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Health-related quality of life in kidney transplant patients and non-renal replacement therapy patients with chronic kidney disease stages 3b–4

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Summary

Background: Patients with a functioning kidney transplant (Tx) and patients with chronic kidney disease (CKD) not in dialysis report better health-related quality of life (HRQoL) than patients requiring dialysis, but poorer than the general population. HRQoL is associated with kidney function, but it is unknown whether the kidney function *per se* is the main determinant of HRQoL. The aim of this study was to compare the HRQoL in 2 groups of patients with CKD: 1 group with native kidneys only (non-renal replacement therapy [non-RRT] group) and 1 group with a functioning kidney transplant (Tx group).

Material/Methods: The study was designed as a paired cross-sectional single-center study including 38 stable Tx patients age- and gender-matched with 38 non-RRT patients with the same kidney function, CKD stages 3b–4. HRQoL was evaluated using the short form-36 (SF-36) and a visual analogue scale (VAS).

Results: The multi-item scales and summary scores in SF-36 were not significantly different between the 2 groups of patients or the general Norwegian population. However, the non-RRT group scored significantly better than the Tx group when HRQoL was evaluated by VAS. The main determinants for HRQoL in both groups of patients were depression estimated by Beck depression inventory scores and comorbidity expressed by Davies comorbidity index scores.

Conclusions: HRQoL evaluated by SF-36 in a group of stable Tx patients in CKD stages 3b–4 is comparable to that of a group of non-RRT patients. However, HRQoL VAS was better in the non-RRT group, suggesting that VAS and SF-36 may evaluate different aspects in HRQoL in the same group of patients.

Key words: **chronic kidney disease • health-related quality of life • kidney transplantation • short form-36 • visual analogue scale**

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Background

Patients with reduced kidney function have reduced health-related quality of life (HRQoL) compared with the general population [1–3]. Impaired HRQoL is associated with reduced kidney function and patients requiring dialysis have the lowest scores in HRQoL measurements [1,4,5]. Patients living with a functioning kidney transplant (Tx) and non-RRT CKD patients have better HRQoL than patients requiring dialysis, but not as good as that of the general population [1,4–8]. Physical health was affected more than mental health in all of these studies [2,3,6,9].

Health-related quality of life

Quality of life (QoL) is a generic concept. WHO defines it as "an individual's perceptions of their position in life in the context of the culture and value system where they live, and in relation to their goals, expectations, standards, and concerns" [10]. HRQoL is generally understood to be a part of the overall QoL related to a person's health, where health is broadly defined to include physical, psychological, and social domains [11]. HRQoL is an important measure of outcome in studies evaluating various health interventions, including studies of Tx patients [12]. HRQoL in patients with CKD, including Tx patients, may be affected by factors other than reduced kidney function, such as depression, hospitalization, comorbidity, psychological distress, medical treatment, and rejection episodes [2,9,13]. HRQoL has recently been shown to be an independent risk factor for mortality in dialysis patients [14]. However, it is unknown whether specific interventions for improving HRQoL will translate into improved survival.

Aim

The aim of this study was to compare the HRQoL in 2 groups of patients with CKD stages 3b–4:1 group with native kidneys only and 1 group with a functioning kidney transplant. The 2 groups were matched for renal function, age, and gender. We are not aware of other studies using the same design in these patient groups.

Material and Methods

The study was designed as a single-center, paired, cross-sectional study including patients >18 years of age with stable CKD with an estimated glomerular filtration rate (eGFR) of 15–44 ml/min/1.73 m^2 (stages 3b–4) in a Tx group and in a non-RRT group of patients. Decreasing renal function is according to K-DOQI, associated with more physical symptoms [15], and this may affect HRQoL [15]. Stable CKD was defined as ⩽5 ml/min/1.73 m^2 decline in eGFR during the last 12 months. The Tx group were age- (±5 years) and gender-matched with a non-RRT group with an eGFR ±10 ml/min/1.73 m^2. GFR was estimated using the modification of diet in renal disease (MDRD) formula, which includes age, gender, ethnicity, and serum creatinine [16].

All patients were recruited from the outpatient clinic of the department of nephrology at Stavanger University Hospital as part of a scheduled routine follow-up visit. Written informed consent was obtained from patients prior to inclusion, and the project was approved by the regional ethics committee. The patients were asked by the study nurse or the nephrologist to complete 3 questionnaires on their own: short form-36 (SF-36), a visual analogue scale (VAS), and Beck depression inventory (BDI). The patients completed the questionnaires before leaving the outpatient clinic.

