REVIEW

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Mechanical treatment of heart failure: The growing role of LVADs and artificial hearts

ABSTRACT

Left ventricular assist devices (LVADs) and artificial hearts are improving. These devices can prolong a patient's life while on a heart transplant list. More exciting, mechanical assistance may provide an opportunity for a damaged heart to recover some function. Still, despite the promise, the use of these devices raises some difficult cost-benefit and ethical questions.

KEY POINTS

LVADs have proved very effective in sustaining very ill patients to transplantation, reversing shock, restoring end-organ function, and improving functional status.

A randomized trial showed that the survival rate was higher among patients with end-stage heart failure who received an LVAD as permanent therapy vs intensive medical therapy, but rates of device failure, pump valve malfunction, and device-related infections were high and worsened quality of life and survival.

When to insert the LVAD poses a dilemma. Putting it in too early could subject the patient to an avoidable procedure with its risk and cost. A delay putting it in could lead to end-organ damage with an increased risk of operative morbidity and mortality.

The next generation of devices will include totally implantable systems and smaller rotary pumps. These should have fewer complications, leading to improvement in the patient's quality of life at a lower overall cost.

This paper discusses therapies that are experimental or that are not approved by the US Food and Drug Administration for the use under discussion.

IS THERE a mechanical fix for end-stage heart failure?

Artificial hearts and left ventricular assist devices (LVADs) were once medical novelties, but they have been improving over the past 30 years, and their use is expanding. The US Food and Drug Administration has approved some of them to keep heart transplant candidates alive until a donor heart becomes available (a "bridge to transplantation").

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Perhaps most exciting, there are indications that in some cases, mechanical support may reverse the remodeling process of heart failure at all levels, leading to functional recovery (a "bridge to recovery"). Unfortunately, to date only a minority of patients can be weaned from the support devices and do well over the long term.

A recent trial found that, in some patients LVADs may have a role as permanent or "destination" therapy. The study found that in patients with severe heart failure who were not transplantation candidates, survival was greater with an LVAD than with intensive medical support.

But the complication rate of this expensive technology remains high, and difficult ethical questions surround who should get this therapy and who should not.

This paper reviews the various types of mechanical circulatory support systems, how they have evolved, and trends for the future.

TABLE 1

National mechanical circulatory support programs

YEAR	INSTITUTE, BRANCH, AND GOALS
1964	National Heart Institute Artificial Heart Program Goals: Component parts for circulatory support systems
1970	National Heart and Lung Institute Medical Applications Branch Goals: Temporary assist systems Permanent assist systems Totally implantable artificial heart
1977	National Heart, Lung, and Blood Institute Devices and Technology Branch Goals: Left heart assist pumps Electrical converters to power and control the pumps
1980	National Heart, Lung, and Blood Institute Devices and Technology Branch Goals: Implantable, integrated, electric left heart assist systems, designed to provide support for more than 2 years
1994	National Heart, Lung, and Blood Institute Devices and Technology Branch Goals: Innovative ventricular assist systems

DATA FROM FRAZIER OH. MECHANICAL CARDIAC ASSISTANCE: HISTORICAL PERSPECTIVES. SEMIN THORAC CARDIOVASC SURG 2000; 12:207–219.

Problems with LVADs:
- **Stroke**
- **Infection**
- **Device failure**

AN EPIDEMIC OF HEART FAILURE

These devices are needed because heart failure is epidemic and other therapies are limited.

Chronic heart failure syndrome is the leading cause of death in the United States and much of the developed world.[1] From 1979 to 1998, deaths due to this disorder increased by 135%. The incidence of chronic heart failure approaches 10 per 1,000 people over the age of 65 years, and the 5-year mortality rate is close to 50%, despite advances in its medical and surgical treatment.[2]

Transplantation, the treatment of choice for heart failure that is intractable despite optimal medical therapy, is limited by a shortage of donor organs and by patient ineligibility due to age and comorbidities.[3] Of the 4,200 patients on the heart transplant waiting list in the United States, only 2,185 per year will receive a transplant, and 15% will die while waiting.[4]

Artificial hearts and LVADs might provide a bridge to transplantation for some of these patients. In addition, thousands of patients each year who are not eligible for transplants may benefit from one of these devices.[5]

HISTORY OF ARTIFICIAL HEARTS

An LVAD was first used clinically in 1963,[6] and an implanted total artificial heart was used as a bridge to transplantation in 1969.[7]

Widespread use of these devices had to wait, however, until the late 1980s and early 1990s, when government-sponsored research (TABLE 1) resulted in reliable and safe pumps. Since then, more than 5,800 patients have received these devices, mostly intended as bridges to transplantation.[8] More recently, LVADs and total artificial hearts have been used as permanent supportive therapy.

