Renal Replacement Therapy

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Prognostic impact of KIHON checklist score in elderly patients with hemodialysis initiation

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Abstract

Background Frailty pervades the demographic of individuals afflicted by chronic kidney disease (CKD) and exhibits a robust correlation with a less favorable prognosis. Nonetheless, the evaluation and prognostication of frailty within the incipient stages of dialysis initiation remain shrouded in ambiguity. The necessity arises for an uncomplicated metric that holistically assesses frailty among aged CKD patients, one which lends itself to pragmatic clinical application.

Methods In our prospective endeavor, we conducted assessments using the "KIHON checklist (KCL)," a questionnaire comprising 25 points, thoughtfully crafted by the Japanese Ministry of Health, Labour and Welfare to provide a thorough evaluation of the elderly population. This assessment was administered at the commencement of hemodialysis in patients aged 65 years or older. Subsequently, we analyzed the prognostic ramifications of the initial KCL scores on the composite primary endpoint, which encompassed the undesirable outcomes of either being bedridden or succumbing to mortality.

Results A total of 24 patients (median age 76 years, 20 men) were included. The median KCL score was 6 [4, 10] points, and it was significantly correlated with the number of components in the revised Japanese Cardiovascular Health Study, which is a diagnostic criterion for frailty ($p < 0.05$). The group with a KCL score ≥ 10 points had a significantly lower 1-year freedom from the primary endpoints than the other group (43% versus 87%, $p < 0.05$). Among the components of the KCL, physical strength was significantly associated with the prognosis ($p < 0.05$).

Conclusion The screening protocol employing the KCL during the commencement of hemodialysis among elderly individuals proved to be a valuable tool for the anticipation of both the state of being bedridden and mortality.

Keywords Bedridden persons, Cardiovascular diseases, Chronic renal insufficiency, Frailty, Sarcopenia

Introduction

The number of patients initiating hemodialysis is increasing in Japan, especially among the elderly cohort [1]. The average age of patients starting hemodialysis was 71 years at the end of 2021 [2]. The quality of life of elderly patients deteriorates when they have multiple comorbidities including sarcopenia and malnutrition. Patients with end-stage renal disease (ESRD) often have these comorbidities, in addition to diabetes mellitus and osteoporosis [3, 4], resulting in progressive frailty [5]. Patients dependent on hemodialysis have higher mortality when frailty is present [6, 7]. Patients dependent on hemodialysis have as high as 58% of mortality and worsening activity of daily life (ADL) during 1-year hospice stay [8]. Patients' worsening activity increases the burden on medical staff and caregivers.

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The indication for aggressive hemodialysis in the elderly patients with chronic kidney disease (CKD) and other multiple comorbidities remains controversial. Some studies have highlighted the risk of death rather than those of ESRD in this cohort [9–11]. Others have denied the superiority of hemodialysis over medical therapy in this cohort [12, 13]. Thus, the prognostic impact of frailty on risk stratification and decision-making for hemodialysis therapy in this cohort is of great concern.

However, there is no established tool in the daily clinical practice to risk stratify patients' prognosis and guide to discuss the indication of hemodialysis in the elderly cohort. Scales should be easy to calculate, practical, and applicable to Japanese patients.

The Japanese government has published a "KIHON checklist (KCL)" to screen the patients who will require nursing care in the near future [14]. The KCL consists of 25 items (yes/no) divided into seven categories: activities of daily living, physical strength, nutrition, oral function, isolation, memory and mood; and the sum of all indices ranges from 0 (no frailty) to 25 (severe frailty); a higher score indicates worse functioning. KCL had a good correlation with other frailty scale and predicated mortality and/or ADL decline in elderly patients with various diseases in individuals of various countries [15–19]. However, prognostic impact of KCL score in patients with hemodialysis remains unknown. We hypothesized that KCL score could predict mortality and worsening ADL in the elderly patients initiating hemodialysis.

