Patient and Caregiver Determinants of Patient Quality of Life and Caregiver Strain in Left Ventricular Assist Device Therapy

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Background—Although current guidelines emphasize the importance of social support to the success of left ventricular assist device (LVAD) therapy, few studies examine the influence of the caregiver on patient outcomes or quantify the impact of LVAD caregiving on caregiver outcomes. The purpose of this analysis was to identify patient and caregiver determinants of patient quality of life (QOL) and caregiver strain in response to LVAD therapy.

Methods and Results—Data on patients receiving LVAD therapy and their caregivers (n=50 dyads) were prospectively collected pre-implantation and 1, 3, and 6 months post-implantation. Growth curve modeling was used to describe change in patient QOL (Kansas City Cardiomyopathy Questionnaire) and caregiver strain (Multidimensional Caregiver Strain Index). Patient QOL improved most in the first month ($\beta=23.22\pm3.76$, $P<0.001$), followed by gradual gains over 6 months ($\beta=1.90\pm0.64$, $P<0.01$). Caregivers experienced worsening of strain in the first month ($\beta=4.30\pm1.42$, $P<0.01$), followed by gradual resolution to pre-implantation levels by 6 months ($\beta=-0.71\pm0.23$, $P<0.01$). Worse pre-implantation patient symptoms were associated with greater improvement in patient QOL ($\beta=0.53\pm0.19$, $P<0.01$) but worsening caregiver strain ($\beta=0.15\pm0.07$, $P=0.04$). Better relationship quality was associated with greater improvement in patient QOL ($\beta=14.39\pm5.85$, $P=0.01$) and less pre-implantation caregiver strain ($\beta=-9.31\pm2.28$, $P<0.001$). Nonspousal caregivers experienced less pre-implantation strain ($\beta=-8.60\pm3.10$, $P=0.01$), and patients with nonspousal caregivers had less improvement in QOL ($\beta=-3.70\pm1.62$, $P=0.02$).

Conclusions—A combination of patient and caregiver characteristics predicts patient and caregiver response to LVAD therapy. Including caregiver factors in future studies may be helpful in developing interventions that improve patient and caregiver outcomes, together. (*J Am Heart Assoc.* 2018;7:e008080. DOI: 10.1161/JAHA.117.008080.)

Key Words: caregivers • heart failure • quality of life • ventricular assist device

People with advanced heart failure (HF) have limited treatment options: many patients with advanced HF are not eligible for transplantation or will die on the wait list without intervention.[1] Thus, mechanical circulatory support with a left ventricular assist device (LVAD) has become a primary therapeutic option for patients who are ineligible for transplantation but would benefit from permanent support (destination therapy [DT]) or who require a bridge to transplantation.[1] For LVAD therapy to be successful, guidelines recommend strong social support, and many centers require patients to have a designated primary caregiver (ie, unpaid family member or friend) to assist with post-LVAD management.[2,3] Despite recent evidence that caregiver characteristics may directly affect LVAD patient mortality,[4] few quantitative studies have examined the influence of caregivers on LVAD patient outcomes or have quantified the impact of LVAD caregiving on the caregiver.

Quality of life (QOL) is a major outcome of interest in LVAD therapy,[5] and although LVAD is typically associated with QOL improvement, there is substantial variability in QOL outcomes post-implantation, with some patients doing well and others not doing well.[6,7] As such, there is a current need for research that better predicts QOL outcomes post-LVAD and identifies potential intervention targets, particularly for DT patients who will permanently live with the device.[8] Similarly, there is a call

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Clinical Perspective

What Is New?

- This is one of the first quantitative studies of caregiver strain (ie, burden) in modern left ventricular assist device therapy, and it is one of the first to examine how the patient-caregiver relationship may influence both patient and caregiver outcomes.
- Caregiver strain worsens immediately after implantation and then returns to pre-implantation levels over 6 months, but it does not further improve.
- The severity of heart failure symptoms was associated with both patient and caregiver outcomes.
- The quality of the patient-caregiver relationship was associated with better outcomes for both, and may be a protective target for future interventions.

What Are the Clinical Implications?

- Given that a combination of patient, caregiver, and relationship factors likely affect both patient and caregiver outcomes in left ventricular assist device therapy, interdisciplinary clinical approaches that consider both the patient and the caregiver as individuals, as well as the characteristics and health of their relationship to one another, may be more effective than solely patient-focused approaches.
- Unlike patient quality of life after left ventricular assist device therapy, which improves on average, caregiver strain does not improve from baseline levels; caregivers likely need support before and after left ventricular assist device therapy to manage caregiver strain and reduce associated morbidity.

for more research on LVAD therapy caregivers, about whom little is known quantitatively but who likely experience considerable caregiver strain (often called "caregiver burden"), a subjective measure of stress related to caregiving that is a known predictor of increased morbidity and mortality.[8–11] More important, caregiver characteristics are known to influence patient outcomes and vice versa, in chronic illness in general and HF in particular,[12,13] supporting quantitative approaches in LVAD therapy that consider both patient and caregiver factors as predictors of patient and caregiver outcomes. Thus, the purpose of this analysis is to identify patient and caregiver determinants of patient QOL and caregiver strain in response to LVAD therapy.

