Psychometric Properties of the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36) in the United States

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Background: The Centers for Medicare & Medicaid Services require that dialysis patients' health-related quality of life be assessed annually. The primary instrument used for this purpose is the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36), which includes the SF-12 as its generic core and 3 kidney disease–targeted scales: Burden of Kidney Disease, Symptoms and Problems of Kidney Disease, and Effects of Kidney Disease. Despite its broad use, there has been limited evaluation of KDQOL-36's psychometric properties.

Study Design: Secondary analyses of data collected by the Medical Education Institute to evaluate the reliability and factor structure of the KDQOL-36 scales.

Settings & Participants: KDQOL-36 responses from 70,786 dialysis patients in 1,381 US dialysis facilities that permitted data analysis were collected from June 1, 2015, through May 31, 2016, as part of routine clinical assessment.

Measurements & Outcomes: We assessed the KDQOL-36 scales' internal consistency reliability and dialysis facility–level reliability using coefficient alpha and 1-way analysis of variance. We evaluated the KDQOL-36's factor structure using item-to-total scale correlations and confirmatory factor analysis. Construct validity was examined using correlations between SF-12 and KDQOL-36 scales and "known groups" analyses.

Results: Each of the KDQOL-36's kidney disease–targeted scales had acceptable internal consistency reliability ($\alpha = 0.83\text{-}0.85$) and facility-level reliability ($r = 0.75\text{-}0.83$). Item-scale correlations and a confirmatory factor analysis model evidenced the KDQOL-36's original factor structure. Construct validity was supported by large correlations between the SF-12 Physical Component Summary and Mental Component Summary ($r = 0.40\text{-}0.52$) and the KDQOL-36 scale scores, as well as significant differences on the scale scores between patients receiving different types of dialysis, diabetic and nondiabetic patients, and patients who were employed full-time versus not.

Limitations: Use of secondary data from a clinical registry.

Conclusions: The study provides support for the reliability and construct validity of the KDQOL-36 scales for assessment of health-related quality of life among dialysis patients.

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Am J Kidney Dis. 71(4): 461-468. Published online November 8, 2017.

doi: 10.1053/j.ajkd.2017.07.020

Patients with a diagnosis of end-stage renal disease (ESRD) must use a renal replacement therapy to sustain life. Of the 678,000 prevalent patients with ESRD in the United States, 71% use some form of dialysis, a process in which a machine filters wastes and excess water from the patient's blood.[1] The majority of these patients receive hemodialysis (90%), whereas a much smaller proportion receive peritoneal dialysis (10%).[1] As the incidence of ESRD has increased during the past 20 years, so has the incidence of patients initiating dialysis therapy: from 1996 to 2014, the number of new patients per year increased from 75,540 to 117,568 in the United States.[1]

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As patient survival on all types of dialysis has improved, care has increasingly focused on enhancing health-related quality of life (HRQoL).[2] According to their *Conditions for Coverage of Dialysis Facilities* (§494.90), the Centers for Medicare & Medicaid Services (CMS) require that all dialysis patients' HRQoL be assessed with an instrument covering their physical and mental health. Then patients' responses to the HRQoL assessment are incorporated into a clinical intervention to develop a personalized plan of care for each patient. The demands of clinical dialysis practice put significant limitations on the available time and necessitate a parsimonious HRQoL assessment. To date, the primary instrument used for this purpose is the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36).[3] Under this requirement, most dialysis patients in the United States are assessed with the KDQOL-36 on at least an annual basis.

The KDQOL-36 was derived from the original 134-item KDQOL instrument[4] and the 79-item Kidney Disease Quality of Life Short-Form Survey (KDQOL-SF).[4] Instead of using the Medical Outcomes Study's 36-Item Short-Form Health Survey (SF-36) as a generic core, as the KDQOL-SF does, the KDQOL-36 includes the Medical Outcomes Study's 12-Item Short-Form Health Survey (SF-12), one of the most widely used generic measures of HRQoL. Furthermore, the KDQOL-36 reduced the number of kidney disease–targeted scales from 11 to 3 and includes the Burden of Kidney Disease (Burden), Symptoms and Problems With Kidney Disease (Symptoms/Problems), and Effects of Kidney Disease (Effects) scales. The items used in these scales are subsets of the KDQOL-SF scales. The original KDQOL scales were supported by a factor analysis, have been found to have adequate to excellent internal consistency reliability, and have evidenced construct validity.[4] Additionally, a factor analysis revealed 4 underlying factors representing general physical health, general mental health, kidney disease–targeted HRQoL, and patient satisfaction.

