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A STUDY ON VARIOUS DEVICES USED FOR ARTIFICIAL HEART TRANSPLANTATIONS

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ABSTRACT

The purpose of this article are to review the treatment options for late stage biventricular heart failure diseases the clinical indications for total artificial heart implantation The first implantation of a total artificial heat (TAH)50years ago the devices and technique have evolved to provide reliable support for patients with biventricular failure as a bridge to heart transplant. In the view of the major technical advances in ventricular assist devices (VAD) in recent years, the authors discuss the question whether these "artificial hearts "are still no more than the temporary measure for patients awaiting heart transplantation (HTx), or whether they can already be used as an independent form of long term treatment.

KEYWORDS: Total artificial heart (TAH), ventricular assist devices(VAD), syncardia etc.

INTRODUCTION

A total artificial is a pump that is placed in the chest to replace damaged heart ventricles and valves. Ventricles are the chambers of the heart that pump blood to the lungs and other parts of the body the total artificial heart has ventricles made from polyurethane, a widely use artificial material that is both durable and flexible[1, Komoda T et al. 2008]. once the pump has been placed in the chest, a machine called a driver controls the pump from outside the body. The pump and driver help blood flow to and from the heart replacing the role of healthy heart [2, Strüber M 2008].

If any surgery total artificial surgery can lead to serious problems such as blood clots or infection. TAH is mainly a temporary measure (often called a bridge to transplant) to keep blood pumping while a person waites for a donar heart for transplant. In the USA only one total artificial heart has been approved by the US food and drug administration (FDA) and it is only approved for use as a bridge to transplant[3, Cooley DA et al. 2003]. The number of patients on the waiting list for a heart transplant in Germany declined each year from 1998 to 2001, but the trend then reversed direction, with a steady increase ever since. The causes of this development are multiple. One explanation may be that the introduction of better conservative treatments for end-stage heart failure, such as beta-blockers and biventricular pacemakers[4, Bücherl ES et al 1985]. Another explanation can be found in the general demographic trend toward an increasing incidence of end-stage heart failure.

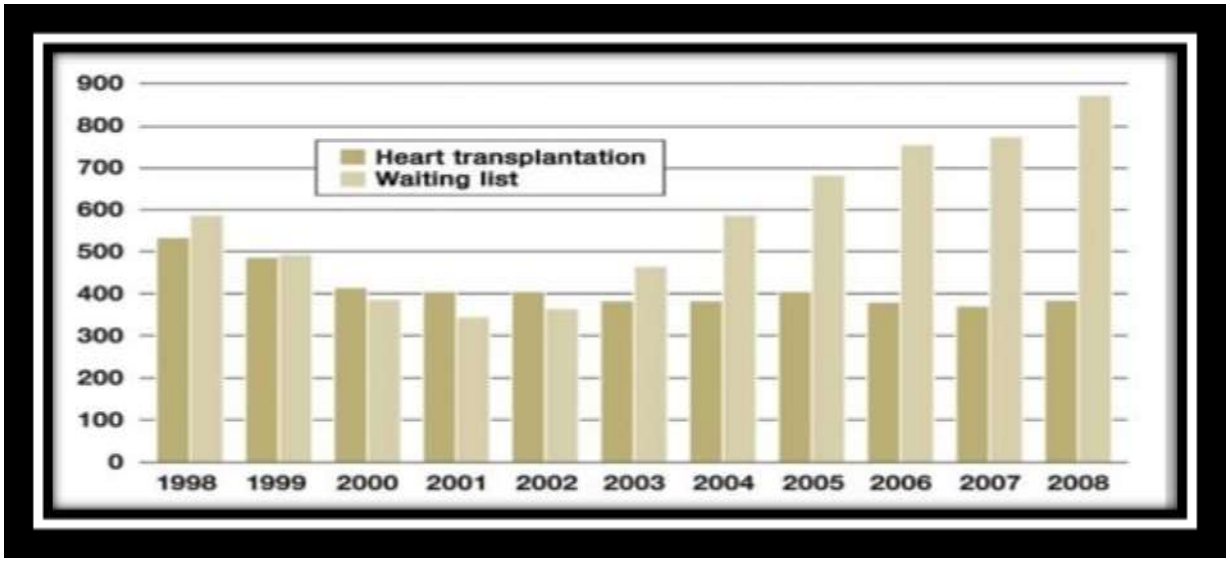


Fig. 1: The length of the waiting list and the number of heart transplantations performed each year in Germany, 1998–2008.

