Reviewer's report

Title: Validity and Reliability of a Novel Immunosuppressive Adverse Effects Scoring System in Renal Transplant Recipients

Version: 1  Date: 25 December 2013

Reviewer: Heather Johnson

Reviewer's report:

MC -
Abstract - language regarding administration of AE tool seems paternalistic - administered - would change - sounds like a survey as opposed to "employed a standardized evaluation" or something like that.

Methods - the methods section is not easy to follow. It would be easier to follow if the authors first explained the development of the tool followed by the implementation of the tool/process.

Why was baseline established as pre-transplant as opposed to at enrollment? Was the assessment performed at a standard time? Was it administered only once or multiple visits after the enrollment period. This should be clear from the methods section. If administered more than once were AEs counted multiple times? i.e if GI sx persisted were they counted in each assessment.

If AEs could be attributed to multiple medications, was this captured? How was it handled clinically?

Why is there only a cumulative score for CNI AEs vs MPA AEs. Was this a decision a priori or after the data was assessed.

Explain the utilization of scales than contain different numbers of ratings - 0-2 vs. 0-4. Can these be compared and accumulated for purposes of analyses?

Was there a patient assessment of AEs. I would think that for really assessing the impact inparticular of aesthetic and gi effects on compliance a patient-centered evaluation of the impact that these adverse effects has would be important to include.

Why was alopecia not included in aesthetic adverse effect? Why was nausea not included in GI effects.

ME - Paragraph 1 - I would change the focus of the background and introduction to put adherence and its impact over the long term on allograft survival. I don't think the stats on the number of people with ESRD is really important for this problem. One might also include the importance of adherence on other disease outcomes which is where this report may extrapolate.

Then the logical segue is to tools to routinely assess adherence in the clinical setting. You might include the contrast of systematic routine for efficacy is an
important aspect of clinical practice

Results - would be clear that the Tac group was in fact a tac/myfortic group and CSA group was a CSA/MMF group when explaining AEs.

GH - did 76.7% of CSA pts experience GH or was it 76.7% of pts total who has GH were on CSA.

Discussion - I believe the inclusion of a systematic clinician assessment for AEs constitutes a major part of this report and that emphasis in your discussion should be given to the opportunity to identify AEs with systematic assessment. The question that remains is a) what was done when AEs were identified and does doing something improve adherence or graft outcome. These questions remain to be answered and addressed, if even hypothetically.

If you have the data about action following AE identification, that would be nice to see.

Discretionary revisions - I would be careful of the use of assessment and assessed. Theses words appear a lot in the abstract and manuscript and would try to find some alternatives to increase readability.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare I have no competing interests.