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Analysis, evaluation and adaptation of the ReTransQoL: a specific quality of life questionnaire for renal transplant recipients

Davy Beauger^{1*}, Stéphanie Gentile^{1,2}, Elisabeth Jouve², Bertrand Dussol³, Christian Jacquelinet⁴ and Serge Briançon^{5,6}

Abstract

Background: End stage renal disease (ESRD) profoundly impacts the lives of patients. Kidney transplantation provides the greatest health-related quality of life (HRQOL) improvement. Its measurement has become an important outcome parameter and a very important criterion in the evaluation of any type of medical treatment, especially in the field of renal transplantation.

In 2007, a specific self-administered questionnaire for renal transplant recipients was developed in the French language: the ReTransQol (RTQ).

After 5 years of use, the properties of the RTQ needed to be re-evaluated in a larger sample.

This paper describes the analysis of the ReTransQol and its adaptation to achieve an improved and revised version.

Methods: The study design included three analysis phases for two samples of adult renal transplant recipients which came from two cross-sectional multicenter studies carried out in France in 2007 and 2012. Psychometrics properties like construct validity, acceptability and feasibility, reliability and convergent validity were evaluated and every analysis resulted in a new version of the questionnaire: the RTQ V2. The construct validity of the new RTQ was assessed with a Confirmatory Factor Analysis on a large sample of patients.

Results: The study samples included 1,059 patients and 1,591 patients, respectively.

After a principal component analysis, item reduction was performed and a total of 13 items were deleted. A final version of the RTQ V2 was created and comprised of 32 items describing 5 domains: Physical Health, Social Functioning, Medical Care, Treatment and Fear of Losing Graft.

The explained variance between the first and second RTQ versions improved from 46.3% to 53.1%. All psychometric properties of RTQ V2 were satisfactory: IIC >0.4, IDV (%) of 100% and Cronbach's Alpha >0.7 in every dimension. The confirmatory analysis showed that the overall scalability of the RTQ V2 was satisfactory; all items showed a good fit to the Rasch model within each dimension, and showed INFIT statistics inside the acceptable range.

Conclusions: Psychometric properties allow this new version of the questionnaire to be used to assess different specific dimensions for the renal transplant population, more effectively than previously possible.

Keywords: Quality of life, Medical outcomes, Specific questionnaire, Renal transplantation, RETRANSQOL

* Correspondence: davy.beauger@ap-hm.fr

¹Faculté de Médecine, Laboratoire de Santé Publique, Université Aix-Marseille, Marseille EA 3279, France

Full list of author information is available at the end of the article

Introduction

End stage renal disease (ESRD) profoundly impacts the lives of patients, leading to activity limitations, social participation restrictions, and dependence caused by the need for renal replacement therapy (RRT) [1-5]. It also represents a significant burden to society caused by the high treatment costs and an increasing prevalence of ESRD [6-9].

The number of patients being treated for ESRD globally was estimated to be 2,786,000 at the end of 2011, and with a 6-7% growth rate, continues to increase at a significantly higher rate than the world population. Of these ESRD patients, approximately 2,164,000 were undergoing dialysis treatment and around 622,000 were living with kidney transplants [10].

In France, between 9,000 and 10,000 new patients with chronic renal failure required the initiation of RRT in 2010, and about 67,000 were treated for renal failure, including approximately 30,000 transplants [11].

As ESRD reduces life expectancy, renal transplantation has become worldwide the treatment of choice over hemodialysis, which remains the only treatment for the majority of patients [12-14]. The aim of renal transplantation is not only to improve renal function, but also to enhance the patient's ability to enjoy life as fully as possible. Kidney transplantation also provides the greatest improvement for health-related quality of life (HRQOL), whose measurement has become an important outcome parameter [15-17]. HRQOL has become a very important criterion in the evaluation of any type of medical treatment [18], especially in the field of renal transplantation, and is associated with the improvement of graft survival [19-22]. Several determinations of HRQOL focus on physical status and symptoms, functional status, mental health, social functioning, and general health perceptions.

Currently, few specific HRQOL questionnaires have been developed for renal transplant recipients and few are validated or available in French [23,24]. Among questionnaires adapted to the general population, the Short Form-36 Health Survey (SF-36) remains the most widely used in quality of life studies [25-27].

In 2007, a specific self-administered questionnaire for renal transplant recipients (RTR) was developed by Gentile et al. in the French language: the ReTransQol (RTQ) [28]. The RTQ was validated in a study of 335 French patients randomly selected from the registry of the transplant center in Marseille.

After 5 years of use in many French studies [29,30], the properties of the RTQ needed to be re-evaluated in a larger sample. In fact, the RTQ has been validated but not established with a Confirmatory Factor Analysis, and the psychometric properties can be improved. Moreover, the questionnaire seems to be

slightly lengthy, and can be better adapted for routine use.

