Standardized Use of the Stanford Integrated Psychosocial Assessment for Transplantation in LVAD Patients

MATTHEW CAGLIOSTRO, MD, MPH,[1,*] ANDREW BROMLEY, MD,[1,*] PETER TING, MD,[1] JOHN DONEHEY,[3] BART FERKET, MD, PhD,[4] KIRA PARKS, LMSW,[3] ELYSE PALUMBO, LCSW,[3] DONNA MANCINI, MD,[1,2] ANELECHI ANYANWU, MD,[1] AMIT PAWALE, MD,[1] SEAN PINNEY, MD,[1,2] NOAH MOSS, MD,[1,2] AND ANURADHA LALA, MD[1,2,4]

New York, New York

ABSTRACT

Background: Increased psychosocial risk portends poor outcomes following heart transplantation. The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) is a validated, psychosocial risk assessment tool that helps stratify candidates for transplantation. We assessed the impact of psychosocial factors as measured by the SIPAT on clinical outcomes following left ventricular assist device (LVAD) implantation at our institution.

Methods and Results: A total of 115 individuals (mean age: 57 years, 75.6% men) who underwent LVAD implantation, for either bridge-to-transplant (63%) or destination therapy, from 2014 to 2016 were included for analysis. Correlations between SIPAT scores, baseline characteristics, and post-LVAD outcomes were assessed through a retrospective correlational design. At 1 year post-LVAD, the higher risk SIPAT group had more emergency department visits, urgent clinic visits, and readmissions in univariate analysis (rate ratio 1.7 [95% confidence interval (CI) 1.0−2.7, $P = .035$]). After multivariate analysis, this association retained near-statistical significance (rate ratio 1.6 [95% CI 1.0−2.8, $P = .051$]). There was also a trend toward more device-associated infections (rate ratio 2.1 [95% CI 0.96−4.4, $P = .064$]). There was no difference in incidence of other adverse events or 1-year mortality between the 2 groups.

Conclusions: Higher psychosocial risk per SIPAT in patients undergoing LVAD implantation is associated with more emergency room visits, urgent visits and readmissions over 1 year, but not LVAD-related complications or mortality. Use of the SIPAT tool may help identify patients at higher risk for hospitalization and/or urgent care beyond traditional factors, but should not preclude LVAD implantation. (*J Cardiac Fail 2019;25:735−743*)

Key Words: Heart failure, LVAD, Stanford Integrated Psychosocial Assessment for Transplantation, driveline-associated infection, orthotopic heart transplantation, device-associated infections.

The advent of durable mechanical circulatory support (MCS) with left ventricular assist devices (LVAD) has greatly improved the survival and health-related quality of life for patients with advanced heart failure. In fact, with >4000 implants performed annually, LVAD implantation now exceeds the number of heart transplants performed each year in the United States.[1]

To determine candidacy for these advanced therapies, it is well established that a psychosocial evaluation is essential, particularly for heart transplantation.[2−8] The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) is a validated, psychosocial risk assessment tool that helps to stratify transplant candidates for outcomes after transplantation; namely rates of rejection episodes, medical hospitalizations, infections, psychiatric decompensations, and support system failure.[9−11] The SIPAT examines distinct psychosocial risk factors to determine an overall risk score ranging from 0 to 115, with higher scores representing higher risk.

Evaluation of psychosocial risk is also important in determining the success of LVAD implantation, yet there are no standardized processes by which risk is assessed for these patients.[12−15] Our center utilizes the SIPAT tool for all patients undergoing evaluation for advanced therapies including transplant and LVAD as a standard of care. We

From the [1]Mount Sinai Hospital, Icahn School of Medicine at Mount Sinai, New York, New York; [2]Mount Sinai Hospital, The Zena and Michael A. Wiener Cardiovascular Institute, New York, New York; [3]Mount Sinai Medical Center, New York, New York and [4]The Department of Population Health Science and Policy, Icahn School of Medicine at Mount Sinai, New York, New York.

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Reprint requests: Anuradha Lala, MD, 1 Gustave Levy Place, New York, NY 10029. Phone: 212-241-7300, Fax: 212-289-5971. E-mail: Anu.lala@mountsinai.org

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sought to assess the impact of the psychosocial risk factors as captured specifically by the SIPAT on clinical outcomes following LVAD implantation.

Methods

Baseline Characteristics

This single-center study utilized a retrospective correlational design aiming to assess correlations between SIPAT scores and baseline characteristics as well as post-LVAD outcomes. After obtaining approval from the Institutional Review Board, medical charts from all adult patients who underwent evaluation for initial durable MCS implantation at the Mount Sinai Hospital between January 1, 2014 and December 31, 2016 were reviewed. Patients who underwent total artificial heart placement were excluded.

