The 11-item modified frailty index (mFI-11) as a tool to predict mortality in older patients on chronic hemodialysis

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Abstract

Objective: To analyze the 11-item modified frailty index (mFI-11) as a predictor of mortality among older adults on chronic hemodialysis. *Method:* A prospective observational study conducted in dialysis units in the municipality of Niterói (RJ, Brazil). A total of 124 patients on hemodialysis (HD) for at least 3 months, who began renal replacement therapy at the age of 65 or older, were followed for 24 months. Frailty was measured using the mFI-11, which comprises 9 comorbidities, 1 functional item, and 1 cognitive item. The comorbidities were obtained through anamnesis and medical record review. Functional dependency was determined by the presence of 2 or more dependencies on the Katz scale, and cognitive deficit was measured by the Mini-Mental State Examination (MMSE). The cutoff point for frailty was defined as mFI-11 ≥3. *Results:* The mean age at the start of the study was 76 years, and 55.6% were men. Of the 124 participants, 56.5% had diabetes, 21% had functional dependency, and 52.9% had cognitive deficits. The prevalence of frailty was 67.7%, and an mFI-11 score of ≥3 was significantly associated with an increased risk of death (HR 2.39, 95% CI 1.21-4.72). *Conclusion:* The mFI-11 demonstrated good performance in predicting mortality in older adults on HD. Its simplicity and feasibility make it a valuable tool for clinical practice, aiding in advanced care planning.

Keywords: Frailty. Hemodialysis. Older adults. Mortality.

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INTRODUCTION

In recent decades, there has been a global increase in the prevalence of individuals with renal failure requiring renal replacement therapy (RRT), with the majority of these being 65 years of age or older[1,2]. The life expectancy of older patients on dialysis is relatively low, ranging from two to five years in the United States[1] and Europe[2], and is negatively impacted by the presence of geriatric syndromes such as cognitive impairment, functional dependence, and frailty[3].

Despite its clinical and epidemiological relevance, the identification of geriatric syndromes in nephrological care is not yet widely implemented in clinical practice[4], leading to underdiagnosis of potentially treatable conditions. Conditions related to comorbidities, disabilities, and frailty present distinct concepts but often interact with each other and may mutually exacerbate. The diagnosis of frailty, however, appears to be more directly associated with worse outcomes than the other conditions individually[5].

Frailty is a clinical syndrome characterized by progressive loss of physiological reserves in the body, leading to increased vulnerability to adverse health outcomes[6]. The oldest model for representing this syndrome is the phenotypic model, which consists of the presence of three or more of the following criteria: unintentional weight loss, self-reported exhaustion, physical inactivity, reduced walking speed, and weakness in grip strength[6]. Although this model has been widely studied[3,7], it has been criticized for not including cognitive deficits, and its weight loss criterion may be challenging in patients with renal failure due to greater variation in hydration status. Moreover, this tool requires special equipment and evaluator training, and is not considered practical[4].

In contrast, the frailty model by deficit accumulation can encompass different dimensions of an individual's vulnerability, such as cognitive and functional performance. In this model, several Frailty Indices (FI) have been proposed, varying primarily in the total number of deficits assessed, ranging from over 90[6] to less than 10[8]. Therefore, when using data from routine medical care, FI has the potential to be efficient and optimize clinical practice time, but these instruments have not yet been widely used and validated in patients with chronic kidney disease[4].

The 11-item modified frailty index (mFI-11) is a simplified frailty index widely used in preoperative assessments[9], which has also demonstrated good ability to predict mortality in specific clinical scenarios of hospitalized patients[10,11]. Thus, the objective of this study was to evaluate the prevalence of frailty by mFI-11 among older individuals on chronic hemodialysis (HD) in four outpatient dialysis units in the municipality of Niterói, RJ, and to analyze this simple FI as a predictor of mortality in this population.

METHOD

This is a prospective observational study conducted from July 2016 to March 2019, with a convenience sample encompassing all four outpatient dialysis units in the municipality of Niterói, RJ, Brazil. Eligible participants were all patients on chronic HD for at least three months, who had started RRT at age 65 or older. Participants who had undergone another form of RRT (peritoneal dialysis or kidney transplant) previously were excluded. The outcome analyzed was all-cause mortality during a 24-month follow-up period. The study was approved by the Research Ethics Committee of the Universidade Federal Fluminense, Niterói (RJ), under approval number: 2,039,175.

