Original Article

Caregivers of Patients With Left Ventricular Assist Devices
Possible Impacts on Patients' Mortality and Interagency Registry for Mechanically Assisted Circulatory Support–Defined Morbidity Events

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Background—How caregivers contribute to positive or negative outcomes for left ventricular assist device (LVAD) patients remains unclear. Our primary study objectives were to (1) identify caregiver support attributes through a retrospective chart review of social workers' psychosocial assessments for LVAD patients and (2) determine how these attributes associated with patients' post-LVAD placement mortality and Interagency Registry for Mechanically Assisted Circulatory Support–defined morbidity events.

Methods and Results—We retrospectively reviewed and recorded social workers' clinical assessments of adult patients implanted with durable continuous-flow LVADs as bridge to transplant, destination therapy, or bridge to decision from January 2010 to December 2014. Associations between caregiver characteristics and patient mortality and morbidity events were analyzed using Kaplan–Meier curves and Cox proportional hazards regression. Patient follow-up time was calculated as the time from hospital discharge until the earliest among death with LVAD, transplant, or the last day of the study (December 31, 2015). Patients were censored for death with LVAD at the time of transplant or the last day of the study. A total of 96 LVAD recipients were included in this study. Having a caregiver who understands the severity of the illness and options available to the patient (as determined and documented by the social worker; $P=0.01$), a caregiver who has identified a backup plan ($P=0.02$), and a caregiver who is able to provide logistical support ($P=0.04$) significantly mitigated risk of death. The risk of death for an LVAD patient was also significantly lower among those who have at least 1 adult child who lives within 50 miles ($P=0.03$) and those who have an extended family who can care for the patient ($P=0.03$). The risk of death was 3.1× more likely among patients who live alone compared with those who do not live alone ($P=0.04$). No caregiver characteristics were significantly associated with morbidity.

Conclusions—This exploratory, hypothesis-generating study suggests that mortality after LVAD placement is impacted by caregiver understanding of patient severity of illness and caregiver presence. This study provides initial evidence to support further work in understanding the associations between caregivers and LVAD patients, as well as interventions that may improve patient outcomes.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT02248974.

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Key Words: adult ■ caregivers ■ death ■ family ■ social workers

The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support emphasize the importance of caregiver support for left ventricular assist device (LVAD) placement, recommending that a lack of support should serve as a relative contraindication to device placement.[1] Despite the integral role that caregivers are expected to play, findings from studies on LVAD caregivers are limited. Most of these studies are qualitative, exclusively focus on caregivers' experiences or burdens, and fail to examine specific mechanisms of support and the impact of caregiver support on patient mortality or morbidity events.[2–9]

How caregivers contribute to positive or negative patient mortality or morbidity events is unclear. Without this foundational understanding, there will be variability across LVAD programs and among candidates with regard to how much emphasis to place on caregiver support, how such support should be assessed, and at what threshold an absence of support becomes

WHAT IS KNOWN

- Professional organizations currently recommend that limited caregiver support should serve as a relative contraindication to LVAD placement; however, despite the integral role that caregivers are expected to play in care, findings from studies on LVAD caregivers are limited.

WHAT THE STUDY ADDS

- We identified caregiver support attributes through a retrospective chart review of social workers' psychosocial assessments for LVAD patients and determined how these attributes are associated with patients' post-LVAD placement mortality and morbidity.
- The risk of death was 3.1× more likely among individuals who live alone compared with those who do not live alone (*P*=0.04).
- Having a caregiver who understands the severity of the illness and options available (*P*=0.01), a caregiver who has identified a backup plan (*P*=0.02), and a caregiver who is able to provide logistical support (*P*=0.04) significantly mitigated risk of patient death.
- On the basis of our findings, we provide preliminary recommendations for weighing psychosocial factors in candidacy for LVAD placement.

a contraindication for LVAD placement, especially as destination therapy (DT).[10] Developing evidence-based practices will be difficult without some understanding of how caregiver support impacts mortality or morbidity, as well as what should constitute caregiver support attributes (eg, a 24-hour care plan; living geographically proximate to or with the patient).

The goal of this study was to investigate the impact of caregiver support on LVAD patient mortality and morbidity and to create hypotheses for future prospective studies. The 2 study objectives were to (1) identify caregiver support attributes through a retrospective chart review of social workers' psychosocial assessments for LVAD patients and (2) determine how these attributes associated with patients' post-LVAD placement mortality and Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)–defined morbidity events. We provide preliminary recommendations for weighing psychosocial factors in candidacy for LVAD placement and for the types of caregiver attributes that should likely be emphasized in the development of assessment instruments.

Methods

This study was approved by the institutional review boards for Baylor College of Medicine and Houston Methodist Hospital. Our multidisciplinary, multi-institutional taskforce (the authors of this article) consists of biostatisticians, heart failure cardiologists, cardiothoracic surgeons, decision scientists, clinical ethicists, medical anthropologists, psychiatrists, and social workers.