PUMP DESIGN

LVADs receive blood from the left ventricle via an inflow cannula and pump it into the aorta via an outflow cannula. If both ventri-

TABLE 2

Comparison of available cardiac devices

SELECTED PULSATILE PUMPS	
Thoratec	
Indications:	Right, left, or biventricular support
Advantages:	Fits in a wide range of patient sizes (body surface area 0.73 to 2.5 m^2) Pump can be changed without invasive surgery Can replace the entire function of the supported ventricle
Disadvantages:	Need for strict anticoagulation with risk of bleeding or thromboembolism Large lines crossing the skin with a high risk of infection Limited patient mobility Not approved for home use
HeartMate	
Indications:	Left ventricular support
Advantages:	No need for anticoagulation Portability of controller and batteries permits good patient mobility and hospital discharge Can replace the entire function of the supported ventricle
Disadvantages:	Drive line crossing the skin poses a risk of infection Left ventricle support only Does not fit in patients with body surface area $\leq$ 1.5 m^2
Novacor	
Indications:	Left ventricular support
Advantages:	Portability of controller and batteries permits good patient mobility and hospital discharge Can replace the entire function of the supported ventricle
Disadvantages:	Need for strict anticoagulation with higher risk of bleeding or thromboembolism Drive line crossing the skin poses a high risk of infection Left ventricle support only Does not fit in patients with body surface area $\leq$ 1.5 m^2
CONTINUOUS-FLOW PUMPS	
Indications:	Left ventricular support
Advantages:	Small size permits greater patient mobility Quiet Fit in a wide range of patient body habitus
Disadvantages:	Need anticoagulation; risk of bleeding and thromboembolism unknown May not replace the entire function of the supported ventricle Nonpulsatile flow Still in early clinical trials
TOTAL ARTIFICIAL HEARTS	
Indications:	Advanced biventricular dysfunction Pulmonary hypertension? Cardiac tumors?
Advantages:	Complete replacement of the heart function
Disadvantages:	Need anticoagulation; risk of bleeding or thromboembolism Due to the size of equipment, they only fit in patients with larger body habitus Still in early clinical trials