Methods

Because of the sensitive nature of the data collected for this study, requests to access the data set from qualified researchers trained in human subject confidentiality protocols may be sent to the corresponding author.

Study Design and Population

This was a prospective longitudinal study of patients receiving an LVAD and their caregivers (n=50 dyads, where each dyad consists of a patient and associated caregiver).[14,15] Because little research has been done to examine patient-caregiver dyads in LVAD therapy, no formal sample size calculation based on expected effect sizes was conducted; rather, sample size was primarily determined by the number of patients and caregivers it was feasible to enroll during the funding period on the basis of center implantation rates. In short, patients were eligible for enrollment if they were ≥21 years of age, eligible to receive an LVAD, and without previous heart transplantation. Adult (≥21 years of age) caregivers were eligible if they were the primary caregiver of the patient, as agreed on by the patient, caregiver, and clinical team. Data were collected at 4 time points: immediately prior (median, 5 days) to implantation and 1, 3, and 6 months post-implantation. Patient and caregiver demographic, psychosocial, and person-oriented outcomes data were collected via survey. Patient clinical information was abstracted from the medical record. Study procedures were approved by the Oregon Health and Science University Institutional Review Board, and all participants provided written informed consent.

Convenience sampling was used to screen and offer enrollment to all patient-caregiver dyads receiving LVAD therapy at the center from July 1, 2013 through December 1, 2015. During this time period, 9 patients undergoing LVAD therapy were implanted at the center and were not enrolled in the study: 2 refusals ("overwhelmed" and felt "too sick"), 2 ineligible (<21 years of age and biventricular assist device use), 3 emergent implantations who were too sick to approach, and 2 LVAD exchanges. There were no differences in sociodemographic characteristics between those enrolled and those not enrolled, but the patients not enrolled because of refusal or emergent implantation were likely sicker. Furthermore, there were 8 patients undergoing LVAD therapy who were enrolled but not included in this dyadic study because of the following reasons: 5 had not identified a primary informal caregiver at the time of implantation, 2 did not have an English-speaking caregiver, and 1 caregiver refused (did not have time). The caregiver who refused was not significantly different sociodemographically from the enrolled caregivers in the study, but the 2 non–English-speaking caregivers were both Hispanic, compared with our enrolled caregivers, who were mostly non-Hispanic. It is not known how this center's LVAD therapy population sociodemographically compares with other LVAD therapy centers in the state of Oregon; however, at the time of enrollment, this center was responsible for implanting the overwhelming majority of patients undergoing LVAD therapy and residing in Oregon (as well as many in southwest Washington).

Measurement

Demographic and clinical characteristics

Patients and caregivers reported demographic information (age, sex, race/ethnicity, marital status, education, and employment), and caregivers reported patient-caregiver relationship type and duration. Patients' pre-implantation clinical characteristics were abstracted from the medical record (cause and duration of HF, New York Heart Association class, ejection fraction, LVAD therapy type, and comorbidities[16]). Caregivers reported their comorbidities using a validated measure.[17]

Patient HF-specific QOL

The Kansas City Cardiomyopathy Questionnaire was used to measure patient QOL.[18] The Kansas City Cardiomyopathy Questionnaire is a multidimensional HF-specific QOL measure that has been recommended for use in LVAD therapy.[5] The 3-item QOL subscale, which asks patients about the overall impact of HF on life enjoyment, rather than about the presence or absence of particular HF symptoms, was used for this analysis. Patients respond on a 5-point Likert scale, and scores are normed to a potential range of 0 to 100, with higher scores indicating better QOL.[18]

Caregiver strain

The Multidimensional Caregiver Strain Index was used to measure subjective perceptions of stress related to the caregiving role (ie, subjective caregiver strain or burden, as opposed to objective quantification of time spent caregiving or number of caregiving activities).[19] The Multidimensional Caregiver Strain Index is a multidimensional measure of strain with an 18-item Total Strain score. Caregivers respond on a 5-point Likert scale, and Total Strain scores are summed for a potential range of 18 to 90, with higher scores indicating greater (worse) strain. Subscale scores can also be calculated for each of the dimensions of caregiving strain the Multidimensional Caregiver Strain Index measures: (1) Physical Strain (ie, declining physical health or fatigue), (2) Social Constraints (ie, compromised social life or unable to leave the home), (3) Financial Strain (ie, financial costs cause strain or resentment), (4) Time Constraints (ie, no time for self-care or to fulfill other obligations), (5) Interpersonal Strain (ie, feeling resentful or strained relationship with the care recipient), and (6) Demanding Patient (ie, patient is overly demanding or manipulative). Subscale ranges vary depending on the number of items; thus, to facilitate comparisons between sources of strain, subscale scores were standardized to range from 0 to 100.

