Psychometric Evaluation of the Kidney Disease Quality of Life 36-Item Survey Instrument (KDQOL-36): A Comparison Between Older and Younger Adults Receiving Dialysis

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Medicare requires that dialysis units assess quality of life in all patients annually using the Kidney Disease Quality of Life 36-item survey instrument (KDQOL-36). However, whether the KDQOL-36 is a valid instrument for older adults receiving dialysis is not known. The objective of this study was to evaluate the reliability and validity of the KDQOL-36 in both older and younger patients receiving dialysis. We used KDQOL-36 item responses from a nationally representative sample of 3500 older (≥ 75 years) and 500 younger (ages 21 to 74 years) patients receiving dialysis in 2012. We assessed subscale means, ceiling/floor effects, internal consistency reliability, and construct validity. Results demonstrated that the KDQOL-36 has comparable reliability and validity in older and younger adults receiving dialysis.

INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) requires annual assessments of quality of life for patients on dialysis. As both a clinical performance measure for its Quality Incentive Program and a quality measure for its Comprehensive End-Stage Renal Disease (ESRD) Care Initiative, annual assessments of quality of life are accomplished using a standard instrument that has been validated in dialysis patients—the Kidney Disease Quality of Life 36-item survey instrument (KDQOL-36). Although CMS requires its use with all patients on dialysis, the instrument was initially validated in a relatively young cohort of dialysis patients; only 10% of the initial validation cohort was aged ≥ 75 years (Hays, Kallich, Mapes, Coons, & Carter, 1994). This is an important limitation because adults aged ≥ 75 years constitute at least 30% of prevalent dialysis patients in the United States and represent a large proportion of patients initiating dialysis (Canaud et al., 2011; Jassal & Watson, 2009; U.S. Renal Data System [USRDS], 2014). It is particularly important to have a validated instrument for measuring quality of life in older adults receiving dialysis, due to limited life expectancy and high prevalence of functional and cognitive impairment, with a resulting need for shared decision-making about dialysis discontinuation or change in modality (Fried, O'Leary, Van Ness, & Fraenkel, 2007; Holley, 2007; Kurella Tamura et al., 2009; Murray et al., 2006; Rosansky et al., 2017). In addition to advanced care planning, validated measures are important for assessing novel therapies aiming to enhance quality of life in older dialysis patients.

There are several reasons to suspect that the KDQOL-36 may not perform as well with older patients. KDQOL-36 items cover five domains of quality of life (physical function, mental function, burden of kidney disease, symptoms and problems of kidney disease, and effect of kidney disease on daily life), but these items may yield different responses in older dialysis patients because they tend to have fewer regular daily activities, more physical limitations, and symptoms attributable to geriatric syndromes (Berger & Hedayati, 2012; Bowling et al., 2014; Hays et al., 1994). These differences may also lead to disproportionate floor or ceiling effects, missingness, or other psychometric issues, resulting in poor test performance in the oldest and most vulnerable dialysis patients (Hickey, Barker, McGee, & O'Boyle, 2005). As clinicians, investigators, and policy makers have a growing interest in using patient-reported outcomes in dialysis settings (Peipert & Hays, 2017), it is essential to investigate the psychometric performance of the KDQOL-36 in older adults. We compared the reliability and validity of the KDQOL-36 in older versus younger patients receiving maintenance dialysis.

METHODS

Study Design and Population

We conducted a psychometric evaluation of the KDQOL-36 using data extracted from a large dialysis organization's (LDO) clinical database. We used random selection to identify a nationally representative cohort of 4000 dialysis patients: 3500 of whom were age ≥ 75 years and 500

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of whom were age 21 to 74 years on January 1, 2012. We included a larger number of older patients to account for greater expected variability in functional and frailty status at older ages; however, financial constraints limited our ability to source a comparable number of younger patients in the cohort. All cohort members received care at dialysis units owned by a single LDO and completed at least one KDQOL-36 assessment in 2012. Social workers either supplied a paper copy of the KDQOL-36 for self-administration or they helped patients to fill it out if they were unable to self-administer. The KDQOL-36 was administered to all patients who were able to understand the questions (i.e., patients who did not have severe cognitive impairment). The Duke University Institutional Review Board approved this study.

