Author’s response to reviews

Title: Effects of Ramadan fasting on cardiovascular risk factors: a prospective observational study

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Version: 2 Date: 16 June 2012

Author’s response to reviews: see over
Dear Dr Nehme Gabriel

Editor-in-Chief, Nutrition Journal

Re: Paper No. 7921226636068740: “Effects of Ramadan fasting on cardiovascular risk factors”.

Mohsen Moohebati. Abdolreza Norouzy.

Many thanks for your email dated 4th of June 2012 regarding above manuscripts. I have amended our manuscripts to address the reviewers concerns. You can find my answers/amends for each of reviewers’ comments as below. I have also changed the manuscripts texts accordingly which is visible by red colour.
If you need any further information, please don’t hesitate to contact me.
I am looking forward to hearing from you.

Yours sincerely,

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Reviewer's report

Title: Effects of Ramadan fasting on cardiovascular risk factors: a prospective observational study

Version: 1 Date: 28 December 2011

Reviewer: Franco Arturi

Reviewer's report:

Thank you very much for giving me the chance to review the paper entitled “Effects of Ramadan fasting on cardiovascular risk factors: a prospective observational study” by Mohsen Nematy et al. The aim of this study was to investigate the effect of Ramadan fasting on cardiovascular risk factors. The authors conclude that the Ramadan fasting induce a significant improvement in cardiovascular risk.

Major Compulsory Revisions

1. Abstract:

Editor: The Abstract should be revised. In the section “Methods”, the authors report that the “study was carried out in a group of individuals with at least one cardiovascular risk factor”. However, it is not indicate as risk factors were considered. The same limitation is present in the section “Subjects and Methods” (page 5, line 20).

Authors: Thank you for pointing this out. The following paragraph is added into the text to clarify this.

This is a prospective observational study that was carried out in a group of patients with at least one cardiovascular risk factor (including history of documented previous history of either coronary artery disease (CAD), metabolic syndrome or cerebro-vascular disease in past 10 y).
**Editor:** Also, the authors report that “individuals with a previous history of either coronary artery disease, metabolic syndrome or cerebrovascular disease were recruited”. However, it is not report if these patients (and not individuals) used drugs (i.e. statins, metformin, antihypertensive and/or antiplatelet drugs). The same limitation is present in the section “Subjects and Methods” (page 6, line 3 and following).

**Authors:** We incorporated the following paragraph in the text (method section) to clarify it.

76 patients were taking medications including 52 patients on antihypertensive agents, 47 patients on statins 26 patients on oral antidiabetic medications including metformin and sulphonyle ureas and 46 patients on antiplatelet aggregation agents. Six patients did not take any medications.

**Editor:** In the Conclusion has been reported that this study shows a significant improvement in cardiovascular risk. This affirmation is not correct. Indeed, in the paper the authors do not calculate the cardiovascular risk (i.e. they no used the Framingham risk score that is considered a useful tool for quantitative assessment of the risk for CVD) but evaluated only the effect of Ramadan fasting on cardiovascular risk factors.

**Authors:** many thanks for your suggestion. Cardiovascular risk was calculated, based on Framingham risk score and these following paragraphs are added into the text.

(ABSTRACT)

**Results:** a significant improvement in 10 years coronary heart disease risk (based on Framingham risk score) was found (13.0±8 before Ramadan and 10.8 ±7 after Ramadan, P<0.001, t test).

**Conclusions:** This study shows a significant improvement in 10 years coronary heart disease risk score and other cardiovascular risk factors
RESULT

10 years coronary heart disease risk

This study shows a significant improvement in 10 years coronary heart disease risk, based on Framingham risk score (13.0±8 before Ramadan and 10.8 ±7 after Ramadan, P<0.001, t test).

CONCLUSION

This study shows a significant improvement in 10 years coronary heart disease risk score and other cardiovascular risk factors such as weight, BMI and waist circumference in subjects with a previous history of cardiovascular disease after an average of 26 d fasting during month of Ramadan.