Severe comorbidity may impair HRQoL more than CKD. Patients were therefore excluded if they had unstable cardiovascular disease (myocardial infarction, TIA, and/or cerebral infarction or bleeding) during the last 6 months or had undergone major surgery during the last 6 months, had active cancer, or had other serious comorbidities with reduced life expectancy. Patients unable to give informed consent were also excluded.

Assessment of HRQoL

HRQoL was assessed using SF-36 questionnaire and a VAS.

SF-36 is a non-disease-specific validated questionnaire containing 36 questions assessing HRQoL, and is recommended by K-DOQI for assessing HRQoL in CKD patients [15]. We used the standard form, which relates to the most recent 4 weeks, in contrast to the acute form, which relates to the last week only. Eight multi-item scales are included: physical functioning (PF), role physical (PR), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). The answers are added in each multi-item scale and transformed into a scale from 1 to100, where 100

is the highest possible score. Higher scores express better self-assessed HRQoL. The 8 multi-item scales were further aggregated into physical component summary measures (PCS) and mental component summary measures (MCS) [17–19]. The summary measures were estimated using normative data from the general Norwegian population [20]. The aggregation into PCS and MCS has been validated by the International Quality of Life Assessment Project and simplifies statistical analyses without a substantial loss of information [18].

VAS is a 100-mm line with anchoring lines at each end [21,22]. The line represents the continuum of an experience, in this case HRQoL, with the left anchoring line representing "worst imaginable HRQoL" and the right "best imaginable HRQoL". The patients were asked to mark a point on the line that represented their HRQoL during the last 4 weeks. The distance from the left anchoring vertical line to the marked point was measured in mm. Higher numbers indicate better self-assessed HRQoL.

Covariate and variables

BDI was used to assess depressive symptoms. BDI is a questionnaire containing 21 questions concerning guilt, pessimism, suicidal thoughts, and other depressive symptoms. The maximum score is 63 and indicates severe depression [23]. Scores from 11 to 63 indicate increasing severity of depressive symptoms. BDI is validated for CKD patients. To detect clinical depression, the cut-off score is commonly set to ⩾11 in CKD patients not on dialysis [24]. HRQoL has previously been shown to be negatively affected by depressive symptoms [25,26].

The Davies comorbidity index (DCI) [27] was used to express comorbidity: active cancer, ischemic heart disease, peripheral vascular disease, left ventricular dysfunction, diabetes mellitus, systemic collagen vascular disease, and other significant pathology (e.g., chronic obstructive lung disease, cirrhosis, and asthma). DCI score 0 – no comorbid condition, DCI score 1 – 1 or 2 comorbid conditions and DCI score 2 – 3 or more comorbid conditions [27].

The medical history with treatment and comorbidities, and results of routine laboratory tests (hemoglobin, creatinine, electrolytes, albumin, parathyroid hormone, and cholesterol) were collected from the patients' medical records. Laboratory test results were collected and analyzed within 2 weeks prior to inclusion.

Statistical analysis

Normally distributed data are reported as mean ±SD, and data not normally distributed as are reported as median and range. Paired t-tests (2-tailed) or Wilcoxon test were used, as appropriate, when testing paired groups of quantitative data. Pearson chi-squared test was used to test the relationship between 2 nominal variables. Multiple backward regression analyses with HRQoL (VAS, SF-36 PCS and SF-36 MCS) as dependent variable and DCI, eGFR, hemoglobin, albumin, BDI scores, and known time with CKD as independent variables were performed to test for associations between HRQoL and these variables. A multiple backward regression analysis was chosen to identify important predictor variables for HRQoL. P-values ⩽0.05 were considered statistically significant. The results were Bonferroni corrected. All statistical analyses were performed using the SPSS packages version 19.

Results

From a total of 177 Tx patients seen regularly at the outpatient clinic of the department of nephrology at Stavanger University Hospital, 63 Tx patients had eGFR 15–44 ml/min/1.73 m^2 (stages 3b–4). Five patients were excluded due to unstable kidney function, 10 patients due to recent change in comorbidity, 5 patients were unable to give informed consent, and 5 patients were unwilling to participate. From September 2011 to February 2012, 38 patients (all but 1 Caucasian) were included in the study: 15 (30.5%) females, 23 (69.5%) males, mean age 56±15 years. These patients were matched with stable non-RRT patients with the same kidney function using the same inclusion and exclusion criteria. The baseline data for the 2 groups of patients are given in Table 1.

