Taskforce 2: Patient Optimization, Consent, and Appropriate Timing for Mechanical Circulatory Support: Modifiable Risk Management Prior to Implantation

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Introduction

Evaluation of a patient for long-term mechanical support parallels the evaluation for cardiac transplantation. Salvage situations certainly exist, precluding the ability to perform a thorough evaluation. Nevertheless, a comprehensive assessment of the patient and preoperative optimization using a multi-systems approach prepares the patient for the best chance of a successful outcome. Preoperative risk scoring systems use markers of physiologic perturbations to estimate outcomes. They provide guidance in preoperative organ optimization, which has been shown to influence outcomes, but they cannot circumvent experienced clinical judgment. The final portion of this section includes a template of a suggested patient consent form (Appendix 1). This template is provided in an effort to develop a standard for which clinicians and health care systems can adapt to meet the needs of their individual institution.

Preoperative Management

Obesity

Although obesity has been shown to increase the perioperative risk for infections, the overall risk for infection after MCSD placement for durable implants is likely to be driven by multiple factors. Although one study has shown an increased risk for driveline infections,¹ most studies have shown that the body mass index (BMI), including the level of morbid obesity, does not have a detrimental effect on infection, or overall outcomes, with careful patient selection.²⁻⁴
To date, published data are limited on the morbidly obese and the utilization of MCS as a “bridge to weight loss” (in BTT patients). MCS resulted in significant weight loss over medically managed patients in one small study.\textsuperscript{5} In another retrospective analysis, patients with the HeartMate XVE device lost weight while those with the HeartMate II device did not.\textsuperscript{6}

**Recommendations for Obesity:**

*Class I:*

1. Obesity (BMI >30) is not a contraindication to MCS.

   **Level of Evidence:** B.

**Patient Expectations**

Mechanical support has demonstrated improved survival, particularly when used as DT. It also results in substantial improvements in quality of life.\textsuperscript{7,8} Nevertheless, this therapy is associated with several risks including infection, bleeding complications, device malfunction, arrhythmias, and stroke. These adverse events and their frequency should be discussed with the patient to facilitate shared decision-making (Universal Consent form, Appendix 1).\textsuperscript{9}

**Recommendations for Managing Patient Expectations:**

*Class I:*

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

   **Level of Evidence:** C.

*Class II:*

1. Quality of life should be assessed prior to and following MCSD implantation to help guide patient decisions. Assessment tools including MLWHF, Sickness Impact Profile, Euroqol and others should be considered to help guide patient care.
Level of Evidence: C.

**Palliative Care**

According to ACC/AHA guidelines, palliative care should be part of the management of stage D patients with heart failure. Palliative care consultation can help frame expectations, address end of life issues and needs, support families, and facilitate physician patient communication. Palliative care issues are discussed in Section 5 of these guidelines.

**Recommendations for Palliative Care:**

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

   Level of Evidence: C.

**Renal Function**

Renal dysfunction at the time of MCSD implantation is common, and it results from a combination of factors including renal hypoperfusion, elevated right atrial pressures, intensive diuretic therapy, pre-existing intrinsic renal disease, and the adverse neurohormonal milieu of heart failure. Preoperative management focuses on addressing these etiologies and avoiding nephrotoxic drugs and intravenous contrast. Renal perfusion pressure is determined by the mean arterial blood pressure minus the central venous pressure. Thus, in order to improve renal perfusion pressure, both forward flow and venous congestion must be addressed. The use of inotropes or vasopressors and even an IABP can improve renal blood flow. Aggressive attempts at diuresis are important, but progressive cardio-renal dysfunction may require the use of mechanical volume removal. Improving renal function is particularly important to optimize patient outcomes. Severe class IV renal insufficiency and end stage renal failure
requiring chronic dialysis after MCS is associated with high levels of morbidity and mortality, particularly in the DT population.\textsuperscript{12-14}

Although there is some evidence from animal studies that continuous flow results in periarteritis in the kidney,\textsuperscript{15} several small studies have shown there are no notable differences in renal recovery with continuous flow versus pulsatile flow devices.\textsuperscript{16-18} In a study of 309 patients from the HeartMate II BTT trial, renal function improved over 6 months of follow-up. However, the mean creatinine at study entry was 1.4 +/- 0.5 mg/dL.\textsuperscript{19} The effects of MCS on patients with more advanced renal dysfunction are not well established, since patients with a creatinine \( \geq \) 3.5 mg/dL or on chronic dialysis were excluded from both the HeartMate II BTT and DT trials.\textsuperscript{20,21} A single center study of both pulsatile and continuous flow devices demonstrated that patients undergoing MCS with a preimplant creatinine clearance <45 mL/min had a substantial overall improvement in renal function at six months as compared to baseline, 34.1 vs. 62.3 mL/min respectively, \( p=0.0001 \).\textsuperscript{22} Despite this overall improvement, only 53\% of this population was able to achieve a CrCl >60 mL/min.

**Recommendations for Managing Renal Function:**

*Class I:*

1. All patients should have their renal function monitored closely prior to MCSD implantation.
   
   **Level of Evidence:** C.

2. Patients with volume overload and/or poor output in the setting of renal dysfunction should have a period of hemodynamic optimization (with inotropic support if clinically indicated) combined with aggressive diuresis or mechanical volume removal.
   
   **Level of Evidence:** C.

3. Assessment of SCr, 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 III:
1. Permanent dialysis should be a relative contraindication for destination therapy.
   
   **Level of evidence: C.**

Nutrition

Poor nutrition is associated with more severe heart failure. There is little prospective evidence that even intensive nutritional interventions are efficacious in patients with advanced heart failure awaiting MCS. Furthermore, the risk of patient deterioration, which is associated with worse outcomes after MCSD implantation, must be weighed against the time needed to make a meaningful impact on the patient’s nutritional status preimplantation. Studies of early aggressive nutritional interventions in ICU patients demonstrated that patients achieved caloric goals more often with aggressive intervention, but these interventions did not result in changes in length of stay or hospital mortality.23 Thus, nutritional assessment may be most useful to risk stratify patients preoperatively and ensure timely intervention postoperatively.

Studies of both pulsatile and continuous flow devices have shown improvement in albumin over time with MCS, but the impact of nutritional interventions before MCS on outcomes after MCS has not been evaluated. Data from INTERMACS have also demonstrated that patients who are less ill at implantation have a significantly higher prealbumin (12.5 vs. 15 vs. 21 vs. 21 mg/dL, INTERMACS profiles 1-4, respectively, p<0.0001) and albumin (2.95 vs. 3.2 vs. 3.6 vs. 3.5 mg/dL, INTERMACS profiles 1-4 respectively, p<0.0001).24

**Recommendations for Nutrition Assessment:**

*Class I:*

1. All patients should have assessment of their nutritional status prior to MCSD implantation with at least a measurement of albumin and prealbumin.

