ORIGINAL ARTICLE

VALIDITY OF MARATHI TRANSLATED KIDNEY DISEASE QUALITY OF LIFE SHORT FORM (KDQOL-SF)™

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HOW TO CITE THIS ARTICLE:
Veena Joshi, Atul Mulay, Tushar Dighe, Tarun Jeloka, Varada Biwalkar. "Validity Of Marathi Translated Kidney Disease Quality Of Life Short Form (KDQOL-SF)™". Journal of Evidence based Medicine and Healthcare; Volume 2, Issue 4, January 26, 2015; Page: 409-420.

ABSTRACT: Kidney Disease Quality of Life (KDQOL) instrument was designed to measure Quality of Life of kidney disease patients. KDQOL has been tested, translated and validated in many countries. KDQOL has not been translated into Marathi language. The primary purpose of this study was to validate Marathi version of KDQOL-SF™ and to evaluate its psychometric properties. This cross sectional study was conducted in two hospitals in Pune from April 2012 to March 2013. Translated Marathi KDQOL-SF™ was evaluated in 93 dialysis patients. Patients' average age was 57 ±12 years and 71% were males. Internal consistency reliability was found to be medium to high ranging from 0.5 to 0.9 except for social interaction. To investigate construct validity, overall health rating scale was correlated with kidney disease targeted scale and with quality of life (SF-36 scales). Significant ($p < .05$) correlations were observed except for cognitive function and social support. Patients with known hypertension, diabetes, low haemoglobin and dialyzing less than thrice a week showed lower score on physical function as compared to higher scores on physical function of patients with no known hypertension and diabetes, HB</= 8 and dialyzing thrice a week. As time on dialysis increased, role emotional ($r = 0.239$, $p = 0.019$) and role physical ($r = .237$, $p = 0.20$) improved showing significant association. These results suggest that Marathi version of KDQOl-SF™ satisfies reliability and validity. The questionnaire provides understanding of health and quality of life of hemodialysis patients and can be used with patients who speak Marathi language.

KEYWORDS: Dialysis, KDQOL-SF™, Validity, Reliability.

INTRODUCTION: In India, the age-adjusted incidence rate of End Stage Renal Disease is 229 per million population (pmp), and >100,000 new patients enter renal replacement programs annually as reported by SEEK (Screening for Early Evaluation of Kidney Disease project).[(1)] Delay in recognizing the disease and failure of intervention at early stage to slow renal progression of renal failure result in predominantly young population with ESRD.[(2)] Family members succumb to both emotional and financial burden imposed by the management of disease. Though renal replacement therapies like dialysis are able to pull on the patients' status for a long time, the quality of life (QOL) gets affected badly.[(3,4)] For this reason, QOL evaluation has emerged as an important outcome measure for disease management.[(5)]

Kidney Disease Quality of Life–short form (KDQOL-SF™) is a disease specific self-reporting instrument developed for patients with kidney disease and on dialysis.[(6)] It has been validated and used in many countries like Iran,[(7)] Singapore,[(8)] Korea,[(9)] Turkey,[(10)] Greece,[(11)] and Brazil.[(12)] It is hypothesized that people in different cultures perceive things differently. QOL is individual's own perception of how he feels and to an extent the environment in which he lives influences

this. In India, English version of KDQOL has been validated in Bangalore by Kuriokos with 101 chronic renal failure patients.[13] Since India is a big country with 28 states and each state has different cultures, it is essential to understand QOL of patients from different cultures within the country. The aim of this study was to test the validity and reliability of Marathi version of KDQOL-SF™ by recruiting Marathi speaking patients from Pune.

METHODOLOGY: This cross sectional study was conducted between April 2012 to March 2013 at two hospitals after getting ethics committee permission from Deenanath Mangeshkar Hospital and Research Centre (DMHRC) and Aditya Birla Memorial Hospital (ABMH). 64 patients of CKD stage V who were on dialysis from DMHRC and 40 patients from ABMH were recruited in the study after getting the consent form signed.

