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The Study of Quality of Life and It's Determinants Among Dialysis Patients Using the KDQOL SF-36 Scoring in a Tertiary Care Center in Tamilnadu

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Abstract: ***Background**: CKD describes disorders affecting the structure and function of the kidney. Both the disease itself and dialysis affect the quality of life in CKD patients. Kidney Disease Quality of Life SF-36 survey is developed by RAND Corporation to access the quality of life in CKD patients. **Methods**: The study was conducted among the patients undergoing dialysis in the Government Rajaji Hospital. The study was conducted among the Tamil-speaking people by translating the KDQOL-SF™ questionnaire into Tamil language. Mean scores were compared for the individual domain and for the three composite scores. The three composite scores are the physical composite score (PCS), mental composite score (MCS), and kidney disease component summary score (KDCS). **Results**: 103 dialysis patients were recruited. The mean scores of PCS, MCS, SPKD, EKD, and BKD were 26.2, 40.9, 59.09, 40.6, and 65.6 respectively. MCS higher than PCS indicates better mental health status than physical health for ESKD patients. PCS and MCS scores were lower among patients more than 60 years of age, illiterate, and with diabetes. EKD and BKD scores were higher among patients less than 30 years of age, patients on CAPD, and Dialysis vintage less than 3 years. **Conclusion**: In our study, HRQOL declined in patients with low serum albumin, anemia, and high CRP levels. HRQOL is not affected by gender in our study. The burden of kidney disease is less in CAPD patients compared to HD patients. An understanding of the socio-demographic determinants of HRQOL will help in formulating a targeted treatment strategy for ESKD patients undergoing dialysis.*

Keywords: renal replacement therapy (rrt), kdqol-sf™, quality of life, kidney disease component summary score, chronic kidney disease

1. Introduction

Chronic Kidney Disease (CKD) is a worldwide health problem with a global prevalence of 13.4% [1]. CKD is defined as kidney damage or GFR <60ml/min/1.73m2 recorded for greater than three months irrespective of the cause [2]. Health-related quality of life is a multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning. It exceeds the direct measure of population health life expectancy and cause of death and focuses on the impact of health status on quality of life. In recent decades, several researchers have found that health-related quality of life (HRQOL) is compromised in CKD patients [3]. Both dialysis and renal transplantation reduce mortality in CKD patients. However, mortality and morbidity data alone are an incomplete measure of the outcome in CKD patients. CKD also compromises physical as well as psychological health, daily functioning, general well-being, and social functioning, which pose significant determinants of a patient's quality of life [4-5].

In recent decades, awareness to measure the HRQOL using a reliable and valid scoring system has increased in CKD patients. Since most of the instruments are in the English language, they are required to be translated into the local language before use [6]. Kidney disease quality of life 36 items short form survey (KDQOL-SF™) is one of the most widely used measures of the HRQOL for patients with End Stage Kidney Disease (ESKD) [7]. The socioeconomic and cultural environment of the patients also plays a key role in determining the HRQOL. Understanding the determinants of the HRQOL would aid the treating physician to acquire a better understanding of the disease from the patient's perspective. As there are only limited studies on HRQOL in CKD patients from South India, our current study intends to assess the HRQOL and its determinants in ESKD patients by employing a kidney disease-specific tool, i. e., KDQOL-SF™.

2. Materials and Methods

The Longer KDQOL instrument was first developed by the RAND corporation in 1994 [8]. The original KDQOL questionnaire consists of 134 survey items. As the original questionnaire is lengthier and time consuming, the KDQOL Short Form TM 1.3 (KDQOL-SF) was later developed in 1997. The SF-36 questionnaire assesses the HRQOL by 36 items survey that provide the generic core and overall health survey including physical functioning, role limitation caused by physical problems, role limitations caused by emotional problems, pain, general health, energy, fatigue, emotional well-being, and social function. The physical and mental composite summary depicts the results from SF-36. The KDQOL-SF™ also includes 43 kidney disease targeted survey items such as the symptoms and problems of kidney disease, the effect of kidney disease, work status, cognitive function, quality of social interaction, sexual function, sleep, social support, patient satisfaction, and dialysis staff management.

