Dying With a Left Ventricular Assist Device as Destination Therapy

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Background—Despite the ability of left ventricular assist device as destination therapy (DT-LVAD) to prolong survival for many patients with advanced heart failure, little is known about the eventual end-of-life care that patients with DT-LVAD receive.

Methods and Results—All patients undergoing DT-LVAD at the Mayo Clinic in Rochester, Minnesota, from January 1, 2007, to September 30, 2014, who subsequently died before July 1, 2015, were included. Information about end-of-life care was obtained from documentation in the electronic medical record. Of 89 patients who died with a DT-LVAD, the median (25th–75th percentile) time from left ventricular assist device implantation to death was 14 (4–31) months. The most common causes of death were multiorgan failure (26%), hemorrhagic stroke (24%), and progressive heart failure (21%). Nearly half (46%) of the patients saw palliative care within 1 month before death; however, only 13 (15%) patients enrolled in hospice a median 11 (range 1–315) days before death. Most patients (78%) died in the hospital, of which 88% died in the intensive care unit. In total, 49 patients had their left ventricular assist device deactivated before death, with all but 3 undergoing deactivation in the hospital. Most patients died within an hour of left ventricular assist device deactivation and all within 26 hours.

Conclusions—In contrast to the general heart failure population, most patients with DT-LVAD die in the hospital and few use hospice. Further work is needed to understand these differences and to determine whether patients with DT-LVAD are receiving optimal end-of-life care. (Circ Heart Fail. 2016;9:e003096. DOI: 10.1161/CIRCHEARTFAILURE.116.003096.)

Key Words: end-of-life care ■ heart failure ■ left ventricular assist device ■ morbidity/mortality

Although it is known that the 1-year mortality after DT-LVAD is around 20%, little is known about the details and events preceding death. For example, in community patients with HF, we know that 22% die in the hospital and 42% enroll in hospice before death, but knowledge of how death in patients with DT-LVAD compares has not been reported. Furthermore, although LVAD deactivation at the end of life is a well-accepted practice, we know little about how often and in what context it occurs. Although a recent study reviewed the causes of death in patients after LVAD and noted that they vary by temporal proximity with implant, the details surrounding death remain undescribed. This information is critical to providing optimal care for patients with DT-LVAD throughout their clinical course, but particularly as they approach the end of life.

To address these gaps in knowledge, the goal of this analysis was to systematically examine the deaths in patients treated with DT-LVAD at a single academic center.
Methods

Identification of Patients
All patients undergoing DT-LVAD at the Mayo Clinic in Rochester, Minnesota, from 2007 to September 30, 2014, who subsequently died before July 1, 2015, were included. Deaths were as noted in the electronic medical record; all notifications of death of our patients implanted with LVADs are entered into the medical record in our practice. As our primary interest was in reviewing patients who died with an LVAD in situ, we excluded patients who were implanted as DT, but subsequently received a heart transplant or had their LVAD explanted before death. The Health Insurance Portability and Accountability Act (HIPAA) permits research using decedent records without authorization, waiver, or deidentification of data when the protected health information is used solely for research. Because this study met these criteria, the Mayo Clinic Institutional Review Board did not require review of this protocol, in accordance with the Code of Federal Regulations, 45 CFR 46.

Patient Characteristics at the Time of LVAD Implantation
All data were abstracted from documentation in the electronic medical record. Clinicians’ diagnoses were used to define hypertension and peripheral vascular disease. Chronic obstructive pulmonary disease was defined based on clinician’s diagnosis or greater than mild obstructive lung disease on pulmonary function testing. Cerebrovascular disease was defined by physician diagnosis or use of medications for diabetes mellitus. Body mass index (kg/m²) was calculated using height and weight pre-LVAD, and obesity included a body mass index ≥30 kg/m². All laboratory data were taken from the day before LVAD surgery. The Leitz–Miller score² (developed to predict in-hospital mortality, although never validated for use in patients with continuous flow LVADs) was calculated using preoperative variables: 7 points for platelets ≤148,000/µL, 5 points for albumin ≤3.3 g/dL, 4 points for international normalized ratio >1.1, 4 points for use of vasodilators, 3 points for mean pulmonary artery pressure <25 mmHg, 2 points for aspartate transaminase >45 U/mL, 2 points for hematocrit ≤34%, 2 points for blood urea nitrogen >51 U/dL, and 2 points for no intravenous inotropes.

