Selection of Candidates for Mechanical Circulatory Support and Risk Management Prior to Implantation for Fixed Comorbidities

Taskforce 1: Patient Selection
Chair: Katherine Lietz, MD
Contributing Writers: see title page

Introduction
Over the last three decades, the field of mechanical circulatory support (MCS) has made tremendous progress with over 30,000 patients receiving durable MCS devices (MCSDs) worldwide. Candidate selection is one of the most important determinants of successful operative and long-term outcomes for patients receiving MCS.

The ISHLT set forth an initiative to address the urgent need for uniform guidelines for MCS candidate selection and management, for use by MCS programs worldwide. These guidelines are intended to help clinicians and programs appropriately evaluate, implant, and manage patients with advanced heart failure who receive MCS. The primary focus of this document is the evaluation and management of patients with surgically implanted durable MCSDs. The management of patients with total artificial hearts (TAH) is not discussed in detail in these guidelines.

Types of MCS Devices
The 2 main types of MCSDs are pulsatile and continuous flow. Currently available MCSDs share the same basic configuration regardless of the manufacturer and include the following components:

a. A blood pump which is implanted in the intracorporeal position
b. A motor housed within the pump
c. Cannulas that connect the pump to the heart and aorta
d. A percutaneous drive line that connects to the pump and exits the patient to allow for communication between the pump and external components

e. A controller which monitors pump parameters and has audible and visual alarms

f. A portable power source to allow unencumbered patient ambulation

g. A system monitor to power the device when the patient is sedentary and to allow for pump adjustment and monitoring

Pulsatile, or positive displacement devices, are commonly referred to as first generation devices. They mimic the beating native heart with filling and emptying phases. Blood is entrained into the pump and forced out into the aorta. The pump consists of a housing divided by a flexible diaphragm, with one half housing the blood chamber and the other half containing the motor or air chamber. For those devices driven by a motor, the rotation of the motor leads to displacement of the diaphragm and ejection of blood. Other devices are driven by compressed air that is used to displace the diaphragm. Cannulas to and from the blood pump contain valves to assure unidirectional blood flow. The pump housing can be inside the body, referred to as an intracorporeal or implantable pump, or outside of the body, referred to as a paracorporeal pump. For many years, these devices provided support for patients awaiting transplantation, or alternatively, as permanent therapy for end-stage heart failure. However, a major limitation of this technology was device malfunction or failure, in large part due to wear of internal bearings.

More recently, continuous flow devices have superseded the positive displacement design. Continuous flow devices have either an axial or centrifugal configured blood pump. In contrast to pulsatile pumps, blood constantly moves through the blood pump, which may be placed next to or within the ventricle itself. Cannulas in these systems are valveless. Axial devices have a torpedo shaped impeller that lies in the same plane as the pump housing, which is connected to ball-and-cup bearings that accelerate blood along its axis. Axial pumps may also incorporate magnetic levitation of the rotor to achieve a design that does not require the use of bearings. Centrifugal devices accelerate blood circumferentially with a rotor that may be suspended within in the blood pool by electromagnetic or hydrodynamic forces.
Although patients with paracorporeal devices can be discharged and supported for long periods of time, they are less suitable than an implantable MCSD for long-term use because of the large external peripherals that do not allow for mobility or ease of use and larger and more numerous percutaneous cannulae.

Devices may be configured to support the left ventricle, the right ventricle, or both. The vast majority of implants are left ventricular assist devices (LVAD), with a minority of patients requiring biventricular (BiVAD) support, TAH, or isolated right ventricular (RVAD) support. The most recent report from the Interagency Registry for Mechanically Assisted Support (INTERMACS) demonstrates that from January 2010 to June 2010, LVADs accounted for 87% of all MCSD implantations in the United States, followed by BiVADs in 10%, and TAH in 3%.

**Indication for MCS Device Implantation**

As of 2012 in the United States, two major indications for MCS are accepted by regulatory bodies and payors: bridge to cardiac transplantation (BTT) or permanent therapy for end-stage systolic heart failure, referred to as destination therapy (DT). Prior to 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. Despite the majority of patients being implanted as BTT, only about half of these patients are actually listed for transplantation at the time of MCS. 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 referred to as “bridge to candidacy” (BTC). Contraindications to transplant such as pulmonary hypertension, renal impairment, or obesity may resolve after a period of MCS 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 deemed DT after a period of support.\textsuperscript{4}

Bridge to recovery may also be a goal of MCS therapy in some patients. However, patients who experience recovery of their ventricles to the point where a device can be explanted account for only about 1-2% of all implants.\textsuperscript{2} Although BTT and DT are formally recognized as different indications in the US, many regulatory bodies do not make a distinction between BTT and DT.

**Evaluation of Candidates for MCS Device Implantation**

*Identification and Treatment of Reversible Causes of Cardiac Disease*

The initial evaluation for MCS or heart transplantation begins with the identification of potentially reversible factors that could contribute to worsening heart failure. The presence and degree of coronary ischemia, valvular heart disease, arrhythmias, or cardiotoxic agents should be determined, and appropriate therapeutic measures taken as indicated. Evidence-based heart failure therapy should be optimized, including consideration of chronic resynchronization therapy (CRT) in appropriate patients. Temporary partial circulatory support systems (e.g. intraaortic balloon pump [IABP] or extracorporeal membrane oxygenation [ECMO]) can be utilized for patients presenting in cardiogenic shock to stabilize hemodynamics and allow for ventricular as well as end-organ recovery. Patients presenting in shock after an acute myocardial infarction may require percutaneous or surgical revascularization in combination with temporary support.

**Assessment of Potential Transplant Candidacy**

Since heart transplantation currently provides superior long-term outcomes in comparison to MCS, patients who are being considered for MCS typically are also assessed for cardiac transplantation. DT is considered for patients deemed ineligible
for transplant. Despite their suitability for transplant, many patients may eventually require MCS as BTT given the shortage of donor organs.

Goals of Evaluation for MCS Device Implantation

A number of factors must be considered during the patient assessment for MCS, beyond the presence of advanced heart failure. Comorbidities, surgical risk, expectation of benefit, psychological and social support, and the type of device must also be determined prior to implant. Many patients also require a period of aggressive pre-operative medical therapy to optimize their condition prior to MCS (see Section 2).

