The Evolution of Mechanical Circulatory Support

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KEYWORDS

• Ventricular assist device • Heart failure • Cardiac transplantation • Mechanical circulatory support • Total artificial heart

KEY POINTS

- Mechanical circulatory support was developed by early pioneers in the field of heart failure, cardiac surgery, and transplantation.
- Mechanical circulation is used to support the heart at the time of open heart surgery.
- Initial devices were large, extracorporeal, pulsatile-flow devices that eventually developed into smaller, intracorporeal, continuous-flow devices, termed *left ventricular assist devices (LVADs)*, which are less prone to mechanical wear with longer support durations.
- Patients receive LVADs as a bridge to transplant (BTT) or as destination therapy (DT) for patients who are ineligible for transplant. Due to insufficient organ supply, more patients globally receive an LVAD as opposed to a cardiac transplant.
- The future application of this therapy will continue to grow as best practices in patient management and device design are identified to mitigate adverse events associated with LVAD therapy.

INTRODUCTION

Heart failure (HF) currently affects an estimated 6.5 million people in the United States. As the population ages, diabetes prevalence grows, and more individuals survive myocardial infarction, the prevalence of HF is expected to increase to greater than 8 million individuals by 2030.[1] Advanced HF recalcitrant to medical therapy (American College of Cardiology/American Heart Association stage D HF) has an estimated prevalence of 250,000 to 300,000 individuals in the United States.[2] Although hospice and/or palliative care with or without intravenous inotrope support may be the most appropriate management for some patients with stage D HF, carefully selected individuals may achieve improved quality of life and survival with advanced HF therapies, including long-term mechanical circulatory support (MCS) or cardiac transplantation.

With an average survival of 50% at 13 years, the gold standard for the treatment of advanced HF remains heart transplantation. Although cardiac

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Abbreviations	
BTT	Bridge to transplant
DT	Destination therapy
FDA	Food and Drug Administration
HF	Heart failure
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
IVAD	Implantable ventricular assist device
LVAD	Left ventricular assist device
LVAS	Left ventricular assist system
MCS	Mechanical circulatory support
NHLBI	National Heart, Lung and Blood Institute
PVAD	Paracorporeal ventricular assist device
REMATCH	Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure
TAH	Total artificial heart
VAD	Ventricular assist device

transplantation has historically been offered to only approximately2200 individuals annually in the United States since 2010, the number of patients receiving a cardiac transplant has gradually increased and is currently approximately 3300 patients a year.[3,4] Each year, approximately 10% of patients on the heart transplant wait list die awaiting a suitable organ.[3]

Continued advancements in durable MCS have significantly altered the landscape of advanced HF by improving survival and quality of life for both those awaiting heart transplantation (ie, bridge to transplant [BTT]) as well as those who may not qualify for transplantation (ie, destination therapy [DT]). In the United States, only 22,000 total ventricular assist device (VAD) implants have been reported to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) since 2006.[5] To contrast outcomes with current-generation continuous-flow LVADs, the Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients (ROADMAP) study compared survival of HF patients who were not inotrope dependent but had advanced HF symptoms (New York Heart Association class III or IV) to a similarly matched cohort of patients who elected to receive a VAD.[6] The medical therapy patients had significantly worse event-free survival. At 1-year and 2-year event-free survival, rates in the medical management group were 63% and 41%, respectively, compared with average survivals of 80% and 70%, respectively, in VAD recipients.[5–7] Furthermore, patients on LVAD support had greater improvements in 6-minute walk distance and quality of life. The ROADMAP data suggest that carefully selected, non–inotrope-dependent patients with advanced HF symptoms may gain benefit from MCS therapy. The Randomized Evaluation of VAD InterVEntion before Inotropic Therapy pilot trial attempted to investigate this hypothesis through randomized study. Unfortunately, the trial was terminated due to a high number of adverse events (especially device thrombosis) in the MCS arm.[8] The Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate3 trial included patients with non–inotrope-dependent systolic HF and a cardiac index less than 2.2 L/min/m^2 but this subgroup only comprised approximately 2200 15% of the cohort and long-term outcomes are not yet available.[9] As adverse event burdens improve with each evolution of device therapy, further study in non–inotrope-dependent patients with advanced HF can be anticipated.

HISTORY OF DURABLE MECHANICAL CIRCULATORY SUPPORT

The field of MCS has matured significantly since the development of the first cardiopulmonary bypass device—the Gibbon-IBM heart-lung machine. The Gibbon-IBM heart-lung machine was first used in 1953 by Dr John Gibbon during an atrial septal defect closure in an 18-year-old woman.[10] The first VAD was implanted in 1963 by Drs Michael DeBakey and Domingo Liotta.[11–13] A patient named George Washington, who suffered cardiac arrest after aortic valve replacement, received the first such device in 1963. The inflow of the VAD was attached to the left atrium and the outflow to the descending thoracic aorta, providing pump flows of 1.8 L/min to 2.5 L/min[14] The patient survived with improvement in pulmonary edema until his death on the fourth postoperative day, attributed to brain damage from the cardiac arrest. In 1966, DeBakey[11,14] implanted another version of an extracorporeal left ventricular bypass pump, the Liotta-DeBakey LVAD, with the inflow attached to the left atrium and outflow attached to the right axillary artery in Esperanza del Valle Vasquez, a woman unable to be weaned from the heart-lung machine after aortic and mitral valve replacements. With pump flows of 1.2 L/min, the patient was successfully weaned from the heart-lung machine. By postoperative day 10, the