   **Level of Evidence: B.**
2. Patients who have indices of malnutrition prior to MCSD implantation should have an evaluation by a nutritional consultation service.

   **Level of Evidence: C.**

*Class IIa:*

1. Patients who have evidence of malnutrition prior to MCSD implantation should receive nutritional interventions prior to implantation.

   **Level of Evidence: C.**

*Class IIb:*

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

   **Level of Evidence: C.**

*Infection Risk*

Chronic heart failure results in a state of both chronic inflammation and immunosuppression, with a linear correlation between the severity of heart failure and the degree of immunosuppression. In addition to heart failure, other chronic conditions such as malnutrition and renal failure can exacerbate the risk for infection. Many patients with heart failure who are being considered for MCSD therapy have had long hospitalizations resulting in an increased risk for colonization with and infection from antibiotic resistant organisms. Furthermore, PICC lines, central venous catheters, IABP, and endotracheal tubes represent ongoing infectious risks to the patient. Care must be taken to remove all unnecessary lines prior to implant. Indwelling lines that are required for the patient’s clinical stability or safety should be inspected and changed with cultures drawn, if suspicious. If time and clinical status permits, a preoperative dental assessment for all patients is warranted.

**Recommendations for Managing Infection Risk:**
Class I:
1. All patients should have all unnecessary lines and catheters removed prior to MCSD implantation.
   Level of Evidence: C.
2. All patients should have a dental assessment, if time and clinical status permits, prior to MCSD implantation.
   Level of Evidence: C.

Active Infection

Patients must be assessed for signs of infection. Any infection identified prior to implant should be aggressively treated and eradicated, if the patient’s clinical status permits. Active infection at the time of implantation can be highly morbid, resulting in seeding of the device that is rarely abated, even with prolonged and aggressive antibiotic therapy. Once a device becomes infected, selected patients with an infection may be chronically suppressed with selected antibiotic therapy; alternatively, sometimes the only recourse is to consider a higher-risk transplant for those patients who will not tolerate explant. For some patients, it may be appropriate in select situations to perform a device exchange. While it is ideal to explant the older device and provide hemodynamic support and antibiotics for a period of treatment, this frequently is not the best clinical course, and it is not feasible for some patients. This strategy should be considered whenever possible because it is common to reseed the newly implanted device. With a pump exchange, treatment of an infection prior to MCSD implantation must be balanced with the risk of recurrent infection and the risk of clinical deterioration. In such cases, consultation with an infectious disease team is critical.

Recommendations for Managing Active Infection:

Class I:
1. Patients with active infections should receive an adequate course of antibiotic therapy as directed by an infectious disease specialist prior to implantation of
Antibiotic Prophylaxis

All patients should receive prophylactic antibiotic treatment. The regimen will vary from center to center, but a patient care pathway should be in place to ensure all patients receive their antibiotics dosed appropriately to the patient’s renal function and timed to be most efficacious with the upcoming surgery. Preoperative antibiotics typically consist of gram-positive coverage, with Methicillin-resistant Staphylococcus aureus (MRSA) coverage if hospitalized >48 hours, broad-spectrum gram-negative coverage, and mupirocin ointment to the nares. Other considerations for antiviral or antifungal coverage should be considered in select high-risk patients or in specific regions known to have potentially pathological organisms endogenous to a given region.29-31

Recommendations for Antibiotic Prophylaxis:

Class I:
1. Patients should receive preoperative antibiotics with broad spectrum gram-positive and gram-negative coverage prior to MCSD implantation.
   
   Level of Evidence: C.
2. Patients should have a nasal swab to screen for MRSA and receive topical treatment if positive prior to MCSD implantation.
   
   Level of Evidence: C.

Hepatic Dysfunction

Hepatic dysfunction is occasionally a result of circulatory shock from acute decompensation. Conversely, chronic-occult hepatic dysfunction is not uncommon with chronic heart failure, especially in the setting of poor RV function, persistently high right atrial pressures, or Fontan circulation. 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 screen such patients with ultrasonography or even CT scanning to assess hepatic architecture for signs of cirrhosis. If there is evidence of cirrhosis, a hepatologist should be involved early in the patient’s management, and there should be consideration given to performing a transjugular hepatic biopsy to assess for the presence and degree of cirrhosis. Those with acute decompensation and elevations of transaminases or bilirubin should receive aggressive therapy with diuresis, inotropes, and IABP as necessary to improve hepatic function prior to implantation. Those patients that have confirmed cirrhosis or end stage liver disease are poor candidates for MCSD except in very rare circumstances.\textsuperscript{32,33}

Centrilobular necrosis manifested by elevation of AST and ALT is a common phenomenon in acute cardiogenic shock. A low cardiac output and elevated central venous pressure in part mediates the etiologic basis for the necrosis. In fact, it has been hypothesized that chronic passive congestion may predispose the liver to injury from hypoperfusion.\textsuperscript{34}

The degree of liver disease may be assessed through both the Childs-Pugh class and the MELD score. The Childs-Pugh class is determined by the presence or degree of ascites, bilirubin, and INR (Table 1). Those with Childs-Pugh class A are generally at increased, but acceptable, risk for acute perioperative hepatic decompensation, whereas those with class B and C are at much higher risk for this complication. The MELD score is a weighted calculation of creatinine, bilirubin, and INR levels. The MELD score is an independent predictor of poor outcome in multivariate analyses of a single-center patient cohort and from the INTERMACS database. An increasing MELD score is associated with the need for more perioperative blood products. An absolute score >13-17 is predictive of poorer surgical outcomes, and in those patient who do survive the peri-operative period, there is a decrease in long-term outcomes with increased morbidity.\textsuperscript{33,35,36}

Even in the absence of hepatic failure, patients with hepatic dysfunction prior to MCSD 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 RV dysfunction, and infection. To minimize the risk of bleeding, coagulation abnormalities should be corrected, and unnecessary antiplatelet agents should be discontinued prior to MCSD implantation, ideally 3-7 days before surgery.

As with renal function, abnormal baseline hepatic function improves after MCSD implantation and to a similar degree for both pulsatile and continuous flow devices. Data from the Heart Mate II study showed that, in the majority of patients, hepatic dysfunction normalized by one month and remained stable through 6 months. Bilirubin initially increased through day 7, but normalized by 2 months and remained stable through 6 months. There are few data on outcomes with MCSD in patients with significant hepatic dysfunction at baseline. The HeartMate II BTT trial excluded patients with an INR >2.5 not due to warfarin therapy, a bilirubin >5 mg/dL, transaminase >2000 IU/mL, or biopsy proven cirrhosis. The HeartMate II DT trial had similar exclusion criteria with the exception of a transaminase elevation >5 times the upper limit of normal.

**Recommendations for Hepatic Dysfunction:**

*Class I:*

1. Patients should have an ultrasound of their liver to screen for cirrhosis prior to MCSD implantation.
   
   **Level of Evidence: C.**

2. Patients who have suspected cirrhosis should receive further radiologic and tissue confirmation in conjunction with a hepatology consultation.
   
