LVAD as Destination Therapy - The Economic Dilemma

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LVAD as Destination Therapy - The Economic Dilemma

Abstract
The artificial heart, after decades of development, remains a long way off as a practical remedy for people with failing hearts. But a related technology, the left ventricular assist device (LVAD), has passed major milestones in its development and is poised for widespread use. This technology, which is an offshoot of the artificial heart program, may well have greater impact on society than the artificial heart. It is time to consider its probable costs to society. A heart transplant is the present treatment of choice for end-stage heart failure (ESHF).

Disciplines
Biomedical Engineering and Bioengineering

Comments

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The artificial heart, after decades of development, remains a long way off as a practical remedy for people with failing hearts. But a related technology, the Left Ventricular Assist Device (LVAD), has passed major milestones in its development and is poised for widespread use. This technology, which is an offshoot of the artificial heart program, may well have greater impact on society than the artificial heart. It is time to consider its probable costs to society.

With about 550,000 new cases and 1 million hospitalizations a year in the United States alone, congestive heart failure is a major health problem and a major cause of death among the elderly. The 4.7 million Americans with mild to severe heart failure face a five-year mortality rate of 50% [1]. Advanced heart failure, experienced by 250,000 Americans, is a debilitating condition whose outcome for the patient is grim.

A heart transplant is the present treatment of choice for end-stage heart failure (ESHF). In part because of a lack of donors, only 3000 heart transplants are performed each year worldwide (two thirds of them in the
United States); 15 000 patients are on waiting lists for transplants. Because of lack of donors, these numbers are not likely to increase substantially in the future.

**Enter the LVAD**

For many years, physicians have dreamed of replacing the failing heart with a mechanical pump. The most visible work along these lines has been the development of the total artificial heart (TAH), which was spurred by massive investments by the Artificial Heart Program, a U.S. program chartered in 1964 by the National Heart, Lung and Blood Institute (NHLBI), part of the National Institutes of Health.

As an offshoot of the artificial heart program, the NHLBI funded the development of ventricular support systems, which do not replace the heart entirely but assist it in pumping blood. The first ventricular support system was used in a human in 1963. Mechanical support systems, notably the Left Ventricular Assist Device (LVAD), came into frequent use in the 1980s as heart transplants became increasingly popular and the need arose to support the hearts of patients awaiting transplant.

LVADs typically bypass the left ventricle (which carries about 80% of the load of the heart) and pump blood directly into the aorta, from which it enters the systematic circulation. More recent systems also assist the right ventricle (which pumps blood through the lungs) as well. The devices are either implanted entirely within the body with power lines and an air vent brought outside the body through the skin, or their pumps are located outside the body and connected to the heart and large blood vessels with tubes passing through the chest. Fig. 1 shows an LVAD of the first type, the HeartMate (Thoratec Corporation, Pleasanton CA).

**LVAD as Bridge to Transplant**

With the growing success of heart transplants, the need arose to sustain patients on a temporary basis until they could receive heart transplants, a role that the LVAD serves well. The FDA approved the first LVAD for use as “bridge to transplant” in 1994. At present, five different LVADs are on the market and several others are in advanced development stages. The FDA has never approved a TAH except for use in clinical trials.

By limiting approving of LVADs for sale as a bridge to transplant, the FDA restricted the device to a very small market consisting of, at most, a few thousand patients eligible for heart transplants, which is a small fraction of individuals suffering from end-stage heart failure. Consequently, medical device companies have undertaken studies to demonstrate the effectiveness of the LVAD for use in patients who are ineligible for a heart transplant because of old age, other serious illnesses, or simply residence too far from a hospital capable of performing heart transplants. For such patients the LVAD would be “destination therapy,” just as a pacemaker is destination therapy for heart arrhythmias.

As destination therapy for end-stage heart failure, the safety and effectiveness of the LVAD would have to be compared to that of the presently accepted treatment using drugs. Important evidence came in 2001

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**Fig. 1.** Thoratec HeartMate® XVE left ventricular assist system. Reprinted with permission from Thoratec Corporation.

Only 3000 heart transplants are performed each year worldwide; 15 000 patients are on waiting lists for transplants.
with the publication of a long-await-
ed study that was jointly sponsored
by the NHLBI and the Thoratec
Corporation [2]. This landmark
study, known as the Randomized
Evaluation of Mechanical Assis-
tance for the Treatment of Conges-
tive Heart Failure (REMATCH)
study, compared the outcomes of
129 patients with end-stage heart
failure who were ineligible for a
heart transplant. Sixty-nine of these
patients received a LV AD (Heart-
Mate VE) and the other 61 were
treated by drugs alone. The results
were dramatic. The median survival
time was 408 days in the device
group and only 150 days in the med-
ical-therapy group (Fig. 2).

