ELSEVIER

Journal of Psychosomatic Research 60 (2006) 495–504

Journal of Psychosomatic Research

Validation of the Kidney Disease Quality of Life-Short Form questionnaire in kidney transplant patients

Szabolcs Barotfi[a,b], Miklos Zs. Molnar[a,c,d], Csilla Almasi[d], Agnes Zs. Kovacs[a], Adam Remport[e], Lilla Szeifert[a], Andras Szentkiralyi[a], Eszter Vamos[a,f], Rezso Zoller[a], Sonya Eremenco[g], Marta Novak[a,h], Istvan Mucsi[a,c,d,*]

[a]*Institute of Behavioral Sciences, Semmelweis University, Budapest, Hungary*
[b]*Quintiles Hungary Ltd., Budapest, Hungary*
[c]*Fresenius Medical Care Dialysis Center, Semmelweis University, Budapest, Hungary*
[d]*First Department of Internal Medicine, Semmelweis University, Budapest, Hungary*
[e]*Department of Transplantation and Surgery, Semmelweis University, Budapest, Hungary*
[f]*Second Department of Internal Medicine, Szent Istvan Hospital, Budapest, Hungary*
[g]*Center on Outcomes, Research and Education, Evanston Northwestern Healthcare, Evanston, IL, USA*
[h]*Sleep Research Laboratory, Department of Psychiatry, University of Toronto, Toronto, Canada*

Received 27 January 2005

Abstract

Objective: The aim of this study was to determine the basic psychometric properties, reliability, and validity of the Kidney Disease Quality of Life-Short Form (KDQOL-SF) questionnaire in kidney transplant patients. **Methods:** The reliability and validity of the instrument were determined in 418 kidney transplant patients followed in a single outpatient transplant centre. **Results:** Internal consistency of all the Medical Outcome Study Short Form 36 (SF-36) domains was very good, and the Cronbach's alpha value was above .70 for all but three of the disease-specific subscales. We found significant, moderate to strong negative correlations between most of the KDQOL-SF domains and the Center for Epidemiologic Studies—Depression (CES-D) scores. Finally, substantial differences in KDQOL-SF scores were seen between groups of transplanted patients who were expected to be clinically different, supporting the discriminant validity of the KDQOL-SF instrument. **Conclusion:** We propose that the KDQOL-SF is a reliable and valid tool and most of its subscales can be used to assess health-related quality of life (HRQOL) in kidney transplant patients and to compare HRQOL between different end stage renal disease (ESRD) patient populations.

Keywords: Chronic kidney disease; Renal transplantation; KDQOL-SF; Health-related quality of life; Psychometric validation

Introduction

In the health care of industrialized countries, treatment of chronic medical conditions, including chronic kidney disease (CKD), has come to the forefront during the past decades. Available renal replacement therapies include peritoneal dialysis, hemodialysis, and kidney transplantation (Tx). Both end stage renal disease (ESRD) and all the renal replacement therapies have large impact on several aspects of everyday life of the affected patients, i.e., on their health-related quality of life (HRQOL).

Recent studies confirmed that successful renal transplantation confers both survival benefit and better HRQOL compared to maintenance dialysis [1–4]. Direct comparison of the different renal replacement therapy (RRT) modalities, however, remains a difficult task. The modalities are quite different in nature with frequent and invasive procedures, strong and immediate dependence on health care staff and medical devices involved with dialysis

* Corresponding author. Division of Nephrology, Humber River Regional Hospital, 200 Church Street, Toronto, Ontario, Canada M9N 1N8. Tel.: +1 416 243 4223; fax: +1 416 243 4421.
E-mail address: mucsist@net.sote.hu (I. Mucsi).

0022-3999/06/$ – see front matter © 2006 Elsevier Inc. All rights reserved.
doi:10.1016/j.jpsychores.2005.09.009

treatments vs. a more traditional, medical management for the transplant patients. Furthermore, transplanted patients have substantial renal function, whereas patients on maintenance dialysis have minimal or no kidney function, and this has a large impact on the health status and also on HRQOL of these patients. On the other hand, the underlying chronic medical condition has significant similarities between these two patient populations. Chronic renal impairment, symptoms, and complications of CKD are present in both populations. Consequently, many health concerns overlap between these treatment groups. Therefore, it is of interest to have psychometrically sound and valid instruments that can be used to assess and compare HRQOL across these patient populations.

The Kidney Disease Quality of Life Questionnaire (KDQOL-SF) has become one of the most widely used QoL measures for CKD patients. The KDQOL-SF is a self-report tool that includes the Medical Outcomes Study Short Form-36 generic core (SF-36) and several multi-item scales targeted at quality-of-life concerns of special relevance for patients with CKD. The KDQOL-SF has been developed in the United States [5] and has been translated into several languages including Spanish, Italian, German, Japanese, French, Chinese, and Dutch. This instrument has been used in several large studies, most notably the multicontinent Dialysis Outcomes and Practice Patterns Study (DOPPS) [6]. Results from these studies showed that KDQOL-SF scores predicted the risk of both mortality and hospitalization in large dialysis populations [7–9].

The KDQOL-SF would also be useful to assess HRQOL in kidney transplant patients and also to compare different ESRD treatment modalities. Psychometric characteristics of the KDQOL-SF both for the original US version and for the Dutch version were assessed in patients on maintenance dialysis [10,11]. Reports of validation of the Japanese and Portuguese versions in dialysis patients have recently been published [12,13]. In these analyses, all of the generic (SF-36) dimensions and most of the kidney disease-specific domains yielded very good psychometric properties. Some of the kidney disease-targeted dimensions, however, yielded less than satisfactory results both for the original US and the Dutch versions. It is therefore important to determine the reliability and validity of the instrument for the different patient populations amongst whom it will potentially be used. The English version of the KDQOL-SF has been used in kidney transplant patients [1,14,15], but the instruments have not been validated previously in this patient population.

In this study, we sought to determine the basic psychometric properties of the KDQOL-SF in kidney transplant patients. We hypothesized that the Hungarian version of the KDQOL-SF is a reliable instrument in that it has an acceptable internal consistency, and the results are reproducible. Furthermore, we proposed that somatic subscales of the instrument correlate better with clinical parameters related to the patients' physical status, whereas domains related to emotional well-being show stronger correlation with depressive symptoms assessed with the Center for Epidemiologic Studies—Depression (CES-D) scale.

