

# Quality of Life in End-Stage Renal Disease Patients after Successful Kidney Transplantation: Development of the ESRD Symptom Checklist – Transplantation Module

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## Key Words

Renal transplantation · Chronic renal failure · Quality of life · Disease-specific questionnaire

## Abstract

The End-Stage Renal Disease Symptom Checklist – Transplantation Module (ESRD-SCL<sup>®</sup>) was developed to assess the specific physical and psychological quality of life of renal transplant recipients, with a special focus on side effects of immune system suppression therapy. A list of potentially relevant items was administered to 458 transplant recipients. The symptoms present in >20% of patients were chosen, and factor analysis was used to create the final questionnaire which consists of 43 items in six dimensions: (1) limited physical capacity (10 items; internal consistency: Cronbach's  $\alpha = 0.85$ ); (2) limited cognitive capacity (8 items,  $\alpha = 0.82$ ); (3) cardiac and renal dysfunction (7 items,  $\alpha = 0.76$ ); (4) side effects of corticosteroids (5 items,  $\alpha = 0.77$ ); (5) increased growth of gum and hair (5 items,  $\alpha = 0.78$ ), and (6) transplantation-associated psychological distress (8 items,  $\alpha = 0.80$ ). All questions are scored on a five-point Likert scale. Validity

was demonstrated in correlation with corresponding SF-36 scales and in a stepwise hierarchical regression model predicting the subscales of the ESRD-SCL by sociodemographic and medical data. The ESRD-SCL was found to have adequate reliability, test-retest correlations in a subsample of 88 stable patients after 1 year, and construct validity.

## Introduction

Since the 1980s, the quality of life (QOL) [1] in patients with end-stage renal disease (ESRD) has received increasing interest [2]. ESRD patients on renal replacement therapy (RT) live with varying degrees of physical and psychological symptoms, especially side effects of immune system suppression therapy, stress, and the fear of rejection [2]. Using a tool mainly developed for healthy people [3, 4] would not be appropriate for investigating the QOL in these patients. Measures of the specific symptomatic severity of ESRD patients after RT are required as experimental, control, and outcome variables in studies on the QOL of these patients.

Until today, a number of questionnaires which measure the disease-specific QOL in ESRD patients have

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been developed. The questionnaire of Parfrey et al. [5] is useful in comparing various renal replacement therapies (including RT), but it fails to measure side effects of immunosuppression therapy. Others [6] have developed a specific measure because of cultural reasons. Some other disease-specific questionnaires are only suitable to dialysis patients [7–10]. The kidney transplant questionnaire of Laupacis et al. [11] measures only patient-specific somatic symptoms; therefore, a comparison of different patients is methodologically unsound.

The current investigation was undertaken to create a QOL questionnaire specific for ESRD patients after RT which is brief, easy to administer, reliable, valid, and incorporates RT-specific somatic symptoms, side effects of immunosuppression therapy, and symptoms of transplantation-related psychological distress. Thus, we describe the development of the End-Stage Renal Disease Symptom Checklist – Transplantation Module (ESRD-SCL®), its final content, and psychometric properties.

## Methods

The study was conducted at the Department of Nephrology, Center for Internal Medicine, University Clinics, University of Essen, Germany, in 1997 during regular outpatient visits. Informed consent was obtained from each study participant. No criterion of therapeutic regimen or duration of ESRD was used in the patient selection process. We excluded patients with graft loss and patients not having command of the German language. Frequencies of nonresponders were around 10%, reasons for nonresponding were lack of time and in few cases suspiciousness of psychological investigation. Nonparticipation was accepted as the patient's legal right.

### Questionnaire

A list of 79 items that could potentially influence the QOL of ESRD patients after RT was collected by (1) identifying items from existing QOL measures that might be relevant to the patients; (2) discussing the problem with physicians and nurses of the nephrological department, and (3) by interviewing transplant recipients. The 79 items were administered to 458 transplant recipients in 1997. All questions were scored on a 5-point Likert scale (from 0 = 'not at all' to 4 = 'extremely'). An example question is: 'How much are you presently distressed by a poor physical capacity?' Instructions and scoring were similar to the Symptom Checklist SCL-90-R of Derogatis [12, 13], measuring psychological distress. In addition to the ESRD-SCL, the SF-36 health survey [14, 15] was used to evaluate the global QOL. Sociodemographic data on gender, age, marital status, and employment were collected. Medical data were collected from the clinical records.