There were, however, numerous
serious complications from use of
the LVAD (Table I). More than a
quarter of the patients contracted
serious infections from the device
within three months after implanta-
tion, and by the end of two years
more than one-third of the devices
had failed [7]. However, only one
patient with the LVAD died of left
ventricular dysfunction, a cause of
death in fifty of the control
patients. Thus, despite its high
failure rate and numerous complica-
tions, the LVAD increased the
two-year survival rate of these
very ill patients. Is this
REMATCH success story con-
vincing enough?

Apparently it was. On Novem-
ber 6, 2002, the FDA approved the
HeartMate LVAD to “be implant-
ed permanently in certain termi-
nally ill patients who are not eligi-
ble for heart transplant.” Noting
the “serious side effects associated
with the device,” the FDA limited
approval of the device for use with
patients with severe ESHF. The
Agency estimated that between 20
000 and 30 000 people a year
could benefit from the device. The
device has been marketed in Europe
both as a bridge and as an alternative
to transplant since 1994.

There is, in fact, good reason to
believe that the LVAD might benefit
a far larger patient population than
those with ESHF, including patients
after myocardial infarction, or suf-
fereing from postsurgical cardiac
failure, acute myocarditis, or dilated
cardiomyopathy. By “unloading”
the heart, the LVAD reduces the
pressures on the heart, providing a
“bridge to recovery” [3]. Many of
these patients can subsequently be
weaned from the LVAD. And also,
by increasing cardiac output, the
LVAD can lead to dramatic improve-
ments in patients with heart
failure, at least for the short term.

How Much Will It Cost?
Implantation of a LVAD, and asso-
ciated medical care, is very expen-
sive. Moskowitz et al. [4] reported
that the first-year cost of LVAD
implantation is presently $220 000,
which includes $141 000 for the ini-
tial implant related hospitalization
and $67 000 for the cost of the de-
vice. This is comparable to the cost
of a heart transplant – and far more
than drug therapy for heart failure.
As the technology improves, the
costs of the device will surely
decline. But also, as the devices
improve, the risk/benefit
calculations of patients
and their physicians will
change, and their usage
will increase.

By expanding the
indications for use of the
LVAD, the FDA will cre-
ate a rapidly growing
market for the devices.
When FDA approval was
limited to use as a bridge
to transplant, the market
for the device (at least in
the United States) was
limited to the number of
patients eligible for heart transplants,
which is in turn limited by the
availability of donors. Approval for
marketing as destination therapy for
ESHF patients who are not can-
didates for heart transplant greatly
expanded its market. Any future
approval for use with less severely ill
patients as a bridge to recovery will
result in further expansion.

Estimates for the ultimate size of
the market for the LVAD in the

**The LVAD has been marketed in Europe both as a bridge and as an alternative to transplant since 1994.**
United States vary considerably. Moskowitz et al. [4] projected that there will be 35,000–75,000 candidates for LVADs per year by 2020. An investment firm recently predicted that the size of the American market for LVADs would be 100,000 units per year if the devices were approved as a “bridge to recovery” [5]. Indeed, the number of firms developing such devices is a measure of their optimism about the future growth of the market.

The aggregate costs of widespread usage of the LVAD could be staggering. At $220,000 per patient, a market of 100,000 devices per year would correspond to an aggregate medical bill of $22B per year in present dollars—just for the costs of implantation and first year care of the patients.

Dialysis provides a good example of the ability of a new technology to incur costs that far exceed original projections. In 1972 the U.S. Congress agreed to include dialysis for patients with end-stage renal disease in Medicare. The best projections at that time were that the program would serve 10,000 patients, at a cost of $250M per year. Today, the program serves more than 20 times this number, at a cost (in present dollars) of $14B per year. While the costs of dialysis (on a per-patient basis) declined in real terms, the demand for treatments far exceeded initial projections.

Government is thus faced with a dilemma. It is clearly unacceptable to deny patients a lifesaving treatment (such as dialysis or LVAD). But the aggregate costs of such treatments can potentially become high enough to have adverse effects in other areas of social welfare.

This same point, from a different perspective, was made in a recent essay entitled “Too Much of a Good Thing: How Splendid Technologies Can Go Wrong” by ethicist Daniel Callahan, who argued that “equity and technological progress are on a profound collision course” [6] because of the impossibility of providing both endless high-tech medical services and ensuring equitable care to the entire population. The issue is fundamentally one of justice: what does a just society provide to its members according to what priorities?