The symptoms and problems scale assesses the extent of bother during the last 30 days (not at all, sometimes, moderately, very much, extremely). Work status is measured in terms of whether each person was able to work full or part time, was currently working or not working and the number of days or months worked in the past 12 months.

Scoring rules were followed according to the instructions provided in the KDQOL-SF™ user's manual. Each domain was scored on a 100-point scale, with higher scores representing better quality of life. In our study we also included the background information regarding the patient, such as gender, income level, education and number of medicines per day.

Our prospective study was conducted among the patients undergoing chronic renal replacement therapy by either hemodialysis (HD) or continuous ambulatory peritoneal dialysis (CAPD) in Government Rajaji Hospital, Madurai, Tamilnadu, India. The study period began in March 2021 and ended in March 2022. Our study was approved by the institutional ethical committee Reg No: ECR/1365/INST/TN2020. The participants of the study were informed of the purpose of the study before obtaining written consent.

Inclusion Criteria:

ESKD patients aged 18 and above, who were on dialysis (HD or CAPD) for more than three months were included in the study.

Exclusion Criteria:

Patients with psychiatric illness, malignancy, and cognitive defects, were excluded from the study.

The study included 103 patients. Among them, 83 and 20 patients were undergoing HD and CAPD, respectively.

The questionnaire was translated into Tamil according to the specifications provided by RAND health. The translation was conducted by a professional translator. A team of medical professionals (two nephrologists, a physician, and two dialysis staff) reviewed the questionnaire to assess its accuracy. One of the authors was trained to administer the questionnaire to illiterate patients, even though KDQOL-SF™ is a self-reported questionnaire.

R-programming and SPSS were used to perform the statistical analysis. All HRQOL domain scores were presented by mean and standard deviation. Unpaired sample t-test and one-way ANOVA were utilized to compare the scores between two groups and more than two groups, respectively. Pearson correlation analysis was also used to find the linear relationship between the continuous variables. A multiple regression model was formulated to predict the HRQOL domains based on the potential independent variables. Statistical significance was considered at a five percent level of significance.

3. Results

In our study, the mean scores of health-related quality of life (HRQOL) domains, such as Physical Component Score (PCS), Mental Component Score (MCS), Symptoms and Problems of Kidney Disease (SPKD), Effects of Kidney Disease (EKD) and Burden of Kidney Disease (BKD) across the demographic and co-morbidity conditions of dialysis patients were 26.2, 40.9, 59.09, 40.6 and 65.6, respectively. The mean scores of HRQOL domains significantly differed among the various age groups of the patients. Moreover, the mean scores of PCS ($P<0.01$) and MCS ($P<0.01$) significantly varied among educated and uneducated ESKD patients. Haemodialysis patients depicted lower scores in EKD and BKD domains compared to the continuous ambulatory dialysis patients.

PCS and MCS scores were not significantly influenced by the mode of dialysis. Similarly, haemodialysis patients with diabetes mellitus had lower scores in PCS and MCS domains compared to patients without diabetes mellitus.

The mean scores of HRQOL domains did not significantly differ among the male and female patients. Furthermore, the mean scores of HRQOL domains did not show significant variance among patients with and without hypertension. Similarly, the patients with and without CAD demonstrated a comparable level of mean scores of HRQOL domains. Therefore, it can be said that gender, hypertension, and CAD did not influence the HRQOL of dialysis patients. The effect of demographic and co-morbidity statuses on health-related quality of life of the patients in mentioned in Table *1*.

