



Supportive care

Standardized Semi-structured Psychosocial Evaluation before Hematopoietic Stem Cell Transplantation Predicts Patient Adherence to Post-Transplant Regimen



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In patients undergoing stem cell transplantation (SCT), nonadherence has potential for significant medical impact and potentially life-threatening complications. No study thus far has demonstrated an effective way to predict adherence in SCT recipients. A structured rating scale, the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT), has been shown to predict psychosocial outcomes and medical morbidity in solid organ transplant recipients. We assessed the SIPAT in SCT recipients. We hypothesized that the SIPAT rating would be associated with nonadherence to the post-SCT regimen. We retrospectively studied SCT recipients who had psychiatric evaluations with the SIPAT before SCT. The primary outcome was nonadherence, defined a priori as at least 1 life-threatening nonadherence event in the first 6 months post-transplant. Association of the SIPAT with outcomes was evaluated by logistic regression, and an optimal cutoff score was determined using a receiver operating characteristic curve. Of 85 patients (mean age 47 years; range, 18 to 74 years), 56 (66%) were male, and 43 (50.5%) received autologous SCT. Eighteen (21%) patients were nonadherent. The SIPAT rating, treated as a continuous variable and controlling for autologous versus allogeneic SCT, was significantly associated with nonadherence (per 1 point; odds ratio [OR], 1.162; $P < .0001$). Allogeneic SCT also conferred a significantly increased risk of nonadherence (OR, 14.184; $P = .005$). Multivariate analysis stratifying for allogeneic versus autologous transplantation and controlling for age, sex, and disease confirmed an independent association between the SIPAT score and nonadherence. A cutoff score of 18 provided optimal specificity (89.6%) and sensitivity (55.6%) for nonadherence. Nonadherence rates were 58.8% and 11.8% for subjects with SIPAT ratings of 18 and above or 17 and below, respectively (relative risk = 4.98, $P < .0001$). Psychosocial risk as quantified by the SIPAT correlated with SCT recipients' adherence to the post-transplant regimen, suggesting that this instrument can contribute to medical risk stratification models. Further study should evaluate long-term mortality data and the effects of intervention on psychosocial risks.

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BACKGROUND

Psychiatric care is an important aspect of hematopoietic stem cell transplantation (SCT) because of high rates of acute and chronic anxiety, depression, delirium, cognitive impairment [1], decreased quality of life, body image disturbances, and post-traumatic stress [2,3]. The use of psychosocial rating scales is potentially useful to integrate psychiatric evaluation findings into medical risk stratification models in transplantation but has not been studied in SCT. The Stanford

Integrated Psychosocial Assessment for Transplantation (SIPAT) is a structured assessment tool with demonstrated inter-rater reliability. It yields a score based on psychiatric, cognitive, and psychosocial domains. In studies of solid organ transplant patients, the SIPAT was shown to predict psychosocial outcomes [4], psychiatric decompensation, support system failure, and episodes of rejection, hospitalization, and infection but not organ failure or mortality [5].

In assessing the relationship between psychosocial evaluations and medical prognosis, adherence to care is a crucial proximal outcome because of its strong relationship to the distal outcomes of morbidity and mortality. In cancer-specific studies, nonadherence has on average been greater than 20% and predicted relapse and worse survival outcomes [6–8]. Considering the cost, high symptom burden, morbidity, and

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mortality of SCT treatment, predicting a patient's ability to adhere to treatment has obvious importance. SCT care is more complex than that of many other serious diseases, requiring not only adherence to the medication regimen but also tolerance for lengthy hospitalizations, frequent appointments, laboratory and radiologic tests, physical therapy, dietary restrictions, avoidance of infection risk, and integrating the advice of multiple specialists after transplantation. Adherence to all recommendations poses a substantial burden for SCT patients.

Currently, there are no well-established objective scales of adherence. Work done in solid organ transplant has found significant correlation between several types of nonadherence and mortality, including nonadherence to immunosuppressive medications, diet, vital sign monitoring, and exercise [9,10]. However, no studies have assessed SCT patients' adherence to any aspects of their care other than outpatient medications [8]. Moreover, no studies have accounted for degrees of nonadherence, looked at factors stratifying risk for nonadherence, or considered how psychiatric evaluation can predict nonadherence or assist in improving patient engagement in care.