   **Level of Evidence: C.**

3. Patients with abnormal liver function and decompensated hemodynamics should receive aggressive therapy aimed at the restoration of hepatic blood flow and reduction of hepatic congestion.
   
   **Level of Evidence: C.**

*Class II:*

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

**Level of Evidence: C.**

*Class III:*
1. Patients with confirmed cirrhosis or increased MELD score are poor candidates for MCSD therapy.

**Level of Evidence: B.**

*Pulmonary Function*

Pre-operative evaluation of pulmonary function and thoracic anatomy is essential to optimize outcomes and prognosticate the potential post-operative morbidity and recovery after surgery. These guidelines do not specifically cover pulmonary hypertension or congenital considerations and serve only to provide some direction regarding the optimization or avoidable pitfalls prior to MSCD surgery.

Characterization of cardiac and extra-cardiac structures is essential for identifying previous grafts, chest irregularities, aortic anatomy, diaphragmatic abnormalities, and possible unforeseen consequences. A pre-operative arterial blood gas and a PA and lateral chest x-ray are useful in determining a baseline and helpful in weaning patients from the ventilator subsequent to surgery. In many cases, consideration should be given to acquiring a chest CT or MRI prior to surgery. These additional imaging modalities may be essential in determining practical surgical feasibility and aid in the evaluation of a MCSD candidate. Pre-operative risk factors can be divided into patient-related and procedural related risk categories.

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.\textsuperscript{42}

Subsequent to a chest x-ray and arterial blood gas, 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 filling pattern, frequently this is the result of heart failure and an anatomical consequence of the patient’s cardiomyopathy.\textsuperscript{43} Thus, treatment of the patient’s anemia, heart failure, and reverse remodeling associated with MCSD placement will frequently 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 2.7-4.7-fold increased risk of post-surgical complications.\textsuperscript{44,45}

An assessment of COPD should begin with a social and occupational history including patients’ social habits, previous history of asthma, systemic or familial diseases affecting pulmonary parenchyma or a history of intubation. Of those patients undergoing a cardiac surgery, COPD is by far the most common cause of pulmonary dysfunction. Failure to properly recognize COPD prior to surgery will likely lead to prolonged intubation after MCSD placement,\textsuperscript{46,47} as pulmonary complications after surgery are the most common form of post-operative impediment, leading to the longest length of stay.\textsuperscript{48} Based on the 2006 American College of Physicians guideline, spirometry is helpful to determine the level of disease and establish a baseline for patients with known asthma or COPD. These studies may be used to identify patients who may benefit from more aggressive preoperative medical management. Spirometry may also be used to evaluate exercise intolerance or shortness of breath not otherwise explained by the patient’s cardiac disease. The results obtained prior to surgery may be confounded by the patient’s overall preoperative constitution, and they should not be used as a single factor to exclude the patient from surgery.\textsuperscript{42,44,45,49}

A significant controversy persists with regard to the prognostic utility of PFTs. In combination with clinical judgment and other known factors, they may
be helpful to identify very high risk patients and those who may benefit from preoperative medication optimization, as well as postoperative incentive spirometry and intermittent positive airway pressure.

Smoking cessation for 4-8 weeks or more prior to surgery (if electively scheduled) will attenuate post-operative complications. Further risk stratification may be achieved by using the multifactorial risk index for postoperative respiratory failure\textsuperscript{50} or the Canet Risk Index.\textsuperscript{51} 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\textsuperscript{52}), 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 underdiagnose younger or taller patients and overdiagnose older and shorter patients.\textsuperscript{53,54} Perhaps the most accurate of these measures is the FEV1/FVC ratio of 65-70% of predicted.\textsuperscript{53}

**Recommendations for Pulmonary and Thoracic Assessment:**

*Class I:*

1. Patients should have a chest x-ray and an arterial blood gas prior to MCSD implantation.
   
   **Level of Evidence:** C.

2. Patients should have some assessment of thoracic anatomy prior to MCSD implantation and if prior surgery or abnormalities are suspected, they should receive further radiologic examination with either CT or MRI.
   
   **Level of Evidence:** C.

3. Smoking cessation 4-8 weeks prior to surgery is recommended if the clinical scenario supports waiting.
   
   **Level of Evidence:** C.

4. 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.
Class III:
1. Spirometry should not be used as a single modality for denying a patient MCSD surgery.

   Level of Evidence: C.

Management of Decompensated Patients

Numerous retrospective studies and collective experience suggest that the mortality and morbidity associated with urgent MCSD insertion or cardiac transplantation in patients with decompensated heart failure remains high.\textsuperscript{55,56} Despite the desire to implant devices earlier before the onset of end-organ dysfunction, it remains inevitable that many patients will continue to present with acute decompensated heart failure, volume overload, and low cardiac output.

Most experienced centers now routinely optimize hemodynamics prior to MCSD implantation. These steps include 1) central hemodynamic monitoring and concomitant addition of inotropes and/or inodilators; 2) optimization of volume status, either by increased dosage of intravenous diuretics administered as intermittent boluses or as a continuous infusion, or by institution of mechanical fluid removal; 3) use of an IABP; and 4) correction of metabolic and electrolyte abnormalities.

Routine monitoring of central venous and pulmonary pressures, serum electrolytes (particularly sodium levels), serum BUN, hemoglobin, platelets, serum creatinine, and markers for hepatic dysfunction (transaminases, bilirubin, and INR) are necessary to monitor the progress of continued aggressive medical management. Reduction of pulmonary vascular congestion and passive hepatopathy, will lead to decreased right ventricular failure and fewer perioperative bleeding complications. This approach can significantly improve the baseline clinical state (INTERMACS level) of the decompensated patient and transition an emergent MCSD implantation into a planned surgical implant.

There is a general lack of consensus regarding the therapy of choice for patients presenting in acute cardiogenic shock with hemodynamic collapse. For
patients with severe biventricular failure, the most recent data from INTERMACS on biventricular support suggests a 55% survival at 6 months.\textsuperscript{57} In addition, total circulatory support with the total artificial heart has demonstrated favorable results with 79% surviving to transplantation in a very sick cohort of patients.\textsuperscript{58} The morbidity associated with these complex operations in patients \textit{in extremis} is high. Frequently under these circumstances, the suitability for transplantation, patient’s neurologic status, or even the patient’s desire to live with a MCSD is unclear. These patients often have multi-organ failure and infection. Temporary MCSD as a bridge to decision are being increasingly used by many centers to restore the circulation while the evaluation process is initiated.