## Caregiver Support Domains

We retrospectively reviewed social workers' clinical assessments documented in the medical records of adult patients implanted with

durable continuous-flow LVADs as bridge to transplant, DT, or bridge to decision from January 2010 to December 2014 at Houston Methodist Hospital (Figure 1). All social workers interviewing LVAD candidates participate in month-long orientation and training sessions devoted to learning how to fully conduct interviews in a consistent fashion. During the interviews, social workers elicit information about caregiver support variables in addition to a patient's self-sufficiency by asking standard questions about patients' social, psychological, behavioral, and cognitive coping abilities; their understanding of the proposed intervention; adherence/compliance histories; familial and social supports (eg, married or single; children; available caregivers); substance use; financial and other resources; living arrangements (eg, Do you have family members who live nearby? Will anyone be staying with you after your LVAD is implanted?); caregiver understanding (eg, What is an LVAD? Does it replace your husband's heart? How long could he be on it?); psychopathology (eg, Does anyone in your family have a history of mental illness?); conflicting obligations (eg, Do you take care of anyone else?); and housing issues.

Social workers' written assessments are completed during or immediately after interviews with all LVAD candidates using standardized, validated instruments (eg, the Stanford Integrated Psychosocial Assessment for Transplantation or Psychosocial Assessment of Candidates for Transplantation).[11] These assessments are documented in patients' electronic medical records in narrative format. These narrative descriptions are highly structured, consisting of 10 close-ended fields, 10 multiple choice questions, and several short-answer responses. The written assessments recapitulate the interview content as noted above. Social workers often record exact quotations from the interviews to minimize bias. In addition to the narrative, free-text component, social workers provide a financial score (1=strained to meet normal living expenses; 2=limited income; 3=adequate income; and 4=substantial income). This financial score derives from the Psychosocial Assessment of Candidates for Transplantation and indicates whether a patient will likely be able to manage LVAD financial costs.[12]

Although standardized instruments guide social workers' assessments for patients, we could not find a validated instrument that comprehensively listed caregiver support domains or a complete caregiver-based conceptual framework to guide our analysis. Therefore, we derived a list of core caregiver support domains from a growing conceptual peer-reviewed literature on the importance of caregiver involvement in LVAD and other health outcomes.[2–9] To create these domains, we incorporated pre-existing domains that were part of social work assessments (using Stanford Integrated Psychosocial Assessment for Transplantation variables as a starting point for our conceptual framework) and then added additional elements of caregiver support proposed anecdotally in other studies as potential factors impacting patient mortality after LVAD placement.

From a content analysis review of the caregiving literature (a PubMed and PsycINFO database search using the terms caregiver, support, spouse, social, and ventricular assist device, conducted in
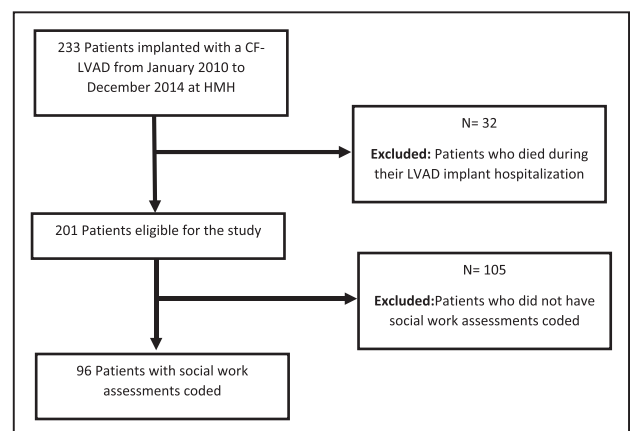
Figure 1. Flow diagram of inclusion and exclusion criteria. CF indicates continuous flow; HMH, Houston Methodist Hospital; and LVAD, left ventricular assist device.

October 2015), we identified other factors that could potentially impact mortality or morbidity, drawing heavily on empirically derived transplant outcomes research. For instance, the transplant literature reports that caregivers' psychopathology can impact mortality; we therefore hypothesized that this factor can impact LVAD mortality or morbidity, and so we created a new domain for caregivers' mental health.[13] Finally, the LVAD literature focuses significantly on caregivers' abilities to assist in maintaining and cleaning LVAD components, as well as helping to troubleshoot mechanical problems.[1] We therefore added a domain about providing practical resources. In short, we used the Stanford Integrated Psychosocial Assessment for Transplantation as a starting point and supplemented it with additional caregiver-centric characteristics that could be potentially relevant to mortality or morbidity for our caregiving conceptual framework.

From our content analysis review of the literature and development of a conceptual framework, we generated 33 caregiver characteristics. These characteristics focused on the presence and quality of caregiver support. Thirty characteristics had binary responses (yes/no). The other 3 characteristics include how often the caregiver is present (0=rarely, 1=sometimes, and 2=often), general support (0=very weak, 1=weak, 2=neutral, 3=strong, and 4=very strong). Where the social worker documented the patient's Psychosocial Assessment of Candidates for Transplantation score, we incorporated this as one of the caregiving domains. Every characteristic included 1 additional category for characteristics that were not described in the social workers' assessment and recorded as missing in our coding scheme. In addition, morbidity and mortality events came from patient hospital records (through a retrospective chart review).