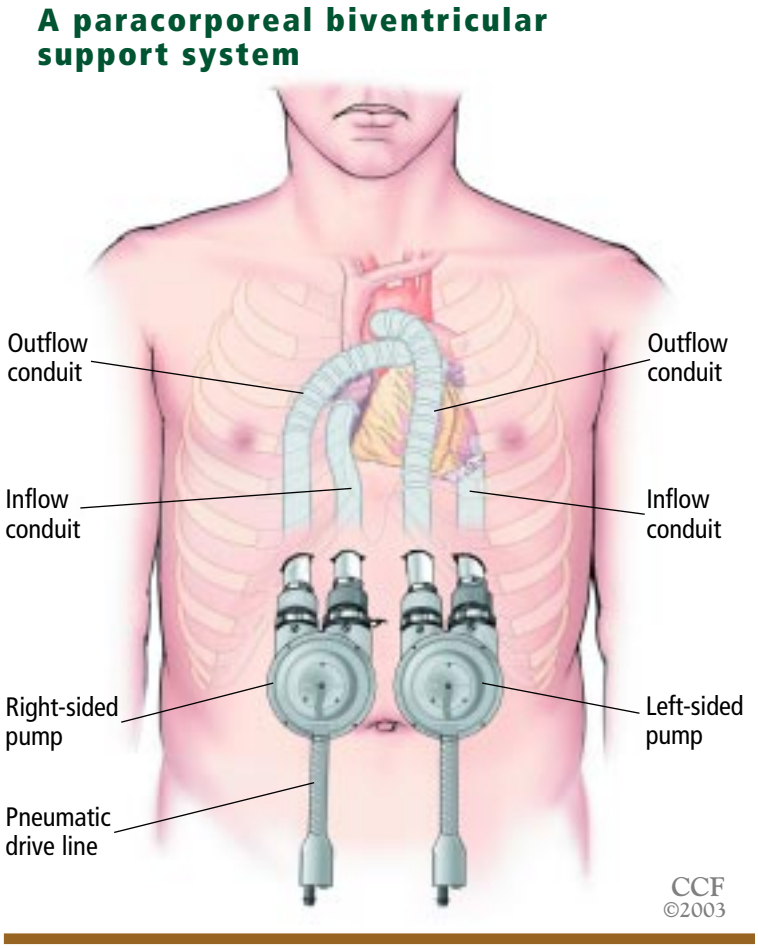

FIGURE 1. The Thoratec biventricular support system.

cles are failing, two pumps or a total artificial heart can be used. Energy and control sources activate and monitor the pump.

Like the body's own heart, most devices pump blood in pulses, which poses an engineering challenge. Pulsatile pumps need both an energy source, either pneumatic or electrical, to drive the pump and a mechanism for air to move in and out as the blood chamber fills and empties.[9]

To solve these problems, all of the first-generation pumps used an external drive mechanism connected by a drive line that passes either compressed air or electricity through the skin. There is also a need for an external vent. Unfortunately, the need for a drive line crossing through the skin creates a high risk of infection, a key complication of these early devices. In addition, the patient's quality of life is reduced by the need to be tethered to an external power source.

For later devices, it has been relatively easy to solve the problem of an external drive line. A controller and powerpack can be placed subcutaneously, and charged through the skin via an induction coil. However, creation of an internal venting system is more difficult. There are three solutions to the problem:

- An internal compliance chamber, a kind of small internal balloon, into which air from the pump can move in and out (used in the LionHeart Left Ventricular Assist System).
- An internal hydraulic pump that oscillates between two chambers (used in the AbioCor Implantable Replacement Heart). In this system a piston moves between two chambers. As it moves in one direction, chamber A fills with blood, while chamber B is emptied. As the piston reverses direction, chamber A is emptied of blood, and chamber B is filled.
- A nonpulsatile system (eg, the Jarvik 2000). In this system, similar to a car's water pump, blood is moved continuously and pulselessly, requiring no venting.

Some of the pulsatile pumps can be synchronized to the patient's heartbeat, but most run by sensing when the pump chamber is full. If the right side of the heart pumps more blood and fills the pump faster, the pump will beat faster. The nonpulsatile or rotary pumps to date run at a fixed rate.

PUMPS IN CLINICAL USE

Before we can discuss the indications for mechanical support, an overview of the types of devices is needed (**TABLE 2**).

Partially implantable pulsatile pumps

The Thoratec Ventricular Assist Device is paracorporeal: the pump is literally outside the body, with inflow and outflow cannulae that traverse the skin. The valves are mechanical.

Quality of life for the patient is not optimal, but this system actually has some advantages. Because the pump is outside the body, it can be used in small patients, and two pumps can be ganged together for biventricular support (**FIGURE 1**).[10] Recently a new, smaller console was released for use. Approximately the size of a small suitcase, it allows for greater

patient mobility and independence than the old console, which was the size of a washing machine.

The Novacor Left Ventricular Assist System and the **HeartMate Left Ventricular Assist System** are both intracorporeal LVADs. They have porcine valves. Both have portable controllers that permit the patient to be discharged from the hospital and to be more mobile.[11,12] The original HeartMate 1000-IP was pneumatically driven, with drive lines that traversed the skin. The newer HeartMate V-E and the Novacor are battery powered with a small portable controller but still have a tube that traverses the skin.[12]

The Novacor and HeartMate devices are approved for use as a bridge to transplantation, and recently, the HeartMate was recommended for approval as destination (permanent) therapy as well. However, these pumps are large and are therefore indicated only for patients with a body surface area of at least 1.5 m^2.[2,3,13] They have enough output to completely take over the function of the left ventricle.[3]

Except for the HeartMate, all pulsatile pumps in current use require anticoagulation to prevent thromboembolism.[12] Modifications in the Novacor design have reduced the incidence of thromboembolic events from a rate of 25% to 12% of devices implanted.

