

LEFT VENTRICULAR ASSIST DEVICE THERAPY:  
FAMILY CAREGIVERS' STRESS,  
PERCEIVED BURDEN AND QUALITY OF LIFE

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## Abstract

**Background:** Individuals implanted with left ventricular assist devices (LVADs) as bridge to transplant or as destination therapy expect to be discharged home.

Responsibility for providing care to those patients has fallen almost exclusively to family caregivers. Yet there is a paucity of research on the experience of family caregivers of LVAD patients. This study assessed the burden and quality of life (QOL) of caregivers over a period of up to 6 months. The influence of stress and select demographic variables on those outcomes was also evaluated.

**Methods:** Subjects recruited from a single LVAD center in the upper Midwest were required to be  $\geq 18$  years old, the identified primary caregiver of an LVAD patient, and able to read and write English. Each was asked to complete a questionnaire at baseline and again at 2, 6, 14 and 22 weeks after the baseline measure. Measures included demographics, the Caregiver Distress Scale, the Caregiver Involvement Instrument, the Caregiver Burden Assessment, the Cantril Ladder scale, the CES-D, and the SF-12.

**Results:** A total of 46 subjects provided data for analysis. The average caregiver was a 58 year old Caucasian female spouse of a bridge-to-transplant patient with a HeartMate II living with the patient and one other adult with an average income of \$40,000-\$59,999. Stress was mildly to moderately elevated over the entire period. Baseline burden was measured at levels that warranted intervention in up to 41% of participants, but decreased steadily over time ( $p=.04$ ). Sixty to eighty-five percent of subjects reported below average quality of life that was largely static across the study. Stress was negatively correlated with QOL. ( $p=.004$ )

**Conclusions:** Interventions to reduce stress are most likely to improve caregiver quality of life.

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## **Chapter One:**

### **Introduction**

Heart disease is the leading killer of Americans, and is the underlying cause of significant disability. Heart failure is one of the leading heart conditions contributing to the morbidity (1.1 million hospital discharges in 2006), mortality (20% at 1 year and 50% at 5 years following diagnosis), and costs of care (estimated \$39.2 billion in the US in 2010) for individuals with this disease (Lloyd-Jones et al., 2010). When the heart no longer pumps effectively, patients develop symptoms associated with inadequate cardiac output such as cognitive changes, activity intolerance and renal compromise.

Subsequently they develop congestion in the venous system, fluid retention, pulmonary and peripheral edema and even death. Numerous pharmacological, medical and surgical procedures have been developed in an attempt to restore forward flow or slow heart failure progression. Heart transplantation has been considered a definitive treatment for heart failure. However, the wait for a donor organ can be unpredictable and a “bridge to transplant” may be needed to support the patient until a donor heart is available. Such a bridge also improves perfusion to end organs that have been progressively starved for blood flow as heart failure worsened. Left ventricular assist devices (LVADs) have been developed to support the life of a patient with end-stage heart failure.

#### **History of Left Ventricular Assist Devices (LVADS)**

In September, 1994 the management of end-stage left ventricular heart failure was revolutionized by the introduction of the first U. S. Food and Drug Administration (FDA)-approved left ventricular assist device (LVAD), the HeartMate<sup>®</sup> IP Left Ventricular Assist System (Thermo Cardiosystems Inc., Woburn, MA), as a bridge to

cardiac transplantation (Center for Devices and Radiological Health, U. S. Food and Drug Administration, 1997). This first generation implantable pneumatically-activated pump, like all that followed, is attached to the apex of the left ventricle from which it receives oxygenated blood. The pump then propels that blood into the aorta and the systemic circulation. The HeartMate IP LVAD is powered by an external pneumatic console. Patients who had been in severe cardiogenic shock (New York Heart Association [NYHA] Class IV) prior to implant demonstrated an 84% survival and a return to NYHA Class I-II functional level (no limitations or slight limitations on physical activity related to heart failure) (Heart Failure Society of America, 2002) following device placement. In addition they were able to participate in physical rehabilitation to the point that they were able to walk on a treadmill as far as 6 miles/day (McCarthy et al., 1994). However, in most centers, patients remained in the hospital on this device until a donor heart became available because of limitations related to transporting the patient with the drive console due to its limited battery life. This meant that the patient remained the principal responsibility of the health care professionals in the hospital who were familiar with the technology.

In September of 1998 the FDA simultaneously approved the use of two similar and more portable LVADs, the HeartMate<sup>®</sup> Vented Electric Left Ventricular Assist System (Thermo Cardiosystems Inc., Woburn MA) and the Novacor<sup>®</sup> N100PC LVAS (Baxter Corporation, Oakland, CA), also as “bridges” to cardiac transplantation (Center for Devices and Radiological Health, U. S. Food and Drug Administration, 1999). These LVADs contained an internal propulsion mechanism, eliminating the need for continuous tethering to a drive console, and thus permitted the patient enhanced mobility and

independence. The use of interchangeable rechargeable batteries facilitated periods of up to 8 hours or more of operation away from standard electrical power connections. More than 70% of patients implanted with the HeartMate device were successfully transplanted following device support (Frazier et al., 2001). Similar successes were achieved with the Novacor device (Robbins & Oyer, 1999). More importantly, patients were able to be discharged from the hospital to resume their life with family, community, work, and school while awaiting a heart transplant (Frazier et al., 2001; Vigano et al., 1997).

### **LVAD Caregivers: Not Just Hospital Personnel Anymore**

With the approval of these more portable devices and the concurrent increased independence of the LVAD recipient, home discharge has been a standard expectation following LVAD implant and initial recovery from the operative procedure. Further, it is assumed that the patient will want to return home and that the family member(s) identified as primary caregiver(s) is/are ready, willing, and able to assume care responsibilities that are transferred from the health care professionals. Discussions about this transition begin with patients and their families during the initial pre-surgical conversations regarding LVAD support in order to set the expectation and provide time to develop a plan for who would be with the patient once discharged. Commonly it has been anticipated that a caregiver would be present around-the-clock for at least the first few weeks after discharge from the hospital, when the patient is most likely to require assistance. Such requirements often find patients and families scrambling to identify such coverage and needed resources.

In other studies of high-tech health care interventions such as heart transplant (Dew et al., 1998), the designated family caregiver(s) has (have) been defined as the family member(s) available to give recipients any needed daily assistance and support. The caregiver may not necessarily be the spouse or even a “blood relation.” In fact, friends, neighbors, or others could serve as the designated “family caregiver” for part or all of the day. For LVAD recipients, a similar mixture of resources has been involved in providing such support.

With the anticipated discharge of patients to home, comprehensive training programs were developed to appropriately educate identified family caregivers so that they would be able to support the patient outside of the hospital setting (Vigano et al., 1997). Patients and caregivers are taught about normal operation of the LVAD and daily caregiving activities, along with alerts and alarms that indicate changes in function or significant device malfunction. With the patient’s circulation being dependent on this type of mechanical support, device failure can rapidly lead to significant complications or death. This level of responsibility and degree of risk can elicit high levels of stress and anxiety in all learners. Nevertheless, once the caregivers have demonstrated competence with the technology, the patient (and family) is discharged from the acute care setting.

### **Introducing the LVAD as a “Destination Therapy”**

In 2002, the HeartMate<sup>®</sup> VE LVAS received FDA approval for second indication beyond bridge to transplant, termed “destination therapy” (Castellucci, 2002; Frazier et al., 2001). In that case, individuals with refractory end-stage heart failure who are not deemed to be candidates for cardiac transplantation are implanted with a device with the goal of improving longevity and quality of life while reducing symptoms

(Kukuy, Oz, Rose, & Naka, 2003). With heart failure affecting approximately 5.8 million adult Americans and resulting in more than 1.1 million hospital discharges annually at an estimated annual cost of \$39.2 billion (Lloyd-Jones et al., 2010), some experts projected that anywhere from 5,000 to as many as 70,000 patients may be candidates for such LVAD therapy by the year 2010 (McCarthy, 1995; Stevenson & Rose, 2003).

Similar to patients who are being bridged to transplant (temporarily supported on an LVAD until a donor heart is found), destination therapy patients (those who will not receive a transplant, and who will live out their life with the device) also are expected to be discharged home with the support of family caregivers after their initial surgical recovery. Different from patients undergoing bridge to transplant, however, their family caregivers can expect to be dealing with the LVAD and the implications of its therapy for the duration of the recipient's life.

### **Statement of the Problem**

Family caregiver support is crucial to the success of an LVAD patient following device implant. In the early days following hospital discharge, patients depend on their caregivers for assistance both with activities of daily living (ADLs) and instrumental activities of daily living (IADLs). In addition, the daily change of the sterile dressing around the device driveline is generally performed by the caregiver. As time progresses, the patient is anticipated to require less assistance from others. However, if complications arise, the patient's needs may remain the same or even exceed those immediately after hospital discharge.

The amount of time that will be required of the caregiver, both in hours per day as well as in months or years of support, cannot be accurately predicted. With increasing

frequency LVAD technology is being applied not only as a bridge to transplant (Fey, El-Banayosy, Arosuglu, Posival, & Korfer, 1997), but also as destination therapy. The introduction of mechanical circulatory assistance such as an LVAD has a profound impact on the family system of which the patient is a part. Family caregivers express feeling inadequately prepared to assume responsibility for care and troubleshooting of the patient and device. As patients are prepared for discharge home in the care of family members, an ethical conflict can develop for nurses and others providing education and support to those patients and caregivers. The conflict arises from the assumption that the caregiver is able and willing to provide the support that the LVAD recipient will require. A working spouse who provides the insurance coverage for the patient receiving the LVAD may not be able to take time off from work as required in the early days following discharge. There may not be other family members or other extended family able to fill that gap. A comprehensive educational program regarding device management attempts to ameliorate the concerns regarding the caregiver's ability to provide technical support, but does little to address the potential stress, resultant burden, and ultimate quality of life implications for the caregiver with these challenges. The nurse or other health care provider can find it difficult to identify an effective resolution to such ethical dilemmas.

It is essential to understand the experience of the caregiver in order to provide them with appropriate support for a successful transition home for patients with LVADs. However, a search of published literature regarding caregivers revealed that very little is known about their experience of caregiving. More information is needed so that the caregivers' experience and needs may be better understood and adequate support offered, and, further, that potentially needed programs, resources and respite may be appropriately

developed. What is their experience of caregiving in the home environment? What stresses do caregivers encounter? How do they cope? What support do they have to help them to traverse this new landscape of a family member at home with a life-support device, possibly for the rest of his/her life, for which the primary caregiver can have significant responsibility? What degree and type of burden does the caregiver report, both in the bridge to transplant and in the destination therapy environments? What impact does LVAD therapy have on the caregiver's quality of life? And how similar or different are those experiences in the same caregiver over time? Are there aspects of the caregiver's environment and personal characteristics that can predict their level of burden and quality of life?

### **Significance of the Problem**

Despite increasing numbers of LVADs being implanted every year, family caregivers of ventricular assist device patients have been the object of little research to date. The literature offers only three studies that specifically address family caregivers of LVAD patients (Casida, 2005; Dew et al., 1999; Dew et al., 2000). The first, authored by Dew and colleagues, addressed family caregivers as part of a larger study of quality of life outcomes of LVAD patients in the inpatient and outpatient environment. Of significance, the researchers reported that family caregivers of LVAD patients perceived themselves as more burdened than comparable groups of caregivers for heart transplant candidates or heart transplant recipient caregivers (Dew et al., 1999). Of additional interest, this perception of increased burden was not shared by the LVAD recipients, who believed that they were less of a burden following LVAD implant than before (Dew et al., 1999). However, this research provided no recommendations for how to address the

perceptions of the caregiver nor how to resolve the differences in perception between the patient and the caregiver. This establishes the first gap in knowledge, a lack of understanding of the experience of the caregiver or strategies for supporting them beyond providing technical knowledge.

