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## Health Related Quality of Life among Egyptian Patients on Hemodialysis

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The present research was carried out to evaluate the physical (PCS) and mental (MCS) component summary scales in hemodialysis patients as compared to healthy subjects at a baseline and two years later. 130 patients on hemodialysis (mean age 40.6±8.1 years) were enrolled in the study between February 2003 to February 2005. The short-form with 36 (SF-36) questionnaire was given every 6 months to hemodialysis patients. Results were compared to the general population and changes in QoL over time were determined. Mean PCS was 34±15.46 and mean MCS was 38.80±15.17 compared to the general population there were significant decline in PCS and MCS at baseline and two years later. There was no significant correlation between causes of End-Stage Renal Disease (ESRD) and Quality of Life (QoL), except for diabetes mellitus as regard MCS. High levels of serum albumin and hemoglobin was associated with highly significant quality of life. Serum albumin was a good predictor for quality of life in this study. Adequacy of dialysis treatment in hemodialysis patients was determined by serum albumin, hematocrit, KT/V and Urea Reduction Ratio (URR). Present results showed the negative impact that ESRD and hemodialysis treatment have on self-assessed physical and mental health and it is important to treat all factors that induce hypoalbuminemia as well as anaemia.

**Key words:** Quality of life, SF-36, ESRD, hemodialysis, renal failure

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## INTRODUCTION

Quality of Life (QoL) as perceived by patients with end-stage renal disease (ESRD) is well recognized as an important measure of outcome of renal replacement therapy. For patients with ESRD, chronic maintenance hemodialysis successfully prolongs life span. A broader goal, however, is to optimize the patient's self perceived sense of well being and quality of life. Studies comparing QoL between dialysis patients and the general population note the negative impact of renal disease and its treatment on patient's lives (Khan *et al.*, 1995; Merkus *et al.*, 1997), although this is not confirmed by all studies (Johnson *et al.*, 1982; Bremer *et al.*, 1989).

Previous studies on health-related quality of life and ESRD have identified that modality of treatment is a factor influencing QoL in ESRD, they reported that patients on dialysis have a reduced QoL compared with transplant patients, who are shown as having a similar QoL to the general population (Merkus *et al.*, 1997; Bremer *et al.*, 1989; Koch and Muthny, 1990).

The potential damaging impact of ESRD on a patient's psychosocial function and the marital strain experienced by patients on dialysis is well documented. QoL is clearly not solely dependent on physical function, nor can it be viewed irrespective of the patient's social circumstances (Binik *et al.*, 1990; Shidler *et al.*, 1998).

The Short Form health survey with 36 questions (SF-36) is a well-documented scoring system that has been widely used and validated as a QoL assessment tool for the general population as well as patients on maintenance hemodialysis (Kalanter *et al.*, 2001). It is used both as a stand alone measure of QoL and as a core component of several major assessment tools, including the kidney disease quality of life survey instrument (Kalanter *et al.*, 2001). It is a self administered standardized assessment of QoL and functional status. It was developed and extensively evaluated as part of the medical outcomes study (Tarlov *et al.*, 1989) and contains essential psychometric criteria that have been shown to be both reliable and valid in a variety of chronic disease states (Khan *et al.*, 1995; Merkus *et al.*, 1997; DeOreo, 1997). It has recently been used in the dialysis population to evaluate self-perceived health status (Khan *et al.*, 1995; Merkus *et al.*, 1997; DeOreo, 1997). Patients on Maintenance Hemodialysis (MHD) experience decreased QoL and significantly greater rates of malnutrition, inflammation, hospitalization and mortality compared with the normal population (Kopple, 1997). QoL measurements are based on a patient's subjective sense of well-being and are commonly used as an important clinical measure for beneficial extent of medical treatments for patients on MHD (Curtin *et al.*, 1999). We prefer to use

this tool because of an ample literature supporting its validity and its ease of administration and interpretation. The responses to items on the SF-36 questionnaire are summed into eight scales of health: Physical Function (PF), Social Function (SF), limitation in role due to physical health (RP), limitation in role due to mental health (RE), Mental Health (MH), Vitality (VT), Bodily Pain (BP), General Health (GH). In clinical practice we have found it difficult to use eight separate measures to guide the detection and treatment of health status problems. Ware *et al.* (1995) and Sanjeev *et al.* (2001), aggregate the eight scale scores into a physical component summary score (PCS) and a mental component summary score (MCS) and we agreed with them. The purpose of this study was to compare the PCS and MCS in hemodialysis patients to the general population and also to evaluate the change in scores over time.