Participation in the study was voluntary. For inclusion in the study, patients above 21 yrs of age with a diagnosis of CKD stage V and on dialysis for at least three months and signed Informed Consent Form were considered.

The disease specific instrument to be tested for reliability and validity was Kidney Disease Quality of Life- Short Form (KDQOL-SF™) version 1.3 which is a self-reported measure developed for individuals who have kidney disease and are on dialysis. It is available in English version but not in Marathi. As majority of patients who visit various hospitals in Pune understand and speak Marathi (local language in Maharashtra State), we got it translated into Marathi. The process involved translation from English to Marathi and back translation from Marathi to English by two language experts in Marathi and English. Our Nephrologists discussed the culture specific changes with these translators. It was then pilot tested on five patients. The consensus was reached and this was treated as a final instrument for the study. To suit the culture, there were some modifications in the Marathi version of KDQOL as highlighted in appendix A.

The instrument consisted of 36 items for general health, 43 items were specific to kidney disease and one overall health-rating item. The general health items were divided into eight subscales**:** Physical functioning, Role physical, Pain, General health, Emotional well-being, Role emotional, social function and Energy/fatigue. Scoring algorithms given in the user manual[16] was used to calculate scores ranging from 0 to 100. The scores represent the percentage of total possible score achieved, with 100 representing the highest quality of life. The items evaluate patient's health and how the patient feels about his care.

INCLUSION CRITERIA:

1. Age ≥ 21 yr,
2. Diagnosed as CKD stage V.
3. Patients have been receiving hemodialysis/peritoneal dialysis at one of the listed hospitals for at least three months.
4. Patient who has voluntarily signed the Informed Consent Form.

EXCLUSION CRITERIA: 1. Patient who in the opinion of the Investigators will not follow the instructions of the study properly due to illiteracy or medical condition that limits his/ her ability to read or comprehend written material.

PATIENT RECRUITMENT: Participation in this study was voluntary. Patients undergoing hemodialysis or peritoneal dialysis in the renal unit were chosen for the study. Nephrologists involved in the study informed the coordinator about such a patient. The coordinator was trained in explaining the study, data collection and data entry. Those patients who agreed to participate were given the questionnaires to complete.

DESIGN, DATA COLLECTION AND CONFIDENTIALITY OF DATA: This was a cross sectional study. The data was captured from patients and clinical records and Nephrologists. Confidentiality of the data was assured before the generation of the data.

STATISTICAL ANALYSIS: Statistical analysis was carried out with the help of software SPSS version 19. We used Cronbach's coefficient α to assess internal consistency reliability for the overall scale, and within individual sub-scales. 0.7 or above was considered high reliability. We also determined the mean ± standard deviation of each sub-scale. We used Pearson Correlation (two tailed) to assess stronger relationships of items within scales and weaker relationships with items outside of the scale. To assess its reproducibility, test retest reliability was assessed.

For analysis of construct validity we used co morbidities and lab test parameters such as haemoglobin and albumin that were expected to be correlated with at least one of the KDQOL subscales. The first measure of construct validity was the correlation between the overall health rating score (the first item of the KDQOL-SF™) and each of the KDQOL-36™ subscales score. We also looked at two-tailed significance of correlation coefficients of scores on the eight subscales and age, income and education to determine convergent and divergent validity. Considering that higher scores on SF-36 variables indicate good quality of life, we hypothesized that SF-36 score would be positively correlated with measure of self-rated health and with socio economic status (measured in terms of income and education).

RESULTS: All the patients were on hemodialysis. Except four patients, all the patients who were contacted responded to our study giving response rate of 99%.

64 patients from DMH and 40 patients from Birla hospital (total 104) completed the study questionnaire. 11 patients answered English KDQOL. Since our objective was to find validity and reliability of Marathi KDQOL, we used the information of 64 +29 = 93 patients who completed Marathi KDQOL.

Demographic and clinical characteristics of study participants are summarized in Table 1. Average age of the patients was 57 ± 12 years. 71% were men. 40 (43%) patients were graduate and/or above level of education. Only 22% were engaged in full time job and 7% were doing part time jobs. 32% of the participants' annual income level was above Rs 500,000. 8% of the participants said they did not know their income level. 32% of the patients had medical insurance.

