Author's response to reviews

Title: Comparison of 1-year therapeutic effect of ranibizumab and bevacizumab for myopic choroidal neovascularization: A retrospective, multicenter, comparative, non-randomized, interventional study

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Author's response to reviews: see over
Dear, Alice Murray

Thank you for your consideration of our manuscript entitled “Comparison of 1-year therapeutic effect of ranibizumab and bevacizumab for myopic choroidal neovascularization: A retrospective, multicenter, comparative, non-randomized, interventional study” under peer review, which first had been submitted on 31, August, 2013. There were a few questions raised by the editor by the name of Erica Cruz, before the manuscript was proceeded into the state of peer review. We would like to answer for the questions (the numbered paragraphs below) point by point.

(1) Requesting trial registration where clinical trials are described (Asking authors for TRN): We notice that you are reporting a clinical trial but have not cited a trial registration number. This must be obtained before we can begin peer review of your manuscript. BioMed Central has always supported initiatives to improve the performance and reporting of clinical trials, part of which includes prospective registering and numbering of trials. BioMed Central requests a trial registration number for manuscripts reporting work that falls within the International Committee of Medical Journal Editors (ICMJE) definition of a clinical trial: any research study that prospectively assigns human subjects to one or more health related interventions to evaluate the effects on health outcomes. We would like you to confirm that your clinical trial is in a publicly accessible registry before we begin peer review. The trial registration number should be included as the last line of the abstract of the manuscript.

We are sorry that there are some misunderstandings for our manuscript. This study was designed by a retrospective study, not a prospective study. We designed the study and started the collection of data in 2010 for the patients diagnosed with myopic CNV from 2007 to 2009. Informed consent was obtained from the patients after the designed study was approved by the institutional review boards, not at the period when the patients had been first treated with anti-VEGF agent. Nevertheless, the study has a characteristic of prospective study in some aspects. There was some consensus among three hospitals that patients diagnosed with
myopic CNV had better be treated with 1+prn protocol (All the ophthalmologists from three hospitals are from one university, Seoul National University). That’s why this study has characteristics of prospective study.

(2) We also require clarification on the nature of your data collection. You state that informed consent was taken from the patients and that the pros and cons of the two treatments were explained to the patients beforehand. You also state that the patients were followed at 4-week intervals from the first injection, suggesting that this was NOT a retrospective study.

a. How you assigned patients to the different treatment conditions.

Which anti-VEGF was used to treat myopic CNV was decided by the patient, not by the ophthalmologist. We just provided the sufficient information associated with Lucentis and Avastin, especially in terms of the effectiveness and safety of the drugs. We changed the manuscript to emphasize it like below.

“After explaining the patients the pros and cons of two anti-VEGF agents sufficiently, one anti-VEGF agent between bevacizumab (Avastin; Genetech, San Francisco, California, USA) and ranibizumab (Lucentis; Genentech, San Francisco, California, USA) was selected by the patients.”

b. what the patients were consenting to.

The patients consented that they would be involved in the retrospective study, not the prospective study. We thought that informed consent was also needed in the retrospective study, although there was not any harm for the patients involved in the study. Furthermore, the documented consent is always needed in Korea to proceed the study irrespective of the prospective or retrospective study these days.

As I already declared in the first cover letter, this manuscript has not been published or presented elsewhere in part or in entirety, and is not under consideration by another journal. All study participants provided informed consent, and the study design was approved by the appropriate ethics review boards. All the authors have approved the manuscript and agree with submission to your esteemed journal. There are no conflicts of interest to declare.
With best regards,

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