ORIGINAL ARTICLE

Comparison between FRAIL Scale and Clinical Frailty Scale in predicting hospitalization in hemodialysis patients

Elisabete Mouzinho Soares Barbosa[1] · Amanda Gomes Pereira[1] · Vitória Mori[1] · Renan da Silva Neves[1] ·
Nayane Maria Vieira[1] · Maryanne Zilli Canedo Silva[1] · Marcos Mitsuo Seki[1] · Hellen Christina Neves Rodrigues[2] ·
Nara Aline Costa[2] · Daniela Ponce[1] · André Luís Balbi[1] · Leonardo Antonio Mamede Zornoff[1] ·
Paula Schmidt Azevedo[1] · Bertha Furlan Polegato[1] · Sérgio Alberto Rupp de Paiva[1] · Marcos Ferreira Minicucci[1] ·
Mariana de Souza Dorna[1]

Abstract

Background To assess the prevalence of frailty by the Clinical Frailty Scale (CFS) and the 5-item FRAIL scale and their association with hospitalization in hemodialysis (HD) patients.

Methods This was a prospective observational study. We included patients of both genders ≥ 18 years old in HD treatment for at least 3 months. Demographic, clinical, and routine laboratory data were retrieved from the medical charts. Two different frailty assessment tools were used, the CFS and the FRAIL scale. Participants were followed up for 9 months and hospitalizations for all causes were evaluated. A Venn diagram was constructed to show the overlap of possible frailty and pre-frailty. Cox regression was used to identify the association between frailty and hospitalization. The significance level was 5%.

Results A total of 137 subjects were included in the analysis. The median age was 61 (52–67) years and 60% were male. The hospitalization rate and mortality in 9 months were 22.6% and 7.29%, respectively. Regarding frailty, the overall prevalence was 13.8% assessed by CFS and 36.5% according to the FRAIL scale. In the Cox regression, frailty by FRAIL scale was associated with a 2.8-fold increase in the risk of hospitalization (OR = 2.880; 95% CI = 1.361–6.096; $p = 0.006$), but frailty assessed by the CFS was not associated with the need for hospitalization.

Conclusion In HD patients, the FRAIL scale proved to be an easy-to-apply tool, identifying a high prevalence of frailty and being a predictor of hospital admission.
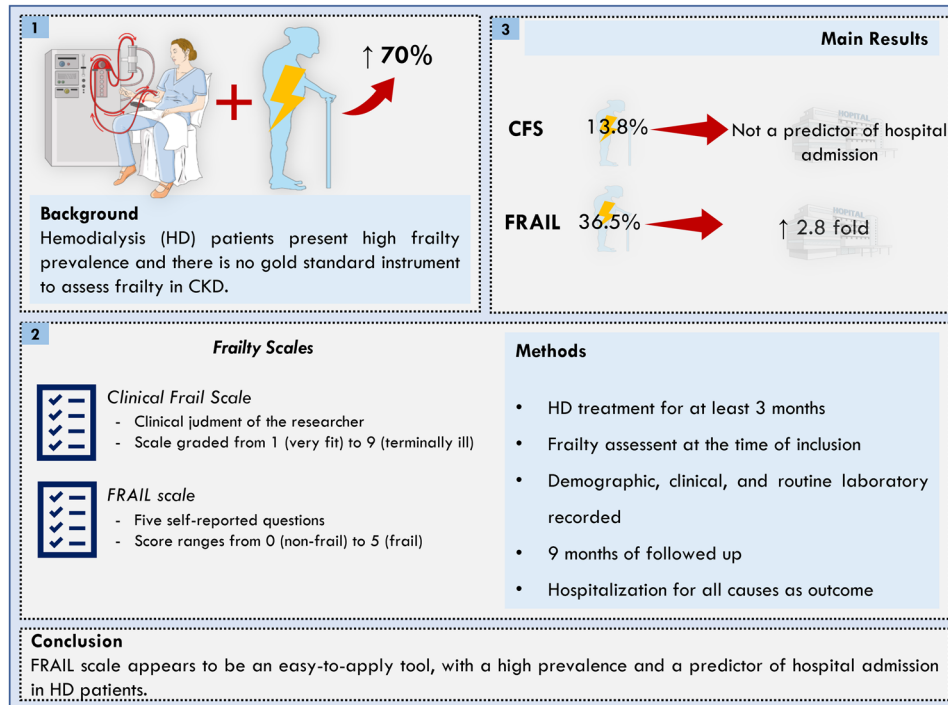
✉ Nara Aline Costa
naracosta@ufg.br

