Advances in Health, Sports and Technology Sciences

DOI: 10.14744/ahsts.2025.91153
Adv Health Sports Technol Sci 2025;2(2):64-71

Original Article

Pulmonary Embolism Severity Index (PESI) and Plasma Lactate in Predicting Thirty-Day Mortality in Pulmonary Embolism

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ABSTRACT

Objective: Acute pulmonary embolism(PE) is a common and fatal complication of venous thromboembolism. Following diagnosis, clinical scoring systems (PESI, sPESI), imaging modalities for right ventricular dysfunction, or blood biomarkers are used to determine prognosis and new parameters and combined scoring systems continue to be developed. Our aim is to evaluate the effectiveness of the PESI score and lactate levels in arterial blood gas for predicting 30-day mortality in patients with PE in the emergency department (ED).

Materials and Methods: This study is a retrospective cross-sectional study conducted between January 1, 2016, and December 31, 2017. A total of 190 patients aged 18 years and older who presented to the adult ED with diagnosed with acute PE by pulmonary multi-detector computed tomography (MDCT) were retrospectively screened through the hospital record management system and patient files. The PESI score was calculated using the patient data obtained and the lactate value in the arterial blood gas analysis was recorded. Deaths within 30 days were examined using the hospital document management system and the Ministry of Health Death Reporting System. The statistical significance of lactate, PESI, troponin, right ventricular dysfunction and the presence of infection accompanying PE in predicting 30-day mortality was evaluated.

Results: Out of 190 patients, 40 (21.1%) died within 30 days. PESI classes were found to be statistically significant in assessing 30-day mortality ($p<0.001$). The sensitivity of PESI was found to be 75%, and the specificity was 74%. Death was observed within 30 days in 28 (17.2%) of 163 patients with low lactate levels and in 12 (44.4%) of 27 patients with high lactate levels ($p=0.001$). The sensitivity of plasma lactate was 30%, specificity 90%; the sensitivity of PESI and lactate was 80%, specificity 71.3%. When lactate, PESI Class IV, and PESI Class V values were analyzed using logistic regression, the contribution of lactate to predicting mortality was statistically significant when PESI was present ($p=0.033$)

Conclusion: In patients diagnosed with acute PE, when PESI and lactate are evaluated together in prognosis assessment, they are found to be more powerful in predicting mortality than PESI alone

Keywords: PESI, plasma lactate, pulmonary embolism

Cite this article as:
Kavakli I, Eneyli MG, Genc S, Gur A, Gokdere CG, Pulmonary Embolism Severity Index (PESI) and Plasma Lactate in Predicting Thirty-Day Mortality in Pulmonary Embolism. Adv Health Sports Technol Sci 2025;2(2):64-71.

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Submitted: 05.06.2025
Accepted: 11.06.2025
Available Online: 09.07.2025

Advances in Health, Sports and Technology Sciences – Available online at www.advanceshsts.com

INTRODUCTION

Acute pulmonary embolism(PE) is a common and often fatal complication of venous thromboembolic disease. In the US, up to 300,000 deaths per year are attributed to PE, ranking among the leading causes of death related to cardiovascular disease. Epidemiological studies report an annual incidence of PE ranging from 39 to 115 per 100,000 people[1–4].

Acute PE is suspected in patients presenting to the emergency department(ED) with any of the following complaints: hemoptysis, syncope, presyncope, chest pain, and shortness of breath[5–7]. The likelihood of PE is assessed using the Wells and Geneva risk scores to determine whether there are any factors that predispose to venous thromboembolism. According to these scores, D-dimer testing is recommended in low-risk patients, and if high values are found according to age, pulmonary multidetector computed tomography (MDCT) angiography is recommended. In high-risk patients, pulmonary MDCT angiography is recommended without the need for D-dimer testing[8,9]. Pulmonary MDCT angiography is the first-line imaging method used for diagnosis in cases of suspected PE[10–13].

