

REVIEW ARTICLE

The artificial heart: Medical improvements on infections and strokes

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ABSTRACT

Artificial hearts are designed to eliminate the need for heart transplants, which are in short supply. However, these devices are prone to creating complications such as infections or strokes. The complications occur from the mechanical aspects of the device. Therefore, the devices' effectiveness is influenced by their design. This paper investigates the advances in technology of different artificial hearts that are being developed. The four devices evaluated in this paper are: the total artificial heart, the left ventricular assist device, the total internal artificial heart, and the HeartWare ventricular assist device. Research shows that the total artificial heart may result in both infections and strokes. The left ventricular assist device lowered the probability of these complications but did not eliminate the risk altogether. While the internal artificial heart was able to eliminate the risk of infections entirely, it introduced new complications. Finally, the HeartWare ventricular assist device decreased the rate of adverse events for the complications occurring over time. Given these results, artificial hearts still require further research to improve the risk of complication before the phasing out of heart transplants can occur.

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INTRODUCTION

Artificial hearts are being engineered as an alternative solution to heart transplants. This issue was addressed by Gray and Selzman (2006). While heart transplantation remains a viable solution, shortages in the donor supply have limited this surgery to less than 2,500 patients per year. Consequently, about 10% to 20% of the patients on a waiting list die annually (Gray and Selzman, 2006). They concluded that “the disparity between the numbers of patients needing transplants and the availability of heart donors has refocused efforts to find other ways to support the severely failing heart” (Gray and Selzman, 2006, p. 4). Therefore, for the past two decades, some biomedical research has been focused on developing a working artificial heart.

Artificial hearts would be an ideal solution to heart transplants; however, there are many complications with them. The two main complications discussed here are infections and strokes (Stewart Garrick, 2012). Infections are caused from bacterial growth due to open incisions on the skin. The incisions, which depend on the specific device, must be made for the tubing to connect the internal components to a battery (DeVries, 1988). In addition, strokes can be caused from clots forming (thrombosis). These clots, called thrombi, are formed due to fragments of blood cells sticking to the mechanical device, and then breaking off (Stewart Garrick, 2012).

Brand new designs are being created to improve the situation. There are two different types of artificial hearts that have been developed: the total artificial heart (TAH), and the left ventricular assist device (LVAD) (Zareba, 2002). This paper investigates how the devices, and variations of these devices, deal with the two main complications, in order to make an appropriate recommendation.

DISCUSSION

I. The total artificial heart

Researchers had to start somewhere, and so the main function of the TAH was to ensure complete blood flow coming from the ventricles by allowing the device to adjust the pressure (Griffith et al., 1987). One of the first TAHs created was the Jarvik-7. This TAH had two “air-powered pumps” that mimicked heartbeats. Each chamber had a “disc-like mechanism” that pushes the blood through the device from the inflowing valve to the exiting valve (Khan & Jehangir, 2014, p. 123). By making cuts on the skin, this device was powered from an “external console” by using a tether (Zareba, 2002, p. 73). Due to the large size of the external power console, patients using this device had to remain immobile (Zareba, 2002).

Since this device required open incisions on the skin, it allowed for infections to occur. DeVries (1988) performed case studies of five patients who had the device implanted. He explained the “neurological, haematological, renal, and infectious complications” experienced by the patients, which lead to each of their deaths within 620 days (DeVries, 1988, p. 849). From these case studies, the risk of infection was seen to increase with the duration of the support from the device (Cohn, Timms, & Frazier, 2015).

The next main complication was stated to be strokes, which occurred from blood cells sticking to the wall of the device and thus forming clots. This complication lead to many secondary problems such as “sepsis, convulsions, kidney failure, respiratory problems, and multi-organ system failure” (Zareba, 2002, p. 73). Many engineers were discouraged with these obstacles, which diminished further interest in TAH research.

Due to the tragic results of the Jarvik-7, the Food and Drug Administration (FDA) suspended further trials in 1990 (Zareba, 2002). Thus, engineers decided to backtrack and instead focus on designing an alternative device. They sought for a device that could at least prolong the life of an existing heart. This would later become the left ventricular assist device.

