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The Prognostic Accuracy of Get With The Guidelines-Heart Failure Score Alone and with Lactate Among Acute Symptomatic Heart Failure Patients: A Retrospective Cohort Study

ABSTRACT

Background: To evaluate the prognostic accuracy of the Get With The Guidelines-Heart Failure (GWTG-HF) score, Shock Index (SI), Modified Shock Index (MSI), and Age Shock Index (Age-SI) alone and with lactate in patients with acute symptomatic heart failure (HF).

Methods: A retrospective cohort study was conducted in the emergency department of a tertiary hospital between January 1, 2019, and December 31, 2019. Patients aged >18 years and diagnosed with acute symptomatic HF were consecutively included in the study. Patients referred from another center and missing medical records were excluded. Arrival type, vital parameters, demographic characteristics, comorbid diseases, consciousness status, laboratory results, and outcomes of the patients were recorded. The primary endpoint of the study was in-hospital mortality.

Results: A total of 368 patients were included in the final analysis. The in-hospital mortality rate of the patients was 7.6%. The GWTG-HF score outperformed other scores in predicting in-hospital, 24-hour, and 30-day mortality (area under the curve (AUC) = 0.807, 0.844, and 0.765, $P < .001$, respectively). The overall performance of the GWTG-HF score with lactate (GWTG-HF+L) was better in predicting in-hospital, 24-hour, and 30-day mortality than the original GWTG-HF score (AUC = 0.872, 0.936, and 0.801, $P < .001$, respectively). Adding lactate values to the SI, MSI, and Age-SI improved their overall performance for all 3 outcomes.

Conclusion: Both the GWTG-HF and GWTG-HF+L scores have acceptable discriminatory power in patients with acute symptomatic HF. The GWTG-HF score, SI, MSI, and Age-SI can be used together with lactate to predict mortality in patients with acute HF.

Keywords: Get With The Guidelines, heart failure, shock index, lactate

ORIGINAL INVESTIGATION

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INTRODUCTION

Heart failure (HF) is among the leading causes of hospitalization globally.[1] The American Heart Association reported that approximately 6 million Americans had HF between 2015 and 2018, and the population rate is expected to be 3.0% by 2030.[2] In Asian countries, its prevalence has been reported to be approximately 4.2 million people.[3] The incidence of HF varies depending on many factors such as risk factors, etiology, region, and race.[1,2,4,5] The risk of encountering HF throughout life increases with the prolongation of lifespan and the addition of individual factors.[2,4,6]

The 5-year mortality has been reported as 53% and 67% after diagnosis of HF.[7] The deaths from HF have remained unchanged despite recent advances in evidence-based treatment modalities.[1] According to the Centers for Disease Control and Prevention data, HF is mentioned in 1 in 8 death certificates among the causes of death.[2] Previous hospital admission due to HF was found to be associated with increased readmission and mortality.[2,6,8] In addition, it is expected that HF expenditures, which were approximately 30 billion dollars in 2012 in the USA, will reach approximately 70 billion dollars in 2030 with an increase of 127%.[2]

Approximately, 80% of acute HF patients are admitted via emergency departments (EDs).[9] Thus, EDs and emergency physicians play a crucial role in the management of patients with acute HF. However, it can be challenging for emergency physicians to decide on admission or discharge. Inappropriate admissions will increase hospital costs, and inappropriate discharges will increase the risk of adverse outcomes.[9] Hence, it is crucial to discriminate between critical and noncritical patients. There is a need for reliable clinical decision support systems that are validated regionally and internationally.

In the literature, various derivation and validation studies of scoring systems have been carried out to discriminate critical HF patients.[3,10-12] However, the majority of studies were conducted among patients admitted to wards and/or intensive care units (ICUs). Studies including acute HF patients discharged from EDs after appropriate treatment and follow-up are limited.

Peterson et al[13] developed and validated the Get With The Guidelines-HF (GWTG-HF) score using the GWTG program data. To the best of our knowledge, the GWTG-HF score has not been validated in the Turkish HF patient population.