Physical symptoms

Patient physical symptoms of HF (eg, fatigue, weight gain, orthopnea, and dyspnea) pre-implantation were measured using the Heart Failure Somatic Perception Scale (HFSPS).[20] The 18-item HFSPS asks patients about how bothersome symptoms are on a 6-point (0–5) Likert scale, with 0 indicating the patient did not have the symptom, and 1 to 5 indicating symptom severity. Scores are summed for a potential range of 0 to 90, with higher scores indicating worse symptoms.

Relationship quality

Caregiver-perceived relationship quality pre-implantation was measured using the 15-item Mutuality Scale,[21] which measures positive dimensions of relationship quality. Caregivers respond on a 5-point Likert scale, and scores are averaged to derive a summary score ranging from 0 to 4, with higher scores indicating better relationship quality.

Statistical Analysis

Standard descriptive statistics were used to describe patients and caregivers at baseline. Paired *t* tests were used to compare reports of patient QOL and caregiver strain between pre-implantation and 6 months post-implantation, respectively; effect sizes were quantified in the metric of Cohen's *d*. Given that previously reported post-LVAD changes in person-oriented outcomes are not typically linear,[22,23] piecewise growth curve models (in which multiple phases of change can be estimated to best reflect differing rates of growth over time) were used to characterize change.[24] We modeled 2 separate phases of change: one for the period from pre-implantation through 1 month post-implantation (during which patients and caregivers experienced the greatest magnitude in change) and another for the period from 1 to 6 months post-implantation (during which patients and caregivers experienced gradual change). Specifically, this was the 2-piece piecewise growth curve model, 1a2b parameterization, as described by Chou and colleagues.[24] In this model, random intercept and slope are modeled for the first phase of change, but the intercept of the second phase of change is assumed to be a function of the intercept and slope of the first phase and is, therefore, not specified in the model. The outcome in the patient model was HF-specific QOL, using the scores for baseline and 1-, 3-, and 6-month time points (no difference scores were used). The outcome in the caregiver model was caregiver strain, also using the scores for all time points (no difference scores were used). Within each phase, change was modeled as a linear trajectory. Baseline values were not included as model covariates.

To facilitate early identification of at-risk patients/caregivers, only baseline variables were considered in model selection. Model covariates were selected using the Berg and Upchurch Developmental-Contextual Model as a guiding framework.[12] Therapy type (DT versus bridge to transplantation, which also served as a proxy for age in our sample, because age and therapy type were highly correlated) and

caregiving relationship type, dichotomized into spousal/nonspousal, were retained as theoretically important controls. Although there were multiple types of nonspousal caregiving dyads in the study (ie, parents, adult children, and neighbors/friends), we were unable to examine differences across all relationship types because of sample size considerations. Additional variables matching the theoretical framework and with significant individual or global effect on the model were retained, with a limit of 5 variables (n=50 dyads). We were particularly interested in patient symptom severity, because symptoms are known to be correlated with patient QOL[25] and caregiver strain[13] in the general HF population. We were also interested in the effects of relationship quality on these outcomes, because relationship quality is potentially modifiable and has known protective benefits.[26] Because both symptom severity and relationship quality had significant effects in both models, they were both retained. Sex was also an important consideration in our selection (either patient or caregiver sex but not both in the same model, given the high proportion of heterosexual couples in the sample and the inclusion of caregiver relationship type as a covariate), but sex only had a significant individual or global effect in the caregiver strain model, which was then full (5 variables). To complete the patient model, we considered readily identifiable pre-implantation clinical characteristics because of their potential utility in risk prediction, of which ischemic cause had a significant effect.

Although patient and caregiver retention was excellent, with only 1 dyad unavailable for follow-up over 6 months, 8 dyads were removed from the study for death or dissolution of the caregiving relationship. Specifically, 4 dyads exited the study because of patient death post-implantation, and 4 dyads exited the study because the caregiver stepped away from the caregiver role (1 because of family conflict over who should be caregiver, 1 because of patient independence and preference, and 2 because of self-described caregiver burnout). Full information maximum likelihood estimation was used to handle missing data across this longitudinal study, with all available data used in analyses (all available data from the 9 dyads who did not complete the study, plus data [95.7% complete] from the 41 dyads who did complete the study). Analyses were conducted in Stata14 (StataCorp, College Station, TX) and MPlus7 (Muthén & Muthén Los Angeles, CA); the primary author of this article (J.T.B.) had full access to all the data in the study and takes responsibility for its integrity and the data analysis.