Although it was created in 2000, to date, there has been little examination of the KDQOL-36's psychometric characteristics among US dialysis patients. One exception is a recent report from Ricardo et al[5] of the KDQOL-36's reliability and validity among English- and Spanish-speaking patients with chronic kidney disease (pre-ESRD) in the Chronic Renal Insufficiency Cohort (CRIC) Study. A significant gap remains around the KDQOL-36's measurement properties among patients with ESRD on dialysis therapy, the primary subgroup that is administered this measure in clinical settings. Given its very broad use in dialysis facilities throughout the United States, it is important that the psychometric properties of the KDQOL-36 are well understood. Therefore, the objectives of this study were to evaluate the factor structure, reliability, and construct validity of the KDQOL-36 kidney-targeted scales with a large US sample of dialysis patients.

Methods

Data Set and Participants

Data for this study were obtained from the KDQOL-Complete scoring service developed by the not-for-profit Medical Education Institute.[6] KDQOL-Complete is aimed at helping dialysis providers meet the CMS requirement to report the number of patients completing the KDQOL-36 instrument each year. This program also uses patients' responses to the KDQOL-36 in the development of a personalized plan of care and permits clinics to share results back to patients in a personalized summary report written at the 6th-grade reading level. The KDQOL-36 is administered to patients during their dialysis treatment using primarily paper-and-pencil administration (tablet administration is used for <1% of surveys). For this study, the Medical Education Institute provided a deidentified data set from clinics that permitted research use of their data from KDQOL-Complete.

Measures

Along with the KDQOL-36, the Medical Education Institute collects dialysis patients' demographic and clinical characteristics. The Medical Education Institute provided a deidentified data set containing patients' responses to the KDQOL-36 from June 1, 2015, through May 31, 2016. Because all data are deidentified, an institutional review board (IRB) exemption was granted by the University of California, Los Angeles Human Subjects Protection Committee (UCLA IRB #17-000313), including waiver from informed consent.

The KDQOL-36 has 36 items: the SF-12 version 1 and another 24 kidney-targeted items. The SF-12 yields the Physical Component Summary (PCS) and Mental Component Summary (MCS), both of which are scored on a T-score metric (mean = 50, standard deviation [SD] = 10, in the US general population).[7] The 3 kidney-targeted scales assess Burden of Kidney Disease, Symptoms and Problems of Kidney Disease, and Effects of Kidney Disease.[8] The Burden scale has 4 items (eg, "My kidney disease interferes too much with my life") that are prompted with the context "How true or false is each of the following statements?" and have 5 response options that range from "Definitely true" to "Definitely false." The Symptoms/Problems scale has 12 items, each representing a symptom or side effect of kidney disease (eg, "Washed out or drained?") that are given the context "During the past 4 weeks, to what extent were you bothered by each of the following?" and have 5 response options ranging from "Not at all bothered" to "Extremely bothered." The Effects scale has 8 items (eg, "Your ability to work around the house?") with the context "How much does kidney disease bother you in each of the following areas?" and the same response options as the Symptoms/Problems subscale. Each of these scales is scored by transforming all items to a 0 to 100 possible range and averaging across the items on each scale to create scale scores. KDQOL-36 items are all scaled so that higher scores indicate better HRQoL.[9] Previously published norms (unadjusted means) for these scales are Burden = 41, Symptoms/Problems = 71, and Effects = 63.[10] Finally, the KDQOL-36 has been translated into more than 25 different languages.[8]

Also documented were patients' race/ethnicity, age, presence of diabetes, dialysis type (in-center hemodialysis, peritoneal dialysis, conventional home hemodialysis, and other types of dialysis, including nocturnal in-center and home hemodialysis and daily home hemodialysis), vascular access site (arteriovenous fistula, arteriovenous graft, venous catheter, and peritoneal dialysis catheter), employment status, and the language of the survey. These variables were collected through CMS Form 2728 in the dialysis facilities or by the dialysis facilities themselves.

Patient Sample Selection

From June 1, 2015, through May 31, 2016, the Medical Education Institute made 77,072 assessments of the KDQOL-36 with dialysis patients in the United States that were available for analysis. Of these, 69,068 were assessments with unique patients, and 8,004 records were of patients with multiple assessments. After selecting the first assessment from those with multiple assessments, 72,982 assessments remained. A further 1,273 assessments were excluded due to uncertainty about the assessment date, and 2 assessments were eliminated for incompleteness, leaving 71,707 assessments from unique patients.