



Peer-Reviewed Original Research

Predicting Left Ventricular Assist Device Outcomes Utilizing the Stanford Integrated Psychosocial Assessment for Transplant Measure

Nicholas J. Chesher,^{1,2,3} Kristina L. Greenwood,² Candace Fanale,^{1,2} Cody Gustavenson,² Brian Jaski,¹ Hirsch S. Mehta,¹ Peter Hoagland,¹ Kristine Ortiz,¹ Marc Verlasky,¹ Robert Adamson,¹ Walter Dembitsky¹

¹Sharp Memorial Hospital, San Diego, California

²Outcomes Research Institute, Sharp HealthCare, San Diego, California

³Department of Psychiatry, University of California, San Diego

*Corresponding author: nchesher@health.ucsd.edu

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Abstract

Objective: Durable mechanical circulatory support is a proven therapy to extend survival for patients with end-stage heart failure (HF). The International Society for Heart and Lung Transplantation guidelines recommend a detailed psychosocial assessment when selecting candidates for durable mechanical circulatory support. Currently, there are no formally validated psychosocial evaluation tools for left ventricular assist device (LVAD) candidacy. The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) uses a multidisciplinary algorithm to evaluate the impact of pre-transplant risk factors on post-transplant outcomes. Emerging literature suggests that the SIPAT might be useful for assessing psychosocial risk factors for LVAD outcomes.

Methods: A total of 268 consecutive patients (median age 66 years, 84.6% male) with terminal HF were evaluated before LVAD implantation with a SIPAT assessment. Key outcomes included readmission and mortality rates at 30 days and two years.

Results: After screening, 234 subjects met the inclusion criteria and were analyzed. The *Patient Readiness* subscale of the SIPAT was statistically significant in predicting two-year mortality ($B = .167$, $P < .001$; Nagelkerke $r^2 = .106$). Scores on the SIPAT did not correlate to 30-day readmission, 30-day mortality, or two-year readmission rates.

Discussion: In this study, only the *Patient Readiness* score was associated with mortality at two-years post-implantation. This research elucidates the potential longer-term impact of psychosocial factors on LVAD outcomes and the SIPAT's utility in evaluating LVAD candidacy.

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Introduction

Approximately 6 million adults in the United States alone are diagnosed with heart failure (HF).¹ Of those, about half, or 3 million, are estimated to die within five years of diagnosis.¹ In addition to mortality, HF is estimated to cost the nation approximately \$30.7 billion each year in ongoing healthcare expenditures as well as decreased productivity with missed days of work.¹ For these reasons, a great deal of innovation and effort is geared toward optimizing advanced therapies for HF.²

Despite guideline-directed medical therapy, a subset of heart failure (HF) patients will decline and progress to end-stage HF. At this point, options to improve survival include heart transplantation or implanting a durable mechanical circulatory support device, such as a left ventricular assist device (LVAD). While heart transplantation is viewed as the gold-standard intervention for end-stage HF, the limited availability of donor hearts necessitates other interventions. It is estimated that annually 35,000 – 100,000 individuals with advanced HF in the United States could benefit from a mechanical circulatory support device.³

LVADs are the most commonly used durable support device for HF; they unload the left ventricle via mechanical pump support, which results in adequate systemic circulation.⁴ When considering pre-surgical candidacy for transplant or an LVAD, The International Society for Heart and Lung Transplantation (ISHLT) guidelines recommend a detailed psychosocial evaluation as part of the multidisciplinary evaluation process. This recommendation is based on the association of various psychosocial risk factors to increased rates of hospital readmission, morbidity, and mortality following surgical intervention in this population. Common psychosocial factors considered in this process include adequacy of social support, psychological/psychiatric stability, degree of patient knowledge and engagement in their own care, treatment compliance, adaptation of key lifestyle factors, adequacy of cognitive functioning, and history with substance use.⁴

