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The value of Stanford integrated psychosocial assessment for transplantation (SIPAT) in prediction of clinical outcomes following left ventricular assist device (LVAD) implantation

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ABSTRACT

Background: The Stanford integrated psychosocial assessment for transplantation (SIPAT) is a validated psychosocial evaluation tool in the transplant population.
Objective: We evaluated SIPAT in predicting post-left ventricular assist device (LVAD) outcomes, including cumulative re-admissions, driveline infections, pump malfunction, pump thrombosis, gastrointestinal bleeding, major bleeding, stroke and right ventricular failure.
Methods: This retrospective study included 50 LVAD patients at an academic institution in the United States who had a pre-implant SIPAT score during the years 2015-2017. Patients were split into two groups based on SIPAT score, separating a "excellent"/"good" from a "minimally acceptable"/"poor" candidate. Poisson regression, using SIPAT as both a categorical and continuous variable, was used to compare the incidence rates of the primary outcome of cumulative re-admissions and secondary outcomes of LVAD complications.
Results: The patient cohort was predominantly male 93.5% vs 89.4% ($p = 0.629$) with a median age of 67.0 vs 58.0 years ($p = 0.037$), planned destination therapy 48.4% vs 68.4% ($p = 0.242$) and median LVAD follow-up time of 241 vs 379 days ($p = 0.10$) in the low- and high- SIPAT groups, respectively. SIPAT was not a significant predictor for cumulative re-admissions, but there was an association between higher SIPAT scores and major bleeding.
Conclusion: In this single-center retrospective study, SIPAT did not predict cumulative re-admissions. Further study is required to validate SIPAT before clinical implementation.

Introduction

Psychosocial assessment is a critical component in the evaluation of patients being considered for advanced heart failure therapies, yet it is largely subjective. Psychosocial assessments available to objectify and standardize the evaluation process in the solid organ transplant population are few, but include the Stanford integrated psychosocial assessment for transplantation (SIPAT), the psychosocial assessment of candidates for transplantation (PACT), the psychosocial levels system (PLS) and the transplant evaluation rating scale (TERS).[1,2] The SIPAT has emerged as a promising tool given its predictive value for post-solid organ transplant outcomes and excellent inter-rater reliability, which holds true even with trainee evaluators.[2]

The SIPAT consists of eighteen psychosocial components that are divided into four domains (readiness level, social support system, psychological stability, substance abuse), and weighted accordingly through assignment of points.[2] The most heavily weighted psychosocial risk factors in the SIPAT include treatment adherence/compliance, availability/functionality of social support system, presence of psychopathology, and illicit substance abuse.[2] At the conclusion of the assessment, points are tallied with higher scores suggestive of higher psychosocial risk with proposed cutoffs as follows: excellent (<7), good ($7-20$), minimally acceptable (≥ 21), poor (> 40).[1]

The SIPAT was validated in the solid organ transplant (heart, liver, lung and kidney) population, with higher scores associated with

Abbreviations: SIPAT, Stanford Integrated Psychosocial Assessment for Transplantation; LVAD, left ventricular assist device; GIB, gastrointestinal bleeding; RVF, right ventricular failure; HVAD, HeartWare VAD; MR, mean ratio; RA, right atrial; PCWP, post-capillary wedge pressure

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increased post-transplant morbidity (rejection episodes, re-admissions, infections, psychiatric decompensation and support system failure), but not with mortality, organ failure or non-adherence.[1,3] It should be noted that only 17% of the patients in that study had heart transplants[1]. The largest study of SIPAT in heart transplant patients consisted of 51 patients and found no associations with clinical outcomes of one-year survival, rejection episodes or re-admissions.[3] Nonetheless, many advanced heart failure programs have not only incorporated SIPAT into their selection meetings to evaluate potential heart transplant candidates, but have also extended the evaluation to left ventricular assist device (LVAD) candidates. The carryover of this psychosocial evaluation tool from the heart transplant to the LVAD population may lie in similarity of treatment challenges and baseline medical characteristics.[4] However, the therapies have significant differences and the predictive value of SIPAT on outcomes in LVAD patients has not been specifically studied. We therefore present a retrospective study designed to investigate the extent to which SIPAT scores predict post-LVAD outcomes with a focus on cumulative re-admissions, but also including other major complications such as driveline infections (DLI), pump malfunction, pump thrombosis, gastrointestinal bleeding (GIB), major bleeding, stroke and right ventricular failure (RVF).

