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

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Objective: Evaluate the reliability and validity of the Kidney Disease Quality of Life Short Form 36 (KDQOL-36™) in Hispanics with mild-to-moderate chronic kidney disease (CKD).

Design: Cross-sectional

Setting: Chronic Renal Insufficiency Cohort Study

Participants: 420 Hispanic (150 English- and 270 Spanish-speakers), and 409 non-Hispanic White individuals, matched by age (mean 57 years), sex (60% male), kidney function (mean estimated glomerular filtration rate 36ml/min/1.73m^2), and diabetes (70%).

Methods: To measure construct validity, we selected instruments, comorbidities, and laboratory tests related to at least one KDQOL-36™ subscale. Reliability was determined by calculating Cronbach's alpha.

Results: Reliability of each KDQOL-36™ subscale [SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS), Symptoms/Problems, Burden of Kidney Disease and Effects of Kidney Disease] was very good (Cronbach's alpha >0.8). Construct validity was supported by expected negative correlation between MCS scores and the Beck Depression Inventory in all three subgroups ($r = -0.56$ to -0.61, $P<.0001$). There was inverse correlation between the Symptoms/Problems subscale and the Patient Symptom Form ($r = -0.70$ to -0.77, $P<.0001$). We also found significant, positive correlation between the PCS score and a physical activity survey ($r = +0.29$ to $+0.38$, $P \leq .003$); and between the PCS and MCS scores and the Kansas City Questionnaire ($r = +0.31$ to $+0.64$, $P<.0001$). Reliability and validity were similar across all racial/ethnic groups analyzed separately.

Conclusion: Our findings support the use of the KDQOL-36™ as a measure of HRQOL in this cohort of US Hispanics with CKD. (*Ethn Dis.* 2013;23[2]:202-209)

Key Words: Validation, Quality of Life, Hispanics

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Introduction

Hispanics, the largest minority group in the United States,[1] are more likely to progress to end-stage renal disease (ESRD) than non-Hispanic Whites,[2] and experience a substantial psychosocial burden resulting from comorbidities (eg, diabetes), and the difficulties of living with a chronic disease.[3] Despite the magnitude of this problem, there are no validated measures to assess health-related quality of life (HRQOL) for Hispanics with mild-to-moderate chronic kidney disease (CKD).

HRQOL has been increasingly recognized as an important medical outcome in patients with CKD.[4,5] A commonly used measure is the Kidney Disease Quality of Life (KDQOL™), which is a 134-item instrument designed to assess generic and kidney-disease targeted aspects of quality of life for individuals on dialysis.[6] An abbreviated version of the KDQOL™, KDQOL-36™, has been translated to Spanish and used in the United States;[7] however, it has not been adequately validated. In addition, the English version of the KDQOL-36™ has not been validated in the US Hispanic population. We studied the validity and reliability of the US Spanish and English versions of the KDQOL-36™ among Hispanic individuals with CKD enrolled in the Chronic Renal Insufficiency Cohort (CRIC) Study and the Hispanic CRIC (HCRIC) Study.

Methodology

Study Design and Participants

We conducted a cross-sectional study of 150 English- and 270 Spanish-speaking Hispanic, and 409 non-Hispanic White adult participants in the CRIC and HCRIC Studies, frequency-matched by age, sex, kidney function, and diabetes mellitus. The design, methods and characteristics of the CRIC and HCRIC Study participants have been previously reported.[8–10] In brief, the CRIC Study is a prospective cohort of 3612 individuals aged 21 to 74 years with mild-to-moderate CKD according to age-based estimated glomerular filtration rate (eGFR) inclusion criteria, recruited from seven clinical centers across the United States from May 2003 to March 2007. HCRIC is a parallel study to the CRIC Study that recruited 327 Hispanic

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individuals from the Chicago area between October 2005 and June 2008. Among Hispanic participants, 69% were Mexican American, 16% were Puerto Rican, and 15% had other Latin American ancestry. Protocols for both studies were approved by the Institutional Review Board of each participating Institution and are in accordance with the principles of the Declaration of Helsinki. All participants provided informed consent.