Analysis

Patient demographics, clinical characteristics, and caregiver characteristics are summarized by means with SD, medians with minimum and maximum values, or frequencies with percentages. Patient follow-up time was calculated as the time from hospital discharge until the earliest of death with LVAD, transplant, or the last day of the study (December 31, 2015). Patients were censored for death at the time of transplant or the last day of the study. Kaplan–Meier curves are used to estimate survival probabilities. Survival probability curves are stratified by each patient demographic and clinical characteristic, and the log-rank test is used to compare curves between groups. Variables significant at the 0.20 level were further assessed in multivariable Cox proportional hazards regression models. Statistical significance for Cox regression results was assessed at the 0.05 level. Because of missing data, separate multivariable regression models were fit for each caregiver characteristics. The Cox proportional hazards regression models were used to estimate hazard ratios (HRs) with 95% confidence intervals (CIs).

A similar analysis was used to examine associations with hospital readmission events. Readmissions included death as an event; however, readmissions were only captured within the first year after receiving the implant. Follow-up time for morbidity analysis was calculated as the time from discharge to the date of the first hospital readmission for any reason (including death), transplant, or 1-year postimplant. Patients were censored for readmissions at the time of transplant or 1-year postimplant if they had not yet been readmitted to a hospital.

Social workers' assessments were reviewed for caregiver characteristic information by 2 reviewers. Inter-rater agreement was measured using the κ statistics and the prevalence-adjusted bias-adjusted kappa (PABAK) statistics with 95% confidence intervals. The point estimates were interpreted using Landis and Koch categorization (Figure 2).[14]

Results

A total of 96 LVAD recipients were included in this study, and baseline characteristics are summarized in Tables 1 and 2. The mean age at implant was 56.1 years, and most patients were male (70%), married (58%), and had at least 1 child. The LVAD was considered as DT for 65% of patients. The majority of patients had a history of hypertension (82%), and about half were diabetic. Approximately one quarter of the participants had chronic obstructive pulmonary disease, and one quarter had chronic kidney disease. Caregiving domains and results are provided in Table 3.

Caregivers were present in the hospital post-LVAD at least twice in 98% of cases and often present and available to help the patient post-LVAD (ie, able to take off work for at least 6 weeks [75%] or a backup system beyond the primary caregiver was established [87%]). Spouses served as the primary caregiver in 65% of cases, and there was a healthy relationship between the caregiver and patient in 87% of cases (as described by the patient and documented by the social worker). Patients lived alone in 13% of cases. Social workers' assessed caregivers as having understood the severity of patients' illnesses and different clinical options in 73% of cases (Table 3).

Mortality

Overall, 36 patients died (38%) during the study period. The 1-year survival rate after discharge from the hospital was 83% (95% CI, 73–89), and the 3-year survival rate was 58% (95% CI, 44–69). Body mass index (BMI) (<29 versus ≥29; P=0.04), hypertension (yes versus no; P=0.07), coronary artery disease (yes versus no; P=0.07), number of children (<3 versus ≥3; P=0.12), and INTERMACS profile (≤2 versus >2; P=0.14) were significantly associated with mortality in the univariable analysis at the 0.20 level. Having body mass index <29, hypertension, coronary artery disease, <3 children, and INTERMACS profile scores ≤2 was associated with an increased risk for death after simultaneous adjustment in a multivariable Cox proportional hazards model that included 65 patients (Table 4, model 1). There were 31 patients (32%) missing information on number of children; therefore, the number of children was excluded from the multivariable regression model including all 96 patients (Table 4, model 2). Coronary artery disease and INTERMACS profile scores were then excluded because the effect sizes were relatively small (HR, 1.66 and 1.54, respectively). Therefore, only hypertension and body mass index were included in the final multivariable regression model (Table 4, model 3) used to assess the association between each caregiver characteristics and mortality.

Table 5 summarizes significant associations between caregiver characteristics and mortality after adjusting for hypertension and body mass index. Having a caregiver who understands the severity of the illness and options available to the patient (as determined and documented by the social worker; P=0.01), a caregiver who has identified a backup plan (P=0.02), and a caregiver who is able to provide logistical support (P=0.04) significantly mitigated risk of death. The risk of death for an LVAD patient was also significantly lower among those who had at least 1 adult child who lived close by (defined as ≤50 miles; P=0.03) and those with an extended family who could care for the patient (P=0.03). The risk of death was 3.1× more likely among patients who lived alone compared with those who did not live alone (P=0.04).

