



UnBLOCK the Chain

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The evolution of left ventricular assist devices

Cutting-edge therapy at a high price

Left ventricular assist devices (LVADs) have transformed the treatment landscape of heart failure. As the number of implants continues to increase, clinicians will have to integrate dedicated programmes in their clinics and be actively involved in the care of patients on LVAD support.



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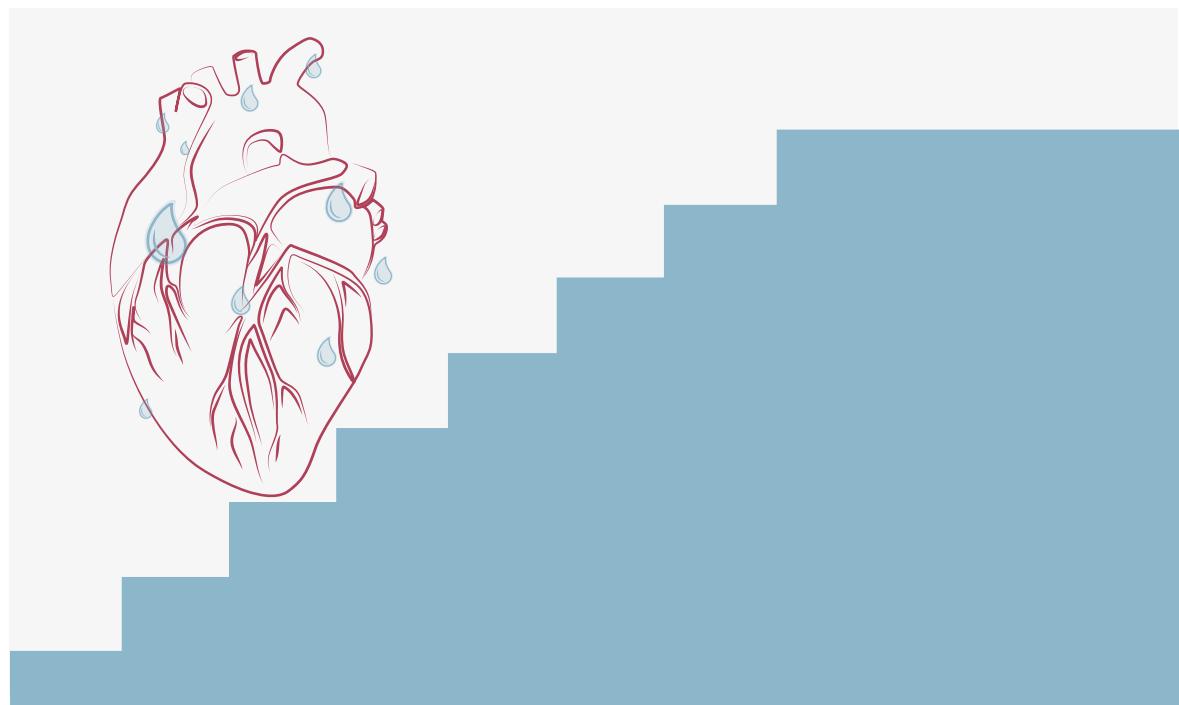
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Heart failure is one of the most common cardiovascular conditions worldwide. The estimated prevalence of heart failure is increasing at epidemic proportions. By the end of 2014, 6.5 million Americans ≥ 20 years of age had been diagnosed with heart failure. This prevalence is projected to increase to > 8 million by the year 2030. (Heidenreich et al. 2013). Data from the NHLBI-sponsored CHA, ARIC and CHS cohorts indicate that heart failure incidence approaches 21 per 1000 people older than 65 years (Huffman et al. 2013). The total costs for HF are projected to reach \$69.7 billion by 2030, which represents an increase of 127% from 2012 (Benjamin et al. 2018).

Approximately 50% of heart failure patients

have reduced ejection fraction, and 10% of these patients experience refractory heart failure symptoms (New York Heart Association functional class IIIb to IV, Stage D), yielding an estimated cohort of 200,000 to 250,000 patients. These patients are typically referred to cardiac transplant centres, where they undergo evaluation to determine their candidacy for heart transplantation. The short- and long-term outcomes following cardiac transplantation have been exceptional, with a median survival of 10.7 years (Stehlik et al. 2011). The major limitation to cardiac transplantation has been the insufficient donor supply, which is currently limited to approximately 2,500 hearts annually in the United States. Obviously, transplantation is not available



for the majority of patients with advanced disease. Fortunately, mechanical circulatory support with the implantation of cardiac assist devices has emerged as a novel therapeutic option for patients with refractory symptoms despite optimal medical and conservative treatment.

