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Catarina Coelho Reis Macedo

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Mestrado em Nutrição Clínica

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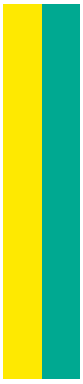

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Malnutrition and Sarcopenia combined increases the risk mortality in older people in hemodialysis

Desnutrição e Sarcopenia combinadas aumentam o risco de mortalidade em pessoas idosas em hemodiálise

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Dedicatory

To my family and especially my mother for encouraging and unconditionally supporting me in all my projects, both personal and professional. To the friends I made in Portugal, who helped and comforted me so much during the pandemic and my adaptation to the new country and who, therefore, make the soil fertile for my growth

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Abstract

Introduction: Sarcopenia and malnutrition are highly prevalent in older adults undergoing hemodialysis (HD) and are associated with negative outcomes. This study aimed to evaluate the role of sarcopenia and malnutrition combined on the nutritional markers, quality of life and survival in a cohort of older adults on chronic HD.

Methods: This was an observational, longitudinal, and multicenter study including 170 patients on HD aged >60 years. Nutritional status was assessed at baseline by 7 point-subjective global assessment (7-SGA), body composition (anthropometry and bioelectrical impedance) and appendicular skeletal muscle mass (Baumgartner's prediction equation). Quality of life was assessed by KDQoL-SF. The cutoffs for low muscle mass and low muscle strength established by the 2019 European Working group on sarcopenia for Older People (EWGSOP) were used for the diagnosis of sarcopenia. Individuals with a 7p-SGA score ≤ 5 were considered malnourished, individuals with low strength or low muscle mass were pre-sarcopenic and those with low muscle mass and low muscle strength combined as sarcopenic. The sample was divided into four groups: sarcopenia and malnutrition; sarcopenia and no-malnutrition; no-sarcopenia with malnutrition and no-sarcopenia and no-malnutrition. Follow-up for survival lasted 23.5 (12.2; 34.4) months.

Results: Pre-sarcopenia, sarcopenia and malnutrition were present in 35.3%, 14.1% and 58.8% of the patients, respectively. The frequency of malnutrition in the group of patients with sarcopenia was not significantly higher than in the patients without sarcopenia (66.7% vs 51.2%; P=0.12). When comparing groups according to the occurrence of sarcopenia and malnutrition, the sarcopenia and malnutrition group were older and presented significantly lower BMI, calf circumference, body fat, phase angle, body cell mass, and mid-arm muscle circumference. In the survival analysis, the group with sarcopenia and malnutrition group showed a higher hazard ratio 2.99 (95% CI: 1.23: 7.25) for mortality when compared to group no-sarcopenia and no-malnutrition. With regard to the domains related to quality of life, the only ones that showed

significant difference were the quality of social interaction, physical role, social function and mental compound SF12, with the group no-sarcopenia and no-malnutrition showing better scores when compared to the remaining groups.

Conclusions: Older adults on HD with sarcopenia and malnutrition combined showed worse nutritional parameters, quality of life and higher mortality risk. In addition, malnutrition can be present even in patients without sarcopenia. These findings highlight the importance of complete nutritional assessment in hemodialysis patients.

Keywords

Chronic kidney disease; hemodialysis; hemodialysis; malnutrition; older adults, mortality

Resumo

Introdução: A sarcopenia e a desnutrição apresentam elevada prevalência em pessoas idosas submetidas a hemodiálise (HD). Além disso, ambas estão associadas com desfechos negativos com aumento de morbi-mortalidade. Esse estudo tem como objetivo avaliar o papel da sarcopenia e da desnutrição combinadas, nos marcadores nutricionais, qualidade de vida e sobrevida numa coorte de idosos em HD crónica.

Métodos: Este foi um estudo observacional, longitudinal e multicêntrico, incluindo 170 participantes em HD com idade superior a 60 anos. O estado nutricional foi avaliado no início do seguimento pela avaliação subjetiva global de 7 pontos (7-SGA), a composição corporal por antropometria e impedância bioelétrica e a massa muscular esquelética apendicular pela equação de predição de Baumgartner. Ademais, a qualidade de vida foi avaliada pelo KDQoL-SF em 154 pacientes. Os pontos de corte empregados para classificar baixa massa muscular e baixa força muscular foram os estabelecidos pelo European Working Group on Sarcopenia for Older People (EWGSOP2). Indivíduos com escore 7p-SGA ≤ 5 foram considerados desnutridos; indivíduos com baixa força ou baixa massa muscular, foram considerados como pré-sarcopénicos; e aqueles com baixa massa muscular e baixa força muscular combinadas, foram classificados como sarcopénicos. A amostra foi dividida em quatro grupos: (1) sarcopenia e desnutrição; (2) sarcopenia e não-desnutrição; (3) não-sarcopenia com desnutrição e, (4) não-sarcopenia e não-desnutrição. O tempo de seguimento para a análise de sobrevida teve mediana de 23,5 meses, com amplitude interquartil de 12,2 a 34,4 meses.

Resultados: A pré-sarcopenia, a sarcopenia e a desnutrição, estiveram presentes em 35,3%, 14,1% e 58,8% dos doentes, respetivamente. A frequência de desnutrição no grupo de doentes com sarcopenia não foi significativamente superior do que nos doentes sem sarcopenia (66,7% vs 51,2%; P = 0,12). Ao comparar os grupos de acordo com a ocorrência de sarcopenia e desnutrição, o grupo sarcopenia e desnutrição apresentou média de idades superior do que o grupo não-sarcopenia e não-desnutrição, ao passo que a média do índice de massa corporal, circunferência da panturrilha, gordura corporal, ângulo de fase, massa

celular e circunferência muscular do braço, foi significativamente inferior no grupo sarcopenia e desnutrição do que no grupo não-sarcopenia e não-desnutrição. Na análise de sobrevida, o grupo com o grupo não-sarcopenia e não nutrição apresentou maior Hazard Ratio: 2,99 (IC 95%: 1,23 - 7,25) para mortalidade quando comparado com o grupo não-sarcopenia e não-desnutrição (grupo referência). No que diz respeito aos domínios relacionados à qualidade de vida, os únicos que apresentaram diferença significativa foram a qualidade da interação social, papel físico, função social e composto mental SF12 com o grupo sem sarcopenia e sem desnutrição apresentando melhores escores quando comparados aos demais grupos.

Conclusões: Pessoas idosas em HD que apresentam combinação de sarcopenia e desnutrição apresentaram piores parâmetros nutricionais, piores domínios de qualidade de vida e maior risco de mortalidade quando comparados com o grupo não-sarcopenia e não-desnutrição. Além disso, a desnutrição pode estar presente mesmo em doentes sem sarcopenia. Esses achados destacam a importância da avaliação nutricional completa em doentes em diálise.

Palavras-Chave

Doença renal crónica; hemodiálise; desnutrição; envelhecimento, mortalidade

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List of Abbreviations

ASM: Appendicular Skeletal Muscle Mass

ASMI: Appendicular Skeletal Muscle Mass Index

7p-SGA: 7 point-Subjective Global Assessment

BIA: Bioelectrical Impedance Analysis

BMI: Body Mass Index

CKD: Chronic Kidney Disease

DXA: Dual-energy X-ray Absorptiometry

EWGSOP2: European Working Group on Sarcopenia for Older People

HD: Hemodialysis

HGS: Handgrip Strength

KDQoL-SF: Kidney Disease Quality of Life - Short Form 1.3

hs-CRP: High Sensitive C-Reactive Protein

MAMC: Midarm Muscle Circumference

PTH: Parathormone

SD: Standard Deviation

SKF: Triceps Skinfold Thickness

25(OH)D: 25-hydroxyvitamin D

MAC: Muscle Arm Circumference

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1. Introduction

Chronic kidney disease (CKD) has been recognized as one of the main and most prevalent public health problems worldwide. In fact, in 2017 it was estimated that 1.2 million people died from CKD with an increase of 41% in the global mortality rate between 1990 and 2017 (1). The global prevalence of CKD is 9.1% (1) which is similar to the CKD prevalence reported of 8.9% in Brazil in 2015 (2). The main factors justifying this increase in CKD are related to population aging of population and to the increase in the prevalence of hypertension, diabetes mellitus, and obesity which are known as the main risk factors for the development of CKD (1).

