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Comparative clinical frailty scale and hospital frailty risk score in identifying frailty and predicting mid-term outcomes in older patients with acute coronary syndrome: a multicenter cohort study in Vietnam

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Abstract

Background We aimed to compare the agreement between two common frailty assessment tools, Clinical Frailty Scale (CFS) and Hospital Frailty Risk Score (HFRS), and their ability to predict mid-term adverse outcomes in older patients admitted with acute coronary syndrome (ACS).

Methods We conducted a prospective analysis of patients aged ≥ 60 admitted with ACS at multiple centers in Vietnam between July 2022 and June 2023. A cross-tabulation method was used to describe the correlation between CFS and HFRS. To test the predictive accuracy of HFRS for identifying patients with frailty according to CFS, we evaluated the area under the curves of receiver operating characteristic (ROC) analysis. Youden J index was used to identify a new optimal probability threshold for HFRS. We employed Cox regression models to investigate the association between frailty assessed by CFS, HFRS (using both old and new cut-offs), and 9-month mortality.

Results We included 504 older patients admitted with ACS (median age 72.7 years; male: 59.9%). The correlation between CFS and HFRS was fair ($AUC = 0.787$, $p < 0.010$). HFRS had a sensitivity of 39.7% and a specificity of 79.2% to detect frailty based on CFS classification. The new optimal probability threshold of HFRS (≥ 1.15 points) improved the instrument's performance with a significantly higher sensitivity of 90.2%. While frailty categorized by HFRS with the original cut-off did not impact mid-term all-cause and cardiovascular mortality, frailty according to CFS and HFRS with the new threshold was shown to be a predictor of mid-term all-cause and cardiovascular mortality ($HR = 4.48$, $p < 0.001$ vs. $HR = 2.29$, $p = 0.001$; $HR = 5.19$, $p < 0.001$ vs. $HR = 1.99$, $p = 0.020$).

Conclusions Although a fair correlation existed between the CFS and the HFRS in older patients with ACS, HFRS demonstrated limited predictive validity for mid-term mortality. We advocate for a revised cutoff (HFRS ≥ 1.15 points) to enhance its sensitivity and predictive accuracy. Future research should prioritize the integration of additional

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clinical biomarkers and conducting longitudinal studies to assess the efficacy of targeted interventions informed by frailty scores, ultimately striving to improve outcomes in this vulnerable population.

Keywords Frailty, Clinical Frailty Scale, Hospital Frailty Risk score, Older patient, Acute coronary syndrome, Mid-term mortality

Introduction

Frailty can be defined as “a medical syndrome with multiple causes and contributors that is characterized by diminished strength, endurance, and reduced physiological function that increases an individual’s vulnerability for developing increased dependency and/or death” [1]. Cardiovascular diseases are the world’s leading causes of mortality and morbidity, imposing significant economic burdens on patients, their families, healthcare services, and societies [2]. The high prevalence of frailty in the older population with cardiovascular disease is becoming a major concern and increasing pressure on the healthcare system [3].

ACS encompasses a range of conditions, including unstable angina (UA), non-ST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction (STEMI) [4]. It is characterized by myocardial ischemia and can lead to serious complications, especially in older patients with frailty. Previous studies have shown that frailty in older patients with ACS is associated with increased frequent hospitalization, hospital stays, costs, mortality, risk of cardiovascular events [5–11], and major bleeding [8, 12–14]. Frailty plays an important role in prognosis as well as in providing appropriate treatment and care strategies for older patients [14]. Therefore, early frailty identification is extremely crucial in older patients with ACS.

In contemporary, although there is no gold standard for diagnosing frailty and criteria for assessing frailty in older patients have not been agreed upon, frailty is a key aspect of comprehensive geriatric assessment. Therefore, geriatricians have studied and developed more than 51 instruments to screen and identify degrees of frailty based on gradations of functional impairment or by specific clinical features [15]. In clinical settings, the CFS continues to be one of the most frequently used tools for assessing frailty in older patients with ACS because of its reliability. CFS, which is a validated and rapid bedside frailty assessment instrument, allows evaluating frailty according to score on a 9-point scale, ranging from very fit to terminally ill through the doctor’s clinical judgment and assessment of the patient [16].