Variables

Developed to be a shorter instrument than the KDQOL Short Form (KDQOL-SF), the KDQOL-36 is a 36-item instrument with five subscales: 1) SF-12 physical component score (PCS) (items 1 to 12); 2) SF-12 mental component score (MCS) (items 1 to 12); 3) burden of kidney disease (items 13 to 16); 4) symptoms of kidney disease (items 17 to 28); and 5) effects of kidney disease (items 29 to 36) (Hays et al., 1995). For each subject, we used item responses from a single KDQOL-36 assessment that they completed in 2012 to calculate subscale scores (range = 0–100) from individual item responses using standardized formulae. There is no validated composite score for the five KDQOL-36 subscales in routine clinical use.

Additional variables available for the cohort included: 1) demographics [age, race, and gender]; 2) insurance status [Medicare vs. Medicare/Medicaid coverage (i.e., dual-eligibility status)]; 3) laboratory data [hemoglobin, Kt/V (a measure of dialysis adequacy; values > 3.5 considered implausible and not included in analyses), and albumin levels at the time of KDQOL-36 assessment]; and 4) dialysis characteristics [modality (hemodialysis vs. peritoneal dialysis (PD), hemodialysis access type (catheter, arteriovenous fistula (AVF) or arteriovenous graft (AVG), and time on dialysis at the time of KDQOL-36 assessment]. To describe comorbidity burden, we used the most recent Charlson comorbidity index recorded in the LDO's clinical data warehouse from patients' medical history as of January 1, 2012.

Statistical Analysis

We compared the demographic and clinical characteristics by age group using t-tests or chi-square tests, as appropriate. For each age group, we summarized subscale scores by calculating mean and standard deviation and used t-tests to compare scores by age group. We examined the psychometric properties shown in **Table 1.** We assessed for floor and ceiling effects by calculating the percentage of responses within the lowest and highest scores of each KDQOL-36 subscale; we considered floor or ceiling effects to be present if more than 15% of responses were at the lowest or highest scores of each subscale (Terwee et al., 2007). We assessed missingness by calculating the proportion of respondents with one or more missing responses in each subscale. Because the SF-12 has been extensively validated in prior studies, we evaluated internal consistency reliability of only the three kidney disease-specific subscales through corrected item-total correlations. Corrected item-total correlations, as determined by polyserial correlations, reflect the strength of relationship between each KDQOL-36 item and its assigned domain subscale score, not including the item itself (Olsson, Drasgow, & Dorans, 1982). Strong corrected item-total correlations (0.5 or higher) are preferred. For construct validity, we determined Pearson correlation coefficients between KDQOL-36 subscale scores and biological markers that have previously been associated with quality of life, specifically, hemoglobin, Kt/V, and albumin levels (Lacson et al., 2009; Lopes et al., 2007; Spiegel, Melmed, Robbins, & Esrailian, 2008). We performed analyses with Stata version SE 14, and used an unadjusted *P* value of 0.05 (StataCorp, 2015).

RESULTS

Cohort Characteristics

The average age of younger members of this cohort was 52.2 years [standard deviation (SD) = 10.2] (range, 28–74), as compared with 80.5 years (SD = 4.4) (range, 75–102) for older members. Compared to the younger cohort, the older cohort had a higher proportion of Caucasian race and female gender, shorter dialysis vintage, lower hemoglobin, lower albumin, higher Charlson index, smaller proportion receiving PD, and larger proportion of hemodialysis patients with AVF (**Table 2**). All older members of this cohort had Charlson index scores ≥ 5, indicating a high prevalence of patients with multimorbidity likely to have functional dependence and/or frailty.

Subscales Scores, Ceiling and Floor Effects, and Missingness

Figure 1 depicts subscale scores for each age group. Mean subscale scores show that younger and older cohort members scored similarly on the symptom subscale and SF-12 (short form) MCS (mental component score) (**Table 3**). Compared to younger patients, older patients had higher mean scores [74.30 (SD = 21.18) vs. 72.14 (SD = 22.10)] on the effects of kidney disease subscale (indicating fewer issues with how kidney disease affected their daily lives) and lower mean scores [52.54 (SD = 29.37) vs. 56.09 (SD = 29.02)] on the burden of kidney disease subscale (indicating greater sense of burden from having kidney disease) and the SF-12 PCS (physical component score) [34.53 (SD = 9.96) vs. 38.69 (SD = 10.55)] (indicating poorer self-reported physical health). Ceiling and floor effects were not present for any of the five subscales. For all subscales, older cohort members generally had more missing responses than younger cohort members. The effects of kidney disease subscale had the highest proportion of missing responses among both younger and older cohort members.

