Decision Making for Destination Therapy Left Ventricular Assist Devices

“There Was No Choice” Versus “I Thought About It an Awful Lot”

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Background—Destination therapy left ventricular assist devices (DT LVADs) are one of the most invasive medical interventions for end-stage illness. How patients decide whether or not to proceed with device implantation is unknown. We aimed to understand the decision-making processes of patients who either accept or decline DT LVADs.

Methods and Results—Between October 2012 and September 2013, we conducted semistructured, in-depth interviews to understand patients’ decision-making experiences. Data were analyzed using a mixed inductive and deductive approach. Twenty-two eligible patients were interviewed, 15 with DT LVADs and 7 who declined. We found a strong dichotomy between decision processes with some patients (11 accepters) being automatic and others (3 accepters, 7 decliners) being reflective in their approach to decision making. The automatic group was characterized by a fear of dying and an overriding desire to live as long as possible: “[LVAD] was the only option I had…that or push up daisies…so I automatically took this.” By contrast, the reflective group went through a reasoned process of weighing risks, benefits, and burdens: “There are worse things than death.” Irrespective of approach, most patients experienced the DT LVAD decision as a highly emotional process and many sought support from their families or spiritually.

Conclusions—Some patients offered a DT LVAD face the decision by reflecting on a process and reasoning through risks and benefits. For others, the desire to live supersedes such reflective processing. Acknowledging this difference is important when considering how to support patients who are faced with this complex decision. (Circ Cardiovasc Qual Outcomes. 2014;7:374-380.)

Key Words: destination therapy ▪ heart-assist devices ▪ heart failure ▪ patient-centered care

The marvels of modern medicine include an increasing array of aggressive interventions that can improve the quantity and even the quality of life for patients who are dying of progressive illness. One such therapy that is becoming increasingly mainstream is the left ventricular assist device (LVAD) for people with advanced heart failure. This therapy, initially developed as a bridge to transplantation for people who were awaiting a heart, is now being used in the much larger population of patients who are ineligible for transplantation. This so-called destination therapy (DT) promises to grow, with an estimated 150,000 to 250,000 patients annually who may potentially be eligible.1

Patients offered a destination therapy left ventricular assist device (DT LVAD) are faced with a choice involving complex trade-offs. For DT LVAD eligible patients who forego this therapy, the 2-year survival is dismal at ≤10%;2 in comparison, 2-year survival after DT LVAD implantation is 58% and heart failure quality of life measures improve by an average by 178% for those surviving the initial recovery.3 Yet, these striking benefits come with a host of risks and burdens. The majority of patients experience a major adverse event within 2 years, including reoperation to replace a malfunctioning pump (10%), disabling stroke (11%), and death (33%).4 Device infection, bleeding, and recurrent hospitalizations are common. Additional burdens include maintaining a constant electric power source, driveline care, costs, and precautions while traveling and bathing. These burdens are borne by patients and caregivers alike. Finally, the most common reasons that patients are ineligible for heart transplantation, and are thus offered a DT LVAD, are advanced age and medical comorbidity.4 Consequently, even after successful DT LVAD implantation, many patients will be left with chronic illness and progressive frailty.5 In short, pursuing a DT LVAD is a complicated decision with the potential for both significant benefits and significant risks and burdens.
WHAT IS KNOWN

• The decision to pursue a destination therapy left ventricular assist device is difficult and complex.

WHAT THE STUDY ADDS

• Patients considering destination therapy left ventricular assist devices seem to have a strong dichotomy in how they approached their decision. Some patients were automatic, focusing on fear of dying and an over-riding desire to live as long as possible. Other patients were reflective, weighing risks, benefits, and burdens as they made their decision.

• Irrespective of approach, most patients experience the destination therapy left ventricular assist device decision as a highly emotional process and many seek support from their families or spiritually.

• Acknowledging this difference in decision-making processes is important when considering how to support patients who are faced with this complex decision.

When making complex medical decisions, one prevailing opinion in the field of decision science argues that if people are able to go through a more effortful, reasoned, and reflective process when making decisions, they will be more likely to make an informed choice consistent with their values. Whether this holds true, particularly among patients with severe illness, is an area of some debate. Currently, no published studies exist exploring how patients considering DT LVAD approach this difficult decision. In this qualitative study, we aimed to understand the decision-making processes of patients who either accept or decline DT LVADs.

Methods

Study Design
We conducted a qualitative study using in-depth, semistructured interviews with patients who were eligible for or had a DT LVAD. A qualitative study design was chosen to gain a comprehensive understanding of a patient’s decisional process surrounding the DT LVAD decision and was especially appropriate given the lack of existing data on the topic. The study was approved by the institutional review board at the University of Colorado. Written or verbal informed consent was obtained from all study participants. Participants were compensated $25 for their time.

