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On predicting outcomes in patients with chronic heart failure with frailty syndrome

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Abstract

Background. The presence of frailty negatively affects the prognosis of patients with chronic heart failure, increasing the frequency of hospitalizations, limiting treatment options, and also increasing the mortality of patients.

Aim. To develop a model for predicting mortality in patients with decompensated chronic heart failure, including frailty syndrome.

Material and methods. 107 patients aged 45–95 years with decompensated chronic heart failure were studied. Four age groups were formed: the first — 29 patients aged 45–59 years old (average age 53.9±4.5 years), the second — 31 elderly patients (60–74 years old, average 68.3±5.0 years), the third — 40 senile people (75–90 years, average age 81.5±4.1 years), the fourth — 7 long-lived patients (>90 years, average 92±1.4 years). A comprehensive geriatric assessment was performed using the program “Optimization of care in geriatrics depending on the degree of frailty”. A multivariate logistic regression analysis was performed to select mortality predictors.

Results. The prognostic model included 6 independent variables: age — 1.05 [0.96; 1.17] ($p=0.28$), male gender — 0.25 [0.03; 1.65] ($p=0.17$), frailty of severe or terminal degree — 5.56 [1.08; 37.14] ($p=0.05$), IV functional class according to the classification of New York Heart Association — 3.41 [0.60; 27.35] ($p=0.19$), ejection fraction 50% or more — 0.29 [0.03; 2.28] ($p=0.26$), ejection fraction 40–49% — 0.40 [0.05; 2.60] ($p=0.36$). The sensitivity of the model was 62%, specificity 82%, prognostic effectiveness 88%.

Conclusion. Severe or terminal asthenia is the strongest predictor of mortality, increasing the risk of an unfavorable outcome by 5.56 times.

Keywords: frailty, chronic heart failure, mortality model, old age, senile age.

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Background

The aging population has increased the number of older individuals, which has required more attention to the issues faced by older people [1]. Currently, one of the most pressing problems is the prevalence of multiple geriatric syndromes and high comorbidity rates among older and senile populations [2]. Frailty syndrome is a prominent geriatric syndrome that reflects the need for care in older age groups [1].

Frailty is diagnosed when three or more of the following symptoms are present: sarcopenia, decreased hand strength, weakness and fatigue, decreased movement speed, and significantly decreased physical activity. The presence of one or two components may indicate senile preasthenia gravis [3].

The prevalence of frailty syndrome varies among age groups. Frailty syndrome affects no more than 10%–16% of older individuals. However, this percentage increases to 25%–50% in the older age group [1]. Frailty is prevalent in up to 74% of patients with chronic heart failure (CHF), depending on the diagnostic method used [4]. Several studies have confirmed the relationship between CHF and frailty syndrome [4–6]. These syndromes have common pathogenetic components, which make them mutually aggravating factors, with each enhancing the negative effect of the other [4, 5].

Patients with CHF must be distinguished from those with decompensated heart failure. This clinical type of acute heart failure accounts for up to 80% of all cases [6]. CHF decompensation is

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characterized by the progression of symptoms of circulatory insufficiency and requires consultation with a cardiologist and hospitalization [7]. Despite the successful treatment of CHF, decompensation remains the primary reason for referral to medical institutions for patients over ≥ 65 years. In the Russian Federation, 1-year mortality rate due to CHF decompensation is as high as 43% [6].

In recent years, improving the accuracy of outcome prediction and optimizing the management of patients with CHF decompensation has received more attention. Several studies have suggested that functional class IV according to the New York Heart Association (NYHA) classification, blood pressure < 100 mm Hg, and decreased glomerular filtration rate < 50 mL/min/1.73 m² are predictors of mortality in patients with CHF [5, 8–10].

Most prognostic scales are based on the assessment of age, NYHA class, ejection fraction (EF), and laboratory parameters [9–11]. However, in older age groups, the presence or absence of frailty syndrome also has a prognostic effect [11, 12]. Therefore, developing a prognostic model that includes frailty assessment is an urgent task.

This study developed a model for predicting the mortality of patients with CHF decompensation while including frailty syndrome.

