ASSESSMENT OF QUALITY OF LIFE IN CHRONIC RENAL FAILURE PATIENTS IN INDIA

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Abstract

Chronic renal failure (CRF) is one of the serious medical disorders and is associated with increase in poor physical and mental health leading to impaired quality of life (QOL). The Kidney Disease Quality of Life Questionnaire–Short Form (KDQOL-SFᵀᴹ) is widely being used as a measure of QOL in CRF patients and very few studies have investigated the QOL in CRF patients not undergoing dialysis. The aim of the present study was to determine the reliability and validity of KDQOL-SFᵀᴹ in CRF patients on haemo-dialysis (CRF-D) and not on dialysis (CRF-ND) in Bangalore, India.
Data was gathered from 101 participants from the nephrology department of age >18 years having CRF. The patients who had undergone renal transplant were excluded in this study. KDQOL-SFᵀᴹ 1.3 composed of 43 kidney-specific items and 36 general health items was used, excluding three questions relating to dialysis staff encouragement and patient satisfaction, sexual function as they were not relevant to our study population comprising of CRF patients on dialysis and not on dialysis. Percentage of floor, percentage of ceiling, and internal consistency reliability (Cronbach's alpha coefficient) were calculated. Complete information was collected from 101 participants with 40 CRF patients undergoing dialysis and 61 CRF patients not on dialysis with the mean age of 50.88 ±14.22 years (CRF-D) and 53.64 ± 13.03 years (CRF-ND). Comparison of KDQOL-SFᵀᴹ

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mean score values between CRF patients on dialysis and not on dialysis group revealed that quality of social interaction, role emotional, emotional well-being had a significant difference (p < 0.05), but the overall health score was almost same. All sub-scales had a Cronbach's α above the recommended minimum value of 0.7 to indicate good reliability (range 0.7) except quality of social interaction (CRF-D and CRF-ND) and sleep, role physical and emotional well being in CRF-D group. Comparison of mean score values revealed that participants < 40 years had a better QOL the > 40 years.

Results from KDQOL-SF™ supported the validity and reliability of KDQOL as a measure of QOL in dialysis and not on dialysis patients in a tertiary care hospital in Bangalore, South Indian Population. Hence, measuring and monitoring these aspects of quality of life could lead to a more patient-centered care and improve the health and well-being among patients with CRF.

Key words*: chronic renal failure, quality of life, HRQOL, KDQOL-SF™*

Introduction

Chronic renal failure (CRF) is now recognized as a significant and rapidly growing global health burden, which affects health related quality of life not only for the patient but the family also. It is up to six times more common in some ethnic minority populations and is twice as common in females as in males (Joshi, 2010; Kimmel, 2006).

A recent and first report of the Indian Chronic Kidney disease (CKD) registry highlights the demographics of 52, 273 adult patients, etiological spectrum and practice spectrum of the country, confirming the emergence of diabetic nephropathy as the pre-eminent cause in India (Rajapurakar et al., 2012). Health related quality of life (HRQOL) is used almost exclusively in clinical studies, with the nephrology community increasingly realizing the potential importance of HRQOL assessment in the clinical care of its patients. HRQOL scores provide additional information on the individual's well being beyond the information gained from the patient's clinical and laboratory assessments. HRQOL is generally poorer than the general population due to the high burden of comorbidity and complications, hence the impact of CRF on a patient's quality of life (QOL) has become increasingly recognised as an important outcome measure (Kim et al., 2012; AL-Jumaih, 2011).

Generic measures such as SF-36, WHO-QOL BREF questionnaire were commonly used to predict patients' outcome and detect changes in quality of life (QOL) whereas in those with CRF is limited (Finkelstein et al., 2009; Sathvik 2008). Disease-specific instruments have been developed to assess aspects of HRQOL in relation to a disease of interest, which are not adequately assessed by generic measures. They focus on concerns that are more relevant to a specific illness and treatment (Joshi, 2010).