Materials and methods

Patient selection

Eligibility criteria encompassed patients aged 65 years or older who commenced hemodialysis at our facility during the period spanning from January 2020 to April 2022. Patients lacking baseline KCL data were subject to exclusion. The decision to initiate hemodialysis was made under the discernment of attending, board-certified nephrologists in adherence to the directives delineated by the Japanese Society for Dialysis Therapy [20]. Informed consents were obtained from all participants beforehand.

Evaluation of KCL and frailty

KCL was obtained at index discharge from hospitalization for the initiation of hemodialysis (Additional file 1: Table 1). KCL was defined as an independent variable in this study [21]. A revised Japanese version of the Cardiovascular Health Study (J-CHS) was also obtained in the same timing (Additional file 1: Table 2) [22]. In this criteria, patients satisfying 1–2 items were assigned to pre-frailty and those satisfying 3 or more items were assigned to frailty.

Other collected data

Baseline characteristics including demographics, comorbidity, and laboratory data were obtained during index hospitalization prior to the initial hemodialysis. Charlson comorbidity index was tabulated from medical record information as an indicator of overall complications [23]. Serum creatinine was measured by enzymatic method. Estimated glomerular filtration rate (eGFR) was calculated using GFR estimation formula for Japanese [24].

Primary endpoint

The primary endpoint was delineated as a composite outcome, encompassing both mortality and the state of being bedridden subsequent to the index discharge. For the purpose of this study, the day of the index discharge was deemed as day 0. The condition of being bedridden was characterized by the requisite for complete assistance in transitioning from the bed.

Statistical analysis

Continuous variables were articulated in terms of the median and interquartile range, while categorical variables were delineated by the number and corresponding percentage. To discern differences between the two groups, the Mann–Whitney *U* test was employed for the analysis of continuous variables, and Fischer's exact test was employed for the analysis of categorical variables.

Spearman test was applied to determine the relationship between KCL score and the number of frailty components of J-CHS. The association between KCL and other clinical characteristics was assessed by linear regression analysis. In this linear regression analysis, we included age, sex, comorbidities, and pre-existing medical conditions, as well as vitamin D use; body mass index as a physical index; albumin, cholesterol, and triglycerides as nutritional indices; hemoglobin, eGFR, and C-reactive protein as indicators of general status; and grip strength and walking speed as incorporated into the diagnostic criteria for frailty.

Receiver-operating characteristic curve was applied to determine the cutoff value of KCL for primary endpoint. Survival time analysis comparing the higher KCL score group with the lower was performed with log-rank test. The prognostic impact of KCL score upon the primary endpoint was assessed by Cox proportional hazard ratio regression model including age and sex. The likelihood ratio test was used to test the goodness of fit for the model.