In a subsequent study by Dew and her team (2000), information was gathered from family caregivers once during the inpatient stay in which the LVAD was placed and at one time point (mean = 68 days post LVAD implant) following discharge. The focus of those semi-structured interviews was on concerns of both patients and caregivers about the LVAD itself. Both groups had very similar opinions about the challenges related to the device and its operation and care. Caregiver burden and stress were not reported in that study, although recommendations coming from the report included increased attention to the content and timing of patient and family training about the LVAD (Dew et al., 2000). With only one time point of post-discharge data collected in this study, another gap in knowledge resulted from the limited follow-up with family caregivers to evaluate if there is a change in their perceptions over time.

The third study was a qualitative investigation of three family caregivers conducted within six months of the end of the patient's LVAD support (following heart transplantation)(Casida, 2005). The results of that analysis provided a framework for understanding the stages of life of LVAD caregivers: emotional distress followed by determination and ultimately by optimism and a new lease on life while awaiting transplantation. No specific recommendations were forthcoming about ways to approach or support the caregiver or about management of the caregiver experience. In addition, the value of this study's findings are limited since there were only three subjects in this

qualitative analysis, and all were interviewed more than six months following the LVAD patient receiving a heart transplant. Questionable ability to accurately recall their LVAD caregiving experience given their intervening caregiving of a heart transplant recipient makes reliance on these results for intervention difficult. Hence, a knowledge gap remains related to the experience of LVAD caregivers over time related to burden and caregiver quality of life.

This study was designed to begin to fill in the gaps in knowledge about the experience of burden and quality of life of caregivers of patients with LVADs, as well as to begin to identify what may potentially influence perceptions of burden and quality of life, in order to provide the health care team with potential areas of intervention to better support LVAD caregivers.

### **Purpose of the Study**

The purpose of this study was to evaluate the level of caregiver burden and quality of life experienced by primary caregivers of LVAD recipients, both in bridge-to-transplant (BTT) and in destination therapy (DT) applications, at multiple time points over a 6 month interval to determine both the degree of burden and perceived quality of life as well as the trajectory of each of those elements over time. In addition, this study was designed to assess the influence of stress and demographic characteristics on caregiver burden and quality of life.

## **Chapter Two:**

### **Literature Review**

While there is little literature about the experience of LVAD caregivers, caregivers of those with other chronic diseases has been well documented. Alzheimer's disease, cancer, stroke, chronic obstructive pulmonary disease (COPD) and human immunodeficiency virus (HIV) present challenges to those caring for patients with those slowly deteriorating and ultimately terminal diseases (Bartolo et al., 2010; Bolden & Wicks, 2010; Carod-Artal, Ferreira Coral, Trizotto, & Menezes Moreira, 2009; Greenberger & Litwin, 2003; Kim & Spillers, 2010; Rigby, Gubitz, & Phillips, 2009; Strumpf & Buhler-Wilkerson, 2010). While LVAD recipients have a disease (heart failure) that may be stabilized by the implanted device, they remain chronically ill with the potential to deteriorate quickly if there is a mechanical malfunction. Thus, they have many comparable attributes to patients of chronic illness, and there is much to be learned from a review of that related literature regarding caregiver stress, burden, and quality of life.

#### **Caregiver Stress**

Understanding and measuring caregivers' stress and the ability to cope with that stress may provide important insight into the experience of caregiver burden. Stress is not a static experience, but waxes and wanes with challenges faced by the caregiver, both in regard to caregiving and to factors outside the caregiving role (e.g., work, family, and other commitments). Stress of family caregivers of LVAD patients is not well described in the literature. However, models of stress and coping provide a starting point to evaluate stress in this group.

## **Stress and Coping: A Theoretical Model**

The stress and coping model developed by Lazarus and Folkman (Lazarus & Folkman, 1984) and later modified by Folkman (Folkman, 1997) provides the theoretical framework for this study. Their original model describes stress as appraisal of an event as threatening, challenging, or harmful (rather than benign or irrelevant). The types of coping response to that stress event were characterized as either problem-focused (identifying a plan of action to resolve the stress and acting on it) or emotion-focused (developing a plan to resolve the emotions stimulated by the stress event). If the coping response was effective, favorable emotions were elicited; if not successful, distress resulted and the individual returned to the beginning of the coping process (see non-italicized black and blue portions of Figure 1).

Folkman later modified the model by adding a third coping strategy termed meaning-based coping. With this addition she was able to account for the positive experiences reported by caregivers when problem-focused and emotion-focused coping had yielded either no resolution or an undesirable resolution of the stress (Folkman, 1997). This modification of the original model incorporated an additional path for achieving positive emotions in the caregiver.

Previous research by this author (Petty, 2007) described additional insights into the stress-coping model provided by the work of Mishel (Mishel, 1981; Mishel, 1988; Mishel, 1990) and Pearlin (Pearlin & Schooler, 1978) regarding factors that have an influence on two aspects of the model, appraisal and coping. In that review, education, social support, cognitive capacity and credible authority were shown to have an important impact on appraisal of the event as stressful. Further, coping was shown to be influenced

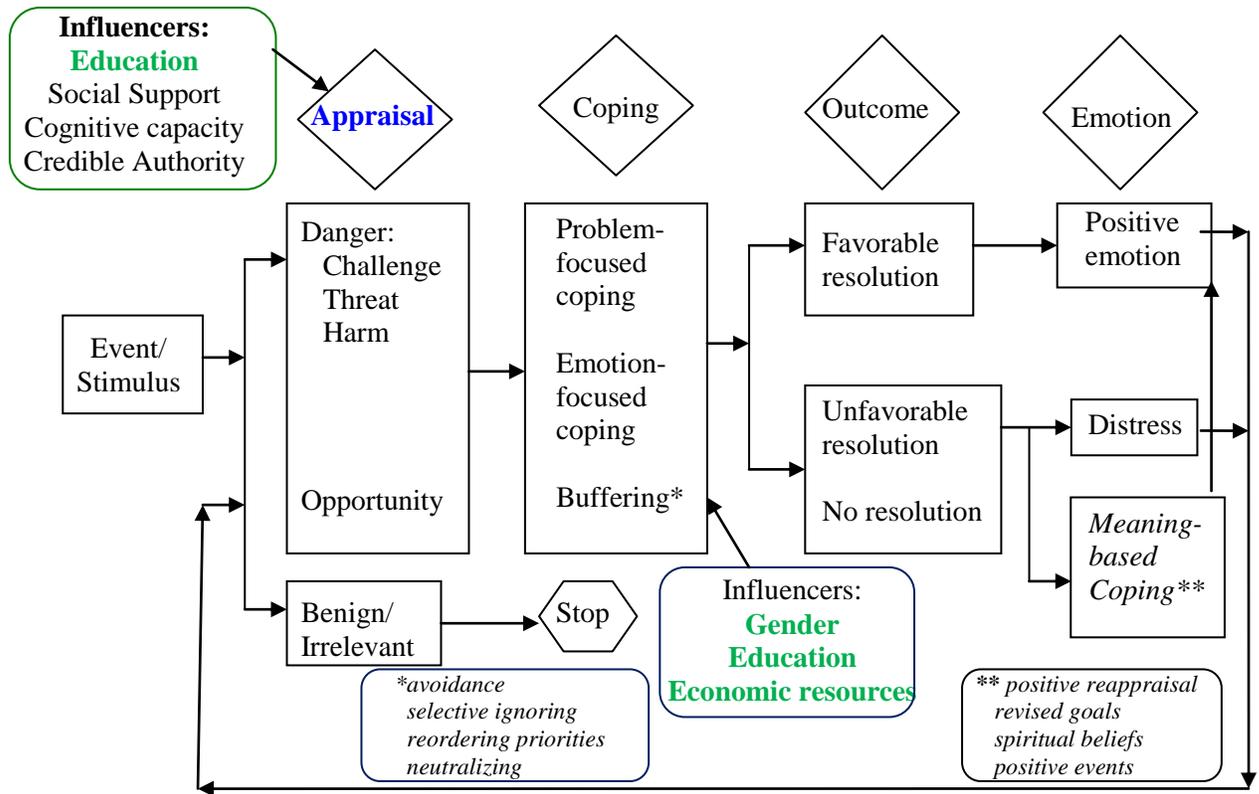
by gender, education, and economic resources. Finally, avoidance as a coping method was added to the problem-focused, emotion-focused, and meaning-based coping strategies previously described. Figure 1 represents a synthesis of this research on the stress and coping model (Petty, 2007).

According to the model, the ability of a family member to function in the role of caregiver is dependent first on that individual's perceptions of stress and second on his/her ability to cope with that stress. Effectiveness of the caregiver in managing stress through coping strategies will directly impact his/her perception of burden, all of which will ultimately affect that caregiver's quality of life. Further, as time passes, stresses, demands and resources often change, with a potential change in both burden and quality of life for the caregiver. Characterizing the trajectory of each of these facets of the caregiver's experience over time that they are caring for a patient with an LVAD could provide insight into the need for and timing of additional planned caregiver support.

### **Caregiver Demographics**

As shown in the model, demographic characteristics of caregivers have been found to have an important influence on their perception of stress and their ability to cope with it. Education can have an important effect on one's appraisal of stressful events. Lazarus and Folkman also cited situational factors such as predictability, event uncertainty, duration, and temporal uncertainty as among the situational factors that have been shown to further impact appraisal (Lazarus & Folkman, 1984, pp. 115-16). In addition, the model reflects that coping with events appraised as stressful can be influenced by gender, education, and economic resources (Petty, 2007).

Figure 1: Synthesized Model of Stress and Coping



Petty, M. (2007). *Stress and coping in family caregivers: concept modeling, current knowledge, and future directions in caring for the caregivers of patients with left ventricular assist devices*. Unpublished manuscript. Model adapted from the work of Folkman and Lazarus (Folkman, 1997; Lazarus & Folkman, 1984), Mishel (Mishel, 1981; Mishel, 1988; Mishel, 1990; Mishel, 1990), and Pearlin (Pearlin & Schooler, 1978).

Because of the influential power of these caregiver characteristics, assessing the impact of gender, education, and family income would be expected to yield information on whether these features should be considered in planning supportive interventions for caregivers. In addition, comparing those caring for patients being supported as bridge to transplant (a proxy for event uncertainty as they await a donor organ) with those supporting patients in destination therapy (a proxy for duration since LVAD support is expected to continue for a long time) can provide insight into whether support directed toward these potential factors impacting appraisal is valuable.

Caregiver stress can be associated with a perception of burden by the individual who has undertaken support of the LVAD recipient. As has been noted previously, stressors can result not only from caregiving itself but also from other aspects of the caregiver's life. In order to understand the degree to which caregiving and burden are linked, it is important to understand the concept of caregiver burden.