The Kidney Disease Quality of Life Questionnaire–Short Form (KDQOL-SF™) has become the most widely used QOL measures for CRF patients (Hays, 1994; Hays, 1997; Veerapan, 2012; Joshi 2010; Mujais et al., 2009). It is a self-report tool that includes the Medical Outcomes Study Short Form-36 generic core and several multi-item scales targeted at QOL concerns of special relevance for patients with CRF. The KDQOL-SF™ has been developed for dialysis patients and has-been translated into several languages. Regular HRQOL monitoring would both improve communication between the patients and the managing team and is useful in the assessment of patient's needs.

A cross-sectional study of dialysis-targeted health measure has been conducted in Singapore, with the aim to determine the reliability and validity of KDQOL-SF™ (Joshi, 2010). Another study was conducted in Korean dialysis patients to reveal the association of self-efficacy and treatment satisfaction by measuring the level of HRQOL (Kim et al., 2012). Mujais et al. and group have investigated the determinants of HRQOL in CRF patients not on dialysis from seven centers in the United States and Canada using KDQOL-SF™ (Mujais et al., 2009).

In India, very few studies have investigated the HRQOL in CRF patients (Sathvik, 2008; Veerapan, 2012). Using KDQOL-SF™ for evaluation in CRF patients not undergoing dialysis in Bangalore, South Indian Population has not been reported. Hence, the present study was aimed to determine the reliability and validity of KDQOL-SF™ in CRF patients on haemo-dialysis (CRF-D) and not on dialysis (CRF-ND) in a tertiary care hospital in Bangalore, India, to increase our knowledge of how our patient population perceives quality of life.

Methodology of Research

Sample

Our study population comprised of 101 patients with CRF sampled from Nephrology department of a tertiary care teaching and 1000 bedded super speciality hospital, Bangalore. CRF patients undergoing dialysis and not on dialysis aged 18 years and above of either sex and be able to provide informed consent to participate were included in the study. The patients who had undergone renal transplant were excluded. Participation in the study was voluntary and data was gathered from July 2011 through February 2012. The complete project was carried out according to the permission granted by the Institutional Human ethics committee. Written consent was obtained from participants prior to study. Demographic data recorded were age, gender, educational status, financial status and co-morbidities. KDQOL-SF™ was administered to CRF patients divided into two groups CRF on dialysis (CRF-D, N = 40) and CRF not on dialysis (CRF-ND, N = 61).

Survey Instrument

The disease – specific instrument used in this study was the Kidney Disease Quality of Life – short form (KDQOL-SF™) version 1.3, from RAND Corporation a self – report measure developed for CRF patients (Hays, 1994; Hays, 1997). The KDQOL-SF™ was available in English and was translated into local language Kannada and validated (almost all the patients used the English version).

The KDQOL-SF™ includes multi-item scales targeted at the particular health-related concerns of individuals who have kidney disease and are on dialysis. The disease-specific component of the KDQOL includes 44 questions, encompassing 43 kidney-disease targeted items and one overall health-rating question. Eleven domains, on a 100-point scale, are generally measured with these questions, including (1) burden of kidney disease; (2) cognitive function; (3) dialysis staff encouragement; (4) effects of kidney disease; (5) patient satisfaction; (6) quality of social interaction; (7) sexual function; (8) sleep; (9) social support; (10) symptom problem; and (11) work status. Since our patient population comprised on CRF patients on dialysis and not on dialysis, two questions relating to dialysis staff encouragement and patient satisfaction that are generally part of the disease-specific component of the KDQOL-SF™ were excluded as they were not relevant to the population under evaluation as reported by Mujais et al., 2009. Question related to sexual function question was also eliminated.

Scoring algorithm was used to calculate scores ranging from 0 to100. The scores represent the percentage of total possible score achieved, with 100 representing the highest quality of life.

Statistical Analysis

The collected data are represented as Mean ± standard deviation. To compare the scores of HRQOL Student's t-test was used. Percentage of floor, percentage of ceiling, and alpha internal consistency reliability coefficient were calculated using SPSS statistical package. Cronbach's co-efficient alpha was used to access internal consistency reliability for the overall scale, and within individual sub-scales (Hays, 1994).