Results

Characteristics of the sample are presented in Table 1. Patients and caregivers were in their mid-50s on average. Patients were largely men, caregivers were largely women,

Table 1. Characteristics of the Sample (n=50 Dyads)

Characteristics	Patients	Caregivers
Age, y	54.6±13.9	54.7±12.5
Sex (male)	42 (84.0)	9 (18.0)
White/non-Hispanic	42 (84.0)	46 (92.0)
Relationship type		
Spousal	…	38 (76.0)
Parental	…	7 (14.0)
Relationship duration, mo	…	318.7±182.8
Relationship quality*	…	3.3±0.6
Education (more than high school)	27 (54.0)	33 (66.0)
Employed	5 (10)	28 (56.0)
Comorbidity Index Score†	2.5±1.5	1.0±1.3
Ischemic HF cause	19 (38.0)	…
Duration of HF, mo	101.4±94.1	…
Ejection fraction, %	20.8±3.5	…
NYHA functional class IV	20 (40.0)	…
HF symptoms‡	39.4±17.5	…
Receiving inotropes pre-implantation	26 (52.0)	…
Destination therapy§	14 (28.0)	…

Data are given as mean±SD or number (percentage). HF indicates heart failure; and NYHA, New York Heart Association.
*Mutuality Index score, range 0 to 4, with higher scores indicating better relationship quality.
†Charlson Comorbidity Index for patients, self-report version for caregivers.
‡Heart Failure Somatic Perception Scale total score, range 0 to 90, with higher scores indicating worse symptoms.
§Therapeutic strategy at time of implantation, as opposed to bridge to transplantation or bridge to decision.

and most identified as white/non-Hispanic. Approximately three quarters of patients were in the bridge to transplantation group, and patients were primarily Interagency Registry for Mechanically Assisted Circulatory Support profile ≥3. The most common caregiving relationship was spousal, followed by parental; the remaining dyads were adult children (n=2), neighbors/friends (n=2), or other/did not specify (n=1). Before implantation, most spousal dyads lived in the same household, whereas nonspousal dyads were less likely to cohabitate (χ^2[1, n=50]=13.2, $P<0.001$); after implantation, almost all dyads cohabitated, and there were no differences by relationship.

Patient HF-Specific QOL

The growth curve for patient HF-specific QOL is presented in Figure 1. Overall, there was a significant and large improvement in QOL in response to LVAD therapy; the greatest improvement was between pre-implantation and 1 month post-implantation ("initial change"), followed by a significant,
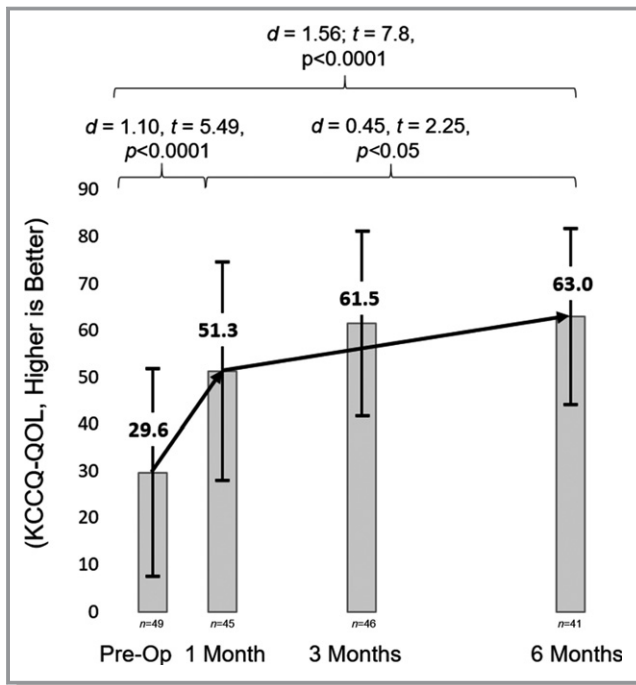
Figure 1. Patient heart failure–specific quality of life. At top, the results of paired *t* tests with associated effect sizes are displayed for the following comparisons: baseline and 1 month, 1 and 6 months, and baseline and 6 months. The arrows in the figure represent piecewise growth curve trajectories for patient heart failure–specific quality of life from pre-implantation through 1 month post-implantation, and from 1 through 6 months post-implantation, superimposed over sample means and 95% confidence intervals for each time point. The number of complete surveys for each time point is also shown. Note that n=49 at baseline, because 1 patient was unable to finish the pre-implantation survey (intubated, sedated). This patient completed all other time points and was not excluded from the analysis. *d* indicates effect size for paired *t* test in metric of Cohen's *d*; KCCQ-QOL, Kansas City Cardiomyopathy Questionnaire–Quality of Life subscale; and Pre-Op, preoperative.

