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Methodological Comments on “The Stanford Integrated Psychosocial Assessment for Transplantation: A Prospective Study of Medical and Psychosocial Outcomes”

Eyal Shemesh, M.D.

Associate Professor of Pediatrics and Psychiatry, Chief, Division of Behavioral and Developmental Health, The Department of Pediatrics and Kravis Children's Hospital, Icahn School of Medicine at Mount Sinai, New York, NY USA

The study by Maldonado et al. (1) purports to be a prospective evaluation of The Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT), which was developed to standardize the pre-transplant psychosocial evaluation. Transplanted organs are a scarce resource and efforts must be made to choose the recipients with the best chances of survival. Therefore, the systematic assessment of risk factors (biological, psychosocial, or others) prior to transplantation is clearly an important topic with substantial clinical and societal relevance (2). An effort to standardize such evaluations is laudable, but it is still not clear how to standardize and whether such standardization will in fact improve our ability to predict graft survival. In this context, the development of the SIPAT and the recently published manuscript (1) are a welcome addition to the literature. However, a few important methodological issues have not been addressed in the article:

1. The study is presented (in the title) as “prospective,” and the authors contend that the prospective design of their investigation is an important improvement over previous studies. However, the methods seem to have been retrospective. The baseline SIPAT evaluation was retrospectively culled from charts of patients who were evaluated well before data collection started; with regards to outcome measures, the authors write that “a... data collection team. *retrospectively* examined the patients’ charts.” This is best described as a retrospective cohort study. Related to this issue is that the study seems to have been registered on clinicaltrials.gov (NCT01633424). The information on this registration is not presented in the article. At clinicaltrials.gov, the study is (appropriately) described as “Observational Model: Cohort / Time Perspective: Retrospective,” which is in my view the accurate labeling of the design. In addition, the registration information does not define primary or secondary outcomes. This is not consistent with the authors’ assertion that there were in fact pre-defined primary and secondary outcomes. It is therefore not clear why the study published in this journal

Corresponding Author: Eyal Shemesh, M.D., Associate Professor of Pediatrics and Psychiatry, Chief, Division of Behavioral and Developmental Health, The Department of Pediatrics and Kravis Children's Hospital, Icahn School of Medicine at Mount Sinai, New York, NY USA, eyal.shemesh@mssm.edu.

was presented as a prospective study, and whether the primary and secondary endpoints were indeed defined prior to conducting the study.

2. The authors write that the SIPAT did not predict the primary outcomes. Given these circumstances, the null hypothesis cannot be rejected. Furthermore, the post-hoc assertion that the study was not powered to detect a difference in the primary outcome and therefore consideration of the secondary outcomes should substitute as support that the measure works is interesting. Was there a power analysis done before the study started? It would probably have been more accurate if the authors would have simply acknowledged that the primary outcomes were not achieved and therefore it cannot be concluded that the SIPAT predicts posttransplant outcomes. The fact that it was predictive of other outcomes, which were not a-priori defined as primary, suggests important avenues for future research, but does not establish validity since those outcomes were not a part of the primary hypothesis.
3. The authors state that the clinical use of SIPAT was “in transition” during the years that this study was conducted, which may have resulted in selection bias, such that only some patients, but not all, were evaluated with the tool. But this issue is not discussed. A CONSORT-type diagram would have been helpful to clarify the extent of such a potential bias.

Given these issues, it would appear that the correct interpretation is that this retrospective (not prospective as it is presented) cohort study found that the SIPAT tool is not predictive of poor transplant outcomes as pre-defined in the primary hypothesis (organ failure or death). This measure also did not predict posttransplant adherence, although the evaluation of adherence in this study, as the authors note, was not optimal. Future studies in other cohorts might attempt to look at other outcomes as suggested by information from the secondary outcome analyses, including organ rejection, rate of hospitalization, and infection episodes.

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