Methods

Study design and setting

We conducted a retrospective study at an urban, tertiary care academic medical center (University of California, San Diego) that implants approximately 40 LVADs per year. The participants were all consecutive patients who received a LVAD and SIPAT score with all of them receiving their follow-up care at our institution post implantation. Data collection occurred between 2015 and 2017. The study was approved by our institutional review board with a waiver of informed consent as this minimal risk study utilized only pre-existing data.

Selection of participants

Patients were eligible for this retrospective study if they received both a LVAD and pre-implant SIPAT score from 2015–2017. Patients with biventricular assist devices (BiVAD) were excluded. SIPAT was calculated at the time of LVAD consideration by a licensed, clinical social worker, who received special training on administration of SIPAT. Points were tallied from the four SIPAT domains of readiness level, social support system, psychological stability and substance abuse.[2] It should be noted that inter-rater reliability of SIPAT is high with a median agreement of 0.853. This was maintained even if novice raters were used with a median agreement of 0.847.[2]

Outcomes

The primary outcome was post-LVAD cumulative re-admissions, defined as any unplanned hospital stay > 24 h. Secondary outcomes included post-LVAD complications, such as DLI, pump malfunction, pump thrombosis, GIB, major bleeding, stroke and RVF. All complications followed the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) definition with the exception of the following: major bleeding excluded GIB and pump malfunction excluded pump thrombosis. Pump malfunction included controller, battery, or cable failure. Patients were censured for the study at the time of heart transplant, death or end of the study.

Procedures

Once the study population was defined, outcome data was collected by three medical providers through review of the electronic medical record (EMR) and INTERMACS. The accuracy of INTERMACS data was confirmed by cross-referencing the EMR. The follow-up time was determined to be from date of LVAD implantation to either the time of heart transplant, death or end of the study. This data was uploaded into an institution approved Research Electronic Data Capture (REDCap) database designed to facilitate clinical and translational research.

Statistical analysis

SIPAT was evaluated as both a categorical and continuous variable. We used a cutoff score of 21, separating a “excellent”/“good” from a “minimally acceptable”/“poor” psychosocial candidate, as done previously and in our clinical practice.[3] Therefore, we designated groups based on SIPAT scores < 21 and ≥ 21 to “low- SIPAT” and “high-SIPAT” groups, respectively. We also found it important to investigate SIPAT as a continuous variable to see how granular, incremental changes in SIPAT affected post-LVAD outcomes. For analysis of baseline characteristics, continuous variables were compared using the Mann-Whitney test and categorical variables were compared using Fisher exact test. Poisson regression analysis was used to compare incidence rates of complications, yielding mean ratios (MR). The Poisson model was adjusted for potential confounders at baseline such as age, HeartWare VAD (HVAD) implantation, right atrial (RA) pressure and pre-implant post-capillary wedge pressure (PCWP) (Table 1). The logarithm of follow-up time (10-person years) was used as an offset in this statistical model. Of note, assumption of Poisson distributed rates was examined by testing for over-dispersion. If over-dispersion

Table 1
Clinical and demographic characteristics of the sample at baseline.

Variable	SIPAT < 21 (n = 31)	SIPAT ≥ 21 (n = 19)	p-value
Age, years	67.0 (58.5, 73.5)	58.0 (46.5, 67.0)	**0.037**
Gender			
Male	29 (93.5%)	17 (89.4%)	0.629
Female	2 (6.45%)	2 (10.5%)	
Race			
Asian	2 (6.45%)	1 (5.26%)	0.148
African American	3 (9.68%)	7 (36.8%)	
Caucasian	15 (48.4%)	6 (31.6%)	
Hispanic	11 (35.5%)	5 (26.3%)	
BMI (kg/m^2)	24 (22.1, 26.4)	25.2 (23.5, 27.2)	0.313
SIPAT	14 (12.5, 18)	29 (25, 36)	<**0.001**
Ejection fraction (%)	18 (14, 24)	16 (13, 22)	0.378
INTERMACS (1 or 2)	10 (32.3%)	8 (42.1%)	0.552
VAD Type [*] *(HVAD)*	14 (45.2%)	2 (10.5%)	**0.013**
Planned destination therapy	15 (48.4%)	13 (68.4%)	0.242
Primary Diagnosis (ischemic)	16 (51.6%)	9 (47.5%)	1.00
Diabetes	16 (51.6%)	6 (31.7%)	0.242
Chronic kidney disease (stage 3 or 4)	18 (58.1%)	12 (63.2%)	0.774
History of previous cardiac surgery/sternotomy	8 (25.8%)	3 (15.8%)	0.498
Pre-Implant RA pressure (mm hg)	10 (8, 14)	14 (11, 17)	**0.043**
Pre-Implant PCWP (mm hg)	22 (20, 26)	26 (25, 31)	**0.011**
Pre-Implant CI (l/min/m^2)	2.0 (1.56, 2.30)	1.92 (1.60, 2.17)	0.511
Pre-Implant PVR (wu)	3.57 (2.89, 5.21)	3.24 (2.50, 6.77)	0.780
Creatinine (mg/dl)	1.33 (1.05, 1.84)	1.54 (1.24, 1.73)	0.704