This study aims to evaluate the prognostic accuracy of the GWTG-HF score and shock index (SI) alone and with lactate in patients with acute symptomatic HF.

METHODS

Study Design

This retrospective cohort study was conducted in the ED of a tertiary training and research hospital between January 1, 2019, and December 31, 2019. The study hospital is a primary percutaneous coronary intervention, stroke, and level 3 trauma center. Approximately 350 000 patients present annually to the study ED. Local Ethics Committee approval was obtained before the study (approval ID: 2021/567; January 3, 2022). The study was conducted in line with the Declaration of Helsinki. Artificial intelligence technologies were not used in the production of the manuscript.

Patient Selection and Groups

Patients aged >18 years and diagnosed with acute symptomatic HF in the ED and patients who were Stage C and Stage D according to the American College of Cardiology and American Heart Association (ACC/AHA) stage definition were consecutively included in the study.[14] Patients referred from another center and missing medical records were excluded. The informed consent was waived due to the retrospective design of the study.

Arrival type, vital parameters, demographic characteristics, consciousness status, comorbid diseases, laboratory results, ED length of stay, and outcomes (in-hospital, 24-hours, and 30-day mortality) of the patients were recorded. Patient data were obtained from electronic medical records and ED files. The values of the patients at the time of the initial examination were used in the calculation of scores and statistical analysis. Patients were divided into groups according to in-hospital mortality.

Acute HF was defined with Framingham criteria, clinical findings, X-ray, and echocardiographic evaluation.[15,16]

Scores

The GWTG-HF score was developed and validated to predict in-hospital mortality in patients hospitalized with HF by Peterson et al[13] in 2010. The GWTG-HF score is calculated with 7 variables (systolic blood pressure (SBP), blood urea nitrogen (BUN) value, sodium value, age, heart rate (HR), chronic obstructive pulmonary disease history, and race). Score points range from 0 to 100 and can be easily calculated using an online calculator (https://www.mdcalc.com/gwtg-heart-failure-risk-score).

The SI, modified SI (MSI), and age SI (Age-SI) are calculated using the parameters of HR, SBP, mean arterial pressure (MAP), and age. The formulas used to calculate the scores are given below.

SI = HR/SBP; MSI = HR/MAP; Age-SI = Age X SI

Outcomes

The primary endpoint of the study was the prognostic accuracy of the scores alone and with lactate in predicting in-hospital mortality in patients with acute HF.

The secondary endpoint is the predictive value of the scores alone and with lactate in predicting 24-hour and 30-day mortality of the patients and factors affecting the in-hospital mortality of the patients.

Statistical Analysis

The sample size was calculated using Kirkwood et al's[17] study as a reference (n = 105 388, mortality rate: 4%).[17] The sample size was calculated as 234 acute HF patients (expected mortality = 8%, power = 80%, and alpha = 0.05). An online calculator was used to calculate the sample size (www.clincalc.com).

Categorical variables are presented as numbers and percentages. Numerical variables are presented as mean ± standard deviation or median (interquartile range). The compliance to the normal distribution of numerical variables of the groups tested by the Kolmogorov–Smirnov normality test. Categorical variables were evaluated with the chi-square test. According to normality test results, numerical variables were evaluated with the Student *t*-test or Mann–Whitney *U*-test. Variables with a *P*-value less than .05 and

HIGHLIGHTS

- Get With The Guidelines-Heart Failure (GWTG-HF) score was developed to predict the in-hospital mortality of patients with heart failure and was validated by several studies in the literature.
- This is the first study in the literature that validates the GWTG-HF score among Turkish heart failure patients.
- Lactate values are among the factors affecting mortality among heart failure (HF) patients.
- Both the GWTG-HF and GWTG-HF score with lactate (GWTG-HF+L) scores have acceptable discriminatory power in patients with HF.

did not correlate strongly with each other in bivariate correlation analyses were included in the logistic regression model. The effects of prognostic factors on HF were analyzed with simple and multiple logistic regression analyses. Odds ratios (ORs) were presented with a 95% confidence interval. The area under the receiver-operating characteristic (AUROC) curve was used to evaluate the performance of the scores. DeLong's test was used to compare ROC curves. The Youden index J point was used to determine the optimal cutoff values. The statistical significance level was determined as $P < .05$. SPSS® for Windows version 23.0 (IBM, Chicago, Ill, United States) was used for statistical analysis.