The patients who agreed to participate underwent a Comprehensive Geriatric Assessment (CGA) conducted by a single geriatric researcher, including evaluation of biological, psychological, and functional aspects. To screen for depression risk, we used the Geriatric Depression Scale (GDS)[12], with a cutoff point of ≥5[13]. Recurrent falls were defined by self-report of ≥2 occurrences in the previous 12 months[14]. Excessive polypharmacy was defined as the use of ≥10 medications[15], and recent hospitalization, if it occurred within the last 3 months. These data were obtained through directed medical history. Clinical-epidemiological characteristics, including vascular access type and other variables related to HD, as well as patients' laboratory data, were extracted from medical records. Laboratory tests were performed

monthly, except for parathyroid hormone and serum albumin, which were conducted quarterly.

The cognitive assessment in the CGA was conducted using the Mini-Mental State Examination (MMSE)[16], with cutoff scores for case/non-case classification based on different educational levels: 0 years, 1-3 years, 4-7 years, and 8 or more years, with cutoff points of 18/19, 22/23, 23/24, and 27/28, respectively[17]. The test was administered immediately before the dialysis session, as there is evidence of cognitive decline during or shortly after dialysis[18]. The functional assessment utilized the Katz Index[19], which measures independence in activities of daily living (ADLs): bathing, dressing, toileting, transferring, continence, and feeding. Widely recognized worldwide, the scale was adapted for use in Brazil in 2008[20]. In this study, significant functional dependence was defined by a cutoff of ≥2 dependencies in ADLs[21].

Frailty was measured using the mFI-11, which includes nine clinical variables, one functional variable, and one cognitive variable[22]. The nine clinical variables of the mFI-11 (hypertension, diabetes mellitus, coronary artery disease, acute myocardial infarction, congestive heart failure, peripheral arterial disease, transient ischemic attack, stroke, and chronic obstructive pulmonary disease) were scored based on medical history and medical record review. The 'functional dependence' variable was considered positive if Katz ≥2, and the cognitive variable was scored in case of cognitive deficit in the MMSE, as described earlier. All criteria of the mFI-11 are detailed in the supplementary material (available at: https://doi.org/10.6084/m9.figshare.26304148.v1). Subsequently, to test a simplified second model of mFI-11 for use in dialysis clinics, we replaced the definition of cognitive deficit based on the MMSE with a diagnosis of dementia reported in medical history or recorded in patient charts. We then repeated the multivariate analysis using the same Cox regression model. The cutoff point for frailty was mFI-11 ≥3[23].

In the statistical analysis, continuous variables were expressed as mean with standard deviation for normally distributed data, or median with interquartile ranges for non-normally distributed data. Categorical variables were presented as frequencies. Patient survival was assessed using Kaplan-Meier curves, and curve comparisons were performed using the Log-Rank test. The risk of death associated with variables was analyzed using the Cox proportional hazards model, and variables with a p-value < 0.20 in univariate analysis were included in the multivariate analysis. Values of $p < 0.05$ were considered significant. Anticipating a participant number between 120 and 130 and estimating an overall mortality rate of 40-45% over two years[1,2], the study would have a statistical power of 80% if the absolute difference in mortality rate between frail and non-frail groups was 25% and the ratio of frail to non-frail participants was 1:1. With a sample size of 124 older adults and a 2:1 ratio between frail and non-frail groups, this study achieved a statistical power of 75% for mortality analysis.

DATA AVAILABILITY

The entire dataset supporting the findings of this study is available upon request to the corresponding author.

RESULTS

Out of the initially eligible 136 patients, 11 were excluded for initiating RRT through another method before transitioning to HD (seven through peritoneal dialysis and four through kidney transplant), and one patient refused to participate. Among the 124 individuals evaluated, the mean age at the beginning of the study was 76.0±6.2 years, and the median time on dialysis was 25 (11-58) months. Men represented more than half of the sample, and a significant portion had diabetes, at least 12 years of education, or private health insurance. Among patients without private health insurance, the frequency of ≥12 years of education was 18.2%. Significant functional dependence was present in approximately one-fifth of the sample, and the majority of participants were classified as frail or had cognitive deficit according to the MMSE. The main baseline characteristics of the study population are detailed in Table 1.

