

## CLINICAL EVALUATION OF THE QUALITY OF LIFE OF HEMODIALYSIS PATIENTS

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### ABSTRACT

In end stage renal disease (ESRD) exploration of the Quality of life (QOL) is an important treatment modulator. This study evaluates the correlation between factors for a decreased quality of life and proposes serum cystatinC as an alternative marker.

**Methods:** Our study included 52 maintenance HD patients. Quality of life of these patients was assessed using Kidney Disease Quality of Life Instrument (KDQOL-SFTM1.3). Clinical, laboratory and socio-demographic variables were investigated. Mean scores were compared for individual domain scores and for the three composite summary scores, namely the mental component summary (MCS), the physical component summary (PCS) and kidney disease component summary (KDCS).

**Results:** Our study concludes with the overall mean score for QOL was 52.98. Where domains with very low scores were 'burden of kidney disease', 'work statuses', 'role limitations-physical', 'general health' and 'role limitations-emotional'. Beside that domains with very high scores were 'dialysis staff encouragement', 'social support' and 'quality of social interaction'. The mean scores for KDCS, MCS and PCS were 59.6, 41.4 and 35.6 respectively. There was a positive correlation between KDCS and MCS ( $r=0.425$ ,  $P=0.002$ ); and between KDCS and PCS ( $r=0.388$ ,  $P=0.004$ ). Positive correlation was also evaluated between time on HD and KDCS and negative correlation between age and CystatinC on KDCS, age and Calcium on MCS, and between Hemoglobin and PCS respectively.

**Conclusion:** There is a correlation between socio-demographic, clinical and laboratory factors for a decreased quality of life in this population. Beside the traditional biochemical markers we propose serum cystatinC as an alternative option for renal function estimation and evaluation of QOL in CKD patients. The possible factors related to QOL were: age, time on HD, employment status, education level, BMI, albumin, serum hemoglobin, serum calcium, serum phosphorous, serum cystatinC, serum uric acid levels.

**Key words:** End Stage Renal Disease, Quality of life, Hemodialysis, KDQOL instrument, Maintenance hemodialysis, Quality of life in ESRD.

### INTRODUCTION

The incidence and prevalence of patients with chronic kidney disease (CKD) is increasing

worldwide. CKD globally resulted in 735,000 deaths in 2010 up from 400,000 deaths in 1990. In 1999 the Chinese Society of Nephrology reported national annual incidence data (15.3 per million population) and point prevalence (33.16 per million population) for end stage renal disease (ESRD). In 2008, the annual incidence and

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point prevalence increase to 36.1 and 79.1 respectively[1].

Quality of life has been defined by the World Health Organization as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns [2]. QOL includes emotional, social, and physical aspects of the individual's life. Health related quality of life (HRQOL) is an assessment of how the individual's well-being may be affected over time by a disease, disability or disorder. Over the past few decades, quality of life research endpoints have emerged as valuable tools in assessing the outcome of the therapeutic intervention in chronic diseases [3]. ESRD is one such chronic disease causing a high level of disability in different domains of the patient's life, leading to impaired quality of life [4]. ESRD is a life-threatening disease managed with hemodialysed has significantly impaired HRQOL that leads to numerous and severe symptoms and complications compared with the general population [5].

Survival of ESRD patients has been largely improved nowadays because of medical progress, advanced technology, and better patient care. Accumulated data in the recent decade shows that HRQOL markedly influences dialysis outcomes, therefore attention required to be focused on quality of living not only the duration. Evaluation of the HRQOL issues of ESRD patients is an important area to explore as because of its high mortality and hospitalization rate along with well documented record of CKD patients. The assessment of HRQOL can help identifying ways to improve the wellbeing of ESRD patients as well as potential threat strategies to prevent the adverse outcomes.

Currently little data are available concerning the quality of life of ESRD patients on maintenance hemodialysis in the developing world. In contrast, assessments of the QOL of ESRD patients in the developed world has been recently attracting much attention and have been used as key outcome measures in several studies examining new approaches to ESRD care. In China we found

few studies regarding QOL of hemodialysis patients using SF-36 instrument [6, 7, 8]. So our effort has been dedicated to contribute and address the QOL issues of maintenance HD patients, also to evaluate the influence of socio-demographic, clinical and laboratory data on HRQOL using KDQOL instrument (as it combines SF-36 along with kidney disease specific items).

