Reviewer's report

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

Version: 2 Date: 6 May 2014

Reviewer: Samar Abd ElHafeez

Reviewer's report:

Major compulsory revisions:

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.

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.

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.

• “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.

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.

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.
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

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?!

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.
   • Description of the different hypotheses like “We hypothesized that patients with lower subscale scores of the KDQOL-36TM 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 [33, 34, 35, 36]. 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”.
   • 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)

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.

• A summary statistic for BDII score is better to be included

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.

Minor essential revisions:
• The English style of the manuscript needs to be revised and the writing was needs to be modified

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

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: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests