# Characterization of the Stanford Integrated Psychosocial Assessment for Transplant (SIPAT) in Lung Transplant Candidates

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## Abstract

The SIPAT is a standardized measure for pre-transplant psychosocial evaluation. Previous SIPAT studies utilized a relatively small lung transplant sample and only included listed patients. This study characterized the SIPAT in 147 lung transplant candidates to better elucidate its utility. The average score corresponded to a minimally acceptable rating and nearly half of the patients had relative or absolute contraindications. Interstitial Lung Disease (ILD) patients scored more favorably than non-ILD patients (U = 7.69, p < .05). The Total ( $\beta = .05$ , SE = .018, p < .01), Social Support Subscale ( $\beta = .133$ , SE = .058, p < .05), and Psychosocial Stability and Psychopathology Subscale ( $\beta = .103$ , SE = .040, p < .05) significantly predicted listing status. The SIPAT has a unique profile in lung transplant candidates and demonstrated utility for guiding transplant decisions. Future research should examine which lung transplant outcomes are significantly associated with SIPAT scores.

*Keywords:* Lung Transplantation, Clinical Psychology, Psychological Interview, Medical Clearance

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#### Introduction

Lung transplantation is a well-established treatment for individuals with end-stage lung disease such as interstitial lung disease (ILD) and chronic obstructive pulmonary disease (COPD) (Chambers et al., 2019). While outcomes have improved in recent years, the survival rate for lung transplant remains the lowest among solid organ transplants, with a median survival of 6.7 years (Chambers et al., 2019). Complications are common including chronic allograft dysfunction and infections which can lead to morbidity and mortality (Chambers et al., 2019; Kugler et al., 2005). As such, a critical research avenue is to identify ways to mitigate risk factors in this population and thereby increase the median survival rate.

Previous studies have indicated that lung transplant candidates have an elevated risk for experiencing psychiatric illnesses (Craven, 1990; Parehk et al., 2003). Adjustment to a progressive chronic illness such as ILD or COPD can trigger some psychiatric disorders while others may have a pre-morbid onset (Craven, 1990; Singer et al., 2001). Additionally, the pre-transplant evaluation period is frequently stressful due to uncertainty of eligibility for transplant, donor organ availability, decline in functional capacity, and limitations in leisure or occupational activities. As such, this may exacerbate pre-existing psychopathology or lead to onset of new psychopathology. Prevalence estimates range from 25%-47% for psychiatric disorders in pre-lung transplant candidates, most commonly anxiety disorder not otherwise specified, panic disorder, major depressive disorder, and adjustment disorder (Parekh et al., 2003; Søyseth et al., 2016; Woodman et al., 1999). Lifetime history of psychiatric illness has been found to be as high as 61% in lung transplant candidates and associated with greater depressive and anxiety

symptoms, more psychological distress, and less social support (Craven, Bright, and Dear, 1990; Søyseth et al., 2016).

Although quality of life is improved for most lung transplant recipients, immense changes to lifestyle are required, including extensive medication regimens and changes to social and occupational functioning. Pre-transplant psychosocial variables have been shown to be strongly associated not only with post-transplant psychosocial outcomes, but also transplantrelated medical outcomes including mortality (Dew et al., 2000; Dew et al., 2007; Dew et al., 2015; Dobbels et al., 2001; Goetzmann et al, 2008; Rivard et al., 2005). Given the high prevalence of psychosocial concerns in this population and poor associated outcomes, medical ethics require us to successfully identify those in need of support prior to transplant and those at elevated risk following transplant in order to optimize graft survival and quality of life (Organ Procurement and Transplant Network, 2019). Organs are a limited resource, as such organ stewardship necessitates not transplanting individuals who are at high risk for psychological complications resulting in loss of the organ.

Consequently, careful pre-transplant psychosocial assessment is indicated for most transplant groups and has the potential to help improve post-transplant outcomes (Dobbels et al., 2001; Orens et al., 2006; Steinman et al., 2001; Weill et al., 2015). Therefore, selection guidelines include absolute psychosocial contraindications such as active substance use and poorly controlled mental illness. However, concerns have been raised about the subjectivity and inconsistency of psychosocial criteria. The Stanford Integrated Psychosocial Assessment for Transplant (SIPAT) was developed by Maldonado and colleagues in 2012 to provide a standardized, objective, and evidence-based psychosocial evaluation (Maldonado, 2012). Since its development, the SIPAT has been successfully implemented in several solid organ transplant populations including heart, lung, liver, and kidney. Studies have demonstrated that this measure has high inter-rater reliability and is predictive of post-transplant psychosocial outcomes (Maldonado et al., 2012; Maldonado et al., 2015).

The authors of the SIPAT posit that it can be applied to all transplant organ candidates, as similar psychosocial variables and behaviors have common negative effects (Maldonado et al., 2012). However, certain behaviors, such as smoking, may be more detrimental in the post-transplant period for lung transplant recipients compared to other transplant groups. Careful psychosocial assessment may be especially critical in lung transplant given the higher mortality rate as compared to other organs. Studies to date on the SIPAT included a relatively small sample size of lung transplant patients (<100) (Maldonado et al., 2012; Maldonado et al., 2015). Additionally, these studies have focused only on lung transplant recipients already deemed acceptable for transplant, instead of all lung transplant candidates. Poor psychosocial status may be a contributing factor to the decision not to list patients, and therefore these patients may have elevated SIPAT scores.

Studies have also not examined the extent to which SIPAT scores may vary based on the type of lung disease. Individuals with diseases such as COPD that are predominately caused by behavioral factors may have elevated scores as compared to patients with diseases such as alpha-1 antitrypsin deficiency that are driven primarily by genetics. Finally, if the SIPAT is a useful clinical tool it should predict listing status, but to date this has not be empirically verified. As such, more work is needed to characterize the SIPAT in lung transplant candidates and evaluate its utility as a tool to inform listing decisions. In the current study, we characterized SIPAT scores in a sample of 147 lung transplant candidates. We examined total and subscale scores across all candidates, compared scores between subtypes of lung disease, and verified that SIPAT scores were predictive of listing status.