After diagnosis, prognosis determination is important because it influences the choice of treatment approach (thrombolytic therapy, parenteral and oral anticoagulant therapy, surgical embolectomy, or direct thrombolysis with a percutaneous catheter) and whether the patient should be hospitalized or treated on an outpatient basis. For prognosis determination, clinical scoring systems (PESI, sPESI), imaging modalities for right ventricular dysfunction, or blood biomarkers are used, and new parameters and combined scoring systems continue to be developed[14]. Plasma lactate concentration can be measured quickly and easily from arterial blood samples using a blood gas analyzer, which is readily available in the ED. In a previous study by Simone Vanni et al. [15], high plasma lactate levels were found to be associated with increased in-hospital mortality in patients with acute PE.

The aim of this study is to evaluate the effectiveness of the Pulmonary Embolism Severity Index (PESI) score and lactate levels in arterial blood gas in predicting 30-day mortality in patients diagnosed with PE in the ED.

MATERIALS AND METHODS

Study Design and Data Collection

This study is a single-center, retrospective, cross-sectional, observational study. The study was conducted between January 1, 2016, and December 31, 2017, at the Department of Emergency Medicine, Faculty of Medicine, Ankara University. Patients who presented to the adult ED of Ibn-i Sina Hospital with a suspected diagnosis of PE and underwent to MDCT and were diagnosed with acute PE were included in the study. Our hospital is a tertiary-level university training and research hospital, which received approximately 40,000 ED visits annually during the study period.

Inclusion criteria for the study were: diagnosis of acute PE based on MDCT angiography, age over 18 years, not pregnant, and measurement of lactate levels via arterial blood gas analysis. Exclusion criteria included patients for whom vital sign parameters and medical history information were unavailable for PESI calculation, and patients in whom lactate levels were not measured in arterial blood gas analysis.

Among 1,378 patients who underwent pulmonary MDCT angiography, 190 patients with acute PE and measured lactate levels in arterial blood gas were examined. In line with the aim of our study, our main parameters for predicting mortality within 30 days in acute PE were the PESI score and the lactate level measured in arterial blood gas. PESI is a scoring system frequently used to determine prognosis and mortality. Five risk classes have been defined, and in our study, the PESI scores of patients who met the inclusion criteria were calculated based on data obtained from hospital record management system records and patient files and categorized according to the score.

Plasma lactate concentration was measured using a blood gas analyzer available in the ED, in accordance with the manufacturer's instructions for use. Based on literature data, patients were grouped according to a lactate level of ≥2 mmol/L, which is considered clinically significant in relation to poor outcomes. Patients were divided into two groups: those with a lactate level of ≥2 mmol/L and those with a lactate level of <2 mmol/L.

Echocardiographic examinations were performed to assess right ventricular dysfunction in patients with pulmonary embolism. Echocardiographic examinations were performed by trained echocardiography technicians using a standard color two-dimensional echocardiographic doppler device. Echocardiographic examinations performed within the first 24 hours in patients with acute PE were used in the study (in 190 patients with acute pulmonary embolism, echocardiography could not be performed in 59 cases within the first 24 hours, while it was performed in 131 cases). In the study, patients were divided into two groups: those with acute right ventricular dysfunction detected by echocardiography and those without.

Another variable that may be associated with mortality in acute PE is the troponin-I value measured from peripheral venous blood samples. Patients were categorized based on their troponin-I levels relative to this threshold value: normal troponin-I (≤0.01 ng/mL) and high troponin-I (>0.01 ng/mL).

The hospital record management system and patient files were reviewed to investigate the effect of comorbidities, including active cancer, chronic lung disease, congestive heart failure, and concomitant infection, on mortality. In the study, patients were examined in two groups: presence of concomitant infection and absence of concomitant infection.

When determining the sample size, logistic regression was used to assume that a 7% increase in serum lactate levels would result in a 25% difference in mortality between patients with and without elevated serum lactate levels. With 80% power and a 5% type I error, it was determined that at least 125 participants should be included in the study.

