

Validation of Kidney Disease Quality of Life Short Form 36 (KDQOL-SF™) in Malayalam among Patients Undergoing Haemodialysis in South Kerala

Abstract

Introduction: Hemodialysis is the most common mode of therapy worldwide for chronic kidney disease (CKD) and is used as a life-sustaining therapy for most of the patients. Studies proved that dialysis affects the Quality of life (QOL) of patients. Health-related quality of life has been increasingly recognized as an important medical outcome in patients with CKD. Kidney disease quality of life short form (KDQOL-SF™) is developed by RAND to assess the QOL in CKD patients. This study was conducted to translate and validate the questionnaire KDQOL-SF™ in Malayalam.

Methods: A cross sectional study was conducted among the patients who were undergoing dialysis in Sree Gokulam Medical College and Research foundation, Trivandrum. The translation was done according the specifications given by RAND. A sample of 112 patients studied. Statistical analysis was done for evaluating item internal consistency, item discriminant validity, equality of item-scale correlations, scale level reliability, and validity. Scale level descriptive statistics were computed. **Results:** Item internal consistency was more than 0.4 for all scales except a few. Item-level discriminant validity was 100% for almost all scales. Scale level reliability and validity were examined; all scales met the required internal consistency criteria. The overall reliability of the tool was 0.81. Scale level reliability varies from 0.71 to 0.92, which support item homogeneity and internal consistency across scales. Overall mean health rating score was 53.43 ± 11.48 .

Conclusion: The Malayalam version of KDQOL-SF™ is reliable and valid which can be used for measuring the health-related quality of life of Malayalam speaking CKD patients.

Keywords: Dialysis, quality of life, questionnaire, reliability, translation, validity

Introduction

In literature, the term “quality of life” is also often referred to as “well-being”. World Health Organization defines Quality of Life as individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.^[1] Chronic kidney disease (CKD) is a worldwide health problem. One potential outcome of CKD is end-stage renal disease (ESRD), requiring costly renal replacement therapy in the form of dialysis or transplantation. The main cause of CKD is diabetes and hypertension. Since the prevalence of these chronic diseases are increasing in India, and about 25–40% of these subjects may develop CKD, the ESRD burden will rise and the health care system would need to take care of them.^[2] A study conducted by Singh *et al.* reported the prevalence of CKD

in India of 17.2%.^[3] Hemodialysis is the most common mode of therapy worldwide, at least 80% of patients are on this mode of therapy.^[4] It is used as a life-sustaining therapy for most of the patients. Studies proved that dialysis affect the Quality of life (QOL) of patients. Health related quality of life has been increasingly recognized as an important medical outcome in patients with CKD.^[5] There are various tools available to measure the QOL, disease specific tools are also available. Kidney disease quality of life short form is developed by RAND to assess the QOL in CKD patients.^[6,7] It was translated in many languages, but not in Malayalam. The objective of the study was to translate and validate the KDQOL-SF™ questionnaire into Malayalam.

Methods

Translation

The questionnaire was translated into Malayalam following the specifications provided by RAND Health.^[8] Translation

How to cite this article: Manju L, Joseph J, Beevi N. Validation of kidney disease quality of life short form 36 (KDQOL-SF™) in malayalam among patients undergoing haemodialysis in South Kerala. Indian J Nephrol 2020;30:316-20.

L. Manju,
Jigy Joseph¹,
Nazeema Beevi

Departments of Community
Medicine and ¹Nephrology,
Sree Gokulam Medical College
and Research Foundation,
Venjaramoodu, Trivandrum,
Kerala, India

Received: 26-04-2019

Accepted: 05-09-2019

Published: 11-02-2020

Address for correspondence:

Dr. L. Manju,
Department of Community
Medicine, Sree Gokulam
Medical College and Research
Foundation, Venjaramoodu,
Trivandrum - 695 581, Kerala,
India.
E-mail: drmanjuhariharan@
gmail.com

Access this article online

Website: www.indianj nephrol.org

DOI: 10.4103/ijn.IJN_139_19

Quick Response Code:



This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

was done by a certified professional translator. The translated questionnaire was reviewed by medical professionals to check the accuracy of the terms used. Back translation was also done by another professional translator. The translated and back translated questionnaires were reviewed by reviewers. Any discrepancy in the translated version was resolved during this phase. During the translation phase suitable cultural adaptations were made to make the questionnaire suitable for Kerala context.^[9] The final version was prepared after a pilot study.