Table 1. Baseline characteristics of patients (N=124). Niterói, RJ, Brazil, 2016/2017.

Variables	Distribution – n(%)
Age (years) - mean ± SD	76.0 ± 6.2
Age ≥ 80 years - n (%)	35 (28.2)
Male - n (%)	69 (55.6)
Private health insurance - n (%)	80 (64.5)
Education ≥ 12 years - n (%)	53 (42.7)
Age at dialysis initiation - mean ± SD	72.9 ± 5.8
Time on dialysis (months) - median (interquartile range)	25 (11 - 58)
Body mass index (Kg/m²) - mean ± SD	23.6 ± 5.2
Albumin < 35g/L - n (%)	13 (10.6)
Hemoglobin (g/dL) - mean ± SD	10.7 ± 1.8
Corrected calcium (mg/dL) - mean ± SD	9.2 ± 0.7
Phosphorus (mg/dL) - mean ± SD	4.7 ± 1.2
Parathyroid hormone (pg/mL) - median (interquartile range)	145 (78 - 344)
Vascular access	
Native arteriovenous fistula - n (%)	96 (77.4)
Vascular graft - n (%)	4 (3.2)
Central venous catheter - n (%)	24 (19.4)
Standard Kt/V urea * - mean ± SD	2.43 ± 0.63
Recent hospitalization - n (%)	25 (20.2)
Excessive polypharmacy - n (%)	69 (55.6)
Benzodiazepine use - n (%)	87 (70.2)
Risk of depression (GDS ≥ 5) - n (%)	59 (48.0)
Recurrent falls - n (%)	44 (35.5)
Frailty (mFI-11 with MMSE) - n (%)	84 (67.7)
Frailty (mFI-11 with dementia) - n (%)	69 (55.6)
Cognitive deficit (MMSE) - n (%)	64 (52.9)
Dementia† - n (%)	5 (4)
Functional dependence - n (%)	26 (21)
Hypertension - n (%)	121 (97.6)
Diabetes - n (%)	70 (56.5)
Coronary artery disease - n (%)	38 (30.6)
Acute myocardial infarction - n (%)	14 (11.3)
Peripheral arterial disease - n (%)	22 (17.7)
Cerebrovascular disease - n (%)	29 (23.4)
Congestive heart failure - n (%)	20 (16.1)
Chronic obstructive pulmonary disease - n (%)	6 (4.8)

GDS = Geriatric Depression Scale; MMSE = Mini-Mental State Examination; weekly dialysis dose; † as per anamnesis or medical record review.

At the end of the follow-up period, 53 patients had died, two had undergone kidney transplantation, one had transferred to peritoneal dialysis, and five were lost to follow-up due to relocation to another municipality. According to the Kaplan-Meier method, the survival rates for all patients at 12 and 24 months were 75.2% and 55.2%, respectively (Figure 1A). The lowest survival rates at 24 months were observed in patients with cognitive deficit by MMSE (45.4% vs. 66.1%, p=0.025) (Figure 1B), in patients with significant functional dependence (34.7% vs. 61.1%, p=0.013) (Figure 1C), and in patients classified as frail (47.1% vs. 71.8%, p=0.021) (Figure 1D).

In the univariate analysis of the Cox regression model, frailty increased the risk of death by 2.15 times (95% CI=1.11-4.17). The other variables significantly associated with the risk of death in this model were age ≥80 years and education ≥12 years. In the adjusted model, frailty maintained a significant association with mortality (hazard ratio [HR] 2.39, 95% CI=1.21-4.72), as did age ≥80 years, time on dialysis, and education ≥12 years (Table 2).

The mFI-11, including the established diagnosis of dementia in place of MMSE deficit as cognitive assessment, was also associated with an increased risk of death (HR 2.47, 95% CI 1.32 - 4.64), as presented in Table 3.

