



Guest Editor: Prof. Doris SF Yu

## **Evolvement of left ventricular assist device: the implications on heart failure management**

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### **Abstract**

Heart failure (HF) is a potentially fatal disease that affects increasing number of people worldwide. Although heart transplant is the “gold standard” therapy for HF, due to the limited availability of organs, many patients died when waiting for the transplant. Left ventricular assist device (LVAD), as a mechanical circulatory support, has become a new light for patients with HF. With the technical advancements, LVADs work not only as a bridge to transplant, but also assist heart recovery and even as a destination therapy in long-term treatment. This observation paper reviewed the development of LVAD and its clinical roles. The challenges and possible solutions in nursing care for patients with LVAD at different stage of implantation were discussed. The healthcare professionals could obtain a better understanding about the LVAD treatment for HF patients.

*J Geriatr Cardiol* 2016; 13: 425–430. doi:10.11909/j.issn.1671-5411.2016.05.015

**Keywords:** Destination therapy; Heart failure; Left ventricular assist device; Nursing

## **1 Introduction**

Heart failure (HF) is a common but potentially fatal condition, occurring when the heart is unable to provide sufficient blood flow to meet the demands of the body.<sup>[1]</sup> After the diagnosis of HF, about 40% of the patients die within one year.<sup>[2]</sup> Implantation of left ventricular assist device (LVAD) has become a common approach for life sustain if heart transplant is not an option. As the technical advances in mechanical circulatory support, LVAD has been widely applied not only as a bridge to transplant (BTT), but also in assisting recovery and long-term treatment. However, as an invasive therapy, patients with LVAD may experience many complications and have complex needs in long term care.<sup>[3]</sup> The aim of this observation paper is to review the development of LVAD and common challenges in nursing care for patients with LVAD implantation, and to raise the awareness of healthcare professionals on managing and supporting this group of patients.

## **2 Prevalence and treatment of HF**

Over 23 million people worldwide have developed HF.<sup>[4]</sup> In Europe, 3.6 million people are newly diagnosed with HF every year.<sup>[5]</sup> In the United States, HF affects 5 million people and causes 58,309 of deaths per year.<sup>[6]</sup> In China, a population-based study reported the prevalence of chronic heart failure (CHF) was 1.26% among 8,459 adults aged ≥ 35 years in Xinjiang Uygur Autonomous Region, northwest of China.<sup>[7]</sup> Moreover, the prevalence of CHF increased markedly with age in that cohort. In those aged 35–64 years, the prevalence ranged from 0.29% to 1.32%, while the prevalence ranged from 2.55% to 4.10% in those aged ≥ 65 years.<sup>[7]</sup> Similar results were also demonstrated in a hospital-based survey among 12,450 patients in Hubei, central region of China, with a CHF prevalence of 6.7% vs. 30.8% among those aged 40–59 years and 60–79 years, respectively.<sup>[8]</sup> Only in the year of 2012, HF caused 18,125 hospital-admissions and 806 deaths in Hong Kong.<sup>[9]</sup> Given the ageing population in China, HF is anticipated to impose an increasing burden to the health care system.

The increased prevalence of HF may be attributed to the success of medical treatment, as well as to the ageing population. As HF advances progressively, pharmacotherapy

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**Received:** December 9, 2015      **Revised:** March 16, 2016

**Accepted:** March 30, 2016      **Published online:** May 28, 2016

may be unresponsive or ineffective to control the symptoms. When the drug therapy fails to provide symptom control to HF patients, their condition is likely to rapidly deteriorate.<sup>[10]</sup> Although heart transplantation is considered as the “gold standard” therapy for HF, not all patients can obtain benefits from this treatment because of the limited availability of organs, increasing age of the patients, and other comorbidities or contradictions to heart transplantation.<sup>[11,12]</sup> Particularly, many patients died while they were on the waiting list for transplant. Hence, alternative treatment options are necessary for patients with advanced HF to improve their survival rate. Under this condition, LVAD was initially developed as a valid therapy used to bridge patients towards heart transplantation.<sup>[13]</sup> To raise the awareness of healthcare professionals on this therapy, the paper will firstly introduce the development of LVAD and its clinical roles.