\textbf{Recommendations for Management of Decompensated Patients:}

\textit{Class I:}

1. Short-term mechanical support including ECMO should be used to support acutely decompensated patients who are failing maximal medical therapy.  
   \textbf{Level of Evidence: C.}

\textit{Temporary Mechanical Support}

Currently, improved short-term devices have become more widely available. Use of these devices can help improve end organ dysfunction, provide hemodynamic support, and facilitate extubation in severely infirm patients. This hemodynamic support allows time for a more comprehensive neurologic, social, and psychological assessment. In experienced centers, results have been favorable with various short-term circulatory support systems as a bridge-to-decision in patients with refractory acute cardiogenic shock and multisystem organ failure.\textsuperscript{59} These same devices have also been used successfully for biventricular support in a limited number of patients.\textsuperscript{60-62} Central placement of these devices ensures that adequate flows can be established with very effective cardiac unloading and no risk of lower extremity ischemia. In addition, several of the short term devices now allow the ability to splice an oxygenator into the circuit, thereby allowing for total cardiopulmonary support of patients in florid
respiratory failure. Although there are a variety of temporary devices, there is little evidence comparing these devices. Thus, the device choice is often made based upon the expertise available at each center rather than on data generated from large studies.

More recently, percutaneous options have also become available which may allow for more rapid establishment of effective circulation. Peripheral placement requires an assessment of peripheral vascular disease, and it may be limited by luminal diameter. These extra-corporeal pumps may utilize an inflow cannula inserted into the left atrium via a trans-septal cannula from the left femoral vein with an outflow cannula placed through the femoral artery into the iliac vessels. This strategy can be very effective in unloading the left ventricle and alleviating pulmonary congestion. Most reports suggest establishment of adequate flows and promising clinical results. Many of these devices can be adapted for right ventricular support as well, with cannula placement in the right atrium and across the pulmonary valve into the pulmonary artery. Limitations include the technical challenge of a transeptal cannulation, and the size of the iliac vessels for accommodating 15 French or larger cannulae. Of note, an additional anterograde cannulation of the distal artery may be a good strategy to preemptively circumvent vascular complications in elderly, small, or PVD patients.

An alternative technology places the device percutaneously from the femoral artery and across the aortic valve into the left ventricle. These devices come in two sizes supporting flows of roughly 2.5 and 5 liters/min respectively. These ventricular placed devices are contraindicated in patients with left ventricular thrombus or significant arrhythmias. In addition, these devices are only approved at this juncture for left sided support; therefore, they are not useful in patients with biventricular failure. However, at the time these guidelines were published, a right-sided device was being evaluated in limited centers. While smaller individual series utilizing percutaneous support have shown promise, there is insufficient evidence to date on the optimal device, timing, or circumstances to apply these technologies. Therefore, these guidelines
conclude at this juncture that there is not enough experience with any one or two devices to warrant recommendations regarding a specific device preference in acute decompenstated heart failure.

**Recommendations for Temporary Mechanical Support:**

*Class I:*

1. 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.**

**Right Ventricular Function**

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.\(^6^8\) Non-cardiac 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 LV support alone.

The impact of MCS on RV function can be both beneficial and detrimental. The beneficial effects are realized through unloading the left ventricle and decreasing filling pressures, thereby reducing RV afterload. The potential detrimental effects include an increase in RV preload from the normalized cardiac support, and the septal shift observed with unloading the left ventricle.\(^6^9,7^0\) With lower left ventricular filling pressures, the septum will tend to shift to the left and decrease the septal contribution to RV output. This septal shift phenomenon can be observed with continuous flow devices due to active, continuous unloading of the left ventricle. In contrast, pulsatile devices have mostly passive filling and tend to have a less dramatic effect on the position of the septum. Thus, based on a determination of the severity and reversibility of
RV dysfunction; clinicians should make an effort to determine if a given patient will need LV support alone, LV support with temporary RV support, or biventricular support.

RV dysfunction after MCS leads to high levels of morbidity and mortality, longer lengths of stay, and worse posttransplant outcomes. Biventricular support, although a reasonable option when necessary, requires a more extensive surgery, has a worse device patient interface than LV support alone, and is not approved for or desirable as DT.

Assessing Right Ventricular Function. Although two dimensional echocardiography is the most widely employed modality to assess RV function, there are challenges with this approach due incomplete visualization of the right ventricle in one particular view, making application of formulas used to evaluate the left ventricle less accurate. RV size can be measured by transthoracic echocardiogram in the apical 4-chamber view at the end of diastole, as well as by the transesophageal method in the mid esophageal 4-chamber view. By qualitative assessment, RV area or mid cavity diameter should be smaller than that of the left ventricle. Other echocardiographic parameters such as tricuspid annular plane systolic excursion (TAPSE) <1.5 cm, right-to-left ventricular end–diastolic diameter >0.72, and RV stroke volume index have been used and demonstrated in some studies to be helpful in predicting postoperative RV failure. While MRI provides excellent assessments of RV ejection fraction and size, it cannot be applied in many heart failure patients due to the presence of an ICD or clinical instability. Regardless of the non–invasive assessment of RV function, obtaining invasive hemodynamics are essential for a comprehensive evaluation.

An RV that appears severely dysfunctional by echocardiography may still be able to maintain low right atrial filling pressures and generate high pulmonary pressures. Conversely, a mildly dysfunctional RV by echocardiography may be severely compromised when hemodynamics are invasively assessed. Pulmonary artery systolic pressure of <50mmHg is thought to be associated with higher risk of developing RV failure. In addition, invasive hemodynamics also
allow the calculation of RV stroke work index (RVSWI): \[ \text{RVSWI} = (\text{mean PA} - \text{mean RA}) \times (\text{CI}/\text{HR}) \]. A value <450 mmHg * ml/m\(^2\) is predictive of RV failure.\(^{78}\) In the setting of marginal RV function, hemodynamically guided therapy with a Swan-Ganz catheter in an ICU setting for several days may be needed to determine if the patient can be managed with MCSD alone or will need biventricular support.

**Recommendations for Assessing Right Ventricular Function:**

*Class I:*

1. All patients should have an echocardiographic assessment of RV function prior to MCSD implantation.  
   **Level of Evidence: C.**

2. All patients should have invasive assessment of intracardiac filling pressures prior to MCSD implantation, with a particular emphasis on RV hemodynamics.  
   **Level of Evidence: C.**

*Incidence of Right Ventricular Failure.* The incidence of RV failure varies in the literature not only by era and by device, but also by the definition of RV failure. While almost all definitions of RV failure include the need for an RVAD, many also include a prolonged period of postoperative inotropic infusion or ventilator support, usually 7-14 days. In the era of pulsatile pumps, the rate of RVAD use was 4-25%, and the rate of overall RV failure was 10-39%.\(^ {79}\) In the current era of continuous flow pumps, there is a lower incidence of RV failure. INTERMACS data for devices implanted between June 2006 and March 2009 demonstrate that the rate of RV failure per100 patient months was significantly lower with continuous flow pumps than with pulsatile pumps, 2.23 vs. 3.15 respectively, p=0.05.\(^ {80}\) Overall, in trials of both axial flow and centrifugal flow devices, there is a 4-6% incidence of RVAD use and a 13-20% incidence of the need for prolonged inotropes.\(^ {38,80,81}\)