As early as the year 2000, a new allocation strategy was adopted to address this problem As early as the year 2000, a new allocation strategy was adopted to address this problem candidate If a patient in the HU category is in danger of dying while waiting for a transplant, ventricular assist devices (VAD) can be used as a temporizing measure until a transplantable organ becomes available. Data from Europe show that, among all patients receiving a VAD as a temporary treatment, only 25% go on to receive a transplant within one year This necessarily creates a state of chronic circulatory support with a left ventricular assist device (LVAD) for patients who are cared for on an ambulatory basis and who must live with such a device for an indefinite period of time[5, Hallman GL et al. 1969].

Recent Findings

The most studied device on the market is the SyncardiaTAH, which has been implanted in over 2000 patients worldwide and is the only device that is currently food and drug Administartion approved as a bridge to transplant[6, Kanter KR et al. 1988]. The overall survival in patients supported by the device at 1 year is 42 % while thtat make it to transplant survival of 83%. A Newer device the Aeson TAH(Carmat, Velizy-villacoublay, France) was the first implanted in france in 2013 and is currently under clinical trail[7, Reedy JE et al. 1991].

Treatment Options: Late-Stage Biventricular Heart Failure

The treatment options for late-stage biventricular failure include optimization of medical therapy, ventricular assist device implantation, definitive orthotopic heart transplant, and temporary TAH transplant[8, Frazier OH et al. 1994]. Advanced heart failure with New York Heart Association class IV and American Heart Association stage D symptoms is associated with a 1-year mortality rate of 60–94% when treated solely with medical therapy. The primary clinical indications for ventricular assist device implantation are bridge to orthotopic transplant, destination therapy for patients not eligible for transplant, and bridge to myocardial recovery (e.g., viral myocarditis, postpartum cardiomyopathy, cardiogenic shock after acute myocardial infarction or cardiotomy, and ventricular dysrhythmias unresponsive to medical therapy)[9, Schmitz C et al. 1995]. Orthotopic human heart transplant involves removing the diseased heart and replacing it with a compatible donor heart. It is the established reference standard for the treatment of end-stage heart disease.

Worldwide, approximately 5400 heart transplants are performed annually, most in the United States Patients who undergo cardiac transplants have a 1-year survival rate of approximately 85% and a 5-year survival rate of 75–80%. Moreover, 90% of cardiac transplant patients are able to lead a relatively normal lifestyle[10, Moskowitz AJ et al. 2001].Approximately 800,000 people have class IV heart disease and are in need of a new heart. The gross disparity between demand for a new heart and the limited organ supply has instigated the development of novel approaches to the management of end-stage heart disease until a human heart becomes available.

Device description

The implantable biventricular pneumatic pulsatile pump replaces the patient's native ventricles and valves[11, Moskowitz AJ et al. 2202]. The TAH pumps blood into both the pulmonary and systemic circulations. The implant and its external controlling console are connected by pneumatic drivelines. The artificial left ventricle is connected via a left atrial inflow connector to the native left atrium and to the native aorta by an aortic outflow cannula. Similarly, the artificial right ventricle is connected to the native right atrium via a right atrial inflow connector and to the native pulmonary artery via a

pulmonary artery outflow cannula[12, Moskowitz AJ et al. 2007]. each artificial ventricle's driveline conduit is tunneled through the chest wall. The right and left artificial ventricle driveline conduits are attached to 7-foot pneumatic drivelines that in turn connect to an external bedside console blood to enter the artificial ventricle. To eject the blood, a calibrated pulse of air pushes diap. Vacuum supplied by the pneumatic driver pulls the diaphragm down, allowing blood to enter the artificial ventricle. To eject the blood, a calibrated pulse of air pushes the diaphragm to the top of the artificial ventricle[13, Spratt P et al. 2007].