but more gradual, improvement between 1 and 6 months post-implantation ("subsequent change"). Initial QOL change was significantly associated with pre-implantation QOL, such that better pre-implantation QOL predicted less dramatic improvement in QOL in the first month after implantation ($P<0.001$). The model predicting patient QOL is presented in Table 2. Patients with greater pre-implantation symptoms had significantly worse pre-implantation QOL but also significantly greater initial improvements in QOL post-LVAD therapy. Patients with a nonischemic cause of HF had significantly greater improvement in QOL from 1 to 6 months post-implantation. Patients with caregivers who reported better relationship quality before implantation also had significantly greater QOL improvement in the first month. Patients with nonspousal caregivers had significant worsening of QOL from 1 to 6 months post-implantation.

Caregiver Strain

The growth curve for caregiver strain is presented in Figure 2. Caregivers experienced significant worsening of strain initially from pre-implantation through 1 month post-implantation, followed by gradual reduction back to baseline levels between 1 and 6 months post-implantation. However, there was no significant change in strain when comparing baseline with 6 months post-implantation. There were no significant associations between pre-implantation strain and either initial or subsequent change ($P=0.80$ and $P=0.70$, respectively). The model predicting caregiver strain is presented in Table 3. Caregivers who reported better pre-implantation relationship quality, and caregivers who were not the patient's spouse, had significantly less pre-implantation strain. Caregivers of patients with more severe pre-implantation HF symptoms had significantly greater worsening of strain in the first month post-LVAD therapy. Female caregivers had significantly greater reduction in strain from 1 to 6 months post-implantation. Specific sources of strain (ie, average scores for each subscale at each time point) are presented in Figure 3. The greatest sources of strain for LVAD caregivers in this sample were time and social constraints, followed by physical strain.

Discussion

Our study revealed a significant change in patient HF-specific QOL and caregiver strain in response to LVAD therapy. Particularly notable aspects of our findings include the nature of change in patient QOL and caregiver strain and the significant predictors thereof. We will discuss the impact of HF symptoms and relationship characteristics (type and quality) on patient QOL and caregiver strain over time, because these are the most novel aspects of our findings and thus expand the current literature.

Change in Patient QOL and Caregiver Strain

In addition to significant overall improvement in patient QOL over time, we observed large initial improvement (from pre-implantation to 1 month post-implantation) in patient QOL in response to LVAD therapy, followed by more gradual improvement. This finding is consistent with previous LVAD studies, which have also demonstrated early and sustained improvement in QOL and functional status.[22,23] Thus, factors predicting robust positive responses to LVAD therapy early after implantation may be the most promising targets for intervention and risk prognostication.

In terms of caregiver strain, to our knowledge, this is the first study to quantify strain in LVAD therapy caregivers from pre-implantation to post-implantation. Although qualitative studies have provided evidence that caregiving is emotionally

Table 2. Determinants of Patient Pre-implantation HF-Specific QOL and Change Over Time

Variable	Pre-implantation QOL (Intercept)	Initial Change in QOL (Slope 1)*	Subsequent Change in QOL (Slope 2)†
Unadjusted model	29.62±3.15 (*P*<0.001)	23.22±3.76 (*P*<0.001)	1.90±0.64 (*P*<0.01)
Nonspousal caregiver‡	4.18±6.89 (*P*=0.54)	0.58±9.28 (*P*=0.95)	−3.70±1.62 (*P*=0.02)
Destination therapy‖	−6.61±6.32 (*P*=0.30)	3.10±7.39 (*P*=0.68)	1.97±1.60 (*P*=0.22)
Relationship quality¶	−7.15±5.13 (*P*=0.16)	14.39±5.85 (*P*=0.01)	−0.72±1.40 (*P*=0.61)
Patient HF symptoms#	−0.62±0.18 (*P*<0.001)	0.53±0.19 (*P*<0.01)	−0.01±0.04 (*P*=0.87)
Nonischemic cause	−3.24±7.10 (*P*=0.65)	−8.82±7.74 (*P*=0.25)	4.31±1.52 (*P*<0.01)

Data are given as β±SE (*P* Value). β±SE for each listed covariate in the above growth curve model results stand for the associated adjusted means with robust standard errors. HF indicates heart failure; and QOL, quality of life.
*Change from pre-implantation through 1 month post-implantation.
†Change from 1 month post-implantation through 6 months post-implantation.
‡Caregiving relationship type: nonspousal vs spousal caregiver.
‖LVAD therapy type: destination therapy vs bridge to transplantation/decision.
¶Mutuality Scale score.
#Heart Failure Somatic Perception Scale total score.

