CE Symptom Management Series

Left Ventricular Assist Device–Destination Therapy for Symptom Management in Heart Failure

Ethical Considerations and Recommendations for Future Practice

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The left ventricular assist device originated as a means to provide temporary circulatory support for patients suffering from end-stage heart failure. The device was originally intended to serve as a bridge to cardiac transplantation. Increasingly, however, the left ventricular assist device is being utilized as a destination therapy for those patients who are not candidates for heart transplantation. It is this utilization as a destination therapy that raises additional significant ethical concern related to the risks and benefits of the devices, factors influencing quality of life, and consequences pertaining to end-of-life care.

KEY WORDS

autonomy, end-of-life, ethics, informed consent, LVAD, palliative care

ARGUMENT

The left ventricular assist device (LVAD) originated as a means to provide temporary circulatory support for patients suffering from end-stage heart failure (HF). The device was originally intended to serve as a bridge to cardiac transplantation. Increasingly, however, the LVAD is being utilized as a destination therapy (DT) for those patients who are not candidates for heart transplantation. It is this utilization as a DT that raises additional significant ethical concern related to the risks and benefits of the devices, factors influencing quality of life, and consequences pertaining to end-of-life care.

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CASE PRESENTATION

A prime example of the extreme burdens associated with continued care is the case of Mr N. Mr N. is a 67-year-old gentleman from a rural community. He and his wife live together in a single family home that is large enough for their sons, daughters, and grandchildren to visit several times a year. He has been diagnosed with HF for the past 12 years. Although Mr N. has received optimal medical care, he has now progressed to end-stage HF. His doctors have recommended an implantable device as a last resort to sustain his life. Mr N. undergoes the operation within 2 weeks of hearing the distressing news.

The continued care of Mr N.'s condition has now escalated to a point that has severely impacted not only his quality of life but that of his family as well. Mr N. has had to move to an apartment within 15 minutes of the medical facility as a result of his implant. His wife is emotionally, physically, and mentally drained from the 24-hours-a-day/7-days-a-week care associated with his condition. Their finances have and continue to be depleted from the direct cost of his care, and their home will soon be placed in foreclosure. The strain placed upon their children as a result of his illness has led to fractured relationships and animosity.

Mr N. had a severe stroke as a result of his implanted cardiac device and is now on life support in the ICU. His wife has asked the medical team to withdraw all treatment. She is now completely and totally depleted—emotionally, physically, and financially. Although her children are providing her with support, they too have suffered greatly as a result of this situation.

In retrospect, the decision to undergo implantation of a cardiac device had profoundly impacted the entire family with little or no comparative benefit. As a result, Mr N.'s family has been fractured and left traumatized by the experience.

BACKGROUND

Heart failure is the most frequent cause of hospital admission and readmission in the United States and is the

singular cardiac-related diagnosis that still has a rising prevalence.[1] As of 2007, nearly 5 million patients were diagnosed with HF, and over 500,000 cases are newly diagnosed each year.[2] For patients with newly diagnosed HF, approximately 20% will die within 1 year; at 5 years after diagnosis, only 40% to 60% will have survived.[3] It is widely believed that the advances in the medical management of HF have led to the dramatic increase in HF prevalence; however, morbidity and mortality data have not improved for patients with advanced HF.[2]

An initial study, the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH), was conducted between 1998 and 2001 to determine the safety and effectiveness of LVADs as a DT (LVAD-DT).[4] In this prospective randomized controlled study of 129 patients, 68 patients were enrolled to receive LVAD, and 61 were assigned to the control group consisting of medical management alone. Those enrolled in the LVAD group had statistically significant higher survival rates at 1- and 2-year follow-up (52% vs. 25% and 23% vs. 8%, respectively). Despite the study's limited generalizability, the US Food and Drug Administration (FDA) and the US Centers for Medicare & Medicaid Services approved LVAD-DT in 2003 for male and female Medicare beneficiaries with chronic end-stage HF.[5]