Table 1 Baseline characteristics

Factor	All patients (*N* = 24)	Lower KCL (*N* = 17)	Higher KCL (*N* = 7)	*p* value
Demographics				
Age (years old)	76 [70, 78]	76 [69,78]	77 [71,80]	0.63
65—69 y.o (number, %)	4 (16.0)	5 (29.4)	2 (28.6)	
70—74 y.o (number, %)	3 (12.0)	2 (11.8)	1 (14.3)	
Over 75 y.o (number, %)	18 (72.0)	10 (58.8)	4 (57.1)	
Men (number, %)	20 (83.3)	13 (76.5)	7 (100)	0.28
Current smoke (number, %)	4 (17.4)	1 (6.2)	3 (42.9)	0.067
Body height (cm)	164 [159, 169]	164 [159, 167]	164 [156, 172]	0.78
Body weight (kg)	59.1 [52.6, 65.4]	56 [52.7, 65.0]	61.6 [55.6, 69.8]	0.59
Body mass index (kg/m^2)	22.0 [20.6, 24.4]	20.9 [20.4, 23.3]	23 [21.8, 25.8]	0.39
Systolic blood pressure (mmHg)	139 [119, 149]	142 [122, 152]	129 [116, 139]	0.22
Diastolic blood pressure (mmHg)	65 [58, 78]	68 [57, 85]	62 [58, 65]	0.28
Diagnosis				
Glomerulosclerosis (number, %)	12 (50.0)	9 (52.9)	3 (42.9)	0.13
Diabetic nephropathy (number, %)	6 (25.0)	5 (29.4)	1 (14.3)	
Chronic glomerulonephritis (number, %)	2 (8.3)	0 (0.0)	2 (28.6)	
Other (number, %)	4 (17.4)	3 (18.6)	1 (14.3)	
Comorbidity				
Diabetes mellitus (number, %)	9 (37.5)	7 (41.2)	2 (28.6)	0.67
History of cardiovascular disease (number, %)	16 (66.7)	12 (70.6)	4 (57.1)	0.65
History of bone fracture (number, %)	3 (12.5)	1 (5.9)	2 (28.6)	0.19
History of hospitalization for infectious disease (number, %)	5 (20.8)	2 (11.8)	3 (42.9)	0.13
History of malignancy (number, %)	5 (20.8)	4 (23.5)	1 (14.3)	1
Malignancy (number, %)	3 (12.5)	3 (17.6)	0 (0.0)	0.53
Charlson comorbidity index (point)	8 [7, 9]	8 [7, 8]	8 [6, 10]	0.72
Medication				
Angiotensin II receptor blocker (number, %)	13 (54.2)	9 (52.9)	4 (57.1)	1
Statin (number, %)	9 (37.5)	6 (35.3)	3 (42.9)	1
Insulin (number, %)	3 (12.5)	3 (17.6)	0 (0.0)	0.53
Vitamin D receptor agonist (number, %)	2 (8.3)	0 (0.0)	2 (28.6)	0.070
Laboratory				
Hemoglobin (g/dL)	9.5 [8.5, 9.9]	9.6 [8.4, 9.9]	9.4 [9.3, 9.9]	0.63
Total protein (g/dL)	5.9 [5.8, 6.7]	6 [5.9, 6.7]	5.8 [4.9, 6.7]	0.35
Albumin (g/dL)	3.2 [3.0, 3.5]	3.3 [3.0, 3.6]	3 [2.5, 3.2]	0.13
Serum urea nitrogen (mg/dL)	72.5 [53.9, 79.6]	73.0 [50.4, 81.6]	72.0 [59.7, 77.5]	0.78
eGFR (mL/min/1.73 m^2)	7.5 [5.5, 8.4]	7.5 [5.2, 8.4]	7.5 [7.0, 8.3]	0.57
C-reactive protein (mg/dL)	0.33 [0.15, 0.57]	0.25 [0.09, 0.38]	0.64 [0.40, 0.84]	0.045*
Triglyceride (mg/dL)	129 [79, 152]	121 [67, 145]	150 [94, 179]	0.33
Total cholesterol (mg/dL)	160 [146, 188]	6 [5.9, 6.7]	5.8 [4.9, 6.7]	0.35

Continuous variables are presented as median and interquartile. Categorical variables are presented as number and percentage. *$p < 0.05$ by Mann–Whitney U test for continuous variables and Fischer's exact test for categorical variables

Charlson comorbidity index is calculated from age, diabetes with diabetic complications, congestive heart failure, peripheral vascular disease, chronic pulmonary disease, mild and severe liver disease, hemiplegia, renal disease, leukemia, lymphoma, metastatic tumor and acquired immunodeficiency syndrome

y.o, years old; eGFR, estimated glomerular filtration rate; KCL, KIHON checklist

In all analyses, 2-tailed $p < 0.05$ was considered statistically significant. Analyses were performed using R software version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Baseline characteristics

A total of 59 patients started hemodialysis during the observation period. Ten patients aged under 65 years were excluded. One patient with bedridden at baseline were excluded. Five patients with lost follow-up were excluded. Both KCL and J-CHS were not obtained from 19 patients. Finally, we included 24 patients (Table 1).

