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## Advantages of bridging to durable left ventricular assist device with the Impella 5.0

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### Abstract

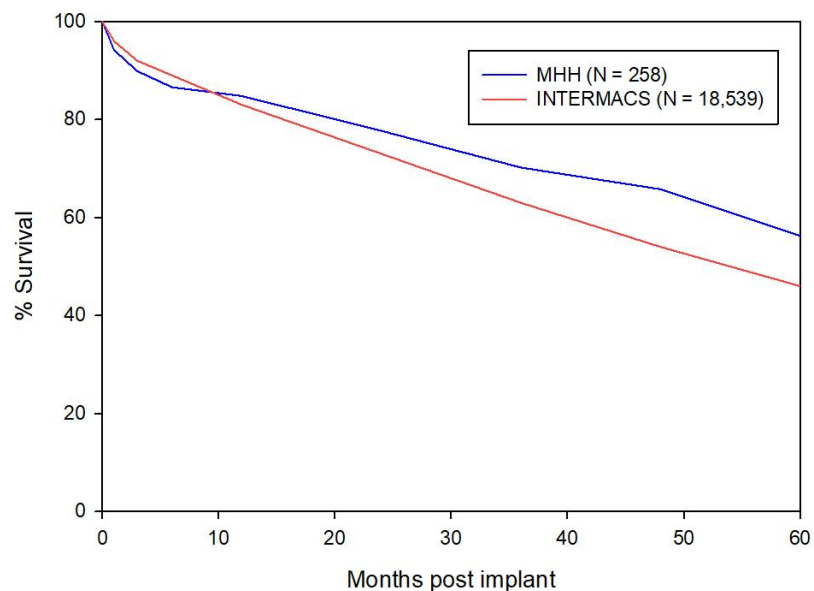
The mainstay therapy for patients in critical cardiogenic shock (CS) is temporary mechanical circulatory support. Although there is a trend toward use of durable left ventricular assist devices (LVAD) in patients that are less ill, we present our experience with using the Impella 5.0 (Abiomed) to illustrate the potential benefits of supporting patients with critical CS before durable LVAD implantation. Since 2012, our use of the Impella has increased from 5 to 38 per year. Mortality is highest early after LVAD implantation, but our long-term survival is better than data reported to the INTERMACS registry. Use of an Impella 5.0 device as a bridge-to-durable LVAD in patients with critical CS may offer long-term survival benefit.



## Summary of Presentation

Cardiogenic shock (CS) refractory to medical therapy is increasing in incidence and is associated with an in-hospital mortality rate of nearly 50%.<sup>1</sup> The mainstay therapy for patients in critical CS is temporary circulatory support with devices such as the intra-aortic balloon pump (IABP), percutaneous assist devices, or veno-arterial extracorporeal membrane oxygenation (VA-ECMO). Data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) show that fewer patients are implanted with durable devices who are in critical CS (INTERMACS profile 1), whereas patients who are less-ill but declining or stable with maximal medical therapy (INTERMACS profiles 2-3) are most commonly implanted<sup>2</sup>. Hence, there has been a trend toward increased use of short-term circulatory support in the sickest patients as a bridge to either transplantation, implantation of durable left ventricular assist device (LVAD), total artificial heart (TAH), or other definitive therapy.<sup>3-5</sup>

At a large urban hospital's advanced heart failure department, the percentage of patients classified as INTERMACS profile 1 before LVAD implantation is considerably higher than reported in the INTERMACS Registry (42% vs 14.3%); however, the short-term survival of this single institution is nearly equivalent to the INTERMACS population and the long-term survival is better (Figure 1).<sup>2</sup> Use of short-term circulatory support as a bridge-to-durable LVAD has allowed for better patient selection and the optimization of patient's condition before implantation. The following case reports and overview of our experience using the Impella 5.0 (Abiomed, Danvers, MA) illustrate the potential benefits of supporting patients with critical CS before durable LVAD implantation.



**Figure 1.** Patient survival from a large, urban hospital (Memorial Hermann Hospital, Houston, TX; MHH) is compared to data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).



### **Patient 1**

A 61-year-old Caucasian male with a history of ischemic heart failure, left ventricular ejection fraction (LVEF) <20%, prior automatic implantable cardioverter defibrillator (AICD), atrial fibrillation, hypertension, peripheral vascular disease, type II diabetes, and chronic obstructive pulmonary disease (COPD) presented with increasing lower extremity and scrotal edema. Further assessment revealed severe malnutrition with deconditioning, uncontrolled type II diabetes (HbA1c = 8.8), a non-healing ulcer of the foot, severe peripheral vascular disease, COPD with CO<sub>2</sub> retention, and coronary artery disease not suitable for surgical repair. Twelve days after admission, percutaneous coronary revascularization was attempted, and an IABP was placed. After nine days of gradual deterioration, an Impella 5.0 ventricular assist device was implanted via the axillary artery. The patient's condition was stabilized, and he underwent successful implantation of a HeartMate 3 LVAD (Abbott, Chicago, IL) after 24 days of Impella support.