Two subsequent studies have been performed: The Chronic Mechanical Circulatory Support for Inotrope-Dependent Heart Failure Patients Who Are Not Transplant Candidates (INTrEPID) trial and the post-REMATCH study.[6,7] In both studies, the average survival time ranged from 12 to 24 months; however, there was a 50% risk of patients developing significant neurologic or infectious complications within that time frame. For the average Medicare recipient, the FDA and the US Centers for Medicare & Medicaid Services indicate that these complications have consequences on quality-of-life (QOL) adjusted survival and on end-of-life trajectory.[5] Furthermore, in all three studies (REMATCH, INTrEPID, and post-REMATCH), the large majority of patients in the LVAD-DT group had died within 2 years of implantation. When combined with the significant risk of serious complication, further recognition of the impact on QOL indicators and clinical situations that impact end-of-life care require further investigation. Kirkpatrick and Kim[8] state that the issues surrounding LVADs are further compounded because "the growth of industry-sponsored research in cardiology and other fields has raised ethical concerns about patient protection, informed consent, and conflict of interest in medical research."[8(p7)]

ETHICAL CONSIDERATIONS

The field of bioethics emerged in response to two distinct societal phenomena that occurred in the 1960s. First, there was a dramatic increase in technological innovation that has continued to present day. Second, this innovation explosion was coupled with the public perception that the traditional paternalistic relationship of the doctor-patient interaction was seriously flawed. Significant infringements upon patient rights in human research were identified by Henry Beecher[9] in 1966. As a result, Americans began to question the intentions of physicians for the first time and began to challenge their previously unquestioned authority. This resulted in the development of a more adversarial relationship between physician and patient. As stated by Jonsen,[10] "In large part, the appearance of a new medicine that offered promise of great benefit initiated the examination of medicine's conscience."[10(p11)]

The increased public scrutiny of the traditional paternalistic approach in medicine led to a movement in which respect for patient autonomy had paramount importance. Accordingly, in an effort to fill the void between paternalistic practice and patient autonomy, the American Medical Association Principles of Medical Ethics (1980) stated that it was no longer permissible for doctors to withhold information from a patient, even on the grounds that a physician considered it harmful.[11] The individualist approach to care with a concerted effort to inform and offer choices to patients had taken a foothold.

This newfound respect for patient autonomy has given rise to several patient rights including the right to informed consent. Bioethicists of this time "assumed the role of protecting the patient from the doctor and intervening on the side of the patient in an adversarial relationship."[12(p204)] This meant that there was a need for disclosures and safeguards to guard against misunderstandings and the abuse of power. Charon[12] states:

> Hence, many of the early concerns of bioethics-informed consent, safeguarding patient autonomy, and resource allocation were powered by the suspicion that doctors, left to their own devices, will exploit patients or in some way harm them and that patients need defense against them.[12(pp204,205)]

These same issues remain clinically relevant today.

Ackerman[13] argues that "the notion of respect for patient autonomy makes noninterference its essential factor… that people are entitled to autonomous determination without limitation on their liberty being imposed by others."[13(p14)] This perception, however, relegates the role of the physician/healthcare provider to that of a glorified technician. Noninterference suggests that physicians are no longer expected to offer their opinions; they are merely to provide individually relevant information and dispense competent care. The concept of noninterference dramatically hinders patient autonomy because "it fails to take account of the transforming effects of

illness."[13(p14)] Moreover, respect for patient autonomy, in the extreme, constitutes abandonment according to Charon[12] and negates the concept of informed consent completely. Charon[12] suggests that when healthcare providers are expected to put their wealth of personal experience and knowledge about the particulars of the situation aside in favor of permitting patients the freedom to choose treatments that may not only have no benefit but may, in fact, be harmful, the concept of respect for individual autonomy has been taken too far.

