Health and Quality of Life Outcomes

Research

Spanish validation of the "Kidney Transplant Questionnaire": a useful instrument for assessing health related quality of life in kidney transplant patients

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Abstract

Background: There is a growing interest in the evaluation of Health Related Quality of Life (HRQoL) among patients undergoing Renal Replacement Therapy. In Spain, no specific questionnaire exists for kidney transplant patients. Here we present the Spanish validation of the first specific HRQoL assessment tool: the kidney transplant questionnaire (KTQ).

Methods: Prospective study of 31 patients on transplant waiting list who received the first kidney. Patients were evaluated before transplant and after 1, 3, 6 and 12 months, using the KTQ and the SF-36 Health Survey. Feasibility, validity, reliability, and sensibility to change were evaluated.

Results: Mean time of administration of the KTQ was 12 minutes. Correlation coefficients among KTQ dimensions range between 0.32 and 0.72. Correlation coefficients of KTQ dimensions with SF-36 PCS were low (r<0.4), and with SF-36 MCS were moderate-high (r>0.4) except for Physical Symptom dimension (r = 0.33). Cronbach's Alpha was satisfactory for all KTQ dimensions (Physical Symptoms = 0.80; Fatigue = 0.93; Uncertainty/Fear = 0.81; Emotional= 0.90) except Appearance (0.69). Intraclass correlation coefficients ranged between 0.63 and 0.85, similar to those of the original KTQ version.

Conclusions: Results of validation study show that feasibility, validity, reliability and sensibility to change of the Spanish version of the KTQ are similar to those of the original version.

Background

The evaluation of Health Related Quality of Life (HRQoL) in chronic diseases is becoming more and more important. The reasons for the importance of HRQoL assessment can be summarized as follows [1]: 1° to determine the efficacy of medical intervention; 2° to improve the process of making clinical decisions; 3° to evaluate the quality of care; 4° to estimate the health care need of the general population; and 5° to gain a better understanding of the causes and consequences of the differences in health. For some authors [2] the assessment of perceived health status is especially important in the evaluation of

the consequences of chronic diseases, because clinicians require information about the effects of a specific disease on patients, and also of the effect of a specific treatment, in order to improve its management and the assessment of the evolution of the patient.

In the Nephrology field, the evaluation of HRQoL involves: 1st determining the efficiency and effectiveness of the different forms of renal replacement therapy (RRT) (hemodialysis, peritoneal dialysis and kidney transplantation); 2nd evaluating the efficiency and effectiveness of the different types of other treatments applied to patients with End Stage Renal Disease (ESRD) (such as rh-EPO treatment, or the different types of immunosuppressive treatments); 3rd follow-up of the evolution of individual renal patients.

In these areas the evaluation of HRQoL can be another element of judgement which, taking into account the point of view of patient, allows a wider vision of the medical care provided to chronic patients. The purpose of medical intervention in chronic patients, such as ESRD patients, cannot be to restore health, but to provide a longer and better life. So, nephrologists who understand the importance of evaluating HRQoL in patients with ESRD are numerous [3–7].

The majority of experts in HRQoL evaluation recommend the use of a specific questionnaire for each disease, together with a generic instrument, when evaluating the HRQoL of any type of patients [7,8]. The generic questionnaire allows the comparison of the group of patients under study in each case, with the general population and with other groups of patients. In the case of ESRD, it also allows the evaluation of the effect of the change of RRT (hemodialysis, peritoneal dialysis and kidney transplant). The disease specific questionnaire is more accurate in measuring changes in the evolution of patients, especially those caused by therapeutic interventions.

On the other hand, the number of ESRD patients bearing a functioning kidney transplant is growing in Spain, 50.6 patients per million population in 1999 [9]. In Spain, although there are specific HRQoL questionnaires for patients on dialysis treatment which are validated, as is the case of the *Kidney Disease Questionnaire-KDQ* [10], and of the *Kidney Disease Quality of Life Instrument-KDQOL* [11], there is no HRQoL assessment tool for evaluating kidney transplant bearers in a more detail and adapted to the specific characteristics of these patients.

This study, therefore intends to provide a HRQoL assessment instrument appropriate for routine use in any Nephrology unit: the Spanish version of the Kidney Transplant Questionnaire (KTQ). This questionnaire will be useful in the clinical follow-up of kidney transplant patients, and in the evaluation of the different types of immunosuppressive treatments that they receive. Results of the assessment of psychometric features of this specific HRQoL questionnaire are presented in this article.