Cause of Death
The cause of death was determined based on review of documentation in the electronic medical record, including autopsy reports, death certificates, and electronic clinical notes.

Circumstances Preceding Death
Palliative care consultations in the month before death and whether patients enrolled in hospice were reviewed. At our institution, palliative care consultation is a routine part of the DT-LVAD preimplantation workup, and ongoing palliative care availability continues longitudinally in accordance with published guidelines.² For patients who were hospitalized at other institutions before death, information about the timing and details of hospitalization were based on notes from physicians and LVAD coordinators in the medical record. It is standard practice at our institution for LVAD coordinators to document, in detail, each phone call that they receive about a patient with an LVAD. LVAD deactivation was defined as turning off the LVAD before the occurrence of clinical death. Implantable cardioverter defibrillator deactivation was defined as turning off therapies for ventricular arrhythmias (tachy therapies).

Clinical Course Prior to Death
Rizzieri et al previously proposed 3 end-of-life trajectories for patients dying with DT-LVAD.⁵,¹⁰ Their classification included one trajectory where patients died very early after LVAD (we will refer to as early course) because of postoperative complications or other issues. They described this to include patients who remained hospitalized after LVAD and died within 90 days of implantation. Their second trajectory included patients who survive for a period of time after LVAD but do not improve clinically and follow a similar quality of life and survival trajectory as patients with end-stage HF managed medically. We interpreted this to include patients who continue to struggle with organ failure, such as right HF or renal failure requiring prolonged or recurrent readmissions from the time of LVAD until death (persistent course). The final trajectory they describe included patients who derive quality of life and survival benefit from LVAD but later develop a gradual decline in quality of life because of a serious complication, such as infection, progression of comorbidity or heart failure, or the development of a new terminal condition, such as cancer. This terminal end-of-life course is similar to that described among patients in the general population dying of cancer.¹¹ In extensively reviewing our population of patients dying with a DT-LVAD, we noted a unique end-of-life trajectory that was not represented in Rizzieri’s classification. Some patients experienced an improvement in quality of life after LVAD therapy, but then suffered an unexpected, acute event (such as intracranial hemorrhage) that led to an abrupt decline in health and resulted in death within 14 days; we term this the acute course. After a detailed review of documentation in the electronic medical record, each patient was categorized into the course that best reflected their documented experience from the time of LVAD implantation until death (early, persistent, terminal, and acute; Figure 1A).

Statistical Analysis
Patient characteristics were summarized using mean with standard deviation, median with interquartile range or number (%), where appropriate. Analyses were performed using STATA version 10.0.

Results

Study Population
A total of 166 patients were implanted with DT-LVAD during the study period, of which 13 (7.8%) subsequently received a heart transplant (n=11) or had their LVAD explanted (n=2). 64 (38.6%) were alive at last follow-up, and 89 (53.6%) died
and were included in the analysis. The characteristics of the deceased patients at the time of DT-LVAD implantation are shown in Table 1. Most patients were men (80.7%) and had ischemic cardiomyopathy as the primary pathogenesis of their HF (58.4%). In total, 84 (94.4%) patients had the HeartMate II device, while 3 patients received a HeartWare (3.4%) and 2 patients had a HeartMate XVE (2.2%).