### Statistics

Items present in >20% of the patients were chosen, and factor analysis (Varimax rotation) was used to create the final questionnaire. To determine the reliability of the ESRD-SCL, Cronbach's  $\alpha$  was calculated as a measure of internal consistency for each of the

**Table 1.** Clinical characteristics of the 458 ESRD patients after successful kidney transplantation

<i>Original disease</i>	
Glomerulonephritis	191 (41.7%)
Pyelonephritis	81 (17.7%)
Polycystic kidney	33 (7.2%)
Diabetic nephropathy	19 (4.1%)
Shrinking kidney	15 (3.3%)
Interstitial nephritis	13 (2.8%)
Reflux	10 (2.2%)
Nephrosclerosis	10 (2.2%)
Alport syndrome	7 (1.5%)
Abuse of analgesics	6 (1.3%)
Others	73 (15.9%)
<i>Transplantation-associated data</i>	
Mean $\pm$ SD duration of life with transplanted kidney, months (range)	77.6 $\pm$ 51.6 (1–291)
Number of transplantations	
1	405 (88.4%)
>1	53 (11.6%)
Weight gain	83 (18.1%)
<i>Blood chemistry (mean <math>\pm</math> SD)</i>	
Creatinine	
mg/dl (range)	1.8 $\pm$ 1.1 (0.5–11.1)
$\mu$ mol/l (range)	157.5 $\pm$ 96.3 (44.2–981.2)
Hemoglobin	
g/dl (range)	13.2 $\pm$ 1.9 (4.8–18.6)
mmol/l (range)	8.2 $\pm$ 1.2 (3.0–11.5)
Cholesterol	
mg/dl (range)	228.8 $\pm$ 49.4 (81–429)
mmol/l (range)	5.9 $\pm$ 1.3 (2.1–11.1)
Triglyceride	
mg/dl (range)	185.8 $\pm$ 102.0 (36–883)
mmol/l (range)	2.1 $\pm$ 1.2 (0.4–10.0)
<i>Medication (mean <math>\pm</math> SD)</i>	
Ciclosporin (n = 300), mg (range)	205.5 $\pm$ 67.7 (75–575)
Prednisolone (n = 432), mg (range)	7.2 $\pm$ 6.7 (1–125)
<i>Comorbidity</i>	
Diabetes	53 (11.6%) (type I: 12, type II: 41)
High blood pressure	361 (78.8%)
Myocardial infarction	13 (2.8%)

multi-item subscales. The construct validity of the ESRD-SCL was evaluated by calculating the correlation coefficient between the dimensions of the questionnaire and the SF-36 (proven construct validity, if the correlations between the dimensions of the ESRD-SCL and the SF-36 are in the direction and magnitude expected). In a study of this size, even weak correlations attain statistical significance, so the p value does not constitute a useful measure of the importance of a relationship. Correlations were classified into ranges of importance: not statistically significant; significant, but weak  $|r| < 0.32$  ( $r^2 < 10\%$ ,  $p < 0.05$ ); modest  $|r|$  from 0.32 to 0.55

( $r^2$  from 10 to 30%), and moderate  $|r| > 0.55$  ( $r^2 > 30\%$ ). The reproducibility was assessed by determining the intraclass correlation coefficient when the questionnaire was administered to stable transplant recipients assessed 12 months after the first investigation. Multiple regression analysis was used to examine the independent associations between the ESRD-SCL subscales and sociodemographic and clinical data.

## Results

### Patient Population

The 458 patients had a mean age of  $48 \pm$  (SD) 13 (range 18–74) years; 55% were males. Two thirds of the sample (64.2%) were married, 4.6% divorced, 6.3% widowed, and 24.9% were single. One third of the sample (32.6%) were employed, 15.7% were housewives, 5.9% were unemployed, and every 2nd patient (45.9%) was retired. Table 1 presents the clinical characteristics of the sample. The majority suffered from glomerulonephritis. The sample was evaluated on average  $77.6 \pm 51.6$  (range 1–291) months after transplantation (total cadaveric kidney transplantation); the mean creatinine concentration was  $1.8 \pm 0.05$  (range 0.5–11.1) mg/dl.

### Item Identification

Table 2 presents the response frequency of the 79 items. Fifty-eight of the initial 79 items demonstrated over 20% prevalence. Limited physical capacity, the uncertainty of how long the transplant will function, and the

feeling of exercising too little were the three items with the highest prevalence.