In our study, the primary endpoint was defined as death within 30 days. For each patient, whether death occurred within 30 days after the diagnosis of acute PE was retrospectively reviewed using the hospital record management system and the Ministry of Health Death Reporting System. In the study, patients were divided into two categories: death within 30 days and no death within 30 days.

Ethical Approval and Declaration of Helsinki

Approval for this study was obtained from the Ankara University Faculty of Medicine Clinical Research Ethics Committee (Ethics Committee date and number: December 10, 2018, Decision No: 20-1362-18). The study was conducted in accordance with the World Medical Association Helsinki Declaration and Good Clinical Practice Guidelines.

Statistical Analysis

The data evaluated in our study were expressed as mean ± standard deviation (SD) for quantitative variables that were normally distributed, median (minimum value-maximum value) for those that were not normally distributed, and frequency (%) for qualitative variables. The dependence and independence of the variables were calculated using the Pearson chi-square test and Fisher's exact probability test. The effectiveness of PESI, lactate, and combined (PESI and lactate together) use in predicting mortality within 30 days, the primary endpoint of the study, was examined using the Receiver Operating Characteristics (ROC) curve and the area under the curve (AUC).

In subgroup analyses, low- and moderate-risk groups (PESI Class I, Class II, and Class III) were combined and compared with high-risk (PESI Class IV) and very high-risk (PESI Class V) groups in terms of 30-day mortality. Factors affecting 30-day mortality were examined using logistic regression. A p-value of <0.05 was considered statistically significant. Statistical analyses were performed using the SPSS (Version 22, SPSS Co Inc, Chicago, IL) software package.

RESULTS

Of the 190 patients included in the study who were diagnosed with acute PE, 40 (21.1%) died within 30 days for various reasons. The mean age of all patients was 67.98 (±16.1). The mean age of patients who did not experience mortality within 30 days was 66.39 (±16.8), while the mean age of patients who experienced mortality within 30 days was 73.95 (±11.2). The demographic and clinical data of the patients are presented in Table 1. The variables examined in our study regarding the relationship between patients diagnosed with acute PE and 30-day mortality are presented in Table 2.

Of the 190 patients included in the study, 85 were female (58.7%). Among the 85 male patients diagnosed with acute PE, mortality was observed in 23 (27.1%) within 30 days, while mortality was observed in 17 (16.2%) of the 105 female patients within 30 days. There was no statistically significant difference in mortality within 30 days between male and female patients (p=0.068).

Of the 190 patients diagnosed with acute PE, 41 patients in the PESI Class IV group, 7 deaths were observed within 30 days, with a mortality rate of 17.1% within 30 days. Among the 69 patients in the PESI Class V group, 30 deaths were observed within 30 days, with a mortality rate of 43.5% within 30 days. Survival rates according to PESI classes are also shown in Table 3.

In our study, the ability of PESI to predict mortality within 30 days was statistically significant (p<0.001). PESI was evaluated in terms of mortality using logistic regression. Logistic regression showed that PESI Class IV was associated with mortality within 30 days with an OR of 5.284 and a p-value of 0.021. PESI Class V was found to be significantly associated with mortality within 30 days with an OR of 19.74 and p<0.001. The area under the ROC curve for PESI was calculated as EAA=0.781 with a standard error of 0.038. The sensitivity of PESI was 0.75, while the specificity was 0.74.