Results of Research

A total of 101 CRF patients participated in the study which included 40 CRF patients on dialysis (CRF-D) and 61 CRF patients not on dialysis (CRF-ND). Demographic data (age, gender, and co-morbidities) is shown in Table no. 1. Overall 75% were male patients greater in number than females (25%) in CRF-D group, whereas CRF-ND comprised of 54% male patients and 45.9% of females. In both the groups, almost 80% of participants were over 40 years with the mean age of 50.88 ± 14.22 (CRF-D) and 53.64 ± 13.03 (CRF-ND). Co-morbidities observed were anaemia, ischemic heart

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disease, diabetic mellitus, and hyper tension. 40% (CRF-D) and 27.9% (CRF-ND) had hypertension followed by 25% (CRF-D) and 32.7% (CRF-ND) having Diabetus Mellitus. 25% (CRF-D) and 32% (CRF-ND) had anaemia with 10% (CRF-D) and 4.9% (CRF-ND) with Ischaemic heart disease.

Education distribution and income is shown in Table 2. Nearly half 58 % (CRF-D) and 52. 40% (CRF-ND) were having income between Rs. 5000 to Rs.1500. Education status showed that 38% (CRF-D) and 50.8% (CRF-ND) participants received primary level of education, 38% (CRF-D) and 27.9 % (CRF-ND) had education up to high school level. CKD workgroup from India have reported 18,555 cases with the mean age of 50.3 ± 14.0 in the south zone population with 44.4 % having income < Rs.5000 and females constituting 27.3% (Rajapurkar et al., 2012).

Table 1.   Demographic characteristics and co-morbidities of CRF patients on dialysis and not on dialysis.

Variables	CRF-D (N = 40) %	CRF-ND (N = 61) %
Age (years)		
< 40	20	17
40-50	20	21
50-60	30	30
> 60	30	32
Mean Age ± Standard deviation	50.88 ± 14.22	53.64 ± 13.03
Gender		
Male	75	54.10
Female	25	45.90
Co-morbidities		
Hypertension	40	27.9
Ischemic Heart Disease	10	4.9
Diabeti Mellitus	25	32.7
Anaemia	25	32.8
Diabetus Mellitus + Ischemic Heart disease	0	1.6

Table 2.   Income and education distribution.

Variables	CRF-D (N = 40) %	CRF-ND (N = 61) %
Education		
Up to primary	38	50.8
High school	38	27.9
Pre-University college	09	6.6
Graduates	15	14
Income (Rs)		
< 5000	35	39.30
5000- 15000	58	52.40
>15000	7	8.20

Table 3. **Central tendency, variability (including floor and ceiling effects), reliability of KDQOL-SF™ scales.**

Measure	No. of Items	Mean ± Standard deviation		% Floor		% Ceiling		Internal Consistency Reliablity	
Kidney disease-targeted scales#		CRF-D	CRF-ND	CRF-D	CRF-ND	CRF-D	CRF-ND	CRF-D	CRF- ND
Burden of Kidney Disease	5	25.63 ± 17.40	20.08 ± 22.25	21.95	30.65	0.00	0.00	0.877	0.834
Cognitive Function	3	28.06 ± 28.06	36.94 ± 22.36	17.07	9.68	0.00	1.61	0.765	0.734
Quality of Social interaction	3	26.50 ± 19.83	33.55 ± 17.89	19.51	8.06	0.00	1.61	0.610	0.681
Symptom/problem	11	78.30 ± 13.99	81.37± 12.22	0.00	0.00	2.44	3.23	0.764	0.724
Effects of Kidney Disease	6	43.13 ± 16.68	45.42 ± 17.75	2.44	0.00	0.00	0.00	0.735	0.763
Sleep	4	59.25 ± 12.70	62.99 ± 12.12	0.00	0.00	0.00	0.00	0.691	0.705
Social Support	2	68.75 ± 27.27	64.48 ± 30.20	2.44	8.06	21.95	17.74	0.754	0.756
Work Status	2	42.50 ± 26.06	47.54 ± 25.12	48.78	41.94	34.15	37.10	0.700	0.723
36-item health survey scales									
Physical Function	10	29.25 ± 24.25	28.85 ± 23.25	14.63	27.42	0.941	9.68	0.941	0.943
Role- Physical	4	31.25 ± 19.78	21.72 ± 15.20	7.32	45.16	0.661	0.00	0.661	0.721
Role-Emotional	3	31.67 ± 26.86	21.31 ± 15.24	12.20	51.61	0.701	4.84	0.701	0.712
Social Function	2	44.40 ± 26.52	46.93 ± 23.57	0.00	3.23	0.710	1.61	0.710	0.721
Pain	2	60.25 ± 30.90	54.02 ± 26.18	21.95	0.00	0.883	4.84	0.883	0.886
Emotional Well –Being	5	44.40 ± 11.77	49.72 ± 12.84	0.00	0.00	0.681	0.00	0.681	0.704
Energy/Fatigue	4	45.25 ± 14.09	49.75 ± 13.34	0.00	0.00	0.783	0.00	0.783	0.764
General Health	5	46.62 ± 11.62	43.20 ± 14.64	0.00	0.00	0.710	0.00	0.710	0.723