### Methods

We studied patients who were evaluated for lung transplant within a 24-month period (October 2017 to October 2019) at a large urban academic medical center. As a standard part of the pre-transplant work-up, all patients underwent a psychological evaluation. Prior to receiving a transplant work-up, all patients were screened for objective contraindications by a transplant nurse coordinator. Psychosocial contraindications included active substance abuse (drugs, alcohol, and tobacco) within the past 6 months, nicotine exposure in the past 6 months, and inadequate social support. Patients who did not meet screening criteria were ineligible to receive a transplant evaluation and thus were excluded from this study. All individuals who completed a psychological evaluation for lung transplantation during the 24-month period were included in this study.

All psychological evaluations were conducted by a licensed clinical psychologist or a license-eligible clinical psychology post-doctoral fellow. This evaluation included a structured clinical interview and self-report measures. The structured interview covers all of the components in the SIPAT, and thus the interview data was used to complete the SIPAT. Data from this evaluation were stored in the patient's electronic medical record as part of clinical protocol. In addition to the psychological evaluation, all pre-transplant patients were followed by the transplant multi-disciplinary team consisting of physicians, transplant nurse coordinators, social workers, dietitians, and pharmacists and additional data available from their assessments were compiled into the medical record as well the Organ Transplant Tracking Record (OTTR) database.

Listing decisions were made during a multidisciplinary team meeting, which included presentations by psychology and social work, and were documented in the patient's chart. While SIPAT scores weren't explicitly discussed in psychology presentations, they were used to inform the presentation, and as such contributed to decisions on transplant eligibility. For example, presentations would often include information on specific contraindications. If patients were given recommendations after the initial committee meeting, they were given the opportunity to optimize their candidacy and could be presented again for listing at a later time. These patients may have been asked to address medical barriers, psychosocial barriers, or a combination of the two. The SIPAT was not completed again or rescored before patients were presented again since psychology did not have follow-up visits with all patients. Therefore, SIPAT scores reflected psychosocial status for lung transplant candidates during their initial psychosocial evaluation. If patients were not listed, had their evaluation closed, and were revaluated again over a year after their initial evaluation the SIPAT was completed again. This could be due to psychosocial or medical contraindication. For example, a patient could be too medically stable initially and then be reevaluated at a later time when their lung function began to decline.

We received ethics approval from the Institutional Review Board for the secondary data analysis of clinical data. A Research Electronic Data Capture (REDCap) project was used to compile the variables for this study. Variables of interest were extracted by reviewing the patient's medical record (variables: SIPAT scores, lung disease, and demographics) and OTTR (variables: lung allocation score and listing status).

## **Patient Groups**

Participants included those diagnosed with interstitial lung disease (ILD), such as idiopathic pulmonary fibrosis, and non-ILD, such as chronic obstructive pulmonary disease (COPD), emphysema, and Cystic Fibrosis (CF).

## Measures

#### Stanford Integrated Psychosocial Assessment for Transplant

The SIPAT is a structured tool for the psychological assessment of organ transplant candidates that has demonstrated excellent inter-rater reliability in previous studies (Pearson's correlation coefficient = 0.85) and predictive ability for negative outcomes (Maldonado et al., 2012). The SIPAT consists of 21 clinician-rated polytomous items falling into four domains: 1) Patient's Readiness Level, 2) Social Support System, 3) Psychological Stability & Psychopathology, and 4) Lifestyle and Effect of Substance Use. Ranges of aggregated scores classify patients as excellent (0-6), good (7-20), minimally acceptable (21-39), poor (40-69), or high risk candidates (>70). In addition to the total and subscale scores, the SIPAT includes a list of contraindications. These contraindications are divided into absolute and relative contraindications. Relative contraindications are further subdivided into high risk, moderate risk, and lower risk. The contraindications are incorporated into the SIPAT scoring and can also directly influence transplant recommendations (e.g. an absolute contraindication such as active substance abuse would defer transplant even if total SIPAT score was in acceptable range). All SIPATs were completed following the psychological interview. See Table 1 for a list of SIPAT psychosocial domains and factors.

## Lung Allocation Score (LAS)

All patients being evaluated for lung transplant are given an estimated lung allocation score (LAS). This score is a measure of the severity of their condition determined by several

factors (lung disease, oxygen level at rest, age, etc.). LAS indicates a candidate's urgency for transplant and thereby helps determine where they will be placed on the transplant waitlist. The LAS scores range from 0-100, with 100 being the most severe.

## **Statistical Analysis**

All analyses were conducted using SPSS software. Total scores on the SIPAT and each SIPAT subscale were calculated and distributions examined. A Kolmogorov-Smirnov test indicated that the SIPAT scores for the Interstitial Lung Disease (ILD) did not follow a normal distribution (D(66) = 0.12, p < 0.05). As such, Mann-Whitney U Tests were used to compare group differences between ILD and non-ILD patients. Logistic regressions were run to determine if scores on the SIPAT total and subscales predicted transplant listing. Age and gender were entered as covariates in block 1 of each regression analysis. To better explore the nature of the effects of the SIPAT total and subscale scores, logits were converted to conditional probabilities. In order to assess the specificity and sensitivity of the SIPAT total score and subscales for predicting listing a receiver operating characteristic (ROC) curve analysis was conducted. Area Under the Curve (AUC) scores were interpreted as follows: outstanding (.90 to 1), excellent (.8 to .9), acceptable (.7 to .8), poor (.6 to .7), and no discrimination (.5 to .6) (Hosmer & Lemeshow, 2000).

### **Results**

## **Demographics**

Participants were 147 lung transplant candidates. Demographic characteristics are presented in Table 2. Most patients were male, Caucasian, and non-Hispanic. Nearly half (48.3%) had a non-interstitial lung disease (ILD). In this sample the LAS scores ranged from 32.36 to 81.71, indicating a wide range of illness severity.

## **SIPAT Characterization**

### Full Sample

Scores and distributions for the SIPAT total and subscales are presented in Figure 1. The average (SD) SIPAT score was 21.13 (12.92), which denotes a minimally acceptable candidate, and the range was 2 to 69. Based on these scores, participants were classified as Excellent (10.2%), Good (43.5%), Minimally Acceptable (38.1%) or Poor (8.2%) candidates. None of the participants was classified as High Risk candidates.

