

Author's response to reviews

Title: A questionnaire for determining prevalence of diabetes related foot disease (Q-DFD): construction and validation

Authors:

Shan M Bergin (shan.bergin@mh.org.au)

Caroline A Brand (caroline.brand@mh.org.au)

Peter G Colman (peter.colman@mh.org.au)

Donald A Campbell (donald.campbell@med.monash.edu.au)

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Author's response to reviews: see over

November 6th 2009

To The Editor,

Thank-you for the opportunity to revise this paper based on the constructive comments provided by the two reviewers. I have addressed the comments from each reviewer separately and have amended the manuscript accordingly. If any of the following requires clarification please don't hesitate to contact me. I have also addressed the editorial recommendations for the preparation of the manuscript and I am hopeful it now meets the required standard.

Kind Regards,



Shan Bergin

Reviewer: Vanessa Nube

1. "The abstract reflects the content of the paper however the author might consider a title that states that the questionnaire is designed to collect prevalence data."

The authors thank the reviewer for making this suggestion. The title has been amended as suggested and now reads, 'A questionnaire for determining prevalence of diabetes related foot disease (Q-DFD): construction and validation'

2. "I am left wondering how peripheral neuropathy was detected using the short questionnaire. Given that we accept clinical screening is necessary to detect sensory loss (the critical deficit associated with ulceration) I am keen to know what questions were used in the survey. The author mentions on page 9 that components of the NSS were used to construct the questions but this is a more comprehensive tool with 17 items. They also reference a paper that reports on a similar tool, the DNS. Other readers may be as interested in knowing what questions were asked in the survey particularly as this may explain the poor agreement between PN and clinical assessment."

With regards to the level of agreement between PN and clinical assessment, kappa scores above 0.40 and below 0.60 are considered to reflect a moderate and therefore acceptable level of agreement, with only those scores of 0.40 or below deemed to reflect a 'poor' level of agreement. Therefore, the level of agreement of 0.57 for survey findings for PN and clinical assessment reported in this study cannot be classified as 'poor' as suggested above.

In terms of the survey questions used to determine presence or absence of PN, these were intended to capture self-report of the most commonly occurring symptoms for sensory loss. In order to clarify this, the symptoms used as the basis for the PN questions (and the PVD questions) in the survey tool have been inserted into the body of the paper (page 9, lines 8-9). Further to this, it has been made clearer that detecting sensory loss is the aim of the survey as opposed to detection of motor and autonomic neuropathy. Where 'PN' appears in the paper this has been modified to read 'sensory PN' where applicable.

Whilst the NSS is in fact comprised of 17 items, as pointed out by the reviewer, only 5 of the items relate to sensory loss with the remainder aimed at detecting motor changes (8 items) and autonomic changes (4 items). The Q-DFD, described in the current study, also has 5 questions relating to sensory loss with the DNS referenced in the paper using only 4 questions based on the same group of symptoms. As stated in the paper, the authors acknowledge that clinical screening is the gold standard for detection of clinical changes however, in the absence of clinical examination validated survey tools such as the NSS are widely used and accepted as an alternative. The authors are confident that the Q-DFD provides another, more comprehensive, alternative to clinical screening for detection of PN and all other aspects of diabetes related foot disease.

Reviewer: Alistair A McInnes

1. Minor revisions:

Page 2, line 4, results section –line should read 'participants'

Page 10, line 3 should read 'callus'

Page 12, line 4, should read survey's ability..'

Page 14, line 19 '....reported from other countries'. Reference required here.

Page 2, this spelling error has been amended.

Page 10, the word callous has been amended to read callus.

Page 12, an apostrophe has been inserted into 'survey's ability'.

Page 14, references have been inserted as recommended by the reviewer.

2. The points to consider are an appreciation of further bias re: sample for survey. In addition to being motivated to participate in the study, the other potential bias is the omission of those subjects who do not possess a telephone.....who may well be significant groups who have DFD.

The authors agree there is potential for selection bias to occur when using this survey tool via telephone. However, the authors believe that a discussion around selection bias as a study limitation would be more relevant within the context of a paper reporting actual prevalence data collected using the survey, where any such bias would have a greater tendency to influence results. Given that the primary aim of this study was to evaluate whether the survey was reliable and valid, as opposed to identifying prevalence rates for DFD, we don't believe the findings for validity and reliability from this study would be unduly affected by selection bias. Although prevalence rates are reported this is not the primary aim of the study.

3. Rationale for search: other electronic databases could have been considered and there is no mention of the time frame that was used for the databases of CINAHL and MEDLINE.

Other databases were considered for the electronic search however, the authors felt that the most robust literature around DRFD was likely to be found within CINAHL and MEDLINE.

The time frames used to search each database has been inserted; page 4, line 23.

4. Recruitment from the clinic. Perhaps this group could have given some time to consider taking part in the study.

The authors agree with this comment from the reviewer and support the idea that participants should not feel pressured into agreeing to become involved in studies such as this. This patient sample were recruited as described in the paper, but were not surveyed until approximately 1 week after recruitment. When they were contacted to be surveyed the interviewer reiterated that participation was voluntary and asked whether the participant was still interested in completing the survey. Each participant therefore had some time to consider agreeing to the study and was given the opportunity to withdraw consent. This has been made clearer within the body of the paper (page 6 last paragraph).

5. Important point to emphasise is the difficult in identifying the presence of foot deformity. For subjects providing information via telephone, particularly those with neuropathy, there are issues in identifying areas of high pressure. Many research studies have difficulty in defining foot deformity. Particularly relating to potential sites for ulceration. The difficulty in defining foot deformity should be highlighted in the text.

The authors feel that for the purposes of this study foot deformity was clearly defined for each participant. Each participant was provided with a 'lay' description of each foot deformity included in the survey making it easier for them to determine its presence or absence. Therefore we don't feel that 'defining deformity' as such, was an issue in this instance. However, we do agree that participants with neuropathy would have difficulty in determining presence or absence of areas of high pressure and have therefore highlighted this as an issue within the text (page 13, lines 1-3). We also acknowledge the difficulty in identifying potential sites for ulceration given that no research has been able to determine the lower limit of pressure required to cause ulceration. What is more clear from the literature however is that those with foot deformity and / or areas of increased pressure are at greater risk of ulceration when this occurs in the presence of neuropathy and it was the aim of this study to provide a prevalence estimate around numbers who present with this increased risk.