Internal Consistency Reliability

For both age groups, each kidney disease-specific item of the KDQOL-36 correlated most highly with its hypothesized subscale (**Table 4**) (Korevaar et al., 2002). For the burden subscale, correlation coefficients of Items 13 to 16 ranged from 0.58 to 0.79 for the younger cohort members and 0.63 to 0.77 for the older cohort members. For the symptom subscale, correlation coefficients of Items 17 to 28 ranged from 0.40 to 0.66 for the younger cohort members and 0.41 to 0.63 for the older cohort members. For the effects subscale, correlation coefficients of Items 29 to 36 ranged from 0.49 to 0.71 for the younger cohort members and 0.46 to 0.69 for the older cohort members.

Construct Validity

Subscale scores were not correlated with contemporaneous albumin, hemoglobin, or Kt/V levels. Across subscales and biomarkers, the correlation coefficients ranged from < 0.01 to 0.12 and -0.03 to 0.11 among older and younger cohort members, respectively.

DISCUSSION

To our knowledge, this is the first study designed to compare the psychometric properties of the KDQOL-36 between older (age ≥ 75 years) and younger (ages 21 to 74 years) adults receiving dialysis. For both older and younger adults, we show the KDQOL-36 subscales have minimal floor effects, ceiling effects, and missingness, as well as good internal consistency reliability. This is consistent with a recent study (Peipert, Bentler, Klicko, & Hays, 2017). Also, construct validity with biological markers known to be associated with quality of life was absent in both age groups. However, mean scores differed by age group in three subscales (effects of kidney disease, SF-12 PCS, and burden of kidney disease) (**Figure 1**), suggesting that the quality of life experiences for older and younger patients receiving dialysis are different. Although scores may differ by age groups, the KDQOL-36 has good psychometric performance in patients of all ages for routine quality of life assessments.

The differences in subscale scores we observed are largely consistent with other published studies that report on quality of life. In a peritoneal dialysis cohort, Griva et al. reported higher scores among older vs. younger adults on the effects of kidney disease subscale (Griva et al., 2014). A separate study revealed that older patients scored better on a satisfaction with life scale than their younger counterparts, and argued that greater life satisfaction or differing expectations may account for older patients having higher scores on the effects of kidney disease subscale (Kimmel et al., 1995). Alternatively, older adults on dialysis may represent a select group of individuals who have selected dialysis over palliative care, based on lower symptom burden. Regarding physical health, several studies show that older adults report poorer physical health (lower SF-12 PCS score) than younger patients (Mingardi et al., 1999). Regarding burden of kidney disease, one study demonstrated that dialysis patients with lower physical health scores (SF-36 PCS) tended to have greater concern for being a burden on caregivers (Suri et al., 2011). Older adults also tend to report that the process of traveling to and from dialysis and the treatment itself is a burden and may even affect decisions about whether to initiate and discontinue dialysis treatments (Aggarwal & Baharani, 2014; Johnston & Noble, 2012). Thus, older and younger adults may have different perceptions of factors that are important to their quality of life. Further research is needed to determine quality-of-life domains of greatest importance to older adults receiving dialysis.

Although prior studies demonstrate associations between albumin, hemoglobin, and Kt/V levels and quality of life, we found that KDQOL-36 subscales are not correlated with these markers in either older or younger patients, suggesting that these biological markers and subscales scores measure different constructs. Average values for each of these biological markers approached clinical practice goals, but members of our cohort seldom reported the highest score on any of the KDQOL-36 subscales. This finding implies that achievement of target levels of albumin, hemoglobin, and/or Kt/V may not be sufficient to ensure patients will report good quality of life on the KDQOL-36.

