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J Heart Lung Transplant. Author manuscript; available in PMC 2014 December 01.

Published in final edited form as:
J Heart Lung Transplant. 2013 December ; 32(12): . doi:10.1016/j.healun.2013.09.005.

PRE-OPERATIVE HEALTH STATUS AND OUTCOMES FOLLOWING CONTINUOUS-FLOW LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION

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Abstract

Background—Health status predicts adverse outcomes in heart failure and cardiac surgery patients, but its prognostic value in left ventricular assist device (LVAD) placement is unknown.

Methods—We examined the association of pre-operative health status, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ), with survival and hospitalization after LVAD using KCCQ as a continuous variable and stratified by KCCQ score quartile plus missing KCCQ in 1125 clinical trial participants receiving the HeartMate II as either destination therapy (n=635) or bridge to transplantation (n=490).

Results—Mean pre-operative KCCQ score was 29.4±18.7 among survivors (n=719), and 27.1±18.3 (n=406) in those who died. In time-to-event analysis for all available follow up using health status as a continuous variable, pre-operative KCCQ score did not correlate with overall mortality after LVAD implantation (p=0.178). Small absolute differences were seen between pre-operative KCCQ quartile and 30-day survival (Q4 95% vs. Q1 89% vs. missing 87%; p=0.0009 for trend), 180-day survival (Q4 83% vs. Q1 76% vs. missing 79%; p=0.060 for trend), and days hospitalized at 180 days (Q4 29.8±25.6 vs. Q1 34.1±27.1 vs. missing 36.5±29.9; p=0.009 for trend).

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Conflicts of interest

Kartik Sundareswaran and David Farrar are employees of Thoratec Corporation. John Spertus owns the copyright to the KCCQ. All other authors have no conflicts of interest to disclose.

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Conclusion—Our findings suggest that pre-operative health status has limited association with outcomes after LVAD implantation. Although these data require further study in a diverse population, mechanical circulatory support may represent a relatively unique clinical situation, distinct from heart failure and other cardiac surgeries, in which heart failure-specific health status measures may be largely reversed.

Keywords

mechanical circulatory support; health status / health-related quality of life; risk prediction; heart failure

Introduction

Left ventricular assist devices (LVAD) are increasingly used in advanced heart failure patients as either bridge to heart transplantation (BTT)[1,2] or destination therapy (DT),[3] and can improve survival and health-related quality of life.[4] Patient selection for LVAD therapy is complex, as patients must have sufficiently poor cardiac function to warrant device placement, without having comorbidity severe enough to limit long-term benefit from the device.[5] Although outcomes have improved, death after continuous-flow LVAD implantation remains significant, with 2-year mortality approximately 30%.[6] Pre-operative risk models have been developed for LVAD populations, but to date have had limited ability to discriminate patients who will do well versus those who will not (c-indices for risk models range from 0.60-0.65 in validation cohorts).[7] Therefore, much work remains in refining patient selection for this risky, costly, but often beneficial intervention.[7,8]

Disease-specific health status measures are an increasingly recognized tool in the evaluation and management of heart failure. Health status encompasses symptoms, function, and quality of life.[9] Poor baseline health status is a strong independent predictor of mortality and hospitalization in heart failure patients[10–13] as well as mortality, symptomatology, and length of hospital stay in patients undergoing coronary artery bypass graft surgery and valve replacement surgery.[14–17] However, the association of pre-operative health status with post-operative outcomes among patients undergoing LVAD placement has not been assessed.