It was found that 17.2% (n=28) of the 163 patients with lactate levels <2 mmol/L and 44.4% (n=12) of the 27 patients with elevated lactate levels died within 30 days. The presence of lactate ≥2 mmol/L was found to be statistically significant in predicting 30-day mortality, with a p-value of 0.001 between the two groups. The 30-day mortality rate between lactate

Table 1. Demographic and Clinical Characteristics of Patients Included in the Study

	Normal lactate (<2) (n=163)	High lactate (>2) (n=27)	All patients (n=190)
Age (years)	67.91±15.497	68.44±19.837	67.98±16.125
Gender, n (%)			
Male	72 (44.2)	13 (48.1)	85 (44.7)
Female	91 (55.8)	14 (51.9)	105 (55.3)
Pulse (beats/min)	97.74±19.485	108.15±18.491	99.22±19.640
Systolic blood pressure (mmHg)	111.42±16.320	98.52±18.116	109.59±17.142
Diastolic blood pressure (mmHg)	69.50±12.456	60.56±11.352	68.23±12.670
Presence of cancer, n (%)	48 (29.4)	9 (33.3)	57 (30)
Presence of congestive heart failure, n (%)	14 (8.6)	2 (7.4)	16 (8.4)
Presence of chronic lung disease, n (%)	29 (17.8)	4 (14.8)	33 (17.4)
Presence of concomitant infection, n (%)	53 (32.5)	13 (48.1)	66 (34.7)
PESI score	112.06±38.974	127.52±43.941	114.25±39.961
PESI classification, n (%)			
Class I	18 (11)	2 (7.4)	20 (10.5)
Class II	21 (12.9)	1 (3.7)	22 (11.6)
Class III	35 (21.5)	3 (11.1)	38 (20)
Class IV	35 (21.5)	6 (22.2)	41 (21.6)
Class V	54 (33.1)	15 (55.6)	69 (36.3)

<2 mmol/L and lactate ≥2 mmol/L was also calculated using the Cox regression method, and the hazard ratio (HR) was determined. With the reference value set at lactate <2 mmol/L, the HR for lactate ≥2 mmol/L was calculated as 3.43. Using logistic regression, lactate ≥2 mmol/L was found to be significantly associated with 30-day mortality, with an OR of 3.857 and a p-value of 0.002. The AUC for lactate was calculated as 0.60, with a standard error of 0.054. The sensitivity of lactate alone in predicting mortality was found to be 0.30, and the specificity was 0.90.

When lactate, PESI Class IV, and PESI Class V values were analyzed using logistic regression, it was determined that lactate contributed to predicting mortality with a moderate level of significance (p=0.033) when PESI was present, but did not contribute sufficiently to classification.

The AUC for the ROC curve drawn for PESI and lactate was calculated as 0.804 with a standard error value of 0.036. The sensitivity of PESI and lactate was calculated as 0.80, and the specificity as 0.713. The negative predictive value (NPV) was found to be 0.93, while the positive predictive value (PPV) was 0.427.

Of the 131 patients who underwent echocardiographic examination within 24 hours, 38 (29%) were found to have right ventricular dysfunction. Of the 38 patients with right ventricular dysfunction detected by echocardiography, 9 (23.7%) died within 30 days, while 13 (14%) of the 93 patients (71%) without right ventricular dysfunction died within 30 days. Although the mortality rate was higher in patients with right ventricular dysfunction detected by echocardiography compared to those without right ventricular dysfunction(p=0.177), indicating no statistically significant difference in mortality between the two groups.

Of the 124 patients with troponin levels above 0.01, 33 (17.3%) died within 30 days(p=0.010). In the logistic regression analysis, with a p-value of 0.013 and an odds ratio (OR) of 3.057, it was concluded that troponin may be a weak prognostic indicator for mortality in the presence of lactate and PESI.

The presence of concomitant infection was found to be significantly associated with mortality compared to the absence of infection(p=0.004).

