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Decline in functional status and mortality in patients on hemodialysis: Results from the Japan Dialysis Outcome and Practice Patterns Study (J-DOPPS)

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Abstract

Objectives: Patients with end-stage renal disease (ESRD) treated with hemodialysis suffer a high burden of poor functional status. Poor functional status is known as a strong, consistent predictor of mortality. However, little is known about the trajectory of functional status and its association with clinical outcomes in the ESRD population. We examined the association between change in functional status over time and all-cause mortality among hemodialysis patients.

Design: Prospective cohort study.

Setting and Subjects: We studied 817 patients with ESRD on hemodialysis with repeat measures of functional status enrolled in the Japan Dialysis Outcomes and Practice Patterns Study (J-DOPPS) phase ☐.

Predictor: Functional status was assessed based on Katz index and Lawton-Brody instrumental activities of daily living scale, and the assessments were conducted twice over a median of 361 (range, 339–378) days between 2012 and 2013. We classified patients into 2 groups based on having or not having at least a 1-point decline in functional status score. To evaluate the association between the decline in functional status and all-cause mortality with adjustment for potential confounders, a Cox regression analysis was conducted.

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Main Outcome: All-cause mortality.

Results: Over the study period, 19.9% of the patients showed decline in functional status score. During the follow-up period, 44 (5.4%) patients died. Using Cox regression analysis adjusting for potential confounders, the decline in functional status score was significantly associated with higher mortality (incidence rate, 2.2 vs. 7.0 per 100 person-years; adjusted hazard ratio, 2.68; 95% confidence interval, 1.31–5.50).

Conclusions: The present study provides evidence that ESRD patients on hemodialysis demonstrating a decline in functional status are at elevated risk of mortality. Our findings strengthen the evidence underpinning the importance of interventions to maintain functional status in this vulnerable population.

Keywords

CKD; exercise; dialysis; frailty; sarcopenia

Introduction

An aging demographic with increasing comorbid burden has led to a worldwide increase in the rate of chronic kidney disease (CKD) requiring renal replacement therapy, including hemodialysis.[1] The mortality rates among patients on hemodialysis are very high despite continual improvements in dialysis technology.[2] One of the potential contributors to poor survival might be the high burden of functional dependence,[3] defined as an individual's inability to perform fundamental tasks of day-to-day life associated with personal care and maintaining a household. Multiple factors including older age, decreased physical functioning, comorbidities, and hospitalizations are likely to contribute to the high prevalence of disability in hemodialysis patients.[4–6]

Expert clinical practice guidelines for people with renal failure reported by the Kidney Disease Improving Global Outcomes Chronic Kidney Disease Work Group (KDIGO),[7] National Kidney Foundation (NKF),[8] and European Renal Best Practice (ERBP) guideline development group[9] strongly recommend an assessment of functional status and strategies in CKD patients. However, the level of evidence to support these recommendations is considered weak. A previous study had demonstrated a high level of disability in daily activities in most hemodialysis patients, and a dose-response association was seen between poor functional status at baseline and adverse clinical outcomes in patients on hemodialysis.[10] However, functional status is dynamic, and little is known about the determinants of decline in functional status and its association with clinical outcomes.

The current study examines the association between change in functional status over a 1-year period and all-cause mortality among patients on hemodialysis using a large population-based sample of participants from the Japan Dialysis Outcomes and Practice Patterns Study (J-DOPPS). We hypothesized that hemodialysis patients who experienced a decline in functional status over a 1-year period would have higher mortality compared with those who did not experience a decline.

Methods

Study Population and Data Sources

We used the data from J-DOPPS, which are part of the data from an international longitudinal study of hemodialysis patients (DOPPS). In J-DOPPS, patients were randomly selected from representative dialysis facilities in Japan. J-DOPPS collected information on demographics, laboratory data, comorbidities, dialysis conditions, and medications every 4 months as well as information on hospitalization and death occurrence. All patients in J-DOPPS provided written informed consent before study enrollment. More detailed information about this cohort study is available in a previous study.[11] Our study included 2,520 patients aged ≥18 years and participating in J-DOPPS phase □ (2012–2015). All eligible patients were selected. We excluded patients without functional status data either in 2012 or 2013 and who had 1 or more disability in their activities of daily living (ADLs), which consisted of not having a maximum score on the Katz index. This study's protocol was approved by the Ethics Committee.