### **Caregiver Burden**

Since the early 1960s, researchers have been concerned about family caregivers' experience of burden in various settings (Chou, 2000; Vrabec, 1997). Vrabec defined family caregiver burden as the strain or load borne by those people caring for a family member needing assistance. Although originally considered to have two dimensions, objective and subjective, it currently is characterized as a multidimensional phenomenon, involving problems in several realms that may be experienced by family members caring for a chronically ill or impaired individual. A consolidation of authors' opinions yields five categories of caregiver burden: physiological, psychological, emotional, social and financial (Chou, 2000; Vrabec, 1997).

Burden has been conceptualized as the result of an imbalance between the demands placed on the caregiver in each of these realms and the perceived resources/support available to meet those demands (Chou, 2000; Hoffmann & Mitchell, 1998; Vrabec, 1997). Demands may come from a variety of sources, including the patient, other family members, work, and/or the society at large. While some of these demands, specifically those coming from the patient, may be obvious, the others are frequently more obscure and require additional effort by the individual performing the assessment to assure they are identified.

## **Impact of Time on Burden**

Burden is not a static phenomenon. Rather, over time the level of burden is anticipated to vary. In the case of LVADs, patients have been supported for as long as five years or more both in bridge to transplant and destination therapy applications. However, with the increasing application of this technology as destination therapy, the last intervention to be offered for the patient's refractory heart failure, the duration of support remains unpredictable, and can be expected to last for many years.

Chou (2000) suggested that the dynamic nature of burden may be due to increasing disability of the care receiver and to the changes in family expectations of the patient. Hence, what may be viewed as burdensome at one point in time may not be so assessed at a different time. Similarly, that which was not considered burdensome at one point may later be viewed as a burden. This is a particularly important concept with regard to technologically supported patients. While they receive the high tech support because they are very ill, patients and families are told (or may believe) that the intervention will "make you feel better than you have felt in a long time." With that in mind, family caregivers may plan to provide only short-term support.

As the patient's health improves, caregiver perceptions of burden may decrease. On the other hand, the level burden may become higher over time if the patient's condition does not improve as anticipated or if the patient experiences complications which require more care than had been expected by the caregiver. Further, in those whose LVAD is implanted as destination therapy, the increasing reliability of LVAD devices means that patients are expected to live significantly longer and to die of something other

than heart failure or device malfunction. This can prove to be another potential source of burden to caregivers.

Beyond burden, it is important to consider the impact of burden on the caregiver's quality of life. It is difficult to predict the amount of burden that may be experienced by the caregiver or the impact of caregiving on the caregiver's quality of life before that individual makes the commitment to become a caregiver. Since caregivers play a key role in the success of LVAD therapy in the treatment of patients with end-stage heart failure, we need to be able to appropriately inform them of the quality of life they may experience as caregivers.

### **Caregiver Quality of Life**

The World Health Organization defines Quality of Life as individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs, and their relationship to salient features of their environment (Division of Mental Health and Prevention of Substance Abuse, World Health Organization, 1997).

Significant research has been dedicated to the quality of life of the recipient of LVAD technology (Allen et al., 2010; Grady et al., 2003; Grady et al., 2004; Rogers et al., 2010; Wray, Hallas, & Banner, 2007). Although Rizzieri and colleagues addressed ethical challenges (including family caregiver burden and quality of life) associated with LVAD therapy and recommended that research additional on the topic be undertaken

(Rizzieri, Verheijde, Rady, & McGregor, 2008), there have been no investigations into the quality of life of the caregivers of these patients.

It is important to understand the similarities and differences in individual caregivers and their perspectives. We also need to explore the similarities and differences in the experience of those caring for patients who have a device as bridge to transplant (with an anticipated finite duration of LVAD support, ending when a donor heart becomes available) and those caring for recipients whose device is the terminal therapy for their heart failure. This latter group faces the potential of untold years of caregiving for patients who may need a wide-ranging level of support.

A more complete understanding of the course of stress experienced by caregivers, as well as the degree of caregiver burden and the caregiver's quality of life will enhance the ability of health care professionals to address the needs of these important "team members" at significant time points in the post-discharge period. Program planning and content development will then be needed to deal with the ongoing and changing needs of the caregivers over time in order to relieve burden and increase caregiver quality of life.

### **Literature Summary**

Research findings published to date do not provide adequate understanding of the challenges of the family caregiver of LVAD recipients over time. The relationship between caregiver demographics, stress, burden, and quality of life remains undescribed. With the insights gained from this research, targeted support and education programs for those caregivers, offered at key points following hospital discharge, can be developed.

## Conceptual Model and Definitions

Figure 2 represents the conceptual model for this study. It was derived from selected portions (the bold, italicized blue and green components) of the theoretical model described previously (Figure 1), and proposes demographic variables and stress as independent variables affecting caregiver burden. In addition, the model uses caregiver burden as an independent variable to predict its impact on the perceived quality of life of the caregiver.

Measures of caregiver stress were included to provide a comprehensive understanding of the types of stress experienced, variations in stress over time, and the potential relationship of stress to burden at each time point. Caregiver quality of life was evaluated and correlations with caregiver burden assessed. Data from these measures along with demographic data were analyzed in keeping with the study aims to identify relationships between key demographic variables (e.g., caregiver gender, age, relationship to the patient, education, family income, caregiver employment status, and device indication) and stress, burden and quality of life.

Figure 2. Conceptual Model for Predicting the Impact of Demographic Characteristics and Stress on Perceived Caregiver Burden and Quality of Life

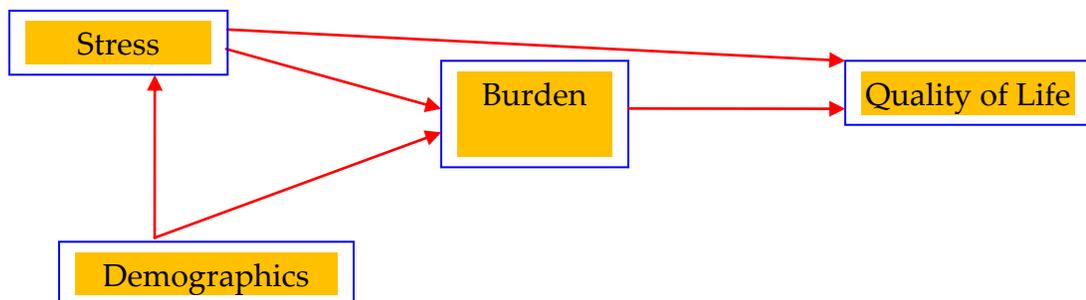


Table 1: Conceptual Definitions

<b>Concept</b>	<b>Definition</b>
Demographics	Age (in years), gender, relationship to patient, indication for LVAD, educational level achieved, family income.
Caregiver Stress	Presence of an event appraised as a source of challenge, threat, or harm to self (Lazarus & Folkman, 1984)
Caregiver Burden	The subjective and objective strain or load borne by people caring for a family member (Vrabc, 1997).
Caregiver Quality of Life	WHO defines Quality of Life as individuals' perception of their position in life in the context of the culture and value systems within which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment (Division of Mental Health and Prevention of Substance Abuse, World Health Organization, 1997).

### **Study Aims and Associated Hypotheses**

Consistent with the study's purposes, the following four specific aims and hypotheses were established:

**Study Aim #1:** To describe and compare the level of caregiver stress experienced at baseline and at 2 weeks, 4 weeks, 12 weeks, and 20 weeks after the baseline data collection.

**Hypothesis #1a:** The level of caregiver stress will decrease steadily over time.

**Hypothesis #1b:** The level of stress will be similar between caregivers of BTT patients and caregivers of DT patients.

**Study Aim #2:** To describe and compare the level of burden experienced by caregivers at baseline and at the four additional defined time points.

**Hypothesis #2:** The level of caregiver burden will decrease over time as the patient rehabilitates and exhibits increased independence in activities of daily living and instrumental activities of daily living.

**Study Aim #3:** To determine the influence, if any, of the selected demographic variables on stress and perceived burden at each time point.

**Hypothesis #3:** Male gender, spousal relationship, higher level of education and higher income will be negatively associated with burden.

**Study Aim #4:** To evaluate the relationship between burden and quality of life at each of the above noted time points.

**Hypothesis #4a:** An increased level of quality of life will be negatively associated with stress and burden.

**Hypothesis #4b:** Quality of life will vary over time, but will maintain the relationship with burden found in #4a.

## **Chapter Three:**

### **Research Design and Methods**

#### **Design**

This study utilized a prospective descriptive correlational longitudinal single-center design. Subjects were recruited from a single LVAD implanting center in the Upper Midwest of the United States. This design was selected in order to permit the researcher to characterize better the ongoing process of caregiving, burden, and quality of life in the caregiver participants.

#### **Sample and Setting**

Primary caregivers were identified and screened by the LVAD coordinators in the LVAD clinic during the LVAD patient's clinic visit at least 2 weeks and not more than 2 years after discharge from the hospital following the LVAD implant surgery. To be deemed a candidate, those screened had to be at least 18 years old, identified as the primary caregiver of an LVAD patient, and be able to read and write English. While caregivers are most commonly spouses, they may also be other family members or friends. No screening or selection restrictions were applied based on the relationship between the patient and the caregiver. Candidates needed to be at least 18 years of age for two reasons: 1) ability to provide their own consent, and 2) because those under 18 years of age were assumed to be dependent children of the LVAD patient which would be expected to have an influence on the respondent's perceptions. Excluding those who do not read and write English was based on the fact that the instruments were only available in English and were self-administered at home.

The time from discharge after LVAD placement to baseline data collection and to subsequent data collection points was verified in the initial and follow-up caregiver demographic data.

### **Power Analysis**

An analysis of required sample size was performed based on a standard significance level ( $\alpha$ ) of 0.05 and standard power ( $\gamma$ ) of 0.80. Since there were no pilot data on which to complete these computations, the first 25 subjects were used to provide beta ( $\beta$ ) and standard error (SE) estimates to be used in the calculation. Using two independent variables in the study (Caregiver Distress Scale and Caregiver Burden Assessment), and one dependent variable (Caregiver Quality of Life), calculation was performed as described by Fitzmaurice (Fitzmaurice, Laird, & Ware, 2004). By dividing the beta by the standard error, Fitzmaurice reported that a dividend  $> 1.96$  reflected an adequately powered sample size to prevent both Type I and Type II error. As demonstrated in Table 2, the 25 subjects provided appropriate power for the CDS scale, but incomplete power for the CBA scale. Utilizing the beta derived from this analysis of the CDS, linear regression estimated that a sample size of approximately 68 would be required to meet the power and significance criteria cited (Fitzmaurice et al., 2004).

Table 2: Power Calculation for CBA and CDS Regressed on Interim Data Analysis

	$\beta$	SE	$\beta/SE$
CBA	0.14	0.086	1.63
CDS	0.095	0.031	3.06

## Measures

The questionnaires used in this study consisted of a demographic survey and eight instruments intended to measure the concepts of interest identified in the study aims and hypotheses. Demographic data were collected at each time point in order to capture changes in family income or hospitalizations of the LVAD patient which might have an impact on the participant's responses. The initial demographic data set included 17 questions, and follow-up demographic data comprised 8 questions.

### Caregiver Demographics

Table 3: Initial Demographic Items

Date of questionnaire completion*
Caregiver's date of birth
LVAD recipient's date of birth
Date of LVAD implant*
Date of hospital discharge following implant*
Reason for LVAD (Bridge-to-Transplant or Destination)
Type of LVAD
Caregiver gender
Caregiver education level
Caregiver health care education
Caregiver employment status
Caregiver relationship to LVAD recipient
Duration of caregiver relationship to LVAD patient
Caregiver living with LVAD recipient
Caregiver family income
Caregiver racial/ethnic background
Caregiver physical health rating*

Initial demographic questions (Questionnaire #1) were collected at baseline and are included in Table 3. In subsequent questionnaires (#2-5), demographic data collected were those 4 items marked with an asterisk (\*) above, along with 4 additional items noted in Table 4.