To clarify the prognostic value of pre-operative health status among LVAD recipients, we examined the association of pre-operative health status, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ),[18] with clinical outcomes in a large cohort of BTT and DT LVAD recipients. Given the known association of lower KCCQ scores with death and hospitalization, our *a priori* hypothesis was that low pre-operative health status would be predictive of increased death and prolonged hospitalization following device implantation, potentially providing prognostic information regarding these endpoints by capturing domains of pre-operative risk (e.g. frailty[19]) that are not optimally captured by traditional covariates used in existing risk models.[7]

Methods

Participants

We included 1125 clinical trial participants who received the HeartMate II (Thoratec Corporation, Pleasanton, CA) LVAD in either the BTT clinical trial or DT clinical trial between 2005-2009. Briefly, the BTT trial was a prospective, observational study of patients who received a HeartMate II device as a BTT.[1,2] The DT trial compared the continuous-flow HeartMate II to the pulsatile HeartMate XVE in patients receiving an LVAD for DT.[3] Patients were eligible for the BTT trial if they were listed for heart transplantation as United Network for Organ Sharing status 1A or 1B and had New York Heart Association (NYHA)

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functional class IV symptoms. In the DT trial, inclusion criteria included ineligibility for heart transplantation, heart failure refractory to optimal medical management, left ventricular ejection fraction < 25%, peak oxygen consumption < 14 ml/kg/min or < 50% predicted, as well as NYHA class IIIB or IV symptoms, or intra-aortic balloon pump (IABP) dependence for at least the past 7 days, or inotrope dependence for at least the past 14 days. Exclusion criteria were similar between the two trials. Complete trial designs and comprehensive inclusion and exclusion criteria have been previously reported.[1–3] The US Food and Drug Administration and each site's institutional review board approved the study protocols. All participants or an authorized representative provided written informed consent.

Data Collection

Baseline data collected upon study enrollment included the KCCQ, the Minnesota Living with Heart Failure Questionnaire (MLHFQ), demographic characteristics, and health history, including New York Heart Association functional class, medications and laboratory data. LVAD measurements, laboratory data, and physical assessments were performed every month. Comprehensive description of the data collection process has been previously published.[1–3] All patients were followed for at least 2 years, unless censored for death, transplant or explantation of the device. Adverse events were recorded as they occurred, and deaths as well as causes of death were confirmed by autopsy, medical records or from speaking with family members. The clinical events committee adjudicated all causes of death.

Disease-specific health status instruments

The Kansas City Cardiomyopathy Questionnaire is a 23-item, self-administered questionnaire. The KCCQ assesses the following domains: physical limitation, heart failure symptoms, social limitation, self-efficacy, and health related quality of life. The validity, reliability and responsiveness to change in clinical status of the KCCQ have been previously reported.[18] Answers to the questionnaire are converted into a scale of 0-100, with lower scores indicating worse health status. The overall summary score (used in this study) is an average of all of the domains captured by the KCCQ.

The Minnesota Living with Heart Failure Questionnaire is a 21-item, self-administered questionnaire. The MLHFQ is aimed at assessing the impact of heart failure and its therapies on patients' day-to-day lives by assessing physical and emotional domains on a 5-point Likert scale.[20,21] The response of MLHFQ scores to changes in clinical status have been previously reported.[22,23] Scores range from 0-105, with lower scores indicating better health status.

The KCCQ and MLHFQ are both widely used health status measures, and have good performance characteristics in validation cohorts.[24] The KCCQ evaluates more domains of health status and has greater sensitivity to clinical change,[24–27] therefore we used the KCCQ as our primary, detailed analysis and MLHFQ as a secondary, confirmatory analysis.

Outcomes

The primary endpoint was overall survival during study follow up. Our secondary endpoints were 30-day survival, 180-day survival, days hospitalized at 180 days, and days alive and out of the hospital in the 180 days following LVAD implantation.

