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# Indications for Ventricle Assist Devices

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## 1. Introduction

Despite widespread use of evidence-based therapies the morbidity and mortality of heart failure has not changed, and it remains the most common hospital discharge diagnosis for patients older than 65 years old of age. Approximately 5 million patients in the United States of America have cardiac failure, and over 550,000 patients are diagnosed with heart failure for the first time each year (Levy et al, 2002; Hunt et al, 2005). The European Society of Cardiology represents countries with a population of more than 900 million, and in their last guidelines they reported that there are at least 15 million patients suffering this disease in those 51 countries (Dickstein et al, 2008). Heart failure is primarily a condition of the elderly (Kannel & Belanger, 1991), and thus the widely recognized "aging of the population" also contributes to the increasing incidence of heart disease. The incidence of cardiac failure approaches 10 per 1,000 population after age 65 years, and approximately about 80% of patients hospitalized with heart failure are older than 65 years old (Masoudi & Havranek, 2002).

There are several reasons that may explain why the prevalence of heart failure is increasing: ageing of the population, the success in prolonging survival in coronary patients, and the success in postponing coronary events by effective prevention in those patients at high risk or those patients who have already survived a first event (secondary prevention) (Senni et al, 1999). Advances in medical therapy have resulted in improved survival in patients with moderate and severe heart failure, but the prognosis for end-stage heart failure patients still remains poor. The conclusion of all these aspects is that there is a change in the demographics of heart failure patients in recent years, and an increased survival of older patients with heart disease.

At present time, cardiac transplantation remains the gold standard of cardiac replacement therapy. However, the supply of donor hearts is limited and therefore is not an option for many patients because of age and other comorbid conditions. Alternative forms of cardiac replacement therapy are being investigating. This includes cell therapy, xenotransplantation, ventricle assist devices implantation and total artificial heart.

Although initially the indications for heart mechanical assistance are similar to those developed in the1960s for the use of intra-aortic balloon pumps the indications have developed into more complex cases which must be considered. Ventricle assist devices are more and more reliable and its size is becoming smaller with the passing of time, improving patient's outcomes.

## 2. Cardiac transplantation: where we are and what can we expect

The first human cardiac transplant was performed by Dr. Barnard in Cape Town in South Africa in 1967. With the development of immunosuppression, orthotopic cardiac transplantation, what exists today, is a highly successful procedure for the treatment of end-stage heart disease. Over time, survival of patients undergoing orthotopic heart transplantation has improved significantly, mainly due to a reduction in rejection rates, better prevention and treatment of opportunistic infections and defined management protocols (Taylor D et al, 2008).

Indications for cardiac transplantation at the present time include patients with severe heart failure symptoms, a poor prognosis, and with no alternative form of treatment (class of recommendation I, level of evidence C). Contraindications to heart transplantation are: current alcohol and/or drug abuse, lack of proper cooperation, serious mental disease not properly controlled, treated cancer with remission and, 5 years follow-up, systemic disease with multiorgan involvement, active infection, significant renal failure (creatinine clearance <50 mL/min), irreversible high pulmonary vascular resistance (6–8 Wood units and mean transpulmonary gradient >15 mmHg), recent thromboembolic complications, unhealed peptic ulcer, evidence of significant liver impairment, or other serious co-morbidities with a poor prognosis. Patients must be well informed, motivated, emotionally stable, and capable of complying with intensive medical treatment.

According to the registry of the International Society for Heart and Lung Transplantation reported in 2008 (Taylor D et al, 2008) the one-year survival after primary orthotopic cardiac transplantations has increased from 79% between 1982 and 1991, to 82% between 1992 and 2001, and to 86% between 2002 and 2005 (p<0.0001). However, long-term mortality has not changed and in fact the overall survival patterns remain largely unchanged with a steep fall in survival up to 6 months and linear decrement in survival thereafter, at approximately 3.5% per year (figure 1)

Some factors need to be in consideration, as they are changing the demographics of heart transplantation. The primary cardiac transplantation has shifted in the last years towards a
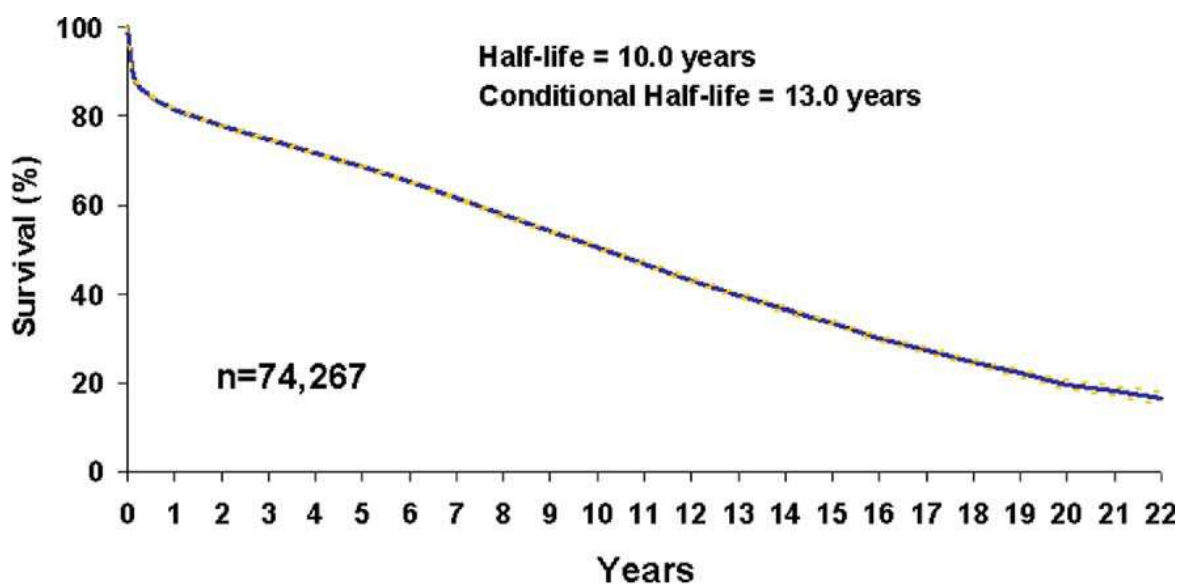


