Author's response to reviews

Title: Determining the Validity and Reliability of the Chinese Version of the Kidney Disease Quality of Life Questionnaire (KDQOL-36TM)

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Author's response to reviews: see over
Dear editor,

Thank you for inviting us to resubmit our manuscript: ‘Determining the Validity and Reliability of the Chinese Version of the Kidney Disease Quality of Life Questionnaire (KDQOL-36TM)’. We appreciate your detailed review of the manuscript.

Below, we explain each of the issues raised by the reviewers and how we have incorporated their suggestions into the manuscript. The revisions were highlighted in red for easy references.

**Editorial Comments:**

- Revision of the conclusion to more clearly represent the limitations of the study, including the concerns about representation of the target population.

  **Response:** The conclusion was revised with clear statements about the limitations of the study, including concerns about generalisability of the study due to the possible sampling bias.

- All comments with particular attention to the review provided by Dr. ElHafeez. There are detailed suggestions that when addressed will significantly enhance this manuscript.

  **Response:** In the following section we have responded to all of the comments made by the two reviewers, and have made corresponding revisions in the manuscript.

**Reviewer 1 (Dr Joshi)**

1. Data is presented in an appropriate manner. One minor correction would be for Table no 1, 4th line from bottom, column 2, the word “not” is not clear.

  **Response:** The format of the table has been revised to make it clear.
2. The strengths and weaknesses of the methods:

Convergent validity and Reliability have been shown and the results look good.
However, proving discriminant validity by showing association of Quality of life variables with clinical parameters, the quality of the results can further be enhanced.
Glomerulonephritis and or number of days on dialysis can be used to show this association.
This can be considered as a Major revision.

**Response:** The correlations between quality of life variables and number of months on dialysis have been included in the manuscript. No significant difference was found between patients with a history of glomerulonephritis and those without. A clinical parameter, the presence of complications, which may have a close relationship with quality of life, was examined in a known-group comparison.

**Reviewer 2 (Dr ElHafeez)**

I. ABSTRACT:

1. Background: it would be better if the authors state the aim of the study clearly by the end of the paragraph because the aim is not mentioned.

**Response:** The aim of the study has been included in the background.

2. Method: it should be mentioned by the beginning of the method by whom the questionnaire was already translated (Amgen company) and the process of its translation, the sample size, sampling procedure and how did they select it?, and the way of validation of the questionnaire by brief describing of different validity procedures used and the way for assessment of the reliability.

**Response:** Additional information has been given on translation issues, sample size, sampling procedures, as well as procedures for evaluating validity and reliability.
3. Result:

• It was mentioned in the method section that the authors checked for convergent, content, and known group validities. Then in the result section, the authors stated that construct validity was checked. I prefer to be consistent regarding the different ways of validity used between the method and result sections.

**Response:** The description of different ways of validity has been unified and is consistent throughout the manuscript. ‘Construct validity’ was specified as either convergent validity or known-group validity.

• “The results of the known-group comparisons indicated that the instrument can discriminate between various subgroups of patients. The Cronbach’s alpha ranged from 0.69 to 0.78, demonstrating adequate reliability”, this previous statement is a conclusion rather than a result. It would be better if being modified by describing which groups showed significant difference in the questionnaire score. Also, you do not need to mention that the results of Cronbach’s alpha demonstrating adequate reliability because it can be concluded from the value.

**Response:** Only descriptive information was kept in the result part. A description of the results on known-group validity was added.

4. Conclusion: I prefer that the following statement “The scale also facilitates cross-country comparisons for patients with chronic kidney disease” to be removed as the study depended on a relatively small sample size which is not representative, so cross country comparison needs further evaluation.
Response: We agree with the reviewer’s comment. The aforementioned statement has been removed.

II. THE MANUSCRIPT

1. Background: there is no data about the burden of CKD in China and also the possible ways of management and what is the commonest modality of CKD management in China. In addition, more description of the importance of HRQOL assessment is required.

Response: Data specific to the Chinese CKD population have been reviewed and added to the background. The quality of life of the CKD population and its relationship to clinical outcomes, such as hospitalisation and mortality rates, are described.

2. Sampling and data collection method: at first, the rationale for including 103 patients is not clear because the authors mentioned several justifications for sample size calculations, based on reliability and validity, but none of it mentioned this 103 patients. SO, UPON WHICH THE AUTHORS HAVE DECIDED TO INCLUDE 103 PATIENTS?!. Moreover, selection bias is evident because enrolled patients included CKD 1-4, PD, and HD patients and the presentation of PD was dominant, although HD is the most common dialysis procedure in China. Moreover, how did the authors include all stages of CKD patients in their sample, and how did they deal with questions specific to dialysis access among non dialyzed patients?.