*Risk of RV Failure after Mechanical Support.* Risk scores may aid clinicians in quantifying the risk of RV failure, although these risk scores also
have important limitations (Tables 2 and 3).\textsuperscript{72,73,79} An analysis from the University of Pennsylvania demonstrated that a cardiac index \(\leq 2.2 \text{ L/min/m}^2\), RVSWI \(\leq 250 \text{ mmHg} \cdot \text{mL/m}^2\), the presence of severe RV dysfunction, serum creatinine \(\geq 1.9 \text{ mg/dL}\), previous cardiac surgery, and systolic blood pressure \(\leq 96 \text{ mmHg}\) were independent predictors of the need for RVAD support. It should be noted that less than 4% of patients in this study had continuous flow devices (Table 2).\textsuperscript{82} The University of Michigan risk score included 197 patients with LVADs, 35% of whom had RV failure defined as inotropes \(>14\) days, use of inotropes for \(\geq 48\) hours, the need for ECMO or RVAD, or discharge from the hospital on an inotropic agent. Only 15% of the devices were continuous flow, and 94% of the patients were implanted as BTT. The multivariate risk factors for RV failure included vasopressor requirement, AST \(\geq 80 \text{ IU/L}\), bilirubin \(\geq 2.0 \text{ mg/dL}\), and serum creatinine \(\geq 2.3 \text{ mg/dL}\) (Table 3).\textsuperscript{78}

The largest study to date of the risk of RV failure after a continuous flow device included 484 patients who had a HeartMate II implanted as part of the BTT trial.\textsuperscript{83} Overall, 6% of patients required an RVAD, 7% required prolonged inotropic support, and another 7% required late initiation of inotropic support. Multiple clinical, echocardiographic, and hemodynamic parameters were assessed, including RVSWI and the University of Michigan RV failure score. The only significant multivariate predictors were the need for ventilator support, a central venous pressure/wedge pressure ratio \(>0.63\), and a BUN of \(>39 \text{ mg/dL}\) (Figure 1).

While risk prediction models for RV failure are useful, they are clearly limited by the significant impact of other peri-operative factors on post-operative RV function, such as bleeding (Table 4).\textsuperscript{13}

\textit{Management of Right Ventricular Dysfunction Pre- and Post MCSD Placement.} RV dysfunction exacerbates venous congestion, which results in renal, hepatic, and intestinal congestion and subsequent organ impairment. In the preoperative phase, potential MCSD patients may require admission to the hospital for optimization of RV function. Intravenous loop diuretics, often administered as a continuous infusion and frequently accompanied by a thiazide
diuretic, are the mainstay of therapy. In severe cases, mechanical volume removal with ultrafiltration or continuous renal replacement therapy (CRRT) may be required to overcome diuretic resistance. Left ventricular inotropic support with dobutamine and/or milrinone is often instituted before MCS. It is critical to maintain LV filling in the setting of RV dysfunction. IABP or other short-term MCS may also be utilized to help optimize hemodynamics with a view to unloading the RV. Once hemodynamics have been aggressively managed, RV function is re-evaluated.

In the post-operative period, diuretics and inotropes are used in conjunction with direct pulmonary vasodilators such as nitric oxide and inhaled prostacyclin to further reduce RV afterload. Phosphodiesterase 5 inhibitors such as sildenafil are receiving increased interest as adjunctive therapies, although they are not proven in this setting of post-operative RV failure. However, they may be more useful as chronic therapy. Refractory RV failure post MCS placement may require subsequent placement of a short or long term right sided mechanical support device.

**Recommendations for Management of Right Ventricular Dysfunction:**

*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. RV dysfunction post MCS should be managed with diuresis, inotropes and pulmonary vasodilators including nitric oxide or inhaled prostacyclin. RV dysfunction refractory to medical management may require placement of a short or long term mechanical RV support device.

   **Level of Evidence: C.**

*Class IIb:*
1. Phosphodiesterase 5 inhibitors may be considered for management of RV dysfunction post MCS.

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

Figure 1. Univariate and Multivariate Risk Factors for RV Failure in the HeartMate II BTT Population. Reprinted with permission from Kormos et al. J Thoracic CardiovascSurg 2010;139:1316-24.\textsuperscript{83}
### Table 1: Assessment of Hepatic Function

#### Child-Pugh Score

<table>
<thead>
<tr>
<th>Measure</th>
<th>1 point</th>
<th>2 points</th>
<th>3 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>&lt; 2.0</td>
<td>2.0-3.0</td>
<td>&gt; 3.0</td>
</tr>
<tr>
<td>Albumin (mg/dL)</td>
<td>&gt; 3.5</td>
<td>2.8-3.5</td>
<td>&lt; 2.8</td>
</tr>
<tr>
<td>Ascites</td>
<td>Absent</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>None</td>
<td>Suppressed with meds</td>
<td>Refractory to meds</td>
</tr>
<tr>
<td>INR</td>
<td>&lt; 1.7</td>
<td>1.7-2.3</td>
<td>&gt; 2.3</td>
</tr>
</tbody>
</table>

Scores

- **5-6**: A
- **7-9**: B
- **10-15**: C

#### MELD score

\[
MELD = [(0.957 \times \ln(\text{Cr mg/dL})) + (0.378 \times \ln(\text{bilirubin (mg/dL)}) + (1.120 \times \ln(\text{INR}))] \times 10
\]

If patient was on HD at least twice in the past week then Cr = 4

<table>
<thead>
<tr>
<th>Score</th>
<th>30-day mortality*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5</td>
<td>3.2%</td>
</tr>
<tr>
<td>6-10</td>
<td>8.6%</td>
</tr>
<tr>
<td>11-15</td>
<td>21.9%</td>
</tr>
<tr>
<td>16-20</td>
<td>44.0%</td>
</tr>
<tr>
<td>21-25</td>
<td>55.6%</td>
</tr>
<tr>
<td>26+</td>
<td>87.5%</td>
</tr>
</tbody>
</table>

*post-op

Teh et al. Gastroenterology 2007;132:1261-1269
# Table 2: University of Pennsylvania RV Failure Risk Score

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odds Ratio</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac index ( \leq 2.2 ) L/min/m(^2)</td>
<td>5.7</td>
<td>18</td>
</tr>
<tr>
<td>RVSWI ( \leq 0.25 ) mmHg*L/m(^2)</td>
<td>5.1</td>
<td>18</td>
</tr>
<tr>
<td>Severe RV dysfunction pre-op</td>
<td>5.0</td>
<td>17</td>
</tr>
<tr>
<td>Serum creatinine ( \geq 1.9 ) mg/dL</td>
<td>4.8</td>
<td>17</td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>4.5</td>
<td>16</td>
</tr>
<tr>
<td>SBP ( \leq 96 ) mmHg</td>
<td>2.9</td>
<td>13</td>
</tr>
</tbody>
</table>