Variables and Measurements

Sociodemographic characteristics, medical history and medications were self-reported at the baseline study visit. Blood pressure (BP) and anthropometric measurements were obtained using standard methods. The CRIC Study definitions of hypertension, diabetes mellitus and history of cardiovascular disease (CVD) have been published elsewhere.[9] Glomerular filtration rate was estimated using the four-variable Modification of Diet in Renal Disease (MDRD) equation.[11]

Participants self-administered the KDQOL-36™ in their language of preference (Spanish or English) at study entry. The KDQOL-36™ is a measure of kidney disease-related quality of life that comprises four subscales: Generic core [Physical Component Summary (PCS, 12 items) and Mental Component Summary (MCS, 12 items)]; Symptoms/Problems (12 items); Burden of Kidney Disease (4 items), and Effects of Kidney Disease (8 items).[6,7] Scores of the different subscales were calculated according to the KDQOL-36™ scoring program.[12,13] Raw, precoded numeric values for each item were transformed linearly to a 0 to 100 range, with higher scores reflecting better quality of life.[13] Subsequently, the scores for the PCS and MCS were converted to T-scores with a mean of 50 and a standard deviation of 10. Most questions in the KDQOL-36™ are focused on the underlying health status during the preceding four weeks. Two items regarding problems with access to dialysis site were not answered because none of the participants were on dialysis at study entry. The KDQOL-36™ US Spanish version was adapted from an existing Spain Spanish version by FACITtrans (affiliate of the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System).[7] This process involved: harmonization of the Spain Spanish version with the existing US Spanish RAND-36; review and suggested modifications by two native Spanish-speaking translators; reconciliation of suggestions by a Consensus Committee; back-translation of modifications into US English by one native English-speaker fluent in Spanish; comparison to the source US English version of the KDQOL-36™ and rating of equivalence by a KDQOL Working Group project coordinator (Benjamin Arnold, www.FACITtrans.org, personal communication).

Statistical Methods

Summary statistics for demographic and KDQOL-36™ subscales were calculated for all three subgroups (Spanish- and English-speaking Hispanics, and non-Hispanic Whites) as a whole and then separately. We used Chi-squared tests for dichotomous variables and analysis of variance (ANOVA) for continuous variables to test differences between groups. When the overall ANOVA was statistically significant ($P<.05$), it was followed by a Tukey's multiple comparisons procedure to determine which pairwise comparisons were statistically significant. In addition, we conducted multiple adjusted comparisons on the least squares means of each KDQOL-36™ subscale score across the three groups. Spearman correlations were used to capture the strength of the monotonic relationship between variables without confining the shape of the relationship to be linear.

Reliability and Validity of the KDQOL-36™

Internal consistency reliability was estimated using Cronbach's alpha for each subscale of the KDQOL-36™. A Cronbach's alpha of >0.7 was considered high internal consistency. For analysis of construct validity we selected instruments, comorbidities, and laboratory tests that were expected to be correlated with at least one of the KDQOL-36 ™ subscales. The first measure of construct validity was the correlation between the overall health rating score (the first item of the KDQOL-36™) and each of the KDQOL-36™ subscales score. Second, we calculated the correlations between the generic core of the KDQOL-36™ and selected measures expected to be correlated with the PCS or MCS including the Beck Depression Inventory (BDI), a 21-item instrument to measure depression;[14] the Multi-Ethnic Study of Atherosclerosis (MESA) Typical Week Physical Activity Survey (TWPAS), which measures how much physical activity of different intensities is undertaken by the study participant summarized as the metabolic equivalent (MET) score for all intentional exercise;[15] and the Kansas City Cardiomyopathy Questionnaire (KCCQ), which focuses on HRQOL in patients with congestive heart failure.[16] Third,

we selected several measures that were expected to be correlated with the kidney-disease specific subscales of the KDQOL-36™ including the Patient Symptom Form derived from a review of the MDRD Study database for symptoms commonly reported in that study,[17] and the Davies comorbidity score.[18] We did not have sufficient data to calculate the Charlson Index used in other validation studies.[19] However, the Davies comorbidity score has similar prognostic value[20] and has been used by other studies of HRQOL in ESRD patients.[21,22] This index (possible range from 0 to 7) comprises seven domains of active comorbid disease including malignancy, ischemic heart disease, peripheral vascular disease, left ventricular dysfunction, diabetes mellitus, systemic collagen vascular disease and other significant pathology (a condition severe enough to have an impact on survival in the general population, such as severe chronic obstructive pulmonary disease).[18] Lower hemoglobin and albumin levels were also evaluated and expected to be associated with lower HRQOL.