Our study has implications for dialysis social work practice. Currently, social workers present subscale scores to patients and highlight low scores as areas for improvement. To facilitate that communication with patients aged ≥ 75 years, social workers can compare their patients' subscale scores to the average subscale scores that we identified (**Table 2**). Because we found that both the SF-12 physical component score and the burden of kidney disease scores were significantly lower in patients aged ≥ 75 years, compared to younger patients < 75, social workers could also proactively plan clinical and/or psychosocial interventions that enhance these quality-of-life domains. Because older adults may interpret KDQOL-36 items differently than younger patients, social workers would likely understand more about quality of life in older patients by using specific KDQOL-36 item responses as a starting point to inform in-depth conversations about the patient's well-being and what matters most to them.

Our study has limitations. First, all subjects received care from dialysis units belonging to a single LDO in the U.S. The characteristics of patients in this cohort are similar to those of the overall U.S. dialysis population, but may differ from older adults receiving dialysis in other countries by race/ethnicity, comorbidity burden, and age distribution (Canaud et al., 2011). Second, our cohort was limited to subjects who had KDQOL-36 responses, so we could not report on the KDQOL-36's performance among patients who did not have any KDQOL-36 responses or how those patients may differ from our study cohort. Still, our findings are representative because the KDQOL-36 annual assessment is routine for all patients, excluding those with significant cognitive impairment who would need a different approach to assessing quality of life. Last, we did not have access to serial KDQOL-36 assessments in our dataset, so were unable to compare

test-retest reliability or responsiveness to change across age groups. However, prior studies have demonstrated that KDQOL scores can change over time (Bakewell, Higgins, & Edmunds, 2002; Hall et al., 2012).

In summary, the KDQOL-36 appears to be a valid instrument for assessing quality of life in adults aged ≥ 75 years who receive dialysis. As a result, it should remain a valuable tool to inform individualized care that optimizes quality of life in these patients.

RELEVANCE TO NEPHROLOGY SOCIAL WORKERS

Nephrology social workers have the critical role of routine administration of the KDQOL-36 in dialysis units. Although the KDQOL-36 is administered to adult patients of all ages, there is reasonable concern that the KDQOL-36 may not assess quality of life appropriately in older dialysis patients. The study answers the following question: does the KDQOL-36 uncover valid information for both older and younger patients? This study revealed that the KDQOL-36 items and their related subscale scores actually do measure the same underlying aspects (or constructs) of quality of life in both older and younger patients. Thus, the KDQOL-36 subscale scores are useful for both age groups, even if older patients may report lower scores in some subscales. Practically, this study supports continued use of the KDQOL-36 in adult patients of all ages. However, if there is suspicion of worsening quality of life in an older dialysis patient that may not be reflected by their KDQOL-36 subscale scores, nephrology social workers are highly encouraged to ask the patient additional questions beyond the KDQOL-36.

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Table 1. Description of Approach to Psychometric Evaluation of KDQOL-36

Psychometric Property	Research Question	Approach
Ceiling or floor effects	Are there ceiling and floor effects more common among older patients?	Proportion of subscale responses with highest or lowest score
Missingness	Is missingness more common among older adults?	Proportion of items missing within each subscale
Internal consistency reliability	In both age groups, are KDQOL-36 items assigned to the appropriate subscale in both age groups?	Corrected item-total correlations of each item with each kidney-specific subscale score
Construct validity	In both age groups, do the KDQOL-36 subscale scores correlate with biological markers associated with quality of life?	Correlations of KDQOL-36 subscale scores with Kt/V, hemoglobin, and albumin levels

