Innovation and improvement of Left Ventricular Assist Devices

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Abstract

Left ventricular assist device is the device which helps assist the heart of the patients suffering with heart failure. It is a device which will allow the blood to flow through the heart as well as pumping the blood to all over the body, providing the oxygen for the organs and tissues to function. Since the first day that this left ventricular assist device has been introduced, it has massively improved including its design, material and how it is able to deal with life threatening risks that the patients may have.

This review paper will provide the comparisons between the left ventricular assist devices in different generations and types, which will help see more about the differences that have been made to the left ventricular assist device. Also, the explanation of how left ventricular assist devices work, the important risks that the medical community still faces nowadays, and the possibilities of future improvement of left ventricular assist devices.

1. Introduction and Background

At present heart failure has become the fastest growing cardiovascular diagnosis with an approximation of 500,000 cases per year according to the research by Dr.Leslie W.Miller. While there are estimated to be about 250,000 in the United states alone which have two options on whether to have a path to a transplant or having an ventricular assist device implanted. The ventricular assist device is a machine designed in purpose of supporting the circulatory system within the body, which is used to partially or to completely replace the work of a failing heart. The pumps used in ventricular assist devices can be divided into two main categories which are pulsatile pumps and continuous flow pump. The pulsatile pump is the pump that imitates the natural pulsing of the heart, whereas the continuous flow pumps are smaller and it is experimented to be more persistent than pulsatile ventricular assist devices and normally use either a centrifugal pump or an axial flow pump in order to let the blood flow. The first Left Ventricular Assist Device (LVAD) system was developed by Domingo Liotta at Baylor College of Medicine in Houston in 1962 and the first LVAD[A] implantation conducted in 1963 by Liotta and E. Stanley Crawford. The first successful implantation of a left ventricular assist device was then completed in 1966 by Dr. Michael E. DeBakey to a 37-year-old woman. However, despite its massive success in the implantation, there are still risks after the implantation in all of the aspects of this devices so, this review paper has aimed to give the more insight knowledge of ventricular assist devices, especially with the left ventricular assist device, including the materials used, functions, improvement and design. Also, to evaluate the benefits and risks of left ventricular assist devices.

2. What is Left Ventricular Assist Devices

A left ventricular assist device is a pump that is used for patients with the stage when the treatment or medicine used in the past no longer works on patients anymore and the patients will have life expectancy less than or equal to six months. The LVADs surgically implanted just below the heart and the left ventricle of the heart is attatched to one end of the devices, while the other end is attached to the aorta, the body's main artery. Blood flows from the heart into the pump. There are two main types of the pump, one is centrifugal-flow pump and the other is axial flow pump. The centrifugal flow pump designed for the intrapericardial placement, it has circular shaped, and in which blood from the left ventricle into the blood inflow cannula drives the motor which is the magnetic hydrodynamically levitated impeller. The blood then flows through the pump housing and to the aorta. However, the axial flow pump has a linear shape and is designed for placement inside the abdomen of the body (intra-abdominal placement). The blood flows from the left ventricle of the heart into the place where in the blood is received to make the blood flow more straightened and smoother, it is called the inlet stator. This inlet stator attached rotor bearing which is the rotating part of the machine by the magnetic field. The blood then flows through the rotor which drives the motor of the devices, and to the aorta to send the oxygenated blood to all over the body. The outer parts of the LVADs includes, driveline and the chord, the part where it is connected to the batteries and often extend out of the body through the skin.The controller, the computer that operates the pump and the batteries which is the power source of the pump, providing the power for the devices to work properly. The LVADs can also, be used as a pathway the to transplant therapy which is a life saving choices available for patients waiting for a heart transplant until a heart becomes available for the transplantation, and the Destination therapy, in which patients are not candidates for heart transplants but rather choose to use the LVADs devices as a support.