### 3 Development of LVAD

LVADs are mechanical devices that assist the pumping function of the left ventricles by diverting blood into an external circulatory circuit connecting the left atrium or ventricle to the aorta.<sup>[14]</sup> The LVAD usually consists of three components: the internal component of pump implanted to the left ventricle, a percutaneous driveline, and external components of a controller and batteries. Since its invention in early 1970s, LVAD has been widely chosen to provide a simple, efficient, and cost effective support to advanced HF sufferers who await a donor’s heart, which is more than often in shortage.<sup>[15]</sup>

The very first successful implantation of LVAD was completed by Dr. De Bakey in 1966 to a 37-year old patient for ten days until her heart transplantation.<sup>[16]</sup> The first LVAD consisted of a titanium frame, and a polyurethane pump. It was pneumatically powered to assist ventricular function. Following technical breakthrough, the first-generation LVADs were improved with creation of the Novacor pump and the HeartMate XVE pump. Connected to two external batteries and a controller, the Novacor LVAD was then electrically powered, and can pump four to ten liters of blood per minute.<sup>[17]</sup> Furthermore, the polyurethane pump was replaced by inflow and outflow tissue valves, and two pusher plates placed at the two ends of a blood sac. The HeartMate LVAD pumped blood using a single motor-powered pusher plate. Instead of these improvements, the first-generation LVADs still possessed unfavorable factors. First, due to the large size with multiple internal and external parts, the first-generation LVAD was inconvenient to carry despite being portable. In addition, the five-hour battery life of the device, to a great extent, limited patients’

freedom. Secondly, the use of a two-part compressing system was associated with mechanical malfunctioning caused by deterioration in either part. Thirdly, the first-generation LVAD posed various risks to patients, such as infection, bleeding, and thrombosis.<sup>[17]</sup> To address the above problems, the second-generation LVAD was invented.

The second-generation LVADs include models such as the HeartMate II, the Jarvik 2000, the Berlin Heart Incorporation, and the Micro-Med-De-Bakey VAD. Compared to the first-generation, the second-generation LVAD adopted a single axial rotatory motor pump to drive circulation.<sup>[18]</sup> This upgrade reduced the chance of mechanical abnormality, hence, enabled higher durability. The removal of the compliance chamber also allowed the device to be a much smaller size.<sup>[19]</sup> According to the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure,<sup>[20]</sup> the second-generation LVADs brought about a 15% increase in survival rate and better quality of life among patients. Although improved, patients with the second-generation LVADs often required taking high dose of anticoagulants, which increases their risks of bleeding.

With the aim to provide higher quality of cardiac care and to minimize inconveniences and risks, the third-generation LVADs are striving for smaller size and with more sophisticated structures. For instance, HeartWare, one of the latest version LVADs, has achieved an enhanced mechanical durability because it has no bearings.<sup>[21]</sup> Its smaller size also facilitates the implantation procedure. Up to now, the most updated LVADs have become smaller in size, more reliable in performance, and less adverse to the overall well-being of the patients.<sup>[15,19]</sup> In order to improve the function and to facilitate the long-term implantation, further technological developments are also currently undergoing, such as the use of more-durable fluid-dynamic pumps and magnetic levitation.<sup>[17]</sup>