Table 2. Characteristics Of Cohort, Overall And By Age Group

Variable	Total sample (N = 4,000)	75+ years (n = 3,500)	21–74 years (n = 500)	P-value
Demographic characteristics				
Age, year	77.0 (10.9)	80.5 (4.4)	52.17 (10.2)	< 0.001
Race, *n* (%)				< 0.001
Caucasian	1,889 (47.2)	1,786 (51.0)	103 (20.6)	
African-American	1,288 (32.2)	988 (28.2)	300 (60.0)	
Hispanic	533 (13.3)	466 (13.3)	67 (13.4)	
Other	289 (7.2)	259 (7.4)	30 (6.0)	
Men, *n* (%)	2,046 (51.2)	1,770 (50.6)	276 (55.2)	0.053
Insurance status, ***n*** (%)				< 0.001
Medicare only	2,884 (72.1)	2,655 (75.9)	229 (45.8)	
Dual Eligible	1,020 (25.5)	798 (22.8)	222 (44.4)	
Other/None[a]	96 (2.4)	47 (1.3)	49 (9.8)	
Medical history				
Time on Dialysis (years)	6.9 (4.5)	5.9 (2.9)	14.1 (7.0)	< 0.001
Kt/V	1.7 (0.3)	1.7 (0.3)	1.7 (0.4)	0.880
Hemoglobin (g/dL)	10.9 (1.1)	10.8 (1.0)	11.0 (1.5)	0.006
Albumin (gm/dL)	3.9 (0.4)	3.9 (0.4)	4.0 (0.4)	< 0.001
Charlson Comorbidity Index	7.0 (1.8)	7.4 (1.3)	4.0 (1.6)	< 0.001
Modality, *n* (%)				< 0.001
Hemodialysis	3,814 (95.4)	3,358 (95.9)	456 (91.2)	
Peritoneal dialysis	185 (4.6)	141 (4.0)	44 (8.8)	
Access type among hemodialysis patients, *n* (%)				< 0.001
Catheter	380 (10.0)	318 (9.5)	62 (13.6)	
Arteriovenous fistula	2,392 (62.7)	2,160 (64.3)	232 (50.9)	
Arteriovenous graft	1,041 (27.3)	879 (26.2)	162 (35.5)	

[a]Other/None includes patients with only state Medicaid insurance (n = 59), other (private medical insurance), or no documented medical insurance.

Table 3. Central Tendency, Floor And Ceiling Effects, And Missingness Of KDQOl-36 Subscale Scores By Age Group

	Mean (SD) Score[a]		Ceiling (%)[b]		Floor (%)[b]		Missing responses (%)[c]	
KDQOL-36 Subscale	75+ years	21–74 years	75+ years	21–74 years	75+ years	21–74 years	75+ years	21–74 years
Burden of kidney disease	**52.54 (29.37)**	**56.09 (29.02)**	307 (8.9)	55 (11.1)	158 (4.6)	14 (2.8)	73 (2.1)	6 (1.2)
Symptoms/ problems	78.2 (15.72)	77.65 (16.38)	119 (3.4)	18 (3.6)	0 (0.0)	1 (0.0)	344 (9.8)	39 (7.8)
Effects of kidney disease	**74.30 (21.18)**	**72.14 (22.10**)	365 (10.4)	53 (10.7)	5 (0.1)	0 (0.0)	461 (13.2)	42 (8.4)
Physical component score	**34.53 (9.96)**	**38.69 (10.55)**	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	175 (5.0)	23 (4.6)[d]
Mental component score	50.96 (10.33)	50.18 (10.41)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		

Data expressed as *n* (%), unless otherwise specified. Significant group differences in mean subscale score ($p < .05$) indicated in bold.

[a] Range of subscale scores is 0 to 100. Higher score indicated better quality of life.

[b] % of patients with highest possible subscale score (100) or lowest possible subscale score (0). Ceiling or floor effect is present if > 15% responses were at the lowest or highest scores of each subscale.

