right sided circulation.
Level of Evidence C.
4. When planning a VAD implantation in a patient with single ventricle, a virtual fit to identify optimal inflow cannula and VAD orientation in the thorax using 3D printed models or virtual reality may help optimize success.
Level of Evidence C.

Management of Associated Conditions:
Class I:
1. In patients with evidence of hepatic dysfunction, evaluation of the degree and etiology prior to DMCS implant is recommended.
Level of Evidence C.
2. In patients with congestive hepatopathy, identification of the mechanism underlying congestion prior to DMCS implant is recommended.
Level of Evidence C.
3. In patients with cardiorenal syndrome, ruling out venous obstruction prior to DMCS implant is recommended.
Level of Evidence C.
Class IIa:
1. All single ventricle patient should be screened for viral hepatitis prior to VAD implantation.
Level of Evidence C.
2. For risk stratification, if VAD placement is planned in a single ventricle patient liver function tests i.e. MELD and/or MELD eXcluding INR (MELD-XI) should be done. Likewise, hepatic imaging with computed tomography, magnetic resonance imaging, elastography or histopathologic assessment with hepatic biopsy should be considered.
Level of Evidence C.
3. Careful psychosocial assessment and appropriate mental health care are required when considering VAD placement. Neurodevelopmental disabilities are common among patients with Fontan circulation and education should be tailored accordingly.
Level of Evidence C.

Task Force 7

Evaluation for myocardial recovery

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Introduction

Myocardial recovery, or reverse remodeling, defined as normalization of cardiac structure and function, has been a much sought-after goal in the care of patients with heart failure and reduced ejection fraction (HFrEF) (1-7). Historically, the concept of the adverse remodeling process was considered largely irreversible once heart failure (HF) was severe or had been present for a long time (years). However, patients with chronic advanced HF supported with an LVAD—which provides near-total unloading of the ventricle—can show a near-normalization of the myocardial phenotype or "reverse remodeling." This is often associated with significant recovery of the underlying cardiac function which can be sufficient to allow removal of the LVAD (myocardial recovery or "remission" of end-stage HF). An increasing number of centers now have patients who have had their device removed (8-20) and have had sustained recovery for many years (9, 11, 12, 21). Studies in pulsatile LVADs demonstrated that ventricular unloading could reverse contractile dysfunction and chamber dilation(8, 11, 13, 16, 19) and although pulsatile devices were initially suggested to be more effective at mechanical unloading than continuous flow (CF) devices, similar reverse remodeling has also been observed with CF-LVAD support (22-26).

Molecular studies from myocardial tissue before and after LVAD implantation show reversal of processes detrimental to cardiac function, including myocyte hypertrophy and fibrosis, adrenergic receptor upregulation, cytokine activation, abnormal calcium handling, and activation of the unfolded protein response(27-38). Yet clinical improvement to levels that allow LVAD explantation is rarer than myocardial improvement occurring at subcellular and cellular levels.(6, 29, 39, 40) However, in most centers, LVADs are implanted either as a bridge to heart transplantation or as destination therapy and patients progress along that course without the underlying cardiac function being tested, many do not routinely optimize pump speed for unloading or reinitiate and up-titrate HF medications after implant. A wider and more aggressive attempt to promote and look for recovery in a larger population of VADs is likely to result in a higher incidence and a broader group of patients that can recover (8, 10, 14, 25).

Table 1 reviews recent published experience with LVAD explantation for recovery. For nonischemic cardiomyopathy (NICM) patients, a range of recovery rates from chronic HF varying between 2% and 73% have been reported mostly in single centers(1, 2, 8-21, 41). This varying data might be related to differences in the degree of ventricular unloading (different selection of pump speeds), differences in medical therapies during VAD support, the weaning experience of the clinicians(8, 10, 14, 25) and to the different selection criteria for explantation used by different centers. Centers with protocols designed to evaluate for, promote and optimize myocardial recovery have reported significantly higher rates of LVAD explant success (Table 1) with excellent long-term survival free of heart failure(8, 10, 25).

Such approaches suggest that recovery in certain patients is attainable. As access to organ transplantation remains limited, and longer term LVAD support is associated with complications, the possibility of recovery and device explanation remains attractive and an active focus of investigation. A significant percentage of LVAD explanted patients achieve cardiac and physical functional capacities that are within the normal range of healthy controls (42, 43). Durability of myocardial recovery has also been shown(21), and patients have a good quality of life(44). Jakovljevic et al. recently assessed the functional capacity of LVAD explanted patients 3.3 ± 1 years after explantation comparing them to patients on a BTT CF LVAD and healthy controls (42). Peak exercise cardiac power output (CPO) was significantly higher in healthy controls and explanted LVAD patients as was peak O_2 consumption. In the LVAD explanted group, 38% of the patients achieved peak CPO and 69% achieved pVO_2 within the ranges of healthy controls, suggesting long term many explanted patients have cardiac and physical functional capacities within the normal range of healthy controls with significantly better cardiac and functional capacities than patients on LVAD support (42). For those weaned from their LVAD, the chances for long-term freedom from HF recurrence are also optimistic (10, 11, 21, 25). The Harefield group compared the long-term outcomes of LVAD patients explanted for myocardial recovery to those transplanted from LVAD support and found similar survival. Creatinine was also significantly better in the explanted group(21).

In these guidelines, we review the data and provide recommendations based on existing evidence for medical and

Table 1 Studies Assessing Recovery and Explant Success

Study	Number of patients	LVAD type	HF etiology	Explant	Follow-up and outcomes
Khan 2003(123)	16	Implantable pneumatic HeartMate	NICM: 12 ICM: 4	9 patients	Mean follow-up 14.3 months Outcomes: 6 alive, 3 died -1 of coagulopathy and bleeding early postexplant -2 of SCD 18 and 34 months postexplant
Birks 2006(8)	15	HeartMate	NICM	11 patients	-1 died in the first 24 hours postexplant. -1 died from malignancy 27 months postexplant. -Freedom from HF: 100% (1-yr), 88.9% (4-yr)
Birks 2011(10)	20	HeartMate II	NICM	12 patients	-2 died in the first 30 days postexplant. - -10 survived at 3 years
Dandel 2008(47), 2011(48)	47 (45: LVAD, 2: BiVAD)	-Novacor, TCI, Berlin Heart EXCOR: 33 -INCOR, HeartMate II: 12	NICM: 42 ICM: 2	All	-Survival: 71.4% (5-yr), 65.7% (10-yr) -Of those who died, 64.3% died from causes not related to LVAD explant.
Maybaum 2007(13)	67	-HeartMate VE: 59 -Novacor: 5 -Thoratec extracorporeal assist devices: 2 -DeBakey: 1	NICM: 37 ICM: 30	6 (2 with NICM)	All 6 alive at 6 months. 2 had stable LVEF and 4 had decline in LVEF at 6 months without clinical sequela
Lamarche 2011 (155)	17	HeartMate II	Idiopathic: 1 ICM: 1 Myocarditis:2	4	. All were NYHA class 2/3 at mean 543 ± 351 days follow up.
Boehmer 2012(142)	14 on LVAD support	-Pulsatile extracorporeal Thoratec BiVAD: 9 -HeartMate XVE: 1 -HeartMate II: 4 -Jarvik 2000: 1	Myocarditis and Acute CM (no further details)	8	Median follow-up 527 days 1 died within 2 months' postexplant. 7 alive at follow up.
Patel 2013(14)	21	HeartMate II and VentrAssist	ICM: 8 NICM: 13	3	All 3 patients remained HF free during follow up period.
Wever-Pinzon 2016 (20)	15,138 (INTER-MACS) 190 (derivation cohort)	Pulsatile and CF LVAD	NICM: 84% NICM: 56%	0.7% (1yr) 2.6% (3yr) 11	Not available
Tchantchaleishvili 2016(156)	223	HeartMate II	ICM: 37.5%	8 (50% NICM)	Follow-up: 276 ± 240 days 2 died (1 perioperatively and 1 during follow up).
Steiner 2017(114)	2	HVAD	ICM: 1 Mixed: 1	1	Patient alive and well at 1 yr.
Holzhauser 2019 (157)	7	-HeartMate II: 4 -HVAD: 3	NICM: 7	2	Not available
Frazier 2015(9)	30 assessed	Heartmate II:28 Heartware;2	NICM;28 ICM;2	27	24 patients NYHA Class I at 1,172 + 948 days, 2 died (341 days sepsis, 1.5 years sudden cardiac death), 1 reVAD 2.7 years postexplant

(*continued on next page*)

Table 1 (*Continued*)

Study	Number of patients	LVAD type	HF etiology	Explant	Follow-up and outcomes
Birks 2020(25) (RESTAGE-HF)	40	Heartmate II	NICM; 40	19	Primary end point (proportion reaching explant criteria ≤18 months with sustained HF remission (freedom from transplant/VAD/death) at 12 months statistically met (*z* value 6.8, $p < .0001$). One patient died from suicide and 1 from pneumonia at 15 and 639 days. One transplanted for and 1 died from recurrent HF at 227 and 577 days postexplant. Remaining 15 patients alive and well at 2.1 ± 0.9 years postexplant (mean EF 47.5%; EDD 5.55cm; ESD 4.5 cm).

BiVAD, biventricular assist device; CF, continuous flow; HCM, hypertrophic cardiomyopathy; HF, heart failure; ICM, ischemic cardiomyopathy; LVEF, left ventricular ejection fraction; NICM, nonischemic cardiomyopathy; RVAD, right ventricular assist device; yr, year.

device optimization, methods to evaluate recovery, explant technique, and postexplant management. We address the special circumstances of recovery and LVAD explant in the setting of acute myocarditis, myocardial infarction with shock, and device infection and malfunction.

Patient selection

A critical need in the field of cardiac recovery is the ability to reliably predict who has the potential for sustained recovery following LVAD circulatory support. We review patient characteristics that have been associated with cardiac recovery.

Heart failure etiology. It is widely accepted that reverse remodeling is seen more frequently in nonischemic cardiomyopathy (NICM) as compared to ischemic cardiomyopathy (ICM)(12, 24, 45, 46), with approximately 4 times the number of NICM patients recovering heart function(46). This is thought to be due to a worse "substrate" for ICM with extensive LV scarring. Further, data on postexplant cardiac function, exercise capacity, and survival are more robust in the nonischemic population compared to the ischemic patients.(8, 10-13, 15, 20, 21, 25, 26, 47-49)

Age and HF duration symptoms at LVAD implantation. Patients with cardiac recovery have been shown to be younger (<40-50 years) and with shorter duration of HF symptoms (<1-5 years) before LVAD(10, 12, 20, 45, 48). However, these data are limited by selection bias, since focused recovery efforts are usually made in these 2 groups of patients. It is possible that a greater proportion of patients without these characteristics would recover if equal effort was employed.

Echocardiographic criteria. Features (seen on echocardiography at full support) that suggest potential recovery that should trigger further (low flow/speed) recovery testing are a normalized LV end-diastolic diameter (LVEDD), improvement of LV wall motion, no or ≤grade 1 mitral and/or aortic valve regurgitation, no right ventricular (RV) dilation and no or ≤grade 2 tricuspid regurgitation (TR) on full LVAD support(50). A progressive increase in the duration and frequency of AV opening during unchanged pump rate also indicates improvement of LV function and should initiate further evaluation.

A single center study (48) analyzed patients with primarily NICM who were weaned from durable LVAD support. During an off-pump study, LVEF ≥ 50% either with LVEDD ≤ 55 mm or with a history of HF ≤5 years; and LVEF ≥ 45% accompanied by LVEDD ≤ 55mm plus a history of HF ≤5 years, showed the highest predictive value for >5 year post-LVAD explant cardiac stability(48). In another prospective study of patients with NICM, pre-LVAD rotational mechanics using speckle tracking echocardiography showed a 92% sensitivity and a 73% specificity in predicting post-LVAD cardiac recovery (51).

Other clinical characteristics. In an INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support)-derived publication investigators, identified as independent predictors of recovery: age <50 years, nonischemic cardiomyopathy, time from cardiac diagnosis <2 years, absence of ICD, creatinine ≤1.2 mg/dl, and LVEDD <6.5 cm. Based on these factors a weighted score termed I-CARS, was formed which effectively stratified patients based on their probability of recovery(20).

Investigational serum and myocardial biomarkers. Using serum and cardiac tissue collected at the time of LVAD implantation, researchers(52) found several pre-LVAD serum inflammatory biomarkers (TNFα IL5, IL6, IL7, IL13, and IFN) were significantly lower in patients who recovered their cardiac function. Further, a multivariable model combining circulating IFN and TNFα was

identified as an independent predictor of LVAD-mediated myocardial recovery. Using pre-LVAD myocardial tissue, investigators(53) showed that low ryanodine receptor−sarcolemma distances pre-LVAD implantation predicted myocardial recovery during mechanical circulatory support (53, 54).

Recommendations

1. *At least one echocardiographic assessment for myocardial recovery should be performed in all patients post-LVAD (especially those intended for heart transplant) (2-4, 6, 7) IIa (Level of Evidence: C).*
2. *A normalized LV end diastolic diameter (LVEDD), change in the duration and frequency of aortic valve opening and improvement of LV function should trigger further assessment of recovery including studies performed at low flow/speed(9, 50). IIa (Level of Evidence: C).*
3. *Patients with nonischemic cardiomyopathy, those with younger age and shorter duration of HF symptoms should be a particular focus and closely managed and assessed with cardiac recovery in mind(12, 20, 24, 45-47). IIa (Level of Evidence: B).*
4. *Use of existing predictive tools may be helpful in identifying individuals with increased likelihood of cardiac recovery(20). IIb (Level of Evidence: C).*

Concurrent surgery considerations at implantation

When myocardial recovery is the potential goal at the time of LVAD implant, structural defects may need to be addressed at implantation. Aortic valve competence is desirable for proper VAD function. Oversewing the aortic valve has been advocated by some centers(55) but replacing an oversewn valve at the time of explant will complicate the procedure and potentially affect the outcome. A bioprosthetic aortic valve replacement at the time of implant may be a better option in such patients with the potential risk of commissural fusion due to continuous flow avoided by maintaining intermittent aortic valve opening(7).

Mitral regurgitation (MR) is another common valvular abnormality in heart failure patients. Annular dilation, papillary muscle displacement and tethered chordae all contribute to increase the MR in the dilated left ventricle (1, 56). Mitral intervention at the time of implant, using a trans-apical edge-to-edge leaflet repair is a safe and quick technique to address significant MR(57). It may be easier to perform this repair once the apex is cored out, before putting in the sewing ring as this enhances the visibility of the leaflets. However, in cases with a severely dilated annulus, or significant leaflet tethering, conventional mitral valve repair through a left atriotomy may be required (58).

Medical and device optimization

Recovery of ventricular function during circulatory support is dependent on adequate pressure and volume unloading. LVADs that provide a greater degree of ventricular unloading result in a greater degree of reverse remodeling(59). While numerous studies have demonstrated the normalization of resting hemodynamics with LVAD support(60, 61), it has also been shown that, despite implantation of an LVAD, a significant number of patients have elevated filling pressures or low cardiac output on right heart catheterization(62, 63). Investigators have described speed optimization for the HeartMate II device using echocardiography, as a ramp test protocol to optimize LVAD speed or to diagnose device malfunction(64), however these protocols were not designed to optimize unloading to promote myocardial recovery. Recommendations for speed adjustment have targeted a composite of the patient's mean arterial pressure, midline interventricular septum position, and intermittent aortic valve (AV) opening while maintaining no more than mild mitral regurgitation (MR)(25, 65). Other investigators have described a Doppler-based algorithm integrating mitral inflow velocities, estimated RA pressure, pulmonary artery pressure, and left atrial volume index which was accurate in distinguishing normal from elevated left ventricular filling pressures(66).

Despite the evolving noninvasive evaluation of LVAD function, invasive assessment of hemodynamics also remains a critical tool as direct assessment of filling pressures is a good way to determine the degree of unloading in LVAD patients. An invasive hemodynamic ramp protocol was tested in a HeartMate 3 cohort(67) where speed optimization was able to normalize CVP and PCWP in 50% of patients with abnormal hemodynamics at baseline. A wide range of baseline hemodynamics with differing responses to speed changes was noted, suggesting a significant benefit in performing speed optimization with the aid of invasive hemodynamics.

A protocolized hemodynamic ramp test to determine the optimal speed change has been reported and has gained increased acceptance(62, 66). Along with the echocardiographic ramp test, right heart pressures are measured. Optimal device settings are chosen with the goal of normalizing filling pressures with RAP <12 mm Hg and PCWP <18 mm Hg and with the secondary goals of intermittent or no AV opening and minimal MR. When this protocol was studied in a prospective, randomized fashion, those in the hemodynamic guided speed optimization arm demonstrated more frequent initiation and titration of neurohormonal blockade(68, 69). A recent report has described the use of left heart catheterization, specifically calculating the difference between the peak systolic aortic and left ventricular pressure, described by the investigators as the transaortic gradient (TAG)(70).

Importantly, LVAD patients with optimized hemodynamics have demonstrated improved functional capacity (71), freedom from hospital readmissions(72), and reduced hemocompatability-related adverse events (HRAEs) compared to those without optimized hemodynamics(28, 73). Echocardiographic ramp studies resulted in improved RV function at 3-month follow-up(74). Although there appear to be clinical and functional benefits of device optimization, the impact on cardiac recovery has not yet been studied.

In the multicenter RESTAGE-HF recovery study(25) an echocardiogram was performed before discharge after

LVAD implantation and the pump speed was set so that the septum was midline, the aortic valve was mostly closed at rest and mitral regurgitation was minimal. Serial echocardiograms were then performed as an outpatient to maintain these parameters and speed increases made to reduce the LVEDD as much as possible, while avoiding suction events to optimize unloading.

Recommendations

1. *LVAD speed adjustments to optimize unloading are likely to enhance the potential for recovery(8, 10, 25, 59, 65, 66, 68, 69, 71). IIa (Level of Evidence: C).*
2. *Both noninvasive and invasive techniques are helpful in optimizing LVAD unloading(8, 10, 25, 65-69, 71, 72) IIb (Level of Evidence: B).*
3. *An echocardiogram should be performed before discharge after LVAD implantation and the speed set so that the septum is in the midline, the aortic valve is mostly or totally closed at rest and the mitral regurgitation is minimal(25). IIa (Level of Evidence: B).*
4. *Echocardiograms should be performed during outpatient visits to optimize left ventricular unloading targeting an LVEDD ≤ 6 cm (ideally ≤5.5 cm) while avoiding suction events(8, 10, 25). IIa (Level of Evidence: B).*

Timing of initiation, frequency of uptitration, and target doses of neurohormonal blockade

The rate of recovery seen during LVAD support is highly influenced by the efforts made to optimize recovery. Combining mechanical unloading with pharmacological therapies designed to maximize recovery can lead to a significant increase in the rate of recover (10, 25, 75, 76). Drugs shown to lead to reverse remodeling in HF can and should be initiated and aggressively uptitrated after LVAD implantation when there is adequate end-organ recovery.

Patients who often did not tolerate large doses of HF medications while in severe HF before LVAD, often tolerate these therapies after LVAD support and moreover, they often can be used at very high doses, not previously tolerated in that patient(8, 10, 25).

Neurohormonal blockade can be initiated immediately after weaning of inotropic support when there is adequate end-organ recovery and rapidly titrated to high doses. Patients can have simultaneous aggressive increases in ACEIs, beta blockers and aldosterone inhibitors (sometimes followed by the angiotensin II antagonists), although the ACE inhibition should be prioritized. ARNIs were not in clinical use when some of these studies were designed, so they were not included in the design but their use in combination with LVAD unloading should be considered going forward, in lieu of the new 2023 HF Guideline update (77, 78).