CRF-D: CRF patients on dialysis; CRF-ND: CRF patients not on dialysis

 # dialysis staff encouragement, patient satisfaction and sexual function not included.

Table 3 summarizes central tendency (mean ± Standard Deviation), percent of floor effects and percent of ceiling effects & internal consistency reliability estimates (Cronbach's alpha) for the KDQQOL-SF™ in CRF patients on dialysis and not on dialysis.

CRF patients on dialysis: The kidney disease targeted scales ranged from 25.63 to 78.30 in the possible (0-100) scores. Kidney disease targeted scales showed that burden of kidney disease (25.63±17.40), Quality of social interaction (26.50± 19.83) cognitive function (35.74±28.06), effects of kidney disease (43.13±16.68), work status (42.50±26.06) had mean score below 50 where as symptom/problem list (78.30±13.99), sleep (59.25±12.70), social support (68.75±27.27) had mean score of above 50.The 36 items health survey scales such as physical function (29.25±24.45), role physical (31.25±19.78), role emotional (31.67±26.86), social function (44.40±26.52), emotional well-being (44.40±11.77), energy/fatigue (45.25±14.09), general health (46.62±11.62) had a mean score below 50. On the other hand pain (60.25±30.90) had mean score of above 50. The overall health score in dialysis patient was 44.55. Percentage of floor effects (participants who have lowest possible score for scale) ranged from 0.00 to 48.78 and percentage of ceiling effects (participants who have the highest possible score for a scale) ranged from the 0.00 to 34.15.

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Internal consistency reliability (Cronbach's α) estimates tend to be quite acceptable for kidney disease–targeted measures, exceeding 0.70 for every scale except quality of social interaction and sleep. Reliability estimates for the eight scales of the 36-items health survey were also quite acceptable for almost all the domains expect for role physical and emotional well-being. Results were consistent with previously reported studies (Hays, 1994; Joshi, 2010).

CRF patients not on dialysis: As seen in Table 3, kidney disease targeted scale ranged from 20.08 to 81.37 in the possible of 0-100 scores. The 36 items health scale ranged from 21.31to 54.02. In kidney disease targeted scales burden of kidney disease (20.08 ± 22.25), cognitive function (36.94 ± 22.36), quality of social interaction, Effects of kidney disease (45 ± 17.75), work status (47.54 ± 25.12) had mean scores below 50 whereas symptom/problem list (81.37 ± 12.22), Sleep (62.99 ± 12.12) and social support (64 ± 30.20) scored above 50. 36 items health survey scales indicated that physical function (28.85 ± 23.25), role physical (21.72 ± 15.20), role emotional (21.31 ± 15.24), social support (46.93 ± 23.57), emotional well-being (49.72 ± 12.84), energy and fatigue (49.75 ± 13.34), general health (43.20 ± 14.64) had a mean score below 50, but pain (54.02 ± 26.18) scored above 50.