Table 1: Effect of demographic and co-morbidity statuses on HRQOL of the patients

		PCS		MCS		SPKD		EKD		BKD	
		Mean±SD	**P**	**Mean±SD**	**P**	**Mean±SD**	**P**	**Mean±SD**	**P**	**Mean±SD**	**P**
Gender	Male	42.57±6.12	0.285	53.02±6.20	0.166	63.38±7.52	0.407	48.77±8.50	0.765	64.66±7.05	0.649
	Female	41.26±6.27		51.19±7.09		64.64±7.86		49.28±8.66		65.30±7.06	
Age Group	<=30	46.74±4.29	0.001 **	56.35±6.57	0.001 **	67.39±7.57	0.001 **	54.26±6.11	0.001 **	63.13±7.56	0.001 **
	31-60	41.23±5.96		51.77±5.72		63.58±7.33		48.36±8.52		65.36±6.55	
	60+	36.64±4.63		46.09±7.20		59.09±7.33		42.00±6.87		66.18±8.73	
Education	Illiterate	36.97±5.78	0.001 **	48.58±6.05	0.001 **	62.61±7.43	0.493	47.35±8.42	0.194	66.29±7.36	0.439
	School Level	43.93±5.01		53.61±6.24		64.39±7.88		49.02±9.09		64.27±6.56	
	Graduate	44.81±5.23		54.19±6.81		65.00±7.46		52.13±5.92		64.75±8.04	
Mode of Dialysis	CAPD	41.45±6.48	0.677	52.90±6.25	0.595	61.75±9.33	0.153	56.25±6.25	0.001 **	69.00±5.74	0.002 **
	HD	42.10±6.16		52.01±6.77		64.48±7.17		47.25±8.10		63.98±6.99	
DM	Absent	44.31±4.94	0.001 **	53.98±6.08	0.001 **	64.61±7.62	0.298	50.28±8.96	0.067	64.79±6.87	0.776
	Present	38.57±6.29		49.57±6.65		63.00±7.71		47.14±7.61		65.19±7.33	

HTN	Absent	42.42±6.24	0.728	50.89±6.15	0.352	66.42±6.65	0.120	47.58±6.23	0.424	62.68±7.77	0.120
	Present	41.87±6.21		52.48±6.76		63.39±7.80		49.32±8.97		65.46±6.79	
CAD	Absent	42.34±6.51	0.436	52.03±7.02	0.766	64.03±7.62	0.893	49.72±8.51	0.276	64.80±7.09	0.777
	Present	41.36±5.66		52.44±6.09		63.82±7.83		47.82±8.55		65.21±7.00	
Dialysis Vintage	<=3 Years	41.84±6.53	0.837	52.88±6.51	0.294	63.14±8.23	0.288	51.08±8.45	0.014 *	65.86±6.59	0.194
	>4 Years	42.10±5.90		51.50±6.78		64.75±7.05		46.96±8.19		64.06±7.39	

**P<0.01, *P<0.05, P < 0.05 is considered statistically significant

PCS-Physical composite score, MCS-Mental composite score, SPKD-Symptoms and problems of kidney disease, EKD-Effect of kidney disease, BKD-Burden of kidney disease, DM – Diabetes Mellitus, HTN-Hypertension, CAD-coronary artery disease,

Pearson's correlation was used for the analysis of biochemical parameters and HRQOL domains. Based on a 5 percent level of significance, SPKD, EKD, and BKD scores were not significantly influenced by BMI, CRP, Serum Albumin, and Hemoglobin (Hb), whereas PCS and MCS scores depicted a positive relationship with serum albumin and Hb. PCS scores were lower in patients with CRP values of more than 10mg/L. Our results imply that in ESKD patients, Physical Component Score and Mental component score would increase as serum albumin and Hb increase. Correlation between biochemical parameters and HRQOL indicators of our patients is mentioned in Table *2*. Scatter diagram of health-related quality of life and biochemical parameters of our patients is shown in Fig *1*.

