

Format for ANSWERING REVIEWERS



August 12, 2013

Dear Editor,

Please find enclosed the edited manuscript in Word format (file name: 3992.doc).

Title: Vildagliptin Versus Sulfonylurea in Indian Muslim Diabetes Patients Fasting During Ramadan

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Name of Journal: *World Journal of Diabetes*

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1 The manuscript has been improved according to the suggestions of reviewers:

2 Revision has been made according to the suggestions of the reviewer

- (1) **Comment from Reviewer:** Some data about study completion rate should be included
Response: In results section under Study patients (page 9 line 2) data on study completion rate is included as suggested by reviewer.
- (2) **Comment from Reviewer:** Although such a study is relevant to the Indian Muslim population, there are a few issues to address including those related to potential conflicts of interest in the Discussion section.
Response: The discussion section is modified as suggested.
 - a. **Comment from Reviewer:** The use of HbA_{1c} levels as a means to assess glycemic control is likely to misestimate the true lowering of average blood glucose levels during Ramadan given that Ramadan lasted only a month and that the blood used for HbA_{1c} assays was not sampled immediately before and after Ramadan. Also, even if blood sampling had occurred close to Ramadan time, changes in HbA_{1c} levels would have led to an underestimation of average changes in blood glucose levels since more than four weeks are required for a given change in blood glucose levels to translate in a stable and maximal change in HbA_{1c} level.
Response: The limitation of the HbA_{1c} measurement in the Ramadan setting is included in the discussion section of the manuscript (page 12, last paragraph).
 - b. **Comment from Reviewer:** The last four lines of the concluding paragraph should be removed and placed in a stand-alone paragraph discussing the low HE risk associated with sulfonylurea.
Response: The last four lines of the concluding paragraph in the earlier version has been shifted to page 13, second paragraph 3-6 lines in the current version for the sake of flow.
 - c. **Comment from Reviewer:** The authors should explain why only this study showed that it is possible for individuals treated with sulfonylurea to go through Ramadan with a

marginal risk of HE. What is the difference between this and the previous studies that have examined the effect of sulfonylurea administration on HE during Ramadan?

Response: The possible reasons for the difference between this study and the previous studies for the incidence of HEs in the sulfonylurea group are included as suggested (page 13, paragraph 2).

- d. **Comment from Reviewer:** Given the prospective nature of this study, the authors should attempt to explain how glycaemic control improved during Ramadan. Although not investigated in this study, a lesser food or CHO intake in the vildagliptin group or an increase in physical activity level might explain this small fall in HbA_{1c} levels. That this is likely to be the case here is suggested by the decrease in body mass in the vildagliptin group and by the evidence from the literature that vildagliptin and sulfonylureas have different effect on body mass.

Response: Possibility of less carbohydrate intake and increase in physical activity is included in the discussion to explain the differential effect of drugs on weight (page 14, last paragraph, and last 5 lines). However this possibility is not included to explain the HbA_{1c} drop. If this is the reason, there should be a similar reduction in HbA_{1c} with sulfonylurea as well. Conversely, there was a significant between-treatment difference in HbA_{1c} reduction; however, the limitation of HbA_{1c} measurement during the Ramadan setting is discussed.

- e. **Comment from Reviewer:** Since the difference in the proportion of patients who experienced at least one episode of hypoglycemia did not differ between treatment groups, the discussion should clearly reflect this finding. Unfortunately, the way this information is described in the Discussion is misleading and conveys the impression that better HE results were achieved with vildagliptin. On page 10, paragraph 1, lines 4-5, it is misleading to only state with respect to HE that “..this...study...reported no HEs in the vildagliptin group, whereas 2 HEs were reported in the sulfonylurea group” since these differences were not statistically significant. This statement should be replaced by a more impartial/objective statement like “..this..study...reported no significant differences in HE between vildagliptin and sulfonylurea groups, with only 0 and 2 HE in those two groups, respectively”.

Response: Replaced as suggested in page 12, paragraph 1, and line 4-6 of the current version.

- f. **Comment from Reviewer:** On page 11, second paragraph, lines 6-8, the statement “the results of present study are in line with the results of VECTOR where no HEs were reported from the vildagliptin group” should also be amended as this study also differs from VECTOR in that no differences in HE were observed between the vildagliptin and sulfonylurea groups.

Response: Sentence was amended in page 14, paragraph 2 and lines 6-9 of the current version.

- g. **Comment from Reviewer:** The authors should explain in more details how the participants were treated with sulfonylureas as in their hands the associated risk of hypoglycaemia was minimal.

Response: Possible reasons for low incidence of hypoglycemia with sulfonylurea are included (page 13, paragraphs 2).

- (3) Corresponding changes are made in the abstract as well. In addition few changes including removal of figure 1 were made as this may misrepresent the greater between-treatment difference for HEs.

3 References and typesetting were corrected

Thank you again for publishing our manuscript in the *World Journal of Diabetes*.

Sincerely yours,



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