This paper describes the analysis of the ReTransQol and its adaptation, in order to achieve an improved and revised version.

Methods

The study design involved analysis of the original version of the ReTransQol (RTQ V1) and its adaptation, and included three phases for two samples of renal transplant recipients (Figure 1).

Data sources

For Phase 1 and Phase 2, both samples came from the same cross-sectional multicenter study, which was carried out in France between March 2007 and March 2008 in eight regions of France participating in the Renal Epidemiology and Information Network (REIN) in 2003.

For Phase 3, the sample came from a cross-sectional multicenter study (QUAVIREIN: French translation of Renal Quality of Life study) which was carried out in France between May 2011 and September 2012, in 21 regions of France participating in the REIN network in 2010 and whose register was complete and exhaustive.

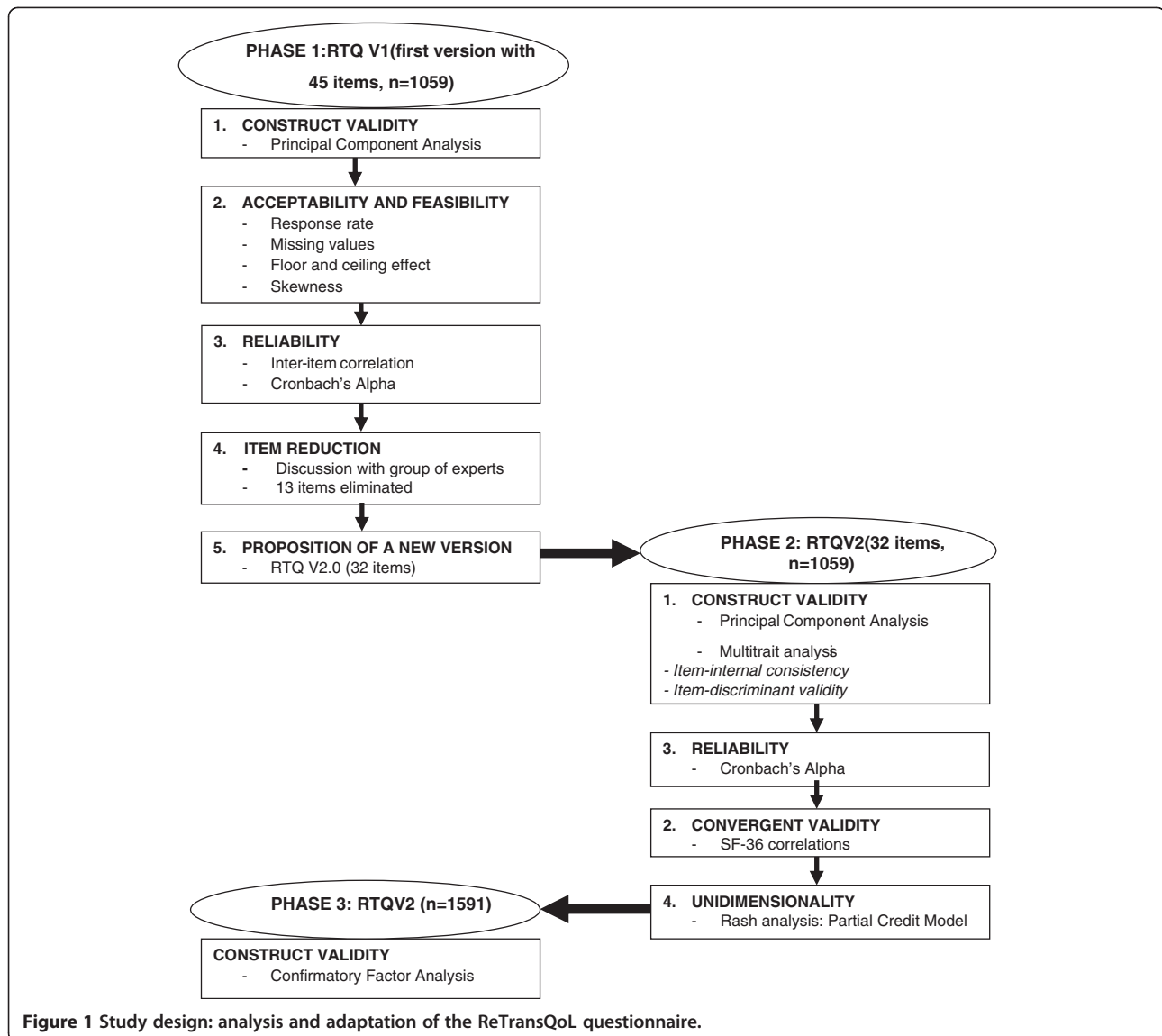
Participants

For each sample, all participants were RTR over 18 years of age with a functioning graft for at least one year. Multi-organ transplant patients before or simultaneously with their kidney transplant were excluded. The samples were stratified by regions and age class, using the same sampling rate for each stratum. The sample size was calculated to detect a difference of 5 points in the SF-36, considering a standard deviation of 20, and assuming a two-sided level of 5% with 80% power. The sample size calculation was 1,000 patients for the first national study, and 1,500 for the QUAVIREIN study. Considering a non-response rate of approximately 30% for each study, 1,300 and 1,800 questionnaires were sent in order to achieve these objectives. The number of self-administered questionnaires returned was 1,059 for the first study and 1,591 for the second, with a response rate of over 70% for both.