[*] In each of the low/high SIPAT groups, 13 patients received Heartmate 2 and 4 received Heartmate 3.BMI, body mass index; VAD, ventricular assist device; RA, right atrial; PCWP, post-capillary wedge pressure; CI, cardiac index; PVR, pulmonary vascular resistance.Categorical data are expressed as numbers and %; continuous variables are median and quartiles (P25, P75)

was present, then a Poisson over-dispersion model was used instead. Statistical analyses and figures were completed using SPSS v.25.0 (IBM Corp., Armonk, NY, USA) and statistical significance was taken to be a two-sided $p < 0.05$.

Results

A total of 58 patients with LVAD were identified to have a pre-implant SIPAT score from 2015-2017, but 8 failed to meet the inclusion criteria due to having BiVADs. Therefore, fifty patients were included in the analysis with 31 belonging to the low- SIPAT group (score < 21) and 19 belonging to the high- SIPAT group (score ≥ 21). Baseline characteristics between the low- and high- SIPAT groups were comparable and predominantly male 93.5% vs 89.4% ($p = 0.629$) with planned destination therapy 48.4% vs 68.4% ($p = 0.242$) in the low- and high- SIPAT groups, respectively (Table 1). Notable differences were observed in age (67.0 vs 58.0 years, $p = 0.037$), HeartWare VAD (HVAD) implantation as opposed to Heartmate 2 or 3 (45.2% vs 10.5%, $p = 0.013$), right atrial (RA) pressure (10 vs 14 mm Hg, $p = 0.043$) and pre-implant post-capillary wedge pressure (PCWP) (22 vs 26 mm Hg, $p = 0.011$) in the low- and high- SIPAT groups, respectively (Table 1). The median SIPAT score for the low- and high-SIPAT groups were 14 (min 9, max 20) and 29 (min 21, max 56), respectively. Median LVAD follow-up time, censored at time of heart transplant or death or the end of the study, was 241 days (Percentile (P) 25, 75; 141, 393) vs 379 days (P25, 75; 175, 592), $p = 0.101$, in the low- and high- SIPAT group respectively. All five deaths occurred in the low- SIPAT group. One patient in the low-SIPAT group required placement of a right ventricular assist device (RVAD) for severe RVF.

The most common complications following LVAD implantation were cumulative re-admissions, RVF and GIB (Table 2). Incidence rates were calculated given range of median follow-up time. There was a non-significant trend for a difference in incidence of cumulative re-admissions (per 10 person-years), between low- and high- SIPAT groups respectively (27.5 vs 19.0, $p = 0.051$), and a statistically significant difference in driveline infections (0.380 vs 4.18, $p = 0.006$) with the high- SIPAT group having a higher incidence (Table 2). Median time to first re-admission following LVAD implantation did not significantly differ between the low- and high- SIPAT groups, respectively (71 days [P25, 75; 190, 494] vs 108 days [P25, 75; 57, 161], $p = 0.250$).

Poisson regression analysis, adjusting for age, RA pressure, PCWP pressure and HVAD, was used to compare the incidence rates of complications. SIPAT was not a predictor for the primary outcome of cumulative re-admissions, whether evaluated as a categorical (MR 1.057, 95% confidence interval (CI) [0.641-1.741], $p = 0.829$) or continuous (MR 1.021, 95% CI [0.998-1.044], $p = 0.068$) variable (Tables 2 and 3). Of note, there was an association between higher SIPAT scores and major bleeding, whether evaluated as categorical (MR 0.104, 95% CI [0.013-0.830], $p = 0.033$) or continuous (MR 1.129, 95% CI [1.020-1.250], $p = 0.019$) variable (Table 2 and 3). The low- SIPAT group was also noted to have a significantly increased risk of gastrointestinal bleeding (MR 2.510, 95% CI [1.123-5.611], $p = 0.025$) (Table 2).

Table 3
Comparison of incidence rate for primary and secondary outcomes using SIPAT as continuous variable.