[c] % of respondents with 1+ missing responses in subscale

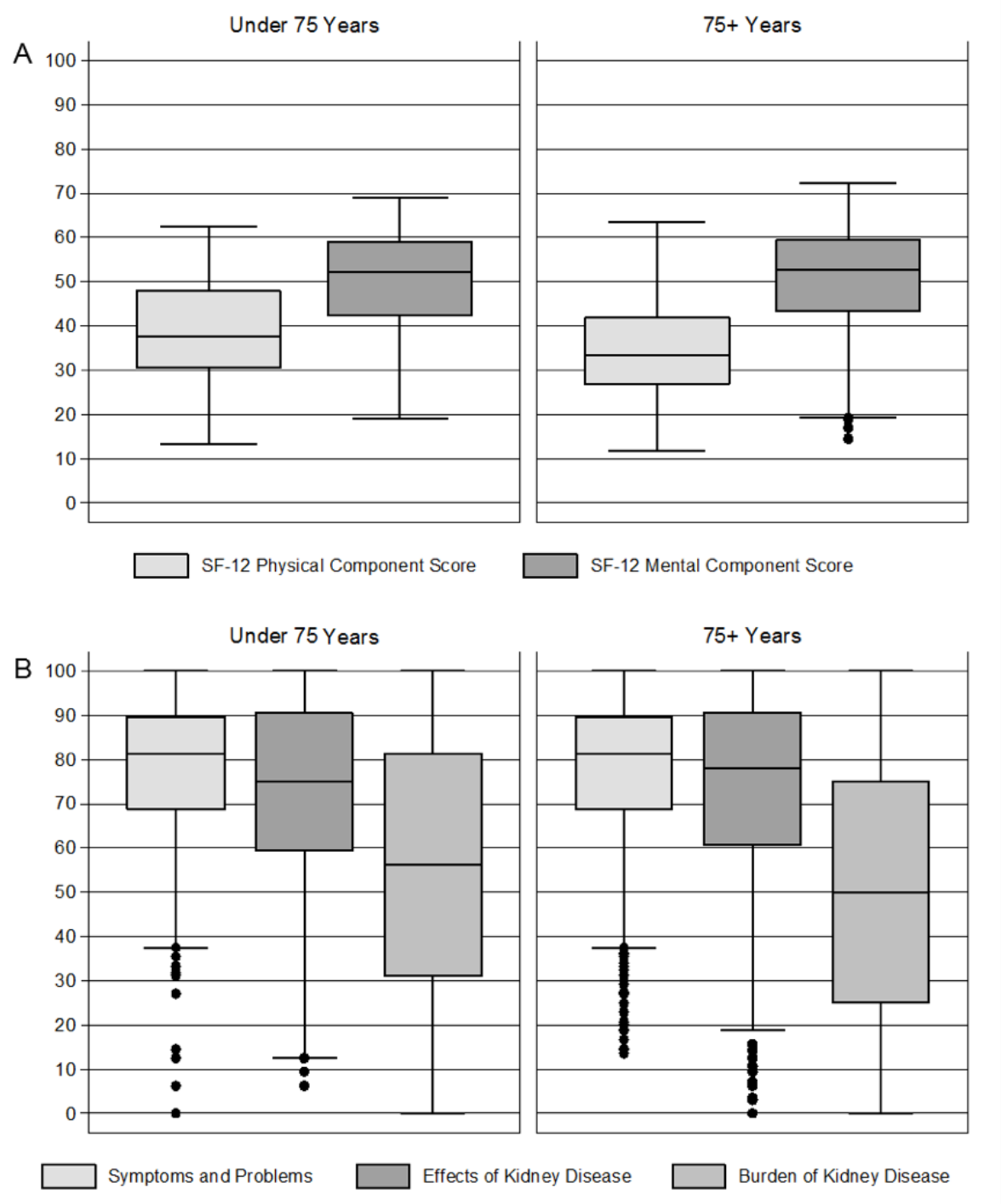
[d] % of missingness is identical for both SF-12 physical component score and mental component score.

Table 4. Corrected Item-total Correlation Matrix by Age Group

	21–74 YEARS			75+ YEARS		
Variable	**Symptoms**	**Effects**	**Burden**	**Symptoms**	**Effects**	**Burden**
Item 13			.76			.74
Item 14			.79			.77
Item 15			.78			.77
Item 16			.58			.63
Item 17	.51			.53		
Item 18	.59			.48		
Item 19	.49			.46		
Item 20	.47			.52		
Item 21	.53			.55		
Item 22	.61			.53		
Item 23	.57			.53		
Item 24	.43			.46		
Item 25	.66			.63		
Item 26	.50			.52		
Item 27	.58			.56		
Item 28	.40			.41		
Item 29		.58			.58	
Item 30		.55			.59	
Item 31		.61			.65	
Item 32		.67			.66	
Item 33		.67			.67	
Item 34		.71			.69	
Item 35		.49			.46	
Item 36		.63			.59	

Calculations for corrected item-total correlation matrix involved pairwise deletion so there was variation in the number of subjects included in each calculation. For those aged 21–74 years, number of subjects varied from 481 to 497. For those aged ≥ 75 years, number of subjects varied from 3137 to 3449.

Figure 1. Kidney Disease Quality of Life (KDQOL-36) Subscale Scores by Age Group



Panel A shows the distributions of SF-12 Physical Component Score (PCS) and SF-12 Mental Component Score (MCS) for patients aged ≥ 75 years and patients aged 21–74 years.

Panel B shows the distributions of the scores in three kidney disease-specific subscales (symptoms/problems; effects of kidney disease; and burden of kidney disease) for patients aged ≥ 75 years and patients aged 21–74 years.