

# Assessment of patients' and caregivers' informational and decisional needs for left ventricular assist device placement: Implications for informed consent and shared decision-making



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## KEYWORDS:

ventricular assist device;  
shared decision making;  
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caregivers

**BACKGROUND:** Several organizations have underscored the crucial need for patient-centered decision tools to enhance shared decision-making in advanced heart failure. The purpose of this study was to investigate the decision-making process and informational and decisional needs of patients and their caregivers regarding left ventricular assist device (LVAD) placement.

**METHODS:** In-depth, structured interviews with LVAD patients, candidates and caregivers (spouse, family members) ( $n = 45$ ) were conducted. We also administered a Decisional Regret Scale.

**RESULTS:** Participants reported LVAD decision-making to be quick and reflexive ( $n = 30$ ), and deferred heavily to clinicians ( $n = 22$ ). They did not perceive themselves as having a real choice ( $n = 28$ ). The 2 most prevalent informational domains that participants identified were lifestyle issues (23 items), followed by technical (drive-line, battery) issues (14 items). Participants easily and clearly identified their values: life extension; family; and mobility. Participants reported the need to meet other patients and caregivers before device placement ( $n = 31$ ), and to have an involved caregiver ( $n = 28$ ) to synthesize information. Some participants demonstrated a lack of clarity regarding transplant probability: 9 of 15 patients described themselves as on a transplant trajectory, yet 7 of these were destination therapy patients. Finally, we found that decisional regret scores were low (1.307).

**CONCLUSIONS:** Informed consent and shared-decision making should: (a) help patients offered highly invasive technologies for life-threatening disease get past the initial "anything to avoid thinking about death" reaction and make a more informed decision; (b) clarify transplant status; and (c) focus on lifestyle and technical issues, as patients have the most informational needs in these domains.

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Several organizations, including the American Heart Association, have recently underscored the crucial need for timely and patient-centered decision tools to enhance shared decision-making in advanced heart failure.<sup>1</sup> This observation stems from a recognition that such tools can help

proactively match treatment choices with patients' values, goals and preferences and, by logical extension, limit unwanted treatment. We responded to these calls by working with the Patient-Centered Outcomes Research Institute to develop a decision aid for LVAD placement according to process-steps set by the International Patient Decision Aid Standards Collaboration.<sup>2</sup> As part of this development, we investigated the decision-making process and informational and decisional needs of patients and their families regarding LVAD placement. The objectives of this study were to explore perceptions of: (a) the decision and options; (b) knowledge, expectations and gaps; (c) values and values clarity; and (d) needs for other support and resources.

Important recent work has been done to understand the decision-making process for LVAD placement. For example, McIlvennan et al studied 22 LVAD patients and found that half described a reflective, reasoned process, and half described an automatic decision-making process, driven by fear of death.<sup>3</sup> Swetz et al studied the attitudes of 12 LVAD patients after placement and found that most felt like they had "no choice" regarding placement, but also found post-placement themes involving feelings of a new lease on life, views on the importance of a support network, and the importance of talking to other patients living with LVADs.<sup>4</sup> Our study sought to build on and expand existing work by: (a) studying the views of candidates prospectively (those in the middle of decision-making about placement) and their caregivers (families, spouses, etc., involved in decision-making and care of LVAD patients) in addition to patients who already have an LVAD; and (b) studying what patients' specific educational, informational and decisional needs are in addition to studying their decisional processes and post-placement attitudes to inform an enhanced, patient-centered consent process.

## Methods

### Framework

The Ottawa Decision Support Framework guided our needs assessment. The Ottawa Framework is a leading framework for the study of decision-making quality, which stresses that decisional needs affect decision quality (informed, values based), which impacts behavior (e.g., delay), health outcomes, emotions (e.g., regret) and appropriate use of resources.<sup>5,6</sup> Within this framework, needs assessment is meant to identify what a patient population needs to make better decisions and what health practitioners need to improve the support they provide to patients during decision-making.<sup>7</sup> Possible decisional needs include addressing deficits in knowledge and expectations, decisional conflict, values clarity and support and resources. Decision support tools, such as patient decision aids, can be developed to address these needs.<sup>8</sup>

### Study design

Mixed methods were used to assess informational and decisional needs of LVAD candidates and their families using in-depth, structured interviews and survey instruments with LVAD patients, candidates and caregivers. The study was approved by the

institutional review boards of Baylor College of Medicine and the Houston Methodist Research Institute. Subjects were compensated for their interview time with a \$25 gift card.