Assessment of Functional Status

Functional status was assessed based on the ability to perform ADLs and instrumental ADLs (IADLs) as self-reported on a questionnaire, namely, the Katz index[12] and Lawton-Brody IADL scale,[13] respectively. The Katz index asks about 5 tasks of ADLs with 2-option answers (Yes/No), and the Lawton-Brody IADL scale asks about 8 tasks of IADLs with 3-option answers (need no help/need some help/unable to do at all). Both questionnaires have been well validated in the general population. We calculated the functional status score by combining the scores of the Katz index and Lawton-Brody IADL scale in accordance with the algorithm developed in the DOPPS.[10] The assessments of functional status were conducted twice between 2012, and 2013. For primary analysis, we classified patients into 2 groups based on having or not having at least a - point decline in functional status score between the 2012 and 2013 assessment. Furthermore, for secondary analysis, we classified the patients into 2 groups based on decline in at least 1 of the 13 functional tasks.

Assessment of Outcome

The primary outcome was all-cause mortality. Mortality was assessed by death records. The follow-up periods of each patient were started at the second assessment of functional status in 2013. J-DOPPS followed patients until one of the following events occurred: death, transplantation, transfer to another facility, change of modality, withdrawal, or study end.

Other Variables

We collected information on age, sex, body mass index, smoke (nonsmokers/ever smokers), and years on dialysis from the initiation date of hemodialysis to the second assessment of functional status. Comorbidities (cardiovascular disease, congestive heart disease, cancer other than skin cancer, other cardiovascular diseases, cerebrovascular diseases, diabetes, gastrointestinal bleeding, hypertension, lung disease, neurologic disease, psychiatric disorder, peripheral vascular disease, and gangrene/recurrent cellulitis) were determined by medical records. Laboratory data (albumin and phosphorus) were measured at the date of the second functional status assessment.

Statistical Methods

Statistical analysis was conducted in patients with no missing variables. We described the baseline characteristics of study patients according to groups of declining or not declining functional status score. The values were expressed as the mean and standard deviation (SD) for age, albumin, and phosphorus; median and interquartile range for years on dialysis; and median and range for baseline functional status score, number, and proportion for other categorical variables. We used the Kaplan-Meier method to estimate the cumulative incidence of any-cause death and evaluated differences with the log-rank test. To evaluate the association between the decline in functional status and all-cause mortality with adjustment for potential confounders, a Cox regression analysis was conducted, and the hazard ratio (HR) and 95% confidence interval (CI) were calculated. We drew log-log hazards curves to confirm the proportional hazard assumption. In primary analysis, we investigated the association of the dichotomous exposure of decline in functional status score as an independent variable adjusting for age, sex, body mass index, years on dialysis, smoking status, albumin, phosphorus, baseline functional status score, and comorbidities. For considering the cluster effects at the facility level, we used robust variance estimates. In secondary analysis, we categorized the dichotomous exposure as decline or no decline in at least 1 of the 13 tasks as an independent variable using the same model as in the primary analysis. In addition, we conducted three sensitivity analyses to confirm the robustness of our results. First, we censored the patients who died in the first 3 months at the time of their death to exclude those at imminent risk of death. Second, we adjusted measured confounders with propensity score calculated using a logistic regression model conditionally on the same confounding variables as the primary analysis. Third, for the patients with missing data in confounders, we conducted the multiple imputations for body mass index and smoking status, of which the numbers of missing were largest (n = 76), using the chained equation method.

All statistical analyses were conducted using STATA version 13.1 (StataCorp, College Station, TX).

Results

Baseline Characteristics

A total of 1,072 of the 2,520 patients were excluded due to the missing data in functional status in 2012. The proportions of patients with functional status score of <8, 8–9, 10–12, and 13 were 10.9%, 10.6%, 19.5%, and 59.0%, respectively. A total of 372 of the 1448 patients were also excluded because of no data at the second assessment of functional status in 2013. After excluding the patients who had baseline disability in their ADLs, 989 patients were included in the final analysis. Finally, 817 patients without missing data in functional status and confounding variables were included in the statistical analysis (Figure 1).