Tool

The questionnaire consists of 36 items describing the perception of health state during the last 4 weeks such as symptoms and problems, effects of kidney disease on daily life, burden of kidney disease, work status, cognitive function, quality of social interaction, sexual function, sleep, social support, dialysis staff encouragement, patient satisfaction, physical functioning, role-physical, pain, general health, emotional well being, role-emotional, social function, energy/fatigue. Background information of the patient such as gender, income level, education, number of medicines per day, etc. were also included. Scoring rules given in KDQOL-SF™ user's manual were followed.^[7] The pre-coded items were transformed into 0-100 scale, with higher score representing better quality of life.

Data collection

A cross sectional study was conducted among the patients who were undergoing dialysis in Sree Gokulam Medical College and Research foundation, Trivandrum after obtaining the ethical committee approval. The study period was from February 2017 to August 2018. The purpose of the study was explained to the patients and assured them regarding the confidentiality of the data collected. Patients were recruited after obtaining the written informed consent. The KDQOL-SF™ questionnaire was given to the patient after explaining it and asked to fill it back during the next dialysis session. One twenty five questionnaires were distributed, 112 were returned. Incomplete questionnaires were filled by the trained staff during the next dialysis session after having a friendly interaction with the patient. Only very few patients answered the three questions related to sexual activity. Majority of the people dislike discussing sexual activities openly; hence, we ignored those questions during this phase and excluded from analysis.

Inclusion criteria

Age >18 yrs. Diagnosed with ESRD. Dialysis treatment at least for three months.

Exclusion criteria

Too ill to take part or if they had significant co-morbidity such that their predominant treatment was for another illness.

Sample size

Sample size is 112. According to Peat *et al.*,^[10] a sample of 100 or more is recommended for reliability and validity studies.

Sampling technique

Consecutive sampling.

Statistical analysis

For statistical analysis SPSS software version 15(Statistical Package for the Social Sciences Inc, Chicago, IL, USA) was used. Reliability of the tool was estimated using Cronbach's alpha coefficient on the whole and for each domain. The value of Cronbach's alpha more than 0.7 is considered as having high internal consistency.^[11] Item level validity was carried out by item internal consistency, equality of item scale correlations, and item-discriminant validity. If an item correlates 0.4 or more with its hypothesized scale, after correction for scale overlap it can be considered as internally consistent. Equality of item-scale correlations is satisfied if item level correlations vary from 0.40 to 0.70 across items in the same scale. Item discriminant validity is achieved if the correlation between an item and its hypothesized scale is significantly higher than the correlation between that item and all other scales.^[12] To assess the scale level reliability and validity we computed the reliability coefficient Cronbach's alpha for each scale and computed the correlation matrix between scales. If the inter-scale correlation is less than their reliability coefficient is an indication that each scale is measuring a distinct health concept.^[13] Scale level descriptive statistics and overall mean health score were computed.

Results

Table 1 shows the demographic characteristics of the people. Of the 112 patients undergoing dialysis, 74 (66.1%) were males. About 38.4% of the patients were in the age group 55–65 years. The mean age was 60.55 years with standard deviation of 11.77. Age ranged from 22 to 84. About 44.6% of patients had only high school education. Fifty percent of patients were getting some kind of insurance coverage. Table 2 describes the item internal consistency, item-discriminant validity and success rate of the KDQOL-SF™ scale. Item internal consistency was more than 0.4 for all scales except burden of kidney disease, sleep, and cognitive function after corrected for item-scale overlap. Success rate of item discriminant validity was 100% in all scales except of kidney disease, cognitive function, and sleep. Table 3 shows the mean, standard deviation (SD), floor and ceiling effects of the KDQOL-SF™ scales. The floor effect was found to be less than 15% except for social support, Role-physical and Role emotional. Ceiling effect was found to be above 15% for most of the scales. Highest mean score of 90.51 ± 18.78 was obtained for dialysis staff encouragement and lowest