Methods

This is a longitudinal prospective study, including 54 ESRD patients undergoing chronic dialysis (hemodialysis or peritoneal dialysis) who entered the kidney transplant waiting list during the years 1999 and 2000. Of these patients, 42 received a first kidney transplant at the "Hospital Central de Asturias" before the end of the year 2000. Transplant patients who were assessed at all stages of the follow-up, during the first year of evolution (N = 31), were included in this study of evaluation of the psychometric features of the Spanish version of the Kidney Transplant Questionnaire (KTQ). The excluded patients (N = 11) had similar sociodemographic and clinical characteristics to those included.

Patients were recruited at the moment of the pre-transplant examination, when they were included on the kidney transplant waiting list.

Patients were interviewed by the medical doctor in charge of the study, or by one of two suitably trained nephrology nurses. In all the cases, the interview was conducted in a relaxed atmosphere.

At the moment of inclusion, the first interview was carried out, starting with the sociodemographic and clinical data collection record: patient identification data; age; sex; level of education in four groups: level 0 (no schooling), level 1 (primary studies completed), level 2 (secondary studies completed) and level 3 (university studies completed); Socioeconomic level, deduced from the monthly family income in three groups: level 1 (less than 900 €/month), level 2 (between 900 and 1,800 €/month) and level 3 (more than 1,800 €/month); living conditions (patients living alone, with at least one person, or in a nursing home); work status (patients who are working or who are not actively working); renal disease diagnosis (Nephrosclerosis-NE; Diabetes Mellitus-DM; Glomerulonephritis-GN; Interstitial Nephritis-IN; Polycystic Kidney Disease-PK; Others, which included an unknown cause); date of initation of renal replacement therapy (dialysis); functional status measured by Karnofsky Scale score; serum analytics including hemoglobin, creatinine and albumin corresponding to the date of interview; and a detailed comorbidity index [12] which includes 24 diseases that are defined by specific criteria, each disease having five possible scores (from zero to four), depending on whether the disease is absent, present but not producing a limitation of physical activity, or present and producing a

slight, moderate, or severe limitation of physical activity. The addition of the score of each item gives a global score that ranges between theoretical values of 0 and 96.

Later in the interview the SF-36 Health Survey (SF-36) and the first part of the KTQ were carried out by the interviewer. Afterwards the second part of the KTQ was self-completed with a previous explanation given by the doctor. The investigator checked that patients have fulfilled all the items before the end of the interview.

The interview was repeated every 6 months while the patients remained on the transplant waiting list, until they received a kidney transplant. From that moment, the interview was carried out at the first, third, sixth and twelfth month after the date of transplantation. At each stage the following data was collected: age; level of education, socioeconomic level, living conditions and work status, using the same groups as in the first interview; date of renal transplantation; functional status measured by Karnofsky Scale score; serum analysis including hemoglobin, creatinine and albumin, and also creatinine clearance and proteinuria; comorbidity index; episodes of infection occurring since the last interview, their duration and severity according to clinical criteria; episodes of initial allograft dysfunction (measured by the number of hemodialysis sessions needed); episodes of acute rejection and of surgical problems related to the kidney transplant; number and duration (in days) of hospital admissions during the period of each interview; and the variations of the immunosupressor treatment and of the doses administered to patients since the last interview.

The SF-36 Health Survey (SF-36) is a generic HRQOL assessment tool [13,14] appropriately translated and validated in Spain [15], which includes eight dimensions (PF-Physical Functioning; RP-Rol Physical; BP-Bodily Pain; GH-General Health; VT-Vitality; SF-Social Functioning; RE-Rol Emotional; MH-Mental Health) and two summary scores (PCS-Physical Component Summary; and MCS-Mental Component Summary). Every dimension of the SF-36 can be scored from 0 (the worst HRQOL) to 100 (the best HRQOL). A standardization of these scores was applied, according to age and gender, using the Spanish population normative data [16], obtained from a study carried out over a random stratified sample of 9,151 subjects of the general population who answered the questionnaire. A standardized score over 0 indicates better HRQOL than that of the general population of the same age and gender; and a score under 0 indicates worse HRQOL [12].

