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Mini Review

Durable and Short-Term Left Ventricular Assist Devices for Decompensated Heart Failure -

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ABSTRACT

The prevalence of heart failure continues to increase in the United States, and the number of patients supported with mechanical circulatory support devices parallels this trend. Left ventricular assist devices (LVADs) have evolved significantly over the past 70 years, temporizing patients to recovery, durable devices, transplantation, or serving as destination therapy. In this review, we briefly summarize the evolution, outcomes, and operative considerations for contemporary durable devices, and we provide an overview of short-term assist devices (Impella, TandemHeart).

INTRODUCTION

Approximately 6.2 million Americans are afflicted with heart failure (HF), and this number is expected to rise to > 8 million by the end of the decade [1]. In refractory HF, temporary and durable left ventricular assist devices (LVADs) can bridge patients to recovery, decision, transplantation, or destination therapy. According to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database, there were > 25,000 patients who received mechanical devices between 2006 and 2017, with the majority (> 18,000) receiving isolated continuous flow LVADs [2]. Thus, LVADs represent a central component in the management of patients with advanced heart failure. In this review, we summarize the evolution, outcomes, and operative considerations for contemporary durable LVADs. We also provide a brief overview of temporary LVADs.

DURABLE DEVICES

Although development of LVAD technology started in the 1960s, the clinical application of FDA-approved devices did not commence until the 1990s [3]. The early iterations of the device, which relied on pulsatile technology, demonstrated superior survival compared with optimal medical management, but the 2-year survival rates were still < 25% [4]. These pulsatile LVADs were soon superseded by continuous flow LVADs. The HeartMate II (Abbott), which utilized an axial-flow pump, was introduced in 2007 and demonstrated superior outcomes compared with the pulsatile HeartMate XVE (Thoratec): 2-year survival of 58% versus 24%, respectively [5]. The complications (e.g., stroke, bleeding, infections) associated with the HeartMate II, however, remained a challenge. The HeartMate HVAD (Medtronic) was introduced as a smaller, intrapericardially placed, centrifugal-flow device that eliminated mechanical bearings [6]. In the ENDURANCE trial, the HVAD was non-inferior with respect to survival but had higher rates of stroke compared to the HeartMate II [7]. Given the persistent complications of thrombosis, stroke, and hemorrhage, a fully magnetically levitated centrifugal-flow device was developed: HeartMate 3 (Abbott). In the MOMENTUM 3 trial, therapy with HeartMate 3 was superior with respect to survival free of disabling stroke and need for replacement or removal of a failed device, compared with HeartMate II (survival of 77% versus 65%, respectively) [8]. The 2-year survival outcomes with HeartMate 3 are particularly impressive, as they approximate the 2-year survival following heart transplantation (82%) [9]. When continuous flow devices are implanted as a bridge-to-transplantation strategy, mortality rates appear to be increased, compared with medical management [10]. Early mortality at 1 year is 9.5% with mechanically bridged patients and 7.2% with medically managed patients. Cardiovascular-related mortality and primary graft dysfunction are the major drivers of this increased early mortality. Mechanistically, the vascular morbidity associated with nonpulsatile circulation may play a role [11]. Overall, these findings highlight the need for careful selection of patients for durable support.

The surgical implantation of HeartMate 3 includes traditional sternotomy approaches, as well as minimally invasive approaches via a left mini-thoracotomy and an upper hemi-sternotomy or bilateral thoracotomies [12-14]. Furthermore, the implantation can be performed off-pump, minimizing the risks associated with cardiopulmonary bypass. The general steps include creation of the driveline tunnel, placement of the sewing ring/apical cuff, coring the myocardium, insertion of the inflow cannula within the apical opening, and aortic anastomosis of the outflow graft. Excellent surgical outcomes have been reported with both traditional and minimally invasive approaches. Under more urgent circumstances, however, short-term LVADs can be placed for temporary support.

SHORT-TERM DEVICES

In the setting of life-threating acute decompensated HF, temporary mechanical circulatory support can be employed as a bridge to recovery, a durable device, or transplantation. The Impella platform (Abiomed), which includes Impella 2.5, Impella CP, Impella 5.0, and Impella 5.5, has emerged as a promising short-term support strategy [15]. The devices contain a catheter-based microaxial pump, which can be implanted via femoral or axillary artery cannulation and deliver flows up to 5.5 L/min.

Outcomes data for Impella are thus far limited to observational studies and small randomized trials. In the ISAR-SHOCK trial (n = 26), Impella 2.5 was associated with a higher cardiac index after 30 minutes of initiation of support, compared with intra-aortic balloon pump (IABP) therapy. This benefit appeared transient, however, and there were no differences in inotropic requirement at 24 hours but increased rates of hemolysis in the Impella group. There were no differences in 30-day mortality (46%) [16]. Similarly, in the IMPRESS trial (n = 48), Impella CP was not associated with a survival benefit when compared with IABP (30-day mortality with IABP and Impella CP: 50% and 46%, respectively) [17]. Among patients undergoing percutaneous coronary intervention in a large-scale cohort (n = 4,782), approximately 10% received Impella, which was associated with higher mortality (OR 1.24, 95% CI: 1.13 to 1.36), bleeding (OR 1.10, 95% CI: 1.00 to 1.21), and stroke (OR 1.34, 95% CI: 1.18 to 1.53). Notably, this study did not specify the type of Impella device used (e.g., Impella 2.5, Impella 5.0, or Impella CP) [18]. Similarly, when compared with a matched cohort from the IABP-SHOCK II trial, the use of Impella was associated with increased rates of bleeding and peripheral vascular complications but no survival benefit [19]. This study, however, only focused on Impella 2.5 and Impella CP devices. In contrast, the Impella 5.0 has been associated with survival rates of 94% at 30 days, 81% at 6 months, and 75% at 1 year [20]. Therefore, Impella 5.0 and Impella 5.5 may be associated with better outcomes, but further prospective studies are needed to better define the role of these devices. Of note, Impella 5.0 has been described as a bridge-to-recovery, bridge-to-device, and bridge-to-transplantation therapy, with 30-day survival rates of 50%, 65%, and 83%, respectively [15].

Similar to Impella, the TandemHeart (LivaNova) provides short-term support and can be deployed rapidly, utilizing a percutaneous approach. The TandemHeart employs a left atrial-to-femoral bypass, using trans-septal cannulation of the left atrium for inflow and femoral artery cannulation for outflow. The circuit is driven by a centrifugal, extracorporeal pump, which is capable of delivering flows up to 4 L/min. Support with TandemHeart has been associated with 30-day and 6-month mortality of 20%-40% and 45%-47%, respectively [21,22]. Along with intra aortic balloon pumps and extracorporeal membrane oxygenation, both the Impella and TandemHeart devices offer suitable options for hemodynamic support. Moreover, temporary MCS is an acceptable option in bridging patients to transplantation. Indeed, recent studies have shown similar post-transplant outcomes compared with medical management and durable device support, which supports recent changes in the United Network Organ Sharing allocation policy [23].

The field of mechanical circulatory support is evolving rapidly. As the technology continues to improve, the devices will become safer, more durable and portable. Although this review focused largely on patients with left-sided heart failure, concurrent right-sided heart failure often coexists in these patients. Although biventricular devices (total artificial heart and tandem devices) are acceptable options, the associated morbidity and mortality remains high. Thus, further research is needed to advance our understanding of device-related complications, to refine patient selection, and to safely and effectively support patients with biventricular failure.

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