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Title: The Prognostic Value of GRACE score for Acute Kidney injury in ST Elevation Myocardial Infarction Patients Complicated with Cardiogenic Shock

Running Title: GRACE score for AKI in Cardiogenic Shock

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Abstract

Introduction

The GRACE (Global Registry of Acute Coronary Events) risk score has been proposed in predicting short-term death in patients who are diagnosed with acute coronary syndrome. In this study, we investigated the significance of the GRACE score for acute kidney injury (AKI) in cardiogenic shock (CS)-ST elevation myocardial infarction (STEMI) patients who were treated with primary percutaneous coronary intervention (PPCI).

Methods

We retrospectively examined a total of 492 consecutive CS-STEMI patients who had undergone PPCI. The GRACE score was calculated for each patient. Patients were stratified by tertiles (T1, T2, and T3) according to the GRACE score and the incidence of AKI was compared between the groups.

Results

In univariate analysis, the incidence of AKI was significantly higher for patients allocated into the T3 group, as compared to patients in the T1 group (Odds ratio (OR): 2.8, 95% confidence interval (CI): 1.8–4.1, $p<0.001$). Following including all confounding variables, participants in the T3 group had a 3.1-fold higher incidence of AKI (OR: 3.1, 95% CI: 1.9–5.4, $p<0.001$). In a receiver operating curve analysis, the GRACE's score of the area under curve value for AKI was 0.70 ($p<0.001$, 95% CI: 0.65-0.74) with 69.2% sensitivity and 68.8% specificity.

Conclusion

The GRACE score provide an independent prognostic marker of AKI in CS patients related with STEMI. Based on our data, we propose that the GRACE score is a simple and clinically applicable directive tool for rapid risk stratification of AKI in STEMI patients complicated with CS.

Keywords: GRACE, acute kidney injury, prognostic value, cardiogenic shock

Introduction

Acute kidney injury (AKI) is an acute medical emergency that is associated with significant morbidity and mortality in patients with acute coronary syndrome (ACS) (1). Principally, patients presented with cardiogenic shock (CS) have a higher risk of AKI due to the inability of the left ventricle to supply an adequate blood flow to the kidneys (2). Prior studies demonstrated that some risk factors -such as chronic renal failure, elderliness, and hemodynamic status upon admission-are independent predictors of AKI in patients with CS (3, 4). Although the tissue hypoperfusion and the venous congestion are the main underlying pathophysiologic mechanisms of the worsening of renal function among these patients, other mechanisms -such as the increase in systemic inflammatory response and the activation of neurohormonal responses- may also play a significant role (5). Since patients presented with CS often have higher mortality rates, the deterioration of renal functions in this condition may further aggravate the cardiac damage that is responsible from the higher incidence of death (6). Hence, an early recognition to initiate some therapeutic modalities including early continuous renal replacement therapy or mechanical circulatory support may improve survival among these patients (7,8).

The GRACE (Global Registry of Acute Coronary Events) score is a guideline based risk calculator that has been proven to be useful to determine the risk of in-hospital and short-term deaths in patients diagnosed with ACS (9, 10). This score estimates the risk of death with using some clinical variables -such as age, Killip class examination findings, and serum creatinine upon admission-. As previously mentioned, some components of the GRACE score have been found to be related to the occurrence of AKI in patients with CS. We therefore hypothesized that the GRACE score may have an appreciable value for the occurrence of AKI in patients presented with CS secondary to STEMI.

Materials and Methods

A total of 492 consecutive CS-STEMI patients who were treated with primary percutaneous coronary intervention (PPCI) from January 2013 to January 2017 in a tertiary heart center were included in this retrospective study. Patients younger than 18 years-of-age and pregnant; having been treated with thrombolytic drugs; active infection(s) and malignancy; and having

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undergone emergency aorta coronary bypass grafting were not included in this study. In addition, we excluded patients who died within 24 hours following admission. We collected patient's baseline demographic characteristics and laboratory findings from the hospital's electronic database. All of the patients received the standard medical therapy according to the current guidelines. The GRACE score was calculated for each patient using an online calculator. In the GRACE score; age, heart rate, systolic blood pressure, creatinine, cardiac arrest at admission, ST segment deviation on electrocardiography, abnormal cardiac enzymes, and Killip class were noted. The ethic committee of Haydarpasa Numune Training and Research Hospital approved the protocol of the current study on the date of 8/4/2019 with an ethic code number of = HNEAH-KAEK 2019/KK/46. Thereafter, the study was conducted in accordance of the principle of the Declaration of Helsinki. There was no need for written informed consent due to the retrospective design, and it was not obtained.

