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# **Quality of Life-Repeated Measurements Are Needed In Dialysis Patients**

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#### Abstract

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**BACKGROUND:** There is a general agreement that, besides survival, the quality of life is a highly relevant outcome in the evaluation of treatment in patients with the end-stage renal disease. Moreover, it is very important to determine whether the quality of life impacts survival.

**AIM:** This study aims to assess whether changes or absolute scores of the quality of life (QOL) measurements better predict mortality in dialysis patients.

MATERIAL AND METHODS: In a longitudinal study comprising 162 prevalent hemodialysis patients QOL was assessed with the 36-item - Short Form Health Survey Questionnaire (SF-36) at baseline and after 12 months. Patients were followed for 60 months. Mortality risk was assessed using Cox proportional hazards analysis for patients with below and above median levels of both physical and mental QOL component scores (PCS and MCS, respectively).

**RESULTS:** At the beginning of the study the mean Physical Component score was 47.43 ± 26.94 and mean Mental Component Score was slightly higher 50.57 ± 24.39. Comparative analysis of the changes during the first year showed a marked deterioration of all quality of life scores in surviving patients. The 5-point decline for PCS was noted in 39 (24%) patients and 42 (26%) for MCS. In the follow-up period of 60 months, 69 (43%) patients died. In the Cox analysis, mortality was significantly associated with lower PCS: HR = 2.554 [95% confidence interval (CI): 1.533-4.258], (P < 0.000) and lower MCS: 2.452 (95%CI: 1.478-4.065), P < 0.001. The patients who had lower levels of PCS and MCS in the second QOL survey 1 year later, had similarly high mortality risk: 3.570 (95%CI: 1.896-6.727, P < 0.000); 2.972 (95%CI: 1.622-5.490, P < 0.000), respectively. The hazard ratios for mortality across categories for the change of PCS and MCS were not significant. In the multivariate model categorising the first and second scores as predictors and adjusted for age, only the second PCS and MCS score were associated with mortality.

**CONCLUSION:** Low QOL scores are associated with mortality in repeated measurements, but only the more recent overwhelmed the power of the decline.

# Introduction

Several studies have investigated the associations of longitudinal changes of quality of life (QOL) with mortality in hemodialysis patients. There is still controversy if the absolute values or relative changes are stronger predictors of mortality [1][2][3].

This study aims to assess whether changes or absolute scores of life quality measurements better predict mortality.

# **Material and Methods**

We conducted a longitudinal study comprising 162 prevalent hemodialysis patients in one dialysis centre. Patients with age above 18 years and regular HD treatment for at least 3 months were included in the study. The lack of mental or physical capacity to communicate were exclusion criteria. The hemodialysis (HD) prescription in our study included 4 to 5 hours of HD thrice weekly for all patients with flow rates of 280 to 300 mL/min using a standard bicarbonate dialysis solution and low flux synthetic

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membranes with a surface area of 1.3 to 1.8 m<sup>2</sup>. Data was collected using medical histories and interviews for demographic and clinical indices.

QOL was assessed with the 36-item-Short Form Health Survey Questionnaire (SF-36) [4]. The SF-36 is a generic multidimensional instrument consisting of eight multi-item scales representing physical functioning, social functioning, role limitations caused by physical problems, and role limitations caused by emotional problems, mental health, vitality, bodily pain, and general health perceptions. The scale scores were transformed to a 0 to 100 scale, with a higher score indicating a better QOL. Finally, the physical and mental components of the eight scales were combined into a physical (PCS) and mental (MCS) component summary score. The PCS primarily reflects the dimensions of physical functioning, role limitations caused by physical health problems, pain, and general health perception. The MCS reflects primarily mental health, role limitations caused by emotional problems, social functioning, and vitality.

At the beginning of the study, during a regularly scheduled mid-week HD treatment, after being given a brief explanation, for each patient, QOL assessment using a 36-Item Short Form Health Survey Questionnaire (SF-36) was performed by a full-time employed psychologist. Assistance was available for patients who were illiterate, with an interactive approach. The SF-36 questionnaire was translated and adapted for the Macedonian population. Informed consent was provided.

Patients were followed for 60 months, until a change of dialysis modality, transplantation or death. Those transferred to other dialysis centres were continued to be followed. At 12 months of the study, the second SF-36 measurement was performed.

Statistical analysis was performed with SPSS 16.0 for Windows. Descriptive data were presented as mean±standard deviation (SD), or a the median. Percentages are given for categorical variables. Mortality risk was assessed using Cox proportional hazards analysis for patients with below and above median levels of both QOL component scores. A P-value of 0.05 or less was considered significant.

#### Results

The mean age of study participants was 56 years and mean dialysis vintage was 100 months. 53% of patients were male, and 24% were diabetics. Most of the patients were dialysed for 4 hours, and had good anaemia management, as shown in Table 1.

At the beginning of the study, the mean component physical score was  $47.43 \pm 26.94$  and

mean mental component score was slightly higher at 50.57 ± 24.39.