Table 2 reports KDQOL scores. Burden of kidney disease had reported the lowest score (25.87 ± 24.83) and staff support has reported the highest score of (88.037 ± 17.95). Average scores for Quality of Life subscales, general health, Role physical and Physical function ranged between 40 to 45. Average scores for Bodily pain, social function and Emotional Wellbeing ranged from 61 to 64 while Role emotional was 57 and Energy Fatigue were nearly 50.

Co-morbidities observed were diabetes (57%), hypertension (77%) and HD (27%). 39% showed edema. We had haemoglobin readings for 58 patients. Average haemoglobin was 9.5 ± 2.1 while, average albumin was 3.4 ± 0.4 for 22 patients.

Very few people (< 50%) had answered the question on sex. Therefore we did not use it for analysis.

INTERNAL CONSISTENCY RELIABILITY ASSESSED BY CRONBATCH ALPHA: Table 2 reports mean and standard deviation, and internal consistency reliability coefficients. Except for work status and quality of social support, reliability coefficients were above 0.6 for Kidney disease targeted scales as well as quality of life scales.

TEST–RETEST RELIABILITY: We could get retest scores for only 12 patients. Paired t test for these 12 patients showed that there was no significant difference between test scores and re test scores of all the sub scales (not shown).

We compared reliability scores of our population with reliability scores from US, Japan, Korea and Singapore (Table 4). Reliability coefficients for our sample were similar to reliability from Korea, Japan, Singapore and US except for Social interaction.

CONSTRUCT VALIDITY: When looked at correlation between overall health and kidney disease targeted scales, six out of ten subscales showed significant association with symptom problem list, effect of kidney disease, burden of kidney disease, sleep, effect of social interaction and work status. All subscales of Quality of life (QOL) showed highly significant ($p<.0001$) association with overall health (Table 3).

We also observed significant association between some of the KDQOL-SF^{TM} subscales with demographic variables. Education showed association with emotional well-being ($r = .223$, $p = .034$) and symptom/ problem list ($r = .309$, $p = .003$). Income showed association with sleep ($r = .231$, $p = .026$).

Higher correlation coefficients were observed between items within the scale for 90% of the time as compared to items outside the scales (not shown).

SIGNIFICANT DIFFERENCES (MEAN ± STANDARD ERROR): Significant differences were observed between those who had no history of hypertension showing high scores on QOL and those who had known hypertension showing low QOL scores for energy fatigue (mean ± st error: 63.80 ± 4.7 vs 46.59 ± 3.1; $p = .007$), effect of kidney disease (71.69 ±4.5 vs 59.28 ± 3.1; $p = .05$), role emotional (74.99 ± 7.6 vs 52.31 ± 5.5; $p = .047$), role physical (71.25 ± 5.8 vs 34.38 ± 5.1; $p = .001$), and Physical function (70.75 ± 5.3 vs 38.40 ± 3.09; $p<.0001$).

Significant difference ($p = 0.019$) was observed between those with no history of DM and patients with history of DM for physical function (mean ± standard error: 53.58 ± 4.5 vs 39.43 ± 3.86).

When differences of < 8 and >/= 8 HB levels were tested, significant difference ($p = 0.022$) was observed only with physical function (mean ± standard error: 17.5 ± 10.57.43vs 50.52 ± 6.05) indicating better physical function for patients with high haemoglobin levels.

Significant difference (p = 0.021) was observed between patients with age <57* years and patients with age ≥57 years for physical function (mean ± standard error: 54.85 ± 4.54 vs 40.47 ± 3.92). (* using average age as cut off) indicating lower physical function with increasing age.

EPO dose showed significant –ve correlation with role emotional (r= -.331, p =.026), pain (r = -.309, p =.036) and symptom/problem list (r = -.382, p =.010). This indicates as EPO dose increased, patients suffered less from chest pain, crams, itchy/ dry skin, and shortness of breath and washed out or drained, they did not have to cut down their time on work or other activities and could do activities more carefully.