RESTAGE-HF (REmission from Stage D Heart Failure) (25) is a recent multicenter prospective, nonrandomized US study of 40 subjects with chronic advanced HF from nonischemic cardiomyopathy who received the Heartmate II CF pump and was designed to study this approach to see if it is reproducible. The 6 investigative institutions all had previous experience in recovering and explanting LVAD patients. The primary endpoint was the proportion of subjects treated with this standardized LVAD plus pharmacologic recovery protocol who underwent LVAD removal with freedom from DMCS or HTx at 1-year post-LVAD removal(25). Aggressive pharmacologic management was started consisting of the drugs in the Harefield protocol intended to enhance reverse remodeling. There was a detailed(25) step-wise protocol for drug uptitration to achieve the maximum doses. They were titrated to a MAP > 60mm Hg if the patient was asymptomatic with normal potassium and renal function. Pump speed optimization and testing of underlying function was assessed during the trial. Overall, 47.5% of enrolled patients and 52.8% of those receiving the protocol were explanted/decommissioned, Figure 1 and the primary end-point was met ($p < .0001$) suggesting aggressive adjuvant pharmacological therapy increases the rate of recovery seen.

There is now strong evidence for the benefit of neurohormonal blockade in LVAD patients. At the molecular level, prolonged mechanical unloading increases myocardial angiotensin II, collagen cross-linking and myocardial stiffness and addition of ACEIs decreases the myocardial angiotensin II, cross-linked collagen, LV mass and myocardial stiffness in these patients.(79-81) In patients with high baseline pre-LVAD myocardial fibrosis, treatment with HF drug therapy was associated with a reduction in fibrosis(82).

A recent very large retrospective analysis showed a significant overall benefit for LVAD patients receiving neurohormonal blocking (NHB) agents, strongly suggesting that they should be given to all LVAD patients who tolerate them. In this INTERMACs cohort analysis of 12,144 patients(83) those receiving any NHB medication at 6 months had a better 4-year survival compared with those not receiving NHB, Figure 2. Patients receiving triple therapy with an ACEI or angiotensin receptor blocker (ARB), BB, and mineralocorticoid receptor antagonist (MRA) had the lowest hazard of death compared with patients in other groups. However, use of any NHB was associated with significantly improved survival compared with medical regimens without NHB 4 years postimplant. Patients receiving triple therapy with an ACEi/ARB, BB, and MRA had the lowest N terminal pro−B-type natriuretic peptide, creatinine level, higher Kansas City Cardiomyopathy Questionnaire score and a longer 6-minute walk test at 2 years.

Another recent retrospective study of LVAD patients showed treatment with ACEIs or ARBs was an independent factor associated with decreased mortality post-LVAD and use of an ACEI or ARB was associated with a reduction in mortality risk (hazard ratio [HR] = 0.53 [0.30−0.95], $p = .03$). Recent single center studies have also shown improvements in reverse remodeling parameters(84) and mortality(85) as well as improvements in NYHA Class, BNP and 6-minute walk distance with ACE inhibitor use in LVAD patients. Additionally, ACE-I combined with digoxin may reduce the rate of gastrointestinal bleeding in LVAD patients(86, 87).

Hence neurohormonal therapy should be initiated early after LVAD implantation when tolerated and where possible these drugs should be aggressively uptitrated to the highest tolerated doses in combination with mechanical unloading to promote recovery. In the RESTAGE-HF(25) protocol the losartan dose was increase to 150mg PO daily (compared to 100mg PO daily in the Harefield studies(8, 10)) as a result of the HEAAL study(88). When antihypertensives are needed in LVAD patients they should be those that have beneficial reverse remodeling effects.

Recommendations

1. *Neurohormonal therapy should be initiated early after LVAD implantation and has been associated with improved outcomes and promotes recovery(1, 8, 10, 14, 25, 75, 80-87). IIa (Level of Evidence: B).*
2. *Neurohormonal therapy should be uptitrated as clinically tolerated to promote recovery(1, 8, 10, 25). Intolerance of guideline directed medical therapy (GDMT) before LVAD is not necessarily a contraindication(1, 8, 10, 25, 76). IIa (Level of Evidence: B).*
3. *In patients managed for recovery, maximally tolerated doses of neurohormonal blockade should be targeted(1, 8, 10, 25, 80-86). Patients may have simultaneous uptitration of ACEIs, ARNi, or ARB in conjunction with beta blockers and aldosterone inhibitors with prioritization of ACE (8, 10, 25). IIa (Level of Evidence: C).*

Measuring blood pressure

Initiation and uptitration of neurohormonal blockade after LVAD implantation requires reliable monitoring of blood pressure. This continues to be a challenge in LVAD patients due to the lack of a conventional pulse. Hypertension limits the ability of the pump to provide adequate unloading of the left ventricle and it has been shown that increased BP is associated with adverse cardiac events including thromboembolic events and progression of aortic insufficiency, which may directly impact myocardial recovery.(89-91) The current ISHLT guidelines advise a target MAP less than 80 mm Hg provided that the adverse effects of low BP can be avoided(92). Often during myocardial recovery attempts, much lower BPs are allowed to be able to uptitrate the neurohormonal therapy.

Currently, measurement with Doppler technology is recommended as these measurements are accurate and helpful in both inpatient and outpatient environments but are not always feasible in the home setting. Unfortunately, Doppler ultrasound has the major limitation of providing a single BP number, and whether this number more closely represents the SBP or the MAP has been a focus of debate among clinicians. In a study by Lanier et al in continuous-flow LVAD patients, the Doppler method underestimated SBP by 4 mm Hg and overestimated MAP by 9 mm Hg. In general, noninvasive blood pressure measurements approximate the mean arterial pressure if a low pulse pressure is present. In the setting of a high pulse pressure and aortic valve opening, noninvasive measurements more accurately represent the systolic peak pressure. It is important to be aware that uptitration of antihypertensives when the SBP is assumed to be the MAP may result in symptomatic hypotension(93) and uptitration against symptoms is important (94). Ambulatory monitoring may offer more comprehensive data and facilitate uptitration of neurohormonal blockade.

As aortic valve opening and pulsatility may signal recovery, the appearance of new hypertension or appearance of a significant pulse pressure should warrant further investigation of underlying LV function. Efforts are underway to identify an easier and more reliable method to measure BP in the setting of continuous flow circulatory support.

Recommendations

1. *Accurate reliable measurement of blood pressure in LVAD is key in reducing LVAD-related adverse events and titrating medical therapy to promote recovery(8, 10, 25, 89-91, 93, 94). IIa (Level of Evidence: B).*
2. *Careful attention should be paid to aortic valve opening, hemodynamic status, and degree of pulsatility when interpreting noninvasive BP measurements(93, 94). IIa (Level of Evidence: B).*
3. *Antihypertensives used (as needed) where possible should be consistent with guideline-directed HF therapy drugs to help promote reverse remodeling and improvement in myocardial function(1, 8, 10, 14, 25, 75, 80-87). IIa (Level of Evidence: C).*
4. *Neurohormonal blockade and beta blockers should be preferentially chosen for the treatment of hypertension during LVAD support(1, 8, 10, 14, 25, 75, 80-87). IIa (Level of Evidence: B).*
5. *The appearance of new hypertension or a significant change in pulse pressure should warrant further investigation for recovery(9, 50). IIb (Level of Evidence: C).*

ICD/CRT considerations

As patients progress to LVAD therapy, many will have previously received device therapies such as ICD and cardiac resynchronization therapy (CRT). It is established that, in appropriately selected HF patients, CRT can improve electromechanical synchrony and thereby improve mortality, induce reverse remodeling, improve functional status, and quality of life.(95-97) However, the benefit of CRT in the setting of an LVAD is unclear. Various retrospective studies have looked at the impact of CRT on outcomes during LVAD support without being conclusive.(98-101) These studies did not directly address the impact of CRT post-LVAD on myocardial recovery.

The majority of patients undergoing LVAD implantation will have an ICD in place for either primary prevention or secondary prevention indications. It has been shown that ventricular arrhythmias are commonly seen in patients after LVAD implantation and new on-set ventricular arrhythmias have been well described(102). In the setting of myocardial recovery, there is a lack of data about benefit for ICD therapy. Individualized assessment of arrhythmia risk and risk

of device therapy should be considered for those demonstrating recovery.(103-106) New ventricular arrhythmias in the setting of recovery during LVAD support, might be due to suction events, as the cavity size normalizes and may resolve on pump removal/deactivation. However, it would still be advisable to implant an ICD in any patient with a history of VT on the pump before discharge after explantation as a precaution(1, 25, 76).

Recommendations

1. *Existing CRT/D devices may offer continued benefit during LVAD support.(95-101) IIb (Level of Evidence: C).*
2. *In patients that have a history of VT and no ICD who undergo LVAD explantation/ for recovery, ICD implant should be considered before discharge(1, 25, 76). IIb (Level of Evidence: C).*

Evaluation for recovery

Techniques to assess recovery during LVAD support

A key component in achieving LVAD explantation for recovery are safe, accurate, and reproducible methods of monitoring myocardial recovery during LVAD support.(1, 50, 76, 107-109) In most centers, LVADs are implanted either as a BTT or as destination therapy, and the underlying myocardial function is not tested. Regular evaluation of myocardial function following device implantation is essential during the recovery process(8, 10, 25, 50, 107, 108). It is important to perform echocardiographic, functional, and hemodynamic tests before deciding whether to explant the pump.

Most of the early weaning protocols did not assess the true native myocardial function because they were based on measurements taken while the device was operating at full support. Patients should be studied during a period of limited or no LVAD support to test the true underlying function,(8, 10, 25, 107-110) although this can be preceded by an assessment on full support to target patient's appropriateness for low speed testing(50, 111, 112). Echocardiographic studies, cardiopulmonary exercise testing, and right and left heart catheterization methods have now been described with the pump providing negligible or net-zero flow that can be performed safely and regularly to monitor and detect recovery(1, 8, 10, 25, 76, 107-110, 112).

Echocardiography is the primary imaging modality for the selection of potential explant candidates and is mandatory for weaning decisions(1, 76, 109, 110, 112, 113). Echocardiographic measurements (see below) include left ventricular end-systolic diameter (LVESD), LVEDD, and EF along with a detailed assessment of valvular regurgitation (particularly mitral, which if significant could lead to an overestimation of LV function and also result in recurrent heart failure by over reloading after explantation)(1, 76, 109). The ASE recommends that LVEF be assessed using Simpson's biplane method of disks when possible (109) for recovery assessment Moreover, LVEDD should be measured in the 2D parasternal long-axis which is considered the most reproducible measure of LV size(109).

In patients supported with pulsatile flow pumps, the inflow and outflow valves prevent regurgitation of blood from the aorta to the left ventricle during device deactivation. Hence, cessation of a pulsatile pump, reflects a physiologic response that reveals the true underlying function of the(108) native left ventricle(107). Reducing the speed of continuous flow devices can result in regurgitant volume flowing from the aorta to the left ventricle causing excessive loading and making assessment of the native left ventricular function less reliable. Hence, with continuous flow pumps it is important to identify a speed closest to the situation in which the net flow across the pump is zero (i.e., antegrade flow in systole and retrograde flow in diastole are the same) so that the underlying myocardial function can be accurately assessed(108). In addition, continuous flow device patients are anticoagulated with warfarin, so supplemental heparin (5,000-10,000 u) is only required if the INR is subtherapeutic (i.e., if >2 that day or >2.5 from the previous days measurement there is no need for additional anticoagulation)(1, 76, 108).

A prospective study of flow across a continuous flow pump (HeartMate II LVAD(108)) measured LV echocardiographic parameters and peripheral hemodynamics serially at 3 device speed settings: the baseline device speed and 15 minutes after reducing the speed to 6,000 rpm then to 5,000 or 4,000 rpm. Reducing the speed to less than 6,000 rpm did not have a significant effect on LVEDD, LVESD, or EF, suggesting that there is no need to reduce the speed of the device to less than 6,000 rpm in the assessment of the native left ventricle. As the LVAD speed was reduced to 6,000 rpm, the blood volume through the inflow cannula decreased significantly, further reductions in the LVAD speed did not change the inflow cannula blood volume significantly, and some backflow started to be seen, confirming that speeds less than 6,000 rpm were not needed to assess the underlying left ventricular function. This testing speed has now been widely used(1, 25) and there have been no adverse events hence this testing method is considered safe.

Hence a continuous flow pump should be reduced to a speed which produces just enough forward flow to counteract the backflow (which is usually around 1 L/min) resulting in as close to "net-zero" flow as possible. For the Heartware pump, the speed at which net-zero flow occurs and hence testing should occur is 1,800 rpm (1, 76). For the HeartMate II, the speed at which net-zero flow occurs is 6,000rpm (108), for the HeartMate III the speed at which "no-net-flow" flow would be expected is around 4,000 rpm (1, 50) (see Table 2). A speed below 3,800 has limited study and may put the patient at higher risk for a thrombotic event.

Cardiopulmonary exercise testing at pump settings that provide net neutral flow is also an important component of the recovery testing process(42, 43, 110, 114-116) of underlying myocardial function (see below), measurements at rest and at peak exercise on a modified Bruce protocol are undertaken(8, 10, 25). Although cardiopulmonary exercise

Table 2

Pump	Speed at which there is zero net flow for recovery/underlying function testing
Heartmate II	6,000 RPM(10, 108)
Heartware	1,800 RPM(1, 50, 76)
Heartmate 3	4,000* RPM(50, 76, 112)

*May be necessary to decrease to 3,800 RPM if significantly more than 1 L of forward flow is recorded at 4,000 RPM to achieve no net forward flow.

testing at net neutral flow speed is important to perform in assessing recovery, peak oxygen consumption does not always normalize with LVAD support and cardiopulmonary exercise test data are influenced many other variables as well as cardiac recovery(117), such as the patients overall condition and hence may be of limited use. Studies have shown that LVAD patients, despite full pump support and regardless of LVAD type (axial or centrifugal), often continued to have low pVO_2 in the approximate range of 12 to 20 mL/kg/min. Hence pVO_2 does not necessarily correlate with hemodynamics(110) and should not be used in isolation to preclude patients from LVAD explant, usually being used as additional data to help(118) an explant decision rather than critical information for that decision.

Some studies showed cardiac power output measured in continuous flow LVAD patients at net neutral flow during cardiopulmonary exercise testing(119) to be a useful and predictive marker of recovery. The 6MWT(120) has also been utilized in various recovery protocols(8, 10, 25).

Patients who tolerate LVAD flow reduction to minimal levels and show echocardiographic signs of recovery should also undergo right and possible left heart cardiac catheterization(8, 10, 25, 110) . During full LVAD support, a patient may demonstrate normal hemodynamics, even if native heart function remains impaired. Therefore, exercise testing and invasive hemodynamic assessment at reduced pump speed are needed. It is important to compare the change in hemodynamics from baseline to those after a period of no net flow(1, 8, 10, 25, 110, 121). The most important hemodynamic variables to suggest significant and sustained myocardial recovery are a stable or improved PCWP and cardiac output following reduction of the pump speed for at least 15 minutes, it is important to make sure that the PCWP does not go up and the resting cardiac index does not drop significantly from the on pump CI(1, 50, 76, 121, 122). For CF LVADs, some centers perform right heart catheterization, while occluding the out-flow cannula with a percutaneously placed inflated balloon, allowing complete pump-stops without retrograde flow through the VAD(111).

Although few studies have used invasive assessment of exercise hemodynamics during LVAD support some studies(110, 122) found those who were successfully explanted demonstrated a higher augmentation in cardiac output with lower filling pressures. Dobutamine stress echocardiography with hemodynamic assessment is also a useful tool in assessing physiologic improvement in myocardial function of patients with LVAD support(123, 124).

Of note, complete pump-stop or pump turn-down to ±zero flow should be considered carefully in patients with a history of stroke or transient ischemic attack, in those with hemolysis or difficulties in anticoagulation therapy, and is usually contraindicated when pump thrombosis is suspected (see below)(50).

Timing and frequency of assessments

In the initial Harefield recovery study(8) with a pulsatile pump, on pump echocardiography was performed weekly after implantation for the first month and then low speed echocardiographic testing and cardiopulmonary exercise tests with the device on and off were performed monthly. Right and left heart catheterization was performed before explantation, with the device on and off for 15 minutes.

The second prospective study(10) in patients receiving a continuous flow pump, had the same regime with the low-speed testing performed at 6,000 rpm (no net flow) rather than off pump. Left heart cardiac catheterization was optional but right heart catheterization (both on full and low speed for 15 minutes) remained essential before explantation. While this schedule of testing is ideal, the frequency of testing may be prohibitive for some programs.

Hence in RESTAGE-HF(25) the frequency of the low speed testing was revised to make it more practical and widely applicable. Low speed echo testing was at 6 weeks, 4-, 6-, 9-, and 12-months postimplant (i.e., an echo was performed at full pump speed and then at 5 and 15 minutes at net zero flow (6,000 rpm) and then repeated after a 6-minute walk test at 6,000 rpm). Only once echocardiographic improvement was seen was cardiopulmonary exercise testing performed at 6,000 rpm (and only one was required). A right with possible left heart catheterization was performed at full and reduced support (for 15 minutes), once echocardiographic improvement was seen. This protocol was successfully and reproducibly performed at 6 sites and resulted in device explantation at all sites(25).

The Montefiore group devised a 3-step testing technique (14, 110) for select patients deemed as candidates for recovery. Restoration of myocardial function was assessed 4 weeks after patients reached maximally tolerated doses of HF medicines. If echocardiography at rest and with diminished support ("turn-down") demonstrated an EF > 40% (step 1, day 1), then they proceed to cardiopulmonary stress test (step 2—bicycle CPX with full support on day 2, followed by combined CPX and stress echo at reduced speed on day 3) and right heart catheterization (step 3—on day 4, a RHC at full and minimal support followed by bicycle exercise hemodynamic assessment at reduced speed)(110). Explant was considered if LV size and function was preserved and if there was no significant elevation in filling pressures with reduction in LVAD flow. They found peak VO_2 did not distinguish explantable patients.

In general, patients demonstrating sinus rhythm, normal LV end-diastolic diameter (LVEDD), improvement of LV wall motion, and no or ≤grade 1 mitral and/or aortic valve regurgitation(8, 37, 45) during full LVAD support should go

on to additional recovery testing(50). A progressive increase in the duration and frequency of AV openings during unchanged pump rate also indicates improvement of LV function and should initiate further evaluation(9). Although these parameters may be used as an initial screening tool for recovery, their sensitivity and specificity remain unknown and further evaluation with a turndown study is recommended.

The Texas Heart Institute have championed a strategy where patients are serially evaluated at reduced pump speeds for normalization of aortic valve opening time and with this reconditioning approach, have removed pumps from over 30 patients.