The mean (SD) scores on the subscales were as follows: Patient's Readiness Level M = 5.01 (SD = 5.05), Range = 0 to 21; Social Support System M = 2.71 (SD = 3.65), Range = 0 to 16; Psychological Stability & Psychopathology M = 7.16 (SD = 5.11), Range 0 to 21; and Lifestyle & Effect of Substance Use M = 6.26 (SD = 4.79), Range 0 to 25. Most patients (69.3%) scored at or below the mean on Patient Readiness, indicating they were overall ready for transplant. Very few patients (13.6%) earned a score of 0 on the Psychological Stability and Psychopathology subscale, indicating most patients had either current or historical psychopathology. Approximately one-fifth of participants (20.4%) earned a score  $\geq$ 4 on the Lifestyle and Effects of Substance Use subscale, indicating a history of substance use.

Most patients (57.8%) had no contraindications for transplant, with only 6.12% with absolute contraindications. Of the patients with at least one contraindication, these were classified as Moderate/Low Risk (78.6%), High Risk (37.1%), and Absolute (10.0%) contraindications for transplant. A total of 40 patients had 2 or more contraindications. Of those patients, 9 were listed, 20 were rejected, and 11 were undecided. The patients who were listed may have resolved the contraindications prior to listing.

Relative contraindications (number of patients) in this sample included active alcohol use suspected to be directly causative/exacerbating medical problems (1), limited adherence with treatment (21), deceptive behavior (12), high degree of ambivalence or denial regarding transplant (10), alcohol use not directly causative of a medical problem (20), inability to understand information and poor receptiveness to education (7), reluctance to relocate near care center (1), absence of adequate living environment (1), limited or restricted access to resources (3), controlled major psychiatric disorder (33), obesity (12), limited literacy (2), and cognitive disorders (5). Absolute contraindications (number of patients) present in this sample included inadequate social support (10), active alcohol dependence/abuse (2), and active manic or psychotic symptoms (2).

## Lung Disease Group Comparison

Patients with cystic fibrosis were excluded from these analyses due to significant differences in age and treatment course (n = 10). Over half (51.8%) of the total participants were diagnosed with a Non-ILD. Ages and Lung Allocation Scores by lung disease are presented in Figure 2. The Non – ILD group had significantly higher SIPAT total scores (Mdn = 22) than the ILD group (Mdn = 15), U = 7.69, p < .05. The Non-ILD group also had significantly higher scores on the SIPAT Patient's Readiness Level subscale (Non – ILD Mdn = 5; ILD Mdn = 3; U = 12.86, p < .0001) and the SIPAT Psychological Stability subscale (Non-ILD Mdn = 8; ILD Mdn = 5; U = 12.86, p < .05). There were no statistically significant differences in scores on Social Support System and Lifestyle & Effect of Substance Use SIPAT subscales. Figure 2 displays SIPAT classifications by lung disease group. Overall, the ILD group had a greater number of individuals in better classification categories compared to the non-ILD group, indicating better psychosocial candidacy for transplant.

## **SIPAT Predicting Listing Status for Transplant**

#### **SIPAT Total Score**

Participants still in the process of being evaluated for transplant were excluded from these analyses (n = 30). The final sample included 117 participants, with 68 patients who were rejected and 49 patients who were listed. For the patients who were listed, the median number of days from evaluation to listing was 112. The average total SIPAT score for the listed patients was within the good candidate classification (M =17.29, SD = 9.68), while the average total score for the patients who were not listed was within the minimally acceptable candidate classification (M = 24.06 SD = 13.72). Similarly, on all subscales, patients who were not listed for transplant had higher (worse) scores than those who were listed.

Logistic regressions were run to determine if scores on the SIPAT predicted transplant listing (see Table 3). Age and gender were entered as covariates in block 1. Neither was significant (ps = .99 and .72, respectively). Entry of SIPAT total score significantly improved the model fit (null -2 log likelihood (-2LL) = 158.966, final -2LL = 149.825  $\chi^2_{(3)}$  = 9.272, p < .05). As indicated in block 2 of Table 3, the likelihood of being listed for transplant was significantly related to SIPAT total score (p < .05). No significant age or gender differences were detected (ps > .05). We also reran the logistic regression excluding the four subjects whose time to listing was 365 days or more, and the SIPAT total score still significantly predicted listing status (p < .05).

To better explore the nature of the effects of the SIPAT total score on likelihood of listing, logits were converted to conditional probabilities. As indicated in Figure 3, as SIPAT Total Score increased, the likelihood of being listed for transplant decreased. For example, after controlling for age and gender, there is a 51% likelihood that a patient with a SIPAT Total Score of 21 (the average score for the overall sample) was listed.

### **SIPAT Subscales**

Logistic regressions were run for each SIPAT subscale total to determine if any of them independently predicted transplant listing (see Table 3). For each regression, age and gender were entered as covariates in block 1. Neither was significant (ps > .05). The Social Support System subscale and the Psychological Stability and Psychopathology subscale each significantly predicted transplant listing (p < .05). Patient's Readiness Level subscale showed a trend towards significant prediction of transplant listing (p = .053). The SIPAT Lifestyle Effect & Substance Use subscale was not a significant predictor of transplant listing (p > .05).

To better explore the nature of the effects of the SIPAT Social Support System subscale on listing probability, logits were converted to conditional probabilities. As indicated in Figure 3, as SIPAT Social Support subscale increased (worse candidate), the likelihood of being listed for transplant decreased. For example, after controlling for age and gender, patients with the lowest score on this subscale had a 60% likelihood of being listed for transplant whereas patients with the highest scores had a 15% likelihood of being listed for transplant. Additionally, as the Psychological Stability & Psychopathology subscale score increased (worse candidate) the likelihood of being listed for transplant decreased. For example, after controlling for age and gender, patients with the lowest score on this subscale had a 73% likelihood of being listed for transplant whereas those with the highest scores had a 24% likelihood of being listed for transplant (see Figure 3).

