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Health-Related Quality of Life as an Early Indicator of Adverse Outcomes in Kidney Transplant Recipients

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ABSTRACT

Background: Health-related quality of life (HRQoL) may provide clinically relevant prognostic information beyond conventional measures of graft function in kidney transplant recipients. This study evaluated whether baseline HRQoL could identify recipients at increased risk of adverse outcomes.

Methods: A secondary observational cohort analysis was conducted among 156 kidney transplant recipients. HRQoL was assessed using the five EQ-5D-5L dimensions and a 0–100 self-assessment score. The primary composite outcome was death or return to dialysis. Group differences were evaluated using Mann–Whitney U, chi-square, or Fisher's exact tests. Kaplan–Meier analysis, log-rank testing, Cox proportional-hazards regression, and receiver operating characteristic analysis were performed.

Results: Twenty-nine recipients (18.6%) experienced the composite outcome. Those with adverse outcomes had lower median self-assessment scores (60 vs. 80, $p < .001$), greater EQ-5D-5L severity, and more affected dimensions. Lower baseline HRQoL was associated with poorer adverse-outcome-free survival. In adjusted Cox analysis, each 10-point increase in self-assessment score was associated with a 24% lower hazard of adverse outcome (HR = 0.760, 95% CI 0.595–0.972). The combined predictive model achieved an AUC of 0.814.

Conclusion: Baseline HRQoL may complement clinical indicators for early risk stratification after kidney transplantation.

Keywords: kidney transplantation; health-related quality of life; EQ-5D-5L; adverse outcomes; survival analysis

1. Introduction

Kidney transplantation usually is the preferred option for kidney replacement in patients with end-stage kidney disease (ESKD) who are eligible for the procedure, since they can live longer, be more functional and have a better quality of life. However, after transplantation, the physical, psychological and social effects of chronic kidney disease and chronic treatment do not completely disappear. Health-related quality of life (HRQoL) is therefore an important patient-centered outcome that should be supplemented by traditional measures like graft function, hospitalization and mortality. Chronic kidney disease has a significant impact on the physical, emotional well-being, symptom burden, and social participation of patients, underscoring the need to assess outcomes beyond laboratory data 1. A global systematic review also showed that there is a close relationship between symptom burden and impaired HRQoL across the kidney disease continuum 2.

Patients often gain significant HRQoL benefits from kidney transplantation overstaying on dialysis or having advanced CKD. Patients who have received a transplant had improved HRQoL compared with those with similar renal function who had not 3. Similarly, older adults who receive kidney replacement therapy (KRT) have also been reported to show improvements in functional and psychological outcomes after transplantation 4. There is more recent evidence that transplantation can

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yield meaningful HRQoL improvement in older recipients as well, thus confirming the importance of considering patient-reported outcomes across age groups 5.

Although these advances have been made, HRQoL following transplantation is still quite variable. Over time, there have been significant improvements in quality of life and other patient-reported outcomes following transplantation, but there have been differences among recipients and over time 6. Demographic, clinical, and psychosocial factors are associated with multidimensional HRQoL trajectories after living-donor transplantation 7. Kidney transplant recipients of older age may also have different patterns of short- and long-term HRQoL, which are not only considered by graft-based endpoints 8.

These differences are partly due to the recipient's nature. HRQoL and symptom experiences of kidney transplant recipients (KT) have been found to be different by age and sex 9. Perceived health after transplantation is also influenced by psychological, physical and treatment-related factors 10. There is also cross-country evidence from the international literature that there is a clinically meaningful impairment in quality of life in various cultural and healthcare contexts 11. The value of focusing on quality of life as part of post-transplant care has been reinforced by multicenter comparisons undertaken with kidney and other solid organ transplant recipients 12.

HRQoL may have relevance beyond the subjective concept of well-being. There is a link between poor patient-reported health status and decreased access to kidney transplantation: HRQoL may capture underlying vulnerability that is not adequately captured by traditional clinical measures 13. Today's reviews elucidate how comorbidity, graft function, symptoms, fatigue, psychological status, and participation are interrelated determinants of post-transplant HRQoL 14. Therefore, patient-reported outcomes are becoming a highly recommended relevant endpoint for kidney transplantation research and clinical trials 15.