Frequency of dialysis was 3 times a week for 50% of the patients. Patients who were dialyzing thrice a week showed significantly better physical function and role physical as compared to those who were dialyzing less than thrice a week (60.6±4.3 vs 36.4± 3.2; p<.0001 and 54.5 ± 5.2 vs 34.6 ± 6.3; p =.017).

As time (number of months) on dialysis increased, role emotional (r = 0.239, p =0.019) and role physical (r =.237, p = 0.020) improved showing significant association.

We looked at the correlation coefficients between Kidney Disease Targeted Scales and SF-36 Quality of Life Scales. We observed that in a 18 by 18 matrix (not shown), Staff support and Work Status did not show significant correlation with Sleep, Quality of Social interaction, Cognitive Function, Symptom problem/ list, General Health, Social support, and Burden of Kidney Disease.

Encouragement from Dialysis staff, and support from Dialysis staff in coping patient's kidney disease showed association with half of important QOL subscales such as Role emotional (r =.289, p =.003), Role physical (r = 0.205, p =.038), Energy fatigue (r =.194, p = 0.049), Social function (r =.282, p =.003), Pain (r =.307, p =.002), Patient satisfaction (r -=.359, p <.0001) and Physical function (r =.280, p =.004).

Gender wise, significant difference was observed only with sleep. Women could sleep better compared to men (73.5 ± 3,4 vs 63.3 ± 2.8, p = 0.038).

In summary, our KDQOL scores were comparable with same scores from US population. Reliability of KDQOL subscales was good and similar to reliability of patients from Japan, Singapore, US and Korea. We could also show test re-test reliability though the number was small. Association of KDQOL subscales with demographic and clinical parameters proved the validity.

DISCUSSION: Most of the earlier studies that have assessed the validity of the KDQOL-SF™ did so in the context of a Western population, while few countries in South East Asia have used the KDQOL-SF™. In India, this is the first time KDQOL-SF™ has been translated into Marathi language and validated.

QOL scores for our study were comparable with scores from US population.[10] Our findings suggest that the KDQOL-SF™ demonstrated an acceptable level of reliability and validity for use in understanding quality of life among hemodialysis patients in Pune. The results of this cross sectional study provided valuable information for the understanding of quality of life among patients on hemodialysis in Pune.

Results of this study showed that the reliability coefficients were similar to reliability coefficients obtained from the similar studies in Japan, Korea, US[9] and Singapore,[8] US Spanish[14] except for work status, quality of social interaction and social status where ά was lower for patients in Pune.

For six out of eight quality of life sub scales, reliability coefficients were above 0.8 and for the two subscales they were between 0.6 and 0.8. The reliability coefficients were good i.e. > 0.8 for symptom/problem list, effect of kidney disease, burden of kidney disease. It was between 0.6 and 0.8 for cognitive function and sleep. Cronbatch alpha was 0.5 for social support and <.5 for work status and quality of social interaction.

Construct validity was established by looking at correlation between overall health rating scale and quality of scale as well as overall rating scale and kidney disease targeted scales. Our results were similar to results from a study carried out in Korea[9] except for sleep and cognitive function.

Strong relation was observed between overall health and all QOL subscales, except for social support, staff support and cognitive function.

As expected, we found that increased age was associated with a corresponding decrease in Physical function. This result is consistent with the result from a similar study carried out in Singapore.[8]

Increase in EPO dose, thrice a week frequency of dialysis and time on dialysis showed linier relationship with QOL subscales. Clinical parameters such as EPO dose showed significant ($p<.05$) inverse relation with Role emotional, Pain and Symptom/problem list. Lower haemoglobin levels were associated with lower QOL in terms of Physical function.

Support and encouragement from dialysis staff showed association with quality of life.

All these results support the use of KDQOL-SF™ with Marathi speaking hemodialysis patients in Pune. The results indicated that work status did not show any association with QOL subscales. Work status wise, 22% were engaged in full time jobs while others were retired or doing household work. The questions asked under work status only asked if you are able to work full time or part time. Under Indian culture, even if the lady considers herself as housewife, she is engaged in doing full time or part time work at home. However housework does not come under full time or part time employment in western culture. The questions under these subscales may not be suitable for our culture and therefore the reliability scores were not very impressive and correlation was not significant. More studies are needed to look at items under the sub scales: work status, and quality of social interaction.