Methods

Description of the KDQOL-SF

The KDQOL-SF is a self-report measure developed for individuals with CKD [16]. The scale includes 43 kidney disease-targeted items as well as 36 items that provide a generic core and an overall health-rating item. The disease-targeted items focus on particular health-related concerns of individuals with kidney disease: Symptoms/problems, Effects of kidney disease on daily life, Burden of kidney disease, Work status, Cognitive function, Quality of social interaction, Sexual function and Sleep. Besides the items above, three additional dimensions are included: Social support, Dialysis staff encouragement and Patient satisfaction. The generic core of the questionnaire is the SF-36 health survey, which contains eight multi-item measures of physical and mental health status: physical functioning, limitation in role functioning for physical reasons, bodily pain, general health perceptions, vitality, social functioning, limitation in role functioning for emotional reasons, and emotional well-being.

Scoring the KDQOL-SF

Scores for each item are computed so that each dimension/domain will have a potential range from 0 to 100, with higher scores indicating better HRQOL [11]. Scores of the different subscales in this study were calculated according to the algorithm of the KDQOL-SF version 1.3 scoring program (v 3.0). Raw data were converted into individual item scores, and then scale scores were computed as described in the *KDQOL 1.3 Manual for Use and Scoring*. One item of the "Symptoms, problems related to kidney disease" domain regarding problems with the arteriovenous shunt or PD catheter was deleted from the questionnaires given to transplanted patients. As the algorithm of the scoring program leaves out all missing items from the calculation of the final scale scores, in this case the final score of the "symptoms/problems list" scale was derived from answers to 11 items (14a-k) for the Tx patient group.

Translation of the KDQOL-SF

The Hungarian version of the KDQOL-SF was prepared from the original US version by the Functional Assessment of Chronic Illness Therapy (FACIT) translation group [Center on Outcomes, Research and Education, Evanston, IL, USA], which followed the FACIT translation methodology [17].

Assessing depressive symptoms

The Hungarian version of the CES-D scale has been prepared according to a recommended procedure and has been validated by our team in Hungarian hemodialysis and kidney transplanted patients. Internal consistency and test–retest reliability of the Hungarian scale were good. Confirmatory factor analysis established a very good fit between the original four-factor structure of the CES-D scale and the data obtained both in Hungarian hemodialysis and in Hungarian transplant patients. Finally, the CES-D score showed moderate–strong correlation with other self-reported measures of emotional well-being/mental health (M. Novak et al., in preparation).

Patients

For pilot testing of linguistic validity of the Hungarian version of KDQOL-SF, 15 patients receiving maintenance dialysis treatment in a single dialysis center in Budapest, Hungary, completed the questionnaire. Subsequently, test–retest reliability was evaluated in a convenience sample of 63 patients receiving maintenance hemodialysis in another dialysis unit in Budapest.

After the above pretesting phase, psychometric characteristics and validity of the Hungarian version of the KDQOL-SF were tested in different CKD patient populations. First, a convenience sample of patients receiving maintenance dialysis for more than 3 months was recruited from nine dialysis units in Budapest (Dial; $n=418$). Secondly, a sample of 418 Tx patients was randomly selected from a larger group of kidney transplant patients ($n=942$) followed at a single outpatient transplant centre at the Semmelweis University Budapest.

Procedure

The translation and validation process is depicted in Fig. 1. Comprehensibility and acceptability of the Hungarian KDQOL-SF were tested during cognitive debriefing involving 15 patients on maintenance hemodialysis. During these sessions, the patients completed the instrument, then a research associate interviewed respondents to determine whether they found any questions irrelevant and/or difficult to comprehend. During the analysis of the data collected in this phase, revisions were made to the wording of two questions utilizing patients' comments to obtain the final version of the Hungarian KDQOL-SF.

Subsequently, test–retest reliability testing was performed using the final version of the Hungarian instrument in a sample of 63 Hungarian patients treated with maintenance hemodialysis in a different dialysis center in Budapest. Two to 3 weeks elapsed between test and retest.

Reliability and validity of the KDQOL-SF questionnaire were then tested in 418 dialysis patients receiving treatment in nine dialysis units in Budapest. These patients received a battery of questionnaires including the KDQOL-SF as part of a survey investigating the attitudes of dialysis patients towards renal transplantation. Finally, to assess the reliability and validity of the KDQOL-SF in kidney transplant patients, 418 patients were randomly selected from the 942 patients enrolled in the TRANS-QoL-HU study, which assessed sleep and mood disorders and HRQOL in Tx patients [18]. The patients enrolled in

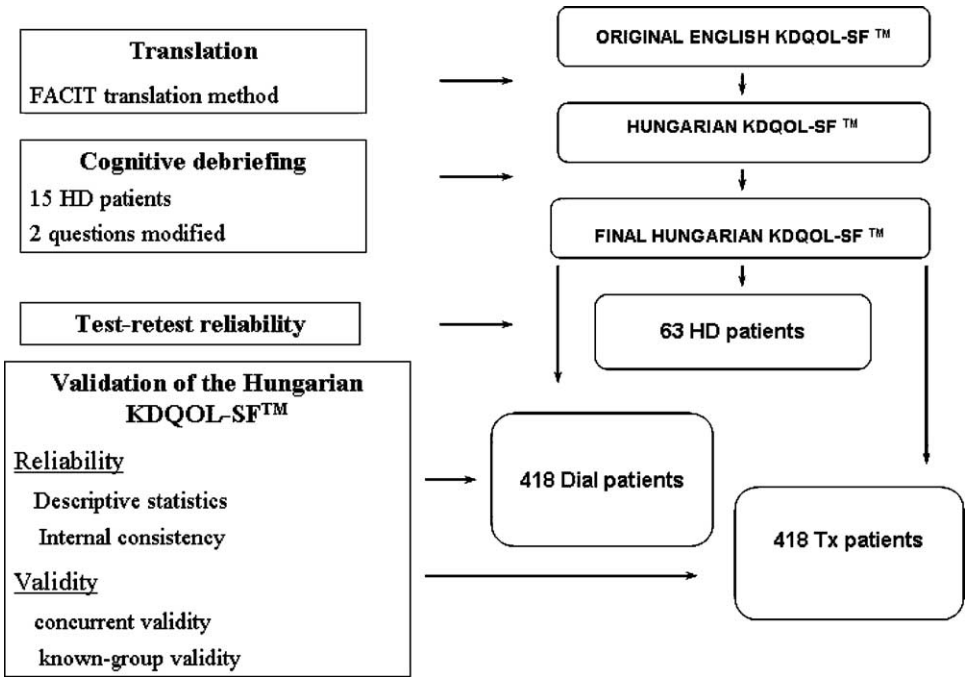

Fig. 1. Flow chart of the validation process.

this study also received a battery of questionnaires including the KDQOL-SF along with other validated instruments, including the CES-D scale [19].