In the present study, we hypothesized that baseline HRQoL could be a useful early marker of negative outcomes in kidney transplant recipients. The scope encompassed assessment of EQ-5D-5L dimensions, self-reported health status, clinical and functional characteristics and subsequent dialysis or death. The aims were to compare HRQoL in the recipients with and without adverse outcomes, evaluate the time to adverse outcome according to baseline HRQoL, determine the independent prognostic value of HRQoL by Cox regression and assess its discriminatory performance by ROC analysis. Goals were to compare HRQoL in the recipients with and without adverse outcome, assess the time to adverse outcome according to baseline HRQoL, determine the independent prognostic value of HRQoL by Cox regression analysis, and assess its discriminatory performance by ROC analysis.

2. Methodology

2.1 Study Design and Participants

A secondary observational cohort study was performed in 156 kidney transplant patients. Demographic, clinical, functional, and health-related quality-of-life data were analyzed with follow-up data. The main outcome measure was the composite of death or return to dialysis. At follow-up, 22 participants died and 7 of them went back to dialysis, which resulted in 29 adverse outcomes and 127 non-events 16.

2.2 Variables and HRQoL Assessment

The clinical variables were age, sex, Charlson Comorbidity Index, heart disease, diabetes, vascular disease, liver disease, neoplastic disorder, fistulation status, time elapsed since transplantation, duration of dialysis, creatinine, GFR, haemoglobin, handgrip strength, 3-m walking test and 30-s stand-up test. The five dimensions of the EQ-5D-5L (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) were used to assess health-related quality of life. Level 1 was no problem, levels 2–5 were impairment. A severity sum (based on the EQ-5D-5L) and the number of dimensions affected were computed. Perceived health was also measured using a self-assessment scale on a 0–100 scale (higher scores indicate better health) for 155 of the participants.

2.3 Statistical Analysis

Means with standard deviations (SD) were used to summarise continuous variables for the total cohort, and frequencies and percentages were used for categorical variables. All 156 participants were used to create domain prevalence for EQ-5D-5L. Median and interquartile ranges were used to describe continuous variables and the Mann–Whitney U test was used for comparison between those with (n = 29) and those without (n = 127) the composite outcome. The Pearson chi-square test or Fisher's exact test was used to compare categorical variables as appropriate. A p value of < 0.05 was statistically significant.

2.4 Survival and Cox Regression Analysis

Time-to-event analysis was based on observation time in months with death or return to dialysis serving as the event. If no event was reported, then the participant was censored at his/her last follow-up. The HRQoL self-assessment score was dichotomized by the median score, 75 points, for Kaplan–Meier analysis. 155 participants were included in this analysis, 84 of whom scored ≥75 and 71 of whom scored <75. The log-rank test was used to compare survival curves. Using Cox proportional-hazards regression, associations were examined between HRQoL and adverse outcomes. The self-assessment score was analyzed at the level of 10-point increments, and the EQ-5D-5L severity sum per 1-point increment. Multivariable models were adjusted for age and GFR and Charlson Comorbidity Index. For the purposes of this study, age and GFR were presented as per unit increase. Data were presented as hazard ratio (HR) (95% confidence interval) and p-values.

2.5 Predictive Performance

The baseline HRQoL was assessed using receiver operating characteristic (ROC) analysis for its predictive capacity. A model based on the self-assessment score only was compared with a model including the self-assessment score, age, GFR and Charlson Comorbidity

Index. The area under the ROC curve (AUC) was used to describe the predictive performance. AUC values were interpreted as internal-sample discrimination since the model development and evaluation were done in the same cohort.

3. Results

3.1 Baseline Clinical and Health-Related Quality-of-Life Characteristics

In all 156 kidney transplant recipients were analyzed. The mean age was 55.33 ± 11.54 years, and 98 participants (62.8%) were male. Mean GFR was 53.35 ± 15.84, serum creatinine was 1.46 ± 0.52, and the mean Charlson Comorbidity Index was 4.38 ± 1.79. The average HRQoL self-assessment score was 73.20 ± 15.72. The baseline characteristics are summarized in Table 1.