The stages of CKD evolve as the glomerular filtration rate decreases and the clinical condition worsens, requiring renal replacement therapy in the later stages of the disease, with hemodialysis (HD) being one of the therapeutic options. If, on the one hand, HD enables patients with CKD to live, on the other, it can contribute to the development of nutritional disturbances, like malnutrition, sarcopenia and, frailty. Among these dialyzed patients, malnutrition and sarcopenia stands-out due to their high prevalence (3).

According to the sarcopenia consensus from the European Working Group on Sarcopenia for Older People (EWGSOP2), sarcopenia is defined as a progressive and generalized skeletal muscle disorder characterized by the occurrence of low muscle strength and low quality or quantity of muscle mass (4). The coexistence of both conditions constitutes the confirmatory criteria for the diagnosis of sarcopenia. Particularly in CKD, sarcopenia has multicausal etiology, with factors that overlap with traditional factors of sarcopenia in the elderly (5). According to a group of experts from the International Society of Renal Nutrition and Metabolism (ISRNM), malnutrition is characterized by multiple changes caused by a set of factors that lead to an increase in protein catabolism, thus leading to a negative protein balance (6). Sarcopenia and malnutrition are highly prevalent in HD patients, with the former varying from 3.9% to 63.3% (7) and the latter varying from 28% to 54% (3), depending on the detection method, disease stage, type of treatment, age, and cut-off points used (7). Both conditions are associated with

adverse outcomes, including not only decreased quality of life and functionality, but also increased susceptibility to infection, high hospitalization rates, healthcare costs, morbidity, and mortality (8, 9).

Moreover, data from the United States shows that 40% of end-stage patients were over 65 in 2013, and projections for 2030 indicate that this proportion will increase to 55% - 61% (10). Given the fast increase in the prevalence of older adults on dialysis in the recent decades, as well as the effect of senescence on decreasing skeletal muscle mass, the assessment of the outcomes of malnutrition and sarcopenia in patients undergoing chronic HD is of major relevance. Importantly, research has shown that early intervention in these patients increases the quality of life and reduces mortality (11). However, the diagnosis and monitoring of malnutrition and sarcopenia in dialyzed patients is not yet carried routinely out in many dialysis clinics, hindering the early intervention for these two conditions. Although it is well known that malnutrition and sarcopenia are related to higher mortality risk, we now investigate the effect of these two conditions combined on markers of nutritional status, clinical condition, quality of life and, mortality.

2. Objectives

2.1. General objectives

- To assess the frequency of malnutrition and sarcopenia in elderly patients undergoing chronic hemodialysis treatment, as well as their association with laboratory tests, nutritional status, and survival outcomes.

- To assess whether there is an association between the presence of sarcopenia and malnutrition combined or assessed separately, with an increased risk of mortality in elderly people undergoing hemodialysis treatment.

2.2. Specific objectives

- To assess the frequency of sarcopenia according to the cutoff points recommended by the European Working Group on Sarcopenia in Elderly People (EWGSOP2).

- To know the frequency of malnutrition using the 7-point global assessment (ASG-7p).

- To investigate the frequency of malnutrition in patients according to different sarcopenia criteria.

- To assess whether laboratory tests, clinical status, nutritional status, domains quality of life, and survival time differ between malnourished but not sarcopenic elderly patients on hemodialysis, sarcopenic but not malnourished, with both nutritional changes and none of them.

3. Methods

3.1. Study protocol

This is an observational, longitudinal, and multicenter study including 170 patients under hemodialysis (HD) treated in six dialysis units in Brazil. A detailed description of the methodology can be found elsewhere (8). All participants were included from March 2010 to February 2014 and were followed for mortality events up to 36 months. Patients that changed dialysis modality or were transferred to other dialysis units or had kidney transplantation were censored.

3.2. Patients

Patients were eligible for inclusion if aged over 60 years, undergoing HD for at least 3 months, 3 times per week, with each session lasting 3.5 to 4 hours. The exclusion criteria comprised patients using wheelchairs, with amputated limbs, and with human immunodeficiency virus, cancer, and, Alzheimer's and Parkinson's disease. The study was approved by the Ethics and Research Committee of Rio de Janeiro State University, Brazil registered with protocol number 039.3.2011, and written informed consent was obtained from all patients before their admission in the study.

3.3. Data collection

At baseline, all participants had the nutritional status assessed by the 7 point-subjective global assessment (7p-SGA) translated to Portuguese (12), by anthropometric measurements (body weight, height, midarm circumference, triceps skinfold thickness (SKF), hip and calf circumference), bioelectrical impedance (BIA) and handgrip strength (HGS) after 30 to 60 min the dialysis session in a midweek dialysis day to minimize the influence of fluids overload on body composition (13).

The body weight was measured using brand Filizola® (São Paulo – SP) with a capacity of 150 kg. Participants were weighed without shoes and wearing light clothing. The height was measured by the stadiometer attached to the scale. Participants were placed on the scale platform barefoot, with heels together, back straight and arms extended at their sides. The reading was performed at the meeting point between the patient's head and the horizontal rod of the vertical bar. To measure the circumference of the calf, the patients were positioned in a sitting position with their knees and ankles flexed at a 90° angle on the leg opposite to the arteriovenous fistula, adopting the measure of the largest perimeter. Midarm circumference was measured following the Lohman's Protocol, using in the opposite arm arteriovenous fistula (14). Skinfolds were measured using a skinfold caliper (Lange, Cambridge Scientific Industries, Cambridge, MD), following Lohman's Protocol (14).

Body fat was estimated by BIA (Biodynamics® 450 – Biodynamics Corporation, Seattle, WA, USA) with the patient in a supine position after 5 minutes of rest. The measurements of body weight, height, resistance, and reactance were entered in the software Fluid & Nutrition (version 3.0) to obtain body fat and phase angle. The cutoff points to classify obesity were established based on the study by Heo et al (15) who assessed body composition by BIA in individuals without CKD. Individuals who had a percentage of body fat above 32.3% for men and above 44.1% for women were considered obese. The arm contrary to the arteriovenous fistula was used for the assessment of arm circumference, triceps SKF, and HGS. Muscle strength was measured by a mechanical handgrip dynamometer (Baseline, Fabrication Enterprises, Inc, Elmsford, NY). The highest value of three measurements was taken, with arms along the body after a voice command asking to use the maximal force in the dynamometer. The midarm muscle circumference (MAMC) was calculated using the Frisancho equation (16). The standard values of MAMC and triceps SKF were calculated by the equation: measured value/ value on P50 from NHANES III) x 100 (9).

The 7p-SGA was applied by experienced renal dietitians. The patient's nutritional status was classified as well-nourished when the 7-SGA score was equal to 7 and 6 and, as malnourished when the 7p-SGA score ≤5 (12).

The Baumgartner's prediction equation (17) was used to estimate appendicular skeletal muscle mass (ASM):

$$\text{ASM (kg)} = 0.2487\ (\text{weight, kg}) + 0.0483\ (\text{height, cm}) -$$

$$0.1584\ (\text{hip circumference, cm}) + 0.0732\ (\text{HGS, kgf (kilogram force)}) +$$

$$2.5843\ (\text{sex}) + 5.8828\ (17)$$

A previous study, conducted by our research group and which included HD patients, showed that this equation had good agreement with the ASM assessed by dual energy x-ray absorptiometry (DXA) with an intraclass coefficient correlation (ICC) of 0.92 (95% confidence interval [CI]: 0.86-0.95) (9). The ASM was divided by the square height (m) for the calculation of the ASM index (ASMI).

The laboratory measurements were performed before the dialysis session and included assessment of serum albumin (method green bromocresol), high sensitive C-reactive protein (hs-CRP; by nephelometry), and 25 hydroxyvitamin D (25 (OH) D); by chemiluminescence immunoassay. Serum urea was assessed before and after the dialysis session for calculation of the urea Kt/V according to the formula of Daugirdas (18) from a midweek dialysis session.

