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Left Ventricular Assist Devices

When the Bridge to Transplantation Becomes the Destination

Kathleen Broglio, DNP, ANP-BC, ACHPN ❍ Frances Eichholz-Heller, MSW, LMSW, ACHP-SW ❍ Shunichi Nakagawa, MD

Heart failure affects more than 5 million people in the United States. Left ventricular assist devices (LVADs), originally designed as a bridge to heart transplantation, are now implanted as either a bridge to transplantation or as a destination therapy for those individuals who are not transplant candidates. Left ventricular assist devices have improved survival and may improve the quality of life for many individuals. However, individuals who originally had LVADs implanted as a bridge to transplantation may be delisted because of changes in health status and, like those with LVADs as destination therapy, will live with this therapy until the end of life. Decision making can become more complicated when adverse effects or comorbid health conditions cause a significant decline in health status. Challenges related to informed consent, advance care planning, quality of life, and end-of-life care in this population will be discussed. Clinical interventions will be addressed to improve care in this growing population.

KEY WORDS

ethics, hospice, left ventricular assist device, palliative care

(This case has been altered to protect the identity of the patient and his family)

Mr M., a 66-year-old man living independently in a large metropolitan area, faced many life challenges. He survived Hodgkin lymphoma as a young adult, lost a brother to lung cancer, and had recently lost his job. A devastating myocardial infarction and resultant congestive heart failure changed his life. During a hospitalization for cardiogenic shock, Mr M was offered left ventricular assistive device (LVAD) implantation as a bridge to heart transplantation (BTT). The medical team presented the risks and benefits of the LVAD therapy, but because of his medical condition at the time, Mr M reported he remembered very little of the discussion. He had never completed advanced directives and did not have the energy to think about it during the hospitalization and did not discuss any wishes with his only living relative- his sister.

After LVAD implantation, Mr M often wondered if these multiple medical procedures had been futile because they had left him living with a "toaster" in his chest. This implanted device made him feel "like a radio" or an "electronic device," not a human being. The LVAD was a persistent reminder that life was extremely tenuous as he was now responsible for the multiple daily activities to prevent infection and ensure continued device function. He now had to take additional medications and attend more medical appointments. He was also hospitalized because of adverse events related to the LVAD.

These changes in his quality of his life were demoralizing and left him depressed and anxious. Before this medical event, Mr M. went out to dinner nightly; attended concerts, theater, and opera; and enjoyed the many activities of life in a big city. He was no longer able to engage in the activities that meant so much to him, including simple activities such as taking a shower. Mr M often felt too tired even to leave his apartment and was forced to rely more on his sister who lived out of state, but came often to assist him in his care and attend medical appointments with him. He had multiple financial stressors due to his job loss, but because of his medical status, he was not in a position to seek new employment.

Grief-stricken and angry, he often lamented that it would have been better if he had died on the operating table. These overwhelming losses became heightened when he learned that because of changes in his cardiac status, he was no longer a candidate for a heart transplant. Mr M. was "devastated and shattered" and described life with LVAD as a state of feeling "too sick to be at home, but too well to be in the hospital." When the BTT became destination therapy (DT), the light at the end of the tunnel now became the wait for impending death. Mr M. questioned

Kathleen Broglio, DNP, ANP-BC, ACHPN, is senior nurse practitioner, Adult Palliative Care Services, Columbia University Medical Center, New York.

Frances Eichholz-Heller, MSW, LMSW, ACHP-SW, is senior social worker, Adult Palliative Care Service, New York Presbyterian, Columbia University Medical Center, New York.

Shunichi Nakagawa, MD, is assistant professor, Adult Palliative Care Service, Department of Medicine, Columbia University Medical Center, New York.

Address correspondence to Kathleen Broglio, DNP, ANP-BC, ACHPN, Adult Palliative Care Services, Columbia University Medical Center, 601 West 168th St 37/38, New York, NY 10032 (kb2735@columbia.edu).

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whether it would be better to just have the LVAD deactivated to end his life, but he had never discussed it with his cardiology team and he was afraid to die.

He became progressively weaker and was hospitalized because of multiple complications. Unable to return home, Mr M. elected to sign on to hospice. He then faced an additional challenge as none of the local hospices had cared for someone with a LVAD and staff had to be trained in LVAD care before his admission.