Various validated psychosocial risk-factor assessment tools exist for the evaluation of transplant candidacy.^{5,6} Although the importance of evaluating psychosocial risk factors before heart transplantation has been established, there is limited literature regarding how psychosocial risk factors predict clinical outcomes for patients undergoing LVAD implantation.⁷⁻¹³ Due to the lack of validated LVAD assessment tools, the same parameters used for transplant candidacy are used before LVAD implantation. It is assumed that a strong psychosocial overlap exists; however, this overlap does not account for differences in specific psychosocial issues or levels of readiness that may have alternate implications for LVAD candidacy. For example, care after an LVAD implantation requires a high level of patient engagement and strong caregiver support for optimal outcomes. Providers need specific and measurable behavioral and observational markers to assess the level of risk and subsequent outcomes related to psychosocial risk factors.

The Stanford Integrated Psychosocial Assessment for Transplant (SIPAT) is one measure for transplant candidacy. The SIPAT is commonly used to evaluate psychosocial risk factors associated with outcomes for heart transplantation but has



not been validated to measure psychosocial candidacy for durable LVAD implantation.

The current study aims to assess the SIPAT measure for use in LVAD candidacy evaluation by (1) demonstrating the utility of SIPAT scores to predict outcomes in those undergoing LVAD implantation and (2) demonstrating the utility of each domain within the SIPAT to predict outcomes differentially. Domains include Patient Readiness, Social Support, Psychological Stability, and Substance Use. Due to the above-noted limitations in the current literature, analysis of the existing scores could clarify the utility of the SIPAT in predicting clinical outcomes for those undergoing LVAD implantation, with the advantage of analyzing these outcomes over a longer period than previously studied (up to two years) and with a larger sample size.

Longer-term evaluation of outcomes related to psychosocial predictors is considered important given the likelihood of delayed consequences due to these factors. This data analysis also identifies the relative contribution of various psychosocial domains to clinical outcomes. From a practical and clinical perspective, enhanced clinical outcomes prediction could significantly reduce readmission rates and mortality related to LVAD intervention.

The primary research questions include the following:

- How do the SIPAT total and subscale scores perform as predictors of clinical outcomes (i.e., 30-day readmission and mortality rates, two-year readmission and mortality rates) for patients undergoing LVAD implantation?
- What is the relative contribution of various demographic variables and psychosocial domains of the SIPAT in predicting clinical outcomes (i.e., 30-day readmission and mortality rates, two-year readmission and mortality rates) for patients undergoing LVAD implantation?

Methods

This single-center, retrospective study included 268 consecutive adults (> 18 years of age) who were evaluated for candidacy by a multidisciplinary team and underwent durable LVAD implantation as a bridge to transplant or destination therapy between 2009 and 2017. To be included in the study, patients had documented pre-surgical psychosocial evaluation for surgical candidacy utilizing the SIPAT **OR** sufficient psychosocial documentation to allow for a retrospective calculation of a pre-surgical SIPAT score. Patients were not excluded based on gender, sex, or racial or ethnic origin. The local Institutional Review Board reviewed the study, and a waiver of informed consent was granted. This study fully complies with the ISHLT Ethics statement.

SIPAT

The SIPAT score consists of 21 items organized into four subscales measuring patient readiness, social support, psychological stability, and substance use. A total score is calculated and used to assess candidacy.⁵ The patient readiness subscale assesses the understanding of the illness and intervention and the willingness and



desire for the intervention. The social support subscale evaluates the availability and ability of the patient's support network to offer appropriate care and reinforce recovery. The psychological stability subscale assesses the patient's current and historical psychological well-being. Finally, the substance use subscale assesses the patient's current and historical use of alcohol, nicotine, and illicit substances.

Trained research assistants, blinded to patient outcome data, retrospectively rated patients on the SIPAT utilizing psychosocial evaluations and data documented in the electronic medical record before implantation. The blinded lead investigator independently confirmed these scores to ensure reliability and consistency.