### Sampling and recruitment

Criteria for participant eligibility included: LVAD patients who had made the decision themselves about LVAD implantation; LVAD candidates who had received education about the LVAD and were in the process of making a decision; and caregivers (family or significant-others) of LVAD patients. Eligible candidates were defined as New York Heart Association (NYHA) Class III and IV patients, 30 to 80 years old and alert with decision-making capacity (as determined by the Aid to Capacity Evaluation [ACE]), with an acceptable surgical risk/benefit ratio for LVAD implantation (meaning the likelihood of achieving the benefits of device therapy, such as quality of life and projected survival improvement, outweighed the projected risks, such as early post-operative risk of dying, multiple-organ failure and failure to thrive on LVAD therapy, as determined by a multidisciplinary medical review board) and with good psychosocial support, coping mechanisms and financial resources, as determined by administration of the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) from the transplant social worker.

We utilized theoretical sampling, which involves purposeful sampling in order to reflect representativeness of the LVAD population, while also obtaining a wide distribution of cases and experiences. Our sample included subjects across a wide distribution of age, ethnicity, socioeconomic status, gender, amount of time post-LVAD and sickness (Table 1).

Participants were recruited through patient rosters distributed once a week by the LVAD/program coordinator. All patients were asked before being referred whether they would be willing to talk with us and, if yes, their names were included on the roster. Participants were then approached before or during their appointments at the LVAD clinic or in the hospital without interfering with clinic flow, and consent was obtained. When patients and caregivers were not readily available, we obtained each subject's consent and contact information to conduct interviews by phone, although this was rare (only 5 of the 45 interviews were conducted by phone).

### Data collection

Structured interview guides were developed from researchers' prior knowledge of domains and areas of interest, literature review and expert opinion (see Appendix available on the [www.jhltonline.org](http://www.jhltonline.org) Web site). Domains included: perceptions of options, outcomes and probabilities; values in decision-making; degree of decision-making difficulty and factors contributing to difficulty; usual and preferred decision-making roles; and decisional barriers and facilitators. All domains and question items were reviewed by clinical experts. A technique called "progressive focusing" was used whereby interview questions were modified iteratively throughout the process of data collection, so that question items with diminishing informational returns were gradually replaced by questions eliciting new information from patient narratives.<sup>9</sup>

The structured in-depth interviews (total  $n = 45$ ) were conducted in person ( $n = 40$ ) or by phone ( $n = 5$ ), depending on participant preference, from March 2014 to August 2014, including patient candidates for LVAD treatment ( $n = 15$ ), patients currently with LVADs ( $n = 15$ ) and caregivers of patients with LVADs ( $n = 15$ ). We identified 1 interviewer from our research

**Table 1** Characteristics of Sample: LVAD Patients, Candidates and Caregivers

Characteristic	LVAD candidates (n = 15)	LVAD patients <sup>a</sup> (n = 15)	LVAD caregivers <sup>b</sup> (n = 15)	Overall (n = 45)
Mean age (range), in years	54 (35–74)	60 (33 – 74)	59 (36–74)	58 (33–74)
Male	13 (87%)	11 (73%)	5 (33%)	29 (64%)
Female	2 (13%)	4 (27%)	10 (67%)	16 (36%)
Ethnicity				
White	6 (40%)	7 (47%)	9 (60%)	22 (49%)
Black	3 (20%)	6 (40%)	5 (33%)	14 (31%)
Hispanic	6 (40%)	2 (13%)	1 (7%)	9 (20%)
Reason for LVAD				
Bridge to transplant	NA	2 (13%)	1 (7%) <sup>d</sup>	3 (10%) <sup>c</sup>
Destination therapy	NA	13 (87%)	14 (93%) <sup>d</sup>	27 (90%) <sup>c</sup>
Hospital status				
Inpatient	14 (93%)	6 (40%)	4 (27%) <sup>d</sup>	24 (53%)
Outpatient	1 (7%)	9 (60%)	11 (73%) <sup>d</sup>	21 (47%)
Mean length of time (range) with LVAD, in days	Not implanted	539 (16–1,894)	634 <sup>d</sup> (range 50–1,845)	586 <sup>c</sup> (16–1,894)
Mean monthly household income (range)	\$3,171 (\$423–10,833)	\$2,383 (\$528–7,916)	\$2,600 <sup>d</sup> (range \$961–6,250)	\$2,730 (\$423–\$10,833)

LVAD, left ventricular assist device; NA, not applicable.