RESULTS

A total of 378 consecutive patients were included in the study. Patients referred from another center (n = 6) and missing medical records (n = 4) were excluded. A total of 368 patients were included in the final analysis. The median age of the patients was 74 (65-81), and 197 (53.5%) were women. All patients had HF with reduced ejection fraction (EF < 40%). All patients received appropriate treatment according to the current guidelines. Mechanical ventilation (MV) support was applied to 145 (39.4%) patients in the ED. Two hundred fifty (67.9%) of them were discharged from the ED after initial treatment and 118 (32.1%) were hospitalized in the ward and ICU. The in-hospital mortality rate of the patients was 7.6% (n = 28). The 24-hour mortality and 30-day mortality rates of the patients were 1.9% and 12.5%, respectively. The baseline characteristics of the patients are shown in Table 1.

In univariate analyses, low blood pressure, peripheral oxygen saturation, and sodium values, and increased BUN, lactate dehydrogenase, C reactive protein, and lactate values were found to be associated with mortality ($P < .05$). Arrival by ambulance, receiving home oxygen therapy, new-onset altered mental status, presence of cerebrovascular disease (CVD), MV need, and ICU admission were found to be associated with mortality ($P < .05$). Gender and chronic obstructive pulmonary disease history were not associated with mortality ($P > .05$). In multivariate analyses, SBP (OR = 0.95, 95% CI: 0.93-0.98, $P < .001$), CVD history (OR = 7.69, 95% CI: 1.03-56.97, $P = .046$), ICU admission (OR = 86.9, 95% CI: 8.4-889.4, $P < .001$), sodium (OR = 0.82, 95% CI: 0.70-0.96, $P = .017$), BUN (OR = 1.08, 95% CI: 1.04-1.13, $P < .001$), and lactate (OR = 1.55, 95% CI: 1.14-2.10, $P = .004$) were found to be predictors of mortality. The factors associated with mortality are presented in Table 2 and Table 3.

The GWTG-HF score outperformed other scores in predicting in-hospital, 24-hour, and 30-day mortality. Adding lactate values to the GWTG-HF (GWTG-HF+L) score significantly improved the overall performance of the GWTG-HF score in predicting in-hospital (AUC = 0.807 vs. 0.872, $P < .05$, DeLong's test), 24-hour (AUC = 0.868 vs. 0.936, $P < .05$, DeLong's test), and 30-day mortality (AUC = 0.770 vs. 0.801, $P < .05$, DeLong's test).

The overall performances of SI, MSI, and Age-SI were moderate to good in predicting in-hospital, 24-hour, and 30-day mortality. Adding lactate values to the SI, MSI, and Age-SI improved their overall performance for all 3 outcomes. The performances of the scores for each of the 3 outcomes are shown in Table 4 and Figure 1.