1 Department of Internal Medicine, Botucatu Medical School, São Paulo State University (UNESP), Botucatu, São Paulo, Brazil

2 Faculty of Nutrition, Universidade Federal de Goiás (UFG), Street 227 Block 68 s/n, East University Sector, Goiânia, Goiás 74605-080, Brazil

Graphical abstract

Keywords Frailty · Scales · Hemodialysis · Hospitalization

Introduction

Frailty is a complex syndrome clinically defining a state of physiological decline associated with marked vulnerability to stressors [1]. The prevalence of frailty in community-dwelling older people varies from 4 to 59% [2], whereas its occurrence in hemodialysis (HD) patients can be over 70% and is associated with adverse clinical outcomes [3–8].

Comprehensive geriatric assessment (CGA) is a reference method in the evaluation of frailty, but it is complex and requires multidisciplinary assessment [9]. Several frailty assessment tools were developed from the CGA, phenotypical frailty model, and accumulation of deficits model [10, 11]. In chronic kidney disease (CKD) patients, two scales have gained attention for their easy application, modality of assessment (self-reported or scored by the evaluator), and associations with outcomes. The Clinical Frail Scale (CFS) [12] is a tool that summarizes the overall level of fitness or frailty of older people and appears to be a good predictor of mortality in dialysis [13] and pre-dialysis patients [14]. Additionally, the 5-item FRAIL scale [15] (fatigue, resistance, ambulation, illnesses, and loss of weight) is also a valid and reliable tool in HD patients and has been shown to be a better frailty metric when compared to other tools [16].

Considering the aging of the population and the association of frailty with adverse outcomes, reducing frailty is a promising therapeutic target. However, there is still no consensus on a standard instrument to identify frailty in different populations, including dialysis patients. Moreover, it is unknown whether contrasting frailty favors kidney function and overall health [17]. Thus, considering the disagreement between the frailty scores tools, this study aimed to assess the prevalence of frailty by the CFS and the FRAIL scale and their association with all-cause hospitalization in patients undergoing HD.

Methods

Study design and setting

This was a prospective, observational, and longitudinal study that evaluated maintenance HD patients from the dialysis unit of Hospital of Clinics at the UNESP Botucatu Medical School (Botucatu, São Paulo, Brazil) between August 2019 and July 2020. This study was approved by the Ethics Committee of our Institution

(CAAE12287319.0.0000.5411), and written informed consent was obtained from all patients. Convenience sampling was applied considering the total number of patients attending the dialysis unit over the study period.

Participants

We included patients of both genders ≥ 18 years old with stage 5 CKD in HD treatment for at least 3 months. The exclusion criteria were age < 18 years old, neoplasia and liver disease, previous diagnosis of immunological diseases, transplantation, psychiatric disorders, clinical signs of kidney infection, infection by SARS-CoV-2 virus, pregnancy, refusal to participate, no follow-up, and missing data.

Stage 5 CKD was defined based on a glomerular filtration rate (GFR) ≤ 15 mL/min/1.73 m^2 using the basal filtration rate value and the creatinine concentration, in accordance with the CKD Epidemiology Collaboration (CKD-EPI). Etiology of CKD was based on the assessment of the nephrologist. The treatment modality used for all patients was conventional HD (performed 3 times a week, 4-h session) and with high-flux membranes (300–400mL/min). Participants were followed up for 9 months, and the prevalence of frailty and hospitalization for all causes was evaluated.