## **MATERIAL AND METHODS**

We conducted a cross-section observational study on 52 randomly selected eligible patients on maintenance HD who were willing to take part in our study. An informed consent was signed to collect required clinical and laboratory data for the study. ESRD patients on maintenance hemodialysis 3 times per week for minimum period of 3 months of more than 18 years old were included in this study. Subjects were identified between June 2014 and November 2014 from Department of Nephrology (Dialysis center), at the first affiliated Hospital of Jiamusi University, Heilongjiang province, China. HRQOL indicators were measured using HRQOL questionnaire (KDQOL Short Form).

The KDQOL-SFTM version 1.3 combines the generic SF-36 instrument with the kidney disease specific instrument [9]. The general measures were based on questions from the 36-item Short-Foam Health Survey (SF-36), developed by Ware and Sherbourne [10]. The questionnaire consists of total 80 items divided into 19 dimensions. The disease specific component of KDQOL-SFTM 1.3 includes 43 kidney disease targeted items. It comprises 11 domains including: symptom/problem list (12 items), effects of kidney disease (8 items), burden of kidney disease (8 items), cognitive function (3 items), quality of social interaction (3 items), sexual function (2 items), sleep (4 items), social support (2 items), work status (2 items), patient satisfaction (1 item) and dialysis staff encouragement (2 items). SF-36 includes 36 items that measure eight domains of functioning and wellbeing on a 100 point scale. The eight domains are: physical function (10 items), role limitations caused by physical problems (4 items), role limitations

caused by emotional problems (3 items), pain (2 items), general health perception (5 items), social function (2 items), emotional wellbeing (5 items), and energy/fatigue (4 items). The final item, the overall health rate item, asks the respondents to rate their health on a 0-10 response scale.

Results from the SF-36 instrument are further summarized into a physical composite summary (PCS) score and a mental composite summary (MCS) score. PCS aggregates items from physical function, role physical, pain, and general health. MCS aggregates items from role emotional, emotional wellbeing, energy, and social function. According to Mapeset al [9], items of the kidney disease targeted scale are also summarized into kidney disease component summary (KDCS) score on a 100 point scale. The standard scoring program of the KDQOL-SFTM1.3 is based on the Microsoft Excel 97 spreadsheet program and includes information about the computation method. The scores for each dimension range from 0-100, with higher scores reflecting better QOL.

The Kidney Disease Quality of Life questionnaire short form version 1.3 (KDQOL-SFTM1.3), from the Rand corporation was used as Quality of life questionnaires. Questionnaire regarding socio-demographic and clinical factors and collected data were also supplied to the patients. Hematological test were analyzed as follows: hemoglobin, albumin, calcium, phosphorous, cystatinC and uric acid. All patients' height, weight and Body Mass Index (BMI) were calculated.

Statistical analysis was done with SPSS package for windows (version 17). The results are presented as percentage of mean±SD. Independent t –test or ANOVA was used to compare means in 2 or more groups respectively. Pearson's correlation test was employed to correlate the PCS, MCS and KDCS results with the other continuous variables. Statistical significance was set at P<0.05, and all tests performed were two-tailed.

## RESULTS

The total number of patient were 52, male represented 53.8% of the total. Mean age was 59.5 (SD 15.1). Regarding marital status 78.8%

married 7.6% unmarried/ separated and 13.4% widowed. Regarding education level 25% had primary level or below, 53.8% middle school and 21.1% high-school/university respectively. On employment status 23.15% employed, 57.7% retired and 19.2% unemployed. Regarding health insurance 96.2% have insurance coverage and 69.23% have monthly family income>2000 Yuan. Detailed socio-demographic characteristic is shown in Table 1.