The Kidney Transplant Questionnaire was developed by Laupacis et al. [17]. It is a HRQOL assessment instrument specific for kidney transplant bearers. Previously, the same authors had developed a specific questionnaire for dialysis patients: the Kidney Disease Questionnaire (KDQ) [10], but they did not develop the KTQ as an adaptation of the KDQ for kidney transplant. They thought that the clinical situation of kidney transplant patients was very different to that of dialysis patients, and that it required a new questionnaire. The original instrument has 25 items grouped in five dimensions: Physical symptoms (6 items), Fatigue (5 items), Uncertainty/fear (4 items), Appearance (4 items) and Emotional (6 items). The first dimension (Physical symptoms) is patient specific. It includes the six main symptoms for each patient, and it is used in the individual follow-up of the patient. All the items have a likert scale with 7 possible answers. In the validation study of the original version of the KTQ, the internal consistency (measured by the Cronbach's alpha) for each dimension was 0.76 (physical symptoms), 0.94 (fatigue), 0.63 (uncertainty/fear), 0.61 (appearance), and 0.80 (emotional). Construct validity was assessed by means of the correlation coefficients between the KTQ dimensions (r coefficient between 0.19 and 0.67) and correlation coefficients between the KTQ dimensions and other HRQOL assessment instruments. Reproducibility was analyzed in the group of patients remaining clinically stable between months 6 and 12 after kidney transplantation, using the Intraclass Correlation Coefficients, which were high (between 0.82 and 0.91). Sensibility to change was also quite adequate: the scores of the dimensions, except that of "Appearance", improved after 6 months from transplantation compared to pre-transplantation scores. The English original version of the KTQ was translated into Spanish by two independent professional translators. English back-translations from the Spanish were done by a professional translator unaware of the original version. Both English versions were compared, and where needed, modifications to the Spanish versions were made. The preliminary version of the questionnaire was reviewed by a group of nephrologists and nurses of dialysis units who approved the final version of the Spanish questionnaire.

Statistical analysis
All the variables collected were entered in a data base for the statistical analysis carried out with the SPSS 7.5 statistical package. The statistical analysis was carried out in steps: feasibility, validity, reliability and change sensibility.

Feasibility
questions not answered or not understood were analyzed, together with the time required to complete the questionnaire.

Validity

construct validity was examined studying the correlation coefficients between the KTQ dimensions. Concept validity was studied analyzing the correlation coefficients between the scores of the KTQ dimensions and the scores of the two Component Summaries of the SF-36 (PCS and MCS), the seric creatinine and hemoglobin, the comorbidity index score, the functional status, the number of infections, and the number and duration of hospital admissions; Pearson correlation coefficients were employed when variables were normally distributed, and Spearman coefficients if they were not. Associations of scores of the KTQ dimensions with episodes of initial allograft dysfunction, acute rejection and surgical problems related to kidney transplantation were also assessed, using the Student's T test. Construct and concept validity were evaluated with the data corresponding to six months after kidney transplantation.

Reliability

Internal consistency was studied calculating the Cronbach's Alpha. This coefficient is acceptable when it is above 0.7, following Nunnally's criteria [18]. Test-retest reliability was assessed by means of the Intraclass Correlation Coefficient.

Change Sensibility

the change in scores of the KTQ dimensions was studied with the data of the first and the last follow-up interview, using the Student's T test for paired samples. This change was also studied by dividing patients into two groups: patients who answered the general health evolution question as "feeling better", and patients who answered as "feeling the same or worse".

The Effect Size of "to have a functioning kidney transplant during one year" was also assessed for each dimension of the Spanish KTQ, dividing the difference between the mean score in the first interview and that of the last one by the standard deviation of the mean score in the first interview [19]. The Effect Size is considered as small if it is under 0.2; moderate if it is near 0.5; and large if it is over 0.8.

Results

Out of 42 patients who had received the kidney transplant before the end of the year 2000, 31 completed all the personal interviews at the required times durign the follow-up year. This is the sample used for the study of validation of the Spanish version of the Kidney Transplant Questionnaire (KTQ) that is presented here.

In Table 1 the sociodemographic, clinical and analytical data are presented, all data collected at the beginning of the study, and also in month 12 of the follow up for some variables. It can be observed in the table that, in the studied sample, the median age was 51 years and there were more males than females (21 men versus 10 women). As

Table 1: Sociodemographic and clinical characteristics of the sample (N = 31)

Sociodemographic and clinical variables at start of follow-up (1 month postransplantation)					
Median age (Interc. range)		51 years (38 − 57)			
Male gender (%)		21 males (68%)			
Economic level (%)	<900 €/month (38%)	900–1,800 €/m. (48%)		>1,800 €/m. (14%)	
Educational level (%)	Primary (43%)	Secondary (38%)		University (19%)	
Living conditions (%)	Alone (10.3%)	In family (86.2%)		Institution (3.4%)	
Work status (%)	Active working (4%)			No active working (96%)	
Main diagnosis (%)	NE (7.1%)	DM (17.9%)	GN (25%)	IN (14.3%)	PK. (17.9%)	Other (17.9%)