This dilemma is also seen in the 41 million American citizens who lack health insurance, and receive basic health services on a hit-or-miss basis (if at all). Government has been unable to extend health insurance to these people. One notable attempt was in President Clinton’s unsuccessful campaign for health care reform early in his Presidency. Clinton’s plan foundered in part because middle-class Americans feared that universal health coverage would mean, for them, loss of coverage for high-tech medical services. “Because the middle classes will not tolerate restrictions on access to [medical] technologies,” historian David Rothman pointed out [7], “the lower classes are left to fend for themselves.”

A recent estimate of the costs of extending health insurance to all Americans was provided in a 2003 plan proposed by the Commonwealth Fund (a New York foundation), which was projected to cost the federal government $70B [8].

Given the present economic climate, the prospects of such a plan are very dim indeed. With the LVAD, the camel’s nose is already under the tent, and U.S. federal and state governments could easily incur annual costs of tens of billions of dollars in coming years. This may be a good example of the “collision

### TABLE I CAUSES OF DEATH OF PATIENTS ENROLLED IN THE REMATCH STUDY

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Medical Therapy Group</th>
<th>LVAD Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left ventricular dysfunction</td>
<td>50</td>
<td>1</td>
<td>51</td>
</tr>
<tr>
<td>Sepsis</td>
<td>1</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td>Failure of LVAD</td>
<td>0</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Miscellaneous noncardiovascular causes</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Cardiac procedure</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Perioperative bleeding</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>54</strong></td>
<td><strong>41</strong></td>
<td><strong>95</strong></td>
</tr>
</tbody>
</table>

*From [2]. Reprinted with permission.*

### Economic Dilemma

The LVAD is a life-giving technology, but its aggregate costs to society could become daunting. Medicare has long covered LVAD therapy as bridge-to-transplant. On November 19, 2003, the Centers for Medicare and Medicaid Services announced that Medicare will cover the cost of implantation of FDA-approved LVADs as destination therapy for patients who do not meet eligibility requirements for cardiac transplantation.
course” that Callahan describes. But the collision is indirect: by pushing up costs of health care, the LVAD (and other expensive technologies) will make it even harder to extend health insurance to all Americans.

Other countries take a different approach. England restricts consumption of high-tech medical services by, in effect, rationing medical care (except for those with the ability to pay for private care). But these countries are also facing the prospect of unsustainable medical costs. Can even wealthy societies afford the splendid technology of modern medicine?

The LVAD is truly a splendid technology, a product of the artificial heart program developed without the hoopla that accompanied the artificial heart. But it creates a dilemma that will also arise with other artificial organs that may be developed in the future: the treatment costs are very high, there are many potential users, and the availability of the devices (unlike those of organs for transplant) is essentially unlimited. To paraphrase Callahan’s question: at what point does a new medical technology become too much of a good thing?

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**References**


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**LETTERS (continued from page 5)**

**Reply by Chester Smith**

I agree with Mr. Avishay Gordon that the term “guerilla” is not exactly what we need to describe internacional activists who have resorted to terrorism from time to time. Actually the Al-Qaeda people have targeted the overthrow of the Saudi Royal family and they do, indeed, have in-country activity with that objective in view. In that sense they might be classified as “guerillas,” but their operations in the international scene exceed the classic narrow definition normally used.

We do not have a clear idea of what motivates these people and our present administration seems to have no interest in finding out. Simply labeling them “bad guys” is not helpful. American interest in the Middle East is primarily economic. “Terrorist” action is an attention getter and in some ways resembles a call for third-party nations to “back off.” The apparently religio-political agenda takes these organizations out of the pure terrorism-for-its-own-sake category. At the moment we do not have a properly descriptive term for them. Perhaps Mr Gordon can suggest one.

Under the restricted definition Mr Gordon proposes, the Palestinian suicide people qualify as guerilla fighters not terrorists on the basis of motivation and not method. Clearly their objective is to reclaim their land from what appears to them to be an occupation by a non-Asiatic (e.g., European/American) culture that was imposed during the first half of the twentieth century. There is no solution to that situation that fails to recognize the essential religio-cultural character of the conflict.

“Terrorism” as such relies on the dramatic and may be entirely idiosyncratic as in the Timothy McVey case and the Oklahoma Federal Building episode. Al Qaeda and other similar groups appear to have definite objectives in view and may or may not use terrorism to accomplish them. If nothing else works, give your opponent a bloody a nose.

The intent of the original piece was to show the incredible efficiency of this type of activity in terms of results versus investment. Evidently there is no quarrel with that premise. My thanks to Mr Gordon. It is nice to know that somebody actually read the article and thought enough to critique the terminology.

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