Sampling and Recruitment
Patients previously offered a DT LVAD and currently followed at the University of Colorado were eligible for the study, including (1) those currently living with an implanted DT LVAD and (2) those who had been offered but declined a DT LVAD. We used cross-sectional sampling of all patients who had gone through DT LVAD decision making and continued purposeful sampling to reach thematic saturation among decliners. The principal investigator (C.M.) directly recruited patients using her established clinical relationships. We excluded patients who were evaluated but ultimately deemed ineligible for DT LVADs, patients initially implanted as a bridge to transplantation, and those who could not provide informed consent. All eligible patients during the study period agreed to participate, and interviews were conducted until thematic saturation was met.

Data Collection
In-depth, semistructured interviews were conducted by C.M. and C.N. in-person or by phone with each of the study participants from October 2012 through September 2013. The principal investigator (C.M.) is a practicing nurse practitioner on the inpatient heart failure service. To avoid bias and coercion related to her clinical relationships, every effort was made to have C.N., who did not have a clinical relationship with the patients, perform the interviews. However, several of the decliners were interviewed by C.M. due to the limited time frame many of them had between the time they declined the DT LVAD and when they transitioned to comfort care. Consistent with study goals and established qualitative research methods, these in-depth, semistructured interviews used broad, open-ended questions to elicit personal thoughts and experiences regarding decision making surrounding DT LVADs. Two question guides were developed (1) for patients who accepted a DT LVAD and (2) for patients who declined a DT LVAD (Supplemental Methods 1 in Data Supplement). The question guides were based on the Ottawa Decision Support Framework. This framework states that participants’ decisional needs (eg, knowledge, values, and support) will affect the decision quality—informed, value-concordant decisions. This impacts subsequent outcomes such as emotions, regret, blame, and behavior. Domains addressed in the interview guide include factors involved in the decision-making process, assessment of clinician interaction, expectations of living with the DT LVAD and unexpected outcomes, future decisions, consideration of alternatives, as well as degree of satisfaction with the decision. The interviews were digitally recorded, professionally transcribed, and reviewed for accuracy.

Patients also completed a short survey with demographic questions, the control preferences scale, and the decision regret scale. Acknowledging this difference in decision-making processes is important when considering how to support patients who are faced with this complex decision.

Qualitative Analysis
Transcripts were entered into ATLAS.ti 7.0 software, and data were analyzed using a mixed inductive and deductive approach. We began with a process of exploring each transcript for the language and phrases used by participants to describe their decision-making experiences. To develop a codebook, D.M. and C.N. each coded a subset of interviews separately. Through an iterative, multidisciplinary team-based process, we reviewed and discussed the codes to ensure their completeness and contextual validity. We developed the final codebook incorporating both data-derived codes and formal domain codes defined a priori consistent with our mixed inductive and deductive approach. Open coding, concomitant with team discussion and data reimmersion, was followed by axial coding in which we established links between the a priori and in vivo codes to provide a conceptual and thematic description. Subsequently, C.N. coded the remainder of the interviews. Confirming and disconfirming cases were discussed until consensus was reached. The entire study team—determined thematic saturation was reached as additional interview data created little or no change to the codebook and no new patterns or themes emerged.

We used several strategies to assure trustworthiness of the findings. To assure dependability, an audit trail was kept by C.N. during the analytic phase of the project. To assure transferability, we have attempted to describe our sample in adequate detail so that others can determine how their populations compare. To assure credibility and confirmability, we triangulated our findings using a multidisciplinary study team, consisting of 2 advanced heart failure and transplant cardiologists (L.A. and A.B.), a heart failure nurse practitioner (C.M.), a geriatric and palliative care physician (D.M.), a cardiothoracic surgeon (J.C.), and a qualitative expert (C.N.). Throughout the data analysis, this team met to discuss the analytic process and emergent themes. Additionally, themes were presented to a cardiac health services research group and a palliative care research group to seek input regarding trustworthiness.
Results

Overview

We interviewed 22 patients who had gone through DT LVAD decision making: 15 who had been implanted with DT LVAD and 7 who had declined. Duration of interviews ranged from 21 to 86 minutes (mean=47 minutes). The average age of patients was 67 years. One patient was a woman and 1 patient was implanted at another center. The time from implant or declination to interview ranged from 90 to 1847 days among accepters and 1 to 93 days among decliners. Only 2 patients with DT LVADs endorsed any decision regret on the decision regret scale, with scores of 20 and 45 on a 100-point scale. All but one patient desired an active role in decision making based on the control preferences scale. Additional summary statistics are provided in Table 1.