Demographic, medical, and psychosocial data were collected starting from a patient's pre-LVAD assessment up until 1 year after LVAD implantation. Data collection was completed by chart review of the electronic medical record, and paper charts when relevant. Pre-LVAD demographic and medical characteristics, including insurance type and INTERMACS profiles were compared between the higher- and lower-risk SIPAT groups.

The Stanford Integrated Psychosocial Assessment for Transplantation

All patients undergoing consideration for advanced therapies including orthotopic heart transplant (OHT) and/or durable MCS are required to meet with a designated LVAD/OHT social worker. Three LVAD/OHT social workers at our institution are trained in administering the SIPAT as part of a comprehensive psychosocial evaluation for each candidate. The SIPAT is routinely employed in both inpatient and outpatient settings. Of note, in rare circumstances, the SIPAT is not completed for patients who are unable to participate due to severe acute clinical deterioration.

The SIPAT score involves 18 items across 4 risk factor domains: 1) patient readiness level and illness management, 2) social support system and level of readiness, 3) psychological stability and psychopathology, and 4) lifestyle and effect of substance use (Fig. 1). Within each domain, certain items are associated with poor clinical outcomes, such as history of non-adherence and active substance abuse, and are therefore weighted more heavily. Based on the calculated score, patients are stratified into risk groups including "excellent", "good", "minimally acceptable", "high risk", and "poor" candidates. Patients' psychosocial risk was categorized by SIPAT score into lower-risk and higher-risk groups based on established thresholds, with scores ≤ 20 defined as lower risk and scores >20 defined as higher risk, out of a total possible score of 115.[9,16]

Outcomes

The primary outcome-of-interest was the composite of total urgent clinic visits, emergency room visits, and admissions at 1 year, hereby referred to as unplanned health-care utilization. Secondary outcomes included mortality during the index hospitalization and at 1 year, index hospital length of stay, intensive care unit (ICU) days during index hospitalization, days in hospital at 1 year, and LVAD-associated complications including ventricular arrhythmia, ischemic or hemorrhagic strokes, gastrointestinal bleeds, infections, right heart failure, pump thrombosis, and venous thromboembolic (VTE) events. We also examined total days of unplanned health-care utilization in aggregate and each individual component. Infection was subcategorized as device-associated infections (DAI) versus other types of infections.

Statistical Analysis

For the statistical analysis, continuous variables were analyzed using the pooled t test if the distribution of the variable was normal and the variance was equal. If the variance was unequal, the Cochran method was used. If the variable did not follow a normal distribution, the Wilcoxon rank sum test was used. A Poisson regression was used for count data when the model was not overdispersed. In the remaining models, to prevent overdispersion from creating understated standard errors, either a negative binomial regression or a Poisson regression model with a scale adjustment for overdispersion estimated by the square root of Pearson's chi-square divided by the degrees of freedom were used. To choose between these 2 models, the model with the lower Akaike's information criteria value and lower Bayesian information criteria value was used. To account for patients with incomplete follow up, the log of the follow-up time was used as an offset variable in the model. The follow-up time was defined as the number of days until OHT, death, or until the patient was lost to follow-up, whichever happened first. For categorical data, the chi-square test was used unless the variable was ordinal, in which case the Mantel−Hansel test was used. To control for age when comparing the frequency of patients who were implanted as destination therapy as opposed to bridge-to-transplant, the Cochran−Mantel−Haenszel test was used. A Kaplan−Meier log rank test was used to compare the time to downgrade from the ICU and time to discharge after LVAD implant between the 2 groups. To decrease potential confounding effects from age and INTERMACS profile on SIPAT score, we created 3 multivariate models for the composite outcome of total urgent care visits, emergency department (ED) visits and admissions, total days admitted, and total days spent in the ED. For all models, we included SIPAT score, INTERMACS profile, and age quartile as the independent variables except for total days spent in the ED, because the model did converge when INTERMACS was included. Analysis was performed using SAS University Edition, version 9.4.

Results

Baseline Characteristics

From 2014 to 2016, 150 patients underwent evaluation for initial implantation of durable MCS at our institution.