However, CFS requires face-to-face assessment, which can be time-consuming and subject to inter-operator error, and variables unlikely to be included in electrical medical records [17]. Therefore, it might be complicated for use to perform individual frailty assessments on older patients in acute care settings. The HFRS is a new

frailty assessment tool that uses a weighted score based on the International Statistical Classification of Diseases, 10th revision (ICD-10) codes for inpatients [18]. HFRS assessed frailty through comorbidities and prior hospitalization data to determine frailty. Although HFRS can be automated and has routine applicability without additional clinical resource use that allows reduced costs and eliminates errors due to manual scoring, they come with potential limitations regarding the relevance and availability of contributing data points and the lack of contextual clinical judgment. Furthermore, while frailty assessed by CFS is a strong predictor of short-, mid-, and long-term mortality and rehospitalization [19–24], the prognostic value of HFRS in older patients with ACS has been only demonstrated in short-term in previous studies [25–28].

This study, therefore, aims to investigate the degree of agreement between CFS and HFRS in determining the frailty and ability to predict mid-term adverse outcomes for older patients admitted with ACS.

Methods

Study design and participants

We conducted a prospective cohort study in patients aged ≥ 60 admitted to Thong Nhat Hospital in Ho Chi Minh City and University Medical Center, Ho Chi Minh City, Vietnam with a diagnosis of ACS from July 2022 to June 2023. Patients who were not Vietnamese or refused to participate were excluded. Patients provided their consent in written form. The ethical principles and the Helsinki Declaration were always followed strictly during the study. This research has been approved by the Ethics Council of the University Medical Center, Ho Chi Minh City, 672/HĐĐĐ-ĐHYD.

Frailty assessment

Clinical frailty score

At admission, the patient’s degree of frailty according to CFS was assessed by one cardiologist and two geriatricians. The CFS assessment was based on the patient’s self-reported baseline functional capacity including the ability to perform activities of daily living and instrumental activities of daily living at least 2 weeks before the presentation. The final levels of frailty severity were confirmed with at least 2 physicians’s agreement. The Clinical Frailty Scale is an inclusive 9-point scale that divides patients into groups from 1 (very fit) to 9 (terminally ill). Very fit, Well, and Managing Well categories on the CFS

instrument with a CFS score from 1 to 3 are defined as non-frailty, and the remaining ones are defined as frailty [29].

Hospital frailty risk score

The HFRS is a frailty risk score that can be retrospectively calculated for all hospitalized patients based on available ICD-10 codes from administrative data regardless of the duration of the diseases at admission. ICD-10 codes from previous admissions, medical reports, and prescriptions are collected [18]. The HFRS score is calculated based on the presence of the first three characters of any of the 109 ICD-10 codes which had a different number of points based on the weight it predicted frailty. A detailed HFRS scoring algorithm can be found in the original HFRS study. The risk of frailty is categorized as low (<5 points), intermediate (5–15 points), or high (>15 points). The low-risk group is defined as non-frailty, and intermediate- and high-risk groups are defined as frailty.

Baseline covariates and outcome data

We collected baseline data including demographic (age and sex), clinical characteristics (BMI, types of ACS), laboratory results (left ventricular ejection fraction, hemoglobin, troponin T, glucose, creatinine), and receiving percutaneous coronary intervention (PCI) of the study population. All patients were followed up for 9 months to evaluate all-cause and cardiovascular mortality.

Statistical analysis

The data were analyzed using the IBM SPSS Statistics, version 27. (IBM Corp., Armonk, N.Y., USA). Continuous variables were presented as mean and standard deviations. Categorical variables were described as frequencies and percentages (%). The differences between frail and non-frail patient groups were performed by the Chi-squared or Fisher's exact test for categorical variables, Student's t-test (normal distribution), or Wilcoxon–Mann–Whitney (non-standard distribution) for the continuous variable.

We used cross-tabulation between CFS and HFRS frailty groups to describe the correlation between the instruments. To test the predictive accuracy of the HFRS in identifying patients with frailty according to the CFS, we assessed the areas under the curves of ROC analysis. The CFS was used as a standard for this analysis because of its widespread validation in many clinical settings, and to set an appropriate cutoff point. We considered test values of 0.5–0.6, 0.6–0.7, 0.7–0.8, 0.8–0.9, and >0.9 to indicate fail, poor, fair, good, and excellent, respectively [30]. The Youden J index was used to maximize the new optimal probability threshold of HFRS [31].