Table 1. Patient Characteristics at Time of Interview

<table>
<thead>
<tr>
<th>Decision on DT LVAD</th>
<th>Automatic (n=11)</th>
<th>Reflective (n=10)</th>
<th>Other (n=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decline, n</td>
<td>...</td>
<td>7</td>
<td>...</td>
</tr>
<tr>
<td>Accept, n</td>
<td>11</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>HeartMate II device, n</td>
<td>9</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Redo device (&gt;1 implant), n</td>
<td>...</td>
<td>1</td>
<td>...</td>
</tr>
<tr>
<td>Decliners: Time from declination to interview in days, median (range)</td>
<td>...</td>
<td>13 (1–93)</td>
<td>...</td>
</tr>
<tr>
<td>Accepters: Time from implant to interview in days, median (range)</td>
<td>579 (241–1847)</td>
<td>262 (217–1249)</td>
<td>90</td>
</tr>
</tbody>
</table>

Demographics

<table>
<thead>
<tr>
<th></th>
<th>Automatic (n=11)</th>
<th>Reflective (n=10)</th>
<th>Other (n=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, median (range)</td>
<td>65 (59–76)</td>
<td>70 (56–82)</td>
<td>66</td>
</tr>
<tr>
<td>Woman, n</td>
<td>...</td>
<td>1 (10.0%)</td>
<td>...</td>
</tr>
<tr>
<td>Nonwhite, n</td>
<td>2 (18.1%)</td>
<td>2 (20.0%)</td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Married, n</td>
<td>9 (81.8%)</td>
<td>5 (50.0%)</td>
<td>...</td>
</tr>
<tr>
<td>Divorced</td>
<td>1 (9.1%)</td>
<td>3 (30.0%)</td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>...</td>
<td>1 (10.0%)</td>
<td>...</td>
</tr>
<tr>
<td>Single/never married</td>
<td>...</td>
<td>1 (10.0%)</td>
<td>...</td>
</tr>
<tr>
<td>Eighth grade or less, n</td>
<td>1 (9.1%)</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Some high school</td>
<td>2 (18.1%)</td>
<td>2 (20.0%)</td>
<td>...</td>
</tr>
<tr>
<td>High school graduate/GED</td>
<td>3 (27.2%)</td>
<td>3 (30.0%)</td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Some college</td>
<td>5 (45.5%)</td>
<td>1 (10.0%)</td>
<td>...</td>
</tr>
<tr>
<td>4-year college graduate</td>
<td>...</td>
<td>3 (30.0%)</td>
<td>...</td>
</tr>
<tr>
<td>More than a 4-year degree</td>
<td>...</td>
<td>1 (10.0%)</td>
<td>...</td>
</tr>
</tbody>
</table>

Morbidities

| Ischemic heart disease (history of MI or coronary revascularization), n | 7 (63.6%) | 7 (70.0%) | 1 (100%) |
| Post-LVAD complications* | ... | ... | ... |
| Device infection          | 6 (54.5%) | ... | ... |
| CVA (post-LVAD)           | 2 (18.1%) | 1 (10.0%) | ... |
| Bleeding (post-LVAD)      | 6 (54.5%) | 1 (10.0%) | ... |

Decision characteristics

| Preferred role (general) | Active=5 | Active=3 | Unable to provide |
| Passive=0 | Passive=0 |
| Preferred role (LVAD)   | Active=7 | Active=4 | Unable to provide |
| Passive=1 | Passive=0 |
| Decision regret (score 0=no regret to 100=high regret), median (range) | 0 (0–45) | 0 (0–30) | Unable to provide |

CVA indicates cerebrovascular accident; DT LVAD, destination therapy left ventricular assist device; GED, general education development; and MI, myocardial infarction.

*Decliners are excluded from post-LVAD complications.
It was obvious from the data that patients considering a DT LVAD had reached their decisions differently. Although this was not an a priori dichotomization, nearly all patients clearly fell into 1 of 2 decision-making approaches: (1) an automatic process of decision making where fear of death and a singular focus on DT LVAD as a chance to prolong life over-rode any weighing of additional risks and benefits and (2) a reflective process where participants reasoned through risks and benefits of DT LVAD therapy and were able to see death in the context of other possible future DT LVAD outcomes. Only one patient’s approach did not clearly fit into either category, largely based on his inability to focus during the interview. Although not statistically significant, there were differences between the automatic and reflective patients. The automatic group was younger (mean=65), they had a mean educational level of a high school graduate, and all but one was married (n=9). By contrast, the reflective group was older (mean=70), they had a higher educational level (mean=4-year college graduate), and only half were married (n=5).

Regardless of their decision-making approach, the process was a highly emotional experience for all participants. Below, we outline salient features of the 2 types of decision processes that emerged from our data as well as describe secondary influences on DT LVAD decision making.

### Dominant Decision Processes: “There Was No Choice” Versus “I Thought About It an Awful Lot”

We found a clear difference in the primary way that patients approached the decision of DT LVAD. Those who seemed to use an automatic decision process had a different decision-making experience than those who seemed to use a reflective decision process. Table 2 includes descriptive exemplars for each type of decision-making process.