Table 2: Correlation between Biochemical parameters and HRQOL indicators

		PCS	MCS	SPKD	EKD	BKD
BMI	r-value	- 0.028	0.097	- 0.167	- 0.091	0.092
	P-value	0.782	0.330	0.091	0.361	0.357
CRP	r-value	- 0.261	- 0.088	- 0.096	- 0.118	0.018
	P-value	0.008**	0.374	0.336	0.235	0.858
Serum Albumin	r-value	0.613	0.270	0.140	0.053	- 0.116
	P-value	0.000**	0.006**	0.158	0.593	0.243
HB	r-value	0.401	0.263	0.103	0.100	- 0.057
	P-value	0.000**	0.007**	0.299	0.315	0.569

**P<0.01, *P<0.05. P < 0.05 is considered statistically significant.

PCS-Physical composite score, MCS-Mental composite score, SPKD-Symptoms and problems of kidney disease, EKD-Effect of kindey disease, BKD-Burden of kidney disease, BMI-Body Mass Index, CRP – C reactive protein, HB-Haemoglobin.

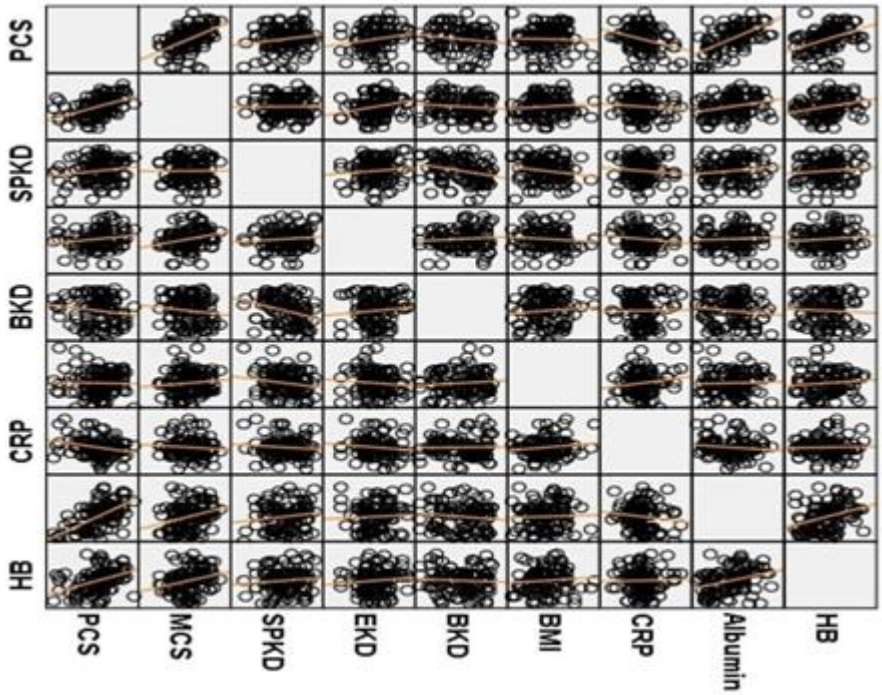

Figure 1: Scatter diagram of health-related quality of life and biochemical parameters

PCS – Physical Composite Score, MCS – Mental Composite Score, SPKD – Symptoms and Problems of Kidney Disease, BKD – Burden of Kidney disease, EKD – Effect of Kidney disease, CRP – C Reactive Protein, HB – Haemoglobin, BMI – Body Mass Index

Multiple regression models for HRQOL in Dialysis patients were obtained. Based on the bivariate analysis, the potential independent variables were extracted to predict the HRQOL domains. The PCS of the patients would increase provided the patients were literate and normoglycemic, along with the serum albumin level being >3.5g/dl, HB level being >8g/dl, and CRP level being low. Similarly, the potential predictor for the MCS and SPKD score was age, which implies that MCS and SPKD would increase if the patients were aged below 60 compared to the patients aged above 60. The age and mode of dialysis were the potential predictors for the EKD scores of the patients, as it was found that the EKD would increase if the patients were aged below 60 and had CAPD. Prediction of health related quality of life of dialysis patients included in our study using demographic and biochemical parameters is mentioned in Table *3*.