Median age was 76 [70, 78] years and 18 (72%) had age over 75 years. Twelve patients (83%) were men. Median body mass index was 22.9 [20.6, 24.4] and 9 (38%) had diabetes mellitus. eGFR was 7.5 [5.5, 8.4] mL/min/1.73 m^2.

KCL score and frailty components of J-CHS

KCL and J-CHS were assessed 7 [2, 10] days after initial dialysis. Distribution of KCL score is displayed in Fig. 1A and detailed scores in each question are summarized in Table 2. A median value of KCL score was 6 [4, 10] points. Seventeen patients (71%) had 0–9 points and 7 patients (29%) had ≥ 10 points.

Distribution of the number of frailty components of J-CHS is displayed in Fig. 1B and detailed scores in each question are summarized in Table 2. A median value was 2 [1, 3] components. Three patients (13%) had 0 component (robust), 12 (50%) had 1–2 components (pre-frailty), and 9 (38%) had ≥ 3 components (frailty).

KCL score was significantly associated only with decreased gait speed and not with age, grip strength or other background factors (Table 3). KCL score and the number of frailty component of J-CHS showed a significant positive correlation ($r = 0.46$, $p = 0.024$).

Calculating cutoff of KCL score

Patients were followed for 429 [174, 623] days on median after the index discharge. During the observation period, 4 patients had bedridden. One patient had bedridden and died later due to chronic myelogenous leukemia. Another patient died due to circulatory failure. Thus, 6 patients (25%) achieved the primary endpoint. All primary endpoints were encountered during the first one year. The baseline age of patients who reached the primary endpoint ranged between 69 and 79 years old.

A cutoff of KCL score to best distinguish the primary endpoint was calculated as 10 points with sensitivity 0.67 and specificity 0.83 (area under the curve 0.722, 95% confidence interval 0.448–0.997. Figure 2). Patients were stratified into two groups: a lower group with KCL 0–9 points ($N = 17$) and a higher group with KCL ≥ 10 points ($N = 7$).

Patients' baseline characteristics were compared between the two groups (Table 1). A higher group tended to have higher prevalence of current smokers (43% versus 6%, $p = 0.067$). C-reactive protein was higher in the