Table 1. Baseline Characteristics of the Patients

Variables	Values
Gender, women n (%)	197 (53.5)
Age, median (IQR)	74 (65-81)
Arrival, n (%)	
Ambulatory	203 (55.2)
Ambulance	165 (44.8)
Comorbid diseases, n (%)	
COPD	69 (18.8)
Chronic heart failure	368 (100.0)
Hypertension	257 (69.8)
Diabetes mellitus	151 (41.0)
Coronary artery disease	368 (100.0)
Active malignancy	9 (2.4)
Chronic renal disease	56 (15.2)
Chronic liver disease	5 (1.4)
Cerebrovascular disease	22 (6.0)
Hypothyroidism	6 (1.6)
Alzheimer	4 (1.1)
Parkinson	1 (0.3)
Home oxygen therapy, n (%)	12 (3.3)
Altered mental status	14 (3.8)
MV need, n (%)	
NIMV need	134 (36.4)
IMV need	11 (3.0)
Disposition, n (%)	
Discharge	250 (67.9)
Ward admission	33 (9.0)
ICU admission	85 (23.1)
Mortality, n (%)	
24-hour	7 (1.9)
In-hospital	28 (7.6)
30-day	46 (12.5)

COPD, chronic obstructive pulmonary disease; ICU, intensive care unit; IMV, invasive mechanical ventilation; IQR, interquartile range; MV, mechanical ventilation; NIMV, non-invasive mechanical ventilation; IMV, invasive mechanical ventilation.

DISCUSSION

In our study, the GWTG-HF score outperformed the SI, MSI, and Age-SI for all 3 outcomes. In addition, our study demonstrated that adding lactate value to the GWTG-HF, SI, MSI, and Age-SI scores improved the overall performance of each score.

The GWTG-HF score demonstrated moderate performance in predicting in-hospital mortality in studies conducted in the United States and Israel.[18,19] Similarly, in Lyle et al's[11] study, the GWTG-HF score demonstrated moderate performance in cardiac ICU patients (with and without HF). In our study, the GWTG-HF score performed better than in other studies

Table 2. Factors Associated with In-Hospital Mortality of the Patients

Variables	All Patients (n = 368)	Survivor (n = 340)	Non-survivor (n = 28)	*P*
Age, years	74 (65-81)	74 (65-80)	76 (68-82)	.243*
SBP, mm Hg	155 (134-181)	158 (137-182)	138 (103-160)	**.001***
DBP, mm Hg	86 (74-101)	86 (75-101)	72 (56.7-95.5)	**.004***
HR, per min	100.1 ± 23.3	99.3 ± 22.8	110.1 ± 26.8	**.019****
RR, per min	24 (22-26)	24 (22-26)	24 (22-30)	.118*
SpO_2, %	90 (85-91)	90 (85-91)	82 (80-89)	**<.001***
Fever, °C	36.4 (36.2-36.5)	36.4 (36.2-36.5)	36.4 (36.2-36.7)	.551*
WBC, per mm^3	9.3 (7.5-12.2)	9.2 (7.3-11.6)	13.1 (8.9-15.8)	**<.001***
Hemoglobin	11.5 2.2	11.5 ± 2.2	11.7 ± 2.1	.648**
Sodium	138 (135-140)	138 (135-140)	135 (132-138)	**.005***
BUN, mg/dL	26.1 (18.6-36.9)	25.4 (18.6-35.0)	37.1 (23.9-51.6)	**.003***
Creatinin, mg/dL	1.1 (0.8-1.5)	1.1 (0.8-1.5)	1.2 (0.9-2.1)	.060*
pH	7.36 (7.30-7.39)	7.36 (7.30-7.40)	7.28 (7.15-7.37)	**.004***
$PaCO_2$, mm Hg	45.8 (39.2-53.8)	45.1 (39.2-53.2)	53.5 (39.3-61.9)	**.020***
Bicarbonate, mmol/L	24.2 ± 4.7	24.3 ± 4.6	23.4 ± 6.4	.497**
Lactate, mmol/L	2.2 (1.6-3.4)	2.1 (1.6-3.0)	5.3 (3.3-6.3)	**<.001***
LDH	296 (241-384)	291 (239-381)	352 (289-535)	**.008***
Albumin	3.6 (3.3-3.8)	3.6 (3.3-3.8)	3.4 (3.1-3.6)	**.016***
Bilirubin	1.0 (0.5-1.0)	1.0 (0.5-1.0)	1.0 (0.6-1.0)	.544*
CRP	13.1 (5.4-29.5)	12.7 (5.0-26.8)	19.9 (9.9-78.1)	**.005***
ED LOS, h	8.5 (6.5-12.0)	8.5 (6.5-12.0)	7.0 (5.0-11.8)	.252*
GWTG-HF	40 (33-45)	40 (33-44)	47 (44-53)	**<.001***
SI	0.63 (0.51-0.74)	0.62 (0.51-0.73)	0.75 (0.62-1.04)	**<.001***
MSI	0.88 (0.73-1.08)	0.87 (0.73-1.05)	1.12 (0.87-1.48)	**<.001***
Age SI	44.6 (36.1-57.6)	44.1 (35.7-56.0)	58.5 (46.1-78.9)	**<.001***