Patient Readiness and Illness Management (Points 0-24)	Social Support System (Points 0-20)	Psychosocial Stability (Points 0-37)	Lifestyle Effects (Points 0-29)
Knowledge/ understanding of medical illness	Availability	Psychopathology (present or past)	Alcohol Use Disorder (present or past)
Knowledge/ understanding of LVAD process	Functionality	Organic psychopathology or Neurocognitive impairment	Risk for Alcohol Use Recidivism
Willingness/desire for LVAD	Living Space Appropriateness	Personality traits/disorder	Substance Use Disorder (present or past)
History of treatment adherence		Truthfulness vs Deceptiveness assessment	Risk for Substance Use Recidivism
Responsiveness to modifications in lifestyle factors		Overall Psychopathology Risk	Nicotine Use Disorder (present or past)

Fig. 1. The SIPAT tool, adjusted for LVAD patients.[9,10]

Of these, 35 patients were excluded from analysis, with 16 total artificial heart implants and 6 patients who underwent LVAD implantation but did not have SIPAT scores recorded. The remaining 13 patients were excluded as they were not offered durable MCS, 5 of whom for social reasons. Thus, a total of 115 patients who underwent initial durable LVAD implantation and had SIPAT scores recorded were included for analysis (Fig. 2). The baseline characteristics for the cohort are shown in Table 1. The group was predominantly male (75.6%) with median age of 57 years old, and median time for follow-up was 365 days (IQR 271−365). There was racial and ethnic diversity in the group, with 38.1% identifying as Non-Hispanic White. A majority (61.7%) had a history of ischemic cardiomyopathy, with 40.4% reporting a history of diabetes mellitus and 42.6% chronic kidney disease. Nearly one-third (30.7%) of patients were INTERMACS profiles 1 and 2, with most patients being INTERMACS profile 3 or higher at time of LVAD implant. A majority of patients received LVAD therapy as bridge-to-transplant (62.6%), and the Heartmate II (Abbott) was the most common LVAD implanted (79.1%). The remainder of LVAD implants were the Heartmate III (Abbott) (13.9%) or HeartWare (Medtronic) (7%). Most patients had public insurance, with >50% having Medicaid or Medicare (Table 1).

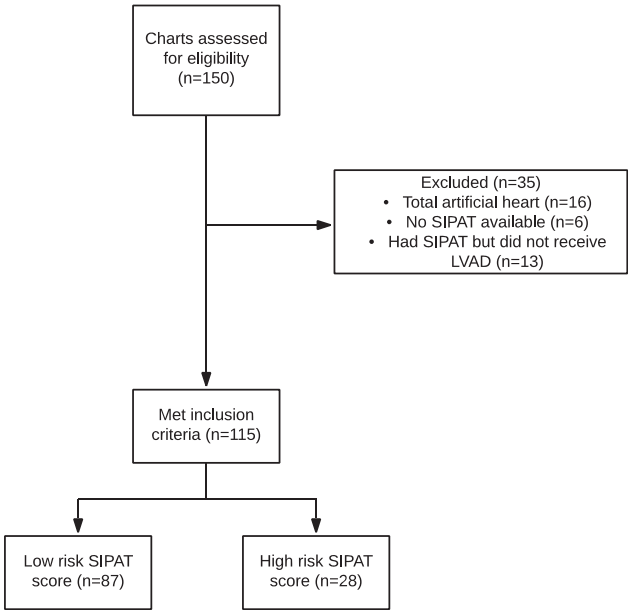

Fig. 2. Flowchart of participant selection.

SIPAT Scores

Most patients were deemed *Excellent* (15/115; 13%) or *Good* (72/115; 62.6%) by SIPAT (ie, score ≤20), and the median SIPAT score was 14.8 (IQR 8−20; Fig. 3). Median time between SIPAT evaluation and LVAD implantation was 13 days (IQR 6−31). Baseline characteristics in the lower (SIPAT ≤20) and higher (SIPAT >20) risk groups were similar (Table 1), except higher SIPAT risk patients were more likely to have had Medicaid insurance, smoking history, or fall into INTERMACS profiles 1−2.

Overall assignment to higher- or lower-risk groups was consistent across all the subdomains of the SIPAT. For example, the lower-risk SIPAT group (score ≤20) had significantly lower subscores across all 4 domains of the SIPAT, including Readiness, Social Support, Psychologic Stability, and Lifestyle and Substance Abuse compared to patients in the higher-risk group. The domain level differences were most notable in the social support category (2.75 vs 10.2, $P < .0001$; Fig. 4).

Table 1. Baseline Characteristics and Comorbidities of Patients Who Received a LVAD by SIPAT Score