Other studies which investigated the validity of the questionnaire enrolled either pre ESRD patients or ESRD patients, to keep the homogeneity of the sample and ensure the generalizability of the data

Response: For the sample size estimation, the decision was made based on suggestions from two references. Since it was recommended that more than 80 subjects would be needed to test for validity and 50 or more subjects for internal consistency, we planned to recruit at least 80 patients for this study.
The psychometric testing was conducted in a mixed sample of CKD patients. There were two reasons for this. First, the KDQOL-36™ can be used on both CKD patients who are not undergoing dialysis and those who are. Second, including a wide range of patients allowed for variations in quality of life and a better determination of the psychometric properties of the KDQOL-36™. Klersy et al. (2007) conducted a similar validation study of the KDQOL. However, due to a limited sample size, we did not analyse whether potential differences in reliability and validity would exist when patients were classified into different groups according to their treatment status and modalities. Further evaluation of this version of the instrument using a larger Chinese sample is warranted to support our findings. Those statements have been included in the manuscript as a limitation.

3. Questionnaires used in the study: how could the authors collect the data from those with primary or below education (12.6% of the total sample size)? Was the questionnaire self-administered or by interviewing?. The authors stated that “The construct validity was supported by the criterion-related validation evidence and the convergent validation approach. Then mentioned that “The construct validity was supported by the concurrent validity and exploratory factor analysis approach”, which way have the authors used to validate the questionnaire, and whether they perform exploratory factor analysis or not?!

Response: All of the questionnaires were completed in a clinic by the patients themselves or with the assistance of trained nurses.

With regard to the psychometric properties of the BDI-II, information in both English and Chinese was provided. Criterion-related validation and the convergent validation approach were adopted in the validation study for the original English version of the BDI-II, while
concurrent validity and the exploratory factor analysis approach were employed to validate the Chinese version of the BDI-II. We have revised this portion of the text to make this clear.

4. Validity and reliability testing of the Chinese KDQOL-SF36:

• The modification added to the questionnaire “replacing bowling and playing golf by ‘walking’ and ‘Tai Chi’ was done by the authors or by Amgen company. Also, could the authors be consistent in describing the ways of validity because in every section they described something different.

**Response:** The modifications were made by the authors through the content validity process. Corresponding information was added in the manuscript.

The description of different ways of validity has been unified and is consistent throughout the manuscript. ‘Construct validity’ was specified as being either convergent validity or known-group validity.

• Description of the different hypotheses like “We hypothesized that patients with lower subscale scores of the KDQOL-36™ would report higher levels of depressive symptoms, as represented by a high BDI-II score” should be shifted to the discussion and compare what the authors have found with what was mentioned in previous studies. The same for “Based on previous studies, we assumed that HRQOL scores would be lower among elderly people, females, the poorly educated, the unemployed, and people without government health insurance. It was also expected that patients who had been hospitalized during the past six months and patients who had undergone dialysis for a longer duration would report lower HRQOL”.

**Response:** A description of the ways to conduct convergent and known-group validity was included and comparisons between the results of the current study and related previous findings were further elaborated upon in the discussion.
With regard to the hypotheses for testing convergent and known-group validity, we prefer to leave them where they are. Those hypotheses were established in the study protocol based on the literature review before the field study was conducted. We wanted to evaluate whether those hypotheses were accepted or rejected based on results that were obtained, so as to accumulate evidence on the validity of the KDQOL-36™.

- Could the authors clearly put subheadings for all the steps followed for assessment of the psychometric properties of the questionnaire (validity, reliability, acceptability, and response burden)

**Response:** Yes, subheadings have been included.

5. Results:

- Acceptability and descriptive analysis of the scale: the concept of floor and ceiling effects are wrong because it means “Ceiling effects were taken as being the percentage of respondents with scores of 100 and floor effects were the percentage of respondents having a score of 0” based on the reference mentioned by the authors. Moreover, Ceiling and floor effects should be less than 20% to ensure that the scale captures the full range of potential responses within the population, and that changes over time can be detected. Based on the previous statement, the present study showed ceiling effect in the symptoms/problem list and burden of kidney disease domains. Also, floor effect was evident for both the effects and burden of kidney disease. This is in contrary to what was mentioned by the authors that there were no ceiling or floor effects identified in the current study.

**Response:** The reporting of the ceiling and floor effects has been revised according to the definitions of the ceiling and floor effects.
• A summary statistic for BDII score is better to be included

**Response**: As suggested, a brief description of the depressive status of the study subjects was added.

6. Discussion: it needs to be modified based on the results and to compare what was found in the current study with what previously mentioned specially in Asian countries like Korea and Japan. Are the results concordant or not and if not what are the justifications of the authors.

**Response**: The discussion was re-organised with more detailed comparisons to other studies according to the results that were obtained.

Minor essential revisions:

• The English style of the manuscript needs to be revised and the writing needs to be modified.

**Response**: The revised manuscript has been edited by a professional editor who is a native speaker of English.

Discretionary Revisions

• It would be better if the authors add to the results correlation between the different domains of specific part of the questionnaire with PCS and MCS. Also, the correlations between the different questions formed the questionnaire to have more idea about the construct validity of the questionnaire

**Response**: Results on the correlation between disease-specific domains and generic domains were added to supplement the construct validity of the questionnaire. In addition, a corresponding discussion was included in the discussion section.