2. Introduction:

Editor: The Introduction should be revised. The aim of the study was to elucidate the possible role of Ramadan fasting on several cardiovascular risk factors. However, the role of main cardiovascular risk factors as type 2 diabetes, obesity and/or insulin-resistance is not mentioned although in the paper the authors assessed body weight, BMI, fasting glucose, fasting insulin and HOMA-IR.

Authors: many thanks for your comment. The following paragraph is added into the text. Many studies reported a significant reduction in type 2 diabetic patients' weight during Ramadan(8;9), some other reported a non-significant reduction in weight of these patients (10). Bouguerra et al showed Ramadan fasting has a moderate effect on glycaemia and lipoprotein levels in type 2 diabetic patients when previous metabolic control was quite good; but fasting induced more deterioration when previous control was poor (9). Although, another study in Iran showed a deterioration of glycaemic control after Ramadan fasting in
Type 2 diabetic patients that was more evident in patients using oral hypoglycaemic medication than diet-controlled patients(11). Shariatpanahi et al showed that the combined change in the number and timing of meals and portioning of the entire intake into only two meals per day may increase insulin sensitivity in Ramadan(8).

3. Results:

**Editor:** In my opinion, the data should be expressed as mean + standard deviation.

**Authors:** We were also advised by statistician to use SD. Data are now changed as suggested in the text and tables.

**Editor:** Paragraph “Lipids profile”: It is reported that the value of LDL-Cholesterol was significantly decreased after Ramadan fasting. On the contrary, in the table 1 it is showed that the value of LDL-Cholesterol was increased after Ramadan fasting (98.0 vs 99.0 mg/dl, before and after Ramadan fasting respectively). This data is unclear and the authors should clarify this point.

**Authors:** The statistics were re-run and it was clarified that these data are correct. The important thing is that, as data were not normally distributed median and interquartiles were presented in the table. Quantitative data were expressed as the mean ± SEM (SD) for normally distributed parameters and median with 25th and 75th percentiles for not normally distributed parameters. Data are now changed as suggested (mean ± SD).

**LDL before Ramadan:** 109.96 ± 46 mg/dL and **after Ramadan:** 96.83 ±35 mg/dL (mean±SD)

**Editor:** In the Paragraph “FBS, insulin, HOMA-IR, homocysteine, hs-CRP” the authors reported that FBS, insulin, and HOMA-IR showed no significant difference after Ramadan
fasting. These data were associated with a significantly reduction of the body weight, BMI and waist circumference (paragraph Anthropometric parameters, page 9, line 25 and following). The authors should give (in the Discussion) an explanation for these data. Indeed, it is well known that a reduction in body weight and/or in waist circumference is associated with a reduction of both plasma insulin and insulin-resistance.

Authors: thank you for your attention. The following paragraph is added into the text to clarify this.

The lack of improvement in HOMA-IR or FBS despite reduction in body weight may be due to decrease in total body water content instead of body fat content after Ramadan fasting.

4. Discussion:

Editor: This manuscript section should be rewritten. Generally, in the Discussion the results are not reported but only discussed and explained.

Authors: We agree and have modified this section.

Editor: Minor Compulsory Revisions:

5. Abstract, page 3, line 6 and through the entire manuscript: “individuals” should be "patients".

Authors: We agree and have modified the text accordingly.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a
statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests'

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**Reviewer’s report**

**Title:** Effects of Ramadan fasting on cardiovascular risk factors: a prospective observational study

**Version:** 1  **Date:** 22 November 2011

**Reviewer:** mahmoud ibrahim

**Reviewer's report:**

* revise the phrasing
* improve the tables
* using charts

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests
Some points to mention:

Due to personal reasons one of the authors has changed his family name from Shakhskalaee to Mahdavi Rashed, and as it is expected his family name should also changed in the main article.

Also, Mrs Sabery’s organization has changed recently. Her new affiliation is “Iranian Applied Research Center for Health and Sustainable Development (IRCPHD), North Khorasan University of Medical Sciences, Iran”

These changes were modified in this new version of the article.