II. The left ventricular assist device

In order to decrease the risk of complications, the main function of the LVAD was to aid the pumping of the left ventricle to the aorta in order to allow better blood flow. A frequently used LVAD is the HeartMateII (Zareba, 2002). The main components of the LVAD usually had a mechanism to create a pulsatile flow using a pumping chamber and multiple valves. Alternatively, it can use a rotary pump that creates continuous-flow (From, Hasan, Froehler, & Goerbig-Campbell, 2013). The main feature of the LVAD was that it could be worn, thus allowing the patient to be mobile. Therefore, the main problem that concerned the TAH is eliminated on the LVAD by removing the tether to the console. Instead, a driveline is used to attach the valves inside the body to the control system that is outside.

This design improves the issue of infections being caused from the open wound. Drivelines are smaller and more stable than tethers (Rose et al., 1999). However, research still showed that a 28% incidence of infection occurred within 3 months (Zareba, 2002). Unlike with the earlier device, these infections can be treated easily, and patients are often taught how to treat their wounds in order to decrease the risk (Zareba, 2002).

The Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) study was done to view the health risks involved with the LVAD (Rose et al., 1999; Travis et al., 2007; Zareba, 2002). The study initially showed that only minor incidents occurred regarding strokes. However, the LVAD still increased the risk of strokes, due to clot formation, despite it not directly causing them. Patients with newer model of a LVAD will not have a pulse because they have a steady and continuous blood flow (Travis et al., 2007). A heart's pulse creates enough force to prevent most clots from naturally forming, and thus reduces the risks of strokes. Therefore, the LVAD also eliminated the heart's natural defence against blood clots forming. LVADs are currently designed to sustain the heart for only a few months since they still need an external power source (Zareba, 2002). Strokes may arise not only from clot formation on a pump component, but also from ingested blood clots that are propelled through the device (Stewart Garrick, 2012). Moreover, a paramedic without much knowledge on LVADs could improperly treat an unconscious patient due to the lack of pulse experienced with LVADs. While this newer technology represented real progress, the search for a better solution continued. According to Zareba (2002), a fully transplantable replacement heart might be possible using "new transcutaneous energy transmission technology" (p. 75).

III. The total internal artificial heart

The total internal artificial heart is a unique type of the TAH. The main difference is that this device contains two pumps instead of one, as well as that the main components are internal. These features have thereby been shown to reduce the risk of infection

by removing the need for incisions used for tubing (Zareba, 2002). The first total internal artificial heart created was the AbioCor Implantable Replacement Heart. The AbioCor is an "advanced medical system" that resembles the function of the human heart. It consists of an "internal thoracic unit, an internal rechargeable battery, an internal miniaturized electronics package, and an external battery pack" (Zareba, 2002, p. 75).

This device involves advanced technology by allowing for wireless charging, which prevents the issue of infections since no open incisions needed to be made in order to apply power to the device. An internal and an external coil are used to form a transcutaneous air-core transformer, which can transfer energy electromagnetically through the skin and tissue. The primary coil is powered by an external power source that drives an oscillator while the secondary coil is simply implanted inside the patient (Zareba, 2002).

Because of the new technologies involved in this device, the FDA approved it to be implanted in humans in 2001 (Zareba, 2002). It was decided that the device would be used in fourteen patients who had a 70% chance of mortality within 30 days. Most of the patients lived up to 512 days. It was later reported that eleven of the patients suffered from non-device-related infections. However, none of them died as a result of the infection (Samak et al., 2015).

Unlike the previous versions, the AbioCor simulates the rhythm of the heartbeat. The device is equipped with an internal motor, which moves the blood through the entire body. The motor allows for pulsing, which can prevent strokes by eliminating natural clots from forming (Zareba, 2002). While theoretically this simulation should minimize the risk of strokes, nine deaths of the fourteen patients were reported due to strokes (Samak et al., 2015). Additionally, new issues are brought up due to its size. This device cannot be placed in most adults who have a smaller stature, and cannot at all be used by children (Zareba, 2002). It is evident that more research needs to be completed.