Demographic and Outcome Variables

Information on study participants included a comprehensive set of structured data elements from an integrated electronic medical record system and facility registries for patients receiving advanced heart failure services. Data elements included age at discharge, sex, race, ethnicity, primary language, marital status, employment status, and type of insurance coverage.

Readmission and Mortality

The primary outcomes were 30-day and two-year post-discharge readmission rates and mortality. Thirty-day mortality was defined as death occurring less than 30 days after the date of hospital discharge for the LVAD implantation procedure; patients who did not survive surgical implantation were excluded. Two-year mortality was calculated when death occurred following discharge for LVAD surgical implantation; of note, those who did not survive 30-days post-discharge were excluded from the calculation. Thirty-day and two-year readmission rates were calculated based on first readmissions during the specified time frame and excluded outpatient procedures and scheduled diagnostic follow-ups in the hospital, such as heart catheterization procedures.

Results

Of 268 total participants, 234 met inclusion and exclusion criteria. Thirty-four participants were excluded due to incomplete historical medical records. Patient demographics are shown in Table 1. The average age was 63.5 ± 13.4 years, and the majority were male, white, and spoke English as their primary language. Most participants were retired or disabled and were covered by Medicare health insurance plans, which is expected for this population.

Table 2 displays descriptive data for all participants and cohorts stratified by primary outcomes, their SIPAT subscale, and total scores. Concerning mortality, 36 participants died within two years, although relatively few died during the index LVAD hospitalization or within 30 days post-discharge. The mean number of days between index discharge and death was 319 (median = 302).



Table 1. Study Population Demographics. A total of 234 patients were included.

Characteristics		N (Frequency)
Age at Discharge (years)		
	<i>Range</i>	20-87
	<i>Mean (±SD)</i>	63.5 (±13.4)
Sex		
	<i>Male</i>	198 (84.6%)
	<i>Female</i>	36 (15.4%)
Race/Ethnicity		
	<i>Asian</i>	19 (8.1%)
	<i>Black or African American</i>	21 (9.0%)
	<i>White</i>	150 (64.1%)
	<i>Other/Unknown</i>	44 (18.8%)
Primary Language		
	<i>English</i>	214 (91.5%)
	<i>Other/Unknown</i>	20 (8.5%)
Employment Status		
	<i>Employed</i>	23 (9.8%)
	<i>Retired</i>	135 (57.7%)
	<i>Disability</i>	57 (24.3%)
	<i>Active-Duty Military</i>	3 (1.3%)
	<i>Unemployed</i>	13 (5.6%)
	<i>Other/Unknown</i>	3 (1.3%)
Type of Insurance		
	<i>Medicare/Supplements</i>	148 (63.2%)
	<i>Commercial/Private</i>	74 (31.6%)
	<i>MediCal/County Services</i>	10 (4.3%)
	<i>Other/Unknown</i>	2 (0.9%)

Over 90% of discharged participants received additional acute care services within the two-year post-discharge period, although less than a quarter was readmitted within 30 days. Among the 147 participants who were readmitted between 30 days and two years, the mean number of days between index discharge and first readmission date was 175 (median = 113). There was considerable variability in the distribution of the SIPAT subscale and total scores among participants. However, the mean total SIPAT score for all cohorts was within the thresholds considered for “good” candidates (range = 7 to 20) or “minimally acceptable” candidates (range = 21 to 39) based on standards for organ transplantation.

Analyses examined the relative contributions of SIPAT total score, and subscales in predicting primary outcomes. Binary logistic regressions were performed to determine if SIPAT total scores predicted mortality or readmission. Variables were assessed to ensure assumptions of the logistic regression were met. In particular, the independent variables did not violate the multicollinearity assumption (VIF range: 1.123 – 1.237). The linear relationship of log odds and independent variables found that all independent variables met this assumption. However, the 30-day mortality outcome exhibited a very low observed occurrence rate of 1.3% and was excluded from additional analysis. This likely reflects how mortality was defined, excluding patients who did not survive surgical implantation/index hospitalization.



