Hemodialysis Patient–Assessed Functional Health Status Predicts Continued Survival, Hospitalization, and Dialysis-Attendance Compliance

Peter B. DeOreo, MD

● We asked patients to assess their functional health status by completing the SF-36. Over 2 years, we studied 1,000 patients (average age, 58 years; 50% male; 25% white; 36% diabetic) in three outpatient, staff-assisted hemodialysis units. We used both the eight-scale scores and two-component summary scores to study the relationship between baseline functional health status and clinical outcomes. The physical component summary (PCS) score was as significant a predictor of mortality as was the normalized protein catabolic rate or the delivered Kt/V. Patients with a PCS score below the median for our patients (<34) were twice as likely to die and 1.5 times more likely to be hospitalized as patients with PCS scores at or above the median score. Either a low PCS score or a low mental component summary (MCS) score correlated with the number of days of hospitalization. While the average dialysis patient has a relatively normal (47 *v* 50) MCS score and a low (37 *v* 50) PCS score compared with the normal population, patients who skipped more than two treatments per month tended to have a relatively higher PCS score (judged themselves physically healthier) and a relatively lower MCS score (judged themselves less mentally healthy) than patients who did not skip two or more treatments per month. The prevalence of depression as defined by an MCS score of ≤42 was approximately 25%. The SF-36 provided a good screening tool for patients at high risk for death, hospitalization, poor attendance, and depression.

INDEX WORDS: Survival; compliance; depression; patient self-assessment; functional health status; health-related quality of life; outcomes measurement.

THE Institute of Medicine's conference on measuring and managing quality in end-stage renal disease (ESRD)[1] and the follow-up workshop on measuring health-related outcomes[2] focused discussion on the practicality and utility of patient-assessed outcomes. Do health-related quality-of-life questionnaires significantly broaden the clinical data set and improve clinical judgment? We report 2 years' experience using the Medical Outcome Study Short Form (MOS SF-36)[3] in 1,000 patients in three freestanding dialysis units. The surveys predicted mortality risk, hospitalization risk, tendency to skip dialysis treatments, and the possibility of depression. The surveys were easy to administer, to score, and to integrate into the patient record. The multidiscipline care team used the information in evaluating and planning patient care.

From the Centers for Dialysis Care, Cleveland and Mentor, OH; and the Dialysis Associates of Greater Cleveland.
Received October 30, 1996; accepted in revised form March 7, 1997.

Presented in part at The American Society of Nephrology 29th Annual Meeting and Exposition, New Orleans, LA, November 3, 1996.
Address reprint requests to Peter B. DeOreo, MD, Centers for Dialysis Care, PO Box 12220, East Cleveland, OH 44112.

0272-6386/97/3002-0006$3.00/0

PATIENTS AND METHODS

Study Design and Patient Population

This was a historical prospective study. The study window included data on all prevalent patients dialyzed in the interval between January 1, 1994, and December 31, 1995, if the patient had completed an SF-36. The usual reasons for not having an SF-36 completed were the patient not being available (hospitalized, missed treatment), being unwilling to answer the questionnaire, or not being suitable (dementia, cognitive impairment, affective disorder). The dialysis centers were not-for-profit, freestanding facilities. We dialyzed patients with polysulfone dialyzers (Fresenius F/8 or F/80) using bicarbonate dialysate on volumetric controlled dialysis machines.

Health Assessment Instrument

Personnel instructed on the use and purpose of the SF-36 (social workers and receptionists) administered the SF-36 to new patients and to other patients every 6 months. For literate, sighted patients, administration required handing the questionnaire to the patient and giving a brief explanation. For patients requiring assistance, we used a standard script. We scored the surveys by computer and filed the results in the medical record. We used only results of the first survey completed in the study window for this analysis.[4]

The SF-36 is an adaptation of the full-length MOS.[3] It is a 36-question generic instrument without questions specific to ESRD or chronic renal failure (CRF). The questions address the patient's ability to perform vigorous activity and the activities of daily life, and to participate in social, family, and occupational activity. The questions ask the patient to describe his or her mood, to describe current and past health, and to judge his or her energy and susceptibility to illness. There are eight scales describing domains of physical func-

