



Decisional regret in left ventricular assist device patient-caregiver dyads

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ABSTRACT

Background: The objective of this study was to investigate decisional regret among left ventricular assist device (LVAD) patients and their caregivers.

Methods: This study was a single center, cross-sectional survey of patients after LVAD implantation and their caregivers. Subjects were recruited at their outpatient heart failure appointments. Patients and caregivers at least three months from LVAD implantation completed a 5-item, validated decisional regret scale. Summative scores on a 0–100 point scale were determined for patient and caregivers (0 = no regret). Subgroup analysis included gender, LVAD indication (bridge to transplant (BTT) or destination therapy (DT)), time from LVAD implantation, and caregiver relationship. Dyad discordance was defined as a patient-caregiver difference of ≥ 2 points on any regret scale question.

Results: Fifty patients were approached for participation. Thirty-three LVAD patient-caregiver dyads were enrolled in the study (19 male, 14 female patients; 8 male, 25 female caregivers). Patients had a mean age of approximately 50 years. Caregivers had a mean age of approximately 54 years. Patients had a median regret score of 10 (Interquartile range (IQR): 0–30), while caregivers had a median regret score of 20 (IQR: 0–25). Median regret scores of female patients were significantly higher than that of male patients (27.5 vs 0, $p = 0.0038$). BTT patients had numerically lower regret than DT patients, but this was not statistically significant. Patients who had been implanted for greater than three years had the highest regret scores. Discordance in at least one domain of the regret scale was present in 19 out of 33 (57.6%) dyads.

Conclusions: While decisional regret was reasonably low in this population, comparatively, there was significantly increased decisional regret among female patients and patients further from LVAD implantation. Differences between patients and caregivers were also observed. These findings highlight the need for robust support and continual attention to expectations before and after LVAD implantation.

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Introduction

The number of left ventricular assist devices (LVADs) implanted continues to increase.¹ Optimizing the pre-LVAD implantation decision-making process^{2,3} and promoting realistic expectations post implantation are particularly important given high morbidity and psychological burdens on patients and caregivers living with an LVAD.⁴ Two studies have directly assessed decisional regret among LVAD patients. Blumenthal-Barby et al. analyzed decisional regret in an interview study conducted with LVAD candidates, LVAD patients, and caregivers.³ They reported that regret was generally low among

both patients and caregivers (mean score of 7.68 and 11.93, respectively), but dyadic concordance was not assessed. In the context of a larger interventional trial of a decision aid for destination therapy (DT) LVADs, decisional regret was found to be relatively low and did not differ significantly between intervention and control groups at one month follow up (mean 17.9 and 14.3, respectively). However, caregiver regret was not assessed.⁵ Bridge to transplant (BTT) LVAD patients were excluded from both studies.

Caregiver perspectives are pivotal as they play an essential role in LVAD outcomes. Risk of death is over three times greater among LVAD patients who live alone compared to those who live with someone.⁶ Only a few studies have evaluated caregiver experiences^{7–10} despite this being an important concern, since approximately 60% of LVAD patients require re-hospitalization within the first 6 months after implant. They continue to require a significant amount of

Abbreviations: LVAD, left ventricular assist device; DT, destination therapy; BTT, bridge to transplant; BTC, bridge to candidacy; IQR, interquartile range; QOL, quality of life

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support throughout their life which can lead to caregiver stress, fatigue and uncertainty.^{4,11}

It is critical to identify and understand the extent to which caregivers' and patients' experiences align and the extent to which experiences of regret are concordant. Identifying predictors of regret among patients and caregivers could lead to improvements in education and shared decision-making processes prior to implantation. Similarly, the presence of appreciable regret or discordance could signal a need to develop better ways to support patients or caregivers after implantation. The objective of this study was to investigate LVAD decisional regret in patients and their caregivers.

Methods

Study design, participants and setting

We conducted a single center, cross-sectional survey of patients after LVAD implantation and their caregivers. The study was conducted at outpatient clinics in the Emory University Center for Heart Failure Therapy, which cared for approximately 80 LVAD patients at the time. Subjects were recruited in the examination room prior to their clinic appointment. Patients and caregivers completed informed consent prior to enrollment. The Emory Institutional Review Board approved this study.

Inclusion and exclusion criteria

Patients and their caregivers were eligible for this study if they were three months or more from implantation. Patients were excluded if they received their LVAD emergently without a decision. Participants were defined as caregivers if they provided the primary caregiving for the patient at home and attended clinic appointments. They were typically the closest related family member, but this was not required.