## Score Interpretation

<table>
<thead>
<tr>
<th>&lt;50 vs. ( \geq 50 )</th>
<th>Sensitivity 83%, specificity 80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVAD alone (%)</td>
<td>Score &lt;30 – 96%</td>
</tr>
<tr>
<td></td>
<td>Score ( \geq 65 ) – 11%</td>
</tr>
</tbody>
</table>

Table 3: University of Michigan RV Failure Risk Score

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odds Ratio</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasopressor requirement</td>
<td>3.9</td>
<td>4</td>
</tr>
<tr>
<td>AST ≥80 IU/L</td>
<td>2.1</td>
<td>2</td>
</tr>
<tr>
<td>Bilirubin ≥2mg/dL</td>
<td>2.4</td>
<td>2.5</td>
</tr>
<tr>
<td>Serum creatinine ≥2.3 mg/dL</td>
<td>2.9</td>
<td>3</td>
</tr>
</tbody>
</table>

Score Interpretation

<table>
<thead>
<tr>
<th>Likelihood Ratio of RV Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤3.0</td>
</tr>
<tr>
<td>4.0-5.0</td>
</tr>
<tr>
<td>≥5.5</td>
</tr>
</tbody>
</table>

Reprinted with permission from Matthews JC et al. J Am Coll Cardiol 2008;51:2163-72.
Table 4: Intra-Operative and Postoperative Characteristics of Patients who Required RV Support in a HeartMateII BTT Population

<table>
<thead>
<tr>
<th>RVF subgroups</th>
<th>No RVF (n=386)</th>
<th>RVF-RVAD (n=30)</th>
<th>RVF-early inotropes (n=35)</th>
<th>RVF-late inotropes (n=33)</th>
<th>P value§</th>
<th>Any early RVF (n=65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of total patients (n=484)</td>
<td>80</td>
<td>6</td>
<td>7</td>
<td>7</td>
<td>---</td>
<td>13</td>
</tr>
<tr>
<td>Reoperation for bleeding*</td>
<td>72 (19%)</td>
<td>12 (40%)†</td>
<td>7 (20%)</td>
<td>9 (27%)</td>
<td>.03</td>
<td>19 (29%)*</td>
</tr>
<tr>
<td>Bleeding &gt;2 units during implantation</td>
<td>269 (70%)</td>
<td>25 (83%)</td>
<td>21 (60%)</td>
<td>20 (61%)</td>
<td>.15</td>
<td>46 (71%)</td>
</tr>
<tr>
<td>Bleeding &gt;6 units during implantation</td>
<td>102 (26%)</td>
<td>16 (53%)†</td>
<td>7 (20%)</td>
<td>8 (24%)</td>
<td>.01</td>
<td>13 (20%)</td>
</tr>
<tr>
<td>Bleeding &gt;2</td>
<td>207 (54%)</td>
<td>15 (52%)</td>
<td>15 (43%)</td>
<td>12 (38%)</td>
<td>.19</td>
<td>30 (46%)</td>
</tr>
<tr>
<td></td>
<td>Units &lt;48 hours</td>
<td>Units &lt;48 hours</td>
<td>Units &lt;48 hours</td>
<td>Units &lt;48 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Bleeding &gt;6 units &lt;48 hours</strong></td>
<td>110 (29%)</td>
<td>9 (31%)</td>
<td>7 (20%)</td>
<td>6 (19%)</td>
<td>.44</td>
<td></td>
</tr>
<tr>
<td><strong>PRBC during &lt;48 hours</strong></td>
<td>5.5 ± 5.8</td>
<td>14.3 ± 18.9*</td>
<td>4.8 ± 4.8</td>
<td>5.1 ± 5.7</td>
<td>.04</td>
<td></td>
</tr>
<tr>
<td><strong>Cardiopulmonary bypass time (min)</strong></td>
<td>106 ± 61</td>
<td>149 ± 76‡</td>
<td>101 ± 41</td>
<td>99 ± 40</td>
<td>.004</td>
<td></td>
</tr>
</tbody>
</table>

RVF, right ventricular failure; RVAD, right ventricular assist device; PRBC, packed red blood cells.

*P<.05; †P<.01; ‡P<.001 compared with the no-RVF group. §P value for differences between the 4 subgroups.

Figure 1: Univariate and Multivariate Risk Factors for RV Failure in the HeartMate II BTT Population

Your heart failure is defined as a condition in which your heart is unable to pump enough blood to support the basic needs of your body. This can make you feel tired, have abnormal rhythms, and shortness of breathe, in addition to causing your other organs to fail (e.g. liver or kidneys). You are being offered this treatment option because you have a marked increase risk of irreversible end-organ damage or death over the \( \text{(time period)} \). For this reason, you are being considered for placement of a Mechanical Circulatory Support Device (MCSD) at \( \text{(XXX Hospital & Health System)} \). The heart pump is designed to take over the pumping action of your heart but before you undergo this procedure, it is important that you and your family understand the options, benefits, risks, and expectations associated with having a MCSD. It is required that you and your proposed caregiver(s) understand and agree with the treatment plan and are willing to participate in the guidelines outlined in the following pages.

At this time, you are being considered for a MCSD or more commonly called a Ventricular Assist Device (VAD) for Bridge to Transplantation. Bridge to transplant (BTT) is when a VAD is used to help extend the life of someone waiting for a heart transplant. This is subject to change pending the results from your evaluation and your Physician’s decision. This consent pertains only to VAD therapy; you will receive information regarding heart transplantation allocation, procedures, and risks from the transplant program at a different time. Although you are being considered for MCSD implantation for Bridge to Transplantation, it is possible that you will not be a transplant candidate after you receive the MCSD if your medical condition worsens.
At this time, you are being considered for a Ventricular Assist Device (VAD) for Destination Therapy. Destination therapy is when a VAD is used as a long-term treatment for patients who are not candidates for transplant, such as those with end-stage congestive heart failure. In these patients, the pumps are placed permanently to help the heart work better. This is subject to change pending the results from your evaluation and your Physician’s decision.

Types Of Mechanical Circulatory Support Devices:
A MCSD is a pump that assists or replaces a weakened heart and carries blood to the rest of your body. There are several different types of mechanical circulatory support devices:

- Left ventricular assist devices (LVAD) help the left side of the heart pump blood to the largest artery of the body, the aorta.
- Right ventricular assist devices (RVAD) help the right side of the heart pump blood to the lungs. Bi-ventricular assist devices (BVAD) help both sides of the heart pump.
- Total Artificial Heart (TAH) that replaces the heart and pumps blood to the body.