OVERVIEW OF LVAD THERAPY

More than 5 million people in the United States are living with heart failure. More than half of these individuals will die within 5 years.[1] Treatments include medication and lifestyle management and, in some cases, heart transplantation. Over the past 2 decades, there has been an increased use of mechanical circulatory support (MCS). Left ventricular assist devices are battery-operated mechanical pumps that take over or support the function of the left ventricle of the damaged heart, improving hemodynamics and end-organ blood flow. In 1996, LVADs were approved as a BTT for those individuals who had been approved for cardiac transplantation but who were not expected to have adequate cardiac function and required MCS until a donor heart becomes available.[2]

In 2003, LVADs were approved by the Center of Medicare and Medicaid Services (CMS) for individuals with worsening heart failure who are not candidates for transplantation and therefore require lifelong MCS as DT. The original CMS-approved indications for LVADs for DT include individuals with New York Heart Association class IV symptoms of end-stage left ventricular failure for at least 90 days with a life expectancy of less than 2 years who are not candidates for heart transplantation. Multiple other requirements (dietary, ejection fraction, medication requirements, functional limitations) are also part of the consideration for LVAD implantation.[2]

EPIDEMIOLOGY—LVAD DEVICES BTT VERSUS DT

According to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database, more than 6000 individuals were implanted with LVADs between June 2006 and June 2012.[3] Originally, pumps had pulsatile flow technology, and even though there was significant survival benefit and improved quality of life,[4] broader application of LVADs had been limited by large device size, clinically significant adverse events, and limited device durability. A pivotal multicenter randomized trial demonstrated that a continuous-flow device compared with a pulsatile-flow device was associated with significantly better 2-year survival.[5] The Heartmate II continuous flow device was approved for BTT in April 2008[6] and for DT in 2010 (Figure).[7] The number of new implants increased from 343 in 2007 to 1516 in 2010.[3] Before 2010, LVAD DT implantations accounted for 3.9% to 12.5% of all implantations, but this increased to 44% of all implants in 2012.[3] Left ventricular assist device implantations that are a BTT or DT are reimbursed by CMS. In reality, there is a large gray area; 40% of individuals implanted are a "bridge to transplant, likely/moderate/or unlikely." Because of changes in health conditions, 43.5% of individuals who received LVAD BTT implants from March 2006 to 2011 were no longer transplant candidates 2 years after LVAD transplantation.[3] Although not a Food and Drug Administration–approved indication, there were a number of LVADs

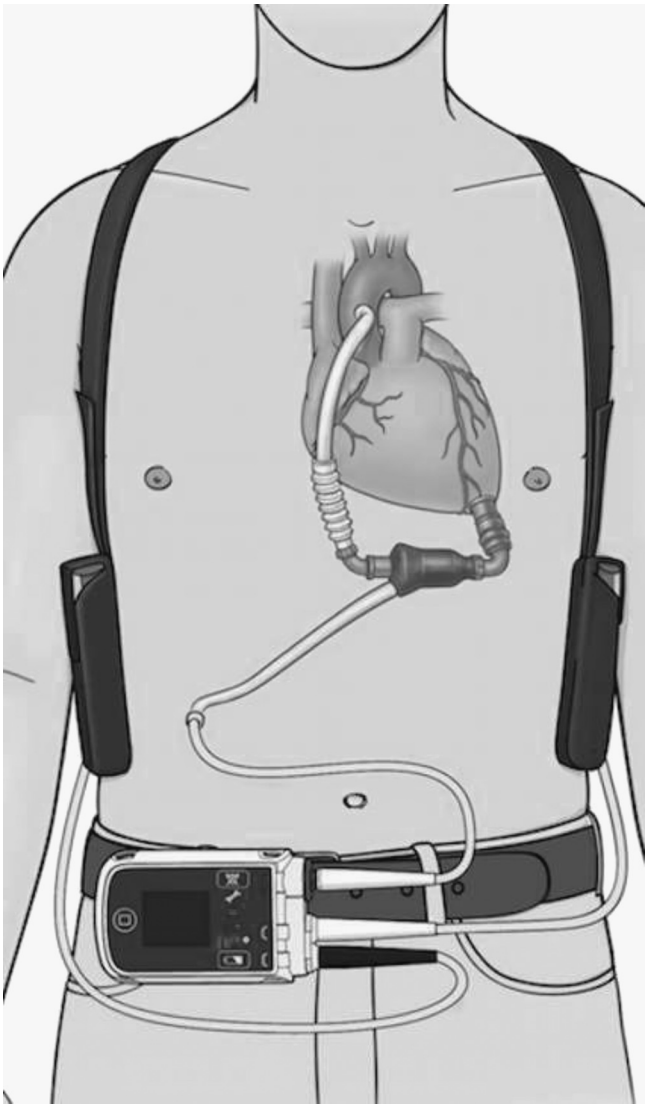

FIGURE. HeartMate II with pocket controller: HeartMate II battery-powered op pocket controller. Reprinted with permission from Thoratec Corporation.