Procedures

Research personnel gave separate but identical surveys to patient and caregiver participants in an empty exam room. Participants completed a 5-item validated scale to measure decisional regret.^{12,13} They were asked to reflect on the decision to receive the LVAD and show how strongly they agreed or disagreed with these statements: "It was the right decision", "I regret the choice that was made", "I would go for the same choice if I had to do it over again", "The choice did me a lot of harm", and "The decision was a wise one". Responses included: "Strongly agree = 1", "Agree = 2", "Neither agree nor disagree = 3", "Disagree = 4", or "Strongly disagree = 5". The scale has a Cronbach's α ranging from 0.81 to 0.92. The survey also included questions about whether expectations in various domains were met. Finally, the survey collected demographics such as age, gender, race, education, family income, marital status, type of health insurance, and the number of months since implant.

Variables and measures

Responses were scored summatively.¹² A 0–100 point "regret score" was generated from the five answers. Scores of the two negatively phrased questions were reversed. To generate the 0–100 point scale, one was subtracted from the mean of the five scores and multiplied by 25. A score of 0 corresponds to no regret and a score of 100 corresponds to high regret. Median regret scores were evaluated across the population, as well as for subgroups. Discordance between patient and caregiver was defined as a difference of ≥ 2 points on the Likert-type scale for a single regret scale question. This threshold was chosen, because any 2-point difference places the response into a

qualitatively different category on a 5-point Likert-type scale. If discordance was present, the member of the dyad with more regret in the single regret scale domain was determined. Another study implemented a similar definition of discordance to compare quality of life (QOL) in non-cancer end of life patients and caregivers.¹⁴ In this study, a 4-point difference or greater (on a 10-point scale) between patient and caregiver was discordant.

Data analysis

Results were reported as frequency and percent for categorical variables. Median and interquartile range are reported for continuous variables. They were compared between demographic groups using the Fisher Exact Test. Statistical significance was determined at a p -value < 0.05 .

Results

Study participants

Fifty LVAD patients were approached for participation. Three patients and their caregivers refused participation. Fourteen participating patients were alone at the clinic appointment and were excluded from analysis due to lack of caregiver participation. This left a total of 33 patient and caregiver dyads for analysis (Table 1). Patients (19 male and 14 female) had a mean age of approximately 50 years (range 20–72 years). Caregivers (8 male and 25 female) had a mean age of approximately 54 years (range 23–77 years). The most common gender combination was male patient and female caregiver (57.6% of dyads). The mean time since implantation was 18.7 months (range 3–51 months). There were 17 patients classified as DT, 13 classified as BTT, and 3 classified as bridge to candidacy (BTC). Most caregivers were spouses ($n = 20$; 61%).

Overall decisional regret

Patient and caregiver overall decisional regret for all participants are shown in Table 2. Patients had a median regret score of 10 (interquartile range (IQR): 0–30), while caregivers had a median regret

Table 1
Clinical and demographic characteristics of the participants

	Patients	Caregivers
Participants, n	33	33
Gender		
Male, n (%)	19 (58%)	8 (24%)
Female, n (%)	14 (42%)	25 (76%)
Age		
Mean \pm SD	49.82 \pm 14.03	54.48 \pm 12.70
Maximum	72	77
Minimum	20	23
Race		
African–American, n (%)	13 (39%)	12 (36%)
Caucasian, n (%)	19 (58%)	18 (55%)
Preferred not to answer, n (%)	1 (3%)	3 (9%)
Education		
High school degree or less, n (%)	13 (39%)	13 (39%)
College graduate or some college, n (%)	13 (39%)	15 (45%)
Postgraduate degree, n (%)	7 (21%)	5 (15%)
LVAD implantation duration (Months)		
Mean \pm SD	18.74 \pm 14.73	
Maximum	51	
Minimum	3	
Insurance		
Medicare, n (%)	21 (64%)	
Private insurance, n (%)	12 (36%)	

Values are n (%), mean \pm standard deviation (SD).

Table 2
Overall decisional regret scores by dyad

	n (%)	Patient median	Patient IQR	Caregiver Median	Caregiver IQR
All participants	33	10	0–30	20	0–25
Gender					
Male PT and Female CG	19 (58%)	0	0–10	15	0–25
Female PT and Male CG	8 (24%)	22.5	16.25–32.5	22.5	3.75–33.75
Female PT and Female CG	6 (18%)	40	28.75–43.75	22.5	16.25–28.75
LVAD indication					
BTT	13 (39%)	0	0–25	15	0–25
DT	17 (52%)	20	0–40	20	5–30
BTC	3 (9%)	10	5–27.5	20	10–27.5
Duration of LVAD implantation					
1st Year	13 (39%)	0	0–30	15	0–25
2nd Year	10 (30%)	0	0–10	22.5	12.5–33.75
3+ Years	10 (30%)	22.5	6.25–40	20	0–22.5
Caregiver relationship					
Spouse	20 (61%)	7.5	0–30	17.5	0–26.25
Parent	8 (24%)	0	0–28.75	7.5	0–21.25
Child	2 (6%)	40	30–42.5	35	32.5–40
Sibling	3 (9%)	12.5	6.25–18.75	20	17.5–22.5

Values are median, interquartile range (IQR) [25th–75th percentile].