3. Design of Left Ventricular Assist Devices

Designing an LVAD[A] must take several factors into regard. The size of the devices must be taken into considerations as they should be in a size which makes it possible for the implantations and be made of consistent materials which will not cause the disease to the body and do not emit the radiation when placed inside the body and the structure that allows the device to stay in the body with no complications of being rejected with low masses and costs. Fluid dynamics, power supply for the devices, and temperature regulations must also be regarded. As numerous interacting physical effects must be explored for each section of development, simulations which involve using large amount of physics knowledges and models are essential to the designing process. Large amounts of model were used in the advancement and improvement of the centrifugal pump of the left ventricular assist device. Important problem related with technology and designing these machines is the prevention of blood clotting in spaces both in and around the pump, the place where most infection happens is the stator inlet. In order to resolve this problem, a rotor which rotated by the mangnetic field was introduced. This eradicated the need for ball bearings and other parts with shape that might promote clotting. The developers also used the Rotating Machinery simulation technology to create the simulation of magnetically rotated rotor and turbulent fluid flow to simulate the conditions . A permanent magnet in the pump rotor is compelled by coils in the stator, which apply a torque[B] on the rotor and provide active control of the location of the rotor axis. The upright position of the rotor is achieved by the magnetic field generated in the devices and does not need an active monitoring. The rotor accept the blood axially and redirects it radially, into the coil. Certain amount of the blood flows back around the outer edge of the rotor and into the rotor inlet, leading to a constant amount of the blood passing through as a consequences, which abolished the sites where the blood can idle and clot.

4. Patients evaluation for Left Ventricular Assist Devices surgery

In order to be able to have a surgery for LVAD[A], there is a need for evaluation including;

- Echocardiogram
- Exercise VO2[C] max test, which shows the amount of oxygen the heart and lung can provide to the muscles in the body
- Right heart Catheterization, measure the pressure in the heart
- Left heart Catheterization[D], which is to use the dye to observe the coronary arteries.
- Electrocardiogram
- Laboratory test for blood group, organ function and exposure to other diseases
- Chest X-Ray
- Pulmonary function test which determines the lung function, in the case that the patients are smokers

5. Benefits of Left Ventricular Assist Devices

LVADs is highly recommended for those patients with a weak and failing left ventricle especially after suffering from myocardial infarction or a heart attack, as a support system before the cardiac surgery takes place in certain cases and most crucial for those patients with an heart failure which the treatment is no longer works on a patients with the patients have a maximum life span of six months. There are numerous benefits of LVADs, first of all, the left ventricular assist device allows the patients to have a better life as well as longer survival chances with more than seven years rather than waiting for the heart transplant. The life expectancy of the patients with end stage heart failure implanted with LVADs is longer than those who are on other medical treatments. The left ventricular assist device also helps relieve some symptoms relating to the heart disease such as breathlessness and constantly fatigued as the blood flow has been restored by the device while before the implantations, the heart can not function properly so, the body did not received enough oxygen for the cellular respiration. This helps patients feel better and take part in daily activities and avoid hospitalization for heart failure. In a very rare cases, the ventricular assist device also allows the heart to recover its normal ability and functions by giving it a chance to rest and for the cardiac muscle cells to recover after suffering with the heart disease. Furthermore, it also improves the function of the kidneys, liver, brain and other organs, and that the patients are able to do exercise after the implantations and allows patients to go through cardiac rehabilitation with the greatest chance of surviving.

6. Risks of Left Ventricular Assist Devices

After the surgery, there are several risks to consider. Firstly, the infection may be caused by the power supply and the control center of the LVADs. As these devices are located outside the patient's body and are linked by a port in the patient's skin which can increases the risk of microorganisms entering and invading the body through those port which has been exposed. Secondly, internal bleeding is also one of the concerns, as the implanting ventricular assist device requires open-heart surgery which means to normally used the heart-lung bypass machine during the transplantations. This can increase the risk of bleeding during and after the procedure. The doctor and surgeon will suggest the patients to take in the medicine which allows the blood to flow better called blood-thinning medication, to prevent bleeding in the gastrointestinal tract and in the brain. The example of blood-thinning medication includes warfarin and aspirin. Moreover, the problems with heart failure, respiratory failure and kidney failure can also lead to further complications and risk the patients' lives. The blood clot can reduce or block the blood flow in the body which then leads to stroke and heart attack. While the patients are required to follow the doctor's instructions carefully as the side effects of the medications might include the liver damage and dizziness. Lastly, the most important possibility is the device malfunction or failure, the ventricular assist device might stop working properly after it is implanted and might not be working correctly. The three most important risks are risk of bleeding and devices malfunction.