Table 4: Follow-up Medical/Demographic Items

Has the LVAD patient been hospitalized since the last questionnaire?
How many times has the patient been hospitalized since the last questionnaire?
What was the longest time the patient was hospitalized since the last questionnaire?
Have there been any changes in your household since the last questionnaire?

#### Caregiver Stress

Caregiver stress was operationalized utilizing the Caregiver Distress Scale (Cousins, Davies, Turnbull, & Playfer, 2002), a 17-item Likert-type scale with a range of 0-4. The tool measures five different aspects of caregiver distress: Relationship distress (range 0-16), emotional burden (range 0-16), care receiver demands (range 0-12), social impact (range 0-12), and personal cost (range 0-12). Scores for each subscale are derived by adding the scores of the subscale's associated questions, with a higher score indicating greater distress. Internal consistency for the total scale is reflected in Cronbach's  $\alpha$  of 0.88 and 0.59 - 0.85 for the five subscales when validated longitudinally with a population of caregivers of patients with Parkinson's disease (Cousins et al., 2002).

#### Caregiver Burden

Two instruments were selected to evaluate caregiver burden. The first employed a component of the *Caregiver Involvement Scale* (Given, Stommel, Collins, King, & Given, 1990). This scale used a simple rating of the frequency with which the participant engaged in helping the LVAD patient with activities of daily living (ADLs) (10 items)

and instrumental activities of daily living (IADLs) (6 items). The respondents were asked how often per week they had performed each of the tasks. The rating scale ranged from 0-14, with 0 meaning they had not done it at all, 7 indicating that they had performed the task once per day, and 14 meaning that they had done so more than once per day. An overall score was obtained by totaling all items (16 items, range 0-224); subsequently, ADLs (10 items, range 0-140) and IADLs (6 items, range 0-84) were calculated in the same manner. Reported reliability by subscale was reported as 0.88 for both the ADL and IADL scales in family caregivers of patients with a variety of diagnoses including stroke, Alzheimer's disease, Parkinson's disease, emphysema, diabetes, cancer, and heart disease (Pfeiffer, 1975). This instrument was included to provide an objective measure of the amount of involvement the caregiver had in the LVAD patient's daily activities. While it was recognized that it may provide an inaccurate representation of the amount of involvement perceived by others, it will offer a "caregiver's eye" view of the level of care provided as reflected by the items asked, and that represents one aspect of the perception of burden by the caregiver.

The second measure of caregiver burden was the *Caregiver Burden Assessment* (Montgomery, Gonyea, & Hooyman, 1985). This 14-item scale requires the respondent, using a 1-5 Likert-type scale, to describe the impact of caring on aspects of the caregiver's life. The responses are grouped into three categories: objective burden, defined as the perceived infringement or disruption of tangible aspects of a caregiver's life (6 items, range 6-30); subjective stress burden, the emotional impact of caregiving responsibilities on the caregiver (4 items, range 4-20); and subjective demand burden, extent to which the caregiver perceives care responsibilities to be overly demanding (4

items, range 4-20). Higher scores indicated higher levels of perceived burden. Scores of > 23 for objective burden, > 15 for subjective demand burden, and > 13.5 for subjective demand burden are considered to be “of concern.” Internal reliability of these 3 subscales have been reported to be .87-.90, .81-.88, and .68-.82, respectively in a population of caregivers of dependent elders (Montgomery et al.).

### Caregiver Quality of Life

Three instruments were selected to evaluate caregiver quality of life. The first was a *Cantril ladder* rating of quality of life on a 1-10 scale, 1 being “the worst time of my life” and 10 being the “best time of my life” (American Thoracic Society Quality of Life Resource, 2007). Adding this single item to the overall questionnaire provided a snapshot rating of the respondent’s perceived quality of life in an overall sense.

Frequently used in population surveys, this tool has demonstrated test-retest reliability of 0.70 in research on aspects of well-being (McDowell & Newell, 1996).

The *Center for Epidemiologic Studies Depression Scale (CES-D)* is a commonly cited 20-item instrument for evaluating quality of life (National Institute of Mental Health, Center for Epidemiological Study, 1977). Subjects are asked to rate, on a 0-3 scale, the frequency with which they experience the feelings described in each statement. Four of the 20 items are reverse-scored (as they represent positive statements), and a total score is calculated (range 0-60). Higher scores reflect higher levels of symptomatology. Internal consistency by Cronbach’s  $\alpha$  is reported between 0.85 and 0.90.

The final instrument included in all questionnaires was the *Medical Outcomes Study Short Form-12 (SF-12)*, a 12-item scale yielding a physical component and a mental component summary (Ware, Kosinski, & Keller, 1996). Frequently utilized in

quality of life research because of its brief number of items and well-established internal validity (median Cronbach’s  $\alpha$  0.67 for the Physical Component Summary, and 0.97 for the Mental Component Summary), the SF-12 demonstrated a high degree of correlation of outcomes with the longer SF-36 instrument (0.911 and 0.918 for physical and mental component summary scores, respectively).

The use of these three instruments in the measurement of caregiver quality of life, the end-point of the conceptual model being tested, provided several perspectives on the question of caregiver quality of life and the impact of caregiver burden on that experience.

**Procedure**

Caregivers who met the inclusion criteria and expressed an interest in participating in the study were contacted by the principal investigator by telephone. After explaining the study and what would be expected of the caregiver, those who agreed were sent a copy of the consent form to review and sign, along with the first packet of questionnaires and a self-addressed stamped return envelope.

Table 5: Timing of Questionnaires

<i>Wave</i>	<i>Time</i>
1	Baseline ( $\geq 2$ weeks after discharge from LVAD surgery, but $< 2$ years)
2	2 weeks after baseline data
3	6 weeks after baseline data
4	14 weeks after baseline data
5	22 weeks after baseline data

Up to 5 waves of questionnaires were distributed to participants over the course of 6 months. The timing of questionnaire distribution was as in Table 5.

### **Human Subjects Considerations**

Approval for the study was granted by the University of Minnesota's Committee for the Protection of Human Subjects in Research (IRB) (Code # 0801P24701) and by the Nursing Research Council of the University of Minnesota Medical Center, Fairview in February, 2008.

### **Statistical Analysis**

Demographic characteristics were assessed using standard frequency and measures of central tendency analyses. Each of the other eight instruments was scored by calculating total and subscale scores (where appropriate) according to the instrument's scoring instructions as described above.

Linear Mixed Modeling (LMM) was used to evaluate the trajectory of caregiver stress, burden, and quality of life over the five waves of data. The advantage to selecting LMM over the more traditional analysis of variance (ANOVA) method lies in part in the difference in the assumptions that form the basis of the two strategies. With ANOVA, the data sets must be balanced and complete, particularly related to the repeated measures, in order to consider the data collected from a given subject. In contrast, when analysis is performed using linear mixed modeling, valid estimates of the change curve over time are established under the assumption that missing data are missing completely at random (Fitzmaurice et al., 2004). Some study participants were expected to drop out before completing all five questionnaires because the LVAD patient for whom they provided care would be transplanted before the end of the caregiver's 6-month

involvement. This was unpredictable within the bridge to transplant group, and thus was treated as a random occurrence. As a result of this issue, the use of LMM in this analysis permitted all subjects' experience to be included in the data set regardless of whether the subject was able to complete all five questionnaires.

There are additional advantages to linear mixed modeling in the analysis of the data obtained. First, LMM can yield models for dependent variables regardless of whether they are distributed normally or non-normally. Second, because data collected are serial in nature and provided by the same subject, trajectories for each individual are not independent. Linear mixed modeling is designed to compensate for those intra-subject dependencies. Finally, data intervals were not consistent across the five questionnaires (2 weeks, 4 weeks, 8 weeks, and 8 weeks), nor were the starting points following discharge the same for all subjects (2 weeks to 2 years following hospital discharge after device implant). Linear mixed modeling is able to adjust for all of these characteristics of the data. ANOVA and multiple regression analysis are not.

Correlations between the selected variables according to the study aims and hypotheses were subsequently analyzed to characterize the relationships between independent and dependent variables identified in the study aims and hypotheses. The analysis strategy follows.

First for those variables with multiple measures, a principal components analysis was performed. Principal components analysis is a standard method for determining whether a combined score derived from individual item scores can be utilized to reflect the behavior of the individual or group, or if components instead should be considered

individually (Armitage, Berry, & Matthews, 2002). This strategy was used to facilitate results analysis with Caregiver Burden and with Quality of Life variables.

Then for each variable, first an assessment of the unconditional means model was performed to determine whether there was variance of individual means around the sample mean. If such variance existed (demonstrated by a significant unexplained variance from the sample mean [intercept]), unconditional growth modeling was performed to see if the slope of change over time in individuals was significantly varied from the slope of change of the overall sample. If this analysis also confirmed significant variance, the next step was to attempt to determine potential factors that would explain the variances between the individual slopes and the slope of the entire sample.

Table 6: Data Analysis Strategy

Frequency, measures of central tendency of demographic variables for the total group and for the subgroups of BTT and DT	SPSS, measures of central tendency	- Initial Caregiver Demographics (ID) - Follow-up Caregiver Demographics (FUD)
Total Score, Subscale Scores (if applicable) at each time point	Scoring instructions, measures of central tendency	- Caregiver Distress Scale (CDS) - Caregiver Involvement Instrument (CII) - Caregiver Burden Assessment (CBA) - Cantril Ladder (CQL) - CES-D - SF-12
Trends of change in measures of caregiver stress over time intervals <i>(Study Aim #1, Hypothesis #1a)</i>	SAS: Linear Mixed Modeling	- Caregiver Distress Scale (CDS)
Differences in change in measure of caregiver stress over time between BTT and DT patient caregivers <i>(Study Aim #1, Hypothesis #1b)</i>	SAS: Linear Mixed Modeling	- Caregiver Distress Scale (CDS)

Table 6: Data Analysis Strategy (cont)