Materials and methods

The study was conducted at the cardiac intensive care unit of the Central Clinical Hospital with the Polyclinic of the Presidential Affairs Department of the Russian Federation. From January 2020 to January 2021, 107 patients with decompensated CHF were recruited. The obtained data were digitized, and an electronic database was created from January to April 2021. The statistical method used to form the mortality model was chosen between April and May 2021. The scientific literature on the problem was analyzed from May to July 2021. Our data were compared with the results of other studies published between July and September 2021, and statistical data processing was completed to determine the final form of the predictive model. Research results and conclusions of studies published between September and October 2021 were compiled.

The study analyzed data from 107 patients aged 45–95 years with decompensated CHF. The patients were categorized into four age groups:

Group 1 included 29 middle-aged people (45–59 years old).

Group 2 consisted of 31 older patients (60–74 years old).

Group 3 consisted of 40 older patients (75–90 years old).

Group 4 consisted of 7 very old individuals (> 90 years of age).

Because of the small sample size of very old patients ($n = 7$), this group was only presented in descriptive statistics and not included in intergroup comparisons. To assess the effect of frailty on mortality, the study participants were further divided into six groups based on the severity of frailty syndrome:

Group 1 consisted of 41 patients with satisfactory geriatric status.

Group 2 consisted of 6 patients with preasthenia gravis.

Group 3 included 17 individuals with mild frailty syndrome.

Group 4 consisted of 16 people with middle frailty syndrome.

Group 5 consisted of 10 patients with severe frailty syndrome.

Group 6 was represented by 17 individuals with terminal frailty.

CHF was verified based on the criteria recommended by the Russian Society of Cardiology [7].

Patients were included in the study if they met the following criterion: presence of CHF decompensation in patients aged 45–95 years.

Patients were excluded from the study based on the following criteria:

- Severe liver dysfunction (Child–Pugh class C)
- Polychemotherapy in patients with oncologic pathology.
- Renal replacement therapy for terminal-stage chronic kidney disease (glomerular filtration rate < 15 mL/min)
- Acute myocardial infarction
- Acute cerebral circulatory disorders of any genesis
- Pulmonary embolism
- Shock of any genesis
- Acute phase of inflammatory diseases
- Any clinical condition that, in the physician's judgment, may interfere with the patient's participation in the study.

To assess frailty syndrome, all patients underwent a comprehensive geriatric evaluation using the original computer program “Optimization of Care in Geriatrics Depending on the Degree of Frailty” (Certificate of State Registration No. 2013660311). Blood pressure, heart rate, and saturation were assessed in all participants using a COMEN STAR 8000A bedside monitor. Echocardiography was performed using a portable ultrasound device (Philips CX50).

All information from the EMIAS paper and electronic medical history was entered into a single electronic database using Excel spreadsheets. The

distribution was evaluated using the Shapiro–Wilk criterion at a significance level of 0.01. Continuous variables were presented as mean and standard deviation if the normal distribution hypothesis was not rejected in all groups. If the normal distribution hypothesis was rejected in at least one group, the variables were presented as median and interquartile range. Fisher’s exact test was used to compare frequencies. The Mann–Whitney U test and Kruskal–Wallis H test were used to compare continuous variables.

A nomogram was used to visualize the prediction model. Predictors of the multivariate logistic regression model were selected using the inclusion–exclusion method based on Akaike’s information criterion. When creating the nomogram, quantitative predictors were converted to ordinal/binary form to optimize prediction and ensure the convenience of using the nomogram.

Multicollinearity was checked by calculating Spearman’s correlation coefficient. Values of variance inflation factor (VIF) <5 were considered to indicate the absence of multicollinearity. Dunn’s test with Holmes correction was used as a post-hoc method. To evaluate the quality of the mathematical model, the coefficient of determination (R^2) proposed by Nigekirk was calculated. This coefficient shows the proportion of influence that all variables included in the model have on the dependent variable’s variance. The model’s prognostic efficiency was assessed by analyzing the ROC curve and calculating the area under the curve.

The significance level was set at 0.05. Statistical calculations were performed using R version 4.1.0 (R Foundation for Statistical Computing, Vienna, Austria) and IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA).

The study was approved by the local ethics committee of the Central Clinical Hospital with the Polyclinic of the Presidential Affairs Department of the Russian Federation (Minutes No. 01 dated January 22, 2020).

Results

The study sample revealed significant sex differences. Group 1 was composed entirely of men, whereas group 2 had 16 (51.6%) men and 15 (48.4%) women. Group 3, which consisted of older participants individuals, was predominantly female (67.5%). Group 4 (aged > 90 years) had a predominance of women (87.5%) (Table 1).