### Description of the ESRD-SCL

Factor analysis was used, regarding the 58 items with the highest response frequency, to produce the ESRD-SCL. Table 3 presents the results of the factor analysis after Varimax rotation. The initial statistics found 16 factors with an eigenvalue  $> 1$  (eigenvalues 13.4, 2.9, 2.3, 2.1, 1.9, 1.7, 1.6, 1.5, 1.4, 1.4, 1.3, 1.3, 1.2, 1.1, 1.1, 1.0). Regarding the Scree test, we decided to define six factors (explanation of variance: 22.6, 4.8, 3.9, 3.5, 3.2, and 2.9%) which contained 43 items; 15 items demonstrated low loadings ( $< 0.40$ ) and were rejected in defining the scales.

The ESRD-SCL questionnaire contains the following six dimensions: (1) limited physical capacity (10 items, internal consistency: Cronbach's  $\alpha = 0.85$ ); (2) limited cognitive capacity (8 items,  $\alpha = 0.82$ ); (3) cardiac and renal dysfunction (7 items,  $\alpha = 0.76$ ); (4) side effects of corticosteroids (5 items,  $\alpha = 0.77$ ); (5) increased growth of gum and hair (5 items,  $\alpha = 0.78$ ), and (6) transplantation-associated psychological distress (8 items,  $\alpha = 0.80$ ; table 3).

### Construct Validity of ESRD-SCL

The correlations between the ESRD-SCL and the SF-36, the correlations among the dimensions of the ESRD-SCL, and the correlations between the dimensions of the

**Table 2.** Response frequency percentage of the 79 items investigated

No. <sup>a</sup>	Item	Answer categories <sup>b</sup>				
		0	1	2	3	4
02	Limited physical capacity	14.6	43.7	27.9	10.3	3.5
10	Uncertainty of how long the transplant will function	22.9	36.7	17.2	12.4	10.7
04	Feeling of exercising too little	26.4	36.5	20.3	10.9	5.9
65	Feeling of being exhausted	32.1	39.5	18.1	7.4	2.8
33	Increased blood pressure	34.3	39.5	15.3	7.2	3.7
24	Decreased visual acuity	34.5	38.9	13.8	10.0	2.8
75	Proneness to hematomas	34.9	27.7	16.4	10.9	10.0
23	Forgetfulness	36.7	44.3	11.6	6.1	1.3
44	Joint pain	37.6	32.8	15.3	10.5	3.9
01	Poor general health	38.0	43.9	14.2	2.6	1.3
20	Nervousness	39.3	38.0	14.0	7.2	1.5
19	Trouble concentrating	41.0	42.1	11.1	4.8	0.9
51	Hirsutism	41.7	31.4	17.0	6.3	3.5
28	Moodiness	43.4	39.5	12.7	3.3	1.1
11	Limited sexual capacity	44.1	32.3	11.8	5.9	5.9
43	Bone pain	46.7	27.9	12.7	9.0	3.7
08	Thoughts about transplantation	48.0	34.5	13.8	2.2	1.5
37	Much stronger appetite than before	52.2	24.2	15.9	4.4	3.3
17	Ill feeling	53.1	32.5	9.8	3.7	0.9
45	Muscle pain	55.0	25.5	10.7	5.9	2.8