Clinical and biochemical data

All patients were evaluated for frailty at the time of inclusion in the study. Demographic, clinical, and routine laboratory data were retrieved from the medical charts. Blood samples were collected after the mid-week dialysis session. The results up to a maximum of 2 weeks before the time of patient inclusion in the study were analyzed.
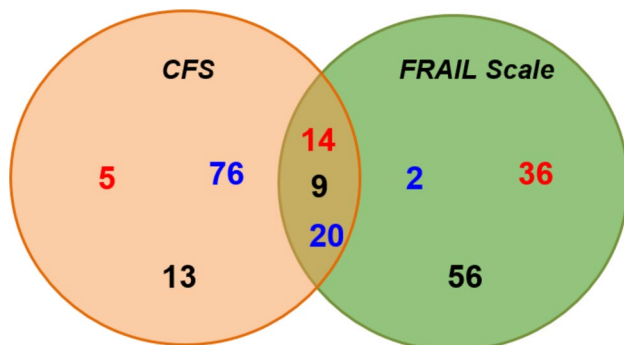
Fig. 1 Venn diagram showing the overlap of possible diagnosis of frailty and pre-fragile according to CFS and FRAIL scale. In red, are patients diagnosed with frailty; in black, pre-fragile patients; in blue, non-frail patients. The intersection of the circles represents patients who received the same diagnosis by CFS and FRAIL scale. *CFS* clinical Frail Scale, *FRAIL* Fatigue, Resistance, Ambulation, Illnesses, and Loss of Weight

Frailty assessment

Two different frailty assessment tools were used: CFS [12] and FRAIL scale [15]. The scales were applied by two trained evaluators.

The CFS is a global measure of frailty based on the clinical judgment of the researcher using available clinical information. The scale is graded from 1 to 9 (1, very fit; 2, well; 3, managing well; 4, vulnerable; 5, mildly frail; 6, moderately frail; 7, severely frail; 8, very severely frail and 9, terminally ill). Classification was considered "non-frail" for a CFS score of 1–3; "pre-frail" for a CFS score of 4, and "frail" for a CFS score of ≥ 5 [12].

The FRAIL scale includes five self-reported questions: Do you feel fatigued? Can you climb a flight of stairs? Can you walk a block without stopping? Do you follow up or treat more than 5 diseases? In the last 6 months, have you unintentionally lost 5% or more of your body weight? Patients were approached during the dialysis session and when they did not present acceptable cognitive conditions, their caregiver was consulted. The score ranges from 0 to 5 points, and each component of the assessment is worth one point. Individuals were classified as "non-frail" (score 0), "pre-frail" (score 1–2), and "frail" (score 3–5) [15].

Statistical analyses

Data are expressed as mean ± SD, median (including lower and upper quartiles), or percentages. Statistical comparisons between groups for continuous variables were performed using Student's t tests for normally distributed parameters and the Mann–Whitney test for non-normally distributed parameters. Fisher's exact test or the Chi-square test were used for all categorical data.

Venn diagrams were constructed to describe the overlap of possible frailty and pre-frailty assessment criteria using R® version R-4.1.2.tar.gz. Cox regression was used to identify the association between frailty according to the scales and hospitalization for all causes. Model 1 adjusted for variables that yielded $p < 0.2$ in univariate analysis (HD vintage, Kt/V, BMI, and etiology of CKD). Model 2 adjusted for age, sex, and variables that yielded $p < 0.2$ (except mortality) in univariate analysis. Data analyses were performed using SigmaPlot software for Windows v12.0 (Systat Software Inc., San Jose, CA, USA). The significance level was 5%.

Results

Overall, 151 consecutive patients met the inclusion criteria. However, 13 patients were excluded due to positive tests for SARS-CoV-2, and one patient was excluded due to a

Table 1 Clinical and laboratory characteristics of patients considered frail according to each scale

Variables	Frailty		*p* value	Frailty		*p* value
	CFS			FRAIL Scale		
	Yes (*n* = 19)	No (*n* = 118)		Yes (*n* = 50)	No (*n* = 87)	
Age (yrs)	65 (5–77)	59.5 (51–62.5)	**0.018**	63 (54.7–70.2)	60 (51–66)	0.117
Male, *n* (%)	8 (42.1)	74 (62.7)	0.147	25 (50)	25 (50)	0.109
HD time (mo)	44 (13–90)	25 (8.7–55)	0.114	31 (11–56)	31 (7–65)	0.593
Kt/*V*	1.48 ± 0.25	1.42 ± 0.26	0.360	1.58 ± 0.27	1.39 ± 0.24	**0.009**
Etiology of CKD						
Diabetes, *n* (%)	13 (68.4)	51 (43.2)	0.073	31 (62)	33 (37.9)	**0.011**
Hypertension, *n* (%)	17 (89.4)	109 (92.3)	0.981	47 (94)	79 (90.8)	0.737
BMI (kg/m^2)	25.1 (22.4–29.9)	26.8 (22.9–29.7)	0.413	26.0 (22.8–30.3)	26.8 (22.9–29.5)	0.874
Smoker, *n* (%)	1 (5.2)	13 (11)	0.719	1 (2)	13 (14)	**0.034**
Laboratory data						
CRP (mg/dL)	1.3 (0.7–3.0)	0.8 (0.5–1.4)	**0.017**	0.9 (0.5–1.3)	0.8 (0.5–1.3)	0.125
Albumin (g/dL)	3.8 (3.6–4.1)	4.0 (3.7–4.2)	0.329	3.8 (3.6–4.1)	4.0 (3.7–4.2)	**0.030**
Urea (mg/dL)	116 (99–131)	119 (101.5–138.7)	0.468	119 (100.7–142.2)	118 (100–138)	0.794
Creatinine (mg/dL)	9.5 ± 2.6	8.6 ± 2.6	0.200	8.8 ± 2.6	9.7 ± 2.6	0.067
Phosphorus (mg/dL)	5.2 (4.5–6.3)	5 (4.2–6.8)	0.713	5.1 (4.6–6.3)	5.3 (4.4–6.3)	0.705
Mortality, *n* (%)	2 (10.5)	8 (6.7)	0.914	4 (8)	6 (6.8)	0.919