<sup>a</sup>All 15 patients received a HeartMate II continuous-flow LVAD.

<sup>b</sup>The term “caregiver” corresponds to the patient’s spouse or family member, which primarily supports the patient.

<sup>c</sup>n = 30.

<sup>d</sup>Designates characteristic of LVAD patients supported by caregivers.

team as the primary interviewer who trained the other interviewers for consistency. None were members of the clinical team so bias was avoided. Interviews lasted from 12 to 87 minutes, with an average interview time of 35 minutes, during which patients replied to structured interview questions based on the domains previously described and were asked to list their informational needs (“key questions”) regarding LVAD placement. Demographic information was also collected. All interviews were digitally tape-recorded, professionally transcribed verbatim and double-checked for accuracy.<sup>10</sup>

We also administered a validated 5-item, 5-point Likert Decisional Regret Scale used to assess distress or remorse after a health-care decision (1 to 5 scale where 1 indicates no decisional regret). The scale has a Cronbach’s  $\alpha$  ranging from 0.81 to 0.92.<sup>11</sup>

## Data analysis

We used the well-established grounded theory method to identify and evaluate decisional needs among our sample.<sup>12</sup> Grounded theory involves inductively identifying themes that are “grounded in” or based on recurring statements (i.e., “quotations”) in data from participants. In our case, “themes” constituted salient decisional needs among patients receiving LVAD treatment and their caregivers.

Interview transcripts were uploaded and analyzed using ATLAS.ti (<http://www.atlasti.com/index.html>),<sup>13</sup> a commonly used computer-assisted qualitative data analysis (CAQDAS) program. ATLAS.ti provides a software platform to analyze qualitative interview transcripts through a systematic process of coding, documentation, analysis and interpretation. The program can accommodate various analytical approaches, including grounded theory. The program allows for the progressive abstraction of themes from raw data using “quotations” (segments of text identified as potentially important), “comments” (spaces for attaching observations and reflections to specific quotations) and “memos” (spaces for making global reflections on a range of

quotations across interviews). Our analytical process involved developing a codebook collaboratively through discussions between our research team and providers of LVAD treatment, including cardiologists and surgeons, nurses, program coordinators and hospital financial advisors. Consensus about code meanings was reached, and codes were organized by the previously noted domains based on key aspects of decision-making and experiences related to LVAD treatment. Next, code assignments to preliminary transcripts were made independently by members of the research team and later compared and discussed until consensus on coding styles was reached. The process of coding involved the identification of participants’ decisional needs, including any mention of values, circumstances, psychosocial factors and preferences, or any other information related to decision-making about treatment options. All coding for the remainder of the interviews was conducted independently by members of the research team and later merged for analysis.

This process of analysis resulted in a non-redundant list of decisional needs identified from patient and caregiver interviews. Frequencies were then calculated to identify high-priority needs. Counting frequencies from qualitative data allows researchers to assess how often qualitative phenomena occur and whether any systematic variation exists across a sample of participants.<sup>14</sup>

## Results

### Sample characteristics

We interviewed a total of 45 participants, including 15 patients, 15 candidates and 15 family or significant-other caregivers. Four pairs of patient–caregiver interviews exist in our data set. Our sample approximated larger demographic trends among LVAD patients and candidates, including distribution of subgroups by: gender (80% male, 20% female); age (mean 58 years); hospital status (53%

inpatient, 47% outpatient); length of time with LVAD (range 16 to 1,894 days); monthly household income (range \$423 to \$10,833); and ethnic subgroups, including 31% African American, 20% Hispanic/Latino and 49% Caucasian. See [Table 1](#) for details of sample characteristics.

## Main themes from interviews

*Theme 1: There was no decision to make.* The major theme identified in participants' perception of the decision and options was that the majority of participants did believe that they or their loved one really had a "decision" to make (patients,  $n = 11$ ; candidates,  $n = 10$ ; caregivers,  $n = 7$ ). They felt as if they did not have any viable options because the alternative was likely death. One patient said, "I am either going to die or we are going to put in a pump. It was a very easy decision based on where I was because there was no other alternative." Another said, "At first I didn't want it. But after I weighed the alternatives, it was either this or the ground. That means it's a no brainer. You either want to live or you don't."