Quality of life was assessed using the Short Form 1.3 questionnaire (KDQoL-SF) (19), which was applied during the dialysis session in 154 patients from the total sample (170 patients). The reason for a smaller sample having data on quality of life is that this assessment did not start at the beginning of the data collection.

For sarcopenia diagnosis, the cutoffs for low muscle mass and low muscle strength established by the 2019 EWGSOP (4) were used. Low muscle strength was considered when HGS was < 27 kgf for males and < 16 kgf for females and low muscle mass was considered when the ASMI was < 7.0 kg/m^2 for males and < 5.5

kg/m^2 for females (4). Patients were considered with pre-sarcopenia when presenting only one of the muscle abnormalities, that is, low muscle mass or low muscle strength, and with sarcopenia when both conditions were present.

The patients were classified into 4 groups considering the presence of malnutrition, pre- sarcopenia, and sarcopenia:

- Group sarcopenia and malnutrition (n=56): Comprised by patients with positive criteria for sarcopenia/pre-sarcopenia and for malnutrition (7p-SGA score ≤5);
- Group sarcopenia and no-malnutrition (n=28): Comprised by patients with positive criteria for sarcopenic/pre-sarcopenia, but without criteria for malnutrition (7p-SGA score=6 and 7);
- Group no-sarcopenia with malnutrition (n=44): Comprised by patients without criteria for sarcopenia/pre-sarcopenia, but with positive criteria for malnutrition (7p-SGA score ≤5);
- Group no-sarcopenia and no-malnutrition (n=42): Comprised by patients without criteria for sarcopenia/ pre-sarcopenia and for malnutrition (7p-SGA score=6 and 7).

3.4. Statistical analysis

The Shapiro-Wilk test was applied to test normality. Categorical variables are described as absolute number and percentage and continuous variables as mean and standard deviation (SD) or as median and interquartile range, as appropriate. The comparisons of the variables among the groups of sarcopenia and malnutrition were performed using chi-square test for categorical variables, and one-way analysis of variance (ANOVA) or Kruskal-Wallis tests for continuous variables, as appropriate. The Bonferroni test was used to verify the differences among the groups for the variables presenting normal distribution.

The comparisons between the survival and deceased groups were done by the chi-square test, independent t-test, or Mann-Whitney test, as appropriate.

The survival analyses were performed by the Kaplan-Meier graphic using the log-rank test to compare the survival curves among the sarcopenia and malnutrition groups. The Cox's proportional risk model adjusted for gender, age and hs-CRP was used to assess the hazard ratio for mortality, using the no-sarcopenia and well-nourished group as reference. The value of P <0.05 will be used for statistical significance. All analyzes will be performed using the SPSS software version 27.

4. Results

Table 1 shows the main characteristic of the studied sample comprised of older adults on chronic HD. In general, the mean age was around 70.6 years, the majority of the sample was comprised of males and the urea Kt/V was indicative of adequate dialysis. The mean BMI, calf circumference, standard triceps SKF and MAMC indicated adequate nutritional status according to cut-offs established for non-CKD individuals, which are well accepted for use in CKD patients (20). However, when the nutritional status was assessed by 7p-SGA, 58.8% of the sample had a score ≤5, indicating malnutrition. As for body composition assessed by BIA, the mean ±SD values for body fat percentage showed that 10% of males and 12% of females were obese. When assessing the presence of sarcopenia, about one-third of the sample had either low muscle mass or low muscle strength, here defined as pre-sarcopenia, while 14.1% had both conditions combined, defined as sarcopenia and 50.6% had no signs of low muscle mass or low muscle strength. The laboratory exams were compatible with that observed for patients on dialysis treatment and the mean serum albumin was within the acceptable values to CKD patients (>3.8 mg/dL) (21).

Table 1: Main demographic, nutritional and clinical characteristics of older adults on hemodialysis

	Results (n=170)
Age (years)	70.6 ± 7.2
Male (n; %)	111 (65.3)
Dialysis length (years)	2.9 (1.3; 5.6)
Urea Kt/V	1.5 (1.3; 1.6)
Diabetes (n; %)	44 (37.7)
BMI (kg/m^2)	25.4 ± 4.5
Pre-sarcopenia (n; %)	60 (35.3)
Sarcopenia (n; %)	24 (14.1)
No sarcopenia (n; %)	86 (50.6)
Standard triceps skinfold thickness (%)	102.5 (72.7; 142.1)
Standard midarm muscle circumference (%)	98.1 ± 14.7
Calf circumference (cm):	
- Male	34.5 ± 3.9
- Female	33.3 ± 3.5
Malnutrition (n; %)	100 (58.8)
Body fat %:	
- Male	27.5 ± 7.0
- Female	37.7 ± 5.3
Phase angle (°):	
- Male	5.5 ± 1.3
- Female	5.3 ± 1.2
Body cellular mass (kg):	
- Male	22.1 ± 4.8
- Female	17.0 ± 3.6
Appendicular skeletal muscle mass index (kg/m^2):	
- Male	7.48 ± 0.77
- Female	4.60 ± 0.81
Pre-sarcopenia (n; %):	
- Low HGS	38 (22.4)
- Low ASMI	22 (12.9)
- Total	60 (35.3)
Albumin (g/dL)	3.9 ± 0.4
Hemoglobin (mg/dL)	11.3 ± 1.6
Hematocrit (%)	34.4 ± 5.0

S Creatinine (mg/dL)	8.7 ± 2.8
S Urea (mg/dL)	138 ± 39.5
PTH (mg/dL)	223 (101; 402)
25(OH)D (ng/mL)	19.2 (12.7; 27.1)
hs-CRP (mg/dL)	0.42 (0.2; 1.1)

BMI: body mass index; hs- CRP: high sensitive c-reactive protein; 25(OH)D: 25-hydroxyvitamin D; PTH: Parathormone.

Data is described as absolute values and their percentage for categorical variables; as mean ± standard deviation as or as median and interquartile range for continuous variables according to the variable's distribution. Malnutrition defined as 7p-SGA ≤ 5.

Pre-sarcopenia was defined as either low muscle mass (appendicular skeletal muscle mass index below 7 kg/m^2 for males and below 5.5 kg/m^2 for females) or low muscle strength (handgrip strength below 27 kgf for males and below 16 kgf for females). Sarcopenia was defined by the concomitant condition of low muscle mass and low muscle strength.

Considering that the presence of two nutritional disturbances – malnutrition and sarcopenia were investigated, we evaluated whether the frequency of malnutrition differed among the sarcopenia groups. Figure 1 shows the frequency of patients with malnutrition (assessed as 7p-SGA≤5) in the groups stratified as sarcopenia, pre-sarcopenia, and no-sarcopenia. As can be observed, the prevalence of patients with malnutrition did not differ among the sarcopenia groups, indicating that malnutrition was present even in the group of no-sarcopenia. We then expanded our analysis by exploring the role that these two conditions combined (sarcopenia and malnutrition) have on other nutritional markers, clinical conditions, quality of life, and mortality events.