Variables Evolution	1st month postrasplantation	12th month postrasplantation
Karnof. Scale. Median (int. range)	90 (80 − 100)	100 (90 − 100)
Comorbidity Index (Mean ± SD)	3.24 ± 2.25	3.45 ± 2.31
Hemoglobina grs/dL (mean ± SD)	11.69 ± 1.19	13.75 ± 13.50 **
SCr mgr/dL (mean ± SD)	1.54 ± 0.50	1.46 ± 0.43
ClCr mL/min (mean ± SD)	66.80 ± 20.18	76.42 ± 25.50 *
Albumin grs/dL (mean ± SD)	3.87± 0.34	5.05 ± 6.27
Proteinuria grs/24 h (mean ± SD)	0.38 ± 0.27	0.37 ± 0.35

Main Diagnosis: NE-Nephrosclerosis; DM-Diabetes Mellitus; GN-Glomerulonephritis; IN-Interstitial Nephritis; PK-Policystic Kidney Disease; Other-other diagnosis Scr: seric creatinine ClCr: creatinine clearance * Paired Student t test. $P < 0.05$ ** Paired Student t test. $P < 0.01$

far employment, there was a predominance of those who did not work during their treatment with chronic dialysis and who remained in that situation during the first year after having received the kidney allograft. More than 40% of patients had elementary studies (no patient without studies) and most of the patients did not live alone and had an medium economic level (between 900 and 1,800 € monthly). As far clinical data, it is observed that the most frequent diagnosis of renal disease was glomerulonephritis. According to Karnofsky Scale score patients demonstrated a good functional state (median = 90) which at the end of the study was even better (median = 100), although they had a mean comorbidity index close to 3 points or diseases at the start of the follow up (3.24 ± 2.25 first postransplant month). The comorbidity index hardly varied at the different stages of the study: 3.58 ± 2.18 at the third postrasplant month; 3.52 ± 2.47 at the sixth postrasplant month; and 3.45 ± 2.31 at the twelfth month of follow up. The analytical figures with statistically significant improvement, comparing the start of the study with the end, were the hemoglobin and the creatinine clearance.

Other variables whose evolution was studied during patient follow-up are not included in Table 1, are described next. Patients who had suffered initial allograft dysfunction were only 7 (22.6%); acute rejection, 4 patients (12.9%); and surgical problems related to the kidney transplant, 5 patients (16.1%). With respect to the hospital admissions throughout the follow-up, 14 patients (45.2%) were admitted at least once; for these patients, the mean number of hospitalized days was 10.6 ± 7.6 days. The number of patients who suffered some infection during the follow up period was very low at all stages: 2 patients (6.5%) in the first postrasplant month; 5 patients (16.1%) during the second and third month; 6 patients (19.3%) in months 4, 5 and 6; and 2 patients

(6.5%) in the last interval between visits. As a whole, 12 patients (38.7%) suffered some infection during the follow up.

All the patients self-completed the Spanish version of KTQ at all stages of the study, in a mean time of 11.9 ± 1.7 minutes (between 10 and 20 minutes). Although in all cases they responded to all items of the questionnaire, there were two questions with problems of understanding in a small percentage of the cases. These items were question 14 (2 patients – 6.5%) and question 15 (4 patients – 13%). Question 14 asks with what frequency, during the two last weeks, the patient has felt "anxious", this is a concept that the patients mentioned said they did not understand well. Question 15 refers to the "fear or panic of rejection". This made the patients doubt whether the interviewer was talking about feeling rejected by society (by being a kidney transplanted patient) or the physical rejection of the kidney allograft.

In Table 2 the mean scores, and the corresponding standard deviations, of the dimensions of the KTQ and the SF-36 questionnaires are presented for the different stages of evolution. As can be observed, the scores increased throughout the follow up. In some cases, the increase is clear ("Physical Symptoms", "Fatigue" and "Uncertainty/Fear") and in other cases the increase is less important (Appearance and Emotions). Also, for the two component summary scores of the SF-36 questionnaire, one showed a clear increase (Physical Component Summary or PCS) and the other did not present such an obvious increase (Mental Component Summary or MCS).