Recommendations for the Evaluation Process of MCS Candidates:

Class I:

1. All patients should have any potentially reversible causes of heart failure addressed prior to consideration for MCS.

   Level of Evidence: A.

2. All patients referred for MCS should have a transplant evaluation prior to implant.

   Level of Evidence: A.

Evaluation of Heart Failure Severity and Timing of MCS Implantation

Clinical Classification of Advanced Heart Failure Severity

New York Heart Association Classification. The New York Heart Association (NYHA) system was introduced in 1928, and it continues to be a useful tool in the assessment of heart failure severity. Patients who have dyspnea with mild activity are considered NYHA Class III. Often, this class is informally divided into Class IIIa and IIIb, with the latter having dyspnea with very mild activity such as bathing or changing clothes. Patients who have persistent dyspnea at rest or who are inotrope dependent, regardless of their functional capacity, are considered NYHA Class IV.

INTERMACS Classification. Limitations of the NYHA classification system with regard to categorization of advanced heart failure lead to the development of INTERMACS profiles. Seven profiles range in heart failure severity from patients who
are NYHA Class IIIb (profile 7) to those in refractory cardiogenic shock (profile 1) (Table 1). These profiles correlate to some extent with patient outcomes, and patients in the lowest INTERMACS profile have the worst outcomes. However, large studies in patients with profiles 4 through 7 are not available, and the outcomes of these patients in comparison to those in profile 3 have not been assessed. Although not prospectively validated, the INTERMACS classification is a very useful tool to characterize the severity of illness for patients with advanced heart failure. Of note, patients with refractory arrhythmias, regardless of INTERMACS profile, constitute a high risk population.

Recommendations for the Clinical Classification of MCS Candidates:

Class I:

1. All patients being considered for MCS should have their NYHA class assessed.
   
   **Level of Evidence: C.**

2. All patients being assessed for MCS should have their INTERMACS profile determined.
   
   **Level of Evidence: C.**

Risk Stratification to Determine Timing of MCS Therapy

MCS 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. Ambulatory patients with advanced heart failure who are not inotrope dependent (INTERMACS profile 4-7), constitute one of the most challenging groups with regard to determining the optimal timing for MCS. Clinicians following these patients over time should remain vigilant to factors known to be associated with worsening prognosis. Clinical indicators of decline include worsening reported functional capacity, inability to tolerate neurohormonal antagonism, problematic volume management, recurrent hospitalizations, and recurrent implantable cardioverter defibrillator (ICD) shocks. Traditionally, physicians have focused on cardiac and hemodynamic indices when assessing prognosis in heart failure patients. However, it
has recently been appreciated that in addition to indices of cardiac performance, measures of end-organ function also need to be assimilated into the decision making algorithm. Several risk scores incorporating cardiac and non-cardiac indices exist, and these may aid in determining prognosis by allowing clinicians to calculate expected survival for their heart failure patients with ongoing medical management at a given point in time. Several examples are described below.

**Seattle Heart Failure Model.** The Seattle Heart Failure Model (SHFM) was originally derived and validated in a cohort of ambulatory heart failure outpatients from four clinical trials and two observational registries. It is comprised of 20 readily available clinical, laboratory and therapeutic variables. These include age, gender, weight, ischemic etiology, NYHA class, LVEF, systolic blood pressure, medications (ACE-I, angiotensin receptor blocker [ARB], beta blocker, mineralocorticoid receptor antagonist, statin, allopurinol, and diuretics with dosage), hemoglobin, lymphocyte percent, uric acid, sodium, total cholesterol, presence of QRS $\geq$120 ms, and use of CRT, ICD or both.\(^7\) Decreasing event-free survival has been associated with low-, medium- and high-risk scores as calculated by the model in a cohort referred for transplantation.\(^8\) When additional variables of IABP, ventilator and inotrope use were added to the model and validated against the REMATCH cohort, there was good correlation between observed outcomes and those predicted by the model in the medically treated and LVAD treated groups.\(^9\) However, some studies have found the model to underestimate risk, for example in African Americans, patients listed UNOS status 2 for cardiac transplantation, and those with INTERMACS level 1. cardiogenic shock, including patients who subsequently require biventricular support.\(^{10-12}\) Since the model has not been validated in hospitalized patients, it should be used cautiously in this population.

**Heart Failure Survival Score (HFSS).** The HFSS includes 7 parameters: resting heart rate, mean blood pressure, left ventricular ejection fraction (LVEF), serum sodium, presence of ischemic heart disease, presence of QRS $\geq$120ms, and peak VO\(_2\) on metabolic treadmill testing. Scores are stratified into low, medium and high risk categories.\(^{13}\) The HFSS provides better discriminative value than peak VO\(_2\) alone among patients of different ages, genders, ethnic groups, in those receiving beta
blockers, and in the era of CRT-D.\textsuperscript{14-17} The need to perform metabolic treadmill testing with its inherent challenges is a limitation of this score. A comparison of the HFSS to the SHFM showed similar discriminative ability to predict outcome in patients referred for heart transplantation.\textsuperscript{8}

\textit{Role of Cardiopulmonary Stress Testing.} Cardiopulmonary testing described by Mancini et al in the early 1990’s has been one of the best tools in predicting long-term outcomes of non-inotrope dependent patients with advanced heart failure. It has been routinely used for many years in the determination of transplant candidacy in ambulatory patients.\textsuperscript{18} The accepted thresholds for listing candidates for heart transplantation include peak VO\textsubscript{2} ≤ 14 mL/kg/min in patients intolerant of a β-blocker and peak VO\textsubscript{2} ≤ 12 ml/kg/min in patients who receive β-blockers. In addition, for young patients (<50 years) and women, it is reasonable to consider using alternate parameters in conjunction with peak VO\textsubscript{2}, such as <50% predicted peak VO\textsubscript{2} and VE/VCO\textsubscript{2} slope with adjustment of peak VO\textsubscript{2} to lean body mass in obese patients.\textsuperscript{19} It is important to note that in the current era of medical and device therapy, interpretation of the cardiopulmonary test in isolation from other predictors of survival may not be sufficient.