MCSDs can also be categorized into short and long-term therapies. Short-term devices are considered when patients are in cardiogenic shock and need help to pump blood for a few short hours to a few days/weeks. Long-term devices are used for patients for months to years. Some patients may receive a short-term device prior to implantation of a long-term device.

When Is A VAD Used?
A VAD is used to assist the pumping action of a severely weakened heart. It works with your heart to improve and increase blood flow; it does not replace your own heart. When medications can no longer help, and other surgical
options have been exhausted, a physician may recommend a VAD. VADs are most often used for patients experiencing New York Heart Association (NYHA) Class III-IV heart failure symptoms.

**Other Medical Options:**
If you are not found to be a candidate for VAD implantation or if you decide that a VAD is not the best option for you, you will continue to receive customary standard of care. You may also continue optimal medical management alone including the use of inotrope therapy. An inotrope is an IV medication that helps the strength of the hearts contraction. However, the reason that you are being considered for VAD implantation is because optimal medical management has not been adequate and without a VAD, your condition is likely to deteriorate over time.

**You May Not Be Eligible To Receive A MCSD If You Are Found To Have Any Of The Following:**
- Uncorrected thyroid disease
- Obstructive or restrictive cardiomyopathy
- Amyloidosis
- Active pericardial disease
- Untreated aortic aneurysm
- Irreversible pulmonary disease or fixed pulmonary hypertension
- Irreversible renal disease
- Irreversible liver disease
- Unresolved stroke or uncorrected cerebral vascular disease
- Irreversible cognitive dysfunction
- History of psychiatric disease, uncontrolled affective disorder, or any cognitive dysfunction that may prevent you from managing self-care
- Diabetes with severe retinopathy or peripheral neuropathy
• Obesity
• Severe chronic malnutrition
• Uncorrected blood disorders
• Active uncontrolled infection
• Pregnancy (positive pregnancy test)
• Inadequate social support to be successful at home after surgery
• A history of chronic noncompliance
• Using illicit drugs or alcohol

Possible Benefits:
The overall goal is improved health and quality of life. In most cases, because circulation has been restored as a result of the MCSD, you can expect to have more energy and also experience less heart failure symptoms. Since MCSDs help deliver more oxygen rich blood, you may feel well enough to resume many of the usual activities and hobbies that you enjoy. The improved circulation may prolong life and may improve some organ damage caused by your heart failure. This is supported by some studies that have shown that LVAD patients have a longer survival than patients treated with medications alone. Although the VAD can improve your chances for survival, the type and severity of your heart disease may outweigh any benefits from the device and you may still die.

Possible Risks:
As with any surgery or procedure, there are risks and the possibility of complications. There are also risks related to the operation itself and undergoing anesthesia, and risks related to the device itself. You will discuss the risks in detail with the Cardiac Surgeon who intends to perform your surgery. Below is a list of risks related to the surgery and the MCSD.

Operative Procedure Risks:
There are many risks with this operation including but not limited to: death, heart attack, stroke, nerve injury, blood clots, bleeding and hemorrhage, hemolysis, infection, development of new antibodies in your blood, mediastinitis, arrhythmia, right heart failure, heart block, or the need for pacemaker or ICD implantation. In addition, the need for re-operation for any cause, renal, hepatic or pulmonary failure resulting in death or long-term need of ventilation or dialysis, and blood transfusion with its risk of HIV, and hepatitis. Studies have also shown that patients may have problems with memory, attention, and speed of processing thoughts after a cardiac surgical procedure. Any of these complications will be explained to you in more detail if you desire. In addition to these potential complications, there may be other risks that are currently unknown. The longer you are on the device, the greater the chances that complications will develop. It is also possible that you may reach a point where your quality of life is so impaired, that the decision to terminate your VAD-support will need to be addressed.

**LVAD Therapy Risks (After The Surgery):**
Include but not limited to: death, need for re-operation, device malfunction or device infection, blood clots, stroke, pain, or bleeding. Patients may also experience a potential decrease in their quality of life including limitations of their normal activities. In addition, 24-hour caregivers may experience increased stress in their day-to-day life as a result of caring for a loved one with a VAD.

**Evaluation Process:**
There will be many people involved in the evaluation process to assure that this is the best choice for you. You will receive a number of tests and consultations. Some of the people that may help evaluate you include Heart Failure Physicians, Cardiac Surgeons, Social Workers and VAD Coordinators. During this process, you will be given education about the MCSD and the care that you would require. After the evaluation, the group will decide if you meet the criteria to have a MCSD
implanted. You may require or have already been implanted with a short-term VAD prior to surgery for a long-term VAD.

**Device Choice:**
MCSDs are currently approved by the Food and Drug Administration (FDA) to be used as Bridge to Transplantation (BTT) or Destination Therapy (DT). A full list will be provided for you and your family to review if desired. This Health System also participates in clinical trials with devices that are considered investigational, and are not yet FDA approved for BTT/DT. Your Surgeon and Cardiologist will discuss with you which device is the best option for you. VADs have four main parts: the implantable heart pump, a tube that passes through the skin of your abdomen (driveline), a controller (small computer) that controls the pump operation, and an external power source (batteries or power device). In addition, there are other VADs that are used temporarily when patients are in cardiogenic shock.

**What if I Change My Mind Prior to Surgery?**
You have the right to refuse surgery at any time. This consent will help you to make an informed decision. If you choose that this is not the best option for you at this time, you may choose to be re-evaluated at a later time and you may choose to receive the implant at a later time if you are still a candidate.

**Surgical Procedure:**
The surgical procedure to implant the VAD will require open-heart surgery and can take on average between 6-12 hours. The surgeon will need to make an incision down the front of your chest to reach your heart. You will have a breathing tube (endotracheal or ET tube) and be under general anesthesia. The VAD is placed below the heart and the surgeon will connect the pump to your heart and secure it in place with sutures. Once the pump is in place, the LVAD along with your natural heart will resume pumping blood through your body. After the surgery is completed, you will return to the ICU.
Post-Operative Care Expectations:

Upon arrival to the ICU, you will receive close monitoring and support from the following medical mechanisms:

- Heart monitor (telemetry) to monitor heart rate and rhythm.
- A breathing tube (endotracheal tube) to assist with breathing and maintain and open airway.
- An oral-gastric tube will be utilized to keep the stomach empty when connected to suction, as well as to give the nursing staff the capability to administer oral medications directly into the stomach.
- A Foley catheter to measure urinary output.
- A Swan-Ganz Catheter to measure pressures within the heart and lungs.
- An arterial line catheter in order to measure arterial blood pressure.
- Chest tubes to collect and measure drainage from surgery.
- A VAD driveline that exits the skin in the abdominal area and is connected to the VAD power source.
- Temporary pacemaker wires which may aid in the event of an arrhythmia associated with heart surgery.