### Characteristics Preceding Death

The patient characteristics and circumstances at the time of death are shown in Table 2. The date of death was available on all patients. In 2 patients, no clinical details around the time of death were available, and very limited information was available on 2 additional patients. Follow-up time from DT-LVAD implantation to death ranged from 1 to 2366 days, with a median (25th–75th percentile) of 14 (4–31) months (Figure 2). The mean age at death was 66.1 years. Most patients died in the hospital (77.6%), of whom 68.2% were hospitalized at a Mayo Clinic hospital. In total, 18 (20.2%) patients died during the initial LVAD implantation hospitalization (ie, were never discharged after surgery); this reflects an index in-hospital mortality rate of 10.8% overall (18 of 166 patients implanted with DT-LVAD), which is similar to the national average.13 Among those 18 patients, the median time from LVAD implantation to death was 16 days (range 1–270 days), with 5 dying within a week of implantation. For patients who died in the hospital, but not during the index hospitalization where the LVAD was implanted, death occurred a median of 4 days after admission (range 0–60 days), with 14 of 48 (29.2%) dying within 24 hours of admission.

Among the 66 patients who died in hospital, 57 patients had a known location of death in the hospital (intensive care unit [ICU] versus non-ICU bed), and 50 (87.7%) of these patients died in the ICU. Of the 45 patients who died at Mayo Clinic Rochester hospitals, 40 (88.9%) died in the ICU, 33 (73.3%) were mechanically ventilated, and 13 (28.9%) received hemodialysis in the 48 hours preceding death. In addition, 40 (88.9%) transitioned to comfort-focused care before death, but the remaining 5 were Full Code status and died despite resuscitative efforts. Of the 40 patients who transitioned to comfort-focused care, 33 (82.5%) transitioned to this approach within 24 hours of death. Despite a transition to comfort-focused care, this did not necessarily mean the LVAD was deactivated; rather, the patients’ care was focused on comfort and not escalating care further. One patient remained hospitalized for >3 days after transitioning to a comfort-directed approach to care (7 days from transition to death), and his care needs were believed to be too complex for safe discharge to another setting.

### Cause of Death

The cause of death was available in 86 (96.6%) patients. The most common causes of death were multiorgan failure (25.6%), hemorrhagic stroke (24.4%), and HF (20.9%, Figure 3). Four patients died of bleeding; 2 of who were in the immediate postoperative setting. Two patients died of a known LVAD mechanical issue that occurred in a nonhospitalized setting (one ran out of batteries, one during controller exchange).

### Palliative Care and Hospice

Although we previously reported that 89% of patients at our institution had palliative care consultation before DT-LVAD implantation,13 only about half (46.3%) of patients saw palliative care in consultation within 1 month before death. All patients were hospitalized at the time of palliative care consultation, though 4 (10.8%) patients were subsequently discharged...
LVAD Deactivation

Information was not available on whether the LVAD was deactivated before death in 8 (9.0%) patients. Of the remaining 81 patients, 49 (60.5%) had their LVAD deactivated before death, and the remaining 32 patients did not have their LVAD deactivated. Of those who underwent LVAD deactivation, the median time from LVAD implantation to death was 419 (range 1–2366) days. The most common causes of death were multiorgan failure (n=18, 36.7%), hemorrhagic stroke (n=15, 30.6%), heart failure (n=7, 14.3%), and infection (n=4, 8.2%). In total, 3 (6.1%) patients had the LVAD deactivated at home, while the remainder had LVAD deactivation in the hospital. The final decision to deactivate the LVAD was usually made by the patient’s family after discussion with the clinical team (85.7% of deactivations), rather than the patient (8.2%) because the patient was frequently unconscious or lacked decision-making capacity. Of the 49 patients who underwent LVAD deactivation before death, the time from deactivation to death (in hours) was known in 47 patients. The vast majority (42 of 47, 89.4%) died within 1 hour of deactivation. The remaining patients survived 4, 9, 11, and 26 hours after LVAD deactivation. All 12 patients who had their LVAD deactivated during their initial (implant) hospitalization died within 1 hour of LVAD deactivation.