Table 1. SF-36 Interpretation of Scale and Component Summary Scores

Scale	Meaning of Scores: Low	High
Physical functioning	Severe limitations in physical activity, including bathing and dressing	Performs vigorous activity without limitations
Role physical	Limited ability to work because of physical health	Physical health does not limit work or other activity
Role emotional	Emotions limit daily function and work	Emotions do not interfere with daily function or work
Social function	Physical and emotional symptoms severely limit normal social activities	No physical or emotional limits to normal social activities
Bodily pain	Severe limiting pain	No pain or limitations due to pain
Mental health	Feels nervous and depressed all the time	Feels peaceful, happy, and calm all the time
Vitality	Feels tired and worn out all the time	Feels full of pep and energy all the time
Health perception	Health much worse than last year	Health better than last year
Physical component summary	The lowest level of the physical scale scores, health generally rated "poor"	The highest level of the physical scale scores, health generally rated "excellent"
Mental component summary	The lowest level the mental, social, and emotional scales, health generally rated "poor"	The highest level of the mental, social, and emotional scales, health generally rated "excellent"

Data from Ware et al.[3,5]

tion, social function, physical and emotional role function, mental health, bodily pain, vitality, and general health perception. The scales are scored on a 0 to 100 possible range. The higher number is the more favorable state. The component summary scores[5] combine the physical and mental components of the eight scales into a physical (PCS) and mental (MCS) component summary score. The component summary scores are normalized to a general population mean of 50 and a standard deviation of 10 (ie, a T-score metric). Table 1 lists the scales used in this review and the meaning of the highest and lowest score in each scale.

Laboratory, Dialysis Adequacy, and Protein Catabolic Rate

We measured serum albumin (bromocresol green reaction, lower limit of normal = 3.5 g/dL) and blood urea nitrogen (BUN) in the clinical laboratory. We used only the first albumin value (baseline) in the study window in this analysis. We calculated the variable volume, single-pool Kt/V, and normalized protein catabolic rate (nPCR) by the methods of Daugirdas.[6] We drew the post-BUN at the end of dialysis from the arterial line 30 seconds after we slowed the blood pump to ≤80 mL/min. We used the patient's first Kt/V and nPCR in the study window, making no allowance for residual renal function.

Statistical Methods

We used standard descriptive statistics. The Cox proportional hazard model was used for survival analysis, actuarial survival plots were used to compare subgroup survival, the log-rank (Mantel-Cox) test was used for actuarial plot comparison, and chi-squared analysis was used for group comparisons.[7] We used regression analysis and unpaired Student's *t*-test to compare continuous variables.[8] $P < 0.05$ (two-tailed) was considered to be statistically significant. Due to the large number of patients with zero days in the hospital, we added "1" to the observed number of hospital days. We used a log-linear model to analyze the hospitalization data. The dependent variable was the natural logarithm of the number of days hospitalized per days of follow-up. The plot of the residuals in this log-linear model had a near-normal distribution, which justifies the use of this model.[9]

To compare the means of SF-36 scale and component scores to normal data or mean data from other series of ESRD patients, we used the significance tables in the scoring manuals.[3,5] For the component summary scales, a group comparison with a sample size of ≥786 patients in each group, a one-point difference between the normal mean and the sample mean is significant at the 5% level (two-tail). For the scale scores, a comparison from sample size ≥366 patients in each group, a five-point difference between the sample scale score and a group norm is significant at the 5% level (two-tail).

RESULTS

Demographics and Descriptive Statistics

The average age of the patients in the study window was 58.2 ± 15.4 (±SD) years. Half the patients were men, 23% were white, and 36% had diabetes as their primary ESRD diagnosis. The average time of observation in the interval was 531 ± 231 days (range, 1 to 728 days).

The average treatment time was 3.23 ± 0.36 hours. The average baseline Kt/V was 1.32 ± 0.21. The average baseline nPCR was 0.86 ±

Table 2. SF-36 Scale Score: Patients and US Reference (Both Sexes, All Ages)

Scale Score	Patients ± SD (n = 1,000)	US Reference ± SD (n = 2,474)[3]
Physical function	44.3* ± 27.8	84.2 ± 23.3
Role physical	39.7* ± 40.4	90.0 ± 34.0
Role emotional	58.2* ± 42.7	81.3 ± 33.0
Social function	66.0* ± 29.9	83.3 ± 22.7
Bodily pain	60.4* ± 29.1	75.2 ± 23.7
Mental health	69.7* ± 21.6	74.7 ± 18.1
Vitality	46.5* ± 22.3	60.9 ± 21.0
Health perception	50.0* ± 22.4	72.0 ± 20.0

* $P < 0.05$, two-tailed comparison.