The correlation coefficients among the dimensions of the KTQ, which evaluate the construct validity, are shown in Table 3. As can be observed, the coefficients ranged between the minimum of 0.32 obtained for "Fatigue" and

Table 2: Evolution of the scores of the HRQoL questionnaires: Kidney Transplant Questionnaire and SF-36 Health Survey (N = 31)

Mean Scores (± standard deviation)				
KTQ	**Month 1**	**Month 3**	**Month 6**	**Month 12**
Physical Symptoms	5.10 ± 1.44	5.21 ± 1.52	5.23 ± 1.42	5.79 ± 1.49
Fatigue	5.71 ± 1.20	5.93 ± 1.22	5.89 ± 1.26	6.12 ± 1.18
Uncertainty / fear	5.21 ± 1.47	5.59 ± 1.40	5.47 ± 1.41	5.76 ± 1.21
Appearance	6.04 ± 1.01	5.89 ± 1.24	5.82 ± 1.15	6.20 ± 0.98
Emotions	5.88 ± 1.19	6.00 ± 1.18	5.69 ± 1.17	6.03 ± 1.04
SF36	**Month 1**	**Month 3**	**Month 6**	**Month 12**
PCS	47.24 ± 9.21	49.72 ± 8.74	51.14 ± 6.48	51.09 ± 8.19
MCS	53.89 ± 11.91	53.00 ± 11.55	51.10 ± 11.73	52.94 ± 10.71

PCS: Physical Component Summary; MCS: Mental Component Summary

Table 3: VALIDITY: Correlation Coefficients among the KTQ dimensions and between the KTQ dimensions and other variables at 6th month postransplantation (N = 31)

	PS	F	U/F	A	E
Physical Symptoms (PS)					
Fatigue (F)	.52				
Uncertainty / Fear (U/F)	.34	.64			
Appearance (A)	.54	.32	.34		
Emotions (E)	.46	.68	.72	.59	
PCS	.28	.24	.11	.25	.017
MCS	.33	.60	.81	.39	.78
Comorbidity Index	.28	.06	.07	.25	.20
Seric Hemoglobine	-.07	.12	.24	.14	.38
Seric Creatinine	-.19	-.54	-.25	-.12	-.35
Karnofsky Scale	.31	.23	-.02	.20	.22
Number of Infections	.04	.12	-.22	-.12	-.08
Number Hosp. Admissions	-.05	-.02	-.18	-.10	-.19
Number Hosp. days	-.06	-.09	-.46	-.05	-.19

PCS: Physical Component Summary; MCS: Mental Component Summary

"Appearance", and the maximum of 0.72 for "Uncertainty/Fear" and "Emotions", being, in most of the cases, moderate. Concept validity, measured by the correlation coefficients between the KTQ and the SF-36 Health Survey dimensions and some clinical variables, is also presented in Table 3. The coefficients for the dimensions of the SF-36 were positive in all the cases. The coefficients between the KTQ dimensions and the mental component summary (MCS) score were moderate-high in all the dimensions, being superior to those observed for the physical component summary (PCS) score, that turned out to be low (< 0.4).

The correlations with comorbidity index turned out to be positive and of a low degree. In general, the correlations of the seric hemoglobin were positive, although of a low degree. The seric creatinina correlated negatively, presenting low and moderate coefficients in some cases ("Fatigue" and "Emotions"). For the Karnofsky's Scale, the correlation coefficients were low, being higher for the dimensions of the KTQ that covers the physical area ("Physical Symptoms" and "Fatigue") than for those of the mental area ("Uncertainty/Fear", "Appearance" and "Emotions"). The number of infections appearing from the date of the kidney transplantation to month six of the follow up, maintained low degrees of correlation with the scores of the dimensions of the KTQ. These correlations were surprisingly positive in the physical dimensions ("Physical Symptoms" and "Fatigue"), and negative in the mental dimensions ("Uncertainty /Fear", "Appearance" and "Emotions"), as had been hypothesized. The number

of hospital admissions and days of hospital stay correlated negatively, with low coefficients, with the scores of the KTQ dimensions, except for the "Uncertainty /Fear" dimension. This dimension showed a moderate correlation with the days of hospital admission. There was no statistically significant association between the scores of the KTQ dimensions and the variables of "initial dysfunction of the graft", "acute rejection" and "surgical problems associated to the kidney transplant". The only association found was for the score of the "Fatigue" dimension that turned out to be lower for those patients with surgical problems (4.84 ± 1.94 versus 6.08 ± 1.01).

Reliability was studied using the Cronbach's Alpha and the Intraclass Correlation Coefficient, which appears in Table 4. Cronbach's Alpha coefficients were over 0.7 for all the dimensions except for the "Appearance" dimension (0.69). Intraclass Correlation Coefficients were also over 0.7 except for two dimensions: "Physical symptoms" (0.63) and "Appearance" (0.67).