Data collection procedures for both studies

The French version of the SF-36 [31] is a generic instrument, with scores ranging from 0 to 100 (worst to best possible HRQOL) for eight domains: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH).

The ReTransQol V1 [28] is a specific instrument consisting of 45 items describing 5 dimensions: physical health (PH), mental health (MH), medical care and satisfaction (MC), treatment (TR) and fear of losing the graft



(FLG). Each score ranges from 0 to 100 and the higher the score, the better the perceived state of health. Data collection included demographic, socio-demographic and medical characteristics, as well as HRQOL. SF-36 and RTQ V1 (first version) were used to evaluate HRQOL for both studies. All measuring instruments were sent to the patient's home with a newsletter and an explanatory letter signed by the project coordinator. Patients returned the completed questionnaires via a pre-stamped envelope. Non-respondents were reminded by a second letter three weeks later and contacted by phone at the same time.

Ethical aspects

The studies' methodology was approved by the local Institutional Review Board, the Advisory Committee

on Information Processing in Health Research (CCTIRS n°06-311 and no. 05-142) and the French consulting committee for treatment of information in health research (CNIL n°906248 and CNIL n° 905263), which ensures the confidentiality of all information collected.

Statistical analysis

During the first phase, the construct validity and dimensional structure of the questionnaire were assessed by studying principal component factor analyses with Varimax rotation. Prior to the extraction of the factors, several tests were used to assess the suitability of the respondent data for factor analysis. These tests included Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy and Bartlett's Test of Sphericity. The KMO index ranges from 0 to 1, with 0.50 considered to be suitable for factor

Table 1 Socio-demographic comparison between the two samples used

		Population 1 N=1059	Population 2 N=1591	Significance*
Male		61.9% (n=656)	60.5% (n=963)	p=0.52
Age (years), mean ± standard deviation		55.2 ± 12.4	55.3 ± 14.2	p=0.85
Level of education	Secondary 1st stage (college & high school)	45.6% (n=483)	45.3% (n=721)	p=0.9
Employment status	Employed	35.5% (n=377)	39.9% (n=635)	p=0.007
	Retired	29.9% (n=317)	36.1% (n=574)	P<0.001

* Chi-square test for frequency comparison. Student t-test for mean comparisons.

analysis [32]. The Bartlett's Test of Sphericity should be significant ($p < 0.05$) for factor analysis to be appropriate. Next, a Principal Component Analysis (PCA) of the RTQ V1 was assessed to analyze the structure of the questionnaire over a larger sample than during the phase of development and validation [33]. Each dimension was examined in order to indicate which items could potentially be deleted due to their low psychometric performance at a dimension level. This was done by studying the inter-item and inter-dimension correlations (Pearson's r). Items which loaded < 0.40 for all the factors were considered as potentially removable.

Acceptability and feasibility were assessed regarding response rate, missing values, skewness, inter-item correlation and floor or ceiling effects. Items were eliminated during the reduction phase with missing values exceeding 5%, high inter-item correlation ($r > 0.80$), floor or ceiling effects over 70%, or an absolute value of skewness exceeding 4.0.

During the item reduction phase, the most clinically relevant items were kept and lowest items were eliminated after analysis and discussion with the group of experts.

This analysis resulted in a new version of the questionnaire: the RTQ V2.0.

During the second phase, the psychometric properties of the RTQ V2.0 were evaluated.

Another factor analysis (PCA) with the items retained was conducted to ensure the construct validity of the RTQ V2.0. The relevance of the grouping of items into the original structure isolated by PCA was examined using multitrait multi-item analyses [34], examining correlations between item scores and dimension scores. Item-internal consistency (IIC) was assessed by correlating each item

with its dimension. Item-discriminant validity (IDV) was assessed by determining the extent to which items correlate more highly with dimensions they are hypothesized to represent than with different dimensions. Each item should be highly correlated with its scale, thus supporting item-internal consistency (IIC); a correlation corrected for overlap of at least 0.4 is recommended [35]. In addition, items should be more highly correlated with their own scale than with the other dimension scales (item-discriminant validity, IDV).

The internal consistency reliability of the RTQ was measured using Cronbach's alpha coefficients [36], which were computed to estimate the internal consistency reliability of each dimension score. A reliability of at least 0.70 is recommended to compare groups of patients [37].

