Role of Durable Mechanical Circulatory Support for the Management of Advanced Heart Failure

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KEYWORDS

• Mechanical circulatory support • Outcomes • Advanced heart failure management

KEY POINTS

- The number of patients with end-stage systolic heart failure (HF) managed with mechanical circulatory support (MCS) has increased more than 100% since 2009 but MCS remains an underused therapy.
- Current 1-year and 4-year average survival rates on MCS are 80% and approximately 50%, respectively, with higher survival in those supported for the bridge to transplant (BTT) indication.
- Early referral to an advanced HF specialist with MCS surgical capabilities is critical to ensure good outcomes for patients with recalcitrant HF (New York Heart Association [NYHA] classes III and IV).
- High-risk HF features include more than 1 admission in 6 months for HF, inability to tolerate guideline doses of HF medications due to hypotension, rising creatinine, escalating diuretic use and/or need for sequential nephron blockade, recurrent ventricular dysrhythmias, and signs of hepatic congestion (elevated international normalized ratio [INR] or bilirubin) and/or anorexia.

INTRODUCTION

HF is a major public health problem resulting in substantial morbidity, mortality, and health care expenditures. Currently there are an estimated 6 million Americans living with HF and this incidence is projected to rise substantially, with HF affecting an estimated 8 million individuals by 2030.[1] Of those with HF, an estimated 5% have end-stage (stage D) HF, recalcitrant to evidence-based medical therapy and/or biventricular pacing.[2]

Management options for advanced HF include MCS, cardiac transplant, inotrope support, and/or palliative care/hospice. Each management option carries its own associated survival expectancy (ranging from 25% to 90% at 1 year) and morbidity, and the care plan must be tailored to patients based on patient wishes and the ability to tolerate a major surgical procedure with acceptable morbidity and mortality. See Kittleson MM: Changing Role of Heart Transplantation; and Ginwalla M: Home Inotropes and Other Palliative Care, in this issue, other articles provide detailed reviews on the roles for cardiac transplant and palliative care/hospice for management of advanced HF. The focus in this article is on MCS.

ROLE OF MECHANICAL CIRCULATORY SUPPORT IN ADVANCE HEART FAILURE

Given strict cardiac transplant criteria and limited donor organ supply in the United States, the utilization of MCS for management of stage D HF has increased. More than 15,000 MCS implants

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have been reported to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), a database that collects outcomes on Food and Drug Administration (FDA)-approved durable MCS devices implanted within the United States.[3] Between 2009 and 2015, the number of MCS implants per year increased more than 100%, from 1000 to more than 2500 implants per year.[3] Although the number of patients supported with MCS is on the rise, MCS is still only applied to a minority of individuals with advanced HF. It is estimated that 150,000 individuals could benefit from MCS therapy in the United States.[4] The goal of this review is to educate practitioners on the types of MCS devices available for advanced HF, survival rates, complications associated with support, and the importance of timely referral for MCS evaluation.

CLASSIFYING MECHANICAL CIRCULATORY SUPPORT

There are a variety of FDA-approved and investigational circulatory pumps available in the United States. Most pumps are implanted with the aim of providing isolated left ventricle (LV) support as an LV assist device (LVAD). Patients with biventricular failure can be supported with biventricular mechanical support in form of a right ventricular assist device (RVAD) plus an LVAD, or via a total artificial heart. Durable RVAD support is not currently FDA approved. More than 612 durable and temporary RVADs (used in conjunction with LVAD support) have been reported to INTERMACS.[3] Total artificial heart support encompasses approximately 301 patients with stage D HF in INTERMACS and is currently approved for patients being supported with the goal for transplant.

MCS can also be classified based on duration of intended support (temporary vs durable), location of device implant (extracorporeal, intracorporeal, or paracorporeal), and device flow profile. Temporary devices are used for days to weeks and are used either as a bridge to myocardial recovery, cardiac transplant, or for eventual exchange to a permanent (also known as durable) MCS device. A detailed summary of temporary mechanical support and use of paracorporeal and extracorporeal devices is provided (see Brown JL, Estep, JD: Temporary Percutaneous Mechanical Circulatory Support in Advanced Heart Failure, in this issue).

Permanent/durable circulatory support devices are all intracorporeal in location. Devices vary on whether they provide continuous flow (CF) or pulsatile flow (**Table 1**). Currently in the United States, more than 90% of MCS patients are supported with a CF profile device. The remaining 10% of patients are largely supported with the pulsatile total artificial heart.[3] CF devices are further subcategorized as CF with axial-flow or CF with centrifugal-flow designs. In a typical CF device configuration, an inflow cannula delivers blood out the LV apex into a contained pump that then propels flood into the ascending aorta via a synthetic graft (**Fig. 1**). The current FDA-approved durable CF pumps are capable of providing up to 10 L of cardiac output.[5,6] Because flow is removed continuously from the LV during the cardiac cycle, intracavity LV pressures during isovolumic contraction often do not exceed aortic systolic pressure; hence, the aortic valve tends to remain closed during CF-LVAD support. As such, many patients on CF-LVAD support do not have a palpable peripheral pulse.

INDICATIONS FOR DEVICE SUPPORT IN THE UNITED STATES

In the United States, MCS devices are largely implanted for 1 of 2 payer-approved indications: as a bridge to cardiac transplant (BTT) or for permanent therapy (also known as destination therapy [DT]) without intent for future transplant. Predicting the postimplant trajectory of HF care prior to ventricular assist device [VAD] implantation is met with challenge, and the DT versus BTT designation for many individuals is payer-driven semantics. Patients who appear very ill pre-VAD can have dramatic functional and end-organ improvements after VAD and subsequently become fit for cardiac

Table 1
Clinically used left ventricular assist device types

	First Generation	Second Generation	Third Generation
Pump design	Pulsatile flow	Continuous-flow (axial pump)	CF (centrifugal pump)
LVAD type	HeartMate IP1000, VE, XVE Novacor LVAD	HMII Incor Berlin Heart Jarvik 2000 MicroMed DeBakey	HVAD DuraHeart HeartMate 3