**Table 1: Socio-demographic characteristics of hemodialysis (HD) patients**

	Patients on HD (n=52)
Gender	
Male	28(53.84)
Female	24(46.15)
Age(years)	59.45±15.12
Marital status	
Unmarried/Separated	04(7.6)
Married	41(78.8)
Widowed	07(13.4)
Education level	
Primary	13(25)
Middle school	28(53.8)
Highschool/University	11(21.1)
Employment	
Employed	12(23.1)
Retired	30(57.7)
Unemployed	10(19.2)
Family income per month(Yuan)	
<2000	16(30.73)
>2000	36(69.23)
Insurance coverage	
Yes	50(96.2)
No	02(3.84)

1) Data are reported as number (%) or mean±SD

Hypertension was the most common cause of renal failure (26.9%) among our patients. 55.7% patients comprised with 1 or absence of comorbidity. The mean time on HD was 25.7months. 78.9% Patients did not require hospitalization for 6 months due to kidney disease related complications. The mean value for hemoglobin, serum albumin, serum calcium, serum phosphorous, serum cystatinC

and serum uric acid was 108.5, 39.4, 2.03, 2.18, 5.4 22.5 respectively. Detailed clinical and laboratory parameters are shown in Table 2.

**Table2: Clinical and laboratory parameters of maintenance hemodialysis (HD) patients**

	Hemodialysis (n=52)
Etiology of CKD	
Glomerulonephritis	11(21.15)
Hypertension	14(26.92)
Diabetes mellitus	09(17.30)
Polycystic Kidney Disease	03(5.76)
Drugs and others	06(11.53)
Do not know the cause	09(17.30)
Time on HD (months)	25.7±23.7
No. of comorbidities	
0-1	29(55.76)
2 or more	23(44.23)
Hemoglobin (g/L)	108.5±18.03
Albumin (g/L)	39.4±2.36
Serum Calcium (mmol/L)	2.03±0.3
Serum Phosphorous (mmol/L)	2.18±0.6
Serum Cystatin C (mg/L)	5.4±1.3
Serum Uric acid (umol/L)	404.98±105.2
BMI (kg/m <sup>2</sup> )	22.5±3.4
Admission on hospital due to renal problem within recent 6 months	
Yes	11(21.15)
No	41(78.84)

Data are reported as number (%) or mean±SD.

The mean score for each domain ranged from 18.5 for 'Burden of kidney disease' to 90.6 for 'Dialysis staff encouragement'. The overall mean QOL score was 45.5(SD 12.5) while score for 'overall health' was 53.8(SD24.9). The scores for the kidney disease component summary (KDCS), mental component summary (MCS) and the physical component summary (PCS) were 59.6(SD9.8), 41.4(SD8.7) and 35.6(8.4) respectively. Detailed QOL score is showed in Table 3.

We also found a positive correlation between the scores for KDCS and PCS ( $r=0.38$ ,  $P=0.004$ ); as well as between KDCS and MCS ( $r=0.43$ ,  $P=0.002$ ).

Evaluating socio-demographic data, patients who had a higher education level

performed better than others in mean MCS. Patients who was employed had better mean MCS compared to unemployed and retired. As for the patient's mean KDCS scores, statistically significant difference in mean score seen only in occupation: better mean score was seen in employed and unemployed group compared to retired. The PCS scores showed no statistically significant differences related to demographic data. No significant difference was found between the PCS, MCS and KDCS mean scores when the patients were evaluated for the number of comorbidity and monthly income. Detailed relation between socio-demographic data, clinical and laboratory parameter and quality of life (QOL) scores is shown in Table 4.

With regard to age, there was a statistically significant negative correlation with the mean MCS ( $r=-0.279$ ,  $P=0.045$ ) and KDCS ( $r=-0.296$ ,  $P=0.033$ ) score. There was positive correlation between time on HD and KDCS ( $r=0.393$ ,  $P=0.004$ ). Negative correlation were observed between hemoglobin and PCS ( $r=-0.351$ ,  $P=0.011$ ), CystatinC and KDCS ( $r=-0.328$ ,  $P=0.017$ ) and between calcium and MCS ( $r=-0.295$ ,  $P=0.034$ ) respectively. Statistically significant correlation was not seen between serum phosphorous, serum uric acid and BMI with mean scores of PCS, MCS and KDCS. Detailed Pearson correlation coefficients among demographic data, clinical and laboratory parameters and quality of life (QOL) are shown in Table 5.