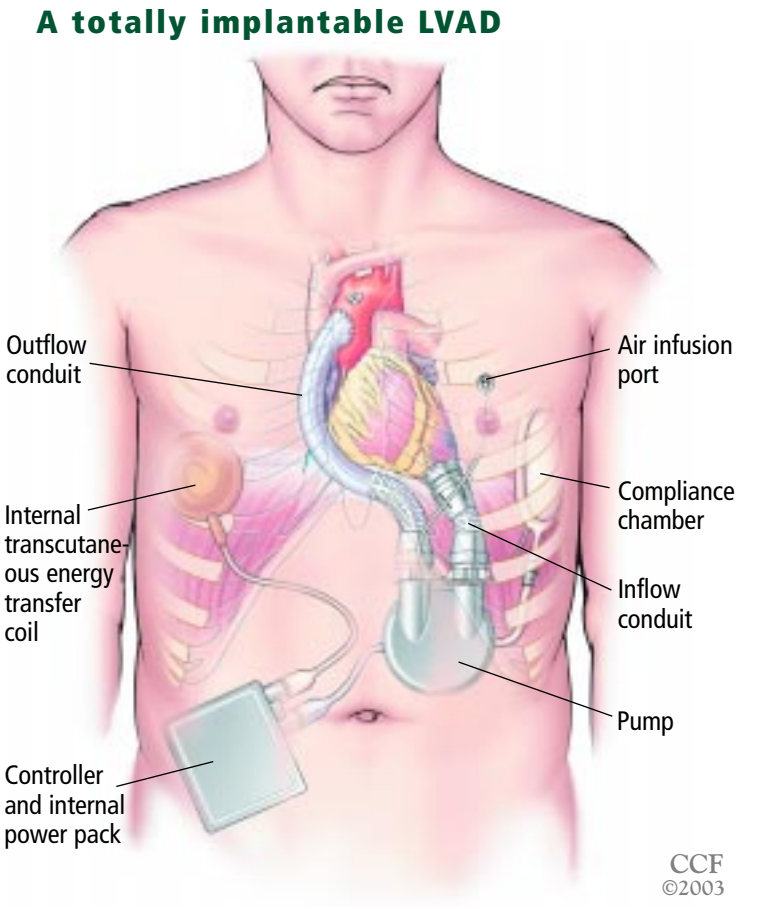

FIGURE 2. A totally implantable left ventricular assist device (LVAD), the LionHeart Left Ventricular Assist System.

Totally implantable pumps

The LionHeart Left Ventricular Assist System (FIGURE 2) is an LVAD with an implantable compliance chamber that provides internal venting and a transcutaneous energy transfer system: that is, a powerpack placed just below the skin that can be recharged by placing an induction coil just over it.[14]

The AbioCor Implantable Replacement Heart is a total artificial heart with a hydraulic pump that oscillates between the right and left chambers; one chamber fills while the other empties.[15] Thus, the ejection of the right and left chambers is sequential instead of synchronous.

Both devices are still under investigation for clinical utility. Placement of the AbioCor requires excision of most of the native heart; for that reason this device will be indicated only for patients with severe biventricular failure; elevated, fixed pulmonary vascular resistance; resectable malignant cardiac tumors; severe heart graft dysfunction; or massive cardiac necrosis after a myocardial infarction.[3]

Both devices completely do away with lines traversing the skin, and there have been no reports of pump or pump pocket infections for either device.

Continuous-flow pumps

Continuous-flow pumps use an impeller, akin to a turbine blade, to pump blood in a continuous stream rather than in pulses. Examples are the **DeBakey/NASA** and **Jarvik 2000** devices[16]; others (eg, **CorAid** and **HeartMate III**) are undergoing development and testing (FIGURE 3).