*Theme 2: Decisions were reflexive, made without deliberation.* Participants reported that their decision-making process was mostly reflexive, devoid of heavy deliberation and discussion (patients,  $n = 13$ ; candidates,  $n = 10$ ; caregivers,  $n = 7$ ). In rare cases where patients heard about the LVAD option earlier and medical management was still an option, they preferred to postpone the decision until they absolutely had to.

*Theme 3: Decisions were based on trust in physician.* Participants expressed a high level of trust in and deferral to their physicians and did not do independent research outside of what their physician told them (patients,  $n = 9$ ; candidates,  $n = 10$ ; caregivers,  $n = 3$ ). One caregiver (spouse) said, "They said that the LVAD is probably the best way to go. And I trust these doctors with his life. And when they said that, that's what we decided. I didn't really ask for statistics. I just went with what they said. They said it would work, so I trusted them." Regarding Themes 1 to 3, there was a slight trend for caregivers to be less deferential to the physician and more deliberative about the decision they were making (or had made) with their loved one compared with the patients or candidates themselves.

*Theme 4: Optimistic expectations regarding transplant.* Of our 15 patient interviews, 9 patients indicated that they believed that they were on the bridge-to-transplant (BTT) trajectory, but 7 of these patients were on a trajectory of destination therapy (DT). One of these patients, whose trajectory was DT, said, "You've got to remember that it's a bridge for the transplant. Maybe not with all of them, but in my case it is." Another patient with DT trajectory said, "DT extends your life expectancy enough to get you back until you pass on. Right now, I need something else. I'm pretty comfortable with the LVAD to bridge to transplant." Of our 15 candidate interviews, 10 indicated that they believed that they were on the BTT trajectory.

Despite some patients believing their destination was transplant even though it is unlikely, or uncertain, many

(patients,  $n = 3$ ; candidates,  $n = 10$ ) indicated that they would still have chosen or would choose the LVAD even if transplant were not an option, and many were comfortable with the uncertainty involved. When asked if he would still move forward if transplant were not an option, one candidate said, "Yeah, I would have no choice because of the fact of how bad my heart is, because if not, I want to at least extend my life expectancy." A few (patients,  $n = 6$ ; candidates,  $n = 3$ ) even indicated that they would prefer to stay with the LVAD if possible, but believe they will probably eventually need a transplant, and believe they will get one. One patient said, "With this LVAD it's just a pump. You've got your same heart. I wish—to be honest with you—I could just keep that."

*Theme 5: Values are clear, include life extension, family and mobility.* We found a high level of values clarity in our participants. The majority of patients easily identified what was important to them (patients,  $n = 12$ ; candidates,  $n = 13$ ). They wanted to live longer—especially for family members—spouses, children and grandchildren (patients,  $n = 10$ ; candidates,  $n = 14$ ), and regain mobility and engagement in the world (patients,  $n = 7$ ; candidates,  $n = 13$ ), which for some meant going to the grocery store and to others meant travel and cruises. One candidate said he wanted, "A better lifestyle, to spend more time with my kids, get out the house more, vacations. Do a vacation. Just normal activity where I can extend a little bit and not be so tired all the time. As long as I see my kids grow up, go to college, have kids and get married, just the basic life experiences with them, I'm happy." Similarly, one said, "[My son] supports the idea: 'Yeah, dad. You know you need it. Why fight it? Get it done and stick around longer because, remember, you've got your granddaughter.' That's my main goal—see her graduate high school. She's only 4 right now." One candidate emphasized the importance of regaining some mobility, "Well, if it does all that they say it does, I can clean my own apartment for one thing—which I can't really do now because I run out of breath. I don't want to be a burden on anybody."

*Theme 6: A need to hear from other patients and caregivers.* Participants (patients,  $n = 12$ ; candidates,  $n = 14$ ; caregivers,  $n = 5$ ) reported that they needed an LVAD community of patients and caregivers who they could see and talk to—to "hear others' stories" during the decision-making process and after the LVAD is implanted if they choose in favor of it. One patient said that the chance to talk to another LVAD patient helped him more than anything. He also said, "I'd like to see a chat room. I would like to build on the idea of this clinic we have. We sit around the waiting room, but if we had available discussion rooms and somebody to lead a discussion for different phases of that, I think that would be very helpful to learn, because every one of us is having different experiences with this."