Statistical Analyses

Summary statistics were derived as percentages for categorical variables, and mean ± standard deviations (SD) for continuous variables. Differences in baseline characteristics

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between the KCCQ groups were assessed using the non-parametric Kruskal-Wallis test since the continuous variables were not normally distributed. KCCQ scores were divided into quartiles, with a fifth category for patients with missing pre-operative KCCQ. Missing KCCQ scores were treated as a separate category because those patients missing KCCQ data were significantly different from those who did fill out the questionnaire, which made imputing missing scores inappropriate. We used a non-parametric Kaplan-Meier method for survival analysis as the rates of death vary depending on the time since LVAD implantation. We used the log-rank test to assess differences among the KCCQ quartile and missing KCCQ categories. For all variables included other than KCCQ, data were missing at a rate of <5%. A $P<0.05$ was considered statistically significant. All statistical analyses were performed using SAS version 9.3.

Results

Baseline Characteristics

Table 1 shows baseline characteristics for the 1125 patients in the cohort, stratified by KCCQ quartiles (total n=965) and missing KCCQ (n=160). The cohort consisted of 490 BTT patients and 635 DT patients. Of the 1125 patients included in this study, 719 (64%) were alive at the time of analysis, and 406 (36%) patients had died. Detailed outcomes for the individual BTT and DT clinical trials have been published previously.[1–3] Follow-up time for the entire cohort was 1562 patient-years. Mean duration of support (per patient) was 506 ± 466 days. There was no difference in duration of support among KCCQ quartile groupings or the missing KCCQ group (p=0.773; data not shown). Overall scores on the pre-operative KCCQ assessment were not associated with most other pre-operative patient characteristics. Compared to those with pre-operative KCCQ data, patients missing a pre-operative KCCQ assessment were significantly more ill, as suggested by a higher rate of mechanical ventilation, higher intra-aortic balloon pump (IABP) use, lower use of a renin-angiotensin-aldosterone system blocker, and significantly higher alanine aminotransferase levels.

KCCQ and Mortality/Hospitalization

In time-to-event analysis for all available follow up with health status considered as a continuous variable, pre-operative KCCQ score did not correlate with overall mortality after LVAD implantation (p=0.178). Mean pre-operative KCCQ was 29.4 ± 18.7 among patients who survived compared to 27.1 ± 18.3 for patients who died. Among BTT patients, overall survivors had pre-operative KCCQ of 31.0 ± 19.2 compared to 29.1 ± 20.8 for those who died (p=0.516). Among DT patients, overall survivors had pre-operative KCCQ of 27.9 ± 18.2 compared to 26.2 ± 17.1 for those who died (p=0.282). When KCCQ scores were broken down by quartile and missing KCCQ, there was no difference in overall survival (Figure). However, patients in higher KCCQ quartiles had a statistically significant but small absolute association with better 30-day survival (Q4 95% vs. Q1 89% vs. missing 87%; p=0.0009 for trend) and a trend for better 180-day survival (Q4 83% vs. Q1 76% vs. missing 79%; p=0.060 for trend; Table 2). A similar association was seen for days hospitalized at 180 days as well as days alive and outside the hospital at 180 days (Table 2). In general, patients whose KCCQ score was missing had worse survival and more days hospitalized compared to patients able to complete the questionnaire.

MLHFQ and Mortality

In time-to-event analysis for all available follow up with health status considered as a continuous variable, pre-operative MLHFQ score did not correlate with overall mortality after LVAD implantation (p=0.357). Results did not differ when the analysis was stratified by device strategy. In the total population (n=967), mean pre-operative MLHFQ score was 72.5 ± 21.1 in survivors and 73.5 ± 19.9 in those who died. In BTT patients (n=400)

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MLHFQ score was 70.9 ± 22.0 in survivors and 73.3 ± 23.2 in those who died (p=0.404). In DT patients (n=567), survivors had MLHFQ mean score of 73.9 ± 20.2, and those who died had a mean score of 73.6 ± 18.4 (p=0.642).