Fig. 1. Kaplan-Meier survival for all cardiac transplants (1/1982-6/2006) (Taylor D et al, 2008)

slight predominance of patients with nonischemic cardiomyopathy (50%) vs. ischemic (34%). It is a fact that the relative contribution of patients with ischemic cardiomyopathy has declined over the last decade. Also the age of donors and recipients has increased in the past 20 years. Almost 25% of cardiac transplant patient recipients in the last years were over the age of 60 years, with a relative fall in the number of recipients aged 40-49 years. Also at the present time the number of transplants being performed worldwide is far outnumbered by the number of potential candidates, as donor hearts are a very limited resource. These aspects are essential in the understanding of patient outcomes and they explain why other alternatives to heart transplantation should be investigated in an effort to offer alternative therapies to those patients suffering severe heart failure.

The need for those alternative therapies include the lack of cardiac donors, long cardiac transplantation waiting list, patients with any contraindication to cardiac transplantation (definitive or temporal) and patients requiring more time for the heart to recover.

The use of ventricle assist devices has acquired an important role in the management of end-stage heart failure and it is very likely that its importance will increase with time. Historically, the development of cardiopulmonary bypass technology in the fifties was the achievement that really started the development of more permanent means of mechanical cardiac support. Technological progress has allowed the design and production of smaller devices that have bridged patients towards recovery and transplantation.

In this chapter we will review the indications of ventricle assist devices implantation. We will star giving some general indications that every patient should follow from a theoretical point of view. Then we will divide the indications in three different groups: 1) bridge to transplantation, 2) bridge to recovery and 3) destination therapy.

We will also discuss when it is required to use a short term ventricle assist device, a long ventricle assist devices and the total artificial heart. Finally we will review in the literature when it is necessary to have a right ventricle assist device especially when a left ventricle assist device is already implanted.

The authors would like to remark that this chapter is a compilation of the literature regarding ventricle assist device therapy. Therefore each patient must be considered as a particular case and there are no strict rules or guidelines to be followed.

## 3. General indications for ventricle assist device implantation

The general rule is simple: ventricle assist devices are used when the heart is incapable of maintaining its function. Therefore, the organism is in danger or is going to be in danger because cardiac output is not enough to maintain vital organ flow. Cardiac dysfunction may be caused in an acute fashion, like in a cardiogenic shock caused by an extensive myocardiac infarction or after a major cardiac surgery when a patient is not able to weaned from the heart-lung machine. Also, cardiac failure may be a consequence of a chronic condition like in the ischemic chronic heart disease or in patients with dilatated myocardiopathy.

There are some registries that compile from different centers the indications for a ventricle assist devices implantation. These registries are a good resource of information about what the indications of ventricle assist device are. One of the databases is the Interagency Registry for Mechanical Assisted Circulatory Support (INTERMACS), which is an audited registry for patients who receive a mechanical circulatory support device to treat advanced medically refractory heart failure. From June 2006 to December 2007, a total of 75 institutions in the United States of America prospectively entered 420 patients. Most of the

patients (n=336) had a mechanical circulatory support device implanted for the indication of bridge to transplantation. The indication of destination therapy was applied in 63 patients whereas the rest of patients received a ventricle assist device as a bridge to recovery (Holman et al, 2009). This perfectly describes what the indications in the clinical practice are at the present time. Several aspects must be considered for indicating a ventricle assist device:

### 3.1 Clinical status

Patients requiring a ventricle assist device suffer severe heart failure acutely or chronically. When cardiac failure has been caused acutely, the patient is in cardiogenic shock. This may be from different causes: extensive acute myocardial infarction (Killip IV), mechanical complications after an infarction (papillary muscle rupture, interventricular septal rupture), patients that cannot be weaned from the cardiopulmonary bypass machine, acute myocarditis and others. It should be noticed that the use of ventricle assist device in the setting of cardiogenic shock must be contemplated when the use of inotropes and intra-aortic ballon pump is not enough to maintain an adequate cardiac output and there is a risk of death or other organ failure. Also, there should be no other options such as major cardiac surgery or other surgical options that may reverse the status of the patient.

However, although ventricle assist devices are not the first treatment option in this type of situation, their implantation should not be delayed. Most cardiologist and cardiac surgeons agree to implant a ventricle assist device in patients with severe heart failure, despite intra-aortic balloon pump or inotropic support with unstable hemodynamics, and with early signs of end-organ dysfunction (Osaki et al, 2009). In the last years, there has been an attempt to prevent deterioration of the ventricle assist device candidate's condition. Actually, whenever possible some co-morbid conditions should be nullified by a period of therapy prior to implant. Some examples are renal dysfunction, localized infection or severe pulmonary edema, which can be reversed with medical therapy prior to a mechanical device implantation. Every patient should be in the best clinical position, considering that these patients are in a really bad clinical status, avoiding the implantation in pre-mortem conditions. This rule should also be applied in those patients with end-stage chronic cardiac dysfunction. Mechanical device implantation should be kept in mind before other organs deteriorate. This will definitely improve clinical outcomes. Other clinical conditions that may indicate the use of some mechanical support are intractable arrhythmias and intractable angina not responsive to medical therapy or revascularization procedures in patients with poor left ventricle function.