Clinical Course Prior to Death

A total of 86 patients were categorized into 1 of 4 groups by their clinical course from the time of LVAD implantation.

from the hospital before death. The median time from palliative care consultation to death was 9 days, and the median number of visits per patient in the last month of life was 4 (range 1–15). In total, only 13 (15.3%) patients enrolled in hospice a median of 11 (range 1–315) days before death, including 4 patients who had cancer, 2 with stroke, 2 with HF, and 5 with multiorgan failure. Of those who enrolled in hospice, 8 received hospice care at home, 4 received hospice care in an inpatient hospice facility, and 1 in a skilled nursing facility. Only 1 patient received hospice care (home) through a hospice agency that was located in close proximity to our institution. Only 1 patient who enrolled in hospice died in the hospital, while the remaining 12 patients died in the outpatient setting. The patient who survived the longest in hospice care chose to enroll after receiving a diagnosis of metastatic solid organ malignancy and lived an additional 10 months after enrollment.

Table 1. Pre-LVAD Characteristics of Decedents

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (n=89)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>64.5 (10.7)</td>
</tr>
<tr>
<td>Male, N (%)</td>
<td>71 (80.7)</td>
</tr>
<tr>
<td>Ischemic etiology of HF, N (%)</td>
<td>52 (58.4)</td>
</tr>
<tr>
<td>Prior sternotomy, N (%)</td>
<td>54 (60.7)</td>
</tr>
<tr>
<td>Comorbidities, N (%)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>53 (59.6)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>41 (46.1)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>25 (28.1)</td>
</tr>
<tr>
<td>COPD</td>
<td>15 (16.9)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>32 (36.0)</td>
</tr>
<tr>
<td>Obese (BMI≥30 kg/m²)</td>
<td>39 (44.3)</td>
</tr>
<tr>
<td>Laboratory data, median (IQR)</td>
<td></td>
</tr>
<tr>
<td>Total bilirubin, mg/dL</td>
<td>1.0 (0.8, 1.7)</td>
</tr>
<tr>
<td>Aspartate aminotransferase, U/mL</td>
<td>37 (26, 62)</td>
</tr>
<tr>
<td>Alanine aminotransferase, U/mL</td>
<td>27 (18, 37)</td>
</tr>
<tr>
<td>Albumin, g/dL</td>
<td>3.8 (3.3, 4)</td>
</tr>
<tr>
<td>Platelet count, 1000/μL</td>
<td>148 (108, 190)</td>
</tr>
<tr>
<td>Blood urea nitrogen, U/dL</td>
<td>30 (21, 41)</td>
</tr>
<tr>
<td>Creatinine, mg/dL</td>
<td>1.4 (1.1, 1.8)</td>
</tr>
<tr>
<td>INR</td>
<td>1.3 (1.1, 1.4)</td>
</tr>
<tr>
<td>Leitz–Miller score*</td>
<td>10.8 (5.6)</td>
</tr>
</tbody>
</table>

*Of the 66 patients who were known to be hospitalized at the time of death.
†Of the 85 patients with an ICD. In 20 patients, it was unknown if the ICD was deactivated before death because they were hospitalized or cared for at another institution, and this information was not documented in the medical records we received.
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until death. The remaining 3 patients could not be completely categorized because of a lack of detailed information around the time of death, though all 3 died several years after DT-LVAD and, thus, did not experience early deaths. Clinical courses observed were early, persistent, acute, and terminal in 18 (20.9%), 17 (19.8%), 31 (36.0%), and 20 (23.3%) patients, respectively. The median time from LVAD implantation to death was shortest in early course patients (16 days), followed by patients with persistent (201 days), acute (602 days), and terminal (892 days) clinical courses. In hospita, death occurred in 100%, 76.5%, 74.2%, and 63.2% of patients experiencing early, persistent, acute, and terminal courses. In the patients with an acute course before death, the time from the acute event until death was <24 hours in 19 (61.3%) patients, 1 to 7 days in 9 (29.0%) patients, and 8 to 14 days in 3 (9.7%) patients. Of the 49 patients who had their LVAD deactivated before death, clinical courses observed were early, persistent, acute, and terminal in 12 (24.5%), 10 (20.4%), 16 (32.7%), and 11 (22.4%). All patients who enrolled in hospice before death experienced a persistent or terminal course. Most patients experiencing early and persistent courses had deaths because of HF and multiorgan failure (Figure 3). Hemorrhagic stroke accounted for 60.0% of deaths in those with an acute course. The most common causes of death in patients with a terminal course were cancer (25.0%) and multiorgan failure (40.0%).