We conducted a study to investigate the relationship between frailty, evaluated by CFS and HFRS, and

mid-term mortality in older patients with ACS. To conduct this analysis, we used Cox multivariable regression. The variables for the multivariable models were chosen based on their association with mid-term all-cause and cardiovascular mortality at a significance level of $p < 0.2$. We created a Kaplan–Meier curve to visualize the probability of survival over time, categorized by the presence or absence of frailty.

Statistical significance was determined based on a two-sided p-value threshold of less than 0.05, indicating a level of confidence in the results.

Result

Characteristics of the study subjects

In this study, 504 patients who were aged 72.7 ± 8.5 years on average were included. The study comprised 306 (59.9%) men and 198 (40.1%) women. Among the hospitalized older patients, NSTEMI was the most common diagnosis (37.1%), followed by UA (35.7%) and STEMI (27.2%).

The baseline characteristics of the patients are displayed in the following Table 1. It is noteworthy that the frail group had an average age of 75.3, which was significantly higher than the non-frail group with an average age of 68.8 ($p < 0.001$). The proportion of men was lower in the frail group (55.4%) as compared to the non-frail group (68.5%) with a p-value of 0.003. Furthermore, the frail group had significantly higher levels of hs-TnT (1148.6 vs. 674.5, $p = 0.027$), creatinine (1.42 vs. 1.13, $p = 0.001$), and GRACE score (133.8 vs. 114.3, $p = 0.001$). However, their left ventricular ejection fraction (53.4% vs. 57.1%, $p = 0.008$) was lower than the non-frail group. Lastly, it is important to note that the proportion of PCI in the frail group was lower (62.5%) than in the non-frail group (79.2%), with a p-value of less than 0.001.

Correlation between the CFS and HFRS

Table 2 shows how frailty is correlated with the CFS and HFRS using the original threshold. Out of the 504 individuals in the cohort, 307 (60.9%) were assessed as frailty by CFS, while only 163 (32.3%) were identified as frail by the HFRS. In the CFS frailty group, the HFRS identified 122 out of 307 patients (39.7%) as frail, while 185 (60.3%) patients were not detected. Among the non-frail individuals according to the CFS, 156 patients (79.2%) were assessed as non-frail by the HFRS, and only 41 patients (20.8%) were classified as frail. The HFRS has a sensitivity of 39.7% and a specificity of 79.2% in detecting frail and non-frail individuals according to the CFS as the criterion standard measurement.

Outcome

The ROC curve analysis of the HFRS to detect frailty is displayed in Fig. 1. It was found that the HFRS showed

Table 1 Baseline characteristics and distribution of frailty by clinical Frailty Scale among hospitalized individuals with acute coronary syndrome ($n = 504$)

Variables	Total ($n = 504$)	Non-Frail ($n = 197$)	Frail ($n = 307$)	p-value
Age – years	72.8±8.5	68.8±6.6	75.3±8.7	< 0.001
Gender: Male - n (%)	305 (60.5)	135 (68.5)	170 (55.4)	0.003
BMI - kg/m ²	22.7±3.1	23.0±3.1	22.5±3.1	0.087
Types of ACS				0.242
UA	180 (35.7)	70 (35.5)	110 (35.8)	
NSTEMI	187 (37.1)	66 (33.5)	121 (39.4)	
STEMI	137 (27.2)	61 (31.0)	76 (24.8)	
Laboratory				
EF - %	54.8±16.1	57.1±14.3	53.4±17.0	0.008
Troponin Ths – pg/ml	962.3±2662.7	674.5±1652.2	1148.6±3133.4	0.027
Hemoglobin – g/dl	13.3±8.1	14.2±10.4	12.8±6.3	0.055
WBC – g/l	10.0±4.2	9.8±3.9	10.2±4.4	0.285
PLT – g/l	253.5±84.1	258.9±79.2	250.0±87.0	0.250
Glucose – mg/dl	164.5±101.7	153.9±92.0	171.2±107.0	0.054
Creatinin – mg/dl	1.31±0.97	1.13±0.85	1.42±1.02	0.001
GRACE score	126.2±31.4	114.3±24.0	133.8±33.2	0.001
PCI – n (%)	348 (69.0)	156 (79.2)	192 (62.5)	< 0.001
Adverse outcomes during hospitalization				
All-cause mortality– n (%)	35 (6.9)	4 (2.0)	31 (10.1)	0.001
Cardiovascular mortality – n (%)	21 (4.2)	3 (1.5)	18 (5.9)	0.017
Adverse outcomes after discharge				
All-cause mortality– n (%)	88 (17.5)	10 (5.1)	78 (25.4)	< 0.001
Cardiovascular mortality – n (%)	65 (12.9)	6 (3.0)	59 (19.2)	< 0.001

