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Left Ventricular Assist Devices – A State of the Art Review

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Abstract

Cardiovascular diseases are the leading cause of mortality rates throughout the world. Next to an insufficient number of healthy donors, this has led to increasing numbers of patients on heart transplant waiting lists with prolonged waiting times. Innovative technological advancements have led to the production of ventricular assist devices that play an increasingly important role in end stage heart failure therapy. This review is intended to provide an overview of current implantable left ventricular assist devices, different design concepts and implantation techniques. Challenges such as infections and thromboembolic events that may occur during LVAD implantations have also been discussed.

Keywords

End-stage heart failure · Mechanical circulatory support · Ventricular assist device · VAD

Keywords and Abbreviations

VAD	Ventricular assist device
LVAD	Left ventricular assist device
RVAD	Right ventricular assist device
BVAD	Biventricular assist device
UMTS 3G	Universal Mobile Telecommunications System, 3. Generation
FDA	U.S. Food and Drug Administration
CE	Communauté Européenne
HTx	Heart transplantation
NYHA	New York Heart Association
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
ICS	Intercostal space

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1 Introduction

Cardiovascular disease is the leading cause of worldwide morbidity rates. Chronic ischemic heart disease, acute heart failure and myocardial infarction are among the primary causes of mortality in Europe (45% of all deaths), the United States of America (34,3%) and worldwide (45% of noncommunicable diseases) (Lloyd-Jones et al. 2010; WHO|NCD mortality and morbidity [Internet] 2016; Wilkins et al. 2017).

There are different options for treating heart failure depending on the severity, cause and course of heart failure. They include adjustments to patients lifestyle (e.g. more sports, diet), drug administration and surgical interventions.

Surgical therapies includes but are not limited to coronary artery bypass grafting, implantation of stents in affected coronary arteries, the repair or replacement of an failing heart valve and finally the heart transplantation, which serves as a gold standard for terminal end stage heart failure in refractory patients. The discrepancy between the number of patients waiting for a heart transplant and the number of donor hearts at hand, shows that this therapy is not available for everyone who needs it (Eurotransplant – Statistics [Internet] 2016). Implantation of long term left ventricular assist devices, offers an alternative treatment for patients falling in this gap or are not eligible for heart transplantation for reasons like comorbidities (Mancini and Colombo 2015). According to the seventh INTERMACS annual report, over 13,000 patients received implants for left ventricular support in the United States of America in 2014, out of whom 955 were implanted pulsatile flow LVADs and 12,030 – continuous flow LVADs respectively (Kirklin et al. 2015). Next to these implantable long term VADs, there are catheter-based, para- and extracorporeal blood pumps. Catheter based rotational pumps like Impella 2.5, RP (Abiomed) or HeartMate PHP (Abbott) provide temporary mechanical circulatory left of right ventricular support in case of e.g. acute cardiogenic shock or percutaneous coronary intervention. Paracorporeal systems, like Excor (BerlinHeart GmbH) are mainly implanted in children with heart failures. Other blood pumps (peristaltic or rotary pumps, e.g. Rotaflow, Maquet, or Centrimag, Abbott) are used in extracorporeal membrane oxygenation systems (ECMO) or heart lung machines for short and midterm support of the circulatory system. Despite this high variety of blood pumps in mechanical circulatory support, this chapter offers a focused overview of the current implantable, rotary left ventricular assist devices (LVAD, also abbreviated as VAD), along with their characteristic designs and implantation strategies. Current challenges involving LVAD implantation have also been discussed.

2 Left Ventricular Assist Devices – Indications and Implantation

A left ventricular assist devices (LVAD) is used for hemodynamic support of the left ventricle in patients suffering from terminal refractory left ventricular failure.