## MATERIALS AND METHODS

**Patients:** Ninety-six hemodialysis patients were entered into the initial data set. Of these, 28 patients who had incomplete or single SF-36 scores were excluded. Of the remaining 68 patients with at least two complete scored questionnaires, 3 were transplanted and 4 patients died during the study period and were excluded.

The results include only those patients who were stable and completed the 2 year study period, thus we report on 61 patients with at least 2 scored questionnaire. The study was performed at different Egyptian outpatient dialysis centers. At time of the study the center treated approximately 96 patients, with all on a thrice weekly dialysis regimen. All patients were dialyzed with conventional, single use, high-efficiency polysulfone dialyzers using bicarbonate dialysate.

Demographic data (age and sex), duration of hemodialysis, prescribed dialysis time, underlying aetiology of ESRD were recorded for each patient. Level of education was graded as high school and university studies; preparatory and primary studies; illiterates. Height and weight were measured in order to estimate the body mass index (BMI), as a measure of obesity. Systolic and diastolic blood pressure was measured

**Quality of life scoring system:** The SF-36, a short form QoL scoring system with 36 items, is self-administered questionnaires that were given every 6 months to all hemodialysis patients.

It consists of 36 questions, 35 of which are compressed into eight multi-item scales: (a) physical functioning is a ten-question scale that capture abilities to deal with the physical requirement of life, such as attending to personal needs; (b) role-physical is a four-

item scale that evaluates the extent to which physical capabilities limit activity; (c) bodily pain is a two-item scale that evaluates the perceived amount of pain and the extent of interference with normal work activities; (d) general health is a five-item scale that evaluate general health in terms of personal perception; (e) vitality is a four-item scale that evaluates feelings, energy and fatigue; (f) Social Functioning (SF) is a two-item scale that evaluates the extent and amount of time that physical health or emotional problems interfered with family, friends and other social interactions during the previous four weeks; (g) Role Emotional (RE) is a three-item scale that evaluates emotional factors that interfere with work or other activities; (h) mental health is a five-item scale that evaluates feelings principally of anxiety and depression. The scales are scored on a 0-100 possible range with a higher score indicating a better state of health (Diaz-Buxo *et al.*, 2000).

The scales of SF-36 are summarized into two dimensions. The first five scales make up the physical component scale (PCS) and the last five form the mental component scale (MCS). The component summary scores are positively scored and normalized to a general population mean of 50 and a standard deviation of 10. The scores of the two scales are based on mathematical averaging of the scale components.

**Methods:** Ten milliliter of fasting venous blood samples were taken from each subject participating in the study and divided into 2 aliquots: the 1st aliquot were taken in a tube contain EDTA for hemoglobin determination using cyanmethemoglobin (Weinkove and McDowell, 1988). The 2nd aliquot were left to clot and the serum was separated by centrifugation for determination of kidney function tests: blood urea nitrogen was determined using enzymatic (urease) method (Sampson *et al.*, 1980), creatinine (Jaffe) (Bacon and Pardue, 1989).

On Roche Hitachi 911 autoanalyzer (Roche diagnostic GmbH Mannheim, Germany), sodium and potassium were performed by automated flame photometer from Eppendorf-NE Thelen-Him2 GmbH, Germany (Jackson and Chen, 1996).

Serum calcium was carried out using atomic absorption spectrometer 3110 (Perkin-Elmer Corporation, 761 Main Avenue, Norwalk, USA) (Slavin, 1982). Serum phosphate was done by Roche Hitachi 911 autoanalyzer (Passing and Bablok, 1983) and serum albumin by BCG method on Hitachi 911 (Doumas *et al.*, 1971).

The kits used on Hitachi 911 autoanalyzer were supplied from Roche, Germany.