Our goal was to determine whether SIPAT ratings based on pretransplantation psychiatric evaluation predict nonadherence and medical outcomes in this population. We hypothesized that psychosocial risk as determined by the SIPAT rating would be associated with nonadherence to the post-SCT regimen. We also evaluated the risk of mortality and causes of death in high-SIPAT and nonadherent groups.

METHODS

Study Design

We conducted a retrospective study at a single large academic urban medical center in New York, which serves a population of diverse ethnic and socioeconomic status. The study was approved by Columbia University Medical Center's Institutional Review Board. Psychiatric evaluations with semi-structured psychiatric interviews summarized contemporaneously with the SIPAT were conducted as part of the overall evaluation of candidates for SCT. Adherence and morbidity were evaluated retrospectively as described below.

Subjects

Study subjects were adult patients who had a psychiatric evaluation with a completed SIPAT before admission for SCT, both occurring between August 1, 2014, and December 31, 2016. Subjects were interviewed by one of the authors (A.D.M.), who performed all psychiatric evaluations for SCT candidates in our program during the study period. Our psychiatric evaluation rate in comparison to the hospital's total adult transplant population was 47.8% for autologous recipients and 84% for allogeneic recipients; all patients who had both a psychiatric evaluation with SIPAT and an SCT during the study period were included (Figure 1). Patients were all followed for 1 year post-transplant for the purpose of this study.

Data

The SIPAT scale assesses psychiatric symptoms, substance use, transplant knowledge, motivation, social supports, and lifestyle factors and assigns points, with a higher score indicating higher risk. SIPAT scores generated by the provider during initial psychiatric evaluations were the independent variable. The primary outcome measure was nonadherence in the first 6 months post-transplant. Nonadherence was defined as a binary variable, defined as occurrence of at least 1 event of life-threatening nonadherence in the 6 months following transplant. Criteria for life-threatening nonadherence events were defined by our interdisciplinary team a priori, in advance of chart reviews, by consensus of the investigators and are listed in Table 1. The nonadherence criteria were created based on a combination of existing evidence from solid organ transplantation (correlating nonadherence to immunosuppressive medications, diet, vital sign monitoring, and exercise with mortality [9,10]) and on our clinical experience. The occurrence of nonadherence events was determined retrospectively by consensus of an interdisciplinary team of 5 SCT clinicians (physician assistants, nurse manager, social worker, and oncologist) who were blind to SIPAT scores and independently reviewed patient electronic medical records. Demographic, medical, and diagnostic characteristics were retrieved from the electronic medical record. These included age, sex, diagnosis, transplant type, donor type, occurrence of graft-versus-host-disease, length of stay, intensive care unit (ICU) admission and days during transplant admission, readmissions within 30 and 60 days post-transplant, date and cause of death, and the Hematopoietic Cell Transplantation-Specific Comorbidity Index.

Statistical Analysis

Patients were stratified by autologous versus allogeneic transplant. SIPAT scores and occurrence of nonadherence were used to create a receiver operating characteristic (ROC) curve and determine a cutoff score with optimal sensitivity and specificity for prediction of nonadherence. This cutoff score, distinguishing groups with "normal" versus "high" psychosocial risk, was tested as a predictor of nonadherence events from 0 to 6 months post-transplant. We used a multivariate logistic regression model with nonadherence as the outcome. A nonparametric Mann-Whitney test was used because data were not normally distributed. The criterion of statistical significance was adjusted for multiple nonindependent comparisons by Bonferroni correction.

RESULTS

Subject Characteristics

We included 85 patients with mean age of 47 years (range, 18 to 74 years). Fifty-six (66%) were male, and 43 (50.5%) received autologous SCT (Figure 1). Of the allogeneic SCT recipients, 15 had matched sibling donors, 2 had haplo-identical sibling donors, 18 had matched unrelated donors, and 7 had single-allele mismatched unrelated donors. The mean (SD) Hematopoietic Cell Transplantation-Specific Comorbidity Index was 3.81 (1.4; range 1 to 8). The most common diagnoses were non-Hodgkin lymphoma (21), acute myeloid leukemia (16), and multiple myeloma (15) (Table 2).

