Author’s response to reviews

Title: Effectiveness and safety of exenatide in Korean patients with type 2 diabetes inadequately controlled with oral hypoglycemic agents: an observational study in a real clinical practice

Authors:

You-Cheol Hwang (khmcilyong@naver.com)
Ari Kim (ari.kim@astrazeneca.com)
Euna Jo (euna.jo@astrazeneca.com)
Yeoree Yang (lambten@gmail.com)
Jae-Hyoung Cho (drhopper@ikoob.com)
Byung-Wan Lee (bwanlee@yuhs.ac)

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Author’s response to reviews:

Dear Alexander Kokkinos,

Editor of BMC Endocrine Disorders

Thank you for forwarding reviewers’ comments to our manuscript (BEND-D-17-00061) entitled “Effectiveness and safety of exenatide in Korean patients with type 2 diabetes inadequately controlled with oral hypoglycemic agents: an observational study in a real clinical practice”, on behalf of all authors. We really appreciate reviewers’ careful and keen comments to improve the quality of our manuscript. We hope that the revised version of manuscript could meet the priority required for publication.

After getting decision letter from BMC endocrine disorders, all of authors had a meeting to achieve consensus for the comments, and there is no conflict. There would be no further change of the member of authors or order of authors. We are following ICMJE authorship guideline.

In terms of English correction, the manuscript was reviewed and revised word-by-word by AstraZeneca Global Byetta publication leader, MaryBeth DeYoung (email: MaryBeth.DeYoung@astrazeneca.com), then approved by her and her team.
The followings are point-by-point answers to reviewer’s specific questions, and the modification of the manuscript is written with clean letters.

We hope you find the revised manuscript suitable for BMC Endocrine Disorder. We appreciate all of the work from BMC Endocrine Disorders, again.

With best regards,

Byung-Wan Lee, M.D., Ph.D.

Response to reviewers

Petros Thomakos (Reviewer 1): Comments:

1) In the methods section please elucidate why the second stratum used target HbA1c level of 7.5%

Corrections and Comments: As known in various randomized controlled trials, mean HbA1c at the end of treatment, the primary endpoint in the majority of studies, was decreased by 0.79 to 1.75% (the median value across these large studies was 1.11%).(Guo 2016) The baseline HbA1c of our study was 8.4% and we assumed responder as patients who would reach HbA1c level at 7.5% after 20 weeks of exenatide treatment. In the method, this explanation is inserted (line 12-16, page 6).

2) In Figure 1, please make clear how 955 out of 722 patients, were reviewed for BMI.

Corrections and Comments: Thank you for finding out small but important typo in the figure. We’ve reviewed the data and chronological analysis sequence, then finally recognized the number for BMI analysis was 655, not 955. In the figure files, you may find the corrected number.

3) In the discussion section it may be helpful to give an explanation why BMI did not affect glucose-lowering effectiveness of exenatide treatment.

Corrections and Comments: In one study which was aiming to investigate metabolic outcomes in patients with type 2 diabetes treated with exenatide, the response in HbA1c reduction was
independent of baseline weight, and BMI. (Buysschaert, Preumont et al. 2010) Also, most subjects enrolled in this PMS study showed high BMI due to Korean insurance policy during the study period. This may have influenced the outcome of the study. In the Discussion section, these are described for supporting our results (line 27, page 11 - line 3, page 12).

John Doupis, M.D. (Reviewer 2): Comments

The authors of this manuscript investigated the effectiveness and safety of exenatide in Korean patients with type 2 diabetes inadequately controlled with oral hypoglycemic agents. The manuscript is nicely written and the results are valid and in accordance with the so far available literature. Although the topic and the results are not novel, real world data are always useful. It would be nice if the authors included the information about the sample size and details in the methods section of the manuscript. Additionally, it would be interesting if authors included data about waist circumference to possibly detect exenatide effect on visceral obesity.

Corrections and Comments: Thank you for your kind advice. As you mentioned, we added the sample size details in Methods section (line 2-8, page 6). But, unfortunately, parameters for visceral obesity such as simple and non-invasive waist circumference could not detected in the study, because they were not mandatory at that time. All of authors feel sad for that.

References