	Entire Cohort	SIPAT Score ≤20 (n = 87)	SIPAT Score >20 (n = 28)	*P*
Age	57 (48, 67)	57 (50, 68)	56.5 (45, 62)	.1065*
BMI	25.2 (21.4, 28.8)	25.7 (21.5, 28.7)	24 (21.3, 30.4)	.9332†
Female gender	28 (24.4%)	22 (25.3%)	6 (21.4%)	.9619‡
Ethnicity (n = 113)				
White	43 (38.1%)	33 (37.9%)	10 (35.7%)	.2199‡
Black	34 (30.1%)	24 (27.6%)	10 (35.7%)	
Hispanic	22 (19.5%)	15 (17.2%)	7 (25%)	
Asian	10 (8.9%)	10 (11.5%)	0 (0%)	
Other	4 (3.5%)	4 (4.6%)	0 (0%)	
Insurance type				
Medicaid	29 (25.4%)	16 (18.6%)	13 (46.4%)	**.0495**‡
Medicare	34 (29.8%)	28 (32.6%)	6 (21.4%)	
Medicare and Medicaid	18 (15.8%)	16 (18.6%)	2 (7.1%)	
Commercial	32 (28.1%)	25 (29.1%)	7 (25%)	
Emergency Medicaid/uninsured	1 (0.9%)	1 (1.2%)	0 (0%)	
Smoking				
Never	56 (58.7%)	51 (58.6%)	5 (17.9%)	<**.0001**§
Former	55 (47.8%)	36 (41.4%)	19 (67.9%)	
Active	4 (3.5%)	0 (0%)	4 (14.3%)	
Comorbidities				
Ischemic CM	71 (61.7%)	53 (60.9%)	18 (66.1%)	.7499‡
CABG	21 (18.3%)	16 (18.4%)	5 (18.5%)	.9493‡
CTS	28 (24.4%)	21 (24.1%)	7 (25.9%)	.9263‡
DM	46 (40.4%)	38 (43.7%)	8 (28.8%)	.1848‡
CKD	49 (42.6%)	36 (41.4%)	13 (47.5%)	.6384‡
Pulmonary disease	23 (20.0%)	15 (17.2%)	8 (28.9%)	.2758‡
MI	35 (30.4%)	26 (29.9%)	9 (33.1%)	.8213‡
Malignancy	8 (7.0%)	6 (6.9%)	2 (7.4%)	.9645‡
Ventricular arrhythmia	31 (27.0%)	20 (23%)	11 (39.4%)	.091‡
ICD	92 (80.0%)	67 (77%)	25 (89.8%)	.1579‡
EF at LVAD implant	16% (13%, 25%)	17% (14%, 25%)	15% (13%, 19%)	.1717‡
INTERMACS profile (n = 114)				
1	12 (10.5%)	8 (9.3%)	4 (14.3%)	**.0482**§
2	23 (20.2%)	13 (15.1%)	10 (35.7%)	
3	70 (61.4%)	57 (66.3%)	13 (46.4%)	
4	4 (3.5%)	4 (4.7%)	0 (0%)	
5	5 (4.4%)	4 (4.7%)	1 (3.6%)	
Goal of therapy				
Bridge to transplant	72 (62.6%)	57 (65.5%)	15 (53.6%)	.2701‡
Destination therapy	43 (37.4%)	30 (34.5%)	13 (46.4%)	.2777‖
LVAD implanted				
HeartMate II	91 (79.1%)	69 (79.3%)	22 (78.6%)	.9965‡
HeartMate III	16 (13.9%)	12 (13.8%)	4 (14.3%)	
HeartWare	8 (7.0%)	6 (6.9%)	2 (7.1%)	
SIPAT (n = 93)				
Mean score	14.8	10.4	29.6	**.0001***
Excellent	15 (13.0%)	15 (17.2%)	0 (0%)	
Good	72 (62.6%)	72 (82.8%)	0 (0%)	
Minimally acceptable	24 (20.9%)	0 (0%)	24 (85.7%)	
Poor	4 (3.5%)	0 (0%)	4 (14.3%)	<**.0001**‡

Values presented as frequency (%) or median (interquartile range) unless otherwise indicated. Unless otherwise indicated, data were available for all 115 patients. Two patients were missing data for ethnicity and 1 patient was missing data for INTERMACS profile. Pulmonary disease included asthma, chronic obstructive lung disease, and pulmonary fibrosis.

BMI, body mass index; CABG, coronary artery bypass surgery; CKD, chronic kidney disease; CM, cardiomyopathy; CTS, cardiothoracic surgery; DM, diabetes mellitus; MI, myocardial infarction, ICD, implantable cardioverter defibrillator; EF, ejection fraction.

All bolded P-values are reflective of comparisons of distributions for these categories.

*Wilcoxon rank sum.

†Pooled *t* test.

‡Chi-square.

§Mantel−Haenszel.

‖Cochran−Mantel−Haenszel (controlled for age).

During the study period, 13 patients were presented for LVAD but were not "accepted" and did not receive LVAD for various reasons. Of these, 5 were excluded predominantly because of social issues. Patient profile and reasons for exclusion are provided in Supplementary Table 1. Because the focus of the present analysis was to assess the association of psychosocial risk per the SIPAT tool with post LVAD outcomes, clinical outcomes of patients who did not undergo LVAD implantation were not analyzed.