Renal diagnoses are presented in Table 2. The patients had disease with similar causes as patients registered in the Norwegian Renal Registry [28]. During 1990–1994, 31% of patients diagnosed with end-stage renal disease (ESRD) had glomerulonephritis as the underlying kidney disease, compared to 15% in 2010. Diabetic nephropathy as the underlying kidney disease causing ESRD has increased from 12% to 17% and hypertensive nephropathy increased from 18% to 38% in the same period of time [28].

Table 1. Baseline data.

	Tx group (n=38)	Non-RRT group (n=38)	Total group (n=76)	P*
Age years, mean ±SD	56±15	57±14	57±15	.91
Male gender, n (%)	23 (60.5)	23 (60.5)	46 (60.5)	
eGFR (ml/min/1.73 m^2), mean ±SD	31±8	30±9	31±8	2.123
Time with known CKD months, median (range)	222 (60–436)	89 (12–359)	156 (12–436)	<.011
DCI, n (%)				
0	19 (50)	24 (63)	43 (57)	
1	16 (42)	13 (34)	29 (38)	2.926
2	3 (8)	1 (3)	4 (5)	
Diabetes mellitus, n (%)	6 (16)	6 (16)	12 (16)	
Ischemic coronary disease, n (%)	10 (26)	8 (21)	18 (24)	
Number of anti-hypertensiva, median (range)	2.5 (0–6)	3.0 (0–5)	3.0 (0–6)	2.046
S-creatinine µmol/l, mean ±SD	185.9±55.8	195.7±60.9	190.8±58.3	1.815
S-hemoglobin g/dl, mean ±SD	12.3±1.6	13.2±1.6	12.7±1.6	.066
S-albumin g/l, mean ±SD	36.8±3.0	37.1±2.7	36.9±2.9	7.568

Patients categorized as kidney transplanted (Tx group), and non-renal replacement therapy (non-RRT) group. Davies comorbidity index (DCI) score 0 = no co-morbid condition, DCI score 1 = 1–2 comorbid conditions and DCI score 2 = three or more (maximum seven) comorbid conditions. * Bonferroni corrected p-values.

Table 2. Renal diagnosis.

	Tx group (n=38)	Non-RRT group (n=38)	Total group (n=76)
Glomerulonephritis n (%)	15 (40)	16 (42)	31 (41)
Hypertensive nephropati n (%)	3 (8)	10 (26)	13 (17)
Diabetic nephropati n (%)	3 (8)	1 (3)	4 (5)
Congenital n (%)	8 (21)	4 (11)	12 (16)
Other n (%)	9 (23)	7 (18)	16 (21)

Patients categorized as kidney transplanted (Tx group) and non-renal replacement therapy (non-RRT) group.

The Tx patients were on immunosuppressive treatment with prednisolone (38 patients, 100%), cyclosporine (32 patients, 84%), mycophenolate (18 patients, 48%), azathioprine (14 patients, 37%), and tacrolimus (3 patients, 8%). In the non-RRT group, 6 patients (16%) received prednisolone, 5 patients (13%) received mycophenolate, 1 patient received cyclosporine, and 1 patient received etanercept.

Fifteen patients had BDI scores ⩾11: 10 patients (26%) in the Tx group and 5 patients (13%) in the non-RRT group (p=0.150).

Time since transplant was 165±92 months, and 21 (51%) of the Tx patients had been treated with dialysis pre-transplant.

There was no significant difference in HRQoL between the Tx and non-RRT group of patients using the SF-36 as outcome measure (Figure 1). None of the multi-item scales or summary scores in SF-36 were significantly different from the general Norwegian population in either group of patients. The non-RRT group of patients scored higher than the Tx group of patients in both the multi-item scales and the summary scores, but the difference was not statistically significant (Figure 1). No significant differences were seen in SF-36 HRQoL scores in gender or in Tx patients who had been on dialysis compared to patients with a pre-emptive transplant. When excluding patients with BDI scores ⩾11, no significant changes in SF-36 scores were observed.