distressing at all stages of LVAD therapy support,[27,28] it is not possible to gain insight into how and when caregiver strain changes in response to LVAD implantation from these studies
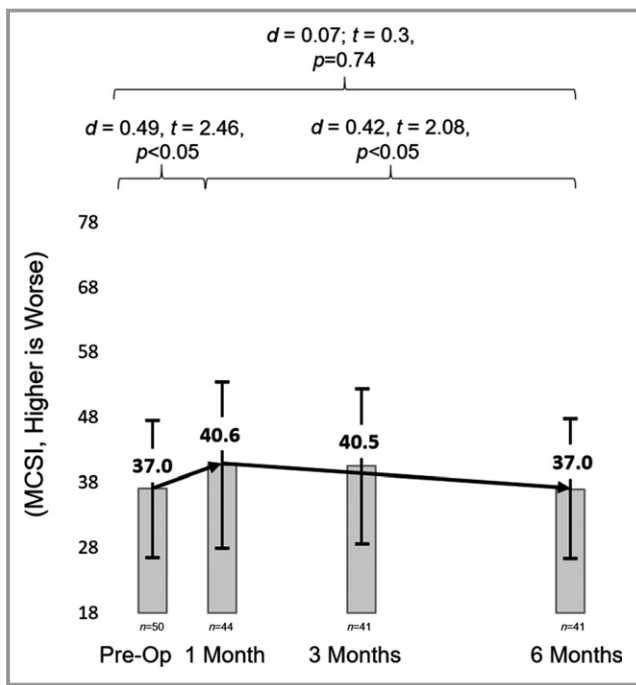

Figure 2. Caregiver strain. At top, the results of paired *t* tests with associated effect sizes are displayed for the following comparisons: baseline and 1 month, 1 and 6 months, and baseline and 6 months. The arrows in the figure represent piecewise growth curve trajectories for caregiver strain from pre-implantation through 1 month post-implantation, and from 1 through 6 months post-implantation, superimposed over sample means and 95% confidence intervals for each time point. The number of complete surveys for each time point is shown. *d* indicates effect size for paired *t* test in metric of Cohen's *d*; MCSI, Multidimensional Care Strain Index; and Pre-Op, preoperative.

or identify when the caregiver is at highest risk. However, in other contexts involving major clinical intervention (eg, bone marrow transplantation and heart transplantation), strain is highest immediately preintervention, followed by reduction postintervention.[29,30] In contrast, we observed no overall change in strain between preintervention and postintervention (LVAD). However, when examining trajectory characteristics, we found significant worsening of strain in the first month post-implantation, followed by return to baseline. It is possible that immediate worsening of strain, followed by slow reduction without net improvement, may be unique to LVAD caregiving, given that day-to-day life with the device often brings new physical, psychosocial, and financial challenges for families.[27] The initial increase in strain, although statistically significant, was not particularly large (ie, moderate effect size). Thus, characteristics associated with pre-implantation levels of strain may have particular value in identifying those at risk for prolonged exposure to elevated strain and its associated impact on morbidity and mortality.[9–11]

Influence of HF Symptoms

HF symptoms predicted both patient QOL and caregiver strain, demonstrating that the symptom experience (a hallmark of the HF syndrome) affects patients and caregivers alike. In patients, we observed that greater physical symptom burden was associated with worse pre-implantation QOL, a finding consistent with the existing literature.[31] Greater symptoms pre-implantation also predicted greater initial QOL improvement, potentially because more symptomatic patients have more to gain from LVAD therapy. In caregivers, greater pre-implantation patient HF symptom burden predicted significant worsening of strain in the first month post-implantation. Given that caregivers often perceive

Table 3. Determinants of Caregiver Pre-implantation Strain and Change Over Time

Variable	Pre-implantation Strain (Intercept)	Initial Change in Strain (Slope 1)*	Subsequent Change in Strain (Slope 2)[†]
Unadjusted model	37.03±1.50 (*P*<0.001)	4.30±1.42 (*P*<0.01)	−0.71±0.23 (*P*<0.01)
Nonspousal caregiver[‡]	−8.60±3.10 (*P*=0.01)	5.48±3.17 (*P*=0.08)	−0.34±0.59 (*P*=0.56)
Destination therapy[‖]	−0.32±2.33 (*P*=0.89)	0.22±3.07 (*P*=0.94)	−0.04±0.49 (*P*=0.94)
Relationship quality[¶]	−9.31±2.28 (*P*<0.001)	0.23±2.61 (*P*=0.93)	0.08±0.42 (*P*=0.84)
Patient HF symptoms[#]	−0.03±0.07 (*P*=0.65)	0.15±0.07 (*P*=0.04)	−0.01±0.01 (*P*=0.50)
Caregiver sex (female)	2.32±3.35 (*P*=0.50)	3.04±2.58 (*P*=0.24)	−0.98±0.46 (*P*=0.03)

