Author's response to reviews

Title: Early versus delayed initiation of antiretroviral therapy for Indian HIV-infected individuals with tuberculosis on antituberculosis treatment

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Author's response to reviews: see over
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Responses to the comments of the Editorial Board

Title: Early versus delayed initiation of antiretroviral therapy for Indian HIV-infected individuals with tuberculosis on antituberculosis treatment.

Date:

Authors: Sinha S, Shekhar R C, Singh G, Shah N, Ahmad H¹, Kumar N, Sharma S K, Samantaray J C¹, Ranjan S, Ekka M, Sreenivas V², Mitsuyasu R L ³

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We thank the Editorial Board for their comments. The required addition has been done in red colour in the revised manuscript.

Our responses are as follows:

**Comment 1:**

I think the authors need to add to their limitations sections. They need to discuss how differential drop-out between the two arms could have affected their results.

**Response:**

The break up for the participants lost to follow up is provided on page 10 of the revised manuscript. Four patients from the early ART arm were transferred out to other ART centers due
to spatial relocation, and another three decided not to continue the treatment. Telephonic contact could be made with all of them and it is known that they were alive at the end of 12 months after their ART was started. However, five patients were untraceable (four in early ART arm and one in delayed ART arm). They were showing good clinical improvement with rising CD4 cell count, falling viral load titer and no new complications, when they were lost to follow up. Though it is unlikely that these five might have died within next few months, we agree that it is possible. It was seen during the analysis that the consideration of the worst outcome for these patients did not alter the overall results of the study significantly.

The required addition has been done in the limitation section of the revised manuscript on page 16.

Comment 2:

I also would like them to address whether there were statistically significantly more EPTB with dissemination in the Early treatment group and how this might have affected their results.

Response:

This is an important point and we thank the editorial board for bringing it up. Even though the early ART group has apparently higher number of cases of EPTB with dissemination, no statistically significant difference was found between the two arms of the study with respect to any type of TB individually, or overall. The required addition has been done in the revised manuscript on page 11.

Response to reviewers comments (Dr N. Patel):
Comment:

The manuscript has been overall greatly improved and the authors have well addressed the reviewer's comments. One small part that is unclear is that the authors say that there is a 2% power to detect a difference between the groups in the Discussion. This statement is unclear. The authors should state that given a baseline rate of X% mortality, there was an 80% power to detect a difference of Y% mortality between early and delayed ART groups. This would make the statement much clearer.

Response: This is an important point and we thank to the reviewer for raising this point. In this study given a baseline rate of 10% mortality, there was an 80% power to detect a difference of 18% mortality between early and delayed ART groups. The required addition has been done in the revised manuscript on page 16.

Thanking you.

Sincerely,

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