The estimated proportion of all patients undergoing DT-LVAD who fit each of the 4 clinical courses is shown in Figure 1B. These estimates are based on the distributions observed among decedents, but were adjusted to account for the fact that many patients who had DT-LVADs implanted in the study period are still alive. By including only decedents in this analysis, we have overestimated the proportion of patients implanted with DT-LVADs who have clinical trajectories with shorter times from LVAD implantation to death (ie, the early postoperative deaths) and underestimated the proportion who would follow the longer survival trajectories (ie, terminal condition and acute event deaths). Accounting for this, we estimate that, in all patients undergoing DT-LVAD, ≈10% would experience early deaths (consistent with national outcomes), 20% would experience a persistent course, 30% terminal, and 40% acute.

Discussion

In this single-center study, the vast majority of patients with a DT-LVAD died in the hospital and most in an ICU setting. Although half of patients saw palliative care in consultation in the month before death, very few enrolled in hospice. LVAD deactivation before death was common, and these patients died shortly after deactivation.

Our findings reveal that patients with DT-LVAD die differently than other patients with HF. Patients with DT-LVAD are far less likely to enroll in hospice (15.3%) and more frequently die in the hospital (77.6%) than either local Olmsted County decedents with HF (42.2% hospice enrollment and 22.4% in-hospital death) or 2007 Medicare beneficiaries dying with HF (38.1% hospice enrollment and 35.2% in-hospital death). The comparatively low rates of hospice enrollment and high in-hospital mortality rates seen in patients with DT-LVAD are also divergent compared with other patients dying with chronic diseases, such as cancer and chronic obstructive pulmonary disease. These outcomes are important because prior studies have demonstrated that patients who die in an ICU or hospital experience worse quality of life and more physical and emotional distress at the end of life compared with patients who die at home with hospice services. Furthermore, their bereaved caregivers suffer more psychiatric illness and are less satisfied with the end-of-life care received by their loved one. Whether these findings are true for patients with DT-LVAD and their caregivers remains to be determined.

There are several potential reasons why end-of-life care for DT-LVAD patients may be so different than for patients with other chronic diseases. First, patient preferences may differ. Patients with DT-LVAD have, by definition, chosen to have a mechanical heart pump implanted and to remain in situ for the rest of their life. Thus, DT-LVAD patients are
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A selected population who have shown that they were willing to undergo invasive procedures to stay alive and may be more likely to choose life-prolonging therapies in other clinical situations, though this is worthy of further examination. Second, in our experience, it can be challenging to find hospice agencies and skilled nursing facilities that are willing to accept patients with LVADs because of a lack of comfort and training in managing the device. Although further work is needed to determine the most appropriate end-of-life options to support patients with DT-LVAD and their caregivers, hospice has been shown to be beneficial to patients dying with a variety of health conditions, and patients with DT-LVAD may also benefit from their services. As such, it will be important to determine ways to provide LVAD education and support to hospice agencies so that DT-LVAD patients may benefit from their services. Third, it may be more challenging to prognosticate in patients with a DT-LVAD compared with other patients with HF. For example, acute deaths from etiologies such as hemorrhagic stroke are common and can be difficult to predict. Finally, clinicians may not be routinely engaging patients with DT-LVAD and their caregivers, hospice has been shown to be beneficial to patients dying with a variety of health conditions, and patients with DT-LVAD may also benefit from their services. As such, it will be important to determine ways to provide LVAD education and support to hospice agencies so that DT-LVAD patients may benefit from their services.