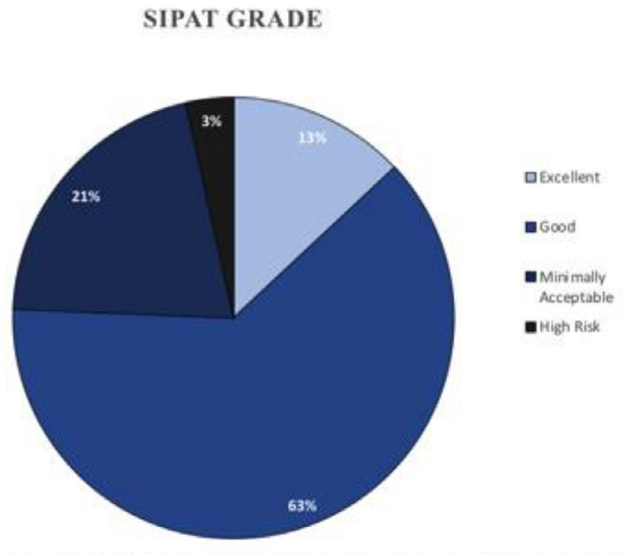

Fig. 3. Pie chart demonstrating the distribution of SIPAT grades in this study. Grade 1 represents, from a psychosocial standpoint, patients at a lower risk of developing complications after transplantation. Grade 4 represents the highest-risk candidates for transplantation.

Unplanned Health-Care Utilization

At 1 year post-LVAD, there were 266 visits for unplanned health-care utilization (including 86 total ED visits, 19 total urgent clinic visits, and 161 hospital readmissions). The higher-risk SIPAT group had a significantly greater number of composite emergency department visits, urgent clinic visits, and/or hospital readmissions (rate ratio 1.7 [95% CI 1.0−2.7, $P = .035$]; Table 2). After multivariate analysis, this association retained near-statistical significance (rate ratio 1.6 [95% CI 1.0−2.8, $P = .051$]). The higher-risk group also had a trend toward more days of unplanned health-care utilization (univariate rate ratio 2.1 [95% CI 1.0−4.3, $P = .052$]); multivariate rate ratio 2.0 (95% CI 1.0−4.2, $P = .058$). With this aggregate divided into individual components, there were significantly more days in the emergency department at 1 year in both univariate and multivariate analyses (multivariate rate ratio 3.3 [95% CI 1.1−9.9, $P = .032$]). There was no statistically significant difference in the number of days in hospital between the 2 groups.