Data are expressed as median (including lower and upper quartiles), percentage, or means ± standard deviation. Student's *t*, Mann–Whitney, Chi-squared, or Fisher's tests were performed. Values lower than 0.05 were considered statistically significant

CFS Clinical Frail Scale, *FRAIL* Fatigue, Resistance, Ambulation, Illnesses, and Loss of weight, *HD* hemodialysis, *CKD* chronic kidney disease, *BMI* body mass index, *CRP* C-Reactive protein

Table 2 Association of frailty and hospitalization according to the CFS and FRAIL scale

Variables	All-cause hospitalization		*p* value
	Yes, *n* = 31	No, *n* = 106	
CFS scale	3 (3–4)	3 (2–4)	0.056
Frailty, *n* (%)	5.0 (16.1)	14.0 (13.2)	0.906
Pre-fragile, *n* (%)	8.0 (25.8)	14.0 (13.2)	0.161
Frailty + pre-fragile, *n* (%)	13.0 (41.9)	27.0 (25.5)	0.121
FRAIL scale	3 (2–4)	2 (1–3)	**0.010**
Frailty, *n* (%)	17.0 (54.8)	33.0 (31.0)	**0.028**
Pre-fragile, *n* (%)	14.0 (45.2)	51.0 (48.1)	0.932
Frailty + pre-fragile, *n* (%)	31.0 (100)	84.0 (79.2)	**0.013**

Data are expressed as median (including lower and upper quartiles) and percentage. Mann–Whitney, Chi-squared, or Fisher's tests were performed. Values lower than 0.05 were considered statistically significant

CFS Clinical Frail Scale, *FRAIL* Fatigue, Resistance, Ambulation, Illnesses, and Loss of Weight

Table 3 Cox regression model of frailty-associated hospitalization according to the CFS and FRAIL scale in hemodialysis patients

	HR	95% CI	*p* value
CFS scale—frailty			
Crude model	1.253	0.481–3.264	0.644
Model 1	1.403	0.529–3.719	0.496
Model 2	1.211	0.429–3.423	0.718
FRAIL scale—frailty			
Crude model	2.276	1.122–4.620	**0.023**
Model 1	2.930	1.409–6.092	**0.004**
Model 2	2.880	1.361–6.096	**0.006**

Model 1: adjusted for variables that presented p < 0.2 in univariate analysis; Model 2: adjusted for age, sex and variables that presented p < 0.2 in univariate analysis

CFS Clinical Frail Scale, *FRAIL* Fatigue, Resistance, Ambulation, Illnesses, and Loss of Weight

lack of follow-up. Therefore, a total of 137 subjects were included in the analysis. The median age was 61 (52–67) years and 60% were male. At baseline, the patients' mean GFR was 5.69 ± 2.76 mL/min/1.73 m^2. The hospitalization rate and mortality in the 9 months of the study period were 22.6% and 7.29%, respectively. The mean follow-up time until hospitalization or death was 122.6 ± 76.4 days. The main causes of hospitalization were cardiovascular events (22.5%), sepsis or septic shock (12.9%), peripheral arterial disease (12.9%), gastrointestinal disorders (12.9%), bloodstream infections (9.6%), and other causes (29.2%).