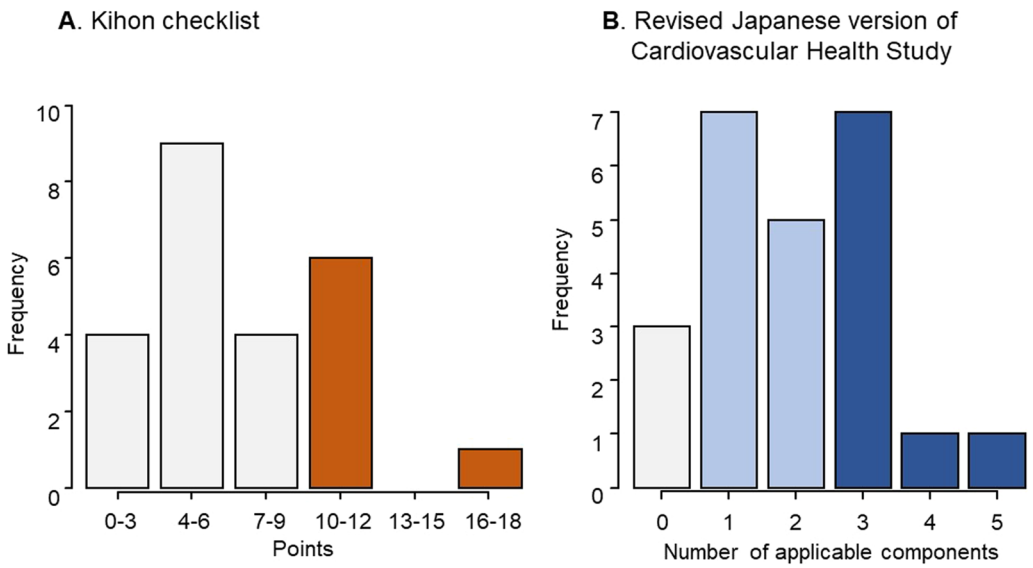

Fig. 1 Distribution of the KIHON checklist score (**A**) and applicable components of revised Japanese version of Cardiovascular Health Study (**B**). In (**A**), the red bars indicate patients with a KCL score of 10 points or higher. In (**B**), the light blue bars indicate patients who diagnosed as pre-frailty and the blue bars indicate patients who diagnosed as frailty. KCL, KIHON checklist

Table 2 Results of KIHON checklist score and revised Japanese version of the Cardiovascular Health Study criteria

Category of questions of KCL or component of J-CHS	Number (%) or Median [interquartile]
KIHON checklist	
Activities of daily living, Q1–5 (points)	1 [0, 2]
Physical strength, Q6–10 (points)	1 [1, 2]
Nutrition, Q11,12 (points)	0 [0, 0]
Oral function, Q13–15 (points)	1 [0, 1]
Isolation, Q16,17 (points)	0 [0, 1]
Memory, Q18–20 (points)	0 [0, 1]
Mood, Q21–25 (points)	2 [0, 3]
All questions, Q1–25 (points)	6 [4, 10]
Revised Japanese version of cardiovascular health study criteria	
Shrinking (number, %)	5 (20.8)
Weakness (number, %)	18 (75.0)
Grip strength, Men (kg)	20.5 [17.5, 28.0]
Grip strength, Women (kg)	13.5 [11.0, 14.5]
Exhaustion (number, %)	9 (37.5)
Slowness (number, %)	11 (45.8)
Gait speed (m/sec)	1.00 [0.76, 1.13]
Low activity (number, %)	4 (16.7)
Total number of frailty component	2 [1, 3]

KCL, KIHON checklist; J-CHS, revised Japanese version of the Cardiovascular Health Study criteria; Q, the question number of KIHON checklist

Table 3 Association between KIHON checklist and other clinical parameters

Factor	Beta value (95% confidence interval)	*p* value
Age	0.09 (−0.24 to 0.41)	0.58
Men	2.05 (−2.81 to 6.91)	0.39
Body mass index	−0.31 (−0.87 to 0.24)	0.25
Diabetes mellitus	−1.00 (−4.78 to 2.78)	0.59
History of cardiovascular disease	0.50 (−3.4 to 4.4)	0.79
History of bone fracture	3.48 (−1.88 to 8.83)	0.19
History of hospitalization for infectious disease	3.08 (−1.24 to 7.41)	0.15
History of malignancy	0.31 (−4.23 to 4.84)	0.89
Malignancy	−1.48 (−7.01 to 4.06)	0.59
Use of vitamin D receptor agonist	4.95 (−1.34 to 11.25)	0.12
Hemoglobin	−0.14 (−1.73 to 1.45)	0.86
Albumin	−2.55 (−5.7 to 0.59)	0.11
Estimated glomerular filtration rate	0.38 (−0.4 to 1.15)	0.32
C-reactive protein	2.38 (−1.09 to 5.85)	0.17
Total cholesterol	−0.01 (−0.06 to 0.05)	0.75
Triglyceride	0.00 (−0.04 to 0.03)	0.78
Grip strength	−0.13 (−0.32 to 0.07)	0.19
Gait speed	−5.45 (−10.43 to −0.47)	0.033*