The baseline characteristics of study patients categorized by decline in functional status score are listed in Table 1. The mean (SD) age of the participants was 62.3 (11.9) years, with men comprising 64.8% of the cohort. The median (interquartile range) years on dialysis was 6.3 (2.8–12.3). Functional status was assessed over a median of 361 (339–378) days, with 197 of 989 (19.9%) patients demonstrating a decline in functional status score.

Decline in Functional Status Is Associated With Poor Survival

During the follow-up period (704 [642, 722] days), 44 of 817 (5.4%) patients died. Participants with a decline in functional status score had decreased survival compared with those who had no decrease in score ($P < 0.001$; Figure 2). Similarly, a decline in at least 1 of the 13 functional tasks was associated with decreased survival compared with no decline ($P < 0.001$; Figure 3).

Effects of Decline in Functional Status on Survival in Cox Proportional Hazards Regression Analysis

The incidence rate for mortality among those who experienced a decline in functional status was 2.2 per 100 person-years, compared with 7 per 100 person-years among those who did not experience a decline. After adjustment for demographics, years on dialysis, comorbidity, and baseline functional status, those who experienced a decline in functional status score were at a 2.68-fold (95% CI, 1.31- to 5.50-fold) greater risk of all-cause mortality compared with those who did not experience a decline (Table 2). The log-log hazards curves showed that the proportional hazards assumption was not violated (Supplemental Figure 1).

The incidence rate for mortality was 1.9 per 100 person-years among those with a decline of at least 1 of 13 functional tasks, compared with 7.4 per 100 person-years among those with no decline. After adjustment, those who had a decline of at least 1 of the 13 functional tasks were significantly associated with a 2.81-fold (95% CI, 1.25- to 6.33-fold) greater risk of mortality compared to those without a decline (Table 3).

Sensitivity Analyses

The censoring of those who died in the first 3 months of follow-up did not noticeably affect the estimates of these associations. The adjusted HRs and 95% CIs were consistent even when the propensity score was used to adjust for measured confounders. After multiple imputations, the results were consistent with those before multiple imputations.

Discussion

To our knowledge, this is the first cohort study of hemodialysis patients investigating the association between longitudinal change in patient-reported functional status and all-cause mortality. Among patients with end-stage renal disease treated with chronic hemodialysis who were free of ADL disabilities at baseline, 19.9% experienced a decline in functional status during 1-year observation. Our study findings demonstrate that decline in functional status was strongly associated with poor prognosis among patients treated with hemodialysis, independent of demographic, laboratory values, and comorbidities. Importantly, even after adjustment of baseline functional status, the decline in functional status still had a negative effect on survival in patients undergoing hemodialysis. These findings underscore the importance of regular monitoring of patient functional status and interventions to prevent deterioration in functional status over time.

The aging demographics poses challenges to health care systems caring for patients with end-stage renal disease treated with chronic dialysis in the United States, Europe, and in particular Japan.[14, 15] The aging demographic contributes to an increased burden of CKD and increasing prevalence of hemodialysis patients with poor functional status.[10] The only prior study investigating the trajectory of functional status before and after initiation of dialysis therapy was limited to elderly nursing home patients with end-stage renal disease.[3] Our study was consistent with results of the general DOPPS study population demonstrating that approximately 2 out of every 5 patients reported needing help with at least one ADL item at baseline.[10] The proportion of subjects with ADL dependence in our study was lower than that of elderly nursing home patients transitioning to dialysis, among whom 87% of the cohort experienced substantial decline in functional dependence within 1 year of dialysis initiation. In comparison, our study focused on ambulatory patients free of baseline ADL disabilities, among whom 20% experienced functional decline. The characteristics of the current study population are reflective of the broader dialysis population likely to benefit from potentially cost-effective, targeted interventions aimed at preserving functional status.