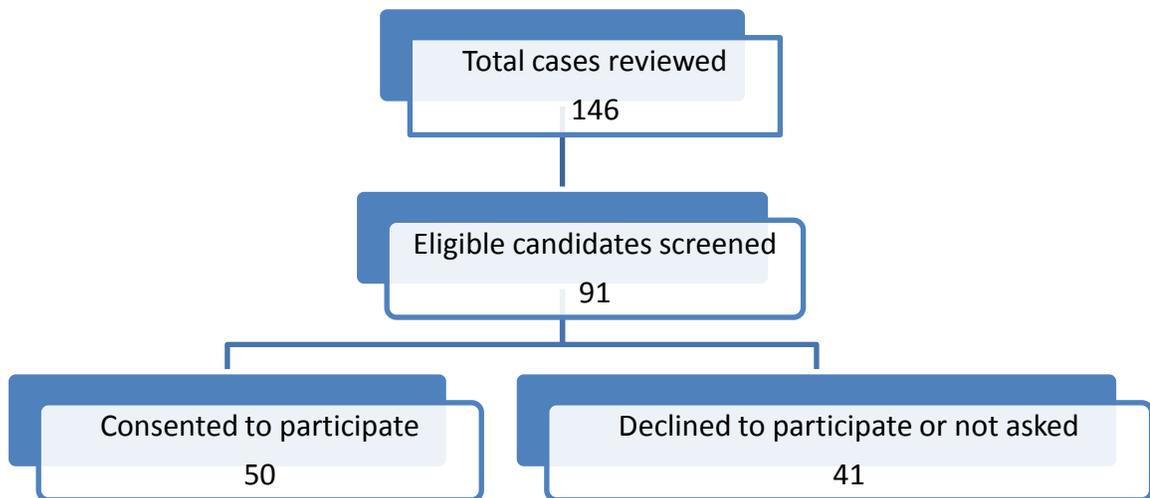
Analysis	Method	Instrument(s)	
Level of Caregiver Burden over the time periods <i>(Study Aim #2, Hypothesis #2)</i>	SAS: Linear Mixed Modeling	- Caregiver Burden Assessment (CBA) - Caregiver Involvement Instrument (CII)	
Analysis of correlations between demographic variables & burden - caregiver gender - caregiver education - caregiver income <i>(Study Aim #3, Hypothesis #3)</i>	SAS: Linear Mixed Modeling	Independent Variable - ID, FUD	Dependent Variable - CBA
Analysis of correlations between: - burden & quality of life <i>(Study Aim #4, Hypotheses #4a &amp; 4b)</i>	SAS: Linear Mixed Modeling	Independent Variable - CDS - CBA - CII	Dependent Variable - CQL - SF-12, - CES-D

## Chapter 4:

### Results

Recruitment for this study began in February, 2008 and continued until August 31, 2009. During that time, the total pool of primary family caregivers of patients implanted with an LVAD beginning February 1, 2006 and ending August 31, 2009 (n=146) were reviewed. A total of 91 subjects were eligible to be screened, of which 50 agreed to participate in the study (54.9%). The results of subject recruitment are summarized in Figure 3.

Figure 3: Subject recruitment



Of those consenting to participate, 46 (92%) returned at least one questionnaire, and 19 (38%) returned all five. Reasons for not returning questionnaires were: Patient transplanted (n=9), patient death (n=4), other/unknown (n=14). A total of 168 questionnaires were returned and were subsequently included in the analyses.

Table 7: Returned Questionnaires by Wave

<i>Wave</i>	<i>Number of Questionnaires Returned</i>	<i>Median time from hospital discharge, days (range)</i>
1	46	53.0 (14 - 663)
2	40	83.5 (27 – 714)
3	34	107.5 (55 – 751)
4	29	172.0 (119 – 677)
5	19	236.0 (169-726)

### **Caregiver and related care recipient demographics**

The majority of LVAD recipients (82.6%) were implanted with pump as a bridge to transplant. Most patients received a HeartMate II (58.7%) or VentrAssist (34.8%) device. Caregivers had a mean age of 58.7 years (range 27.64 – 76.72), and were primarily Caucasian (82.6%), female (91.3%), spouses (73.9%), without healthcare background (82.6%) living with the LVAD recipient (93.5%). The vast majority of these caregivers had other adults living at home with them (93.5%), and more than half had at least some college education (65.2%). The majority had a household income of less than \$60,000 per year (64.4%). These demographic characteristics are summarized in Table 8. Caregivers and patients lived in five states in the upper Midwest including Minnesota (71.7%), North Dakota (10.9%), South Dakota (6.5%), Iowa (6.5%), and Wisconsin (4.3%).

Caregivers of individuals who had received their LVAD as a bridge to transplant were significantly younger than those who had an LVAD as destination therapy ( $56.1 \pm 11.2$  v.  $72.7 \pm 3.2$  years,  $p < .001$ ). This result is consistent with the enrollment criteria for each application; specifically, patients implanted for destination therapy are not transplant candidates most often due to age, compromise of other organ systems, and/or other contraindications to transplant.

Table 8: Caregiver Demographic Characteristics

Characteristic	Mean (range) or n (%)
Age in yrs ( <i>combined sample</i> )	58.7 (27.6-76.7)
<i>Bridge-to-Transplant</i>	56.1 (27.6-68.7)
<i>Destination Therapy</i>	72.7 (63.4-76.7)
	n (%)
Gender, female	42 (91.3)
Indication for LVAD, bridge-to-transplant	38 (82.6)
LVAD Type	
HeartMate XVE	2 (4.3)
HeartMate II	27 (58.7)
VentrAssist	16 (34.8)
Thoratec	1 (2.2)
Education	
Less than HS diploma	3 (6.5)
HS Diploma/GED	13 (28.3)
< 4 years college	24 (52.2)
College degree or more	6 (13.0)
Healthcare Worker Education, yes	8 (17.4)
Employment	
Full time	18 (39.1)
Part time	6 (13.0)
Homemaker	4 (8.7)
Retired	15 (32.6)
Other	3 (6.5)
Relationship to LVAD recipient	
Spouse	34 (73.9)
Partner/committed relationship	3 (6.5)
Parent	4 (8.7)
Adult child	3 (6.5)
Sibling	2 (4.3)
Live with LVAD recipient, yes	43 (93.5)
Other adults in home (excluding recipient)	
0	3 (6.5)
1	20 (43.5)
2	15 (32.6)
3	7 (15.2)
4	1 (2.2)
Annual household income	
< \$20,000	4 (8.9)
\$20,000 – 39,999	13 (28.9)
\$40,000 – 59,999	12 (26.7)
\$60,000 – 79,999	10 (22.2)
≥ \$80,000	6 (13.3)

Table 8: (continued)

	n (%)
Race	
Caucasian	38 (82.6)
Asian/Pacific Islander	6 (13.0)
Native American/Alaska Native	2( 4.3)

**Caregiver Stress:**

Caregiver stress was measured using the Caregiver Distress Scale, comprised of the total score and 5 subscale scores. The mean caregiver distress total score was 23.6 (maximum score 68), representing a mild to moderate degree of distress. The subscale reflecting the highest degree of distress was the Social Impact Scale (total mean score 5.7, possible score 0-12). LVAD caregivers undergo extensive education in order to be able to care for the patient with an LVAD, and their level of responsibility to care for that patient is emphasized. Hence they recognize that another trained caregiver must be present when they cannot be. However, frequently there *is* nobody else. Leaving the patient alone for any period of time may result in caregiver anxiety and inability to enjoy their time away. This may result in the increased perception of social isolation.

It is also important to note that the scale contributing the least to the level of distress was the care-receiver demands sub-scale (total mean score 3.5, possible score 0-12). In conversations with caregivers, it is common for them to report that the patient is kind and appreciative of the caregiver’s efforts, and therefore patient demands are not perceived as a source of stress to those caregivers.

Table 9: Caregiver Distress Scale Scores by Subscale and Wave

	Wave #1			Wave #2			Wave #3			Wave #4			Wave #5			Total		
	Mean	SD	N	Mean	SD	N												
CDS Total	24.1	15.0	46	24.7	16.2	40	21.8	14.4	34	24.4	16.2	30	22.0	17.3	20	23.6	15.5	170
CDS-RD	4.0	4.3	46	4.7	4.8	40	3.9	4.2	34	4.5	4.9	30	4.7	5.4	20	4.3	4.6	170
CDS-EB	5.4	4.0	46	5.3	4.2	40	4.6	3.9	34	5.5	4.3	30	4.2	4.0	20	5.1	4.0	170
CDS-CRD	3.5	2.8	46	3.6	3.0	40	3.3	3.3	34	3.6	3.2	30	3.7	3.4	20	3.5	3.0	170
CDS-SI	6.2	4.2	46	6.0	3.8	40	5.5	3.3	34	5.5	3.6	30	4.9	3.7	20	5.7	3.7	170
CDS-PC	5.0	3.3	46	5.1	3.4	40	4.4	3.1	34	5.2	3.3	30	4.6	3.6	20	4.9	3.3	170

Note: CDS Total – total CDS Scale Score; CDS-RD = Relationship Distress Subscale Score; CDS-EB = Emotional Burden Subscale Score, CDS-CRD = Care Receiver Demands Subscale Score, CDS-SI = Social Isolation Subscale Score, CDS-PC = Personal Cost Subscale Score

### Caregiver Burden

Caregiver burden measures included the Caregiver Involvement Instrument (CII) tool which had subscales of activities of daily living (ADL) and instrumental activities of daily living (IADL) and the Caregiver Burden Assessment (CBA) As expected, the CII decreased steadily from the first wave (mean score 29.1) to the last wave (mean score 15.1) (the measures are summarized by scale/subscale in Table 10). In addition, although fewer items measured IADLs (6) than ADLs (10), the majority of the caregiver involvement was in the IADL subscale.

Similar to caregiver involvement, caregiver burden as assessed by the Caregiver Burden Assessment Scale and its three subscales demonstrated a reduction in perceived burden over time with a CBA total score falling from 45.9 to 40.5 (possible score 14-70)

(Table 11). The objective burden subscale (OB) (possible score 6-30), which assesses the degree to which caregiving infringes or disrupts tangible aspects of the caregiver’s life, contributed the most to the total score (range 22.2-19.4). Mean scores of this scale at all 5 time points were at or below a score of 23 which the scale’s authors identified as the level at or above which caregivers should seek outside services to assist them. However, a frequency analysis of responses found that 21 of the 46 subjects (45.7%) had at least one score above that cutoff, and that 24.7% (42/170) of all scores were above 23 (Table 11). No subject scored above the cutoff in all responses. This reflects that the need for services changes over time.

Table 10: Caregiver Involvement Instrument and Subscales by Wave

	Wave #																	
	1			2			3			4			5			Total		
	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N
CII Total	29.1	27.8	46	19.1	23.0	40	17.2	16.6	34	15.1	17.1	30	15.1	21.7	20	20.3	22.7	170
ADL Sub	9.3	14.6	46	4.6	9.7	40	2.9	3.4	34	2.7	3.1	30	3.4	4.9	20	5.0	9.6	170
IADL Sub	19.9	18.6	46	14.5	15.4	40	14.4	15.7	34	12.4	16.8	30	11.7	18.3	20	15.2	17.0	170

The subjective stress burden subscale (SSB) (possible score 4-20), evaluating the emotional effect of caregiving on the person providing care, consistently was the next highest contributor to total score. Again, the mean scores fell below the authors’ cutoff score of 15 above which they would recommend that the caregiver be offered counseling. But 19 of the 46 respondents (41.3%) rated themselves above that cutoff at least once during the study period, with a total of 27 of the 170 scores (15.9%) falling in the 16-20 range. In this scale as well there was no participant who always scored outside the normal range. Again, while overall subjects did not appear in need of counseling

services, there were times over the study period that they would have benefitted from such support.

Finally, subjective demand burden (SDB) (possible score 4-20), also demonstrated mean scores below the cutoff of 13.5 defined by the instrument’s authors as reflecting a need for an informational intervention. Frequency analysis found that 28.3% of participants responded at least once with a score that demonstrated that more information was needed, with a total of 28/170 scores (16.5%) scoring above the normal target of 13.5.

