Author's response to reviews

Title: A randomized comparative study of patients undergoing myocardial revascularization with or without cardiopulmonary bypass surgery: The MASS III Trial

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Author's response to reviews: see over
To reviewer

I am really grateful for your carefully analyses of the manuscript. The criticisms are entirely appropriate and I believe that these have improved the manuscript. Specific responses and stated in this letter and changes to the text of the manuscript are outlined in colors.

Question 1 - (study and test the hypothesis)

You are right. The sample size does not considered the crossing – over because there were a few episodes of electric or homodynamic instability requiring change of procedures. Our results with 308 patients found only 03 patients that needed crossing-over to on-pump strategy. Even thus I will considerer your suggestions and added a phrase in method section. (In red).

In fact. The primary composite endpoint was the incidence of cardiovascular mortality, cerebrovascular accident, nonfatal myocardial infarction, and refractory angina requiring revascularization. The primary end point will be stressed in method section. (In red)

You are right again. The MASS III trial provided external blinded committee. So, all nonfatal clinical events, including MI, Stroke, refractory angina requiring revascularization, will undergo central adjudication by an independent clinical events committee (CEC). The role of CEC will be to insure that all primary endpoint are adjudicated uniformly. This information will introduce in methods section. (In red).

Question 2 – (sufficient details)

I am sorry for this terrible error. The correct phrase is five years of follow-up. I will introduce in red, the corrected sentence. The primary endpoint should be a composite of cardiovascular mortality, cerebrovascular accident, nonfatal myocardial infarction, and refractory angina requiring revascularization across 5 years of follow-up.

Question 3 – (Interim analyses)

Thank you for this observation. The MASS III trial has a Data and safety Monitoring Board. So I will introduce (in red) this matter in method section. A cardiopulmonary surgeon, a cardiologist and a neurologist formed the clinical event committee and confirm and classify the major adverse cardiac and cerebrovascular events (MACCE), blinded to the treatment. To verify whether important differences in the incidence of MACCE exist between the treatment groups, the Data Monitoring Committee performed an interim analysis after the first patients 100 had entered each arm of study. The three members of this committee are experienced in patient-oriented research, are independent of the study, and may also offer unsolicited recommendations.

Question 4 – (acceptable writing)

Thank you again for this observation. I agree with your suggestions.

The abstract and objectives was re writing. (In red)

Once again thank you very much for your assistance.