## DISCUSSION

Health related quality of life (HRQOL) is a highly valuable tool and often studied as an outcome of clinical research [15]. Levy NB and Wynbrandt BD took a historic step to evaluate the quality of life on maintenance hemodialysis (HD) titled as "The quality of life on maintenance hemodialysis" [11]. This revealed a striking change in the life of most patients compared with the period before illness. Since then different methods and dimensions on quality of life on HD patients have been discovered, validated and employed [12, 13, 14].

QOL measurements bear a particular importance in patients with ESRD, based on

**Table 3: The mean scores for each domains of the Kidney disease quality of life instrument (KDQOL-SF TM1.3) among studied HD patients (n=52)**

	n	Mean (SD)
KDCS		
Symptoms/Problems list	52	67.19±19.48
Effects of kidney disease	52	59.74±21.41
Burden of kidney disease	52	18.51±20.11
Work status	52	21.15±31.85
Cognitive function	52	69.62±21.83
Quality of social interaction	52	72.69±17.97
Sexual function	22	44.89±41.13
Sleep	52	57.16±16.71
Social support	52	81.09±28.40
Dialysis staff encouragement	52	90.63±15.03
Patient satisfaction	52	63.46±21.40
Overall health	<b>52</b>	<b>53.85±24.90</b>
PCS		
Physical functioning	52	55.77±25.17
Role limitation- physical	52	25±34.66
Pain	52	58.22±23.69
General health	52	33.65±21.54
MCS		
Emotional well being	52	59.92±19.98
Role limitations – emotional	52	35.26±39.28
Social function	52	49.52±23.48
Energy/fatigue	52	42.21±20.23

(PCS= Physical component summary; MCS= Mental component summary; KDCS= Kidney disease component summary)

**Data are reported as number (%) or mean ± SD**

patient's physical and mental status and his/her subjective status of well-being. In addition to traditional 'hard outcome measures' (mortality, morbidity and hospitalization), patient-reported outcomes, such as 'health related quality of life' have been increasingly recognized as equally important aspects of healthcare delivery in chronic medical conditions such as ESRD. Assessing the QOL in maintenance HD patients in order to compare the effectiveness of the different treatment modalities has been increasingly important over the past decades [7, 16].

Hemodialysis therapy is time-intensive, expensive, and requires fluid and dietary restrictions. Long-term dialysis therapy itself often results in a loss of freedom, dependence on caregivers, disruption of marital, family, social life, and reduced or loss of financial income [18]. Hemodialysis alters the life style of the patient and family and interferes with

their lives. Though advance technologies has reduced the severity of symptoms and resulted in longer survival of ESRD patients [17]. The major areas of life affected by ESRD and its treatment include employment, eating habits, self-esteem, social relationships, and the ability to enjoy life [19, 20]. But with passage of time and improvement in technology QOL of ESRD patients is increasing.

We have used the Chinese version of Kidney Disease Quality of Life Instrument (KDQOL-SFTM1.3), to evaluate quality of life, validated and employed in different countries in Europe, Asia, America, Middle East and Africa [21,22,23,24,25,26]. Our objective was to evaluate the quality of life (QOL) and the influence of socio-demographic, clinical and laboratory data on QOL in patients on maintenance hemodialysis (HD). Different socio-demographic, clinical, laboratory data we analyzed to evaluate its possible effect on QOL were: age, gender, marital

**Table 4: Relation between socio-demographic data, clinical and laboratory parameters and quality of life (QOL)**

	PCS	MCS	KDCS
Gender			
Male	35.1±7.8	43.2±8.2	59.1±9.7
Female	36.2±9.2	39.2±9.1	60.3±10.3
Marital status			
Unmarried/separated	35.4±11.3	41.1±3.4	63.5±14.3
Married	35.9±8	42±8.9	60.1±8.7
Widowed	33.1±11.7	36.1±8.7	51.9±13.2
Education level			
Primary level or below	35.9 ±6.8	33.5±7.5*	57.6±10.4
Middle school	36.3± 9.1	43.1±8.3	60.5±9.9
High school/College	34.5± 7.4	44.8±7.4	60±12.4
Occupation			
Employed	38.7± 9.9	46.9 ±7.8*	64.3±7.7
Retired	33.9 ±7.4	39.2±8.7	56±9.4*
Unemployed	37.1±8.7	41.2±7.6	65.1±9.5
Income(monthly in Yuan)			
Less than 2000	37.4±9.8	39.1±9.6	58.7±11.4
More than 2000	35 ±7.9	42.2± 8.3	59.9±9.4
Comorbidity present			
1 or no	37.5±8.5	41.3±7.6	59.4±10.5
2 or more	33.3±8.1	41.2±10.3	59.9±9.2