Before enrollment, all the patients received detailed written and verbal information regarding the aims and protocol of the study and signed informed consent. Patients who volunteered completed the KDQOL-SF questionnaire and other self-report instruments during the dialysis sessions or while waiting for their regular follow-up visit at the transplant center.

In addition to the questionnaires, basic demographic and laboratory data (serum albumin—alb, hemoglobin—Hb, single pool Kt/V—spKt/V) were also tabulated. Estimated glomerular filtration rate (eGFR) was calculated for Tx patients using the abbreviated Modification of Diet in Renal Disease study formula [20]. Based on the eGFR, patients were classified into groups corresponding to CKD stages suggested by the Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines (Group 1: eGFR >60 ml/min; Group 2: eGFR 30–60 ml/min; Group 3: eGFR <30 ml/min) [21].

The studies were approved by the ethics committee of the Semmelweis University Budapest and also by the Regional Ethics Committees in whose jurisdiction the participating dialysis centres belonged.

Data analysis

Analysis was carried out with SPSS v. 12.01 statistical software. Pearson correlation coefficients between the test and retest scores were computed.

Subsequent psychometric analysis was done for Dial and Tx patients separately. Cronbach's alpha was computed as the index of internal consistency of the individual dimensions/domains of the KDQOL-SF questionnaire [22]. The individual dimension means and standard deviations of the Hungarian KDQOL-SF were compared between the Tx and Dial groups. Means obtained in the Dial group were also compared to the means and standard deviations of the original US version [11].

To establish concurrent validity, we selected two other tests that measure different aspects of HRQOL, and we tested whether the scores on the subscales of the KDQOL-SF would correlate with the results of those tests. Specifically, we selected the overall health rating score, an independent item in the KDQOL-SF questionnaire and the CES-D scale measuring psychological distress. Age- and gender-adjusted correlations between domain scores and the overall health rating score, and also the CES-D scale scores were computed. To account for the large number of statistical tests performed for this set of analysis, the Bonferroni correction was used to adjust the alpha levels. Consequently, $P<.001$ is considered significant.

To confirm whether the KDQOL-SF is able to differentiate between patient groups with different clinical characteristics, ANOVA with Bonferroni correction was used to compare KDQOL-SF scores between Dial vs. Tx patients, between patients in the lowest and the highest tertiles of age and of serum albumin, and also between patients in groups formed by eGFR. Similarly to the analysis of concurrent validity, alpha level $P<.001$ is considered a significant difference in this set of analyses.

Results

The response rate in the study was 93% for the Dial and 89% for the Tx group. There was no difference in the age and gender distribution of the responder and nonresponder groups in either populations (not shown). Demographic characteristics of the patients who completed the questionnaire are presented in Table 1. Transplanted patients were somewhat younger; the proportion of diabetics was less in the Tx group; the mean hemoglobin and albumin concentration was higher.

Descriptive statistics of the Hungarian KDQOL-SF

The mean scores and standard deviations for the Hungarian dialysis group were overall similar to the means and standard deviations obtained with the original US version of the KDQOL-SF and also to the mean scores obtained with a Dutch version of the instrument (kidney disease-targeted dimensions only) (Table 2). For some of the kidney disease-targeted subscales ("effects of kidney disease", "sexual function", "staff encouragement") and for some of the generic dimensions ("social support"); however, the Hungarian scores seemed to be substantially higher. The majority of the kidney disease-specific domains did not have high floor or ceiling effects. However "work status" suffered from high percentage of floor scores, whereas "sexual function", "social support", and "staff encouragement" had a high percentage of ceiling scores. Three of the generic domains ("bodily pain", "role function emotional", and "social function") suffered from high floor effect (Table 3).

Test–retest and internal consistency

Test–retest correlation was above .60 for 7 out of 11 kidney disease-targeted domains and for 7 out of 8 of

Table 1
Main characteristics of the study populations

	Tx ($n=418$)	Dial ($n=418$)	P value
Age (years) mean±S.D.	49±12	53±14	<.01
Proportion of females (%)	41	44	NS
Diabetes (%)	17	28	<.01
Serum albumin (g/L), mean±S.D.	41±3.5	40±4	<.01
Serum hemoglobin (g/L), mean±S.D.	133±19	112±14	<.01
eGFR (ml/min), mean±S.D.	50±24	NA	NA
Kt/V, mean±S.D.	NA	1.29±0.3	NA

Table 2
Descriptive statistics of the results obtained with the Hungarian, US, and Dutch version of the KDQOL-SF

	Number of items	Mean (S.D.) Hungarian Tx	Mean (S.D.) Hungarian Dial	Mean (S.D.) original (USA)	Mean (S.D.) NECOSAD (Dutch)
Kidney disease-targeted domains					
Symptoms/problems	12	83 (17)	75 (19)	71 (17)	76 (16)
Effects of kidney disease	8	80 (19)	68 (21)	57 (25)	75 (19)
Burden of kidney disease	4	70 (26)	49 (26)	50 (30)	47 (26)
Work status	2	37 (40)	29 (39)	25 (38)	22 (32)
Cognitive function	3	79(19)	78 (20)	79 (20)	77 (20)
Quality of social interaction	3	77 (18)	76 (18)	77 (19)	81 (16)
Sexual function	2	87 (14)	85 (21)	69 (36)	61 (35)
Sleep	4	73 (19)	63 (21)	61 (29)	61 (20)
Social support	2	70 (35)	70 (31)	65 (28)	82 (22)
Staff encouragement	2	82 (21)	77 (25)	70 (23)	83 (21)
Patient satisfaction	1	70 (23)	70 (22)	71 (22)	73 (24)
Generic (SF-36) domains					
Physical function	10	70 (26)	58 (29)	52 (30)	NA
Role function—physical	4	57 (43)	47 (43)	33 (40)	NA
Bodily pain	2	74 (29)	67 (32)	60 (30)	NA
General health perception	5	48 (23)	34 (21)	43 (24)	NA
Vitality	4	65 (25)	53 (25)	46 (24)	NA
Social function	2	78 (26)	72 (29)	64 (30)	NA
Role function—emotional	3	65 (41)	59 (43)	58 (44)	NA
Emotional well-being	5	72 (24)	65 (25)	70 (20)	NA

the generic dimensions (Table 4). The lowest test–retest correlation was seen for the subscales assessing "quality of social interactions" (.40) and "cognitive function" (.48). Relatively low correlations were also found for the subscales measuring "staff encouragement" (.54), "general health perception" (.56), and "patient satisfaction" (.58).