Table 4. Mental Component Summary Scores (Totals and Age Ranges, Both Sexes)

Group	Patients ± SD (n)	US Normal (n)[5]
All	47.9* ± 11.6 (1,003)	50.0 (2,472)
18-25 yr	47.5 ± 12.9 (13)	49.1 (173)
25-35 yr	48.3 ± 9.9 (81)	48.6 (474)
35-45 yr	45.4 ± 11.2 (133)	49.9 (503)
45-55 yr	46.4 ± 11.5 (147)	50.5 (338)
55-65 yr	48.1* ± 12.2 (224)	51.1 (269)
65-75 yr	49.5* ± 11.5 (281)	52.7 (442)
≥75 yr	48.4 ± 12.3 (123)	50.4 (264)

* $P < 0.05$, two-tailed comparison.

0.15 g/kg/d. The average baseline albumin was 3.7 ± 0.43 g/dL.

SF-36 Scale and Component Summary Scores

Table 2 shows the baseline average and standard deviations for the patients' scale scores. For comparison, the tables show normal US population values (both sexes, age >18 years). All the scores are significantly lower ($P < 0.05$) than normal. The role function physical is farthest from normal (−50.3) and the mental health is the closest to normal (−5.0).

Table 3 shows the mean PCS scores (total and in age groupings) for both sexes compared with the US population norm. In each age group except the 18 to 25 and greater than 75 age groups (the sample sizes were too small for the observed difference to be significant), patients rated their physical health lower than the normal population. A patient with a PCS score less than 34 is likely to report difficulty walking one block or climbing a flight of stairs. The data show the expected decline in scores with age.

Table 4 shows the mean MCS scores (total and in age groupings) for both sexes compared with the US population norm. Where indicated, the scores were lower than the normal population. These scores were closer to normal than were the PCS scores. A patient with an MCS score less than 47 is likely to describe himself as "down hearted or blue," to report "accomplishing less than hoped for," and is not likely to describe himself as "happy." Similar to the normal population, patients aged 55 to >75 years rated their mental health better than patients in the >35 to 55 years age group.[10]

In a simple regression analysis, Kt/V predicted only $8 \times 10^{-5}\%$ of the observed variation in the PCS score ($P = 0.98$) and 0.5% of the variation in the MCS score ($P = 0.023$).

There were no statistically significant differences when we compared results among or between the three dialysis facilities.

Table 3. Physical Component Summary Scores: Patients and US Reference (Totals and Age Ranges, Both Sexes)

Group	Patients ± SD (n)	US Reference (n)[5]
All	35.2* ± 9.9 (1,003)	50.0 (2,472)
18-25 yr	46.9 ± 7.2 (13)	53.4 (173)
25-35 yr	40.8* ± 10.5 (81)	53.7 (474)
35-45 yr	36.1* ± 8.7 (133)	52.2 (503)
45-55 yr	35.2* ± 9.7 (147)	49.6 (338)
55-65 yr	34.1* ± 9.4 (224)	45.9 (269)
65-75 yr	34.0* ± 10.3 (281)	43.3 (442)
≥75 yr	33.7 ± 9.4 (123)	37.9 (264)

* $P < 0.05$, two-tailed comparison.

Survival Analysis

We entered nine covariates (age, race, sex, ± diabetes, Kt/V, nPCR, albumin, PCS score, and MCS score) into a Cox proportional hazard survival analysis. The number of days the patient survived from the first dialysis in the study window (continued survival) was the dependent variable.[11] We censored patients at transfer, transplant, change to peritoneal dialysis, discontinuation of dialysis, or survival through December 31, 1995. Table 5 shows the sign of the model coefficients, the unit of analysis, the percent change in the probability of survival per unit change in the covariate, the confidence interval