Compared with the rapid development in western countries, the development of LVAD devices in China is not up to the pace. The first LVAD system, named Luo-Ye pump, has been approved by China Food and Drug Administration (CFDA) for clinical trials since 1998.<sup>[22]</sup> The Luo-Ye pump was pneumatically powered with a spiral vortex flow (the first-generation LVAD). Till 2013, 23 patients were implanted with the Luo-Ye pump and 15 (65.2%) died during hospitalization.<sup>[23]</sup> Among the eight patients discharged with Luo-Ye pump, five died within 30 days and three has been supported in long-term (2.5 years to 15 years).<sup>[23]</sup> In 2012, an axial blood pump (FH-I, the second-generation LVAD), designed by Fu Wai Hospital (the National Center for Cardiovascular Disease of China) was approved by CFDA for clinical trial.<sup>[24]</sup> Anecdotal evidence provided by the head

nurse of Fu Wai Hospital revealed that around 60 patients received implantation of FH-I for BTT in short-term during hospitalization. In addition, several other types of domestic LVAD devices are undergoing animal experiments, including an intra-aorta pump developed by Beijing University of Technology,<sup>[25]</sup> a magnetic–liquid suspension blood pump designed by TEDA International Cardiovascular Hospital and China Academy of Launch Vehicle Technology,<sup>[26]</sup> and the ChinaHeart VAD by Suzhou Tongxin Co. Ltd.<sup>[27]</sup>

Besides the few implantations of domestic devices in clinical trials, the use of imported LVAD in mainland China is also limited. Fewer than 30 Abiomed paracorporeal pneumatic LVADs were implanted every year since this device obtained approval from CFDA in 2013.<sup>[28,29]</sup> The slow application of LVAD may be ascribed to multiple factors, including the lack of approved devices, the high cost of the device and lack of medical insurance coverage. According to the national requirements for clinical application of ventricular assist devices,<sup>[30]</sup> only a few medical centers are qualified for the LVAD implantation, including Fu Wai Hospital, Guangdong General Hospital, Shanghai Eastern Hospital, and TEDA International Cardiovascular Hospital.<sup>[28]</sup> Therefore, a small number of health care professionals have participated in caring for patients with LVAD. More opportunities for education and training on management of LVAD are needed. Given the increasing clinical needs and active research of current teams, the development of LVAD in China is expected to have an impact on HF management.

#### 4 The clinical roles of LVAD

LVADs were originally designed with an intention to be a bridge to enhance the survival rate of patients waiting for heart transplantation. Accordance with the advancements in the size and performance of the device, the clinical roles of LVAD also change. Currently, LVADs not only serve as a BTT, but also assist cardiac recovery and even as a destination therapy (DT) in long-term treatment for those terminally ill patients who are ineligible for heart transplantation.<sup>[15]</sup>

As a BTT, LVADs are generally used when a patient experiences cardiogenic shock or sudden deterioration in clinical status to temporarily maintain the normal blood circulation while waiting for a suitable heart. One of the best examples that illustrate the importance of this device was when it was first implanted into a 37-year-old female patient. With the assistance of the device, the patient successfully maintained normal circulatory functioning for 10 days before heart transplant.<sup>[16]</sup> Since its invention, LVADs have

benefitted over 8000 patients and have afforded the survival rate ranging from 60% to 71% for HF patients.<sup>[31]</sup> Given the improvements in technology, an even higher survival rate can be expected with the use of the new generations LVADs. Therefore, LVADs are successful as a BTT for patients with advanced HF.

Significant myocardial recovery due to LVAD assistance has been reported.<sup>[32,33]</sup> Prolonged use of LVADs had demonstrated close association to structural reverse remodeling, which may be ascribed to the chronic assistance of the device in unloading the burden of the left ventricle.<sup>[17,33]</sup> Therefore, the implantation of LVADs can ultimately assist heart recovery. At this point, LVAD has often been used together with medication to promote patients' recovery.