Left Ventricular Assist Devices

Left ventricular assist devices (LVADs) have revolutionised the management of patients with advanced heart failure, providing an alternative to heart transplantation. LVADs were initially implanted as a bridge to transplant, aiming to reduce the high mortality rates among hospitalised patients awaiting donor hearts. However, the paucity of donor organs alongside a substantial increase in the burden of comorbidities and the ageing of the heart failure population has put the focus to non-transplant surgical therapies for advanced heart failure. LVAD therapy was shown to improve survival and quality of life, either as a bridge to transplant or as a destination therapy (Slaughter et al. 2009; Aaronson et al. 2012). Following FDA approval for destination therapy (DT) in 2010, LVAD implantations have rapidly increased. The proportion of patients allocated to DT increased from 19.6% during the period 2008–2010 to 45.7% of all implants in 2014. The miniaturisation of devices, the evolution of device technology and the improvisation of the operative techniques as well as better patient selection and complication management have led to a significant improvement in survival rates. The 8th Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) report on > 20.000 LVAD implantations from 2006 to 2016 announced 1-year survival of 81% and 2-year survival of 70% (Kirklin et al. 2017). Nowadays, LVAD therapy constitutes an established treatment option for well-selected patients with advanced heart failure. As a result, the number of transplant and non-transplant centres integrating LVAD programmes in their facilities is rapidly expanding, and a further increase in device implantations is anticipated in the near future.

Economic impact of LVAD on healthcare

Despite these advantages, LVAD therapy is accompanied by a disproportionately high resource consumption and has an immense economic impact on the healthcare system. This results from the frequent hospital readmissions, the broad spectrum of severe device-related complications and the

need for a dedicated team of qualified healthcare workers in order to ensure appropriate long-term care in the outpatient setting. Previous analyses have demonstrated that LVAD was accompanied by volatile increases in healthcare expenses, compared to heart transplantation. Compared to non-bridged heart transplant recipients, receiving an LVAD as a bridge to transplantation increased survival, with greater associated cost (range, \$84964 per life-year to \$119574 per life-year for high-risk and low-risk patients, respectively). Open heart transplantation increased life expectancy and was cost-effective (8.5 years with <\$100000 per quality-adjusted life years [QALY] relative to medical therapy), but LVAD either as a bridge to transplantation (12.3 years at \$226 000 per QALY) or as destination therapy (4.4 years at \$202000 per QALY) was not cost-effective (Alba et al. 2013; Baras et al. 2016). These conflicting interests are reflected to an ongoing dialogue between healthcare policymakers, hospital leaders, and front-line clinicians, aiming to counteract healthcare disparities in a cost-effective manner and improve clinical outcomes of this devastating disease.

“ LEFT VENTRICULAR ASSIST DEVICES (LVADS) HAVE REVOLUTIONISED THE MANAGEMENT OF PATIENTS WITH ADVANCED HEART FAILURE, PROVIDING AN ALTERNATIVE TO HEART TRANSPLANTATION ”

Under these circumstances, clinics pursuing to initiate LVAD programmes are confronted with a challenging environment and have to take into consideration various aspects of this exceptional mode of therapy before moving to capital investments. In general, an LVAD programme is considered a challenging endeavour with regard to receiving funding, administrative support, and local acceptance from affiliated institutes and healthcare providers. Hereafter, we summarise some aspects from our own experience:

- Ideally, an LVAD programme should be part of an interdisciplinary heart failure unit consisting of a cardiology and a cardiac surgery department with an adequate number of potential LVAD candidates.

- Considering the multi-organ manifestations of advanced heart failure and the broad spectrum of non-surgical interventions indicated in this patient cohort, the candidate centre should be able to provide interventional and surgical cardiac procedures, cardiac electronic device implants and intensive care. A dedicated outpatient clinic is part of the required infrastructure in order to provide high-quality care of the ambulatory patients on the long term.
- The physician leadership team is the core of the LVAD project. An experienced heart failure cardiologist and a cardiothoracic surgeon with expertise in mechanical circulatory support should supervise all aspects of device implementation, including patient selection, staff training, quality controls, and cost-effectiveness.
- A qualified team of surgeons, heart failure cardiologists, and nurses familiar with the complexity of LVAD therapy should be of high priority. Two VAD coordinators should oversee the entire process from candidacy to follow-up care and take on administrative and organisational tasks. Staff training in special skills and familiarity with psychosocial, technical and pharmaceutical issues is of paramount importance for all parties. Rehabilitation physicians should be part of the caring team and stay interconnected with the implantation clinic if not regionally located.
- At last, an in-hospital heart transplant programme or a transplant centre affiliation is vital for patients who are or may become eligible for bridging therapy and should be offered transplantation candidacy. Participation in a palliative care network or at least an

on-site consulting service should be available for the end-of-life care of LVAD patients.

LVADs have transformed the treatment landscape of heart failure and are now adopted for long-term ambulatory support of patients with advanced disease. As the number of implants is anticipated to rise, clinicians in administrative positions will be surged to integrate dedicated programmes in their clinics and be actively involved in the care of patients on LVAD support. Consequently, all aspects of this mode of therapy will have to be considered, in order to provide optimal care at a reasonably acceptable cost. ■

KEY POINTS



- ✓ LVADs have revolutionised the management of patients with advanced heart failure
- ✓ LVAD therapy improves survival and quality of life, either as a bridge to transplant or as a destination therapy
- ✓ An LVAD programme should be part of an interdisciplinary heart failure unit consisting of a cardiology and a cardiac surgery department
- ✓ The physician leadership team is the core of the LVAD project
- ✓ An in-hospital heart transplant programme or a transplant centre affiliation is vital for patients who are or may become eligible for bridging therapy



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