The overall health score in CRF-ND group was 44.24. Percentage of floor effects ranged from 0.00 to 45.16 and percent of ceiling effects ranged from 0.00 to 37.10. Internal consistency reliability estimates (Cronbach's α) were also quite acceptable exceeding 0.70 for every scale except quality of social interaction. Results were consistent with previously reported studies (Hays, 1994; Joshi, 2010).

Table 4. **Comparison of mean scores based on age < 40 years and > 40 years.**

Measure	CRF-D		CRF-ND	
	< 40 years	> 40 years	< 40 years	> 40 years
Kidney disease targeted scales				
Burden of Kidney Disease	18.06 ± 20.60	33.42 ± 31.28	19.53 ±23.03	19.47 ± 19.07
Cognitive Function	27.41 ± 31.17	36.52 ± 28.06	30.00 ± 22.84	38.46 ± 16.69
Quality of Social interaction	27.41 ± 23.67	24.35 ± 20.85	29.17 ± 14.78	31.54 ± 14.43
Symptom /problems	81.06 ± 16.39	77.08 ± 14.87	80.26 ± 13.35	83.13 ± 11.43
Effect of Kidney Disease	48.15 ± 15.61	39.31 ± 18.67	48.44 ± 20.91	46.15 ± 12.74
Sleep	65.56 ± 12.17*	57.72 ± 14.06*	65.31 ± 14.29	61.83 ± 13.14
Social Support	66.66 ± 20.41	63.04 ± 30.96	79.16 ± 19.72	70.51 ± 27.21
Work Status	33.33 ± 43.3	52.17 ± 46.41	34.38 ± 43.66	51.92 ± 45.78
36 items health survey scales				
Physical Function	50.56 ± 39.88*	23.26 ± 32.28*	38.44 ± 37.80*	18.27 ± 23.06*
Role-Physical	44.44 ± 34.86	27.17 ± 35.29	28.13 ± 28.69*	11.54 ± 16.17*
Role-Emotional	37.04 ± 30.93	33.33 ± 36.24	29.17 ± 31.91	14.10 ± 16.79
Social Function	44.44 ± 28.03	46.20 ± 27.81	51.56 ± 22.30	43.27 ± 20.38
Pain	69.44 ± 20.64	60.98 ± 36.59	59.22 ± 20.89	52.12 ± 25.51
Emotional Well Being	42.67 ± 13.56	43.48 ± 11.20	49.33 ± 13.82	51.38 ± 11.58
Energy and Fatigue	47.78 ± 14.60	44.13 ± 15.79	54.38 ± 11.09*	46.35 ± 13.01*
General Health	51.11 ± 10.54	43.91 ± 11.18	40.00 ± 11.69	48.27 ± 14.21