\textit{Need for Inotropes.} Inotrope dependence is an important threshold to consider for MCS. Several studies have demonstrated that patients who are inotrope dependent have extremely poor outcomes on medical therapy. Subgroup analysis from the REMATCH trial showed that randomization to VAD conferred a survival benefit in comparison to medical therapy alone in patients who were on inotropes at baseline. No survival benefit of VAD therapy was detected in the subgroup of patients who were not receiving inotropes at baseline.\textsuperscript{20} Single center and multicenter trials have demonstrated very high mortality in patients on chronic inotropic therapy.\textsuperscript{21,22} Heart transplantation and MCS have been shown to provide a significant survival benefit at this stage of heart failure and, in the current era, these therapeutic options should be routinely considered for patients demonstrating inotrope dependency.
Prediction of Survival Post MCS

Several risk scores have been developed to predict outcomes after MCS, which may be helpful in decision making. Proceeding with a futile implant places the patient and their family through undue anguish and also drains limited health care resources. Patients proceeding to MCS should have a reasonable chance of survival and improvement in quality of life.

Risk scores, including the Columbia risk score, the Lietz-Miller score, the APACHE II score, the INTERMACS level and SHFM were retrospectively applied to a cohort of continuous flow LVAD patients, and the scores' correlation with 30 day, 90 day and 1 year mortality were evaluated. This study found that the Columbia and Lietz-Miller scores, originally developed in patients with pulsatile MCSDs, were not predictive of mortality at any time point in this group of continuous flow patients. The APACHE II and INTERMACS scores correlated with 90 day and 1 year outcomes, and the SHFM correlated with outcomes at all three time points with a superior ability to stratify continuous-flow LVAD patients into low- and high-risk groups and in its prediction of post-implantation mortality. In other studies, the Lietz-Miller score was only modestly discriminative in continuous flow patients who were classified into the high-risk group, with increased observed in-hospital mortality. The INTERMACS score was useful in risk-stratifying patients in a multicenter analysis. More recently, the HeartMate II risk score (HMRS), derived using data from the HeartMate II BTT and DT trials, showed incremental improvement in survival stratified by high, medium and low risk scores. The multivariate predictors of mortality were age, albumin, international normalized ratio (INR), implantation after May 2007, and if the implant center had performed at least 15 implants. Not only was this risk prediction model based entirely on continuous flow devices, but the score was also validated in a separate cohort of patients with continuous flow devices.

Decision Making for Advanced Therapy: MCS versus Transplantation

Once the decision to proceed with advanced therapy has been made, it can be challenging to determine whether to proceed with MCS or await a donor organ. In
patients who are hemodynamically tenuous, MCS should be considered early because post-transplant outcomes may be adversely affected by the development of irreversible end-organ dysfunction and pulmonary venous hypertension. This decision has to be weighed against local donor availability, the recipient’s blood group, and body size. A general approach to the decision making for MCS (BTT and DT) is presented in Figure 1.

**Recommendations for Risk Stratification for Consideration of MCS:**

*Class Ila:*

1. Long-term MCS 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.

   **Level of Evidence: C.**

2. Patients who are inotrope dependent should be considered for MCS, 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 MCS. This determination may be aided by risk assessment calculators and cardiopulmonary stress testing.

   **Level of Evidence: C.**
4. Heart failure patients who are at high-risk for one year mortality using prognostic models should be referred to advanced therapy including heart transplant, or MCS (BTT or DT) as appropriate.  

**Level of Evidence: C.**

**Cardiovascular Considerations for MCS Device Implantation**

*Coronary Artery Disease*

Ischemic heart disease is the most common indication for device implantation, accounting for nearly half of all MCSD implants.\(^{29,30}\) Surgical revascularization may take place with a predetermined plan for temporary MCS if the patient cannot be weaned from bypass. However, this practice is not an approved indication for an intracorporeal device. For those with prior bypass surgery, the number of prior sternotomies affects surgical risk and the location of bypass grafts should be identified by computed tomography (CT) scanning to allow proper surgical planning.

**Recommendations for Patients with Coronary Artery Disease:**

*Class Ila:*

1. Patients being considered for MCS 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.**

*Acute myocardial infarction.* Acute myocardial infarction with cardiogenic shock presents several challenges. Use of anticoagulation and antiplatelet therapy during the percutaneous intervention can substantially increase the bleeding risk at the time of device placement. For those who were not revascularized prior to their hemodynamic deterioration, temporary MCS may allow for stabilization and subsequent percutaneous or surgical revascularization. Permanent MCS in the first several days after ischemia of the LV apex can be complicated as the ischemic tissue can be friable and compromise the placement of the inflow cannula. Patients presenting with an acute infarction may
not have sufficient remodeling of the LV cavity to allow the proper functioning of a continuous flow device, pulsatile devices may need to be considered in such a setting (see restrictive myopathy below).

**Recommendations for Patients with Acute Myocardial Infarction:**

*Class IIb:*

1. If possible, permanent MCS should be delayed in the setting of an acute infarct involving the LV apex.

   **Level of Evidence:** C.

**Non-Ischemic Cardiomyopathy**

Non-ischemic cardiomyopathy is the second most common indication for MCSD implantation. Potentially reversible causes of myopathy such as myocarditis, peripartum myopathy, or environmental or self-induced toxins should be considered prior to implantation.

**Restrictive and Hypertrophic Cardiomyopathies**

LV support for patients with advanced heart failure due to restrictive or constrictive physiology, such as constrictive pericarditis, hypertrophic cardiomyopathy, cardiac amyloidosis or other infiltrative heart disease should be considered with caution. Many of these processes affect both the left and right ventricles. Therefore, left ventricular (LV) support alone may be inadequate, and biventricular support or a TAH may be required. These myopathies may also present in their end-stages with little to no dilation of the LV chamber, which may compromise the function of a continuous flow device due to frequent suction events. For patients who require MCS but who do not have a dilated left ventricle, a pulsatile device(s) or a TAH may need to be considered.

**Congenital Heart Disease**

While many patients with congenital heart disease may be candidates for MCS, a careful assessment of prior surgeries, shunts, and the anatomy of the heart, great
vessels, and venous system are essential. Single ventricle physiology, multiple shunts or atypical situs may be prohibitive for proper pump function or placement.