Table 1. Baseline characteristics of kidney transplant recipients

Characteristic	Overall, N = 156
Age, years	55.33 ± 11.54
Male sex, n (%)	98 (62.8)
Female sex, n (%)	58 (37.2)
Charlson Comorbidity Index	4.38 ± 1.79
Heart disease, n (%)	52 (33.3)
Diabetes mellitus, n (%)	34 (21.8)
Vascular disease, n (%)	25 (16.0)
Liver disease, n (%)	41 (26.3)
Neoplastic disorder, n (%)	18 (11.5)
AVF present, n (%)	82 (52.6)
Time since transplantation, months	108.34 ± 64.46
Total dialysis duration, months	35.32 ± 31.56
Serum creatinine	1.46 ± 0.52
GFR	53.35 ± 15.84
Haemoglobin	14.33 ± 1.62
Right handgrip strength	36.87 ± 12.54
3-m walking test	7.71 ± 2.00
30-s stand-up test	16.61 ± 4.23
HRQoL self-assessment score	73.20 ± 15.72
Observation period, months	32.10 ± 9.86
Death, n (%)	22 (14.1)
Return to dialysis, n (%)	7 (4.5)
Composite adverse outcome, n (%)	29 (18.6)

Many recipients reported a health-related restriction to some extent. Overall, 102 out of 156 recipients (65.4%) reported having a problem in one or more dimensions of the EQ-5D-5L. The most affected domain was pain/discomfort (50.6%), anxiety/depression (41.7%), mobility (35.3%), and usual activities (27.6%). Self-care impairment was relatively rare (8.3%). The overall distribution of these is presented in Table 2.

Table 2. Distribution of responses across EQ-5D-5L domains

EQ-5D-5L domain	Level 1, n (%)	Level 2, n (%)	Level 3, n (%)	Level 4/5, n (%)	Any problem, n (%)
Mobility	101 (64.7)	31 (19.9)	15 (9.6)	9 (5.8)	55 (35.3)
Self-care	143 (91.7)	9 (5.8)	3 (1.9)	1 (0.6)	13 (8.3)
Usual activities	113 (72.4)	25 (16.0)	17 (10.9)	1 (0.6)	43 (27.6)
Pain/discomfort	77 (49.4)	51 (32.7)	20 (12.8)	8 (5.1)	79 (50.6)
Anxiety/depression	91 (58.3)	52 (33.3)	11 (7.1)	2 (1.3)	65 (41.7)

Figure 1 shows that pain/discomfort and anxiety/depression contributed the greatest HRQoL burden, whereas self-care was comparatively preserved.