### 3.2 Hemodynamic parameters

A hemodynamic study may be required in some situations to assure that cardiac function is severely deteriorated. Table 1 summarizes hemodynamic data that represent severe left and right ventricle dysfunction.

## 4. Ventricle assist device as bridge to transplantation

As we have previously descibed in the introduction section, orthotopic cardiac transplantation is the gold standard for treating end-stage heart failure. The International Society for Heart and Lung Transplantation (ISHLT) has reported outcome data on transplant recipients for more than 25 years with data that includes more than 74,000 patients (Taylor et al, 2008).

| Left ventricle assist device | Right ventricle assist device | Biventricular ventricle assist device |
|---|---|---|
| Systolic blood pressure <90mmHg | Right atria pressure > 20mmHg | Right atria pressure > 20mmHg |
| Left atria pressure > 20mmHg | Left atria pressure < 15mmHg | Left atria pressure > 20mmHg |
| Systemic vascular resistance >2,100 dynes-sec/cm | No tricuspid regurgitation | No tricuspid regurgitation |
| Urine output <20mL/h | | Inability to maintain left ventricle assist device flow >2.0L/min/m² with right atrial pressure >20mmHg |

Table 1. Haemodynamic indications for circulatory assist device

This registry includes data mainly from USA and European countries. We see from those reports that primary indications for cardiac transplantation has changed with an increase of patients with nonischemic cardiomyopathy and less ischemic patients. In addition, the age of donors and recipients has been increasing in the last 20 years, especially in Europe. It is clear that heart donors are a limited resource and some patients die while awaiting cardiac transplantation due to that lack of donors. Actually, in the last two decades, decreasing numbers of organ donors have led to longer waiting times for cardiac transplantation and subsequently increasing mortality. Other patients´ statuses may worsen while waiting and they may need some kind of cardiac circulatory support in order to maintain vital blood flow and preserve organ systems like kidney, hepatic, or brain function.

Therefore, we can summarize that ventricle assist device as a bridge to transplantation is indicated in those patients that are candidates for cardiac transplantation and need some cardiac support while they are waiting for the heart. This indication includes a wide spectrum of patients. On one side, we may have patients that suffer an acute event (postinfarction cardiogenic shock, postcardiotomy) which leads them into an irreversible severe heart failure that requires urgent cardiac transplantation. Until a donor is found, cardiac mechanical support is necessary to save patients life and to preserve their vital organs. As we will see later, organ failure is associated with a worse prognosis after heart transplantation. On the other side, there are patients that are awaiting cardiac transplantation and whose conditions become refractory to medical therapy.

At present time, ventricle assist devices are an important tool in the management of this kind of patient (Frazier at al, 2001; Miller et al, 2007; Russo et al, 2009). Also, in the last decade, the number of heart transplant recipients supported by ventricle assist devices at the time of transplantation has more than doubled to over 400 per year in the USA (Taylor DO et al, 2008) as well as in European countries. This clearly reflects the need of mechanical circulatory support in patients awaiting transplantation. Also as previously described, if we consider some registries as the INTERMACS, bridge to transplantation is by far, the most frequent indication for a ventricle assist device implantation (Holman et al, 2009).

There are some questions that should be answered regarding mechanical circulatory support as a bridge to transplantation.

1. Does the use of a ventricle assist device as a bridge to transplantation affect the outcome of patients when compared to those patients who receive transplants without the need of mechanical assistance?
2. When should one implant a mechanical device in a patient awaiting cardiac transplantation?
3. What kind of device should be implanted?

Although several studies have demonstrated the benefits of ventricle assist devices in the pretransplant period, findings from studies analyzed the impact of mechanical circulatory support on posttransplant outcomes have conflicted. The majority of studies have concluded that short term, but not long term, survival is diminished in recipients bridge with a mechanical device (Taylor DO et al, 2008; Cleveland JC et al, 2008). However, there are some reports that do not confirm these findings. In a recently published study (Osaki et al, 2009) Osaki et al compared patients´ outcomes undergoing cardiac transplantation with and without the use of a ventricle assist device. They also divided patients in two different time groups as an attempt to analyze both, the experience of the group and the improvement of devices technology. A total of 531 consecutive heart transplant recipients in a 17 years period were included. They concluded that post-transplant survival has improved in the last years. Actually in their study, outcomes for orthotopic heart transplantation after bridge to transplantation have become equivalent to that of orthotopic heart transplantation without ventricle assist device. The data suggest that advances in device technology and multidisciplinary programs, have improved survival and allowed bridges to transplantation candidates to have an outcome equivalent to that of non-ventricle assist device in recent times (Figure 2).
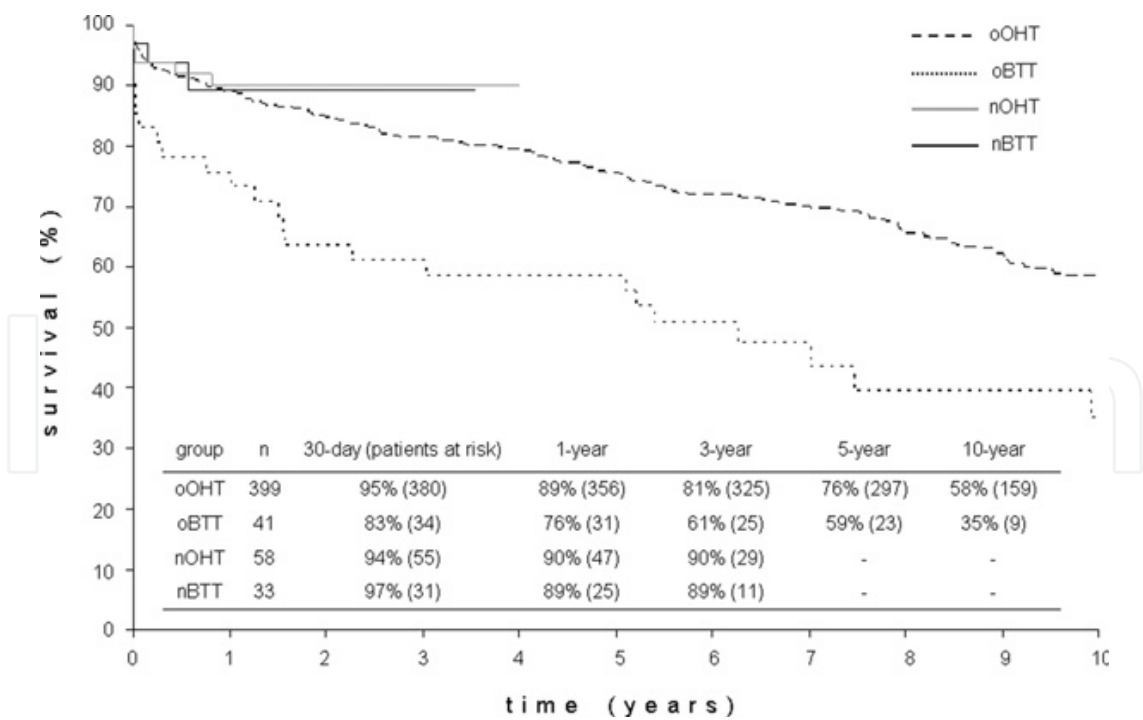