Table 11: Caregiver Burden Assessment Scores by Wave

	Wave #																	
	1			2			3			4			5			Total		
	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N
CBA Total	45.9	10.6	46	43.4	11.7	40	40.8	9.6	34	42.2	7.9	30	40.5	9.3	20	43.0	10.2	170
CBA-OB	22.2	5.2	46	20.3	6.1	40	19.4	4.9	34	19.7	3.6	30	19.5	4.5	20	20.4	5.1	170
CBA-SSB	13.4	3.7	46	12.7	4.1	40	12.0	3.5	34	12.4	3.3	30	11.2	4.0	20	12.5	3.8	170
CBA-SDB	10.3	4.0	46	10.4	4.2	40	9.4	3.6	34	10.0	4.0	30	9.8	4.3	20	10.0	4.0	170

Note: CBA Total = Total Score; CBA-OB = Objective Burden Subscale Score, CBA-SSB = Subjective Stress Burden Subscale Score, CBA-SDB = Subjective Demand Burden Subscale Score

Table 12: Caregiver Burden Subscale Scores Above Normal Range

	# of Subjects (%)	# of Episodes (%)	Wave 1	Wave 2	Wave 3	Wave 4	Wave 5
CBA-OB >23	21/46 (45.7)	44/170 (24.7)	19	12	6	4	3
CBA-SSB >15	19/46 (41.3)	28/170 (15.9)	12	7	4	3	2
CBA-SDB > 13.5	13/46 (28.3)	28/170 (16.5)	9	9	3	4	3

In summary, the participants in this study, while demonstrating a mild to moderate level of burden, did not reveal a level of burden that warranted interventions at all the time points in which the measures were completed. However, more than 25%

provided responses which indicated that at various points in time additional support was needed with services, counseling or information. Further, the responses demonstrated that the largest need for support in all those areas occurred earlier in the cycle than later (Table 12).

### Caregiver Quality of Life

Four measures were administered to evaluate caregiver quality of life: The Cantril Ladder Scale, the CES-D, and the MCS and PCS subscales of the SF-12. The Cantril Ladder Scale (Table 13) had a possible score of 1-10, with 1 representing the worst time in the respondent’s life and 10 representing the best time in the respondent’s life. The total mean score on this scale was  $4.6 \pm 1.8$ , with a range of mean scores by wave of 4.5 to 4.7. These scores fall just below the score of 5, labeled on the scale as “my life is about the same as always,” meaning that respondents overall rated their quality of life as slightly lower than normal. This subjective measure provided important information about their overall quality of life rating at the time they completed each questionnaire. Of course, the influences on that perception may have been more global than simply their caregiving responsibilities; influences other than caregiving.

Table 13: Cantril Ladder Scores by Wave

	Wave #																	
	1			2			3			4			5			Total		
	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N
CLQ	4.5	1.6	46	4.6	1.8	39	4.8	1.9	34	4.6	1.8	30	4.7	2.0	20	4.6	1.8	169

The CES-D scores (Table 14) in this sample yielded a relatively low level of depressive symptoms, with a total mean score of 14.0 with a possible score of 0-60. The higher the score on this scale, the more symptoms of depression are reflected in the

caregiver’s responses. The range of scores by packet was 11.4-15.2. Scores of 16-26 are considered to represent mild depression on this instrument, and scores of 27 or greater indicate major depression (Zich, Attkisson, & Greenfield, 1990). Thus, these participants did not report significant depression, indicating a more positive quality of life reflected as a low level of depression as measured by this scale.

Table 14: Centers for Epidemiologic Studies-Depression (CES-D) Scores by Wave

	Wave #																	
	1			2			3			4			5			Total		
	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N
CES-D	14.7	10.4	46	13.8	11.4	40	13.4	9.5	34	15.2	12.0	30	12.4	11.3	20	14.0	10.1	170

On the SF-12 subscales of Physical Component Summary (PCS) and Mental Component Summary (MCS) (Table 15), scores are adjusted to a standardized score ranging from 0-100, with 0 representing the lowest level of health and 100 representing the highest level of health. A score of 50 represents the population mean for this instrument, and the meaningfulness of the results is drawn from the variation of values above or below that population mean. Using standard error measurements for the instrument, a mean PCS score beyond the 95% confidence interval for the subscale of  $50 \pm 7.0$  or MCS score beyond the 95% confidence interval for the subscale of  $50 \pm 6.2$  is considered to be outside the normal range. In this sample, all mean scores for both PCS and MCS scales fell outside the confidence interval, indicating a decreased level of quality of life as measured by physical and mental health functioning compared with the normal population. Since the standardized mean score can vary with age, an additional age-based calculation appropriate for the mean age of the sample (range of 55 – 64 years

old) was computed. Adjusted age-based mean scores for PCS (50.2) and MCS (53.1) were applied, demonstrating even more difference in both realms of quality of life.

It is important to note that the fluctuation in the mean scores of both scales was modest across time points. The range of PCS scores was 38.0 – 41.3, and of MCS scores was 32.5 – 35.6. With a potential range of 100 points, these variations did not appear particularly remarkable.

Table 15: Standardized SF-12 Subscale Scores by Wave for the Whole Sample and as Adjusted for Age

	Wave #														
	1			2			3			4			5		
	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N
Standardized Scores															
PCS-12	38.02	6.77	46	38.44	7.21	38	38.12	6.28	34	39.17	5.98	29	41.27	5.69	20
MCS-12	35.42	10.33	46	34.16	9.44	38	33.98	10.07	34	35.58	10.98	29	32.45	9.43	20
Variance Scores (Mean Score - 50)															
PCS-12	-11.98			-11.56			-11.88			-10.83			-8.73		
MCS-12	-14.58			-15.84			-16.02			-14.42			-17.55		
Variance Scores (Adjusted for age 55-64)															
PCS-12	-12.20			-11.78			-12.10			-11.05			-8.95		
MCS-12	-17.72			-18.98			-19.16			-17.56			-20.69		

Note: MCS-12 = Mental Composite Scale of the SF-12; PCS-12 = Physical Component Scale of the SF-12

### Study Aim 1: Caregiver Stress

**Hypothesis #1a:** The level of caregiver stress will decrease steadily over time.

Caregiver stress as measured by the CDS total scale revealed expected and unexpected variations. Stress levels fell somewhat between the second and the third waves as was anticipated in the hypothesis (see Figure 4). However, the level rose again between the third and fourth waves. This increase was followed by a second reduction to the lowest level of the five waves. While this suggests an overall reduction in stress level

over the 6 months of data collected, the differences were not significantly different than one, suggesting a flat line (Table 16). Of note, all five subscales (relationship distress, emotional burden, care receiver demands, social impact, and personal cost) varied consistently with the total score (Figure 4), suggesting that there was no particular aspect of distress that had an excessive influence on the level of distress experienced by the participants (relationship distress scale shown in Table 16 as an example). Therefore, the hypothesis that caregiver stress would decrease over time was not supported.

Table 16: Paired Comparisons Over Time to Time1 in Caregiver Distress on 2 Scales

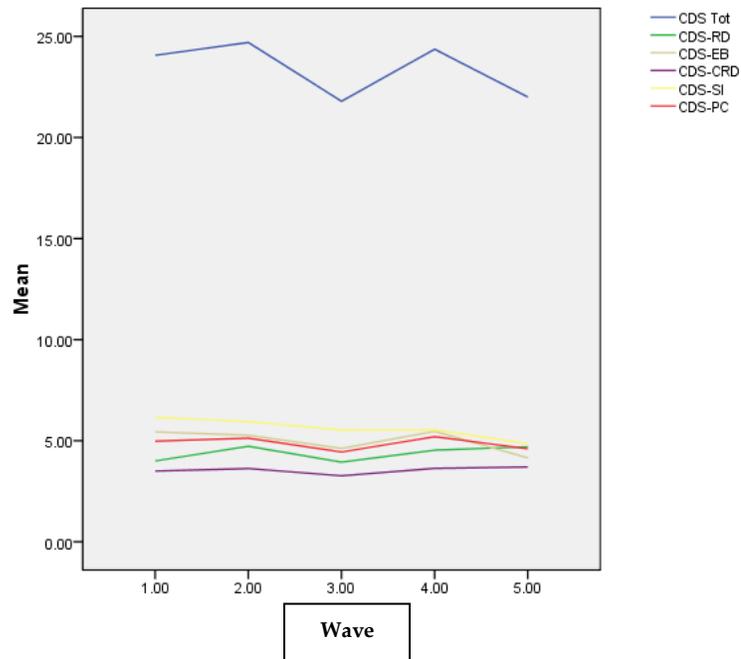
	CDS-tot	p-value	CDS-RD	p-value
Time2	-.007(1.22)	.99	.62(.36)	.09
Time3	-1.4(1.3)	.29	.22(.38)	.57
Time4	.41(1.4)	.76	.35(.40)	.38
Time5	-2.6(1.6)	.10	.08(.46)	.87

Note: CDS-tot = CDS Total Score, CDS-RD = CDS Subscale Relationship Distress score

**Hypothesis #1b:** The level of stress will be similar between caregivers of BTT patients and caregivers of DT patients.

Analysis of the trajectory of Caregiver Distress Scale results demonstrated no significant difference in the stress experienced over time by caregivers between groups (bridge to transplant or destination therapy). Select mean scores appeared to differ widely between the groups, including CDS Total, CDS-RD, CDS-SI, and CDS-PC (Table17). Analysis was undertaken of CDS Total and CDS-RD to further explore whether the significant differences between the scores of bridge-to-transplant caregivers and destination therapy caregivers existed. The results demonstrated the absence of significant effect of the indication for device placement on the stress level of participants in this sample over time.

Figure 4: Caregiver stress level over time



Thus, while there were differences in the stress experienced by caregivers over time, neither time nor indication for device implant explained those differences (Table 18).

Table 17: Caregiver Distress Total Score for All Waves by LVAD Indication

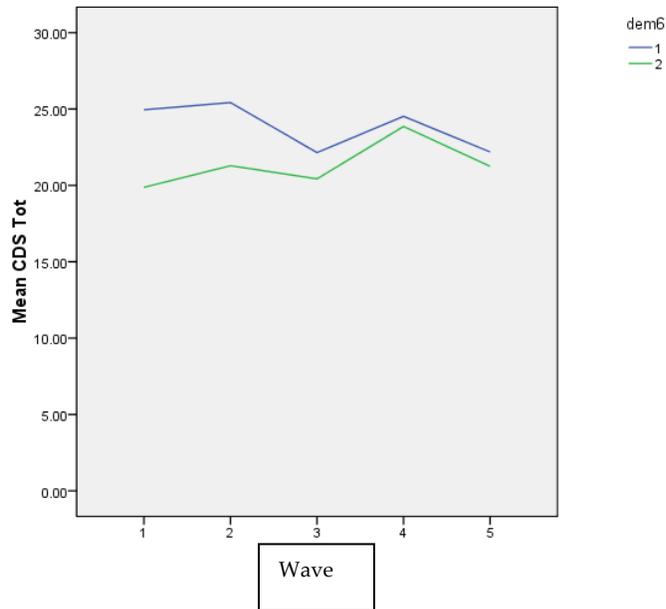
	Total								
	Demographic 6: BTT vs. DT								
	Bridge to Tx			Destination Therapy			Total		
	Mean	SD	N	Mean	SD	N	Mean	SD	N
CDS Total	25.0	15.2	38	19.9	13.9	8	24.1	15.0	46
CDS-RD	3.9	4.0	38	4.5	5.8	8	4.0	4.3	46
CDS-EB	5.4	3.8	38	5.6	5.1	8	5.4	4.0	46
CDS-CRD	3.6	2.8	38	3.3	2.6	8	3.5	2.8	46
CDS-SI	6.8	4.1	38	3.1	3.6	8	6.2	4.2	46
CDS-PC	5.3	3.4	38	3.4	2.4	8	5.0	3.3	46

Note: CDS Total – total CDS Scale Score; CDS-RD = Relationship Distress Subscale Score; CDS-EB = Emotional Burden Subscale Score, CDS-CRD = Care Receiver Demands Subscale Score, CDS-SI = Social Isolation Subscale Score, CDS-PC = Personal Cost Subscale Score

Table 18: Effect on Caregiver Stress of Indication for Implant

	CDS-tot	p-value	CDS-RD	p-value
Time	-.39(.34)	.24	.01(.10)	.89
Indication (2 [DT] set as reference value)	2.1(5.8)	.72	-.91(1.7)	.59
AIC	1201.2		791.4	
BIC	1204.9		795.0	

Figure 5: Total Caregiver Stress Level over time by Indication for Implant



Note: 1 = Bridge to Transplant indication, 2 = Destination Therapy indication

### Study Aim #2: Caregiver Burden -

**Hypothesis #2:** The level of caregiver burden will decrease over time as the patient rehabilitates and exhibits increased independence in activities of daily living and instrumental activities of daily living.