Table 5. Survival Proportional Hazards Model*

Covariate	Sign of Coefficient	Unit of Analysis	Percent Survival Change Per Unit Change†	95% Confidence Interval for Percent Survival Change Per Unit	*P* Value‡
Albumin	−	0.1 g/dL	+10.0	6.2 to 14	<0.0001
Age	+	1 yr	−2.8	1.4 to 4.1	0.0002
nPCR	−	0.1 g/kg/d	+17.2	5.4 to 27	0.0053
PCS	−	5 points	+10.4	1.1 to 18	0.0226
Kt/V	−	0.1 Kt/V	+10.8	0.6 to 19	0.0373
Is diabetic	+				0.1739
Is not white	−				0.1773
Is male	+				0.4492
MCS	−	5 points	+1.4	−6.5 to 8.9	0.7280

* For the model, $P < 0.0001$ (Wald).
† The percent change in the probability of survival per unit change of the covariate.
‡ Chi-squared.

for that percent change, and the *P* value. A negative sign on the covariate's coefficient means that an increase in the absolute value of the covariate is associated with higher probability of survival. A 0.1 g/dL increase in albumin was associated with a 10% increase in the probability of survival. The 95% confidence interval for the improved probability of survival was from 6.2% to 14%. Table 5 lists covariates by ascending magnitude of *P* value. Albumin and age had the most significant effects on the model. nPCR, Kt/V, and PCS score had the same relative effects on the model. Race, sex, ± diabetes, and MCS score were not statistically significant in the model.

The overall actuarial survival for the cohort was 92% at 1 year and 83% at 2 years. The 1- and 2-year survival rates for the group with a PCS score equal to or greater than the median (34.6) were 95.5% and 88.5%, respectively. The 1- and 2-year survival rates for the group with a PCS score lower than the median (34.6) were 90.5% and 78.5%, respectively. The 1- and 2-year survival rates for the group without an SF-36 study were 50% and 35%, respectively ($P <$ −.0001 compared with the patients with a study irrespective of score).

For every increase of Kt/V by 0.1 or of PCS score by five points, there was an approximately 10% increase in the probability of survival. The odds ratio for death was 2.03 (95% confidence interval, 1.44 to 2.85; $P = 0.0003$, chi-squared) when the PCS score was lower than the median value (34.6). Figure 1 shows the actuarial survival plots for patients with PCS scores equal to or greater than the median and for patients with PCS scores lower than the median. There is a survival advantage ($P < 0.0001$, Mantel-Cox) for patients with a PCS score equal to or greater than the median.

Serum Albumin, PCS Score, and MCS Score

We used PCS score, MCS score, and nPCR as independent covariates in a linear regression model, with albumin as the dependent variable. The combination of PCS score and nPCR explained 5% of the observed variation in albumin (adjusted $R^2 = 0.053$). The coefficients for PCS score (0.008; $P < 0.0001$) and nPCR (0.384; *P*

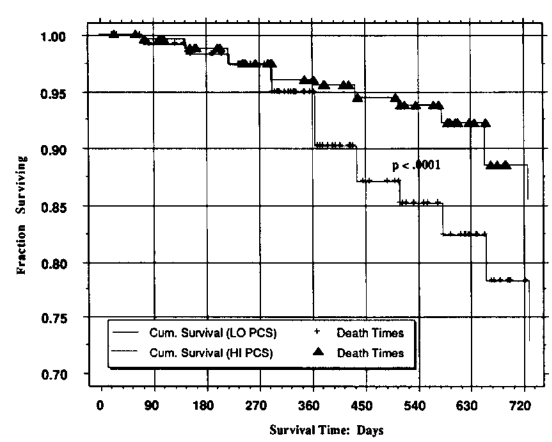

Fig 1. Actuarial cumulative survival plot. The bottom curve indicates low PCS scores (<34.6) and the top curve indicates high PCS scores (≥34.6). The difference between the curves is significant ($P < 0.0001$, log-rank [Mantel-Cox]). The + and ▲ markers indicate deaths.

Table 6. Regression Model for Hospital Days*

Covariate	Sign of Coefficient	Unit of Analysis	Percent Change in Hospital Days Per Unit Change†	95% Confidence Interval for Hospital Days Percent Change Per Unit	*P* Value
Albumin	−	0.1 g/dL	−3.6	2.7 to 4.5	<0.0001
PCS	−	5 points	−5.8	4.0 to 7.7	<0.0001
nPCR	−	0.1 g/kg/d	−5.2	2.8 to 7.7	<0.0001
MCS	−	5 points	−2.0	0.5 to 3.4	0.0113
Not white	+				0.1250
Is diabetic	+				0.1433
Is male	−				0.5035
Age	+	1 yr	+0.1	−0.3 to 0.2	0.5147
Kt/V	−	0.1 Kt/V	−0.3	−1.7 to 2.3	0.7580

* For the model, $P < 0.0001$ (ANOVA).
† The percent change in the number of hospital days per unit change of the covariate.