In all of the patients, venous samples were collected at admission to the emergency department. A Coulter LH 780 hematology analyzer (Beckman Coulter, Inc., Brea, CA, USA) was used to evaluate all basic hematologic parameters. Biochemical measurements were performed using Siemens kit and calibrators (Siemens Healthcare Diagnostic GmbH, Marburg, Germany). All of the patients underwent a detailed echocardiographic examination by a trained cardiologist. The Simpson method was used to estimate the left ventricle ejection fraction (LVEF).

All coronary angiographies were performed by experienced interventional cardiologists via femoral artery within 90 minutes. All of the patients received the standard anti-platelet regimen of 300 mg acetylsalicylic acid along with a loading dose of either 300-600 mg clopidogrel or 180 mg of ticagrelor before the procedure. In accordance with hospital protocol, the choice of infusion a glycoprotein IIb/IIIa inhibitors and the use of either a drug-eluting stent or a bare metal stent was left to the operator's discretion. In case of a high coronary thrombus burden, manual thrombectomy was not mandatory as per hospital protocol. In all procedures, a non-ionic, iso-osmolar, contrast material was used.

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STEMI was defined using the universal definition of provided in the myocardial infarction guideline of the European Society of Cardiology (11). CS was accepted as systolic blood pressure of less than 90 mm Hg that was not responsive to fluid and/or inotropic resuscitation or systolic blood pressure drop greater than or equal to 40 mmHg for more than 15 minutes without new-onset arrhythmia, hypovolemia, or sepsis (12). Dopamine infusion was the first treatment option in CS in our department and noradrenalin infusion was concomitantly started if hemodynamic collapse did not solely recover with dopamine infusion. AKI was accepted as increase of serum creatinine level greater than or equal to 0.5 mg/dL or 25% increase of serum creatinine from the baseline within 48 hours following the contrast administration (13). Modification of Diet in Renal Disease (MDRD) equation was used to determine estimated glomerular filtration rate (eGFR). Chronic kidney disease was defined as decreased as decreased kidney function shown by GFR of less than 60 mL/min per 1.73 m^2, or markers of kidney damage, or both, of at least 3 months duration, regardless of the underlying cause (14).

IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Chicago, Illinois) was used to convey the statistical analysis. First, the study population was sectioned into three tertiles: T1, T2, and T3 based on the GRACE score. The Kolmogorov-Smirnov test assessed the distribution pattern. Continuous variables with normal distribution were analyzed using the variance test. Mean ± standard deviation was used to describe the continuous variables with normal distribution. The categorical data were expressed as the number of cases and percentages. The Fisher's exact test or $\chi 2$-test was used to compare the categorical parameters. The ANOVA test was performed to compare the groups. As a *post-hoc* analysis, Tukey's method was preferred. The odds ratio (OR) assessed the relative risk of AKI of the T3 group compared with the T1 and the T2 group. Multiple binary logistic regression was performed for the multiple analyses. Multiple models included all relevant confounders in multiple analyses as predictors of AKI. Model I was unadjusted and model II was adjusted for all confounders. The goodness-of-fit test

presented adequate calibration for model II. (The Hosmer-Lemeshow goodness-of-fit= 9.176, p=0.328) The variables included in model II were gender, hypertension, diabetes mellitus, hyperlipidemia, smoking, chronic renal failure, previous cerebrovascular accident, myocardial infarction, and PCI, peripheral artery disease (PAD), chronic obstructive lung disease (COPD), atrial fibrillation, anterior myocardial infraction, the culprit artery, type of stent, multi-vessel intervention, thrombus aspiration, the laboratory parameters including baseline serum creatinine, blood urea nitrogen, hemoglobin, and echocardiographic parameters such as the LVEF, the left ventricular diastolic diameter, the left ventricle systolic diameter, pulmonary artery systolic pressure, and tricuspid annular plane systolic excursion (TAPSE). A receiver operating characteristic (ROC) curve analysis was utilized to determine the optimal value of the GRACE score for predicting AKI. A 2-tailed *p* value of < 0.05 was considered as statistically significant.

