



## Care of Patients With Heart Failure

## Patients' decision making process and expectations of a left ventricular assist device pre and post implantation



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## ARTICLE INFO

## Article history:

Received 1 January 2015  
Received in revised form  
10 December 2015  
Accepted 12 December 2015  
Available online 29 December 2015

## Keywords:

Heart failure  
Decision making  
Ventricular assist device  
Palliative care  
Qualitative  
Longitudinal

## ABSTRACT

**Objectives:** To examine patients' pre-implantation decision-making and pre and post-implantation expectations of left ventricular assist devices (LVADs).

**Background:** LVADs have been shown to improve both quantity and quality of life of patients living with Stage D heart failure (HF). However, they also pose significant risks.

**Methods:** 15 LVAD participants followed in a longitudinal study of Stage D HF patients were included in this thematic analysis.

**Results:** Three themes were identified: no choice; I thought I would be doing better; I feel good, but now what. Evidence from pre-implantation to post-implantation suggested that patients' perceived expectations of quality of life improvement were not met.

**Conclusions:** In light of their declining health, most patients felt their only alternative to implantation was death. In the post-implantation period, patients expected greater improvements in their quality of life. Evidence based guidelines for discussions of goals of care, post-implant expectations, and palliative care are necessary.

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## Introduction

Heart failure (HF) impacts nearly 6 million Americans with 10% of patients considered to be at an advanced stage of disease.<sup>1</sup> It is anticipated that the prevalence of HF will continue to rise with 8 million expected diagnoses by 2030.<sup>2</sup> Continued advances in patient management will increase the number of patients surviving to develop advanced Stage D HF. Currently, 5%–10% of all HF patients are classified as Stage D as defined by the presences of progressive, persistent signs and symptoms of HF despite optimal medical, surgical, or device management.<sup>3</sup> Heart transplantation is one of the most promising treatment options for Stage D HF patients, however organ scarcity has made heart transplantation an improbable treatment modality.<sup>4,5</sup> Moreover, many Stage D HF patients do not meet the minimum eligibility standards for

transplant.<sup>6</sup> Therefore, alternative strategies have been developed for the treatment of advanced HF including left ventricular assist devices (LVADs).

LVADs were originally developed as a bridge to transplantation (BTT) for patients awaiting heart transplant and are now being used as destination therapy (DT) for patients who are not transplant eligible due to advancing age and comorbidities.<sup>7</sup> As of 2014, LVAD implantations have reached almost 2500 per year with more than 40% of devices implanted as DT.<sup>7</sup> The main goals of LVAD implantation are to improve quality of life, improve survival, and help to decrease the number of inpatient hospital days experienced by chronic, advanced HF patients.<sup>5,7–9</sup> Currently, the one year survival rate after LVAD-DT implantation is 68% and the 2-year survival rate is 58% as compared to 10% (2-year) for those patients who forego implant and are medically managed.<sup>7</sup> Improvements in quality of life are seen at 3 months after implantation and remain stable through the duration of support for patients implanted for both BTT and DT.<sup>10</sup> Although the increase in quantity and quality of life are positive outcomes with LVADs, they also pose significant risks and burdens to patients. The majority of patients experience a major adverse event within 2 years of implantation including: disabling stroke, replacement of a failed or malfunctioning pump, and death.<sup>11</sup> Thrombosis, right ventricular failure, bleeding, life-threatening arrhythmias, infection, and frequent hospital

The authors have no conflicts of interest to disclose.

Funding: Research reported in this manuscript was supported by National Institute of Nursing Research of the National Institutes of Health under award number 1R01NR013419. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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readmissions are also common.<sup>12</sup> Advancing age and existing medical comorbidities are two of the primary reasons patients may be considered for LVADs; however, even after successful LVAD implantations, these patients still have progressive chronic illnesses and advancing age.<sup>11–15</sup> LVAD implantation often occurs during a period of rapid clinical decline and medical instability and in many cases consent is obtained on an emergent basis.