- **Risks of bleeding**

Bleeding is the most common risk after left ventricular assist device (LVADs) implantation. Patients with LVADs[A] require antiplatelet and anticoagulant treatment to prevent high blood pressure, as well as prepare them for bleeding complexity. Bleeding that arises in the first 14 days after the implantation surgery is mostly related to the surgery (during the processes of surgery). However, the incidence of haemorrhagic events or bleeding constantly within six months of releasing out of the hospital is low. Determining the likely causes and risk factors for bleeding is necessary for the progress of overall outcomes as well as the quality of life of patients with LVAD[A] devices. One of the areas in which bleeding usually occurs is in the gastrointestinal area. The bleeding occurs at a mean of 33 days from surgery, with the greatest risk within the

first postoperative month.The cumulative risk of gastrointestinal bleeding for patients receiving the HeartMate II and the HeartWare is 21%, 27% and 31%, at one, three, and five years, respectively. The other important site of bleeding is bleeding into the central nervous system however, central nervous system bleeds occur comparatively late.

- **Risks of infections**

Infections are a frequent source of disease, and are the second most common source of mortality in patients six months after LVAD surgery. Infections are also one of the foremost causes of readmission to the hospital in these patients implanted with LVAD. The rates of LVAD-related infections are large, and can happens to almost half of all the patients after the surgery. The most recent information from the INTERMACS registry stated that pneumonia and sepsis are the most common cause of infectious and complications in patients implanted with LVADs, also the second common area of infections is at the driveline site which is the area where it is needed to extend out of the body, which occur in LVAD recipients within one year after implantations. Pump interior infections and infections in the pocket of the devices are rare as they are located inside the body. The most common organisms accounted for causing severe infections related to LVADs are skin microorganisms, including staphylococcus species (*Staphylococcus epidermidis* and *Staphylococcus aureus*), corynebacterium species, followed by pseudomonas species and enterobacteriaceae, they are often found in a great number after a longer period of time in the patients with LVAD support. In the patients who suspected to have an infections, the diagnosing and investigations should include quick culture of outflow from the driveline exit site to determine the species of bacteria or microorganisms that caused the infection and so the further treatment can be given. The doctor often take three sets of blood cultures, chest radiography, and echocardiography in order to determine the conditions of the patients.

- **Devices malfunction**

According to the device malfunction studies in ahajournals published on the 3rd of July 2017, types of Device malfunctions included controller failure, battery failure, patient cable failure and pump failure. The most types of malfunction is the controller failure and the least common is the pump failure. The LVAD[A] malfunction is an important cause of disease and death. Device failure was the second most frequent reasons of death in the REMATCH trial; at 24 months' post-implant, more than a quarter of patients faced the problems with the device failure. Nowadays, as the cardiologists offer care for more LVAD[A] patients, it is very important that they are able to resolve and adjust a malfunctioning device.

7. Evolvement of Left Ventricular Assist Devices

Since the LVADs invention in early 1970s, LVAD[A] has been widely chosen to provide a simple, efficient, and cost effective support to the advanced heart failure sufferers who is waiting for a donor's heart, which is more than often in shortage, and who decided to rely on this devices. The foremost succession of LVAD[A] implantation of was completed by Dr. De Bakey in 1966 to a women patient and stayed for ten days until her heart transplantation taken place, as referred in the introduction. The foremost generation of LVADs[A] still possessed the unfavorable features. First of all, it has a huge size with multiple internal and external parts, this makes the first generation LVAD[A] inconvenient to carry regardless of claiming to be portable. Also, its duration of battery of only 5 hours decreases the convenience of the patients as the patients would needed to stay near the charger or having available battery supports for all the time. Furthermore, the use of two part compressing systems, which require two parts to work together could cause the mechanical and devices malfunctioning caused by the deterioration in either part. Lastly, the first generation LVAD[A] possesses a variety of risks to the patients includings infection, bleeding, and thrombosis. Until the second generation of LVAD[A], the model such as HeartMate II, the Jarvik 2000 and the Berlin Heart incorporation. In comparison to the first generation, the second generation of LVAD[A] used the single axial rotatory motor pump which allow the high fluid flow rates and low pressure to be generated and promote circulation. This innovation lowered the possibilities of mechanical abnormalities and malfunctioned, hence, enabled higher durability. The HeartMate II can be in smaller size due to the removal of the compliances. The second generation LVADs[A] allowed 15% of patients to have higher survival rates, lifespan and the better quality of life. Even though improved, It is necessary for patients with second generation of LVAD[A] to take a high dosage of anticoagulants to help reduce the bleeding and blood clot. The third and newest generation of LVADs[A] is HeartMate III which aims to have a smaller size with more advanced structures. Nowadays, the new generation LVADs[A] have smaller size, more reliability with lower risks of infections, blood clot and devices malfunctions. Moreover, there are further technological developments and are also currently being on trials including more durable fluid-dynamic pumps, rotation created by magnetic field and artificial pulses.