< 0.0001) were statistically significant; that of MCS score (0.001; $P = 0.2692$) was not. The model predicts that either a five-point increase in PCS score or a 0.1 g/kg/d increase in nPCR was associated with a 3% to 4% increase in serum albumin.

Hospitalization

There were 720 patients admitted to the hospital over the 2 years (71.8% of the patients). The average length of stay was 6.7 days. Comparing patients who were admitted with those who were not, the PCS score correlated with the probability of hospitalization. The odds ratio for hospitalization was 1.67 (95% confidence interval, 1.43 to 1.95; $P = 0.0003$, chi-squared) when the PCS score was lower than the median value (34.6). Patients who were hospitalized had a significantly lower PCS score (34.1 *v* 37.9; $P < 0.0001$, unpaired *t*-test). The difference was not significant for the MCS score (47.5 for patients admitted *v* 49.1 for patients not admitted; $P = 0.0547$).

A log-linear regression model using the natural logarithm of days hospitalized as the dependent variable and age, albumin, ± diabetes, sex, race, Kt/V, nPCR, PCS score, and MCS score as independent covariates predicted 16% (adjusted $R^2 = 0.159$; $P < 0.0001$) of the observed variation in the hospital days. Table 6 shows the model covariates in ascending order of their *P* value. If the number of days of hospitalization decreases as the absolute value of the covariate increases, then the sign of the coefficient of the covariate is negative. Table 6 shows the unit of the covariate associated with the percent change in hospital days and the confidence interval for that percent change. That is, if the value of albumin increases by 0.1 g/dL, the number of days of hospitalization decreases by 3.6% with a 95% confidence interval of 2.7% to 4.5%. Only albumin, PCS score, nPCR, and MCS score had significant unique effects on the dependent variable. Dialysis adequacy, as measured by Kt/V, did not have a significant unique effect on hospital days.

Skipping Dialysis Treatments

We defined a "skipper" as a patient who missed ≥2 dialysis treatments per month. Fifty-nine (6%) patients met this definition. Skippers were younger than the average patient and younger than patients who did not skip as many treatments (45.5 years *v* 59.0 years; $P < 0.0001$, unpaired *t*-test). Skippers had a higher PCS score (37.8 *v* 34.9; $P = 0.029$) and a lower MCS score (44.0 *v* 48.2; $P = 0.006$) than nonskippers. The ratio of PCS score to MCS score was higher for skippers (0.90 *v* 0.79; $P = 0.014$) than nonskippers.

Depression

For the SF-36 Mental Health scale and the SF-36 MCS, scores of ≤52 and ≤42, respectively, provide the best cut-offs for detecting depression (sensitivity = 74%; specificity = 81%).[5] In our study, the prevalence of depression by either or both of these cut-offs was 25%. We did not use an additional test to validate the SF-36 estimate of the prevalence of depression.

DISCUSSION

The preponderance of analysis of clinical ESRD outcomes such as mortality, hospitalization, and nutrition has been limited to laboratory values, demographic characteristics, diagnostic categories, and dialysis parameters. Lowrie and Lew[12] have shown that the baseline serum albumin is a strong predictor of survival. As the albumin decreased from ≥4 g/dL to less than 2.5 g/dL, the relative crude risk of death increased from twofold to sevenfold. Held et al[13] showed that the relative risk of mortality is inversely proportional to the delivered Kt/V. These investigators estimated that there is an 8% increase in the probability of survival for every 0.1 increase of the delivered Kt/V up to a Kt/V of 1.5.

It is possible to broaden the set of independent covariates of the survival model by including measurements representative of the hemodialysis patient's assessment of his or her functional status. Functional status assessment puts the patient's statement into the medical database in a standard, validated manner. In the MOS study, the PCS scores were correlated with 5-year survival.[5] Subjects with a PCS score between 25 and 34 (mean, 29.9) had a 15% 5-year mortality rate, representing a 4.8 increase in the relative risk of dying compared with age-matched subjects. Parkerson et al[14] showed that baseline measurements of patient-assessed functional status predicted utilization and cost in a primary care practice.