Table 3: Prediction of HRQOL of haemodialysis patients using demographic and biochemical parameters

Outcome	Predictors	Unstandardized Coefficients		P-value
		Beta (β)	SE (β)	
PCS	(Constant)	26.219	3.713	.000
	Age: Reference "60+"			
	Age <=30	2.850	1.683	.094
	Age 31-60	.298	1.450	.838
	Education: Reference "Illiterate"			
	School Level	3.066	1.065	.005**
	Graduate	3.614	1.420	.013*
	DM: Reference "Negative"			
	DM Positive	- 2.806	.883	.002**
	CRP	- .266	.104	.012*
	Serum Albumin	2.858	.755	.000**
	HB	1.234	.439	.006**
MCS	(Constant)	40.986	5.108	.000
	Age: Reference 60+			
	Age <=30	6.487	2.421	.009**
	Age 31-60	2.933	2.099	.166
	Education: Reference "Illiterate"			
	School Level	2.353	1.553	.133
	Graduate	2.886	2.064	.165
	DM: Reference "Negative"			
	DM Positive	- 2.401	1.287	.065
	Serum Albumin	.036	1.094	.974
	HB	.950	.637	.139
SPKD	(Constant)	59.091	2.225	.000
	Age: Reference "60+"			
	Age <=30	8.300	2.706	.003**
	Age 31-60	4.489	2.396	.064
EKD	(Constant)	40.615	2.239	.000
	Age: Reference "60+"			
	Age <=30	10.413	2.687	.000**
	Age 31-60	5.426	2.351	.023*
	Mode of Dialysis: Reference "HD"			
	CAPD	7.658	1.841	.000**
	Dialysis Vintage: Reference "4 and above Years"			
	<=3 Years	1.894	1.471	.201
BKD	(Constant)	65.694	2.034	.000
	Age: Reference "60+"			
	Age <=30	- 3.964	2.482	.113
	Age 31-60	- 1.343	2.190	.541
	Mode of Dialysis: Reference "HD"			
	CAPD	5.368	1.687	.002**

**P<0.01, *P<0.05. P <0.05 is considered statistically significant.

PCS-Physical composite score, MCS-Mental composite score, SPKD-Symptoms and problems of kidney disease, EKD-Effect of kidney disease, BKD-Burden of kidney disease, DM – Diabetes Mellitus, HTN-Hypertension, CAD – Coronary artery disease, HD-Hemodialysis, CAPD – Continuous ambulatory peritoneal dialysis, DM – Diabetes Mellitus, CRP-C reactive Protein, HB – haemoglobin

4. Discussion

Our study demonstrated that quality of life is negatively impacted by renal failure as it influences the physical, psychological, and personal life of the patients. Improving the quality of life in ESKD patients will help them become more compliant with therapy and improve their survival. DOPPS study demonstrated that a five-point increase in quality of life scores by targeting mental and physical health issues related to kidney disease in ESKD patients was significantly associated with a 48% and 9-23% reduction in hospitalization and mortality, respectively [9]. Most ESKD patients are required to leave their occupations and families due to the long duration of their treatment as well as to get access to the nearby dialysis center. The mean overall score of all 19 domains in our study was observed to be 46.4. Among the composite domains in our cohort, the lower score was observed in PCS (26.2), followed by MCS (40.9). This indicates that patients with ESKD presented better mental health than physical health. This pattern has also been identified by Van Kn et al, Yang Fe et al, and Kim Jy et al [10-11].

Previous research has demonstrated that socio-demographic factors may have an impact on HRQOL in ESKD patients [12]. Our study found that age, education, and diabetes had a significant impact on HRQOL scoring.

