Author’s response to reviews

Title: Community based study to assess the prevalence of diabetic foot syndrome and associated risk factors among people with diabetes mellitus.

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Author’s response to reviews:

Dear Editor-in-chief and Reviewers

We thank the editor-in-chief and reviewers for the valuable and constructive comments to which we have responded point-by-point below addressing each of the reviewers' suggestions, and highlighted these in the text (manuscript) and gave page and line numbering of the revisions.

Technical Comments:

1. Please change the heading 'Objectives' to "Background" in the Abstract section.

2. Please change the heading 'Materials and Methods' to "Methods".

Response: We have done the above said changes in the manuscript.
REVIEWER COMMENTS

Reviewer reports:

Pavlina Andreeva-Gateva (Reviewer 1) : The aim of the presented paper was to assess the prevalence of diabetic foot syndrome (DFS) and the associated risk factors among people with diabetes mellitus. Authors evaluated 620 people from Udupi district in India and 51.8% of them were found to be with DFS. Multivariate logistical regression was used and factors as age, socio-economic state, sedentary activity and duration of the diabetes were found to be statistically significant.

The following information has to be completed:

1. What is the health care system in this region of the world and how easy is for patients to enter in the health care system?

Response: We thank the reviewer for this feedback and have made relevant changes in the manuscript.

The study site situated along the coastal belt of Udupi District of Karnataka state, India covering a population of 45,246 spread out over 13 villages. The healthcare services are provided by both public and private sectors. The area has good collaboration between two sectors with primary, secondary and tertiary care facilities in the vicinity.

This we included in methods section (Page 2, Lines 40 -44).

2. Additional values to report for the multivariate logistic regression analysis: intercept, β coefficients, SE, Wald χ².

Response: The additional values to report for the multivariate logistic regression analysis: intercept, β coefficients, SE, Wald χ² are mentioned in Table 5.
3. About MNSI - did the physical examination was performed or only the questionnaire was applied? If yes, please describe the physical examination of the neuropathy.

Response: Yes. Physical examination was performed. The questionnaire was followed by a brief clinical examination involving

1) Foot inspection for deformities, dry skin, callus, infection, or ulceration,

2) Semi quantitative assessment of vibration sensation at the dorsum of the great toe (normal, reduced, or absent)

3) Grading of ankle reflexes as normal, reduced, or absent.

4) Monofilament Testing applied to 10 points in the foot and responses were graded as normal, reduced, or absent depending on the number of correct responses.

Foot deformities included hammer toes, overlapping toes, halux valgus, joint subluxation, prominent metatarsal heads, and medial convexity (Charcot foot). Abnormality was determined by the number of positive responses or abnormal clinical findings.

Patients screening positive on the clinical portion of the MNSI (greater than 2.5 points on a 10 point scale) was considered neuropathic.

This detailed description has been added to methods section. (Page 3 and 4, Lines 64-72)

4. Table 2- how does the physical activity was assessed as "light" or "moderate"?

Response: Physical activity was assessed according to a survey questionnaire used by Ramachandran et al. (Please refer to reference no 10)

This tool is validated for Indian settings and used a scoring system to grade the physical activity. Four categories of occupation are considered. (i) Manual labourers (including masons, carpenters and those who carry loads, and agricultural work, e.g. ploughing and tilling); (ii) Office jobs or desk work; (iii) Housewives and retired persons; (iv) Persons unable to work.
Duration of activities for each day and number of working days were considered to calculate the score. Minimum score is 1 and maximum score is 70.

Based on the scores physical activity graded as Sedentary (Score: 1–17); Light (Score: 18–34); Moderate (Score: 35–51); Strenuous (Score: >51).

5. Table 3 - the same question for BMI, waist circumference, blood pressure - "normal", "high"etc. Cut-offs?

Response:

Body Mass Index (BMI): It was calculated using the formula

\[
\text{BMI} = \frac{\text{Weight in kilograms}}{\text{Height}^2 \text{ in metres}}
\]

The subjects were classified as Underweight (< 18.5), Normal (18.5 – 24.9), Overweight (25 – 29.9) and Obese (≥ 30).

Waist circumference: Cut off points can be 90 cm for males and 80 cm for females, above which subjects was considered as high risk category.

Blood pressure: The person was considered have high BP if current systolic blood pressure was ≥140 mm Hg and/or diastolic blood pressure was ≥90 mmHg.

These cut-off values are mentioned in Table 3.

6. Table 4. - The same question for the "adherence to medication" and "frequency of the consultation". How it was assessed?

Response:

Adherence to medication: Subject was considered adherence to medication, if he/she taking prescribed medicines for 6 days or more in a week.

Physician consultation details were asked and were considered regular if they are visiting once in 3 months or less.
Valerie L Marmolejo (Reviewer 2): Overall, the information provided in the manuscript is good to add to the literature. The following recommendations are made to strengthen the manuscript:

1. Line 12 and 166 - stating tissue breakdown and then "resulting in ulceration" is redundant.
   Response: We thank the reviewer for this feedback and have made relevant changes in the manuscript.
   The word "resulting in ulceration" has been removed from Line 12 and 174.

2. The paragraph in Lines 18 - 22 doesn't contribute to the "Background" section.
   Response: The paragraph has been removed.

3. I would reorganize/rewrite the "Materials and Methods" section. The first two sentences of the second paragraph (Lines 42 - 45) should be at the beginning of the first paragraph.
   Response: We reframed methods section (Page 2, lines 34 – 37)

4. Line 53 should be at the beginning of the "Materials and Methods" section.
   Response: We reframed methods section (Page 2, line - 33)

5. Line 60 - 61. The instrument used to obtain blood pressure does not need to be stated. Where any other vital signs recorded? Why or why not? Why just blood pressure?
   Response: Only blood pressure was measured as high blood pressure considered being a risk factor for diabetic foot syndrome.
6. Lines 69 - 70, delete "2015" as one would hope the most recent version of the classification system was used. Also, delete "based on comprehensive foot examination". This must be done in order to utilize the classification system so it’s redundant.

Response: The above said corrections were made in manuscript. (Method section, Page 4, Lines 78-79)

7. Line 72 - "Health Education" needs to be defined. The importance of health education is stated in the abstract and conclusion yet it is never expanded upon throughout the paper. Delete this aspect or expand upon it.

Response: Health education regarding foot care practices was given to all subjects in local language.

Regular comprehensive foot examination, patient education on foot care like simple hygienic practices, provision of appropriate footwear, and prompt treatment of minor injuries and a multi-disciplinary team approach can decrease ulcer occurrence by 50% and amputations by up to 85%.[3],[8].

This description is added to the background section (Page 1 and 2, Lines 22 – 25) and relevant references are added in references section.

8. Basic paragraph structure needs to be addressed in the "Results" and "Discussion" section.

Response: The paragraphs structure is based on the objectives. So authors felt it would be appropriate to retain the same structure. But if the reviewers and Editors insist, we will do as per the advice.
9. The last paragraph before the "Conclusion" section should start with weaknesses/limitations of the study. Use the study strengths to support how they minimize the limitations of the study.

Response: The paragraph containing strengths and limitations of the study is modified according to the above comments. (Page 11, Lines 247 – 255)