Recommendations

1. *Echocardiography is the primary imaging modality for the selection of potential explant candidates and is essential for assessment of recovery(8, 10, 25, 107-110, 113). IIa (Level of Evidence: C).*
2. *Echocardiographic measurements for recovery should include LVEF, LVEDD and LVSD(8, 10, 25, 109).*
3. *LVEF should be assessed using Simpson's biplane method and LVEDD measured in the 2D parasternal long-axis when possible(1, 25, 109). The degree of mitral and aortic regurgitation and RV function should also be assessed(1, 50). IIa (Level of Evidence: C).*
4. *An on pump assessment (at normal operating speed) may be used for screening(50, 111), however low speed testing is required for complete evaluation of myocardial recovery(8, 10, 25, 107-110, 112). IIa (Level of Evidence: B).*
5. *For low speed testing with a continuous flow LVAD, the pump speed should be reduced to net zero flow (6,000 RPM for a HeartMate II(10, 108), 1,800 (1, 76) RPM for a HVAD and 3,800-4,000 (25, 50, 112) RPM for a HeartMate 3). Low speed testing should be performed with the patient fully anticoagulated(108). IIa (Level of Evidence: B).*
6. *Echocardiographic assessment should be performed after 15 minutes at net zero flow and repeated after the patient performs a 6-minute walk(8, 10, 25). IIa (Level of Evidence: C).*
7. *Low speed testing that provokes symptoms and/or cardiac arrhythmias suggests inadequate recovery(50). Further attempts at testing may be performed after a longer period of mechanical unloading and further neurohormonal optimization(50). IIa (Level of Evidence: C).*
8. *Before a decision about LVAD explant, intracardiac filling pressures (swan-ganz catheter ± exercise) should be obtained at full pump speed and after 15 minutes of net zero flow(8, 10, 25, 121, 122). IIa (Level of Evidence: C).*
9. *Significant elevation in pulmonary capillary wedge pressure during low speed studies should raise concerns about candidacy for device explantation(110, 122). IIb (Level of Evidence: C).*
10. *CPET results should be interpreted in the context of other parameters (echocardiography and hemodynamics). A low peak oxygen consumption should not, on its own, preclude a decision to explant(25, 110, 117, 119). IIa (Level of Evidence: C).*

The explant criteria from the original Harefield studies(8, 10) have been widely used over the last few years. Recently they were adapted in the largest multicenter prospective study (25) and are recommended in guiding clinical decision making. In that study patients were considered for explantation if when studied at zero net flow they met the following criteria (25).

1. LVEDD < 60 mm, LVESD < 50 mm, LVEF > 45%, and
2. LVEDP or PCWP ≤ 15 mm Hg, and
3. Resting cardiac index (CI) > 2.4 L/min/m^2
4. ± a maximal oxygen consumption with exercise (mVO_2) > 16 mL/kg/min

Importantly, these criteria are minimal requirement for explantation and if these measures are improving, LVAD support should be continued until the maximum improvement has been achieved. The mVO_2 criteria is optional to reflect the issues with the prognostic ability of cardiopulmonary exercise testing in predicting recovery. Attention should also be paid to the presence of mitral regurgitation and if moderate or greater this would be a significant concern for explant.

Recommendations

1. Patients undergoing assessment for recovery may be considered for explantation if they meet (117)the following criteria measured after the patient has been at zero net flow for 15 minutes(8, 10, 25).

a. LVEDD < 60 mm, LVESD < 50 mm, LVEF > 45%, and
b. LVEDP or PCWP ≤ 15 mm Hg, and
c. Resting cardiac index (CI) >2.4 L/min/m^2

A maximal oxygen consumption with exercise (mVO_2) ≥16 mL/kg/min would enhance the decision to explant but is not a requirement(25) due to the inaccurate prognostic ability of cardiopulmonary exercise testing in predicting recovery(116, 117). IIa (Level of Evidence: C).

1. If recovery parameters continue to improve, explantation should be deferred until the maximum improvement has been achieved(25). IIa (Level of Evidence C).

Explant technique

Various explant techniques have been described in the literature(1, 125-133). Redo median sternotomy, institution of cardiopulmonary bypass and complete removal of the device and outflow graft with reconstruction of the apical defect carries with it the added morbidity of an extensive procedure. This may jeopardize a recovering myocardium,

increase risk of blood product use and the chances of cardiac injury. As such, short effective procedures with the strategy to "do no harm" may be the key to successful LVAD explantation. One technique is the use of a left subcostal incision to occlude the ventricular sewing ring with specially designed plugs which can be directly inserted into the ventriculotomy, thereby precluding the need for extensive ventricular reconstruction. With the HeartWare LVAD, the outflow graft is clamped, ligated and transected through the left subcostal incision(129, 130). The sewing ring screw is then opened and the pump is withdrawn. The apical cannulation site is occluded with an individually manufactured titanium plug, and the driveline is divided (129, 130). With the HeartMate II LVAD, a similar incision is used to excise the inflow bend relief to allow ligation of the inner graft with retention of the inlet cannula(125). A felt plug can then be fashioned intraoperatively using a spare sewing ring. This plug is inserted into the attached sewing ring to completely fill the apical defect(125). Recently, the use of a customized metal plug designed to fit the HeartMate III LVAD sewing ring has also been reported(131, 132).

Another successfully reported technique of explant is device decommissioning. In this minimally invasive procedure, the device is essentially left in place, the driveline is transected and the outflow graft is transected/ligated(1, 15, 127, 133, 134). This can be performed through a small thoracotomy or a subcostal incision, with little or no dissection required. Decommissioning can also be performed by occluding the outflow graft in a percutaneous endovascular fashion.[142] Although this procedure is less-invasive, potential disadvantages of decommissioning include leaving the apical cannula in the left ventricle that may subject the patient to the risk of thromboembolic events. Also, leaving a large amount of hardware in the patient that may serve as a nidus for infection, and the possibility of retrograde leak around the outflow graft percutaneous occlusion device leading to significant volume overload in a borderline ventricle are some of the other pitfalls(1, 134). Nonetheless, a few reports have demonstrated that decommissioning is a promising modality of device withdrawal with postoperative outcomes comparable to traditional explantation in regard to long-term survival(15, 133, 134).

Less-invasive methods of simply dividing the driveline, leaving the entire pump in situ have also been described (127). The pump ultimately then develops a contained thrombus. All methods of pump deactivation and explant have been reported to be feasible, with similar early and late survival and clinical outcomes(15, 127). Minimally invasive methods for explant, avoiding the need for redo-sternotomy and possibly cardiopulmonary bypass are generally recommended, with the exception being the presence of significant device infection(15, 128). In these cases, complete removal of the device is important. Many of the surgical techniques will continue to evolve as our understanding of the management of myocardial recovery continues to improve.

Recommendations

1. *In the setting of recovery, less invasive approaches for device explant such as a left subcostal incision may be considered(1, 15, 125-135). IIb (Level of Evidence: C).*
2. *In the presence of significant device infection if a decision has been made to remove the DMCS, then complete explantation of the device and hardware should always be performed(1, 15, 128). IIb (Level of Evidence: C).*
3. *Use of specially designed plugs or repair of the apical ventriculotomy which avoids the need for extensive ventricular reconstruction should be considered(125, 127-132). IIb (Level of Evidence: C).*
4. *LVAD decommissioning is an alternative less invasive approach for the surgical management of cardiac recovery in select patients(15, 127, 128, 133, 134). IIb (Level of Evidence: C).*

Postexplant management and surveillance

Careful postexplant management and surveillance is very important(1, 76). It is wise, however well the patient appears to be doing, to treat the patient as if they have "heart failure in remission" to protect against the risk of heart failure recurrence. The following description of postexplant management is based on the author's experience.

Perioperative care. Immediate periexplant management is particularly important. ACE inhibitors/ARBs/Sacubitril/Valsartan and aldosterone antagonists should be held 36 hours before the explant surgery to lessen potential vasoplegia and protect renal function but the beta blocker should be continued right up until the explant surgery and even given the morning of surgery if possible(1). This is to protect against perioperative tachycardia. If the patient has had any driveline or pump infection antibiotics should be considered according to the patient's existing sensitivities to cover the explant surgery and continued for approximately a week and often 10 to 14 days afterward. If there is no known infection 48 hours of broad spectrum coverage should still be given. It is important to lessen the potential detrimental effect of infection on the newly explanted heart.[1]

Once in the ICU postexplantation IV fluids should be minimized, a Swan Ganz catheter should be left in place postoperatively for at least 48 hours and the fluid balance titrated to invasive hemodynamics(1). Diuretics should be used to maintain the PA diastolic pressure (which reflects the left-sided filling pressure) below 20 mm Hg.(1, 76) Inotropes are usually continued for the first few days after explant and then slowly discontinued. Caution is advised with high dose milrinone immediately postoperatively since these patients tend to demonstrate systemic vasodilation which can be exacerbated by milrinone so avoidance or an early wean is advised.

As the inotropes are weaned off after explantation, the ACE inhibitor should be reintroduced followed by the beta blocker(8, 10, 25), both should be uptitrated as rapidly as possible and the aldosterone antagonist should also be reintroduced while monitoring the potassium(25). Aggressive uptitration of the ACE/ARB and beta blocker and aldosterone

antagonist addition is a very important part of the postexplant management and in the prevention of the recurrence of heart failure(1, 25). The highest possible doses of ACE/ARB and beta blocker should be achieved and if the very high doses suggested in the prior section had been achieved while the patient was on the pump the goal should be to target the same high doses(25). In addition to ACE an ARB can be reinstituted if the patient tolerated both ACE and ARB during LVAD support(25). If the patient was on Entresto then Entresto can be restarted postexplant instead of the ACE or ARB, although it should be noted that postexplant experience with Entresto is extremely limited to date(77, 78).

Regular echocardiograms should be performed after explantation (25)—a transoesophageal echo should be performed during the explantation surgery, a transthoracic echo early postoperatively on the ICU and echocardiograms performed at least weekly(1, 25) while still an inpatient after the explant. There should be a low threshold to give diuretics in the perioperative period, they are usually required in the first 24 hours as described above to keep the filling pressures down and in the first few days after surgery, although usually patients can be ultimately weaned off diuretics. It is not uncommon to see some reduction in EF around 1-week postexplant, which usually recovers especially when GDMT is restarted. Uptitration of ACE/ARB, beta blocker and aldosterone is very important for the long-term outcome of these patients(25) and we would recommend achieving at least mid-range doses before discharge even if this delays discharge by a few days.

Postdischarge. After discharge the patient should be seen every 1 to 2 weeks until maximal tolerated goal directed medical therapy is achieved. The frequency of follow up can be reduced once the patient is stable and on maximally tolerated doses of the HF drugs, ultimately 6 monthly follow up is appropriate. An echocardiogram should be performed at most visits. Anticoagulation is given according to the explant technique and varies by center.

It is important that the patient is closely followed postexplant at least initially in the LVAD center with long-term follow-up in the LVAD center wherever possible. Patients are often young and may feel very well but should be warned that they are still susceptible and should be advised not to drink alcohol, to follow up regularly and not to stop their heart failure medications.[136,143] If they should need other surgeries, they should be performed in their LVAD center where possible and nonurgent procedures (such as hernias, etc.) should be delayed until at least a year after explant to give them a long period of initial stability.

Recommendations

1. *Patients should be followed closely after LVAD explantation at an LVAD center(1, 76). IIa (Level of Evidence: C).*
2. *If the patient has had any prior driveline or pump infection perioperative antibiotics should be given according to the patient's existing/prior sensitivities and continued for approximately a week afterward. If there is no history of infection 72 hours of broad spectrum coverage should be given(1, 76). IIa (Level of Evidence: B).*
3. *Close attention to fluid balance and hemodynamics are required after explant surgery and the pulmonary artery diastolic pressure maintained <20mm Hg with judicious diuretic use in the early postoperative period(1, 76) IIa (Level of Evidence: C).*
4. *Soon after explantation an ACE inhibitor should be reintroduced followed by beta blockade, both should be rapidly uptitrated as tolerated(8, 10, 25). An Aldosterone antagonist should be reintroduced (while monitoring potassium) (8, 10, 25). ARB can be reinstituted if the patient tolerated both ACE and ARB during LVAD support(8, 10, 25). IIa (Level of Evidence: C).*
5. *Intraoperative transoesophageal echo should be performed during the explantation surgery and frequent echocardiograms should be performed in the perioperative period(1, 25). IIa (Level of Evidence: C).*
6. *If the pump is fully removed with no plug (i.e., apical inflow site sutured) anticoagulation is not recommended(1, 8, 10, 126). If the pump is fully removed with use of an apical plug, warfarin is given for 6 to 12 weeks (to allow endothelialization of the plug)(1, 76, 125), then the warfarin may be changed to Aspirin. If the pump is decommissioned with the pump left in place coumadin is continued indefinitely(1). IIb (Level of Evidence C).*

Special circumstances acute myocarditis

Most patients with acute myocarditis have a relatively benign course and present with mild symptoms, such as fatigue, fever and pleuritic chest pain(137, 138). However, a minority of patients have fulminant disease and may require inotropes or mechanical support(139-141). There is growing evidence to support the use of temporary and durable devices in severe myocarditis(139-141). In a multicenter trial, 50.9% of the patients with fulminant myocarditis were treated with temporary mechanical circulatory support(138, 140-142). Temporary and DMCS should be considered in fulminant myocarditis as a bridge to recovery, and an effort should be made to identify and reverse the offending cause(142-144) (drugs, infection, inflammation, etc.). Assessment of the underlying myocardial function should occur before proceeding to long-term LVAD support or heart transplantation as the rate of myocardial recovery in this patient population is high(1, 142).

Recommendations

1. *For patients with myocarditis on short-term support an assessment of the underlying myocardial function should be performed before proceeding to DMCS or heart transplantation(1, 139-141, 145). I (Level of Evidence: C).*
2. *When tolerated, adjuvant medical therapy with neurohormonal and beta blockade should be considered during mechanical support for acute myocarditis to promote recovery(75, 83-86). IIa (Level of Evidence: C).*

Cardiogenic shock post-MI

Cardiogenic shock as a complication of acute myocardial infarction carries a high mortality with estimates at 40% to 50%(146). While revascularization remains the primary therapy, it may not be adequate to reverse the multiorgan dysfunction stemming from the initial injury. In the setting of MI and cardiogenic shock, use of temporary mechanical circulatory support devices as a bridge to recovery, especially after revascularization, is being increasingly utilized(147).

Mechanical unloading of the left ventricle and reduction of ventricular wall stress has the potential to increase the chance for myocardial recovery in acute MI. Indeed, use of temporary MCS with a delayed revascularization strategy has been proposed as a means to reduce infarct size and promote a greater degree of myocardial recovery(148). In small, largely observational studies, early unloading of the infarcted myocardium and hemodynamic support with temporary support devices such as Impella or ECMO has been shown to improve overall outcomes in patients with acute MI complicated by cardiogenic shock(149, 150). An additional trial showed that the Impella CP device and IABP support in the setting of severe cardiogenic shock demonstrated a similar overall mortality(151). Limitations of this study were the small number of patients ($n = 48$) and the severity of shock which may have limited the benefit of either therapy. In another study of patients who received VA-ECMO or CentriMag VAD for cardiogenic shock after acute MI. A substantial number of patients were explanted due to myocardial recovery during the index hospital stay. Ultimately, 31% of the entire cohort achieved myocardial recovery. The authors concluded that MCS was not only feasible for patients with acute MI and cardiogenic shock, but suggested improved survival compared with conventional management(152).

Existing data suggest a low rate of recovery in patients supported with durable LVADs after MI. However, there have not been clinical trials in this patient population and further investigation is warranted. Investigators who queried the INTERMACS registry assessed patients who underwent VAD placement in the setting of acute MI. The authors noted that at 1-year post-VAD, 52% of AMI patients were alive with ongoing VAD support, 25.7% had been transplanted, and 1.6% had the LVAD explanted for recovery.[160] It should be also noted that these data likely underestimates recovery since there was no initiative to seek or promote recovery in these patients.

Recommendations

For patients with hemodynamic compromise post-MI, use of short-term MCS to provide hemodynamic support can allow for myocardial recovery particularly after revascularization(148-154). IIb (Level of Evidence: C).

Device malfunction and infection—considerations for explantation for partial recovery

When there is a suspicion of pump thrombosis, low speed testing should generally be suspended as there is a risk that speed adjustment might dislodge a thrombus. However, if pump thrombosis is so severe that pump exchange is being considered, a low speed study may be considered to assess the presence of recovery and possibility of device explant in favor of device exchange. If previously obtained clinical data satisfy the explant criteria above, or is close to it, then further low speed/explant testing is warranted due to the potential benefit of an explant over pump exchange. In this situation, only the very necessary testing is performed with no exercise component(50). When possible, testing is combined so that there is only one turndown, to minimize the risk of dislodgement of thrombus. Particular attention should be paid to the turndown anticoagulation protocols as described above. Once the turndown study is completed, the pump speed should be slowly returned to normal. If the echo and hemodynamic data exceed or are close to the explant criteria described above explantation should be considered. In the situation of pump thrombosis, explantation might be considered with partial recovery but this would be a local team decision based on the individual patient's clinical condition, the risk of explant vs pump replacement, the patient's wishes and the likelihood that the patient would tolerate heart failure medications after explantation. The presence of symptoms during LVAD support are an important consideration(1, 50). Symptoms and signs of heart failure during LVAD support would likely preclude explant.

In the instance of pump thrombosis, the simplest surgical procedure is indicated, especially in the setting of augmented anticoagulation(1, 128). A minimal surgical approach might be to tie off the outflow graft and decommission the LVAD (stopping the hemolysis) and remove the driveline if possible. The driveline can even be fully removed at a later date when the patient is on lower levels of anticoagulation.

The presence of infection also influences the decision for explant for recovery. If infection of the driveline or pump or sepsis is present it is important to remove the whole system and not leave any pump parts or pieces of graft behind(1, 128). Anecdotally the authors have noticed that the presence of infection can impair myocardial function. In this setting, low speed tests should be deferred and performed when the infection has resolved. Further, initiation and rapid uptitration of neurohormonal blockade may be more challenging.

If the patient has a chronic infection (such as a driveline infection) and sufficient recovery has been demonstrated to consider explant, the explant decision-making process should be accelerated before function worsens and the window is lost.[1,82] In the presence of infection there is likely to be a greater hemodynamic challenge at the time of explantation due to fever and tachycardia, it is therefore important for these patients to meet or exceed explant criteria and explant for partial recovery should be undertaken with great caution.

Recommendations

1. *In the setting of pump thrombosis clinical data should be reviewed for signs of recovery before pump exchange occurs(1). IIb (Level of Evidence: C).*

2. *In the presence of pump thrombosis:*

a. *recovery testing techniques should be combined into the minimal number of turndown studies. and performed with care due to the risk of dislodging thrombus(1, 50). IIa (Level of Evidence: C).*
b. *close attention should be paid to adequate anticoagulation during turndown studies(1, 50). IIa (Level of Evidence: C).*
c. *explantation may also be considered if echocardiographic and hemodynamic data are close to (but fall below) normal explant thresholds(9). IIb (Level of Evidence: C).*
d. *the simplest surgical procedure for explant is favored (125, 127-130, 133, 134). IIa (Level of Evidence: C).*

3. *In the presence of infection (driveline/pump/sepsis)*

%1. The potential enhanced hemodynamic demand of surgery should be factored into the explant decision. IIb (Level of Evidence: C).

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Task Force 7 Summary:
Myocardial Recovery Guidelines (New)

Patient Selection:
Class IIa:
1. At least one echocardiographic assessment for myocardial recovery should be performed in all patients post LVAD (especially those intended for heart transplant).
Level of Evidence C.
2. A normalized LV end diastolic diameter (LVEDD), change in the duration and frequency of aortic valve opening and improvement of LV function should trigger further assessment of recovery including studies performed at low flow/speed.
Level of Evidence C.
3. Patients with non-ischemic cardiomyopathy, those with younger age and shorter duration of HF symptoms should be a particular focus and closely managed and assessed with cardiac recovery in mind.
Level of Evidence B.
Class IIb:
1. Use of predictive tools may be helpful in identifying individuals with increased likelihood of cardiac recovery.
Level of Evidence C.