	SIPAT Score (1 point) Mean ratio (MR) (95% CI)	p-value
Cumulative re-admissions	1.021 (0.998-1.044)	0.068
Late right ventricular failure	1.012 (0.958-1.068)	0.677
Major bleeding	1.129 (1.020-1.250)	**0.019**
Gastrointestinal bleeding	0.999 (0.964-1.035)	0.936
Driveline infection	1.038 (0.952-1.132)	0.394
Pump thrombosis	1.060 (0.952-1.180)	0.291
Pump malfunction	1.100 (0.962-1.257)	0.164
Stroke	1.038 (0.953-1.131)	0.390

Adjusted for age, right atrial (RA) pressure, pulmonary wedge (PCWP) pressure, HeartWare (HVAD); CI, confidence interval.

The association between age and incidence rates for primary and secondary outcomes was evaluated. With SIPAT as a continuous variable, age had a significant association with major bleeding (MR 1.154, 95% CI [1.030–1.292], $p = 0.013$) and driveline infection (MR 0.873, 95% CI [0.793- 0.961], $p = 0.006$).

Lastly, we evaluated whether SIPAT scores predicted frequency of heart transplant or post-transplant outcomes. Patients with LVAD received a heart transplant with frequency of 52% (16 patients) vs 47% (9 patients), $p = 1$, in the low- and high- SIPAT group respectively and were followed for complications after heart transplant with median follow-up time of 315 days (P25, 75; 190, 494) vs 150 days (P25, 75; 94, 399), $p = 0.276$. Post-transplant complications, including primary graft failure, cellular rejection, and cumulative re-admission, did not significantly differ between the two SIPAT groups. Median time to first re-admission after heart transplant was not statistically different between low- and high- SIPAT groups respectively (89 days [P25, 75; 49, 146] vs 118 days [P25, 75; 24, 305], $p = 1$).

Discussion

In this single-center, retrospective study, SIPAT, whether used as a categorical or a continuous variable, was not a significant predictor for the primary outcome of post-LVAD cumulative re-admissions. However, there were significant associations between SIPAT and post-LVAD bleeding. Although correlations were found between the SIPAT score and bleeding, interpretations of these results are limited

Table 2
Comparison of incidence rates for primary and secondary outcomes using SIPAT as categorical variable.

	SIPAT < 21 ($n = 31$)		SIPAT ≥ 21 ($n = 19$)			
	Events	Incidence rate	Events	Incidence rate	Mean ratio (MR) (95% CI)	*p*-value
Cumulative Re-admissions	73	27.5	50	19.0	1.057 (0.641-1.741)	0.829
Late right ventricular failure	17	6.40	9	3.39	1.312 (0.434-3.961)	0.631
Major bleeding	6	2.26	6	2.28	0.104 (0.013-0.830)	**0.033**
Gastrointestinal bleeding	24	9.04	15	5.70	2.510 (1.123-5.611)	**0.025**
Driveline infection	1	0.38	11	4.18	0.555 (0.068-4.520)	0.582
Pump thrombosis	2	0.75	4	1.52	1.259 (0.146-10.85)	0.834
Pump malfunction	3	1.13	4	1.52	1.711 (0.246-11.904)	0.587
Stroke	7	2.64	2	0.760	1.591 (0.176-14.391)	0.680

Adjusted for age, right atrial (RA) pressure, pulmonary wedge (PCWP) pressure, HeartWare (HVAD); CI, confidence interval

as this data was not adjusted for associated confounders (i.e. anticoagulant use, antiplatelet use, previous history of bleeding, etc.).

It is generally assumed that psychosocial factors are associated with adverse outcomes in patients with durable mechanical circulatory support (MCS).[5] Psychosocial evaluation is hence recommended prior to implantation of these devices, but evaluating psychosocial factors is challenging and is often reliant on subjective information. Given that "life or death" decisions are made based on this psychosocial information, development and validation of an objective tool for the psychosocial evaluation of advanced heart failure therapy candidates would be highly desirable.

SIPAT has emerged as an objective tool for psychosocial risk stratification and offers a more comprehensive assessment than the previously accepted, PACT, expanding on details of social support and understanding of medical illness.[5,6] Maldonado et al. completed the landmark study of 217 transplant patients, of which only 36 were heart transplants, demonstrating that higher SIPAT scores predicted higher rates of rejection episodes, medical hospitalizations, infections rates, psychiatric decompensation and support system failure, but did not predict organ failure, mortality, or non-adherence.[1] The largest study of SIPAT in heart transplant patients (n = 51) was conducted by Vandenbogaart et al. and found that the "minimally acceptable/high risk" group (SIPAT $\geq$ 21) were more likely to miss clinic visits (53% vs 13%, p = 0.004) and develop psychiatric problems or relapse after heart transplant compared to the "excellent/good" group (SIPAT $<$ 21) (33% vs 10%, p = 0.05).[3] However, no associations were found with regards to clinical outcomes of one-year survival, rejection episodes or re-admissions.[3]