Table 1: Socio-demographic characteristics of the people

Variables	n (%)
Age	
<35	6 (5.4)
35-45	8 (7.1)
45-55	17 (15.2)
55-65	43 (38.4)
>= 65	38 (33.9)
Gender	
Male	74 (66.1)
Female	38 (33.9)
Educational qualification	
Middle school	28 (25.0)
High school	50 (44.6)
Plus Two/Vocational higher secondary	26 (23.2)
Degree/Diploma	6 (5.4)
PG	1 (0.9)
Professional	1 (0.9)
Marital Status	
Married	101 (90.2)
Unmarried	11 (9.8)
Insurance coverage	
Yes	56 (50.0)
No	56 (50.0)
Income	
<5000	46 (41.1)
5001-10000	31 (27.6)
10001-20000	10 (8.9)
20000-40000	5 (4.5)
40000-75000	10 (8.9)
>75000	8 (7.1)
Don't know	2 (1.8)

mean score of 26.87 ± 12.16 was for work status. The overall health score was 53.43 ± 11.48 . Table 4 shows the scale level reliability and inter scale correlations. Reliability coefficient can be considered as the correlation between a scale and itself. The overall reliability of the tool was 0.81. Scale level reliability varies from 0.71 to 0.92, which support item homogeneity and internal consistency across scales. Since the reliability coefficients of each scale were greater than the inter-scale correlations, each scale can be considered to measure a distinct concept.

Discussion

Many western studies are there in the literature regarding the validation of KDQOL-SF™ tool.^[14-22] Among Indian language, KDQOL-SF™ had been translated into Hindi,^[23] Kannada,^[24] Marathi^[25] and Tamil.^[26] But KDQOL-SF™ has not been translated and validated in Malayalam. This first Malayalam translated version was found to have good internal consistency of 0.81. The reliability coefficient Cronbach's alpha ranges from 0.71 to 0.92 in the 18 subscales. This is similar to the previous Indian studies, but the Marathi translated tool showed an internal consistency of more than 0.70 for all scales except the seven subscales. A study conducted in Bangalore using the English version of the tool also reported an internal consistency ranges from 0.61 to 0.94.^[27] Results of the present study also agrees with the Western studies.^[14-16,22] A study conducted in Egypt reported the value of Cronbach's alpha more than 0.7 for all scales except three subscales.^[17] Translated version in Urdu, the national language of Pakistan also reported an internal consistency of more than 0.70 for 12 sub scales.^[28] Thai version of

Table 2: KDQOL-SF™ item-internal consistency and item-discriminant validity

Kidney disease targeted scales	Item-internal consistency ^a (Success rate)	Item-discriminant validity ^b (Success rate)
Symptom/problems	0.41-0.67 (100%)	0.03-0.40 (100%)
Effect of kidney disease	0.42-0.64 (100%)	0.01-0.41 (100%)
Burden of kidney disease	0.23-0.56 (75%)	0.02-0.44 (88%)
Work status	0.62 (100%)	0.00-0.24 (100%)
Cognitive function	0.36-0.68 (67%)	0.03-0.41 (94%)
Quality of social interaction	0.40-0.57 (100%)	0.00-0.32 (100%)
Sleep	0.24-0.54 (75%)	0.00-0.44 (88%)
Social support	0.79 (100%)	0.01-0.21 (100%)
Dialysis staff encouragement	0.69 (100%)	0.00-0.55 (100%)
Patient satisfaction	NA	NA
36-Item Health Survey Scale (SF-36)		
Physical functioning	0.45-0.71 (100%)	0.01-0.43 (100%)
Role-Physical	0.47-0.68 (100%)	0.06-0.41 (100%)
Pain	0.58 (100%)	0.03-0.43 (100%)
General health	0.46-0.67 (100%)	0.00-0.37 (100%)
Emotional well-being	0.50-0.71 (100%)	0.00-0.38 (100%)
Role-emotional	0.40-0.68 (100%)	0.03-0.36 (100%)
Social function	0.64 (100%)	0.02-0.24 (100%)
Energy/fatigue	0.42-0.73 (100%)	0.07-0.38 (100%)