Table 1. Device comparisons between Heartware (HVAD), Heartmate 2 and Heartmate3

Functions	**Heartware (HVAD)**	**Heartmate II**	**Heartmate III**
Pump design	centrifugal flow 1800-4000 rpm	Axial flow 6000- 15,000 rpm	Centrifugal flow 4800-6500 rpm
flow (pump)	Centrifugal	Axial	Axial
pump location	intrapericardial space	intraperitoneal space	intrapericardial space
pump speed	10L/min flow	10L/min flow	10L/min flow
Bearing	-	mechanical (blood washed)	Magnetic
implantation location	Extrathoracic	Extrathoracic	Intrathoracic
quick pump attachment	No	No	Yes
electronic corporate	No	No	Yes
textured surface	No	No	Yes
software incorporated pump	No	No	Yes
artificial pulse	No	No	Yes
battery running time	5 hours	-	20% longer than Heartmate II

Table 2. The ventricular assist devices and improvement in increasing patient's quality of life and lifespan after implantation.

Medical complications and information of LVADs devices	**Heartmate II**	**Heartmate III**
Number of patients	26600	-
clinical and scientific publications	900	-
life expectancy rates	76%	80%
transplant survival after 2 Years	82%	79%
Heart related infections	-53%	-76.9%
Bleeding	-61%	-76.9%
Stroke	-36%	10%

8. Future of Left Ventricular Assist Devices

There are several problems with the ventricular assist device which needed to be solved. During the ventricular assist device placement surgery, the full open-chest surgery, where the chest is cut open and the surgery performed on the artery of the heart, this type of surgery is required which creates large scars on the patients' body. This gives the room to the microorganisms to enter the body of the patient. Also, in the process of implanting, the approach is invasive in order to place the device correctly which also makes the patient recover in a long period of time as the tissues have been damaged by the implantations. The pumps are large and heavy which might cause damage to the surrounding cells and tissues in the body. Next, the energy transfer system is large and heavy as the patients need to carry the battery around which might lower the quality of life of the patient. The battery is not waterproof therefore, the patients cannot do everyday activities comfortably. Lastly, the price of the devices are high and due to these high costs, not every patient is able to afford the devices which can improve their living qualities without the financial and health care system help from the government, which are not available in the undeveloped and some developing countries. So, if these problems are solved in the near future, more LVADs[A] will be available for the patients around the globe and saved more lives in the future.

9. Conclusion

In conclusion, since the left ventricular assist device has first been introduced, it has created beneficial contributions to society as well as being one of the factors which could increase the life expectancy of patients suffering with the heart disease. The left ventricular assist device has been developed in order to minimise the life threatening risk such as risk of infection, blood clotting, bleeding, and device failure. This allows the patients to have a longer life span as well as having higher quality of life as a patient so that they can do their normal daily activities and being an alternative treatment other than the heart transplantation. Nowadays, there are many improvements made to the left ventricular assist device since the introduction of the heartware (HVAD) until the heartmate III. All of the devices are now interfering and relying on the magnetic field to drive the pumps with intrathoracic implantation and the artificial pulses which can improve and increase patients' life span. The batteries are also able to stay longer than the old version of the devices. So, in the future, the devices might be wireless, longer life span of batteries and waterproof which can further support the patients and give larger benefits to the patients in the future ahead of us.

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Abstract

A. LVAD Stands for Left Ventricular Assist Device

B. Torque is a twist or turning force resulted in a rotation

C. VO2 max test is test for the maximum amount of oxygen utilize during exercise

D. Catheterization is procedure used to diagnose and treat certain cardiovascular conditions.

E. Colonoscopy is an exam used to detect changes or abnormalities in the large intestine (colon) and rectum.