P < .05 was considered significant, indicated in bold.
Age-SI, Age Shock Index; BUN, blood urea nitrogen; CRP, C-reactive protein; DBP, diastolic blood pressure; ED LOS, emergency department length of stay; GWTG-HF, Get With The Guidelines-Heart Failure; HR, heart rate; IQR, interquartile range; LDH, lactate dehydrogenase; MSI, Modified Shock Index; RR, respiratory rate; SBP, systolic blood pressure; SI, Shock Index; SPO2, peripheral oxygen saturation; WBC, white blood cell.
*Mann–Whitney *U*-test.
**Student *t*-test

Table 3. Factors Affecting In-Hospital Mortality of the Patients

	Odds Ratio	95% CI	*P*
Arrival, ambulance	3.01	0.58-15.51	.188
Home oxygen therapy	2.61	0.11-61.50	.552
Altered mental status	0.87	0.10-7.52	.906
Cerebrovascular disease	7.69	1.03-56.97	**.046**
Mechanical ventilation need	2.12	0.38-11.74	.388
ICU admission	86.93	8.49-889.45	**<.001**
Systolic blood pressure	0.95	0.93-0.98	**<.001**
Heart rate	0.99	0.96-1.02	.739
SpO_2, %	1.04	0.94-1.14	.421
CRP	1.00	0.99-1.01	.816
Sodium	0.82	0.70-0.96	**.017**
BUN	1.08	1.04-1.13	**<.001**
$PaCO_2$, mm Hg	1.02	0.96-1.07	.435
Lactate	1.55	1.14-2.10	**.004**
LDH	1.00	0.99-1.00	.264
Albumin	0.95	0.81-1.11	.567

Hosmer and Lemeshow test: 0.975. *P* < .05 was considered significant, indicated in bold.
BUN, blood urea nitrogen; CRP, C reactive protein; ICU, intensive care unit; SPO2, peripheral oxygen saturation; LDH, lactate dehydrogenase.; SPO2, peripheral oxygen saturation.

in the literature in predicting in-hospital mortality [AUC = 0.807 (95% CI 0.763-0.846)]. The GWTG-HF score may be useful in discriminating critically ill patients with acute HF.

In another study, Shiraishi et al[3] found moderate performance for the GWTG-HF score in the Japanese patient population and improved the overall performance of the GWTG-HF score by adding the BNP values. In our study, we added lactate value which is associated with mortality to the GWTG-HF score. The overall performance, sensitivity, and specificity of the GWTG-HF+L score were better than those of the original score. Thus, we can say that the GWTG-HF+L score is more successful than the original score in evaluating patients with acute HF.

After the initial stabilization of acute HF patients in the ED, it can be challenging to decide on hospitalization or discharge.[9] In our study, both the GWTG-HF and GWTG-HF+L scores had high sensitivity (89.2% and 92.8%, respectively) in predicting in-hospital mortality. Therefore, both forms (original and with lactate) of the GWTG-HF score can be used safely in discriminating noncritical acute HF patients, especially in the ED.