These pumps are simple and small and

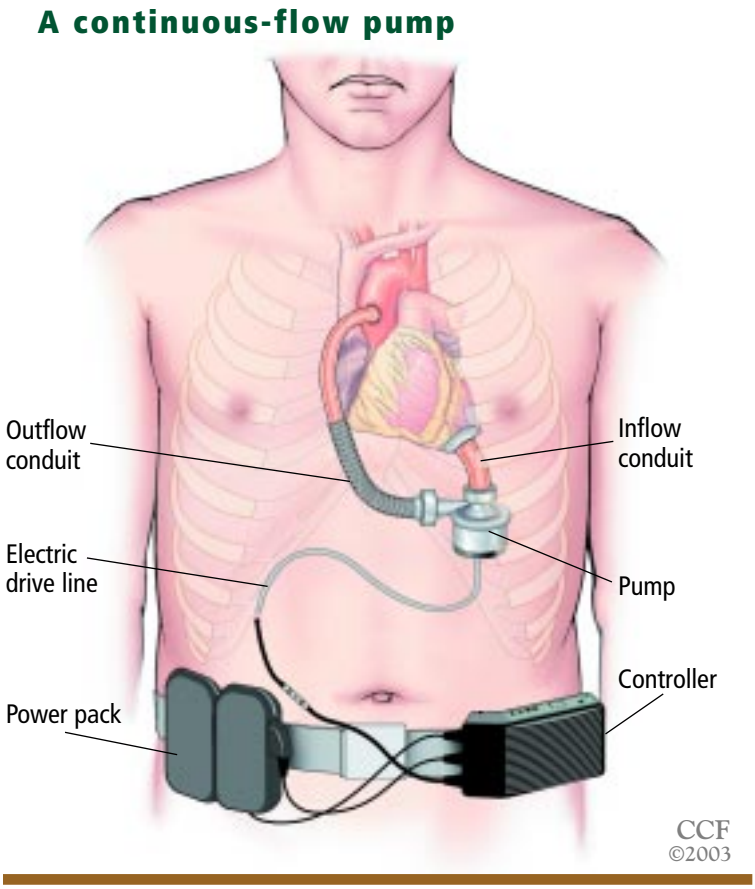

FIGURE 3. The CorAid ventricular assist device.

have the potential for wider use.[9] However, they do not have enough output to replace the entire function of the left ventricle. Rather, they are intended for patients with end-stage heart failure who retain some ventricular function (New York Heart Association class III or IV), in whom they provide a "boost" to support the circulation, thus unloading the failing heart enough to get it back into accordance with the Frank-Starling mechanism.[3] That is, by reducing the load on overstretched myocytes, mechanical stress is reduced, giving them a chance to heal and improving contractility.

Multiple animal studies on continuous flow suggested that, after an initial period of adaptation, the neurohormonal changes of heart failure such as elevated epinephrine and B-type natriuretic peptide levels return to baseline.[9,16]

It is not known if a pulse is necessary for long-term organ function, but when these devices are used for partial support the patient still has a pulse. Problems with thrombolysis have been minimal. Thromboembolism and pump clotting have been seen, but the magnitude of this problem is not yet known.

Although clinical experience with the continuous-flow devices is in its early stages, they seem to hold promise as a bridge to transplantation or recovery or possibly as destination therapy.[9] Two of them might be used together for biventricular support.

INDICATIONS FOR ASSIST DEVICES

In general, an assist device is indicated in patients with hemodynamic instability in the face of maximum medical therapy (including inotropes, an intra-aortic balloon pump, or both).[3,13]

The hemodynamic criteria for LVAD implantation usually include a cardiac index of less than 2 L/minute/m^2 and a pulmonary wedge pressure of more than 20 mm Hg. Most patients present with an acute insult such as a myocardial infarction, myocarditis, or postcardiotomy syndrome, or with decompensated chronic cardiomyopathy. At present, patients must be transplant candidates to receive an LVAD.[13]

What type to use?

The type of device to use depends primarily on availability and the surgeon's experience, but we have found the following principles to be quite useful.

About 90% of patients can be successfully supported with a pulsatile LVAD, but 10% to 30% of patients supported with an LVAD will manifest significant right ventricular dysfunction that might dictate right ventricular support as well.[17]

For patients with a right ventricular infarct, recurrent ventricular tachyarrhythmias, or severe right ventricular dysfunction with low pulmonary artery pressures and a high central venous pressure, a Thoratec Bi-Ventricular Assist Device (ie, two Thoratec pumps, one for each ventricle) (FIGURE 1) is the best choice.[10] Smaller patients (body surface area < 1.8 m^2) can be very uncomfortable with the large implantable pulsatile devices. Currently, the Thoratec system is the best choice in these patients. In the future, the

much smaller continuous-flow pumps will work well not only in these patients but also in children.