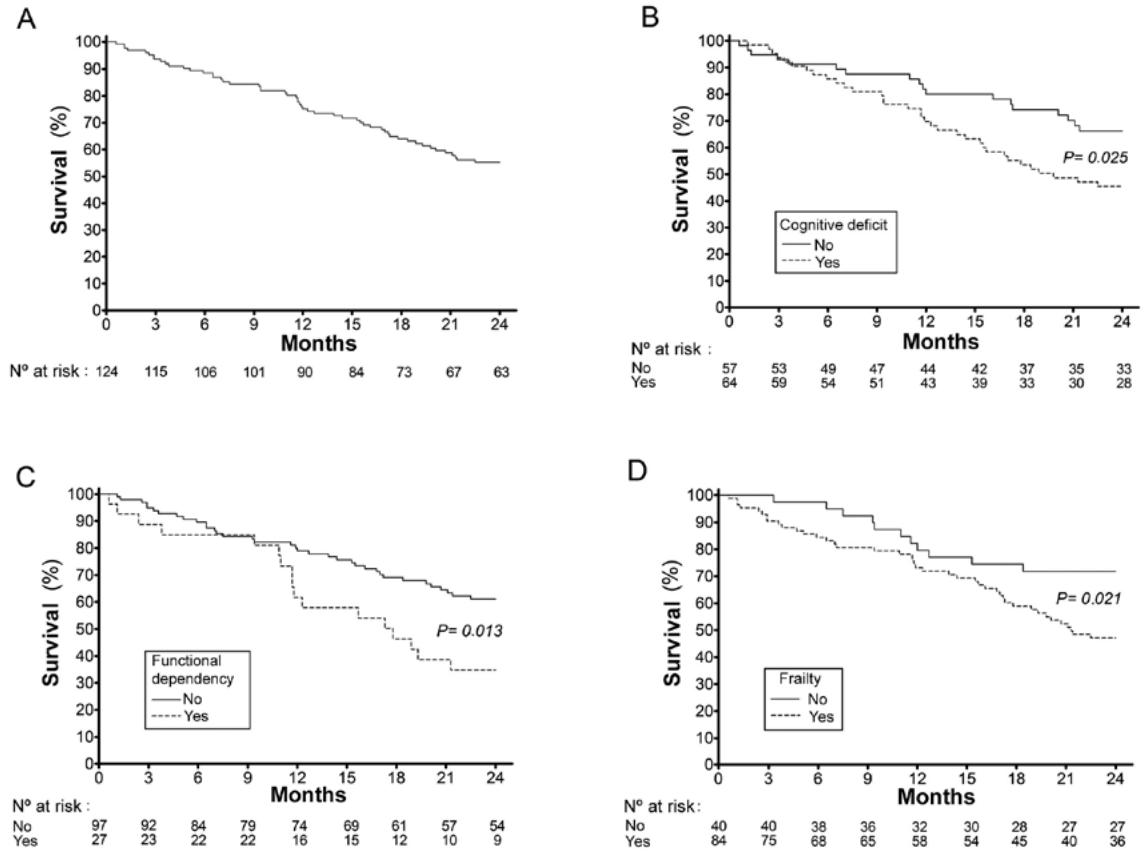

Figure 1. Survival analysis by Kaplan-Meier curves. A) Overall survival of patients; B) Survival of patients with cognitive deficit by Mini-Mental State Examination (MMSE); C) Survival of patients with significant functional dependence; D) Survival of frail patients. Niterói, RJ, Brazil, 2016/2019.

Table 2. Cox regression analyses for mortality prediction, using MMSE as a measure of cognitive deficit within the frailty instrument (N=124). Niterói, RJ, Brazil, 2016/2018 and 2017/2019.