A decrease in the mean saturation value was observed with increasing age. The lowest value was recorded in the senile group [88.5 (86.8–95.0)], which was significantly lower than that in the older group [95.0 (89.0–96.0)] ($p = 0.041$) and

middle-aged group [96.0 (92.0–97.0)] ($p = 0.001$) (Table 1).

No significant difference in systolic blood pressure was found between the middle-aged and older groups ($p = 0.534$). However, the senile group had significantly lower mean systolic blood pressure values than the older group ($p = 0.001$). In addition, no significant difference in mean diastolic blood pressure values was noted between the middle-aged and older groups ($p = 0.750$). However, the senile group had significantly lower mean diastolic blood pressure values than both the older ($p = 0.013$) and middle-aged ($p = 0.008$) groups.

The mean heart rate values of the middle-aged group were comparable to those of the older and senile groups ($p = 0.329$ and $p = 0.254$, respectively). No patients in the middle-aged group required vasopressor/cardiotoxic hemodynamic support. The proportions of patients in the older (16.1%) and senile (25%) groups requiring drug support for hemodynamics were comparable ($p = 0.414$). Among patients in the senile group, the proportion of patients with indications for vasopressor/cardiotoxic drugs was higher than that of the middle-aged group ($p = 0.012$; Table 1).

Moreover, 51.7% of the patients in the middle-aged group had reduced EF ($<40\%$), whereas the proportion was lower at 19.4% in the older group ($p = 0.038$). The proportion of patients with reduced EF was similar between the middle-aged and older groups ($p = 0.121$). The proportion of patients in all three age groups with intermediate EF (40%–49%) was comparable ($p = 1.0$). Only 13.8% of the patients in the middle-aged group had preserved EF ($\geq 50\%$). In the older group, the proportion of patients with preserved EF was higher (45.2%; $p = 0.023$). The proportion of middle-aged patients with preserved EF was comparable to that of the elderly group ($p = 0.112$; Table 1).

The study found that 82.8% of patients in the middle-aged group exhibited symptoms of CHF at the NYHA class III level. In the older group, more than half (67.7%) also had CHF of NYHA class III, which was comparable to that in the middle-aged group ($p = 0.115$). Notably, the proportion of older patients with CHF of NYHA class III was more than twice as high as that in the senile group (30%; $p = 0.026$). The proportion of patients with NYHA class III CHF was lower in the senile group than in the middle-aged group ($p = 0.001$). In the middle-aged group, only 17.2% of the patients had CHF class IV, which was comparable with that of the older group (32.3%, $p = 0.212$). Majority of the patients in the senile group (70%) had NYHA class IV CHF, which was higher than the proportions in the middle-aged and older groups ($p = 0.001$; Table 1).

Table 1. General characteristics of the study participants

Parameters	Middle-aged group, n = 29 1	Older group, n = 31 2	Senile group, n = 40 3	Longevity group, n = 7 4	p
Mean age, years	55,0 (50,0–57,0)	68,0 (64,0–72,5)	81,5 (78,0–84,2)	92,0 (91,5–93,0)	p ₁ =0,001 p ₂ =0,001 p ₃ =0,001
Men, n (%)	29 (100,0)	16 (51,6)	13 (32,5)	1 (14,3)	p ₁ =0,001 p ₂ =0,153 p ₃ =0,001
Women, n (%)	0 (0)	15 (48,4)	27 (67,5)	6 (85,7)	p ₁ =0,001 p ₂ =0,144 p ₃ =0,001
Saturation, %	96,0 (92,0–97,0)	95,0 (89,0–96,0)	88,5 (86,8–95,0)	88,0 (87,0–90,0)	p ₁ =0,041 p ₂ =0,041 p ₃ =0,001
Systolic blood pressure, mmHg	146,0 (132,0–151,0)	142,0 (107,0–156,0)	102,0 (89,0–143,0)	91,0 (86,0–93,5)	p ₁ =0,534 p ₂ =0,015 p ₃ =0,001
Diastolic blood pressure, mmHg	82,0 (73,0–89,0)	76,0 (67,5–90,0)	67,0 (61,0–82,2)	60,0 (54,0–62,5)	p ₁ =0,750 p ₂ =0,013 p ₃ =0,008
Heart rate, ppm	92,0 (75,0–107,0)	98,0 (83,5–110,5)	93,5 (85,0–110,2)	106,0 (97,0–108,0)	p ₁ =0,329 p ₂ =0,797 p ₃ =0,254
Hemodynamic support, n (%)	0 (0)	5 (16,1)	10 (25,0)	3 (42,9)	p ₁ =0,113 p ₂ =0,414 p ₃ =0,012
EF <40%, n (%)	15 (51,7)	6 (19,4)	12 (30,0)	2 (28,6)	p ₁ =0,038 p ₂ =0,623 p ₃ =0,121
EF 40%–49%, n (%)	10 (34,5)	11 (35,5)	13 (32,5)	4 (57,1)	p=1,0
EF ≥ 50%, n (%)	4 (13,8)	14 (45,2)	15 (37,5)	1 (14,3)	p ₁ =0,023 p ₂ =0,752 p ₃ =0,112
CHF NYHA class III, n (%)	24 (82,8)	21 (67,7)	12 (30)	2 (28,6)	p ₁ =0,115 p ₂ =0,026 p ₃ =0,001
CHF NYHA class IV, n (%)	5 (17,2)	10 (32,3)	28 (70)	5 (71,4)	p ₁ =0,212 p ₂ =0,001 p ₃ =0,001