The overall reliability pattern of the domains was remarkably similar to the pattern observed with the original US version. Cronbach's alpha values were above .70 [23] for all of the generic dimensions and for all but four of the kidney disease-targeted domains (quality of social interaction, .54; cognitive function, .62; social support, .64; work, .64) for the Dial group (Table 4).

Similar results were obtained in the Tx group. Internal consistency of all the SF-36 domains was very good with alpha values ranging between .71 (social function) and .92 (bodily pain). Furthermore, internal consistency was above .70 for all except three of the disease-specific subscales. For these domains, the alpha values were between .70 (sleep) and .95 (sexual function). The three subscales for which alpha was less than the recommended .70 were the ones for which problems were encountered in the Hungarian (and also in the US or in the Dutch) dialysis population, as well: quality of social interaction (.52), work (.65), and cognitive function (.68).

Concurrent validity

As hypothesized, the overall health rating score correlated positively with most of the disease targeted and all of the generic dimensions of the KDQOL-SF (higher scores on the subscales of the instrument indicate better HRQOL) (Table 5). Of the generic domains, the strongest correlation was seen for the "general health perception" subscale ($r=.57$, $P<.001$), whereas the weakest association was found for the "role emotional" subscale ($r=.36$, $P<.01$). Of the kidney disease-targeted domains, the strongest correlation was demonstrated for the "burden of kidney disease"

Table 3
Floor and ceiling percentages of the Hungarian KDQOL-SF dimensions in the Dial and Tx patient populations

	Number of items	Floor		Ceiling	
		Dial	Tx	Dial	Tx
Kidney disease-targeted domains					
Symptoms/problems	12	0.5	0.3	6.0	9.8
Effects of kidney disease	8	0.2	0.2	7.6	12.7
Burden of kidney disease	4	2.7	1.2	8.3	13.6
Work status	2	56.5	40.0	16.3	18.4
Cognitive function	3	0.8	0.2	24.4	20.8
Quality of social interaction	3	0.5	0.2	15.3	11.0
Sexual function	2	1.5	0.7	46.6	25.4
Sleep	4	0.2	0.2	4.8	5.3
Social support	2	7.9	10.8	38.2	33.5
Staff encouragement	2	2.3	0.5	38.1	33.6
Patient satisfaction	1	0.7	1.4	22.6	20.1
Generic (SF36) domains					
Physical function	10	3.1	1.2	3.6	10.5
Role function physical	4	33.0	23.4	29.7	33.7
Bodily pain	2	4.1	0.7	32.5	33.0
General health perception	5	2.9	0.7	0.5	1.2
Vitality	4	1.2	1.4	2.4	6.5
Social function	2	2.2	1.7	35.9	36.8
Role function emotional	3	26	18.6	44	42.3
Emotional well-being	5	0.7	1.2	7.4	9.6

Table 4
Internal consistency and test–retest reliability of the Hungarian version of the KDQOL-SF

		Cronbach's alpha				
	Number of items	Dial HU	Tx HU	Original US	Necosad	Test–retest correlation
Kidney disease-targeted domains						
Symptoms/problems	12	0.83	0.88	0.84	0.80	0.73
Effects of kidney disease	8	0.80	0.82	0.82	0.76	0.60
Burden of kidney disease	4	0.73	0.81	0.83	0.80	0.73
Work status	2	0.64	0.62	0.83	0.39	0.68
Cognitive function	3	0.62	0.62	0.68	0.83	0.48
Quality of social interaction	3	0.54	0.59	0.61	0.39	0.40
Sexual function	2	0.70	0.95	0.89	0.95	0.88
Sleep	4	0.71	0.70	0.9	0.72	0.74
Social support	2	0.64	0.76	0.89	0.67	0.63
Staff encouragement	2	0.74	0.85	0.9	0.78	0.54
Patient satisfaction	1					0.58
Generic (SF-36) domains						
Physical function	10	0.92	0.91	0.92		0.81
Role function—physical	4	0.88	0.90	0.87		0.69
Bodily pain	2	0.88	0.92	0.90		0.63
General health perception	5	0.78	0.77	0.78		0.56
Vitality	4	0.83	0.85	0.80		0.68
Social function	2	0.77	0.71	0.86		0.62
Role function—emotional	3	0.87	0.86	0.87		0.65
Emotional well being	5	0.89	0.86	0.90		0.61

(r=.49, P<.001) and the "symptoms, problems list" (r=.48, P<.001) subscales, whereas negligible or nonsignificant correlation was seen for the "social support" (r=.15, P<.05), "sexual function" (r=.14, P<.05), and "staff encouragement" (r=.07, P=NS) domains.

Depression has been shown to interact with chronic illness to determine different aspects of HRQOL in several chronic conditions [24]. We found significant, moderate to strong negative correlations between most of the KDQOL-SF domains and the CES-D scores (higher scores on the CES-D scale reflect more psychological distress) (Table 5). As expected, the correlations were the strongest with KDQOL-SF dimensions reflecting different aspects of mental health: "emotional well being" (r=−.74, P<.001); "role emotional" (r=−.53, P<.001); "vitality" (r=−.70, P<.001); sleep (r=−.56, P<.001); "burden of kidney disease" (r=−.57, P<.001). The observed correlations, similarly what was seen with the "overall health rating", were the weakest for "sexual function", "staff encouragement", "work status", "social support", and "patient satisfaction".

Some of the disease-targeted dimensions ("sexual function", "staff encouragement", "social support", "patient satisfaction") showed no substantial correlation with any of the scales used to assess concurrent validity.