What remains more unclear is whether SIPAT applies to the LVAD population, as current evidence is scarce.[4] In our study, SIPAT was not associated with the primary outcome of cumulative re-admissions even when adjusting for potential confounders. Though we did not formally test frailty in this cohort, the younger individuals seen in our high- SIPAT group generally are less frail. This may explain why these patients with "high psychosocial risk" had no significant differences in cumulative re-admissions. Furthermore, these "high psychosocial risk" patients had mortality rates that are similar if not better than previously published studies on MCS devices.[7] This raises an interesting question: is the psychosocial "bar" we impose on our advanced heart failure patients applicable to all advanced heart failure patients, regardless of their comorbidities? For example, does an otherwise healthy 40-year-old male need the same psychosocial support as a frail 80-year-old male with multiple comorbidities? Ultimately, larger prospective studies will be required to explore this question. Another interesting finding was that frequency of heart transplants and post-transplant morbidity in this LVAD population did not differ between low- and high- SIPAT groups. Again, this may be due to the low frailty in the younger patient population and is consistent with previous studies of SIPAT in heart transplantation. Ultimately, we recognize that, due to our small sample size, short follow-up time of less than 6 months and the fact that post-transplant morbidity was low in our cohort, these conclusions cannot be made with certitude.

As stated above, this study is limited by its retrospective nature, small sample size and single-center design. Though a power analysis was not completed prior to initiation of this retrospective study, we specifically recognize it is likely underpowered and hence our findings are largely hypothesis generating. It is also feasible our study results could be used for power analyses in future prospective studies on this topic, which are ongoing at our institution. In addition, heterogeneity of pre-implant baseline characteristics, including age, HVAD implantation, RA pressure and PCWP, between the two groups could serve as potential confounders, but were adjusted for in the statistical model. Selection bias was also present since patients with very high SIPAT scores likely did not receive LVAD. To account for this selection bias, an exploratory analysis for cumulative re-admissions was performed on the 31 patients in the low SIPAT group, who all presumably had no psychosocial contraindications to LVAD implantation. In this case, SIPAT, as a continuous variable, was still not a significant predictor for cumulative re-admissions (MR 1.035, 95% CI [0.961-1.114], p = 0.363). Finally, it is possible that patients were admitted to other institutions with complications not accounted for in the analysis. However, from our experience, this is a rare phenomenon and local hospitals always notify our institution and/or ultimately transfer these patients as we are more qualified to manage post-LVAD complications.

It is clear that an objective psychosocial assessment tool that predicts outcomes in advanced heart failure patients is sorely needed, as advanced heart failure therapies selection meetings have rapidly shifted from discussions on medical criteria to extensive debates surrounding psychosocial and behavioral factors. Studies have suggested that the three psychosocial factors most important in LVAD are depression, functional status and self-care.[4] Perhaps the external validity of SIPAT in the LVAD population can be enhanced by weighting certain psychosocial evaluation criteria differently compared to the transplant population.[4] The role of the caregiver also plays a much larger role in the MCS device population given reliance on assistance from these individuals for device maintenance, hygiene and maneuvering.[4] Perhaps a psychosocial LVAD score should weigh the stability of the caregiver more heavily. Our data hypothesizes that the development of a LVAD specific psychosocial evaluation screening tool may be helpful.[4]

Current psychosocial evaluation practices vary greatly by institution due to inconsistent definitions/measures of outcomes, which can affect offering of advanced heart failure therapies. An objective assessment tool is needed to ensure that expensive, life-saving therapies such as MCS devices are used judiciously. Nonetheless, our data suggests that evaluation of psychosocial factors using SIPAT should be used cautiously when evaluating patients for durable MCS treatment. Our findings suggest that a multicenter study is mandated to garner enough power to decipher which psychosocial variables are most important in this unique population. From there, appropriate revisions to the assessment tool can be made and studied prospectively to evaluate the predictive value for post-implant outcomes. Furthermore, these future studies will also require concomitant evaluation of quality of life (QOL) measures and SIPAT, as this was not done in this study.

Conclusion

In this single-center observational study, SIPAT did not predict cumulative re-admissions following LVAD implantation. Our study results suggest that caution should be taken in using SIPAT, a tool yet to be validated in the LVAD population, to make definitive decisions on advanced heart failure therapies. Further studies are required to validate SIPAT in the LVAD population before clinical implementation and to discern the essential psychosocial factors in this unique population.

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Supplementary materials

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