Abbreviations: PT = patient; CG = caregiver; BTT = bridge to transplant; DT = destination therapy; BTC = bridge to candidacy.

score of 20 (IQR: 0–25). In 13 of the dyads, the patient had a higher regret score than their caregiver (mean difference = 24.6). In 14 dyads, the caregivers had a higher regret score than the patient (mean difference = 23.2). Six dyads had equal patient and caregiver regret scores.

Regret scores were stratified by gender. Female patients' regret scores were significantly higher than male patients' regret score (median 27.5 vs 0, $p = 0.0038$). Male patients' regret score IQR was 0–10, while female patients' regret score IQR was 20–40. Caregiver males and females, however, had similar regret scores (median 22.5 vs 15, respectively, $p = 0.1983$). Male caregivers' regret score IQR was 3.75–33.75, while female caregivers' regret score IQR was 0–25.

Regret scores among dyads with different LVAD indication were compared (Table 2). BTT patients had the lowest regret score (median = 0, IQR: 0–25). DT patients had the highest regret scores (median = 20, IQR: 0–40). The difference between BTT patients and DT patients was not statistically significant ($p = 0.209$). The three BTC patients had regret scores with median = 10. Caregiver regret scores did not differ based on LVAD indication.

Dyads were also evaluated based on the duration of implantation period. Dyads with greatest time since implantation (≥ 3 years) had higher patient regret scores (median = 22.5, IQR: 6.25–40) compared to those in which implantation was within the first year (median = 0, IQR: 0–30) or second year (median = 0, IQR: 0–10).

Regret scores based on caregiver relationship are displayed in Table 2. Dyads with a spousal relationship had patient median regret score of 7.5 (IQR: 0–30) and caregiver median regret score of 17.5 (IQR: 0–26.25). The three dyads with children as caregivers had similar median regret scores for patients (median = 40, IQR: 30–42.5) and caregivers (median = 25, IQR: 32.5–40).

Discordance

Nineteen dyads had discordance in at least one domain (Table 3), as defined by a difference of ≥ 2 points on the Likert-type scale for a single regret scale question. Discordance was observed more commonly in dyads with female patients (71%) as compared to dyads with male patients (47%). In dyads with male patients, discordance

Table 3
Presence of discordance in dyads

	Dyads, n (%)	Discordant, n (%)	Patient has more regret, n	Caregiver has more regret, n
Total	33	19 (58%)	9	10
Gender				
Male PT and Female CG	19 (58%)	9 (47%)	2	7
Female PT and Male CG	8 (24%)	6 (75%)	3	3
Female PT and Female CG	6 (18%)	4 (67%)	4	0
LVAD indication				
BTT	13 (39%)	6 (46%)	3	3
DT	17 (52%)	11 (65%)	5	6
BTC	3 (9%)	2 (67%)	1	1
Duration of LVAD implantation				
1st Year	13 (39%)	5 (38%)	3	2
2nd Year	10 (30%)	8 (80%)	2	6
3+ Years	10 (30%)	6 (60%)	4	2
Caregiver relationship				
Spouse	20 (61%)	13 (65%)	5	8
Parent	8 (24%)	3 (38%)	2	1
Child	2 (6%)	3 (100%)	2	1
Sibling	3 (9%)	0 (0%)	0	0

Discordance between patient and caregiver was defined as a difference of ≥ 2 points on the Likert-type scale for a single regret scale question. If discordance was present, the member of the dyad with more regret in the single regret scale domain is demonstrated in the last 2 columns.

Values are n (%).

Abbreviations: PT = patient; CG = caregiver; BTT = bridge to transplant; DT = destination therapy; BTC = bridge to candidacy.

was generally due to more female caregiver regret in the single discordant domain (seven dyads had caregivers with more regret, compared to only two dyads who had more patient regret). Eleven DT dyads and six BTT dyads experienced discordance. More discordance was seen after the first year post-implantation. Overall, there was no numerical difference in whether the patient or caregiver had more regret in the discordant domain.