Uyar et al[20] reported that high lactate levels were associated with cardiovascular death and hospitalization in patients

Table 4. Area Under the Curve, Sensitivity Specificity, and Likelihood Ratios of the Scores

	Cutoff	AUC	95% CI	Sensitivity	Specificity	+LR	−LR	*P*
In-Hospital Mortality								
GWTG-HF	42	0.807	0.763-0.846	89.2	66.4	2.66	0.16	**<.001**
SI	0.73	0.709	0.660-0.755	57.1	75.8	2.37	0.56	**<.001**
MSI	1.01	0.727	0.679-0.722	71.4	71.4	2.50	0.40	**<.001**
Age-SI	54.97	0.748	0.701-0.792	67.8	73.5	2.56	0.44	**<.001**
GWTG-HF+L	46	0.872	0.833-0.904	92.8	71.7	3.29	0.10	**<.001**
SI+L	3.63	0.851	0.810-0.886	89.2	73.8	3.41	0.15	**<.001**
MSI+L	3.85	0.860	0.820-0.894	89.2	72.9	3.30	0.15	**<.001**
Age-SI+L	57.17	0.777	0.731-0.818	75.0	73.2	2.80	0.34	**<.001**
24-Hour Mortality								
GWTG-HF	46	0.868	0.830-0.901	85.7	83.1	5.07	0.17	**<.001**
SI	0.91	0.811	0.767-0.850	71.4	91.4	8.32	0.31	**.010**
MSI	1.03	0.803	0.759-0.843	85.7	71.7	3.03	0.20	**.019**
Age-SI	78.69	0.827	0.785-0.865	71.4	96.4	19.84	0.30	**.005**
GWTG-HF+L	52.7	0.936	0.906-0.959	85.7	91.1	9.67	0.16	**<.001**
SI+L	5.31	0.949	0.922-0.969	100	88.6	8.80	0.0	**<.001**
MSI+L	5.99	0.951	0.924-0.971	100	90.0	10.03	0.0	**<.001**
Age-SI+L	86.85	0.848	0.807-0.883	71.4	97.5	28.65	0.29	**.001**
30-Day Mortality								
GWTG-HF	43	0.770	0.724-0.812	73.9	73.2	2.77	0.36	**<.001**
SI	0.66	0.645	0.593-0.694	67.3	57.7	1.60	0.56	**.001**
MSI	1.01	0.653	0.602-0.702	60.8	72.3	2.20	0.54	**.002**
Age-SI	54.96	0.696	0.646-0.743	58.7	74.2	2.28	0.56	**<.001**
GWTG-HF+L	47	0.801	0.757-0.841	73.9	78.8	3.50	0.33	**<.001**
SI+L	3.39	0.692	0.642-0.739	60.8	69.5	2.0	0.56	**<.001**
MSI+L	3.14	0.700	0.650-0.747	78.2	56.2	1.79	0.39	**<.001**
Age-SI+L	57.17	0.709	0.660-0.755	63.0	74.2	2.45	0.50	**<.001**

P < .05 was considered significant, indicated in bold.
Age-SI, Age Shock Index; AUC, area under the curve; CI, confidence interval; GWTG-HF, Get With The Guidelines-Heart Failure; L, lactate; LR, likelihood ratio; MSI, Modified Shock Index; SI, Shock Index.