*Theme 7: A need for an involved and supportive clinical team and caregiver.* Participants reported the need for a supportive, informed and prepared caregiver who could help receive, remember and translate information (patients,  $n = 10$ ; candidates,  $n = 11$ ; caregivers,  $n = 7$ ), and a readily available clinical team who they could call whenever

for even minor questions (patients,  $n = 6$ ; candidates,  $n = 4$ ; caregivers,  $n = 6$ ). One caregiver stressed the importance of being involved from an informational (not just caregiving) point of view, "I have been through so many things with my husband, and I write everything down, and I research. You see this book [referring to book of notes]? It's too important. That's my husband's life." One patient said, "The doctor would say stuff and I would hear what I thought the doctor said. But me hearing it and then trying to tell her [my wife]—I'm telling her what I thought I heard. So, by the time it gets back around to the doctor, he's confused and we're all confused." Caregivers, candidates and patients all talked about the importance of the LVAD team. One caregiver said, "I don't—I don't hesitate anymore, since the first infection, to call [the VAD coordinator] or to send pictures. They become part of your family almost. To know that all I have to do is pick up the phone. It kind of gives you piece of mind." Another said, "I bought some breakfast blend juice that had cranberries in it. I was concerned. They said no cranberry juice, so I called the emergency line. Then I had some concerns because they upped her speed on the pump. Why does it say 9,200? I'm getting on the phone to see what's going on."

### Participant-generated list of informational needs

Many of our participants (patients,  $n = 6$ ; candidates,  $n = 8$ ; caregivers,  $n = 10$ ) believed that they were well informed about the risks, benefits and challenges of LVADs. When asked specifically about what they wanted to know about when they were considering and preparing for LVAD placement, they provided us with an extensive list of knowledge needs (Table 2). The knowledge needs fell into 8 domains: lifestyle; rehospitalization; complications; prognosis (with and without LVAD); technical (drive-line, battery); the surgery experience; financial; and caregiver lifestyle. Although caregivers and patients/candidates had many of the same knowledge needs, caregivers had specific informational needs regarding their lifestyle and responsibilities (see "Caregiver lifestyle" domain in Table 2).

### Decisional regret scores

We found low levels of decisional regret, indicating that most participants made decisions that were consistent with their values (Table 3). Regret did not seem to be different for those patients further out from LVAD placement compared with others, or between caregivers and patients. The average decisional regret score was 1.307 for patients and 1.477 for caregivers (on a 1 to 5 scale, where 1 indicates no decisional regret).

### Discussion

In this study we have used qualitative methods supplemented by questionnaires to explore the information needs of LVAD patients, candidates and their caregivers regarding decision-making about placement of the device. One of our

most salient findings is that, in many ways, LVAD candidates conceptualize the decision-making process for LVAD placement differently than researchers and clinicians. They seem to *prefer shared information exchanges to help them prepare rather than help them make a decision, as many feel that the decision has already been made*. This finding is in accordance with what other researchers have found as well.<sup>1,2</sup> Toward that end, they want help imagining what life with an LVAD would be like for them and their family—what psychologists refer to as help with "affective forecasting." Our study found evidence that caregivers may be more likely to encourage more deliberation and information-seeking than the actual patients or candidates themselves.

Related to the first finding, patients' self-expressed knowledge needs may be different than clinicians' views on LVAD candidate knowledge needs. Although clinicians may focus more narrowly on providing information about possible adverse events such as death, infection, bleeding or other complications, *patient-reported knowledge needs centered much more on lifestyle issues, particularly mobility, along with technical issues about the device* (Table 2).

A third finding with major implications for the informed consent process involves the role of the caregiver (spouse, family members). *Caregiver-interviewees considered it a moral imperative to fully inform them about what their responsibilities might be, how their daily lives might be interrupted, and when the transitioning period would end (e.g., when they could return to work)*. Moreover, a number of patients seemed to value a supportive, informed and prepared caregiver who could help receive, remember and translate information, indicating that supportive networks are an emotional and informational need just as much as an actual physical need. Thus, our findings are consistent with recent observations that highlight the importance of caregiver resources and support,<sup>15-19</sup> but also go beyond them in that they stress the importance of the involvement of the caregiver in the decision-making process.

