Author's response to reviews

Title: Comparison of Drug-Eluting Balloon first and then bare metal stent with drug-eluting stent for treatment of de novo lesions (DEB first): A randomized controlled single center clinical trial

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Dear Dr. Stefan James and Editor-in-Chief

RE: Revision of the manuscript
Manuscript ID: 1768278613755606
Title: “Comparison of Drug-Eluting Balloon first and then bare metal stent with drug-eluting stent for treatment of de novo lesions (DEB first): A randomized controlled single center clinical trial”

Dear Dr. Stefan James and Editor-in-Chief

We appreciate the thoughtful and careful comments of reviewers. Constructive points that reviewers pointed out, were well taken by all the authors. My colleagues and I have tried to address all of the points that the reviewers have raised. The section below provides a point-by-point response to the issues raised by the reviewers. Each comment is excerpted and addressed in detail with reference made to the locations of any changes in the manuscript. The revised parts in the new manuscript have been underlined and colored for the
convenience of the editors and reviewers.

We hope that the revised manuscript better meets the standards of the journal.

Best regards,

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Reviewer

[Comment #1]
- “I don't understand the reason for designing a non-inferiority trial rather than superiority. It would not be unethical to provide stronger evidence.”

Response:
Thank you for this valuable comment.
In advance, we are sorry for that we didn’t thoroughly explain the reasons why the non-inferiority design was used in our study.

In treatment of de novo lesion in patients with native coronary artery, drug eluting stent (DES) has been used as the standard treatment. Since the drug eluting balloon (DEB) showed the efficacy in treatment of in-stent restenosis and small vessel coronary artery disease, PEPCAD III trial was to assess the efficacy of DEB in combination with premounted bare metal stent (BMS) for the treatment of de novo lesion. On above study, however BMS premounted on DEB was inferior to DES showing higher in-stent late loss.

Although our DEB first strategy (DEB followed by BMS) is different to that of PEPCAD III trial, there are no data for the efficacy of DEB with BMS on treatment of de novo lesion in patients with native coronary artery. Therefore, we thought that it would be proper to assess whether DEB first strategy are as effective as a DES by using the non-inferiority design.

We definitely agree with you that non-inferior trial have a number of inherent weaknesses that superiority trials do not. However our study may give more clear information for use of DEB with BMS on treatment of de novo lesion in patients with native coronary artery.

We have precisely described above changes in the manuscript (Sample size calculation part). We deeply thank you for this constructive comment.

[Comment #2]
- “The sample size section I get the impression that there are three treatment arms. This needs to be re written”

Response: We thank you for this very important comment. Some sentences in sample size calculation part may give you confuse. We deleted the sentence that
might give the impression that there are three treatment arms and addressed the changes in the revised manuscripts.