The changes in the scores obtained in the KTQ dimensions between the first and last interview of the follow up, appear in Table 5, along with the Effect Size coefficients for each. As can be seen, the mean scores improved, throughout the first year of evolution, with a statistical significance in the "Physical Symptoms", "Fatigue" and "Uncertainty/Fear" dimensions; however, they did not in the other two: "Appearance" and "Emotions". The Effect Size of "to have a functioning kidney transplant during one year" calculated for each dimension was only small, except for the "Physical Symptoms" dimension. That same change was also studied by separating the patients who, in the question regarding evaluation of general state of health had affirmed they felt better, from those that had said they felt the same or worse. This way it was verified that, for the group of patients who had affirmed they felt better, the effect size was moderate for most dimensions (Physical Symptoms = 0.82; Fatigue = 0.76; Uncertainty / Fear = 0.53; Appearance = 0.59) with the exception of the "Emotions" dimension, which hardly varies during the follow up (Emotions = 0.03).

Table 4: RELIABILITY: Cronbach's alpha coefficient and Intraclass Correlation Coefficient (ICC) (N = 31)

	Cronbach's Alpha	ICC
Physical Symptoms	0.80	0.63
Fatigue	0.93	0.82
Uncertainty / Fear	0.81	0.81
Appearance	0.69	0.67
Emotions	0.90	0.85

Table 5: Differences between mean scores at start and at the end of follow-up: Effect Size. (N = 31)

| | Differences between mean scores at start and at the end of follow-up | | | | |
	1st month mean ± S.D	12th month mean ± S.D	Mean difference	p	Effect Size
Physical Symptoms	5.10 ± 1.44	5.79 ± 1.49	0.68 ± 1.54	0.026	0.48
Fatigue	5.71 ± 1.20	6.12 ± 1.18	0.41 ± 1.02	0.046	0.34
Uncertainty / Fear	5.21 ± 1.47	5.76 ± 1.21	0.55 ± 1.38	0.043	0.37
Appearance	6.04 ± 1.01	6.20 ± 0.98	0.17 ± 1.11	0.42	0.17
Emotions	5.88 ± 1.19	6.03 ± 1.04	0.15 ± 1.12	0.49	0.12

Discussion

The psychometric properties of the Kidney Transplant Questionnaire (KTQ) evaluated in the present article have proven to be satisfactory and so allow the recommendation of the use of this questionnaire in clinical practice. This is the first specific instrument, translated and validated in the Spanish language, for the measurement of the HRQoL of patients bearing a functioning kidney transplant.

The sample of the present study was formed through the prospective recruitment of 54 patients at the moment they were included on the kidney transplant waiting list. 42 of them subsequently received a kidney allograft. A possible skew is that out of the 42 patients included at first, 11 were excluded because they had not completed all the interviews at each of the stages required. Nevertheless, the excluded patients had similar sociodemographic and clinical characteristics to those included. The sample size of studies evaluating the psychometric properties of specific HRQoL assessment instruments, as is the case of the present study, can never reach the magnitude of the validations of generic instruments, given the shortage of patients available with a certain disease. The study of validation of the original version of the Kidney Transplant Questionnaire [17] was carried out with a sample of only 26 kidney transplant patients. The sociodemographic and clinical characteristics of the included patients were similar to those of any other study previously carried out with patients who had received a kidney allograft [12]. Also, the incidence of adverse post-transplant events (initial dysfunction of the graft, acute rejection and/or surgical problems related to the transplant) were within the limits that are observed in other series of kidney transplantations.

The feasibility of the questionnaire is good, as is shown by the low number of items not answered or not understood by the interviewees, and also by the average time of administration of only 12 minutes. The short time required makes the questionnaire suitable for everyday clinical use, being no greater than that of other questionnaires in common use, such as the SF-36 Health Survey. It should also be borne in mind that, in most cases, the questionnaire was self-completed after brief instructions that were unnecessary in subsequent interviews, further facilitating its incorporation in transplant unit routine.

As was shown, the scores of the KTQ dimensions increased throughout the follow up, indicating improvements in the HRQoL of patients, mainly in the physical area, as had been hypothesized. This improvement in the physical area is better determined by the change in the scores of the KTQ, than by the physical component summary (PCS) of the SF-36. In fact, in the "Physical Symptoms" dimension of the KTQ the change between the basal and the last stage is of 0.69 points. This change in score is over the limit of 0.5 points that sets out "clinically outstanding" for dimensions constructed on Likert scales of 7 answers. However, in the case of the PCS, the change is hard to evaluate since it is within the margins of the expected average (50± 10), and no other reference exists. It can also be concluded that the KTQ provides more information than the SF-36. This is shown if we take into account the fact that the evolution of the scores in "Uncertainty /Fear" is centered on the evaluation of emotional problems (anxiety or fear) of the kidney transplanted patients, which are not included in the mental component summary (MCS) score of the SF-36.