Patients who seemed to use an automatic decision process did not view DT LVAD implantation as a choice (n=11; 11 accepters). These patients discussed valuing life above any other considerations, including risks of the procedure or burdens of living with the device. Multiple patients in this category talked about having “no choice” but to receive the DT LVAD to ‘live, not die,” or not “push up daisies.” All were accepters, essentially by definition, because declining a DT LVAD was antithetical to the over-riding goal of this decision.

### Table 2. Decision Process Exemplars

<table>
<thead>
<tr>
<th>Automatic Decision Process (n=11; All Accepters)</th>
<th>Reflective Decision Process (n=10; 3 Accepters, 7 Decliners)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death not seen as an option</strong></td>
<td><strong>Death viewed as an option</strong></td>
</tr>
<tr>
<td>I was willing to do anything they told me I had to do to get better (Accepter 01; &gt;1 y since implant)</td>
<td>…and it was a hard choice. It wasn’t an easy choice for me to make. But then I started focusing on my life. On myself. You know, what could go wrong? If I get the LVAD and I live, if I don’t get it I die. So I have to focus on that. Do I choose to live? Or do I choose to die? And if I died while I was getting it, would that make a difference?...so I fumbled with that for a little while before I made the decision to do it (Accepter 03; &lt;1 y since implant)</td>
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<tr>
<td>(When asked about the pros and cons of the decision) No. No. Didn’t even think twice about it…when they told me that…you couldn’t take a transplant and this was the only option I had, you know? That or push up daisies you know? So I automatically took this (Accepter 09; &gt;1 y since implant)</td>
<td>…I don’t know if the pump would keep me alive. And even if it does, I’m not sure it would be worth living. Cause I’m not one of those persons who is going to claw and hold on to the wall to stay alive. I have absolutely no fear of death (Decliner 03; &lt;1 mo since declination)</td>
</tr>
<tr>
<td><strong>Risks not considered</strong></td>
<td><strong>Weighing of risks</strong></td>
</tr>
<tr>
<td>The risk of the procedure? I didn’t really ask him any…’cause I really didn’t care. I was going to do it and that was it. Regardless of the risk (Accepter 05; &gt;1 y since implant)</td>
<td>So I was like on the fence. I would say that if I don’t do it, if I do it. If I don’t do it, then what’s going to happen? …if I do it and I have a stroke problem getting it done…or right after, or whatever. A bleed or…precautions to getting it. And then I said “Well, if I get it, I could live a good life you know, for maybe another 3 or 4 y” (Accepter 03; &lt;1 y since implant)</td>
</tr>
<tr>
<td>…what I wanted to hear was just the living and not the bad things and the dying…at the time… (Accepter 13; &gt;1 y since implant)</td>
<td>You have to carry these batteries around. You have this thing implanted and you have to be careful even about showers and stuff like that. It uh…it is not the same quality of life (Decliner 03; &lt;1 mo since declination)</td>
</tr>
<tr>
<td><strong>Emotion: fear</strong></td>
<td><strong>Emotion: sadness, melancholy</strong></td>
</tr>
<tr>
<td>Like I said, I had too many things I wanted to live for yet. And it was the emotional part. And I knew what was going to happen if I didn’t do something (Accepter 04; &lt;1 y since implant)</td>
<td>The hard part is leaving my family. I still cry over that (starts to cry) So we can’t talk about that. That’s the hard part…is the family (Decliner 04; &gt;1 mo since declination)</td>
</tr>
<tr>
<td>I didn’t want to die, basically… I’ll do anything. I don’t want to die (Accepter 13; &gt;1 y since implant)</td>
<td>…I just said, when it’s my time I’m ready. (starting to choke up…cry). I mean I know what’s on the other side. So it doesn’t bother me (Decliner 02; &lt;1 mo since declination)</td>
</tr>
</tbody>
</table>
| I’m not scared of it [death]. I’m tired of this…being in pain and suffering and stuff (Decliner 01; <1 mo since declination) |}
approach. Although not directly using the words scared or afraid, for many, their fear of dying was palpable during the interviews. Some patients told us that they did not want to know about the risks of a DT LVAD because they had decided to move forward with implantation and did not want to hear negative aspects of a therapy that they “had to have.”

By contrast, patients who seemed to use a reflective decision process had a different experience (n=10; 3 accepters, 7 decliners). These patients viewed death as an option worthy of consideration, examined the meaning of their lives, and reflected on their values, particularly around quality versus quantity of life preferences. Even the 3 reflective patients who ultimately accepted the DT LVAD acknowledged the risks involved and the potential trade-off of choosing life with a potentially risky and burdensome device. Those who declined generally indicated that death was an acceptable alternative to continuing or prolonging a life of pain and suffering, with many saying that they “don’t fear death.”