Medical and Device Optimization
Optimizing unloading for recovery:
Class IIa:
1. LVAD speed adjustments to optimize unloading are likely to enhance the potential for recovery.
Level of Evidence C.
2. An echocardiogram should be performed prior to discharge after LVAD implantation and the speed set so that the septum is in the midline, the aortic valve optimized and closed at least intermittently at rest and the mitral regurgitation is minimal.
Level of Evidence B.
3. Echocardiograms should be performed during outpatient visits to optimize left ventricular unloading targeting when possible LVEDD 6cm (ideally 5.5cm~~)~~ while avoiding suction events.
Level of Evidence B.
Class IIb:
1. Both non-invasive and invasive techniques are helpful in optimizing LVAD unloading.
Level of Evidence B.

Timing of initiation, frequency of up-titration and target doses of neuro-hormonal blockade.
Medications and Blood Pressure:
Class IIa
1. Neurohormonal therapy should be initiated early after LVAD implantation and has been associated with improved outcomes and promotes recovery.
Level of Evidence B.
2. Neurohormonal therapy should be up-titrated as clinically tolerated to promote recovery. Intolerance of guideline directed medical therapy (GDMT) prior to LVAD is not necessarily a contraindication.
Level of Evidence B.
3. In patients managed for recovery, maximally tolerated doses of neurohormonal blockade should be targeted GDMT~~.~~ Patients may have simultaneous up-titration of ACEIs, ARNi, or ARB in conjunction with beta blockers and aldosterone inhibitors with prioritization of ACE inhibition.
Level of Evidence C.

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Task Force 7 Summary:
Myocardial Recovery Guidelines (New)

Measuring Blood Pressure:

Class IIa:

1. Accurate reliable measurement of blood pressure in LVAD is key in reducing LVAD related adverse events and titrating medical therapy to promote recovery.

Level of Evidence B.

2. Careful attention should be paid to aortic valve opening, hemodynamic status, and degree of pulsatility when interpreting non-invasive BP measurements.

Level of Evidence B.

3. Anti-hypertensives used (as needed) where possible should be consistent with HF GDMT to help promote reverse-remodeling and improvement in myocardial function.

Level of Evidence C.

4. Neurohormonal blockade and beta blockers should be preferentially chosen for the treatment of hypertension during LVAD support.

Level of Evidence B.

Class IIb:

1. The appearance of new hypertension or a significant change in pulse pressure should warrant further investigation for recovery.

Level of Evidence C.

ICD/CRT considerations:

Class IIb:

1. Existing CRT/D devices may offer continued benefit during LVAD support.

Level of Evidence C.

2. In patients that have a history of VT and no ICD who undergo explantation for recovery ICD implant should be considered prior to discharge.

Level of Evidence C.

Evaluation for Recovery:

Class IIa:

1. Echocardiography is the primary imaging modality for the selection of potential explant candidates, and is an essential tool for assessment of recovery.

Level of Evidence C.

2. Echocardiographic measurements for recovery should include LVEF, LVEDD and LVSD.

Level of Evidence C.

3. LVEF should be assessed using Simpson's biplane method and LVEDD measured in the 2D parasternal long-axis when possible. The degree of mitral and aortic regurgitation and RV function should also be assessed.

Level of Evidence C.

4. An on pump assessment (at normal operating speed) may be used for screening; however low speed testing is required for complete evaluation of myocardial recovery.

Level of Evidence B.

5. For low speed testing with a continuous flow LVADs, the pump speed should be reduced to net zero flow (6000 RPM for a HeartMate II, 1800 RPM for a HVAD and 3800-4000 RPM for a HeartMate 3. Low speed testing should be performed with the patient fully anticoagulated 114.

Level of Evidence B.

6. Echocardiographic assessment should be performed after 15 minutes at net zero flow and repeated after the patient performs a 6-minute walk.

Level of Evidence C.

7. Low speed testing that provokes symptoms and/or cardiac arrhythmias suggests inadequate recovery[56]. Further attempts at testing may be performed after a longer period of mechanical unloading and further neurohormonal optimization.

Level of Evidence C.

8. Prior to a decision about LVAD explant, intracardiac filling pressures (Pulmonary Artery Catheter with +/- exercise) should be obtained at full pump speed and after 15 mins of net zero flow.

Level of Evidence C.

Class IIb:

1. Significant elevation in pulmonary capillary wedge pressure during low speed studies should raise concerns about candidacy for device explantation.

Level of Evidence C.

2. Cardiopulmonary pulmonary exercise test (CPET) results should be interpreted in the context of other parameters (echocardiography and hemodynamics). A low peak oxygen consumption should not, on its own, preclude a decision to explant.

Level of Evidence C.

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Task Force 7 Summary:
Myocardial Recovery Guidelines (New)

Explant Criteria:

Class IIa:

1. Patients undergoing assessment for recovery may be considered for explanation if they meet the following criteria measured after the patient has been at zero net flow for 15 minutes: A maximal oxygen consumption with exercise (mVO2) 16 ml/kg/min would enhance the decision to explant, but is not a requirement due to the inaccurate prognostic ability of cardiopulmonary exercise testing in predicting recovery.
   a. LVEDD < 60mm, LVESD < 50 mm, LVEF > 45%, and
   b. LVEDP or PCWP 15 mmHg, and
   c. Resting cardiac index (CI) > 2.4L/min/m2

Level of Evidence C.

2. If recovery parameters continue to improve, explantation should be deferred until the maximum improvement has been achieved.

Level of Evidence C.

Explant Technique:

Class IIb:

1. In the setting of recovery, less invasive approaches for device explant such as a left subcostal incision may be considered.

Level of Evidence C.

2. In the presence of significant device infection, if a decision has been made to remove the DMCS, then complete explantation of the device and hardware should always be performed.

Level of Evidence C.

3. Use of specially designed plugs or repair of the apical ventriculotomy which avoids the need for extensive ventricular reconstruction should be considered.

Level of Evidence C.

4. LVAD decommissioning is an alternative less invasive approach for the surgical management of cardiac recovery in select patients.

Level of Evidence C.

Post Explant Management, Surveillance & Special Circumstances:

Class IIa:

1. Patients should be followed closely after LVAD explantation at an LVAD center.

Level of Evidence C.

2. If the patient has had any prior driveline or pump infection peri-operative antibiotics should be given according to the patient's existing/prior sensitivities and continued for approximately a week afterwards. If there is no history of infection 72 hrs of broad spectrum coverage should be given.

Level of Evidence B.

3. Close attention to fluid balance and hemodynamics are required after explant surgery and the pulmonary artery wedge pressure maintained 20mmHg with judicious diuretic use in the early post-operative period.

Level of Evidence C.

4. Soon after explantation an ACE/ARB/ARNi inhibitor should be reintroduced followed by beta blockade, both should be uptitrated as tolerated. An Aldosterone antagonist should be reintroduced (whilst monitoring potassium). ARB can be reinstituted if the patient tolerated both ACE and ARB during LVAD support.

Level of Evidence C.

5. Intraoperative transoesophageal echo should be performed during the explantation surgery and frequent echocardiograms should be performed in the perioperative period.

Level of Evidence C.

Class IIb:

1. If the pump is fully removed with no plug (i.e. apical inflow site sutured) anticoagulation is not recommended. If the pump is fully removed with use of an apical plug, warfarin is given for 6-12 weeks (to allow endothelialization of the plug), then the warfarin may be changed to Aspirin. If the pump is decommissioned with the pump left in place it may be reasonable to continue coumadin indefinitely.

Level of Evidence C.

Special Circumstances Acute Myocarditis:

Class I:

1. For patients with myocarditis on short term support an assessment of the underlying myocardial function should be performed before proceeding to DMCS or heart transplantation.

Level of Evidence C.

Class Iia:

1. When tolerated, adjuvant medical therapy with neurohormonal and beta blockade should be considered during mechanical support for acute myocarditis to promote recovery.

Level of Evidence C.

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Task Force 7 Summary: Myocardial Recovery Guidelines (New)

Cardogenic Shock Post MI:
Class Iib:
1. For patients with hemodynamic compromise post MI, use of short term MCS to provide hemodynamic support can allow for myocardial recovery particularly after revascularization.
Level of Evidence C.

Device Malfunction and infection:
Class IIa:
1. In the presence of pump thrombosis recovery testing techniques should be combined into the minimal number of turndown studies and performed with care due to the risk of dislodging thrombus.
Level of Evidence C.
2. In the presence of pump thrombosis, close attention should be paid to adequate anticoagulation during turndown studies.
Level of Evidence C.
3. In the presence of pump thrombosis and recovery the simplest surgical procedure for explant is favored.
Level of Evidence C.
Class IIb:
1. In the setting of pump thrombosis clinical data should be reviewed for signs of recovery before pump exchange occurs.
Level of Evidence C.
2. In the presence of pump thrombosis, explantation may also be considered if echocardiographic and hemodynamic data are close to (but fall below) normal explant thresholds.
Level of Evidence C.
3. In the presence of infection (driveline/pump/sepsis), the potential enhanced hemodynamic demand of surgery should be factored into the explant decision.
Level of Evidence C.

Task Force 8

Biventricular replacement and support—TAH and BiVADs

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Topic 1: Patient selection

Biventricular heart failure (BHF), due to concomitant or progressive right ventricular failure is more frequently observed with nonischemic cardiomyopathies (CMP) vs ischemic CMP. The greater incidence of BHF in nonischemic CMPs, occurs from the diffuse myocardial involvement of the nonischemic pathologic mechanisms, as compared to a more localized, specific, arterial bed involvement in ischemic CMP affecting predominantly, the left ventricle. Certain cardiomyopathies are at the highest risk of developing BHF in the postoperative state, such as chemotherapy-induced CMP, congenital heart disease, and restrictive CMPs.(1) INTERMACS class 1 to 2, with "crash and burn" and worsening cardiogenic shock physiology, requiring high doses of inotropes, vasoconstrictors, percutaneous temporary mechanical circulatory support (MCS), or venoarterial ECMO, also tend to have a high incidence of RV dysfunction and failure.(2)

In patients with BHF, reversible causes should be addressed before consideration for any form of biventricular MCS. Patients with new left or biventricular failure should be thoroughly evaluated for any and all reversible or identifiable causes of CMP. A detailed history, assessment of comorbid conditions, review of exposure to illicit substances, exotoxins, and rare infections should be entertained. A thorough diagnostic workup should include complete blood count with differential, metabolic panel, HbA1c, thyroid, liver function tests, serum ferritin, transferrin saturation, inflammatory markers, infectious and autoimmune serology, chest radiography, electrocardiography, and echocardiography.(3)

Evaluation of biventricular heart failure

If the patient resides in the age group >35 years of age, with risk factors for ischemic heart disease, then invasive cardiac catheterization should be undertaken. Patient's with identified obstructive coronary artery disease should be evaluated for coronary revascularization.(4) Careful evaluation for ischemic, stunned, and hibernating myocardium should be done with advanced imaging techniques including cardiac myocardial resonance imaging (MR) or position emission tomography (PET) perfusion imaging.

Arrhythmias often accompany diagnosis of new onset heart failure. It is often difficult to ascertain if these are cause or effect. Tachycardia-induced cardiomyopathy is a time-dependent phenomenon, usually taking months to years to develop, but the presence of an underlying structural abnormality may hasten its course.(5) Ablative procedures for ventricular tachycardia, and concomitant use of implantable cardioverter defibrillators (ICD) are gaining ground as more data regarding their efficacy and safety is emerging under different clinical conditions.(6, 7)

In patient presenting with severe heart failure or cardiogenic shock in extremis, the occurrence of ventricular tachyarrhythmia's or advanced AV blocks should arouse suspicion of acute fulminant myocarditis.(8)

Recommendation

All patients presenting with biventricular failure should be thoroughly screened for any potentially reversible conditions. An extensive metabolic, biochemical and serological panel should be obtained, including complete blood count with differential, comprehensive metabolic panel, thyroid panel, ferritin, serum transferrin, HbA1C, inflammatory markers, autoimmune and infectious serologies. (Class I, Level of evidence: C.)

Diagnosis of biventricular heart failure

Echocardiography or comparable imaging modalities, as well as hemodynamic evaluation, are key to the diagnosis of BHF. In the EUROMACS study to establish an RHF prediction score, the diagnosis of RHF after LVAD implantation was based on the need for postoperative mechanical RV support, the need for prolonged postoperative inotropic support and the need for prolonged NO ventilation.(9) Right ventricular failure after LVAD implantation is defined by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) as persistent signs and symptoms of RV dysfunction, central venous pressure (CVP) >18 mm Hg with a cardiac index (CI) <2.0 L/min/m^2 without signs of increased left atrial filling pressure/pulmonary capillary wedge pressure (PCWP) >18 mm Hg, cardiac tamponade, ventricular arrhythmias, and/or pneumothorax not requiring neither right ventricular assist device (RVAD) implantation nor inhaled nitric oxide or inotropic therapy for ≥14 days after LVAD implantation.(10)

The role of multimodality imaging, including 2D and 3D-echocardiography and cardiac MRI, have been crucial in assessing RV anatomy and physiology.(11, 12) Traditionally, 2D echocardiography most commonly utilizes systolic and dimensional indices, namely TAPSE, S', RV fractional area change (RVFAC), right ventricular and right atrial volumes to ascertain the degree of RV dysfunction.(13)

Hemodynamic data are complementary to anatomic data obtained by imaging. Information obtained from right heart catheterization is vital for the risk stratification of the preoperative patient. It provides valuable insight into the hemodynamic profile and offers clinicians an opportunity for optimization before surgery. Individual parameters such as central venous pressure (CVP), pulmonary artery systolic pressure (PASP), pulmonary vascular resistance (PVR), and derived indices, namely pulmonary artery pressure index (PAPi), right ventricular stroke work index (RVSWI), and the ratio of CVP/PCWP have shown to robustly correlate with diagnosis as well prognostication in BHF/RHF patients.(14),(15) To improve sensitivity and positive predictive value, several investigators have suggested utilizing risk scores models, which are often a composite of clinical variables and also take into account hemodynamic profile.(16) Scores such as Michigan risk score and others have shown a reasonable degree of success in identifying patients at risk and predicting postoperative RV failure.(17, 18) Adding longitudinal strain imaging to the Michigan risk score was shown to be of incremental value in single series.(19) The EUROMACS Right Sided Heart Failure Risk Score incorporates 5-items (severe RV dysfunction on semiquantitative echocardiography, ratio of RA to PCWP ≥ 0.54, INTERMACS class 1 through 3, need of ≥3 inotropic agents, hemoglobin ≤10 g/dL) to predict early severe postoperative RV failure. With a C-index of 0.7 and 0.67 in the derivation and validation cohort is the best performing risk score developed so far.(9)

Recommendations

All patients undergoing advanced therapy evaluation must have a comprehensive baseline 2D-echocardiogram to assess for RV function and volume. (Class I, Level of evidence: A.)

Calculation of RVSWI, PAPi, CWP/PCWP, and RV Risk score should be routine at the index right heart catheterization before proceeding with surgery. (Class IIa, Level of evidence: B.)

Diagnosis of persistent/irreversible biventricular failure

In the ambulatory setting of chronic heart failure, dobutamine stress testing can demonstrate RV and LV contractile reserve which is associated with good short-term outcome, and may be of prognostic value in patients with severe heart failure.(20) In addition to traditional heart failure, one must suspect BHF in acute or chronic allograft failure, restrictive cardiomyopathy, hypertrophic cardiomyopathy, and extensive biventricular intracavitary thrombus. Right ventricular contractile reserve has been defined as the difference between these values obtained at baseline and peak stress (ΔTAPSE < 16 mm and $\Delta S' <$ <10 cm/sec, respectively). In this evaluation dobutamine was increased at increments of 5 μg/kg/min at 3-minute intervals up to a maximum of 20 μg/kg/min or until limited by side effects.

In the setting of ongoing acute left heart failure, coexistent RV failure should be suspected when CI < 2.2 L/min/m^2 or cardiac power <0.6 W and any of the following: A. Ongoing hemodynamic evidence of: 1. CVP >15 mm Hg, or 2. CVP/PCWP ratio >0.63), 3. pulmonary artery pulsatility index (PAPI) < 1.85 and B. Echo/imaging evidence of RV dysfunction (TAPSE <14 mm; increased RVEDV).(21)

Failure of weaning of temporary MCS support or high dose inotropes after 72 hours of hemodynamic optimization and complete revascularization, suggested by worsening hemodynamics or refractory arrhythmias or end-organ dysfunction, may require escalation to TAH, BiVAD or transplant in suitable candidates.

Recommendation

The right ventricular contractile reserve must be evaluated by echo and hemodynamic testing in a patient undergoing left ventricular support to determine the need for biventricular support. (Class I, Level of evidence: C.)

Topic 2: Management of biventricular dysfunction

A patient with a diagnosis of BHF should be advanced to TAH or BiVAD if their response to temporary RVAD or ECMO is poor. Persistent and rapid clinical status deterioration supports and accelerates this advancement. The decision and choice to advance to TAH or BiVAD should take into consideration the underlying etiology of BHF.

Decision for advancement to TAH or durable BiVAD therapy

Right ventricular failure is a frequent complication in patients with biventricular failure where univentricular support in the form of a left ventricular assist device (LVAD) is implanted and is associated with increased mortality and lower chances of heart transplantation. (22-25)

Adjudication criteria of adverse events related to right heart failure in the context of MCS have been recently updated.(26) Early right ventricle (RV) dysfunction is defined as signs and symptoms of RV failure accompanied with persistent central venous pressure (CVP) elevation >18 mm Hg, with CI < 2.0 L/min/m^2, in the absence of elevated left atrial/ pulmonary capillary wedge pressure (<18 mm Hg), cardiac tamponade, ventricular arrhythmias, or pneumothorax, requiring either inotropic support, inhaled nitric oxide or right ventricular assist device support 14 days after LVAD implantation. (27) It could be further classified into mild, moderate, or severe depending on the degree of support. The need for a right ventricular assist device (RVAD) classifies it as severe, whereas inotropic or nitric oxide support places it in the category of moderate RV dysfunction. Mild RV dysfunction exists when RV failure criteria are present in the absence of RVAD/inotropic or nitric oxide support.(28)

Patients with severe RV failure requiring temporary RV support after LVAD implantation are the sickest of the cohort. Patients on venoarterial ECMO or temporary RVAD support should be considered for a switch to BiVAD or TAH support strategy to avoid irreversible end-organ damage. Similarly, for patients on prolonged high dose inotropic support, serious consideration should be given to BiVAD vs TAH therapy as prolonged inotropic use could lead to deleterious end-organ damage and make the candidate eventually not eligible for OHT. Sustained ventricular tachyarrhythmias lead to RV failure and portend poor outcomes. Experience with ablation of these arrhythmias on patients with LVAD is still in the early phase and has shown little success, with the added risks of pump thrombosis and thromboembolic events.(29) This subset of patients with ventricular tachyarrhythmias refractory to medical therapy, with recurrence after ablation, or with "ventricular storm," should be considered for TAH. (5-8, 30) Additionally, patients with implanted LVADs that develop progressive and worsening clinically important aortic insufficiency, who cannot be treated by transfemoral aortic valve replacement, should be considered for advancement to TAH, as worsening AI is in this setting is associated with significantly worse outcomes and increased mortality.(31) (32)

Recommendation

Composite scores should be utilized to predict and identify patients at the highest risk for postoperative RV failure. (Class I, Level of evidence: C.)

Early application of right ventricular mechanical support should be considered in patients with severe RV failure to avoid multiorgan dysfunction. (Class IIa, Level of evidence: B.)