➤

**Table 2** (continued)

No. <sup>a</sup>	Item	Answer categories <sup>b</sup>				
		0	1	2	3	4
05	Appearance	55.2	29.0	9.8	4.1	1.7
55	Puffy face	55.2	29.0	9.2	4.4	2.2
29	Dry mouth	56.1	30.3	8.5	4.4	0.7
46	Colds or influenza	56.6	31.4	8.3	3.3	0.4
16	Sleeplessness	57.4	27.3	8.1	6.3	0.9
13	Headaches	57.9	28.8	8.7	3.9	0.7
07	Limited cognitive capacity	58.3	26.0	9.8	5.0	0.9
70	Stronger growth of hair	58.3	26.0	9.4	3.5	2.8
49	Alterations of the skin	59.4	21.2	11.1	6.1	2.2
58	Swollen feet	59.6	28.4	6.6	3.7	1.7
73	Swollen legs	60.7	27.1	6.3	3.9	2.0
52	Gingival hyperplasia	60.9	22.9	8.5	5.2	2.4
53	Bleeding of the gingiva	62.0	27.1	7.0	3.1	0.9
25	Decreased hearing capacity	63.3	21.1	9.2	4.6	1.7
06	Feeling of not being able to travel often	63.5	17.7	10.5	5.5	2.8
31	Disorders in the heart rhythm	63.5	23.1	8.1	4.6	0.7
67	Alterations of the gingiva	63.8	24.0	6.8	3.7	1.7
41	Heartburn	64.2	23.8	6.6	3.5	2.0
76	Stronger thirst	64.2	18.8	11.6	3.7	1.7
79	Memory disturbance	64.6	24.2	7.4	3.1	0.7
54	Hair loss	65.7	20.3	7.9	3.5	2.6
62	Paresthesia in the legs	66.6	18.3	8.3	3.7	3.1
09	Brooding about kidney donor	66.8	24.2	5.5	2.2	1.3
35	Difficulties in breathing	66.8	21.6	8.3	3.1	0.2
15	Uncontrollable trembling	67.5	21.4	7.6	2.4	1.1
32	Chest pain	69.2	22.9	4.8	2.0	1.1
26	Buzzing in ears	69.4	18.8	6.6	2.8	2.4
56	Proneness to infections	70.3	20.7	6.6	2.2	0.2
71	Puffy face in the morning	72.5	19.2	4.4	3.1	0.9
21	Strong dizziness	72.7	19.4	5.0	2.2	0.7
59	Stomach pain	73.4	20.5	3.9	1.5	0.7
22	Anxiety	73.8	17.2	5.9	1.7	1.3
57	Prolonged wound healing	75.1	15.9	6.1	2.2	0.7
27	Cramps	75.3	16.2	6.1	2.2	0.2
47	Urinary tract infections	75.5	14.8	4.8	1.7	3.1
50	Proneness to sunburn	75.8	15.3	4.8	2.6	1.5
72	Alterations of the face	76.4	16.6	3.1	2.8	1.1
12	Nightmares	78.2	12.4	4.8	3.1	1.5
03	Problems in activities of daily life (shower, dressing)	80.0	11.7	5.7	2.2	0.4
39	Diarrhea	80.1	13.8	3.7	1.5	0.9
74	Prolonged bleeding of wounds	80.1	13.5	3.9	1.7	0.7
18	Confusion	81.4	15.1	3.3	0.2	0
34	Nausea	81.4	12.0	4.8	1.1	0.7
60	Acne	82.8	10.7	4.6	1.3	0.7
40	Constipation	83.0	10.7	3.1	2.2	1.1
48	Allergies	84.7	10.0	2.4	2.0	0.9
30	Speech disorders	85.6	11.1	2.2	0.7	0.4
77	Difficulties in breathing without physical exercise	87.3	8.7	2.8	0.4	0.7
38	Loss of appetite	89.1	8.3	2.0	0.7	0
78	Lack of smell or taste	89.3	7.0	2.4	0.9	0.4
14	Migraine	89.5	6.3	2.6	0.9	0.7
68	Shivering fits	89.5	7.9	1.7	0.2	0.4
61	Purging	90.4	8.1	0.9	0.7	0
42	Stomach ulcer	91.0	6.6	1.7	0.4	0.2
64	Jaundice	91.7	6.8	1.1	0.2	0.2
66	Cancer	93.7	3.3	1.5	1.3	0.2
69	Fever	95.2	3.5	1.1	0.2	0
36	Asthma	95.9	2.8	0.7	0.7	0
63	Gallbladder colics	96.7	2.2	0.4	0.2	0.4

<sup>a</sup> Position of the item in the original version of the checklist.

<sup>b</sup> 0 = Not at all; 1 = a little bit; 2 = moderately; 3 = quite a bit; 4 = extremely.