A final key finding from our study is that most patients, including destination therapy patients, believed that they would eventually get a transplant, even where it is unlikely. Here, we introduce a new term, "destination mythical transplant," to denote the awkwardness in patients recognizing that they are "currently listed" as LVAD-DT, while still hoping and fully expecting that they would be candidates for transplant at some point, despite the reality that, of the 5,408 patients followed during the period from January 2012 to March 2014, only 876 (16%) had received a transplant by the end of that time frame ([www.intermacs.org](http://www.intermacs.org)).<sup>20</sup> Although we did not formally investigate the reasons for this phenomenon, we do not believe that it is necessarily primarily due to a lack of communication or transparency on the physicians' part. In fact, all patients receive a formal letter communicating their status as DT or BTT. Potential causes may be optimism bias on the part of patients, various team members giving hope to patients that they may be re-evaluated and become BTT (which is possible, but may not be probable for many patients who may nonetheless anchor on that hope), and patients hearing stories from other LVAD

**Table 2** Patient-centered LVAD Knowledge Needs

<b>Lifestyle</b>	
Mobility (44%)	Diet (19%)
Spending time with family and friends (40%)	Driving (14%)
Overall feeling of well-being/quality of life (35%)	Changes in work life (14%)
Maintaining activities and hobbies (gardening, golfing, cooking) (33%)	Sleep disruptions (12%)
Psychosocial/cognitive improvements (30%)	Alleviate suffering (12%)
Overall activity restrictions (28%)	Airport security (9%)
Independence and control (28%)	Feeling "normal" (9%)
Medication regimes (type, frequency) (28%)	Drinking alcohol (7%)
Travel (26%)	Improved coordination/energy/reflexes (7%)
Prospect of being a burden (23%)	Exercise (7%)
Water activities (swimming, fishing) (21%)	Volunteering (2%)
	Sex life (1%)
<b>Rehospitalization</b>	
Transportation challenges (16%)	
Frequency of rehospitalization (12%)	
Quality of care during rehospitalization (7%)	Adverse events during rehospitalization (5%)
Chances of rehospitalization due to drive-line dysfunction (5%)	Average duration of rehospitalization (2%)
<b>Complications</b>	
Infections (average number, type, frequency, consequences) (30%)	
Bleeding (gastrointestinal or other) (19%)	Heart attack (5%)
Effects of comorbidities on complications (16%)	Risks (general) (5%)
What to do in an emergency (9%)	Effect of VAD on transplant chances (2%)
<b>Prognosis (with and without LVAD)</b>	
Effect of age on outcomes (19%)	Probability of getting a transplant with comorbidities (obesity, alcohol use, resolved pulmonary hypertension, recent malignancy, reversible organ dysfunction) (7%)
Life expectancy without VAD (16%)	"Window of opportunity" for LVAD (5%)
Comparison of VAD to transplant (12%)	Life expectancy without LVAD (2%)
Possibility of heart repairing itself from VAD (9%)	Recovery time after implantation (2%)
Length of LVAD treatment (7%)	Longest possible duration of LVAD survival (2%)
Re-implantation (frequency, likelihood) (7%)	Effects on transplant eligibility (2%)
Probability of transplant (7%)	
Possibility of heart continuing to beat if LVAD stops (7%)	
<b>Technical (drive-line, battery)</b>	
Effort needed for care of drive-line (33%)	Difference in VAD from pacemaker and other heart devices (7%)
Difficulty/burden of carrying battery pack (28%)	Lack of confidence in LVAD technology (7%)
Description of device (appearance, function, mechanism) (21%)	Pain/discomfort from drive-line (5%)
Weight of battery pack (16%)	Whether LVAD shocks patient (5%)
Method of wearing battery pack (14%)	
Everyday appearance of battery pack to others (14%)	
Process of changing batteries (14%)	
Effort needed for care of battery pack (14%)	
Frequency of battery change (12%)	
Negative image/stigma of LVAD (12%)	
<b>Surgery</b>	
Probability of death (23%)	Suffering (14%)
Pain during/after (14%)	Rehabilitation after (12%)
Probability of stroke (14%)	Pain before (2%)
<b>Financial</b>	
Out-of-pocket cost (including medicines, co-pays, dressings, gas) (21%)	Disability insurance (7%)
Insurance coverage (21%)	Hospital bills (5%)
	Possible financial scenarios (2%)
<b>Caregiver lifestyle</b>	
Degree of impact and involvement, quality of Life (28%)	Methods to encourage independence (16%)
Risks of leaving patient alone (21%)	Daily responsibilities (e.g., dressing change) (12%)
Changes in work life (19%)	

LVAD, left ventricular assist device.

