Project Title: A multicenter trial of a shared decision support intervention for patients and their caregivers offered destination therapy for end-stage heart failure: DECIDE-LVAD

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Extended Statistical Analysis Plan

Baseline characteristics between participants enrolled in the study and those screened but not enrolled, and between those enrolled during the control period and those enrolled during the intervention period, will be compared using chi-square tests and t-tests.

Reach is defined as the proportion of the target population who participate in the intervention.[1] We will assess reach by calculating the percentage of patients and caregivers who received the pamphlet and video decision aids out of the total number of patients and caregivers enrolled in the intervention period.

Effectiveness of the intervention will be assessed through the primary outcome of decision quality: the extent to which medical decision making reflects the considered preferences of a well-informed patient.[2,3,4] As such, co-primary endpoints were chosen comprising the two main International Patient Decision Aid Standards domains of decision quality—knowledge and values-choice concordance.

Knowledge: A 10-item knowledge test was developed by the study team and validated by clinicians and patients. Consistent with methods of Sepucha et al.,[5] the study team created a list of knowledge items based on clinical needs, local post-LVAD education standards, and needs assessment work with patients. We then surveyed patients, caregivers, MCS coordinators, and physicians to narrow the list and determine the key knowledge items and assure content validity. The acceptability of this measure was further assessed with patients and caregivers in a pilot of the trial protocol.[6] Improvement in knowledge from baseline 1 (enrollment) survey to baseline 2 (post-education) survey was a co-primary endpoint.

To assess the change in patient DT LVAD knowledge over time, we will fit a linear mixed model proposed for the analysis of stepped wedge designs. This model accounts for the repeated measures within subject, included a random effect for site and fixed effect indicators of intervention group and stepped wedge time period. This model adjusts for trends over time, assuming that changes occur similarly across all sites. We will assess any differences in baseline covariate distribution by intervention group, and will include covariates that are imbalanced by group in this linear mixed model. We will evaluate whether the change in knowledge score (percent correct) between baseline 1 and baseline 2 was different between the control and intervention groups.

Values-Choice Concordance: A values scale was also developed, modeled after a well-accepted values evaluation tool.[7] During previous needs assessment work,[8,9,10] one value rose above all others in considering DT LVAD: maximizing chances of survival with aggressive medical care versus not. We developed a single-item, 10-tier Likert values measure using the dichotomy of “Do everything I can to live longer, even if that means having major surgery and being dependent on a machine” (score 1) versus “Live with whatever time I have left, without going through major surgery or being dependent on a machine” (score 10). For caregivers, this read as “Do everything my loved one can to live longer, even if that means having major surgery and being dependent on a machine” (score 1) versus “Have my loved one live with whatever time he/she has left, without going through major surgery or being dependent on a machine” (score 10). At 1 month post-enrollment, we will create a dichotomous variable of whether the patient wanted to get the LVAD or did not want to get the LVAD (DT LVAD or medical management without LVAD), and patients and caregivers will report the patient’s treatment choice. Concordance between 1-month value score and patient/caregiver-reported treatment choice at 1-month is the other co-primary endpoint. Secondary outcome of concordance between 1-month value score and actual treatment received by 6-months will also be assessed. Actual treatment received by 6

months is recorded on the patient's medical record review and is defined as whether the patient had been implanted with the LVAD by 6 months or not implanted.

To assess values-choice concordance, we will calculate the Kendall's tau correlation coefficient between the stated values score at 1 month and each of the treatment outcomes (patient/caregiver-reported treatment choice at 1 month, actual treatment received at 6 months), and look at the difference in this correlation coefficient by intervention group. To generate a confidence interval for this difference, we will perform 500 bootstrap samples and calculate the 2.5 and 97.5th percentiles.

Secondary outcomes measures include the following for both patients and caregivers:

- Acceptability: We will measure acceptability of education materials by using a modified version of decision aid acceptability developed by Barry et al.[11]
- Decision Conflict: We will use the validated 15-item decision conflict measure developed by O'Connor et al.[12]
- Decision Regret: We will use the validated 5-item decision regret scale.[13]
- Patient Health Questionnaire-2: To assess depression in patients and caregivers at baseline and after their decision.[14]
- Perceived Stress Scale: To assess the stress patients and caregivers feel during the decision making process.[15]

And the following for patients only:

- Control Preferences Scale (preferred and actual): We will measure the participants' preferred role in decision making using the validated Control Preferences Scale and their actual control participation.[16]
- PEACE Illness Acceptance Measure: For patients, we will assess patients' acceptance of their current heart failure illness and whether that impacts their decision to accept or decline DT LVAD.[17]
- Quality of Life (EQ Visual Analogue Scale): For patients, we will assess their self-reported quality of life score through only the Visual Analogue Scale portion of the EQ5D, both pre and post decision.[18]

And for caregivers only:

- The Preparedness for Caregiving Scale: For caregivers, we will assess their level of preparedness, both mentally and physically, pre and post decision.[19]
- Family Satisfaction with Care: For caregivers, we will assess their satisfaction with the decision making process and their involvement.[20]

Secondary outcomes data will be scored and summarized according to the methods previously validated and published for each measure. Significance for differences by intervention group at specified time points for the categorical outcome scales will be determined using Chi-square tests. Differences in the continuous outcome scales by intervention group will be assessed via the linear mixed model described previously.

Missing data will be characterized at each time point. Analysis will account for missing data and will relax the missing data assumptions to missing at random conditional on observed data.

Adoption is defined as the absolute number, proportion, and representativeness of settings who are willing to initiate a program.[1] We will calculate the total number of programs in the study who used the intervention at their program.

Implementation is defined as the extent to which the intervention is implemented as intended.[1] Decision aid use will be reported by the study team with a checklist for each patient enrolled. We will calculate the percentage of patients who received the pamphlet and the video decision aids in certain ways (e.g. percent who received the decision aids from clinical personnel, percent who viewed the video in a clinical setting).

Maintenance will be assessed primarily by calculating the total number sites that decide at the conclusion of the study to maintain, modify, or discontinue the use of the decision aids.

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