Reviewer’s report

Title: Associations of Foot Ulceration with Quality of Life and Psychosocial Determinants among Patients with Diabetes; A Case-Control Study

Version: 1 Date: 08 Oct 2019

Reviewer: Shannon Munteanu

Reviewer's report:

Thank you for allowing me to review this manuscript that investigates the association of foot ulceration with quality of life, anxiety and depression, somatic symptoms and self-management in individuals with diabetes residing in Saudi Arabia.

The manuscript is generally well-written. However, there appears to be an over-emphasis on the analysis of the correlations between QOL with scales for depression and anxiety - this was a secondary aim.

I have the following specific comments:

Title:

Please consider revising based on the primary major study aim (for example: Association of foot ulceration with quality of life, anxiety and depression, somatic symptoms and self-management in individuals with diabetes residing in Saudi Arabia)

Abstract:

Results - For SDSCA, can you please consider reporting statistically significant differences as mean differences with 95CIs. For significant correlations, please include the associated r-values.

Conclusions - Please review the conclusion based on my comments above - need to consider that there are no differences in quality of life, anxiety and depression, somatic symptoms, but differences in self-management in individuals with diabetes with and without foot ulceration residing in Saudi Arabia.
The word 'predict(ors)' is used. The study is cross sectional. I understand that the term 'predictor' is appropriate for the multi-variate statistics from a statistical perspective, but it may falsely leave the reader with the impression that your findings infer causality. Please carefully review wording to avoid giving the impression that there is a causal relationship between your independent and dependent variables. Please consider the wording 'associated/association' instead.

Background:

P?L24: please delete 'probably'.

P?57 - in the cited studies (refs 17,18) the study design / analysis is cross-sectional. Please consider revising the wording to avoid using 'predictors'.

P?L11-19 (study aims): Please can you reconsider using the word predictor here and throughout manuscript (determinant? ). Please can you include in brackets what 'determinants' were assessed (depression, anxiety, somatic pain, etc) for clarity for the reader. The second objective needs rewriting (A secondary aim was to…).

Methods:

Study design: Who was responsible for classifying participants? Do you have any other inclusion and exclusion criteria for your participants? How closely were participants matched by age? E.g. +/- 2 years?

Population: do you mean using 'convenience sampling'? Please review the sentence on line 44.

Sample size: Was the sample size based on the WHOQOL-BREF? How did you determine that 10 points was the minimally important difference - please provide a reference. Please include the sample size estimation software details here. Was the sample size appropriate to detect differences between groups for your other outcome measures (you should defend this as you found no differences between groups).

Statistical analysis:

Multivariate modelling - can you please specify (i) the dependent variable and (ii) what was specifically adjusted for (the independent variables) in the model(s). Did you check for assumptions of the test? What method did you use (e.g. simultaneous/enter versus hierarchial versus forward selection, backward selection and stepwise selection). Did you calculate R values for your variables that were associated with the dependent variable?
Results:

Please consider using sub-headings to break up this section to improve the readability.

P?L12: The word 'approximately' can be removed.

You observed a number of statistically significant correlations, some likely to be spurious (possibly SDSCA). Is it possible to simplify the writing of this section - overall, it appears that there were correlations for most of the domains of the WHO QOL with HAD anxiety, HAD depression and PHQ-15, but few with the SDSCA. Similar trends for observed for cases and controls.

Table 5: please can you include detail - is Beta standardised or unstandardized?

Discussion:

Please can you start by including a summary paragraph of the results to orientate the reader.

Can you please consider structuring your paragraphs to describe the findings of the comparison between those with and without ulceration for the outcomes QOL, anxiety and depression, somatic symptoms, as well as SDSCA, prior to the correlations of your outcomes with QOL.

What are the clinical implications of your findings?

Limitations:

Please reinforce that the study was cross-sectional so you have found associations (hence avoid using the word 'predictors’). There is a need for longitudinal studies to better explore causality.

Conclusions:

Please consider deleting the word 'further' (as the current study is not an interventional study).

References:

Please ensure that references are formatted to be consistent with journal guidelines.
Tables:

Table 2/3: please can you consider including another column that contains an estimate of the magnitude of difference with 95% CIs (rather than just p values) for your variables that you have performed inferential statistics for. For continuous data - mean difference and 95% CI with p value; For nominal data - odds ratio and 95% CI and p value.

Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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Please complete a declaration of competing interests, considering the following questions:

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