Abdominal and pelvic ultrasonography was done to assess kidney size, echogenicity and parenchymal thickness.

The SF-36 questionnaire was administered to all patients every 6 months starting in February 2003. We have extracted data on all patients dialyzed in the period between February 2003 and February 2005, who neither died nor transplanted. To perform the SF-36 measurements in our patients, we reformatted the questionnaire into a more easy style without modifying the content of the original questions. We also translated the SF-36 into Arabic for our patients.

**Dialysis indicators:** KT/V (urea) and Urea Reduction Ratio (URR) were followed for all patients during the study period.

Daugirdas *et al.* (1997) formula for calculating KT/V;

$$KT/V = -1n(C2/C1 - 0.008 \times T) + (4 - 3.5 \times C2/C1) \times UF/W$$

Where

C1 = predialysis blood urea concentration,

C2 = postdialysis blood urea concentration,

T = dialysis duration (hours),

UF = ultrafiltration volume per dialysis (L),

W = postdialysis body mass of the patient (kg)

URR equation

$$\text{Urea reduction ratio} = 1 - (\text{postdialysis BUN} / \text{predialysis BUN}) \times 100$$

Current guidelines in the US target a URR of at least 65% and KT/V of at least 1.20 (Eknoyan and Levin, 2001).

**Statistical methods:** Data entry and verification was done using the SPSS for windows version 9, Chi-square test of significance was used in order to compare proportions between two categorical variables. For comparing between two means, t-test of significance was done and one way analysis of variance was used when comparing between more than two means. When data were not normally distributed, non-parametric Mann-Whitney test was used for comparing between two means and Kruskal-Wallis test when comparing between more than two means. Multivariate logistic analysis was done in order to define the independent predictor variables significantly associated with lower score of QoL. Backward Wald analysis was used with >0.1 for removing criteria.

## RESULTS

Characteristics of the studied group (Table 1) shows a case control study of sixty-one patients, 54.1% male and

**Table 1: Characteristics of the studied group**

		Case	Control	p-value
Age		40.6±8.1	40.97±9.0	0.293
BMI		23.64±13.18	28.55±5.13	0.001
PCS		34.08±15.46	67.24±18.8	0.0001
MCS		38.80±15.17	60.22±23.2	0.0001
Patient demographic		N (%)		
Sex n (%)	Male	33 (54.1)		
	Female	28 (45.9)		
Education	Well	12 (19.7)		
	Medium	22 (36.1)		
	Bad	27 (44.3)		
Aetiology	HTN	13 (21.3)		
	DM	11 (18)		
	GN	12 (19.7)		
	Bilharzia	11 (18)		
	Lupus	4 (6.6)		
	Renal stone	4 (6.6)		
	Polycystic	1 (1.6)		
	Unknown	5 (8.2)		
Dialysis adequacy	KT/V	1.38±0.76		
	URR	63.4±10.8%		
	HB	8.48±2.38		
	ALB	4.17±2.38		

BMI: Body Mass Index, HTN: Systemic Hypertension, DM: Diabetes Mellitus, GN: Glomerulonephritis, URR: Urea Reduction Ratio, HB: Hemoglobin Level, ALB: Albumin Level, PCS: Physical Component Score, MCS: Mental Component Score

**Table 2: Comparison between QoL according to etiology of dialysis at base line**

	Physical component score X±SD	Mental component score X±SD	Total component score X±SD
Hypertension	36.92±17.79	44.01±16.34	40.87±18.27
Diabetes	28.31±10.41	29.29±9.46	29.14±10.25
Renal causes	31.72±15.58	37.93±11.47	34.30±13.90
Bilharziasis	31.46±11.55	34.33±17.80	33.58±14.92
p-value	0.36	0.00	0.30

**Table 3: Correlation between PCS, MCS, TCS and different risk factors**

	Physical component score Correlation coefficient (r)	Mental component score Correlation coefficient (r)	Total component score Correlation coefficient (r)
Age	0.140	0.222	0.208
Education	0.196	0.065	0.132
Duration	-0.023	0.05	0.042
BMI	0.001	-0.018	-0.11
Systolic blood pressure	-0.082	0.101	0.000
Diastolic blood pressure	0.035	0.218	0.110

45.9% female compared to one hundred age and sex matched normal control. Body mass index and physical and mental component summary scores were done to all patients and controls, education of patients and causes that lead to end-stage renal disease, serum albumin, hemoglobin, pre and post dialysis blood urea which is known as KT/V and urea reduction ratio of all patients illustrated in Table 1.