Poor physical functioning is a strong factor of unfavorable prognosis in patients with CKD treated with or without hemodialysis[16–19] and potentially modifiable by exercise interventions. Poor physical functioning at baseline, especially in the domains of impaired mobility and muscle weakness, is associated with an increased likelihood for ADL dependence in community-dwelling older adults.[20–22]

Exercise trials among patients living with CKD have demonstrated that mobility and muscle strength are amenable to structured physical activity interventions.[23–25] Recent findings from a multicenter randomized controlled trial of exercise in dialysis patients revealed that a home-based walking exercise program managed by the dialysis staff improved the physical functions such as walking ability and muscle strength compared with usual care.[25] High-intensity progressive resistance training, which was delivered during routine hemodialysis treatment sessions, also improved their muscle function, and compliance was high because it was delivered in a fully supervised setting.[26] These findings are supported by multiple systematic reviews and meta-analyses of exercise training studies among hemodialysis patients that demonstrate significant beneficial effects on exercise tolerance, walking ability, muscle strength, and quality of life in these populations.[23, 24, 27] Hence, encouragement for hemodialysis patients to participate in individualized exercise programs may prevent ADL dependence by helping maintain physical functioning.

Goal setting of habitual physical activity is known to be a key motivational factor critical for successful lifestyle interventions aimed at preventing ADL decline among sedentary populations. Patients on hemodialysis are substantially less active than the general healthy sedentary people,[28] and sedentary lifestyle is strongly associated with poor prognosis among hemodialysis patients.[29] We recently proposed 4,000 steps per nondialysis day as an initial minimum recommendation of physical activity for hemodialysis patients as a realistic and specific goal.[30] Kidney health providers regularly need to encourage patients requiring hemodialysis to undertake regular physical activity to prevent a deterioration of functional status over time.

This study had some limitations. First, the present multicenter study is limited by its relatively small sample size and observational design. This prevents any assumptions of causality that maintenance or improvement in functional status by an interventional approach improves prognosis, which would require a clinical trial investigating clinical outcomes over a long follow-up period. Second, our study was limited to Japanese patients on hemodialysis, thereby limiting the generalizability of our findings to the broader international hemodialysis population. Third, the relatively small amount of deaths during follow-up precludes any further granular analysis. The current study would be unsatisfactory due to the small sample size and/or the relative short observational duration.

In conclusion, the present study provides important evidence that a decline in functional status over 1 year is associated with an elevated risk of mortality among patients requiring hemodialysis, even after adjustment for multiple confounding variables. Our findings provide a strong basis for targeted interventions to prevent functional decline by highlighting the importance of maintaining functional status on improving survival in the hemodialysis population.

Practical Application

The current investigation tests the association of change in functional status over 1 year with all-cause mortality among patients on hemodialysis using data from J-DOPPS. Decline in functional status is strongly associated with poor prognosis among hemodialysis patients independent of potential confounders. These findings underscore the importance of interventions directed at preventing deterioration in functional status over time among patients with end-stage renal disease treated with hemodialysis.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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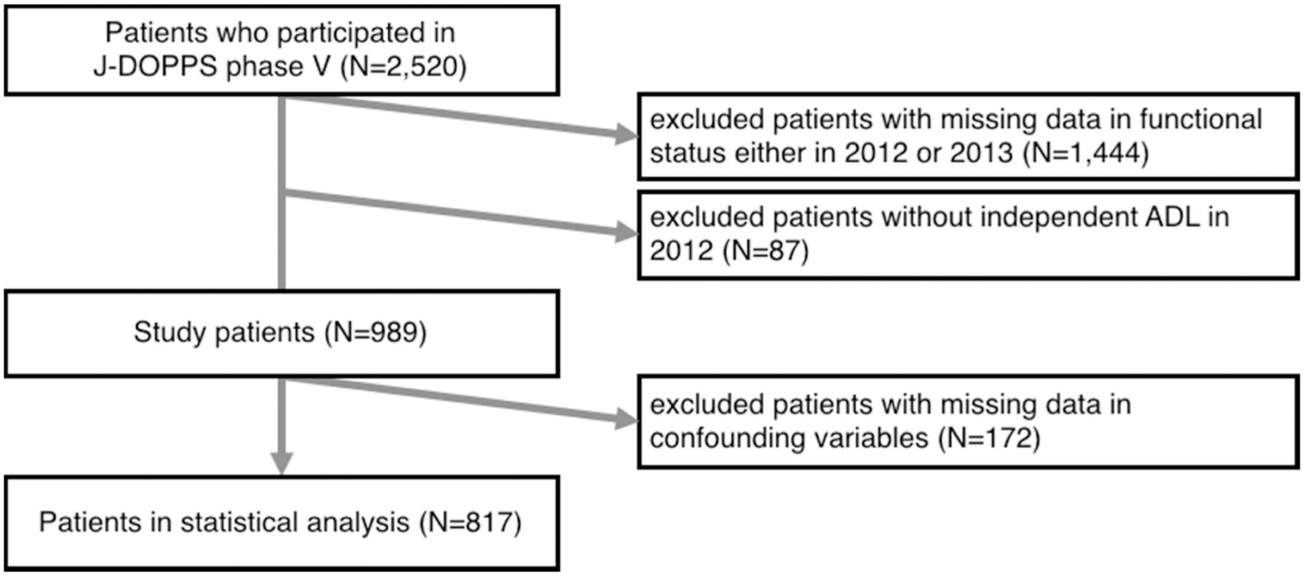