Results

The study population mean age was 69 ± 13 years, and a total of 185 (37.6%) patients were female. Baseline demographic features and interventional data of all patients are depicted in **Table 1**. The frequency of diabetes mellitus, hyperlipidemia, current smoker, previous cerebrovascular accident, myocardial infarction, PCI, PAD, COPD, cardiopulmonary arrest at admission, anterior myocardial infarction were not different between the groups ($p > 0.05$ for each). Whereas the frequency of hypertension, chronic renal failure, and atrial fibrillation were significantly elevated in patients allocated into the T3 group ($p < 0.05$ for each). The groups were indifferent in term of systolic arterial pressure and heart rate upon admission ($p > 0.05$ for each). The right coronary artery as the infarct-related artery (IRA) and multivessel involvement were significantly elevated in patients formed the T3 group ($p < 0.05$ for each). The choice of drug-eluting stent was more common in a high GRACE score patients. The mean GRACE score was 171.8 ± 13.8 for T1 group, while it was 201.5 ± 6.2 and 222.0 ± 7.5 for T2 and T3 groups, respectively ($p < 0.001$ for comparison of each group).

Laboratory and echocardiographic findings of each group were shown in **Table 2**. Comparison of echocardiographic parameters did not differ between the groups ($p > 0.05$ for each). Patients formed the T3 group had lower hemoglobin levels and higher creatinine and blood urea nitrogen levels compared to those formed the T1 and T2 groups ($p < 0.05$ for each).

The incidence rate of AKI and in-hospital mortality rates according to the groups are shown in **Table 3**. Of note, patients formed the T3 groups had higher in-hospital deaths compared to those formed the T1 and the T2 group (54.9% *vs.* 45.1% *vs.* 34.8%). The unadjusted risk of AKI was 2.8 (95% CI: 1.8–4.1) for patients formed the T3 group. Also, adjusted risk including all covariables for AKI was 3.1 (95% CI: 1.9–5.5) for patients formed the T3 group. In a ROC curve analysis, the area under the curve (AUC) of the GRACE score was 0.70 ($p < 0.001$, 95% CI: 0.65-0.74). The optimal value of the GRACE score for AKI was found to be 200.5 with 69.2% sensitivity and 68.8% specificity (**Fig. 1**)

Discussion

In the present study, we observed that after adjusting all potential confounders, CS patients with high GRACE score have three-fold higher incidence of AKI compared to those with an intermediate and low GRACE score. Our study appears to be the first study in the literature to show that the GRACE score may have a prognostic value for AKI in patients presented with CS.

CS is a state of medical emergency characterized by the reduce of blood flow to multiple vital organs including the kidneys due to the extensive damage of the ventricle (15). Although CS may be caused by a variety of cardiovascular conditions, the most common reason is STEMI (15). Although there have been great improvements in pharmacological treatment and reperfusion therapy of CS patients in the last two decades, the mortality rate among these patients remains still high (16). Additionally, this condition is frequently complicated with the deterioration of renal functions that has been related with further increase in mortality rates (17, 18). Hence, an adequate intravenous hydration, a timely start of continuous renal replacement

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therapy, and mechanical circulatory support would be crucial steps after identification of these patients.