**Recommendations for the Evaluation of MCS Candidates with Congenital Heart Disease:**

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

*Class IIa:*
1. Patients with complex congenital heart disease, atypical situs, or residual intraventricular shunts who are not candidates for LV support should be considered for a TAH.
   
   **Level of Evidence: C.**

**Valvular disease**

*Aortic*

*Pre-existing aortic mechanical valves.* The presence of a mechanical aortic prosthesis presents a risk with MCS because the valve opens infrequently, if at all, and places the valve at risk for thrombus formation and subsequent embolic events. As such, patients who are considered for MCS typically have the mechanical valve replaced by a bioprosthetic valve at time of implant. Another option is to oversew the aortic root. However, if the patient experiences a device failure, then the ability to maintain even marginal cardiac output through the aortic valve is lost. Notably, a functioning bioprosthetic valve does not require replacement.
Recommendations for Aortic Valve Disease:

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.

Aortic regurgitation. One of the most important anatomic requirements for MCS implantation is a competent aortic valve. In the setting of aortic insufficiency, the flow from the outflow cannula regurgitates through the aortic valve back into the left ventricle and then back into the pump, creating a bind loop of flow that does not contribute to perfusion.

Recommendations for Aortic Regurgitation:

Class I:
1. More than mild aortic insufficiency should prompt consideration for surgical intervention during device implantation (see section 3).

   Level of Evidence: C

Aortic stenosis. Aortic stenosis usually does not require correction before implanting an MCSD. However, significant stenosis often coexists with aortic insufficiency and may need to be surgically addressed as discussed in section 3.
Recommendations for Aortic Stenosis:

*Class Ila:*
1. Patients with aortic stenosis of any degree that is accompanied by more than mild aortic insufficiency should prompt consideration for aortic valve replacement during MCS implant (see section 3).

   **Level of Evidence:** C.

*Class Iib:*
1. Patients with severe aortic stenosis should be considered for aortic valve replacement, regardless of the degree of concomitant aortic insufficiency.

   **Level of Evidence:** C.

*Aortic root disease.* The presence of severe aortic root dilation may be a causal or contributing factor to aortic insufficiency and should be a consideration when approaching patients with aortic insufficiency. There are few data on lone aortic root aneurysms at the time of MCS, but the need for extensive root repair clearly adds to the risks of MCS. Lastly, aortic root calcification should be considered as it is the location of the anastomosis of the outflow graft. Extensive atheromatous disease of the ascending aorta may increase the risk of thromboembolic events at the time of implantation, and a careful pre-operative approach should include such considerations (see Section 3).

Recommendations for Aortic Root Disease:

*Class Ila:*
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.
Mitral Valve Considerations

Mitral valve regurgitation. A significant proportion of mitral regurgitation (MR) in end-stage heart failure is from annular enlargement secondary to LV dilation. Once the LV is decompressed with MCS, the MR frequently resolves or is only trace to mild in severity and can often be managed through adjustment in pump speeds and optimizing medical therapy. If a patient is deemed likely to recover, then the valvular surgery may be considered at the time of implant or explant (see section 3).

Recommendations for Mitral Valve:

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

   Level of Evidence: C.

Class III:
1. Routine mitral valvular repair or replacement for severe MR is not recommended.

   Level of Evidence: C.

Mitral valve stenosis. Unlike aortic valve stenosis, mitral stenosis will limit LV filling and thus pump inflow, therefore limiting proper decompression of the left atrium and pulmonary circulation. Thus, significant mitral stenosis needs to be addressed at the time of implant to allow for proper decompression of the left atrium and functioning of the device.

Recommendations for Mitral Valve Stenosis:

Class I:
1. Valve replacement with a tissue valve should be considered if there is moderate or worse mitral valve stenosis at the time of LVAD implantation.

   Level of Evidence: C.
Mechanical mitral valves. The high transvalvular flow associated with an apical inflow LVAD ensures thorough washout. Therefore, the presence of a mechanical valve in this position is not felt to increase chance of embolization. However, higher maintenance INRs may be warranted.

Recommendations for Mechanical Mitral Valves:

Class III:

1. Routine replacement of properly functioning mechanical mitral valve is not recommended.

   Level of Evidence: C.

Tricuspid valve (TV). Mild to moderate tricuspid regurgitation (TR) generally is tolerated during LVAD support and frequently improves after MCSD implant due to the reduction in RV afterload. However, the resolution of TR is multifactorial and depends on TV annular anatomy, leaflet anatomy (e.g., leaflet scarring secondary to pacing leads), degree of RV afterload reduction, and resolution and reversibility of high pulmonary vascular resistance. Thus, an analysis of these factors may prompt consideration for TV repair. Generally, severe TR may compromise right ventricular (RV) function, thereby exacerbating post-operative RV function and should be addressed at the time of MCSD implant (see section 3). However, there are numerous factors which contribute to the decision to repair the tricuspid valve such as the leaflet morphology, the presence and number of pacing wires, or the presence of pulmonary hypertension.

Recommendations for Tricuspid Valve Regurgitation:

Class Ila:

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

   Level of Evidence: C.
**Infectious Endocarditis**

In the presence of active endocarditis, there is a high risk of seeding the implanted device. These patients are considered ill-advised for MCS.

**Recommendations for Infectious Endocarditis:**

*Class III:*
1. Acute valvular infectious endocarditis is an absolute contraindication to MCS implantation.
   
   **Level of Evidence: C.**
2. Active infection of an ICD or pacemaker is an absolute contraindication to MCS implantation.
   
   **Level of Evidence: C.**

**Intracardiac shunts**

Atrial septal defects, ventricular septal defects, or other congenital shunts may severely impact pump function and systemic oxygenation (cardio-pulmonary function) and should be addressed at the time of implantation.

**Recommendations for Intracardiac Shunts:**

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

*Class III:*
1. An LVAD alone in the setting of an unrepairable ventricular septal defect or free wall rupture is not recommended.
   
   **Level of Evidence: C.**
**Intracardiac Thrombus**

The presence of intracardiac thrombus is relatively common in the setting of LV dysfunction and dilation. If not recognized at the time of implantation, such thrombi may embolize distally or be ingested into a continuous flow VAD and result in pump dysfunction, hemolysis, pump thrombosis, stroke, or peripheral embolus. Right ventricular thrombi are less common, but they should be considered prior to implanting a RVAD.