Abbreviations: BMI, Body mass index; UA, unstable angina; ACS, Acute coronary syndrome; NSTEMI, Non-ST-segment elevation myocardial infarction; STEMI, ST-segment elevation myocardial infarction; EF, ejection fraction; WBC, white blood cells; PLT, platelets; PCI, percutaneous coronary intervention

Table 2 Cross-tabulation of the HRFS (using the original threshold of HRFS, HRFS ≥ 5 points and the new threshold of HRFS, HRFS ≥ 1.15 points) and CFS Frailty groups

CFS, patients, No. (%)			
HRFS ^a	Non-Frail	Frail	Total
Non-Frail	156 (79.2)	185 (60.3)	341
Frail	41 (20.8)	122 (39.7)	163
Total	197 (39.1)	307 (60.9)	504
	Sp: 79.2%	Se: 39.7%	
CFS, patients, No. (%)			
HRFS ^b	Non-Frail	Frail	Total
Non-Frail	131 (66.5)	30 (9.8)	161
Frail	66 (33.5)	277 (90.2)	343
Total	197 (39.1)	307 (60.9)	504
	Sp: 66.5%	Se: 90.2%	

Abbreviations: HRFS, Hospital Frailty Risk Score; CFS, Clinical Frailty Scale; Sp, specificity; Se, Sensitivity

Notes: a, HRFS using the original threshold (≥ 5 points); b, HRFS using the new threshold (≥ 1.15 points)

fair performance in detecting frailty compared to CFS, with an acceptable validity (AUC=0.787, $P < 0.01$). The Youden index was used to identify the optimal probability threshold of HRFS to determine frailty, which was equal to or greater than 1.15. Using this new cut-off, out of 307 patients, 277 patients were identified as frailty, and

out of 197 patients, 131 were identified as non-frailty. The sensitivity and specificity of the new HRFS cut-off were found to be 90.2% and 66.5%, respectively, as shown in Table 2.

During the hospitalization, 21 deaths caused by cardiovascular issues were recorded, compared to 35 deaths caused by any other reason. After the follow-up period, 21 patients were lost to follow-up, and among the 123 recorded deaths, 86 (69.9%) patients died due to cardiovascular causes. The univariate and multivariate analysis revealed that frailty assessed by CFS and HRFS, with the new threshold, was linked to an increased risk of mid-term all-cause and cardiovascular mortality. The Hazard ratio (HR) was 4.48 with a 95% confidence interval (CI) of 2.50–8.04 and p-value less than 0.001 for all-cause mortality, while the HR was 5.19 with a 95% CI of 2.52–10.68 and p-value less than 0.001 for cardiovascular mortality. The HR was 1.01 with a 95% CI of 0.69–1.48 and p-value of 0.971 for all-cause mortality, while the HR was 0.88 with a 95% CI of 0.56–1.39 and p-value of 0.585 for cardiovascular mortality. These results were obtained from Table 3, Supplementary Table S1, and Fig. 2.