| group | n | 30-day (patients at risk) | 1-year | 3-year | 5-year | 10-year |
|-------|-----|---------------|-----------|-----------|-----------|-----------|
| oOHT | 399 | 95% (380) | 89% (356) | 81% (325) | 76% (297) | 58% (159) |
| oBTT | 41 | 83% (34) | 76% (31) | 61% (25) | 59% (23) | 35% (9) |
| nOHT | 58 | 94% (55) | 90% (47) | 90% (29) | - | - |
| nBTT | 33 | 97% (31) | 89% (25) | 89% (11) | - | - |

Fig. 2. Post-transplant survival by Kaplan–Meier analysis. oOHT, old orthotopic heart transplant (January 1990 to July 2003); nOHT, new orthotopic heart transplant (August 2003 to August 2007); oBTT, old bridge to transplant (January 1990 to July 2003); nBTT, new bridge to transplant (August 2003 to August 2007).

In that study, multivariate analysis revealed that diabetes and biventricular (but no univentricular) support were the only independent predictors of post-transplant mortality. These findings have been confirmed by other groups (Russo et al, 2009). In the study published by Russo et al, they included more than 10,000 heart transplantation recipients from the United Network for Organ Sharing in a seven-year period. They concluded that the use of implantable left ventricle assist devices (both intracorporeal and extracorporeal devices) as bridges to transplantation are not associated with diminished posttransplant survival. However, an increase in 90-day mortality was seen in patients bridged with extracorporeal devices.

These findings suggest that more than 80% of well-selected patients implanted with intracorporeal devices as a bridge to transplantation are successfully transplanted, providing additional evidence that a more aggressive use of implantable devices may benefit candidates whose condition is refractory to medical management. Outcomes seem to be better when implantable device support is implemented before patients clinical status deteriorates badly. The findings further suggest that a more aggressive use of implantable support may benefit candidates who are likely to face long waiting times as candidates with higher body mass index or blood type O. The fact that patient survival is diminished in patients with extracorporeal devices may suggests that in some cases, candidates supported by an extracorporeal device may benefit from further optimization before transplantation, and that this type of devices may be best used as a bridge to an implantable device especially in those patients that may have long waiting times.

As it has been suggested in other studies (Cleveland et al, 2008), the general perception among most cardiac transplantation centres is that explantation of a ventricle assist device confers a more technically challenging operation and therefore, might adversely affect survival not in medium term but in a short term. In the Cleveland group experience, one year survival was similar in those recipients receiving a heart transplantation with or without a mechanical circulatory support. However, when they analyzed patients who died after transplantation, most of the ventricle assist device group died within 30 days of transplant. In contrast, only a minority of patients without a mechanical assist device died within those thirty days.

This may reflect an inherent complexity and higher risk operation that occurs in the explantation of a ventricle device.

It is essential to have a good knowledge of the heart transplantation situation in every country. There are some countries such as Spain, where there is a high prevalence of donors and where the waiting times are not to long. Short term extracorporeal devices may be used as they are less expensive and very simple to use. Good results can be achieved this way (Reyes et al, 2007). In other countries like Germany or the USA where the waiting times are much longer, long term assistance may be a better option (Korfer et al, 1999).

## 5. Ventricle assist device as bridge to recovery

Ventricle assist devices have been successfully implanted in patients who are expected to recover sufficient myocardial function and it is not expected that they will need a cardiac transplantation. In this type of patient a short-term bridge to recovery device may be a good option as these devices are less expensive and very easy to use (Samuels et al, 2005; Nicolini & Gherti, 2009). The most frequent clinical settings in which a mechanical circulatory support may be needed are described below:

### 5.1 Post-cardiotomy

Patients with compromised left ventricle function who have undergone long operations may need a ventricle assist device because the severity of the postoperative circulatory shock. It is estimated that about 5% of patients undergoing coronary or valve cardiac procedures will have some degree of postcardiotomy cardiogenic shock (Pae et al, 1992). Short term mechanical support as bridge to recovery has been successfully used in patients who are expected to recover sufficient myocardial function. Since the ABIOMED system was approved by the Food and Drug Administration in 1992, it has become the second most commonly used mechanical support device for patients with post-cardiotomy ventricular dysfunction after the intra-aortic balloon pump with excellent rates of myocardial recovery and device removal after short-term support (Morgan et al, 2004). We highly recommend the early implantation of mechanical circulatory assistance in this clinical setting to provide mechanical unloading of the ventricle and rapid restoration of normal end-organ perfusion in order to improve survival rates.