RESULTS

Demographic and clinical characteristics of study participants are summarized in Table 1. Compared with non-Hispanic Whites (W), Spanish-speaking Hispanics (SH) were more likely to have 6th grade education or less, lower hemoglobin, and less likely to have a self-reported history of CVD. Compared with non-Hispanic Whites, English-speaking Hispanics (EH) were more likely to be younger, have lower hemoglobin, and greater self-reported hypertension; and less likely to have a high school diploma.

Statistical Properties and Reliability of the KDQOL-36™

The mean scores for each KDQOL-36™ subscale ranged from 45.0 (MCS) to 83.0 (effects of kidney disease) among Spanish-Speaking Hispanics; from 37.8 (PCS) to 87.1 (effects of kidney disease) among English-Speaking Hispanics; and from 41.2 (PCS) to 88.8 (effects of kidney disease) among non-Hispanic whites (Table 2). The majority of the dimensions did not suffer from ceiling effects. However, burden of kidney disease and effects of kidney disease had high percentages of floor effects. Internal consistency reliability for all the subscales was very good with Cronbach's alpha values ranging from 0.80 to 0.87 (Table 2). The largest pairwise difference in Cronbach's alpha across ethnicity/language subgroups within any KDQOL-36™ subscale was 0.03.

Construct Validity of the KDQOL-36™

The overall health rating score correlated inversely with all of the KDQOL-36™ subscales among all three subgroups (Tables 3). Of the generic domains, the strongest correlation with the overall health rating scale was seen

Table 1. Demographics and KDQOL-36 subscale scores overall and by participants' group

Variable	Total *N*=829	Spanish-Speaking Hispanics Group 1 *n*=270	English-Speaking Hispanics Group 2 *n*=150	Non-Hispanic Whites Group 3 *n*=409	*P*	Significant[b] Pairwise Differences
						Group 1 vs 2
Age, mean (SD)[a]	57.0 (11.6)	58.1 (10.6)	53.8 (12.8)	57.4 (11.6)	<.001	Group 2 vs 3
Male, *n* (%)	497 (60%)	163 (60%)	90 (60%)	244 (60%)	.9	n/a
Education *n* (%)					<.001	
≤ 6th grade	183 (22.1%)	147 (54.4%)	35 (23.3%)	1 (0.24%)		Group 1 vs 2
7th–12th grade	121 (14.6%)	60 (22.2%)	40 (26.7%)	21 (5.1%)		Group 1 vs 3
>12th grade	525 (63.3%)	63 (23.3%)	75 (50.0%)	387 (94.6%)		Group 2 vs 3
Creatinine, mg/dL, mean (SD)	1.9 (0.56)	1.9 (0.64)	2.0 (0.59)	1.9 (0.48)	.01	Group 2 vs 3
eGFR[c] ml/min/1.73m^2 mean (SD)	35.9 (11.0)	36.0 (11.7)	34.4 (11.1)	36.4 (10.5)	.2	n/a
						Group 1 vs 3
Hemoglobin, g/dL, mean (SD)	12.3 (1.8)	11.8 (1.7)	12.0 (2.2)	12.7 (1.7)	<.001	Group 2 vs 3
						Group 1 vs 3
Serum albumin, g/dL, mean (SD)	3.8 (0.52)	3.7 (0.53)	3.6 (0.60)	4.0 (0.43)	<.001	Group 2 vs 3
History of diabetes, *n* (%)	580 (70%)	186 (69%)	109 (73%)	285 (70%)	.7	n/a
History of hypertension, *n* (%)	724 (87%)	242 (90%)	139 (93%)	343 (84%)	.008	Group 2 vs 3
History of CVD[d], *n* (%)	264 (32%)	64 (24%)	51 (34%)	149 (36%)	.002	Group 1 vs 3
Davies Comorbidity Score, mean (SD) (range 0 to 7)	1.25 (0.99)	1.13 (0.85)	1.29 (0.99)	1.31 (1.07)	.06	n/a

[a] SD, standard deviation.
[b] by Bonferroni adjustment, alpha level for statistical significance is 0.0167.
[c] eGFR, estimated glomerular filtration rate.
[d] CVD, cardiovascular disease.