"Known groups" validity

To ascertain whether the dimensions of the Hungarian KDQOL-SF were able to discriminate between groups who are known or expected to differ clinically and expected to differ in their QoL, a series of analyses were carried out.

First, we compared the mean scores of the Tx and the Dial groups (Fig. 2). It has been shown that the QoL of kidney transplant patients is significantly better than HRQOL of patients on dialysis treatment [2,25]. Consequently, we hypothesized that most if not all of the domains should be higher in the Tx group. The KDQOL-SF scores were significantly different between the two patient groups for all the generic domains and for 7 out of the 11 kidney disease-targeted dimensions. These differences remained significant even after adjusting for age and gender (not shown). The differences between the two groups exceeded 10 points for most of the domains where a difference was seen.

Subsequently, KDQOL-SF scores of patients in the lowest and the highest age tertiles were compared (Fig. 3A,B). We expected that older patients would have worse scores along the dimensions related to physical health or physical functioning, but we expected less difference or even an inverse relationship (i.e., worse QoL in the younger patients) along the mental health domains and along some of

Table 5
Concurrent validity of the Hungarian KDQOL-SF in kidney transplanted patients.

	Overall health rating	P value	CES-D	P value
Kidney disease-targeted domains				
Symptoms/problems	0.481	<.001	−0.571	<.001
Effects of kidney disease	0.420	<.001	−0.547	<.001
Burden of kidney disease	0.494	<.001	−0.574	<.001
Work status	0.376	<.001	−0.210	<.05
Cognitive function	0.346	<.01	−0.553	<.001
Quality of social interaction	0.358	<.01	−0.648	<.001
Sexual function	0.139	<.05	−0.225	<.05
Sleep	0.409	<.001	−0.562	<.001
Social support	0.146	<.05	−0.249	<.01
Staff encouragement	0.067	NS	−0.194	<.05
Patient satisfaction	0.208	<.05	−0.266	<.01
Generic (SF-36) domains				
Physical function	0.501	<.001	−0.476	<.001
Role function—physical	0.449	<.001	−0.446	<.001
Bodily pain	0.411	<.001	−0.473	<.001
General health perception	0.572	<.001	−0.475	<.001
Vitality	0.554	<.001	−0.697	<.001
Social function	0.450	<.001	−0.629	<.001
Role function—emotional	0.358	<.01	−0.534	<.001
Emotional well-being	0.464	<.001	−0.736	<.001

Age- and gender-adjusted correlation between KDQOL-SF subscales vs. an overall health rating score and the CES-D score.

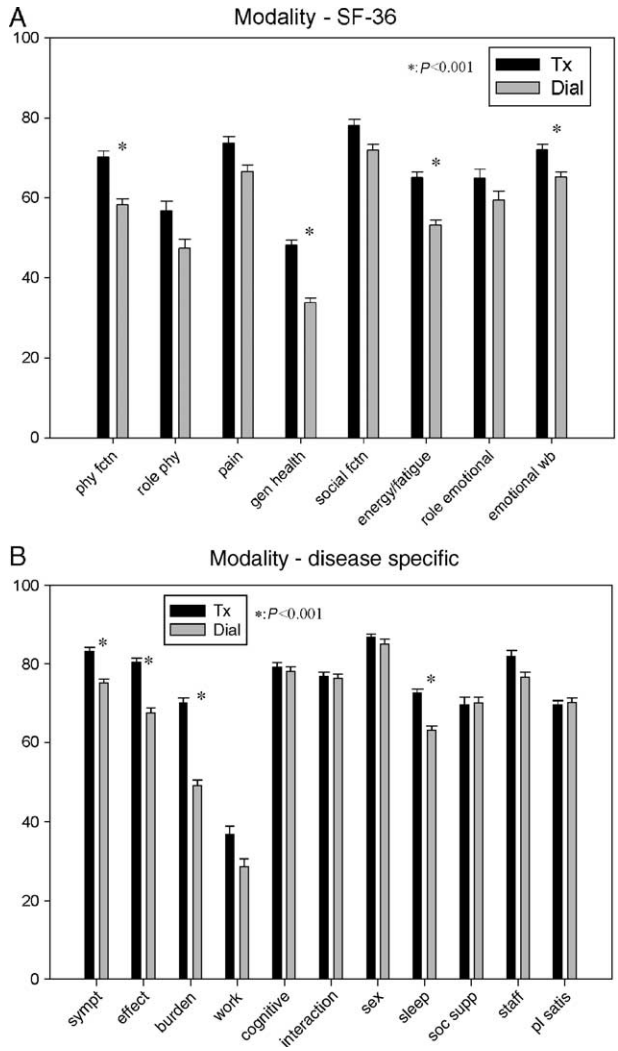

Fig. 2. KDQOL-SF scores (mean±S.E.M.) of the Dial vs. Tx groups. (A) SF-36 dimensions. (B) Kidney disease-targeted subscales. Abbreviations used: phy fctn: physical function; rol phy: role function physical; pain: bodily pain; gen health: general health perception; social fctn: social function; role emotional: role function emotional; emotional wb: emotional well being; sympt: symptoms/problems; effect: effects of kidney disease; burden: burden of kidney disease; work: work status; cognitive: cognitive function; interaction: quality of social interaction; sex: sexual function; soc supp: social support; staff: staff encouragement; pt satis: patient satisfaction.

the disease-specific subscales (e.g., "burden of kidney disease", "effects of kidney disease", "patient satisfaction").

As expected, older patients had substantially worse scores along the generic QoL domains reflecting physical function [59±3 vs. 83±4 (mean±S.E.M.), for the oldest vs. youngest tertile, respectively; $P<.001$] (Fig. 3A). The difference was less marked or not significant on the mental subscales ("emotional well being", "role emotional", "vitality").

The picture obtained with the disease-specific subscales was somewhat different (Fig. 3B). Overall, the differences were smaller along these dimensions. The most striking difference was seen in the "work" subscale, where obviously the younger group had better scores [31±4 vs. 53±4 (mean±S.E.M.), for the oldest vs. youngest tertile, respectively; $P<.001$]. Interestingly, there was no difference between these age groups on the kidney disease-related subscales ("symptom list", effect and "burden of kidney disease"). On the other hand, there was a trend for better HRQOL scores for the oldest tertile on the "social support" and "staff encouragement" scales. Remarkably, these two age groups had similar scores on the "sexual function" subscale. The association between the QoL scores and age groups was quite similar in the Dial group, as well (not shown).