In those patients in whom a high risk of cardiac failure is anticipated (severely impaired ventricular function undergoing high risk cardiac procedures) transplant evaluation should be initiated preoperatively and the procedure performed with a ventricle assist device back up. If needed it, mechanical support may be used as bridge to recovery or bridge to transplantation.

### 5.2 Post acute myocardial infarction shock

Despite the advances in the management of cardiogenic shock secondary to acute myocardial infarction, the prognosis is still poor with mortality rates as high as 70% (Goldberg RJ et al, 1999). There are some aspects that must be considered in this clinical setting. One of the surgical dilemmas, when implanting an LVAD into a patient with an acute anterior wall myocardial infarction, is the safety of apical cannulation in the presence of acutely infarcted apical myocardium, which is typically necrotic and friable. Ventricular disruption and bleeding from the cannulation site are major concerns with lethal consequences. Although left atrial cannulation is an option, it is suboptimal as it affords inadequate left ventricular decompression and limits LVAD inflow. Furthermore, left atrial cannulation has been shown to have independent risk factors for the development of left ventricular thrombus and stroke. There are some surgical techniques that should be considered. Some authors have maintained that left ventricle devices can be safely implanted into acutely infarcted, friable myocardium by modifying their surgical technique. This involves placing cannulation sutures through the full thickness of the infarcted ventricular myocardium and reinforcing their suture line with pericardium or Teflon felt (Park SJ et al, 2000; Chen et al, 1999). Other technique used in patients with cardiogenic shock and with extensive anterior wall infarcts, consists of securing the cannula with interrupted, pledgeted, horizontal mattress sutures through the full-thickness of the infarcted myocardium. If significant bleeding is observed, additional sutures and/or haemostatic products can be applied to the cannulation site (Leshnower et al, 2005).

It is important to highlight that patients with ventricle assist devices due to cardiogenic shock after an acute myocardial infarction may follow different outcomes. In this situation there should be flexibility to the treatment algorithm that these patients may follow. Mechanical circulatory system may be used as a bridge to recovery, a bridge to bridge (to other long term assist device system) or as a bridge to transplant. Also, some authors consider that the use of a biventricular assist device is important in these patients

(Leshnower et al, 2005). This must be taken in consideration in right ventricular heart failure, intractable arrhytmias and in the presence of shock with multisystem organ failure. Recently, some authors consider that less invasive percutaneous ventricular assist devices may be helpful in the decision making of the treatment as they are less expensive and sternotomy is not required, which may helps subsequent transplantation or surgically ventricle assist device insertion (Brinkman et al, 2010).

### 5.3 Myocarditis

Myocarditis may cause severe cardiac failure, sometimes very acutely. It is believed that almost every infectious agent can cause myocarditis (bacterias, virus, spiroquetas, mycotic infections, parasital agents, ricketsias). Also there may be immunologic causes as the so call giant cells myocarditis in which, apart from inmunosupresor therapy, ventricle assist device may be needed. These patients trend to be younger (many of them children) and it is characterized by an unpredictable clinical course. Actually it remains a real challenge to determine which group of patients will recover and which will require mechanical support or heart transplantation (Houel R et al, 1999). As myocarditis is an inflammatory process that affects the whole myocardium (both the right and left ventricle) it is frequent that biventricular support is required (Grinda JM et al, 2004). As we have previously said it is important anticipate the prognosis of the patient in order to convert a short-term assist device into a long term assist device or cardiac transplantation in those patients in which an optimal recovery is not expected.

## 6. Destination therapy

Ventricle assist device as a destination therapy has some aspects that may concern cardiologists and cardiac surgeons. It is necessary to know how the mechanical devices may affect survival rates compared with alternative treatment strategies, the durability of the devices, and its safety profile. Also we must take into account the quality of life of these patients and if the up-front costs of implantation may be offset by the long-term benefits of the patients.

The *R*andomized *E*valuation of *M*echanical *A*ssistance for the *T*reatment of *C*ongestive *H*eart Failure (REMATCH) trial is a multicentered study supported by the National Heart, Lung, and Blood Institute. It compares long-term implantation of left ventricular assist devices with optimal medical management for patients with end-stage heart failure who require, but do not qualify to receive cardiac transplantation. This trial demonstrated that the implantation of left-ventricular assist devices decreased the 1-year mortality by a third (from 75% down to 51%) and the two year survival rate was 29% for left ventricle assist device patients versus 13% for medical patients (95% CL; 5%-22%), representing a 48 percent reduction in the risk of death from any cause, compared with the optimal medical therapy.

The survival advantage was associated with a considerable improvement in the quality of life and functional status of these patients, as compared with their medical counterparts (Rose et al., 1999). The MLHF scores, (Minnesota Living with Heart Failure questionnaire) for left ventricle assist device patients were 75.1 (0 being the best – 105 the worst). The REMATCH trial demonstrated that is superior to any available medical therapy in patients with end-stage heart failure who are not eligible for transplantation (Lietz & Miller, 2005). The Thoratec HeartMate was subsequently approved in 2003, by the Food and Drug Administration (FDA), for long-term support of this kind of patient.