The GRACE score is derived from the GRACE registry that included more than 100.000 patients in 30 countries (19). This score determines the risk by including the appropriate number of points for each of the 8 variables into the calculation (age, heart rate, systolic blood pressure, and serum creatinine, etc.). In previous studies, this risk score has been proven to be useful to estimate the risk of short- and long-term deaths in patients presented with ACS (9, 10). Besides that, several previous studies have extended the role of this risk tool to other clinical conditions such as pulmonary embolisim, heart failure, and stroke (20-22). Additionally, in a recent prospective study, which included 209 consecutive STEMI patients, Koonsiripaiboon et al. revealed that high GRACE score patients might have elevated risk of CS compared to those with a low GRACE score upon admission (23). Although the GRACE score has been extensively investigated in different cardiovascular conditions, the data regarding the suitability of the GRACE score to predict AKI in patients with CS has not been tested before. Based on the study findings, we observed that patients whose GRACE score was higher had also elevated risk of AKI in addition to the increase in-hospital mortality rates. As the possible explanations of our study findings, we considered that patients with a high GRACE score were older patients with chronic renal failure and had higher Killip class; hence, these patients might be at higher risk of AKI because all of these variables have been shown as an independent predictor of AKI in CS patients in previous studies (3, 4, 17, 18). In addition, a well-known risk model that is developed and validated for the assessment of AKI includes similar variables (24).

In terms of clinical applicability, our results may point up to significant findings because the GRACE score is a simple tool that can be obtained after the first medical evaluation. According to the study findings, the patients with high-risk GRACE score should be closely followed-up for the development of AKI since some early prophylactic treatment modalities may improve survival among these patients. However, the definitive recommendations could not be given because our study had a retrospective design. Therefore, prospective studies with larger

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population are necessary to understand the exact role of the GRACE score to predict AKI in patients with CS.

Study limitations

The present study has following limitations. First, this study had a retrospective and observational design with the possibility of selection bias. Second, we only included CS patients due to STEMI; hence, our result might not be generalized all CS patients. Third, even though all potential confounders were included in a multiple model, there might be some unmeasurable confounders that might affect the result of the study. Fourth, the component of the GRACE score, namely systolic blood pressure, was obtained by a non-invasive method. Fifth, other well-known risk scores such as the TIMI (thrombolysis in myocardial infarction) and the PAMI (primary angioplasty in myocardial infarction) were not evaluated and compared with the GRACE score in our study. Sixth, the contrast media volume, which is an important contributor for the development of AKI, was not evaluated in the study due to the missing data. Seventh, there is a limited data in terms of intravenous hydration and statin therapy following the reference procedure.

Conclusion

We showed that CS patients with an elevated GRACE score might have higher risk of AKI. Our study appears to be first study in the literature to demonstrate the relation between the GRACE score and AKI in STEMI patients complicated with CS.

Ethical approval

The ethic committee of Haydarpasa Numune Training and Research Hospital approved the protocol of the current study on the date of 8/4/2019 with an ethic code number of = HNEAH-KAEK 2019/KK/46.

Conflict of interest

All authors declare that they do not have conflict of interest.

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Legend

Figure 1

A ROC curve analysis showed that the area under curve value of the GRACE score for acute kidney injury was 0.70 (p<0.001, 95% CI: 0.65-0.74).

Abbreviation: ROC; Receiver Operating Characteristic, GRACE; Global Registry of Acute Coronary Events.

Table 1 Baseline demographic characteristics and angiographic data of all patients