## Assessing Clinical Sensitivity and Specificity of the SIPAT

ROC analyses were performed for the SIPAT total score and four SIPAT subscales to examine sensitivity and specificity. As shown in Figures 4a and 4b, the SIPAT total score and Psychological Stability & Psychopathology total showed poor sensitively and specificity in predicting listing status (AUC = .64, 95% CI: 0.54-0.74, p < .01 and AUC = .64, 95% CI: .53-.73, p < .05, respectively). The SIPAT subscales Patient's Readiness Level total (AUC = .59, 95% CI: 0.48-0.69, p > .05; Figure 4c), Social Support System total (AUC = .60, 95% CI: .50-.71, p > .05; Figure 4d), and Lifestyle & Effect of Substance Use subscale total (AUC = .56, 95% CI: .46-.67, p > .05; Figure 4e) showed no discrimination.

#### Discussion

The SIPAT is a clinician rating measure developed by Maldonado and colleagues in 2012 meant to standardize the psychological evaluation process of organ transplant candidates (Maldonado et al., 2012; Maldonado et al., 2015; Olbrisch, Levenson, Hamer, 1989; Twillman et al., 1993). Our current study extends the original authors' findings by applying the SIPAT to a larger sample of lung transplant candidates. We examined the total and subscale scores across all candidates, compared scores between types of lung disease, and verified that SIPAT scores predict listing status.

## **SIPAT Characterization in Lung Transplant Candidates**

In this study patients were most likely to be categorized either as good or minimally acceptable candidates, together accounting for nearly 80% of all candidates. Scoring as an excellent candidate was far less common (10.2%). These findings are consistent with a prior study on the SIPAT, which included lung transplant patients and also classified the majority of those patients in the good and minimally acceptable ranges (Maldonado et al., 2012; Maldonado et al., 2015). A substantial minority of patients were deemed poor candidates (8.2%). This is in contrast with previous studies that did not classify any lung transplant patients as poor candidates, which is likely driven by these studies including only patients who ultimately received transplants (Maldonado et al., 2012; Maldonado et al., 2015). This provides some preliminary evidence that the SIPAT may be useful for identifying individuals who are poor candidates. No patients scored within the high risk range. Obtaining a score this high indicates significant dysfunction across multiple domains. High risk candidates may have been excluded during the prescreen completed by the nurse coordinators and referring physician. High risk patients may also have self-selected out of the evaluation process upon attending the transplant information session which included information on psychosocial barriers to candidacy. However, it is possible that the SIPAT's criteria for high risk may be too stringent, which is a potential limitation of the SIPAT in identifying high risk candidates.

In addition to the categorical classification of transplant candidates, the SIPAT also allows for specification of contraindications. These contraindications are divided into absolute and relative categories. Relative contraindications are subdivided into high risk, moderate risk, and lower risk. Patients may score in the good candidate range based on their total SIPAT score but still have a significant number of contraindications, including ones in the high risk range. For example, someone who has good social support, good compliance, no current or recent substance problems, and borderline personality disorder would likely have a total score in the good range, but still have a high risk factor of a personality disorder.

In this study, slightly less than half of patients reported a contraindication. Of these contraindications: 78.6% were moderate/low risk, 37.1% were high risk and 10% were absolute. Given the high risk nature of lung transplant and the importance of careful organ stewardship, absolute psychological contraindications in the absence of medical contraindications may be sufficient reason to not list a patient. Such contraindications would likely put patients at an elevated risk for poor outcomes given the relationship between post-transplant psychological problems and Bronchiolitis Obliterans Syndrome (BOS), graft failure, and mortality (Rosenberger et al., 2016). In this sample, only 6.12 % of patients presented with absolute contraindications. This may be because many patients with absolute contraindications were eliminated during pre-screening. Thus, the psychosocial transplant evaluation process in lung transplant candidates is rarely guided by excluding patients with absolute contraindications, but rather by assessing the severity of one or multiple relative contraindications. Currently the SIPAT indicates that 2 or more high risk or 3 or more moderate/low risk contraindications may be sufficient reason to not list a patient. As such, the presence of relative contraindications is rarely an automatic rule-out, but rather requires the use of clinical judgment to determine if such factors are sufficient reason to not list a patient in the absence of medical contraindications. Additional research is needed to determine the extent to which absolute and relative contraindications are predictive of poor transplant outcomes, and if certain contraindications are more predictive of poor outcomes than others.

SIPAT Scores by Lung Disease Type

We examined the extent to which SIPAT scores differed between types of lung disease. Patients with ILD scored more favorably on the SIPAT total score and subscales compared to non-ILD patients, suggesting that the underlying lung disease influences SIPAT scores. This suggests that ILD patients have a better psychosocial profile, and therefore may be more likely to be listed. Despite having a higher LAS score, ILD patients may be otherwise healthier with more readily available resources that have not been already depleted by chronic illness such as COPD, resulting in better SIPAT scores. Future work with a larger sample size is needed to compare SIPAT scores between additional subtypes of lung disease such as COPD and CF.

## SIPAT as a Predictor of Listing Status

The utility of the SIPAT rests on its ability to provide meaningful data to help inform listing decisions. Thus, if it is incorporated into the psychosocial evaluation and provides meaningful data it should predict listing status. However, to date this has not been empirically verified. In this study, 41.88% of patients were listed for transplant. We confirmed that the SIPAT total score was a significant predictor of being listed for transplant, even after controlling for age and gender. Although SIPAT scores were just one element of the decision making for listing status, our findings demonstrate that the SIPAT rating process was effective in both informing and predicting transplant listing decisions in this sample of lung transplant candidates. The presence of a psychologist may have resulted in a slight inflation in the relation between SIPAT score and listing status, but this is likely offset by the deflation caused by patients being excluded for reasons unrelated to psychosocial factors.