A principal components analysis was performed on the CII total and the 3 subscales of the CBA: objective burden (OB), subjective stress burden (SSB), and subjective demand burden (SDB). The results of this principal components analysis suggested that grouping the three subscales of the CBA would explain 64% of the

variance in burden, and that the CII should be considered independently since it contributed negatively to the variance explained (Table 19).

Table 19: Principal Components Analysis: Burden

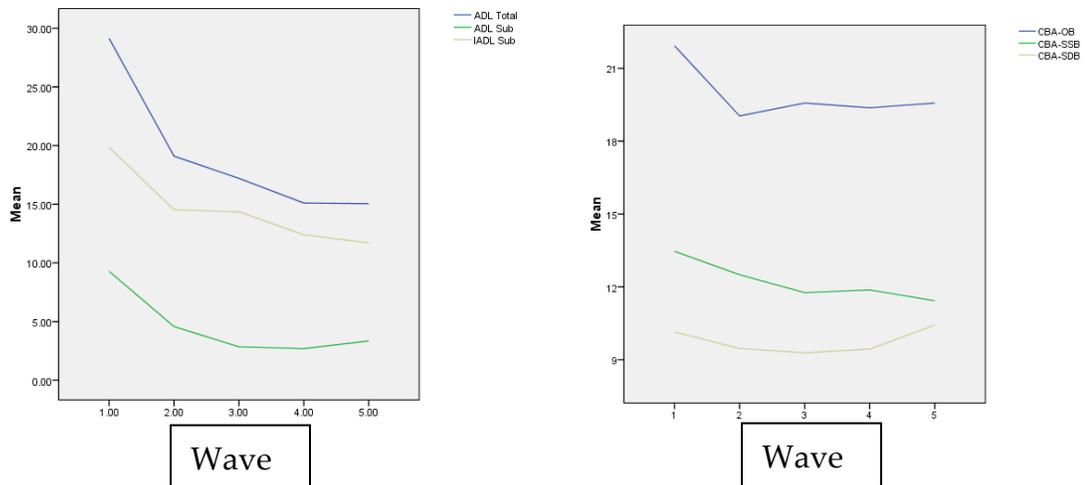
Measure	Loading on first principal component	Measure	Loading on first principal component
CII-TOT	.436		
CBA-DB	.460	CBA-DB	.53
CBA_OB	.521	CBA_OB	.55
CBA_SB	.571	CBA_SB	.64

Variance explained = 55%

Variance explained = 64%

Caregiver involvement, measured on the CII, decreased steadily and significantly over the course of the study. As graphically demonstrated, the reduction in caregiver involvement fell in both the ADL and the IADL realms (Figure 6). This finding was consistent with the anticipated reduction in dependence of the LVAD recipient as he/she recovered from surgery and rehabilitated from the impact of heart failure prior to device implant.

Figure 6: Trajectory of Caregiver Burden by CII Sub-scale and CBA Sub-scale



The CII results further demonstrated a large variation between subjects related to their degree of involvement in providing care to the LVAD recipient (Table 20, unconditional means model). The reduction in total caregiver involvement over time achieved significance with a slope of  $-3.8 \pm 1.2$ ,  $p = .003$  (Table 20).

A CBA composite score was constructed, weighting the values of the 3 subscales according to the results of the Principal Components Analysis. Caregiver burden measured by the CBA, also noted to vary significantly between subjects, was found to

Table 20: Activities of Daily Living Total

		Estimates (SE)	p-value
Unconditional means model	intercept	22.48(3.1)	
	Unexplained variance	610.69(103.58)	< .001
Unconditional growth model	Intercept	31.84(4.29)	
	Wave	-3.8(1.24)	.003
	Unexplained variance	578.65(97.8)	<.001

decrease over time although the trajectories were not as consistently, nor as deeply downward as those of the CII. The slope of the change in the composite score demonstrated a statistically significant reduction in caregiver burden over time (slope = -0.67,  $p = .04$ ) (Table 21). As was consistent with the caregiver involvement scale, the trajectory of this measure of caregiver burden also demonstrated the predicted downward slope over time. However, like the CII, time only partially explained the differences in measurements of burden over time. Thus, while the hypothesis is confirmed that burden decreased over time, time was not the only factor impacting caregiver burden.

Table 21: Caregiver Burden Composite Score

		Estimates (SE)	p-value
Unconditional means model	Intercept	25.0(.69)	
	Unexplained variance	34.3(5.0)	< .001
Unconditional growth model	Intercept	26.7(1.1)	
	Wave	-.67(.33)	.04
	Unexplained variance	33.2(4.8)	<.001

**Study Aim #3:** To determine the influence, if any, of the selected demographic variables on stress and perceived burden at each time point.

**Hypothesis #3:** Male gender, spousal relationship, higher level of education and higher income will be negatively associated with burden.

While both measures of caregiver burden demonstrated a reduction in perceived burden over time, there was no statistically significant relationship between those changes and caregiver gender, spousal relationship to the patient, caregiver education or family income. Assessing the change in CII that took place in individuals, only time demonstrated a significant association with change (slope -4.39,  $p = .007$ ) (Table 22).

In contrast, when considering the further explanation of the variation in individual burden measured by the composite CBA score against time and the same demographic factors, none played a significant role in the decrease in burden experienced by the caregiver. The fact that the level of burden described by the caregivers was overall below levels identified as benefiting from intervention may have had an impact on these results (Table 23).

Table 22: Caregiver Involvement Instrument

		Estimates (SE)	p-value
Unconditional means model	Intercept	22.48(3.1)	
	Unexplained variance	610.69(103.58)	< .001
Unconditional growth model	Intercept	31.84(4.29)	
	Wave	-3.8(1.24)	.003
	Unexplained variance	578.65(97.8)	<.001
Conditional growth model	Intercept	9.58(33.99)	
	Wave	-4.39(1.57)	.007
	Gender	11.9(15.6)	.45
	Spouse	2.28(12.2)	.85
	Caregiver Education	-.49(9.62)	.96
	Family Income	-4.18(9.4)	.66

Table 23: Caregiver Burden Assessment: Composite Score

		Estimates (SE)	p-value
Unconditional means model	Intercept	25.0(.69)	
	Unexplained variance	34.3(5.0)	< .001
Unconditional growth model	Intercept	26.7(1.1)	
	Wave	-.67(.33)	.04
	Unexplained variance	33.2(4.8)	<.001
Conditional growth model	Intercept	26.2(6.5)	
	Wave	-.59(.41)	.16
	Gender	1.37(2.95)	.65
	Spouse	-1.91(2.44)	.44
	Caregiver Education	-1.46(1.85)	.44
	Family Income	-.21(1.74)	.91

**Study Aim #4:** Burden and Quality of Life.

Four measures comprised the quality of life measure in this study: Cantril Ladder Scale, CES-D, SF-12 Physical Component Summary, and SF-12 Mental Component Summary. Again a Principal Components Analysis was performed to determine whether and which elements might be combined into a composite score to rate respondents' perceived quality of life. First, for purposes of this analysis, scores had to be recoded

since a higher score on CES-D reflects more symptoms and a worse quality of life, while higher scores on the Cantril Ladder, PCS-12 and MCS-12 indicate a better quality of life. The Cantril Ladder scores were reverse coded, so that a higher score indicated a worse quality of life. The PCS-12 and MCS-12 scores were recoded as the number of points below the normal value of 50, with a higher score indicating a worse quality of life. Results of the principal components analysis revealed that combining the CLS, CES-D, and MCS-12 would explain 76% of variance in quality of life, but that the SF-12 PCS should be considered separately (Table 24).

Table 24: Principal Components Analysis – Quality of Life

measure	Loading on first principal component	measure	Loading on first principal component
CLQ	.523	CLQ	.526
CES-D	.606	CES-D	.604
MCS-12	.599	MCS-12	.599
PCS-12	.002		

Variance explained = 57%

Variance explained = 76%

**Hypothesis #4a:** An increased level of quality of life will be negatively associated with stress and burden.

Mean scores for the three elements of the composite score (CLQ, CES-D, and MCS-12) were weighted using the loading values generated by the principal components analysis, then added together to create the quality of life composite score. While there was variance in the quality of life between subjects over the course of the study, time (wave) did not have a significant influence on the composite score. Further, the caregiver burden composite score and the caregiver involvement scale had no significant correlation with quality of life for participants. However, caregiver stress (CDS) was significantly, although weakly, associated with quality of life (slope = + 0.09, p= .004).

Keeping in mind the reverse scoring of the quality of life measures, this positive slope means that the higher the level of caregiver stress, the lower the quality of life.

Therefore, caregiver quality of life was negatively associated with caregiver stress as hypothesized, but was not correlated with time or caregiver burden (Table 24).

Analysis of the PCS, independent of the other components of quality of life, reflected significant variation between subjects, and time was significantly associated with a reduction in PCS-12 scores. However, in contrast with the other measures of quality of life, none of the measures of burden or stress demonstrated a significant correlation with the individual’s trajectory in PCS-12 over the course of the study (Table 25).

Table 25: Quality of Life Composite Score (CLQ, CES-D, and MCS-12), Time, Burden, and Stress

		Estimates (SE)	p-value
Unconditional means model	Intercept	20.8(.43)	
	Unexplained variance	12.8(1.65)	< .001
Unconditional growth model	Intercept	20.70(.76)	
	Wave	.09(.25)	.71
	Unexplained variance	17.22(2.0)	< .001
Conditional growth model	Intercept	18.3(1.69)	
	Wave	.21(.22)	.35
	CBA total	-.03(.07)	.72
	CII	.03(.02)	.08
	CDS total	.09(.03)	.004

**Hypothesis #4b:** Quality of life will vary over time, but will maintain the relationship with burden found in #4a.

Results of this study revealed a stable quality of life across the 5 sampling points. (Table 25, unconditional growth model, slope = 0.09, p= .71) While looking at mean scores there is some variation in the individual components, the differences are small.

Looking at the conditional growth model, there is significant variance in the quality of life of individuals but it is not the result of time (Table 25, by Wave,  $p = .35$ ). Analysis of the PCS-12 confirmed that, while a negative trend in this scale was revealed, there was no statistically significant influence in that aspect of quality of life by time, burden, caregiver involvement, or caregiver stress (Table 26).