*$p < 0.05$ by linear regression analysis

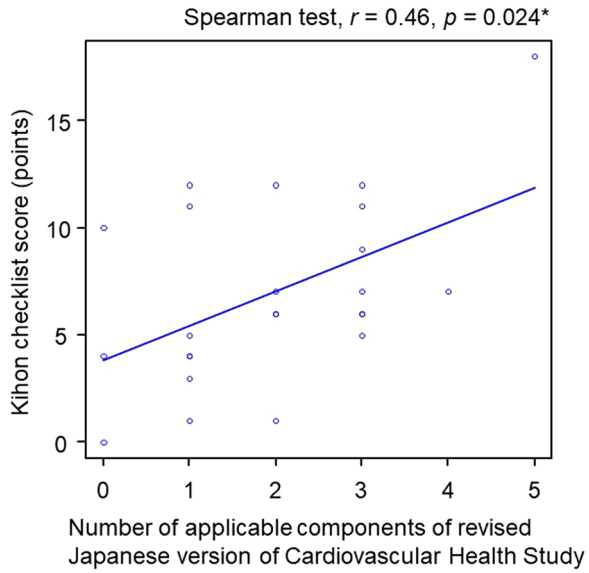

Fig. 2 Correlation between Kihon checklist score and number of applicable components of revised Japanese version of Cardiovascular Health Study. *p <0.05 by Spearman test

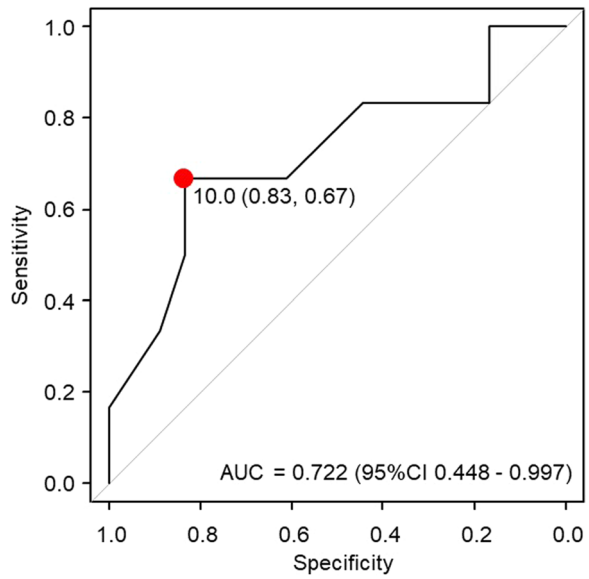

Fig. 3 Receiver-operating characteristic curve to determine the cutoff value of KIHON checklist for primary endpoint

higher group ($p=0.045$). There was no inter-group difference in the Charlson comorbidity index, consisting of the presence of cardiovascular disease, chronic organ disorder, autoimmune disease, and others.

Prognostic impact of KCL score upon primary endpoint

Among 7 patients assigned to the higher group, 4 patients had the primary endpoint. A 1-year freedom from the primary endpoint was significantly lower in the higher group than the lower group (43% versus 87%, $p=0.008$; Fig. 3).

A higher KCL score was independently associated with the primary endpoint with a hazard ratio of 6.41 (95% confidence interval 1.14–36.0, $p=0.035$), which was adjusted for age and sex (Table 4).

In this cohort, diagnosis of frailty by J-CHS was not associated with the primary endpoint. The prognostic impact of KCL score was also significant when it was assumed as continuous variable (adjusted hazard ratio 1.24, 95% confidence interval 1.01–1.53, $p=0.042$). Among each question of KCL, only a physical strength was significantly associated with the primary endpoint ($p=0.007$) (Fig. 4).

Discussion

In this investigation, we delved into the prognostic implications of the KCL score concerning mortality and bedridden status in elderly patients suffering from ESRD who embarked on hemodialysis. Our findings are as follows: (1) The baseline KCL score exhibited a considerable variance among patients with CKD commencing hemodialysis; (2) a discernible correlation was observed between the KCL score and the level of frailty, as assessed by the J-CHS scale; (3) a KCL score of ≥ 10 displayed a significant association with a heightened incidence of both mortality and the development of bedridden status following the initiation of hemodialysis.