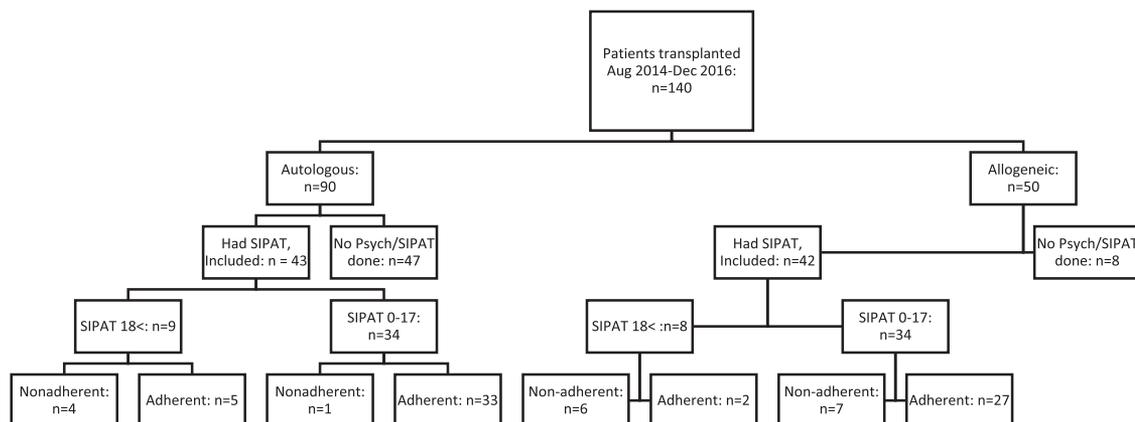


Figure 1. Numbers of patients undergoing transplantation, enrolled, binary SIPAT scores and adherence.

Table 1
Definitions of Nonadherence

Category	During Transplant Admission	After Transplant Admission (Inpatient or Outpatient)
Drug use	<ul style="list-style-type: none"> • Illicit drug use • Smoking 	<ul style="list-style-type: none"> • i.v. drug use • Smoking marijuana • Any <i>DSM-IV</i>-defined substance abuse/dependence
Medications	<ul style="list-style-type: none"> • Refusal of transplant medications* 	<ul style="list-style-type: none"> • >2 consecutive days of missing medications • Missing any medications without informing the team
Hospitalization	<ul style="list-style-type: none"> • Leaving AMA or elopement 	<ul style="list-style-type: none"> • Refusing readmission if advised by transplant physician
Diet	<ul style="list-style-type: none"> • Intentional indiscretions regarding low microbial diet[†] before physician advises to discontinue low microbial diet 	
Infection risk (visitors)	<ul style="list-style-type: none"> • Unauthorized child visitors • Animal visitors • Intentional interaction with sick (infected) visitors • Sexual intercourse 	<ul style="list-style-type: none"> • Intentional interaction with sick (infected) family members or friends in first 100 days post-transplant
Infection risk (PPE)	<ul style="list-style-type: none"> • Refusal to wear PPE outside the room 	<ul style="list-style-type: none"> • Refusal to wear PPE outside the home
Appointments and examinations	<ul style="list-style-type: none"> • Refusing VS, physical examination, or scheduled medications, if • \emptyset >24 consecutive hours or • \emptyset as a consistent pattern or • \emptyset if last VS/examination/laboratory tests were abnormal and require urgent follow-up 	<ul style="list-style-type: none"> • Refusal/no show of important tests • Refusal/no show of 2 consecutive follow-up appointments • Lost to follow-up
Psychiatric	<ul style="list-style-type: none"> • Intentional self-injury or self-harm • Assaulting or threatening staff (while not delirious) 	
Physical therapy	<ul style="list-style-type: none"> • Consistent refusal to participate in recommended physical activity or therapy 	<ul style="list-style-type: none"> • Not allowing PT⁸ visit (if it is part of the discharge plan) • Leaving AMA from SAR

DSM-IV indicates fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders*; AMA, against medical advice; PPE, personal protective equipment; VS, vital signs; PT, physical therapy; SAR, Subacute Rehab.

