Mechanical Circulatory Support Indications and Patient Selection

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Introduction

Patients suffering from end-stage heart failure who are failing medical therapy should be considered for advanced therapies such as a heart transplant or placement of durable mechanical circulatory support (MCS) device to prolong life. Guidelines published by heart failure, transplant, and surgical societies have been developed to aid clinicians with determining patient candidacy for MCS placement. In addition to meeting the clinical criteria for durable MCS, adherence to reimbursement criteria established by government and commercial payers must be considered. This chapter will discuss the indications for durable MCS placement from the clinical as well as the reimbursement perspectives and patient selection criteria.

Indication for MCS

Intentions for Treatment

Durable MCS is considered for those patients with chronic end-stage systolic heart failure as well as those presenting with an acute event who likely will not survive without MCS. The indications for MCS are described by intention to treat and clinical criteria.

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Intention to treat indications include bridge to recovery (BTR), destination therapy (DT), bridge to candidacy (BTC), and bridge to transplant (BTT) [1–3]. Clinical factors define each indication and guide device selection [3].

The BTR indication includes patients presenting with an acute event (i.e., myocardial infarction, myocarditis) in cardiogenic shock failing medical management requiring escalation of care with a short-term MCS device. This indication allows time to assess for myocardial recovery or demonstrate the need for advanced therapies [1–3]. Evaluation for next-level therapies should be ongoing while monitoring for recovery.

Patients who are unable to be listed for transplant however meet the criteria for durable MCS are designated as DT candidates. This designation indicates patients will remain on durable MCS for the remainder of their life. BTT indication includes those patients that have been evaluated and listed for heart transplant at the time of device implant [3]. Patients with reversible contraindications to transplant (i.e., actively smoking, organ dysfunction) may be placed in the BTC indication as opposed to DT given the potential for transplant once the contraindication is resolved [3].

Further definition of the indications for MCS must include a discussion of the clinical criteria. The clinical criteria are outlined by both a regulatory and clinical perspective. The clinical criteria defined by regulatory bodies are connected to reimbursement and will be discussed first.

Reimbursement Indications

Reimbursement for placement of MCS in the United States (US) is regulated by the Centers for Medicare and Medicaid Services (CMS). CMS requires institutions to be credentialed as an implanting center by either The Joint Commission or the Det Norske Veritas (DNV) Healthcare VAD (ventricular assist device) Credentialing Program [4–6]. Institutions in the United States must adhere to both CMS and their chosen credentialing organization's requirements to obtain and then remain certified by CMS. Incorporating the indications and patient selection requirements in the institution's clinical practice guidelines will assist with meeting specified criteria.

Clinical requirements for MCS institutions are outlined by CMS in their National Coverage Determination (NCD) [4]. The NCD was recently updated (December 2020) and removes the intention to treat requirement [4]. This means determining BTT or DT candidacy prior to implant is no longer necessary. The clinical criteria outlined in the NCD have provisions for both end-stage heart failure patients and those presenting with acute processes. Despite this removal, VAD programs still often discuss patients based on implant indication.

CMS requires potential MCS patients to have an ejection fraction (EF) of ≤25% and be exhibiting New York Heart Association (NYHA) functional class IV symptoms [4]. Additionally, CMS requires that patients must demonstrate either inotrope dependence or demonstrate a low output state evidenced by a cardiac index <2.2 L/min/m^2 despite treatment with guideline-directed medical therapy for a minimum of

45 out of 60 days [4]. To assist with provisions for those patients presenting more acutely or unable to meet the 45 of 60-day requirement, patients may qualify for MCS if they have exhibited advanced heart failure for the last 14 days and are dependent on either an intra-aortic balloon pump or other short-term MCS device for 7 days [4].

Having reviewed the regulatory requirements of CMS, further explanation of the clinical requirements is necessary, specifically, those failing optimal medical management. Despite utilization of guideline-directed medical therapy, advanced heart failure eventually becomes refractory to angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, angiotensin receptor-neprolysin inhibitors, beta-blockers, and mineralocorticoid receptor antagonists [7, 8]. Over time, patients frequently also require an increased diuretic dose to remain euvolemic with advancing disease. Patients suffering with NYHA IIIb–IV symptoms who have functional limitations despite medical therapy often experience frequent hospital readmissions for decompensated heart failure. Patients may also require initiation of inotropic therapy to either aid in diuresis or to improve cardiac function during a decompensated state [9].