Questions around future discontinuation of DT LVAD therapy reinforced this dichotomous decision-making approach. All 3 reflective patients with DT LVADs were able to consider device deactivation in the context of quality of life. For example, when asked if quality of life were low, 1 patient responded: “By all means, I [would] want the LVAD to be turned off.” This was in stark contrast to automatic patients, who were either more tentative in their responses about device deactivation or absolutely would not consider it: “Unless somebody shoots me and I’m bleeding to death…and nobody is coming to help….other than that, I don’t intend to turn it off at any time.”

Importantly, for all patients, emotion was apparent in their decision-making process. Both automatic and reflective patients became emotional and even shed tears during their interviews when recalling the decision-making time period.

### Secondary Influences
Several other factors seemed to color patients’ DT LVAD decision-making process: severe illness, relationships, spirituality, finances, clinician bias, and media influences. Table 3 includes descriptive exemplars for each secondary influence.

#### Severe Illness
Some patients described themselves as “drugged up” or “confused” while in intensive care units prior to and during their decision, creating a less than optimal decision-making situation.

#### Relationships
Many patients viewed their families and friends as the most important factor in choosing to receive a DT LVAD. Some patients desired to be with family longer before death. For both accepters and decliners, several patients’ families did not agree with their decisions creating tension within relationships.

#### Spirituality
Many of the patients indicated that spirituality played a role in their decision, from prayers for guidance and protection to church friends’ support, or talking with a pastor or spiritual leader about past behaviors.

#### Finances
Most patients told us their insurance covered or would cover nearly all expenses related to DT LVAD, and consequently, cost was minor or absent in their decision-making process. A few, however, indicated that they were concerned about related expenses that would create a financial burden.

#### Clinician Bias
Several patients mentioned awareness of the clinicians’ preferences that they accept the DT LVAD therapy. Others commented how clinicians’ framing of the therapy, including comparison to larger devices no longer in use, helped make the device seem more acceptable.

### Table 3. Secondary Influences Exemplar Quotes

<table>
<thead>
<tr>
<th>Secondary Influences</th>
<th>Exemplar Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Illness</td>
<td>I don’t remember much of it, cause they had me drugged up pretty well (Accepter 07; &gt;1 y since implant) Learning all I’ve learned (about the LVAD), and with my sickness I’ll probably have a rougher time, so I decided I don’t think I want to do this (Decliner 07; &lt;1 y since declination)</td>
</tr>
<tr>
<td>Relationships</td>
<td>My major thought was not really for me. I was ready to die. My major thought was what is going to happen to my family? (Accepter 07; &gt;1 y since implant) (about great-granddaughter) She’s just 4 yr old and we’ve had her since she was several days old and I’m her Papa and she just goes crazy when I’m not there…. So I would have it done again no matter what. Mainly because of her (Accepter 09; &gt;1 y since implant)</td>
</tr>
<tr>
<td>Spirituality</td>
<td>I just said “God you’re in charge. Do what you do.” So they decided to put an LVAD in me (Accepter 11; &lt;1 y since implant) In the last 6 mo or so I’ve learned to accept my mortality. It isn’t easy but it’s facing everyone in the face every day. And I wouldn’t say it’s made me more religious, maybe more spiritual (Decliner 05; &gt;1 y since declination)</td>
</tr>
<tr>
<td>Finances</td>
<td>…I was wondering how was I going to pay for this? And the co-pays and everything and it’s like…when they wanted to send me to rehab I couldn’t afford to go. And then I went to rehab here as an outpatient and it’s very expensive to me (Accepter 03; &lt;1 y since implant)</td>
</tr>
<tr>
<td>Clinician bias</td>
<td>I says, “You know, what are my alternatives?” And he says “Well, the device will improve your quality of life for what you know it. Or you might not have one [life].” (Accepter 07; &gt;1 y since implant) …when they showed me it, I did kind of take a second breath, “Cause I didn’t expect it to be that big… but then they showed me the old style one… how big it was…. and I’m sure glad I didn’t have to get that!” (Accepter 05; &gt;1 y since implant)</td>
</tr>
<tr>
<td>Media</td>
<td>They (the LVAD team) basically, right there at the end, were trying to shove it down my throat (Decliner 04; &gt;1 mo since declination) …it wasn’t really a deciding factor…. but I found out that Vice-President Cheney had an LVAD in him and he had it for 12 y before he had a heart transplant…that is a pretty good indication there that it would work (Accepter 04; &lt;1 y since implant)</td>
</tr>
</tbody>
</table>
The Cheney effect seemed to have a sizeable impact on patients’ decisions to accept the DT LVAD. Although we heard misinformation from patients about former Vice-President Cheney’s LVAD, many conveyed a sense of security because Mr Cheney seemed to have done well.