(n =1162 between 2006 and 2011) implanted as a bridge to candidacy, of which only 29% were listed for transplant.[8] The outcome is a growing number of people living with LVADs for the remainder of their lives.

Survival

According to results from a systematic review of continuous flow LVADs, Year 1 survival ranges from 56% to 87% and at Year 2 ranges from 43% to 84%.[9] This is a significant improvement as mortality is about 90% at Year 2 for those with significant heart failure without LVAD therapy.[4] Higher mortality rates occur in people who are older and have cardiogenic shock and progressive cardiac decompensation, right ventricular failure, and renal dysfunction.[9] As LVAD DT implantation increases, one may expect a variation in survival rates dependent on the premorbid conditions.

Adverse Effects

Adverse event rates have declined with the use of continuous flow devices[10] but are still common. According to the fifth INTERMACS annual report (2013), 70% of people will have a major adverse event in the first year.[3] More than 50% are rehospitalized in the first year, with bleeding and device-related infections being the most common complications.[9] The risk of more serious complications such as stroke or device malfunction requiring a pump replacement increases the longer the device is implanted.[3,11]

POTENTIAL ETHICAL DILEMMAS LVAD THERAPY

Informed Consent

Before LVAD implantation, individuals receive extensive evaluation to ensure they are appropriate candidates and have adequate resources and support to maintain the LVAD therapy. Individuals who chose implantation versus continuation of medical therapy often felt they had "no choice"—it was either death or the LVAD.[12] In our experience of providing palliative care consultations in this population, hospitalized individuals may only know about LVADs for less than 7 days before implantation (S. Nakagawa, personal communication). According to the INTERMACS report, more than 50% of LVADs implanted were in individuals with critical cardiogenic shock or progressive decline.[3] In these cases, the decision to implant is made by individuals who are critically ill, perhaps without a full assessment of comorbid health issues.[13] Thus, a dilemma can arise if people choose LVAD therapy without consideration to the complexities of the therapy and comorbid health conditions.

Advance Care Planning

The Joint Commission requires that a palliative care specialist be part of the interdisciplinary MCS team in those facilities who have advanced certification in left ventricular assist device therapy.[14] The CMS has recommended advance care planning conversations before LVAD DT implantation, but there are no specific guidelines.[3] These recommendations do not apply to individuals having LVADs implanted as a BTT. These individuals may be delisted because of worsening health conditions and may not have had the opportunity to reflect on what would be an acceptable quality of life. Individuals who have participated in advanced care planning may not have discussed or written down their wishes in terms of LVAD withdrawal. In a chart review of 68 people who had undergone LVAD placement, 32 people had completed advanced directives and 25 had done so before LVAD implantation. However, none of the advance directives included documentation about LVAD support or withdrawal at the end of life.[15] Thus, undue strain in terms of decision making may be placed on the surrogate if the individual is not able to express his/her wishes during a decline in health status.

For individuals who have an LVAD as a BTT, the inconveniences of being "hooked up" to an external device that is battery controlled may be a short-term acceptable lifestyle. However, if they are never listed or are delisted for transplant because of changes in health status, they are faced with the reality of being connected to a LVAD for the remainder of their lives. For some individuals, this may not constitute an acceptable quality of life. Yet, if they have never participated in advance care planning, they may have never explored alternative care options.