Figure 1.
Flowchart of Study Participants.

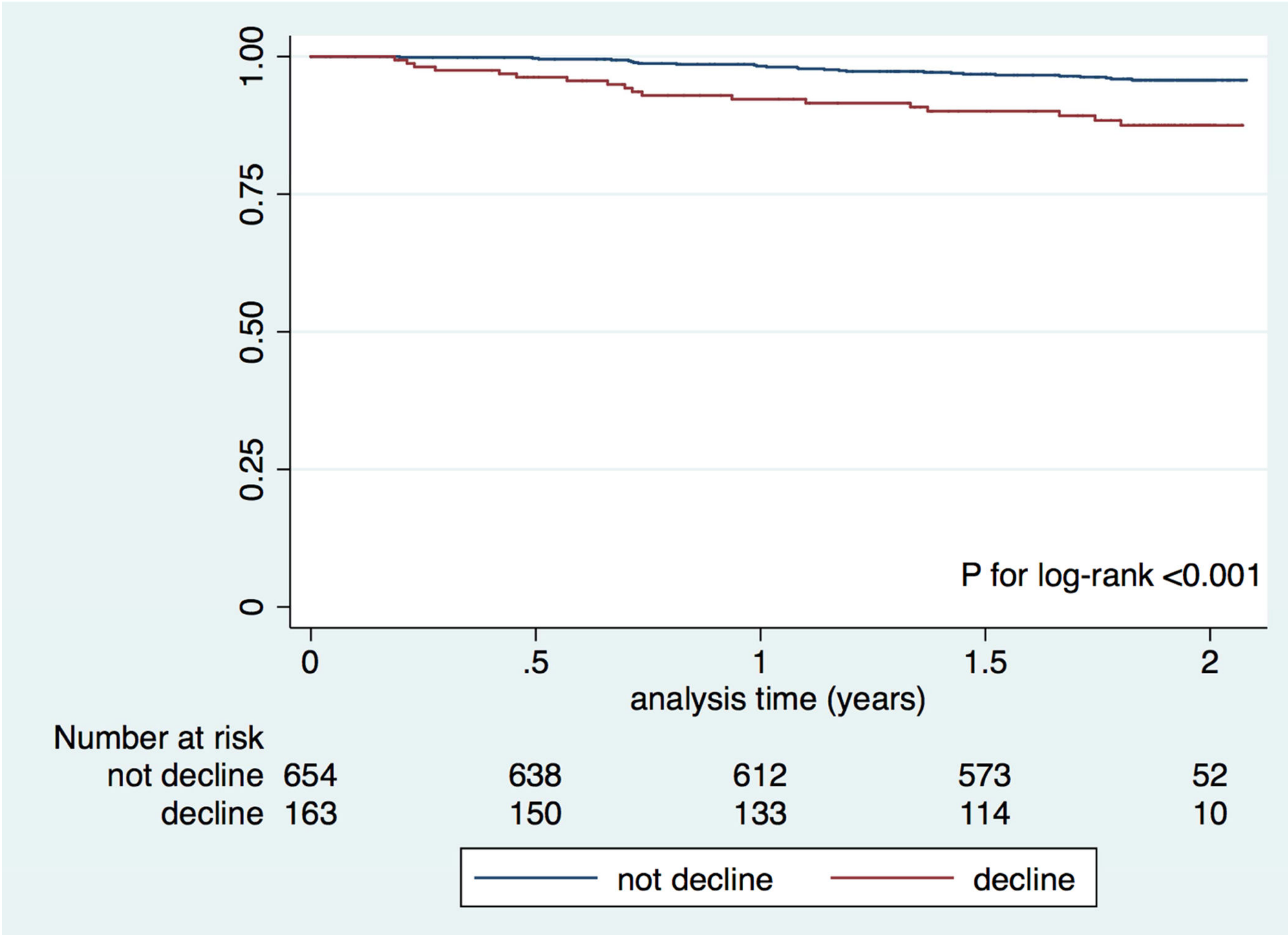

Figure 2.
Kaplan-Meier Survival Curve for Decline or No Decline in Functional Status Score.