Frequent hospitalization with NYHA class IV symptoms is an indicator of worsening heart failure and the need for MCS when on guideline-directed medical therapy. Additional clinical indications include a combination of the following: intolerance to neurohormonal antagonist, increasing diuretic requirements, symptomatic despite cardiac resynchronization therapy, inotrope dependence, low peak VO_2 (<12–14 or 50% of age predicted), and/or end-organ dysfunction attributable to low cardiac output [2, 3, 7, 9–11].

Contraindication for MCS

There are both absolute and relative contraindications to durable MCS. Table 1 summarizes this list. Absolute contraindications to MCS implantation include those patients with irreversible end-organ dysfunction/failure (renal, hepatic), active untreated infection, severe psychosocial limitations, and some institutions include medical non-adherence [1, 10]. Illnesses such as malignancies with a life expectancy of less than 2 years with or without systemic organ involvement are also believed to be an absolute contraindication [2, 11].

Table 1 Contraindications to MCS support [1, 2, 10–16]

Absolute contraindications	Relative contraindications
• Irreversible renal or hepatic disease • Active untreated infection • Severe psychosocial limitations • Any illness with a life expectancy less than 2 years • Right ventricular or biventricular failure if DT LVAD planned	• Age • BMI • Substance abuse • Psychiatric disorders • Limited social support • Non-compliance with medical regimen

DT destination therapy, *LVAD* left ventricular assist device, *BMI* body mass index

Relative contraindications to MCS implant may vary by institution and have been the source of some debate. Patient age, body mass index (BMI), active or recent history of substance use/abuse, psychiatric disorders, and available social support are often more fluid and evaluated on a case by case basis within an institution. Some institutions suggest an age cutoff of 75 years, as recent studies demonstrate a higher mortality post implantation in patients greater than 75 years of age [12]. There is growing evidence that preoperative frailty assessment aids in the decision-making process. Preoperative assessment of hand grip strength has been shown to provide some prognostic value during the evaluation of appropriate MCS candidates [13].

Obesity has also sparked some debate when determining a BMI parameter for VAD implantation. Obesity, defined by a BMI of greater than 35, may be considered a relative contradiction at some centers, with some citing concern for poor outcomes. However, it was found that even patients with a BMI of 40 or greater (extreme obesity) show no difference in survival at 30 days and 1 year post-implant, suggesting BMI remains a relative contraindication [14].

Psychosocial factors are highly debated when determining MCS candidacy. Impaired cognitive function, active substance abuse, unmanaged psychiatric disorders, and/or lack of social support may be prohibitive for safe MCS implantation [10]. Life for a patient post-implant requires ongoing, daily self-care related to equipment maintenance, adherence to a complex medical regimen including proper dosing of anticoagulation, ongoing wound care using sterile technique, frequent lab monitoring, and frequent office visits all in order to ensure the MCS device is adequately supporting the patient. An extensive psychosocial assessment of a patient's cognitive status, psychopathology, social support, and past adherence to medical regimens is part of the process to determine candidacy for MCS placement [15, 16].

Patient Selection

Understanding the regulatory as well as the clinical indications, along with both the absolute and relative contraindications for MCS placement will help guide patient selection. To determine candidacy for MCS placement, patients undergo a thorough evaluation based on the presenting comorbidities along with age-related risk factors [17]. Table 2 outlines the suggested routine age-related and comorbidity testing to be considered. Risk assessment is needed to assist the multidisciplinary team with making a decision for MCS placement [11, 17]. Clinical risks will be discussed followed by psychosocial risks.

