The Psychosocial Assessment of Transplant Candidates: Inter-Rater Reliability and Predictive Value of the Italian Stanford Integrated Psychosocial Assessment for

The psychosocial assessment of transplant candidates: inter-rater reliability and predictive value of the Italian Stanford Integrated Psychosocial Assessment for Transplantation

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Psychosomatics

Abstract

Objective: Since neither established assessment procedures nor standardized tools designed to perform pre-transplant psychosocial evaluation are currently available in Italy, the current study was designed to develop and preliminarily validate the Italian version of the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT). Methods: First, our team developed the Italian version of the SIPAT, following standard forward-back translation procedures. Then, the Italian version of the SIPAT was retrospectively and blindly applied to 118 randomly selected transplant cases (40 heart, 40 lung, and 38 liver) by two independent examiners. Information about the patients' final transplant listing recommendation (i.e., listing vs. deferral) were independently collected from the respective transplant teams. Results: The inter-rater reliability of the Italian version of the SIPAT scores was substantial (Cohen's kappa = 0.77; $p < 0.001$). Moreover, the predictive value of the SIPAT ratings on the final transplant listing recommendation (i.e., listing vs. deferral) for each examiner was significant (both ps < 0.05). Conclusion: Current findings suggest that SIPAT is a promising and reliable instrument also in its Italian version. Given these excellent psychometric characteristics, the use of the SIPAT as part of the pre-transplant psychosocial evaluation in Italian medical settings is highly encouraged.

Key words: SIPAT; Psychosocial assessment; pre-transplant evaluation; validation; psychometrics.

Introduction

The psychosocial assessment of transplant candidates is an essential part of the pre-transplant evaluation process[1-4]. A variety of pre-transplant psychosocial factors (i.e., dysfunctional coping, treatment non-adherence, anxiety, depression, substance use disorders, and poor social support) have been associated with unfavorable post-surgical outcomes, particularly post-transplant treatment non-adherence, an increased rate of post-transplant surgical complications (e.g., infection rates, hospital admissions, transplant organ survival)[5-8], worsening rates of mortality[8-11], increased episodes of rejection[7,8], and increased rates of post-transplant malignancies[12]. Multiple studies have found a relationship between the findings of the psychosocial evaluation and the ultimate transplant success[8,13-17]. In fact, the association between pre-transplant psychosocial issues and post-transplant psychosocial outcomes (i.e., developing new or worsening psychiatric syndromes, psychiatric hospitalizations, relapse of substance use post transplantation, problems with treatment adherence) is largely documented[7,8,18-20]. In fact, a prospective study of solid organ transplant patients demonstrated that higher SIPAT scores predicted higher rates of multiple medical (i.e., rejection episodes, medical hospitalizations, infection rates), as well as psychosocial (i.e., psychiatric decompensation, support system failure) post-transplant complications[21]. Therefore, and considering the limited availability of organs, it makes sense for our transplant team to adopt a psychosocial assessment procedure capable of effectively identifying the psychosocial variables associated with transplant success.

Maldonado et al. outlined the need for establishing standardized psychosocial listing criteria to evaluate prospective transplant candidates, given the heterogeneity of tools and techniques usually employed during psychosocial evaluation[1,8]. Based on a systematic review of the literature his research team developed the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT), a comprehensive instrument including eighteen psychosocial factors found to predict transplant outcomes[1]. Items are grouped into four domains evaluating: (1) patient's readiness level and illness management, (2) social support system level of readiness, (3) psychological stability and

psychopathology, and (4) lifestyle and effect of substance use (see Table 1)[1]. The deriving overall risk severity score varies between 0 and 120: the higher the score, the greater the risk for both, post-transplant medical and psychosocial complications[8,21]. Furthermore, a risk scoring rating classifying psychosocial risk from "excellent candidate" to "high risk candidate" is provided, together with recommendations for proceeding to transplant listing (ranging from "list without reservation" to "listing not recommended while identified risk factors present").

Table 1. SIPAT domains, items, and scoring system.

Psychosocial domain	Item	Score
A. Patient's readiness level	1. Knowledge & understanding of the medical illness process (that caused specific organ failure)	0-4
	2. Knowledge & understanding of the transplant process	0-4
	3. Willingness/Desire for treatment (transplant)	0-4
	4. Treatment compliance/Adherence (pertinent to medical issues)	0-8
	5. Lifestyle factors (including diet, exercise, fluid restrictions; and habits according to organ)	0-4
B. Social support system	6. Availability of social support system	0-8
	7. Functionality of social support system	0-8
	8. Appropriateness of physical living space & environment	0-4
C. Psychological stability and psychopathology	9. Presence of psychopathology (mood, anxiety, psychosis & others)	0-8
	9a. Depression assessment	0-3
	9b. Anxiety assessment	0-3
	9c. Mania assessment	0-5
	9d. Psychosis assessment	0-5
	10. Organic psychopathology or neurocognitive impairment (current or history): Illness or treatment/medication induced psychopathology	0-5