**Table 3** Decisional Regret Scores by Number (%) of LVAD Patients and Candidates

DRS items <sup>a</sup>	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
LVAD patients ( <i>n</i> = 15)					
1. It was the right choice	10 (66.7)	4 (26.7)	1 (6.7)	0	0
2. I regret the choice that was made	0	0	1 (6.7)	3 (20.0)	11 (73.3)
3. I would make the same choice if I had to do it over again	12 (80.0)	3 (20.0)	0	0	0
4. The choice did me a lot of harm	0	0	0	3 (20.0)	12 (80.0)
5. The decision was a wise one	11 (73.3)	2 (13.3)	2 (13.3)	0	0
Average decisional regret: 1.307 (SD = 0.483) <sup>b</sup>					
LVAD caregivers ( <i>n</i> = 13) <sup>c</sup>					
1. It was the right choice	10 (76.9)	2 (15.4)	1 (7.7)	0	0
2. I regret the choice that was made	0	1 (7.7)	1 (7.7)	1 (7.7)	10 (76.9)
3. I would make the same choice if I had to do it over again	9 (69.2)	1 (7.7)	3 (23.1)	0	0
4. The choice did me a lot of harm	0	1 (7.7)	2 (15.4)	2 (15.4)	8 (61.5)
5. The decision was a wise one	10 (76.9)	1 (7.7)	2 (15.4)	0	0
Average decisional regret: 1.477 (SD = 0.777) <sup>c</sup>					

DRS, Decisional Regret Scale; LVAD, left ventricular assist device; SD, standard deviation.

<sup>a</sup>DRS items were completed by subjects after the following statement was read to them: "Please think about the decision you (or your loved one) made about VAD placement after talking to your (his/her) clinical team."

<sup>b</sup>1 = lowest decisional regret, 5 = highest decisional regret.

<sup>c</sup>Two of our 15 LVAD caregivers declined to complete the DRS.

patients (in the clinic or online) resulting in the hope of transplant being a strong theme. One way to counter this misalignment is to carve out "decision points" as the case progresses for the purpose of revisiting the likelihood or unlikelihood of transplant with the patient. A multidisciplinary team assessment should occur at defined intervals to assess transplant candidacy—even where it is unlikely—to help reinforce the likelihood or unlikelihood of transplant with the patient and family, allowing for greater decisional transparency. This should help foster an alignment of expectations between clinicians and surrogate decision-makers or patients.<sup>21</sup>

There are limitations to this study that are associated with qualitative methodologies, including a possibility that some decisional needs were not discussed due to perceived stigma of some personal concerns (e.g., impacts of LVAD on sexual or psychological functioning) or to the fact that interviews were sometimes conducted in hospital settings prone to interruption. Efforts were made to encourage patients to convey their full repertoire of decisional needs. An additional limitation is that this was a single-site study. A third limitation is that only 2 patients were LVAD-BTT, which some may argue makes this a study about the informational and decisional needs of LVAD-DT patients only. However, a total of 19 patients and candidates in our sample perceived themselves to be LVAD-BTT (see Theme 4), making our findings in this study generalizable beyond just LVAD-DT patients. We did not find marked differences between the 2 groups. Finally, although we found low decisional regret scores about LVAD placement, and this is in concordance with the findings of other studies,<sup>1</sup> these results should be interpreted with caution. Persons could have cognitive dissonance around admitting regret when making life-and-death decisions of this magnitude.

## Conclusions and implications for practice

Informed consent and shared decision-making with LVAD patients should help patients offered highly invasive technologies for life-threatening disease get past the initial "anything to avoid thinking about death" reaction and make a more informed decision. Decision support tools such as decision aids are ideal in this regard. Our team has developed and alpha-tested such a tool, which can be found at <http://lvaddecisionaid.com>. Second, a patient-centered process will focus on lifestyle and technical issues (for both the patient and the caregiver), as patients have the most informational and decisional needs in these domains. Interactions with existing LVAD patients and caregivers who are willing to discuss both the benefits and challenges of life with an LVAD would be particularly helpful, and guidelines exist for patient-to-patient encounters.<sup>22,23</sup> This is not to say that risks (of the surgery, of complications, of rehospitalization) and prognosis are not important, but it is to say that they are potentially secondary in patients' decision-making processes. Finally, transplant probability in particular should be transparently communicated to patients and revisited regularly.