The uni-dimensionality of the new version (RTQ V2.0) was assessed using Rasch analyses, the Partial Credit Model [38,39]. The scalability of each dimension's scale was assessed by the pattern of the item's goodness-of-fit statistics (INFIT). Items with INFIT included in the] 0.7;1.3 [interval were kept ensuring that all the items of the scale tended to measure the same concept.

External validity and convergent validity were explored by calculating Pearson's correlation coefficients between the RTQ scores and SF-36 scores. Dimensions measuring the same concept were expected to be correlated with each other.

Finally, we tested the scores of HRQOL of the RTQ V2.0 with comparisons of subgroups (sex and age class) to confirm good properties of measurement compared with results of other studies.

For the third phase, the construct validity was confirmed with a Confirmatory Factor Analysis (CFA) for the second

Table 2 Comparison of RTQ V1 scores between the two samples

Dimensions	Population 1		Population 2		T-test
	n	mean ± SD (min-max)	n	mean ± SD (min-max)	p-value
PH	1039	59.5 ± 18.7 (0-100)	1573	58.8 ± 19.0 (0-100)	0.34
MH	1042	77.1 ± 19.3 (0-100)	1571	76.5 ± 19.0 (4.8-100)	0.45
MC	1027	72.7 ± 17.6 (0-100)	1572	72.3 ± 17.8 (0-100)	0.61
TR	1030	79.0 ± 15.9 (25-100)	1575	75.8 ± 17.8 (8.3-100)	<0.001
FLG	1042	58.4 ± 20.4 (0-100)	1566	59.8 ± 19.5 (0-100)	0.07

SD, standard deviation; PH, Physical health; MH, Mental health; MC, Medical care and satisfaction; TR, Treatment; FG, Fear of losing graft.

sample of 1,591 patients. Robust maximum likelihood Confirmatory Factor Analysis was performed to test the fit to the model assessed by the computation of the root mean square error of approximation (RMSEA: <0.05, good fit; 0.05–0.08, fair or reasonable; >0.08 unsatisfactory fit), the comparative fit index (CFI), the Standardized Root Mean Square Residual (SRMR) and the Goodness of Fit Index (GFI) [34,40]. The CFI and the GFI are expected to be greater than 0.9 if the fit is adequate and the SRMR must be close to 0 [41-43]. All correlations between each dimension and its items were extracted from the CFA.

Data analyses were performed using SPSS 19.0, Winstep and LISREL softwares.

Results

The study sample for the first two phases included 1,059 patients; 1,591 patients were enrolled in the third phase. The data set was jointly normally distributed.

The characteristics of the two samples (Table 1) and the HRQOL scores (Table 2) were not significantly different, except concerning the second sample where the proportion of retired patients was slightly higher and the “treatment dimension” which was slightly lower.

For the first phase, the PCA of the RTQ V1 showed an unsatisfactory structure of the items with the dimensions, with a KMO of 0.841. The 5 dimensions were confirmed with a variance of about 50%, but several items were not classified in the appropriate component and had a low psychometric performance (<0.40). At the end of this step, 10 items were removed (Table 3).

The analysis of the response rate, the inter-item correlation and the floor and ceiling effects allowed us to remove 3 more items for which the response rate was <30%, inter-item correlation was 0.845, and a ceiling effect of >70%. Item reduction was performed at the end of the first step, where a total of 13 items were removed (Table 3). The iterative process of item selection resulted in a final version of the RTQ V2.0 comprised of 32 items describing 5 domains: Physical Health, Social Functioning, Medical Care, Treatment and Fear of Losing Graft (Table 4). The set of the 32 items kept and the 13 items deleted was

Table 3 Number of items deleted according to dimensions and versions of RTQ

	RTQ V1	RTQ V2	Items deleted
Dimensions	PH = 10	PH = 8	2
	MH = 9	SF = 5	4
	MC = 11	MC = 8	3
	TR = 9	TR = 5	4
	FLG = 6	FLG = 6	0
Total	45	32	13

PH, Physical health; MH, Mental health; MC, Medical care and satisfaction; SF, Social functioning; TR, Treatment; FG, Fear of losing graft.

Table 4 Principal component analysis of the RTQ V2 with Varimax rotation (n=1059)

	Component					Total variance	
	1	2	3	4	5		
% of variance	23.8	11.7	6.7	6.1	4.8	53.1	
Item number						Dimension Labels	
q1	.645					Physical Health	
q3	.682						
q4	.567						
q5	.720						
q6	.602		.303				
q7	.618						
q8	.663						
q9	.708						
q40		.770					Medical Care
q41		.670					
q42		.819					
q43		.849					
q44		.730					
q45		.672					
q46		.729					
q49		.761					
q15			.525			Fear of losing graft	
q16			.615				
q29			.642				
q30			.694				
q31			.759				
q32			.740				
q19				.833			Social Functioning (previously Mental Health)
q20				.737			
q21				.596			
q22				.595			
q28				.604			
q11		.363		.544		Treatment	
q17				.336			
q37				.758			
q38			.301	.682			
q39				.750			

discussed by a pluridisciplinary group (nephrologists, interviewers, and methodologists), who accepted and validated the modifications.