The role of continuous-flow pumps and the total artificial heart is unclear at present. Early experience suggests that continuous-flow pumps will be most useful as true assist devices in patients with some intrinsic cardiac reserve.[3] End-stage heart failure appears to be best supported with a pulsatile LVAD, which can completely unload the heart.

OUTCOME STUDIES AND CASE SERIES

LVADs as a bridge to transplantation

LVADs have proved very effective in sustaining very ill patients to transplantation, reversing shock, restoring end-organ function, and improving functional status.[18,19]

At The Cleveland Clinic Foundation, 264 patients received 275 LVADs as a bridge to transplantation between January 1991 and December 2002. The devices used were Novacor, HeartMate 1000-IP, and HeartMate V-E.

Sixty-nine percent of the patients survived to transplantation. Infection risk was high at 0.56 episodes per patient at 30 days, 1.28 at 3 months, and 1.88 at 6 months. Cerebral infarction risk was 0.15 at 30 days, 0.25 at 3 months, and 0.30 at 6 months. The device failed in 21 cases; all but one were HeartMates.[20] After transplantation, the 1-year survival rate of the patients who had received LVADs was similar to the rate in patients who received transplants without the need for LVADs.[13]

The results reveal excellent success in an extremely ill group of patients who might have died without the technology.

When to put in the LVAD poses a dilemma. Putting it in too early could subject the patient to an avoidable procedure with its risk and cost. On the other hand, a delay putting it in can lead to end-organ damage with an increased risk of operative morbidity and mortality.

Bridge to recovery

Assist devices were initially developed as a bridge to recovery in patients with postcardiotomy heart failure.[1]

In a series of 965 such patients, 433 (45%) were weaned from support and 237 (25%) improved enough to be discharged from the hospital. Of the patients who were discharged, 86% were in New York Heart Association heart failure class I or II. Their 2-year actuarial survival rate was 82%.[21]

Other reports showed similar results in patients with myocarditis and cardiogenic shock or shock due to a reversible injury.[22]

However, these patients had acute, reversible injuries. Chronic heart failure is different, and the idea of using mechanical circulatory support to promote recovery of myocardial function in chronic heart failure has generated a great deal of excitement.

Chronic heart failure starts with an index injury (eg, acute myocardial infarction) that leads to alteration in the mechanical properties of the muscle, which in turn leads to a remodeling process at the cellular, molecular, and neurohormonal levels, resulting in progressive changes in chamber size and geometry.[22] Functional deterioration causes perfusion abnormalities and congestion, which give rise to the clinical features of the syndrome.

Several studies showed that with LVAD support there is a reversal of the remodeling process at all levels, leading to functional recovery.[22–24]

In a series of 105 patients with dilated cardiomyopathy who received LVADs,[25] 24 patients were weaned from the device. Fourteen patients enjoyed stable cardiac function after being weaned from the device over an observation period between 3 months and 4.5 years. Heart failure recurred in 7 patients over a period of 4 to 24 months. Compared with the patients whose condition remained stable, those whose condition deteriorated had a longer duration of heart failure, needed longer periods of support to meet the criteria for LVAD removal, and had bigger chamber sizes and lower ejection fractions.

Of great interest was that improvement in function on the LVAD disappeared if the support was continued for longer than 6 months, suggesting that prolonged rest may lead to atrophy and fibrosis of the myocardium.[25]

The results are encouraging, but only a minority of patients could be weaned and did well over the long run. This approach needs to be studied further to determine prospec-

Criteria for LVAD use:
- **Cardiac index <2**
- **Wedge pressure >20**
- **Transplant candidate**