The computer-operated external console contains two compressed air tanks and a backup power supply (battery). The external console operates and monitors the TAH. The console includes a laptop computer that provides noninvasive diagnostic and monitoring data[14, Riedl M, Schima H et al. 2007]. Device rate, dynamic stroke volumes, and calculated cardiac outputs are displayed on a beat-to-beat basis. Drive pressure, flow wave forms, cardiac output trends, and patient-related alarms (e.g., low cardiac output) are also displayed [15, Vrtovec B et al. 2007]. The device is designed so that the maximum dynamic stroke volume of each artificial ventricle is 70 mL. However, it is possible to manually adjust systole and diastole for proper ventricular filling and emptying[16, Zimpfer D et al. 2006]. The left ventricular drive pressure is 150–200 mm Hg, and the right ventricular drive pressure is 55–90 mm Hg. The TAH can generate a cardiac output up to 9.5 L/min[17, Litwak P et al. 1999].

Device Components

The TAH consists of two separate artificial ventricles made of semirigid polyurethane housing with four flexible polyurethane diaphragms (a seamless blood-contacting diaphragm, two intermediate diaphragms, and an air diaphragm, or eight diaphragms in toto) that separate the blood chamber from the air chamber. The diaphragms allow the artificial ventricle to fill and then eject blood when compressed by air from the external console [18, Geisen U et al. 2008]. The artificial right and left polyurethane ventricles are attached via a midline Velcro strip (Velcro Industries). Four mechanical Hall valves (Medtronic) (two 27-mm inflow, two 25-mm outflow) are mounted on the housing,[19] Lietz K et al. 2007]. Flexible polyurethane right and left atrial inflow connectors are attached to the recipient's respective native atrial chambers. A synthetic aortic outflow cannula is connected to the native aorta, and a synthetic pulmonary artery outflow cannula is also connected to the native pulmonary artery [20, Potapov EV 2008]. The normal excursion of the air diaphragm is from one wall of the housing to the other. The air diaphragm for each respective artificial ventricle is connected to a pneumatic driveline,[21] (Fig. 2). The drivelines connect to either a standard bedside console (Big Blue, SynCardia Systems) (Fig.3) or a portable driver system (Freedom Driver, SynCardia Sysnecessitates continued hospitalization until orthotopic transplant. The portable Freedom Driver is the first wearable power supply for the temporary TAH and can be worn in a backpack or as a shoulder bag[22, Osaki S 2008].

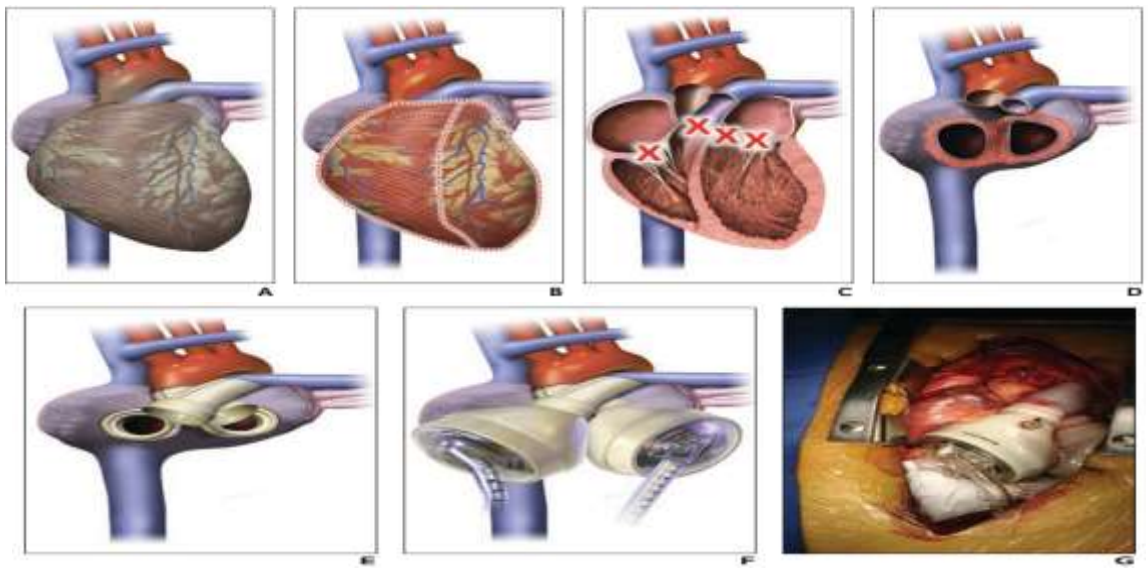
[Fig. 2: Photograph shows implant with synthetic arterial outflow conduits and pneumatic drivelines.