LIMITATIONS: We could get very few patients for the re-test. Response rate for the re test could have been enhanced by the renal physicians personally contacting each patient to encourage participation. Secondly, since this instrument had been tested and retested for different populations and has been proven reliable and valid, we decided to conduct only the cross-sectional study to establish the reliability and validity for ESRD patients in Pune.

Future studies should check the test-retest reliability of the KDQOL-SF™ and examine the associations of QOL with demographic characteristics. More Clinical information such as pre and post dialysis BUN, pre and post dialysis weight should also be collected to analyze the effect of

clinical parameters on QOL, and to gain a greater understanding of the possible associations between QOL scores and clinical outcomes.

CONCLUSION: Our findings suggest that the KDQOL-SF™ demonstrated an acceptable level of reliability (as indicated by Cronbach's α values) and validity for use in understanding quality of life among haemodialysis patients in Pune, India. The results of this cross-sectional study provide valuable information for the understanding of HRQOL among patients on haemodialysis in Pune.
The study has shown that Marathi version of KDQOL is reliable and valid and can be used to understand quality of life of dialysis patients.

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APPENDIX A: To suit the culture, there were some modifications in the Marathi version of KDQOL as mentioned in the table below.

ENGLISH	MARATHI
Q.03 Does your health now limit you in the following activities? Option H) walking several blocks Option I) walking one block	**Q. 03** Does your health now limit you in the following activities? Option H) walking for a mile Option I) walking around 200 feet
Q.32 How do you describe yourself? African American or black Hispanic or Latino Native American or American Indian Asian or Pacific Islander White Other (please specify)	**Q.32** What is your religion? Hindu Muslim Christian Buddha Parse Other
Q.35 What kind of health insurance do you have? None, I have no health insurance Medicare only Medicare and any other insurance Medicaid or Medi-Cal only Private, fee for service health insurance (prudential, aetna, etc) HMO, PPO, IPA or other prepaid plan (e.g., Kaiser, Cigna, FHP, etc.) Other	**Q.35** What kind of health insurance do you have? None, I have no health insurance CGHS, ECHS, KGS like government schemes Private, fee for service health insurance Private personal scheme Other
Q.36 What was your total household income? Options mentioned in Dollars	**Q.36** What was your total household income? Options mentioned in rupees

Demographics	No (%)
Age (years) (missing =5)	
< 40	12 (13.6%)
40 – 60	30 (34.1%)
>60	46 (52.3%)
Mean ± STD	56.79 ± 12.52
Gender	
Male	66 (71%)
Female	27 (29%)
Education (Illiterate=1)	
Below Graduate	52 (56.5%)
Above graduate	40 (43.5%)
Occupation (missing=3)	
Working	26(28.9%)
Non-working	64(71.1%)
Family Income (Rs)/annum (Missing=7)	
Below Rs. 2,00,000/-	21(24.4%)
Rs. 2,00,000 to Rs. 5,00,000	35(40.7%)
Above Rs 5,00,000	30(34.9%)
Insurance	
Yes	30(32.3%)
No	63(67.7%)
Co morbidities (Yes)	
HBP	72(77.4%)
DM	53(57%)
HD	25(26.9%)
EDEMA	36(39.1%)
HB (n=58)	9.85 ± 2.06
ALB (n=22)	3.46 ± 0.39
CA (n=36)	10.57 ± 12.95
P (n=47)	6.38 ± 8.55

Table 1: Demographic and clinical Characteristics of Dialysis patients in Pune (N = 93)