While durable MCS is specific to left ventricle support, evaluation of right ventricular function is also required to determine the risk of right heart failure following placement of the device and to plan if biventricular support is needed. Right heart catheterizations along with echocardiography help to provide an assessment of the right ventricle [1, 2]. Right atrial pressure, right ventricular stroke work index (RVSWI), tricuspid annular plane systolic excursion (TAPSE), and pulmonary artery pulsatility index (PAPI) are objective methods for assessment of RV function [2, 3,

Table 2 Evaluation checklist [1–3, 11, 12, 15–17]

- Laboratory assessment
  - Complete metabolic panel
  - Complete blood count
  - Prothrombin time/international normalized ratio
- Chest X-ray
- Electrocardiogram
- Assessment of NYHA class and INTERMACS profile
- Echocardiogram
- Cardiopulmonary exercise stress test (unless on inotrope or on short-term MCS)
- 6-minute walk test
- Hemodynamic assessment with pulmonary artery catheter/right heart catheterization
- Coronary angiogram as indicated
- Computed tomography of chest (non-contrast)
- Internal cardiac defibrillator check
- Spirometry ± bronchodilator
- Complete abdominal ultrasound (assess liver, spleen, kidneys, pancreas, abdominal aorta)
- Bilateral carotid artery ultrasound/duplex
- Bilateral lower extremity peripheral vascular study (ankle-brachial index)
- Consults:
  - Social work for psychosocial assessment
  - Dietician for nutritional assessment
  - Cardiothoracic surgeon
  - Palliative care
  - Other consults as presentation dictates
    - Endocrinology
    - Pulmonology
    - Hematology
    - Hepatology
    - Neurology
    - Nephrology
    - Bioethics
- Additional testing as indicated
  - Neuropsychology testing
  - Urine toxicology screen
  - Wellness testing (if time permits and patient's condition)
    - Dental
    - Colonoscopy (age and comorbid condition dependent)
    - Female patients: Mammogram and pap smear (as indicated by age)
    - Male patients: Prostate specific antigen (as indicated by age)

Note: Not all testing is indicated. Testing based on institution's requirements, patient's age, and comorbidities. Additional testing may be needed based on findings

17]. A right heart catheterization provides intracardiac and pulmonary artery pressures. Findings of pulmonary hypertension may rule out transplant candidacy but MCS may be an option. The echocardiogram reveals right and left ventricular dimensions and function, in addition to the structure of the aortic, mitral, tricuspid, and pulmonic valves. Evidence of aortic, mitral, and/or tricuspid regurgitation or stenosis deserves further attention to determine if valve repair or replacement is needed at the time of MCS implant [1, 18]. Additional surgery at the time of MCS placement adds complexity to the surgery and must be included in the risk assessment [1, 18].

For patients with prior cardiac surgery, a computed tomography (CT) of the chest helps determine re-entry risk, and provides further information about the condition of the aorta. These also assist with determining overall surgical risk [1]. A coronary angiogram will determine if corrective measures for heart failure are possible or determine the need for concomitant surgery at the time of MCS implant [1, 18]. For patients having had prior aortic valve replacement with a mechanical aortic valve, replacement with a bioprosthetic valve should be considered at the time of MCS placement taking into consideration the cumulative risk [18].

Many patients with chronic heart failure present with atrial and/or ventricular arrhythmias, some already having had an ablation(s), a pacemaker, or internal cardiac defibrillator. Patients with pre-MCS history of atrial fibrillation and ventricular tachycardia are at risk for post-MCS implant atrial fibrillation and ventricular tachycardia. Atrial arrhythmias are not a contraindication to MCS, but attention is focused on rate control with medications. If atrial arrhythmias are problematic, an electrophysiologist should be consulted to determine whether an ablation is warranted [1, 17, 18]. Consideration may be given to ligating the left atrial appendage at the time of MCS implant [1]. Ventricular arrhythmias pre-MCS are more problematic, and require specific attention. In addition to the use of antiarrhythmics, hemodynamic optimization may decrease the incidence of ventricular arrhythmias for those patients found to be in decompensated heart failure. Coronary ischemia should be considered for those patients exhibiting persistent ventricular tachycardia despite treatment warranting a left heart catheterization, especially for those patients with known coronary artery disease [1]. Attempts are made to decrease the burden of ventricular arrhythmias pre MCS implant in an effort to prevent the need for a right ventricular support device post implant if ventricular arrhythmias persist despite left ventricular unloading [1].