The next logical step for expanding the indications for mechanical circulatory assistance would be to use the left ventricle assist device as an alternative to cardiac transplantation. However, heart transplantation cannot serve the estimated 30,000–60,000 people who die of heart failure in the US each year and could be candidates for heart transplantation or some form of mechanical circulatory support. More than 40% of the patients waited more than 1 year for a cardiac transplantation, and the waiting time is increasing every year. In 1995, the average waiting time for cardiac transplantation was over 200 days (Penningtonet al., 1999), but the average national waiting time in 2003 for a heart was 230 days (UNOS/OPTN Annual Report 2003). Each year, approximately 4000 new patients are added to the waiting list for cardiac transplant, and about 28,000–30,000 are apparently not considered viable candidates to be placed on the list. About 50%of the patients not included in the waiting list (13,000) would be candidates for a permanent ventricular assist device. An important deterrent to being listed may be advanced age.

The most obvious advantage of these mechanical device systems over transplantation would be their immediate availability. They could be placed in UNOS status II rather than UNOS status I hospital-bound patients. Table 2 shows the indications and characteristics of the total artificial heart.

| Total artificial heart | Characteristics | Use | Cost |
|---|---|---|---|
| Abiomed Total Artificial Heart | Is inserted orthotopically; this procedure is accompanied by removal of the patient's own ventricles | TAH is currently undergoing clinical trials | The cost of these devices is likely to be quite high, but may not be very different from the cost of heart transplantation, therapy and immunosuppression. |
| CardioWest device | | Pneumatic TAH that has been used investigationally as a bridge to transplantation | |

Table 2. Indications and characteristics of the total artificial heart. TAH: Total artificial heart.

## 6.1 Exercise capacity

An important determinant of quality of life in cardiac transplant recipients and left ventricle assist device recipients is exercise capacity.

Studies in cardiac transplant recipients demonstrate that, at rest, they have an increased heart rate, increased blood pressure, and low normal cardiac output. During exercise, peak heart rate, stroke volume, cardiac output, peak power output, pulse pressure, heart rate reserve, total VO2, and absolute VO2 at ventilatory threshold are all less than normal. Their exercise capacity may increase with time up to 5 years and may improve with an increase in muscle mass and lean body weight. Autonomic reenervation may actually increase the peak heart rate during exercise, although this is quite controversial. Recent studies suggest that cavo-caval anastomosis may increase atrial emptying, resulting in better functional capacity. While some individual patients with cardiac transplantation function well, most patients have important physiological limitations.

The exercise capacity of patients with implantable mechanical cardiac devices is based on the results obtained during the use like bridge to transplant, it is apparent that improvement

in exercise tolerance occurs. Maximum VO2 is a well-characterized indicator of functional status and prognosis in patients with advanced heart failure.

Peak oxygen consumption with upright treadmill exercise increased from 10 to 14 mL O2/kg/min in a group of patients supported for a mean of 50 days after left ventricle assist device implantation. Pennington et al remarked that many postoperative studies suggest that the native left ventricle may contribute to this function during exercise by actively filling the left ventricle assist device, which reduces filling time and overcomes inflowing cannula impedance. It may also augment total cardiac output with parallel ejection out of the native aortic valve and reduce ventricular interaction-related changes in functional right ventricular diastolic compliance.

It is clear that exercise capacity increases during the first several months after ventricle assist device insertion because patients have improved organ function, reducing pulmonary edema and pulmonary artery resistance. These changes significantly augment right ventricular function, which also usually improves with time.

It is anticipated that patients with long-term left ventricle assist devices will achieve reasonably high levels of exercise capacity and they will not be limited by activities of daily living. Whether they will be able to participate in athletic events and vigorous work is not entirely clear, but seems feasible (Pennington et al., 1999).

### 6.2 Psychological factors

A common sensation between the patients with left ventricle assist devices is that of being machine-dependent. It is important to indicate a definitive cardiac assist device in very strongly motivated patients which may need to be prepared from a psychological point of view. A positive psychological feature is the fact that left ventricle assist device insertion does not require removal of the natural heart, which might be able to temporarily support the circulation, or recover sufficiently to allow for device removal.

Quality of life may be reasonably satisfactory. Despite externalized battery sources, these patients are capable of recovering their daily activities, even returning to work. Although patients are capable of concealing external batteries so that it is not so obvious that they are supported mechanically, they cannot forget that they are dependent on the device. This factor may be resolved with new more modern devices that can be completely implanted inside the pericardium or the peritoneum. Presuming the availability of a safe and effective, totally implantable, electrically driven, left ventricle assist devices prompts a comparison with the current strategy of cardiac transplantation as a universal therapy for patients with severe heart failure.

### 6.3 Economical factors

It is very important to be aware of the cost of the implantation of definitive mechanical devices. Since there are limited resources availables, it is necessary to demonstrate that they are economically feasible. The average total cost to insert a left ventricle assist device in the REMATCH patient population was $210,187 which includes a $60,000 charge for the device. When implantation hospitalization costs are compared between hospital survivors and nonsurvivors, the mean costs increase from $159,271 ± 106,423 to $315,015 ± 278,713.

Sepsis, pump housing infection, and perioperative bleeding are the major drivers of implantation cost, established by regression modeling. In the patients who survived the procedure, bypass time, perioperative bleeding, and late bleeding were the drivers of cost.

The average annual readmission cost per patient for the overall cohort was $105,326, the cost of which was considerably influenced by device reliability (Oz et al, 2003).

In a recent study published by the Institute of Medicine, cost effectiveness was measured by the relationship of costs to quality-adjusted life years (QALYs). It was estimated that the cost per quality-adjusted life years in dollars for hemodialysis was $50,000, for two-vessel coronary artery bypass grafting, $34,000, and for a total artificial heart for 2 years, approximately $105,000.

The cost calculation of quality-adjusted life years for left ventricle assist devices was not calculated, but it was estimated that it would be significantly less than that for a total artificial heart.

If the devices can be relatively problem free and not require multiple readmissions for replacement of parts or devices, employers may be receptive to these patients returning to work. It is not known whether the relatively low reemployment percentage for cardiac transplant patients is related to their need to continue to take expensive medications or other medical problems.