Ethicists and, more recently, society as a whole often condemn "paternalistic" practices of physicians without considering why they employ these practices to begin with. It is important to understand that illness itself can undermine the perception of equality. Callahan[14] emphatically describes the need to revisit the emphasis on patient autonomy stating that:

> The doctor-patient relationship, which was the point of departure for an ethic of autonomy in the 1970s, is due for a course correction. Doctors are not plumbers or hired help. Their vocation is to serve our health and well-being, not our autonomy. This can be done only if doctors are allowed their own view of what constitutes our good.[14(p33)]

More importantly, physicians should rely on their past experiences and share this valuable insight in the form of recommended courses of action.[15,16]

The emergence and prevalence of life-sustaining technology have blurred the line between a natural death and otherwise. Furthermore, this technology has certainly compounded the difficulty in determining what can be construed as truly informed consent. The decision to initiate life-sustaining technology is no longer a purely medical question, as it now has ethical, moral, social, and legal ramifications. Machado[17] indicates "Patients and their relatives as well as healthcare professionals experience new types of end-of-life situations that fail to fit established ways of categorizing, perceiving, judging, and acting in such situations."[17(p794)] This transposition from a natural death to one that is unnatural has created significant controversy and emotion. What has evolved is an arena of negotiated deterministic death, and there are many voices that ought to be considered. In addition, these decisions must be integrated with current understandings of patient autonomy and provider informed consent practices.

To highlight the significant burden placed upon healthcare providers when life-sustaining technology is utilized, we need to look no further than the increasing utilization of LVADs. Bramstedt and Wenger[18] were the first to pose this dilemma, stating that "inadequate informed consent and failure to appoint a surrogate decision maker in advance of the implant procedure resulted in a complex ethical dilemma for the patient's family and medical team."[18(p544)] These difficulties are becoming even more apparent when these devices are utilized in patients who both lose decision-making capacity and are no longer transplant candidates.

The determination to utilize LVAD technology poses significant ethical challenges. In the case of LVADs and other life-sustaining treatment, careful consideration must be given to the benefits and burdens of such treatment, not only for the patient but also the impact this technology has upon the family and the primary caregiver. The discontinuation and significant rate of complications associated with LVADs may themselves contribute to and hasten a patient's death. Additionally, technology does not lend itself to the simple withdrawal; the surgical removal of the device poses significant risk. Even if the device is turned off, the implant alone impairs cardiac function. Many opponents to this practice consider this a form of physician-assisted death. As a result, the utilization of LVAD-DT has significantly increased the burden placed upon physicians with regard to obtaining truly informed consent.

RECOMMENDATIONS

Initiation of LVAD

If truly informed consent is to be obtained, the discussion about whether to initiate LVAD-DT must be grounded in the risk-benefit ratio. Additionally, it is imperative that the topic of device discontinuation (termination of treatment) should be broached as part of the initial discussion, as it may involve numerous implications that must be considered. According to several authors,[2,5,19,20] it is widely believed that patients undergoing invasive cardiac surgery have a poor understanding of not only their disease, but also the associated interventions and their potential complications. Also, LVAD-DT has considerable implications for the caregivers of the recipient as well. Rizzieri et al[5] suggest that in an effort to obtain informed consent for the implantation, "it is essential to conduct a balanced discussion of medical management, palliation (including early palliative care consultation), and hospice care options, as well as to discuss the surgical procedure itself."[5(p7)] Furthermore, the discussion should include potential complications, including the development of neurologic sequelae and new diseases that may hasten death or complicate care. It is clear that this process is one that may take several days to complete, specifically if the recipient and loved ones are to be given time to comprehend the totality of the situation. Surgical implantation should proceed only when the patients and their caregivers fully understand the risks and benefits of the procedure, the implications

of discontinuing therapy, and the burdens this procedure will incur.

Withdrawal of LVAD

Although it is generally accepted that the withdrawal of life-sustaining therapy is ethically equivalent to the withholding of such therapy, an ethically complex situation arises when considering the withdrawal of an LVAD. The quandary exists because the turning off of the device or its surgical removal itself may hasten death. Once the device is powered off, blood no longer flows through the device, leading to pooling, which will often lead to thrombosis.[18] Additionally, when the device is turned off, heart contractility is disrupted, impeding natural function. The surgical removal of the device poses significant risk as well such as bleeding, infection, tissue perforation, and thrombus, which all may ultimately hasten death.