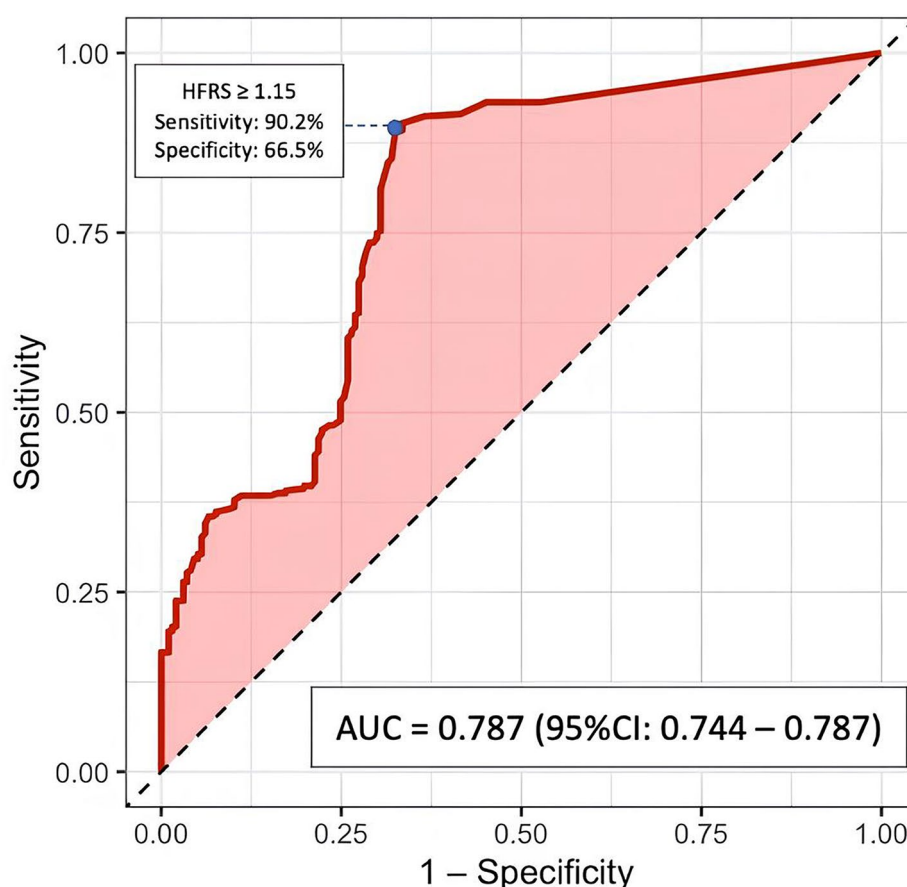


Fig. 1 Receiver operating curve (ROC) analysis with optimal probability threshold for hospital frailty risk score (HFRS)

Table 3 Hazard ratio of the association between frailty and mid-term all-cause mortality and cardiovascular mortality in older patients with ACS

Frailty assessment	All-cause mortality		Cardiovascular mortality	
	HR (95% CI)	p-value	HR (95% CI)	p-value
CFS	4.48 (2.50–8.04)	< 0.001	5.19 (2.52–10.68)	< 0.001
HFRS ^a	1.01 (0.69–1.48)	0.971	0.88 (0.56–1.39)	0.585
HFRS ^b	2.29 (1.40–3.75)	0.001	1.99 (1.12–3.54)	0.020

Abbreviations: CI, confidence interval, HR, hazard ratio

Notes: a, HFRS using the original threshold (≥ 5 points); b, HFRS using the new threshold (≥ 1.15 points)

Variables that had a P-value < 0.2 in the univariate regression were included in the multiple regression

Discussion

This study focused on assessing frailty in older patients with ACS (Acute Coronary Syndrome) and provided new insights into the subject. The study found three key outcomes. Firstly, the agreement between frailty assessment based on HFRS (Hospital Frailty Risk Score) and CFS (Clinical Frailty Scale) was fair, with an AUC (Area Under the Curve) of 0.787. Secondly, the study found that the new optimal probability threshold of the HFRS (≥ 1.15 points) improves the instrument's performance with significantly higher sensitivity (90.2% vs. 39.7%) and slightly lower specificity (66.5% vs. 79.2%) when determining frailty based on the CFS classification. Thirdly, the study

found that while frailty assessed by HFRS with the original threshold did not significantly impact mid-term all-cause and cardiovascular mortality, frailty assessed by CFS and HFRS with the new threshold were shown to be predictors of mid-term all-cause and cardiovascular mortality.

In the previous study, a low level of agreement was found in defining frailty in a previous study of the correlation and agreement between HFRS and eFI [32]. Similar results were seen in other previous studies that evaluated the correlation between HFRS and CFS in a group of patients with COPD exacerbation and those admitted to the ICU [33–35]. These studies also showed poor or