Subscales from the SIPAT also provided meaningful data for informing listing status. The SIPAT's Social Support System and Psychological Stability and Psychopathology subscales significantly predicted listing status. The Lifestyle and Effect of Substance Abuse subscale may not have been an effective predictor of listing status due to prescreening on this domain reducing variability in scores. The Patient Readiness subscale only approached significance, possibly due to its skewed distribution. On this scale, there was a clustering of patients at low levels of the scale, which may speak to its inability to capture patients across the entire range of transplant readiness. However, the Social Support System subscale significantly predicted listing status despite being highly skewed with a substantial floor effect. This may be because inadequate social support represents a significant barrier to transplant listing. These patterns in the subscales contribute to the overall skewedness of the SIPAT. Overall, this suggests that the subscales provide useful data, but the SIPAT total score may be most meaningful for informing listing decisions. Additionally, our results suggest that the subscales may not carry equivalent weight in listing decisions. The social support and psychosocial stability may be especially important predictors of listing, and/or problems in these areas may be less likely to be identified during prescreening.

Finally, none of the SIPAT scores demonstrated good sensitivity and specificity for predicting listing status. This is likely because psychosocial variables are only one component of the decision making process. Individuals who are good psychosocial candidates might not be listed due to medical barriers. The total score and the psychological stability and psychopathology scores showed the best specificity and sensitivity, which is consistent with these scales significantly predicting listing.

### **Conclusions and Future Directions**

The current study helped confirm that the SIPAT is a useful tool for psychosocial evaluation of lung transplant candidates. While this study had a larger sample of lung transplant patients than previous SIPAT studies, this was a single center design with medium sample size. Additional work should verify these findings in a large multi-site sample. Additionally, while the inter-rater reliability of the SIPAT has been shown to be high in previous studies, we did not explicitly measure this. Another limitation is that we did not readminister the SIPAT to patients who were given the opportunity to optimize their candidacy prior to being presented at another committee meeting. However, we found that when we excluded the subjects whose time to listing was greater than or equal to 365 days the SIPAT total score still significantly predicted listing. It is likely that those patients who had the opportunity to optimize their psychosocial candidacy and were later listed had a reduction in their SIPAT score. As such, the ability of the SIPAT to predict listing status may be underestimated in this study.

Though this study did help to examine the utility of the SIPAT in lung transplant patients, we did not directly measure its validity. The construct validity of the SIPAT has been understudied thus far. The extent to which the SIPAT measures a unidimensional underlying construct has strong implications into the utility of its scoring system, which this study suggests strongly influences patients' likelihood of being listed. The finding from the current study that few patients score within the categories indicating the highest levels of psychosocial severity, yet substantially more patients present with absolute or high-risk psychosocial contraindications calls into question the construct validity of the SIPAT. A forthcoming study from our team addresses this issue.

Finally, an important future direction for research is to evaluate the predictive ability of the SIPAT for post-lung transplant outcomes such as mortality and complication rates. Differentiating the predictive utility of SIPAT subscales would also be beneficial to understand if certain items or subscales are more valuable than others. Optimizing the psychosocial evaluation of lung transplant candidates is critical area of research that has the potential to help optimize post lung transplant outcomes and improve the lives of these patients.

Table 1. Psychosocial Domains and Factors Measured by the SIPAT

### A.PATIENT'S READINESS LEVEL AND ILLNESS MANAGEMENT (5 items)

Item 1: Knowledge and understanding of medical illness process (that caused specific organ failure)

Item 2: Knowledge and understanding of the process of transplantation

Item 3: Willingness/desire for treatment (transplant)

Item 4: History of treatment adherence/compliance (pertinent to medical issues)

Item 5: Life-style factors (Including diet, exercise, fluid restrictions, and habits, according to organ system)

#### **B. SOCIAL SUPPORT SYSTEM LEVEL OF READINESS (3 items)**

Item 6: Availability of social support system

Item 7: Functionality of social support system

Item 8: Appropriateness of physical living space and environment

### C. PSYCHOLOGICAL STABILITY AND PSYCHOPATHOLOGY (5 items)

Item 9:Presence of psychopathology (other than personality disorders and organic psychopathology)

Item 10: History of organic psychopathology or neurocognitive impairment (i.e., illness or medication induced psychopathology)

Item 11: Influence of personality traits versus disorder

Item 12: Effect of truthfulness versus deceptive behavior

Item 13: Overall risk for psychopathology

## D. LIFE-STYLE AND EFFECT OF SUBSTANCE USE (5 items)

Item 14: Alcohol use, abuse, and dependence

Item 15: Alcohol abuse-risk for recidivism

Item 16: Illicit substance abuse and dependence

Item 17: Illicit substance abuse-risk for recidivism

Item 18: Nicotine use, abuse, and dependence

|                         | Table 2: Background and medical characteristics |
|-------------------------|---|
| Age, years              | 19 - 72 years ( $M = 57.2$ , $SD = 11.7$ )      |
| Male, sex, <i>n</i> (%) | 55.1%   |
| Race                    | 89.1% Caucasian                                 |
|                         | 6.8% Black/African-American                     |
|                         | 0.7% Asian                                      |
|                         | 1.4% Unknown/Not Reported                       |
| Ethnicity               | 75.5% Non-Hispanic/Latino                       |
|                         | 2.0% Hispanic/Latino                            |
|                         | 19.7% Unknown/Not Reported                      |
| Lung Disease            | 48.3% Non – interstitial lung disease           |
| 0                       | 44.9% Interstitial lung disease                 |
|                         | 6.8% Cystic fibrosis                            |
| LAS                     | $32.36 - 81.71 \ (M = 37.85, SD = 8.47)$        |
|                         |   |