For patients with persistent/incessant arrhythmias, the TAH may offer advantage over BiVAD. (Class IIb, Level of evidence: C.)

Biventricular failure—not on any MCS

The decision and choice to advance to TAH or BVAD should take into consideration the underlying etiology.

De novo severe biventricular failure—such as chemotherapy-induced cardiomyopathy, cardiomyopathy in congenital heart disease (CHD) patients, some forms of dilated

Table 1 Current Types of Devices for Biventricular Support

Device	Type of flow	Placement	Outpatient use	Duration of use	Comment
CentriMag	Continuous	Extracorporeal	No	Weeks	Hybrid for temporary RVAD or BiVAD
Impella RP	Continuous	Percutaneous	No	<2 weeks	Temporary RVAD or hybrid with Impella LP or other
TandemHeart	Continuous	Percutaneous	No	Days-weeks	Use with Protek Duo Cannula
VA-ECMO	Continuous	Extracorporeal	No	Days	Recovery or bridge to bridge
HeartMate 3	Continuous	Intrapericardial	Yes	Long-term	Two devices; RVAD and LVAD
Jarvik 2000	Continuous	Intraventricular	Yes	Long-term	Two devices; RVAD and LVAD
Berlin Excor	Pulsatile	Paracorporeal	Yes	Short or long-term	Pneumatic; Pediatric

cardiomyopathy, and restrictive cardiomyopathies, potentially require upfront total artificial heart/biventricular support strategies.

End-stage heart failure is growing in prevalence due to improved awareness, as well as surgical treatment of congenital heart disease patients who eventually develop heart failure, e.g., failed Fontan. It has been noted that these patients tend to be younger, are more sensitized, have worse RV function, and often require bridging device therapies. (33) They tend to have unique anatomical challenges and multivalvular dysfunction related to the chronicity of their condition.

Patients with chemotherapy-induced CMP often are not transplant candidates due to ongoing or previous malignancy. It has been observed that up to ~20 % of these patients have significant RV dysfunction, of which a significant proportion required TAH/BiVAD support. Patients with infiltrative, e.g., amyloid, restrictive or hypertrophic cardiomyopathies who are not candidates for heart transplantation due to high pulmonary vascular resistance pose a significant challenge. (34) These patients are suboptimal candidates for LVAD implant due to the biventricular nature of dysfunction, anatomical and physiologic considerations. The TAH presents a unique opportunity for therapy in this subset of patients. Lastly, patients with dilated cardiomyopathy who present with significant end-organ dysfunction, including renal and liver metabolic abnormalities, need bridge therapies before they can be transplant eligible. Biventricular support, either with an LVAD/temporary RVAD or durable BiVADs, offers a chance to reverse the process.

Recommendations

Selected patients with end-stage heart failure due to congenital heart disease should be considered for TAH/BiVAD after an initial evaluation to assess surrogates for RV dysfunction. (Class IIa, Level of evidence: C.)

Selected patients with infiltrative, restrictive or hypertrophic CMP should be considered for the total artificial heart when timely heart transplantation is not feasible. (Class IIa, Level of evidence: C.)

Acute biventricular failure—acute myocardial infarction

Complete revascularization for patients with STEMI and multivessel coronary artery disease should be considered in the setting of ongoing biventricular elevated filling pressures with coexistent right ventricular failure and may require escalation to temporary BiVAD. (35)

Failure to wean off temporary MCS support or high dose inotropes suggested by worsening hemodynamics or refractory arrhythmias or end-organ dysfunction after 72 hours of hemodynamic optimization and complete revascularization may require escalation to BiVAD or TAH or emergent transplant in suitable candidates.(36) Similarly, patients with extensive myocardial infarction, with associated anatomic defects such as severe ventricular septal defects or wall rupture, not amenable to surgical repair should be advanced to TAH.

Recommendation

Worsening hemodynamics, refractory arrhythmias, or end-organ dysfunction after a trial of temporary MCS support with hemodynamic optimization and complete revascularization may require escalation to BiVAD or TAH as a life-saving maneuver. (Class IIb, Level of evidence: C.)

Patients with massive myocardial infarction with accompanying anatomic defects, e.g., VSD and wall rupture, not amenable to surgical repair may be considered for TAH. (Class IIb, Level of evidence: C.)

Chronic biventricular failure

Most end-stage heart failure treatment efforts have been directed at providing left ventricular support. However, between 10% and 30%, if not higher, of all advanced heart failure patients have a true chronic biventricular failure, requiring consideration for biventricular support strategy.(37) Historically, these patients are channeled toward the OHT option if no contraindications exist, and it is also well recognized that these patients succumb to adverse outcomes if treated with a univentricular approach. Biventricular support exists in various permutation and combinations, including the total artificial heart, durable LVAD + extracorporeal RVAD, and or durable BiVADs. It is common knowledge that biventricular patients have a worse prognosis likely related to advanced disease, multiorgan involvement, and the critical nature of these patients. Hence, there is a growing need for identifying clinical characteristics to better predict and provide upfront biventricular support to such patients to optimize

outcomes. Preimplant characteristics of higher levels of creatinine, blood urea nitrogen, bilirubin, international normalized ratio (INR), and lower albumin and prealbumin ratio in a patient presenting with INTERMACS 1 status reflect worse organ perfusion and should raise concerns of the need for biventricular support. Hemodynamic indices of elevated right atrial pressure, lower pulmonary artery pressure in conjunction with these clinical characteristics support the likelihood of upfront TAH or BIVAD strategy.(38) There are no comparative studies to evaluate the efficacy of the total artificial heart vs other strategies of biventricular support in such a population.(39)

BiVAD patients tend to have a stormy perioperative course with higher adverse events, in form of bleeding, stroke, and infections.(39) Multiple devices, including the HVAD (Medtronic, Inc., Minneapolis, MN) and HeartMate 3 (Abbott Labs, Chicago, IL) have been used for durable BiVAD support.(40, 41) The SynCardia TAH (70 cc; Syncardia, Tucson, AZ) has been approved a bridge therapy to transplant since its landmark trial since 2004.(42) This trial used the TAH in patients with severe biventricular failure at imminent risk of death, particularly where BiVADs would be contraindicated, e.g., those with large ventricular septal defects, and requiring high cardiac outputs. On March 5, 2020, the SynCardia 50 cc TAH, as well, received FDA approval for BTT, extending options for smaller patients.

Recommendations

Patients presenting with Intermacs I and II status, with laboratory evidence of elevated bilirubin, INR, creatinine, blood urea nitrogen and clinical manifestations of severe malnutrition, in conjunction with hemodynamic profile of disproportionate RV failure, with elevated RA pressure and lower pulmonary artery pressure index may be considered for the total artificial heart or BiVAD, the choice related to selection issues of patient size, flow demand, fit, and related individual considerations. (Class IIb, Level of evidence: C.)

Topic 3: Implantable BiVAD

Currently, there are devices that provide continuous or pulsatile flow and maybe located extracorporeal, paracorporeal, intrapericardial, intraventricular, or intravascular (Table 1). The selection of MCS devices for BiVAD support is mostly dependent on patient characteristics, such as intended duration of support, patient size, and surgical risk. For patients requiring short-term support with a high probability of recovery, short-term percutaneous and paracorporeal devices suffice. For patients that are not expected to recover, and long-term outpatient support is desired, intrapericardial, intraventricular, and paracorporeal devices are most suitable. Durable devices generally require implantation via sternotomy with cardiopulmonary bypass and may not be the best option for patients with high surgical risk.

A very small proportion of patients with biventricular support show promise of recovery with RVAD explant, however, current literature does not provide adequate granularity to understand the characteristics of such patients. BiVADs patients tend to have a prolonged perioperative course with higher adverse events in the form of bleeding, stroke, and infections.(39)

Recommendations

Choice of BiVAD systems for a given patient should be determined by individual patient issues, surgical/HF Team familiarity/experience, system specifications, and availability. (Class I, Level of evidence: C.)

Biventricular assist device—BiVAD

Temporary biventricular support options

The CentriMag (Abbott Inc., Chicago, IL) offers versatility with regards to patient size, cannulation techniques, and it may be configured for univentricular or biventricular support and ECMO.(43, 44) Central cannulation and transthoracic externalization of cannula limit patient mobility and the duration of support with this system. The CentriMag is often used for temporary right heart support following LVAD implant or heart transplant. (45)

The Impella RP (Abiomed, Danvers, MA) is a catheter mounted microaxial flow pump intended to provide temporary right heart support.(46) This device is inserted percutaneously through the femoral vein and is positioned with the inflow in the inferior vena cava and the outflow in the main pulmonary artery. The Impella devices are restricted by the target vessel size. The device will provide up to 4.0 L/min of support and is approved for up to 2 weeks of use. Biventricular support may be accomplished using the RP device with an Impella 5.0/5.5 for left ventricular support.(47, 48)

The TandemHeart system (LivaNova, UK) was originally a left ventricular support device that involved percutaneous insertion of cannulas with the inflow transseptally placed in the left atrium and the outflow in the descending aorta. Incorporation of the dual lumen Protek Duo (LivaNova, UK) allows this system to provide right heart support with a hybrid configuration.(49, 50) The Protek Duo is inserted percutaneously with the inflow lumen in the vena cava and the outflow lumen in the main pulmonary artery. (51) This cannula allows for right heart support with the TandemHeart or CentriMag pumps. The Protek Duo cannula offers the advantage of patient mobility, and it can be removed at the bedside.(52)

Venoarterial ECMO is widely used for acute severe cardiogenic shock and provides total cardiac support for short durations.(53) The major advantage of ECMO is that it can be inserted rapidly, in multiple health care settings, and in a broad range of patients. Venovenous ECMO may be used for isolated right heart support in cases of severe respiratory failure. Long-term use of ECMO, i.e., >14 days, has been shown to lead to a significant increase in mortality.(54) For those patients deteriorating on ECMO earlier conversion to more robust BiVAD/TAH therapy should be strongly considered.

Recommendation

The reversibility of right heart failure must be thoroughly assessed to help determine if temporary or durable BiVAD support is needed. (Class I, Level of evidence: C.)

Durable biventricular support devices

The HeartWare HVAD (Medtronic, Inc., Minneapolis, MN), HeartMate 3 (Abbott Labs, Chicago, IL), and the Jarvik 2000 (Jarvik Heart, NY) are continuous-flow LVAD systems that have been used clinically for biventricular support.(41, 55, 56) The HVAD and HeartMate 3 were designed for placement at the left ventricular apex with inflow conduits inserted through the ventricular wall. The Jarvik device is placed through the apex and within the left ventricle. Modifications for placement at the right ventricle or right atrium requires some modifications from the standard left ventricular implant techniques.(41, 57) The outflow grafts are attached to the main pulmonary artery. To avoid excessive flow to the lungs, RVAD flows are limited by lower pump speed or by banding the outflow graft.(58) The use of an LVAD in the right ventricle is off label in the United States. Implanting 2 LVADs is a complex procedure, is similarly off label in the United States, and adds significant cost.

The Berlin Heart Excor (BerlinHeart, Berlin, Germany) is a pneumatically driven paracorporeal system that can provide univentricular or biventricular support. The Excor pumps are available in 50, 60, and 80 mL to meet various patient sizes. The Excor device is now principally used for pediatrics and less often in adults.(59)

A durable system specifically designed and intended for RVAD or BiVAD is currently unavailable. There are numerous anecdotal reports of off-label biventricular support using LVADs. Also, hybrid biventricular support with durable LVADs and temporary RVADs is common with a number of variations. Other devices used for uni- or biventricular support include Capiox (Terumo, Tokyo, Japan), Gyropump (Medtronic, Minneapolis, MN), Rotaflow (Maquet, Rastatt, Germany), and the Nirpo paracorporeal pneumatic pump (Osaka, Japan).

Recommendations

Implantation of 2 durable LVADs for biventricular support requires careful consideration of the complexity and cost. (Class IIb, Level of evidence: C.)

Implantation of a combination of continuous-flow LVAD and paracorporeal pulsatile RVAD may be considered for selected patients but requires careful consideration and an experienced team due to the complexity and risks of this treatment option in biventricular failure. (Class IIb, Level of evidence: C.)

Total artificial heart—TAH

TAH implantation for a given patient should be determined by individual patient issues, surgical/HF Team familiarity/experience, system specifications and availability.

The SynCardia TAH is the only TAH to receive full FDA approval for human use—for both in hospital and out-of-hospital use; and as bridge to transplantation, with ongoing study for long-term (destination) use. The SynCardia Heart is a pneumatically driven system with 2 independently positionable ventricles driven by an external driver.(60, 61) To date, the SynCardia TAH has been implanted in >1,900 patients. The SynCardia Total artificial heart exists in 2 forms: a 70 cc for use in patients with BSA to 1.7 m^2 and a 50 cc size for patients with BSA <1.7 m^2, i.e., small stature, women and children, operated by the Companion 2 hospital driver, or the Freedom portal driver—allowing patient discharge and full mobility.

The TAH is recommended in patients with severe biventricular failure without the potential of native myocardial recovery.(38, 62) The TAH delivers high pulsatile flows free from dependency on inotropes, right heart function or transient RV support in patients with end-organ failure. Moreover, by resecting native ventricle and cardiac valves, implanting a TAH is very useful and particularly recommended in difficult situations. These include patients with massive left sided infarction with persistent cardiogenic shock; dilated cardiomyopathy with intraventricular thrombus—with risk of embolization, or for patients with intracardiac defects, e.g., VSD, ventricular rupture, hypertrophic cardiomyopathy with excessive hypertrophy and limited ventricular cavity size. Furthermore, patients with infiltrative cardiomyopathies—e.g., amyloid, congenital malformations, cardiac tumors, stone heart will be ideal candidate for TAH implantation. Patients with failed transplants, failed VADs, or failed BiVADs, LVAD patients with progressive AI, failed Fontan, or other congenital repair surgery, as well as patients with VT storm and incessant arrhythmias are also able to be rescued and benefit from TAH implantation. In patients with prior prosthetic valve surgery—in particular patients with aortic or mitral prosthesis with thrombus formation due to low flow conditions; and other complex re-operative conditions not amenable to repair, TAH implantation should be considered. (60) Other considerations to be entertained in TAH selection include the size of the patient and the accompanying flow demands needed, the length of anticipated support, and the anticipated use—i.e., short-term support (bridge to transplantation) vs longer term support (previously termed destination therapy).

For larger patients, the TAH, by virtue of it having high levels of biventricular output—capable of >10.5 L/min of flow, can achieve the output needed to boost and sustain cardiac index CI > 2.0. Several studies recently have demonstrated that the TAH enhances long-term transplant survival rates, affording transplantation into a more physiologically recovered patient through up front use. Recently the group in Nantes examined long-term survival with the TAH and found a 72% transplant survival at 12 years post-transplant. (63) Similarly, a 6-center-group in the United States demonstrated 74% survival at 5 years postheart transplantation and TAH implantation.(64)

Over many years, survival with the TAH has been compared to BiVADs in the setting of bridge-to-transplantation using the INTERMACS registry, reporting a 71% transplantation rate with the TAH at 6 months vs 35% with BiVAD in 2009, with a similar trend in 2014.(65) A more recent analysis found 71% transplanted or alive on the device at 12 months with the TAH.(38) A multicenter French study in 2012 evaluated 383 patients, comparing TAH with BiVAD, found a significantly higher rate of stroke in patients receiving BiVADs. (66)

The Aeson Carmat total artificial heart is an implantable electro-hydraulically actuated pulsatile biventricular pump with pressure sensor-based autoregulation that is implanted in the pericardial sac, and it is made of bioprosthetic materials. (67) Initial clinical experience has been published and large pragmatic trials are underway. (68, 69) Approval by the Food & Drug Administration in the United States for a clinical feasibility study on 10 transplant-eligible patients was granted early in 2020. The Aeson is currently exclusively available within the framework of clinical trials in the United States. CARMAT SA received the CE mark for its total artificial heart in December 2020. Aeson is commercially available in Europe only, indicated as bridge-to-transplant treatment option in patients suffering from end-stage biventricular heart failure (INTERMACS classes 1-4) who are not amenable to maximal medical therapy or LVAD and are likely to undergo heart transplant in the 180 days following device implantation.

The manufacturer recommends a preimplant chest CT scan to assess anatomic compatibility. The most important measure is the spine-sternum distance at the level of the mitral valve; a minimal distance of 125 mm is advised. The Aeson is available for patients with body surface area ≥ 1.88 m2 or height ≥170 cm.

Recommendations

TAH implantation for a given patient should be determined by a balance of individual patient issues, surgical/HF Team familiarity/experience, system specifications and system availability. (Class IIa, Level of evidence: C.)

A chest CT scan analysis should be performed to assess anatomic compatibility before any TAH implantation. (Class I, Level of evidence: C.)

Topic 4: Anatomic considerations

Anatomic issues

In general, patients with a reasonable probability of myocardial recovery should be supported by temporary percutaneous devices, and patients with a low probability of recovery should be supported by durable BiVAD or TAH. Anatomic considerations related to surgical implantation and subsequent recovery influence the choice of BiVAD/TAH systems. In patients with a durable LVAD implant and have a reasonable expectation that right heart function is recoverable, should receive temporary percutaneous RVAD support. In nonrecoverable patients, durable BiVAD or TAH is selected based on anatomic fit. For small adults and children in whom the TAH is too large, there are options for BiVAD support with paracorporeal or extracorporeal devices or implantable devices placed in the pericardial space.

Total artificial heart

The 70 cc SynCardia TAH can be implanted in large adult patients with a BSA of ≥1.7 m^2, and the average size of patients implanted is 2.1 m^2.(38) The distance from the anterior vertebral body to the inner table of the sternum at the 10th thoracic vertebra must be ≥10 cm on computed tomography.(42)

The 50 cc SynCardia TAH may be suitable for small adults and large children with a BSA < 1.7 m^2; however, there are currently no guidelines for minimum thoracic cavity size.(70)

The Aeson TAH is available for patients with body surface area ≥ 1.88 m2 or height ≥ 170 cm, with minimal distance of 125 mm spine-sternum distance at the level of the mitral valve.

Recommendation

The 70 cc SnyCardia TAH can be implanted in large adult patients with a BSA of ≥ 1.7m^2, and the 50 cc SynCardia TAH for patients ≤ 1.7m^2. (Class IIa, Level of evidence: A.)

For the Aeson TAH implantation, spine-sternum distance at the level of the mitral valve should be at least 125 mm and in patients with a body surface area ≥ 1.88 m^2 or height ≥ 170 cm. (Class I, Level of evidence: C.)

Continuous flow permanent LVADs

The HeartMate 3 are relatively small LVADs that are normally positioned within the pericardial space at the apex of the left ventricle. The size of these devices offers the possibility for adding a second device for right heart support, especially in small patients who are not suitable for TAH. (71) Implantation of the HeartMate 3 for right heart support requires modified techniques. Due to the relative thinness of the right ventricle or right atrium, spacers should be placed between the pump and the wall of the right heart to avoid inflow occlusion.(72) The outflow graft of these devices can be reduced in diameter to increase RVAD afterload to adjust for the lower resistance of the pulmonary circulation.(73) The utility of the banding, however, must be reconsidered for each patient as the utility of that measure may not be as important as shown in earlier studies.(74) In patients with elevated PVR, a lesser banding should be performed, especially in cases of irreversible PVR elevation.(73)

Recommendation

Intrapericardial durable LVADs may be implanted for BiVAD support with possible modification of the inflow conduit space and the outflow graft diameter. (Class IIb, Level of evidence: C.)