For the 2nd phase, the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO = 0.880) and Bartlett’s Test of Sphericity (p<0.01) were also used to assess the suitability of the respondent data for factor analysis. The structure of the 5 factors was fixed and supported by PCA with Varimax rotation and accounted for 53.1% of the total

variance (Table 4). The inter-dimension correlations were all significant ($p < 0.001$) and ranged from $r = 0.16$ for MC with FLG dimension, to $r = 0.43$ for PH with TR dimension. All other inter-dimension correlations were between $r = 0.27$ and $r = 0.38$.

The correlation between each item and its contributive dimension was higher than the correlation with other dimensions. Internal consistency was acceptable for each dimension (> 0.4). Item-discriminant validity (IDV) results were acceptable for every dimension of the RTQ (IDV $<$ IIC ranges). The floor effect ranged from 0% to 0.7%, and the ceiling effect ranged from 0.6% to 11.7%. Cronbach's alpha was > 0.7 in every dimension (0.7 to 0.9), satisfying the internal consistency reliability.

Finally, the overall scalability of the RTQ was satisfactory; all items showed a good fit to the Rasch model within each dimension, and showed INFIT statistics inside the acceptable range (0.7 – 1.3). The dimension scales' characteristics are summarized in Table 5.

The results of the convergent validity of the RTQ V2.0 with SF36 dimensions are shown in Table 6. The PH dimension of the RTQ showed high correlations with Vitality, General Health, Physical Functioning and Bodily Pain ($r > 0.6$). The new SF dimension (previously MH) of the RTQ V2.0 was correlated with Mental Health and Social Functioning.

However, the specific MC dimension was globally uncorrelated or was weakly correlated with the SF36 dimensions ($r < 0.3$). The highest correlations of the TR dimension of the RTQ were with Vitality and General Health. Finally, the FLG dimension was best correlated with General Health and Mental Health.

Comparisons of HRQOL scores of different demographic subgroups (Table 7) showed that women have lower scores in comparison with men in every dimension ($p < 0.05$). Three dimensions differed according to age: PH ($p = 0.002$), MC ($p = 0.009$) and FLG ($p = 0.019$). The PH dimension score is lower between patients > 65 years and 35–50 years (post hoc Bonferoni test; $p = 0.003$). In contrast, the MC and the FLG dimensions were lower between patients < 35 years than > 65 years (post hoc Bonferoni test; $p = 0.04$ and $p = 0.01$).

Table 6 Correlation between SF36 and RTQ V2 scores

	PH	SF	MC	TR	FLG
Physical functioning	.682	.227	.141	.217	.229
Role limitations due to physical health	.595	.237	.098	.269	.192
Bodily pain	.668	.229	.149	.326	.236
Mental health	.560	.516	.297	.394	.430
Role limitations due to emotional problems	.494	.328	.127	.263	.231
Social functioning	.556	.465	.251	.398	.340
Vitality	.781	.340	.306	.402	.339
General health	.704	.304	.289	.470	.462

PH, Physical health; SF, Social functioning; MC, Medical care and satisfaction; TR, Treatment; FG, Fear of losing graft; Data are Pearson's r correlation coefficient; significance of correlation coefficient tests were $p < 0.01$ for all correlations. Bold characters indicate main correlation between RTQ and SF36 dimension.

In the third and last phase, the structure of the RTQ V2.0 was established with a confirmatory factor analysis providing satisfactory indicators: RMSEA = 0.05, SRMR = 0.049, CFI = 0.97 and GFI = 0.91. Strongest correlations of each item in their own dimension and between dimensions are shown in Figure 2 and highlighted in bold.

Discussion

This paper describes the analysis, item reduction, and validation of a specific self-administered instrument assessing the HRQOL of renal transplant recipients: The ReTransQol (RTQ).

First, we analyzed the structure of the RTQ V1 over a sample of 1,059 RTR from a French cross-sectional multi-center study carried out between March 2007 and March 2008. Our sample size was much larger than those used in other studies to develop HRQOL's questionnaires, and larger than the first validation of the RTQ (1,059 vs. 355 patients). The construct validity of the RTQ V1 was supported by principal component analysis and showed an unsatisfactory structure, with some correlations below 0.3. However, five dimensions were confirmed by the results of the PCA. At the end of the first phase of the study, 13 items were removed (Table 3) to obtain a better version of the RTQ: the RTQ V2.0. Some items from the

Table 5 Dimensions characteristics of the 32-item 2nd version of the ReTransQol (n=1059)