Table 1: Patients characteristics (N = 162)

N = 162	Mean ± SD/%
Age (years)	56,15 ± 13.35
Male (%)	85 (53%)
Dialysis vintage (months)	100.69 ± 76.08
Diabetes (%)	40 (24%)
Hemoglobin (g/L)	116.5 ± 8.5
Albumin (g/L)	38.8 ± 2.5
C-reactive protein (mg/L)	6.95 ± 8.46
Dialysis session time (hours)	4.07 ± 0.21
spKt/v	1.38 ± 0.20
Body mass index (kg/m²)	23.86 ± 4.6

Comparative analysis of the changes during the first year showed a marked deterioration of all quality of life scores in surviving patients (Table 2). The median level of PCS scores at twelve months was 43, and for MCS the value was 51. The 5-point decline for PCS was noted in 39 (24%) patients and 42 (26%) for MCS. Improvement of both scores was noted in 8 (6%) patients. The mean delta values varied in different QOL domains from minus 0.2 to minus 7.9 (Physical functioning: -4.2, Role-physical: -4.2, bodily pain: -7.2, general health: - 2.0, Role-emotional: -3.0, Social functioning: -4.9, Vitality: -7.9, Mental health: -0.2). Overall delta for PCS was -3.8 and for MCS was -3.7 points. The median of changes for both scores was 0.

Table 2: Comparison of Quality of life scores in two annual measurements

SF-36 scores	Patients at the start of the study (N = 140)	Survived after 12 months (N = 140)	Р
Physical functioning	53.87 ± 32.58	49.60 ± 32.89	0.003
Role-physical	42.26 ± 42.25	39.86 ± 41.10	0.204
Bodily Pain	63.45 ± 56.17	56.17 ± 30.69	0.0001
General health	36.48 ± 18.00	34.47 ± 19.23	0.052
Role-emotional	48.57 ± 24.98	45.57 ± 24.19	0.010
Social functioning	61.96 ± 31.83	57.12 ± 33.27	0.0001
Vitality	55.64 ± 20.16	49.65 ± 44.93	0.002
Mental health	52.15 ± 23.50	55.40 ± 19.47	0.833
Physical component (PCS) score	48.93 ± 26.10	45.13 ± 26.38	0.0001
Mental component (MCS) score	52.50 ± 23.50	48.44 ± 24.61	0.0001

In the follow-up period of 60 months, 69 (43%) patients died. We evaluated associations between mortality and the absolute PCS scores, and also the different grades of scores declinations. In the univariate analysis the basal PCS values (45 < PCS > 45), PCS values at twelve months (43 < PCS > 43), delta PCS (declination more than 5 points)  $< \Delta PCS >$ (declination more than 5 points), delta PCS (declination more than 10 points)  $< \Delta PCS >$ (declination more than 10 points), were included. In analysis, mortality was significantly associated with lower PCS: HR = 2.554 [95% confidence interval (CI): 1.533-4.258], (P < 0.000) and lower MCS: 2.452 (95%CI: 1.478-4.065), P < 0.001. The patients who had lower levels of PCS and MCS in the second QOL survey 1 year later had similarly high risk of mortality: 3.570 (95%CI: 1.896-6.727), (P < 0.000); 2.972 (95%CI: 1.622-5.490, P < 0.000), respectively. The Hazard Ratios for mortality across

categories for PCS and MCS change were: 1.164 (95%CI: 0.840-2.551), P < 0.178 and 0.706 (95%CI: 0.404-1.233), P < 0.221 for a change -5 points; 1.205; (95%CI 0.606-2.395), P < 0.595 and 1.202 (95%CI: 0.567-2.546), P < 0.632 for >10 points decline.

Table 3: Cox proportional hazard multivariate analysis on mortality and Physical Component Score (PCS)

Variable	Р	Hr	95% CI Lower upper
PCS at baseline (< 45)	0.685	1.189	0.514-2.751
Age (> 65)	0.021	2.030	1.111-3.708
PCS second survey (< 43)	0.001	2.982	1.556-5.715

In the multivariate model categorising the first and second scores as predictors, adjusted for age, only the second PCS and MCS score were associated with mortality (Table 3 and 4).

Table 4: Cox proportional hazard multivariate analysis of mortality and Mental Component Score (MCS)

Variable	р	HR	95% CI
			lower upper
MCS at baseline (<52)	0.802	1.101	0.520-2.328
Age (>65)	0.007	2.255	1.245-4.086
MCS second survey (<50)	0.002	2.583	1.398-4.772

# **Discussion**

As published before, the study presented here found that low physical and mental scores predicted mortality [5] [6]. There are few studies addressing the impact of the annual change of the quality of life scores on mortality. Liebmans group compared the 1year mortality rates in patients whose PCS and MCS increased or decreased ± 5 points vs those who did This retrospective study demonstrated an increased risk in mortality only for MCS score [7]. In the HEMO study, patients older than 70 years showed no substantial mean declines in both component scores over 3 years [3]. The clinical importance of the changes in QOL scores is still under investigation [8] [9]. DOPPS study data did not find the score change clinically relevant. Only the second QOL score predicted outcomes, which implicates the importance of frequent measurements and not the sharpness of decline. Our study observation is in agreement with those findings. Even the decline of 10 points did not achieve significance in predicting life quality scores. We speculate that marked individual variations of change among patients and slightly higher mean scores in our dialysis population when compared to

European patients'-data [7], could contribute to these findings.

In conclusion, deteriorated physical and mental aspects of quality of life in hemodialysis patients are accompanied by further deterioration. Low QOL scores are associated with mortality in repeated measurements, but only the more recent overwhelmed the power of the decline. Medical, psychological and social interventions of preventable factors are expected to improve the well-being of dialysis patients. Particularly important is the increased awareness for the need for regular QOL assessments.

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