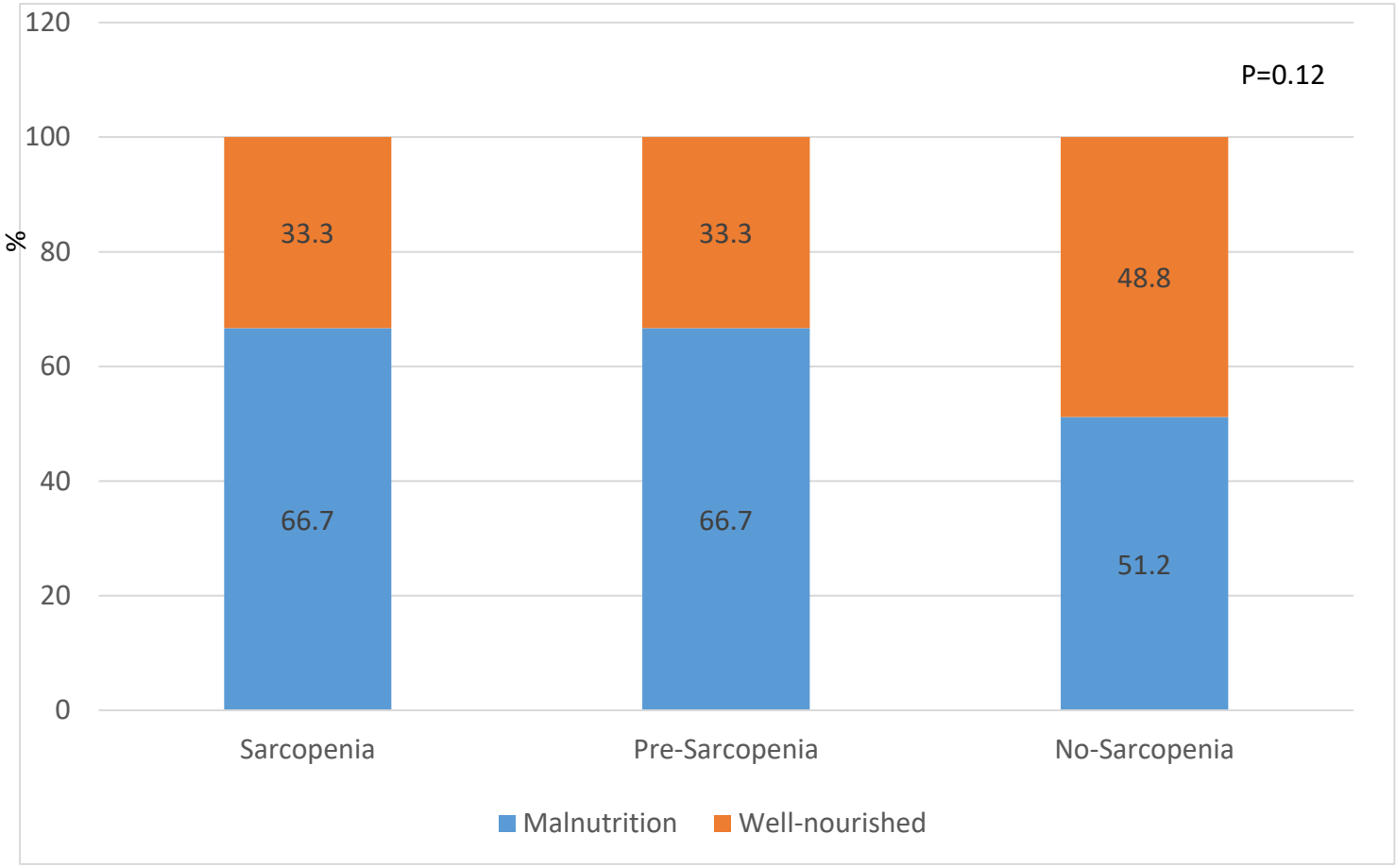

Figure 1: Frequency of malnutrition (assessed by 7p-SGA) in groups classified as Sarcopenia, Pre-sarcopenia.

Differences among groups tested by Chi-square test

Table 2 shows the comparison of demographic, nutritional, clinical characteristics, and quality of life among the groups classified by the presence of sarcopenia and malnutrition. Age and the percentage of males differed significantly among the groups, with the age higher in the group where sarcopenia and malnutrition and sarcopenia no-malnutrition and male gender had higher prevalence in the group comprised of sarcopenia and no-malnutrition. Except for

serum albumin that did not differ among the groups, the other nutritional markers differed significantly among the groups, indicating worse nutritional status in the group Sarcopenia and Malnutrition as compared to the group No-sarcopenia and No-malnutrition. Regarding clinical condition, the urea Kt/V and 25(OH)D Vit D differed among the groups, being the group sarcopenia and malnutrition presenting higher Kt/V and lower 25(OH)D Vit D as compared to the group no-sarcopenia and no-malnutrition. Regarding the domains related to the quality of life, most of them did not differ among the groups. Those that showed significant differences were quality of social interaction, role physical, social function and, SF12 mental composite with the group no-sarcopenia and no-malnutrition showing better scores when compared to the remaining groups.

Table 2: Comparisons of demographic, nutritional, clinical characteristics and quality of life of older adults on hemodialysis according to the groups sarcopenia and malnutrition

	Sarcopenia and Malnutrition (n=56; 33%)	Sarcopenia and No-malnutrition (n=28; 16.5%)	No-sarcopenia and Malnutrition (n=44; 25.8%)	No-sarcopenia and No-malnutrition (n=42; 24.7%)	P *
Age (years)	73.2 ± 8.0 [a]	72.4 ± 7.9 [a,c]	69.3 ± 6.0 [b,c]	67.4 ± 5.4 [b,d]	<0.001
Male (n; %)	34 (60.7)	24 (85.7)	23 (52.3)	30 (71.4)	0.02
Dialysis length (years)	3.01 (1.66; 5.60)	2.96 (1.37; 6.32)	2.08 (0.93; 5;87)	3.15 (1.24; 5.60)	0.67
Urea Kt/V	1.51 (1.40; 1.70)	1.34 (1.22; 1.71)	1.47 (1.30; 1.63)	1.41 (1.28; 1.53)	0.04
Diabetes (n; %)	14 (25)	12 (42.8)	24 (54.5)	14 (33.3)	0.06
BMI (kg/m^2)	23.6 ± 4.7 [a]	25.0 ± 3.3 [a,c]	25.9 ± 4.6 [b,c]	27.7 ± 3.9 [b,d]	<0.001
Standard triceps skinfold thickness (%)	89.5 (63.6; 125.7)	110.1 (91.4; 175.7)	96.15 (72.1; 121.2)	134.4 (96.5; 169.1)	<0.001
Standard midarm muscle circumference (%)	93.6 ± 13.4 [a]	94.0 ± 13.2 [a, c]	100.9 ± 16.7 [a, b, c]	103.9 ± 12.7 [b]	0.001
Calf circumference (cm)	32.6 ± 3.4 [a]	33.7 ± 2.3 [a]	33.6 ± 4.6 [a]	36.6 ± 2.9 [b]	<0.001
Body fat %	28.5 ± 7.8 [a]	30.0 ± 8.5 [a, b]	32.3 ± 8.2 [a, b]	33.9 ± 7.3 [b]	0.007
Phase angle (°)	4.9 ± 1.2 [a]	5.2 ± 0.9 [a, c]	5.4 ± 0.9 [a, b, c]	6.2 ± 1.4 [b]	<0.001
Body cellular mass (kg)	17.7 ± 4.3 [a]	20.0 ± 3.8 [b]	19.2 ± 3.8 [a, b]	24.2 ± 5.0 [c]	<0.001
Appendicular skeletal muscle mass index (kg/m^2)	6.42 ± 1.1[a]	7.03 ± 0.83 [a, b, c]	6.99 ± 0.96 [b]	7.56 ± 0.94 [c]	<0.001
Albumin (g/dL)	3.83 ± 0.41	3.98 ± 0.40	3.92 ± 0.41	3.91 ± 0.41	0.44
Hemoglobin (mg/dL)	11.3 ± 1.9	11.2 ± 1.7	11.2 ± 1.3	11.4 ± 1.5	0.96