RTQ dimension (number of items)	Mean ± SD	IIC	IDV	MV (%)	Floor (%)	Ceiling (%)	Cronbach's α	INFIT
PH (8)	59.5 ± 18.7	0.61 - 0.75	0.09 - 0.44	1.9	0.1	0.6	0.83	0.81 – 1.3
SF (5)	77 ± 19.3	0.65 - 0.77	0.11 - 0.35	1.6	0.3	11.7	0.74	0.83 – 1.22
MC (8)	72.7 ± 17.6	0.71 - 0.84	0.09 - 0.33	3	0.3	6.9	0.9	0.74 – 1.3
TR (5)	79 ± 15.8	0.42 - 0.76	0.10 - 0.40	2.7	0.7	0.6	0.7	0.88 – 1.29
FLG (6)	58.4 ± 20.4	0.60 - 0.74	0.01 - 0.40	1.6	0	9.9	0.78	0.89 – 1.2

PH, Physical health; SF, Social functioning; MC, Medical care and satisfaction; TR, Treatment; FG, Fear of losing graft; IIC, item-internal consistency (min-max of Pearson's r correlation coefficient); IDV, item-discriminant validity (min-max of Pearson's r correlation coefficient); MV, percentage of missing values; Floor, floor effect (%); Ceiling, ceiling effect (%); Cronbach's α, Cronbach's alpha consistency coefficient; INFIT, min-max Rasch statistics.

Table 7 HRQOL scores of the RTQ V2 for renal transplant recipients according to gender and age class

			PH	MH	MC	TR	FLG	
Gender	Men	n	643	645	633	635	643	
		Mean ± SD	62 ± 17.6	79.2 ± 17.5	74.1 ± 17	79.8 ± 16	60.3 ± 19.7	
	Women	n	396	397	394	395	399	
		Mean ± SD	55.4 ± 19.7	73.6 ± 21.5	70.4 ± 18.3	77.8 ± 15.5	55.2 ± 21	
		t-test	p-value	p<0.001	p<0.001	p<0.001	p=0.04	p<0.001
Age	Less than 35 years	n	67	67	65	65	66	
		Mean ± SD	62.6 ± 16.8	81.2 ± 15.3	68.1 ± 18.1	75.8 ± 15.7	51.9 ± 22.3	
	35 to 50 years	n	267	270	269	269	269	
		Mean ± SD	62.6 ± 17	75.9 ± 20.4	70.7 ± 17.6	77.9 ± 15.9	58.2 ± 19.4	
	50 to 65 years	n	473	475	468	469	475	
		Mean ± SD	58.7 ± 19.2	76.3 ± 19.6	73.4 ± 18	79.3 ± 16	58.2 ± 20.6	
	More than 65 years	n	232	230	225	227	232	
		Mean ± SD	56.7 ± 19.5	78.8 ± 18.3	74.7 ± 16.3	80.7 ± 15.5	60.8 ± 20	
		ANOVA	p-value	0.002	0.083	0.009	0.082	0.019

PH, Physical health; SF, Social functioning; MC, Medical care and satisfaction; TR, Treatment; FLG, Fear of losing graft; ANOVA, Analysis of variance to compare; RTQ, scores between age class.

first version were moved to other more appropriate dimensions after considering the results of the ACP. The meaning of questions was not changed or modified at all in the second version of the RTQ. Each dimension was named identically to the first version of RTQ, according to the composition of its items, except for Mental Health (MH) which was named Social Functioning (SF) because these items are essentially oriented around the patient's family, friends and social isolation.

The RTQ V2 is currently comprised of 32 items to specifically assess the HRQOL for the renal transplant recipient. Then, another PCA was performed, which showed a very good structure of the new version of the questionnaire. All items had a factor loading over the recommended threshold of 0.40 for their specific dimension, except for one item (q17: Are you satisfied with your graft?). Nevertheless, item q17 was retained due to the clinical relevance in terms of content validity and to assure a Cronbach's Alpha ≥ 0.7 in its dimension. This structure provided better results for reliability, content validity and clinical validity. The explained variance between the first and second RTQ versions improved from 46.3% to 53.1% (an increase of 6.8%).

All psychometric properties of RTQ V2 were satisfactory: IIC > 0.4 , IDV (%) of 100% and Cronbach's Alpha > 0.7 in every dimension. The acceptability was excellent with a low percentage of missing data and low floor and ceiling effects. The high psychometric properties could be related to the development of the RTQ V2 based on the first version of the RTQ. The new RTQ is shorter than the previous version and should be better accepted by patients, with a shorter average completion time (± -4 min to -5 min).

Convergent validity of the RTQ scores was overall well correlated with that of the generic SF36 questionnaire.

Dimensions relative to physical aspects taken from the SF36 were correctly correlated with the ReTransQol Physical Health dimension, and high correlations were also found between both the Social Functioning dimension and the Mental Health score and ReTransQol Mental Health dimension [renamed Social Functioning (SF)]. Indeed, due to the item reduction step, the 5 items of the previous MH dimension of the RTQ now essentially describe a social functioning dimension.