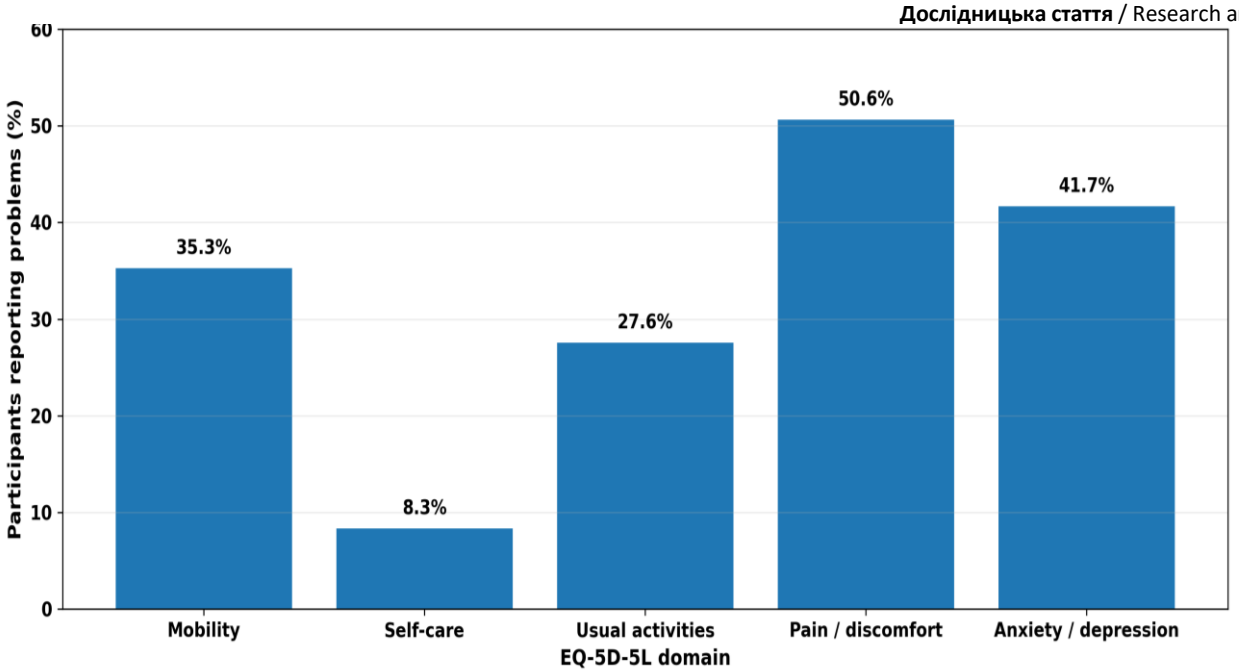

Figure 1: Prevalence of problems across EQ-5D-5L domains

3.2 HRQoL and Clinical Characteristics According to Adverse Outcome Status

Those who progressed to death or back to dialysis had a less favorable baseline profile compared to those who did not have the composite endpoint. The median age was 64 years in subjects with adverse outcome versus 55 years in those without an adverse outcome ($p < .001$). The Charlson Comorbidity Index was also higher and GFR was lower in the adverse-outcome group. Most importantly, the median self-assessed HRQoL was 60 compared to 80 ($p < .001$) and included more EQ-5D-5L severity and more impacted domains (Table 3).

Table 3. Comparison between recipients with and without the composite adverse outcome

Variable	No adverse outcome (n = 127)	Adverse outcome (n = 29)	p-value
Age, years	55 (45–63)	64 (61–69)	<.001
Charlson Comorbidity Index	4 (3–5)	5 (5–7)	<.001
GFR	56 (45–65)	45 (36–56)	.023
Creatinine	1.33 (1.11–1.59)	1.41 (1.23–1.96)	.097
Haemoglobin	14.6 (13.4–15.5)	14.2 (13.1–14.9)	.059
HRQoL self-assessment score	80 (70–85)	60 (50–72)	<.001
EQ-5D-5L severity sum	6 (5–8)	8 (6–12)	<.001
Affected EQ-5D-5L domains	1 (0–2)	3 (1–4)	.001
Right handgrip strength	39 (28–49)	33 (27–36)	.019
3-m walking test	7.05 (6.21–8.17)	8.04 (7.16–9.99)	.004
Any EQ-5D-5L problem, n (%)	78 (61.4)	24 (82.8)	.029
Heart disease, n (%)	36 (28.3)	16 (55.2)	.006

The magnitude of the difference in baseline health perception is shown in Figure 2, which is a separate distribution of the HRQOL self-assessment scores of recipients that later experienced the composite endpoint.