**Discussion**

Arguably, DT LVAD is one of the most invasive therapies available in modern medicine. Patients going through this decision process have reached the terminal stage of a chronic progressive illness where they are effectively faced with the decision to live out the remainder of their life dependent on mechanical circulatory support or transition to comfort care. We found that patients considering a DT LVAD diverged sharply in their decision-making processes. Some patients, both accepters and decliners, described going through a reflective decision process involving cognitive weighing of risks and benefits and a consideration of both quality and quantity of life. By contrast, other patients went through an automatic decision process where they never really perceived there to be a decision. They viewed DT LVAD implantation as the only reasonable choice because all other considerations were over-ridden by the central desire to live as long as possible. This group exhibited a strong fear of death. Consequently, other considerations, such as the risks of the procedure and the potential burdens on quality of life, were not important to these patients.

To improve decision making for patients with end-stage chronic disease, much work remains to be done. Currently, no published literature exists summarizing the process that patients go through when considering a DT LVAD. More importantly, there is a scarcity of literature on how people make decisions around any major procedure for advanced heart failure (eg, implantable cardioverter-defibrillators and transcatheter aortic valve replacement) and also for other noncardiac terminal diseases (eg, mechanical ventilation for progressive lung disease and chemotherapy for metastatic cancer). Our study demonstrates that for many people, major interventions designed to delay impending death appeal directly to their primary desire for self-preservation and help alleviate their fear of death. This is so strong that many patients do not necessarily wish to know the extent to which the DT LVAD actually accomplishes this stated goal. This is discordant with the current paradigm for informed consent for LVAD, which requires that patients understand the risks of therapy and are offered a description of reasonable alternatives. Interestingly, few patients—regardless of decision-making process—discussed statistical risks or benefits when recalling their experience. Although information is essential for informed consent and helpful to some patients, our results show that cognitive weighing of theoretical risks and benefits played a secondary role in most of the patients’ decision-making process. To truly support patients making life-and-death decisions, such as with DT LVAD, one must acknowledge the fears inherent to the dire situation that the patients find themselves in before they will be able to consider additional information or planning for the future.

Further, engaging patients cognitively does not necessitate the removal of emotion from the decision; even our most reflective patients were emotional. We found that during this complex medical decision, emotion was deeply embedded in the decision-making process and was a major tangible theme throughout the interviews. Fear, sadness, and melanchoy were pervasive. Notably, the reflective patients could use these emotions to guide values exploration and, with adequate recognition, could complement the cognitive decision-making process. By contrast, some automatic patients seemed paralyzed in their ability to explore various options by their fear of death. Providers must recognize that fear and emotion envelop the decision-making process for any patient. It is important to attend to these emotions throughout their decision as part of any patient-centered process.

The Dual-Process Theory of decision making argues that people make decisions either intuitively, drawing on past experiences and emotion, or rationally, using an analysis dominant and reasoned process. Research suggests that people prefer to use intuition for most decisions because making decisions using a reflective process takes cognitive effort, something that we as humans attempt to avoid. Our data provide a clear example of the Dual-Process Theory of decision making, with patients divided between an intuitive, automatic process and a reasoned, reflective process.

An example of how the Dual-Process Theory can help us interpret our data relates to the status quo bias. The status quo bias is a cognitive bias where people would rather accept the default decision than use a reflective decision process. Among patients referred to an academic medical center for consideration of a DT LVAD, the default choice is the DT LVAD, particularly because that is often the primary reason for the referral. In our sample, the automatic patients universally accepted this default therapy. In comparison, a key factor in approaching the DT LVAD decision reflectively is having the ability to consider a shorter life with heart failure and comfort care. These reflective patients were able to see the decision not as life versus death but rather that death was inevitable regardless of the choice made. Consequently, they were able to explore important trade-offs, such as potential modes of death and the balance between quantity and quality of life.

Future research aiming to support DT LVAD decision making should explore the degree to which addressing the fear and emotion associated with this decision can help automatic patients traverse a more reflective process and whether a more reflective process is even a good thing for patients in this situation. Further, future research should test whether a reflective process leads to patients and caregivers who are better informed and better prepared for downstream consequences. Finally, we know that patients resolve cognitive dissonance over time; a prospective study aiming to explore patients’ decision processes at the time of decision making for DT LVAD and then follow their reactions over time would validate or refute our findings.