Table 2. Statistical properties and internal consistency reliability of each KDQOL-36™ subscale by participants' group

KDQOL-36™ Subscale	Mean (SD)	Ceiling, %	Floor, %	Reliability
				Cronbach's α
Spanish-Speaking Hispanics, *n*=270				
Burden of kidney disease	59.1 (29.4)	3.7	20.8	0.84
Symptoms/problems	80.6 (15.2)	0	5.6	0.83
Effects of kidney disease	83.0 (17.6)	0	21.9	0.82
Physical component summary	40.1 (10.2)	0	0	0.84
Mental component summary	45.0 (11.5)	0	0	0.81
English-Speaking Hispanics, *n*=150				
Burden of kidney disease	65.0 (30.1)	3.4	27.5	0.87
Symptoms/problems	80.4 (15.7)	0	8.7	0.82
Effects of kidney disease	87.1 (17.6)	0	36.2	0.83
Physical component summary	37.8 (10.7)	0	0	0.82
Mental component summary	49.2 (11.4)	0	0	0.80
Non-Hispanic Whites, *n*=409				
Burden of kidney disease	83.9 (20.8)	0	44.7	0.85
Symptoms/problems	83.9 (14.1)	0	7.3	0.83
Effects of kidney disease	88.8 (14.5)	0	32.9	0.81
Physical component summary	41.2 (11.5)	0	0	0.84
Mental component summary	50.9 (9.9)	0	0	0.82

with the PCS (r= −0.58 [EH], −0.54 [SH] and −0.65 [W]). Of the kidney disease-specific domains, the strongest correlation was found for the Symptoms/problems subscale (r= −0.46 [EH], −0.50 [SH] and −0.54 [W]). We also found significant negative correlation between the BDI and MCS scores (r= −0.56 [EH], −0.59 [SH], and −0.61 [W]). There was significant negative correlation between the Davies comorbidity score and the PCS scores (r= −0.32 [EH], −0.30 [SH], and −0.37 [W]). We also found significant positive correlation between the KCCQ clinical summary and the PCS scores (r= +0.48 [EH], +0.38 [SH], and +0.64 [W]). The Patient Symptom Form score had a significant, negative correlation with the Symptoms/problems subscale (r= −0.71 [EH], −0.70 [SH], and −0.77 [W]).

Table 3. Spearman correlations between KDQOL-36™ subscales and independent measures by participants' group

KDQOL-36™ Subscale	Independent Measure	Spearman correlation (*P*)		
		English Speaking Hispanics (*n*=150)	Spanish Speaking Hispanics (*n*=270)	English Speaking Non-Hispanics (*n*=409)
Burden of kidney disease	Overall health rating score	−0.44 (<.001)	−0.37 (<.001)	−0.42 (<.001)
	Davies comorbidity score	−0.04 (.6)	−0.18 (.003)	−0.11 (.03)
	Hemoglobin	0.12 (.2)	0.03 (.6)	0.20 (<.001)
Symptoms/problems	Overall health rating score	−0.46 (<.001)	−0.50 (<.001)	−0.54 (<.001)
	Davies comorbidity score	−0.16 (.05)	−0.22 (<.001)	−0.22 (<.001)
	Patient symptom form	−0.71 (<.001)	−0.70 (<.0001)	−0.77 (<.001)
	Hemoglobin	0.13 (.1)	0.10 (.1)	0.18 (<.001)
Effects of kidney disease	Overall health rating score	−0.36 (<.001)	−0.37 (<.001)	−0.37 (<.001)
	Davies comorbidity score	0.01 (.9)	−0.13 (.04)	−0.16 (.001)
	Hemoglobin	0.06 (.5)	0.08 (.2)	0.15 (.002)
SF-12 physical component summary	Overall health rating score	−0.58 (<.001)	−0.54 (<.001)	−0.65 (<.001)
	Davies comorbidity score	−0.32 (<.001)	−0.30 (<.001)	−0.37 (<.001)
	KCCQ[a] clinical summary	0.48 (<.001)	0.38 (<.001)	0.64 (<.001)
	Serum albumin	0.18 (.03)	−0.01 (.9)	0.18 (<.001)
	Hemoglobin	0.22 (.007)	0.14 (.02)	0.19 (<.001)
	TWPAS[b]	0.30 (<.001)	0.29 (<.001)	0.38 (<.001)
SF-12 mental component summary	Overall health rating score	−0.32 (<.001)	−0.44 (<.001)	−0.29 (<.001)
	Beck depression inventory	−0.56 (<.001)	−0.59 (<.001)	−0.61 (<.001)
	Davies comorbidity score	−0.08 (.3)	−0.11 (.07)	0.02 (.70)
	KCCQ clinical summary	0.36 (<.001)	0.31 (<.001)	0.33 (<.001)

[a] Kansas City Cardiomyopathy Questionnaire.
[b] Typical Week Physical Activity Survey.