	10a. Assessment of current cognitive functioning	0-2
	11. Influence of personality traits vs. disorder	0-4
	12. Problems with truthfulness or deceptive behavior during treatment or evaluation process	0-8
	13. Overall risk for psychopathology	0-4
D. Effect of substance use	14. Alcohol Use Disorder	0-8
	15. Alcohol Use Disorder – Risk for relapse	0-4
	16. Substance Use Disorder – Including prescribed & illicit substances	0-8
	17. Substance Use Disorder – Risk for relapse	0-4
	18. Nicotine Use/Abuse/Dependence	0-5

Overall risk severity score	**Rating**	**Recommendation**
0-6	Excellent candidate	Recommend to list for transplantation without reservations.
7-20	Good candidate	Recommend to list for transplantation – although monitoring of identified risk factors may be required.
21-39	Minimally acceptable candidate	Consider Listing. Identified risk factors must be satisfactorily addressed before representing for consideration.
40-69	Poor candidate	Recommend deferral while identified risks are satisfactorily addressed.
>70	High risk candidate, significant risks identified	Surgery is not recommended while identified risk factors continue to be present.

Of note, some items are differently weighted because of data suggesting that some psychosocial variables are more predictive of clinical outcomes and nonadherence than others[1,8,21]. In the original validation study, five examiners (two psychiatrists, an advanced licensed clinical social worker, and two psychiatric residents) blindly applied the SIPAT to 102 transplant cases (52 liver, 25 heart, and 25 lung)[1]. Excellent inter-rater reliability and strong intra-user consistency between the SIPAT and the Psychosocial Assessment of Candidates for Transplantation scale[22]

were observed. The SIPAT risk severity score allows predicting post-transplant behavioral and psychiatric outcomes, and findings from both retrospective and prospective studies demonstrated that SIPAT ratings are predictive of the transplant psychosocial outcomes[1,8,21,23].

The present study aimed at translating and assessing the inter-rater reliability and the predictive value of the Italian version of the SIPAT. It is important to highlight that, neither established assessment procedures, nor standardized tools designed to perform an accurate pre-transplant psychosocial evaluation are currently defined in the Italian Transplantation literature or guidelines. Therefore, the present research was designed to fill a crucial gap in current Italian clinical practice. To pursue this aim, we followed a procedure similar to the one used in the original validation of the instrument, thus the SIPAT was retrospectively applied to 118 transplant cases. Consistent with findings by Maldonado et al.[1], we expected to observe excellent inter-rater reliability on the SIPAT ratings provided by independent examiners. Moreover, we expected the SIPAT ratings to significantly predict the final transplant listing recommendation (i.e., listing vs. deferral).

Material and Methods

The Italian version of the SIPAT

The Italian version of the SIPAT was developed following well-established, standard forward-back translation procedures[24]. Initially, three independent researchers translated the questionnaire from English to Italian and then reached agreement on a common version. Moreover, the researchers reviewed the common version to ensure there were no colloquialisms, slang, or esoteric phrases that would make interpretations difficult. The Italian version was then back-translated by a bilingual professional with extensive knowledge of psychological research; the back translation proved to be nearly identical to the original one, yielding the final Italian SIPAT tool used in this study.

Participants and Procedure

In the current study, the newly translated Italian version of the SIPAT was retrospectively applied to 118 randomly selected transplant candidates (40 heart, 40 lung, and 38 liver) who underwent medical and psychosocial pre-transplant evaluations for listing purposes, between 2014 and 2017, by two independent examiners. This was the same procedure utilized in the initial validation of the original SIPAT tool[1]. All cases were randomly identified by the respective organ transplant teams, independent from the research group. Selected cases were then provided to the research team. At the General Hospital-University of Padova, the psychosocial evaluations of transplant candidates are usually carried out by clinical psychologists and/or psychiatrists. Accordingly, in the current study, the examiners were two licensed clinical psychologists, who received specific training on the administration of SIPAT from three senior experts (a psychiatrist and two clinical psychologists) and the Principal Investigator. Following the procedures utilized in the study by Maldonado et al.[1], examiners applied the SIPAT to the selected transplant patient's clinical chart, which included psychological and/or psychiatric evaluations, while blinded to the patients' names and other identifying information, as well as to the final transplant listing recommendation (i.e., listing vs. deferral). Once all cases had been independently rated by both examiners, the Principal Investigator, herself blinded to the SIPAT scores, obtained information regarding the patients' final transplant listing recommendation from documentation in the General Hospital-University of Padova data system.

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee for Clinical Practice of the General Hospital-University of Padova (protocol number: 0048756). All participants provided their informed consent for potential research analysis and anonymous reporting of findings in aggregate form, in accordance with Italian legal and ethical requirements.

