The American Association for Thoracic Surgery 2016 Ethics Forum: "Cost-effectiveness and the ethics of left ventricular assist device therapy"

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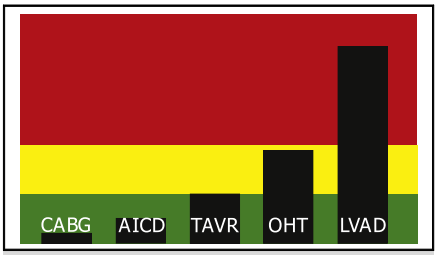

ICERs for select cardiac procedures.

Central Message

The principle of justice requires clinicians to consider cost-effectiveness when choosing candidates for LVAD therapy. High-risk implantations should be limited to carefully vetted situations.

Left ventricular assist devices (LVADs) are the standard for many patients with end-stage cardiac failure. Improved quality of life (QOL) and survival come at the expense of ventricular assist device (VAD)-specific complications and stress on the family and caregivers. The ethics of patient selection remain unclear for this expensive therapy that offers limited benefit. In the United States, there are strict medical criteria for permanent LVAD support. However, unlike the situation for heart transplantation, exclusion criteria are not well delineated. This has the potential to produce inconsistent distribution of LVAD therapy and the ethical implications that ensue.

The framework for bioethics put forth by Beauchamp and Childress[1] includes 4 nonhierarchical principles. Autonomy, beneficence, nonmaleficence, and justice carry equal weight when assessing the ethical course of action. When 2 or more of the principles are in conflict, the appropriateness of an action is determined from the relative good and harm of the individual principles in question. Analysis of these 4 principles is necessary when examining the ethics of the distribution of LVAD therapy.

Under the principle of autonomy, a patient has the right to choose their plan of care. LVAD candidates are facing death from heart failure, the imminence of which is determined by the degree of illness. When a patient is bed-bound with congestive heart failure, they will almost always opt for an LVAD,[2] because they feel they have "no choice." In this situation, autonomy is not the deciding factor to determine whether a patient should be offered an LVAD.

Beneficence, or acting to relieve suffering or lengthen life, usually is fulfilled with LVAD therapy. LVADs can provide years of life compared with medical therapy, and there is a significant and durable improvement in QOL.[3] Even patients at high risk for mortality are likely to benefit if they survive the initial hospitalization. Beneficence strongly favors LVAD therapy in patients at reasonable operative risk, but it is less clear that this principle favors an LVAD when the chance of survival is low and the chance of complications is high.

Nonmaleficence requires that the physician avoids excessive risk to minimize the chance of producing harm. In LVAD candidates at higher risk, hospital mortality rates approach 20%, and many of these patients will experience significant complications. Acceptance of high rates of morbidity and mortality may be reasonable when the other principles favor implantation, but this should not be the norm because a high complication rate would violate the principle of nonmaleficence.

The principle of justice requires that all patients be treated fairly without bias. Although the other principles are often viewed as patient-centric, justice requires a larger view. When faced with a scare resource, such as an organ for transplantation, justice requires that all transplant candidates have an equal opportunity to receive that organ. A different view of justice may be more appropriate in the case of an unlimited but expensive therapy such as an LVAD. Under this view, justice requires that all persons have an equal opportunity to receive adequate healthcare. The use of a large amount of resources for a single patient may affect the availability of resources necessary to treat other patients. Justice is only served when the implantation of an LVAD does not consume excessive resources.

The principles of autonomy and beneficence favor LVAD implantation most of the time, whereas nonmaleficence favors an LVAD in the absence of elevated risk. However, when risk is sufficiently high such that the chance of benefit

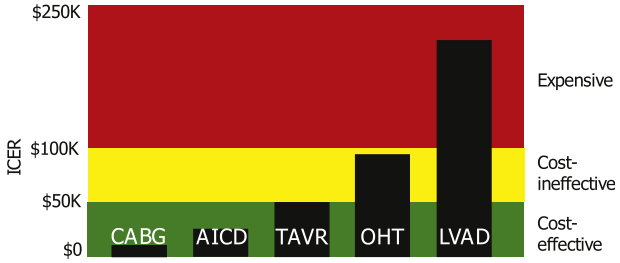

FIGURE 1. ICER for select cardiac procedures with assessment of cost-effectiveness by accepted criteria. *ICER*, Incremental cost-effectiveness ratio; *CABG*, coronary artery bypass grafting; *AICD*, automatic implantable cardioverter-defibrillator; *TAVR*, transcatheter aortic valve replacement; *OHT*, orthotopic heart transplantation; *LVAD*, left ventricular assist device.

is low, beneficence is less clear and justice may help lead to the most ethical action.