Qualitatively similar pattern was seen when QoL scores of the lowest and highest tertiles of the serum albumin (a general marker of the overall clinical condition) were analyzed (not shown). As expected, the differences were more marked for the domains related to physical functioning ("physical function", "role physical").

Finally, we compared the scores obtained with the Hungarian KDQOL-SF between groups formed on the

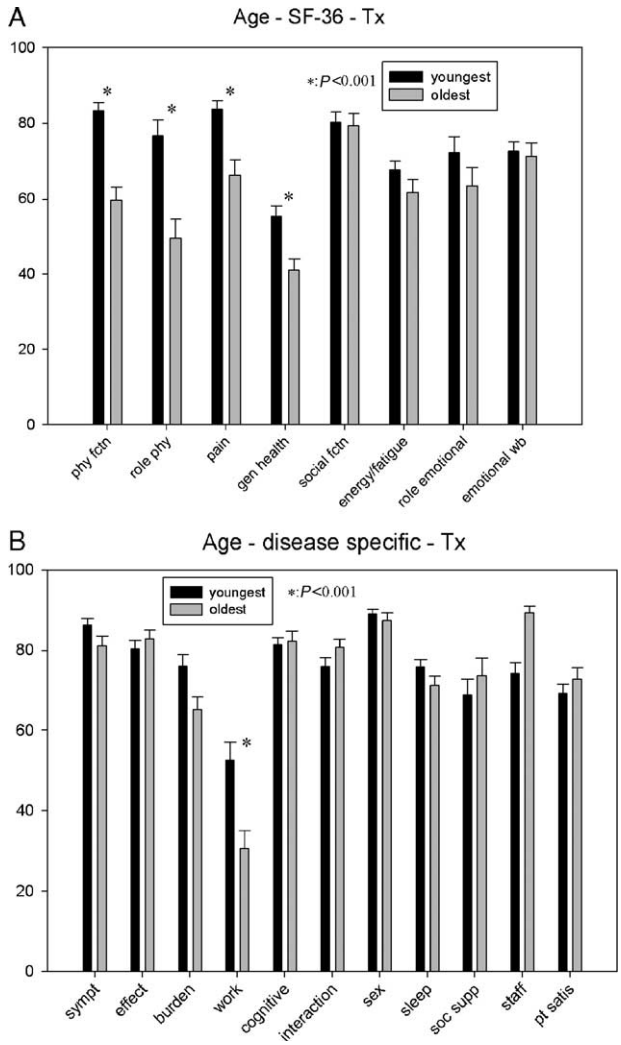

Fig. 3. KDQOL-SF scores (mean±S.E.M.) of the lowest vs. highest age tertiles. (A) SF-36 dimensions. (B) Kidney disease-targeted subscales.

basis of the estimated renal function of the Tx patients (Fig. 4A and B). Based on the eGFR, patients were classified into groups corresponding to CKD stages suggested by the K/DOQI guidelines (Groups 1–3, see Methods). Quality of life scores were significantly different between the groups formed by the eGFR for all the generic and for most of the disease-targeted dimensions, the best scores obtained by the group with the best renal function and the worst scores for the group with the worst eGFR. For a few domains, the difference did not reach statistical significance ("social function", "work status", "quality of social interaction", "staff encouragement"), but the trend was similar to other domains. For two domains ("sexual function" and "social support"), the results were almost identical. The difference seen on most of the subscales between the groups with the best and worst renal function was around 10 points.

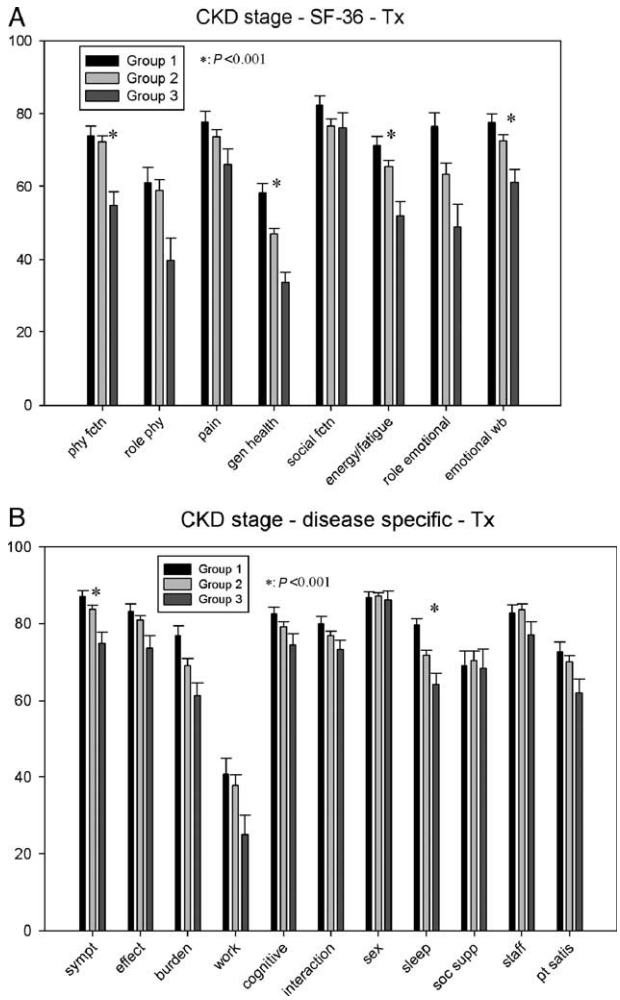

Fig. 4. KDQOL-SF scores (mean±S.E.M.) of groups formed by the calculated renal function (eGFR) (Group 1: eGFR >60 ml/min; Group 2: eGFR 30–60 ml/min; Group 3: eGFR <30 ml/min). (A) SF-36 dimensions. (B) Kidney disease-targeted subscales.

Discussion

In this paper, analyzing data obtained in a large sample of Tx patients, we showed that the KDQOL-SF instrument is a valid and reliable tool to assess HRQOL in kidney transplant patients.

The basic psychometric characteristics of the Hungarian version were first assessed in a sample of Hungarian dialysis patients to establish the reliability of the translated instrument. The results obtained in the Hungarian dialysis sample were quite similar to results reported for the original US and Dutch versions [10,11], suggesting good reliability of the Hungarian version of the instrument.