* Transplant medications include chemotherapy, steroids, and rejection medications.

[†] Low microbial diet includes raw/undercooked meat, food not prepared in a food-safe manner, food from restaurants without an “A” grade, unwashed raw produce, foods from buffets or self-service bins, fast food, fountain beverages, soft serve ice cream/yogurt, unpasteurized items, uncooked pepper, and leftovers >2 days old.

SIPAT Predicts Nonadherence

SIPAT scores in our population ranged from 0 to 40 (mean [SD], 11.5 [9.6]; median, 8) (Figure 2). The SIPAT score, treated as a continuous variable, was significantly associated with nonadherence (odds ratio [OR], 1.106; $P = .001$), and adjusting for autologous versus allogeneic transplantation increased the effect size (OR, 1.162; $P < .0001$). Multivariate analysis stratifying for allogeneic versus autologous transplantation and controlling for age, sex, and disease confirmed an independent association between the SIPAT score and nonadherence. Allogeneic transplantation also independently conferred a significantly increased risk of nonadherence (OR, 14.184; $P = .005$). The difference between SIPAT ratings for patients undergoing autologous (mean [SD], 13.2 [10.8]) and allogeneic (mean [SD], 9.88 [7.74]) SCT was not significant. There were no differences in mean SIPAT score, rate of high SIPAT scores, or rate of nonadherence between sexes. SIPAT ratings varied by diagnosis, with the highest risk rating in patients with sickle cell disease and the lowest in patients with amyloidosis (Table 3). The mean (SD) SIPAT score in the adherent (9.44 [7.85]) and nonadherent (18.84 [11.63]) groups were significantly different ($P = .001$) (Figure 3).

Defining a Cutoff Score

A ROC curve was constructed to locate the most appropriate cutoff value to define psychosocial “high-risk” status (Figure 4). Ratings of 11 to 18 showed similar total sensitivity and specificity for both allogeneic and autologous recipients. A cutoff score of 18 provided optimal specificity (89.6%) and fair sensitivity (55.6%) for nonadherence. Nonadherence rates

were 58.8% and 11.8% for subjects with SIPAT ratings of 18 and above or 17 and below, respectively (relative risk = 4.98; $P < .0001$). Autologous and allogeneic recipients had similar rates of high SIPAT scores: 8 of 42 (19%) for allogeneic patients and 9 of 43 (21%) for autologous patients, contrasting with their significantly different rates of adherence.

Prediction of Morbidity and Mortality

Using our cutoff of 18 to signify a high-risk score and adjusting for allogeneic versus autologous transplantation, high-risk patients had an increased risk of being admitted to the ICU (OR, 11.679; $P = .002$) and spent 3.5 more days in the ICU than patients with normal risk ($P = .001$). Continuous SIPAT score also correlated with need for ICU admission (OR, 1.09; $P = .021$) and with number of days in the ICU during the transplant admission ($P = .034$; coefficient, 3.485). As expected based on overall severity of illness, allogeneic transplantation also conferred significantly increased risk of ICU admission (OR, 6.867; $P = .034$). No relationship was found between SIPAT and length of stay, readmissions, or graft-versus-host-disease.