Frailty in patients with CKD

Frailty, a reversible physiological decline in multiple body systems, is defined as a state of increased vulnerability to the stress that carries an increased risk of disability, functional decline, hospitalization and mortality in older adults, and is a precursor to the need for long-term care [25]. CKD has a significant association with frailty, due to uremic syndrome, chronic inflammation, malnutrition, and abnormal muscle metabolism [3]. Frailty has a negative prognostic impact in patients with any stage of CKD. Patients dependent on hemodialysis have more advanced frailty and a higher prevalence of frailty [4]. However, the prognostic impact of frailty in patients dependent on hemodialysis has not yet been well clarified so far, probably due to the complexity to quantifying the degree of frailty.

KCL to screen frailty

The CHS, which was originally proposed by Fried and colleagues, consists of weakness, slowness, fatigue, low activity, and weight loss, and is one of the practical tools to diagnose frailty [26, 27]. However, several procedures

Table 4 Prognostic impact of KIHON checklist or revised Japanese version of the Cardiovascular Health Study criteria upon the primary endpoint in elderly hemodialysis initiation patients

	Hazard ratio	95% Confidence interval	*p* value	*p* by Likelihood ratio test	Concordance index
KCL score, per 1 point	1.24	1.01–1.53	0.042*	0.07	0.790
KCL higher, 10–25 points (vs 0–9 points)	6.41	1.14–36.0	0.035*	0.06	0.803
Activities of daily living, Q1–5, per 1 point	1.60	0.98–2.61	0.063	0.1	0.798
Physical strength, Q6–10, per 1 point	2.71	1.30–5.63	0.007*	0.02*	0.824
Nutrition, Q11,12, per 1 point	2.83	0.68–11.7	0.15	0.2	0.676
Oral function, Q13–15, per 1 point	1.18	0.29–4.83	0.82	0.5	0.651
Isolation, Q16,17, per 1 point	1.58	0.45–5.56	0.48	0.4	0.697
Memory, Q18–20, per 1 point	1.38	0.55–3.44	0.50	0.4	0.710
Mood, Q21–25, per 1 point	1.14	0.67–1.94	0.63	0.4	0.735
Diagnose of frailty by J-CHS criteria (vs robust and pre-frail)	0.62	0.12–3.07	0.56	0.4	0.685

*$p < 0.05$ by Cox proportional hazard model adjusted by age and sex

KCL, Kihon checklist; J-CHS, revised Japanese version of the Cardiovascular Health Study; Q, the question number of KIHON checklist

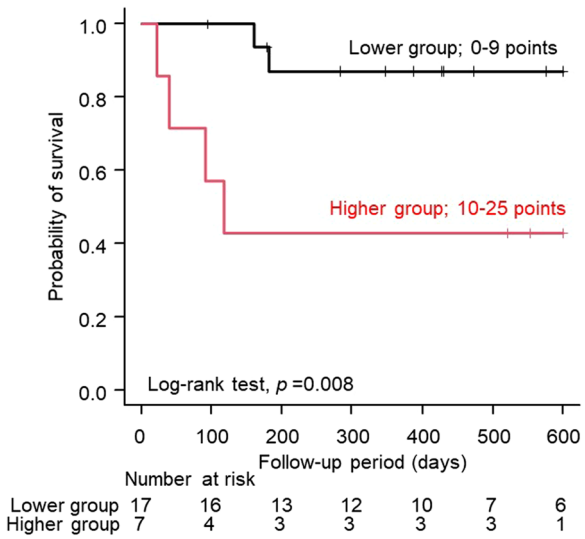

Fig. 4 Freedom from death and bedridden stratified by KIHON checklist score. *$p < 0.05$ by log-rank test. Patients were stratified at the cutoff 10 points of KIHON checklist score

are required to complete CHS, including grip test and gait speed, which are sometimes challenging to perform in busy clinics.