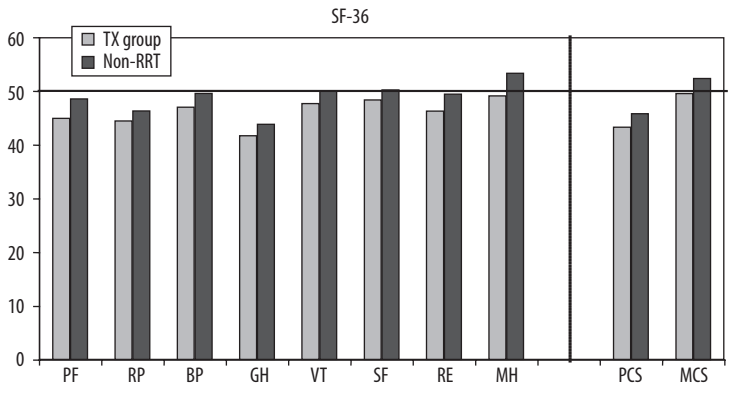

Figure 1. The short form-36 (SF-36) scores in kidney transplant patients (Tx group) and non-renal replacement therapy patients (non-RRT group) compared to the general Norwegian population. The multi-item scales: physical functioning (PF), role-physical, bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH). Physical component summary scores (PCS) and mental component summary scores (MCS). Line 50 represents the mean SF-36 scores in the general Norwegian population.

Table 3. Health-related quality of life (HRQoL) measures and Beck depression inventory (BDI) scores in the different group of patients.

HRQoL	Tx group (n=38)	Non-RRT group (n=38)	Total group (n=76)	P*
VAS mm, mean ±SD	57.2±22.0	67.9±21.0 (n=36)	62.4±22.0	.036
BDI, median (range)	7 (0–31)	4 (0–36)	5 (0–36)	.680
SF-36 PCS, mean ±SD	43.3±11.6 (n = 36)	45.9±9.7	44.6±10.7	1.756
SF-36 MCS, mean ±SD	49.6±9.9 (n = 36)	52.4±10.1	51.0±10.1	.308

Patients categorized as kidney transplanted (Tx group) and non-renal replacement therapy (non-RRT) group. Visual analogue scale (VAS), short form-36 physical component summary measures (SF-36 PCS), and short form-36 mental component summary measures (SF-36 MCS). P-values refer to Tx group *vs.* non-RRT group. * Bonferroni corrected p-values.

Using VAS, the HRQoL was significantly better in the non-RRT group (p=0.036). When excluding patients with BDI scores ⩾11, the VAS was still significantly different between the 2 groups of patients (Table 3). No differences in HRQoL VAS scores were observed between genders or in Tx patients with a pre-emptive transplant compared to patients with a post-dialysis transplant.

In the total group of patients, multiple backward linear regression analysis with HRQoL VAS as dependent variable, increasing BDI scores and DCI, and decreasing kidney function (eGFR) were inversely associated with HRQoL scores (HRQoL VAS mm =56.10–7.69 DCI score – 1.40 BDI score +0.65 eGFR, R^2=0.44). When using SF-36 PCS as the dependent variable, increasing BDI scores and increasing DCI scores were inversely associated with HRQoL scores (SF-36 PCS =51.77–6.94 DCI score and 0.54 BDI score, R^2=0.38). Using SF-36 MCS as the dependent variable, increasing BDI scores and decreasing DCI scores were inversely associated with HRQoL scores (SF-36 MCS =56.26+2.97 DCI score and 0.98 BDI score, R^2=0.49). When multiple backward linear regression analyses were performed separately in the 2 groups of patients, the determinants of HRQoL were the same as in the total group of patients.

Discussion

We observed no significant differences in HRQoL evaluated by SF-36 in a group of stable Tx patients compared with an age- and gender-matched group of non-RRT patients with similar eGFR. This may suggest that a history of kidney transplantation in itself is not a major determinant for HRQoL. However, the HRQoL was significantly better in the non-RRT group compared with the Tx group when HRQoL was evaluated by VAS. In multiple regression analyses, the main determinants of HRQoL were BDI and DCI scores. The HRQoL was not significantly different in the 2 groups of patients compared with the SF-36 norm data for the general Norwegian population.