	GRACE score			
	T1(n=164)	T2(n=164)	T3(n=164)	P value
Age, years	60 ± 12	68 ± 9	76 ± 10	<0.001
Male gender, n (%)	112 (68.3)	100 (61.0)	95 (57.9)	0.138
Hypertension, n (%)	63 (38.4)	82 (50.0)	89 (54.3)	0.012
Diabetes mellitus, n (%)	46 (28.0)	65 (39.6)	54 (32.9)	0.083
Hyperlipidemia, n (%)	41 (25.0)	36 (22.0)	39 (23.1)	0.807
Current smoker, n (%)	65 (39.6)	56 (34.1)	52 (31.7)	0.306
Chronic renal failure, n (%)	20 (12.2)	20 (12.2)	45 (27.4)	<0.001
Previous CVA, n (%)	7 (4.3)	5 (3.0)	8 (4.9)	0.694
Previous MI, n (%)	27 (16.5)	22 (13.4)	36 (22.0)	0.117
Previous PCI, n (%)	37 (22.6)	36 (22.0)	40 (24.4)	0.861
PAD, n (%)	10 (6.1)	12 (7.3)	8 (4.9)	0.653
COPD, n (%)	7 (4.3)	10 (6.1)	14 (8.5)	0.280
CPA, n (%)	39 (23.8)	35 (21.3)	53 (32.3)	0.058
Atrial fibrillation, n (%)	20 (12.2)	14 (8.5)	6 (3.7)	0.018
Anterior MI, n (%)	99 (60.4)	95 (57.9)	113 (68.9)	0.098
At admission				
Systolic blood pressure, mmHg	70.4 ± 10.0	69.9 ± 9.4	70.1 ± 9.5	0.843
Heart rate, beats per minute	91.1 ± 21.4	91.8 ± 20.2	96.7 ± 20.7	0.178
Culprit artery				
LMCA, n (%)	7 (4.3)	9 (5.5)	7 (4.3)	0.833
LAD, n (%)	92 (56.1)	86 (52.4)	106 (64.6)	0.072
CX, n (%)	22 (13.4)	16 (9.8)	20 (12.2)	0.579
RCA, n (%)	50 (30.5)	62 (37.8)	38 (23.2)	0.016
Additional ≥70% stenosis to culprit artery				
LAD and/or branches, n (%)	70 (42.7)	75 (45.7)	53 (32.3)	0.034
CX and/or branches, n (%)	84 (51.2)	81 (49.4)	82 (50.0)	0.945
RCA and/or branches, n (%)	58 (35.4)	56 (34.1)	62 (37.8)	0.781
Intervened coronary artery				
LMCA, n (%)	7 (4.3)	6 (3.7)	6 (3.7)	0.947
LAD, n (%)	79 (48.2)	69 (42.1)	78 (47.6)	0.912
CX, n (%)	18 (11.0)	7 (4.3)	16 (9.8)	0.065

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RCA, n (%)	41 (25.0)	47 (28.7)	31 (18.9)	0.114
Multivessel, n (%)	19 (11.6)	35 (21.3)	33 (20.1)	0.041
PTCA, n (%)	130 (79.3)	120 (73.2)	116 (70.7)	0.189
Stent (DES), n (%)	141 (86.0)	147 (89.6)	131 (79.9)	0.043
Stent number>1, n (%)	49 (29.9)	51 (31.1)	50 (30.5)	0.972
Non-compliant balloon usage, n (%)	66 (40.2)	66 (40.2)	66 (40.2)	1.000
Thrombus aspiration, n (%)	7 (4.3)	8 (4.9)	16 (9.8)	0.081
Tirofiban usage, n (%)	72 (43.9)	73 (44.5)	83 (50.6)	0.404
GRACE score, n (%)	171.8 ± 13.8	201.5 ± 6.2	222.0 ± 7.5	<0.001
Acute kidney injury, n (%)	52 (31.7)	84 (51.2)	109 (66.5)	<0.001

Continuous variables are presented as mean ± SD, nominal variables presented as frequency (%).

Abbreviations: CVA indicates cerebrovascular accident; PAD, Peripheral Arterial Disease; COPD, Chronic Obstructive Pulmonary Disease; CPA, CardioPulmonary Arrest; MI, Myocardial Infarction; LMCA, Left Main Coronary Artery; LAD, Left Anterior Descending Artery; CX, Circumflex Artery; RCA, Right Coronary Artery; PTCA, Percutaneous Transluminal Coronary Angioplasty; DES, Drug Eluting Stent; PCI, Percutaneous Coronary Intervention; GRACE, Global Registry of Acute Coronary Events.