Data are given as β±SE (*P* Value). β±SE for each listed covariate in the above growth curve model results stand for the associated adjusted means with robust standard errors. HF indicates heart failure.
*Change from pre-implantation through 1 month post-implantation.
[†]Change from 1 month post-implantation through 6 months post-implantation.
[‡]Caregiving relationship type: nonspousal vs spousal caregiver.
[‖]LVAD therapy type: destination therapy vs bridge to transplantation/decision.
[¶]Mutuality Scale score.
[#]Heart Failure Somatic Perception Scale total score.

patients' symptom burden to be greater than the patients themselves report,[32] and greater severity of HF has been associated with greater caregiver strain,[13] it is possible that elevated symptom severity pre-implantation has a lagged effect on caregivers' ability to cope with caregiving post-implantation, potentially as a function of sustained hyper-vigilance.[33] In short, the influence of pre-implantation HF symptoms on both dyad members underlines the importance

of symptoms for patient and caregiver outcomes and suggests that the experience of HF symptoms is a shared one.

Influence of Caregiver Characteristics

Relationship quality

Relationship quality was protective for both patient QOL and caregiver strain, with better relationship quality predicting greater initial improvement in patient QOL and less pre-implantation caregiver strain. Notably, these were the most clinically meaningful points in both patient and caregiver trajectories: (1) any QOL gains the patient made in the first month were sustained on average, and (2) caregiver strain increased slightly from baseline, but eventually returned to pre-implantation levels. More important, relationship quality is a measurable modifiable factor with established benefit. In chronic illness in general, relationship quality is associated with better caregiver emotional health outcomes.[26] In HF dyads, relationship quality is a determinant of better HF management behaviors[34] and is protective against patient and caregiver psychological distress.[35] This is the first study, to our knowledge, to demonstrate the positive impact of relationship quality in LVAD therapy. Its known benefits in similar populations make it a promising factor for future LVAD research.

Relationship type

Relationship type (spousal/nonspousal) was a determinant of QOL change for patients and pre-implantation strain for caregivers. Patients with nonspousal caregivers had significant worsening in QOL from 1 to 6 months post-LVAD therapy, whereas spousal caregivers had greater baseline strain. It is not surprising that spousal caregivers (many of
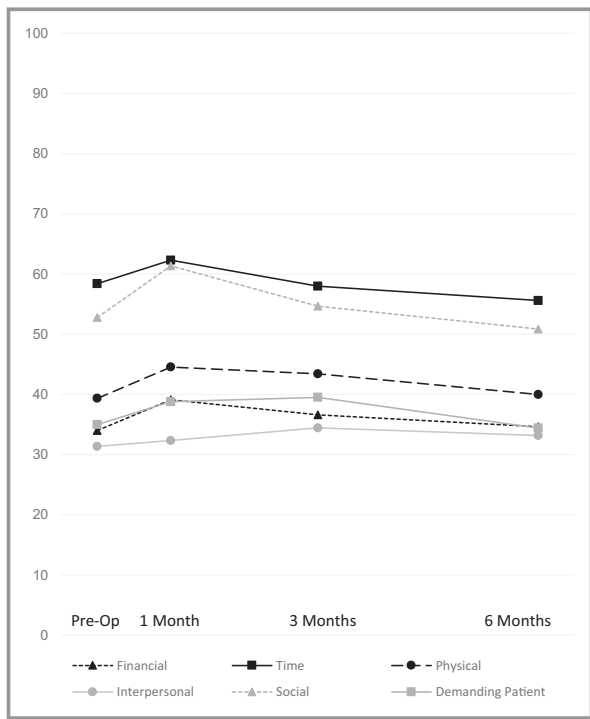

Figure 3. Sources of caregiver strain over time. Trajectories have been plotted using the sample averages for each dimension of the Multidimensional Caregiver Strain Index at each time point. Pre-Op indicates preoperative.

whom were working) had significantly higher strain pre-implantation, because similar results have been demonstrated in caregivers in other patient populations.[36] The finding of worsening patient QOL in nonspousal dyads, however, is novel. It may be that physical/emotional proximity of spousal caregiving holds benefits and drawbacks. For caregivers, strain pre-implantation may be heightened by the threat of losing a partner and/or the added burden of caring for someone who was previously able to contribute to household responsibilities. For patients, long-term QOL may suffer because nonspousal caregivers, who were less likely to live with the patient before implantation but almost exclusively lived with the patient up through 6 months post-implantation, may be stretched by the unexpected demands of an extended caregiving role; thus, they may possibly reduce caregiving contributions for practical or emotional reasons. In short, our study demonstrates that the caregiving relationship type influences LVAD patient and caregiver outcomes. In future studies, relationship type should be further examined or, at minimum, controlled.

