Mechanical Circulatory Support in Advanced Heart Failure #205, 2nd ed.

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Editor's Note: Due to rapid changes with these technologies, this Fast Fact is meant to fully replace the first edition of #205, 'Destination Ventricular Assist Devices for Heart Failure' by Heather Ferris, MD and Susan Hunt, MD, published August 2008.

Introduction

ABOUT 250,000 Americans have end-stage heart failure, meaning they cannot carry out any physical activities without discomfort (dyspnea or angina) and are potentially eligible for advanced therapy such as transplantation. Less than 1% of patients, however, will receive a heart transplant. The left ventricular assist device (LVAD) was initially designed as an implanted mechanical circulatory support (MCS) to extend the life of patients awaiting heart transplants ("bridge-to-transplantation" (BTT)). In 2002, the FDA approved the LVAD not only as BTT, but also as "destination therapy" (DT) where the patient would keep the device for life, with no expectation of heart transplantation.

The Technology

Rapid growth in the types and numbers of MCS has occurred in the last decade, including the development of the total artificial heart and biventricular support. Basically, an LVAD involves surgical implantation of a pump to support cardiac output. Most often, this includes a conduit implanted in the left ventricle and another into the aorta. Blood is pulled from the left ventricle and mechanically moved into the aorta, increasing cardiac output and reducing heart failure symptoms. First generation LVADs did this with a pumping motion (pulsatile flow), but second generation LVADs move the blood continuously (continuous or axial flow). A third conduit (the driveline) passes from the pump through the abdominal wall and attaches to the device's battery and

control system. This is of particular importance, as serious life-threatening infections can result via the driveline.

Right and biventricular assist devices also exist but are not currently approved for DT. DT patients can go home with their assist devices using a wearable battery system. Previously, to qualify for destination LVAD therapy, a patient needed to have severe, refractory Class IV heart failure including severe systolic dysfunction (ejection fraction <25%), inotrope dependence or very low peak oxygen consumption (<12 ml/kg/min), and sufficient body surface area to accommodate the LVAD. Now, patients with other situations are being considered (e.g., heart failure with preserved ejection fraction, congenital heart disease). Also, some advocate for expanding into patients who are less sick (Class IIIB), arguing that waiting until their heart failure is severe and refractory is too late and raises their operative risk to unacceptably high levels. This hypothesis is currently being investigated.

Outcomes and Considerations

- In randomized studies, LVADs have shown significant mortality benefits, with a two-year survival of 58% for the newer continuous-flow devices compared to 24% with pulsatile flow LVADs and 8% with optimal medical therapy alone.^{1,2} Observational studies demonstrate two-year survivals of 72%, but these databases are heterogeneous and patients may be healthier than the patients enrolled in the original randomized trials.³
- Poorer survival is predicted by poor nutritional status (hypoalbuminemia), coagulopathy, baseline renal dysfunction, right heart dysfunction, and care at a less experienced MCS center.^{3,4}
- Of those patients who are alive at two years, 79% will improve their NYHA functional class from class IV to

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class I, and health-related quality of life will improve by 178%.⁵ Readmission rates have reduced significantly as well.⁶

- While markedly improved, continuous-flow LVADs have many potential complications, including stroke (lifetime risk of 18%), infection (49%), sepsis (36%), bleeding requiring transfusion (81%), bleeding requiring surgery (30%), malfunctioning or thrombosed pump requiring pump replacement (10%), and readmission (94%).² Perioperative mortality has improved dramatically (often less than 10%) with improved patient selection and technology; however, palliative medicine providers and ICU staff often see MCS patients at their worst when critically ill or with a protracted, complicated recovery. This can be a source of moral distress; nevertheless many patients go on to perform all activities of daily living and have improved quality of life.
- MCS requires a high degree of ongoing device care including daily self-care (e.g., controller self-tests, changing and maintaining power sources, and driveline exit site dressing changes); safety precautions (e.g., no emersion in water, showering with a shower kit, precautions while driving and traveling, need for a trained caregiver); and the ability to troubleshoot emergent MCS-related malfunction. Due to this, social stability and patient/family responsibility are key selection criteria when considering MCS implantation.

Discontinuing MCS and Advance Care Planning

MCS may be implanted as BTT but later become DT if patients are no longer transplant candidates. In the rare instance of myocardial recovery, some devices can be explanted. More often, MCS is removed at cardiac transplantation or, in the case of DT, when severe complications arise (such as pump thrombosis, mechanical pump failure, etc).

MCS is a surgical therapy that can prolong life and improve function in appropriately selected patients, but can be associated with significant morbidity, treatment burden, and mortality. Discussions with patients and surrogates to clarify prognosis, goals, and endpoints for MCS therapy should take

place before implantation. These discussions should address the quality of life below which a patient would no longer want to continue MCS and would want to initiate comfort focused care only. Having open and honest discussion regarding goals of care prior to MCS is encouraged, and a suggested process for these discussions will be in a future *Fast Fact*. Practical aspects of discontinuing an LVAD in a dying patient are discussed in *Fast Fact* #269.

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Deactivation of a Left Ventricular Assist Device at the End of Life #269

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Introduction

THE INCREASED USE of left ventricular assist devices (LVADs) is expected, particularly as destination therapy for patients with advanced heart failure who are not trans-

plant candidates. *Fast Fact* #205 discusses LVAD technology in general. This *Fast Fact* discusses important considerations at the time of LVAD deactivation. **Note:** Published clinical outcomes with LVAD therapy have improved further after the initial publication of *Fast Fact* #205; please refer to the