Statistical analyses

Statistical analyses were performed with the statistical software R[25] and the package *irr*[26]. Inter-rater reliability was estimated by using the Cohen's kappa[27] on the ratings (i.e., SIPAT

interpretation) provided by the two examiners. Values between 0 and 0.20 indicate extremely poor, 0.21–0.40 poor, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1 excellent agreement[28]. In order to test whether the SIPAT rating was predictive of the final transplant listing recommendation (i.e., listing vs. deferral), univariate logistic regression models were performed on the overall sample for each examiner.

Results

Descriptive analyses

The sample included 118 transplant cases, including the three major solid organ groups (40 heart, 40 lung, and 38 liver). In our sample, 23.1% of subjects were female. The mean age of our sample was 54.8 years (*SD*=10.4). Marital status was 75.2% married/in a domestic relationship, 17.9% single/widowed, and 6.9% divorced. The employment profile of the sample was 78.8% employed and 21.2% unemployed/retired. Table 2 displays demographic information in detail. Lastly, as far as the final transplant listing recommendation is concerned, 58.3% were listed and 41.7% were deferred by the transplant teams.

Table 2. Demographic information (grouped by organ).

	Heart (*N* = 40)	Lung (*N* = 40)	Liver (*N* = 38)
Gender (% female)	10.0	30.0	28.9
Age (*M*±*SD*)	56.95±10.48	53.33±10.49	54.83±9.43
Marital status (% married/in a domestic relationship)	77.5	77.5	75.2
Occupation (% employed)	67.5	92.37	76.0

Interrater reliability

The Italian version of the SIPAT showed substantial inter-rater reliability: the Cohen's kappa estimated on the agreement between the overall ratings of the two independent examiners for

each patient was equal, on average, to 0.77 ($p < 0.001$). According to the SIPAT scores, 5.5% were classified as "excellent candidate", 51.9% "good candidate", 25.9% "minimally acceptable candidate", and 16.7% "poor candidate". None of the patients were rated as "high risk candidate", suggesting our transplant team has already implemented mechanisms to screen out extremely high-risk candidates.

Prediction of the final transplant listing recommendation

Univariate logistic regression models of our study sample demonstrated that the higher the SIPAT scores, the higher the probability that the patient had been deferred by the transplant team. In other words, the SIPAT rating was a good predictor of the final transplant listing recommendation (Table 3).

Table 3. Predictive power of the SIPAT ratings on the final transplant listing recommendation (i.e., listing vs. deferral) for each examiner.

Examiner	Coefficient	*OR*	*p*
1	-0.613	0.542	0.013
2	-0.594	0.552	0.023

Note: *OR* = Odds Ratio.

As displayed in Table 3 and in Figure 1, an increase of one unit of interpretation significantly increased the probability of being deferred from the transplant list. *[Figure 1 here]*

These findings are consistent with those of previous SIPAT studies, which suggest that higher SIPAT scores were associated with a higher probability of both medical and psychosocial outcomes.[1,8,21,23]

Discussion

Organ transplantation is a highly complex procedure, which may determine significant changes for patients suffering from end-organ failure and their families, at the physical, emotional,

and social levels. The assessment of transplant candidates is challenging and includes potential clinical, ethical, and social factors. Therefore, an accurate, standardized psychosocial evaluation process of transplant candidates should comprise an in-depth investigation of the cognitive, behavioural, psychological, and social risk factors that may impact the transplant process and post-transplant outcomes[1, 4]. In this regard, Maldonado et al. outlined that psychosocial listing criteria are less standardized than medical ones which, on the contrary, are well established for each organ[1, 21]. The SIPAT was thus developed to address this issue and extant literature supports its utility in predicting outcomes both in solid organ transplant populations[1, 21, 23] and in left ventricular assist device candidates[29]. The current study sought to replicate the original SIPAT study in order to explore the inter-rater reliability and predictive value of its Italian version on a sample of 118 heart, liver and lung transplant candidates. Inter-rater reliability was good, consistent with previous literature employing similar study designs and procedure on comparable samples. For example, in the original validation study, agreement on a mixed sample of liver, heart, and lung cases was excellent (Pearson's $r = 0.85$)[1]. Subsequently, Vandenbogaart et al.[23] applied the SIPAT to 51 heart cases and similarly found excellent inter-rater reliability among examiners (intra-class correlation coefficient = 0.89). Of note, pre-transplant psychosocial evaluations are performed by different professionals according to the peculiarities of the various countries (in the cases at hand, the United States of America and Italy); thus, allowing for a significant degree of variability in the psychosocial assessment of transplant candidates. Since the SIPAT demonstrated substantial inter-rater reliability, independent of the examiners' qualification and experience (i.e., clinical psychologists in our study, psychiatrists and clinical social workers in the study by Maldonado et al.), our study findings provide further evidence of the reliability of the SIPAT as a tool to be used across different specific national contexts and solid organ transplant groups.