No other caregiver characteristics were significantly associated with patient mortality at the 0.05 level. However, having friends who can care for the patient (HR, 0.43; 95% CI, 0.18–1.04) and having a healthy, positive relationship between
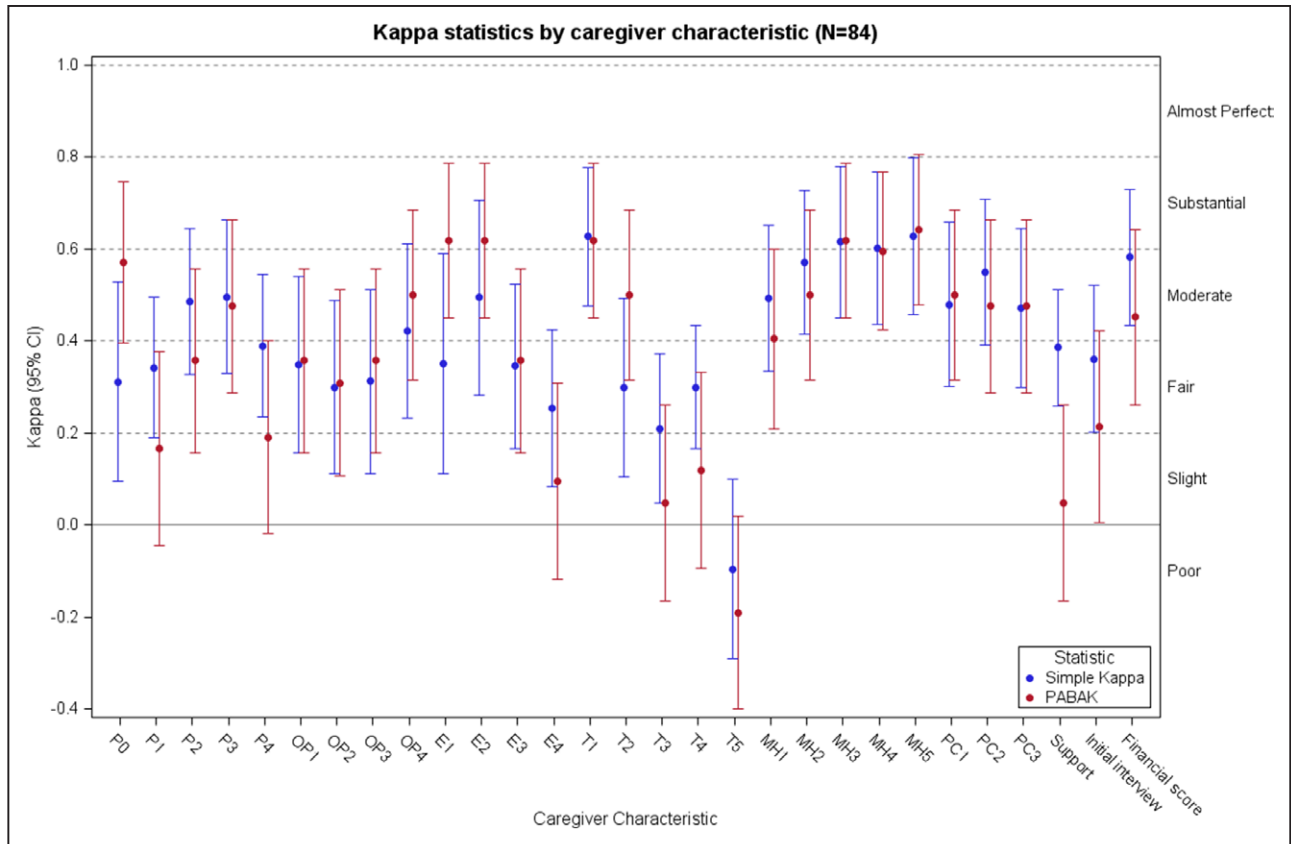
Figure 2. Inter-rater agreement. CI indicates confidence interval; E1, caregiver is supportive of the patient and device placement; E2, there is a healthy relationship between caregiver and patient; E3, other people beyond the primary caregiver are involved in caregiving; E4, patient is explicitly dependent on caregiver for physical or emotional support; OP1, caregiver understands severity of illness/ options; OP2, caregiver eager/willing/ready to give care; OP3, caregiver describes making concrete plans after device placement; OP4, caregiver describes feeling mentally ready for device placement and recovery; MH1, caregiver has anxiety; MH2, caregiver has depression; MH3, caregiver has substance abuse issues; MH4, caregiver has emotional outbreaks; MH5, gambling or other high-risk activities; PO, caregiver presents infrequently or limited presence; P1, caregiver is often present; P2, caregiver is able to take off work for at least 6 weeks; P3, caregiver has identified a backup system beyond the primary caregiver; P4, caregiver explicitly mentions conflicting obligations aside from caregiving; PC1, caregiver is able to perform physical demands required; PC2, caregiver is financially able to set up in-home support; PC3, caregiver is able to provide logistical support; T1, spouse is involved in caregiving; T2, immediate family is involved in caregiving; T3, extended family is involved in caregiving; T4, friends are involved in caregiving; and T5, patient uses hired help only as support.

the caregiver and patient improved mortality (HR, 0.47; 95% CI, 0.20–1.09). Explicit detection of substance abuse issues by social workers negatively impacted mortality (HR, 5.0; 95% CI, 0.995–25.2).