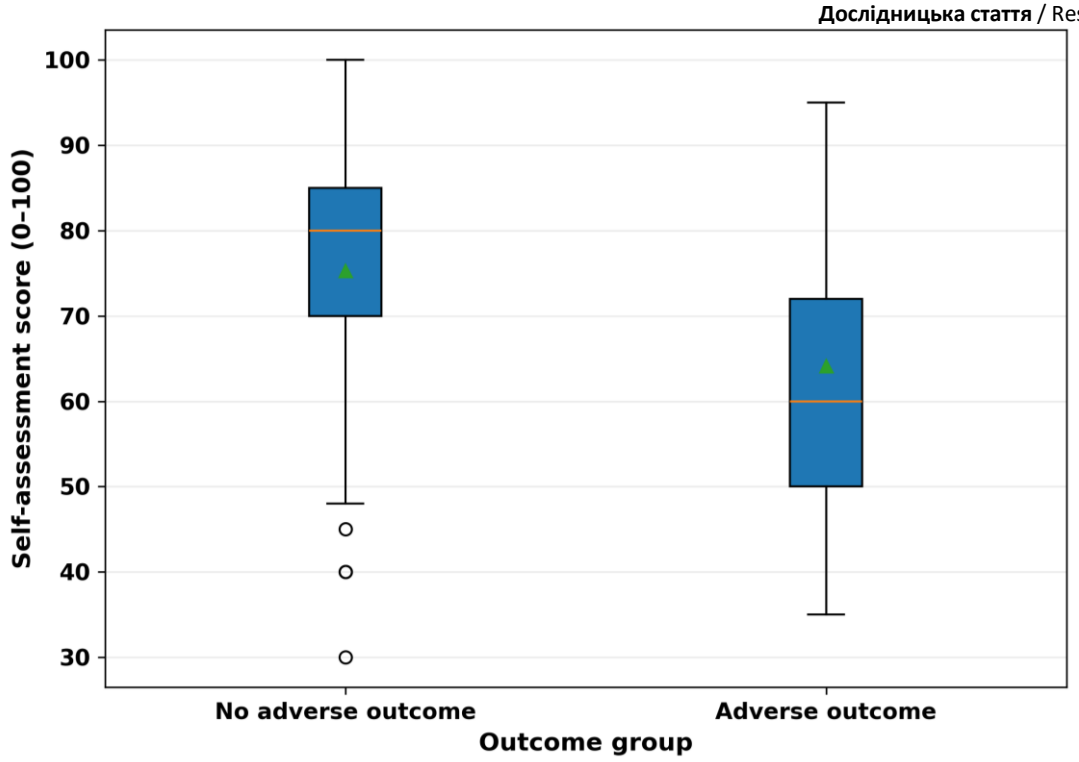

Figure 2: Baseline health self-assessment according to adverse outcome

3.3 HRQoL and Adverse-Outcome-Free Survival

In the time to event analyses, subjects were divided into two groups, those with a baseline assessment score below 75 and those with a score above 75. There were 155 subjects who scored and 84 (54%) had scores ≥75, and 71 (46%) had scores <75. The composite endpoint occurred in 22 (31.0%) of the lower-HRQoL group, but in only 7 (8.3%) of the higher-HRQoL group. Figure 3 shows that the recipients with the lowest baseline HRQoL had significantly worse adverse-outcome-free survival than other recipients (log-rank $p < .001$) as demonstrated by the Kaplan–Meier curves.

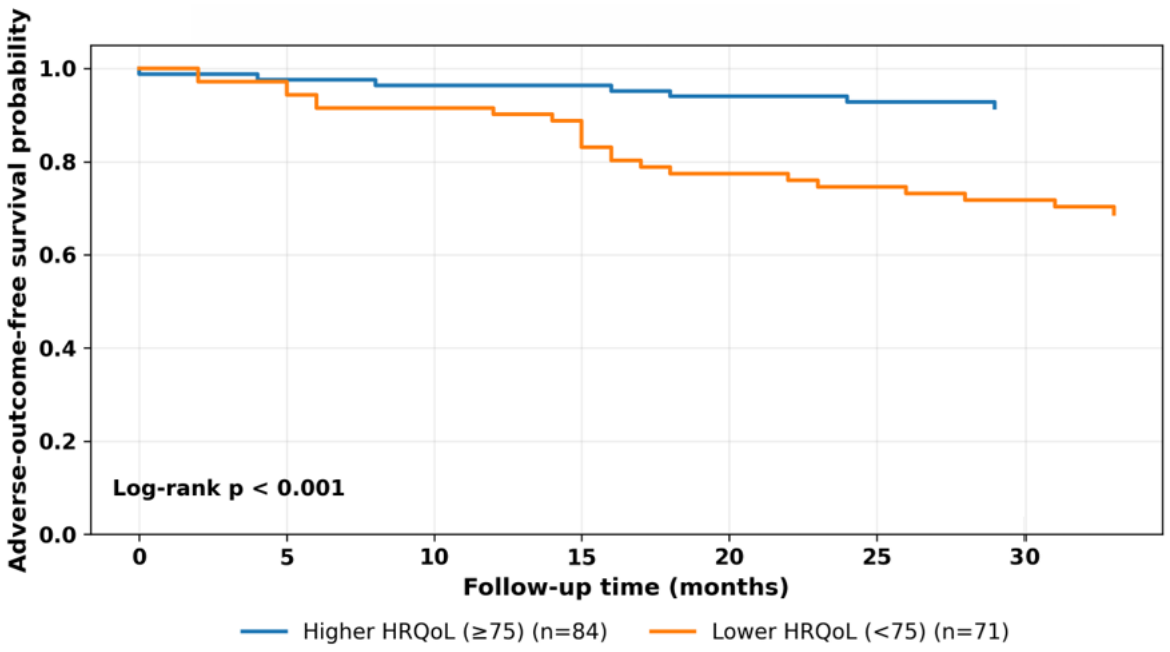

Figure 3: Event-free survival according to baseline HRQoL

3.4 Predictive Value of HRQoL for Adverse Outcomes

For every 10-point increase in the self-assessment score, the hazard for death or return to dialysis was decreased by 32.0% (HR = 0.680, 95% CI 0.545–0.848, p = .001) in univariable Cox analysis. The relationship remained significant following adjustment for age, GFR and Charlson Comorbidity Index (adjusted HR = 0.760, 95% CI 0.595-0.972, p = .029). Table 4 shows that, as the severity of the EQ-5D-5L increased by one point, the hazard also increased by 16.2% (adjusted HR = 1.162, 95% CI 1.033–1.308, p = .012), independent of each other.