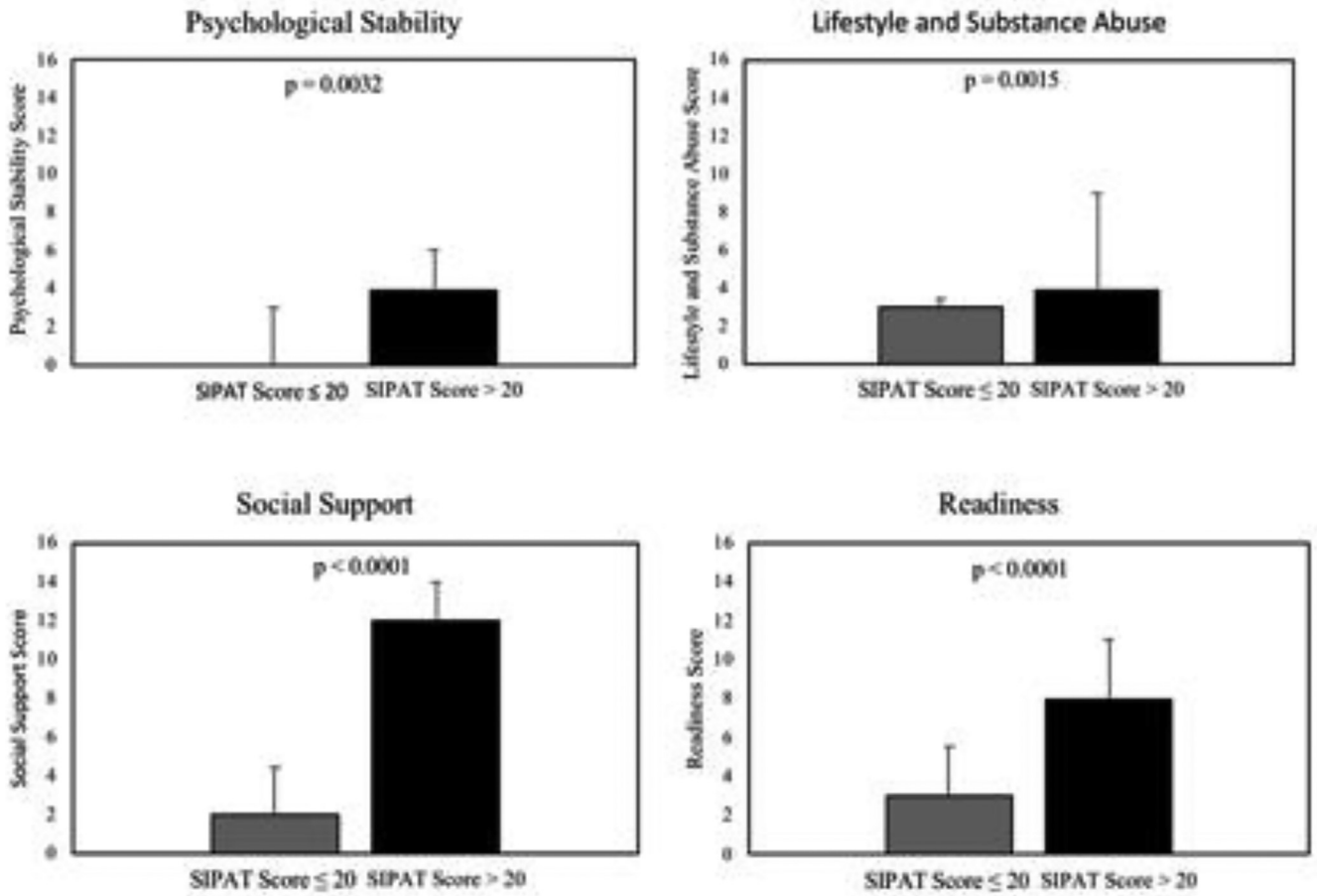

Fig. 4. Subsections of the SIPAT score separated by SIPAT score ≤20 and >20. The 4 subsections are patient's readiness level (Readiness), social support system (Social Support), psychological stability and psychopathology (Psychological Stability), lifestyle and effect of substance abuse (Lifestyle and Substance abuse). The median score with the positive error bars for the interquartile range were graphed. Data were available for the breakdown of the score for 72 patients with SIPAT scores <20, and for 21 patients with SIPAT scores >=20.

Table 2. Unplanned Health-care Utilization by SIPAT score

	SIPAT ≤20	SIPAT >20	Univariate Rate Ratio	Multivariate Rate Ratio*
Urgent care days (mean, n = 108)	14 (0.17)	5 (0.19)	1.1 (95% CI 0.3−3.7, P = .937)	1.0 (95% CI 0.3−3.5, P = .95)
ED days (mean, n = 109)	32 (0.39)	50 (1.92)	3.8 (95% CI 1.3−10.9, P = .0123)	3.3 (95% CI 1.1−9.9, P = .0315)
Days admitted (mean, n = 109)	1008 (12.1)	780 (30)	1.9 (95% CI 0.8−4.4, P = .1203)	1.9 (95% CI 0.8−4.3, P = .1378)
Days of unplanned health care use (mean, n = 109)	1054 (12.4)	835 (32.1)	2.1 (95% CI 1.0−4.3, P = .0520)	2.0 (95% CI 1.0−4.2, P = .0576)
All health-care visits (mean, n = 108)	160 (1.9)	100 (3.8)	1.7 (95% CI 1.0−2.7, P = .0349)	1.6 (95% CI 1.0−2.8, P = .0510)

Univariate and multivariate negative binomial regressions accounting for follow-up time were performed for the number of urgent care days, ED days, days admitted after index hospitalization, days of unplanned—a composite of the number of urgent care days, ED days, and days admitted after index hospitalization—and all health-care visits—a composite of the number of admissions, ED visits or urgent care visits—comparing SIPAT score >20 and <20. The multivariate model also included INTERMACS profile and age quartile.

*One additional patient missing from the multivariate analysis because 1 patient was missing INTERMACS data.

LVAD-Related Complications

There was a notable trend toward more DAI over 365 days of follow-up in the higher-risk SIPAT group compared to the lower-risk SIPAT group (total DAI 20 vs 15, rate ratio 2.1 [95% CI 0.96−4.4, P = .064]; Table 3). The incidence of the remainder of the total and individual adverse events, including overall infections, ventricular arrhythmia, stroke (ischemic and hemorrhagic), GI bleed, right-heart failure, pump thrombosis, and VTE, were not significantly different between the lower- and higher-risk groups. Both groups were also equally likely to proceed to OHT within the year post-LVAD implantation (17.9% vs 20.7%, P = .745). There was no difference between the groups in survival on index hospitalization (96.4% vs 96.6%, P = .975) or mortality at 1 year (7.1% vs 12.6%, P = .424). There was also no statistically significant difference between total or ICU length of stay during index hospitalization.