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		Patient Readiness			Social Support			Psychological Stability			Substance Use			SIPAT Total Score		
		Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD
All Study Participants																
	234 (100%)	0-18	5.6	4.0	0 - 19	3.3	3.5	0 - 18	6.2	4.3	0 - 23	4.3	4.2	3 - 64	19.3	10.8
No Documentation of Mortality within 2 Years																
	176 (75.2%)	0-16	5.1	3.6	0-14	2.9	3.0	0-17	5.9	4.0	0-23	4.1	4.3	3-57	17.8	9.5
Mortality within 2 Years																
<i>Died Before Discharge</i>	19 (8.1%)	0-15	6.6	4.1	0-15	4.8	4.4	0-14	6.4	4.8	0-9	4.0	2.9	8-47	21.8	9.5
<i>Within 30 Days Post-Discharge</i>	3 (1.3%)	0-9	5.0	4.6	1-3	2.0	1.0	0-5	1.7	2.9	0-1	0.7	0.6	3-13	9.3	5.5
<i>Between 31 Days and 2 Years Post-Discharge</i>	36 (15.4%)	1-18	7.8	4.8	0-19	4.6	4.9	0-18	7.7	5.3	0-18	6.1	4.4	3-64	26.2	14.5
<i>Total</i>	58 (24.8%)															
Readmission for Acute Care Services within 2 Years*																
<i>Within 30 Days Post-Discharge</i>	48 (22.3%)	0-12	5.1	3.3	0-19	3.2	3.8	0-14	5.4	3.9	0-11	3.7	3.0	3-44	17.3	8.2
<i>Between 31 Days and 2 Years Post-Discharge</i>	147 (68.4%)	0-18	5.7	4.1	0-14	3.1	3.3	0-18	6.4	4.3	0-23	4.6	4.6	3-64	19.7	11.3
<i>Total</i>	195 (90.7%)															



Results from the binary logistic regression indicated that total SIPAT scores were not statistically significant in predicting 30-day readmission, two-year readmission, or two-year mortality.

Analyses using stepwise logistic regression models indicated that scores of the individual SIPAT subscales (Patient Readiness, Social Support, Psychological Stability, and Substance Use) did not predict 30-day or two-year readmission. However, results from a model including all SIPAT subscales indicated that the Patient Readiness subscale was statistically significant in predicting two-year mortality ($B = .167$, $P < .001$; Nagelkerke $r^2 = .106$). This study's SIPAT total scores did not significantly predict 30-day readmission, two-year readmission, or two-year mortality.

Figure 1 below compares the distributions of SIPAT subscale scores by participant cohorts based on the occurrence of mortality within two years.