**Recommendations for Intracardiac Thrombus:**

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

**Arrhythmias**

*Atrial.* Atrial tachycardia or fibrillation is usually tolerated in LVAD recipients, and these arrhythmias often resolve after a period of MCS due to decompression of the left ventricle and therefore the left atrium. For patients with an LVAD, refractory tachyarrhythmias may precipitate or induce RV dysfunction.

**Recommendations for Atrial Arrhythmias:**

*Class I:*
1. Atrial flutter or fibrillation is not a contraindication to MCS.

   **Level of Evidence: C.**

*Class Ila:*
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.**
Ventricular. Ventricular tachycardia (VT) or fibrillation (VF) often induces or worsens RV dysfunction and thus affects proper filling of an LVAD. VT/VF associated with decompensated hemodynamics prior to implant often resolves with resolution of the heart failure state. However, VT/VF that is not associated with decompensated hemodynamics, such as in the setting of scar or myocarditis, is less likely to resolve after MCS and may require surgical ablation or warrant consideration of biventricular support. Patients who present with VT storm and require urgent MCS should be considered for a BiVAD or a TAH.

Recommendations for Arrhythmia Therapy:

Class IIa:
1. Patients with recurrent sustained ventricular tachycardia or ventricular fibrillation in the presence of untreatable arrhythmogenic pathologic substrate (e.g., giant cell myocarditis, scar, sarcoidosis) or in VT storm, should be considered for biventricular support or for a TAH.
   
   Level of Evidence: C.

Class IIb:
1. Patients with recurrent sustained ventricular tachycardia or ventricular fibrillation in the presence of untreatable arrhythmogenic pathologic substrate (e.g., giant cell myocarditis, scar, sarcoidosis) or in VT storm, should be not be considered for LV support alone. Biventricular support or for a TAH is recommended.

   Level of Evidence: C.

Peripheral Vascular Disease

Peripheral vascular disease itself is not a contraindication to MCS. However, patients undergoing MCS evaluation should be assessed for the presence and severity of peripheral vascular disease. There may be concern for perioperative cerebral complications in patients with severe (>70%) carotid stenosis, especially if bilateral. In asymptomatic patients, however, carotid revascularization may not be necessary prior
to MCS, as successful neurologic outcomes have been shown in patients undergoing cardiopulmonary bypass (for coronary bypass surgery) who have severe carotid disease.\textsuperscript{31,32} In patients who are symptomatic with transient ischemic attack (TIA) or stroke, it may be preferable to proceed with carotid revascularization prior to consideration of MCS.\textsuperscript{33} With regards to femoral artery stenosis, there is a theoretical risk of compromising limb perfusion if urgent cannulation is necessary at that site for cardiopulmonary bypass.

**Recommendations for Peripheral Vascular Disease:**

*Class Ila:*
1. All patients should be screened for peripheral vascular disease prior to MCS.

  **Level of Evidence:** C.

*Class Iib:*
1. Peripheral vascular disease may be a relative contraindication to MCS based on the morbidity and severity.

  **Level of Evidence:** C.

**Life-Limiting Comorbidities and Multi-Organ Failure**

Any severe noncardiac disease that significantly adversely affects two-year survival should be considered a relative-contraindication to device implantation, while systemic disease that limits one year survival is an absolute contraindication. Such diseases include, but are not limited to, advanced or irreversible pulmonary disease, advanced hepatic disease (cirrhosis and portal hypertension), severe peripheral vascular disease, metastatic cancer, and irreversible neurologic or neuromuscular disorders. Multi-organ failure, defined as multiple, progressive, end-organ dysfunction not responsive to medical therapy is almost invariably associated with poor post-implant outcome after MCS.\textsuperscript{2}
Recommendations for Life-Limiting Comorbidities and Multiorgan Failure:

Class III:
1. Consideration of MCS in the setting of multiorgan failure is not recommended.
   
   Level of Evidence: C.

Pulmonary Hypertension

Increased pulmonary vascular resistance has traditionally been associated with increased risk of early cardiac allograft dysfunction.\textsuperscript{34,35} Pulmonary vascular resistance must be assessed with invasive hemodynamics. A transpulmonary gradient >15 mmHg or a fixed pulmonary vascular resistance >5 Wood units has been associated with an increased 30 day mortality rate.\textsuperscript{35} Patients with elevated pulmonary vascular resistance refractory to sequential aggressive heart failure medical therapy, continuous inotropy, and/or an oral prostaglandin inhibitor for 4 to 8 weeks as determined with serial right heart catheterization should be considered for MCS device implantation. Chronic LVAD support can effectively reduce elevated pulmonary arterial pressures even in those deemed refractory to aggressive medical therapy.\textsuperscript{36}

Recommendations for Pulmonary Hypertension:

Class I:
1. All patients being considered for MCS, particularly those being implanted as BTT, should have an invasive hemodynamic assessment of pulmonary vascular resistance.

   Level of Evidence: C.

Neurologic Function

Knowledge about the neurologic and neurocognitive status and history of patients referred for MCS is critical, particularly for those referred emergently. A thorough neurologic examination should be performed to determine potential neurologic risk factors and contraindications for device implantation.\textsuperscript{37} Specifically, post-stroke deficits should be assessed to determine the cognitive ability of the patient to
understand device limitations, alarms, and troubleshooting, and their physical ability to care for the device, such as changing batteries or controllers. All patients should be screened for dementia and those that screen positively should have more formal neuropsychological testing. In emergency cases with uncertain neurologic recovery, a short-term MCS may be considered to allow for proper assessment of the neurologic status of the patient. A recent or evolving stroke is considered at least a temporary contraindication.

**Recommendations for Neurologic Function:**

*Class I:*

1. A thorough neurologic examination should be performed on every patient being considered for MCS. Neurologic consultation should be obtained for patients with significant neurologic disease or significant atherosclerotic vascular disease of their carotid or vertebral systems.

   **Level of Evidence:** C.

2. All patients being considered for MCS 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. MCS is not recommended in patients with neuromuscular disease that severely compromises their ability to use and care for external system components, or to ambulate and exercise.