Internal consistency of all the generic scales was very good, and the respective alpha values were quite similar in both patient populations studied. Furthermore, the kidney disease related domains ("symptom list", "effect of kidney disease", and "burden of kidney disease") and also the subscale assessing sleep quality yielded satisfactory characteristics both in the dialysis sample and for transplanted patients, as well. The alpha values for four subscales ("work status", "cognitive function", "quality of social interaction", and "social support") were lower than the recommended .70 [23]. Alpha values for two of these subscales, namely, for "cognitive function" and "quality of social interaction", were less than satisfactory for the original US version. Furthermore, the "quality of social interaction" dimension was found to be problematic in the Dutch version of the instrument, as well [10].

During the validation of the Dutch questionnaire, some of the items of these two subscales correlated with the other scale more strongly than with their own dimensions. This was not the case for the Hungarian instrument (not shown). Moreover, the Dutch researchers found an improved alpha after deleting one of the items (Item 13e) from the "quality of social interaction" subscale [10]. Again, we found no such change. For the Hungarian scale, both inter-item correlations and item-internal consistency were satisfactory. Initial linguistic assessment of these questions in the pretest phase did not raise any concerns about the wording of the items. Currently, we suggest that these subscales should be used and interpreted very cautiously if at all until further work is done to refine these dimensions.

Alpha values for the subscale assessing work status were also below the recommended value for both the Dial and the Tx groups, respectively. Furthermore, a high proportion of the patients reported "floor" level scores on this scale. Similar findings were reported by the Dutch, but not the US group, assessing the psychometric parameters of the KDQOL-SF [10]. These problems could possibly be explained in part by the irrelevance of some of the items on this scale for patients above retirement age. When the internal consistency of the "work status" subscale was computed after omitting patients above the age of 60 years (retirement age in Hungary), alpha values were higher than .70 (.75 and .78 for the Dial and Tx groups, respectively).

Accordingly, the age distribution of the study population will have to be taken into account when interpreting data obtained with this dimension.

Reliability of the "sexual function" domain is also questionable. Although the alpha value for this subscale was acceptable for both patient populations, the subscale had very high "ceiling" level data. The mean scores obtained on this dimension from Hungarian patients were much higher than the scores seen in both the original US population and in the Dutch validation study [10,11]. Furthermore, correlation of this domain with the different QoL measures used to assess concurrent validity in this work was quite weak. Finally, the "sexual function" scores were similar in clinically different groups (treatment modality, age, albumin, renal function). These results raise concerns about the reliability of the "sexual function" subscale in Hungarian CKD patients. One possible explanation is that sexuality is still quite a taboo in the Hungarian population, as also suggested by our results obtained during the validation of the Hungarian version of the Illness Intrusiveness Rating Scale [26].

Notwithstanding these problems with some of the kidney disease-targeted subscales, our results suggest that all the generic domains of the KDQOL-SF (i.e., the SF-36 instrument) and also most of the kidney disease-targeted dimensions are reliable in the Hungarian version both in dialysis and in kidney transplant patients.

In this work, we employed a multifaceted approach to test the validity of the Hungarian KDQOL-SF in transplanted patients. First, to establish concurrent validity, we selected two other tests that measure aspects of HRQOL, and we tested whether scores on the subscales of the KDQOL-SF would correlate with the results of those tests. Specifically, we selected the overall health rating score, an independent item in the KDQOL-SF questionnaire and the CES-D scale measuring psychological distress. The overall health rating score will give an estimate of the subjective rating of the individuals health status, and it is also a reflection of the extent the individual feels his health interferes with his life. We hypothesized that the overall health rating score would show stronger correlation with more closely illness-related subscales (such as most of the generic domains, the symptoms list, effect and burden of kidney disease, sleep) than with domains relatively independent of health status (cognitive function, social support, patient satisfaction). These assumptions were supported by the results of the survey. The SF-36 scores and most of the disease targeted domains showed moderate positive correlations with the overall health rating score and moderate to strong negative correlation with the CES-D score that measures psychological distress. Those dimensions that measure the mental/emotional aspects of HRQOL correlated more strongly with the CES-D scores than those that assess physical functioning. These results support the underlying construct validity of the instrument in the transplant population.

The clinical discriminant validity of the SF-36 scales and most of the disease targeted dimensions is supported by the statistically significant differences found in the mean scores of groups that are expected to be clinically different. Quite substantial, statistically strongly significant differences were seen between the Dial and the Tx groups. Furthermore, older patients had significantly lower scores along the domains that assess physical functioning, and the differences were less pronounced along the domains assessing mental aspects of HRQOL. We found similar results in groups formed by tertiles of the serum albumin concentration, which reflects overall clinical condition and also in groups formed on the basis of renal function in the Tx group. These results suggest that most of the subscales of the KDQOL instrument are able to capture meaningful differences between groups with significant differences in their clinical conditions that are likely to have an impact on the QoL of transplanted patients.

When assessing HRQOL in a specific patient population, the instrument utilized will depend on the specific aims of the study and the hypothesis to be tested. We suggest that the KDQOL-SF instrument will be very useful in assessing HRQOL in the transplant population, and also it can be used to compare different aspects of HRQOL between different kidney disease patient populations. Most of the transplanted patients have significantly impaired kidney function that will make them quite similar in many aspects to other groups of patients with CKD. Some of the complications and symptoms of uremia (anemia, bone disease, chronic inflammation, malnutrition, certain sleep disorders) are sometimes carried over from dialysis and also may reappear as the function of the transplanted kidney will gradually decline. Therefore, issues related to HRQOL in general and also specifically kidney disease-related concerns are of great importance in the transplanted population, and many of these concerns can be assessed by the KDQOL-SF instrument.

In certain instances, however, this instrument may not be sensitive enough. If we want to capture the effect of immunosuppressive medications on QoL in kidney transplanted patients, for example, we may also need to include tools that specifically focus on that issue.