Implications for Research and Practice

Overall, this study demonstrates the transactional nature (ie, bidirectional influence) of the LVAD patient-caregiver dyad, with a combination of individual and caregiver characteristics predicting key patient and caregiver outcomes. To understand and leverage the dynamic relationship context in which patients and caregivers manage LVAD care together, we recommend research and clinical approaches that examine and treat patients and caregivers as a dyad. Second, the HF symptom experience is important for both patient and caregiver outcomes. Continued symptom research from a dyadic perspective is needed, particularly given that joint patient-caregiver symptom management is a critical component of successful HF self-care.[37,38] Third, relationship type (spousal versus nonspousal) was an important factor in our analysis, and we recommend that it be examined further in future research, because different types of dyads may require different types of support at different points in the pre-implantation/post-implantation course. Fourth, the greatest sources of strain for caregivers in this study were time and social constraints, followed by physical strain. This suggests that strain in LVAD caregivers may be partly ameliorated by advocating for respite, home care, or other services that might provide caregivers with time and support to attend to other obligations, maintain a healthy social life, practice better self-care, and protect their own physical health. More important, the trajectory of strain in this study demonstrates that these services may be necessary and appropriate not only in the early postoperative period, but for at least 6 months postoperatively and likely beyond. Finally, relationship quality was a significant protective factor, and,

given its modifiability, research examining relationship quality may hold promise for improving the health and well-being of patients undergoing LVAD therapy and caregivers alike. We recommend that relationship quality be measured in both members and studied at the dyadic level. In addition, we recommend that information across disciplines and illness contexts be integrated to better understand how to support healthy relationships throughout the course of HF and LVAD therapy.

Study Limitations

This study has limitations. First, as one of the earliest forays into quantitative patient-caregiver research in modern LVAD therapy, this study was largely exploratory, with no formal sample size calculations. Although, to our knowledge, this is the largest quantitative sample of patient-caregiver dyads receiving continuous-flow devices, it remains relatively small, precluding us from controlling for all known predictors of strain or HF-specific QOL and reducing statistical power. However, we hope that one of the contributions of this study is that anticipated effect sizes can be calculated from the models published herein, to assist future researchers in adequately powering future studies. Second, our choice of instrument for HF symptoms may be considered a limitation, because the HFSPS has not previously been used in patients undergoing LVAD therapy. Although we chose the HFSPS over the more well-established Minnesota Living With Heart Failure Questionnaire in an effort to reduce potential conceptual overlap with the outcome of HF-specific QOL, some degree of overlap likely still exists; validity work with the HFSPS in this population may be warranted. Third, although our models included patient health variables, the physical health of the caregiver (ie, comorbidities) was not included, largely because it was not significantly correlated with either outcome. However, this may be a function of the overall sample characteristics, in which caregivers were fairly young on average and comorbid burden was relatively low. On a related note, this is a single-center study of mostly male patients and female spousal caregivers who are white. Multisite studies with diverse samples are needed, in terms of both sociodemographic and health characteristics and particularly caregivers. Although single-center studies are typical for this type of LVAD research, work like this is increasingly multi-institutional. Having a single center is a significant limitation because there are significant programmatic differences in the patients who are considered for LVAD therapy, the process of consent, and even the requirements of caregivers. The fact that three quarters of patients were in the bridge to transplantation group and 52% were receiving inotropes are examples: such differences affect generalizability of the results, given that approximately half of patients undergoing

LVAD therapy nationally are DT, and a much larger proportion are likely receiving inotropes at the time of implantation.[39] Finally, generalizability is also limited to the 6-month period after implantation. Because mechanical circulatory support is typically a long-term therapeutic strategy, particularly for DT patients, longer-term research of LVAD dyads is warranted.

Conclusions

We observed significant changes in patient HF-specific QOL and caregiver strain in response to LVAD implantation, with the most substantial change occurring in the first month post-implantation. Patient QOL improved dramatically in the first month, followed by gradual improvement over the remaining 6 months. For caregivers, strain increased significantly in the first month post-implantation, followed by gradual reduction to pre-implantation levels. More important, a combination of individual and caregiver characteristics predicted patient QOL and caregiver strain. Worse HF symptoms adversely affected patients and caregivers alike, whereas better relationship quality was protective. There were also significant differences in patient QOL and caregiver strain by relationship type. Overall, this study demonstrates that the patient-caregiver relationship has a measurable impact on key patient and caregiver outcomes after LVAD implantation and that future dyadic research in this population is warranted.

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Disclosures

None.

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