Morbidity
Overall, 79 patients (82%) were readmitted to the hospital within the first year after discharge, and the median time to readmission was 1.6 months (95% CI, 1.2–2.8) after discharge. The morbidity events requiring readmission to the hospital are summarized in Table 6.

Income (<adequate versus ≥adequate; log-rank $P=0.06$), education (<college versus ≥college; log-rank $P=0.13$), and diabetes mellitus (log-rank $P=0.19$) were associated with hospital readmission in the univariable analysis at the 0.20 level. Patients with less than adequate income, patients who have an education level less than a college level, and patients with diabetes mellitus had an increased risk for readmission. None of these variables were significantly associated with readmission after simultaneous adjustment in a multivariable Cox proportional hazards

model that included 31 patients (Table 4, model 1). There were 48 patients (50%) missing information on education and 49 patients (51%) missing information on income. Diabetes mellitus alone was not significantly associated with hospital readmission ($P=0.19$) after excluding education and income from the model. Therefore, caregiver characteristics were assessed using Cox proportional hazards models without adjusting for any patient demographics or clinical characteristics.

None of the caregiver characteristics were significantly associated with hospital readmission within the first year after discharge at the 0.05 level. However, patients who are explicitly dependent on the caregiver were about 1.7× (95% CI, 0.995–3.0) more likely to be readmitted to the hospital within the first year. This model (Table 4, model 1) included 66 patients with information about caregiver dependence.

Inter-Rater Agreement
A total of 84 out of 96 LVAD patients were reviewed for caregiver characteristic information by 2 reviewers (Figure 2). Overall, the mean simple κ statistics for all 29 caregiver

Table 1. Patient Demographics

Demographic	Summary Statistic
Age at implant (y)	
n	96
Mean (SD)	56.1 (12.9)
Median (min, max)	58.6 (15.6, 77.2)
Sex, n (%)	
Female	26 (27)
Male	70 (73)
Married, n (%)	
No	31 (32)
Yes	58 (60)
Missing	7 (7)
No. of previous marriages, n (%)	
0	29 (30)
≥1	25 (26)
Missing	42 (44)
No. of children, n (%)	
0	7 (7)
1	14 (15)
2	18 (19)
≥3	26 (27)
Missing	31 (32)
Highest degree of education completed, n (%)	
High school or less	33 (34)
College or above	15 (16)
Missing	48 (50)
Race, n (%)	
White	47 (49)
Black	38 (40)
Hispanic	8 (8)
Asian	1 (1)
Missing	2 (2)
Financial score, n (%)	
Strained	7 (7)
Limited	14 (15)
Adequate or better	26 (27)
Missing	49 (51)
PACT score	
N (n missing)	37 (59)
Mean (SD)	29.2 (7.5)
Median (min, max)	31.0 (3, 45)

PACT indicates Psychosocial Assessment of Candidates for Transplantation.

characteristics was 0.41 (SD=0.16, min=−0.10, and max=0.63) which suggests a moderate level of agreement between the 2 raters. The mean PABAK statistics was 0.38 (SD=0.21, min=−0.19, and max=0.64) suggesting only fair agreement. The lowest levels of agreement tended to occur when interpreting whether or not extended family (T3, κ=0.21), friends (T4, κ=0.30), or hired help (T5, κ=−0.10) were available to help take care of the patient (Figure 2). PABAK statistics were 0.05, 0.12, and −0.19 for these 3 characteristics, respectively. This suggests poor to slight agreement between raters for these

Table 2. Clinical Characteristics

Characteristic	Summary Statistic
Indication, n (%)	
Nonischemic cardiomyopathy	39 (41)
Ischemic cardiomyopathy	57 (59)
Therapy goal, n (%)	
Bridge to decision	19 (20)
Bridge to transplant	15 (16)
Destination therapy	62 (65)
INTERMACS profile, n (%)	
1	26 (27)
2	18 (19)
3	30 (31)
4/5	22 (23)
IABP, n (%)	
No	63 (66)
Yes	33 (34)
Diabetes mellitus, n (%)	
No	49 (51)
Yes	47 (49)
Hypertension, n (%)	
No	17 (18)
Yes	79 (82)
CAD, n (%)	
No	41 (43)
Yes	55 (57)
COPD, n (%)	
No	73 (76)
Yes	23 (24)
CKD, n (%)	
No	69 (72)
Yes	27 (28)
BMI	
n	96
Mean (SD)	29.4 (6.5)
Median (min, max)	29.0 (17.0, 50.8)

BMI indicates body mass index; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; IABP, intra-aortic balloon pump and INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support.