In summary, we provided evidence that most of the subscales of the Hungarian KDQOL-SF are psychometrically sound and reliable. Validity of the instrument in kidney transplant patients was supported by the results of several sets of analyses yielding significant correlations in the expected directions between KDQOL-SF scores vs. alternative measures of different aspects of QoL. Finally, clinically and statistically significant differences were seen along many of the assessed dimensions between patient groups who are expected to have different clinical characteristics. Consequently, we propose here that the KDQOL-SF is a useful, reliable and valid tool that can be used to assess and compare different aspects of HRQOL in different CKD patient populations.

Acknowledgments

The study was supported by grants from the National Scientific Research Funds (OTKA TS 040889, OTKA T038409, NKFP 1/002/2001—M.N., I.M.), the Ministry of Health (218/2003), and a grant from the Hungarian-Canadian Intergovernmental S & T Cooperation Programme (Can-5/04, M.N.). I.M. is a Békésy Postdoctoral Fellow of the Hungarian Ministry of Education; M.M.Zs. was a recipient of a research scholarship from the Hungarian Kidney Foundation; M.N. was a recipient of the Eötvös Hungarian State Scholarship. The authors thank the help provided by the social workers of Fresenius Medical Care Hungary in the data collection. We are also grateful for the useful discussion and comments of the participants of the University of Toronto University Health Network Quality of Life Manuscript Review Seminar.

References

[1] Wight JP, Edwards L, Brazier J, Walters S, Payne JN, Brown CB. The SF36 as an outcome measure of services for end stage renal failure. Qual Health Care 1998;7(4):209–221.
[2] Tomasz W, Piotr S. A trial of objective comparison of quality of life between chronic renal failure patients treated with hemodialysis and renal transplantation. Ann Transplant 2003;8(2):47–53.
[3] Reimer J, Franke GH, Lutkes P, Kohnle M, Gerken G, Philipp T, Heemann U. Quality of life in patients before and after kidney transplantation. Psychother Psychosom Med Psychol 2002;52(1):16–23.
[4] Jofre R, Lopez-Gomez JM, Moreno F, Sanz-Guajardo D, Valderrabano F. Changes in quality of life after renal transplantation. Am J Kidney Dis 1998;32(1):93–100.
[5] 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(5):329–38.
[6] Mapes DL, Bragg-Gresham JL, Bommer J, Fukuhara S, McKevitt P, Wikstrom B, Lopes AA. Health-related quality of life in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis 2004;44(5 Suppl 3):54–60.
[7] DeOreo PB. Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. Am J Kidney Dis 1997;30(2):204–12.
[8] Mapes DL, Lopes AA, Satayathum S, McCullough KP, Goodkin DA, Locatelli F, Fukuhara S, Young EW, Kurokawa K, Saito A, Bommer J, Wolfe RA, Held PJ, Port FK. Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Int 2003;64(1):339–49.
[9] Knight EL, Ofsthun N, Teng M, Lazarus JM, Curhan GC. The association between mental health, physical function, and hemodialysis mortality. Kidney Int 2003;63(5):1843–51.
[10] Korevaar JC, Merkus MP, Jansen MA, Dekker FW, Boeschoten EW, Krediet RT. Validation of the KDQOL-SF: a dialysis-targeted health measure. Qual Life Res 2002;11(5):437–47.
[11] Hays RD, Kallich JD, Mapes DL, Coons SJ, Carter WB. Kidney Disease Quality of Life Short Form (KDQOL-SFTM), version 1.3: a manual for use and scoring. Santa Monica (Calif): RAND, 1997 [P-7994].
[12] Green J, Fukuhara S, Shinzato T, Miura Y, Wada S, Hays RD, Tabata R, Otsuka H, Takai I, Maeda K, Kurokawa K. Translation, cultural adaptation, and initial reliability and multitrait testing of the Kidney Disease Quality of Life instrument for use in Japan. Qual Life Res 2001;10(1):93–100.
[13] Duarte PS, Miyazaki MC, Ciconelli RM, Sesso R. Translation and cultural adaptation of the quality of life assessment instrument for chronic renal patients (KDQOL-SF). Rev Assoc Med Bras 2003;49(4):375–81.
[14] Khan IH, Garratt AM, Kumar A, Cody DJ, Catto GR, Edward N, MacLeod AM. Patients' perception of health on renal replacement therapy: evaluation using a new instrument. Nephrol Dial Transplant 1995;10(5):684–9.
[15] Kalantar-Zadeh K, Kopple JD, Block G, Humphreys MH. Association among SF36 quality of life measures and nutrition, hospitalization, and mortality in hemodialysis. J Am Soc Nephrol 2001;12(12):2797–806.
[16] 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(5):329–38.
[17] Bonomi AE, Cella DF, Hahn EA, Bjordal K, Sperner-Unterweger B, Gangeri L, Bergman B, Willems-Groot J, Hanquet P, Zittoun R. Multilingual translation of the Functional Assessment of Cancer Therapy (FACT) quality of life measurement system. Qual Life Res 1996;5(3):309–20.
[18] Molnar MZ, Novak M, Ambrus C, Szeifert L, Kovacs A, Pap J, Remport A, Mucsi I. Restless legs syndrome in patients after renal transplantation. Am J Kidney Dis 2005;45(2):388–96.
[19] Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Meas 1977;1:385–401.
[20] Levey A, Greene T, Kusek J, Beck G. A simplified equation to predict glomerular filtration rate from serum creatinine. (Abstract). J Am Soc Nephrol 2000;11:A0828.
[21] National Kidney Foundation. K/DOQI clinical practice guidelines for kidney disease: evaluation, classification and stratification. Am J Kidney Dis 2002;39(Suppl 1):S1–S266.
[22] Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297–334.
[23] Nunnally JC. Psychometric theory. New York: McGraw-Hill, 1978.
[24] Vazquez I, Valderrabano F, Jofre R, Fort J, Lopez-Gomez JM, Moreno F, Sanz-Guajardo D. Psychosocial factors and quality of life in young hemodialysis patients with low comorbidity. J Nephrol 2003;16(6):886–94.
[25] Terada I, Hyde C. The SF-36: an instrument for measuring quality of life in ESRD patients. EDTNA ERCA J 2002;28(2):73–76, 83.
[26] Novak M, Mah K, Molnar MZ, Ambrus C, Csepanyi G, Kovacs A, Vamos E, Zambo M, Zoller R, Mucsi I, Devins GM. Factor structure and reliability of the Hungarian version of the Illness Intrusiveness Scale: invariance across North American and Hungarian dialysis patients. J Psychosom Res 2005;58(1):103–10.