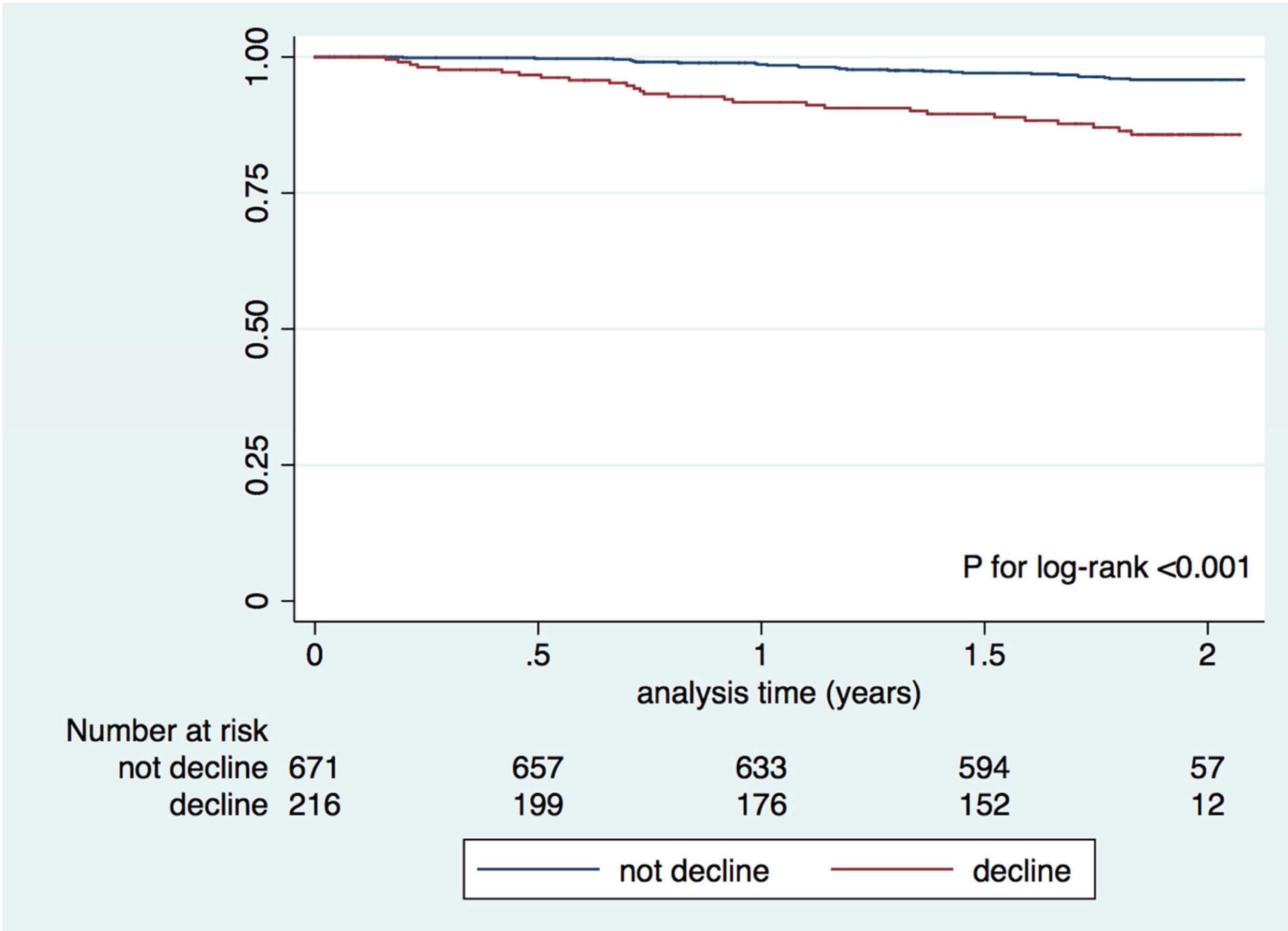

Figure 3.
Kaplan-Meier Survival Curve for Decline or No Decline in at Least 1 of the 13 Tasks in Functional Status.