Discussion

This exploratory study evaluated LVAD patient and caregiver decisional regret after LVAD implantation, with a specific emphasis on analyzing discordance between patients and caregivers. The objective was to gain a better understanding of potential drivers of decisional regret in order to identify targeted areas for improvement in supportive care pre- and post-LVAD implantation. Previous studies have investigated LVAD QOL and decision-making^{15–18} but this is the first study to our knowledge to assess regret among patient-caregiver dyads. It is reassuring to emphasize that overall, patients and caregivers had low regret scores, similar to previous studies.^{3,5}

Our results are hypothesis-generating and demonstrated meaningful patterns in decisional regret. Most strikingly, we observed a prominent disparity in gender regret scores. Female patients had significantly higher regret scores as compared to male patients. This disparity persisted in analysis of dyads, where discrepancies in decisional regret appear to have been primarily driven by greater regret among females, whether they were the patient or the caregiver. Prior data on gender-related differences of LVAD patients have been limited. However, women have been found to be at significantly higher risk of developing severe complications, such as cerebrovascular events or right heart failure which may explain higher female LVAD patient regret.¹⁹ Unfortunately, due to anonymity, we did not have access to data regarding the patients' medical history in this study. While increased morbidity may explain greater regret among female patients, it does not explain greater regret among female caregivers when patient-caregiver discrepancies were present. Gender analysis on decisional regret following a surgical procedure in non-LVAD patients have been evaluated and did not find a statistical difference between male and female regret, unlike this study.^{20,21} However, in a study of thyroid cancer patients, when compared to males, females experienced higher levels of burden at diagnosis and during treatment, which was thought to be due to higher anxiety, fatigue and depression.²² In another study, distress levels in couples coping with cancer were higher in women, regardless of patient or caregiver role.²³ Such gender differences may offer insight into LVAD patients and highlight the necessity for further study.

LVAD indication also appears to have an effect on regret. DT patients had numerically higher regret scores compared to BTT patients, and more DT dyads were discordant compared to BTT dyads. A possible reason for these findings is that DT LVAD patients have been shown to have increased morbidity and mortality⁴ compared to BTT patients, most likely due to comorbidities that preclude them from receiving a heart transplant. BTT patients may also view their LVAD with less regret, as they maintain hope for transplant. DT patients have no alternative therapy and will have their LVADs indefinitely, regardless of outcomes. As more DT patients receive LVADs,¹ addressing the morbidity and possible regret will be paramount to improving the decision-making process.

It has been well documented that patients with LVADs experience improvement in QOL up to 24 months post-implantation.^{15,16,18} It is interesting that our analysis found that patient regret scores were highest in those who were greater than or equal to three years post-implantation. These patients would be considered a "success" based on the metric of survival. Yet, the data suggest that for some, the experience of prolonged life with an LVAD may lead to regret. It is

particularly important to continue to assess these drivers of regret to improve support of patients, who are, by other accounts, doing well.

Finally, discordance is a valuable tool to evaluate patient and caregiver dynamic. Although not previously used in LVAD decisional regret research, QOL discordance was studied in terminal cancer patients and their caregivers.²⁴ Factors associated with QOL discordance included poor patient emotional function, emotionally distressed caregiver, caregiver professing religion and low social support. This emphasized that the presence of discordance can affect individual (patient or caregiver) QOL, as well as indicate emotional fragmentation. Future studies are needed to determine whether dyad regret discordance has similar associations. It is important that our findings demonstrated some level of discordance in nearly 60% of the dyads. Independent of predictors of regret, this finding alone suggests the need for increased attention and evidence-based approaches to supporting patients and caregivers after LVAD implantation. While improving initial shared decision-making is important, this issue of post-implant regret will likely persist. Trials of post-LVAD support tools (akin to those recently conducted of pre-implantation decision aids) may be necessary.

Multiple potential factors could contribute to the regret experienced by patients in this study. LVAD complications,⁴ hospital readmissions,²⁵ medical co-morbidities,²⁶ lifestyle adjustments,²⁷ and financial costs,²⁸ likely play a role in decisional regret. Further research could help determine the extent to which these factors influence regret, or whether there are additional triggers present. Discerning the degree of regret caused by individual factors should be the objective of future research to personalize pre-implantation education and post-implantation management.

This study has notable limitations. First, this was a single institution study with 33 dyads. These issues warrant study on a larger scale to assess whether these hypothesis-generating findings are broadly true in other, more diverse populations. Additionally, in-depth qualitative work could help to understand more substantially the nature and drivers of regret in both groups. This would allow for a more detailed evaluation of dyad discordance as our definition is limited by only requiring presence in a single question of the regret scale. Second, we did not assess for variations in LVAD decision-making strategies, post LVAD supportive care, or possible changes in regret over time. Further work to identify what forms of care and support help to minimize regret is important. Third, it will be important for future studies to adjust for medical co-morbidities and LVAD complications in order to assess the extent to which regret is driven by primary medical experiences.

Conclusion

The shared decision-making process for LVAD implantation and experience of living with an LVAD continue to evolve. This study was a focused effort to determine the presence of regret in patient-caregiver dyads and to identify differences in regret between them. Although it is reassuring that many patients and caregivers experienced relatively low regret, the high frequency of discrepancies between them, along with appreciably higher levels of regret among female patients, signal the importance of developing and refining interventions to optimize both the implantation decision and post-implantation support.

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Supplementary materials

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