The KCL is a recently proposed tool to screen elderly patients who will need care in the near future. KCL consists of only a few closed-ended questions and is easy to complete [14]. KCL has a good correlation with J-CHS in the general elderly cohorts [28, 29]. Therefore, we preferred the KCL to the J-CHS to assess the degree of frailty in this study.

In a large study of the general elderly population, a KCL score of 8 was taken as a cutoff point [15]. On the other hand, some reported 13 points, so there is no settled opinion [17].

We consider that the KCL was related to gait speed because there were questions about the ability to walk and stand up, or the range of activities. On the other hand, there was no question on muscle strength, which is one of the diagnostic criteria for sarcopenia, suggesting that the screening for frailty or sarcopenia may be inadequate in this respect.

Prognostic impact of KCL score

There are several reports on the relationship between prognosis and indices used to assess elderly patients in the initiation phase of dialysis [8, 30–32]. For all measures, poorer scores were associated with worse prognosis. Some of these indices require testing of physical function, some are uniaxial (ADL only), and some include comorbidities in their assessment. The KCL appears to be superior in that it comprehensively assesses function in the elderly in seven categories and is easy to use, but the impact of clinical information that is not included on the accuracy of prognostic prediction should be considered.

Among several questions of the KCL, physical strength, which is one of the main components of sarcopenia, was dominantly associated with the primary endpoint. Sarcopenia is a syndrome characterized by progressive and generalized loss of skeletal muscle mass and strength with a risk of adverse outcomes such as physical disability, poor quality of life, and death. Sarcopenia plays a key role in frailty [33]. In patients with CKD, as in frailty, multifactorial effects lead to loss of muscle homeostasis and sarcopenia, which is directly associated with reduced

muscle strength, and indirectly with poorer quality of life, increased susceptibility to adverse outcomes such as falls, reduced independence, and ultimately higher rates of hospitalization and mortality [34]. The KCL also includes nutritional category. In our cohort, serum albumin tended to be lower in the group with higher KCL. The prognosis of hemodialysis patients has been shown to be significantly worse when hypoalbuminemia and decreased muscle mass are concomitantly present [35].

Clinical implication of KCL

We may estimate the incidence of death or bedridden in the near future despite hemodialysis therapy by using KCL, which can be easily calculated. KCL may be useful in shared decision-making among clinicians, patients, and their relatives and determining the indication of hemodialysis. Clinical implication of KCL-guided shared decision-making should be validated in the next study.

Limitations

This study is a proof-of-concept including a small sample size. The sample size may have been insufficient to demonstrate statistical significance in some of our analyses. The frailty is a reversible concept, and further studies are needed to investigate the trajectory of frailty after dialysis intervention. We assessed KCL just before index discharge, when hemodynamics was stable. Nevertheless, we cannot complexly deny the vulnerability of data. Body weight can be increased soon after the initiation of hemodialysis, and the body weight loss as a sign of progressive frailty may have been masked. It is possible that the improvement in uremia with dialysis also affected the KCL. Attempts to improve KCL score in patients with end-stage renal failure and prognosis is a subject for further study. The cutoff for KCL remains also debatable.

Conclusions

The employment of the KIHON checklist for screening during the commencement of hemodialysis in elderly patients demonstrated its utility in forecasting both bedridden status and mortality after the initiation of hemodialysis. The clinical implication of KCL-guided management remains the next concern.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s41100-024-00519-1.

Additional file 1: Table 1. KIHON checklist. **Table 2.** Revised Japanese version of the Cardiovascular Health Study criteria.

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Author contributions
HF treated patients, collected and analyzed data, and wrote the paper; TI designed the study and wrote the paper; SY, SM, KKa, and HY treated patients; TK and KKi were supervisors. Each author contributed important intellectual content during manuscript drafting and revision, agreed to be personally accountable for the individual's contributions, and to ensure questions about the accuracy or integrity of any portion of the work, even one in which the author was not directly involved, are appropriately investigated and resolved. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
This study was approved by our institutional review board (IRB approval number 27-162) and carried out following the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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