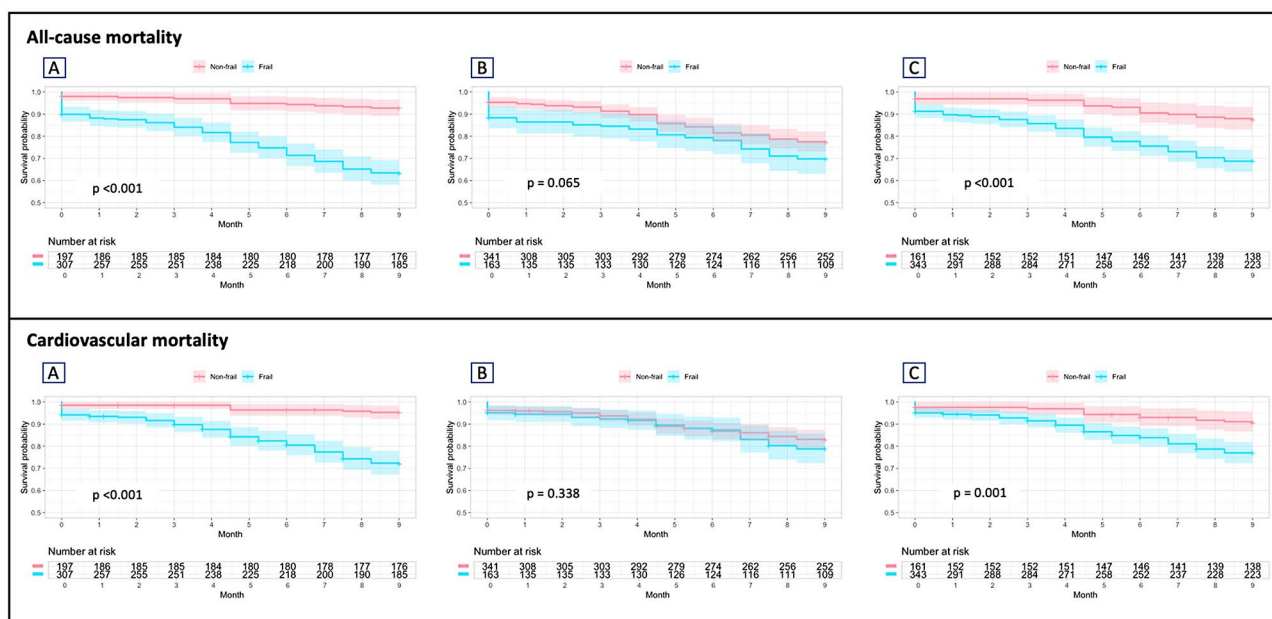


Fig. 2 Relationship between frailty and mid-term mortality in older patients with ACS

(A) Kaplan–Meier survival curves illustrate the probability of survival with and without frailty assessed by CFS. (B) Kaplan–Meier survival curves illustrate the probability of survival with and without frailty assessed by HFRS with the original threshold (≥ 5 points). (C) Kaplan–Meier survival curves illustrate the probability of survival with and without frailty assessed by HFRS with the new threshold (≥ 1.15 points)

slight levels of agreement between the two instruments. However, in our study, we found a higher correlation between CFS and HFRS with a fair level of correlation. This difference may have come from using a lower cut-off of CFS to define frailty. Instead of scores of 5 or 6, we used a score of 4 to classify frailty according to CFS [35]. This change is due to the updated version of CFS in frailty assessment. Patients with a score of 4 are now defined as very mildly frail instead of the previous term vulnerable [28]. Although, there was a slight improvement in correlation between the two scales, agreement between CFS and HFRS was still not good. This may be because the scales use different aspects to assess frailty. While the CFS is a clinical frailty assessment tool that emphasizes the level of functional impairment, HFRS is an instrument based on previous administrative comorbidity that focuses on the multimorbidity aspect to identify frailty.

Our research found that the prevalence of frailty in older patients hospitalized with ACS was almost twice as high as when assessed using the CFS compared to the HFRS. Moreover, more than 60% of patients with frailty according to CFS were not detected as frail according to HFRS. This could be attributed to several limitations in using population-based administrative data indices to determine frailty or its risk. For instance, the electronic medical record system is incomplete, and several diagnoses may not have been encoded into ICD codes. Additionally, a lack of connectivity between hospitals in developing countries makes the use of HFRS difficult

and inaccurate. As a result, many diagnoses were not recorded or calculated, leading to lower HFRS scores and reduced sensitivity of the instrument in determining frailty according to the original cut-off. Compared to HFRS, CFS requires training for users and manual assessment, which may introduce bias in the results. However, CFS demonstrates accuracy when relying on clinical judgment rather than incomplete data [16]. Secondly, the points for each diagnosis used in HFRS are based on cohort studies in the group of older patients (> 75 years) in the UK [18]. While several studies have used HFRS on different groups of patients, including those aged 18 years and above, no study has redefined the weight of each ICD code in determining frailty in younger populations [26–28, 36, 37]. Furthermore, differences in demographics and co-morbidities between regions and ethnicities also contribute to the differences. For instance, in a meta-analysis, the prevalence of comorbidities in Europe and high-income countries was higher than in Asian and lower-middle-income countries [38], which means that the HFRS score is also lower. Additionally, codes that are commonly recorded in studies in European and American countries, such as Z.91, and Z.87, are rarely used in the Vietnamese health system [26–28, 36]. Therefore, future studies should focus on redefining the ICD codes used in HFRS and recalculating the weight of each diagnosis, which is appropriate for each age group and population.