Table 2: Background and medical characteristics

Data are presented as mean (standard deviation) unless otherwise indicated

|                                    | В     | S.E.      | $\frac{\text{SIPAT Total}}{\text{Wald } (df = 1)}$ | P - value     | Odds Ratio  | 95% CI |       |
|------------------------------------|-------|-----------|--|---------------|-------------|--------|-------|
|                                    | Ъ     | 5.2.      | (u) I)   | i vulue       | Ouus Ruito  | Upper  | Lower |
| Block 1: Covariates                |       |           |  |               |             |        |       |
| Age                                | .000  | .017      | .000   | .997          | 1.00        | .967   | 1.035 |
| Gender                             | .136  | .378      | .130   | .718          | .873        | .416   | 1.830 |
| Intercept                          | 124   | 1.131     | .012   | .913          | .884        |        |       |
| Block 2: Linear Model              |       |           |  |               |             |        |       |
| Age                                | 010   | .019      | .302   | .582          | .990        | .954   | 1.027 |
| Gender                             | 117   | .401      | .085   | .770          | 1.124       | .513   | 2.464 |
| SIPAT Total Score                  | 051   | .018      | 8.038  | .005          | .950        | .917   | .984  |
| Intercept                          | 1.139 | 1.253     | .827   | .363          | 3.124       |        |       |
|                                    |       | SIPA      | T Social Support S                                 | ystem Subsca  | le          |        |       |
| Block 1: Covariates                |       |           |  |               |             |        |       |
| Age                                | 001   | .017      | .003   | .958          | .999        | .966   | 1.034 |
| Gender                             | 102   | .376      | .074   | .786          | .903        | .432   | 1.887 |
| Intercept                          | 133   | 1.131     | .014   | .906          | .875        |        |       |
| Block 2: Linear Model              |       |           |  |               |             |        |       |
| Age                                | 008   | .018      | .198   | .656          | .992        | .957   | 1.028 |
| Gender                             | .062  | .391      | .025   | .874          | 1.064       | .495   | 2.289 |
| Subscale Total                     | 133   | .058      | 5.273  | .022          | .875        | .781   | .981  |
| Intercept                          | .405  | 1.193     | .115   | .734          | 1.500       |        |       |
|                                    | SIPA  | T Psychol | ogical Stability & I                               | Psychopatholo | gy Subscale |        |       |
| Block 1: Covariates                |       |           |  |               |             |        |       |
| Age                                | 001   | .017      | .003   | .958          | .999        | .966   | 1.034 |
| Gender                             | 102   | .376      | .074   | .786          | .903        | .432   | 1.887 |
| Intercept                          | 133   | 1.131     | .014   | .906          | .875        |        |       |
| Block 2: Linear Model              |       |           |  |               |             |        |       |
| Age                                | 010   | .018      | .310   | .577          | .990        | .955   | 1.026 |
| Gender                             | .027  | .389      | .005   | .945          | .974        | .454   | 2.086 |
| SIPAT Psychological                | 103   | .040      | 6.651  | .010          | .902        | .834   | .976  |
| Stability &                        |       |           |  |               |             |        |       |
| Psychopathology                    |       |           |  |               |             |        |       |
| Subscale Total                     |       |           |  |               |             |        |       |
| Intercept                          | 1.019 | 1.249     | .66  | .414          | 2.772       |        |       |
|                                    |       | SIPAT     | Patient's Readines                                 | s Level Subsc | ale         |        |       |
| Block 1: Covariates                | 0.0.1 | 017       | 002  | 059           | 000         | 0((    | 1.024 |
| Age                                | 001   | .017      | .003   | .958          | .999        | .966   | 1.034 |
| Gender<br>Intercont                | 102   | .376      | .074   | .786          | .903<br>875 | .432   | 1.887 |
| Intercept<br>Block 2: Linear Model | 133   | 1.131     | .014   | .906          | .875        |        |       |
| Age                                | 004   | .018      | .064   | .800          | .996        | .962   | 1.031 |
| Gender                             | 004   | .383      | .055   | .800          | .914        | .902   | 1.963 |
| SIPAT Patient's                    | 080   | .041      | 3.757  | .053          | .924        | .852   | 1.001 |
| Readiness Level                    |       |           | 5.757  |               |             |        | 1.001 |
| Subscale Total                     |       |           |  |               |             |        |       |
| Intercept                          | .452  | 1.179     | .147   | .702          | 1.571       |        |       |

Table 3: Logistic Regressions: SIPAT Scores Predicting Transplant Listing

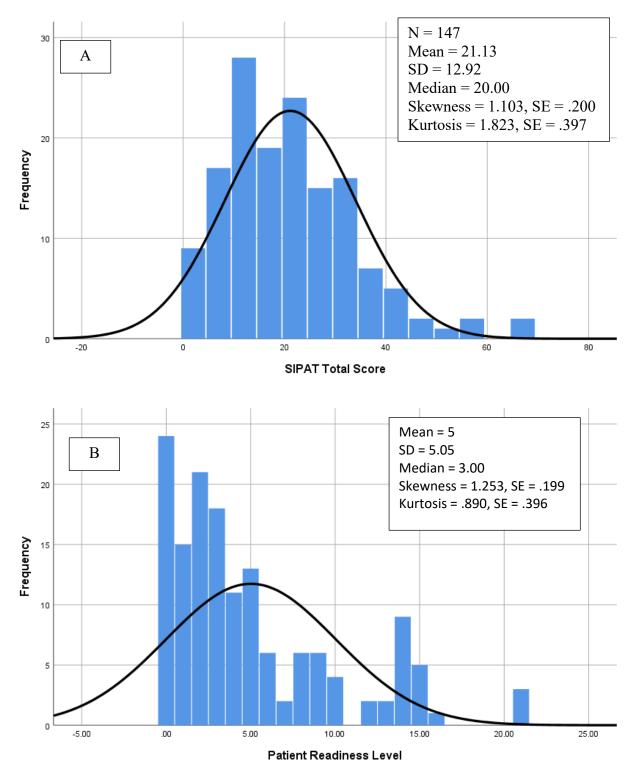
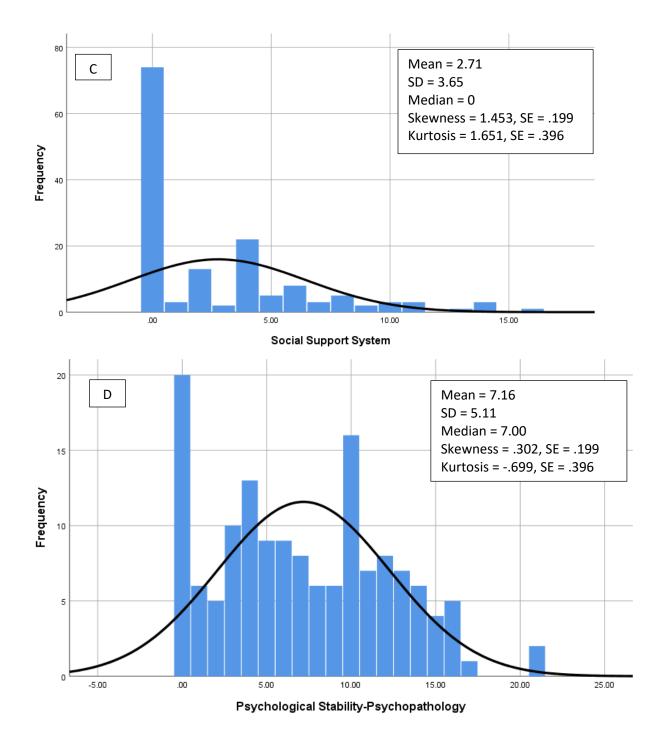
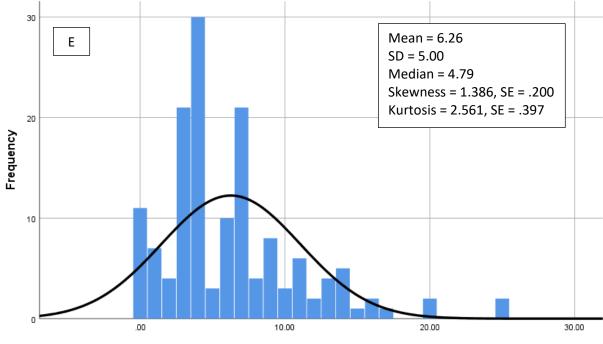