Hematocrit (%)	34.6 ± 6.0	34.3 ± 5.2	34.0 ± 4.1	34.4 ± 4.5	0.94
S Creatinine (mg/dL)	8.5 ± 2.4	8.9 ± 2.9	8.2 ± 2.8	9.4 ± 3.1	0.24
S Urea (mg/dL)	130.6 ± 41.7	150.8 ± 40.9	137.2 ± 37.2	140.4 ± 36.7	0.16
PTH (mg/dL)	165.3 (59.6; 331.6)	218.3 (111.6; 454.1)	262.3 (106.6; 442.8)	256 (171.2; 402.6)	0.23
25(OH)D (ng/mL)	17.5 (11.7; 30.1)	14.7 (10.5; 21.4)	18.0 (13.5; 25.4)	25.7 (19.0; 34.0)	0.001
hs-CRP (mg/dL)	0.37 (0.20; 1.23)	0.26 (0.09; 0.69)	0.52 (0.26; 1.18)	0.52 (0.22;1.15)	0.19
Quality of life domains					
Symptom problem list	75.1 ± 16.8	74.5 ± 21.6	67.7 ± 24.0	75.6 ± 18.4	0.24
Effects of kidney disease	68.7 (50.0; 84.4)	71.9 (40.6; 90.6)	59.4 (42.2; 78.1)	75.0 (66.7; 91.7)	0.38
Burden of kidney disease	37.5 (18.8; 56.3)	50.0 (18.8; 75.0)	25.0 (12.5; 50.0)	50.0 (25.0; 68.8)	0.10
Work status	50.0 (0.0; 50.0)	50.0 (0.0; 50.0)	50.0 (0.0; 50.0)	50.0 (0.0; 100.0)	0.83
Cognitive function	80.4 ± 21.0	78.3 ± 26.4	75.9 ± 25.8	83.5 ± 19.4	0.50
Quality of social interaction	81.5 ± 17.9 [a]	77.1 ± 20.4 [a]	70.7 ± 24.0 [a,b]	82.8 ± 19.2[a,c]	0.03
Sexual function	95.8 ± 10.2	85.9 ± 14.5	77.3 ± 26.8	84.2 ± 19.7	0.50
Sleep	65.0 (47.5; 83.8)	57.5 (35.0; 75.0)	57.5 (46.3; 70.0)	72.5 (52.5; 81.3)	0.08
Social support	100.0 (66.7; 100.0)	83.3 (66.7; 100.0)	100.0 (66.7; 100.0)	100.0 (66.7; 100.0)	0.78
Dialysis staff encouragement	75.0 (56.3; 93.8)	87.5 (75.0; 100.0)	100.0 (75.0; 100.0)	87.5 (75.0; 100.0)	0.07
Overall health	60.0 (50.0; 100.0)	50.0 (50.0; 100.0)	60.0 (50.0; 85.0)	60.0 (50.0; 80.0)	0.61
Patient satisfaction	68.4 ± 19.3	75.4 ± 21.2	72.4 ± 21.6	71.9 ± 20.2	0.56
Physical functioning	45.0 (22.5; 80.0)	50.0 (25.0; 70.0)	40.0 (25.0; 70.0)	55.0 (40.0; 75.0)	0.21
Role physical	50.0 (0.0; 75.0)	50.0 (0.0; 100.0)	0.0 (0.0; 62.5)	50.0 (25.0; 100.0)	0.009
Pain	62.5 (45.0; 90.0)	70.0 (45.0; 90.0)	55.0 (22.5; 95.0)	67.5 (45.0; 100.0)	0.43
General health	60.0 (30.0; 70.0)	50.0 (35.0; 75.0)	50.0 (32.5; 62.5)	65.0 (40.0; 82.5)	0.15
Emotional wellbeing	76.0 (52.0; 92.0)	84.0 (60.0; 96.0)	68.0 (42.0; 90.0)	80.0 (64.0; 92.0)	0.18

Role emotional	33.3 (0.0; 100.0)	66.7 (0.0; 100.0)	33.3 (0.0; 66.7)	66.7 (33.3; 100.0)	0.09
Social function	62.5 (37.5; 100.0)	87.5 (62.5; 100.0)	62.5 (25.0; 87.5)	75.0 (62.5; 100.0)	0.04
Energy fatigue	55.0 (32.5; 75.0)	60.0 (40.0; 80.0)	45.0 (32.5; 75.0)	65.0 (42.5; 80.0)	0.27
SF12 Physical Composite	37.9 (31.1; 45.8)	36.4 (32.3; 45.3)	36.5 (26.2; 46.5)	40.6 (35.1; 47.2)	0.22
SF12 Mental Composite	44.9 ± 11.1 [a]	50.3 ± 13.5 [a,b]	44.3 ± 12.3 [a]	50.5 ± 10.1[b]	0.02

NA= non-applicable; Hs-CRP: high sensitive C-reactive protein; 25(OH)D: 25(OH)D, 25-hydroxyvitamin D; PTH: Parathormone. Quality of life was evaluated in a subgroup of 154 patients (n=49; n=23; n=41; n=41; respectively in the 4 groups). Data is described as absolute values and their percentage for categorical variables; as mean ± standard deviation as or as the median and interquartile range for continuous variables according to the variable's distribution. *Chi-square or One-way Analysis of Variance (ANOVA) or Kruskal-Wallis test, as appropriate. Bonferroni Post-hoc test for ANOVA $P \leq 0.05$: Significant differences among the groups are signed by the different superscript letters.

After 23.5 (12.2; 34.4) months of follow-up (median and interquartile ranges), there were 62 events of death. The group of deceased patients was older, with higher Kt/V and hsCRP as compared to the patients that survived (Table 3).

Table 3: Comparison of older adult patients on hemodialysis according to the group alive and deceased (n=170)

	Alive (n=108)	Deceased (n=62)	P*
Male	71 (65.7)	40 (64.5)	0.87
Age (years)	69.6 ± 6.7	72.5 ± 7.8	0.013
Kt/V	1.42 ± 0.3	1.60 ± 0.5	0.002
hsCRP	0.34 (0.18; 0.82)	0.58 (0.27; 1.48)	0.004
Dialysis length (years)	2.9 (1.2; 5.4)	2.9 (1.3; 6.0)	0.68

HsCRP: high sensitivity C reactive protein; * T-test; Chi-square test or Mann Whitney test, as appropriate.

The survival analysis showed that there was a significant difference in the survival curves among the groups, being the group combining both conditions (sarcopenia and malnutrition) the one with lower survival rate (Figure 2, Kaplan-Meier; Long-Rank test, P=0.019). This finding was confirmed in the Cox regression analysis adjusted for age, gender, and hsCRP, where the group with sarcopenia and malnutrition had a hazard ratio of 2.99 (95% CI: 1.21; 7.28) as compared to the reference group no-sarcopenia and no-malnutrition (Table 4).

Table 2 shows the comparison of demographic, nutritional, clinical characteristics, and quality of life among the groups classified by the presence of sarcopenia and malnutrition. Age and the percentage of males differed significantly among the groups, with the age higher in the group where sarcopenia and malnutrition and sarcopenia no-malnutrition and male gender had a higher prevalence in the group comprised of sarcopenia and no-malnutrition. Except for serum albumin that did not differ among the groups, the other nutritional markers

differed significantly among the groups, indicating worse nutritional status in the group sarcopenia and malnutrition as compared to the group no-sarcopenia and no-malnutrition. Regarding clinical condition, the urea Kt/V and 25(OH)D Vit D differed among the groups, being the group sarcopenia and malnutrition presenting higher Kt/V and lower 25(OH)D Vit D as compared to the group no-sarcopenia and no-malnutrition. Regarding the domains related to the quality of life, most of them did not differ among the groups. Those that showed significant differences were quality of social interaction, role physical, social function, and SF12 mental composite with the group no-sarcopenia and no-malnutrition showing better scores when compared to the remaining groups.