Table 4. Cox proportional-hazards models for the composite adverse outcome

Predictor	Model	HR	95% CI	p-value
HRQoL self-assessment, per 10-point increase	Unadjusted	0.680	0.545–0.848	.001
HRQoL self-assessment, per 10-point increase	Adjusted	0.760	0.595–0.972	.029
Age, per 10-year increase	Adjusted HRQoL model	1.569	0.913–2.698	.103
GFR, per 10-unit increase	Adjusted HRQoL model	0.749	0.581–0.966	.026
Charlson Comorbidity Index, per 1-point increase	Adjusted HRQoL model	1.206	0.931–1.562	.156
EQ-5D-5L severity sum, per 1-point increase	Unadjusted	1.230	1.108–1.367	<.001
EQ-5D-5L severity sum, per 1-point increase	Adjusted	1.162	1.033–1.308	.012

ROC analysis showed an AUC of 0.710 for baseline HRQoL self-assessment alone. Combining HRQoL with age, GFR, and Charlson Comorbidity Index increased the AUC to 0.814 (Figure 4), indicating improved internal-sample discrimination.

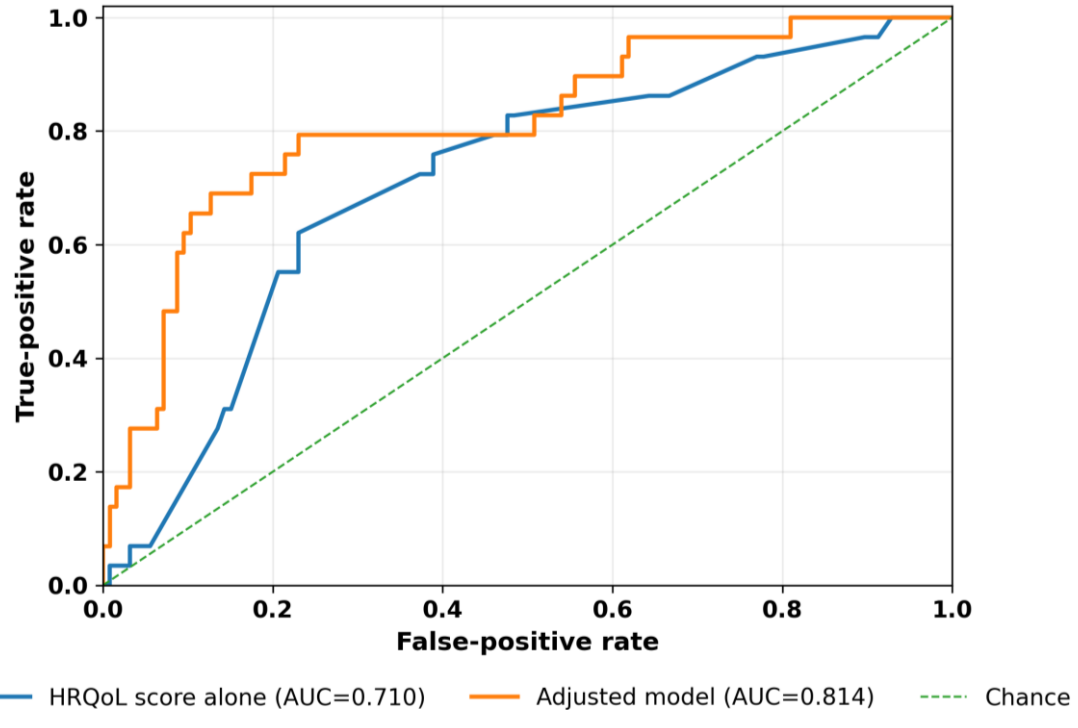

Figure 4: ROC curves for prediction of the composite adverse outcome

4. Discussion

The current results suggest that baseline HRQoL is a significant risk factor for worse outcomes after kidney transplantation. Recipients who died or went back to dialysis had lower scores on the perceived-health section of the instrument, higher EQ-5D-5L impairment, more affected dimensions of quality of life, and less favourable clinical and functional profiles. The results are consistent with longitudinal studies that revealed that worsening HRQoL courses may be associated with worse symptom distress and graft failure in renal transplant patients 17.