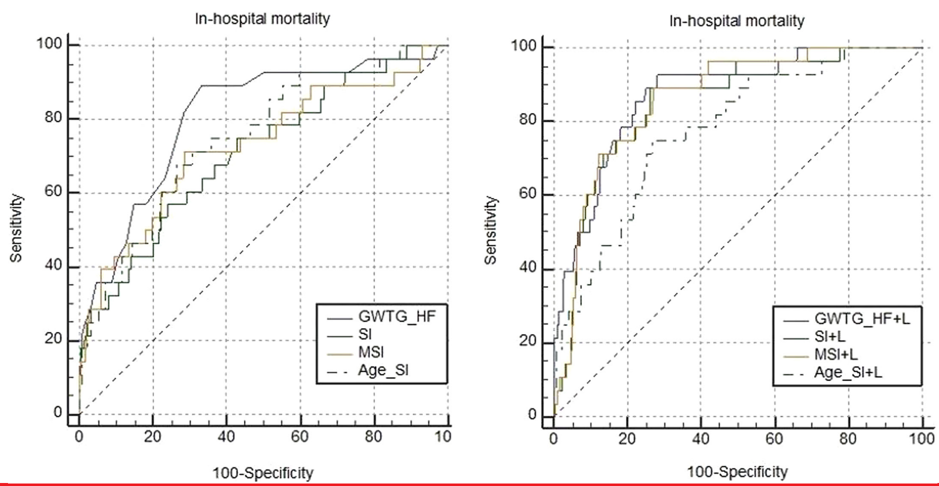

Figure 1. ROC curves for GWTG-HF, SI, MSI, and Age-SI with and without lactate for prediction of in-hospital mortality. Age-SI, Age Shock Index; GWTG-HF, Get With The Guidelines-Heart Failure; L, Lactate; MSI, Modified Shock Index; ROC, receiver operating characteristics; SI, Shock Index.

with acute HF during a 6-month follow-up. In another study, SI and lactate demonstrated moderate-to-good overall performance in predicting 24-hour and 28-day mortality in patients with acute HF.[10] In our study, SI, MSI, and Age-SI demonstrated moderate-to-good overall performance in predicting 24-hour, 30-day, and in-hospital mortality. Adding lactate to the SI, MSI, and Age-SI improved the overall performance of the scores for all 3 outcomes. Besides, adding lactate to SI and MSI produced 100% sensitivity for both and 88% and 90% specificity in predicting 24-hour mortality. The GWTG-HF+L score achieved 85% sensitivity and 91% specificity in predicting 24-hour mortality. The existing scores and lactate can be used together to predict early mortality in patients with acute HF.

In our study, the GWTG-HF+L score, SI+L, and MSI+L had high sensitivity in predicting in-hospital and 24-hour mortality (92%, 89%, 89%, and 85%, 100%, 100%, respectively). According to these results, the GWTG-HF+L score, SI+L, and MSI+L can be used safely to discriminate noncritical HF patients in the ED.

Age, SBP, HR, sodium, and BUN were found to be predictors of mortality in 2 cohort studies (ADHERE and GWTG-HF registry).[13,21] In the present study, SBP, sodium, BUN, and lactate were found to be predictors of mortality. Among these variables, lactate, which is not among the GWTG-HF score and SI variables, was added to the scores and improved the overall performance of the scores. Lactate, which is used in the evaluation of the severity of many diseases, can also be used in the evaluation of critical acute HF patients.

Study Limitations

The present study had several limitations. The first is that it is single-center and retrospective. Second, since there were no Black race patients in our study, no comment could be made on the effect of race. Third, the values of the patients at the initial examination were used in the analysis. Changes during follow-up may have affected the patients' prognosis. Only the ACC/AHA stage C and stage D patients were included in the study. Although the sample size is acceptable, further studies need to represent the general population. Since the GWTG-HF score was not developed for a specific HF population, we did not evaluate the effect of specific devices (cardioverter defibrillator and cardiac resynchronization therapy), and no comments could be made on this issue.

CONCLUSION

Both the GWTG-HF and GWTG-HF+L scores have acceptable discriminatory power in patients with acute symptomatic HF. The GWTG-HF score, SI, MSI, and Age-SI can be used together with lactate to predict mortality in patients with acute HF. The presence of CVD, SBP, sodium, BUN, lactate, and ICU admission are independent predictors of in-hospital mortality among patients with acute HF.

Ethics Committee Approval: The study protocol was approved by the Ethics Committee of Bakırköy Dr. Sadi Konuk Training and Research Hospital (approval ID: 2021/567; date: January 3, 2022). This study was performed in line with the Declaration of Helsinki.

Informed Consent: The informed consent could not be obtained because of the retrospective nature of the study.

Peer-review: Externally peer-reviewed.

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