Consider 2 patients in class IV heart failure with cardiogenic shock, identical except for age. They have reasonable family support, yet neither is an ideal transplant candidate. The first patient is 40 years old, and the second patient is 70 years old. Either would likely require short-term support before a long-term device. In each case, is LVAD implantation ethically appropriate? Is it ethically reasonable to make a different decision for each patient? How is the decision made to proceed with LVAD or continue medical management?

Unlike heart transplantation, device availability is not a factor. The cost of implantation is not an adequate factor either, because many expensive therapies such as transplantation are widely accepted. Effectiveness of the therapy also is not appropriate, because LVADs are effective in prolonging life and improving QOL regardless of age or medical condition. Even with a 10% chance of survival, one can make the argument that such a low rate of success is effective when compared with certain death.

A commonly used standard in this situation is cost-effectiveness. The incremental cost-effectiveness ratio (ICER) is the difference in cost of 2 treatments divided by the difference in quality-adjusted life years (QALYs) that each produces. A procedure with an ICER of $10,000 costs $10,000 per QALY gained over standard therapy. In general, therapies with an ICER less than $50,000 are considered cost-effective, and those that are significantly higher are cost-ineffective (Figure 1). Some argue that therapies with an ICER between $50,000 and $100,000 or more are expensive yet may be accepted as cost-effective.[4] In patients facing death, an end-of-life premium is sometimes invoked,[5] whereby the cost-effectiveness threshold is raised for therapies when death is imminent, justifying an ICER up to $100,000 or more. The cost-effectiveness of LVAD therapy is critical in determining the justice in offering LVAD support.

The pulsatile HeartMate device (Thoratec Corp, Pleasanton, Calif) used in the REMATCH Trial had an ICER of $802,700,[6] whereas the ICER for newer devices is approximately $200,000 when compared with optimal medical management.[7-9] Despite exceeding the usual cost-effective criteria, implantations are covered by insurance and continue at a rapid rate. Is it possible for LVADs to be cost-effective under the threshold of $50,000 to $100,000/QALY? The answer is "possibly," but only with very careful patient selection. The ICER can be lowered through longer survival and fewer costly complications. Patients who receive an implant before inotropes are necessary have a 3-year survival in excess of 90% compared with 50% when they undergo urgent operation.[10] The costs of implantation were nearly twice as high in patients who died during the index hospitalization compared with those who survived, and costs were 7.25 times higher in those with sepsis, bleeding, and pump pocket infection compared with those with none of these complications.[11] Better patient selection can lead to higher long-term survival with fewer complications and lower costs, leading to a lower ICER for the care of these patients. Readmissions are a large part of the cost of LVAD care and decrease the chance of achieving cost-effectiveness. Strategies to limit the readmission rate and outpatient costs by 50% would decrease the ICER 2.4-fold to approximately $87,000.[9]

Limiting LVAD implants to situations in which they are cost-effective may be unpalatable for several reasons. First, this is the cost of progress. LVADs would not be available today if cost-effectiveness were an initial limitation. Results and cost-effectiveness have improved with better technology and patient selection, and further improvements are likely. Second, patients may live a decade or longer on device support. Unlike some expensive palliative cancer therapies in which an additional 3 months of life may define success, an LVAD may "cure" heart failure and allow the patient to experience many years of productive life. Next, the best alternative to LVAD therapy is heart transplantation, which is expensive and organ availability is limited. Finally, the precedent has been set that LVADs are an acceptable therapy, and denying coverage now would be difficult.

The challenge moving forward is balancing the use of a very expensive, lifesaving technology with the need to be good stewards of our healthcare dollars and to allocate this resource in an ethical manner. If this is accomplished, those with a good chance for success with an LVAD will have the opportunity to benefit, those with the potential for many years of productive life ahead will get the chance to reach their potential, and those who would not receive appropriate healthcare if resources are diverted to poor-risk LVAD candidates will not be denied their opportunity.

Using an ICER of $100,000 to strictly limit implantations is not reasonable because the therapy already significantly exceeds this threshold. Even if the device were steeply discounted, the cost of the index hospitalization, daily care,