### **Patient 2**

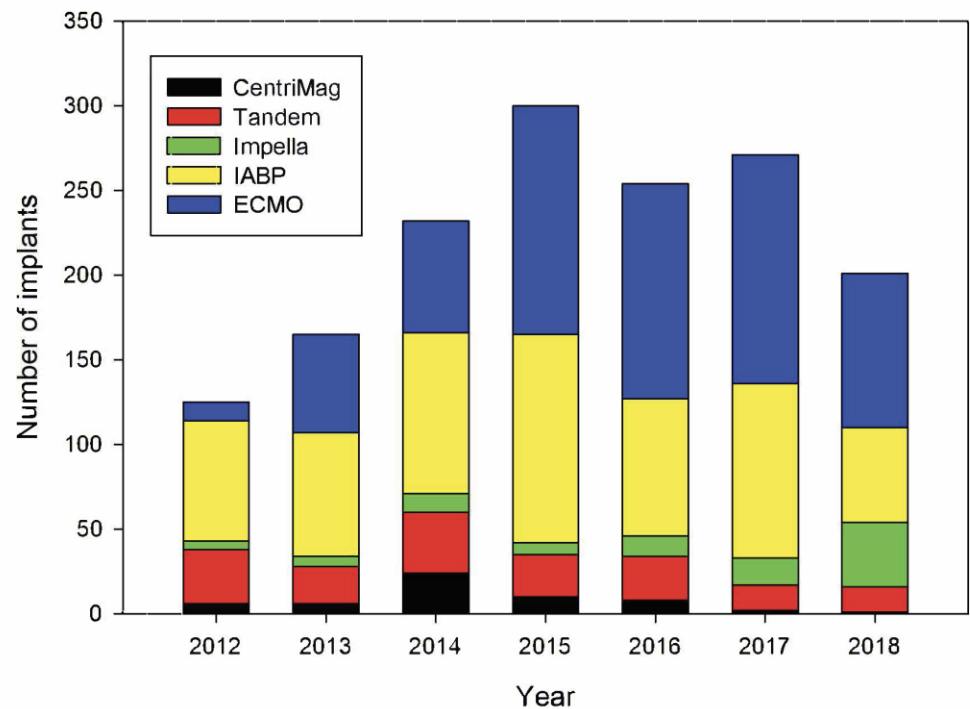
A 31-year-old African American male with non-ischemic cardiomyopathy, LVEF <20%, AICD, hypertension, hyperlipidemia, hypothyroidism, obstructive sleep apnea, and morbid obesity was transferred for management of decompensated heart failure. Upon admission, the patient was in severe CS and was not able to tolerate inotropic therapy. One day after admission, the patient was taken to the operating room and experienced cardiac arrest requiring defibrillation, CPR, and he was placed on extracorporeal membrane oxygenation (ECMO) support. An Impella 5.0 was placed via the axillary artery which provided adequate support, allowing ECMO removal and extubation. The patient was stabilized on Impella support for 4 days when a HeartMate 3 LVAD was successfully implanted.

## **Summary of Experience**

Temporary circulatory support at this institution has been provided by the Impella 2.5 and 5.0 devices, TandemHeart (LivaNova, USA), CentriMag (Abbott, Chicago, IL), IABP, and/or ECMO (Figure 2). Since 2012, our use of the Impella has increased from 5 to 38 per year. In our recent experience using the Impella 5.0 as a bridge to durable LVAD, 17 devices have been implanted and 3 patients were transferred to our institution with the device in place. In 7 cases of CS following acute myocardial infarction, patients who were initially supported by Impella 2.5, Impella CP, IABP, or ECMO were converted to support with the Impella 5.0 inserted via the axillary artery. Of the 9 patients who received Impella 5.0 support, 5 were bridged to a durable LVAD and 3 underwent a successful heart transplantation.

## **Discussion**

In spite of inotropic support, many patients with CS cannot be hemodynamically stabilized and have refractory low-cardiac output. Long-term assist devices are an expensive option, and their implantation is complicated by a high rate of right heart failure and mortality. Bridging patients with temporary circulatory support is intended to stabilize hemodynamics and improve end-organ function and may improve survival. Also, surgical risk may be reduced, and more time is allowed for complete evaluation of prognosis and therapy.



**Figure 2.** Use of temporary circulatory support at Memorial Hermann Hospital from 2012-2018. Abbreviations: Tandem, TandemHeart; IABP, intra-aortic balloon pump; ECMO, extracorporeal membrane oxygenation.

In general, patients requiring temporary circulatory support before durable LVAD implantation are much sicker and experience a higher rate of adverse events and mortality after LVAD implantation.<sup>6</sup> In our experience, mortality is also highest early after implantation, but our long-term survival is better than data reported to the INTERMACS registry. Patients requiring ECMO have a very high mortality and adverse event rates, likely due to the severity of illness on presentation and may be classified as INTERMACS profile 0.<sup>6</sup> Use of an Impella 5.0 device as a bridge-to-durable LVAD in patients classified as INTERMACS profile 1 may offer long-term survival benefit; however, further multi-center, prospective studies are needed.

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