Discussion

Assessment of psychosocial risk is an integral part of evaluation for LVAD candidacy, yet standardized processes are lacking. The present single-center study experience of routine implementation of the SIPAT to measure psychosocial risk revealed the following findings: 1) higher psychosocial risk, as measured by a SIPAT score >20, correlated with greater illness severity (lower INTERMACS profile) at the time of LVAD implant; 2) higher SIPAT score before LVAD implantation correlated with a greater number of unplanned urgent clinic visits, emergency room visits, or re-hospitalizations as well as a trend toward more DAI following LVAD implantation; and 3) there was no difference in mortality on index hospitalization or at 1 year between higher- and lower-risk SIPAT groups. These findings support the routine implementation of the SIPAT as readily feasible, and that stratification based on SIPAT into higher and lower psychosocial risk groups may be associated with baseline illness severity. The SIPAT may also identify patients at higher risk for increased health-care utilization post-LVAD implantation, but not mortality.

Psychosocial Risk and Clinical Characteristics

The International Society of Heart and Lung Transplantation recently published consensus guidelines calling for

Table 3. LVAD-related Complications at 1 year by SIPAT Score

	No. of Events		
	SIPAT Score <20 (n = 87)	SIPAT Score >20 (n = 28)	Rate Ratio (95% CI, P)
Ventricular arrhythmia	8	2	0.87 (95% CI 0.11−6.9, P = .8935)
Ischemic CVA*	4	0	NA, P = .2479
Hemorrhagic CVA*	3	1	0.93 (95% 0.02−47, P = .9722)
Gastrointestinal bleed	29	7	0.67 (95% CI 0.26−1.7, P = .4112)
Infection	63	28	1.1 (95% CI 0.61−2.1, P = .6840)
Device associated	20	15	2.1 (95% CI 0.96−4.4, P = .0636)
Other infections	43	13	0.75 (95% CI 0.29−1.9, P = .5565)
Right heart failure	13	8	1.8 (95% CI 0.45−6.9, P = .4220)
Pump thrombosis	3	2	2.5 (95% CI 0.21−31, P = .4639)
VTE†	4	0	NA, P = .1179
Thrombotic events	22	4	0.62 (95% CI 0.089−4.4, P = .6355)
Bleeding events	64	16	0.73 (95% CI 0.21−2.6, P = .6261)
Total complications	127	48	1.0 (95% CI 0.46−2.1, P = .9846)

LVAD-related complications at 1 year in the higher-risk SIPAT group are compared to the lower-risk SIPAT group. They are compared using a univariate negative binomial regression. The confidence intervals and P values were not corrected for the number of comparisons.

CVA, cerebrovascular accident.

*A Poisson-regression model with a scale adjustment for over-dispersion estimated by the square root of Pearson's chi-square divided by the degrees of freedom was applied as it better fit the data. This was validated with Akaike's information criteria and Bayesian information criteria.

†A Poisson-regression model was used because there was no over-dispersion.

standardized approaches to completing psychosocial evaluations for patients as a part of the pre-LVAD implantation assessment.[17] The SIPAT is one such practical and informative tool for assessing psychosocial risk. Multiple studies have shown its reliability, validity, and utility for predicting clinical outcomes in the OHT population, however, studies evaluating its utility to estimate risk in the MCS population have been small and yielded discrepant findings.[9–11,16] The present study included 115 patients who underwent LVAD implantation over a nearly 3-year period, wherein employment of the SIPAT was routine by 3 designated specialty advanced heart failure social workers for all patients undergoing consideration for MCS.

Our institution's experience demonstrates that the SIPAT may allow for patient stratification into lower and higher-risk groups that correlate with higher acuity of presentation as determined by the INTERMACS profile. Higher psychosocial risk has been linked with higher rates of medication nonadherence, relative lack of access to health care, and increased burden of cardiac disease including coronary artery disease and heart failure.[18,19] The present findings further substantiate the association between higher psychosocial risk and baseline clinical risk.

Higher-risk SIPAT patients had significantly higher scores across all the individual domains compared to the lower-risk SIPAT patients, including patient readiness level and illness management, social support systems, psychological stability and psychopathology, and lifestyle and effect of substance use. Higher SIPAT risk patients were expectedly more likely to have had a history of tobacco use as this is factored into the substance abuse domain scoring system, yet differences compared to lower-risk SIPAT groups were greatest in the domains of patient readiness and social support systems. Though insurance is not a part of the SIPAT assessment of psychosocial risk, Medicaid insurance has been linked with greater illness severity and suboptimal outcomes in the OHT and LVAD populations.[20] Thus, it was not surprising to note that health insurance at time of LVAD also differed between higher and lower-risk SIPAT groups, with the higher-risk group having a larger proportion of patients on Medicaid.