The smaller size and more stable performances make the long-term application of LVAD possible. In 2010, the continuous flow HeartMate II was approved by the Food and Drug Administration (FDA) of the United States as DT.<sup>[21]</sup> According to the sixth annual report of Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), the number of primary LVAD implantation in the United States significantly increased from 1652 in 2010 to 2506 in 2013.<sup>[31]</sup> Consistent with the increasing prevalence of HF, the number of heart transplant and the number of patients with LVADs listed for heart transplant have been increasing. Till the end of 2013, 3373 (36.0%) patients were implanted with continuous flow LVADs for DT. Accordingly, the proportion of patients with LVAD listed for heart transplant in the United States reduced from 42.4% in 2006–2007 to 21.7% in 2011–2013.<sup>[31]</sup>

In Hong Kong, the first LVAD (Berlin Heart Device) was implanted to a 7-year-old boy with acute fulminant myocarditis in 2004. Since then, the number of LVAD implantation has been increased. In 2010, the continuous flow LVAD (HeartMate II) was firstly successfully done in Hong Kong. Till May 2013, nine patients with end stage HF received LVAD implantation and seven were discharged home.<sup>[34]</sup> After discharge, five patients were back to full-time or part-time work and two died: one developed multiple organ bleeding and thromboembolic stroke at 2-month; the other one developed massive cerebral hemorrhage at 6-month.<sup>[34]</sup> With the extended roles of LVAD in recovery and DT, more patients with advanced HF in Hong Kong will benefit from the implantation of LVAD.

#### 5 Challenges for nurses in caring patients with LVAD

Although the LVADs are effective in improving the survival rate and quality of life, there are many challenges in

caring for the patients who receive the implantation.<sup>[3]</sup> With the increasing implantations of LVAD as a long-term treatment, the patients would have to meet their complex needs in daily living with the device, in terms of the physical, psychological, and social issues.<sup>[35]</sup> Therefore, nurses are expected to provide specialized and multifaceted cares to these patients at different stages of the implantation.

Before the implantation, medical treatments and related nursing interventions should be administered to ensure that the physical and hemodynamic conditions of the patient are suitable for the implantation. Moreover, consultations are normally provided not only by cardiologists but also by nurse specialists and related healthcare professionals regarding to the risks and benefits of the LVAD therapy. Regardless of health care systems, issues about financial hardship, body image, loss of control, and burden to the family should also be discussed prior to the implantation.<sup>[36,37]</sup> The quick development in usage of LVAD definitely creates a new horizon for nursing knowledge and practice to be further elevated. In order to provide high quality of care to these patients and their families, nurses should be equipped with up-to-date knowledge on LVAD care.

Following the implantation surgery, the patient should normally be placed in the intensive care unit. The hemodynamic status, renal and hepatic functions, infection, and wounds are carefully monitored. Once physically stabilized, the patient will be transferred to a progressive care unit for further rehabilitation, such as early ambulation, cardiac rehabilitation, and discharge planning.<sup>[38]</sup> Patients with LVAD and their caregivers are required to operate the device independently. Previous research revealed the complex needs of patients and their families in living with LVAD.<sup>[38,40]</sup> Physically, the patients need to make numerous changes in activities of daily living, including hygiene (such as showering and dressing for the driveline), sleeping, clothing, and modifying the home environment to ensure appropriate power supplies to the device.<sup>[35]</sup> Psychologically, most participants need to overcome their fear and anxiety, which are usually caused by the worry about the device (such as malfunction, power supply, troubleshooting alarms, and related complications) and uncertainty about the future.<sup>[35]</sup> In addition, the patients also have higher levels of needs in socialization, self-esteem, and self-actualization, such as adjusting interpersonal and social relationships, and restoring normalcy in public.<sup>[38,39]</sup> The patients and their care-givers have to learn various strategies and develop a routine to manage LVAD, and consistently adhere to the home care regimes in daily living at home.<sup>[38,40]</sup>