The involvement of palliative care clinicians in the care of patients with HF approaching the end of life has been a key part of our practice. Palliative care consultations were obtained in a similar proportion of patients dying with DT-LVAD (47%) and those dying with HF (44%) in our community. Although palliative care clinicians are routinely involved in preparedness planning for patients before DT-LVAD in accordance with guidelines, they were often reconsulted only in very close proximity to death. While in our local community, increased consultations from palliative care specialists at the end of life coincided with increased use of hospice services and decreased rates of in-hospital death in patients with HF, we observed low rates of hospice enrollment and high rates of in-hospital death for patients with DT-LVAD, despite frequent input from palliative care specialists. This may reflect the fact that patients with DT-LVAD are choosing to continue with life-prolonging therapies even when prognosis is grim more often than other patients with HF. As previously noted, it may also reflect the challenge of transitioning patients with DT-LVAD to the outpatient setting at the end of life because of the lack of adequate training of skilled nursing facilities and hospice agencies in LVAD management. Further work is needed to understand the optimal role of palliative care specialists in the longitudinal care of patients with DT-LVAD.

DT-LVADs were deactivated in most patients before death, and death occurred within 26 hours in all cases. By comparison, one previous study reported on time from LVAD deactivation to death in 17 patients, and death occurred in <20 minutes in all cases. The time from deactivation to death will inevitably vary based on native cardiac function and by whether the aortic valve was sutured close at the time of LVAD; however, this information has important implications on how patients and families are counseled regarding what to expect after LVAD deactivation.

Limitations

There are limitations that are important to consider when interpreting these data. First, this is a single-center study, and results from other centers may differ. Some details about deaths that occurred in other hospitals were unavailable. Quality of life was not routinely assessed during follow-up after LVAD. However, there is no LVAD-specific quality-of-life measure available, and heart failure–specific

Figure 3. Cause of death in patients with left ventricular assist device (LVAD) as destination therapy (DT-LVAD). The number of patients (x axis) experiencing various causes of death and their associated clinical course before death are shown. The 85 patients with a known clinical course and cause of death are represented.
quality-of-life measures, such as the Kansas City Cardiomyopathy Questionnaire, may not adequately capture domains that impact quality of life in patients with LVADs. As such, patients were categorized into end-of-life trajectories based on available clinical data, which could result in misclassification.

**Clinical Implications and Future Directions**

These data provide a first step toward quantitatively understanding the end-of-life care of patients dying with DT-LVAD. The next step would be to examine whether end-of-life care for DT-LVAD follows a similar pattern at other institutions and to examine reasons for differences if they exist. Second, we need a better understanding of the reasons that hospice use is so low and in-hospital death is so high in this population. A recent qualitative study of 8 bereaved caregivers of patients with LVAD found that caregivers felt confused about the involvement of other care providers, such as palliative care and hospice clinicians, at the end of their loved one’s life.21 Further qualitative inquiry to include various stakeholders, such as physicians, LVAD coordinators, social workers, patients, and caregivers, are needed to fully delineate the factors that may be contributing to our observations. Finally, better models to predict death and poor quality of life in patients after DT-LVAD implantation are needed, which may enable clinicians to provide more accurate prognostic information to patients so that they may make informed decisions about their care.

**Conclusions**

In contrast to patients dying with HF and other chronic conditions, most patients with DT-LVAD die in the hospital and very few enroll in hospice. Potential reasons that patients with DT-LVAD may experience different end-of-life care than other patients with HF exist, including that they often experience sudden changes in health status before death from acute events and that arranging for safe out-of-hospital care at the end of life can be particularly challenging. However, further work is needed to understand these differences and to determine how to optimize end-of-life care for patients with DT-LVAD.

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**Disclosures**

None.

**References**

In this analysis of 89 decedents with left ventricular assist device as destination therapy at a single center, we found that most patients died as a result of multiorgan failure, hemorrhagic stroke, or heart failure. About one third of decedents did well for a period of time after left ventricular assist device, but then experienced an unexpected, acute event that led to an abrupt decline in health and resulted in death. In contrast with the general heart failure population, the vast majority of left ventricular assist device recipients died in the hospital, most often in the intensive care unit, and few patients enrolled in hospice. Left ventricular assist device deactivation before death was common, and most patients died within an hour of deactivation. These data provide a first step toward understanding the current state of end-of-life care of patients dying with left ventricular assist device as destination therapy. Future work is needed to understand the reasons that hospice use is so low and in-hospital death is so high in this population. Ultimately, efforts toward determining optimal end-of-life care in patients with left ventricular assist device as destination therapy are needed.
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