(PCS= Physical component summary; MCS= Mental component summary;KDCS= Kidney disease Component summary)

Data are reported as number (%) or mean ± SD.

\*P<0.05 (The mean difference is significant at the 0.05 level)

status, education level, monthly income, employment, insurance coverage or not, cause of chronic renal failure, number of comorbidity, time on HD, BMI, hemoglobin, albumin, serum calcium, serum phosphorous, serum cystatinC, serum uric acid. Various studies have shown that level of hemoglobin, socio-economic status, literacy, dialysis program, ethnic groups, sex, mobility, comorbidity, malnutrition and depression affect QOL of dialysis patients [27, 28].

The results of various studies suggest that the QOL of hemodialysis patients is considerably impaired compared to that of the healthy subjects especially with respect to the physical, psychological and social relationship domains [29, 30]. In previous DOPPS study low scores in several measures of HRQOL particularly PCS were found to be strongly associated with higher risk of death in Japan, Europe and the United States [31].

Our study also reveals a decrease pattern of all domains of KDQOL like PCS, MCS, and KDCS with a mean score of 41.4, 35.6 and 59.6 respectively. Among ESRD patient's better quality of life is associated with better therapeutic compliance and improved survival.

In our study, the main cause of ESRD was hypertension (26.9%), followed by Glomerulonephritis (21.2%), DM, Unknown, Polycystic kidney disease (PCKD), Drugs and other causes in decreasing order. DM and HTN are the main causes of ESRD in western countries and United States. Although a total score of HRQOL includes MCS, PCS and KDCS the majority of KDCS items (8/11) had a scale of 50 percent and more, but only 1/2 of PCS and 1/4 of MCS items had more than 50% scale.

Our study shows no significant difference in QOL scores in between male and female.

**Table 5: "Pearson Correlation coefficients" among demographic data, Clinical and laboratory parameters and quality of life (QOL)**

N=52	PCS	MCS	KDCS
Age (years)	-0.241	-0.279*	-0.296*
Time on hemodialysis (months)	0.00	-0.227	0.393**
Hemoglobin (g/L)	-0.351*	-0.104	-0.069
Serum calcium (mmol/L)	-0.096	-0.295*	-0.114
Serum albumin (g/L)	-0.076	0.235	0.229
Serum phosphorous (mmol/L)	-0.198	0.137	0.064
Serum uric acid ( $\mu$ mol/L)	0.020	0.015	0.189
Serum Cystatin C (mg/L)	-0.220	-0.117	-0.328*
BMI ( $\text{kg}/\text{m}^2$ )	-0.131	-0.067	0.041

PCS= Physical component summary; MCS= Mental component summary;

KDCS= Kidney disease component summary

\*P<0.05.

\*\*P<0.01.

Where previous studies had shown better QOL in male compared to female [32, 33]. Unmarried and married had almost similar QOL scores compared to widow group, this was increased though statistically insignificant. There was statistically significant decreased mean MCS score in group with education level primary or below in comparison to those with middle school or above. Regarding occupation, retired group had statistically significant decreased MCS and KDCS mean score compared to employ. But regarding monthly income, there QOL scores were almost similar in both groups with monthly income less or more than 2000 Yuan, as almost every patients had health insurance (96.2%), which is a good aspect of health care in our patients. Similarly, QOL scores were similar in patients with 1 or no comorbidity in comparison with those with 2 or more comorbidity, while analyzing this issue we found that 78.9% of patients did not require hospitalization within 6 months due to kidney disease related complications.