You will receive medications for sedation and to control your pain in order to achieve a tolerable level of comfort. You will also be on IV medications until your blood pressure and fluid status are stable. Your home medications will be resumed as soon as possible if still medically relevant. In addition to your previous taken medications, patients with VADs are commonly prescribed medications for anticoagulation/anti-platelet, antibiotics, blood pressure, and vitamin/mineral supplements. Your length of stay in the ICU will depend on how fast you recover. Once you are more stable, breathing on your own with your lines and tubes out, you will be transferred to a general care unit where you can expect to stay for another 1-3 weeks. On average, your total length of stay will be about three weeks after your surgery. During this time, it is expected that you and your family will
begin to learn to manage the device and learn how to manage your care at home. Most patients are able to return home after VAD implantation, but this cannot be guaranteed. Complications may require a prolonged period of hospitalization. If you are unattended and the device fails, you may not be able to perform the emergency procedures yourself, which could result in death and/or blood clots in the device.

**Education:**
Verbal, written, and visual educational materials are provided throughout your hospitalization and are available to anyone involved in your care at home. You and your caregiver(s) will be trained by a VAD Coordinator on how to manage your care and device. Other staff such as your bedside Nurse, the Occupational and Physical Therapists will also provide training to you. You and your caregiver(s) must show ability to manage the device, understand how it operates, troubleshoot problems, and care for your driveline exit site. It is expected that a caregiver(s) will be present and available while you are in the hospital to learn how to manage the device and how to care for you when you are at home. The education will be an ongoing process while you are here at the hospital. Near the time of your expected discharge, your family and/or caregivers will be required to show competency in the care and management of you and your VAD. Once it has been determined that you and your caregiver(s) are competent in your MCSD care, you will participate in an outing away from the hospital with a trained hospital team member in attendance with you. Following the supervised outing, you and your caregiver(s) will perform an unsupervised outing away from the hospital. In addition, a VAD Coordinator will ensure that your local fire department, emergency personnel, and any other community members will be given education materials and training as necessary. Your home must have consistent electricity and phone services; the outlets must be three pronged and grounded. Any additional safety needs are arranged during this time.

**Discharge Process:**
Your daily progress will be followed by a team of people involved in your care including your Surgeon, Cardiologist, VAD Coordinators, Staff Nurses, Nurse Practitioners, Physician Assistants, Physical/Occupational Therapy, Social Workers, and a Discharge Planner. They will monitor your recovery and help you to adjust to life with a VAD. Soon after your surgery, it will be very important to begin preparing for your discharge. You will have to be both physically recovered and show competence in the management of your VAD to be discharged. Most patients return home after successful outings; however, some patients choose to live with a caregiver or need a rehabilitation facility for a short period before returning home. If resources allow, a Visiting Nurse may be recommended to come to your home and assist you in your care when you return home. The length of time that the Visiting Nurse will come to your home will depend on your overall recovery. It is recommended after you return home that you enroll in a Cardiac Rehab program to continue to improve your physical health.

**Follow up care:**
After you are discharged, you will follow up with your Surgeon, your Heart Failure Cardiologist and your VAD coordinator. They will collaboratively care for you and make decisions about your treatment. Typically, your first visit will be 1-2 weeks after discharge, then monthly thereafter while you have the VAD. Once you are considered a stable established patient, your Physicians may decide that you can follow-up every 2-3 months. Along with seeing your Cardiologist and Surgeon, you will have laboratory testing, and other physiological testing done on a regular basis in order to monitor and maintain your progress and health. The types of testing that you may need and the frequency will be decided by your Physicians but can include blood tests, EKG, Echocardiogram, Right Heart Catheterization, VO2 Treadmill Stress Test, and Implantable Cardioverter Defibrillator (ICD) device
check. If you have received an investigational VAD, you may have other testing that will be required for the research study. Many VADs require patients to take anticoagulation medications, also known as “blood thinning” medications. You will also be in frequent contact with a VAD Coordinator who will make phone calls to assess how you are doing at home and assist you with any problems that may arise. A VAD Coordinator, a Heart Failure Cardiologist and a Surgeon are also available 24 hours a day in the event that you have an emergency. On average, you can expect that within 12 weeks after surgery, you will be able to return to most activities, with the permission of your VAD Team.

**Lifestyle Changes:**
You will have few limitations and can resume most usual activities. Certain activities are hazardous or fatal after implant. Persons with implantable LVADs must not allow their controller/computer and electrical equipment to submerge in water. Showering is possible with proper protective equipment. You may only resume showering once your driveline has healed and your surgeon gives their permission. Swimming and baths are prohibited. Contact sports, repetitive jumping, or impact with an airbag are examples of activities that may cause trauma to the pump attachments and must be avoided. Medical care after implant includes lifetime follow up to monitor device function and health status. You may not have a magnetic resonance imaging (MRI) test because of the magnetic fields. You may not vacuum due to the static electricity. You will also not be permitted to drive, as this is a risk to yourself and others. LVAD therapy requires significant self-care responsibility and a willingness to participate with you LVAD team. Driveline exit site dressings must be performed daily using sterile technique or as directed by the VAD team. Maintenance care of the device components, batteries, and driveline is necessary to prevent pump failure, infections, or other serious complications.

**VAD Equipment:**
Along with the device that is implanted inside your body, you will have a number of other external pieces of equipment that will require care and maintenance. You will have a driveline that exits your body through your abdomen that will power a controller, which is the “computer” component that tells the heart pump how to perform. The controller will also tell you about alarms, sounds, and words, on how your pump is operating and if there are any problems. In order to power the device and the controller, you will have batteries and a battery charger and/or power device. The batteries allow you to be mobile and move freely without being attached to outlet power. The charger or power device allows you to be connected to power for long periods of time such as when you are sleeping. Different MCSDs have similar pieces of equipment, but will vary depending on the device you receive. You will receive education and teaching before you leave the hospital to make sure you understand clearly how to operate the equipment and troubleshoot problems that may occur.

By signing this form, you understand and have reviewed the implant procedure as well as the potential benefits and risks involved with the getting a VAD. You also acknowledge and understand the care that will required to maintain this device and yourself, including changes in your lifestyle, and impact on your independence.

I HAVE READ AND UNDERSTAND THE INFORMATION ON THIS FORM AND ON THE PREVIOUS PAGES BEFORE I SIGN THIS CONSENT FORM.

________________________
Signature of Patient or Legally Authorized Representative (if patient is a minor or
Unable to sign)

Printed Name of Legally Authorized Representative (if patient is a minor or unable to sign)
Relationship: Spouse Parent Next-of-Kin

Consent Obtained, Explained and Witnessed by:
Legal Guardian DPOA

Signature of Surgeon

Date: ____/____/_____ Time: ____________ A.M. / P.M.

Questions
We encourage you to learn everything you can about the potential benefits and risks of having a VAD. If you or your family has any questions, you should feel free to contact your Transplant Coordinator, your Cardiologist or your Cardiac Surgeon @ xxx-xxx-xxxx.
Reference List


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