It is possible that within four years, one could return to society with an income greater in value than the investment if the individual earns an annual salary of $40,000 per year. However, by Poirier's estimation, circulatory support systems represented a potential to increase our gross national product, leading to a higher standard of living.

The current generation of pumps continue to undergo incremental improvement. These devices exhibit smaller and more flexible drivelines or use a totally implantable design that eliminates a major gateway for infection. They are being introduced in clinical trials that may more fundamentally address the device´s shortcomings observed in the REMATCH study.

## 7. Short, long and intermediate ventricle assists devices

We can divide the ventricle assist devices according to its capacity to be used as support during a short, long, or intermediate time, depending on the requirements of patients. The following tables describe the indications and the more notable characteristics of the different kinds of ventricular assist devices.

### 7.1 Intermediate ventricle assist devices



Fig. 3. ABIOMED BVS 5000 blood pump.

| Intermediate term devices | Indications | Versions | Use | Advantages |
|---|---|---|---|---|
| Thoratec VAD | Bridge to transplantation<br><br>Bridge to recovery | Thoratec Paracorporeal ventricular Assist Device (PVAD)<br>Thoratec Implantable Ventricular Assist Device (IVAD) | RVAD<br>LVAD<br>BiVAD | The device uses suction drainage with pulsatile flow. Each ventricle costs approximately $50,000 but can be maintained with minimal personnel<br>PVAD has supported patients for up to 3.3 years |
| Abiomed AB 5000 | | | | It is compatible with the cannulae for the Abiomed BVS 5000 support system |

Table 3. Intermediate ventricle assist devices: Indications and characteristics. Intermediate term devices can be thought of as the true "bridges" to transplantation. They are intended to be removed during transplantation and are not designed for constant, permanent support.

## 7.2 Short ventricle assists devices

| Short term VAD | Specific indications | Common indications | Use | Insertion | Limitation |
|---|---|---|---|---|---|
| Centrifugal pumps:<br>• Bio-Medicus<br>• Sarns | Patients who cannot be weaned from cardiopulmonary bypass.<br>Patients who are awaiting cardiac transplantation. | VAD/cardiac transplant backup in patients undergoing high risk surgical procedures<br>Patients with unanticipated post-operative cardiac dysfunction who required mechanical support with VAD support of the right ventricles or less commonly both ventricles.<br>Post-operative cardiogenic shock. | RVAD<br>LVAD<br>BiVAD | Sternotomy Percutaneously (in the catheterization laboratory) | Non-pulsatil flow<br>The devices are traumatic to blood, causing hemolysis. Patients are unable to ambulate or exercise with the device in place. |
| Extracorporeal pump:<br>• Abiomed biventricular system (BVS 5000)<br>• AB5000 | It allows recovery of end organs and is approved for postcardiotomy use.<br>Patients with potentially reversible heart failure.<br>Donor heart dysfunction following transplantation. | | RVAD<br>LVAD<br>BiVAD | Sternotomy | The devices are more expensive than centrifugal pumps, but can be maintained with minimal personnel. |
| Axial flow pumps: Impella microaxial flow device | Postcardiotomy failure | | | Sternotomy Percutaneously | Nonpulsatile flow. Moderate degree of hemolysis and thrombocytopenia. |
| Percutaneous left atrial-to-femoral-arterial VAD: Tandem Heart™ | Stabilization until recovery of jeopardized myocardium.<br>Bridge to definite surgical treatment. | | | Percutaneously | Complications such as severe bleeding and acute limb ischemia are more common |

Table 4. Intermediate ventricle assist devices: Indications and characteristics.

## 7.3 Long ventricle assists devices

| Long term devices | Indications | Versions | Use | Advantages | Disadvantages |
|---|---|---|---|---|---|
| Novacor device | Replacement therapy for patients with heart failure | | LVAD | | Requires normal native aortic valve |
| HeartMate I (pulsatil flow) | Bridge to transplantation. Destination therapy. | HeartMate I is a paracorporeal device that comes in two versions: implantable pneumatic (IP) and vented-electric (XVE) versions | XVE only in a LVAD | Anticoagulation with warfarin not required. Low thromboembolic rate. Outpatient support appears to be cost-effective Improvement in renal function and reduction in pulmonary hypertension prior to transplantation. Improvement in hemodynamic measurements at rest and during exercise and exercise capacity | Expensive device |
| HeartMate II | | Smaller devices and greater durability | | Improvements in NYHA functional class, six minute walk, and quality of life | |
| Axial-flow impeller pumps | Bridge to myocyte recovery. Transplantation Long-term support | Jarvik 2000 pump DeBakey pump | RVAD | Small size Low noise Absence of a compliance chamber. The device is practically encapsulated by the native myocardium, reducing the risk of infection around the device. Quality of life improved significantly | |
| Centrifugal continuous flow pumps | Undergoing a clinical trial as a bridge to transplantation in the US. | Ventrocor VentrAssist LVAD. Heartware HVAD. Terrumo Duraheart. | | Energetically more efficient Lower tolerances so manufacturing is easier and they are less prone to thrombosis They are potential very durable (>10 year life-span) Fits in the pericardial space. | |

Table 5. Long ventricle assist devices: Indications and characteristics.

## 8. Biventricular assist device: why and when should it be implanted?

It is well described in the literature that between 15-25% of patients with a left ventricle assist device will develop a right heart failure, even in those patients with a good preoperative right cardiac function. Severe right ventricle failure, requiring insertion of a right ventricles assist device, has been proved to negatively affect a successful bridge to transplant, increase device-related morbidity, prolong hospital length of stay, and increase total hospital cost (Slater JP et al, 1996; Karavan et al, 2002). This can be explained with the following:

1. Pre-existing right ventricle dysfunction. This dysfunction may be latent secondary to the augmented preload presented to the right side following left mechanical device implantation.
2. Interventricular septal shifting movement. The mechanical unloading of the left ventricle may displace the interventricular septum which may contribute to impaired right-sided function.
3. Other perioperative conditions as ischemia, myocardial stunning, embolism or arrythmias.