Variable	Unadjusted Model			Adjusted Model		
	HR	95% CI	*p*	HR	95% CI	*p*
Frailty	2.15	1.11 – 4.17	0.024	2.39	1.21 – 4.72	0.012
Men	1.42	0.81 – 2.47	0.221	-	-	-
Age ≥80 years	2.29	1.33 – 3.95	0.003	2.01	1.13 – 3.57	0.017
Education ≥12 years	0.51	0.29 – 0.91	0.023	0.54	0.29 – 0.99	0.046
Time on dialysis (years)	1.07	1.00 – 1.16	0.074	1.01	1.00 – 1.02	0.040
BMI (Kg/m²)	0.95	0.90 – 1.00	0.060	0.98	0.93 – 1.04	0.490
Vascular catheter	1.57	0.82 – 2.99	0.170	1.81	0.89 – 3.69	0.10
Albumin <35 g/L	1.08	0.46 – 2.53	0.859	-	-	-
Risk of depression	1.34	0.77 – 2.30	0.298	-	-	-
Excessive polypharmacy	1.00	0.58 – 1.71	0.990	-	-	-
Benzodiazepine use	1.46	0.85 – 2.51	0.166	1.41	0.81 – 2.45	0.230

HR= Hazard Ratio; 95% CI = 95% Confidence Interval; BMI = Body Mass Index.

Table 3. Cox regression analyses for mortality prediction, using dementia history as a measure of cognitive deficit within the frailty instrument (N=124). Niterói, RJ, Brazil, 2016/2018 and 2017/2019.

Variables	Unadjusted Model			Adjusted Model		
	HR	95% CI	*p*	HR	95% CI	*p*
Frailty*	2.19	1.22 – 3.95	0.009	2.47	1.32 – 4.64	0.005
Men	1.42	0.81 – 2.47	0.221	-	-	-
Age ≥80 years	2.29	1.33 – 3.95	0.003	1.98	1.12 – 3.54	0.021
Education ≥12 years	0.51	0.29 – 0.91	0.023	0.53	0.29 – 0.98	0.042
Time on dialysis (years)	1.07	1.00 – 1.16	0.074	1.01	1.00 – 1.02	0.034
BMI (Kg/m²)	0.95	0.90 – 1.00	0.060	0.99	0.93 – 1.04	0.662
Vascular catheter	1.57	0.82 – 2.99	0.170	2.07	1.01 – 4.24	0.048
Albumin <35 g/L	1.08	0.46 – 2.53	0.859	-	-	-
Risk of depression	1.34	0.77 – 2.30	0.298	-	-	-
Excessive polypharmacy	1.00	0.58 – 1.71	0.990	-	-	-
Benzodiazepine use	1.46	0.85 – 2.51	0.166	1.24	0.70 – 2.21	0.460

HR= Hazard Ratio; 95% CI = 95% Confidence Interval; BMI = Body Mass Index; *cognitive deficit in mFI-11 was defined, in this model, by the diagnosis of dementia based on anamnesis or medical record review.

DISCUSSION

The findings presented here highlight the impact of frailty on mortality in older individuals undergoing maintenance hemodialysis, and to date, this study is the first to correlate the mFI-11 with adverse health outcomes in this population. In this study, frailty was associated with more than a twofold increase in the risk of death, surpassing the influence of age. In addition to frailty, advanced age and longer time on dialysis were also associated with higher mortality risk, while higher education level was associated with reduced risk of death. Furthermore, functional dependence and cognitive deficit were also associated with lower survival, contributing to the performance of the frailty instrument in predicting mortality risk.

The association of mortality in this population with advanced age is already well-established in the literature[1,2], as well as the longer time on HD[24]. However, the association of mortality with education has not been widely studied among individuals on HD[25]. In the general population, education level is one of the strongest social determinants of health and mortality, possibly due to its ability to enhance individuals' capacity to adopt healthy lifestyles, secure good employment, seek medical knowledge, and develop social bonds[26].

Regarding the prevalence of frailty and the risk of death among older and frail individuals on HD, the data from the present study are consistent with findings from a systematic review[7]. This review indicated that frailty, present in 30% to 86% of participants, doubled the risk of death, but primarily included studies that measured frailty using the phenotypic model, as those using the deficit accumulation model are still scarce in HD.

Instruments based on the deficit accumulation model, such as the mFI-11, offer advantages in frailty assessment as they facilitate database analyses[22,27]. The present study reinforces the prognostic value of the FI, with greater feasibility than FI versions of 24[27] or 53[28] items used in previous studies with HD patients. The concise nature of the mFI-11 makes it an easy-to-use tool in clinical practice and future research. Although the standard procedure for creating a FI has suggested that frailty estimates may be unstable when the number of deficits in the index is small[29], the mFI-11 has been proven sufficiently accurate in predicting adverse outcomes across different populations[9-11].