Table 3. Caregiver Characteristics

Key	Characteristic	Missing	Frequency	Percent
Physical presence of caregivers				
P0*	Caregiver present	9	85/87	98
P1	Often present	12	57/84	68
P2	Caregiver able to take off work for at least 6 wk	20	57/76	75
P3	Caregiver has identified backup system	20	66/76	87
P4	Caregiver explicitly mentions conflicting obligations	23	34/73	47
	At least 1 adult child lives close by	41	43/55	78
	Estrangement of adult children or others	49	8/47	17
	Presence of logistical constraints	64	8/32	25
	Patient lives alone	35	8/61	13
Overall preparedness for device placement and recovery				
OP1	Caregiver understands severity of illness/options	52	32/44	73
OP2	Caregiver eager/willing/ready to give care	52	37/44	84
OP3	Describes making concrete plans after device placement	53	37/43	86
OP4	Describes feeling mentally ready for device placement and recovery	61	27/35	77
Emotional presence and support (as described by patient and documented by social worker)				
E1	Caregiver is supportive of the patient and device placement	9	82/87	94
E2	Healthy relationship between caregiver and patient	14	71/82	87
E3	Others involved in care besides caregiver	11	71/85	84
E4	Patient is explicitly dependent on caregiver for physical or emotional support	30	23/66	35
Who is involved in caregiving				
T1	Spouse	3	60/93	65
T2	Immediate family	4	80/92	87
T3	Extended family	11	30/85	35
T4	Friends	12	27/84	32
T5	Hired help	65	7/31	23
Mental health of caregiver (as described by patient and documented by social worker)				
MH1	Anxiety	43	16/53	30
MH2	Depression	47	12/49	24
MH3	Substance abuse issues	55	2/41	5
MH4	Emotional outbreaks	53	3/43	7
MH5	Gambling or other high-risk activities	55	0/41	0
Providing practical resources				
PC1	Caregiver is able to perform physical demands required	21	66/75	88
PC2	Caregiver is financially able to set up in-home support	22	53/74	72
PC3	Caregiver is able to provide logistical support	22	62/74	84
Support	General support (strong or very strong)	23	52/73	71
Initial Interview	Caregiver was part of the initial assessment	31	49/65	75
Financial score	PACT score (missing, median, range)	64, 31, 3–45		

PACT indicates Psychosocial Assessment of Candidates for Transplantation.

*Abbreviations only given to characteristics assessed for inter-rater agreement (Figure 2).

Table 4. Multivariable Cox Proportional Hazards Model Results

Outcome Measure	Models	Covariate	Hazard Ratio (95% CI)
Mortality	Model 1 (n=65)	BMI (<29 vs ≥29)	2.3 (0.82–6.39)
		Hypertension	2.5 (0.53–11.7)
		CAD	1.9 (0.66–5.31)
		No. of children (<3 vs ≥3)	1.5 (0.54–4.37)
		INTERMACS (≤2 vs >2)	1.4 (0.55–3.37)
	Model 2 (n=96)	BMI (<29 vs ≥29)	2.4 (1.20–4.70)
		Hypertension	3.4 (0.78–15.3)
		CAD	1.7 (0.76–3.63)
		INTERMACS (≤2 vs >2)	1.5 (0.79–3.01)
	Model 3 (n=96)	BMI (<29 vs ≥29)	2.3 (1.17–4.52)
		Hypertension	4.3 (1.02–18.1)
Morbidity	Model 1 (N=31)	Income (<adequate vs ≥adequate)	1.9 (0.58–6.04)
		Education (<college vs ≥college)	1.7 (0.48–6.19)
		Diabetes mellitus	0.5 (0.18–1.13)

BMI indicates body mass index; CAD, coronary artery disease; and INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support.

characteristics. There was also only slight to fair agreement on whether or not the patient was explicitly dependent on the caregiver (E4, κ=0.25, PABAK=0.095). General support also had a very low PABAK score of 0.05, but κ=0.385. Otherwise, characteristics tended to have fair to moderate agreement.

Discussion

This study extends and deepens the understanding of LVAD caregiving. To our knowledge, this is the first study to investigate how caregiver support could impact LVAD patient mortality and morbidity. Without this foundational understanding (and subsequent studies building on this hypothesis-generating study), LVAD programs cannot reliably identify indications and contraindications related to caregiving support.[10,15] In what follows, we elaborate on our key findings from the multivariable analyses which remained significant predictors when controlling for clinical factors.

Caregiver Understanding

A major finding from our study is that caregivers' understanding and appreciation of patients' severity of illness decreases mortality risks, yet has no impact on INTERMACS-defined morbidity events. It is difficult to interpret the juxtaposition of these 2 findings. As to the mortality findings, we suspect that engaged caregivers listen carefully to informed consent discussions about device placement, come to understand disclosed information, ask clinicians questions to help them retain information, and then actively participate in patient care to reduce mortality risks. If caregivers do not fully appreciate how sick their loved ones are, they may be less likely to engage in conversations about patients' health and their options, and they may not recognize the integral role they as caregivers can

play in impacting patients' mortality. With regard to the morbidity finding, we suspect that caregiver understanding only impacts patient metrics at a particular threshold or a certain point in time, perhaps once the patient is critically ill, in the intensive care unit, and facing death. More work is needed to confirm these findings and identify possible explanations as to why caregiver understanding could impact mortality yet not impact morbidity events.

