Author’s response to reviews


Authors:
Tingting Jiang (ting5680@126.com)
Junxiang Gu (eent_gu@126.com)
Peijun Zhang (eent_zhang@126.com)
Wenwen Chen (eent_chen@126.com)
Qing Chang (eent_chang@126.com)

Version: 2 Date: 23 Nov 2019

Author’s response to reviews:

Dear Editor:

We have enclosed a copy of our revised manuscript, titled "The effect of adjunctive intravitreal conbercept at the end of diabetic vitrectomy for the prevention of post-vitrectomy hemorrhage in patients with severe proliferative diabetic retinopathy: a prospective, randomized pilot study". We would like to thank the reviewers and the editor for their important and instructive comments. The manuscript has undergone a revision accordingly and the point-by-point response are listed on the following pages.

Thank you very much for your careful considerations. We sincerely hope that our efforts have resulted in a better presented manuscript that could be acceptable for publication in BMC Ophthalmology.

Sincerely,

Qing Chang, MD, Ph.D.
Point-by-point response to Referee(s)' Comments to Author:

Reviewer reports:

David Steel, MD (Reviewer 1): Thank you - the authors have made a comprehensive reply - but they omitted to include:

1) Rationale for sample size for this pilot- why 30 patients ?

Response: Thank you for raising this question. The purpose of this study was to investigate the effect of intravitreal conbercept injections on the incidence of postoperative vitreous hemorrhage in eyes undergoing surgery for severe proliferative diabetic retinopathy. In this study, the inclusion criteria were very strict, and patients were excluded if there was a previous history of vitreoretinal surgery, intravitreal injection of long-acting gas or silicone oil at the end of surgery, a history of ocular diseases other than diabetic VH, a history of intravitreal anti-VEGF within the 3 previous months, ocular surgery within the previous 6 months, uncontrolled hypertension, a history of coagulopathy, and a follow-up period less than 12 months. However, proliferative diabetic retinopathy of the patients in our study were very severe. In addition to vitreous hemorrhage, most of the patients in our study had severe fibrovascular proliferation and many had firm adhesions between the vitreous and retina. Therefore, many patients could not meet the inclusion standard mentioned above (especially no intravitreal injection of long-acting gas or silicone oil at the end of surgery) and were excluded. After one year of follow-up, although the sample size is small (only 30 patients were included), we think the obtained data could provide a preliminary result in this pilot study. At present, this randomized and prospective study is still going on, and a more powered conclusion with large sample sizes, will be shared with you in the future.
2) Details of masking - both assessments and also for the randomisation table - eg did the surgeons know what the next randomisation was going to be prior to surgery? - this could have introduced significance bias in terms of recruitment eg based on diseases activity rather than extent of NVs. Were the assessors masked to group?

Response: Thank you for raising this question. When there was a patient with proliferative diabetic retinopathy who met the inclusion criteria, a doctor in our group determined whether the patient should be assigned to the injection group or the control group according to randomized table. The surgeon then performed the operation based on the randomized results. However, if there is long-acting gas or silicone oil filling in the eye at the end of surgery, this patient was excluded. Assessors were masked to group.

3) When was randomisation done? - presumably at the completion of surgery just before injection (if in intervention group)? as patients requiring oil and long acting gas were excluded

Response: Thank you for raising this question. The randomisation was done before the surgery. When there was a patient with proliferative diabetic retinopathy who met the inclusion criteria, a doctor in our group determined whether the patient should be assigned to the injection group or the control group according to randomized table. The surgeon then performed the operation based on the randomized results. However, if there is long-acting gas or silicone oil filling in the eye at the end of surgery, this patient was excluded.

the authors should also describe the study as a pilot RCT in the abstract ie 'This was a pilot randomized study'. The words prospective and comparative, are superfluous as all RCts are prospective and comparative, and a pilot RCT carries different significance to a fully powered RCT.

Response: Thank you for raising this question. We have revised the paper accordingly.

Kyung Seek Choi, M.D., Ph.D. (Reviewer 2): Please include all comments for the authors in this box rather than uploading your report as an attachment. Please only upload as attachments annotated versions of manuscripts, graphs, supporting materials or other aspects of your report which cannot be included in a text format.

Please overwrite this text when adding your comments to the authors.

Response: Thank you for raising this question. We have revised it accordingly.