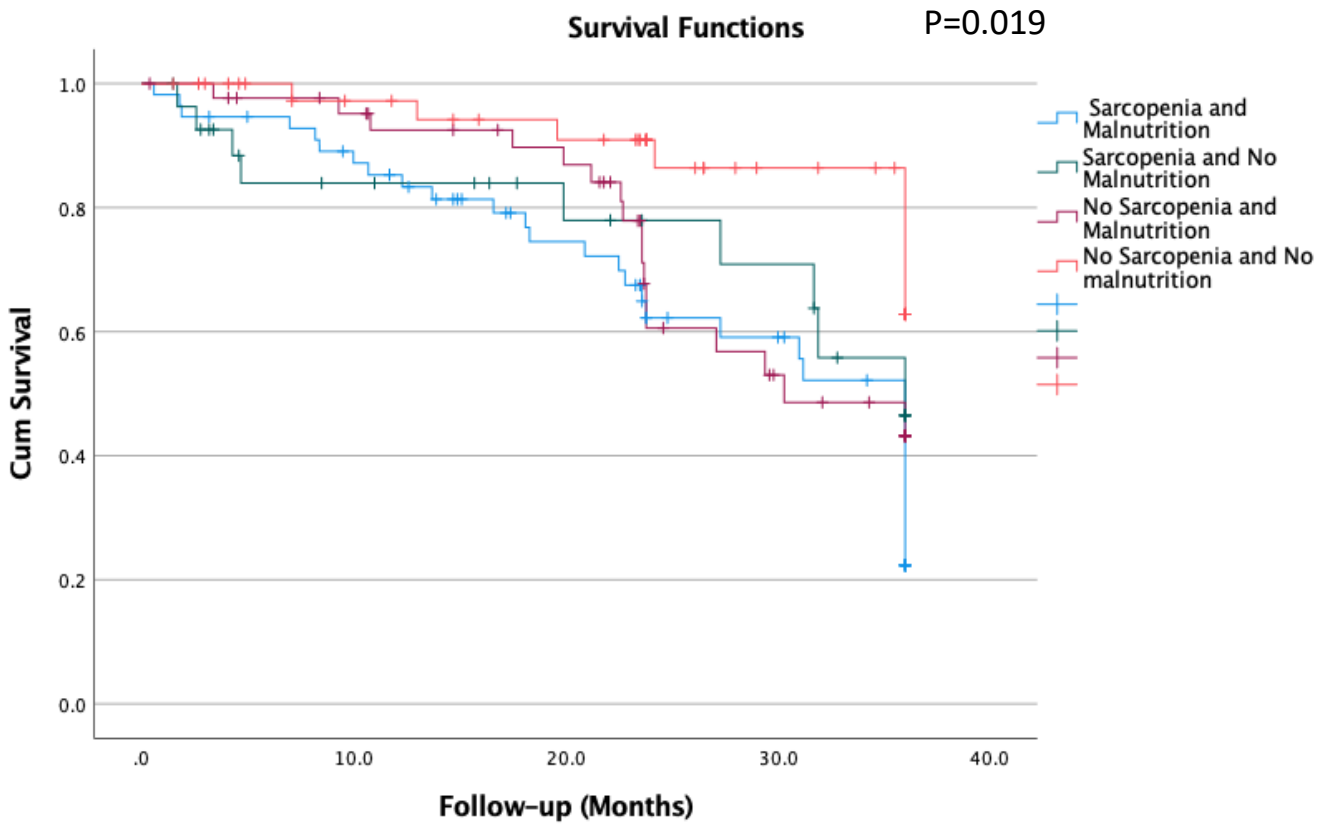

Figure 2: Kaplan-Meier curves according to the groups of sarcopenia and malnutrition of elderly patients on hemodialysis (n=170). Long-Rank test, P=0.019.

Table 4: Risk for mortality events, expressed as hazard ratio* according to the combination of group of sarcopenia and malnutrition in older adults undergoing maintenance hemodialysis (n=170)

		95% Confidence Interval		
	Hazard ratio*	Lower	Upper	P value
Male	0.44	0.24	0.83	0.01
Age (years)	1.02	0.96	1.06	0.27
hs-CRP (mg/dL)	1.35	2.00	1.58	0.03
No-Sarcopenia + No-malnutrition (reference group) (n=42)				
Sarcopenia + No-malnutrition (n=28)	2.65	0.86	7.05	0.09
No-Sarcopenia + Malnutrition (n=44)	2.43	0.97	6.05	0.06
Sarcopenia + Malnutrition (n=56)	2.99	1.23	7.25	0.03

Hs-CRP: High sensitivity C-reactive protein; * Cox's proportional risk model

5. Discussion

In this study, we aimed to evaluate the role of sarcopenia and malnutrition on the nutritional markers and survival in a cohort of older adults on chronic HD. Malnutrition (diagnosed by 7p-SGA) was present in 58.8%, which was similar to that found by Cianciaruso et al where 51% of older adults (>65 years) in HD and peritoneal dialysis had malnutrition assessed by SGA (22). Moreover, in a meta-analysis aiming to describe the prevalence of malnutrition in CKD patients (assessed by SGA or malnutrition inflammation score), it was shown that the 25th-75th percentile ranges of malnutrition among studies on dialysis patients was 28-54% (3). Therefore, our findings on the presence of malnutrition are somehow higher than that from previous studies, most likely due to the inclusion of only older adults on HD.

Markers of muscle abnormality, such as low muscle strength or low muscle mass, named as pre-sarcopenia in the current study, were present in 35.3% of the patients, a percentage similar to that found by Isoyama et al in incident dialysis patients (39% of the patients with either low muscle strength or low muscle mass) (23). Moreover, we found that sarcopenia (diagnosed by the concomitance of low muscle mass and low muscle strength) was present in 14.1% of the patients, a frequency lower than that from previous studies in dialysis patients (20% to 40%) (23-25). This discrepancy is most likely due to the diagnostic methods used, the cutoffs applied for the diagnose of low muscle mass and low muscle strength, as previously shown by Lamarca et al in HD patients (7). In addition, these divergent results, when compared with findings from other studies, can also be explained by different characteristics from the studied sample, such as the CKD stage, dialysis modality, presence of comorbidities, and the sample's mean age (5).

Also of interest, we identified that among the groups stratified by sarcopenia status, 66.7% of the patients from the group sarcopenia had also malnutrition (Figure 2). In another study including older adults (>65 years) with CKD stages 3b to 5, not on dialysis, 52% of the patients with sarcopenia were diagnosed with protein energy wasting (PEW) using the diagnostic criteria from the International Society in Renal Nutrition and Metabolism (26). In incident dialysis patients, 64.7%

of the patients with sarcopenia had malnutrition diagnosed by SGA (23). The similar frequency of sarcopenia and malnutrition combined found in our study and in the aforementioned one's underlines that this nutritional disturbance can coexist and a careful assessment for both conditions should be performed in patients on HD.

Surprisingly, when comparing the frequency of malnutrition among the sarcopenia groups (Figure 1), 51.2% of the patients in the group no-sarcopenia had malnutrition, a proportion not different from that observed in the groups sarcopenia and pre-sarcopenia. Similarly, in two previous studies including either patients on CKD stages 3b to 5 or before the start of dialysis therapy, 14% to 20% of the patients with no-sarcopenia had malnutrition (23, 26). In other words, the absence of sarcopenia does not exclude the existence of malnutrition. This finding highlights that although sarcopenia and malnutrition share some common criteria, these are different nutritional abnormalities, and the investigation of both is crucial. In the current study, malnutrition was diagnosed by 7p-SGA which evaluate several domains of nutritional status (involuntary loss of body weight, food intake, gastrointestinal symptoms, poor appetite, functional status, comorbidities, and physical exam for subcutaneous fat and muscle loss (27). Therefore, it provides a broad assessment of nutritional status including aspects not included in the criteria for sarcopenia diagnosis. This likely explains the reason why individuals in the group no-sarcopenia had malnutrition when diagnosed by 7p-SGA. Adding to these findings, we also demonstrated, as expected, that when sarcopenia and malnutrition occurred concomitantly (group sarcopenia and malnutrition), all parameters of nutritional–status, except for albumin, were worse when compared with the group with no-sarcopenia and no-malnutrition.

The non-difference in serum albumin among the groups of sarcopenia and malnutrition corroborates the findings from Gama-Axelsson et al. (28). The authors reported that in prevalent dialysis patients, serum albumin correlated poorly with markers of nutritional status, including SGA score and body composition parameters, but it was significantly correlated with hs-CRP (28). Altogether, this is aligned with the statement from the updated guidelines in

Nutrition and CKD from the NKF-KDOQI that albumin is a predictor of hospitalization and mortality, and not a marker of nutritional status (29).