Meyer and colleagues[15,16] showed the feasibility and utility of using health status measurements in the management of individual hemodialysis patients. McClellan et al[17] prospectively studied a cohort of 249 incident hemodialysis patients. They showed that a patient's assessment of his or her ability to give social support to friends and family correlated positively with survival. When adjusted for age, race, sex, diagnoses (diabetes and coronary artery disease), and the Karnofsky score, patients in the lowest quartile of giving social support had a twofold relative risk of death. In a prospective study, Kutner et al[11] showed that continued survival in a prevalent cohort of dialysis patients over the age of 60 years was related to functional status. In that study, functional status was defined by the patient's reporting the time spent in a bed or chair each day, the ability to do self-care, and the ability to walk, climb stairs, and do light to heavy work.

Our study showed that the predictive power of self-reported functional status data, as measured by the SF-36, is comparable to laboratory, dialysis adequacy, and nutritional adequacy measurements in the evaluation of mortality and hospitalization. Our results showed the expected effect of the serum albumin as a predictor of survival and the same order of magnitude reported[13] for the predictive power of Kt/V. In our proportional hazard model, the PCS score had the same effect on survival as did the Kt/V and the nPCR. The PCS score had an effect of similar magnitude to the nPCR in predicting the variation of the serum albumin.

Our study showed that the baseline functional status measurements were more powerful than the clinical diagnosis of diabetes in predicting death or days of hospitalization. Patients with a PCS score less than the median value of 34.6 were more likely to be hospitalized than those reporting physical health status at or above the median value. A PCS score of 34 represents substantial limitations in self-care and role activities, and a perception of poor health. The diagnosis of diabetes (as taken from the Health Care Financing Administration 2728 report), when corrected for age, PCS score, MCS score, and nPCR, had no unique effect on the regression model for mortality or days of hospitalization. Kutner et al[11] showed that diabetes as the cause of renal failure was not related to continued survival in a model that included functional status as a covariate. The PCS score may be a better index of comorbidity for hemodialysis patients than an unqualified clinical diagnosis of diabetes.

Improving patient compliance with the dialysis and dietary prescription is a desirable clinical outcome. Held et al[13] found that skipping one treatment per month increased the risk of death by a factor twice that predicted by the estimated reduction in Kt/V delivery. These investigators concluded that missing dialysis was associated with other patterns of harmful noncompliance.

Kimmel et al[18] showed that compliance with different components of the dialysis prescription varied, but tended to be stable over time. The patients with poor time compliance in the study by Kimmel et al tended to be younger than the time-compliant patients. Low indices of social support and evidence of depression were also prevalent in poorly compliant patients, although no scale was significantly related to poor attendance compliance. McClellan et al[19] showed that poor indices of social support increased risk of death. While they did not discuss compliance specifically, the report by McClellan et al did demonstrate some "barrier" issues that might contribute to poor compliance.

In his "biopsychosocial assessment" of dietary compliance in dialysis patients, Moore[20] studied factors that had a negative impact on compliance. He drew his subjects from the same dialysis unit as the majority of the patients in our study. Moore's study was prospective and completed 10 years before our study. He noted that dialysis patients who were poorly compliant with their diet and fluid restriction were younger (51 years *v* 60 years), more likely to report "feeling better or well," and, at least for fluid compliance, had higher indices of depression (assessed by the Beck Depression Index).

Our study examined a very gross measure of compliance, namely, missing more than two treatments per month. As was true for the noncompliant (various categories) patients in the studies of Kimmel et al and Moore, our study showed that patients with poor compliance (attendance) were younger (45 years *v* 59 years) and more likely to have rated their health better.

Patient compliance depends on their understanding, the value they give to the expected health outcome, and their estimate of their vulnerability to the negative impact of noncompliance.[21] The intention of patients to comply may be severely limited by practical obstacles (finances, transportation, conflicting priorities, etc). By identifying patients with better than average physical health but worse than average mental health, the SF-36 can help clinicians ask questions[21] about and focus on issues important to the patient that are barriers to compliance.