Note: p₁ = p₁₋₂, p₂ = p₂₋₃, p₃ = p₁₋₃; CHF, chronic heart failure; EF, ejection fraction; NYHA, New York Heart Association.

During the observation period in the intensive care unit (ICU) of the study cohort, 15 (14%) patients died. On day 1 of ICU stay, 1 (1.07%) patient died. No significant differences in mortality were found between the groups on day 1 of ICU stay ($p = 1.0$). The age groups did not differ significantly in terms of mortality during the ICU stay ($p = 0.1$). However, in the long-lived group, 85.7% had a fatal outcome (Table 2).

Further analysis of ICU mortality, considering the severity of frailty syndrome, was conducted and intergroup differences in mortality were found ($p = 0.001$). Among patients without frailty syndrome, the mortality rate was 2.4%. In patients with senile preasthenia and mild frailty, a 100%

survival rate was observed. Fatal outcomes were recorded in 12.5% of the patients with moderate frailty. No patients with severe frailty died. The highest mortality rate was observed among those with a terminal degree of frailty (70.6%; Table 3).

Multivariate logistic regression analysis was used to assess the influence of various factors on the clinical outcome. The prognostic model included six independent variables: age, male sex, and severe and terminal frailty, EF 40%–49%, EF ≥ 50%, and NYHA class IV. Risk factors for mortality were as follows: age, 1.05 [0.96; 1.17] ($p = 0.28$), severe or terminal frailty, 5.56 [1.08; 37.14] ($p = 0.05$), and NYHA class IV, 3.41 [0.60; 27.35] ($p = 0.19$). Protective variables were male sex, 0.25

Table 2. Mortality rates in patients with decompensated chronic heart failure

Parameters	Middle-aged group, n = 29 1	Elderly group, n = 31 2	Senile group, n = 40 3	Longevity group, n = 7 4	p
Mortality on day 1 of ICU stay, n (%)	0 (0)	0 (0)	0 (0)	1 (14,3)	p=1,0
Mortality in the ICU, n (%)	1 (3,4)	1 (3,2)	7 (17,5)	6 (85,7)	p ₁ =1,0 p ₂ =0,142 p ₃ =0,142

Note: $p_1 = p_{1-2}$, $p_2 = p_{2-3}$, $p_3 = p_{1-3}$; ICU, intensive care unit.

[0.03; 1.65] ($p = 0.17$), EF 40%–49%, 0.40 [0.05; 2.60] ($p = 0.36$), and EF $\geq 50\%$, 0.29 [0.03; 2.28] versus EF <40% ($p = 0.26$; Table 4).

A nomogram was created to evaluate the risk of a lethal outcome in the ICU based on the analysis. The factors included in the nomogram were age, male sex, severe or terminal frailty, EF, and NYHA class IV. In the prognostic model, each indicator has a corresponding score.

The patient age was the first variable.

– The minimum age of the patients (45 years) included in the study was scored 0, and the maximum age (95 years) was scored 100.

– The second parameter was the sex of the study participants. Male sex was scored 0 points, whereas female sex was scored 34 points.