The one-year and two-year survival rates of 75.2% and 55.2% in the studied sample are also consistent with international data[1,2], emphasizing the importance of palliative care for HD patients[30]. Therefore, this study can assist nephrology professionals in identifying frail older patients whose demand for supportive care is naturally higher. Understanding prognosis is crucial for communicating with patients and discussing therapeutic options focused on quality of life[30].

In the sample of the present study, the use of MMSE as a variable in mFI-11 increased the prevalence of frailty compared to using a pre-established diagnosis of dementia. However, the application of this cognitive test did not modify the performance of the FI in predicting death in the multivariate Cox analysis. The advantage of using MMSE instead of a history of dementia lies in its ability to identify individuals in a pre-frail state and detect subclinical cognitive deficits that may be potentially reversible[31]. This approach is particularly interesting for the implementation of preventive interventions. However, integrating the FI as a predictive tool in clinical practice, especially in settings without experienced assessors, may pose challenges related to the time required to train in the use of MMSE. This could contribute to underdiagnosis or act as a barrier to frailty screening. Therefore, it is suggested that simply using a pre-established diagnosis of dementia based on history or medical record review may be sufficient to identify individuals at higher risk of death and assist in advance care planning.

Regarding the measure of disability, assessing instrumental ADLs instead of basic ADLs would increase sensitivity in identifying early stages of the frailty continuum. If we were investigating disability as a consequence of frailty, we wouldn't even select a frailty instrument that includes ADL items. However, when the outcome of interest is mortality, disabilities are predictors of higher risk than other factors such as cognitive deficits and chronic diseases[32]. Standardizing the assessment of activities of daily living (ADLs) through a simple and quick instrument, such as the Katz scale[19], could facilitate the identification of functional deficits by dialysis clinic professionals unfamiliar with the assessment of geriatric syndromes. Ease of use is important for integrating a frailty instrument into care. Therefore, the Clinical Frailty Scale (CFS), a direct measure based on clinical judgment, has been considered the most popular[33]. However, in a recent study with hemodialysis patients, a CFS obtained directly by a medical professional performed differently in assessing frailty compared to a CFS obtained after multidisciplinary team discussion. Since this scale is subjective, there is a risk of classification error[33].

The present study has several limitations. Firstly, it included only prevalent HD patients with an inherent survival bias, which may explain the low prevalence of hypoalbuminemia in the cohort. Secondly, the sample was limited to a single municipality, which may not represent the older dialysis population in the rest of the country. For example, the proportion of patients with higher education levels was higher than national averages[34], as well as the proportion of patients with private health insurance[35]. Finally, another limitation was the relatively small number of participants, resulting in statistical power below 80%. In contrast, the uniform application of the CGA by the same geriatric researcher is a strength, as well as the precise description of each item of the mFI-11, such as the use of the Katz scale. Although many FIs include ADLs items derived from whole scales, poorly detailed psychometric properties do not contribute to the validity and reliability of the frailty measurement instrument[32].

CONCLUSION

The prevalence of frailty was high in the studied population of older patients undergoing chronic hemodialysis. Diagnosing this syndrome is important not only for geriatricians but also for clinicians and nephrologists to identify the most vulnerable patients. Given the lack of consensus on which frailty assessment approach would be superior, tools that are easy to apply are important to increase screening for this condition. The 11-item modified frailty index (mFI-11) demonstrated good performance in predicting mortality in this population, which still needs to be confirmed in future studies with a larger number of participants and more diverse sociodemographic characteristics. However, it is worth noting that this tool is simple and could be easily incorporated into the routine of dialysis units, aiming to assist in prognostic evaluation and advanced care planning.

AUTHORSHIP

- Fernanda S. Viana – data collection and organization, data analysis and writing and approval of the manuscript.
- Rodrigo B. Serafim – data organization, data analysis and publication and approval of the manuscript.
- Yolanda E. M. Boechat – organization of data and publication and approval of the manuscript.
- Jocemir R. Lugon – study design, statistical analyzes and publication and approval of the manuscript.
- Jorge P. Strogoff-de-Matos – study design and involvement in each stage of the project and approval of the manuscript.

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