The correlation coefficients between the dimensions of the KTQ were moderate, conferring the instrument an adequate construct validity. The fact that three of the coefficients turned out to be smaller than 0.4 is probably due to the large number of aspects of the kidney transplant that the questionnaire includes.

The positive correlation coefficients found between the dimensions of the KTQ and the summary components of the SF-36, demonstrate that both instruments evaluate the same concept. Nevertheless, the correlations with the physical component of SF-36 (PCS) were discrete, lower than 0.4 in all cases. It is quite likely that the KTQ meas-

ures this area of the HRQoL better and in more detail, as has already been explained.

Regarding the correlation of KTQ dimensions with other variables collected in the study, the associations always followed the hypothesized direction, except for the comorbidity index. Thus, the correlations with the seric hemoglobin were in general positive, as well as the correlations with the Karnofsky's Scale. This is the logical direction of the association: the greater the seric hemoglobin or the better the functional state is, the better the HRQoL evaluated by the KTQ will be. Also the correlation of the dimensions of the KTQ with the figure of seric creatinine confirms what was expected: the higher the seric creatinine is, the worse the HRQoL will be. It should not be surprising that the association with the number of infections is slightly positive in some dimensions and negative in others, since the infections suffered were not serious, being taken care of in the preclinical period in most cases. In our hospital protocols for early detection of antigenemia for different virus (CMV, HerpesVirus...) and for the taking of biological specimens for cultures are followed. The correlation with the comorbidity index is confusing. Although it should follow a negative association, that is to say the greater comorbidity is, the worse HRQoL should be, it follows a positive tendency. The explanation may be that the patients already had the comorbidity when undergoing dialysis, and probably these are the patients who are most likely to notice an improvement in their quality of life following the transplant. Probably the slight variations of the index from the beginning of the follow up also influence the absence of correlation: 17 patients had the same, in 6 it diminished, and in 7 it increased during the first six months. The correlation coefficients calculated for the hospital admissions and days of hospital stay followed the negative sign which had been hypothesized: the greater the number of admissions and/ or days, the smaller the score in the dimensions of the KTQ was, that is to say, the worse the HRQoL. The fact that associations between the scores of the KTQ dimensions and the initial allograft dysfunction, the acute rejection and surgical problems, were not found is not surprising if we take into account the low number of patients who showed adverse effects after transplantation.

Cronbach's alpha coefficients confer the instrument evaluated a suitable Reliability even for their use in the individualized follow-up of the kidney transplanted patients. Also the Intraclass Correlation Coefficients calculated for the Spanish version of the KTQ are very good, being higher to those of the original version [17] in three dimensions ("Fatigue", "Uncertainty/Fear" and "Emotions"), and lower in two dimensions ("Symptoms" and "Appearance").

For the evaluation of sensibility to change of the original version of the KTQ [17], the pre-transplantation scores were compared with those obtained at 6 months after transplantation. However, the use of a questionnaire adapted to patients with a functioning kidney transplant does not seem absolutely correct applied to other groups of different patients, as is the case of patients undergoing hemodialysis. Thus, in the present study the changes in the scores from month one to month twelve were used. It was hypothesized that throughout the first year after transplantation, the HRQoL would improve. The hypothesis was confirmed, obtaining improvements in all the dimensions, which were statistically significant in three of the cases. The effect size of "to have a functioning kidney transplant during one year" in the KTQ dimensions was small except for the "Physical Symptoms" dimension, that turned out to be moderate. Nevertheless, selecting only the patients who in the question regarding the overall change in their state of health (SF-36) had affirmed they felt better, it was verified. For these patients the Effect Size was moderate, except for the "Physical Symptoms" dimension that was high, and for the dimension "Emotions", that was very small.

Conclusions

The feasibility, validity, reliability and sensibility to change of the Spanish version of the Kidney Transplant Questionnaire are therefore similar to those of the original instrument. Thus, a specific HRQoL assessment instrument is now available in the Spanish language. This instrument will be useful for use in the individual evaluation of patients with end-stage renal disease who receive a kidney transplant, and also for the evaluation of the different types of inmunosupresor therapies and other types of therapies which influence the evolution of the kidney transplant.