Characteristics	N	Mean ± Std. for Pune	Mean ± Std US*	Internal consistency reliability Pune	Internal consistency reliability US*
Sympton/ problem list	92	74.55 ±16.31	71.21± 16.27	0.84	0.84
Effect of kidney disease	93	62.08 ±25.60	57.3 ± 24.53	0.89	0.82
Burden of kidney disease	93	25.87 ± 24.83	49.62 ± 30.27	0.82	0.83
Work status	93	52.68 ±35.63	25.26 ± 37.82	0.47	0.83
Cognitive function	93	82.29 ±19.17	79.11 ± 19.75	0.61	0.68
Quality social interaction	93	73.76 ± 18.48	76.75 ± 18.71	0.20	0.61
Sleep	93	65.027 ± 22.59	60.68 ± 28.61	0.68	0.90
Social support	93	84.59 ± 20.58	64.61 ± 27.73	0.53	0.89
Staff encouragement	93	88.03 ± 17.96	69.90 ± 29.19	0.84	0.90
Patient satisfaction	93	62.18 ± 15.17	71.38 ± 22.04	NA	NA
36-item health survey scales					
Physical function	92	45.43 ± 28.92	51.83 ± 29.73	0.92	0.92
Role physical	92	42.39 ±43.18	32.46 ± 39.68	0.89	0.87
Bodily Pain	93	64.49 ±28.05	49.62 ± 30.27	0.68	0.90
General health	93	40.53 ±18.17	42.88 ± 24.32	0.60	0.78
Emotional well being	91	61.23 ±22.57	69.34 ± 20.36	0.78	0.80
Role emotional	92	57.25 ±45.38	57.76 ± 43.90	0.89	0.86
Social function	93	61.56 ±34.09	63.57 ±29.77	0.91	0.87
Energy fatigue	93	50.48 ±26.20	45.89 ± 24.06	0.85	0.90

Table 2: Central tendency, variability and Reliability of KDQOL-SF™ scales

[Participants from US and Pune, India. (N = 93)]

*Ref: KDQOL_SF™ user manual version 1.3, Page 13.

Characteristics	N	r	P VALUE
Kidney disease targeted			
Symptom/problem list	92	0.489**	<0.0001
Effect of kidney disease	93	0.511**	<0.0001
Burden of kidney disease	93	0.442**	<0.0001

Work status	93	0.312**	0.002
Cognitive function	93	0.170	0.103
Quality social interaction	93	0.221*	0.033
Sleep	93	0.444**	<0.000
Social support	93	0.142	0.174
Staff support	93	0.078	0.459
Patient satisfaction	93	0.169	0.105
36-item health survey scales			
Physical function	93	0.460**	<0.0001
Role physical	92	0.375**	<0.0001
Bodily Pain	93	0.414**	<0.0001
General health	-	0.508**	<0.0001
Emotional well being	91	0.479**	<0.0001
Role emotional	92	0.391**	<0.0001
Social function	93	0.450**	<0.0001
Energy fatigue	93	0.483**	<0.0001

Table 3: Pearson Correlation coefficient between Kidney Disease targeted Scales and overall health rating scale, Quality of life scales and overall health rating scale

Variables	Korea	Japan	Singapore	Pune (India)
Symptom/problem list	0.85	0.84		0.84
Effect of kidney disease	0.82	0.79		0.89
Burden of kidney disease	0.74	0.81		0.82
Work status	0.68	0.69		0.47
Cognitive function	0.64	0.73		0.61
Quality social interaction	0.58	0.35		0.20
Sleep	0.45	0.61		0.68
Social support	0.78	0.76		0.53
Staff support	0.84	0.80		0.84
36-item health survey scales				
Physical function	0.92	0.90	0.95	0.92
Role physical	0.88	0.88	0.89	0.89
Bodily Pain	0.73	0.83	0.85	0.68
General health	0.65	0.80	0.77	0.60
Emotional well being	0.74	0.83	0.74	0.78
Role emotional	0.90	0.92	0.92	0.89
Social function	0.73	0.73	0.66	0.91
Energy fatigue	0.67	0.81	0.72	0.85

Table 4: Comparison of Cronbatch Alpha reliability with Korean, Japan, US and Singapore patients

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Date of Submission: 02/01/2015.
Date of Peer Review: 03/01/2015.
Date of Acceptance: 19/01/2015.
Date of Publishing: 24/01/2015.