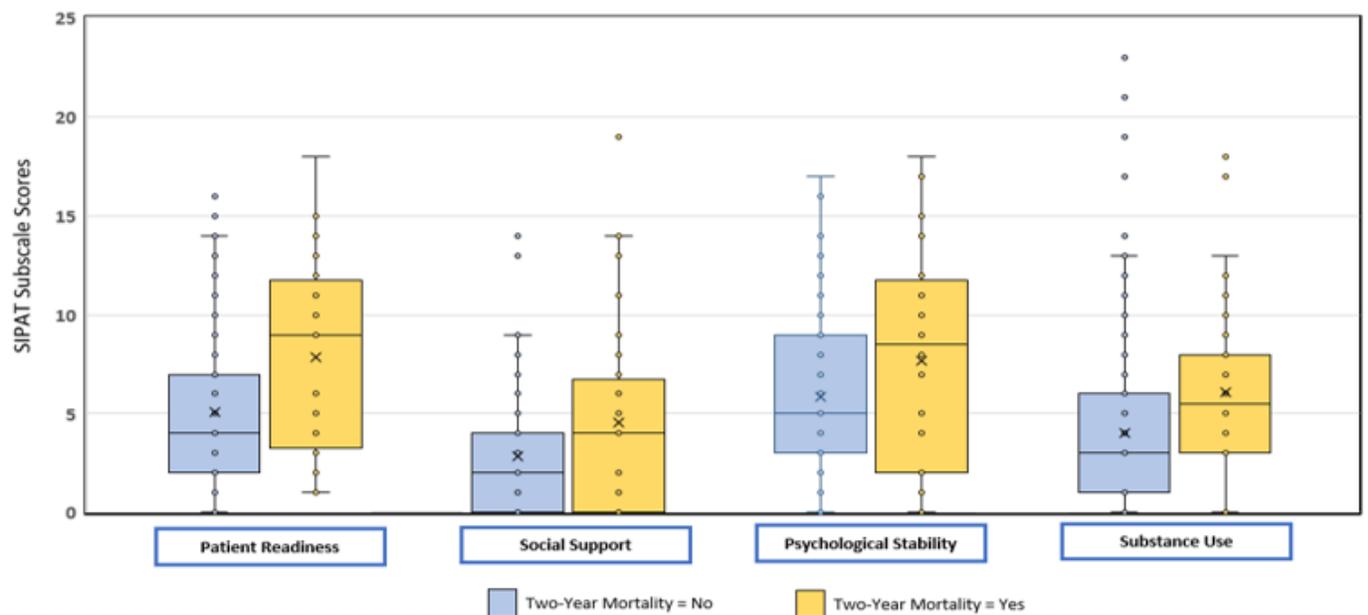


Figure 1. SIPAT Subscale Score Distributions. Cohorts are compared by two-year mortality. Within each box plot, “X” denotes the mean score of the distribution. Amount the SIPAT subscales, Patient Readiness was a statistically significant predictor of two-year mortality ($B = .167$, $P < .001$; Nagelkerke $r^2 = .106$)

Discussion

This retrospective study evaluated the usefulness of the SIPAT psychosocial assessment score as a predictor of outcomes among patients who underwent durable LVAD implantation. Of the SIPAT’s subscales, the Patient Readiness subscale was statistically significant in predicting survival after two years. In addition to assessing the patient’s knowledge of heart failure causes and surgical



procedures, the Patient Readiness subscale evaluates medical treatment compliance and comprehension of patients' current disposition and responsiveness to medical intervention. These results have implications for optimizing patient selection, reducing risk before surgery, optimizing compliance, and monitoring psychosocial function, particularly during longer post-surgery periods. Analyses of total SIPAT scores were not statistically significant for any outcome measures.

Study limitations include the extrapolation of a standardized measure originally designed to assess heart transplantation in a population receiving durable LVAD support. Other psychosocial or environmental factors the SIPAT does not evaluate may be relevant in predicting outcomes for patients undergoing LVAD implantation. The study retrospectively calculated pre-surgical SIPAT scores based on examining medical records at a single center. As with any investigation that is not population-wide, there are limits to generalizing results beyond the patient, practitioner, and setting characteristics within the regional integrated healthcare delivery system where the study was conducted. Finally, these data suggest implications for assessing general candidacy for LVAD implantation; however, this study specifically focuses on assessing preoperative psychosocial risk for adverse outcomes in a subset of candidates who were accepted for and underwent LVAD implantation. It does not address the cohort of potential candidates who never underwent LVAD implantation due to psychosocial or medical contraindications. The study contributes to an existing body of research by having a substantially larger sample size while evaluating readmission and mortality rates during a two-year post-discharge time frame in addition to the standard 30-day metric.

Future directions include conducting a prospective study that assesses the impact of the SIPAT and other psychosocial determinants of health on outcomes for LVAD patients. The integration of variables such as stage of heart failure, co-morbidities, and biomarkers could further refine predictive algorithms for post-surgical outcomes. Although the study results emphasize the importance of patient readiness for LVAD implantation outcomes, further research on interventions to improve patient readiness and resilience and subsequently improve outcomes is needed. Additionally, addressing the status and impact of cognitive functioning on outcome, readiness, or on response to psychological intervention are important factors to consider when addressing risk for poor outcomes.

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