A history of chronic lung disease, smoking history, or use of oxygen at the time of evaluation warrant further investigation. Baseline pulmonary function testing will determine the degree of pulmonary dysfunction in patients with lung disease and should be completed to assess potential issues with weaning from mechanical ventilation following surgery [1, 3]. Further testing may be needed depending on the results. Patients on mechanical ventilation prior to MCS support are at increased risk for adverse events [3].

A history of gastrointestinal bleeding prior to MCS requires further investigation to determine the cause, due to the need for anticoagulation following MCS implant. A baseline colonoscopy may be required and should be considered for age-related wellness testing if not previously completed to rule out malignancy [1–3].

Further investigation of the renal and hepatic systems is warranted with any abnormal blood tests and/or imaging. Renal failure post implant complicates the patient's postoperative course and may not provide the quality of life the patient is seeking. Patients should understand their risks prior to implant [1–3]. Chronic dialysis is a contraindication for MCS in many institutions [2]. Abnormal liver function tests that do not resolve with improved cardiac output should be further investigated. Cirrhosis is a contraindication to MCS support [1].

Patients presenting with a history of a cerebrovascular accident (CVA) require further investigation that at a minimum requires a baseline head CT and carotid ultrasound [1]. Formal assessment of residual deficits and neurocognitive function are needed to determine the patient's ability to manage the MCS device. Additionally, patients should understand the risk of a stroke with MCS as part of making an informed decision. Patients with severe neurocognitive deficits or demonstrate an inability to care for self is a contraindication to MCS [1, 3].

Other comorbidities to be taken into consideration include rehabilitation ability for those with peripheral vascular disease or chronic back, knee, or hip issues. Peripheral vascular studies are indicated for patients with neuropathy or known circulation issues [1, 3, 18].

A full psychosocial evaluation is completed similar to evaluation for a heart transplant, and is needed to identify risk factors for post implant care [15, 16]. Understanding a patient's past compliance with medical care, social support, substance use, and psychiatric history is relevant for assessing patient's risk for recidivism and failure post implant. Further testing is warranted if there are signs of neurocognitive issues [3]. Efforts are made to mitigate risks to improve patient outcomes [15]. As stated previously, classification of psychosocial issues as relative or absolute contraindications continues to be an area of debate for MCS placement.

Once the evaluation is completed, patients are presented to a multidisciplinary advanced heart failure team for decisions regarding candidacy. Typically, these teams consist of cardiac surgeons, advanced heart failure cardiologists, MCS coordinators, social workers, dieticians, a member of the palliative care, and ideally a team member from bioethics, case management, physical and occupational therapists [11]. Patient demographics, history of present illness, past medical history, pre MCS testing, psychosocial evaluations, and assessment of the patient's support system are presented. The multidisciplinary team discusses any potential barriers they foresee postoperatively and determine a plan for mitigation of risks to promote good patient outcomes. Team members then make recommendations weighing the risks and benefits of MCS therapy specific to the patient. The presentation should acknowledge whether the patient meets CMS and institutional criteria with findings clearly documented in the patient's medical record.

The last phase of the patient selection process is to obtain insurance approval for MCS placement. CMS criteria have previously been discussed above. For those patients with commercial insurance, it is necessary to understand the payers' criteria for device placement. In the current environment, most payers in the United States continue to require the designation of BTT or DT. With the indication for device therapy defined, patients will need to meet these specific designation requirements. For example, if the device is being placed as BTT, the patient will need to be listed for transplant prior to device implant as required by the payer. It is essential for each MCS program to work closely with their finance department or pre-authorization department to fully understand the various payers served and those payers' individual patient-specific selection criteria.

The indications, contraindications, and relative contraindications of MCS guide clinicians to understand the appropriateness of completing a full evaluation for

MCS. After a full evaluation is completed, the multidisciplinary team decides candidacy for MCS device placement based on patient selection criteria specified by the institution, government, and commercial payers. Patient selection criteria should be included in each institution's clinical practice guideline to remove selection bias as well as to inform patients.

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