Deactivation of LVAD Therapy

It has been generally accepted within the medical community that individuals may refuse treatment or request withdrawal of therapy. In a retrospective review, Mueller and colleagues describe withdrawal of LVAD support in 14 patients. All but 2 patients had lost decision-making capacity and were critically ill, with most experiencing multiorgan failure. Ethics consultation was requested in only 1 case. The authors concluded that withdrawal of support was permissible and akin to withdrawing other forms of life-sustaining therapy.[16] Brush and colleagues reported on active end-of life-decision making in 20 patients with LVAD DT, of which 11 died at home. Seventeen chose withdrawal of LVAD therapy, and in all cases, the MCS team participated in deactivation and provision of palliative care. Loss of consciousness and death occurred in less than 20 minutes for all individuals.[17]

Although these reports support the acceptability of LVAD deactivation, there may be discomfort with LVAD withdrawal among clinicians. In an Internet survey of clinician attitudes of withdrawal of LVAD support for those approaching end of life (n = 303), 46% had discontinued LVAD support in 2 or more patients. Only 26%

felt comfortable with discontinuing LVAD support and 13% considered LVAD discontinuation physician assisted death.[18] There have not been many studies evaluating attitudes about withdrawal of LVAD support, but studies about clinician views on withdrawal of life-sustaining support may provide insight into this issue. Kramer et al[19] showed that significantly more physicians feel comfortable discussing withdrawal of mechanical ventilation, feeding tube, and hemodialysis than discussing implantable cardioverter defibrillator or pacemaker (PM) deactivation. Significantly more physicians had actual experience in terms of withdrawing mechanical ventilation, dialysis, and feeding tubes compared with deactivation of cardiac devices.[19] Kapa et al[20] elicited medical, legal, and patient perspectives on withdrawal of implantable cardioverter defibrillator or PM therapies at end of life. Medical professionals had greater discomfort about withdrawal of cardiac support in individuals who were PM dependent,[20] thus highlighting the discomfort about withdrawal of life sustaining therapy that may hasten death.

In an opinion article, Rady and Verheijde[21] have proposed that discontinuation of MCS without coexisting lethal conditions such as circulatory shock, multiorgan failure, or device failure may constitute physician-assisted death if the patient is not imminently dying. Morris and Shore[13] have proposed in another opinion article that termination of LVAD therapy should be challenged in some cases such as during the postoperative period. They propose that programs implement a contractual agreement to prevent LVAD discontinuation during the first 90 days after implantation.[13]

The results from the survey studies and opinion pieces that equate device deactivation with physician-assisted death may reflect views held by some providers within the medical community. An individual who is delisted for transplant will live with LVAD therapy until death and may face challenges related to decisions regarding end of life. If this individual does not have an overwhelming catastrophic event and wants the LVAD deactivated because of an unacceptable quality of life, this may result in an ethical dilemma for the clinician, as deactivating the device in most cases will result in death akin to withdrawing other life support measures such as balloon pumps or inotrope therapy if the person is totally dependent on this level of cardiac support. There may be clinicians who will not be comfortable discontinuing therapy and there may be resultant moral distress on the parts of the clinicians. If the clinician refuses, the patient may also experience increased feelings of hopelessness and perhaps abandonment. Conversely, individuals from certain religious backgrounds may never feel it is acceptable to deactivate a LVAD even after a catastrophic event. In these cases, LVADs may prolong life and, potentially, suffering at the end of life.

Quality of Life

Quality of life has many definitions but is generally thought to be the subjective measure of how happy a person is with his/her individual situation or level of functioning taking into consideration the following states: physical, emotional, financial, and social.[22] Although there have been many advances in LVAD technologies to prolong the lives of individuals with end-stage heart failure, the impact of these technologies on quality of life as measured by patient-reported outcomes has not been widely studied.[23]

Individuals with LVADs and their caregivers encounter many challenges, including emotional distress, anxiety and fear. Others have reported cognitive decline, difficulty sleeping often due to anxiety and noise emitted from the LVAD, concerns around sexual activity, restrictions in travel and driving, and overall loss of independence.[22] Loneliness, helplessness, loss of control, and feeling useless to others are common complaints.[23]

Caregivers specifically experience increased stress and burdens related to the activities of caregiving. They are frequently responsible for taking vital signs, monitoring the LVAD, changing dressings, measuring and recording daily weights, and dealing with emergencies.[24] Overall, individuals and/or their caregivers may not have fully comprehended the necessary changes to their lives and the increased burden of care.