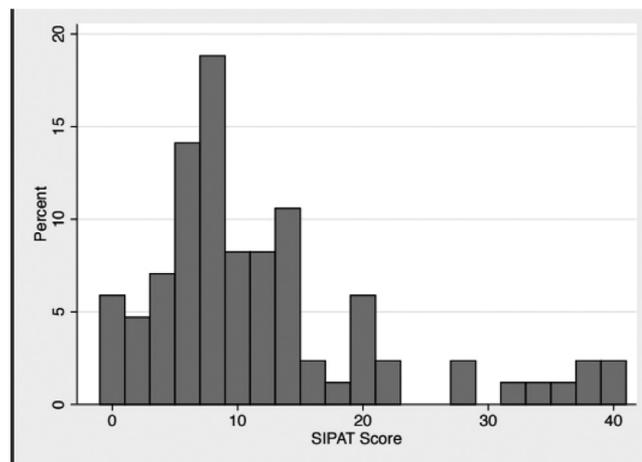
Overall 1-year mortality was 24.7% (21/85). No significant associations were found between SIPAT rating and survival or between adherence rated at 6 months and subsequent survival. Only 3 autologous SCT patients died; the remaining deaths all occurred in the subgroup of subjects undergoing allogeneic SCT for a cancer diagnosis ($n = 36$). In this subgroup, 1-year mortality was 50%; 4 of 18 (22%) patients who died and 2 of 18 (11%) surviving patients had high-risk SIPAT scores. Eight deaths were attributed to progression or relapse of cancer, and 10

Table 2
Patient Characteristics (n = 85 Patients)

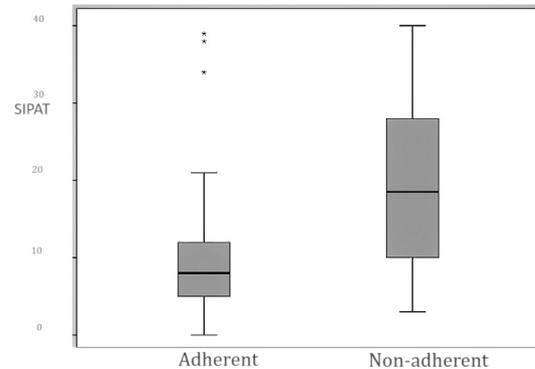
Characteristic	Value
Sex, male, n (%)	56 (66)
Age, median (range), yr	49 (18–74)
HCT-CI score, mean (range)	3.8 (1–8)
0, n	0
1–2, n	13
3, n	72
Nonadherence, n (%)	18 (21)
SIPAT score, mean (range)	11.5 (0–40)
Length of stay, median (range), d	25 (14–118)
ICU days, median (range), d	0 (0–25)
30-day readmissions, n (%)	16 (18.8)
100-day readmissions, n (%)	31 (36.5)
12-month mortality, n (%)	21 (25.0)
Transplant-related mortality	13 (15.3)
Relapse mortality	8 (9.4)
GVHD, n (%)	28 (32.9)
Diagnosis, n	
Non-Hodgkin lymphoma	21
Acute myeloid leukemia	16
Multiple myeloma	15
Myelodysplastic syndrome	10
Hodgkin lymphoma	10
Amyloidosis	4
Sickle cell disease	4
Other	5
Donor, n	
Autologous	43
Matched related donor	15
Matched unrelated donor	18
Mismatched unrelated donor	7
Haploidentical related donor	2
Conditioning, n	
Autologous	43
Myeloablative conditioning	22
Reduced-intensity conditioning	20

HCT-CI indicates Hematopoietic Cell Transplantation-Specific Comorbidity Index; GVHD, graft-versus host disease.

were transplant related. Transplant-related mortality accounted for 7 of 14 deaths (50%) in patients with low-risk scores versus 3 of 4 deaths (75%) in patients with high-risk scores.

**Figure 2.** Distribution of SIPAT scores in the entire cohort.**Table 3**
SIPAT Score and Nonadherence by Diagnosis

Diagnosis	Mean SIPAT Score	Nonadherence, n (%)
Non-Hodgkin lymphoma	12.8	5 (23.8)
Acute myeloid leukemia	9	4 (25.0)
Multiple myeloma	12.5	2 (13.3)
Myelodysplastic syndrome	10	2 (20.0)
Hodgkin lymphoma	12.8	1 (10.0)
Amyloidosis	7.3	0 (0)
Sickle cell disease	14.3	4 (100)
Other	13.6	0 (0)