**Table 3.** Results of a factor analysis (Varimax rotation of the 58 items with the highest response frequency)

No.	Dimensions and items	h <sup>2</sup>	F1	F2	F3	F4	F5	F6
<i>Limited physical capacity</i>								
44	Joint pain	0.53	0.61					
43	Bone pain	0.49	0.57					
65	Feeling of being exhausted	0.49	0.56					
45	Muscle pain	0.51	0.55					
01	Poor general health	0.50	0.54					
02	Limited physical capacity	0.50	0.53					
59	Stomach pain	0.27	0.46					
21	Strong dizziness	0.35	0.46					
13	Headaches	0.27	0.44					
46	Colds or influenza	0.35	0.43					
47	Urinary tract infections	0.24	0.38					
41	Heartburn	0.23	0.35					
06	Feeling of not being able to travel often	0.28	0.32					
15	Uncontrollable trembling	0.21	0.28					
<i>Limited cognitive capacity</i>								
23	Forgetfulness	0.60		0.69				
19	Trouble concentrating	0.58		0.61				
07	Limited cognitive capacity	0.42		0.57				
79	Memory disturbance	0.43		0.55				
25	Decreased hearing capacity	0.37		0.52				
20	Nervousness	0.54		0.50				
24	Decreased visual acuity	0.38		0.47				
26	Buzzing in ears	0.27		0.44				
32	Chest pain	0.35		0.39				
11	Limited sexual capacity	0.31		0.38				
57	Prolonged wound healing	0.30		0.36				
35	Difficulties in breathing	0.34		0.34				
27	Cramps	0.23		0.32				
<i>Cardiac and renal dysfunctions</i>								
73	Swollen legs	0.56			0.69			
58	Swollen feet	0.57			0.68			
33	Increased blood pressure	0.31			0.46			
76	Stronger thirst	0.30			0.44			
62	Paresthesia in the legs	0.38			0.44			
75	Proneness to hematomas	0.37			0.43			
31	Disorders in heart rhythm	0.37			0.43			
29	Dry mouth	0.33			0.37			
50	Proneness to sunburn	0.25			0.37			
<i>Side effects of corticosteroids</i>								
55	Puffy face	0.63				0.74		
72	Alterations of the face	0.57				0.72		
71	Puffy face in the morning	0.53				0.64		
05	Appearance	0.43				0.53		
56	Proneness to infections	0.46				0.48		
49	Alterations of the skin	0.24				0.36		
54	Hair loss	0.22				0.35		
37	Much stronger appetite than before	0.25				0.33		
04	Feeling of exercising too little	0.20				0.30		
<i>Increased growth of gum and hair</i>								
52	Gingival hyperplasia	0.70					0.82	
67	Alterations of the gingiva	0.70					0.81	
53	Bleeding of the gingiva	0.58					0.75	
70	Stronger growth of hair	0.36					0.50	
51	Hirsutism	0.36					0.48	
<i>Transplantation-associated psychological distress</i>								
08	Thoughts about transplantation	0.55						0.52
09	Brooding about kidney donor	0.46						0.64
12	Nightmares	0.47						0.55
10	Uncertainty of how long the transplant will function	0.40						0.53
17	Ill feeling	0.60						0.50
16	Sleeplessness	0.43						0.49
28	Moodiness	0.52						0.48
22	Anxiety	0.41						0.46

Numerals in italics indicate items with loadings  $\geq 0.40$ ; only these items define the final dimension.

h<sup>2</sup> = Communality; F1–F6 = loadings of the items on the six dimensions of the ESRD-SCL.

**Table 4.** Correlations between the ESRD-SCL and the SF-36, correlations between the dimensions of the ESRD-SCL, and correlations between the dimensions of the ESRD-SCL and the same dimensions, measured 12 months after the first investigation in 88 stable ESRD patients after RT

Psychological data	ESRD-SCL scale <sup>a</sup>					
	1	2	3	4	5	6
<i>SF-36<sup>b</sup></i>						
PFI	-0.62**	-0.40*	-0.49*	-0.26 <sup>+</sup>	-0.17 <sup>+</sup>	-0.35*
Rolph	-0.53*	-0.36*	-0.35*	-0.24 <sup>+</sup>	-0.09	-0.31 <sup>+</sup>
Pain	-0.70**	-0.45*	-0.42*	-0.21 <sup>+</sup>	-0.19 <sup>+</sup>	-0.38*
GHP	-0.55**	-0.39*	-0.39*	-0.31 <sup>+</sup>	-0.22	-0.36*
Vital	-0.59**	-0.46*	-0.35*	-0.31 <sup>+</sup>	-0.19 <sup>+</sup>	-0.42*
Social	-0.54*	-0.43*	-0.36*	-0.29 <sup>+</sup>	-0.17 <sup>+</sup>	-0.48*
Rolem	-0.45*	-0.33*	-0.31 <sup>+</sup>	-0.19 <sup>+</sup>	-0.14 <sup>+</sup>	-0.35*
MHI	-0.48*	-0.48*	-0.29 <sup>+</sup>	-0.34*	-0.19 <sup>+</sup>	-0.55**
<i>ESRD-SCL autocorrelation</i>						
1	-	0.64**	0.59**	0.42*	0.31 <sup>+</sup>	0.57**
2	-	-	0.50*	0.39*	0.30 <sup>+</sup>	0.59**
3	-	-	-	0.42*	0.36*	0.43*
4	-	-	-	-	0.32*	0.40*
5	-	-	-	-	-	0.27 <sup>+</sup>
<i>ESRD-SCL repeated measurement (n = 88)</i>						
1	0.72**	0.53*	0.54*	0.27 <sup>+</sup>	0.21 <sup>+</sup>	0.40*
2	-	0.74**	0.43*	0.34*	0.37*	0.43*
3	-	-	0.70**	0.36*	0.31 <sup>+</sup>	0.42*
4	-	-	-	0.75**	0.30 <sup>+</sup>	0.29 <sup>+</sup>
5	-	-	-	-	0.48*	0.23 <sup>+</sup>
6	-	-	-	-	-	0.72**