Heart failure standard of care in the form of mechanical circulatory support by left ventricular assist devices may differ between countries and is often dependent on the funding available for LVAD implantation programs (Birks 2010). The clinical indications for VAD implantation may vary with patients. Such indications include VAD support either until a suitable donor heart is transplanted (bridge to transplant or BTT), or until the patient stabilizes such that eventual entry on the heart transplant waiting list is possible (bridge to candidacy or BTC), or until a decision on further treatment options for patient into question can be made (bridge to decision or BTD). VAD implantation may also serve as an alternative lifelong treatment for patients on cardiac transplant lists (destination therapy or DT) or until myocardial recovery occurs (bridge to recovery or BTR). The LVAD is then usually explanted, in other cases it remains in place, the outflow graft is ligated and the driveline is removed (Rodriguez et al. 2013; Frazier et al. 2015; Khvilivitzky et al. 2012). A special application of LVADs is the support of both, the left and the right ventricle (biventricular assist device, BVAD) or as a total artificial heart (TAH). Both implantation scenarios are very rare and off-label uses (Frazier et al. 2010). The distribution between the implantation purposes differ from country to country mainly due to approval status of the devices and availability of donor hearts. As stated by the INTERMACS registry, the distribution between BTT, BTR and DT implantations were 53.5%, 45.7%, and 0.2% respectively in 2014 in the US (0.5% of all implantation were rescue and other) (Kirklin et al. 2015). This chapter focuses on long-term, implantable VAD system with the main implantation purpose BTT, BTR and DT.

Costs of LVAD therapy depends on several entries like device costs, hospitalization frequency, duration, costs, as well as follow-up length and costs. Literature presents wide spread data for total LVAD costs and should be interpreted carefully. Total LVAD costs found in literature ranges from $316,078 to $1,025,500 (Seco et al. 2017), a German-French group presented accumulated 2-years costs of €281,361 ± 156,223 (Aissaoui et al. 2017). The key component of a ventricular assist device is the blood pump. The pump establishes a parallel blood flow path (ventricles > cardiac support pump > aorta ascendens) to physiological bloodstream (ventricles > aortic valve > aorta ascendence). The pump draws blood from the left ventricle by an inflow cannula which is connected to the apex by a suture ring with a fixing and sealing mechanism, and giving it back into the systemic circulation by means of an outflow graft. Typically the outflow graft is sewn to the ascending aorta. In a few cases it can also be useful to anastomose the descending aorta (Zucchetta et al. 2014). The blood pump is connected with a powersupply by means of a cable (driveline). The driveline passes from the pump, through the musculus rectus abdomini and fascial layers into the abdominal region of the patient. The cable exits the body through a small incision in the skin (Slaughter et al. 2010). The cable sheath (usually made of silicone or polyurethane) is covered in the implanted part with a woven or non-woven material, which ensures an optimal ingrowth (Dean et al. 2015; Camboni et al. 2016). The driveline is immobilized close to the exit site to the skin by means of a fixing system and to protect the exit site from mechanical manipulation. The exit site of the cable is protected from possible infections, by a mandatory sterile dressing. The pump is externally connected to a control unit (controller). Constant power supply through the controller is ensured either by two batteries or a battery and an AC adapter. Some VAD manufacturers still offer other options, such as a 12 V AC adapter, which provides power supply through a car battery. Peripheral components (such as controller and batteries) may be carried in a portable system (a bag, rucksack, etc.), giving the patient mobility for several hours. To enable constant power supply the patient receives a replacement controller and spare batteries. The batteries are charged at home using a special battery charging station.

Additional devices for adjusting the VAD-speed and other VAD parameters are available at the clinical centers: Every complete VAD system contains a monitor which can be connected to the controller with a cable. One manufacturer (ReliantHeart, Inc.) provides an additional remote monitoring system that transmits the VAD parameters to a server by means of a UMTS mobile phone standard (3G). The parameters can then be accessed by the clinical VAD team using a web-based interface.