Figure 1A-E: Distribution for SIPAT Total Scale and Subscales





Lifestyle & Effect of Substance Abuse

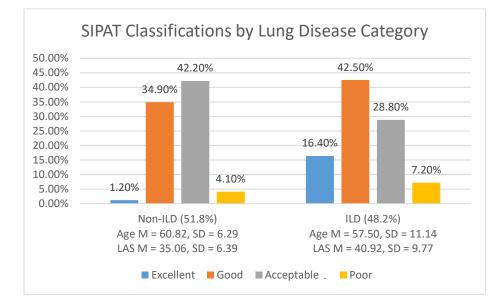
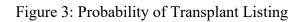
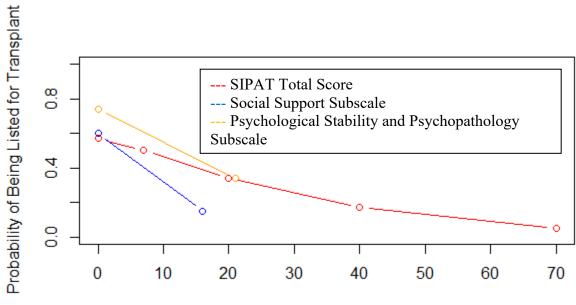


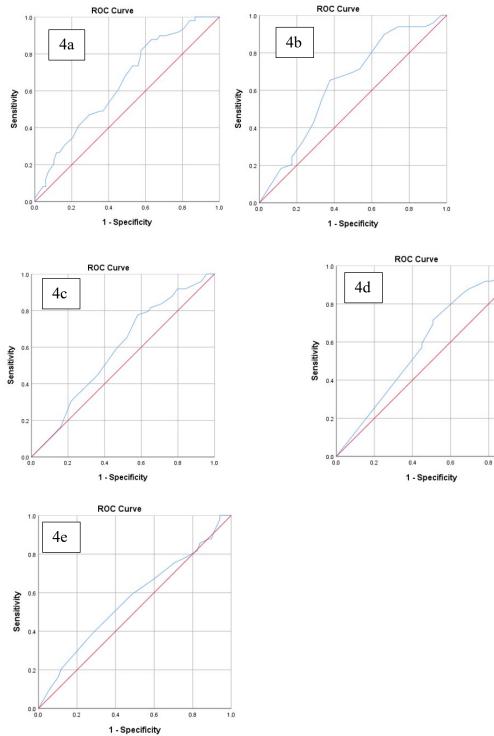
Figure 2. SIPAT Classifications by Lung Disease Category





SIPAT Scores

Figure 4a-4e. ROC Curve of SIPAT Total Score, SIPAT Psychological Stability and Psychopathology, Patient's Readiness Level, Social Support System, and Lifestyle & Effect of Substance Use Subscale Totals



1.0

## References

- Chambers, D. C., Cherikh, W. S., Harhay, M. O., Hayes, D., Hsich, E., Khush, K. K., ... & Singh, T. P. (2019). The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation: Thirty-sixth adult lung and heart–lung transplantation Report—2019; Focus theme: Donor and recipient size match. *The Journal of Heart and Lung Transplantation*, 38(10), 1042-1055.
- Craven J. (1990). Psychiatric aspects of lung transplant: The Toronto Lung Transplant Group. *Canadian Journal of Psychiatry*, 35, 759–764.
- Craven, J. L., Bright, J., & Dear, C. L. (1990). Psychiatric, psychosocial, and rehabilitative aspects of lung transplantation. *Clinics in chest medicine*, 11(2), 247-257.
- Dew, M. A., Switzer, G. E., DiMartini, A. F., Matukaitis, J., Fitzgerald, M. G., & Kormos, R. L. (2000). Psychosocial assessments and outcomes in organ transplantation. *Progress in Transplantation*, 10(4), 239-261.
- Dew, M. A., DiMartini, A. F., Dabbs, A. D. V., Myaskovsky, L., Steel, J., Unruh, M., ... & Greenhouse, J. B. (2007). Rates and risk factors for nonadherence to the medical regimen after adult solid organ transplantation. *Transplantation*, 83(7), 858-873.
- Dew, M. A., Rosenberger, E. M., Myaskovsky, L., DiMartini, A. F., Dabbs, A. J. D., Posluszny, D. M., ... & Greenhouse, J. B. (2015). Depression and anxiety as risk factors for morbidity and mortality after organ transplantation: a systematic review and metaanalysis. *Transplantation*, 100(5), 988.
- Dew, M. A., DiMartini, A. F., Dobbels, F., Grady, K. L., Jowsey-Gregoire, S. G., Kaan, A., ... & Crone, C. C. (2018). The 2018 ISHLT/APM/AST/ICCAC/STSW recommendations for the psychosocial evaluation of adult cardiothoracic transplant candidates and candidates for long-term mechanical circulatory support. *Psychosomatics*, 59(5), 415-440.
- Dobbels, F., De Geest, S., Cleemput, I., Fischler, B., Kesteloot, K., Vanhaecke, J., & Vanrenterghem, Y. (2001). Psychosocial and behavioral selection criteria for solid organ transplantation. *Progress in Transplantation*, 11(2), 121-132.
- Goetzmann, L., Ruegg, L., Stamm, M., Ambühl, P., Boehler, A., Halter, J., ... & Spindler, A. (2008). Psychosocial profiles after transplantation: a 24-month follow-up of heart, lung, liver, kidney and allogeneic bone-marrow patients. *Transplantation*, 86(5), 662-668.
- Hosmer, D. W. & Lemeshow, S. (2000). *Applied Logistic Regression (2<sup>nd</sup> Ed.)*. John Wiley and Sons.
- Kugler, C., Fischer, S., Gottlieb, J., Welte, T., Simon, A., Haverich, A., & Strueber, M. (2005). Health-related quality of life in two hundred-eighty lung transplant recipients. *The Journal of heart and lung transplantation*, 24(12), 2262-2268.
- Maldonado, J. R., Dubois, H. C., David, E. E., Sher, Y., Lolak, S., Dyal, J., & Witten, D. (2012). The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT): a new tool for the psychosocial evaluation of pre-transplant candidates. *Psychosomatics*, 53(2), 123-132.
- Maldonado, J. R., Sher, Y., Lolak, S., Swendsen, H., Skibola, D., Neri, E., ... & Standridge, K. (2015). The Stanford Integrated Psychosocial Assessment for Transplantation: a prospective study of medical and psychosocial outcomes. *Psychosomatic medicine*, 77(9), 1018-1030.
- Oh, C. K., Murray, L. A., & Molfino, N. A. (2012). Smoking and idiopathic pulmonary fibrosis. *Pulmonary medicine*, 2012, 1-13.