In the context of not being able to obtain weights for ICD codes, our study uses the ROC curve to find a new optimal cutoff to improve the performance of HFRS. With the new optimal probability threshold of the HFRS (≥ 1.15 points), 277 patients (55.0%) were categorized as frail according to HFRS. The new cut-off improved the sensitivity of HFRS when 90.2% of patients categorized as frail according to CFS were captured as being at risk for frailty by the HFRS compared to 39.7% of the old threshold. Similarly, a new cut-off with a lower HFRS point (≥ 1.4) was also proposed to detect frailty among hospitalized patients with COPD exacerbation [33].

In the previous study, both CFS and HFRS were shown to be predictors of adverse outcomes including 30-day mortality, length of stay > 10 days, and 30-day readmission in older people with emergency care needs [35]. In patients admitted to ICU, frailty according to both HFRS and CFS was also an independent factor that predicted up to 1-year survival following [34]. The risk of adverse outcomes, including 90-day mortality, 90-day emergency readmission, and care home admissions within 1-year was also higher for the increased frailty risk for HFRS [32]. Interestingly, in our study, while CFS-categorized frailty, adjusted for related factors, was independently associated with 9-month all-cause and cardiovascular mortality, HFRS was not predictive of mid-term all-cause and cardiovascular mortality. However, with the new threshold (≥ 1.15 points), frailty according to HFRS was independently predictive for all-cause and cardiovascular mortality after a 9-month follow-up period. With the new threshold (≥ 1.15 points), HFRS improves the performance of both sensitivity and predictive ability for 9-month all-cause and cardiovascular mortality. Therefore, along with available advantages including speed, simplicity, less time-consuming, automation capabilities allow for limited inter-operator error and can be used wherever an ICD-10 coding system is available, HFRS with the new instead of the original cut-off was an appropriate instrument to determine frailty in acute care setting.

This study has several important benefits. To the best of our knowledge, it is the first to examine the predictive value of HFRS for mid-term adverse outcomes in older patients with ACS. Additionally, the study's strengths come from its design. This was the first prospective study to evaluate frailty in older patients using HFRS. Clinicians and geriatricians directly assessed CFS-categorized frailty, rather than collecting it from medical records, as in previous comparative studies between HFRS and CFS. The prospective study design accurately recognized adverse outcomes and avoided biases. However, certain limitations should be noted. The single-province sampling and small sample size limit generalizability nationally and cross-culturally without replication. The

assessment of frailty using HFRS is challenging and may be insufficient due to limited data available and being done manually. Therefore, more extensive and population-based studies are needed to verify the findings.

Conclusion

This study rigorously compared the CFS and the HFRS in their ability to identify frailty and predict mid-term outcomes in older patients with ACS. While both instruments demonstrated substantial agreement at admission, the HFRS fell short in predicting mid-term mortality. We recommend a revised cutoff (HFRS ≥ 1.15 points) to enhance its sensitivity and predictive validity. These findings underscore the importance of selecting appropriate frailty assessment tools, thereby optimizing treatment and care strategies for the aging population.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12877-025-05690-6>.

Supplementary Material 1

Acknowledgements

We thank all the participants for their participation in this study.

Author contributions

Study conception and design: Tan Van Nguyen and Huy Minh Tran. Ethics application, recruitment, data acquisition: Tan Van Nguyen and Huy Minh Tran. Project management: Tan Van Nguyen and Trinh Kim Thi Ngo. Statistical analysis: Huy Minh Tran and Tan Van Nguyen. Drafting of the manuscript: Huy Minh Tran, Tan Van Nguyen, and Trinh Kim Thi Ngo. All authors were involved in the interpretation of data and revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

Funding

This study received no funding.

Data availability

The datasets generated and/or analyzed during the present study are not publicly available due to institutional regulations and privacy restrictions but are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam (reference number: 672/HĐĐĐ-ĐHYD August 2022). Participants were informed of the study and provided written consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Clinical trial number

Not applicable.

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Received: 4 August 2024 / Accepted: 7 January 2025

Published online: 24 February 2025

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