– The third predictor was frailty syndrome. The absence of frailty syndrome or presence of mild or moderate frailty corresponded to zero points. The presence of severe or terminal frailty scored 54 points.

– The fourth indicator was EF. Preserved EF ($\geq 50\%$) corresponded to zero points, moderate EF reduction (40%–49%) scored 8 points, and reduced EF (<40%) scored 28 points.

– The final parameter was NYHA class IV. If the severity of CHF symptoms was lower than NYHA class IV, it was scored 0 points. The presence of NYHA class IV was scored 38 points.

After analyzing all variables, the scores were summed and transferred to the linear predictor value scale (Fig. 1). This value can be used to calculate the risk of an unfavorable clinical outcome (Fig. 2).

The proposed model exhibited a sensitivity of 62%, specificity of 82%, and prognostic efficiency of 88%. The coefficient of determination (R^2) by Nagelkerk was 0.43 (Fig. 3).

Discussion

This article continues the previously published work on identifying predictors of mortality in patients with decompensated CHF admitted in the ICU [13]. On the basis of the previous data, a prognostic model for mortality in patients with decompensated CHF was constructed.

Table 3. Mortality rates in patients with decompensated chronic heart failure in groups with different severity levels of frailty syndrome

Degree of frailty	Mortality in the ICU, n (%)
Absence of frailty, n = 41	1 (2,4)
Preasthenia gravis, n = 6	0 (0)
Mild frailty, n = 17	0 (0)
Moderate frailty, n = 16	2 (12,5)
Severe frailty, n = 10	0 (0)
Terminal frailty, n=17	12 (70,6)
p	0,001

Note: ICU, intensive care unit.

In this study, we constructed a nomogram, which is a widely used method of data analysis. A nomogram is a graphical representation of a function from several variables, which allows us to study functional dependencies without calculations using simple geometric operations.

Logistic regression, along with other multivariate analysis methods, requires a sufficient sample size. Some observations and events can significantly reduce the statistical power of a study [14]. In the present study, the dependent variable (lethal outcome) had a low frequency of positive values, at only 14%. Before the modeling era, the traditional approach involves randomly dividing the entire sample into training and test samples. The model is then developed using the training sample and tested on the test sample. However, because of the asymmetry of the sample and the limited number of events analyzed, we decided to forego this approach and limit it to the initial stage of model development.

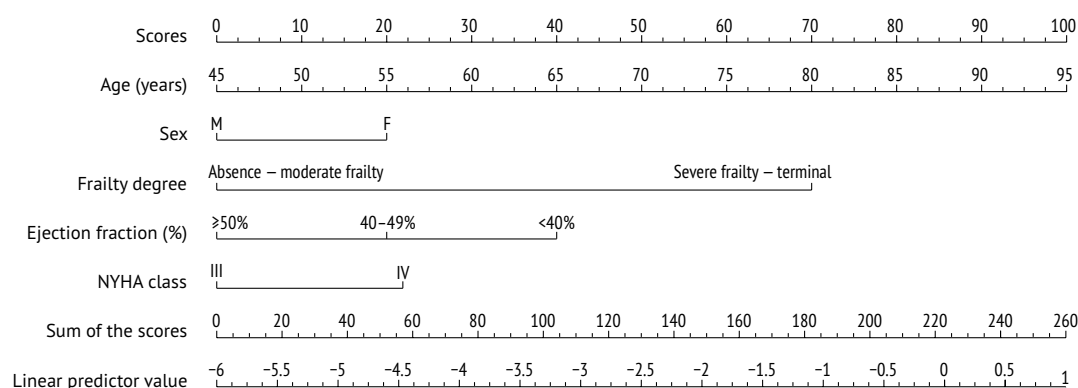
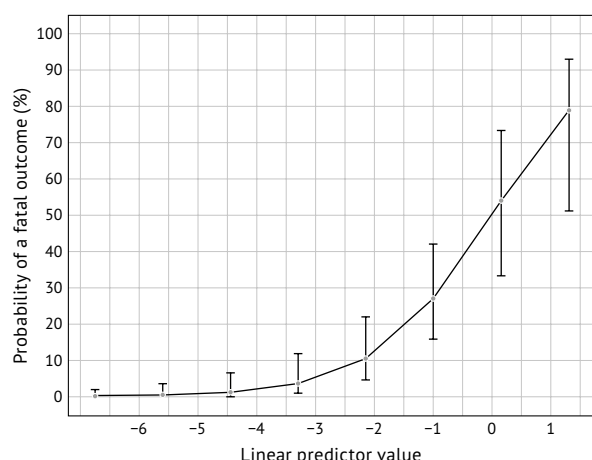
Predictors are selected in two stages. In the first stage, a starting list of independent variables was made. The second stage involved reducing the number of predictors that were highly correlated with each other.