^aCorrelations between items and hypothesized scale corrected for overlap; ^bCorrelation between items and other scales

Table 3: KDQOL-SF™ scale descriptive statistics, floor and ceiling effects

Scale	Transformed scores (0-100)					
	Mean	SD	Observed/possible values		% at floor	% at ceiling
			Lowest	Highest		
ESRD-targeted Areas						
Symptom/Problem list	77.43	15.61	20.83/0	100/100	1.2	64.4
Effect of kidney disease	66.10	18.84	17.86/0	100/100	1.2	32.6
Burden of kidney disease	28.40	21.07	0/0	100/100	5.9	37.2
Work status	26.87	12.16	0/0	50/100	73.2	6.2
Cognitive function	68.86	19.03	20/0	100/100	1.2	26.8
Quality of social interaction	70.42	18.85	33.33/0	100/100	0.5	12
Sleep	53.66	19.50	5/0	100/100	2.4	7.1
Social Support	51.78	36.92	0/0	100/100	25.6	14.1
Dialysis staff encouragement	90.51	18.78	0/0	100/100	1.2	69.8
Patient satisfaction	62.05	24.11	33.33/0	100/100	5.6	19.8
36-item health survey (SF-36)						
Physical functioning	38.97	32.18	0/0	100/100	5.9	3.9
Role-physical	27.67	24.12	0/0	100/100	45.4	25.6
Pain	55.20	29.78	0/0	100/100	2.3	17.2
General health	32.99	21.96	0/0	85/100	36	2.3
Emotional wellbeing	55.28	18.70	20/0	100/100	2.3	12.8
Role-emotional	32.44	27.55	0/0	100/100	31.5	51.2
Social function	60.49	26.55	0/0	100/100	3.5	25.6
Energy/fatigue	42.58	16.68	0/0	90/100	2.3	1.2
Overall health rating	53.43	11.48	33.12/0	82.14/100	100/100	NA

Table 4: Reliability coefficients and inter-scale correlations

	Reliability	Inter-scale correlations*
Kidney disease targeted scales		
Symptom/problems	0.87	0.08-0.58
Effect of kidney disease	0.82	0.12-0.64
Burden of kidney disease	0.71	0.04-0.54
Work status	0.89	0.23-0.48
Cognitive function	0.83	0.33-0.59
Quality of social interaction	0.74	0.17-0.47
Sleep	0.72	0.20-0.62
Social support	0.92	0.33-0.64
Dialysis staff encouragement	0.78	0.07-0.55
Patient satisfaction	-	-
36-Item Health Survey Scale (SF-36)		
Physical functioning	0.92	0.07-0.60
Role-Physical	0.78	0.24-0.48
Pain	0.83	0.12-0.57
General health	0.81	0.27-0.64
Emotional well-being	0.84	0.04-0.47
Role-emotional	0.79	0.08-0.62
Social function	0.85	0.12-0.61
Energy/fatigue	0.75	0.04-0.54

*Correlation matrix is of dimension 18 × 18, included only the range of correlations

the KDQOL-36 questionnaire had reliability coefficient from 0.799-0.827.^[29] Sinhala, which is the most common language spoken in Sri Lanka had Cronbach's alpha more than 0.70 for all sub scales except cognitive function.^[30]