<sup>a</sup> 1 = Limited physical capacity; 2 = limited cognitive capacity; 3 = cardiac and renal dysfunction; 4 = side effects of corticosteroids; 5 = increased growth of gum and hair; 6 = transplantation-associated psychological distress.

<sup>b</sup> PFI = Physical functioning; Rolph = role, physical; Pain = bodily pain; GHP = general health; Vital = vitality; Social = social functioning; Rolem = role, emotional; MHI = mental health.

<sup>+</sup> Weak correlation (statistically significant,  $r < 0.32$ );

\* modest correlation ( $r \geq 0.32$  and  $r < 0.55$ );

\*\* moderate correlation ( $r \geq 0.55$ ).

ESRD-SCL and the same dimensions measured 12 months after the first investigation in 88 stable ESRD patients after RT were similar to those expected (table 4). The scale limited physical capacity of the ESRD-SCL correlated most closely with the scale bodily pain of the SF-36. The scales limited cognitive capacity and transplantation-associated psychological distress of the ESRD-SCL correlated strongest with the mental health scale of the SF-36. The ESRD-SCL scale cardiac and renal dysfunction correlated most closely with the physical function scale of the SF-36. In summary, the two scales of the ESRD-SCL measuring side effects of medication correlated weakly with the SF-36. The weak to moderate auto-correlations were of the expected dimension.

#### Reproducibility

The correlation coefficients between the first and the second measurement for 88 stable patients after 12 months were moderate in five and modest in one of the six scales.

#### Associations between the ESRD-SCL Subscales and Sociodemographic and Clinical Data

Correlations between the ESRD-SCL and sociodemographic and medical data are given in table 5, demonstrating that single ESRD-SCL scores are weakly associated with some sociodemographic and medical data. Stepwise hierarchical regression models were used (table 6) to determine the predictive value of the ESRD-SCL subscales

**Table 5.** Correlations between ESRD-SCL and sociodemographic and medical data

	ESRD-SCL scale <sup>a</sup>					
	1	2	3	4	5	6
<i>Sociodemographic data</i>						
Gender	0.15 <sup>+</sup>	0.04	0.19 <sup>+</sup>	0.16	0.07	0.13 <sup>+</sup>
Age	0.19 <sup>+</sup>	0.19 <sup>+</sup>	0.27 <sup>+</sup>	-0.13 <sup>+</sup>	-0.08	0.02
Marital status	-0.07	-0.06	-0.16 <sup>+</sup>	0.01	0.00	-0.03
Employment	0.27 <sup>+</sup>	0.19 <sup>+</sup>	0.22 <sup>+</sup>	-0.01	-0.02	0.16 <sup>+</sup>
<i>Transplantation-associated data</i>						
Mean duration of disease	0.04	0.07	0.13 <sup>+</sup>	-0.05	0.01	-0.01
Number of transplantations	0.05	0.10 <sup>+</sup>	-0.04	0.07	-0.03	0.04
Mean weight gain	0.10 <sup>+</sup>	0.14 <sup>+</sup>	0.10 <sup>+</sup>	0.23 <sup>+</sup>	0.12 <sup>+</sup>	0.07
<i>Blood chemistry</i>						
Creatinine	-0.02	0.02	0.06	0.11 <sup>+</sup>	-0.14 <sup>+</sup>	0.02
Hemoglobin	-0.06	-0.01	-0.04	-0.03	-0.03	0.02
Cholesterol	0.07	0.11 <sup>+</sup>	0.07	0.11 <sup>+</sup>	0.09	0.05
Triglyceride	0.11 <sup>+</sup>	-0.01	0.11 <sup>+</sup>	0.14 <sup>+</sup>	0.01	0.06
<i>Medication</i>						
Ciclosporin	0.09	0.03	0.05	-0.02	0.31 <sup>+</sup>	0.04
Prednisolone	0.06	0.07	0.13 <sup>+</sup>	0.01	0.07	0.10 <sup>+</sup>
<i>Comorbidity</i>						
Diabetes	0.14 <sup>+</sup>	0.03	0.10 <sup>+</sup>	0.10 <sup>+</sup>	-0.01	0.06
High blood pressure	0.05	0.05	0.12 <sup>+</sup>	0.07	0.06	-0.03
Myocardial infarction	0.06	0.06	0.06	-0.07	-0.02	-0.03