An implication of this caregiver-understanding mortality finding is that it may be misguided to focus exclusively on patients in conversations about the severity of their illness, the implications of their disease, treatment options, and treatment choices, even though going beyond the patient would deviate from existing ethical theory and clinical practice.[16] That is, ethical and legal guidelines encourage directing conversations toward patients when they have decision-making capacity to respect patient autonomy. In the context of LVAD placement, however, we think it would be appropriate to conceptualize presentation of information and decision-making as a family-centered process, explicitly encouraging caregivers to be engaged in conversations when nature, purpose, risks, benefits, alternatives, and severity of illness are described. We hypothesize that caregiver participation in these educational conversations will help caregivers increase their appreciation of the severity of patients' illnesses.

Several initiatives underway to assess patient understanding using standardized instruments could be applied to caregivers to assess their understanding and appreciation of the severity of illness and of treatment options. For instance, Gordon et al[17] developed and prospectively evaluated the initial psychometrics of a tool designed to evaluate living liver donor's comprehension. Our group recently published an instrument primarily designed to assess patients' comprehension for LVAD placement.[18] Here, based on these findings, we encourage adapting and adopting such instruments for caregivers to assess caregiver comprehension.

Table 5. Adjusted HRs for Mortality by Caregiver Characteristic

Caregiver Characteristic	No. of Patients Included in Model	% of Total Sample (Total n=96)	Adjusted HR* (95% CI)
Caregiver understands severity of illness/options	44	46%	0.24 (0.08–0.73)
Caregiver has identified a backup system	76	79%	0.27 (0.09–0.83)
Extended family to care for patient	85	89%	0.41 (0.18–0.91)
At least 1 child lives close by	55	57%	0.28 (0.09–0.91)
Patient lives alone	61	64%	3.15 (1.07–9.29)
Able to provide logistical support (household tasks)	74	77%	0.42 (0.18–0.97)

BMI indicates body mass index; CI, confidence interval; and HR, hazard ratio.
*Mortality: HR with 95% CI adjusting for hypertension and BMI group.

Table 6. Type of Morbidity Events

Event Type	Frequency	Percent
Acute renal failure	3	3.80
Arrhythmia	7	8.86
Bleeding (non-GI)	2	2.53
Died	4	5.06
Dizziness/syncope	3	3.80
GI bleeding	15	18.99
Heart failure	5	6.33
Hemolysis/pump thrombosis	5	6.33
ICD troubleshooting	2	2.53
Infection (not VAD related)	8	10.13
LVAD alarm/troubleshooting	2	2.54
LVAD-related infection	4	5.06
Medication adjustment	3	3.80
Neurological dysfunction	3	3.80
Non-CV surgery	4	5.06
Other non-VAD infectious disease	2	2.53
Pain	3	3.80
Pleural effusion	1	1.27
Pulmonary embolism	1	1.27
Respiratory failure	1	1.27
Suicide attempt	1	1.27

CV indicates cardiovascular; GI, gastrointestinal; ICD, implantable cardioverter defibrillator; LVAD, left ventricular assist device; and VAD, ventricular assist device.

Caregiver Support and Presence

A striking finding from our study is that the risk of death was 3.1× more likely among patients who live alone compared with those who did not live alone. This suggests that having a caregiver present and available is strongly associated with mortality. Further supporting the interpretation, we also found that the risk of death for an LVAD patient was significantly lower among those who had at least 1 adult child living close by (defined as ≤50 miles). Theorizing why we found these associations, it could be that these better mortality risks are related to adherence to medical regimens and self-efficacy (the latter being a person's ability to complete a skill successfully and confidently).[19] In the absence of caregivers who can routinely assist and monitor patients (and other caregivers to provide backup support if the primary caregiver is unavailable), mortality risks may increase because patient self-efficacy lowers in the absence of support. Specific examples include patients not taking Coumadin without reminders from caregivers, resulting in thrombosis or stroke and patients not properly adhering to hygienic practices for dressing changes or cleaning drivelines without caregiver assistance, either because of patients' cognitive detriments or because of physical limitations. There is some support for hygienic practices influencing mortality because our previous work demonstrated that persistent bloodstream infections (related to driveline infections) strongly

correlated with mortality and risks of stroke.[20] It may also be the case that without support, patients may become burned out or are otherwise so burdened that they cannot fully contribute.

Further studies are needed to confirm these suppositions. In the interim, however, we provide preliminary recommendations based on these findings. First, we suggest that greater emphasis should be placed on caregivers' willingness and abilities to physically help patients because of their impact on mortality. Casida et al recently published instrument designed to measure caregivers' abilities and willingness to tend to instrumental home-based LVAD needs could be used by LVAD programs in determining whether and how caregivers could provide physical support.[19]

Second, we do not think that it should be considered sufficient to show adequate caregiving simply by having a 24-hour care plan in place for 30 days postdischarge, even though this expectation is advocated by professional societies and device companies.[1,21] Our findings are based on the mortality results extending well beyond the immediate postdischarge period, suggesting that caregivers' abilities are instrumental in ways that may not be well-represented in using the 24-hour, 30-day rule that focuses on presence rather than quality of caregiving network. Instead, we advocate a more nuanced approach that focuses on the willingness and ability of caregivers to support patients throughout the first year, either living with the patient or close by.