The implantation procedure is individual for each VAD type. The Instruction of Use (IFU) of the specific LVAD provides all requirements and implantation and application instructions to be followed by the physician. The following section should give an simplified principle of the implantation steps of VADs:

- The chest is opened by median sternotomy or minimally invasive techniques
- The sewing ring is sutured to the apex with felt pad sutures
- The myocardium within the suture ring is punched out as an access for the inflow cannula (also in reverse order to the fixation of the suture ring)
- The ventricle is checked for thrombi, any existing thrombi are removed
- Positioning and fixation the inflow cannula of VADs in sewing ring
- Placement and anastomosis of outlet graft at the aorta ascendens
- Subcutaneous placement of the connecting cable, with the exit point at the right or left upper quadrant of the abdomen
- Fixation of the cable
- After hemostasis the thorax and the cable exit point are closed and the wounds are dressed

Prior to LVAD application, it is necessary to prepare the pump in the sterile field in the operating room. The sterile system components

removed from the sterile outer packaging are visually inspected for integrity. Inlet and outlet cannula are mounted as required and the driveline is connected to the control unit and power line. A test run is performed in a bowl with sterile dextrose solution. The pump, sewing ring, outflow graft and driveline are usually soaked with antibiotic solution dependent on the pump type.

A default access for pump implantation is full sternotomy. After the pericardium is opened the heart and great vessels are exposed. The heart lung machine (HLM) is cannulated right-atrial and aortic. This approach provides a good overview of the heart and adjacent large vessels, the larger surgical field allows more options for treatment. This approach is favorable, if concomittant interventions such as heart valve replacement and repair, closing of an atrioventricular septal defect or implantation of epicardial pacemaker leads are required.

There are also less invasive techniques available with two access points to the thorax defined by the apex of the left ventricle (pump inlet placement) and upper mediastinum (outlet graft anastomosis) (Schmitto et al. 2014; Hanke et al. 2015). The opening to the apex is performed through a left thoracotomy at the level of the 6th intercostal space (ICS). The exact position of the left ventricular apex and thus the thoracotomy is detected by echocardiography before incision. For the opening of the upper mediastinum two approaches are possible: an upper hemisternotomy that is only partially opening the sternum, or a right-sided thoracotomy at the level of 1–2 ICS. After opening the thorax, the pericardium is only partially opened as far as it is necessary to provide access. The pericardium surrounding the right ventricle is left largely uninspected and the heart remains in its original position. Both facilitate the prevention of a possible right heart failure in the course. This technique is linked to additional benefits such as less adhesion complications, less bleeding complications, shorter ICU stays, potential reduction of infections, and cosmetic aspects. The implantation is performed using an extracorporeal circulation, heart-lung machine (HLM). A cardioplegia of the heart is not always carried out ("beating heart" approach).

There are several strategies for placement and anastomosis of the outlet graft includingthe anastomosis to the descending aorta, and placement of outlet graft in the sinus transversus pericardii or a bulge in the pericardial cavity (Hanke et al. 2016a, b).

The driveline is typically implanted in a large arc in the abdominal fascia and/or in the muscle sheath of the rectus, it exits the body in the abdomen (usually upper right or left quadrant). Here there are different tunneling techniques with one, two or three small incisions to implant the longest possible part of the driveline cable as an infection barrier. The driveline exit site is then supplied with a sterile wound dressing and a cable fixation, which is changed regularly. The patient retains the sterile dressing procedure even after the wound has healed, in order to constantly protect against infection and (micro) injuries (Slaughter et al. 2010; Fleissner et al. 2013).

3 Left Ventricular Assist Device – Design Aspects of the LVAD

Various types of blood pumps are currently used in clinical treatment. These mechanical pumps are used for extracorporeal circulation, as part of a cardiopulmonary bypass, extracorporeal membrane oxygenation system, or dialysis system, as an implantable version for a ventricular assist or as a total artificial heart (Der Deutsche Herzbericht [Internet] 2016). The application timespan can vary from a few hours for the short-term usage up to several years for long-term usage. Depending on the application, blood pumps can be built as positive displacement pumps or rotary pumps. Implantable ventricular assist pumps for long-term applications in terms of LVAD application nowadays employ only rotary pumps and will be discussed in this section. The VADs design implements wide-spread user specification areas, including hemodynamic function, hemo- and biocompatibility, durablility, usability during the implantation and explantation and daily in later handling, storage and transport conditions before implantation and during subsequent application (Girdhar et al. 2012; Schmitto et al. 2014; Geidl et al. 2009; Sabashnikov et al. 2013; Pagani et al. 2009; Schmitto et al. 2015).