Authors' contributions

P participated in the design of the study, carried out some interviews with patients, and drafted the manuscript. F conceived of the study and participated in its design and coordination. T carried out some interviews with patients, and performed some statistical analysis (scoring questionnaires). C carried out part of the interviews with patients. M performed the statistical analysis. E participated in the coordination of the study. All authors read and approved the final manuscript.

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References

1. Ware JE, Brook RH and Davies-Avery A: **Choosing measures of health status for individuals in general populations.** *Am Public Health* 1981, **71:**620-625.
2. Patrick DL: **Prologue to "La medida de la Salud. Guía de escalas de medición en español".** In "*La medida de la Salud. Guía de escalas de medición en español*" Edited by: *Badía X, Salamero M, Alonso J. Barcelona: Ed PPU*; 1996:11-12.
3. Kutner NG: **Assessing end-stage renal disease patients' functioning and well-being: measurements approaches and implications for clinical practice.** *Am J Kid Dis* 1994, **24:**321-333.
4. Schrier RW, Burrows-Hudson S, Diamond L, Lundin AP, Michael M, Patrick DL, Peters TG, Powe NR, Roberts JS and Sadler JH *et al.*: **Measuring, managing, and improving quality in the end-stage renal disease treatment setting: committee statement.** *Am J Kidney Dis* 1994, **24:**383-388.
5. Kurtin PS: **Assessing patient outcomes with higher hematocrit levels.** *Am J Kidney Dis* 1995, **suppl 1:**8-11.
6. Meers C, Hopman W, Singer MA, Mckenzie TA, Morton AR and McMurray M: **A comparison of patient, nurse, and physician assessment of health-related quality of life in end-stage renal disease.** *Dialysis and Transplantation* 1995, **24:**3-13.
7. Laupacis A, Keown P, Pus N, Krueger H, Ferguson B, Wong C and Muirhead N: **A study of the quality of life and cost-utility of renal transplantation.** *Kidney Inter* 1996, **50:**235-242.
8. Dew MA and Simmons RG: **The advantage of multiple measures of quality of life.** *Scand J Urol Nephrol* 1990, **131:**31-37.
9. **Registry of "Organización Nacional de Trasplante-ONT"** [http://www.msc.es/ont/esp/estadisticas/f_estadisticas.htm]
10. Laupacis A, Muirhead N, Keown P and Wong C: **A disease-specific questionnaire for Assessing Quality of Life in Patients on Hemodialysis.** *Nephron* 1992, **60:**302-306.
11. Hays RD, Kallich JD, Mapes DL, Coons SJ and Carter WB: **Development of the Kidney Disease Quality of Life (KDQOL) Instrument.** *Qual Life Res* 1994, **3:**329-338.
12. Rebollo P, Ortega F, Baltar JM, Alvarez-Ude F, Navascués RA and Alvarez-Grande J: **Is the loss of Health Related Quality of Life (HRQOL) during renal replacement therapy lower in elderly patients than in younger patients?** *Nephrology Dialysis Transplantation* 2001, **16:**1675-1680.
13. Ware JE and Sherbourne CD: **The MOS 36-Item Short-Form Health Survey (SF-36). I. Conceptual Framework and Item Selection.** *Medical Care* 1992, **30:**473-483.
14. McHorney CA, Ware JE, Lu JFR and Sherbourne CD: **The MOS 36-Item Short-Form Health Survey (SF-36): III. Tests of Data Quality, Scaling Assumptions, and Reliability Across Diverse Patient Groups.** *Medical Care* 1994, **32:**40-66.
15. Alonso J, Prieto L and Antó JM: **La versión española del SF-36 Health Survey (cuestionario de salud SF-36): un instrumento para la medida de los resultados clínicos.** *Med Clin (Barc)* 1995, **104:**771-776.
16. Alonso J, Regidor E, Barrio G, Prieto L, Rodríguez C and de la Fuente L: **Valores poblacionales de Referencia de la versión española del Cuestionario de Salud SF-36.** *Med Clin (Barc)* 1998, **111:**410-416.
17. Laupacis A, Pus N, Muirhead N, Wong C, Ferguson B and Keown P: **Disease-Specific Questionnaire for Patients with a Renal Transplant.** *Nephron* 1993, **64:**226-231.
18. Nunnally JC: *Psychometric theory New York: McGraw-Hill*; 1978.
19. Cohen J: *Statistical power analysis for the behavioral sciences* 2nd edition. *Hillsdale, New Jersey: Lawrence Erlbaum Associates Inc*; 1988.