BerlinHeart Excor

The Excor pumps are available in 50, 60, and 80 mL to meet various patient sizes. The Excor device is now principally used for pediatrics and less often in adults. (59, 75) The maximum flow from the Excor is 7.5 L/min. These flow capabilities can meet the metabolic demand of all patients.

Recommendation

Paracorporeal devices should be considered for durable BiVAD support in small patients that are not suitable for the TAH. (Class I, Level of evidence: C.)

Topic 5: Surgical considerations for TAH and BiVAD implantation

While preoperative chest CT scanning is increasingly common in cardiac surgical patients in general, it is required in patients undergoing pulsatile-flow TAH implantation and is highly recommended in all prospective BiVAD/TAH recipients.

Recommendation

Preoperative high-resolution chest imaging (CT scan) is recommended in all patients undergoing BiVAD/TAH implantation. (Class I, Level of evidence: C.)

Surgical access

Total artificial heart fitting is best assessed via anteroposterior dimensions assessed on CT scanning.(70) The size of the artificial ventricles for the pulsatile TAH mandates sternotomy, while this is less of a consideration if using continuous-flow BiVAD, however, median sternotomy is preferred approach.(76) In rare instances, bi-thoracosternotomy ("clamshell" incision) may be a useful approach for cardiac and great vessel access.

Recommendation

Median sternotomy, whether primary or re-operative, is the standard incision and should be considered as the preferred mode of chest entry for all durable BiVAD/TAH implantation. (Class I, Level of evidence: C.)

Cannulation

Cannulation for cardiopulmonary bypass ought to be performed with consideration for subsequent reoperation, most commonly OHT. Systemic arterial cannulation may be peripheral or central. If thoracic aortic cannulation is performed, it should be relatively proximal, such that more distal cannulation may be performed at the time of OHT if a central cannulation approach is chosen for OHT. The aorta and main pulmonary artery should be transected at the levels of their respective sinotubular junction.

Systemic venous cannulation is functionally bicaval for both BiVAD and TAH implantation, whether peripheral or central strategies are used. For central cannulation, the superior vena cava may be cannulated through the right atrial appendage rather than directly. The inferior vena cava may be cannulated through the body of the right atrium, again preserving direct cannulation for OHT. Peripheral cannulation for cardiopulmonary bypass should be strongly considered in patients who have undergone a previous sternotomy. Peripheral arterial access may be femoral or axillary.

For TAH implantation, inflow anastomoses should be sutured at the level of atrioventricular annuli.

Recommendation

Peripheral cannulation may be considered for access for cardiopulmonary bypass for sternal reentry in patients requiring BiVAD/TAH implantation. (Class IIa, Level of evidence: C.)

For TAH implantation, the aorta and main pulmonary artery should be transacted at the levels of their respective sinotubular junctions. (Class I, Level of evidence: C)

For TAH implantation, inflow anastomoses should be sutured at the level of atrioventricular annuli. (Class I, Level of evidence: C.)

Hemostasis

Careful and exhaustive surgical hemostasis should be achieved to avoid postoperative hemorrhagic complications with present adhesions, as well as avoid future adhesion formation. Intrapericardial hemostasis ought to be achieved before the connection and positioning of the artificial ventricles of TAH patients.

Right ventricle in- and outflow (BiVAD)

Although both the RA and the RV have been used in reported series for inflow access to the RVAD, the RA approach is increasingly preferred and appears to confer better long-term results.(39, 57, 71, 73, 77-80) This seems to particularly of note if the HeartMate 3 VAD is utilized as an RVAD.(41, 81, 82) When choosing the RV approach, trabeculae or tricuspid valve chordae traversing the inflow cannula might cause inflow obstruction and should be avoided. For the right atrial approach, the inflow cannulation site should be selected with the aid of intraoperative transesophageal echocardiography, as low as possible on the right atrial free wall, and such that the inflow cannula faces the tricuspid valve orifice. The intracavitary protruding length of the RVAD inflow cannula should be shortened. This can be accomplished using several self-made felt ring spacers glued or sutured to each other.(83)

Because the impedance of the pulmonary circulation is substantially lower than that of the systemic circulation, holding all other factors (continuous flow (CF) VAD choice, operating speed, and outflow graft diameter and length) constant, a CF VAD will generate higher volumetric flow rates when used as an RVAD. Thus, there is a hypothetical risk that RVAD output could persistently exceed LVAD output, thereby creating pulmonary edema. In the case of the HVAD, some authors have advocated the intentional creation of an RVAD outflow graft stenosis to reduce RV output for a given RVAD speed.[39,74, 77] However, systemic circulatory afterload and LVAD speed can be respectively decreased and increased, with or without RVAD speed reduction, such that LVAD and RVAD output can be maintained equal or with LVAD output greater than RVAD output. Thus, downsizing of the RVAD outflow graft remains a case-by-case decision with a longer RVAD outflow conduit producing enough afterload to the device. (74) Currently, in most reported cases of HVAD and HeartMate 3 VAD used as RVADs, downsizing of the outflow graft was used in about a third of the patients.(41) The RVAD

Table 2 Early Postoperative Anticoagulation Management for SynCardia TAH and BiVAD

Timing	Heparin	Oral	Goals
<24 hours	Monitor	Monitor	Hemostasis
24-48 hours	IV Heparin	ASA 81mg	aPTT 50-70
>48 hours	IV heparin	ASA 81 mg	aPTT 60-75
>72 hours or after drains removed	IV heparin till INR bridged	ASA+ warfarin	INR goal 2.5-3.5

outflow graft can be directed either rightward or leftward toward the main pulmonary artery, with the latter route providing a longer graft length and afterload augmentation

Recommendations

The RVAD inflow anastomosis may be preferred in the low RA free wall, directing the inflow cannula toward the tricuspid valve orifice, after placement of spacers between the atrial wall and inflow cannulation sewing ring. (Class of Recommendation IIb, Level of evidence C.)

The RVAD inflow anastomosis may be performed to the inferior surface of the RV, after resection of RV trabeculations (if needed) and placement of spacers between the ventricular wall and inflow cannulation sewing ring. (Class of Recommendation IIb, Level of evidence: C).

The diameter of the RVAD outflow graft to the main pulmonary artery can be downsized. It may be directed either on the right or the left side of the heart, depending on the patient's anatomic fit. (Class of Recommendation IIb, Level of evidence: C).

Wrapping and closure

Both BiVAD and TAH should be carefully wrapped before chest closure with PTFE sheets to facilitate chest reentry and system removal at transplantation. (84)

Special care should be given to an RVAD protruding extra-pericardially, to the right pleural space, to avoid lung adhesions. Placement of a PTFE band around both vena cava is suggested as well to facilitate reoperation. Drivelines should be tunneled with caution to avoid bleeding and facilitate tissue healing. The exit orifice should be located to allow stabilization of the external drive and facilitate quality of life. LVAD and RVAD drivelines exit sites should be kept on their corresponding body sides to avoid devices' handling mistakes.(85) Finally, some patients with fit issues following BiVAD/TAH may benefit from delayed sternal closure.

Special anatomic and physiological considerations

Some patients with complex congenital cardiac malformations, whether previously surgically treated or not, develop biventricular failure in the context of intracardiac shunts that cannot be treated, or at least cannot be treated safely or effectively. BiVADs are inadequate in this setting because intracardiac shunting remains untreated. In such extremely challenging patients, cardiac extirpation and TAH implantation are appropriate, particularly as part of a bridge-to-OHT strategy.

Cardiac tumors with extensive chamber involvement are rarely encountered and often pose surgical challenges. Some patients may be approached via standard resection and cardiac reconstruction,(86) of whom auto-OHT has been employed in a subset.(87,88) However, adequate resection in some instances may render the heart unreconstructible. TAH implantation is usually appropriate in these patients. Similarly, extensive endocarditis may be approached via cardiac extirpation and TAH implantation, although debridement adjacent to the atrioventricular valves may make the creation of the inflow anastomoses challenging.(89) Finally, tumors requiring full atrial reconstruction are less suitable for TAH-based approaches, in these patients BiVADs may be considered as an alternative. (90) As cited above, patients with massive left sided infarction with intracardiac defects, e.g., VSD, or ventricular rupture, not amenable to surgical repair should be considered for TAH.

An increasingly recognized subset of end-stage HF patients has predominantly diastolic ventricular dysfunction, with normal or even small intracavitary dimensions. While direct OHT is the preferred treatment option, it may not be achievable in a reasonable timeframe. Patients with predominant diastolic ventricular dysfunction resulting in end-stage HF who are not projected to receive OHT, if LV dimensions are small, are best treated via TAH implantation.

Recommendations

Cardiac extirpation and TAH placement are indicated in patients with biventricular failure and difficult-to-repair or untreatable intracardiac shunts arising from congenital or acquired heart disease. (Class I, Level of evidence: C.)

For selected patients with extensive infective endocarditis or cardiac tumors without atrial involvement, which cannot be managed readily using conventional cardiac surgical techniques, TAH implantation is useful and may be considered. (Class IIb, Level of evidence: C.)

In patients with tumors requiring full atrial resection, the use of the TAH should be avoided due to implantation difficulties and risk. (Class III, Level of evidence: C.)

For patients with diastolic ventricular dysfunction/ restrictive cardiomyopathies, TAH implantation may be preferable to BiVAD implantation if cardiac transplantation is not feasible. (Class IIb, Level of evidence: C.)

Table 3 Supratherapeutic INR Guidelines—Inpatient or Outpatient <6 Weeks Postop

INR	No bleeding	Minor bleeding	Major bleeding
3.5-3.9	Decrease warfarin and check INR in 12 hours	Hold warfarin And check INR in 12 hours	IV Vitamin K 2.5 mg or PCC/FFP Recheck INR in 4hrs
4-5.9	Vitamin K 1.25 mg po and check in 12 hours	Vitamin K 1 mg IV and check INR in 12 hours.	IV Vitamin K 2.5-5 mg or PCC/ FFP Recheck INR in 2 hours
6- 7.9	Vitamin K 2.5 mg po and check INR in 12 hours	Vitamin K 2 mg IV and check INR in 12 hours	IV Vitamin K 5-10 mg or PCC/ FFP Recheck INR 2 hours
>8	Vitamin K 1-2 mg IV and check INR in 2 hours	Vitamin K 3mg IV and check INR q2hours till INR <4	IV Vitamin K 5-10 mg or PCC/ FFP Recheck INR in 2 hours

Table 4 Supratherapeutic INR Guidelines—Outpatient >6 Weeks Postop

INR	No bleeding	Minor bleeding	Major bleeding
	Ambulatory/Admit	Admit	Admit
5-6.5	Vitamin K 1 mg po and check in 24 hours	Admit and follow inpatient protocol	Admit and follow inpatient protocol
6.6-7.9	Admit. Vitamin K 2 mg po and check in 12 hours	Admit and follow inpatient protocol	Admit and follow inpatient protocol
>8	Admit. Vitamin K 2 mg IV and check in 12 hours	Admit and follow inpatient protocol	Admit and follow inpatient protocol

Topic 6: Anticoagulation specific to BiVAD and TAH

Anticoagulation

In the first 24-hour post-TAH and BiVAD implantation anticoagulation is generally NOT recommended. Following this time period, patients should be bridged with heparin, or another antithrombin agent (e.g., in the case of HIT), to warfarin.

Direct-acting oral anticoagulants (DOACS) are not indicated for TAH or BiVAD MCS patients.

Aspirin (ASA) should be administered in TAH and BiVAD patients following implantation as soon as postop bleeding has stopped, and hemostasis is established. ASA dose should be tempered by individual patient considerations, but in general should be kept lower to avoid bleeding complications—particularly in the Syncardia TAH patient. Low dose antiplatelet therapy with 81 to 325 mg ASA per day should be started when indicated by improved platelet function (e.g., with TEG).

Anticoagulation with unfractionated heparin (UFH) within 24 hours should be utilized targeting aPTT of 50 to 70 sec once hemostasis is achieved (Table 2). Following this time period, patients with SynCardia TAH or BiVAD should be bridged with heparin to warfarin after all chest drains removed with an INR 2.5 to 3.0 typically. The INR should range from 2.5 to 3.5 in patients with the SynCardia TAH. For management strategies in patients with supratherapeutic INR values, please refer to Table 3 and 4.

In patients receiving support with an Aeson, it is recommended to switch from UFH to low molecular weight heparin (LMWH) s.c. at therapeutic doses should be considered, when renal function is normalized (creatinine clearance >30 mL/min; Cockcroft and Gault equation), and if there is no indication for imminent invasive procedures, while maintaining ASA (76-100 mg) treatment. Common LMWH drugs used are tinzaparin (175 IU/kg/24 h) and enoxaparin (150 IU/Kg/24 h) for daily injections. When markers of the coagulation activation have decreased and stabilized, the LMWH may be reduced by 50% to prophylactic dose. Anti-Xa needs to be checked when dictated by the clinical situation.

Long-term treatment consists of Aspirin 75 to 100 mg and prophylactic dose LMWH.

Recommendations

Anticoagulation therapy with warfarin in patients with BiVAD or TAH should be initiated with concomitant heparin bridging. (Class I, Level of evidence: C.)

Direct-acting oral anticoagulants (DOACS) are not indicated for TAH or BiVAD patients. (Class III, Level of evidence: C.)

In patients supported with the Aeson, a switch from UFH to LMWH s.c. should be considered, when renal function is normalized and if there is no indication for imminent invasive procedures. (Class I, Level of evidence: C.)

When markers of the coagulation activation have decreased and stabilized, LMWH may be reduced by 50% to prophylactic dose and anti-Xa needs to be checked when dictated by the clinical situation. (Class IIb, Level of evidence: C.)

Antiplatelet therapy

Antiplatelet agent management is geared primarily toward prevention of thrombosis driven by the 4 mechanical valves of the TAH, for TAH implanted patients,(91) as the TAH

intrinsically impart lower shear stress (greater than an order of magnitude lower) than BiVADs.(92) In contrast ASA use in BiVADs should be utilized sparingly to avoid bleeding in that ASA has limited efficacy in limiting shear-mediated platelet activation imparted by shear of continuous flow and rotary VADs in current use today.(93, 94) Aspirin (ASA) should be administered in TAH and BiVAD patients following implantation as soon as postop bleeding has stopped and hemostasis is established after 24 hours. ASA dose may be adjusted based upon individual patient platelet considerations and platelet function tests, but in general should be kept lower than higher to avoid bleeding complications—particularly in the TAH patient early on to avoid postop bleeding; and long term in BiVAD patients to avoid more chronic bleeding.(95-97) Patients with the Aeson TAH, ASA 75 to 100 mg treatment can be administered 4 days after chest drain(s) removal and in absence of active bleeding.

Recommendations

Antiplatelet therapy with aspirin (81−325 mg daily) in addition to warfarin should be started in TAH/BiVAD patients when indicated by improved platelet function. (Class I, Level of evidence: C.)

Antiplatelet therapy with aspirin (81−325 mg daily) should be monitored clinically and/or with appropriate and available platelet function testing to reduce bleeding complications with long-term use. (Class IIa, Level of evidence: C.)

In Aeson TAH patients, anticoagulation and antiplatelet therapy initiated postoperatively in the ICU setting should be continued with the aim of achieving device-specific recommended INR for warfarin and desired antiplatelet effects as to the manufacturer's recommendation. (Class I, Level of evidence: C.)

Surgical bridging anticoagulation

Bridging anticoagulation is similar to the ISHLT guidelines for Mechanical Circulatory Support. (85) The patient should be made aware that anytime there is a discontinuation of warfarin and antiplatelet therapy there is always a risk of a thromboembolic event. Therefore, they should report any concerning symptoms promptly.

Recommendation

For emergent procedures, warfarin should be rapidly reversed with FFP or PCC. Vitamin K can be administered with caution due to slower onset of action. (Class I, Level of evidence: C.)

Topic 7: Management of renal and hepatic dysfunction

Renal dysfunction

Many patients will experience significant volume overload, tissue, and/or pulmonary edema after biventricular MCS implantation. A proactive approach including intravenous diuretics and early initiation of continuous renal replacement therapy (CRRT) should be part of management. (98) Assessment of euvolemia and intravascular volume is challenging as there is no single absolute clinical measure for volume status in the critically ill patient. Utilizing a comprehensive approach, volume status is determined on the continual interpretation of central venous pressure, pulmonary capillary wedge pressure, chest radiograph, echocardiogram, daily weight, and clinical signs of tissue edema. Some groups have advocated the use of nesetiride in the context of a dramatic decrease in brain natriuretic peptide after removal of RV and LV during implantation of SynCardia TAH showing an improvement in urinary output.(99)

Recommendation

Postimplantation, efforts should be exerted to achieve euvolemic volume status as soon as clinically tolerated. Utilization of IV diuretics and /or early initiation of CRRT is recommended. (Class I, Level of evidence B)

Hepatic dysfunction

Chronically increased central venous pressure in patients with biventricular failure leads to hepatic congestion and liver dysfunction. Functional liver abnormalities are often seen in patients with a cardiac index of <1.5 L/min/m^2. Short- and long-term morbidity and mortality in patients undergoing both cardiac and noncardiac surgery are linked to abnormal liver function.(100) No specific clinical parameters are defined for liver dysfunction in heart failure patients. Nevertheless, there are echocardiographic parameters correlating with abnormal liver laboratory tests. Right ventricular end-diastolic diameter, right atrial area, tricuspid regurgitation, TAPSE, portal vein pulsatility index, and left ventricular ejection fraction are significant predictors of total bilirubin elevation. However, only portal vein pulsatility index is statistically significant as a predictor of total bilirubin level. Left ventricular end-diastolic diameter indexed to body surface area and right ventricular end-diastolic diameter can be correlated with elevation of transaminases.(101) The influence of right ventricular diastolic dysfunction on congestive hepatopathy is stronger than the influence of right ventricular systolic function. Jaundice, by passive congestion causing elevations of liver enzymes and both direct and indirect serum bilirubin, plus acute hepatocellular necrosis with marked elevations in serum aminotransferases, caused by impaired liver perfusion from the decreased cardiac output, are 2 characteristics of severe congestive HF. (102, 103) In addition preexistent liver disease may have a profound impact in cardiovascular response and perioperative outcomes and coordinated evaluation with hepatology is recommended.(104)

Recommendation

Hepatic function should be monitored by liver enzymes and direct and indirect bilirubin for congestive hepatic dysfunction. Optimally, hepatic enzyme monitoring should be coordinated with the monitoring of CVP. (Class I, Level of evidence: C.)

Use of drugs with a hepatotoxic profile should generally be avoided in the early postimplant period. (Class I, Level of evidence: C.)

Topic 8: Device monitoring and patient optimization

For postimplantation monitoring in the intensive care unit (ICU), it is mandatory to understand either the new pump circuit implanted and overall operation of the BiVAD system or TAH employed. For BiVADs, since the inflow and outflow cannula are placed in the right atrium and pulmonary artery, most of the circulating blood travels through the pump circuit, rendering the pulmonary artery flow measured by the catheter incorrect. The RVAD flow bypasses the thermistors that measure the temperature changes needed for the cardiac output measurement. Users should be cautioned that the usual thermodilution methods for measuring total cardiac output may be inaccurate, and pump flow may not represent the total cardiac output. However, in most cases, the mixed venous oxygen saturation may be used to estimate changes in total cardiac output based on the Fick principle.