VAS and SF-36 are both validated and reliable tools to assess HRQoL [29,30]. VAS is an overall subjective measure of HRQoL, whereas SF-36 is divided into different subscales and involves an external weighting of the different multi-item scales to produce summary measures. The VAS relies only on the patients' ability to form an

overall judgement of their own HRQoL, and it has been shown to be an excellent tool to evaluate overall QoL [29]. VAS has been tested against the MOS SF-20, which is a shorter version of the SF-36, and showed moderate to high correlations with all the subscales of the MOS SF-20. VAS and SF-36 may therefore explore different aspects of HRQoL as reflected in different results between the 2 groups of patients depending on the instrument used.

Other studies have reported significantly worse HRQoL in CKD patients, including Tx patients, using the SF-36 and other instruments for evaluating HRQoL compared to the general population [1–3,5,6]. In many of these studies, patients with CKD Stage 5 and also patients with an unstable kidney function were included. This is in contrast to our study, in which only patients with a stable kidney function stages 3b–4 were included, and this may explain why patients in the present study have HRQoL comparable to that of the general Norwegian population [2,3,6].

HRQoL in both Tx and non-RRT patients have in previous studies been associated with eGFR, but the level of eGFR at which HRQoL declines varies between studies [31–33]. In a longitudinal chronic kidney disease study that included CKD patients stages 3–5 [34,35], no association was observed between GFR and HRQoL. This is in accordance with our findings when using SF-36 as an outcome measure. As the kidney function of the included patients was well defined within a narrow range, an association between eGFR and HRQoL was not expected. However, there was a weak association between eGFR and HRQoL when VAS was used as the outcome measure. This may reflect that HRQoL as measured by VAS is more dependent on kidney function than is SF-36.

The 2 groups of patients were well matched, and the number of comorbidities and use of anti-hypertensives were not significantly different. The main differences between the 2 groups of patients were the use of immunosuppressive treatment and the duration of known renal disease. The use of immunosuppressive medication has been associated with reduced HRQoL [9,36]. The similar scores of the 2 groups of patients using the SF-36 may, for the Tx group, be influenced by a sense of gratitude for having received a kidney transplant and a stable transplant function over many years (the average time since transplant was >13 years). Over time, patients adapt to life with a transplant, and the fear of rejection has in previous studies been found to diminish 5 years after transplantation, which may result in better HRQoL [37,38]. In the multiple regression analysis, increasing DCI was associated with increased SF-36 MCS. There were only 4 patients with DCI=2. DCI was included in the model with a p-value of 0.05 and the β coefficient was low. This possible association should be studied in a larger number of patients.

The association between depression and HRQoL is well known [26], and the BDI scores were the major determinant of HRQoL in this study. However, there was no significant difference in BDI scores between the 2 groups of patients, and the results did not change if the patients with a BDI score of 11 or more were excluded from the analysis. The HRQoL was not significantly different from that of the general Norwegian population, and a study including 2066 individuals found a lifetime prevalence of depression in the general population of 18% [39]. The prevalence of depression as estimated by BDI is therefore similar to that found in the general Norwegian population.

Hemoglobin and albumin have in previous studies been associated with SF-36 PCS and SF-36 MCS [3,35]. In the present study, all patients were stable and the serum levels of hemoglobin and albumin were within the reference interval for >80% of the patients. This may explain the lack of association between these 2 parameters and HRQoL assessed by SF-36.

The HRQoL was, however, significantly different between the 2 groups of patients when assessed by VAS, with better HRQoL in the non-RRT group compared with the Tx group. The use of immunosuppressive medication with potentially adverse effects may explain this difference.

The strengths of our study are a well-defined population with 2 well matched groups of patients in a single center, nearly complete inclusion of defined patients (92%), and complete data sets. The main limitation is the relatively small study sample. A very large single-center or a multicenter design would be required to increase the number of defined patients to increase the statistical power.

Conclusions

Despite having had a significantly longer duration of known kidney disease than the non-RRT

group, the transplant experience and a strict lifelong need for immunosuppressive medication, the HRQoL in the Tx group was not significantly different from an age-, sex- and eGFR-matched group of non-RRT patients using the SF-36 questionnaire as the outcome measure. Both groups of patients were stable and without acute, serious comorbidities. However, HRQoL VAS was better in the non-RRT group, suggesting that VAS and SF-36 may evaluate different aspects in HRQoL in the same group of patients. The HRQoL was generally good in both groups of patients and not significantly different from the general Norwegian population. The HRQoL may differ in the same group of patients depending on the tool used, reflecting the complexity of HRQoL as a concept and the slightly different approaches of the tools measuring it.

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