<sup>a</sup> 1 = Limited physical capacity; 2 = limited cognitive capacity; 3 = cardiac and renal dysfunction; 4 = side effects of corticosteroids; 5 = increased growth of gum and hair; 6 = transplantation-associated psychological distress.

<sup>+</sup> Weak correlation (statistically significant,  $r < 0.32$ ).

with sociodemographic data (gender, age, marital status, employment) and medical data (transplantation-associated data: duration of disease, number of transplantations, weight gain; blood chemistry: creatinine, hemoglobin, cholesterol, and triglyceride levels; medication: ciclosporin and prednisolone doses; comorbidity: diabetes, high blood pressure, myocardial infarction; see table 1).

Global results indicated that all six subscales were predictive by sociodemographic and medical data (4–17% explanation of variance). Employment was the strongest indicator of a high QOL in the scales concerning limited physical and cognitive capacities as well as in the scale measuring transplantation-associated psychological distress (beta weight 0.26, 0.13, and 0.15, respectively). Age predicted cardiac and renal dysfunction (beta weight 0.21) and three other scales at step three of the stepwise regression analyses. It is important to note that older patients suffered more from limited cognitive capacity

and less from side effects of corticosteroids and increased growth of gum and hair. Gender predicted distress in five of six scales; the marital status had a low predictive value.

Regarding the medical data, hemoglobin was an important predictor for disease-specific QOL in limited physical capacity, cardiac and renal dysfunction, and side effects of corticosteroids (a higher level of hemoglobin indicated a higher QOL). A high level of cholesterol (beta weight 0.10) predicted only limited physical capacity, but a high level of triglyceride predicted a low QOL in three of six scales (beta weight 0.10–0.12). Ciclosporin predicted increased gum and hair growth (beta weight 0.32) and limited physical capacity (beta weight 0.09). As the third predictor, prednisolone was associated with cardiac and renal dysfunction (beta weight 0.13) and transplantation-associated psychological distress (beta weight 0.10).

**Table 6.** Hierarchical multiple regression analysis of the predictive value of the subscales of the ESRD-SCL

ESRD-SCL subscales <sup>a</sup>	Step entered <sup>b</sup>	Variable	Multiple r	d.f.	r <sup>2</sup> change	F (p < 0.0001)	β	r <sup>2</sup>
1	1 (SD)	employment	0.27	1, 456	0.07	34.69	0.25	0.07
	2 (SD)	gender	0.31	2, 455	0.02	23.32	0.13	0.09
	3 (BC)	triglyceride	0.33	3, 454	0.01	17.83	0.10	0.10
	4 (ME)	ciclosporin	0.34	4, 453	0.01	14.74	0.09	0.11
	5 (BC)	hemoglobin	0.35	5, 450	0.007	12.76	-0.10	0.11
	6 (CO)	diabetes	0.36	6, 451	0.01	11.53	0.10	0.12
2	1 (SD)	employment	0.19	1, 456	0.03	16.15	0.13	0.03
	2 (TA)	weight gain	0.23	2, 455	0.02	12.77	0.13	0.05
	3 (SD)	age	0.25	3, 454	0.01	10.41	0.12	0.06
	4 (TA)	number of transplantations	0.28	4, 453	0.01	9.41	0.11	0.07
	2 (BC)	cholesterol	0.29	5, 452	0.01	8.52	0.10	0.08
3	1 (SD)	age	0.27	1, 456	0.07	37.14	0.21	0.07
	2 (BC)	hemoglobin	0.34	2, 455	0.04	29.02	-0.13	0.11
	3 (ME)	prednisolone	0.36	3, 454	0.02	22.87	0.13	0.13
	4 (SD)	gender	0.38	4, 453	0.01	19.12	0.13	0.14
	5 (SD)	employment	0.39	5, 452	0.02	16.49	0.12	0.15
	6 (BC)	triglyceride	0.41	6, 451	0.01	14.75	0.11	0.16
	7 (TA)	duration of life	0.42	7, 450	0.01	13.38	0.09	0.17
4	1 (TA)	weight gain	0.23	1, 456	0.05	24.69	0.21	0.05
	2 (BC)	hemoglobin	0.27	2, 455	0.02	18.45	-0.11	0.07
	3 (SD)	age	0.31	3, 454	0.02	16.23	-0.17	0.09
	4 (BC)	triglyceride	0.33	4, 453	0.01	14.19	0.12	0.10
	5 (SD)	gender	0.36	5, 452	0.01	12.99	0.13	0.12
	6 (CO)	diabetes	0.38	6, 451	0.007	11.68	0.10	0.12
5	1 (ME)	ciclosporin	0.31	1, 456	0.10	48.81	0.32	0.10
	2 (TA)	weight gain	0.34	2, 455	0.01	29.06	0.13	0.11
	3 (SD)	age	0.34	3, 454	0.01	20.98	-0.10	0.12
	4 (SD)	gender	0.36	4, 453	0.006	16.90	0.09	0.12
6	1 (SD)	employment	0.16	1, 456	0.02	11.45	0.15	0.02
	2 (SD)	gender	0.20	2, 455	0.02	9.51	0.12	0.04
	3 (ME)	prednisolone	0.22	3, 454	0.008	7.96	0.10	0.04