Little is known about the patient's decision-making process prior to LVAD implantation, expectations for the LVAD, and whether these expectations were met post-implantation. Recent studies indicate that most patients feel gratitude for receiving the LVAD as it has improved quality of life; however, they also report little recollection of the decision to implant due to their failing health at the time of the consent.<sup>16</sup> In addition, some patients have reported feeling they had little choice but to consent when facing the alternative of death; whereas others made unrushed, thoughtful decisions to implant.<sup>8</sup> The literature highlights a need for improved patient/provider conversations, prior to implantation, that ensure patient appreciation of risks, benefits, and burdens of LVAD implantation and outline realistic expectations post-implantation.<sup>16–18</sup> Palliative care involvement from the pre-implantation decision through the post-implantation is recommended and guidelines specific to mechanical circulatory support that provide well defined methods to engage patients in discussions regarding goals of care, values and preferences.<sup>19</sup> The decision to consent to LVAD implantation is complex given the considerable risks and burdens associated with implantation. Therefore, the purpose of this study was to examine the patient's pre-implantation decision-making process and expectations for the device both pre and post-implantation.

## Methods

### Study design

A longitudinal qualitative design using in-depth, semi structured interviews was used for data collection and analysis. A descriptive thematic analysis as described by Miles, Huberman, and Saldana was utilized.<sup>20</sup> Qualitative methodology was chosen in order to gain a comprehensive understanding of the pre-implantation decision-making process and post-implantation expectations and is appropriate due to the lack of existing data exploring this phenomenon. The longitudinal design with serial interviews was incorporated to examine the experiences of participants over time to better capture the evolving and dynamic experience.<sup>21</sup> The study was approved by the University's Institutional Review Board. Written informed consent was obtained from all participants upon enrollment. Participants were compensated for their time.

### Participant recruitment

This secondary analysis used semi-structured interviews from a longitudinal study of the palliative care needs of participants with Stage D HF, when the patient had a predicted survival of less than two years as determined using the Seattle Heart Failure Model<sup>22</sup> (NIH/NINR 1R01NR013419). Participants were interviewed individually monthly for up to two years or until the patient's death. A total of 15 participants had LVADs implanted and were included in this sub-analysis.

### Data collection

Initially, all LVAD participants were interviewed using the guide developed for the parent study. The monthly interviews all

included similar probes, but were framed to ask specific questions based on a patient's individual parameters. The probes for the LVAD recipients included questions related to the patient's perspective on the LVAD decision-making process prior to implant, and expectations for the LVAD pre- and post-implantation.

The interview guide was developed congruent with the longitudinal design of the study. The pre-LVAD interviews contained questions addressing: the decision-making process pre-implantation, the information provided by health care providers during the decision-making process including other treatment options, and the pre-implantation expectations of living with the LVAD. The follow-up interviews contained questions to capture the post-implantation experiences and the patient's future expectations of living with an LVAD. The initial interviews were 45–60 minutes in length and the monthly follow-up interviews averaged 15–20 minutes in length. Participants were followed on a monthly basis for two years or until death of the participant, whichever came first. Interviews were digitally recorded, professionally transcribed, de-identified, and verified for accuracy prior to analysis by the research team.

### Data analysis

A qualitative thematic approach was used for the analysis of the raw data.<sup>20</sup> The initial codebook was developed based on the domains addressed in the interview guide and was further refined throughout the analysis process incorporating both the initial domain codes and data driven codes. Independent coding of caregiver interviews was conducted by the research team consisting of the parent study's two PIs and two PhD students. An iterative process of coding followed by team analysis and data immersion occurred with the initial interviews and then with the follow-up interviews. The longitudinal data set was analyzed to provide a rich thematic description.<sup>23</sup> Findings were confirmed at a group analysis session using an iterative team-based approach. The research team concluded that thematic saturation was reached as additional interview data was consistent with existing data and no new themes emerged.

Several strategies were employed to ensure the trustworthiness of the data and subsequent findings throughout the analysis process. To assure dependability, an audit trail was documented during the team analysis sessions. Any discrepancies in coding were reviewed by the research team and discussed among the coders and investigators until a consensus was met. To assure credibility, the final codes and subsequent thematic description was agreed upon by all members of the multidisciplinary research team.

## Results

### Demographics

The study included 15 participants who received an LVAD (11 males and 4 females). The participants ranged in age from 39 to 75 years of age (mean 59) and were 93% white. The reason for LVAD implantation was for destination therapy ( $n = 5$ ) and as a bridge to transplant ( $n = 10$ ). All of the participants had an axial flow design LVAD implanted.

### Qualitative themes

Participants described in detail the decision-making process and provided rich descriptions of their post-implantation experiences and expectations in the follow-up interviews. Analysis revealed three consistent themes in both the DT and BTT participants. The main theme in the pre-implantation period was: *no choice*. The

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