**Figure 3.** Continuous SIPAT and adherence.

DISCUSSION

We found that high psychosocial risk, as represented by the SIPAT score, was associated with impaired adherence to the inpatient and outpatient post-transplant medical regimen and that a score of 18 or above optimally identified, with high specificity, those patients who did not adhere. To our knowledge, this is the first study characterizing the SIPAT in SCT patients and the first study finding a quantifiable psychosocial measure that predicts adherence outcomes in SCT recipients. It is among few studies that have found psychiatric evaluations to predict medical adherence. Other studies of SCT and solid organ transplant patient adherence have followed a single parameter, such as medication adherence. A 2017 meta-analysis found limited research in SCT medication adherence, locating only 5 total studies with highly variable methods but concluding that nonadherence is a common (5.3% to 67%) occurrence after SCT and an important area for

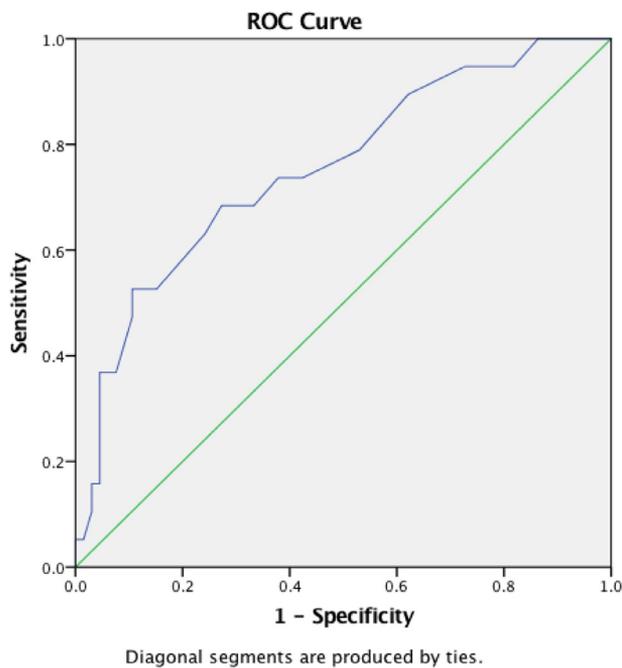


Figure 4. ROC curve.

research and intervention [11]. A review of studies of psychiatric evaluation in SCT patients found that these evaluations predicted quality-of-life ratings but not survival or medical outcomes. Many limitations were noted in the reviewed studies, including the use of different rating scales and failure to stratify or adjust for covariates such as diagnosis [12].

We believe ours to be the first study of SCT patients' ability to adhere to multiple aspects of their treatment plan, including medication adherence, diet adherence, engagement with follow-up appointments, and multiple other domains of both inpatient and outpatient care. We also found that allogeneic SCT recipients had significantly higher rates of nonadherence than autologous recipients, which we attribute primarily to the significantly more extensive demands of their post-transplant regimen: autologous patients have a shorter duration of hospitalization, have less intensive follow-up, and are not prescribed long-term immunosuppression, among other differences. Although rates of high SIPAT and nonadherence were both higher in allogeneic recipients, the relationship between SIPAT score and rate of nonadherence was parallel in our autologous recipients. We also found that SIPAT scores predicted number and duration of ICU admissions following transplantation, which is a serious adverse intermediate outcome.

Previously published SIPAT studies defined nonadherence as team consensus about potentially dangerous nonadherence [4,5]. A strength of the present study is the explicit operationalization of this concept of nonadherence with specific anchor behaviors about which a consensus could be reached by an interdisciplinary group of raters. Another strength is the use of a conservative threshold for nonadherence, avoiding inclusion of difficult behaviors that did not directly affect the patients' health and adding to the clinical relevance and predictive power of our adherence variable. In addition, ascertainment of potentially problematic behaviors was greatly facilitated by the very close interdisciplinary clinical follow-up of all subjects in the study. Another strength of this study is the use of a ROC curve to find the ideal clinical cutoff to raise psychosocial concerns. We prioritized specificity over sensitivity to best reflect

the clinical purpose of the SIPAT, which is to identify the patients with the greatest psychosocial concern entering the transplant process in order to intervene early when possible.