Hemodynamic monitoring

In the immediate postimplant period, hemodynamic monitoring should be strongly considered to assist for patient stabilization—i.e., either via PA catheter (BiVADs) or LA catheter (TAH or BiVADs). In the TAH patient, CVP should be maintained at 12 to 15 mm Hg. Invasive hemodynamic monitoring is standard and essential in BiVAD/TAH recipients, in addition to device-based monitoring. Adequate filling pressures, CVP, and left atrial pressure (LAP) must be carefully monitoring and should guide volume management and device settings. A note of caution though, following removal of LA catheter in TAH patients, Swan-Ganz catherization or other invasive line monitors are strictly contraindicated to avoid inadvertent migration across mechanical valves which may lead to device malfunction.(105) Some invasive monitoring components are standard for all cardiac surgical patients, whereas others are specific to BiVAD or TAH patients. It is useful to work retrograde through the circulation. Biventricular assist devices and TAH recipients both require invasive systemic arterial blood pressure monitoring via an indwelling catheter in the intra- and early perioperative periods. Although peripheral arterial blood pressure waveforms differ from central aortic pressure waveforms, the mean central aortic pressure is only slightly greater than mean peripheral arterial pressure in the absence of peripheral arterial stenosis in the catheterized artery. The goal means arterial pressures are between 65 and 80 mm Hg.

Left ventricular pressure is not monitored in durable VAD- or TAH-implanted patients. In contrast, left atrium (LA) pressure-monitoring catheters, which are relatively commonly used in pediatric cardiac surgery, have substantial utility. For TAH recipients, in whom pulmonary artery (PA) catheters cannot be placed, LA pressure monitoring is valuable in assessing the filling of the left-sided device, with a goal LA pressures are between 8 and 16 mm Hg.

Pulmonary artery catheters can be placed intraoperatively before the incision in BiVAD recipients; however, many surgeons prefer to perform BiVAD implantation without the presence of PA catheters because of the possibility of damage to the RVAD, relying on LA and RA catheters, along with device-based monitoring. Due to the presence of non-native inflow and outflow valves in the TAH pumps, PA catheters cannot be placed. In BiVAD recipients with PA catheters, pressure and blood gas data may be reliable, but pulmonary blood flow assessments may not be, owing to the presence of dual flow paths (RV -> PA via native ejection, and RV -> RVAD -> PA) that confound thermodilution-based assessment. If a PA catheter is used, it ought to be advanced into position before insertion of the inflow cannula of the RVAD and before the creation of the outflow graft-PA anastomosis. This decreases the possibility of entrainment of the PA catheter in the RVAD system. Goal PA occlusion pressures are 8 to 16 mm Hg, without a particular target mean PA pressure. Goal PA oxygen saturations are ≥60%, and if pulmonary blood flow assessment is reliable, goal cardiac indices are ≥2.2 L/min/m^2. Finally, central venous introducer catheters are standard in both BiVAD and TAH patients. Large-bore introducer sheaths are preferred because of the ability to rapidly infuse intravenous fluids.

Confirmation of the central venous line position in TAH patients is crucial; the tip of the line should not be placed in the right atrium to prevent catastrophic complications. Placement of a central venous line is best done with fluoroscopic guidance.

Recommendations

For patients undergoing BiVAD/TAH implantation, invasive systemic arterial pressure monitoring is essential in the perioperative period. (Class I, Level of evidence: C.)

For patients undergoing BiVAD implantation, PA catheter placement may be reasonable to monitor mixed venous saturation (Class IIb, Level of evidence: C.)

For patients undergoing BiVAD implantation, PA catheter placement is not reasonable for pulmonary blood flow assessments, owing to the presence of dual flow paths that confound thermodilution-based assessment. (Class III, Level of evidence: C.)

For patients undergoing BiVAD/TAH implantation, LA catheter placement may be reasonable to monitor LA pressure. (Class IIb, Level of evidence: C.)

Pump flows

In the early postimplant period, pump flows, for both TAH and BiVADs, should be at a level that will achieve a cardiac index >2.2 L/min/m^2. Of note, L side flow should be kept > R sided flow by 5% to 10%.

Recommendation

Device flow rate should be maintained to achieve a cardiac index >2.2 L/min/m^2. (Class I, Level of evidence: A.)

Laboratory evaluation

In addition to general laboratory values utilized to monitor clinical status, the onset of adverse events, and recovery, a postimplant patient should have serial evaluation of hematologic and coagulation parameters, biochemistry, and markers of hemolysis, as well as renal and hepatic function parameters.

Topic 9: Patient discharge with BiVAD or TAHpt

→ **This topic is further discussed in Task Force 5.**

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Task Force 8 Summary:
Bi-Ventricular Replacement and Support – TAH and BiVADs *(New)*

Topic 1: Patient selection
Evaluation of Biventricular Failure:
Class I:
1. All patients presenting with biventricular failure should be thoroughly screened for any potentially reversible conditions. An extensive metabolic, biochemical and serological panel should be obtained, including complete blood count with differential, comprehensive metabolic panel, thyroid panel, ferritin, serum transferrin, HbA1C, inflammatory markers, autoimmune and infectious serologies.
Level of Evidence C.

Diagnosis of Biventricular Failure:
Class I:
1. All patients undergoing advanced therapy evaluation must have a comprehensive baseline 2D-echocardiogram to assess for RV function and volume.
Level of Evidence A.
Class IIa:
1. Calculation of RVSWI, PAPi, CWP/PCWP, and RV Risk score should be routine at the index right heart catheterization prior to proceeding with surgery.
Level of Evidence B.

Diagnosis of Persistent/Irreversible Biventricular Failure:
Class I:
1. The right ventricular contractile reserve must be evaluated by echo and hemodynamic testing in a patient undergoing left ventricular support to determine the need for biventricular support.
Level of Evidence C.

Topic 2: Management of biventricular dysfunction
Decision for Advancement to TAH or Durable BiVAD Therapy:
Class I:
1. Composite scores should be utilized to predict and identify patients at the highest risk for postoperative RV failure.
Level of Evidence C.
Class IIa:
1. Early application of right ventricular mechanical support should be considered in patients with severe RV failure to avoid multi-organ dysfunction.
Level of Evidence B.
Class IIb:
1. For patients with persistent/incessant arrhythmias, the TAH may offer advantage over BiVAD.
Level of Evidence C.

Biventricular Failure – Not on any MCS:
Class IIa:
1. Selected patients with end-stage heart failure due to congenital heart disease should be considered for TAH/BiVAD after an initial evaluation to assess surrogates for RV dysfunction.
Level of Evidence C.
2. Selected patients with infiltrative, restrictive or hypertrophic CMP should be considered for the total artificial heart when timely heart transplantation is not feasible.
Level of Evidence C.

Acute Biventricular Failure – Acute Myocardial Infarction:
Class IIb:
1. Worsening hemodynamics, refractory arrhythmias or end-organ dysfunction after a trial of temporary MCS support with hemodynamic optimization and complete revascularization may require escalation to BiVAD or TAH as a life-saving maneuver.
Level of Evidence C.
2. Patients with massive myocardial infarction with accompanying anatomic defects, e.g. VSD and wall rupture, not amenable to surgical repair may be considered for TAH.
Level of Evidence C.

Chronic Biventricular Failure:
Class IIb:
1. Patients presenting with Intermacs I and II status, with laboratory evidence of elevated bilirubin, INR, creatinine, blood urea nitrogen and clinical manifestations of severe malnutrition, in conjunction with hemodynamic profile of disproportionate RV failure, with elevated RA pressure and lower pulmonary artery pressure index may be considered for the total artificial heart or BiVAD, the choice related to selection issues of patient size, flow demand, fit and related individual considerations.
Level of Evidence C.

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Task Force 8 Summary:
Bi-Ventricular Replacement and Support – TAH and BiVADs *(New)*

Topic 3: Implantable BiVAD
Biventricular Assist Device – BiVAD:
Class I:
1. Choice of BiVAD systems for a given patient should be determined by individual patient issues, surgical/HF Team familiarity/experience, system specifications, and availability.
Level of Evidence C.
Temporary biventricular support options:
Class I:
1. The reversibility of right heart failure must be thoroughly assessed to help determine if temporary or durable BiVAD support is needed.
Level of Evidence C.
Durable biventricular support devices:
Class IIb:
1. Implantation of two durable LVADs for biventricular support requires careful consideration of the complexity and cost.
Level of Evidence C.
2. Implantation of a combination of continuous-flow LVAD and paracorporeal pulsatile RVAD may be considered for selected patients but requires careful consideration and an experienced team due to the complexity and risks of this treatment option in biventricular failure.
Level of Evidence C.

Total Artificial Heart – TAH:
Class I:
1. A chest CT scan analysis should be performed to assess anatomic compatibility before any TAH implantation.
Level of Evidence C.
Class IIa:
1. TAH implantation for a given patient should be determined by a balance of individual patient issues, surgical/HF Team familiarity/experience, system specifications and system availability.
Level of Evidence C.

Topic 4: Anatomic considerations
Total artificial heart:
Class I:
1. For the TAH implantation, spine-sternum distance at the level of the mitral valve should be at least 125 mm and in patients with a body surface area $\geq$ 1.88 m2 or height $\geq$ 170 cm. Level of Evidence C.
Class IIa:
1. The 70cc SynCardia TAH can be implanted in large adult patients with a BSA of $\geq 1.7m^2$, and the 50 cc SynCardia TAH for patients $\leq 1.7m^2$.
Level of Evidence A.

Continuous flow permanent LVADs:
Class IIb:
1. Intra-pericardial durable LVADs may be implanted for BiVAD support with possible modification of the inflow conduit space and the outflow graft diameter.
Level of Evidence C.

BerlinHeart Excor:
Class I:
1. Paracorporeal devices should be considered for durable BiVAD support in small patients that are not suitable for the TAH.
Level of Evidence C.

Topic 5: Surgical Considerations for TAH and BiVAD implantation
Class I:
1. Preoperative high-resolution chest imaging (CT scan) is recommended in all patients undergoing BiVAD/TAH implantation.
Level of Evidence C.

Surgical access:
Class I:
Median sternotomy, whether primary or re-operative, is the standard incision and should be considered as the preferred mode of chest entry for all durable BiVAD/TAH implantation.
Level of Evidence C.

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Task Force 8 Summary:
Bi-Ventricular Replacement and Support – TAH and BiVADs *(New)*

Cannulation:
Class I:
1. For TAH implantation, the aorta and main pulmonary artery should be transacted at the levels of their respective sino-tubular junctions.
Level of Evidence C).
2. For TAH implantation, inflow anastomoses should be sutured at the level of atrioventricular annuli.
Level of Evidence C.
Class IIa:
1. Peripheral cannulation may be considered for access for cardiopulmonary bypass for sternal reentry in patients requiring BiVAD/TAH implantation.
Level of Evidence C.

Right ventricle in- and outflow (BiVAD):
Class IIb:
1. The RVAD inflow anastomosis may be preferred in the low RA free wall, directing the inflow cannula towards the tricuspid valve orifice, after placement of spacers between the atrial wall and inflow cannulation sewing ring.
Level of Evidence C.
2. The RVAD inflow anastomosis may be performed to the inferior surface of the RV, after resection of RV trabeculations (if needed) and placement of spacers between the ventricular wall and inflow cannulation sewing ring.
Level of Evidence C.
3. The diameter of the RVAD outflow graft to the main pulmonary artery can be downsized. It may be directed either on the right or the left side of the heart, depending on the patient's anatomic fit.
Level of Evidence C.

Special anatomic and physiological considerations:
Class I:
Cardiac extirpation and TAH placement are indicated in patients with biventricular failure and difficult-to-repair or untreatable intracardiac shunts arising from congenital or acquired heart disease.
Level of Evidence C.
Class IIb:
1. For selected patients with extensive infective endocarditis or cardiac tumors without atrial involvement, which cannot be managed readily using conventional cardiac surgical techniques, TAH implantation is useful and may be considered.
Level of Evidence C.
2. For patients with diastolic ventricular dysfunction/restrictive cardiomyopathies, TAH implantation may be preferable to BiVAD implantation if cardiac transplantation is not feasible. Level of Evidence C.
Class III:
1. In patients with tumors requiring full atrial resection, the use of the TAH should be avoided due to implantation difficulties and risk. (Class III, Level of Evidence C).

Topic 6 Anticoagulation Specific to BiVAD and TAH
Anticoagulation:
Class I:
1. Anticoagulation therapy with warfarin in patients with BiVAD or TAH should be initiated with concomitant heparin bridging.
Level of Evidence C.
Class IIa:
In patients supported with the TAH, a switch from unfractionated heparin to low molecular weight heparin should be considered, when renal function is normalized and if there is no indication for imminent invasive procedures.
Level of Evidence C.
Class IIb:
1. When markers of the coagulation activation have decreased and stabilized, LMWH may be reduced by 50% to prophylactic dose and anti-Xa needs to be checked when dictated by the clinical situation.
Level of Evidence C.
Class III:
1. Direct-acting oral anticoagulants (DOACS) are not indicated for TAH or BiVAD patients.
Level of Evidence C.

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(*Continued*)

Task Force 8 Summary:
Bi-Ventricular Replacement and Support – TAH and BiVADs *(New)*

Antiplatelet Therapy:
Class I:
1. Anti-platelet therapy with aspirin (81–325 mg daily) in addition to warfarin should be started in TAH/BiVAD patients when indicated by improved platelet function.
Level of Evidence C.
2. In TAH patients, 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 as to the manufacturer's recommendation.
Level of Evidence C.
Class IIa:
1. Anti-platelet therapy with aspirin (81–325 mg daily) should be monitored clinically and/or with appropriate and available platelet function testing to reduce bleeding complications with long term use.
Level of Evidence C.

Surgical bridging anticoagulation:
Class I:
1. For emergent procedures, warfarin should be rapidly reversed with FFP or PCC. Vitamin K can be administered with caution due to slower onset of action.
Level of Evidence C.

Topic 7: Management of Renal and Hepatic Dysfunction
Renal Dysfunction:
Class I:
1. Post-implantation, efforts should be exerted to achieve euvolemic volume status as soon as clinically tolerated. Utilization of IV diuretics and /or early initiation of CRRT is recommended.
Level of Evidence B.

Hepatic Dysfunction:
Class I:
1. Hepatic function should be monitored by liver enzymes and direct and indirect bilirubin for congestive hepatic dysfunction. Optimally, hepatic enzyme monitoring should be coordinated with the monitoring of CVP.
Level of Evidence C.
2. Use of drugs with a hepatotoxic profile should generally be avoided in the early post-implant period.
Level of Evidence C.

Topic 8: Device Monitoring and Patient Optimization
Hemodynamic monitoring:
Class I:
1. For patients undergoing BiVAD/TAH implantation, invasive systemic arterial pressure monitoring is essential in the perioperative period.
Level of Evidence C.
Class IIb:
1. For patients undergoing BiVAD implantation, PA catheter placement may be reasonable to monitor mixed venous saturation.
Level of Evidence C.
2. For patients undergoing BiVAD/TAH implantation, LA catheter placement may be reasonable to monitor LA pressure.
Level of Evidence C.
Class III:
1. For patients undergoing BiVAD implantation, PA catheter placement is not reasonable for pulmonary blood flow assessments, owing to the presence of dual flow paths that confound thermodilution-based assessment.
Level of Evidence C.

Pump Flows:
Class I:
1. Device flow rate should be maintained to achieve a cardiac index $> 2.2 L/min/m^2$.
Level of Evidence A.

Topic 9: Patient Discharge with BiVAD or TAH
Recommendations for discharge and home care with durable MCS are addressed in TF 5.

Task Force 9

Benchmarking, quality assurance/performance improvement (QAPI), program volume ratios, and volume metrics for durable mechanical circulatory support programs

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Introduction

Durable Mechanical Circulatory Support (DMCS) programs depend on benchmarking and quality assurance/performance improvement projects to identify and address weaknesses within organizations to further the success of individual programs. Benchmarking may vary based on individual programmatic goals. However, all DMCS implanting programs should establish internal benchmarking to maintain satisfactory care of the DMCS patient, meet the mission and goals of the program, and to continue driving success within each program.

To establish benchmarking and quality assurance/performance improvement within an individual program, the DMCS programs should establish and maintain a minimum yearly programmatic and individual surgeon DMCS volume; have standardized educational plans for healthcare professionals for initial and continued medical education about DMCS care standards and guidelines; and have mechanisms in place for regular review of performance measures such as 30-day readmissions, serious adverse events (SAE) rates, and overall survival. Significant deficiencies in any of these factors may affect an individual program's outcomes, financial stability, and long-term success within the DMCS field.

Task Force 9 provides initial basic recommendations for topics affecting DMCS programs including benchmarking, quality assurance/performance improvement (QAPI), DMCS program staffing ratios and staff education. A review of the literature yields a lack of contemporary studies to guide recommendations with a high level of evidence, but the content herein serves to provide initial guidance on these topics. The approach to the recommendations below is split in to 3 subcategories: Benchmarking, quality assurance and performance improvement monitoring, and DMCS provider staffing and education.

Topic I: Benchmarking

Identification of valid benchmarks for durable DMCS readmissions, SAEs and mortality is integral to programmatic QAPI. Benchmarks should be representative of the DMCS devices implanted at the center of evaluation, and should be regularly updated to ensure benchmarks reflect current national, regional, or global outcomes. Rates from major clinical trials or national registries may be used as benchmark targets for programmatic assessment. Programs should also establish clinical practice guidelines and protocols to assist in ongoing individual programmatic improvement regarding clinical outcomes specific to chosen clinical outcomes. Once benchmarks and clinical practice guidelines are established, DMCS programs are responsible for monitoring DMCS benchmarked outcomes, which will vary based on the overall goals and quality initiatives established for the individual program.

Performance measures selected for programmatic monitoring should be those with the greatest impact on patient morbidity and mortality and/or those with high health care resource utilization/costs. Recommended performance measures for monitoring DMCS QAPI include 30-day readmission, SAEs, and patient-reported outcome measures (PROM).

Thirty-day readmissions following index DMCS implant are a common and important benchmarked performance measure, occurring at a frequency of 21% to 23% (1). Most frequently, readmission occurs within the first 10 days post-discharge, and readmissions are more common in those with index implant lengths of stay over 30 days (2, 3). The top causes of 30-day readmissions include heart failure, arrhythmias, stroke, infection and gastrointestinal bleeding (1-3). Regular review of early readmissions can allow programs an opportunity to identify necessary improvements in patient care and/or opportunities for reductions in care costs.

Given the impact of major SAEs on readmissions, morbidity, quality of life, and health care resource utilization, establishing valid rates for key SAE benchmarks is also integral to DMCS programmatic quality assessment (4, 5). Current device success is most compromised by strokes, device malfunction, major bleeding or lower gastrointestinal bleeding, infection, and/or right heart failure. Benchmarks selected should be devised from literature that best reflects the program's patient characteristics (destination therapy (DT) only vs both DT and bridge to transplant) and device models implanted.

Center and surgeon experience through procedural volume assessment has been shown to impact outcomes in general surgical and general cardiac surgery literature (6, 7). Literature regarding implant volumes and DMCS outcomes is scarce. In an analysis of 14,014 patients who underwent durable DMCS implant in the United States, very low center surgical DMCS volumes (<10 implants yearly) were associated with inferior 90-day and overall survival (8). Given the paucity of contemporary data, specific recommendations for center and individual surgeon volumes needed to maintain competency and favorable patient outcomes cannot be devised with precision. It is recommended

that mortality is evaluated on a center- and surgeon-specific level within each institution during quality assessment.

Recommendations for Programmatic DMCS Quality Assessment and Performance Improvement (QAPI) Through Benchmarking

Class 1

1. Programmatic benchmarks for survival, 30-day readmissions and serious adverse events after DMCS should be established using data from major clinical trials or national registries.

Level of Evidence: B.