As expected, the Medical Care dimension was uncorrelated with SF36 dimensions because it is a unique concept of our questionnaire, highlighting the need for a specific HRQOL questionnaire. In addition, strong correlations were found between the Vitality and General Health dimensions of the SF36 and with the Treatment dimension of the RTQ.

Furthermore, as we could expect, the Fear of Losing Graft dimension was correlated with the Mental Health and General Health dimensions of the SF36. All items showed a good fit to the Rasch model within each dimension, and strengthened the unidimensionality of the questionnaire.

Comparisons between different demographic subgroups confirm previous empirical data showing their variations. For example, our results confirm that women have lower QOL scores in comparison with men, in every dimension [44,45]. Concerning age, patients > 65 years have a significantly lower score in the PH dimension, with relatively similar scores on the MH and TR dimensions when compared to patients aged 35–50 years, but higher scores on the MC and FLG dimensions compared with younger

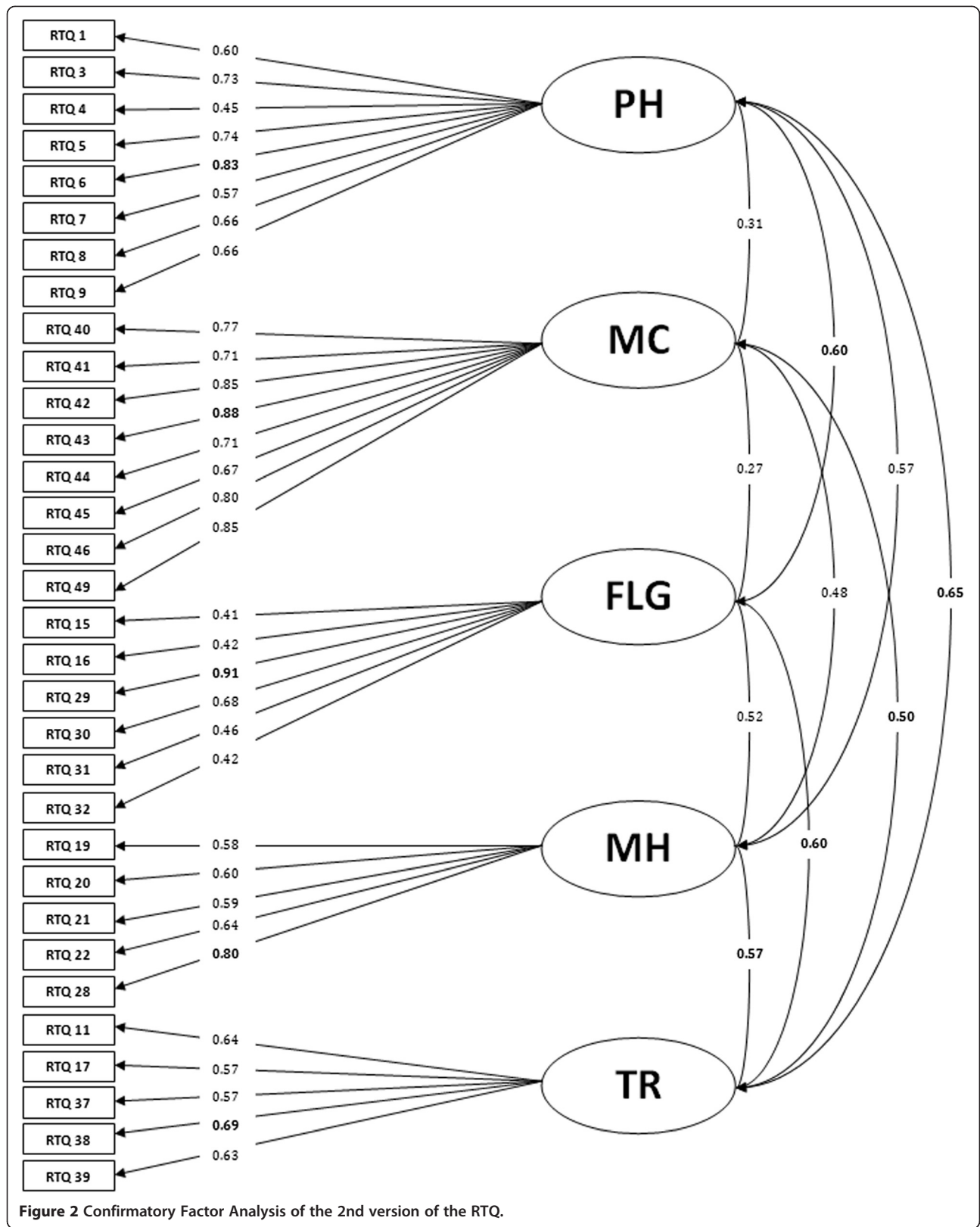


Figure 2 Confirmatory Factor Analysis of the 2nd version of the RTQ.

patients (<35 years). This may be explained by the fact that elderly patients are satisfied with medical care they receive in the hospital, less anguished to lose their graft because of their advanced age, and that they are limited due to their reduced physical capacity [46-48].