   **Level of Evidence:** C.
Coagulation and Hematologic Disorders

Attempts should be made to correct or improve clotting abnormalities, similar to the assessment of a patient undergoing any major surgical procedure. All patients should have their PT/PTT, INR, and platelet count assessed. Pre-operative coagulopathies are common in heart failure patients due to hepatic dysfunction and the use of anti-coagulant or anti-platelet medications. When possible, these medications should be stopped prior to implant. There is controversy about continuing the use of clopidogrel during the peri-operative period in patients who have recently received a drug-eluting stent. Few data are available to guide this decision; thus, the risks and benefits for each patient must be weighed individually. Heparin-induced thrombocytopenia (HIT) is a clotting abnormality that warrants consideration for patients who have a platelet count <150,000 or in those who have had a >20% decrease in their baseline platelet count. The serotonin release assay is the most reliable test for establishing the diagnosis of HIT. The presence of HIT may require the use of alternative anti-coagulants (e.g. argatroban and bivalirudin). However, if the patient is stable, HIT can be reassessed over time and if negative, heparin can then be re-considered.

Recommendations for Coagulation and Hematologic Disorders:

Class I:

1. All patients evaluated for MCS therapy should have a PT/INR, PTT, and platelet assessed pre-operatively.

   **Level of Evidence:** C.

2. Baseline abnormalities in coagulation parameters not due to anticoagulants or antiplatelet agents should prompt an evaluation to determine the etiology prior to implant.

   **Level of Evidence:** C.
3. Patients with a history of thrombophilia prior to MCS should have a hypercoagulable assessment prior to implant.
   
   **Level of Evidence: C.**

**Class Ila:**
1. Patients with a clinical syndrome of HIT should have confirmatory testing performed.
   
   **Level of Evidence: C.**
2. Clopidogrel should be stopped at least 5 days prior to surgery unless there is a compelling indication for continued use.
   
   **Level of Evidence: C.**

**Malignancies**

Recent malignancies are an absolute contraindication to heart transplantation. However, in selected cases, MCS can be used to allow for proper oncologic follow up. Patients who have maintained disease free status may be candidates for transplantation. Collaboration with oncology should occur to assess the risk of tumor recurrence in patients being evaluated for BTT who have a history of a treated malignancy. Alternatively, patients who have a reasonable cancer recurrence-free life expectancy (>2 years) may be candidates for MCS as DT.

**Recommendations for Malignancy:**

**Class I:**
1. Patients with a history of a treated cancer who are in long-term remission or who are considered free of disease may be candidates for MCS as BTT, with the involvement of an oncologist to determine risk of recurrence or progression.
   
   **Level of Evidence: C.**
Class IIa:

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

   **Level of Evidence: C.**

Class III:

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

   **Level of Evidence: C.**

Diabetes

Diabetes in and of itself is not a contraindication to MCS. Rather the burden of end-organ disease determines the risk for patients with diabetes. As many as 10% of patients who undergo device implantation have diabetes. Single center studies have reported that carefully selected patients with diabetes on insulin or oral therapy can undergo successful pump placement without increased one year mortality. However, poorly controlled diabetes with end-organ damage, such as peripheral neuropathy, may lessen a patient’s quality of life.

Recommendations for Diabetes:

Class I:

1. All patients should be screened for diabetes prior to MCS 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.

   **Level of Evidence: C.**

**Class IIb:**

1. MCS is relatively contraindicated in the setting of diabetes related proliferative retinopathy, very poor glycemic control, history of foot ulceration, or peripheral neuropathy.

   **Level of Evidence: C.**

**Pregnancy**

   Although successful pregnancy has been reported in LVAD recipients, pregnancy remains a relative contraindication to MCS.\(^{46-49}\) Women who are of child bearing potential who have MCS should be counseled to use contraception. The use of hormonal-based contraception has known thrombotic risks and these risks must be considered in the setting of MCS. However, evidence is lacking to quantify this risk.

**Recommendations for Pregnancy:**

**Class I:**

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

   **Level of Evidence: C.**

**Class III:**

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

   **Level of Evidence: C.**

**Advanced Age**

   Although the risk of operative complications with LVAD implantation increases with patient age,\(^{50}\) encouraging survival outcomes with device implantation have been observed in patients >70 years old.\(^{51}\) While advanced age in and of itself does not
constitute a contraindication to MCS implantation, older patients may be more vulnerable to complications due to their many coexisting co-morbidities. Moreover, daily living with the device may present much greater physical, psychological, and emotional challenges than those experienced by younger patients.

**Recommendations for Age:**

*Class IIb:*

1. Patients >60 years old should undergo thorough evaluation for the presence of other clinical risk factors prior to MCS implantation.

   **Level of Evidence:** C.

**Psychosocial evaluation of MCS candidates**

Potential candidates considered for MCS implantation should undergo comprehensive psychosocial evaluation. The goals of the evaluation process are to (1) identify and appraise any potential psychosocial risks for poor outcome after MCS including risks related to the individual’s psychiatric history or social stability; (2) ensure that the prospective MCS recipient comprehends the risks, benefits and implications of device implantation to the patients and caregiver; (3) determine the patient’s and caregiver’s ability to cope with major surgery and the requirements of life on MCS and review lifestyle circumstances (e.g. employment, family relationships) that might be impacted by MCS; (4) determine that support systems are in place and ensure a realistic plan for recovery and living with the device.

Psychosocial evaluation of MCS candidates should be conducted by a clinical social worker, psychologist, or other similarly qualified health-care professional. The evaluation should be done as soon as device therapy is considered, so that pump implantation can be avoided if major psychosocial contraindications are apparent. The complete psychosocial evaluation should cover the following elements: (1) assessment of the general demographic information; (2) physical functioning; (3) psychological and psychiatric status; (4) behavior and coping; (5) family and support network and (6)
financial situation, as shown in Table 2. Patients in cardiogenic shock may require a brief psychosocial evaluation to exclude the major contraindications.

Assessment of Psychosocial Risk Factors

*Physical functioning.* Patients should be assessed for their physical and cognitive ability to safely operate the device in their home situation. In situations where deficits exist, an individualized plan of assessing competency and safety should be devised. Patients and/or caregivers should be pre-assessed to determine competency to safely assume responsibility for the following: changing power sources, charging batteries, managing alarms and emergencies, stabilizing the driveline and changing the driveline dressing, monitoring and reporting signs and symptoms to the device coordinator.