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Table 2 Echocardiographic and laboratory findings of all patients

	GRACE score			
	T1 (n=164)	T2 (n=164)	T3 (n=164)	P value
LVEF, %	33.0 ± 10.0	31.9 ± 8.9	31.5 ± 10.0	0.105
LVEDD, cm	5.38 ± 0.46	5.37 ± 0.46	5.47 ± 0.53	0.061
LVESD, cm	4.17 ± 0.62	4.19 ± 0.58	4.33 ± 0.71	0.050
PASP, mmHg	26.9 ± 8.1	26.1 ± 7.3	28.8 ± 10.0	0.153
Tapse, cm	1.82 ± 0.26	1.76 ± 0.23	1.76 ± 0.20	0.051
MR ≥+3, n (%)	27 (16.5)	22 (13.4)	31 (18.9)	0.402
TR ≥+3, n (%)	6 (3.7)	10 (6.1)	14 (8.5)	0.182
Hemoglobin, g/dL	13.4 ± 2.8	12.5 ± 2.0	12.2 ± 1.8	<0.001
Leucocyte, x10^3/µ/L	16.2 ± 6.3	15.6 ± 5.4	15.2 ± 5.0	0.719
Platelet, x10^3/µ/L	256.1 ± 87.5	256.7 ± 94.6	248.4 ± 100.1	0.447
Glucose, mg/dL	127.7 ± 42.2	130.6 ± 40.3	131.2 ± 49.0	0.629
Creatinine, mg/dL	1.11 ± 0.33	1.13 ± 0.48	1.27 ± 0.60	0.004
BUN, mg/dL	29.3 ± 14.4	30.2 ± 15.1	35.0 ± 18.6	0.011
ALT, U/L	68.1 ± 85.6	90.0 ± 189.7	70.3 ± 121.2	0.087
AST, U/L	216.5 ± 251.2	231.4 ± 310.7	180.4 ± 174.5	0.411
Lactate, mmol/L	4.58 ± 3.43	4.68 ± 3.30	4.92 ± 3.65	0.768
pH	7.32 ± 0.10	7.31 ± 0.12	7.31 ± 0.12	0.627
pCO2	35.4 ± 7.8	34.3 ± 7.9	34.0 ± 7.6	0.106
pO2	97.3 ± 54.7	87.3 ± 31.5	96.3 ± 41.1	0.058

Continuous variables are presented as mean ± SD; nominal variables presented as frequency (%).

Abbreviations: LVEF indicates Left Ventricle Ejection Fraction; LVEDD, Left Ventricle End-Diastolic Diameter; LVESD, Left Ventricle End-Systolic Diameter; PASP, Pulmonary Artery Systolic Pressure; MR, Mitral Regurgitation; TR, Tricuspid Regurgitation; GRACE, Global Registry of Acute Coronary Events.

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Table 3 In-hospital event rates and multiple binary logistic regression models for in-hospital mortality and AKI by GRACE score tertiles

	GRACE score		
	T1	T2	T3
In-hospital mortality			
Number of deaths	57	74	90
Mortality, %	34.8	45.1	54.9
Mortality, OR (%95 CI)			
Model I:unadjusted	1[Reference]	1.5 (0.9–2.4)	1.8 (1.2–2.6)
Model II: adjusted for all covariates[a]	1[Reference]	1.9 (1.0–3.5)	2.1 (1.3–3.5)
Acute kidney injury			
Number of events	52	84	109
Events, %	31.7	51.2	66.5
Events, OR (%95 CI)			
Model I:unadjusted	1[Reference]	2.3 (1.4–3.5)	2.8 (1.8–4.1)
Model II: adjusted for all covariates[a]	1[Reference]	2.5 (1.5–4.1)	3.1 (1.9–5.4)

Abbreviations: OR, Odds Ratio; CI, Confidence Interval; AKI, Acute Kidney Injury; GRACE, Global Registry of Acute Coronary Events.

[a]Includes gender; hypertension; diabetes mellitus; hyperlipidemia; current smoking; chronic renal failure; previous cerebrovascular accident; previous myocardial infarction; previous percutaneous coronary intervention; peripheral artery disease; chronic obstructive lung disease; atrial fibrillation; anterior myocardial infarction; percutaneous coronary transluminal angioplasty; culprit artery; drug-eluting stent; multivessel intervention; thrombus aspiration; the first measurement during hospitalization of the following laboratory values including baseline serum creatinine, blood urea nitrogen, hemoglobin; the left ventricle ejection fraction; left ventricle diastolic diameter; the left ventricular systolic diameter; pulmonary artery systolic pressure; and tricuspid annular plane systolic excursion.

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