Finally, the new version of the RTQ V2 was established by a confirmatory factor analysis with a population of 1,591 RTR. Results of the CFA showed that the model converged with a good index of overall fit (GFI >0.91) and confirmed

the satisfactory structure of the new version of the RTQ. Moreover, the CFA showed an interesting correlation between different dimensions: PH and FLG, MC and TR, FLG and PH, FLG and TR, MH and TR, and TR and PH.

Sensitivity to change and reproducibility testing were not performed because the two samples were extracted from two cross-sectional studies. An analysis is currently underway on a French cohort of 334 patients followed over a period of one year.

Table 8 Final version of the RTQ V2

Items number	Dimension affectations	Items label	Response modalities
1	FLG	Are you anxious about your state of health?	
2	PH	Have you had physical pain?	
3	SF	Do you feel isolated?	All most time
4	PH	Have you felt tired?	Most of time
5	FLG	Do you think about a possible return to dialysis?	A good bit of the time
6	PH	Do you feel energetic?	Some of the time
7	FLG	Does waiting for the results of medical tests distress you or make you feel scared?	A little of the time
8	PH	Do you engage in physical exercise?	None of time
9	FLG	Do you still sometimes think about dialysis?	
10	MC	Do you feel like you are sufficiently informed about the side effects of your treatments?	
11	TR	Are you annoyed by the side effects of treatment?	
12	MC	Are you satisfied by your medical follow-up?	
13	FLG	Do you often think about your graft?	
14	TR	Are you satisfied with your graft?	
15	SF	Does your family offer you moral support?	
16	MC	Do you have trust in the prescribed treatments?	
17	TR	Are you scared of the possible side effects of the anti-rejection treatment?	
18	SF	Do you feel close to your friends?	Not at all
19	TR	Is taking medications a constraint for you?	A little bit
20	MC	Do you feel supported by the medical team?	Moderately
21	TR	Are your doctor's orders restrictive?	Quite a bit
22	MC	Do you trust your nephrologist?	Extremely
23	SF	Do you feel misunderstood by the people around you?	
24	MC	Do you feel sufficiently informed by your nephrologist?	
25	SF	Has your family accepted your illness?	
26	MC	Do you feel like you are sufficiently informed about complications of the graft?	
27	FLG	Have you been able to forget that you received a graft?	
28	MC	Are you satisfied by your nephrologist's ability to listen?	
29	PH	You are as well as anyone else	Definitely agree
30	PH	You have stopped doing certain things.	Mostly agree
31	PH	You feel autonomous.	Not agree not disagree
32	PH	You can do your housework and errands by yourself.	Mostly disagree Definitely disagree

Although further studies may be needed to test the questionnaire in various cultural contexts, the RTQ V2 (Table 8) should provide a valid measure to assess the HRQOL of RTR.

Conclusion

This study reported the different phases of analysis, adaptation and validation of the RTQ and the resulting new version: the RTQ V2 (Table 8). It is a HRQOL questionnaire for renal transplant recipients which was developed and improved in response to a lack of any validated instrument for these patients in the French language. The quality of life for patients with chronic diseases has become a public health priority in France, especially since the new Public Health Law.

Psychometric properties allow this new version of the questionnaire to be used to assess different specific dimensions for the renal transplant population, more effectively than previously possible. We envision continuing this work by the follow-up of a prospective cohort to study the sensitivity to change, reproducibility and clinically significant threshold. Furthermore, we plan to adapt and validate this new version of the questionnaire in English.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

DB performed statistical analysis, analyzed and interpreted the data, collected some data and drafted the manuscript. SG conceived the study and its design, coordinated the data management, revised the manuscript critically; EJ participated in the design of the study, collected the data and performed the statistical analysis BD participated in the design of the study, collected medical data and participated to the interpretation of data. CJ et SB conceived the study and its design, coordinated the data management, revised the manuscript critically for important intellectual content and have given final approval of the version to be published. All authors read and approved the final manuscript.

Author details

¹Faculté de Médecine, Laboratoire de Santé Publique, Université Aix-Marseille, Marseille EA 3279, France. ²CHU Marseille, Service Santé Publique et Information Médicale, Marseille, France. ³CHU Marseille, Centre de Néphrologie et de Transplantation Rénale, Marseille, France. ⁴Agence de la Biomédecine, Paris, France. ⁵CHU Nancy, Epidémiologie et Evaluation Cliniques, Nancy, France. ⁶Université de Lorraine, Université Paris Descartes, Apemac, Nancy EA 4360, France.

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