It was interesting to note that within the sarcopenia and malnutrition group, the mean values of body fat markers, such as BMI, percentage of body fat, and percentage of standard triceps skinfolds were within the normal range for non-CKD individuals (15, 30, 31). Similarly, Lee et al also observed in a group of older adults on HD that patients with low gait speed and low HGS combined had BMI within the normal range (32). Additionally, in the study from Ren et al (24), no significant differences were found between no-sarcopenics and sarcopenics in relation to anthropometric indexes, namely TSF, BMI, MAC, and MAMC. The remaining markers of nutritional status differed among the groups stratified as malnutrition and sarcopenia status, being this difference more marked between the group sarcopenia and malnutrition and group no-sarcopenia and no-malnutrition. Among those, the phase angle, which is not much explored in HD patients, could discriminate adequately the nutritional status in the four studied groups. In our study, the phase angle differed mainly between the sarcopenic and malnourished group and the group no-sarcopenia and no-malnutrition. This finding is in agreement with studies in non-elderly adults on HD, where phase angle also differed significantly between malnourished and non-malnourished (24, 33, 34). Therefore, one marker of nutritional status should not be used alone to evaluate nutritional status, but rather a combination of markers, as in fact stated in the guideline for Nutrition and CKD from the NKF-KDOQI (29).

Regarding the quality of life, the domains most affected were social interaction, role physical, social function and, SF12 mental composite, which had worse scores in the group sarcopenia and malnutrition group. We are not aware of studies in CKD patients evaluating the role of sarcopenia and malnutrition combined on quality-of-life domains, but in a previous study from our group, we showed that patients on HD with low muscle strength had worse quality of life domains than that of the group with low muscle mass (9). Moreover, in other studies including patients on dialysis, malnutrition was associated with worse

quality of life (35-37) and with the presence of depression and sleep disorders (35).

Finally, when evaluating survival, we found that the mortality risk of the groups with sarcopenia and malnutrition was close to three times higher than the group without any of these abnormalities. As far as we are concerned, there are no previous studies assessing the role of malnutrition and sarcopenia combined in older adults on HD, but studies in older adults hospitalized without CKD showed that older adults with combined sarcopenia and malnutrition had a risk for mortality of close to five times higher when compared to the group with none of these nutritional disturbances (38). In patients on dialysis, previous studies have consistently shown that malnutrition (36, 39), sarcopenia (25), and low muscle strength (23, 32, 40) were associated with increased mortality.

Some limitations and strengths of this study can be listed. As limitations, the observational study design impair the identification of a causality-effect association. Second, the relatively small sample size can underpower the comparison among the sarcopenia and malnutrition groups, although statistical differences were already listed with this sample size. Third, the lack of robust methods to estimate muscle mass can hinder muscle abnormalities related to muscle mass. In order not to compromise the statistical analysis, we chose to group the individuals with sarcopenia and those with only low strength or low muscle mass in the same group. This is because the sample was small to divide into more groups and there would be notable heterogeneity in the size of the groups, considering that 14.1% of the individuals were sarcopenic, 35.3% with some disorder, and 58.8% with malnutrition. As positive aspects, we consider the originality of evaluating the concomitance of malnutrition and sarcopenia in elderly patients on HD, as well as the relationship of these conditions with quality of life and survival. Also, although the methods used to evaluate muscle mass could be influenced by the variation in the hydration status, all measurements were performed after the dialysis session to minimize the influence of fluid retention. In addition, since these are the methods used in the routine care of dialysis clinics and also recommended by the updated guidelines in nutrition and

CKD from NKF/KDOQI (29), our findings can be used to support a nutritional assessment with methods that are suitable for the routine use.

6. Conclusion

In conclusion, patients on HD aged 60 years and older that have sarcopenia and malnutrition showed worse nutritional parameters, quality of life domains, and higher mortality risk. In addition, we reported that malnutrition can occur in patients without sarcopenia, and that body fat markers within the normality range can occur concomitantly with malnutrition and sarcopenia. Altogether, these findings highlight the importance of complete nutritional assessment in dialysis older patients. Further studies to better understand the role of these abnormalities in the health of older adults undergoing maintenance hemodialysis are needed.

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APPENDIX A

Termo de Consentimento Livre e Esclarecido aprovado pelo Comitê de Ética em Pesquisa da UERJ

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Você foi selecionado (a) e está sendo convidado (a) para participar da pesquisa intitulada "Análise do estado nutricional de pacientes idosos com doença renal crônica em tratamento crônico de hemodiálise", e desde já agradecemos.

Esta pesquisa faz parte do Curso de Pós-graduação em Alimentação, Nutrição e Saúde do Instituto de Nutrição da Universidade do Estado do Rio de Janeiro. Esse projeto tem por objetivo geral avaliar o estado nutricional de pacientes idosos com doença renal crônica em tratamento crônico de hemodiálise; e os seguintes objetivos secundários: descrever a prevalência de desnutrição energético proteica em uma população de pacientes idosos em hemodiálise; comparar o estado nutricional e o gasto energético de repouso de pacientes idosos em hemodiálise com o de indivíduos idosos não renais crônicos; avaliar se marcadores de massa muscular e a gordura corporal total e abdominal de pacientes idosos em hemodiálise difere do de indivíduos idosos não renais crônicos; avaliar se a prevalência de desnutrição energético proteica de pacientes idosos em hemodiálise difere da de indivíduos idosos não renais crônicos; avaliar se avaliação subjetiva global empregada em pacientes com doença renal crônica é capaz de avaliar adequadamente o estado nutricional de pacientes idosos com essa enfermidade, avaliar se o estado nutricional se modifica após 24 meses e avaliar qual marcador nutricional melhor se associa com morbidade e mortalidade. O tempo de duração da pesquisa será de três anos.

Sua participação nesta pesquisa consistirá em realizar uma avaliação do estado nutricional, a fim de verificar a composição corporal através dos exames de absorciometria de duplo feixe de energia de raio X (DXA); bioimpedância elétrica; aferição de peso corporal; estatura; dobras cutâneas; força de preensão manual; estimativa do gasto energético em repouso através da calorimetria

indireta; aplicação de dois formulários diferentes, um a ser realizado por você, denominado de registro alimentar, que deverá conter anotações de toda a sua ingestão alimentar habitual durante 3 dias específicos, e o outro sobre a avaliação subjetiva global que será realizada pelo pesquisador; e coleta de 10ml de sangue, por profissional capacitado, para dosagem de creatinina, uréia, albumina, colesterol total e frações, triglicerídeos e proteína C-reativa.

Com exceção do exame de DXA e de calorimetria, essas medidas serão repetidas após 24 meses de sua inclusão no estudo. A pesquisa possibilita riscos de dimensão física apenas durante o procedimento de punção venosa para a coleta de sangue, onde poderá ocorrer dor no local, vermelhidão, inchaço e hematoma. O sangue colhido poderá ser armazenado por até dois anos para outras análises laboratoriais e após este período o material será descartado em local adequado.

Os exames de avaliação antropométrica e de bioimpedância elétrica serão realizados nas dependências da sua clínica de diálise, após a sessão de hemodiálise. Os exames de avaliação da força de preensão manual, avaliação subjetiva global e avaliação do consumo alimentar, DXA e calorimetria indireta serão realizadas em um dia sem hemodiálise, no Instituto de Nutrição da Universidade do Estado do Rio de Janeiro (UERJ), localizada na Rua São Francisco Xavier, 524, 12° andar, bloco F, Maracanã. Os exames laboratoriais (dosagem sérica de uréia, creatinina, albumina, colesterol total e frações, triglicerídeos e proteína C-reativa) serão realizados por um laboratório terceirizado na sua própria clínica de diálise. Não haverá ressarcimento dos deslocamentos entre a residência do participante e a clínica de diálise e/ou a UERJ, sendo este de inteira responsabilidade do participante da pesquisa. Será dado a você um laudo contendo o resultado dos exames relacionados ao estado nutricional.

Você, participante, deverá ir a UERJ apenas uma vez, em um dia que não tenha que fazer hemodiálise e necessariamente em jejum para realização da calorimetria indireta. Após esse exame será oferecido um lanche de café e biscoitos para posteriormente ser feito o DXA e demais avaliações listadas acima. As avaliações deverão ser realizadas de segunda a sexta feira, conforme data a ser agendada entre você e o avaliador.