Discussion

Our study found that pre-operative health status, as measured by the KCCQ, is not associated with overall post-HMII survival and is only weakly associated with a variety of 30- and 180-day outcomes. Patients missing KCCQ data, presumably because they could not fill out the questionnaire, tended to have the highest rate of 30- and 180-day adverse events, although absolute differences in outcomes were small. Overall, these results are in contrast to the prognostic relevance of KCCQ in patients with heart failure failure[10–13] or those undergoing coronary bypass or heart valve surgery.[14–17]

There are several potential reasons why pre-operative health status does not predict outcomes as well in the LVAD setting compared to other clinical settings. One possible explanation is that the pathophysiologic link between poor baseline health status and adverse outcome can be negated by LVAD therapy. In patients who undergo LVAD implantation, poor pre-operative health status is primarily determined by severe heart failure, as the presence of other severe comorbidities is generally a contraindication to LVAD. Thus, decrements in health status that are primarily related to heart failure may function poorly as predictors of long-term outcomes because the underlying heart failure is largely reversed after LVAD. Another potential reason for why health status performed marginally in our study is that change in health status may carry greater prognostic significance than the severity of health status at one point in time. For example, Kosiborod et al studied a cohort of 1358 patients with heart failure after myocardial infarction, and reported that each 5-point improvement in KCCQ score was associated with an approximate 10% reduction in the hazard of death or hospitalization.[28] Given previous studies showing marked but varied improvement in KCCQ scores after LVAD placement,[4,29] future study may clarify the relationship between early improvements in health status following LVAD implantation and longer-term clinical outcomes. While the nature of change scores precludes them from being used to refine patient selection for LVAD, such information may predict a difficult post-implantation course and help determine the appropriate intensity of follow-up care. Another reason for the weak association may be the homogeneous nature of patients who met strict inclusion criteria for HeartMate II clinical trials. A stronger association between post-operative mortality based upon pre-operative KCCQ may be observed in a post-approval population with greater variation in baseline health status.

Clinical implications and future directions

Based on data from other surgical settings and clinical intuition, we hypothesized that health status measures may help identify patients likely to suffer adverse outcome following LVAD therapy. The data here suggest that such pre-implantation information is not predictive of post-implantation survival. Although we did find statistically significant differences in 30- and 180-day outcomes among KCCQ quartiles, the absolute difference in mortality and hospitalization between the highest and lowest quartiles was relatively small. Based on this evidence, poor pre-operative health status should not be considered a contraindication for LVAD.

The negative result seen here highlights the need for novel methods of risk assessment in patients being evaluated for LVAD. While extending measures of health status from heart failure and surgical populations to the related area of mechanical circulatory support would seem logical, LVAD implantation has the capacity to markedly reverse most cardiac contributions to health status. Therefore, an effective health status measure for LVAD

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selection would not only quantify the overall reduction in health status, but would also help distinguish LVAD-responsive from LVAD-independent reductions in health status.[19] Perhaps a tool specifically designed for the patient being considered for mechanical circulatory support, with specific attention to long-term non-heart failure comorbidity and risks for common complications of LVAD therapy, could demonstrate greater prognostic value than the KCCQ, which was derived in an ambulatory population with a wide range of symptomatology.[18]

Limitations

This was a retrospective post-hoc analysis of prospectively collected clinical trial data. Our population was drawn from a relatively homogeneous heart failure population, with consistently low pre-operative heath status measures. Accordingly, we analyzed our data based on KCCQ score quartiles, rather than using more standard cut points. These patients were clinical trial participants; therefore the additional care and attention they received due to their study participation may have influenced their health status, making our findings more difficult to apply widely. Although it is common practice to compare the association of a disease-specific health status measure such as the KCCQ with a more generic health status instrument, the latter was not included in the original clinical trial design, and therefore such a comparison was not possible in our population.

Conclusion

In this population of advanced heart failure patients undergoing LVAD implantation, lower or absent pre-operative measure of health status was associated with a small absolute increase in some short- and medium-term adverse events, but was not associated with overall survival following HeartMate II implantation. This suggests that poor health status alone should not be considered a contraindication to LVAD placement. Mechanical circulatory support may represent a unique clinical situation, distinct from chronic heart failure and most other cardiac surgeries, in which heart failure-specific health status measures may be largely reversed.

