What are the effects of left ventricular assist device (LVAD) implantation on level of caregiver burden experienced by primary caregivers of patients with end-stage heart failure?

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A. Study Purpose and Rationale

Background

The prevalence of heart failure has been increasing, partially as a result of the aging population. Left ventricular assist devices (LVADs) were initially developed to address the shortage of available donor hearts for cardiac transplantation. The majority of mechanical circulatory devices have been implanted as "bridge to transplant" therapy, providing support to patients as they wait for cardiac transplantation. However, in 2003, LVAD therapy was expanded to also include the intent of long-term "destination therapy (DT)[1]." Under this course of treatment, patients who are not transplant eligible undergo LVAD implantation with the goal of improving and prolonging the remainder of their lives[2]. Recent advances in LVAD technology, such as the evolution from pulsatile to continuous flow pumps, have dramatically improved patient outcomes. The average 2-year survival among DT patients after LVAD implantation is now 62%, compared to 80% for patients 2 years after cardiac transplantation[1].

LVAD recipients typically return home after device implantation and recovery. Before discharge, the patient is expected to designate a primary caregiver who will assume care responsibilities and provide necessary support. Both patients and caregivers are taught the fundamentals of LVAD management prior to discharge[3]. However, this educational program primarily focuses on normal LVAD operation and troubleshooting strategies and does not significantly address quality of life implications and lifestyle adjustments for the primary caregiver[3,4]. Caregiver burden is a term used to describe the physical, psychological, emotional, social and financial toll experienced by caregivers of patients with chronic illness[5]. Despite the growing use of LVADs, there is little in the literature about the effects of device implantation on caregiver burden for the caregivers of LVAD patients.

Purpose

The purpose of this study is to determine whether LVAD therapy affects caregiver burden. The study will focus exclusively on patients undergoing LVAD implantation with a HeartMate II device as DT, since the caregivers of these patients are faced with the challenge of managing the LVAD for the duration of the recipient's life. It is hypothesized that caregiver burden may actually increase in the immediate post-implantation period, as patients extensively depend on their caregivers to assist with post-operative care and activities of daily living. However, as time progresses and the patient regains independence, it is secondarily hypothesized that caregiver burden will decrease.

B. Study Design and Statistical Analysis

This study is designed to be a prospective, longitudinal, single-center study that will take place at Columbia University Medical Center.

A list of all patients who have undergone LVAD evaluation at CUMC and were approved for a HeartMate II device as DT will be provided to a study coordinator. At the time of the LVAD patient's preoperative clinic visit, a study coordinator will identify and screen the LVAD patient's primary caregiver for inclusion in the study.

In order to be included in the study, caregivers must: 1) be at least 18 years old and 2) be the designated primary caregiver for a patient undergoing HeartMate II implantation as DT.

Caregiver burden will be assessed through administration of the Zarit Burden Interview (ZBI), a 22-question survey. The ZBI is an objective measure of caregiver burden that has been to shown to be highly reliable and valid in multiple diseases, languages, and across a wide range of cultural and geographic settings[6]. Each question in the ZBI is scored from 0 to 4, and degree of caregiver burden is determined by the cumulative score (range: 0 to 88). A score of 0-20 indicates little or no burden, 21-40 mild to moderate burden, 41-60 moderate to severe burden, and 61-88 severe burden. The ZBI will be administered to the primary caregiver via telephone a total of four times: 1) after the LVAD patient's pre-operative clinic visit but prior to LVAD implantation, 2) 3 months after implantation, 3) 6 months after implantation, and 4) 12 months after implantation. ZBI scores at each time period will be compared for each subject.

The data will be analyzed using a paired *t*-test where the ZBI scores of primary caregivers prior to LVAD implantation and after LVAD implantation (at each time point) will be compared. Assuming that a 10 point difference in ZBI score is clinically significant and assuming a standard deviation of the difference of 20, a total of 34 patients will need to be recruited (assuming $\alpha = .05$, $\beta = .20$).

Clinically Significant Mean Difference in ZBI Score: 10
Expected Variability in Difference: 40 (biggest pos. difference) – -40 (biggest neg. difference) = 80
Approximate Standard Deviation = 80 / 4 = 20

Sample Size Estimate: $n = 2 + 8(SD/effect)^2$

$n = 2 + 8(20/10)^2$

$n = 34$

C. Study Procedures
No procedures will be performed during this study.

D. Study Drugs
There will be no drugs used in this study.

E. Medical Device
There will be no medical devices in this study.

F. Study Questionnaires
The survey being used is the Zarit Burden Interview, a 22-question survey used to assess feelings of caregiver burden. The questions address common problems cited by caregivers, such as caregiver health, well-being, finances, social life, and relationship with the care recipient[7] (see Appendix 1).

G. Study Subjects
The study subjects will be designated primary caregivers of patients undergoing LVAD implantation as DT at New York-Presbyterian Hospital, Columbia University Medical Center. Subjects must be at least 18 years old to be included in the study.

H. Recruitment of Subjects
Subjects will be recruited by study coordinators during the LVAD patient's pre-operative clinic visit. Written consent will be obtained by all subjects prior to the initial administration of the Zarit Burden Interview.

I. Confidentiality of Study Data
Only the investigators will have access to the study materials. Data will be stored on an encrypted, password protected computer. A unique code will be generated for each subject and the code key will be kept on a password-encrypted computer accessible only to the conductors of the study. The code key will be destroyed 1 month after the completion of data analysis.