As such, the decision to withdraw an LVAD relies heavily on the risk-benefit ratio. Bramstedt and Wenger[18] suggest that the decision to withdraw an LVAD must consider all of the same issues as those involved in a futility decision. Deciding to halt a functioning LVAD relies heavily on the quality of life of the recipient and the burden placed upon the caregivers. The informed consent should explicitly indicate that the removal or inactivation of the device may hasten death.

THE ROLE OF PALLIATIVE CARE

Left ventricular assist device as a DT is a relatively new life-sustaining technology that raises awareness of "wrinkles" in end-of-life care that we were not aware of before. What is necessary in an effort to mitigate an ethical conundrum is the practice of preventive ethics.[18] In this case, a concerted effort is levied on the part of the healthcare team to openly and transparently communicate with patients and their loved ones in an effort to obtain truly informed consent. It is imperative that physicians and nurses be allowed and encouraged to provide both data-based assessment of the clinical situation and their personal experience-based assessments as well. An approach such as this provides for the needed balance between factual information and consideration of values. In this way, autonomy is enhanced, and patients are afforded the opportunity to make the best possible decision for themselves.

Early palliative care consultation may be the most effective means of enhancing patient autonomy and ensuring that truly informed consent occurs. Temel and colleagues[21] conducted a randomized control study of 151 patients with newly diagnosed metastatic non–small cell lung cancer. Half of the patients were assigned to early palliative care consultation, and half were provided with standard oncologic care alone. In this seminal study, those patients with integrated early palliative care had higher QOL scores ($P = 0.03$) and less depressive symptoms ($P = 0.01$). Most surprisingly, however, was that the palliative care group was less likely to request "aggressive" end-of-life care ($P = 0.05$), and their median survival was longer ($P = 0.02$). The results of this study can provide the impetus necessary to change the prevailing culture surrounding palliative care. If physicians and patients alike can recognize the benefits of early palliative care consultation and replace their notions that equivocate its use with hospice care, we may very well make the turn from more discussions surrounding quantity-of-life to more substantive ones of quality of life.

Perhaps much of the success of palliative care teams can be afforded to their multidisciplinary approach. Palliative care teams are composed of physicians, nurses, social workers, psychologists, and spiritual counselors. Each member of the team is regarded as an equal, and each member's input is highly valued. When dealing with terminally ill individuals (as in the case of LVAD-DT patients), it is the nurse who takes a pivotal role as he/she is most intimately involved with the patient and the family. As such, the nurse can provide the healthcare team with much needed information regarding the patient's own expectations of care and can identify areas where further inquiry is necessary.

Lastly, Kirkpatrick and colleagues[22] indicate "With the increase in length of life provided by these devices and their substantial cost, the question is whether there is enough improvement in morbidity to justify lengthening a wretched life."[22(p269)] Further research is necessary to determine the risk-benefit ratio of the utilization of LVAD-DT, not only for the patient but also for the care provider. In an effort to understand the totality of the experience, quantitative analysis of QOL measures should be combined with qualitative measures to determine the lived experiences of surviving care providers for this growing cardiovascular population.

CONCLUSION

Despite the high rates of significant complications associated with LVAD-DT, the utilization of this therapy continues to rise. This article has identified the ethical issues surrounding LVAD-DT, has offered recommendations for future practice, and has identified areas where further research is necessary. The use of any life-sustaining technology brings with it numerous implications for obtaining informed consent. However, LVAD-DT is unique in that its use has additional associated burdens. As such, LVAD-DT has placed a greater burden on healthcare providers in their effort to obtain truly informed consent. The process is a lengthy one, but it is one that must be undertaken. Of utmost importance is an approach to care that involves open dialogue between the patient and

healthcare team members. The resulting relationship is one that is founded upon mutual respect and acknowledgement and can serve to enhance the lives of both the healthcare recipient and provider.