Gender has been shown to have a significant impact on HRQOL in previous studies [13-14]. Females scored less in PCS and MCS domains in most of the studies using the KDQOL-SF™ instrument for assessing the quality of life in ESKD patients. However, in our study, gender has no impact on the quality of life.

Furthermore, literacy has shown a crucial influence on HRQOL in a previous study [15]. In line with the previous studies, our study also showed that literate patients had significantly better scores in PCS and MCS domains compared to illiterate patients. Our study results also showed that employed patients lived a better quality of life compared to unemployed patients. Ikonomou et al demonstrated that an increase in age has a negative influence on HRQOL [16]. The current study confirmed this aspect as patients greater than 60 years of age had a lower quality of life compared to patients below 60 years of age.

Anaemia is also associated with reduced quality of life in ESKD patients [17-18]. Our study sample demonstrates that PCS and MCS were lower among the patients with haemoglobin less than 8gm/dl. However, DOPPS and CHOIR studies showed no significant difference in HRQOL in ESKD patients with Hb below 11gm/dl and above 11gm/dl [19].

Haemodialysis and peritoneal dialysis patients have equivalent levels of HRQOL in the United States. This was also reflected in a study by Manavalan et al in Tamil Nādu [19]. Our study reported similar PCS and MCS scores in HD and PD patients. Nevertheless, the effect of kidney disease and burden of kidney disease scores were higher in HD patients than in CAPD patients. Frequent hospitalization, multiple cannulations, access failure, and intradialytic complications might account for the high disease burden in HD patients [20].

Serum albumin is one of the strongest predictors of adverse outcomes and mortality in ESKD patients [21, 8]. Our study also demonstrated better PCS and MCS scores in patients with albumin levels greater than 3.5gm/dl.

In a study conducted by Wyld et al, patients with both CKD and diabetes depicted a faster decline in PCS scores than those with either one of the diseases [22]. Our study also demonstrated that dialysis patients with diabetes have lower scores in PCS and MCS.

HRQOL scores were not significantly impacted by the presence of hypertension or coronary artery disease in our patients. Higher CRP levels and cardiovascular disease were found to be significant predictors of HRQOL in dialysis patients in a study conducted by Agenta et al [23]. In our study, CAD did not influence the quality of life; however, patients with high CRP (CRP > 5mg/dl) values depicted poor PCS scores. High CRP levels correlate with increased inflammatory cytokines, leading to a poorer quality of life [24].

Ayumi et al previously reported that PCS scores significantly decreased as dialysis vintage lengthened [25]. In our present study, dialysis vintage had no impact on PCS; however, the effects of kidney disease (EKD) domain scores were lower in ESKD patients as dialysis vintage lasted for more than three years.

5. Limitations of our study

The impact of parameters, such as gender and dialysis modality, could not be determined correctly due to the relatively small number of participants. Many other confounding factors, including access to the dialysis centre, religious practices, and compliance with drugs may have impacted HRQOL, for which data were not collected. KDQOL is a self-reported questionnaire. However, a few of our patients were illiterate, and hence, one of the authors was trained to ask questions and collect the answers from illiterate patients.

6. Conclusions

Our study demonstrates that HRQOL declines in a patient with low serum albumin, anaemia, and with high CRP levels. ESKD patients in CAPD depicted a reduced burden of the disease compared to patients in haemodialysis. Educated and employed ESKD patients lived a better quality of life compared to unemployed and illiterate patients. Contrary to previous studies, gender and CAD had no influence on HRQOL in our study. An understanding of the socio-demographic determinants of HRQOL will help in formulating a targeted treatment strategy for ESKD patients undergoing dialysis.

Additional Information Disclosures

Human subjects: All authors have confirmed that this study did not involve human participants or tissue.

Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue.

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following:

Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work.

Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work.

Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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