Correlation With Outcomes

Beyond correlation with illness severity prior to LVAD implantation, higher psychosocial risk was associated with important clinical outcomes post-LVAD. Namely, patients with higher-risk SIPAT scores were more likely to present for an urgent clinic visit, to the emergency room, or be readmitted in the year following their LVAD placement. Additionally, the higher psychosocial risk group spent a greater number of days in the emergency department compared to lower-risk patients. Despite advances in LVAD technology and the improved survival and quality of life conferred,[20] readmission rates for patients on LVAD support remain unacceptably high.[21–24] Identification of patients at higher risk for increased health-care utilization as described may lead to targeted interventions such as more frequent follow-up, greater home support services, and more robust outreach programs in an effort to decrease unplanned health-care utilization. Though quality of life was not routinely measured in this cohort, it could be postulated that a greater number of days spent in the ED could be linked to worse health-related quality of life as has been observed for increased number of hospital days in the care of end-stage cancer patients.[25,26]

One reason higher psychosocial risk patients in our cohort may have had more frequent unplanned health-care utilization post-LVAD could be because of the observation that there was a trend toward more frequent DAI than the lower psychosocial risk groups. Once again, such patients may require more involved targeted interventions, such as intensive teaching on driveline care on index hospitalization, more frequent surveillance, or increased home-nursing programs to reduce infection risk. Interestingly, the higher-risk patients were no more likely to experience any of the other measured adverse events classically associated with LVAD including gastrointestinal bleeding, pump thrombosis, or stroke. Last, there was no difference in mortality during index admission or at 1 year between the 2 groups.

Prior Studies and Contribution to Current Literature

Until recently, most papers have not investigated psychosocial risk as assessed by a standardized tool. Bruce et al[12] investigated the utility of the SIPAT in outcomes post-transplant and LVAD implantation in a single-center study of 130 patients, with 28 receiving LVAD implantation, and found that higher SIPAT scores were associated with higher 1-year mortality for LVAD patients.[16] Conversely, Bui et al[27] evaluated the role of SIPAT in predicting outcomes in a population of 50 individuals who underwent LVAD implantation and found that higher SIPAT score was not associated with increased mortality or readmission risk. There was, however, a trend toward significance, when SIPAT was used as a continuous variable. Our paper further contributes to this growing and increasingly important area of research by demonstrating the feasibility and utility of the SIPAT, performed in 95% of a large, ethnically and racially diverse group of LVAD recipients, and provided stratification of patients in higher and lower psychosocial risk groups with clinically important differences.

Despite increased unplanned health-care utilization, higher psychosocial risk patients per SIPAT did not experience an increase in LVAD-associated adverse events, including mortality compared to lower-risk SIPAT patients. The one exception to this was risk of DAI, for which a trend toward statistical significance was demonstrated among the higher-risk population. These results support that higher psychosocial risk alone should not preclude patients from LVAD implantation, especially considering the high mortality encountered by stage D patients treated medically.

Still, the use of the SIPAT may allow identification of areas for actionable improvement: interdisciplinary advanced heart failure teams could potentially work to mitigate risks identified prior to LVAD implantation, but more importantly, following discharge from the index admission. In fact, Petty et al[28] advocate that the results of the psychosocial assessment be used to direct the heart failure team in identifying individual needs following implantation. By demonstrating the correlation between psychosocial risk as assessed by SIPAT and clinical outcomes in this ethnically diverse group of patients, future studies could focus on whether more personalized approaches based on psychosocial risk would allow for improved outcomes in high-risk patients.

Limitations

Of note, several limitations may impact the generalizability of these findings. First of all, some associations may have been underestimated because of underpowering, further impacted by the conservative statistical model used to analyze our data. The retrospective design inherently limits the causative conclusions that can be drawn from the associations found. Second, the single-center experience may not render our findings applicable to other centers or other geographic locations. The SIPAT evaluation sits within a broader psychosocial evaluation wherein other factors may influence SIPAT scoring, which is ultimately a subjective assessment. There are other factors that play into a psychosocial assessment including education level, insurance, socioeconomic status, and access to health care that are not directly measured by the SIPAT and may also influence outcomes. Such factors were not uniformly available in all patients. Assessments of quality of life were not available for patients but it would be of interest to see how this outcome was impacted by psychosocial risk profile. Last, with increasing duration of MCS, extended follow-up beyond 1 year may offer additional insights.

Conclusion

In summary, higher psychosocial risk as identified by the SIPAT tool in patients who undergo LVAD implantation is associated with greater unplanned health-care utilization, and a trend toward more DAI. Higher psychosocial risk by SIPAT did not however correlate with other LVAD-associated adverse events or mortality, implying that high psychosocial risk by itself should not preclude patients from LVAD implantation. In this context, the use of the SIPAT tool may help risk stratify eligible patients for LVAD implantation beyond traditional factors, providing future avenues for research and intervention to improve outcomes post-LVAD implantation.

Disclosures

Dr. Sean Pinney is a consultant for Abbott.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.cardfail.2019.06.006.

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