É importante que ao participar desta pesquisa, você saiba que os seguintes aspectos estarão assegurados:

- A garantia do respeito ao anonimato e a confidencialidade das respostas, não sendo, em nenhum momento, divulgado o seu nome;

- Os resultados dos exames poderão ser divulgados na forma de artigos, dissertações e em trabalhos científicos;

- A garantia da participação voluntária, podendo desistir da pesquisa a qualquer momento, sem com isto gerar prejuízos tanto com o pesquisador, quanto com a instituição;

- Serão respeitados os valores culturais, sociais, morais, religiosos e éticos, bem como os hábitos e costumes dos participantes;

- Recebimento de um laudo contendo os resultados dos exames realizados, além de uma cópia para a clínica de diálise;

- Caso seja verificado algum problema nutricional, será realizada uma notificação ao Nutricionista da clínica de diálise;

- Será assegurado aos participantes da pesquisa o benefício resultante do estudo, seja em termos de retorno social, acesso aos procedimentos, condições de acompanhamento e produção dos dados;

- Lembramos que o sucesso dessa pesquisa depende da sinceridade de suas respostas e atos;

- Você receberá uma cópia deste termo onde consta o telefone e e-mail do pesquisador, podendo tirar suas dúvidas sobre o projeto e sua participação, agora ou a qualquer momento.

Certos de contar com a sua colaboração.

Atenciosamente,

_____

Profª Drª. Carla Maria Avesani

Orientadora – INU/UERJ

CRN-3:

Cel.: (21)_____

E-mail: _____

Declaro estar ciente do inteiro teor deste TERMO DE CONSENTIMENTO e estou de acordo em participar do estudo proposto.

Rio de Janeiro, _____ de _____ de 20____.

Nome: _____

IDENT. Nº_____ CPF Nº _____

Caso necessário:

_____ Data _____/_____/_____

Testemunha

_____ Data _____/_____/_____

Testemunha

Observação:

Caso haja dificuldade de contato com o pesquisador e o orientador, fazer contato com o Comitê de Ética em Pesquisa da Universidade do Estado do Rio de Janeiro no endereço: Rua São Francisco Xavier, 524, 3º andar, sala 3018, bloco E – Maracanã, Rio de Janeiro – RJ – CEP 20550-900 – tel 2334-2180 - e-mail: etica@uerj.br

ANNEX A

Aprovação Comitê de Ética em Pesquisa da

Universidade do Estado do Rio de Janeiro

Universidade do Estado do Rio de Janeiro/Sr2
Comissão de Ética em Pesquisa – COEP
Rua São Francisco Xavier, 524, bloco E, 3º. andar, sala 3018 - Maracanã.
CEP 20550-900 – Rio de Janeiro, RJ.
E - mail: etica@uerj.br - Telefone: (21) 2334 2180

PARECER COEP 086/2011

A Comissão de Ética em Pesquisa – COEP, em sua 7ª Reunião Ordinária em 11 de agosto de 2011, analisou o protocolo de pesquisa **nº.039.3.2011,** segundo as normas éticas vigentes no país para pesquisa envolvendo sujeitos humanos e emite seu parecer.

Projeto de pesquisa: ***"A análise do estado nutricional de pacientes idosos com doença renal crônica em tratamento crônico de hemodiálise".***
Pesquisador Responsável: Carla Maria Avesani
Instituição Responsável: Instituto de Nutrição - UERJ
Área do Conhecimento: 4.00 – Ciências da Saúde – 4.05 Nutrição
Palavras-chave: Doença renal crônica, hemodiálise, estado nutricional, composição corporal e desnutrição energético proteica

Sumário Trata-se de um projeto de pesquisa que pretende "avaliar o estado nutricional de pacientes idosos com doença renal crônica em tratamento crônico de hemodiálise", a fim de compreender as alterações da composição corporal e o seu impacto na condição nutricional e no gasto energético em repouso dessa população. Esse conhecimento possibilitará o aprimoramento da atenção ao idoso, especialmente no que se refere ao atendimento nutricional. O estado nutricional dos idosos será avaliado por meio de parâmetros antropométricos, de composição corporal, de gasto energético de repouso, de consumo alimentar e de exames laboratoriais. O projeto tem financiamento da FAPERJ (APQ1 – E26/111.653/2010) inclusive para o pagamento das dosagens laboratoriais.

Objetivo geral: Compreender as alterações da composição corporal e o seu impacto na condição nutricional e no gasto energético em repouso dessa população

Considerações Finais: Após debate entre os membros a COEP concluiu que o presente projeto de pesquisa apresenta pertinência científica; clareza e objetividade no que se refere aos objetivos, justificativa e metodologia.

Após o atendimento à solicitação do Parecer COEP nº049/2011, a Comissão deliberou pela **aprovação** do projeto.

Faz-se necessário apresentar Relatório Anual - **previsto para dezembro de 2012,** para cumprir o disposto no item *VII. 13.d da RES. 196/96/CNS.* Além disso, a COEP deverá ser informada de fatos relevantes que alterem o curso normal do estudo, devendo o pesquisador apresentar justificativa, caso o projeto venha a ser interrompido e/ou os resultados não sejam publicados.

Situação: Projeto Aprovado

Rio de Janeiro, 07 de dezembro de 2011.

Profa. Dra. Celia Caldas
Coordenadora da Comissão de Ética em Pesquisa/UERJ
Mat 32.359-2

ANNEX B

Avaliação Global Subjetiva – 7 pontos

Avaliação Global Subjetiva – 7 pontos	
Paciente: **Data:** **Pesq Id:**	
HISTÓRIA	
	Pontuação: 1 a 7
PESO / MUDANÇA DE PESO 1. Peso anterior (kg) _____ (peso seco de 6 meses atrás) Peso atual (kg) _____ (peso seco hoje) Perda de peso / últimos 6 meses _____ (%) / _____ (Kg): perda desde início ou da última ASG. 2. Mudança de peso nas últimas 2 semanas: _____ Sem mudança_____ Aumento _____ Redução	
INGESTÃO ALIMENTAR Sem mudança (adequada): ____Sem mudança (inadequada) ___ 1. Mudança: ingestão reduzida: ___proteína: ___kcal: ___tempo observado ___ apenas líquida: ___ líquida hipocalórica: ___ Jejum: ___	
SINTOMAS GASTROINTESTINAIS **Sintomas** **Frequência** **Duração** ___ Nenhum _____ _____ ___ Anorexia _____ _____ ___ Náusea _____ _____ ___ Vômito _____ _____ ___ Diarréia _____ _____ Frequência: Nunca, diariamente, 2 a 3x/semana; 1 a 2 x/semana Duração: > 2 semanas / < 2 semanas	
CAPACIDADE FUNCIONAL	

Descrição **Duração** ____ Sem alteração _____ ____ Com alteração _____ ____ dificuldade para deambular _____ ____ dificuldade em realizar atividades (aquelas "normais" ao paciente) _____ ____ atividade leve _____ ____ sentado/acamado com pouca ou nenhuma atividade _____ ____ melhora para realizar atividades _____	
DOENÇAS E COMORBIDADES RELACIONADAS COM AS NECESSIDADES NUTRICIONAIS Diagnóstico principal: _____Comorbidades: _____ Requerimento: Normal:____Aumentado: ____Reduzido: ____ Estresse metabólico agudo:Nenhum: ____ Baixo: ____ Moderado: ____ Elevado: ____	
EXAME FÍSICO	
___ redução de gordura subcutânea (tríceps, bíceps, peito, abaixo dos olhos) Todas áreas: ___ Algumas áreas: ___ ___ redução de muscular (Têmporas, clavículas, escápulas, costela, quadríceps, panturrilha, joelho e interósseos) Todas áreas: ___ Algumas áreas: ___ ___ Edema (relacionado à desnutrição/ usar este item para avaliar mudança de peso)	
Pontuação Geral	
Risco muito leve para desnutrição a bem nutrido= 6 a 7 para maioria das categorias ou com melhora continuada ou significante. **Desnutrição Leve a moderada**= 3, 4 ou 5. Sem sinais evidentes de desnutrição severa ou de estado nutricional normal. **Desnutrição grave**= 1 ou 2 na maioria das categorias/ com sinais importantes de desnutrição.