Acknowledgments

The authors thank Jerry Heatley for his statistical review of the manuscript.

Funding and Support

Thoratec sponsored the clinical trial and provided the analytic support. Larry Allen is currently supported by grant 1K23HL105896 from National Heart, Lung and Blood Institute. All other authors have no source of funding to disclose.

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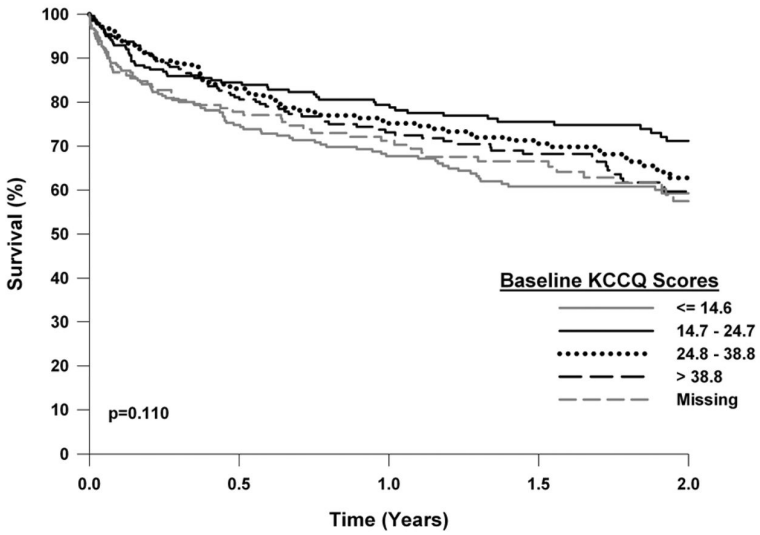

Figure.

Kaplan-Meier survival curve of KCCQ scores stratified by KCCQ quartile groupings plus patients with missing pre-operative KCCQ data. Lower KCCQ score indicates worse functional status. KCCQ, Kansas City Cardiomyopathy Questionnaire.

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Table 1

Pre-operative patient characteristics collected at the time of study enrollment, stratified by KCCQ score quartile and missing KCCQ.

