Candidate Selection for Durable Mechanical Circulatory Support

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KEYWORDS

• Left ventricular assist device support • Heart failure • Mortality • Risk stratification

KEY POINTS

- Heart failure (HF) risk stratification is important for guiding the timing of durable mechanical circulatory support (MCS), and it is integral to the shared decision-making process with HF patients and families.
- HF risk stratification includes estimating patient morbidity and mortality with ongoing medical management alone versus that of MCS.
- Although several HF risk models have been devised, accuracy of the tools for predicting outcome in the advanced HF population remains poor.
- Patients with recurrent HF admissions, hemodynamic instability, progressive end-organ dysfunction, or frequent ventricular arrhythmias may benefit from MCS evaluation.
- The operative period is the highest risk for mortality in MCS patients. Although many risk scores exist, advanced age, medical comorbidities, preoperative right ventricular dysfunction, renal dysfunction, and measures of hemodynamic instability are common covariates of mortality after MCS.

INTRODUCTION

The evolution of mechanical circulatory support (MCS) for management of end-stage heart failure (HF) has been rapid, imparting an exponential impact on patient survival and quality of life. Compared with a survival rate of 54% in patients supported with the first-generation pulsatile-flow HeartMate (Abbott, Abbott Park, Illinois) XVE left ventricular assist device (LVAD), survivals averaged 76% and 83% at 2 years for patents supported with the second-generation axial-flow HeartMate II (HMII) LVAD and third-generation centrifugal-flow HeartMate 3 LVAD, respectively.[1,2] In addition to marked improvements in device technology, surgical technique, and patient management, gains in patient survival after LVAD implant have been achieved through refinement of patient selection. This article focuses on the critical interplay of preexisting patient comorbidities and instantaneous hemodynamic status in determining the risk versus benefit of MCS. This article expands on predictors of operative risk and correlates of long-term success on MCS.

IMPORTANCE OF RISK PREDICTION

HF encompasses a wide spectrum of patient phenotypes. Some patients with HF have no or minimal limitations to their functional capacity (New York Heart Association [NYHA] classes I–II), whereas others have severe shortness of breath

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with minimal exertion (NYHA classes III–IV). Patient clinical status can vary from long-term stability with excellent 5-year prognosis to rapid decompensation with impending mortality. Forecasting patient risk for death from HF is often challenging but is nevertheless critical for timing of the implementation of advanced HF therapies (including transplant and MCS) to ensure the best outcomes for these complex patients.

Information gleaned for prognostication is integral to shared decision making with patients and their families, especially during the complex process of education about MCS and as part of informed consent. Although there are models used to estimate average HF patient risk as a starting point for shared decision making, patient-specific details are crucial for a more precise estimation of patient morbidity and mortality. In the evaluation for durable MCS, practitioners must present the risk of ongoing medical management of HF compared with the risks of surgical implantation of the LVAD and the sizable morbidity and mortality associated with long-term MCS. Although this article focuses on mortality risk prediction, the impact of morbidities encountered during LVAD support as well as the impact on quality of life and functional capacity are summarized in the articles, Saima Aslam's article, "Ventricular Assist Device Infections," and Tonya Elliott and Lori G. Edwards's article, "Ambulatory Ventricular Assist Device Patient Management," and Ju H. Kim and colleagues article, "Continuous-Flow Left Ventricular Assist Device–Related Gastrointestinal Bleeding," and Ajay Kadakkal and Samer S. Najjar's article, "Neurologic Events in Continuous-Flow Left Ventricular Assist Devices," in this issue. It is important that all these factors are taken into consideration and are discussed and well outlined in the shared decision-making process between advanced HF patients and the practitioner.[3–6]

Assessing Patient Morbidity and Mortality from Medical Management of Heart Failure

The first step in assessing candidacy for durable MCS is assessing patient risk of death from ongoing medical management of HF. For those with advanced HF (encompassing late stage C and stage D HF), survival is uniformly poor but also highly variable. A meta-analysis of 20 studies encompassing 2877 patients requiring extracorporeal membrane oxygenation for management of postcardiotomy shock demonstrated survivals of 34% at discharge.[7] In the population of patients who are less critically ill but are dependent on inotropes at home, survival averages were marginally better, at 25% to 60% at 12 months.[2,8,9] The more complex patients to prognosticate are those who are less ill with severe systolic dysfunction—the ambulatory patient with systolic HF.

Several clinical trials, cohort studies, and registries have identified markers of mortality in ambulatory patients with HF.[10–16] Commonly identified risks include advanced patient age, renal dysfunction, hyponatremia, major comorbidities (eg, chronic obstructive pulmonary disease and diabetes), recurrent HF admissions, recurrent ventricular dysrhythmias, lower systolic blood pressures, poor functional capacity (reduced peak oxygen consumption or 6-minute walk test distance), and/or advanced NYHA class. The utility of an individual parameter to prognostic risk, however, is often poor due to the presence of many coexistent positive or negative risk factors. To allow for a more individualized estimation of patient risk using a set of patient-specific characteristics, various risk prediction models have been devised (**Table 1**).[11,13,15,17–19] Two of the most commonly used tools include the Meta-Analysis Global Group in Chronic Heart Failure (MAGGIC) risk score and the Seattle Heart Failure Model (SHFM).[11,13] The MAGGIC model was devised using data from 39,372 patients with HF enrolled into 30 different cohort studies.[13] Patients in the MAGGIC cohort included both reduced left ventricular ejection and preserved left ventricular ejection fractions (LVEF), but average mortality was high at 40% over a median follow-up of 2.5 years. Using 13 predictors of mortality (see **Table 1**), MAGGIC can be used to estimate an individual's probability of dying within 1 and 3 years.[13] The SHFM was derived from patients enrolled into the Prospective Randomized Amlodipine Survival Evaluation (PRAISE) study, which included 1125 patients with an LVEF less than or equal to 30% and NYHA class IIIb to class IV symptoms.[11,20] The SHFM was then validated in 9902 patients enrolled into 5 other trials, including those with preserved systolic function and NYHA class II to class IV.[11] Mortality variables are shown in **Table 1**, and when entered into the online model, practitioners are given 1-year, 2-year, and 5-year mortality estimates.[21] Both MAGGIC and the SHFM tools have been independently validated to assess risk, but the accuracy in the subset of patients with advanced HF remains suboptimal.[10,22–24] For example, when the SHFM was examined in 445 patients referred for cardiac transplant, the SHFM showed acceptable discrimination (which captures the ability of a model to correctly identify patients with vs without event-free survival) but poor calibration (which measures how close the mortality values predicted by the