**Limitations**

There are several limitations to our study that should be considered when interpreting our data. First, this study was performed at a single academic center with a relatively homogenous sample, including only one female patient; however, we had 100% participation of eligible patients during
the first 6 months of the study with only 2 additional decliners subsequently interviewed to assure thematic saturation among decliners. Second, the hospital is a tertiary medical center and patients are referred specifically for advanced heart failure therapies. Consequently, patients who declined DT LVAD therapy upstream in the referral pathway were not included in our sample. However, patients who declined DT LVAD therapy in our study went through the entire evaluation process and their experience most closely represented current DT LVAD decision making. Third, the sample of patients who declined DT LVAD was small although the team is confident that thematic saturation was met. Fourth, patients were interviewed after their decision about DT LVAD. This could bias the results because the patients would be influenced by the outcomes; however, we chose this strategy deliberately so as not to influence the DT LVAD decision-making process with our interviews. Future work could explore the DT LVAD decision process prospectively. Last, themes from qualitative research may reflect the biases of the investigators. To minimize bias, we used several methods, including using a primary interviewer and analyst with no clinical relationship as well as triangulating our findings among the multidisciplinary team.

Conclusions
Overall, decisions surrounding end-stage illness are complex and occur in the setting of high emotion. Patients must be supported in this process, in part, by recognizing that patients will either go through a reflective decision process where they will weigh the risks and benefits or they will go through an automatic process in which they do not perceive there to be a choice. Therefore, any decision support interventions, such as decision coaches or decision aids, will need to consider the psychological, emotional, and cognitive decisional needs of all patients.

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Disclosures
None.

References
Decision Making for Destination Therapy Left Ventricular Assist Devices: "There Was No Choice" Versus "I Thought About It an Awful Lot"

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Supplemental Methods 1. Interview Guides.

Supplemental Methods 2. Survey and Scales.
**Supplemental Methods 1.**

<table>
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<th>Domain</th>
<th>Specific interview items</th>
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| **Background**          | • When were you diagnosed with HF? What was it like to learn about your diagnosis? When did you have LVAD placed? (decline the LVAD)? How have things been going for you?  
                          | • Decliners: before you were offered an LVAD, did you take medications for HF? How did you weigh the risks/benefits? Did you consider any alternatives?                                                                               |
| **Making the decision** | • What were the reasons you were considering getting the LVAD? Were you told that it was the LVAD versus death/hospice? Were you dying of your heart failure? Can you tell me about the advantages and disadvantages? What did you think about these? How did you weigh them?  
                          | • How did certain factors weigh into your decision making?  
                          | o Spirituality  
                          | o Family  
                          | o Finances  
                          | • How did you go about making this decision?: “cognitive/head” vs. “emotional/gut”  
                          | • What was difficult about the decision? And what did you find easy about the decision?  
                          | • What did your doctor/clinician say about the risks and benefits of the LVAD?  
                          | • What were the risks you were concerned about? Anything you were worried about? (bleeding, infections, swimming/showering?)  
                          | • What information were you given about the LVAD?  
                          | • How was this information presented to you?  
                          | • Did it contain any information on how much benefit you could expect?  
                          | • What benefits did you expect from the LVAD?  
                          | Decliners: In what way were you involved in the discussion around the LVAD?  
                          | • Can you tell me about why you declined the LVAD?  
                          | • How did you feel when making this decision? How did you go about making this decision?: “cognitive/head” vs. “emotional/gut”  
                          | • How did certain factors weigh into your decision making?  
                          | o Spirituality  
                          | o Family  
                          | o Finances  
                          | • What options do decision makers have?  
                          | • What did you see as the main advantages and disadvantages of the LVAD?  
                          | • What were the risks you were concerned about? What were the benefits you expected? Why?  
                          | • What was difficult about the decision? And what did you find easy about the decision?  
                          | • Some people have regrets while others don’t. What about you?  
                          | • What advice would you give someone who has to decide whether or not to receive an LVAD?  
                          | • What are the goals for the rest of your life?  
| **Interactions with clinician** | • What did your doctor/clinician say about the risks and benefits of the LVAD?  
                          | • What were the risks you were concerned about? Anything you were worried about? (bleeding, infections, swimming/showering?)  
                          | • What information were you given about the LVAD?  
                          | o How was this information presented to you?  
                          | o Did it contain any information on how much benefit you could expect?  
                          | o What benefits did you expect from getting the LVAD?  
                          | • On a scale from 1-10, with the doctor(s) simply making the recommendation with little discussion being a “1” and “10” being a thorough, in-depth discussion between the doctor and the patient, how would you describe your interaction with your doctor? (Can you tell me about how you decided on xx number?)  
                          | • What were your hesitations or concerns about getting the LVAD? How seriously did your doctor/clinician take your concerns?  
                          | • Is there something that you wish your doctor/clinician would have told you? That you wish they would have done or handled differently? Is there something you wish you’d
<table>
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<th>Section</th>
<th>Questions</th>
</tr>
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| Involvement in decision | • On a scale of 1-10, how involved would you say you were, with 1 “not at all involved” vs. 10 “very involved” in making the decision. Can you tell me more about the number you chose? If less than 100% own decision, ask: who else was involved in the decision? What role did they play?  
  - Family or informal caregivers, others  
  Decliners: Who else was involved in making this decision? What were their roles?                                                                                         |
| Consideration of         | • Some patients who decided not to get the LVAD have told us that they felt there are worse things than death, and that they are OK with not getting the LVAD and not living longer. What do you think about this?  
  - Can you imagine a time or a situation where you might feel this way?                                                                                                            |
| alternatives             |                                                                                                                                                                                                         |
| Decision satisfaction    | • How satisfied are you with your decision at this point in time? (1=not at all satisfied and 10=totally satisfied) Can you tell me about your rating? What would it take for you to rate it a 10?                                                                 |
| Living with your LVAD    | • What do you know NOW that would have been helpful to know from the beginning? If you were to speak to someone considering a LVAD, what is the one thing (or the main things) you would want to tell him or her?  
  • Do you have any worries or unanswered questions about the LVAD? What things would you like to know now about the LVAD?  
  • How are things different than before the LVAD? Has anything surprised you? Anything you expected would happen that hasn’t happened?  
  • Some people have told us they didn’t expect:  
    o Having to be re-admitted to the hospital multiple times  
    o So many follow-up visits to the clinic  
    o Nose bleeds that were difficult to stop  
  • What do you think would help people make the decision to whether or not to have an LVAD implanted? If you could tell patients who are considering an LVAD and their loved ones anything about what it’s like, what would you tell them? What’s most important for them to know? |
| Future Decisions         | • My last set of questions has to do with any future decisions you might need to make. What decision(s) do you see on the horizon?  
  - What are the reasons you might consider xxx?  
  - Can you tell me about the advantages and disadvantages? What do you think about these? How would you weigh them? What might be most important to you? (e.g. living longer or possibly living less long but having possibly fewer hospitalizations?)  
  - How involved would you want to be in any future decisions? (1-10 scale) Can you tell me about the number you chose? Reasons?  
  - Is there anything you would do differently in making a future decision? Anything you’d like to do differently next time?  
  [If not already discussed above] Can you see a time when you might have to consider turning off the LVAD?  
  - Have you talked about this possibility with your doctor or family?  
  - Under what circumstances might you have to consider it?  
  - Have you ever put anything in writing about how you want the LVAD to be handled at the end of life?                                                                 |
| Anything else?           | Is there anything else you would want us to know? Any last thoughts?                                                                                                                                        |
Supplemental Methods 2.