2. Programmatic benchmarks should be regularly reviewed for update to mirror contemporary DMCS outcomes and characteristics of the program (DT vs DT/BTT capacity) and device models implanted.

Level of Evidence: C.

Class IIa

1. Despite limited evidence, it is reasonable for DMCS programs to follow a minimum standard (>10 durable DMCS implants per year) of durable DMCS implantations to allow for proper programmatic benchmarking.(8, 9)

Level of Evidence: B.

Recommendations for patient-reported outcome considerations and benchmarking

Class 1

1. Each DMCS program should regularly review results of DMCS specific and validated nonspecific quality of life metrics (e.g., EQ-5D, KCCQ and QOLVAD questionnaire) (10-15) and validated measures of functional capacity (e.g., 6-minute walk test or 5-m (16 feet) walk test).

Level of Evidence: C.

2. Impediments to successful acquisition of testing should also be identified and addressed.(5, 16)

Level of Evidence: C.

3. Every DMCS program should deliver high-quality care while maintaining fiscal awareness. This includes having the most appropriate and experienced support staff in place for programmatic fiscal evaluation and cost-measurements.(17, 18)

Level of Evidence: B.

Topic II: Quality assurance/performance improvement (QAPI)

The development of performance measures and goals is important for enabling DMCS programs the ability to monitor the individual program's success and to continue striving for internal programmatic performance improvements. Quality assurance is important in every DMCS program as this process drives programs toward care excellence established through performance improvement. Unfortunately, there are limited research and guidelines in DMCS to guide optimal frequency and best means of quality assurance assessment.

The DMCS Multidisciplinary team is integral to the QAPI process and should be actively engaged in QAPI review. Regular QAPI review with the DMCS Multidisciplinary team affords a great avenue to discuss ongoing programmatic QAPI efforts in order for the team to stay up to date on improvement metrics. Engagement of the multidisciplinary team also allows for regular evaluation and editing of a program's clinical practice guidelines for DMCS patient selection and care. Despite the lack of recommendations and guidelines, evaluating QAPI through these avenues allows for clinical outcomes to be monitored, aiming to limit adverse events and to maintain a cost-conscious program when considering patient-reported outcomes (PROM) in relation to QAPI. Programs need to establish ways to monitor and evaluate these outcomes. Performance improvement plans should encompass PROM monitoring, including quality of life and health status improvement following DMCS implantation. There are data to support utilization of disease-specific health-related quality of life metrics devised within an DMCS cohort rather than metrics derived in a general heart failure sample. Disease-specific QOL metrics may improve the sensitivity of these metrics to detect DMCS-specific complications and impediments to life quality that may impact overall LVAD success (11-14, 19).

Recommendations for clinical outcome considerations based upon QAPI

Class 1

1. DMCS programs should have an ongoing and individualized quality improvement processes in place to monitor occurrences of events such as strokes, infections, bleeding events and survival as they relate to valid national or regional benchmarks (20).

Level of Evidence: C.

2. The members of DMCS Multidisciplinary team should be present and engaged in regular QAPI review and informed of changes to clinical practice guidelines in response to QAPI initiatives (9).

Level of Evidence: C.

3. DMCS programs should monitor 30-day readmission frequencies following index DMCS implantation and target quality and performance improvement interventions toward those with SAEs that occur at rates higher than benchmark. SAEs prompting readmission could include infection, heart failure recurrence, device malfunction, and bleeding episodes.(2, 3, 15)

Level of Evidence: B.

4. The rates of DMCS SAEs should be monitored and compared with benchmarks at least annually as part of performance improvement and quality assessment. These could include early and late rates of stroke (ischemic and hemorrhagic), device malfunction, infection (categorized as device related or unrelated), nonsurgical bleeding, heart failure events and mortality (21).

Level of Evidence: B.

5. DMCS program clinical practice guidelines should be established for patient selection and care using data

gleaned from published DMCS guidelines and studies as a means of reducing care variations that many contribute to adverse patient outcomes. The clinical practice guidelines should be reviewed and updated regularly.

Level of Evidence: C.

Recommendations for economic impact considerations based upon QAPI

Class IIb

1. Cost analyses of adverse events monitored through quality assurance and performance improvement efforts may be beneficial (18, 22).

Level of Evidence: C.

Topic III: Staffing DMCS programs

Program staffing numbers should be monitored to ensure that the DMCS programs are fiscally sustainable with staffing numbers that are sufficient for safe and quality patient care. There is insufficient research to support recommendation of a particular patient to staff ratio including patient to DMCS coordinator ratios. Available data supported a disregard for achieving a specific patient to staff ratio and instead recommended that programs monitor the ability of staff to meet the daily duties and patient care needs of the each DMCS patient in the program (23).

DMCS coordinators serve an invaluable role to the DMCS program due to the multitude of duties included in this role. Ensuring that the numbers of DMCS coordinators are sufficient to meet patient care and education needs is imperative for good program outcomes. In addition, having an appropriate complement of DMCS trained cardiologists and surgeons available for routine and emergency patient care is mandatory.

Maintaining appropriate staffing for all other members of an DMCS program allows for ongoing monitoring of quality improvement plans, clinical and patient-reported outcomes, and ultimately ensures a fiscally sound and successful DMCS program.

Staffing Recommendations for Good Programmatic Outcomes

Class I

1. DMCS program leadership should ensure appropriate numbers of each facet of the multidisciplinary team are available to provide timely patient care according to programmatic clinical practice guidelines. (23-26)

Level of Evidence: C.

2. DMCS program leadership should ensure an appropriate complement of DMCS trained cardiologists and surgeons are available for routine and emergency patient care with 24-hour care coverage. (26)

Level of Evidence: C.

3. Standard patient to DMCS coordinator ratios should be determined by the scope of work required of the DMCS coordinator(s) to meet the needs of the individual program's patient volumes, rather than by a fixed coordinator to patient ratio. (9, 24)

Level of Evidence: C.

4. DMCS programs should monitor the scope of work of all DMCS coordinators within each program, ensuring that the numbers of DMCS coordinators are sufficient to meet patient care and education and programmatic cost-effectiveness (22, 24, 27)

Level of Evidence: C.

Topic IV: Education of health care provider and hospital support service members

DMCS programs should ensure educational plans have been put in place to maintain adequate DMCS competency. Health care providers and hospital support service members who engage with patients on DMCS should complete regular competency training in DMCS. Data to support specific recommendations on the frequency and content of training are lacking. The recommendations put forth herein can be adjusted and tailored to programmatic needs.

In general, health care provider training should be tailored to the educational needs of the staff according to tiers of CMS patient care responsibility (Table 1) and frequency of patient contact, ranging from basic DMCS awareness (limited patient contact) to the expert DMCS provider (directly responsible for DMCS management). Given the evolution of devices and the new information gleaned from clinical study, DMCS providers should update training regularly. Institutional DMCS curricula should also be reviewed and updated regularly to ensure content is contemporary.

Recommendations for staff education

Class I

1. Advanced Heart Failure Specialists and fellows, DMCS specialty nurse practitioners, physician assistants, and coordinators should receive annual DMCS competency training and maintain certification according to local governing board requirements. This DMCS "expert" training should be inclusive of an in-depth understanding of device management, alarms, complications, and a detailed understanding of considerations during routine and emergency patient care. Level of evidence: C

Class IIa

1. Health care consultants who have frequent contact with DMCS patients, especially during surgical, intensive care unit, and critical care periods, likely benefit from advanced DMCS provider training. It is reasonable for training to provide an understanding of device function and management, recognition and *response to urgent DMCS alarms, an awareness of common device complications, and a clear understanding of how to contact the DMCS team. Level of evidence: C.*

Class IIb

2. It is reasonable to provide basic awareness training about DMCS, including "what is a VAD" and how to activate emergency assistance to support services and/or health care providers with limited contact with DMCS patients. Level of evidence: C.

Table 1 Considerations for Tiered Training for Health Care Providers and Support Staff Who Have Contact With DMCS Patients

	Patient contact	Examples of trained staff	Examples of training provided	Recommended hands-on DMCS education
Basic DMCS Awareness	- Limited/Rare DMCS patient contact -Provides indirect medical care	-Radiology Technicians -Patient Transport Teams -Nutrition -Social Work	-What is a DMCS? -How to activate emergency assistance? -How to reach the DMCS team?	No
General DMCS Training	-Frequent contact without primary day-to-day responsibility of patient care	-Catheterization Lab medical staff -Gastrointestinal Endoscopy medical staff -Echocardiography technicians -Infectious disease teams -Community Emergency Response Teams	-Provide basic understanding of DMCS to ensure safe device function -Discuss routine and emergency care for special circumstances -Demonstrate clear understanding of how to avoid DMCS power loss, maintaining exit site dressing occlusion and fixation, and avoidance with moisture -How to reach the DMCS team?	No
DMCS Advanced Provider Training	-Frequent and high level contact with DMCS patients -Contact during surgical, intensive care unit and critical periods	-Cardiac and surgical nurses who manage DMCS patients -General Cardiology Fellows -Cardiac Anesthesia -Emergency Medicine -Critical Care Providers -Hospital Resuscitation teams	In-depth Understanding of the follow information -Device function and management -Recognition of and response to urgent DMCS alarms -Awareness of common device malfunctions -Clear understanding of how to reach the DMCS team -How to assess and manage DMCS patients during resuscitation efforts	Yes -Demonstrate device interrogation -Provide safe power source connections (batteries and A/C power unit) -Demonstrate driveline dressing integrity and fixation to decrease risk of infection and site trauma
DMCS Expert Provider Training	-Responsible for primary, direct and day-to-day DMCS patient management -Annual and detailed medical management training including emergency response	-DMCS Surgical and Cardiology Attendings -DMCS Specialty Nurse Practitioners and Physician Assistants -DMCS Coordinators	-Gained through internal training or through participation at national and international conferences providing DMCS education -Includes ISHLT and MCS Academias, and local board certification requirements -In-depth understanding of device management, alarms, complications, and considerations needed during routine and emergency care	Yes -Demonstrate ability to interrogate device; interpret, respond to and problem solve alarms; provide safe power source connections; maintenance of driveline dressing integrity and fixation; and knowledge of how to activate or de-activate a device

3. DMCS program leadership to establish internal volume minimums to meet the needs of the patient population served while maintaining competency in patient selection, surgical skill, and post-DMCS care (8). Level of evidence: B.

Recommendations for community outreach by the DMCS team

Class I

1. Community outreach should be performed by the implanting center's DMCS team to inform the local health care providers, including emergency medical services personnel, emergency department staff, and referring physicians, of the reintegration of the DMCS patient to his or her local environment. Education should be delivered so providers have knowledge of the concepts involving DMCS 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 economic impact considerations based upon volume metrics

Class IIb

1. Each multidisciplinary DMCS team should maintain internal cost-measurement strategies with high-degree of care deliverance in candidacy selection of each patient (18). Level of evidence: B.

2. Based upon predetermined volume metrics for each program, it may be beneficial to financially analyze the program's implants and readmissions to effectively determine strategies to maintain cost-effectiveness within DMCS programs, while maintaining deliverance of high-level of care (18). Level of evidence: B.

Topic V: New DMCS programs

Before starting a durable DMCS program, internal steps should be taken to establish the needs for a successful program, including the individual components and skill sets required of the physician and nurse leadership teams; the facilities and space required for inpatient, operative, and outpatient care; the availability of subspecialty consultants (e.g., neurology, infections disease) for noncardiac care; and the specific financial and administrative leadership support that will be integral for programmatic success. Centers without transplant capabilities need to establish and maintain a close relationship with a nearby cardiac transplant program to ensure appropriate candidates for transplant are offered evaluation for transplant listing when appropriate. (28)

Recommendations for new DMCS programs

Class I

1. DMCS Centers without transplant capabilities should maintain an active relationship with a local cardiac transplant center to allow for regular evaluation of patients for transplant candidacy.

Level of Evidence: C.

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Task Force 9 Summary:
Benchmarking, Quality Assurance/Performance Improvement (QAPI), Program Volume Ratios, Community Education and Volume Metrics (New)

2013 Guidelines recommendations (not in original guidelines)	New and modified in 2020 Updated Guidelines
Topic I: Benchmarking	
Not addressed in 2013 Guidelines.	**Recommendation for Programmatic MCS Quality Assessment and Performance Improvement (QAPI) through Benchmarking:** ***(New)*** Class I: 1. Programmatic benchmarks for survival, 30-day and one-year readmissions, and serious adverse events after DMCS should be established using data from major clinical trials or national registries. Level of Evidence B. 2. Programmatic benchmarks should be reviewed regularly for update to mirror contemporary DMCS outcomes and characteristics of the program (DT vs DT/BTT capacity) and device models implanted. Level of Evidence C. Class IIa: 1. Despite limited evidence, it is reasonable for DMCS programs to follow a minimum standard (>10 DMCS implants per year) of DMCS implantations to allow for proper programmatic benchmarking Level of Evidence B.

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Task Force 9 Summary:
Benchmarking, Quality Assurance/Performance Improvement (QAPI), Program Volume Ratios, Community Education and Volume Metrics (New)

2013 Guidelines recommendations (not in original guidelines)	New and modified in 2020 Updated Guidelines
Not addressed in 2013 Guidelines.	**Recommendations for patient-reported outcome considerations and benchmarking: *(New)*** Class I: 1. Each DMCS program should regularly review results of DMCS specific and validated non-specific quality of life metrics (e.g., EQ-5D, KCCQ and QOLVAD questionnaire) and validated measures of functional capacity (e.g., 6-minute walk test or 5-meter (16 feet) walk test). Level of Evidence C. 2. Impediments to successful acquisition of testing should also be identified and addressed Level of Evidence C. 3. Every DMCS program should deliver high-quality care while maintaining fiscal awareness. This includes having the most appropriate and experienced support staff in place for programmatic fiscal evaluation and cost-measurements. Level of Evidence B.
Topic II: Quality Assurance/Performance Improvement (QAPI)	
Not addressed in 2013 Guidelines.	**Recommendations for clinical outcome considerations based upon QAPI: *(New)*** Class I: 1. DMCS programs should have ongoing and individualized quality improvement processes in place to monitor occurrences of events such as strokes, infections, bleeding events and survival as they relate to valid national or regional benchmarks. Level of Evidence C. 2. The members of DMCS Multidisciplinary team should be present and engaged in regular QAPI review and informed of changes to clinical practice guidelines in response to QAPI initiatives. Level of Evidence C. 3. DMCS programs should monitor 30-day and one-year readmission frequencies following index DMCS implantation and target quality and performance improvement interventions toward those with SAEs that occur at rates higher than benchmark. SAEs prompting readmission could include infection, heart failure recurrence, device malfunction, and bleeding episodes. Level of Evidence B. 4. The rates of DMCS SAEs should be monitored and compared with benchmarks at least annually as part of performance improvement and quality assessment. These could include early and late rates of stroke (ischemic and hemorrhagic), device malfunction, infection (categorized as device related or unrelated), non-surgical bleeding, heart failure events and mortality. Level of Evidence B. 5. DMCS program clinical practice guidelines should be established for patient selection and care using data gleaned from published DMCS guidelines and studies as a means of reducing care variations that many contribute to adverse patient outcomes. The clinical practice guidelines should be reviewed and updated regularly. Level of Evidence C.

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Task Force 9 Summary: Benchmarking, Quality Assurance/Performance Improvement (QAPI), Program Volume Ratios, Community Education and Volume Metrics (New)

2013 Guidelines recommendations (not in original guidelines)	New and modified in 2020 Updated Guidelines
Not addressed in 2013 Guidelines.	**Recommendations for economic impact considerations based upon QAPI: *(New)*** Class IIb: 1. Cost analyses of adverse events monitored through quality assurance and performance improvement efforts may be beneficial. Level of Evidence C.
Topic III: Staffing MCS Programs	
Not addressed in 2013 Guidelines.	**Staffing Recommendations for Good Programmatic Outcomes: *(New)*** Class I: 1. DMCS program leadership should ensure appropriate numbers of each facet of the multidisciplinary team are available to provide timely patient care according to programmatic clinical practice guidelines. Level of Evidence C. 2. DMCS program leadership should ensure an appropriate complement of DMCS trained cardiologists and surgeons are available for routine and emergency patient care with 24-hour care coverage. Level of Evidence C. 3. Standard patient to DMCS coordinator ratios should be determined by the scope of work required of the DMCS coordinator(s) to meet the needs of the individual program's patient volumes, rather than by a fixed coordinator to patient ratio. Level of Evidence C. 4. DMCS programs should monitor the scope of work of all DMCS coordinators within each program, ensuring that the numbers of DMCS coordinators are sufficient to meet patient care, education and programmatic cost-effectiveness. Level of Evidence C.
Topic IV: Education of Health Care Providers, Hospital Support Service Members and the Community	
Recommendations for Health Care Provider Education: 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.	**Recommendations for Health Care Provider Education:** *Replaced by the new and modified recommendations below* Class I: 1. Advanced Heart Failure Specialists and fellows, DMCS specialty nurse practitioners, physician assistants, and coordinators should receive annual DMCS competency training and maintain certification according to local governing board requirements. This DMCS "expert" training should be inclusive of an in-depth understanding of device management, alarms, complications, and a detailed understanding of considerations during routine and emergency patient care. Level of Evidence C (*Modified*) Class IIa: 1. Health care consultants who have frequent contact with DMCS patients, especially during surgical, intensive care unit, and critical care periods, likely benefit from advanced DMCS provider training. It is reasonable for training to provide an understanding of device function and management, recognition and response to urgent DMCS alarms, an awareness of common device complications, and a clear understanding of how to contact the DMCS team. Level of Evidence C. (New)

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Task Force 9 Summary: Benchmarking, Quality Assurance/Performance Improvement (QAPI), Program Volume Ratios, Community Education and Volume Metrics (New)

2013 Guidelines recommendations (not in original guidelines)	New and modified in 2020 Updated Guidelines
	2. It is reasonable to provide basic awareness training about DMCS, including "what is a VAD" and how to activate emergency assistance to support services and/or health care providers with limited contact with DMCS patients. Level of Evidence C. (New) 3. DMCS program leadership should establish internal volume minimums to meet the needs of the patient population served while maintaining competency in patient selection, surgical skill, and post DMCS care. Level of Evidence B. (New)
Recommendations for community outreach by the DMCS team:	**Recommendation for Community Outreach:**
Class I: 1. Community outreach should be performed by the implanting center's DMCS team to inform the local health care providers, including emergency medical services personnel, emergency department staff, and referring physicians, of the reintegration of the DMCS patient to his or her local environment. Education should be delivered so providers have knowledge of the concepts involving DMCS and the associated physiologic changes. Level of Evidence C.	Class I: 1. *Continuing approval without change*
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.	Class IIa: 1. *Continuing approval without change*
Topic V: DMCS Program Fiscal Responsibility	
Not addressed in 2013 Guidelines.	**Recommendations for economic impact considerations based upon volume metrics: *(New)*** Class IIb: 1. Each multidisciplinary DMCS team should maintain internal cost-measurement strategies with high-degree of care deliverance in candidacy selection of each patient. Level of Evidence B. 2. Based upon pre-determined volume metrics for each program, it may be beneficial to financially analyze the program's implants and readmissions to effectively determine strategies to maintain cost-effectiveness within DMCS programs, while maintaining deliverance of high-level of care. Level of Evidence B.
Topic VI. New MCS Programs	
Not addressed in 2013 Guidelines.	**Recommendations for new DMCS programs: *(New)*** Class I: 1. DMCS centers without transplant capabilities should maintain an active relationship with a local cardiac transplant center to allow for regular evaluation of patients for transplant candidacy. Level of Evidence C.