*Home environment.* The patient’s physical surroundings should be safe. There should be grounded electricity outlets available, access to telephone, free of clutter or unsafe surroundings and accessible by patient, support network and emergency services.

Recommendations for Psychological and Psychiatric Evaluation:

*Class I:*

1. All patients should have a psychological assessment prior to MCS.
   
   **Level of Evidence:** C.

2. All patients should have a screen for cognitive dysfunction prior to MCS.
   
   **Level of Evidence:** C.

3. Family, social, and emotional support should be assessed prior to MCS.
   
   **Level of Evidence:** C.
Class III:
1. MCS 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.

Psychological and psychiatric risk factors. All MCS candidates who are of high psychosocial risk should undergo a thorough psychiatric evaluation to determine potential risk factors and contraindications for MCS implantation. Patients who suffer from active psychiatric illness, and in particular major depression, schizophrenia, or anxiety are at high risk for non-adherence to therapy which may jeopardize device outcomes. Patients with lower levels of social support are at particularly high risk of developing significant psychiatric difficulties post-heart transplant or implant. In addition, morbidity and mortality after transplantation is increased in the setting of serious psychiatric illness. Patients with a significant psychiatric history should be referred to a psychiatrist or therapist as early as possible to ensure that proper treatment is initiated or optimized.

Recommendations for Psychological and Psychiatric Evaluation:

Class IIb:
1. Patients with history of psychiatric illness who are considered for MCS should undergo a thorough psychiatric and psychological evaluation to identify potential risk factors.

   Level of Evidence: C.

Class III:
1. MCS is not recommended in patients with active psychiatric illness that requires long-term institutionalization or who have the inability to care for or maintain their device.

   Level of Evidence: C.
**Adherence to Medical Therapy and Coping Skills.** Compliance with medical recommendations, drug therapy, lifestyle changes and regular follow-up are crucial to the long-term success of MCS.

Medical non-compliance is associated with inferior MCS outcomes. Patients who have displayed non-adherent behaviors prior to pump implantation are at significant risk of displaying the same behaviors after surgery.\(^{59-61}\) Higher levels of social support seems to be an important factor in mitigating non-adherence behaviors.\(^{62,63}\) Therefore, in patients being actively considered for MCS with a history of non-adherent behavior, a strong social support system should be available. Assessment of coping strategies should include standardized testing where possible, as this may provide more objective information regarding coping strategies of patients and their caregivers and the ability to provide structured intervention where necessary.

**Family and Social Network.** Due to the similarities related to ongoing medications, attendance at medical appointments, and the stresses experienced by MCS patients, the social support requirements should be similar to those expected for heart transplantation recipients. The patient’s social support network becomes more important when complications post implant occur. In the case of high risk patients such as those who have been previously non-adherent or those with psychiatric illness, lack of social support has been shown to significantly predict poor outcomes.\(^{62,63}\) Although not demonstrated specifically in VAD patients, lack of a social partner is a significant predictor of graft loss after heart transplantation.\(^{64}\)

**Recommendations for 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 MCS device implantation.

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

   Level of Evidence: C.

Class III:
1. Poor compliance with medical regimens is a risk factor for poor outcomes related to MCS, and rejection 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.

   Tobacco use. Tobacco exposure has been correlated with the development of cardiovascular disease, chronic obstructive pulmonary disease, and lung cancer. Life sustaining therapy with MCS should not be offered to patients who continue unhealthy habits. The patient and family members should understand that continuing to use tobacco while supported on MCS may jeopardize heart transplant candidacy and has unknown effects on platelet function and risk of pump thrombosis. Centers should provide the recommended smoking cessation support for patients and family members if necessary.

Recommendations for Tobacco Use:

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

   Level of Evidence: C.
Class IIa:
1. Previous tobacco use should not preclude rescue 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.**

*Alcohol and Substance Abuse.* Patients who abuse alcohol and other substances experience higher non-adherence and mortality rates. Excessive alcohol or illegal drug use should be a contraindication to elective device implantation. If a patient is already involved in a recovery program, the continuation of this form of treatment should be mandatory. Referral to a substance abuse expert should be made as an adjunct to therapy.

**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 in order to be considered for MCS therapy.

   **Level of Evidence: C.**

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

   **Level of Evidence: C.**

**Caregiver Burden**

It must be kept in mind that caregiver burden is significant in many cases of MCS support. Informed consent from the caregiver designated to assist the LVAD recipient is just as important as acquiring consent from the patient, as caregivers are informally “recruited” to provide continuous care after patients are discharged home. Caregivers undergo vigilant device education and are expected to respond to device emergencies 24 hours a day. This imposes significant physical, psychological, and financial strain on
caregivers.\textsuperscript{66,67} Fear of device emergencies, depression, anxiety and posttraumatic stress disorders have all been described among caregivers.\textsuperscript{68,69} For this reason, a substantial caregiver burden may occasionally become the reason to forgo LVAD surgery for the patient. This is not uncommon in elderly patients who would have to rely on their spouses for help, who often have their own medical problems. MCS programs should therefore have support mechanisms in place for caregivers of MCS patients.

\textbf{Recommendations for Caregiver Burden:}

\textit{Class I:}

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

\textbf{Level of Evidence: C.}

\textit{Class IIb:}

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

\textbf{Level of Evidence: C.}

\textit{Financial Situation and Insurance Coverage.} In countries where socialized medicine is unavailable, a complete assessment of the patient’s financial situation should be performed. Insurance and prescription coverage, or a charity care initiative must be thoroughly established to determine whether the patient has adequate financial support to undergo VAD therapy or heart transplantation.

\textit{Class IIa:}

1. A mechanism must be in place to provide financially for post-operative care.

   Depending on the country, this may be provided by the government, insurance agent or an individual’s family.