It is essential to anticipate which patients will develop right side heart failure, however, this may be a difficult task. Several papers have reported preoperative risk factors for development of right ventricle failure in patients with implantable left ventricle assist devices. A study from Ochiai and colleagues (Ochiai et al, 2002) reported in a large number of patients that preoperative circulatory support, female gender, and non-ischemic etiology of heart failure were significant predictors of right ventricle failure. Other risk factors that have been related with the need of right circulatory support are low pulmonary artery pressure, low right ventricle stroke work index, preoperative ventilation and higher left ventricle assist device scores (Fukamachi et al, 1999, Morgan et al, 2004).

Apart from the difficult task of anticipating which patient will require a right ventricle assist device, another important problem is the difficulty associated with anticipating when it is the right moment to implant a right ventricle device. It is important to note that while optimal timing of right ventricle assist device insertion for severe right ventricle failure after left ventricle assist device implantation has yet to be clearly defined, a low threshold for early right ventricle assist device insertion may be preferable to subsequent development of multisystem organ failure that could potentially develop with a more conservative approach.

Some studies describe that patients with an implantable left ventricle assist device and with a prompt right ventricle assist device insertion (within 24 hours) have a better outcome than patients in which the right mechanical device was inserted after the first 24 hours (Morgan et al, 2004). In general, it is believed that right ventricle assist device insertion should be performed early after the development of severe right ventricle failure after left ventricle assist device implantation, and that right ventricle assist device support should be continued for an adequate duration to allow for right ventricle recovery or until transplantation. It is essential that while on RVAD support, opportunities to maximally improve the patient's hemodynamic status and fluid balance, such as the use of continuous veno-venous hemofiltration and dialysis, should be pursued.
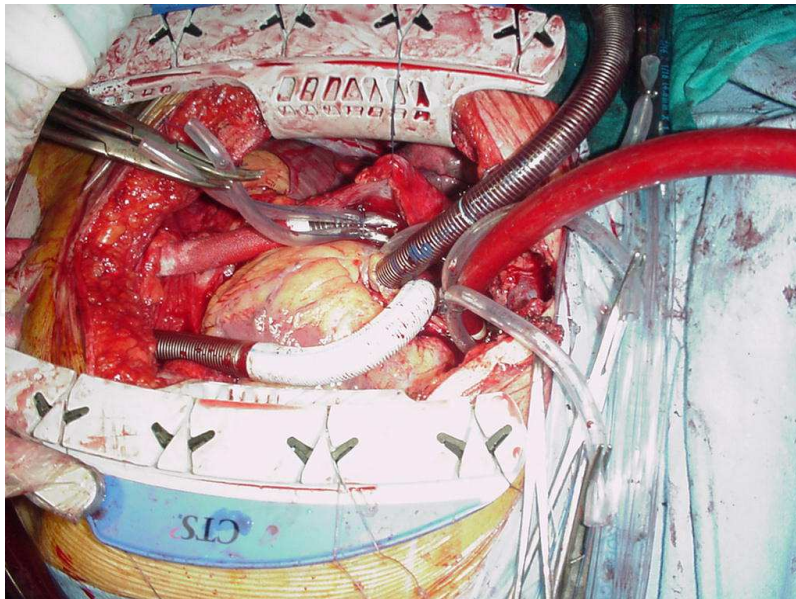
Fig. 4. Biventricular assist device. Cannula implantation.

## 9. Conclusions

Heart transplantation is the gold standard therapy for end stage heart failure disease. However, there is a lack of donors and some patients have some kind of contraindications.

Ventricle assist devices can be used in different clinical situations. The most common indication nowadays is bridge to transplantation. As more experience and more modern devices are available, better the outcomes. Patients being transplanted with a mechanical device can have as good results as patients without a ventricle device.

In some cases an external cardiac support is required while the heart recovers from an acute event. Ventricle assist devices can also be used as a bridge to recovery with excellent results using a short term ventricle device. In patients awaiting a transplantation or with a contraindication for transplantation a long term cardiac device or the total artificial heart are very good options in which a high quality of life can be expected.

It is important not to delay ventricle device implantation till there is a severe multi-organ dysfunction. Patients need to be in the best clinical status when receiving a mechanical cardiac support. Biventricular assist devices should be kept in mind as right ventricle failure can happen after a left ventricle device implantation.

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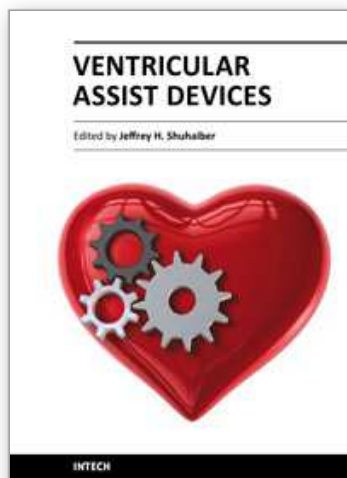
**Ventricular Assist Devices**

Edited by Dr. jeffrey Shuhaiber

The assist devices will continue adding a large number of years of life to humans globally and empower the medical society to optimize heart failure therapy. While expensive and cumbersome task, the foundation provided in this book reflects a contemporary product of original research from a multitude of different experts in the field. We hope this cumulative international effort provides the necessary tools for both the novice as well as the active practitioner aiming to change the outcome of these complex patients.

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