The single-factor analysis included nine predictors: age, male sex, moderate frailty, severe/terminal frailty, EF 40%–49%, EF $\geq 50\%$, CHF stages IIB and III according to Strazhesko-Vasilenko, and

Table 4. Multivariate logistic regression analysis of mortality rates

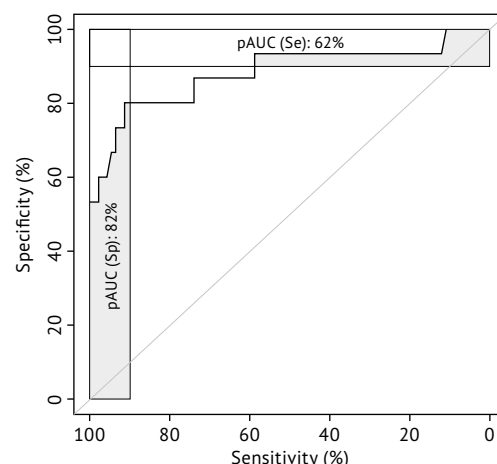
Predictors		OR [95% CI]	p	VIF
Age		1,05 [0,96; 1,17]	0,28	1,36
Male sex		0,25 [0,03; 1,65]	0,17	1,43
Severe or terminal frailty		5,56 [1,08; 37,14]	0,05	1,30
EF (to a EF <40%)	40%–49%	0,40 [0,05; 2,60]	0,36	1,59
	≥50%	0,29 [0,03; 2,28]	0,26	1,70
NYHA class IV		3,41 [0,60; 27,35]	0,19	1,13

Note: CHF, chronic heart failure; CI, confidence interval; EF, ejection fraction; NYHA, New York Heart Association. OR, odds ratio; VIF, variance inflation factor

**Fig 1.** Nomogram for estimating the probability of death; NYHA, New York Heart Association**Fig 2.** Estimation of the probability of a lethal outcome for the values obtained in the nomogram

NYHA class IV. Frailty syndrome was included as a predictor because of its high mortality rates in the longevity group (85.7%). Among the patients, those with the most severe forms of frailty (severe and terminal degree) had the highest mortality rates. Subanalysis of mortality in relation to the severity of frailty syndrome revealed that patients with terminal frailty had a mortality rate of 70.6%.

None of the other predictors were significant beyond the α threshold of 0.05. After including the above predictors in the multivariate analysis, only

**Fig 3.** Receiver operating characteristic curve of the predictive efficiency of the model

severe/terminal frailty was found to be statistically significant at the 0.05 level. The presence of this syndrome was significantly associated with a 5.56-fold increase in ICU mortality.

The proposed model achieved a predictive efficiency of 88%, with a sensitivity of 62% and a specificity of 82%. However, it falls short of the modern requirements for medical artificial intelligence systems, which demand a sensitivity of at least 95% and a specificity of >80%. This is likely due to the small sample size and low frequency

of the events analyzed. However, even under imbalanced conditions, a significant association was found between severe/terminal frailty syndrome and mortality in patients with decompensated CHF in the ICU.

Conclusions

1. Of the variables included in the model, severe or terminal frailty was the strongest predictor of adverse outcomes, increasing ICU mortality 5.56-fold.

2. The severity of frailty syndrome positively correlated with ICU mortality. Specifically, the mortality rates were 0%, 12.5%, and 70.6% in patients with mild, moderate, and terminal frailty, respectively ($p = 0.001$).

3. A prognostic model for mortality was developed using components of comprehensive geriatric assessment, which has a sensitivity of 62%, specificity of 82%, and prognostic efficiency of 88%.

Authors' contribution. I.V.P., study conception, supervision of work, data analysis and interpretation; N.M.H.A., and data analysis and interpretation; L.V.T., data analysis and interpretation, and statistical treatment of data; M.V.S., critical revision of significant intellectual content, clinical consultation; A.S.P., clinical consultation.

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