The demographic and clinical data of the patients undergoing HD are presented in Supplementary Table 1. The patients who needed hospitalization had lower Kt/V and

higher mortality. There were no differences in the other variables analyzed.

Regarding frailty, the overall prevalence was 13.8% ($n=19$) assessed by CFS and 36.5% ($n=50$) according to the FRAIL scale. In addition, pre-frailty was very common among the evaluated patients, corresponding to 16.0% (CFS) and 47.4% (FRAIL scale). Figure 1 shows the Venn diagram with the overlap of possible diagnosis of frailty and pre-frailty according to the CFS and FRAIL scale. The prevalence of frailty and pre-frailty was higher with the FRAIL scale when compared to the CFS. Fourteen individuals presented frailty and nine presented pre-frailty by the 2 tools simultaneously. Table 1 shows the clinical and laboratory characteristics of patients considered frail according to each scale. Frail patients according to CFS were older and had a higher serum CRP concentration compared to non-frail patients. According to the FRAIL scale, frail patients had a higher Kt/V value, were non-smokers, and had a lower serum albumin concentration.

Table 2 shows the association between frailty and hospitalization according to the CFS and FRAIL scale. Patients who needed hospitalization had a higher FRAIL scale score when compared to those who did not progress to hospital admission. Frailty assessed by the FRAIL scale was associated with hospitalization for all causes, but the same result was not observed when considering the CFS. According to the FRAIL scale, when frailty and pre-frailty were analyzed concomitantly, 100% of the individuals were hospitalized. With CFS, the need for hospitalization was observed in 41.9% of the patients and there was no statistically significant difference.

In Cox regression, frailty according to the FRAIL scale was associated with a 2.8-fold increase in the risk of hospitalization (HR $=2.880$; 95% CI $=1.361$–6.096; $p=0.006$), after adjustment for age, sex, and variables that yielded $p<0.2$ in univariate analysis. Frailty assessed by the CFS was not associated with the need for hospitalization in either the crude model or the adjusted models (Table 3).

Discussion

This study aimed to evaluate the prevalence of frailty by the CFS and FRAIL scale and their association with hospitalization in patients undergoing HD during the 9 months of follow-up. Frailty diagnosis was about 2.6 times higher when the FRAIL scale was used, as compared to CFS. Also, frailty determined by the FRAIL scale was associated with hospitalization for all causes.

Commonly, frailty is referred to as a geriatric syndrome, as it is usually present in the ≥ 65 age group. However, it is important to highlight that HD patients have additional health issues, such as multiple comorbidities, decreased physiologic reserve, and CKD itself, all of which can lead to frailty development regardless of age. Frailty is highly prevalent in dialysis-dependent patients. It is reported that around 71% of dialysis patients over 65 years of age are classified as "older people living with frailty", whereas frailty can be diagnosed in 47% of dialysis patients aged 65 or less (differing according to the assessments used) [18]. Not unexpectedly, our overall population was considerably younger (average age of 61 years) and there was no difference between older people living with or without frailty with regard to age when the FRAIL scale was used. In contrast, when we applied the CFS, frailty was detected mostly in older patients. However, we did not observe any difference between age and duration of HD when considering frailty by the FRAIL scale. This can be attributed to the self-perception of weariness and the presence of chronic diseases, even among younger people and with shorter duration of treatment. It is important to note that the scales were developed with the same purpose (to assess frailty); however, they are different tools. FRAIL is a self-reported tool and CFS is a clinical judgment-based scale. Thus, the lack of association between age, HD time and frailty by the FRAIL scale is understandable. Additionally, significant differences in some baseline variables differed according to the tool employed. The higher Kt/V in frail individuals should not be directly associated with frailty itself, but it may reflect a previous metabolic imbalance (and therefore the highest dose of dialysis prescribed), or be the effect of malnutrition, which contributed to the need for hospitalization during the follow-up period. On average, the patients' Kt/V was above 1.4, regardless of the presence of frailty and the tool used, confirming that all patients reached the minimum recommended dialysis dose. In addition, the main causes of hospitalization were cardiovascular events, sepsis or septic shock, common conditions in dialysis patients. This suggests that different scales identify different phenotypes of frail patients.