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References

1. Roger VL, Weston SA, Redfield MM, et al. Trends in heart failure incidence and survival in a community-based population. *JAMA*. 2004;292:344-350.
2. Stuart B. Palliative care and hospice in advanced heart failure. *J Palliat Med*. 2007;10(1):210-228.
3. Constanza MR, Mills RM, Wynne J. Characteristics of "stage D" heart failure: insights from the Acute Decompensated Heart Failure National Registry Longitudinal Model (ADHERE LM). *Am Heart J*. 2008;155(2):339-347.
4. Rose EA, Gelijins AC, Moskowitz AJ, et al. Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) study group: long-term mechanical left ventricular assistance for end-stage heart failure. *N Engl J Med*. 2001;345:1435-1443.
5. Rizzieri AG, Verheijde JL, Rady MY, McGregor JL. Ethical challenges with the left ventricular assist device as destination therapy. *Philos Ethics Human Med*. 2008;3(20):1-15.
6. Rogers JG, Butler J, Lansman SL, et al. Chronic mechanical circulatory support for inotrope-dependent heart failure patients who are not transplant candidates: results of the INTrEPID trial. *J Am Coll Cardiol*. 2007;50(8):741-747.
7. Lietz K, Long JW, Kfoury AG, et al. Outcomes of left ventricular assist device implantation as destination therapy in the post-REMATCH era: implications for patient selection. *Circulation*. 2007;116(5):461-462.
8. Kirkpatrick JN, Kim AY. Ethical issues in heart failure: overview of an emerging need. *Perspect Biol Med*. 2006;49(1):1-9.
9. Beecher HK. Ethics and clinical research. *N Engl J Med*. 1966; 274(24):1354-1360.
10. Jonsen AR. Life is short, medicine is long: reflections on a bioethical insight. *J Med Philos*. 2006;31(6):667-673.
11. Bostick NA, Sade R, McMahon JW, Benjamin R. Report of the American Medical Association council on ethical and judicial affairs: withholding information from patients: rethinking the proprietary of "therapeutic privilege." *J Clin Ethics*. 2006;17(4): 302-306.
12. Charon R. *Narrative Medicine: Honoring the Stories of Illness*. New York, NY: Oxford University Press; 2006.
13. Ackerman TF. Why doctors should intervene. *Hastings Cent Rep*. 1982;18(2):14-17.
14. Callahan D. Rationing: theory, politics, and passions. *Hastings Cent Rep*. 2011;41(2):23-27.
15. Caplan AL. Cancer and bioethics: caring and consensus. *Cancer*. 2008;113(suppl 7):1801-1806.
16. Caplan AL. Will evidence ever be sufficient to resolve the challenge of cost containment? *J Clin Oncol*. 2011;29(12):1946-1948.
17. Machado N. Discretionary death: conditions, dilemmas, and normative regulations. *Death Stud*. 2005;29:791-801.
18. Bramstedt KA, Wenger NS. When withdrawal of life-sustaining treatment does more than allow death to take its course: the dilemma of left ventricular assist devices. *J Heart Lung Transplant*. 2001;20(5):544-548.
19. McGregor M. Implantable ventricular assist devices: is it time to introduce them in Canada? *Can J Cardiol*. 2000;16(5):629-640.
20. Powell TP, Oz MC. Discontinuing the left ventricular assist device: ethical considerations. *Soc Thorac Surg*. 1997;63:1223-1224.
21. Temel JS, Greer JA, Muzikansky A, et al. Early palliative care for patients with metastatic non–small-cell lung cancer. *N Engl J Med*. 2010;363:733-742.
22. Kirkpatrick JN, Fedson SE, Verdino R. Ethical dilemmas in device treatment for advanced heart failure. *Curr Opin Support Palliat Care*. 2007;1:267-273.