\textbf{Level of Evidence: C.}
Table 1. INTERMACS Classification

<table>
<thead>
<tr>
<th>INTERMACS profile</th>
<th>Description</th>
<th>Time frame for intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profile 1</td>
<td>Critical cardiogenic shock: Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels.</td>
<td>Definitive intervention needed within hours.</td>
</tr>
<tr>
<td>Profile 2</td>
<td>Progressive decline: Patient with declining function despite intravenous inotropic support, may be manifest by worsening renal function, nutritional depletion, inability to restore volume balance. Also describes declining status in patients unable to tolerate inotropic therapy.</td>
<td>Definitive intervention needed within few days.</td>
</tr>
<tr>
<td>Profile 3</td>
<td>Stable but inotrope dependent: Patient with stable blood pressure, organ function, nutrition, and symptoms on continuous intravenous inotropic support (or a temporary circulatory support device or both), but of weeks to few months. Demonstrating repeated failure to wean from support due to recurrent symptomatic hypotension or renal dysfunction.</td>
<td>Definitive intervention elective over a period of weeks to few months.</td>
</tr>
<tr>
<td>Profile 4</td>
<td>Resting symptoms: Patient can be stabilized close to normal volume status but experiences daily symptoms of congestion at rest or during ADL. Doses of diuretics generally fluctuate at very high levels. More intensive management and surveillance strategies should be considered, which may in some cases reveal poor compliance that would compromise outcomes with any therapy. Some patients may alternate between 4 and 5.</td>
<td>Definitive intervention elective over period of weeks to few months.</td>
</tr>
<tr>
<td>Profile 5</td>
<td>Exertion intolerant: Comfortable at rest and with ADL but unable to engage in any other activity, living predominantly within the house. Patients are comfortable at rest without congestive nutrition, organ function, and activity. Symptoms, but may have underlying refractory elevated volume status, often with renal dysfunction. If underlying nutritional status and organ function are marginal, patient may be more at risk than INTERMACS 4, and require definitive intervention.</td>
<td>Variable urgency, depends upon maintenance of nutrition, organ function, and activity.</td>
</tr>
<tr>
<td>Profile 6</td>
<td>Exertion limited: Patient without evidence of fluid overload is comfortable at rest, and with activities of daily living and minor activities outside the home but fatigue after the first few minutes of any meaningful activity. Attribution to cardiac limitation requires careful measurement of peak oxygen consumption, in some cases with hemodynamic monitoring to confirm severity of cardiac impairment.</td>
<td>Variable, depends upon maintenance of nutrition, organ function, and activity level.</td>
</tr>
<tr>
<td>Profile 7</td>
<td>Advanced NYHA III: A placeholder for more precise specification in future, this level includes patients who are without current or recent episodes of unstable fluid balance, living comfortably with meaningful activity limited to mild physical exertion.</td>
<td>Transplantation or circulatory support may not currently be indicated.</td>
</tr>
</tbody>
</table>

Modifiers for Profiles

<table>
<thead>
<tr>
<th>TCS</th>
<th>Temporary Circulatory Support</th>
<th>Can modify only patients in hospital (other devices1,2,3 in hospital). Includes IABP, ECMO, TandemHeart, Levitronix BVS5000 or AB5000, or Impella.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Arrhythmia</td>
<td>Can modify any profile. Recurrent ventricular tachyarrhythmias that have any profile. Recently contributed substantially to clinical compromise. This includes frequent ICD shock or requirement for external defibrillator, usually more than twice weekly.</td>
</tr>
<tr>
<td>FF</td>
<td>Frequent Flyer</td>
<td>Can modify only outpatients, designating a patient requiring frequent visits to the emergency visits or hospitalizations for diuretics, ultrafiltration, or temporary intravenous vasoactive therapy. Can modify profile 3 if at</td>
</tr>
</tbody>
</table>
home, 4,5,6, and rarely profile 7

From:
<table>
<thead>
<tr>
<th>Component</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>Age, gender, educational level, living situation, cultural background, religious beliefs and practices, significant relationships, employment, lifestyle, community activities, legal offense history and citizenship</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>Ability to safely operate and care for the device (e.g. degree of sensory or physical impairment). In the case of patient disability, the caregiver's ability to safely operate and care for the device.</td>
</tr>
<tr>
<td>Psychological and psychiatric status</td>
<td>• Presence of current and prior psychiatric disorders, including but not limited to mood, anxiety, substance use and personality disorders.</td>
</tr>
<tr>
<td></td>
<td>• Current or prior therapeutic interventions (counseling, medications).</td>
</tr>
<tr>
<td></td>
<td>• Psychological stressors.</td>
</tr>
<tr>
<td>Cognitive ability and capacity to comprehend information</td>
<td>Formal neurocognitive evaluation</td>
</tr>
<tr>
<td>Behavior and coping</td>
<td>Coping skills used to manage previous life or health-related stressors.</td>
</tr>
<tr>
<td>Adherence</td>
<td>Determine history of adherence to medical therapy, keeping clinical appointments and following diet and exercise</td>
</tr>
<tr>
<td>recommendations</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td></td>
</tr>
<tr>
<td>Substance abuse</td>
<td></td>
</tr>
<tr>
<td>Current and prior use of cigarettes, alcohol and illicit drugs</td>
<td></td>
</tr>
<tr>
<td>Family and support network</td>
<td></td>
</tr>
<tr>
<td>• Social support networks available during recovery from surgery.</td>
<td></td>
</tr>
<tr>
<td>• Ability of support network to provide care on an ongoing basis if needed.</td>
<td></td>
</tr>
<tr>
<td>Caregiver burden and support systems</td>
<td></td>
</tr>
<tr>
<td>Caregiver age, physical function and general health</td>
<td></td>
</tr>
<tr>
<td>Financial support</td>
<td></td>
</tr>
<tr>
<td>• Financial stability.</td>
<td></td>
</tr>
<tr>
<td>• Ability to handle financial obligations.</td>
<td></td>
</tr>
<tr>
<td>• Disability assistance available</td>
<td></td>
</tr>
<tr>
<td>• Health insurance (if relevant)</td>
<td></td>
</tr>
</tbody>
</table>
Figure 1. Approach to MCSD implantation: BTT and DT

* MCSD – mechanical circulatory support device, HT – heart transplant, RV – right ventricle, LVAD – left ventricular assist device, BIVAD – biventricular assist device, TAH – total artificial heart, DFT – destination therapy, BTD – bridge to decision, BTT – bridge to transplantation
Reference List