J. Potential Conflict of Interest
There are no potential conflicts of interest with this proposed study.

K. Location of the Study
The study will take place at New York-Presbyterian Hospital at its Columbia University Campus, located in New York, NY.

L. Potential Risks
Participation in the study will involve minimal risks. Personal health information will be de-identified and kept in a secure location. No patient will be asked to take any medication, be exposed to radiation, or partake in any form of physical activity as part of this research study. There is a theoretical risk in all studies that administer surveys meant to measure the presence or degree of a disease entity that the survey respondents may come to falsely identify themselves as having a disease because of the nature of the survey itself. Specifically with regards to this study, it is theoretically possible that caregivers who complete a Zarit Burden Interview questionnaire may falsely identify themselves as having a high degree of caregiver burden because of the survey process. This risk will be minimized by ensuring that the word "burden" is not used when administering surveys. Study coordinators will also provide a list of resources available to people with high caregiver burden.

M. Potential Benefits
It is unlikely that the subjects themselves will benefit directly from participation in the study. However, the results could potentially lead to a better understanding of how the experience of caregiving changes for the primary caregivers of patients underdoing LVAD implantation as DT. By identifying time periods of particularly high caregiver burden, this study can help primary caregivers receive support and resources when they need them most.

N. Alternative Therapies
This study does not involve an experimental therapy, thus no alternative therapies are available.

O. Compensation to Subjects
No compensation will be provided for the participants of this study.

P. Costs to Subjects
Subjects will incur no additional costs as a result of participating in the study.

Q. Minors as Subjects
This study will not involve minors.

R. Radiation or Radioactive Substances

No radiation or radioactive substances will be used.

References:

1. Kirklin JK, Naftel DC, Pagani FD, et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? *The Journal of Thoracic and Cardiovascular Surgery.* 2012;144(3):584-603.
2. Starling RC. Advanced heart failure: Transplantation, LVADs, and beyond. *Cleveland Clinic Journal of Medicine.* 2013;80(1):33-40.
3. Casida J. The lived experience of spouses of patients with a left ventricular assist device before heart transplantation. *American Journal of Critical Care.* 2005;14(2):145-151.
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5. George LK, Gwyther LP. Caregiver Well-Being: A Multidimensional Examination of Family Caregivers of Demented Adults. *The Gerontologist.* 1986;26(3):253-259.
6. Hébert R, Bravo G, Préville M. Reliability, validity and reference values of the Zarit Burden Interview for assessing informal caregivers of community-dwelling older persons with dementia. *Canadian Journal on Aging/La Revue canadienne du vieillissement.* 2000;19(04):494-507.
7. Arai Y, Hosokawa T, Washio M, Miura H, Hisamichi S. Reliability and validity of the Japanese version of the Zarit Caregiver Burden Interview. *Psychiatry and Clinical Neurosciences.* 1997;51(5):281-287.
8. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *The Gerontologist.* 1980;20(6):649-655.

Appendix:

1. The Zarit Burden Interview[8], adopted from http://www.rgpc.ca/best/GiiC%20Resources/GiiC/pdfs/3%20Caregiver%20Support%20-%20The%20Zarit%20Burden%20Interview.pdf

THE ZARIT BURDEN INTERVIEW

Please circle the response the best describes how you feel.

	Never	Rarely	Sometimes	Quite Frequently	Nearly Always	**Score**
1. Do you feel that your relative asks for more help than he/she needs?	0	1	2	3	4	
2. Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0	1	2	3	4	
3. Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0	1	2	3	4	
4. Do you feel embarrassed over your relative's behaviour?	0	1	2	3	4	
5. Do you feel angry when you are around your relative?	0	1	2	3	4	
6. Do you feel that your relative currently affects our relationships with other family members or friends in a negative way?	0	1	2	3	4	
7. Are you afraid what the future holds for your relative?	0	1	2	3	4	
8. Do you feel your relative is dependent on you?	0	1	2	3	4	
9. Do you feel strained when you are around your relative?	0	1	2	3	4	
10. Do you feel your health has suffered because of your involvement with your relative?	0	1	2	3	4	
11. Do you feel that you don't have as much privacy as you would like because of your relative?	0	1	2	3	4	
12. Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4	
13. Do you feel uncomfortable about having friends over because of your relative?	0	1	2	3	4	

14. Do you feel that your relative seems to expect you to take care of him/her as if you were the only one he/she could depend on?	0	1	2	3	4	
15. Do you feel that you don't have enough money to take care of your relative in addition to the rest of your expenses?	0	1	2	3	4	
16. Do you feel that you will be unable to take care of your relative much longer?	0	1	2	3	4	
17. Do you feel you have lost control of your life since your relative's illness?	0	1	2	3	4	
18. Do you wish you could leave the care of your relative to someone else?	0	1	2	3	4	
19. Do you feel uncertain about what to do about your relative?	0	1	2	3	4	
20. Do you feel you should be doing more for your relative?	0	1	2	3	4	
21. Do you feel you could do a better job in caring for your relative?	0	1	2	3	4	
22. Overall, how burdened do you feel in caring for your relative?	0	1	2	3	4	
Total Score (out of 88)						

Interpretation of Score:	
0 – 21	little or no burden
21 – 40	mild to moderate burden
41 – 60	moderate to severe burden
61 – 88	severe burden

Score values and interpretation are guidelines only, as discussed in:
Hebert R, Bravo G, and Preville M (2000). *Canadian J Aging* 19: 494-507.