Table 4. Adjusted[a] regression models for KDQOL-36 subscales scores comparing Spanish- and English-Speaking Hispanics vs Whites

KDQOL-36™ Subscale	Spanish-Speaking Hispanics (Group 1) *n*=270	English-Speaking Hispanics (Group 2) *n*=150	Non-Hispanic Whites (Group 3) *n*=409	*P*	Significant Pairwise Differences[b]
	Least Square Means (Standard Error)				
Burden of kidney disease	60.5 (2.1)	66.0 (2.5)	79.5 (2.3)	<.001	Group 2 vs 3 Group 1 vs 3
Symptoms/problems list	80.0 (1.2)	80.9 (1.5)	82.4 (1.3)	.3	n/a
Effects of kidney disease	82.2 (1.3)	88.3 (1.6)	88.7 (1.4)	.001	Group 1 vs 2 Group 1 vs 3
SF-12 physical component	39.5 (.9)	37.0 (1.0)	38.8 (.9)	.07	n/a
SF-12 mental component	45.7 (.9)	50.4 (1.1)	52.0 (1.0)	<.001	Group 1 vs 2 Group 1 vs 3

[a] Adjusted for age, educational attainment, serum creatinine, hemoglobin, albumin, history of hypertension, CVD, and Davies comorbidity score.
[b] Using Tukey's multiple comparisons procedure.

KDQOL-36™ Scores by Language and Ethnic/ Racial Group

After adjustment for clinical and demographic characteristics, the scores of three KDQOL-36™ subscales (Burden of Kidney Disease, Effects of Kidney Disease and MCS) were significantly lower in Spanish-speaking Hispanics than in non-Hispanic Whites ($P<.01$) (Table 4).

DISCUSSION

In these cohorts of US Spanish- and English-speaking Hispanics with mild-to-moderate CKD, we found that the KDQOL-36™ is a reliable and valid tool to assess HRQOL. Consistent with results from studies validating other language versions of the KDQOL™ instrument, we found significant correlation between each KDQOL-36™ subscale and the overall health rating score.[23–26] Similar to other studies,[23] we found that individuals with depressive symptoms tend to have lower HRQOL as measured by the mental component summary of the KDQOL-36™. Furthermore, the correlation between the Patient Symptom Form score and the Symptoms/Problems subscale of the KDQOL-36™ was strong and in the anticipated direction.

A secondary objective of this study was to evaluate HRQOL in Hispanic and non-Hispanic individuals with mild-to-moderate CKD. Overall, the KDQOL-36™ scores were similar to those reported in other US studies of non-dialysis CKD and kidney transplant recipients,[27,28] and higher than in dialysis patients.[29] Similar to findings from the Dialysis Outcomes and Practice Patterns Study,[29] we observed that Hispanics with CKD had lower HRQOL than non-Hispanics. Hispanics in the United States are known to be at socioeconomic disadvantage,[30] and this is evident in our study cohort by the significant disparities in educational attainment. However, differences in HRQOL between ethnic groups were not fully explained by differences in age, education or clinical factors. The lower HRQOL in Hispanics may also be related to differences in disease burden, which were not measured, or to reporting bias, which is supported by a study by Marin et al[31] suggesting that Hispanics are more likely to choose extreme categories in a response scale.

Our study had several limitations. First, the majority of Hispanics in our study were recruited from a single clinical center perhaps limiting the generalizability of findings. However, the characteristics of Hispanics in CRIC and HCRIC are reflective of the heterogeneity of the US Hispanic population.[1,32,33] Second, the KDQOL-36™ was originally developed for patients with ESRD; however, it has been previously used in non-dialysis CKD individuals.[27,28] Third, the KDQOL-36™ was administered once and we could not evaluate test-retest reliability. Nonetheless, we were able to demonstrate good internal consistency reliability within three different ethnic/ language subgroups.

In conclusion, based on our study findings, the KDQOL-36™ can be used to assess HRQOL in US Hispanics with CKD. Future research is needed to evaluate HRQOL as a predictor for adverse health outcomes and responsiveness to interventions aimed at improving HRQOL in Hispanics with CKD.

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