The presence of cancer significantly affected mortality within 30 days in acute PE patients(p<0.001). The chi-square test

Table 2. Relationship between Primary Outcome (Mortality Observed Within 30 Days) and Variables

	No deaths within 30 days	Deaths within 30 days	p
Age (year)	66.39±16.867	73.95±11.264	
Gender			
Male	62 (32.63)	23 (12.10)	0.068
Female	88 (46.31)	17 (8.94)	
PESI			
Class I	20 (10.5)	0 (0)	<0.001
Class II	22 (11.57)	0 (0)	
Class III	35 (18.42)	3 (1.57)	
Class IV	34 (17.89)	7 (3.68)	
Class V	39 (20.52)	30 (15.78)	
Lactate	1.14±0.57	2.10±1.75	0.001
Troponin I	0.14±0.37	1.91±8.45	0.01
Right ventricular			
Dysfunction present n (%)	29 (15)	9 (4.7)	0.177
Dysfunction absent n (%)	80 (42)	13 (6.8)	
Cancer			
Present, n (%)	36 (18.9)	21 (11)	<0.001
Absent, n (%)	114 (60)	19 (10)	
Congestive heart failure			
Present, n (%)	9 (4.7)	7 (3.6)	0.047
Absent, n (%)	141 (74.2)	33 (17.3)	
Chronic lung disease			
Present, n (%)	24 (12.6)	9 (4.7)	0.335
Absent, n (%)	126 (66.3)	31 (16.3)	
Underlying infection			
Present, n (%)	44 (23.15)	22 (11.5)	0.004
Absent, n (%)	106 (55)	18 (9.47)	

Table 3. Survival Rates in Low-Moderate, High, and Very High Risk Groups According to PESI

PESI Class	Total n (%)	Deaths n (%)	Survivors n (%)
PESI Class 1+2+3 (Low-medium risk)	80 (42)	3 (3.75)	77 (96.3)
PESI Class 4 (High risk)	41 (21.5)	7 (17.07)	34 (82.9)
PESI Class 5 (Very high risk)	69 (36.3)	30 (43.47)	39 (56.5)
Total	190 (100)	40 (21.05)	150 (78.9)

showed a low level of significance (p=0.047) in the relationship between mortality within 30 days and congestive heart failure. The Pearson Chi-Square test showed p=0.335, indicating that a history of chronic lung disease was not associated with mortality within 30 days in patients diagnosed with acute PE (Table 2).

DISCUSSION

PESI, sPESI, Genova prognostic scoring, SHIeLD score, mortality rates within 30 days after diagnosis, and prognosis determination for identifying low-risk patients have been developed.

It is known that plasma lactate ≥ 2 mmol/L increases mortality rates in cases of acute PE and indicates a poor prognosis. In addition to the PESI score recommended by the ESC in its 2019 Acute Pulmonary Embolism guidelines and the detection of right ventricular dysfunction through imaging and blood biomarkers, we hypothesized that plasma lactate levels in arterial blood gas could contribute to mortality prediction[16]. Our study was planned based on the hypothesis that lactate elevation could identify high-risk patients not predicted by PESI.

The mean age of patients included in our study and diagnosed with acute PE was 67.9 years. The mean age of patients who died within 30 days was 73.9 years. The finding that age-related risk increases mortality risk, as emphasized in the PESI validation study conducted by Chan CM et al.[18], was also confirmed in our study[17]. As age increases, the 30-day mortality rate from all causes increases in cases of acute PE.

In PESI Classes IV and V, the mortality rates within 30 days are 17.1% and 43.5%, respectively. In the study of Drahomir Aujesky et al.[19] in 2005, the expected mortality rates in Classes IV and V are 4-11.4% and 10-24.5%, respectively. In our study, the mortality rate is notably higher than those reported in the literature, particularly in Classes IV and V. This may be due to the high proportion of elderly patients and those with malignancies, as well as the fact that the criterion of an expected survival period of more than 6 months for patients with malignancies was not included in our study's inclusion criteria. Since the study was designed retrospectively, information regarding the life expectancy and terminal status of patients with malignancies could not be clarified. In our study, the sensitivity of PESI was found to be 75%, and the specificity was 74%. In a study comparing sPESI with PESI conducted by Wei-Ying Jen et al.[21], the sensitivity of PESI was 81.8% and the specificity was 36.1%, while in the validation study of the RIETE score conducted by E. Jaquet et al.[20], the sensitivity of PESI was 96% and the specificity was 36%