p < 0.05

Table 4 depicts the comparison of mean scores between the age group < 40 years and > 40 years in CRF-D patients revealed that sleep and physical function showed the significant difference with p <0.05 whereas in CRF-ND patients physical function, role physical, energy and fatigue had a significant difference (p < 0.05).
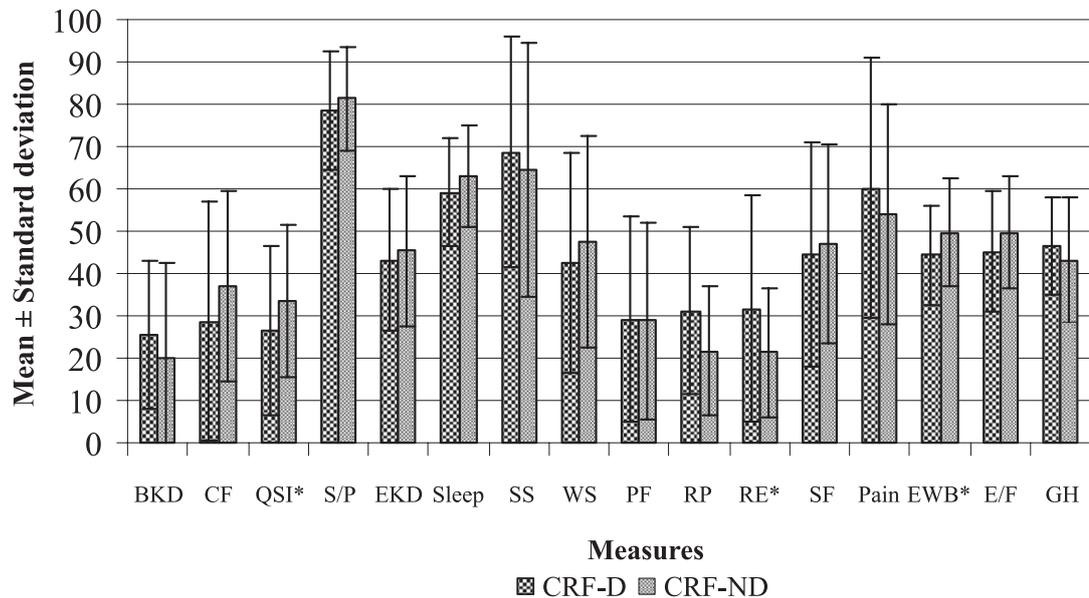
Figure 1.   Comparison of mean scores of KDQOL-SF™ between CRF patients on dialysis and not on dialysis.

p< 0.05

BKD-Burden of Kidney Disease; CF-Cognitive Function; QSI-Quality of Social interaction;

S/P-symptom/problems;EKD-Effect of Kidney Disease;SS-Social Support; WS-Work Status; PF- Physical Function; RP-Role-Physical;

RE-Role-Emotional; SF-Social Function, EWB-Emotional Well Being;E7F-Energy and Fatigue; GH-General Health

Comparison of mean score as shown in Figure 1, between CRF-D and CRF-ND groups revealed that quality of social interaction, role emotional, emotional well-being had a significant difference (p< 0.05), but the overall health score was almost similar in both groups, 44.55 (CRF-D) and 44.24 (CRF-ND).

Discussion

Measuring the impact of CRF treatment on patients' quality of life is being recognised as an important outcome measure. The main aim along with treatment in patients with chronic medical conditions, such as CRF, in particular, is to reduce disease burden and suffering caused by the disease. This means to improve the overall well being of the patient and to improve the individual's quality of life.

Various studies have assessed the validity of KDQOL-SF™ in the European, American and Singapore population. Our study carried out in a tertiary care hospital in Bangalore, demonstrated an acceptable level of reliability (as indicated by Cronbach's α values) and validity for use in understanding quality of life in CRF patients undergoing dialysis and not on dialysis. In CRF-D patients, internal consistency reliability estimates was found to be acceptable for kidney disease-targeted measures, exceeding 0.70 for every scale except quality of social interaction and sleep, in case of general health survey scales, role physical and emotional well-being were slightly lower than 0.7 value. A study conducted in development of KDQOL™ instrument also reported a lower value for quality of social interaction (Hays, 1994). On the other hand, in CRF-ND patients, in-

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ternal consistency reliability estimates for kidney-disease targeted measures and general health survey measures exceeded 0.7 except for quality of social interaction.

As reported previously (Joshi, 2010; Bakewell, 2009) increase in age was associated with decrease in physical function and sleep with $p < 0.05$ in patients undergoing dialysis. In case of patients not on dialysis; physical function, role-physical, energy and fatigue showed a significant difference ($p < 0.05$). A study conducted in patients not on dialysis also reported that age impacted physical function and general health (Mujais et al., 2009).

Conclusions

Use of KDQOL-SF™ as a QOL assessment tool, may be valuable in the global assistance of these patients and allow timely health care intervention in the course of the disease. Results obtained from the use of KDQOL-SF™ in CRF patients undergoing dialysis and not on dialysis supports the reliability of the instrument in Bangalore population, South India. Hence, KDQOL-SF™ would help physicians in routine monitoring of patient's perception of their well being as it forms an integral part to impart better patient care.

Acknowledgements

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