[Fig:3] Photograph shows standard bedside external controlling and monitoring console ("Big Blue").

[Fig: 4] Photograph shows portable device ("Freedom Driver"), which may be worn in backpack or shoulder bag and allows patient to be discharged to home.

IMPLANTATION PROCEDURE

Implantation of the TAH requires a median sternotomy, complete surgical excision of the native ventricles, and partial excision of the ventral surface of the atria, ascending aorta, and proximal pulmonary artery [23, Jung K et al. 2005]. Inflow right and left atrial cuff connectors are sewn into their respective native atrial remnants. A synthetic thoracic aorta and pulmonary artery outflow conduit are then anastomosed with the native great vessels. The artificial left and right ventricles with their seamless blood-contacting diaphragms are then installed. The left and right ventricular pneumatic drivelines are then placed through a tunneled port in the subcutaneous tissues of the left upper quadrant[24, Hokanson JF et al. 1995]. The native pericardial sac is left open, but the implant itself is enfolded in three 15 × 20 cm sheets of less adhesion-prone expanded polytetrafluoroethylene (Gore-Tex, W. L. Gore & Associates) that function as a neopericardium. This step facilitates eventual device explantation. The right sheet is anchored to pericardial reflections at the superior vena cava, pulmonic veins, and inferior vena cava level[25, Pae WE et al. 2007]. The left sheet is anchored to pericardial reflections anterior to the pulmonary veins. The diaphragmatic sheet covers the entire diaphragmatic pericardial surface. A tissue expander (Mentor smooth-walled silicone filled with saline solution, 150–225 mL, Mentor World Wide) may be placed between the artificial left ventricle and the neopericardium to reduce postsurgical space cavity contraction and adhesions associated with the device and to facilitate eventual TAH explantation[26,. Neubauer S 2007]. A varying number of mediastinal and pleural drains are placed as needed. The thoracic cage may be immediately closed in uncomplicated cases, or the surgeon may elect to leave it open in cases of perioperative bleeding and close the thorax 1–3 days later. The sequential steps in the surgical excision of the native diseased heart and TAH implantation [27, Aronow WS et al. 1999].



[Fig:5] Drawings show surgical steps in total artificial heart implantation.

A) Diseased native heart.
B) Planned surgical excision of native cardiac chambers (dotted lines).
C) Partial excision (X) of native cardiac chambers, ascending aorta, and proximal pulmonary artery.
D) Complete excision of ventricular chambers, ventral atrial chambers, and great vessels.
E) Inflow right and left atrial cuff connectors, outflow aorta, and pulmonary artery conduits installed.
F) Left and right artificial ventricles, seamless blood-contacting diaphragms, and pneumatic drivelines installed.
G) Photograph shows intraoperative view of recently installed total artificial heart in patient with nonischemic cardiomyopathy

CONCLUSION

Chronic VAD therapy has become a clinical reality. Because of the greater number of patients awaiting HTx, many will not receive their transplants in time. When the decision to treat with VAD is made early, it can be used as an alternative form of treatment with a comparable one-year survival (>75%).

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