It was found that plasma lactate ≥ 2 mmol/L in arterial blood gas significantly increased 30-day mortality. The sensitivity of lactate in our study was 30%, and the specificity was 90%. In the study by Simone Vanni et al.[15], the sensitivity of lactate in relation to 30-day mortality in acute PE was 70%, and the specificity was 74%. The lower sensitivity of plasma lactate in our study compared to the literature may be due to the heterogeneous distribution of patients or the retrospective nature of the study. The higher specificity compared to the study in the literature indicates that lactate levels were lower in cases where there was no death within 30 days after the diagnosis of acute PE in our study, and that low lactate levels may be a good prognostic indicator for 30-day mortality.

The presence of signs of right ventricular dysfunction on echocardiography is known to be a high-risk factor and a poor prognostic indicator for determining the patient's treatment strategy, as emphasized in the ESC's 2019 Acute Pulmonary Embolism guidelines[16]. In our study, echocardiography was performed on 131 of 190 patients diagnosed with acute PE, and the detection of right ventricular dysfunction was not found to be statistically associated with 30-day mortality (p=0.177). This result, which is consistent with the current literature, is thought to be due to the fact that echocardiography was not performed in one-third of the patients.

Becattini C. et al.[22] found elevated troponin levels in blood samples taken at admission to be associated with poor prognosis in PE. In the study of Mangal et al.[23], troponin levels were found to be statistically significantly higher in patients diagnosed with acute PE who died within one month compared to the group that survived; however, due to low specificity and sensitivity results, they do not recommend the use of troponin levels as a mortality marker. In our study, elevated troponin I levels were found to be associated with 30-day mortality in acute PE, consistent with the literature (p=0.01). However, in the multivariate analysis, its significance was lost in the presence of lactate and PESI.

In our study, lactate, PESI, lactate+PESI, and troponin I levels were found to be statistically significantly associated with mortality rates observed within 30 days in patients diagnosed with acute PE accompanied by infection. Lactate alone provides less prognostic information than PESI, but when used in combination with PESI, its prognostic value is statistically increased. Troponin is a weak prognostic indicator alongside PESI and lactate. The high NPV value of PESI+lactate, the presence of low lactate levels, and the absence of PESI in the high-risk group may indicate a low probability of death within 30 days following a diagnosis of acute PE.

CONCLUSION

Approximately 13 out of every 100 pulmonary MDCT angiographies performed in the ED for suspected acute PE were found to confirm the diagnosis. Among the 190 patients, 40 died within 30 days, resulting in a mortality rate of 21%, which is a significant figure, highlighting the critical importance of diagnosis and treatment. Therefore, even if the number of cases is small, pulmonary MDCT angiography should be performed without delay in suspected cases to confirm acute PE. In patients diagnosed with acute PE, PESI and lactate have been shown to be more powerful than PESI and lactate alone in prognosis assessment; therefore, plasma lactate values available in the ED should also be considered.

Limitations

This study has several limitations. First, our study is a single-center and retrospective study. These factors resulted in our small size of samples and loss of data. Second, in our study, there was high proportion of elderly patients and those with malignancies. Since the study was designed retrospectively, information regarding the life expectancy and terminal status of patients with malignancies could not be clarified.

DECLARATIONS

Ethics Committee Approval: This study was approved by Ankara University Faculty of Medicine Clinical Research Ethics Committee (Date: 10/12/2018, Number: 20-1362-18).

Author Contributions: Concept – IK; Design – SG; Supervision – MGE; Resource – IK; Materials – SG; Data collection and/or processing – IK; Analysis and/or interpretation – MGE; Literature review – IK; Writing – IK; Critical Review – AG., DCG.

Conflict of Interest: The authors declared no conflict of interest.

Use of AI for Writing Assistance: The authors declared that no AI tool was used.

Financial Disclosure: The authors declared that no funding.

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