IV. The HeartWare ventricular assist device

Researchers wanted to incorporate the advances found in continuous-flow LVADs into the TAH design in order to reduce the risk of complications even further (Cohn et al., 2015). In 2005, the Researchers at the Texas Heart Institute succeeded in developing two continuous-flow LVADs, thereby creating a continuous-flow TAH. A wide variety of LVAD pumps were designed, such as the HeartWare Ventricular Assist Device (HVAD), over the following 8 years (Cohn et al., 2015). However, it was expected that complications would be similar to experiences with both single-ventricle mechanical circulatory support. The most apparent complications are once again infection and thrombosis, which causes strokes (Mulvihill et al., 2017). It was expected that the HVAD would limit the risk of strokes compared to the LVAD, but results showed that stroke events occurred in patients regardless of the type of device used (Maxhera, 2017).

Maltais et al. (2017) conducted the ADVANCE bridge to-transplant (BTT) and continued access protocol (CAP) trial, approved by the FDA. In the ADVANCE BTT CAP trial, 382 patients were assessed for infection and hemorrhagic stroke, among other complications, during predetermined time periods after HVAD implant for 3

years. Immediately post implant, incidence of infections and strokes were highest. These complications occurred in lower rates after 6 months. Furthermore, after 1 year, all complications exhibited stable rates. This changing risk over time has clinically meaningful implications toward improving patient management. For instance, the decreased risk for complications over time suggests the HVAD is effective for patients who require longer duration of mechanical circulatory support (Maltais Simon, 2017).

Researchers reported that implantation of HVAD is safe and offers benefits in regard “to less bleeding and fewer transfusion requirements, shorter operating room times, and also decreased need for mechanical ventilation” (Gregoric Igor, 2017, p. 71). Therefore, the HVAD provides significant improvements in survival and quality of life. Additionally, unlike the AbioCor, the HVAD permits biventricular support in smaller patients (Cohn et al., 2015). Advances in LVAD design are likely to further reduce device-related complications in the future (Gregoric Igor, 2017).

CONCLUSION

Each of the four aforementioned devices approach the problem of heart transplants their own way. While each of the devices accomplished their goal of providing the functions of a human heart, they still had to deal with the complications of infections and strokes. As previously stated, infections were caused from bacterial growth due to open incisions on the skin. Strokes were caused from clots forming due to fragments of blood cells sticking to the mechanical device, and then breaking off.

The use of TAHs was discontinued due to excessive complications relating to infections and strokes. This was proven in several case studies and showed that the TAH (Jarvik-7 in particular) was a failure. Next, the LVAD allowed patients to be mobile by attaching the battery to a belt. This improved their quality of life as they could still go about their daily routine. The device still showed complications relating to infections and strokes. The LVAD is an improvement from the Jarvik-7; however, patients do not generate a pulse. Moreover, the LVAD still had risk of complications, particularly strokes. As such, the LVAD should only be seen a temporary solution. The AbioCor improved upon some of the design problems of its predecessor. The AbioCor was the first wireless mechanical heart to be created by using coils to electromagnetically transfer energy without the use of wires. By doing so, the AbioCor finally made a big improvement on complications with infections because open incisions were unnecessary. However, strokes are still a reoccurring problem. The device is also too big; therefore, it cannot be used by men of smaller stature, women, or children. While the AbioCor is the most successive artificial heart technology to date, it should be avoided until further improvements are done to this design to make it more accessible. The HVAD still had the same issues as the LVAD; however, the improved design decreased the rate of adverse events occurring over time, thus decreasing the chance of infection or stroke. Therefore, complications and risk of death were greatly decreased after the first year of implantation.

Each time a new device emerged, the quality of life for the patients improved. Although the technology has improved as

well, patients continue to experience these serious complications. With the changes in adverse events being documented over time, researchers should focus on developing patient management strategies to minimize the occurrence of specific complications when the patients are most at risk.

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