Characteristic	Missing KCCQ *N=160*	Quartile 1: KCCQ ≤ 14.6 *N=244*	Quartile 2: KCCQ 14.7 – 24.7 *N=239*	Quartile 3: KCCQ 24.8 – 38.8 *N=241*	Quartile 4: KCCQ >38.8 *N=241*
Demographics					
Age	52.9 ± 16.1	59.8 ± 13.0	58.7 ± 12.8	60.2 ± 13.5	59.2 ± 13.3
Male	106 (66%)	187 (76%)	185 (77%)	197 (82%)	200 (83%)
Cardiac Status					
Ischemic etiology for heart failure	79 (49%)	129 (53%)	127 (53%)	136 (56%)	128 (53%)
Left ventricular ejection fraction	17.7 ± 6.3	16.0 ± 5.8	16.8 ± 6.0	17.1 ± 6.0	16.3 ± 6.1
NYHA class IV	127 (79%)	204 (84%)	184 (77%)	168 (70%)	160 (63%)
Therapies					
Mechanical ventilation	48 (30%)	4 (2%)	7 (3%)	0 (0%)	5 (2%)
Intra-aortic balloon pump	84 (53%)	75 (31%)	65 (27%)	62 (26%)	49 (20%)
Implantable cardioverter-defibrillator	93/159 (58%)	200/242 (83%)	207 (87%)	200/239 (83%)	205/238 (85%)
Cardiac resynchronization therapy	61 (38%)	145 (59%)	141 (59%)	145 (60%)	138 (57%)
Inotropes	137 (86%)	209 (86%)	200 (84%)	192 (80%)	188 (78%)
ACE inhibitor or ARB	17 (17%)	65 (27%)	63 (26%)	75 (31%)	85 (35%)
Beta-blocker	49 (31%)	87 (36%)	111 (46%)	114 (47%)	136 (56%)
Furosemide dose equivalent (mg/kg)	3.18 ± 4.42	3.04 ± 4.66	2.30 ± 2.92	2.11 ± 2.49	2.17 ± 3.18
Vitals, Hemodynamics, Tests					
SBP (mmHg)	101 ± 15	100 ± 15	100 ± 14	101 ± 16	105 ± 17
CVP (mmHg)	14.2 ± 6.3	13.8 ± 7.1	12.8 ± 6.3	11.9 ± 6.3	11.5 ± 6.3
PCWP (mmHg)	24.7 ± 7.6	25.2 ± 8.4	25.4 ± 8.2	23.8 ± 8.3	24.7 ± 8.5
Cardiac Index (L/min/m^2)	2.06 ± 0.60	1.99 ± 0.63	2.05 ± 0.68	2.06 ± 0.68	2.00 ± 0.51
Sodium (mEq/L)	133.8 ± 5.7	133.6 ± 4.5	133.9 ± 4.4	134.7 ± 4.9	135.5 ± 4.0
Albumin (mg/dl)	3.39 ± 2.10	3.34 ± 0.53	3.44 ± 0.56	3.52 ± 0.54	3.66 ± 0.56
BUN (mg/dl)	32.3 ± 21.8	34.0 ± 19.6	33.1 ± 18.8	32.7 ± 23.7	31.8 ± 18.5
Creatinine (mg/dl)	1.48 ± 0.61	1.46 ± 0.53	1.47 ± 0.53	1.44 ± 0.54	1.50 ± 0.53
ALT (U/L)	129 ± 292	63 ± 143	61 ± 194	53 ± 100	45 ± 77
Hemoglobin	10.9 ± 1.9	11.2 ± 1.8	11.6 ± 1.9	11.6 ± 1.9	12.1 ± 2.0
Platelets per mm^3	213 ± 90	222 ± 92	222 ± 93	214 ± 83	208 ± 75

Values are expressed as mean ± standard deviation or number (percent). KCCQ = Kansas City Cardiomyopathy Questionnaire; NYHA = New York Heart Association; ACE = angiotensin converting enzyme; ARB = angiotensin II receptor blocker; SBP = systolic blood pressure; CVP = central venous pressure; PCWP = pulmonary capillary wedge pressure; BUN = blood urea nitrogen; ALT = alanine aminotransferase; Lower KCCQ scores indicate worse health status

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Table 2

Outcome stratified by pre-operative KCCQ score quartiles and missing KCCQ.

	Missing KCCQ *N=160*	**Quartile 1: KCCQ ≤ 14.6 *N=244***	**Quartile 2: KCCQ 14.7 – 24.7 *N=239***	**Quartile 3: KCCQ 24.8 – 38.8 *N=241***	**Quartile 4: KCCQ >38.8 *N=241***	**P value***
30-day survival	139 (87%)	217 (89%)	222 (93%)	232 (96%)	229 (95%)	0.0009
180-day survival	126 (79%)	186 (76%)	204 (85%)	203 (84%)	199 (83%)	0.0596
Days hospitalized at 180 days	36.5 ± 29.9	34.1 ± 27.1	33.7 ± 25.8	30.8 ± 24.3	29.8 ± 25.6	0.0090**
Days alive and outside the hospital at 180 days	103.0 ± 64.4	104.2 ± 64.7	109.3 ± 62.2	119.4 ± 54.3	118.3 ± 58.2	0.0043**

Data are expressed as either number (percent) or mean ± standard deviation Missing category considered lowest of the 5 categories.

KCCQ = Kansas City Cardiomyopathy Questionnaire; Lower KCCQ scores indicate worse health status

*P-values comparing trend across categories.

**Kruskal-Wallis non-parametric test.