End-of-Life Care

Individuals with LVADs as DT will eventually face end-of-life care decisions, which may include the setting for care. Families and caregivers may not be able to manage the complexity of daily care owing to worsening health status. Individuals may require care in long-term skilled care settings or hospice inpatient settings.[25] Many individuals will face challenges finding facilities with trained staff able to manage the LVAD and provide the needed care at the end of life. For individuals who wish to die at home, hospice staff may not have the skill or resources to provide the care of this technology or to deactivate the LVAD.[23] In a survey of caregivers of patients who had LVADs deactivated, family members reported concerns about knowledge deficits among hospice staff about LVAD pump function and expressed a desire for hospice staff to better educated about this therapy.[17] In the case presented here, Mr M's sister was angered that her brother was offered "state-of-the-art treatment with no plan for state-of-the-art end-of-life care."

INTERVENTIONS TO MINIMIZE ETHICAL DILEMMAS

Preparedness Planning

The use of disease-specific advance health care directives has been proposed as a solution to empower individuals

and their caregivers.[11] In a retrospective review in 1 institution, 13 individuals undergoing LVAD for DT received a palliative medicine consultation for goals of care and quality of life preferences, which contributed to better overall care.[25] Because most individuals and caregivers are unfamiliar with LVADs, preferences should be explored with individuals and caregivers before implantation.[26] The use of a disease-specific advanced directive can address issues that are specific to the LVAD, such as preferences in relationship to catastrophic complications, debilitative medical conditions, malfunctions of the device, and unacceptable quality of life. Treatment goals should be discussed before implantation and reviewed each time there is a complication or change in the person's health status.[22] Surrogates will be empowered to honor the individual's wishes. Knowing the individual's preferences may also decrease the burden of making a decision about continuation versus discontinuation of life-sustaining measures in cases when the surrogate has to speak for the individual. Understanding preferences versus reacting to an emergency due to a change in health condition may help caregivers/families at the end of life and during the bereavement process. This understanding may also offer protection against complicated grief or other posttraumatic stress bereavement disorders.[22]

Maximizing Quality of Life

Supportive interventions to maximize quality of life can include meeting with a palliative care clinician before implantation. This meeting may improve informed consent through a careful exploration of common risks associated with LVAD placement and the ensuing impact that these risks can have on quality of life.[27] By exploring the individual's values and preferences, the locus of control remains with the individual. Other psychosocial interventions designed to support and improve quality of life may include supportive psychotherapy, meaning-centered therapy, relaxation/meditation exercises to address anxiety, and life review and legacy projects.

Caregivers report that the act of providing support, doing the practical caregiving tasks, and bearing witness provides its own reward and satisfaction that helps them to cope with this change in lifestyle. However, taking breaks from the hospital or home caregiving responsibilities, working, and receiving support from other close family members or friends can help caregivers to improve or maintain their quality of life.[28] Coping strategies to support caregivers include positive thinking, developing a routine, acceptance of the situation, prayer, faith, and hope.[24] Working with caregivers/families to break down complex situations into manageable tasks may increase feelings of competence and decrease feelings of being overwhelmed. Coaching families/caregivers in communication strategies with the medical team to articulate their questions, fears, and concerns can result in an improved sense of control over their situation and may reduce anxiety.

End-of-Life Care

Individuals with LVADs will eventually face decisions about the end of life. When there are catastrophic complications with the LVADs, these individuals may be hospitalized and die in the acute care setting. However, others may develop comorbid conditions such as metastatic cancer. Death may occur secondary to these comorbid events, not because of complications of the LVAD. Hospices may not have the trained staff or capability to manage individuals with these devices. These individuals should not be consigned to making decisions to have end-of-life care provided in acute care institutions or be forced to make the decision to deactivate these devices to be eligible for hospice care. It is incumbent for medical centers with advanced MCS programs to partner with hospices and long-term care facilities to provide the training and support to staff. Hospices should implement policies and procedures to care for this growing population. Individuals with LVADs or other advanced MCS devices can then be assured quality end-of-life care is provided at home or in facilities offering hospice care.

CONCLUSION

The use of LVAD DT therapy or emerging forms of MCS devices will continue to grow given the number of people with end-stage heart failure. Individuals with advanced MCS devices may face complex decisions and will need expert care as their clinical condition changes. Clinicians in hospice and palliative care can assist individuals and their families/caregiver to ensure that care is consistent with their preferences and to provide quality care throughout the continuum and at the end of life. It will be important for clinicians to obtain the necessary knowledge and skills to provide excellent care to this growing population.

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