An MCS score of ≤42 or a mental health scale score of ≤52 is correlated with a diagnosis of clinical depression. Hays et al[22] showed that depression accounted for as much loss of well-being as does chronic medical illness. In an essay on depression in ESRD, Kimmel et al[23] speculated on the possible contributions of depression to mortality. They theorized that depression may be a treatable cause of mortality. In his thesis, Moore[20] cited a prevalence of depression in hemodialysis patients of 13% to 60%. Using the

Table 7. Comparison of the Baseline SF-36 Scores of Two Similar ESRD Samples

Scale Score	Our Study ± SD (n = 1,000)	Beusterien* ± SD (n = 1,004)
Physical function	44.3 ± 27.8	46.5 ± 28.5
Social function	66.0 ± 29.9†	57.5 ± 34.0
Bodily pain	60.4 ± 29.1	61.0 ± 34.6
Mental health	69.7 ± 21.6	68.5 ± 19.9
Vitality	46.5 ± 22.3	45.0 ± 22.6
Health perception	50.0 ± 22.4†	44.5 ± 21.8
PCS	35.2 ± 9.9	35.5 ± 11.3
MCS	47.9 ± 11.6†	45.8 ± 11.6

* Data from Beusterien et al.[27]
† $P < 0.05$.

Beck and Cognitive Depression Indices, Kimmel et al[18] showed that the prevalence of depression was 25%. Using the SF-36 criteria as a screen, the prevalence of depression in our patients was similar to that reported by Moore and Kimmel et al. The SF-36 identifies patients at risk for clinical depression, allowing the clinician to evaluate further and treat if appropriate. It is interesting to note that Kt/V had a small, although statistically significant, effect on the MCS score but not on the PCS score.

The use of aggregate or summary scales minimizes the reported limitations of using scale scores for the most commonly used functional health status instruments (including the SF-36)[24-26] for decision-making for individual patients. The MCS and PCS scores define more levels of health than the individual scales and therefore have greater statistical power.[5] These instruments have been submitted to more rigorous validation than has individual clinical judgment. When physician and patient self-assessments have been compared, physicians were more likely to underestimate patients' physical and psychosocial disabilities.[24]

If the PCS score provides a reasonable index of the burden of illness of a cohort of hemodialysis patients, it also may provide a basis for comparing different cohorts. For example, Beusterien et al[27] reported baseline functional health status measured by the SF-36 for a study of patients previously treated with or about to be treated with erythropoietin. Table 7 shows that their baseline data were very similar to ours when compared with a normal population. However, our patients reported higher MCS scores, social function, and health perception than did patients of Beusterien et al. The comparison is useful in the similarities and differences. Kutner[28] commented that hemodialysis patients have a consistent "profile" of SF-36 scores. Hemodialysis patients report low physical scores, but rather more normal mental and emotional scores. As functional status measurements are more widely used as outcomes in clinical trials, more specific patterns within the broad patterns already described may be discerned.

A practical use of functional health status data is to measure changes over time or postintervention. Our study involved only baseline data. Beusterien et al,[27] using the SF-36, and Moreno et al,[29] using the Sickness Impact Profile and the Karnofsky Index, showed significant improvements in various physical and emotional scales after patients' hematocrit values improved as a result of treatment with erythropoietin. The use of these instruments adds a standardized measurement of patient-assessed improvement.

It remains to be proven that there are timely and cost-effective intervention strategies that can be implemented based on "risk factors" derived from demographic, laboratory, and functional status data. To improve the quality of our care, we need to understand the components of quality. Patient-perceived outcome data are an important element of quality assessment. Patients can judge their satisfaction with the structure of care (the facilities, the amenities, the accessibility), the process of care (courtesy and competence of the staff), and the outcome of care (functional status).[30]

If the value of medical care is a function of its quality and cost, and the quality is judged by the achievement of "desired health outcomes,"[31] then it is necessary that we have operational measurements of outcomes. Functional health status measurements are useful in that they measure changes from the patient's perspective that are important to the disease process or the therapy.[32] Our study showed that a well-validated health status instrument predicts clinically relevant outcomes.

ACKNOWLEDGMENT

The authors appreciate the substantive, syntactical, and statistical assistance of the members of the ESRD Health Status Outcomes Working Group: John Sadler (chairman), Christopher Blagg, Ron Hays, Klemens Meyer, George Parkerson, Richard Rettig, John Wasson, and Jay Wish.

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