The historical development of implantable cardiac assist pumps started with the pulsatile displacement pumps with pneumatic or electromechanical drives from the 1970s ("1st generation"), which, while still paracorporeal, were often not fully implantable. Rotary pumps with mechanical rotor bearings ("2nd generation") came up in the 1980s and 1990s, while last generation ("3rd generation") rotary pumps with contactless bearing concepts were first reported in the 1990s and 2000s (Reul and Akdis 2000; Heart Assist Devices – Texas Heart Institute [Internet] 2016; Tang et al. 2009). The currently approved systems in use for adults are 2nd and 3rd generation systems, which are significantly smaller and lighter than their predecessors from the first generation. They can be implanted in the mediastinum above the diaphragm, smaller pump types may be implanted within the pericardium. These turbine-like machines transmit energy through the swirl on the blood to move the blood forward. The designs vary between axial-flow rotors, diagonal- or mixed-flow rotors, and radial- or centrifugal-flow rotors. In general, as the size and the hydraulic power of axial to radial designs increase, the number of revolutions per minute decreases correspondingly.

The forces acting on the rotor from the blood flow and the motor drive are leveled with a suitable hemocompatible bearing. There are two bearing design principles applicable for for axial, radial or mixed rotor forms: mechanical contact bearings, or free-floating, contactless bearings which may be hydrodynamic, passive-magnetic or active-magnetic.

Mechanical bearings are used in the 2nd generation LVAD, which arefriction type, "lubricated" mechanical bearing forms such as a ball-cup bearing antagonizing axial and radial forces on the rotor. They are relatively easy to manufacture and maintain the rotor stable in its position. Disadvantages of these contact bearings include heat development, high shear forces or insufficient wash out and stagnation areas, resulting in subsequent insufficient haemocompatiblity (hemolysis and thrombus formation). Appropriate operation of the bearing is only assured when completely immersed in blood (or blood substitute).

Wearless rotor bearings are typical for 3rd generation LVADs. Hydrodynamic bearing surfaces are designed to produce a local pressure in a fluid film between rotating rotor and housing, thus creating a fluid force. This is achieved with tilted surfaces or spiral grooves. Such bearings solely operate in moving liquid environments with a specific viscosity range. With increasing rotational speed a fluid film is built up and the bearing functions effectively. Disadvantage of this bearing design includes operating point dependency, narrow gaps, which are required for moderate hydrodynamic forces, subsequent tight manufacturing tolerances, which require a complex and expensive manufacturing process, and generation of high shear stresses on the blood, resulting in elevated blood damage as well as activation of coagulation.

Magnetic bearing types contain permanent magnets or active magnetic systems. While permanent magnet deposits do not produce stable equilibriums of forces and are therefore used mainly in hybrid bearings, active magnetic systems with the help of distance sensors are able to control rotor-position in housing and work with larger rotor to housing gap dimensions. These design characteristics result in excellent hemocompatibility (Loree et al. 2001; Schmitto et al. 2017; Wieselthaler et al. 2010). As far as disadvantages are concerned, complexity (many active components, including sensors and regulation hardware and software) and the associated overall size of pump itself and its external system components should be mentioned. Table 1 provides an overview of actual LVADs in clinical application.

3.1 Additional Components

Along with the pump, additional components and tools complete the LVAD system. Surgical tools include a circular knife or punching system for opening of the left ventricular apex. Depending on the manufacturer and system another tool

Table 1 Information on clinically relevant VADs

LVAD (manufacturer)	Pump type	Generation	CE/FDA approval	Characteristics
HeartAssist 5 (ReliantHeart, Inc.)	Axial	2.	2014/IDE trial	Implantable blood flow sensor, remote monitoring
HeartMate II (Abbott.)	Axial	2.	2005/2010	First continuous VAD with FDA approval
HeartMate 3 (Abbott.)	Centri-fugal	3.	2015/IDE trial	Latest VAD with CE approval
HVAD (Medtronic)	Centri-fugal	3.	2009/2012	First LVAD with minimally invasive implant approval
Incor (BerlinHeart GmbH)	Axial	3.	2003/–	First implantable VAD with active-magnetic bearing
Jarvik 2000 (JarvikHeart, Inc.)	Axial	2.	2005/clinical trial	Retroauricular implantable plug for power supply