- Olbrisch, M. E., Levenson, J. L., & Hamer, R. (1989). The PACT: A rating scale for the study of clinical decision-making in psychosocial screening of organ transplant candidates. *Clinical Transplantation*, *3*(3), 164-169.
- Orens, J. B., Estenne, M., Arcasoy, S., Conte, J. V., Corris, P., Egan, J. J., ... & Martinez, F. J. (2006). International guidelines for the selection of lung transplant candidates: 2006 update—a consensus report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation. *The Journal of heart and lung transplantation*, 25(7), 745-755.
- Organ Procurement and Transplantation Network. General Considerations in the Assessment for Transplant Candidacy. Available at: <u>https://optn.transplant.hrsa.gov/resources/ethics/general-considerations-in-assessment-for-transplant-candidacy/</u>.
- Owen, J. E., Bonds, C. L., & Wellisch, D. K. (2006). Psychiatric evaluations of heart transplant candidates: predicting post-transplant hospitalizations, rejection episodes, and survival. *Psychosomatics*, *47*(3), 213-222.
- Parekh, P. I., Blumenthal, J. A., Babyak, M. A., Merrill, K., Carney, R. M., Davis, R. D., ... & INSPIRE Investigators. (2003). Psychiatric disorder and quality of life in patients awaiting lung transplantation. *Chest*, 124(5), 1682-1688.
- Paris, W., Muchmore, J., Pribil, A., Zuhdi, N., & Cooper, D. K. (1994). Study of the relative incidences of psychosocial factors before and after heart transplantation and the influence of posttransplantation psychosocial factors on heart transplantation outcome. *The Journal* of heart and lung transplantation, 13(3), 424-30.
- Rivard, A. L., Hellmich, C., Sampson, B., Bianco, R. W., Crow, S. J., & Miller, L. W. (2005). Preoperative predictors for postoperative problems in heart transplantation: psychiatric and psychosocial considerations. *Progress in Transplantation*, 15(3), 276-282.
- Rosenberger, E. M., DiMartini, A. F., Dabbs, A. J. D., Bermudez, C. A., Pilewski, J. M., Toyoda, Y., & Dew, M. A. (2016). Psychiatric predictors of long-term transplant-related outcomes in lung transplant recipients. *Transplantation*, 100(1), 239.
- Shapiro, P. A., Williams, D. L., Foray, A. T., Gelman, I. S., Wukich, N., & Sciacca, R. (1995). Psychosocial evaluation and prediction of compliance problems and morbidity after heart transplantation. *Transplantation*, 60(12), 1462-1466.
- Singer, H. K., Ruchinskas, R. A., Riley, K. C., Broshek, D. K., & Barth, J. T. (2001). The psychological impact of end-stage lung disease. *Chest*, *120*(4), 1246-1252.
- Smith, P. J., Blumenthal, J. A., Trulock, E. P., Freedland, K. E., Carney, R. M., Davis, R. D., ... & Palmer, S. M. (2016). Psychosocial predictors of mortality following lung transplantation. *American Journal of Transplantation*, 16(1), 271-277.
- Søyseth, T. S., Lund, M. B., Bjørtuft, Ø., Heldal, A., Søyseth, V., Dew, M. A., ... & Malt, U. F. (2016). Psychiatric disorders and psychological distress in patients undergoing evaluation for lung transplantation: a national cohort study. *General Hospital Psychiatry*, 42, 67-73.
- Steinman, T. I., Becker, B. N., Frost, A. E., Olthoff, K. M., Smart, F. W., Suki, W. N., & Wilkinson, A. H. (2001). Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplantation*, 71(9), 1189-1204.
- Twillman, R. K., Manetto, C., Wellisch, D. K., & Wolcott, D. L. (1993). The transplant evaluation rating scale: A revision of the psychosocial levels system for evaluating organ transplant candidates. *Psychosomatics*, 34(2), 144-153.

- Weill, D., Benden, C., Corris, P. A., Dark, J. H., Davis, R. D., Keshavjee, S., ... & Snell, G. I. (2015). A consensus document for the selection of lung transplant candidates: 2014—an update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation.
- Woodman, C. L., Geist, L. J., Vance, S., Laxson, C., Jones, K., & Kline, J. N. (1999). Psychiatric disorders and survival after lung transplantation. *Psychosomatics*, 40(4), 293-297.