There was a highly significant difference between cases and control as regard body mass index ( $p < 0.001$ ), also there was a very high significant difference between cases and control as regard physical and mental component summary scales ( $p < 0.0001$ ).

As regard renal disorders that lead to ESRD, there was no significant relation except between diabetes mellitus and MCS,  $p < 0.001$  as shown in Table 2. As sexual and psychosocial function were included in the mental component summary scale. There was no significant difference between males and females as regard all domains of QoL in this study at baseline and at follow-up. As shown in Table 3, there was a positive significant ( $p < 0.001$ ) correlation between PCS and MCS and serum albumin and hemoglobin, high levels of serum albumin and hemoglobin were associated with highly significant QoL (PHS and MHS) ( $p < 0.001$ ).

**Table 4: Multiple regression analysis for prediction of QoL score**

	Regression coefficient	Slandered error	t-test	Significance
Prediction of physical health score	4.961	2.178	2.278	0.026
Prediction of mental health score	11.277	4.176	2.701	0.009
Prediction of total health score	6.495	3.203	2.028	0.04

**Table 5: Quality of life at base line and at follow-up**

p-value	Follow-up	Base line	
0.00	41.64±16.83	58.11±14.55	Physical function
0.00	23.16±32.58	67.21±22.15	Role physical
0.00	38.23±24.00	68.82±27.14	Body pain
0.00	32.21±11.57	56.64±15.91	General health
0.00	35.14±12.41	55.84±14.61	vitality
0.71	46.39±29.50	45.41±27.42	Social function
0.00	40.28±24.15	71.39±21.33	Role emotional
0.33	40.36±11.87	42.56±16.70	Mental health
0.00	34.08±15.46	62.70±13.39	Physical health score
0.00	38.80±15.17	53.80±18.64	Mental health score
0.00	36.70±15.80	58.25±13.64	Total score

mean±SD

There was a negative correlation between duration of hemodialysis and PCS. Also between BMI and MCS and between KT/V and PCS and MCS, but not to a significant level as shown in Table 3.

Multiple regression analysis for prediction of QoL score revealed that low education had a negative impact on QoL as regard physical health, while high serum albumin had a significant predictor of QoL as regard mental health and total score. So serum albumin and level of education are good predictors for QoL as shown in Table 4. Mean PCS was 34.08±15.46 and mean MCS was 38.8±15.17 compared to the control group, mean PCS was 67.24±18.8 and mean MCS was 60.22±23.22 (p<0.0001) for both components. These represent a highly significant decline in PCS and MCS in ESRD compared to the control group.

There was a significant reduction in both PCS and MCS of ESRD patients as compared to healthy subjects both at baseline and at follow-up as shown in Table 5.

### DISCUSSION

The need for hemodialysis treatment imposes a significant psychosocial burden on patients. Aside from the time commitment, the increased dependence on family members, and the anxiety that the treatment causes, many patients feel tired or depressed after treatments.

Physical debility experienced by patients with uremia can be insidious and have grave consequences (Tarlov *et al.*, 1989; DeOreo, 1997). Monitoring a patient's functional status and the subjective state of

well-being, together known as QoL measurements, is of particular importance in patients with end-stage renal disease (ESRD). The study provides a detailed description of the quality of life of patients who started hemodialysis and their progress 2 years later. All patients were under adequate dialysis confirmed by KT/V and urea reduction ratio.

In recent years, more attention has been drawn toward reexamining the overall role and potential application of patient self-reported states of well-being and functioning by use of self-administered QoL questionnaire in the dialysis population (DeOreo, 1997; Diaz-Buxo *et al.*, 2000). The SF36 is one of the most commonly used instrument for QoL evaluation in patients undergoing maintenance dialysis and include eight independent scales, each of which measures physical and mental aspects of functioning to varying degree (DeOreo, 1997; Hays *et al.*, 1994). Because of the increased use of the SF36, it has become possible to compare mean scale scores among groups of patients undergoing dialysis and between different populations of individuals.