Floor effects is highest for work status scale and ceiling effects higher for dialysis staff encouragement which is concurrent with Kuriakose *et al.*^[27] and Park *et al.*^[15] This is not agreeing with Mateti *et al.*,^[24] however that study didn't report all the domains in ESRD-targeted areas. Item internal consistency of more than 0.4 is attained in most of the scales and item discriminant validity success rate varied from 88% to 100%. This is reported as 0.5 to 1.0 in Joshi *et al.*^[22] Overall health rating score was obtained as 53.22 ± 11.48. Scale wise mean score in ESRD-targeted areas are in congruence with the findings of other south Indian studies,^[24-26] but not agreeing with the Role-Physical and Role-emotional mean scores of Mateti *et al.*^[24] Among all the scales highest score was for Dialysis staff encouragement which is consistent with previous studies.^[15,22,28,30] Least score is obtained for Work status which is agreeing with previous studies.^[15,28]

Conclusion

In summary, Malayalam version of KDQOL-SF™ is found to have good internal consistency, convergent validity and discriminant validity. So, this tool is a sound tool to access the QOL of Malayalam speaking patients with CKD.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

- Group W. Development of the WHOQOL: Rationale and current status. *Int J Ment Health* 1994;23:24-56.
- Sharma R, Grover V. Kidney disease in India. *Indian J Med* 2009;50:30-3.
- Singh AK, Farag YM, Mittal BV, Subramanian KK, Reddy SRK, Acharya VN, *et al.* Epidemiology and risk factors of chronic kidney disease in India—results from the SEEK (Screening and Early Evaluation of Kidney Disease) study. *BMC Nephrol* 2013;14:114.
- Zhang QL, Rothenbacher D. Prevalence of chronic kidney disease in population-based studies: Systematic review. *BMC Public Health* 2008;8:117.
- Unruh ML, Weisbord SD, Kimmel PL. Psychosocial factors in patients with chronic kidney disease: Health-related quality of life in nephrology research and clinical practice. In: *Seminars in Dialysis*. Wiley Online Library; 2005. p. 82-90.
- Hays RD, Kallich JD, Mapes DL, Coons SJ, Carter WB. Development of the kidney disease quality of life (KDQOL™) instrument. *Qual Life Res* 1994;3:329-38.
- Hays RD, Kallich JD, Mapes DL, Coons SJ, Amin N, Carter WB, *et al.* Kidney disease quality of life short form (KDQOL-SF), Version 1.3: A Manual for Use and Scoring. St Monica CA Rand; 1997. p.1-39.
- Monica 1776 Main Street Santa, California 90401-3208. Basic Guide for Translating Surveys [Internet]. Available from: https://www.rand.org/health/surveys_tools/about_translations.html. [Last cited on 2018 Nov 21].
- Wagner AK, Gandek B, Aaronson NK, Acquadro C, Alonso J, Apolone G, *et al.* Cross-cultural comparisons of the content of SF-36 translations across 10 countries: Results from the IQOLA project. *J Clin Epidemiol* 1998;51:925-32.
- Peat J, Mellis C, Williams K, Xuan W. *Health Science Research: A Handbook of Quantitative Methods*. First. London: Sage Publications Ltd; 2002.
- Nunnally JC, Bernstein IH. *Psychometric Theory* (McGraw-Hill Series in Psychology). Vol. 3. McGraw-Hill New York; 1994.
- Ware JE Jr, Gandek B. Methods for testing data quality, scaling assumptions, and reliability: The IQOLA Project approach. *J Clin Epidemiol* 1998;51:945-52.
- Campbell DT, Fiske DW. Convergent and discriminant validation by the multitrait-multimethod matrix. *Psychol Bull* 1959;56:81-105.