Clinical Implications of Our Findings

We anticipate criticism that it would be ethically inappropriate to assess caregivers' willingness and ability to contribute to patient care, especially given that caregivers are outside of the clinician–patient relationship. While we recognize the validity of this perspective, our data challenge the assertion that caregivers are not part of the clinician–patient relationship precisely because these findings demonstrate that they are integral to mortality metrics.

There is, however, a legitimate, related concern: whether it would be appropriate to exclude someone from consideration for LVAD placement if caregivers could not fulfill physical and cognitive demands, or if the patient lives alone. Our findings should not be interpreted to suggest that these individuals should be excluded from LVAD consideration. Further study is needed to confirm the relationship between variables and examine whether there might be mitigating factors. However, at a minimum, our findings suggest that LVAD clinical personnel should strongly encourage such patients to explore all reasonable options for strengthening their support networks.

Limitations and Calls for Systematic Documentation

The study limitations are a product of the types of records we reviewed. The primary data in the assessments were entered by 3 social workers. Coders' interpretations were necessary when reviewing the free-text fields. This could be 1 reason that our inter-rater reliability was not higher for some domains, despite the fact that all 3 coders have extensive experience and training in thematic analyses. To offset limitations, as noted, a data codebook for assigning variables to free-text entries was used.

A related limitation is that, of the 201 patients eligible for this study, 105 were excluded because of incomplete social work documentation. Social work documentation was judged to be incomplete when there was no full predevice implantation assessment in the electronic medical record (Figure 1). A full assessment might not have been placed in the electronic medical record for a variety of reasons including (1) social workers were waiting for more data to complete the assessment and therefore marked it as incomplete, (2) the device was placed urgently and social workers conducted a preliminary or abbreviated assessment, or (3) the full assessment was placed in the bedside chart but not in the electronic medical record.

Most commonly, however, the basis for excluding social workers' notes was coders' subjective determination that they could not clearly and unequivocally code the quality of caregiver support because the social workers did not explicitly ask or document questions about caregivers. Specifically, rather than having the coders interpret a lack of discussion in patients' chart notes about caregiver support as suggesting an adequate support network, coders looked for affirmative, unequivocal responses about caregiver attributes to be as confident as possible in their coding and reporting. This conservative approach explains the missing data. We consider a conservative coding approach preferable to the alternative of generously (and likely over) interpreting social workers' assessments to suggest that little or no reporting about a caregiver meant that there were no caregiving issues. Missing variables are typical of retrospective chart analyses, but more consistent documentation may lead to greater insights about the importance of these caregiver variables on patient mortality or morbidity. Importantly, despite having to exclude a high number of patients on the basis of incomplete social workers' documentation, our remaining cohort of 96 patients is above adequate for purposes of conducting this research.

Finally, we investigated social support in a heterogeneous sample by including patients who were approved for LVADs for different purposes, that is, bridge to transplant, DT, and bridge to decision. Our justifications for considering these patients together are 4-fold. First, the categorization of purposes and patients within Centers for Medicare and Medicaid Services' nomenclature is not hard and fast, perhaps 1 reason why Centers for Medicare and Medicaid Services dropped the bridge to decision designation recently.[22] Patients commonly move from one category to another as clinical factors change. Some bridge to transplant patients who do not perform and expected or intended on a device become ineligible for a heart transplant (eg, patients who experience disabling strokes). On the other hand, ≈17% of patients classified as DT receive a transplant after correcting psychosocial or medical contraindications to transplantation, for example, kidney dysfunction or a lack of supportive networks.[23] Second, our emphasis is on caregiver support (as opposed to patient characteristics). Caregiver support should be present and is traditionally evaluated regardless of the purpose of the device. Third, we knew that, because of limitations associated with our sample size, we would not be able to elucidate distinctions among caregiver support by implant strategy, thus undermining the benefit of treating the categories of patients separately. Finally, for many of these reasons, there has been a trend in the field to focus on extended support, as opposed to providing an up-front strategy (bridge to transplant versus DT), as exemplified by the current study design of the ongoing Multi-center Study of MagLev Technology in Patients Undergoing mechanical circulatory support therapy with HeartMate 3 (MOMENTUM).[24] We opted to follow recent trends in the field as part of our study design.

Conclusions

To our knowledge, this is the first study identifying attributes of caregiver support and their impact on LVAD patient mortality or INTERMACS-defined morbidity outcomes. By showing how important caregiver presence is for impacting mortality, we hope to provide an empirical basis for outlining a sufficient—or even optimal—constellation of caregiver characteristics. Although our findings buttress previous conceptual and anecdotal evidence about the importance of caregiver support, they challenge current ethics-based views about who should be included in the privileged physician–patient relationship and the informed consent process. We call for greater systematic documentation of those caregiver variables that we suspect to promote and enhance patient benefit.

Disclosures

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Caregivers of Patients With Left Ventricular Assist Devices: Possible Impacts on Patients' Mortality and Interagency Registry for Mechanically Assisted Circulatory Support–Defined Morbidity Events

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