In this study, we found a reduction in the mental health status at a baseline greater than physical health due to decrease in sexual and psycho-social function, as both were included in the mental function but two years later we found a reduction in nearly all domains of quality of life. Also there was a significant relation between diabetes mellitus as a cause of renal failure and mental health (p<0.001).

Several studies have reported that for the physical functioning, SF, and RE scales of the SF36, reliability estimates are the same or even slightly greater in patients undergoing dialysis compared with the nondialytic population (Hays *et al.*, 1994).

Other studies have reported a significant reduction in self-assessed physical and mental health compared to the general population. Interestingly, the reduction in scores compared to normal was greater for physical rather than mental health (Sanjeev *et al.*, 2001). This finding is in agreement with other reports of studies of functional health status of hemodialysis patients (Tarlov *et al.*, 1989; Diaz-Buxo *et al.*, 2000; Unruh *et al.*, 2003).

Other studies suggest that there were no change in QoL (Jonge *et al.*, 2003), or improvement in QoL over time (Harris *et al.*, 2002) and (Carmichael *et al.*, 2000). A greater effect on self assessed physical compared to mental health has also been found in other chronic diseases (Majkovicz *et al.*, 2000). The disease states previously reported to cause the greatest reduction in physical health have been congestive heart failure and limitation in the use of an arm or leg (Hays *et al.*, 1995), however, in

another study the effect of ESRD and hemodialysis on perceived physical health were found to exceed the effect of these chronic diseases (Hays *et al.*, 1994; Carmichael *et al.*, 2000; Sanjeev *et al.*, 2001).

Our study reported several factors that explained reduction in PCS scores in hemodialysis patients, including female sex, low education, high body mass index, duration in months, low levels of serum albumin and hemoglobin. Inverse correlations between duration and PCS score were observed ( $r = -0.023$ ). Also, inverse correlations between BMI and MCS score and total score were observed ( $r = -0.018$  and  $r = -0.11$ ), indicating that obese patients with higher body mass index had lower quality of life score.

We could not find any significant correlation between measures of dialysis adequacy (KT/V, URR), dialysis time and PCS and MCS. Similarly (Curtin *et al.*, 1999) and (Morton *et al.*, 1996) failed to show any relationship between dialysis adequacy and QoL.

The serum albumin remains a powerful predictor of poor outcome in ESRD (Kalanter-Zadeh *et al.*, 2001). Low serum albumin concentration reflects the presence of inflammation and malnutrition (Kalanter-Zadeh *et al.*, 2001; Sanjeev *et al.*, 2001; Keller *et al.*, 2004). The association we have found between serum albumin and patients perception of their physical health is consistent with the general perception that low serum albumin levels may reflect poor overall physical health. We found also a significant correlation between MCS scores and serum albumin.

Our study confirmed a positive impact of hemoglobin on physical, mental and total health score, which was in agreement with others (Morton *et al.*, 1996; Merkus *et al.*, 1997; Keller *et al.*, 2004), that postulated that hemoglobin positively influence QoL in dialysis patients.

Among laboratory values, serum hemoglobin correlated significantly with the SF36 score, denoting that anemic patients had a worse perceived QoL.

A practical use of functional health status measures is to estimate changes over time and evaluate the impact of various treatment interventions. As an example, significant improvements in various physical and emotional scales have been reported as a result of treatment with recombinant human erythropoietin (rHuEpo) (Beusterien *et al.*, 1996; Moreno *et al.*, 1996).

In our study, it seemed that erythropoietin deficiency is the most important factor in reducing the QoL in hemodialysis patients. Overall, we found a significant mean change in self-assessed physical and mental health of our patients during the 2-year study period.

## CONCLUSIONS

The results indicate the important negative impact that ESRD and hemodialysis treatments have on self-assessed physical and mental health.

It is important to treat all factors that induce hypoalbuminemia and anemia such as malnutrition, chronic infections, inflammations and iron deficiency anemia in order to improve health state.

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