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## Supplementary data

Supplementary data associated with this article can be found in the online version at [www.jhltonline.org](http://www.jhltonline.org)

## References

- Allen LA, Stevenson LW, Grady KL, et al. Decision making in advanced heart failure: a scientific statement from the American Heart Association. *Circulation* 2012;125:1928-52.
- Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 2006;333:417.
- McIlvennan CK, Allen LA, Nowels C, et al. Decision making for destination therapy left ventricular assist devices: "there was no choice" versus "I thought about it an awful lot.". *Circ Cardiovasc Qual Outcomes* 2014;7:374-80.
- Swetz KM, Ottenberg AL, Cook KE, et al. The choice for patients "without a choice": interviews with patients who received a left ventricular assist device as destination therapy. *J Card Fail* 2012;18 (suppl):S43.
- O'Connor AM, Drake ER, Fiset V, et al. The Ottawa patient decision aids. *Eff Clin Pract* 1999;2:163-70.
- O'Connor AM, Tugwell P, Wells GA, et al. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Counsel* 1998;33:267-79.
- Jacobsen MJ, O'Connor AM, Stacey D. Decisional needs assessment in populations 1999 [updated 2013]. Ottawa: University of Ottawa. [https://decisionaid.ohri.ca/docs/Implement/Population\\_Needs.pdf/](https://decisionaid.ohri.ca/docs/Implement/Population_Needs.pdf/). Accessed May 29, 2015.
- Stacey D, Légaré F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 20141.
- Polkinghorne DE. Language and meaning: data collection in qualitative research. *J Counsel Psychol* 2005;52:137.
- Brod M, Tesler LE, Christensen TL. Qualitative research and content validity: developing best practices based on science and experience. *Qual Life Res* 2009;18:1263-78.
- Brehaut JC, O'Connor AM, Wood TJ, et al. Validation of a decision regret scale. *Med Decis Making* 2003;23:281-92.
- Strauss A, Corbin JM. Basics of qualitative research: grounded theory procedures and techniques. New York: Sage Publications; 1990.
- Muhr T, Friese S. User's manual for ATLAS.ti 5.0. Berlin: ATLAS.ti Scientific Software Development; 2004.
- Bazeley P. Analysing qualitative data: more than 'identifying themes'. *Malaysian J Qual Res* 2009;2:6-22.
- Feldman D, Pamboukian SV, Teuteberg JJ, et al. The 2013 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support: executive summary. *J Heart Lung Transplant* 2013;32:157-87.
- Kaan A, Young Q, Cockell S, et al. Emotional experiences of caregivers of patients with a ventricular assist device. *Progr Transplant* 2010;20:142-7.
- Marcuccilli L, Casida JM. From insiders' perspectives: adjusting to caregiving for patients with left ventricular assist devices. *Progr Transplant* 2011;21:137-43.
- Bunzel B, Laederach-Hofmann K, Wieselthaler G, et al. Mechanical circulatory support as a bridge to heart transplantation: what remains? Long-term emotional sequelae in patients and spouses. *J Heart Lung Transplant* 2007;26:384-9.
- Bunzel B, Laederach-Hofmann K, Wieselthaler G, et al. Posttraumatic stress disorder after implantation of a mechanical assist device followed by heart transplantation: evaluation of patients and partners. *Transplant Proc* 2005;37:1365-8.
- Kirklin JK, Naftel DC, Myers SL, et al. Interagency Registry for Mechanically Assisted Circulatory Support. Quarterly statistical report, 2nd quarter. Birmingham, AL: INTERMACS; 31.
- Bruce CR, Smith ML, McCullough LB. Clarification of the intent of ventricular assist devices before patient consent. *J Thorac Cardiovasc Surg* 2013;145:A1-32.
- Bekker HL, Winterbottom AE, Butow P, et al. Do personal stories make patient decision aids more effective? A critical review of theory and evidence. *BMC Med Inform Decision Making* 2013;13(suppl 2): S9.
- Bruce CR, Majumder MA, Loebe M. Patient-to-patient encounters: benefits and challenges. *J Heart Lung Transplant* 2013;32:658-9.