We did not find a correlation between SIPAT score or nonadherence and morbidity, readmissions, or mortality, despite identifying a correlation between SIPAT score and ICU admission and duration. This may be caused by limited power, insufficient follow-up, or because the relationship found in other fields between nonadherence and mortality does not apply to this patient population. It also may be that a binary definition of nonadherence was insufficiently nuanced to fully assess the relationship between nonadherence and mortality, an issue we plan to address in our prospective follow-up study. ICU admission did not significantly correlate with mortality, suggesting that outstanding clinical care may mitigate the risks of patient nonadherence. Limitations of the study include its limited power to detect associations between the SIPAT ratings and mortality or readmissions or between the 6-month adherence rating and mortality, both likely a consequence of the low number of patients with cancer enrolled, the limited duration of follow-up, and confounding by intervention. Interventions may include individual psychotherapy, family therapy, psychiatric medication management, provision of instrumental supports, reminder calls, and engagement with other support systems. Intervention on risk factors may confound the relationship of risk factors to outcomes but is a clinical imperative, and it better represents a realistic clinical scenario in which these data may be applied. This confounding factor biases the current study—and all research in this area—toward retention of the null hypothesis. This bias in design renders all the more striking the positive finding in the present study of an association between pretransplant SIPAT psychosocial risk rating and adherence following SCT.

Additional limitations of our approach include retrospective design, binary adherence scoring, and imperfect blinding (raters did not know SIPAT scores but were clinically involved with the patients). We used a simple binary adherence model because we felt that attempting to complete retrospectively a count of events for every patient using a definition created after the fact would be unreliable; this is a limitation we plan to address in future work. As autologous recipients were only partially captured and not selected randomly, our study design does not provide a good estimate of incidence of nonadherence or of the normal range of SIPAT scores in this population. Autologous patients, although found in our study to have a comparable nonadherence prediction rate, are significantly different in medical acuity and should be considered separately from allogeneic recipients, and our prospective follow-up study will recruit for allogeneic recipients only. In addition, the lack of a validated adherence scoring system required that we create our own definition. In prospective future work, we intend to bring further meaning to our adherence definition and our ability to compare adherence with outcomes by counting events in each category, separating inpatient and outpatient adherence, comparing with self-reports, and analyzing for the relationship between number and type of nonadherence events and morbidity and mortality.

Finally, our psychosocial rating was completed at the first evaluation, although we recognize that relevant information often became apparent later. Patients may omit information they believe would make them a less attractive candidate for transplantation or avoid personal details until building trust with a clinician. The blanket denial of all concerns in the setting of life-threatening illness, however, may also indicate an inflexible primitive denial as a defense against fear of mortality. However, this limitation in data collection is consistent

Table 4
SIPAT Score and Nonadherence by Conditioning Regimen

Conditioning Regimen	Mean SIPAT Score	Nonadherence, n (%)
Autologous	13.2	5 (11.6)
Allogenic		
Myeloablative conditioning	9.5	6 (27.3)
Reduced-intensity conditioning	10.4	7 (35.0)

with real-world clinical application of our findings and would bias our study toward the null hypothesis.

We also note that there were differences between diagnosis groups with respect to SIPAT ratings and adherence rates. There are socioeconomic differences between diagnosis groups, particularly for the patients with sickle cell disease, that we were not able to account for in this analysis. There are also significant potential behavioral differences between patients with chronic and acute illnesses. In future prospective work, we hope to further investigate these factors.

In summary, in a sample of both autologous and allogeneic stem cell transplant recipients at a large urban hospital, psychosocial risk as quantified by the SIPAT strongly correlated with SCT patients' ability to adhere to the post-transplant regimen, suggesting that findings of this validated psychosocial rating instrument could contribute to medical risk stratification models. Oncologists estimating an individual patient's degree of total risk can take advantage of information about the patient's ability to adhere to a complex regimen and can potentially tailor a plan that incorporates this information. Further study with a larger sample and longer duration of follow-up is necessary to test whether the SIPAT predicts morbidity and mortality in SCT patients and to evaluate the effects of interventions to modify identified psychosocial risk on SCT outcomes (Table 4).

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