With respect to the predictability of the final transplant listing recommendation, findings from our study confirmed that the SIPAT is an excellent predictor of listing outcomes. Specifically, the higher the score, the lower the likelihood that a given candidate would be listed for

transplantation. Of note, in our sample, based on the SIPAT scores none of our cases was determined to have significant risk factors (i.e., "high risk candidate"). Similarly, after having satisfactorily addressed identified risks factors, deferral was recommended only in 16.7% cases (i.e., "poor candidate"). Both these findings suggest that our group has done a good job with candidate pre-selection criteria (i.e., determining who may be an appropriate candidate to initiate the pre-transplant evaluation process).

Nevertheless, a review of candidates' medical records suggested that of all candidates evaluated for transplantation, 41.7% of cases were deferred from transplantation. Such a discrepancy suggests that, independent of the results of the psychosocial evaluation, a portion of patients were deferred based exclusively on medical listing criteria. Our review also found that several cases identified by SIPAT as "poor candidate" were actually listed. It is also important to note that current Italian guidelines do not identify neither absolute, nor relative psychosocial contraindications for transplantation. Accordingly, in our transplant program no patient was deferred solely on the basis of identification of psychosocial risk factors. Rather, in our cohort, remediation interventions were carried out and secondary reassessments were performed after a three-month period to evaluate whether candidates had modified their behaviours, thus correcting identified deficiencies.

The assessment of transplant candidates is challenging and riddled with potential clinical, social, and ethical factors.[30] The data available to date confirms that in addition to the usual medical factors, psychosocial and behavioral issues may affect the ultimate transplant outcome. In fact, the data suggests that pre-transplant psychiatric history can predict post-transplant psychological outcomes, and that these, in turn may predict physical morbidity and mortality[30]. Our findings suggest that given the excellent psychometric characteristics of the Italian version of SIPAT, its use as part of the pre-transplant psychosocial evaluation in Italian medical settings is highly encouraged. Our results also add to the body of literature that demonstrates that linguistic and

cultural adaptations of SIPAT, such as its recent translation into Spanish, have excellent inter‐rater reliability and internal consistency[31].

Our study had some limitations. First, only two examiners retrospectively applied the SIPAT. Although this does not represent a major issue, we acknowledge that the higher is the number of raters, the more likely it is to obtain accurate information regarding the inter-rater reliability of an instrument. Second, the only available information to assess the predictive value of the SIPAT was the final transplant listing recommendation. Future studies assessing the SIPAT's Italian version should consider taking into account diverse psychological, behavioral (e.g., psychological relapses, nonadherence to medications/to clinic visits), and medical (e.g., number of rejection episodes, number of hospitalizations for rejection/infection) outcomes in order to provide a more comprehensive description of the predictive value of the tool. Third, information about candidates who might have received remediation interventions (i.e., "poor candidates" that were listed after reassessment) was not available in the General Hospital-University of Padova data system. We recommend that future prospective research should take these factors into account. Fourth, it was not possible to assess convergent validity of the SIPAT, due to the lack of standardized, validated measures in Italian language. Finally, our study was, by design, as a retrospective one. The main purposes of our research were to (1) develop a validated Italian version of the SIPAT instrument, and (2) to assess its validity (i.e., inter-rater reliability and predictive value) in a clinical population. We believe both goals were satisfactorily achieved.

Conclusions

Notwithstanding the above-mentioned limitations, taken as a whole, current results suggest that the Italian version of the SIPAT tool is a promising instrument for the comprehensive and standardized evaluation of transplant candidates and, consequently, its use in Italian medical settings should be encouraged. An advantage of using validated, pre-transplant assessment tools, such as the SIPAT, is that it standardizes the psychosocial assessment evaluation process so all

transplant candidates undergo the same rigorous psychosocial scrutiny, Thus, allowing clinicians to identify areas of psychosocial strengths that can be built upon, and areas of weaknesses needing assistance or further assessment and management. This process helps transplant teams know as much as they need to about a given patient's individual psychosocial factors that may negatively influence transplant outcomes.

Future, prospective studies should confirm our preliminary findings, as well as determine the ability of the SIPAT to predict both medical (i.e., morbidity, mortality, graft survival, medical complications and quality of life) and psychosocial (i.e., psychological complications, treatment adherence, and psychosocial stability) post-transplant outcomes.

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Figure caption.

Figure 1. Association between SIPAT ratings and the final transplant listing recommendation (listing vs. deferral) for each examiner. SIPAT rating: 1 = “excellent candidate”, 2 = “good candidate”, 3 = “minimally acceptable candidate”, 4 = “poor candidate”.

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