Please answer the following questions. This is completely voluntary; you may skip any question that you do not want to answer.

1. Please select the option that best represents your preferred role in making decisions about your health care *in general*?

- I prefer to make the final selection about which treatment I will receive.
- I prefer to make the final selection of my treatment after seriously considering my doctor’s opinion.
- I prefer that my doctor and I share responsibility for deciding which treatment is best for me.
- I prefer that my doctor make the final decision about which treatment will be used, but seriously considers my opinion.
- I prefer to leave all decisions regarding treatment to my doctor.

2. Please select the option that best represents your preferred role in making decisions about the left ventricular assist device (LVAD) or heart pump?

- I made the final selection about the heart pump.
- I made the final selection about the heart pump after seriously considering my doctor’s opinion.
- My doctor and I shared responsibility for deciding about the heart pump.
- My doctor made the final decision about the heart pump (LVAD) after seriously considering my opinion.
- My doctor made the final decision about the heart pump (LVAD).

Reflect on the first decision you made about whether or not to have a left ventricular assist device (LVAD) or heart pump after talking with your doctor. Show how strongly you agree or disagree with these statements by checking the box that best fits your views about your decision.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree Nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It was the right decision</td>
<td></td>
<td>☐</td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. I regret the choice that was made</td>
<td></td>
<td>☐</td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. I would go for the same choice if I had it to do over again</td>
<td></td>
<td>☐</td>
<td></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. The choice did me a lot of harm</td>
<td></td>
<td>☐</td>
<td></td>
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</tbody>
</table>
The next few questions are to give us a little information about you

1. How old are you? ________

2. What is the highest grade or level of school that you have completed?
   - 8th grade or less
   - Some high school
   - High school graduate/GED
   - Some college
   - 4-year college graduate
   - More than a 4 year degree

3. Are you of Hispanic or Latino origin or descent?
   - Yes, Hispanic or Latino
   - No, not Hispanic or Latino

4. How would you describe your race? (Check all that apply)
   - American Indian or Alaskan Native
   - Asian or Pacific Islander
   - Black or African-American
   - White
   - Another race or multiracial

5. Where do you receive your LVAD or pump?
   - The University of Colorado
   - Other: ______________________________________________

6. What is your current family income?
   - Less than $15,000
   - $15,000-30,000
   - $30,001-60,000
   - $60,001-100,000
   - Over $100,000

7. Which best describes your marital status:
   - Married
- Divorced
- Separated
- Widowed
- Single / Never married
- Common law (living as married)
- Other