Age is one of the important predictor of QOL of HD patients [34]. According to Liu WJ et al [35], age more than forty years was significant risk factors of QOL of HD patients. As age increases QOL impairs. Our study signifies statistically negative correlation of age with the mean MCS ( $r=-0.279$ ,  $P=0.05$ ) and KDCS ( $r=-0.296$ ,  $P=-0.05$ ) score. So, there was reduction in MCS and KDCS with increase in age. The deterioration of HRQOL with time

in patients with CKD has been observed in patients on dialysis [36]. Positive correlation was observed between duration on hemodialysis and KDCS ( $r=0.393$ ,  $P=0.001$ ), i.e. there is increase in KDCS with increased duration of HD. Anemia is one of the common and important complication of CKD though Cardiovascular disease (CVS) remains the principle cause of mortality. The association of anemia with cardiovascular outcomes is well known, but underlying mechanisms are not well understood [37]. On the other hand, targeting of higher hemoglobin (Hb) with higher doses of erythropoiesis- stimulating agents (ESAs) worsens cardiovascular outcomes in CKD [38, 39]. The reason for higher mortality in patients targeted for the higher hemoglobin is an area of intensive research. Our study showed negative correlation of Hb with PCS ( $r=-0.351$ ,  $P=0.05$ ) which signifies a decreased PCS score with increased Hb, and mean Hb value was 108.5g/L.

Studies done by Pearlman et al [40] and Usama Feroze et al [27] describe a negative impact on HRQOL with low albumin level. In our study mean albumin, serum phosphorous and serum uric acid values were 39.4g/L, 2.18mmol/L and 430mmol/L respectively. This was statistically insignificant for QOL score. Beside that mean BMI was 22.23 ( $\text{kg}/\text{m}^2$ ) and most of the patients had a BMI, so it was also statistically insignificant. Some studies have reported that low BMI and malnutrition is

associated with decreased QOL, increased morbidity and mortality [27]. Mean value of calcium was 2.03, this was negatively correlated with all domains of QOL like PCS, MCS and KDCS. Also statistically significant to PCS ( $r=-0.295$ ,  $P=0.05$ ). A negative correlation of cystatinC with all domains of QOL (PCS, MCS and KDCS) and statistically significant negative correlation with KDCS ( $r=-0.328$ ,  $P=0.05$ ) was found. CystatinC is being treated with high importance as an alternative serum marker for estimation of GFR and kidney function. Its role is obvious for the decreased QOL score in our study. So we approach using serum cystatinC as an alternative serum marker option for estimation of kidney function and evaluation of QOL in CKD patients.

Other factors that need to be considered in assessing QOL in HD patients are nutritional status, anemia, cognitive function, sleep disorders, depression, physical and social functioning, family support and comorbidities [41, 42]. Analysis of HRQOL surveillance data can identify subgroups with relatively poor perceived health and help to guide interventions to improve their situations and avert more serious consequences. It is important to keep in mind that a variety of factors that have an impact on QOL need to be considered in the developing world and that there are likely unique points to be considered in each country.

## CONCLUSION

Measurement of quality of life is an essential part of assessing the outcome of treatment by hemodialysis for ESRD patients which requires more studies to assess the QOL of patients in the developing world. Though our study has limitation with the sample size, geographic boundaries and individual's assessment of their health status which is strongly subjective and affected by surrounding socio-environmental factors, but we provided a detailed description of the QOL scores of a group of Chinese maintenance hemodialysis patients and the impact of certain factors on their QOL. It was possible to correlate socio-demographic, clinical and laboratory factors

for a decreased quality of life in this population. Beside the traditional biochemical markers we propose serum cystatinC as an alternative option for renal function estimation and evaluation of QOL in CKD patients. The possible factors related to QOL were: age, time on HD, employment status, education level, BMI, albumin, serum hemoglobin, serum calcium, serum phosphorous, serum cystatinC, serum uric acid levels. It is likely that culturally specific instruments are required to be developed and validated with individual boundaries. We hope this study will serve as a useful resource for assessing QOL of maintenance HD patients; also we could use KDQOL Instrument as a useful method to assess HRQOL. Newer developments of hemodialysis related technologies, early treatment of comorbidities and complications, continuous patient's education and care, social and psychological support may improve the health related quality of life of these patients.

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