Evidence demonstrated that a better understanding on the relevant operation of the device among the patients and ca-

regivers was associated with better quality of life and lower anxiety levels.<sup>[37]</sup> Therefore, education and trainings must be provided before discharge to ensure that they obtain the essential knowledge and skills for living with LVAD. These knowledge and skills include, but not limited to: (1) monitoring and maintaining the function of the LVAD, e.g., charging of the batteries and checking the functions; (2) daily care of the driveline, such as driveline immobilization and sterile dressing techniques; (3) taking prescribed medications and monitor the side-effects, e.g., bleeding and thrombosis; (4) appropriate lifestyle adjustments in diet (e.g., low-sodium and low-fat diet, and limited foods rich in Vitamin K), physical activities, and activities of daily living (e.g., showering, clothing, and sleeping); and (5) learning adaptive methods and positive strategies to cope with the psychological distress imposed by LVAD in the early stage (e.g., a good sense of humor, religious activities, and active social participation), and preparing for acceptance of LVAD as a vital component of living.<sup>[11,35,38]</sup> Moreover, the patients and caregivers must be trained to seek appropriate medical assistance under emergency conditions, such as malfunction of the controller, failure pump, exacerbation symptoms of HF, and complications of anticoagulation therapy.<sup>[38,40]</sup> The American Heart Association recently updated the scientific statement for mechanical circulatory support.<sup>[41]</sup> However, no guideline was available for nurses to provide care to LVAD patients at home.

After discharge, nurses should also provide continuous education, training, and consultation to ensure their competence and commitment in long-term living with LVAD. Regular follow-ups and close communications with the LVAD team are essential to prevent complications, maintain health, and improve the quality of life of the patients.<sup>[42]</sup> It was reported that a specialist nurse delivered weekly telephone follow-up improved patients' confidence levels in self-care, reduced the hospital readmission rate of patients with LVAD by 15.5%, and shorten their length of stay in hospital by 20.9%.<sup>[40]</sup>

Currently, patients are required to document their vital signs, related LVAD parameters, and medication in a logbook, and share the information with the LVAD team during follow-up visits.<sup>[35]</sup> However, this monitoring approach could not provide real-time information to the health care professionals since the logbook could only be accessed during clinic visits. The evolving technologies in telemedicine enable opportunities to provide constant monitoring and treatment for this group of patients. Tele-cardiology is a modern medical practice using tele-communications to achieve remote diagnosis and treatment of heart diseases, such as hypertension, acute coronary syndrome, arrhythmias,

and HF.<sup>[43,44]</sup> Tele-cardiology with home-monitoring has been applied in patients with implantable cardiac defibrillators or cardiac-resynchronization therapy, and revealed positive effects in reducing clinical adverse events (23.8% vs. 48.7%, hazard ratio = 0.14,  $P < 0.001$ ), reducing the time for reviewing device alerts (1.4 vs. 24.8 days,  $P < 0.001$ ), reducing the number of clinic visits (21% differences,  $P < 0.001$ ), and improving the quality of life ( $P = 0.026$ ).<sup>[45,46]</sup> These positive outcomes indicated the promising future of employing tele-cardiology in LVAD patients. With the power of specialized devices, health care professionals could access to the real-time information of the patients and the device, and provide timely and continuous support to this group of patients.

Nurse researchers are also exploring LVAD-specific self-management outcomes, including self-efficacy for and adherence to the complex LVAD home care regime among patients and family caregivers.<sup>[47,48]</sup> In addition, prevention of HF cannot be overlooked. More than half of patients with heart disease are physical inactive, overweight, and/or with hyperlipidemia, and HF could be an end result of coronary heart diseases.<sup>[49]</sup> Therefore, education on promoting heart health should also be provided to all patients.

In summary, HF is a growing and serious public health concern affecting over 23 million people worldwide. With the technology improvements, LVAD, a type of mechanical circular support, has been widely used among HF patients not only as a BTT, but also as recovery assistance and DT. With the continuous efforts in device development and clinical application, more patients with advanced HF in China will be benefited from LVAD implantation. In a nutshell, the healthcare professionals, patients, and their caregivers should have a comprehensive understanding on LVAD and the challenges in caring at different stages of implantation. In order to improve the nursing care provided to this group of patients with unique needs, further nursing research on physical, psychological, and social aspects of caring for these patients are needed. Tele-cardiology with the power of specialized devices could be employed to provide close monitoring and improve the quality of care for this group of patients.

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