- Ricardo AC, Hacker E, Lora CM, Ackerson L, DeSalvo KB, Go A, *et al.* Validation of the kidney disease quality of life short form 36 (KDQOL-36™) US Spanish and English versions in a cohort of hispanics with chronic kidney disease. *Ethn Dis* 2013;23:202-9.
- Park HJ, Kim S, Yong JS, Han SS, Yang DH, Meguro M, *et al.* Reliability and validity of the Korean version of kidney disease quality of life instrument (KDQOL-SFTM). *Tohoku J Exp Med* 2007;211:321-9.
- Molsted S, Heaf J, Prescott L, Eidemak I. Reliability testing of the Danish version of the Kidney Disease Quality of Life Short Form™. *Scand J UrolNephrol* 2005;39:498-502.
- ElHafeez SA, Sallam SA, Gad ZM, Zoccali C, Torino C, Tripepi G, *et al.* Cultural adaptation and validation of the “Kidney Disease and Quality of Life-Short Form (KDQOL-SF™) version 1.3” questionnaire in Egypt. *BMC Nephrol* 2012;13:170.
- Duarte PS, Ciconelli RM, Sesso R. Cultural adaptation and validation of the “Kidney Disease and Quality of Life-Short Form (KDQOL-SF™ 1.3)” in Brazil. *Braz J Med Biol Res* 2005;38:261-70.
- Tao X, Chow SKY, Wong FKY. Determining the validity and reliability of the Chinese version of the Kidney Disease Quality of Life Questionnaire (KDQOL-36™). *BMC Nephrol* 2014;15:115.
- Chow SKY, Tam BML. Is the kidney disease quality of life-36 (KDQOL-36) a valid instrument for Chinese dialysis patients? *BMC Nephrol* 2014;15:199.
- Chen JY, Choi EP, Wan EY, Chan AK, Tsang JP, Chan KH, *et al.* Validation of the disease-specific components of the kidney disease quality of life-36 (KDQOL-36) in Chinese patients undergoing maintenance dialysis. *PLoS One* 2016;11:e0155188.
- Joshi VD, Mooppil N, Lim JF. Validation of the kidney disease quality of life-short form: A cross-sectional study of a dialysis-targeted health measure in Singapore. *BMC Nephrol* 2010;11:36.
- Patil PP, Pawar S, Thakurdesai P. Translation and validation of kidney disease and quality of life (KDQOL-SFTM 1.2) instrument to measure health related quality of life of Indian patients with kidney disease. *Value Health* 2014;17:A813.
- Mateti UV, Nagappa AN, Attur RP, Nagaraju SP, Mayya SS, Balkrishnan R. Cross-cultural adaptation, validation and reliability of the South Indian (Kannada) version of the Kidney Disease and Quality of Life (KDQOL-36) instrument. *Saudi J Kidney Dis Transplant* 2015;26:1246-52.
- Joshi V, Mulay A, Dighe T, Jeloka T, Biwalkar V. Validity of Marathi translated kidney disease quality of life short form (KDQOL-SF)™. *J Evid Based Med Heal* 2015;2:409-20.
- Manavalan M, Majumdar A, Kumar KH, Priyamvada PS. Assessment of health-related quality of life and its determinants in patients with chronic kidney disease. *Indian J Nephrol* 2017;27:37-43.
- Kuriokose AV, KenchaappaV, Hiremath SKA, Varghese BM, Sproge S, Cevere R. Assessment of quality of life in chronic renal failure patients in India. *Quality Issues and Insights in the 21st century* 2012;1: 20-28.
- Anees M, Ibrahim M, Imtiaz M, Batool S, Elahi I, Malik MR. Translation, validation and reliability of the kidney diseases quality of life-short form (KDQOL-SF Form) tool in Urdu. *J Coll Physicians Surg Pak* 2016;26:651-4.
- Thaweethamcharoen T, Srimongkol W, Noparatayaporn P. Patient reported outcomes (pro) or QOL studies, Validity and reliability of KDQOL-36 in Thai kidney disease patient. *Value Health Reg Issues* 2013;2:98-102.
- Senanayake S, Gunawardena N, Paliawadana P, Kularatna S, Peiris TSG. Validity and reliability of the Sri Lankan version of the kidney disease quality of life questionnaire (KDQOL-SF™). *Health Qual Life Outcomes* 2017;15:119.