Table 1.

Baseline Characteristics

	Total n=989	Not declined in functional status N=792	Declined in functional status N=197	Missing
Age, mean (SD)	62.3 (11.9)	61.6 (12.0)	65.2 (11.3)	
Male, number (%)	641 (64.8)	514 (64.9)	127 (64.5)	
Body Mass Index, mean (SD)	21.6 (3.7)	21.6 (3.6)	21.5 (4.1)	76
Years on dialysis, median [IQ range]	6.3 [2.8 – 12.3]	6.5 [3.0 – 12.7]	5.4 [2.6 – 11.1]	4
Smoke (ever), number (%)	278 (30.5)	224 (30.8)	54 (29.0)	76
Albumin (g/dL), mean (SD)	3.7 (0.4)	3.7 (0.4)	3.6 (0.5)	27
Phosphorus (mg/dL), mean (SD)	5.4 (1.3)	5.4 (1.3)	5.2 (1.3)	2
Functional status score in 2012, median [range]	13 [5 – 13]	13 [5 – 13]	12.5 [6 – 13]	
Comorbidities, number (%)				
Cardiovascular disease	204 (20.7)	158 (20.1)	46 (23.4)	4
Congestive heart disease	136 (13.8)	108 (13.7)	28 (14.2)	4
Cancer (nonskin)	92 (9.4)	76 (9.7)	16 (8.1)	5
Other cardiovascular diseases	180 (18.3)	138 (14.5)	42 (21.3)	3
Cerebrovascular diseases	69 (7.0)	49 (6.2)	20 (10.2)	2
Diabetes	347 (35.3)	253 (32.2)	94 (48.2)	7
Gastrointestinal bleeding	35 (3.6)	26 (3.3)	9 (4.6)	12
Hypertension	779 (79.3)	625 (79.6)	154 (78.2)	7
Lung disease	27 (2.7)	22 (2.8)	5 (2.5)	4
Neurologic disease	31 (3.1)	23 (2.9)	8 (4.1)	2
Psychiatric disorder	36 (3.7)	31 (3.9)	5 (2.5)	3
Peripheral vascular disease	107 (10.9)	77 (9.8)	30 (15.2)	4
Gangrene/recurrent cellulitis	21 (2.1)	14 (1.8)	7 (3.6)	5

SD, standard deviation.

Table 2.

Association between Decline in Functional Status Score and All-Cause Mortality

			All-cause mortality	
	N	Incidence rate[a]	Crude HR (95%CI)	Adjusted HR[b] (95%CI)
Functional status score				
No decline	654	2.2	Ref	ref
Decline	163	7.0	3.19 (1.75 – 5.82)	2.68 (1.31 – 5.50)

HR, hazard ratio; CI, confidence interval.

[a]Incidence rate per 100 person-years.

[b]Cox proportional hazards model with adjustment for age, sex, body mass index, years on dialysis, smoking status, albumin, phosphorus, baseline functional status score, and 13 comorbidities (listed in Table1).

Table 3.

Association between Decline in At Least 1 of the 13 Tasks in Functional Status Score and All-Cause Mortality

			All-cause mortality	
	N	**Incidence rate[a]**	**Crude HR (95%CI)**	**Adjusted HR[b] (95%CI)**
At least 1 of the 13 tasks in functional status				
No decline	630	1.9	ref	ref
Decline	187	7.4	3.87 (2.10 – 7.12)	2.81 (1.25 – 6.33)

HR, hazard ratio; CI, confidence interval.

[a] Incidence rate per 100 person-years.

[b] Cox proportional hazards model with adjustment for age, sex, body mass index, years on dialysis, smoking status, albumin, phosphorus, baseline functional status score, and 13 comorbidities (listed in Table1).