Currently, there are at least 67 different ways to define and measure frailty [19]. The widest definition used is the physical frailty phenotype (PFP) proposed by Fried et al., which is associated with morbidity and mortality in several clinical settings, including HD patients [10, 19]. The PFP classification is based on the presence of three or more frailty domains: unintentional weight loss, weakness, exhaustion, slowness, and low physical activity level, and is considered a standard reference method [20]. However, assessment of its components is not always feasible in the clinical practice or in large epidemiological studies due to the need for specific tools, such as a dynamometer, and of considerable time and space to assess gait speed [21]. Alternatively, the CFS and FRAIL scales are valid instruments for frailty screening that require fewer resources and are less time-consuming.

The CFS was developed by the Canadian Study of Health and Aging and combines clinical judgment with objective measurement [12]. It can be applied in several clinical settings and considers broad frailty domains, including comorbidity, function, and cognition. The FRAIL scale [15] is an easy and short-duration 5-item screening questionnaire that can be self-administered, with a good prediction for outcomes [22].

In this study, we showed that diagnosis of frailty by the FRAIL scale is associated with a 2.8-fold increase in the risk for hospitalization during the follow-up period (9 months). In contrast, HD patients defined as living with frailty according to CFS were less likely to have hospital admission. To date, only a few studies have measured frailty by the FRAIL scale in the HD population.

In a small cohort of rural Chinese subjects undergoing chronic dialysis, the FRAIL scale demonstrated a good correlation with several clinical parameters, such as age, presence of comorbidities, and dialysis complications, better than the other six types of established self-report questionnaires (Strawbridge questionnaire, Edmonton Frail Scale, simple FRAIL scale, Groningen Frail Indicator, G8 questionnaire, and Tilburg Frail Indicator), although outcomes such as mortality or hospitalization were not assessed [16]. Additionally, another observational study [23] showed that frailty identified by the FRAIL scale was associated with an increased risk of hospitalization in adults treated with any dialysis modality (peritoneal dialysis, intermittent HD, or home HD). Also, the risk of death did not differ by frailty status, as observed in our study. However, patients living with frailty in this cohort had a mean age of over 65 and the study follow-up lasted 18 months, which was longer than ours.

The CFS has been extensively used to detect frailty and its association with diverse outcomes among dialysis patients [13, 23–27]. The available studies with CFS are heterogeneous regarding study design, type of dialysis (peritoneal or HD), ethnicity, follow-up time, time of dialysis start, and patients' age. Despite this, the CFS seems to perform well screening HD patients for frailty, presenting a strong association with outcomes, such as mortality [13, 28], comorbidity [27, 28], physical activity and muscle mass and strength [26–28], but none of these studies assessed hospital admissions in this context.

Unfortunately, frailty is very difficult to reverse, and its development is inherent to aging and comorbidity. However, early recognition of vulnerability can possibly improve the patient's prognosis, reducing also healthcare costs. Particularly in the CKD population, multiple hospitalizations can lead to poor quality of life, worse treatment response, and decrease in survival [29].

A previous study performed in our dialysis unit showed that 36.7% of individuals were considered frail before kidney transplantation and, of these, more than 90% were on HD. Furthermore, the risk of surgical complications was significantly higher among individuals living with frailty (RR = 2.14; 95% CI = 1.01–4.54; $p = 0.035$) [29].

Kidney transplantation could lead to an improvement in frailty in patients with CKD. In keeping with this statement, in a recent observational study Mantovani et al. [30] reported a significant reduction of frail individuals (15.6–4.5%) 12 months after kidney transplantation. Such findings reinforce the need to evaluate frailty longitudinally and at different stages of CKD.

The present study has some limitations that need to be considered. We collected data from a single center, the sample size is relatively limited, and the follow-up time was relatively short. However, it included 90.7% of patients undergoing HD at our center. These limitations are enhanced by the difficulty in collecting data and monitoring patients during the Covid-19 pandemic. However, this study reports on the first application of two different measures of frailty in predicting hospitalizations, an important outcome in patients on HD.

In conclusion, the identification of frailty using the FRAIL scale appears to be an easy-to-apply tool, revealing a high prevalence of frailty in HD patients, and is a predictor of hospital admission in HD patients.

Declarations

Conflict of interest None of the authors has any conflict to declare related to the present study.

Ethical approval All procedures used in this study adhere to the tenets of the Declaration of Helsinki. Approval was granted by the Ethics Committee of São Paulo State University (UNESP), Botucatu, São Paulo, Brazil (CAAE12287319.0.0000.5411). Written informed consent was obtained from all patients.

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