<sup>a</sup> 1 = Limited physical capacity; 2 = limited cognitive capacity; 3 = cardiac and renal dysfunction; 4 = side effects of corticosteroids; 5 = increased growth of gum and hair; 6 = transplantation-associated psychological distress.

<sup>b</sup> SD = Sociodemographic data: gender, mean age, employment; ME = medication: ciclosporin, prednisolone; BC = blood chemistry: hemoglobin, cholesterol, triglyceride; CO = comorbidity: diabetes; TA = transplantation-associated data: mean duration of life with the transplant, number of transplantations, weight gain.

## Discussion

The purpose of this study was to develop a disease-specific QOL instrument, measuring psychological and physical distress with a special focus on side effects of immune system suppression therapy in ESRD patients after RT. Factor analysis of the potentially relevant symptoms with a response frequency >20% in 458 ESRD patients after RT produced six reliable [14] scales (Cron-

bach's  $\alpha$  0.76–0.85). The contents of each scale were as follows: (1) limited physical capacity scale, including questions about pain, exhaustion, and dizziness; (2) limited cognitive capacity scale, including questions about forgetfulness, trouble concentrating, and decreasing hearing and visual capacities; (3) cardiac and renal dysfunction, containing items concerning edema in the lower extremities, increased blood pressure, etc.; (4) side effects of corticosteroids, including questions about alterations



of the face, decreased satisfaction with appearance, and proneness to infections; (5) increased growth of gum and hair, containing items concerning gingival hyperplasia and increasing growth of body hair, and (6) transplantation-associated psychological distress, including items dealing with the uncertainty of how long the transplant will function, anxiety, and sleeplessness.

Construct validity was demonstrated by correlations expected in direction and magnitude, with corresponding scales of the SF-36 health survey [12, 13] as a global measure of QOL. Another approach to investigate construct validity is to examine the independent association between the ESRD-SCL subscales and sociodemographic and clinical data in multiple regression analysis. In summary, the sociodemographic variables (gender, age, and employment) and the clinical variables (transplantation-associated data: duration of life after transplantation, number of transplantations, weight gain; blood chemistry:

hemoglobin, cholesterol, and triglyceride levels; medication: ciclosporin and prednisolone levels; diabetes as an aspect of comorbidity) were predictive for the single scales of the questionnaire (explanation of variance 4–17%).

Limitations of the study are based on the restriction to successfully transplanted patients only. Data limitation is due to the data-collecting process in a university hospital. Future studies should evaluate patients after graft loss as well as patients before and after kidney transplantation.

The development of the ESRD-SCL is work in progress until today, requiring several future studies in large samples to verify its usefulness in the clinical practice [2]. In this study, the ESRD-SCL was found to have adequate reliability, test-retest correlations in a subsample of 88 stable patients after 1 year, and construct validity. It is easy to administer and suitable as a sensitive indicator of the specific QOL in renal transplant recipients.

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