Table 26: Quality of Life (PCS-12), Time, Burden, and Stress

		Estimates (SE)	p-value
Unconditional means model	Intercept	11.48(.88)	
	Unexplained variance	13.2(2.0)	< .001
Unconditional growth model	Intercept	12.6(1.09)	
	Wave	-.42(.23)	.07
	Unexplained variance	13.3(2.0),	< .001
Conditional growth model	Intercept	12.3(2.5)	
	Wave	-.35(.24)	.14
	CBA total	-.04(.10)	.71
	CII	.03(.02),	.19
	CDS total	.014(.05)	.78

As noted previously, caregiver burden measured by the CII and CBA, demonstrated significant reductions across time (Tables 22 and 23). That there was no significant change in quality of life associated with these measures, yet significant change in burden, reflected a disconnect between these two aspects of the caregivers' experience. Remembering that a higher score in CII reflected increased involvement, while a higher score in QOL demonstrated worse quality of life, the CII demonstrated a very weak trend toward significant negative association (slope 0.03,  $p = 0.08$ ).

This hypothesis was not supported by the data. Quality of life did not vary significantly (null hypothesis supported) while burden did. As a result, burden was not demonstrated to impact the trajectory of quality of life in this study.

In summary, hypotheses related to steadily decreasing caregiver burden and a negative correlation between stress and caregiver quality of life were supported in this study. However, demographic variables did not prove to have an influence on caregiver burden, nor was burden shown to have a correlation with caregiver quality of life.

## **Chapter 5:**

### **Discussion**

This study has provided the first longitudinal quantitative data on the experience of caregivers of patients with implanted left ventricular assist devices. The results have permitted characterization of caregiver stress, burden and quality of life and have provided insight into what caregivers face personally when they accept responsibility to care for individuals with LVADs.

In the majority of programs, adequate caregiver support is considered an important component in the evaluation and selection of patients to receive such devices (Lietz & Miller, 2004; Lietz & Miller, 2009). Understanding the burden and quality of life of caregivers of LVAD recipients is crucial for the health care team to be able to support those individuals over time. Such insight also can provide stimulus to develop an individualized plan to address the needs of caregivers either before the device is implanted or early in the post-implant period. This plan of care, focused on the caregiver, will assure that the LVAD patient has adequate support throughout the implant period in order to be able to experience the improved quantity and quality of life that is the promise of this therapy.

The results of this study clearly point to the importance of managing stress in the caregiver. Scores of the Caregiver Distress Scale revealed a mild to moderate degree of stress in the caregivers across the period of study. In addition, the caregivers' elevated stress and reduced quality of life were negatively correlated at a statistically significant level. While it is not possible to pinpoint the source of stress discovered in this study, such outcomes are consistent with the findings of other researchers in other populations

in which a higher life satisfaction was reported if, among other things, subjects appraised their role as a caregiver to be less stressful (Haley, LaMonde, Han, Burton, & Schonwetter, 2003). These observations are consistent with reports from caregivers of other populations that have found that the biggest impact of caregiving is increased social isolation (Cuellar & Butts, 1999; Levine, 1999).

Caregivers of patients with LVADs as bridge to transplant generally have an average expected end-point to the therapy of 9 months, the average wait time for a donor heart to become available, although nationally 11% of patients on the heart transplant waiting list wait more than 5 years (Organ Procurement and Transplantation Network (OPTN), 2011). Once the patient receives a heart transplant, the patient's needs will change, and the caregiver's anxieties surrounding potential problems with the LVAD will be ameliorated. In contrast, the caregiver of a patient with the device implanted as destination therapy has no such concrete end to device therapy. The results of this study did not demonstrate a difference in stress between the caregivers of bridge-to-transplant recipients and those of destination therapy patients. This finding may have been influenced by the small proportion of destination therapy caregivers (n=8, 17.4%) among the total sample.

To improve quality of life, strategies to reduce stress in caregivers must begin with adequate preparation of those who have accepted the caregiver role for LVAD patients. The Joint Commission's Disease Specific Certification (DSC) program for ventricular assist device centers emphasizes in its requirements for certification evidence that adequate information and education is provided to family members. The most recent guidelines go further to require documentation of the patient's (and caregiver's)

awareness of preoperative, intra-operative, and postoperative expectations as evidenced by the inclusion of these criteria on the signed consent form. The consent also must document that the patient and the providers jointly are in agreement about those expectations (The Joint Commission, 2011).

A second strategy to reduce stress is caregiver education before the LVAD recipient is discharged from the hospital. A frequently used measure of patient and caregiver satisfaction in the LVAD population is a survey to evaluate the effectiveness of pre-discharge teaching. These surveys ask the patient and caregiver to rate a series of statements on a 5-point Likert-type scale from “1 = Completely disagree” to “5 = completely agree.” Two important statements included in that survey are: “I have no general feeling of anxiety” and “The education provided to me helped with any fears that I might have had.” The most recent analysis of the results of that survey in the program from which the present study participants were derived (Table 25) demonstrated that anxiety remained higher in the patient (mean score = 4.0 on a scale of 1-5, with a lower score meaning increased anxiety) than in caregivers (mean score = 4.3 on the same scale). In addition, results reflected that the pre-discharge education was more effective in allaying fears of the caregivers (mean score = 4.6, on a scale of 1-5, higher score meaning more effective reducing fear) than in patients (mean score = 4.4 on the same scale). Thus, for caregivers it appears that education can have an impact on reducing anxiety and fear, components of stress (Source: Quality Data, UMMC LVAD Program, January, 2011).

Recently, expressive writing has been described as a third strategy to reduce caregiver stress (Dellasega & Haagen, 2004; Mackenzie, Wiprzycka, Hasher, &

Goldstein, 2007; Mackenzie, Wiprzycka, Hasher, & Goldstein, 2008; Mastel-Smith, McFarlane, Sierpina, Malecha, & Haile, 2007; Warner et al., 2006). In this therapeutic intervention, subjects were encouraged to write down their feelings as a means of reducing stress. Researchers in that study reported an improvement in both physical and mental health after the subjects participated in expressive writing. Although other investigators have concluded that the impact of expressive writing on stress was equivocal when they attempted replicate these earlier findings (Mackenzie et al., 2007), there remains potential that this type of intervention may be beneficial. Because LVAD caregivers often can live far from the implanting center, and because stress can wax and wane as demonstrated by the results of this study, developing an intervention that can meet caregiver needs wherever they are is important. Providing a therapeutic modality such as expressive writing does not require them to travel, does not involve using the telephone or require the use of a computer, does not expect them to speak openly in a large group about deep-seated feelings, and can provide them relief of their feelings of stress. Thus, it can be a valuable source of support and assistance that can be recommended by the health care team. Research into the benefits of this intervention as an approach to caregiver distress in order to improve quality of life in this special population is an important future direction.

### **Strengths and Limitations**

*Strengths.* There are several important strengths of this study. First, the discrete variables studied have been shown to have an influence on the ultimate dependent variables, burden and quality of life. Second, the longitudinal mixed methods applied to assess the trajectory of change provided important information about the caregivers'

stress, burden, and quality of life over time. This is in contradistinction to other studies that have provided single or two-point cross-sectional analyses, which, by their nature, provided a snapshot of the subjects at those points in time rather than a more comprehensive characterization. In addition, this model of analysis provided the opportunity to identify caregiver high and low points in the post-LVAD experience that can provide targeted time points for the health care team to design supportive interventions to enhance the success and quality of the caregivers' experience. Finally, because at least part of the subject pool was expected to drop out before the end of six months due to transplant of the care recipient, longitudinal mixed methods permitted inclusion of partial data sets in the analysis.

*Limitations.* The limitations of this study are related to several factors. First, as a single center study, the results may simply reflect the degree of effectiveness of the center from which the subjects were drawn at supporting caregiver quality of life, and therefore may not be generalizable to the LVAD population in other centers. Second, the convenience sample technique may have introduced bias to the outcomes that would have been avoided with a randomized subject selection. It is possible that those caregivers who were more burdened and had a different quality of life than those who agreed to participate self-selected themselves out of the study because of their perception that they were already excessively burdened. Third, although the study is longitudinal in nature, it only captured information at discrete points in time after study enrollment and may have missed variations at times between the data collection points or prior to the baseline data collection. Finally, the sample size was relatively small. Although the power analysis performed after the first 25 subjects appeared to be approaching adequate power with the

caregiver burden analysis, the increased sample size from 25 to 46 in the end did not provide adequate power to demonstrate the anticipated influence of caregiver burden on quality of life. Based on linear regression of the data derived from the first 25 subjects, a projected sample size of 68 would have been required to achieve statistical power for the CBA measure. Unbalanced sample size also may explain the lack of variation in caregiver stress between bridge-to-transplant and destination therapy indications for LVAD implantation. Finally, the small sample size limits the generalizability of these results to other populations.

### **Conclusions and Recommendations**

*Conclusions.* In conclusion, this research has demonstrated that caregivers experienced variable but elevated levels of stress. Over time they reported a consistent and significant reduction in burden. Their quality of life does not vary greatly over time, but was consistently measured as below normal in more than 75% of subjects at all time points measured. This finding revealed similarities between caring for someone with an LVAD and caring for someone with end-stage heart failure. However, with improvements in the patient's condition and increased independence, it was unexpected that the caregiver's quality of life did not improve as a consequence or that stress was not reduced. The only predictor of quality of life was found in a negative correlation between stress and quality of life. Stress, like quality of life, remained relatively unchanged across time periods, but was noted to be consistently elevated and to have a slightly negative trajectory over the course of the study. No association was identified between burden and stress, nor between burden and specified demographic variables.

*Recommendations for Practice.* Based on the outcomes of this research, it is evident that stress plays a significant role in the life of the caregiver once the LVAD patient is released from the hospital. Attending to ways to ameliorate that stress through classes, support groups, expressive writing, or other creative means bears promise in having a positive influence on the caregiver's quality of life over time. Pre-discharge education for patient and caregiver can provide some relief, but should not be held out as the only way to reduce stress.

As much as they might try to hide it, patients know their caregivers well. As a result, stress and reduced quality of life in the caregiver can cause similar feelings in the patient with the device. For the sake of both the caregiver and the patient, continued attention to reducing stress and increasing quality of life for the caregivers on whom so much responsibility is placed is important.

*Recommendations for Future Research.* Further research is needed to explore these and other variables that might predict the experience of the caregiver of LVAD patients. Given the important role that caregivers play in the long-term success experienced by the LVAD patient, research to identify additional factors impacting the caregiver's quality of life, potential points of intervention, and strategies to improve caregiver quality of life are warranted. Replication studies with larger sample sizes would allow confirmation of these findings and enhance the generalizability of the conclusions. Multi-institutional trials could eliminate the potential bias associated with the single center model used in this research.

In addition, based on these findings intervention trials are needed. Targeting the early post-discharge period with additional support and information, researchers will be

able to determine if those interventions help to reduce the stress and early burden reported in this study. Interventions targeted to improve quality of life, such as respite care, may improve the quality of life of caregivers.

Health care systems depend on family caregivers to provide extensive amounts of care to patients who no longer meet criteria to remain in an acute care or rehabilitative environment. By their behavior as much or more than by their words, caregivers communicate to the healthcare team the degree to which they experience joy as well as burden in providing care to loved ones with mechanical interventions to control their symptoms of end-stage heart failure. Health care team members must remain vigilant to the signals they receive, and identify ways to help caregivers in need. Without them, patient's survival may be at significant risk.

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