Left ventricular assist devices improve survival as 'destination' therapy

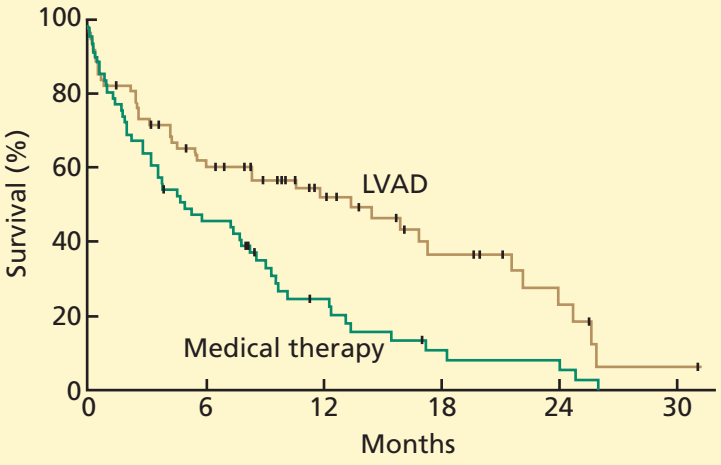

FIGURE 4. Kaplan-Meier survival curves for 129 patients with end-stage heart failure randomized to receive a left ventricular assist device (LVAD) or medical therapy in the REMATCH trial.

FROM ROSE EA, GELIJNS AC, MOSKOWITZ AJ, ET AL. LONG-TERM MECHANICAL LEFT VENTRICULAR ASSISTANCE FOR END-STAGE HEART FAILURE. N ENGL J MED 2001; 345:1435–1443. REPRODUCED WITH PERMISSION.

tively which patients are candidates, what parameters indicate recovery, and if any therapies enhance recovery.

To date, most successful weanings were in patients with acute and reversible injury. Of patients with chronic heart failure who were weaned from LVAD support, those with dilated cardiomyopathy seemed to fare better than those with ischemic cardiomyopathy.[22]

Destination therapy

Fewer than half of patients in advanced-stage chronic heart failure on maximum medical support survive 1 year. Could LVADs have a role as destination therapy in this population?

The REMATCH trial (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) recently explored that role.[26] One hundred and twenty-nine patients who were not transplant candidates were randomized to receive medical treatment or a HeartMate LVAD.

At 1 year, the mortality rate was 48% lower in the LVAD group than in the medical group. The Kaplan-Meier estimates of survival (**FIGURE 4**) at 1 year were 52% for the LVAD group and 25% in the medical therapy group; at 2 years the survival rate was 23% in the LVAD group and 8% in the medical therapy group.

Terminal heart failure caused the majority of deaths in the medical treatment group, whereas the most common cause of death in the LVAD group was sepsis (41%) followed by device failure (17%).

The probability of infection with the device was 28% at 3 months. Most of these infections were at the drive line site or in the pocket. No system failures were reported at 12 months, but at 24 months the probability of system failure was 35%.[26]

How can permanent LVAD therapy be made safer?

The complication rate of this expensive technology remains high, but this trial shows that an LVAD as destination therapy has the potential for better survival than does optimal medical therapy. Considering that 58% of deaths in the LVAD group were due to infection or mechanical failure, this survival advantage could be maximized and extended by improving the design to make it more durable and to reduce the propensity for infection. The first goal could be reached by simplifying the design, and the second possibly by making the devices totally implantable.

Tough ethical questions about 'destination' therapy

In many cases now, and when destination therapy becomes a reality, mechanical support is an "end-of-life" decision. Devices prolong life, but do they provide for an acceptable quality of life? At what age is a patient too old or too sick to consider mechanical support? If the patient finds life intolerable with the device, who will turn it off?

In most cases the well-established bioethical principles of respect for patient autonomy and surrogate decision-making and rejection of futile care will help guide physicians. In other cases, the answers will be much more difficult and will need a careful examination of these guiding principles.

COSTS

The cost of therapy with mechanical support is roughly similar to the cost of heart transplantation. The devices cost approximately $65,000, and the mean hospital cost aside from the device is about $200,000 but varies widely depending on complications.

MECHANICAL SUPPORT WILL BECOME MORE COMMON

We predict that more and more patients with end-stage heart failure will be offered a variety of devices that will fit their needs.

For patients with some retained function, a booster of support can be given as a bridge to recovery, a bridge to transplantation, or even as destination therapy, using small continuous-flow pumps that are quiet and fit in small patients as well as large.

For patients who need LVAD support, the option of a totally implantable LVAD will be available in the near future.

For patients with biventricular failure, a total artificial heart that is completely implantable will offer an excellent option.

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