This was especially true for the difference in self-assessed health. The median score was 60 for those that had a bad outcome and 80 for those that did not have an adverse outcome. This indicates that the patients' health perception might include multidimensional vulnerability other than biochemical parameters. Kidney transplant recipients have been shown to have a clinically

significant symptom burden that could signal issues other than those identified by routine clinical assessment 18. Other clinical factors linked to HRQoL and unfavorable outcomes in transplant recipients are anxiety and depression 19.

The renal function was different across outcome groups, with those who had adverse events having lower GFR. HRQoL, however, was still an important factor after correction for GFR, age and comorbidity burden, suggesting prognostic information in addition to these clinical factors. Patient-reported outcomes have been associated with potentially modifiable biological factors such as iron deficiency and anemia 20. Additionally, impaired HRQoL after transplantation may be caused by fatigue, sleep problems, and restriction in social functioning 21.

The Kaplan–Meier analysis gave additional separation of prognosis. Side effects were seen in 31.0% of those who self-assessed scores are below 75; and in 8.3% who scored 75 or above. Data from transplant populations also show that there can be a combination of increased mortality risk and functional vulnerability and HRQoL problems 22. HRQoL changes have also been observed following transplantation in other solid organ transplantations 23.

Multivariable Cox regression analysis revealed that for every 10-point increase in self-assessed HRQoL, the adjusted hazard of death or return to dialysis was decreased by 24%. Hazard increased with the severity of the EQ-5D-5L, independently. The treatment exposure–patient experience interaction has been suggested in previous work to impact quality of life outcomes 24. The gut microbiome is another example of how biological factors are associated with HRQoL, further highlighting the multidimensionality of post-transplant health 25.

The predictive model that included HRQoL and was combined with age and GFR and comorbidity had an AUC of 0.814, whereas HRQoL alone was 0.710. Therefore, it seems that HRQoL is most valuable as an additional instead of an alternative prognostic factor. The same focus on multidimensional evaluation has been noted in HIV positive transplant recipients 26. Among other studies on kidney donors, we find that psychosocial traits can influence long-term HRQoL 27. Clinical complications and perceived health can change in parallel across follow-up in longitudinal donor studies 28, and kidney-exchange donor studies emphasize the importance of structured HRQoL monitoring 29.

The last is the improvement in patient-reported outcomes after combined pancreas-kidney transplantation, which shows that outcomes beyond just survival and organ function should be assessed following transplantation 30. HRQoL has also been demonstrated to be clinically significant in acute situations like COVID-19 among renal transplant recipients 31.

The present findings, taken together, indicate the benefit of integrating brief HRQoL assessment into the routine follow-up of all recipients to help identify those who may need more frequent clinical follow-up. However, validation of the specific cut-off points or prediction model outside the study is still needed before they can be applied to clinical practice in larger multi-center cohorts.

5. Conclusion

This study shows that quality of life, as a measure of health-related quality of life, could be a useful early predictor of poor outcomes among kidney transplant recipients. Patients who later went on to die or return to dialysis had lower baseline perceived health, higher EQ-5D-5L impairment scores, higher number of affected quality-of-life dimensions, lower kidney function and higher burden of comorbidity. Importantly, HRQoL remained an independent predictor of adverse outcomes even after controlling for age, GFR and Charlson Comorbidity Index. The survival analysis also revealed that the baseline self-assessment scores of the recipients were significantly associated with adverse-outcome-free survival, with lower scores indicating worse survival outcomes. Furthermore, the predictive model including HRQoL, age, kidney function, and comorbidity showed better discrimination than HRQoL alone. The results indicate that patient-reported health status could be used in conjunction with traditional clinical markers and could be beneficial in determining who is more at risk for a transplant patient and who needs to be monitored more closely. Routine use of brief HRQoL measures in post-transplant care may then be useful for better risk stratification in the early stage and facilitate more patient-centred clinical management. Larger multicenter studies with external validation would be required before specific thresholds of or prediction models for HRQoL could be recommended for routine clinical use.

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