Berlin Heart [Internet] (2016), Welcome to Reliant Heart [Internet] (2016), HeartWare [Internet] (2016), Thoratec – Innovative Therapies for Advanced Heart Failure [Internet] (2016), Jarvik Heart Inc. The Jarvik 2000 [Internet] (2016) and Food (2016)

(dynamometric key) is necessary to fix the pump inlet in the sewing ring. For intramuscular and subcutaneous implantation of the driveline, a tunneling tool (trocar) is used, that may be pre-bent and has a tip along with a connecting mechanism for the cable connector. A small incision to penetrate the skin is created with either a surgical standard tool (scalpel or scissors) or a small circular knife, which is included in the pump-set. Finally, a sterile extension cable is often used, which is later removed, in order to connect a non-sterile control unit with a sterile cable in the sterile field.

4 Achievements and Current Research Topics

Since the first use of cardiac assist pumps, physicians and developers have learned a lot about the systems and their interaction with the human body. In addition to improvements and adjustments in patient management and operating techniques, this experience led to numerous technical improvements and new developments which in its turn brought radical changes into the concepts of the blood pump. Fatigue strength was improved immensely with the transition from pulsatile displacement pumps to centrifugal pumps and non-contact bearing concepts. The downsizing of the systems has improved implantability and reduced surgical trauma, especially when combined with new surgical techniques. Advancements in electrical engineering such as battery, microprocessor technology and (electro) magnets have contributed to both the internal and external components of the VAD systems to be smaller and lighter. Though the control and regulation of the pumps have become more complex but also more potent and consequently an increased quality of life for patients could be achieved. The hemocompatibility, biocompatibility and interaction with the (hemodynamic) system were substantially improved by adapting materials and surfaces, rotor and housing design taking into consideration hemodynamics and blood flow in the system including global and local shear stresses as well as residence times. This technical progress has been flanked by new manufacturing and development processes as well as further developments in the field of materials science.

Despite the rapid technical and clinical advancements, LVAD therapy still has to deal with serious complications. As the latest annual report of US-based VAD register INTERMACS (over 15,000 patients included) shows, the overall complication rate has decreased (Kirklin et al. 2015). The rate of hemolysis, strokes, renal dysfunction and lung failure, however, increased. Major complications accompanying the months after implantation include infection, bleeding, system malfunction, stroke or death.

These statistics provide a good overview of the challenges arising during the therapy with implantable cardiac support pumps in the future.

Firstly, it is not enough to focus solely on a technical optimization of the devices, but it also is necessary to examine the relation between the pump and physiology of patients along with a deeper understanding of infections and (anti-) coagulant events. Current research topics deal with new and optimized diagnostic procedures for early complication detection and intervention or complication prevention. Secondly, new technical and/or pharmaceutical therapy options need to be developed to address encountered complications fast and in a conservative manner. The psychological and ethical as well as quality of life aspects of a VAD implantation are addressed in additional research areas. To avoid infection and improve the quality of life of patients with ventricular assist pumps, ongoing work is focused on systems that allow transcutaneous energy transfer (TET). Feasibility was shown in few patients, today's and future developments in battery and pump technology may contribute for successful translation in clinical practice (Mehta et al. 2001). Telemonitoring is another current research topic, which will allow clinicians to view patient data online and thus assist them immediately. As a consequence (as known from other areas of heart failure therapy), patients may benefit from less routine clinic visits, early detection of complications and subsequent early and presumably more safe and cost-saving therapy (Welcome to Reliant Heart [Internet] 2016; johan.van.der.heide[at]itea3.org J van der H. 14003 Medolution [Internet] 2016).

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