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Original Contribution

Fibrinogen level on admission is a predictive marker of the need for massive blood transfusion after pelvic fracture

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ABSTRACT

Objective: This study aimed to evaluate the usefulness of coagulation biomarkers as predictors of the need for massive transfusion (MT) in patients with pelvic fractures.
Methods: Patients who were treated for pelvic fractures in our hospital were divided into 2 groups: MT and non-MT. MT was defined as the transfusion of packed red blood cells (PRBCs) ≧10 units caused by bleeding within 24 h after admission. We compared variables between two groups, including vital signs, the scoring system and blood sample test. Additionally, we performed a multiple logistic regression analysis and a receiver operating characteristic curve analysis to reveal which value was the most useful predictive marker for MT in patients with pelvic fracture.
Results: There were 22 patients in the MT group and 78 patients in the non-MT group. Patients in the MT group had significantly higher ISS than did those in the non-MT group. In contrast, the patients in the MT group had significantly lower RTS, TRISS Ps, sBP, Hb, lactate, BE, and Fbg levels. Lower sBP and Fbg levels were independent predictors for MT. The optimal cut-off values for sBP and Fbg levels were ≦109 mmHg and 193.0 mg/dL, respectively.
Conclusions: The results of the study indicated that Fbg levels on admission can be an independent predictor of MT in patients with pelvic fractures. The optimal cut-off value of Fbg for MT prediction in this study was 193.0 mg/dL.

1. Introduction

Pelvic fractures are present in between 10% and 20% of patients who sustain high-energy blunt trauma and account for 3% to 8% of all skeletal injuries [1]. Pelvic fracture has been shown to be an independent risk factor for death after blunt trauma [2]. In patients with a pelvic fracture, hemorrhage is one of the most common causes of death [3,4]. Mortality rates in hemodynamically unstable patients with a pelvic fracture range from 18% to 40%. Death within the first 24 h of injury commonly results from blood loss [5,6].

Severe trauma and subsequent hemorrhagic shock cause trauma-induced coagulopathy (TIC). In TIC, the consumption of platelets and coagulation factors, as well as hyper-fibrinolysis, induce the bleeding tendency that leads to massive hemorrhage [7-9]. Hemodynamically unstable patients need to immediately receive transfusions to ensure stable blood volume. In patients with unstable pelvic fractures, the development of TIC occurs frequently [10,11].

Routine laboratory-based coagulation tests, such as prothrombin time/international normalized ratio (PT/INR), activated partial thromboplastin time (aPTT), fibrinogen (Fbg), platelet count, and hemoglobin (Hb) concentration are used to assess a patient's coagulation status [12]. However, when severe bleeding occurs, coagulation factors do not decrease in a predictable manner. It was recently reported that the Fbg level decreased earlier than that of other blood coagulation factors [13-15]. Therefore, Fbg might play an important role in mortality and predict the need for massive transfusion (MT). On the other hand, a consensus has not been established regarding whether Fbg administration affects the morbidity and mortality of pelvic fractures patients. Moreover, there has been no investigation to define the optimal plasma Fbg level that would indicate if MT is required. The purpose of the present study was to evaluate the usefulness of coagulation biomarkers,

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including Fbg, as predictors of the need for MT in patients with pelvic fractures.

2. Materials and methods

2.1. Participants

This is a single center, retrospective observational study. A total of 122 patients were treated for pelvic fractures at our institution between October 2012 and August 2018. Patients were excluded if they had an abbreviated injury score (AIS) greater in a region other than the pelvis, were treated with anti-coagulant/platelet therapy, or had a history of hepatic cirrhosis or, bleeding diathesis. A total of 100 patients with pelvic fractures were enrolled (Fig. 1). Patients were classified into 2 groups: MT and non-MT. MT was defined as the transfusion of packed red blood cells (PRBCs) ≧10 units due to bleeding within 24 h after admission. There were 22 patients (11 males and 11 females) in the MT group and 78 patients (43 males and 35 females) in the non-MT group. We compared the two groups with respect to age, sex, Injury Severity Score (ISS), Revised Trauma Score (RTS), probability of survival based on Trauma and Injury Severity Score (TRISS Ps), Glasgow Coma Scale (GCS) (evaluated on arrival), systolic blood pressure (sBP), heart rate (HR), respiratory rate (RR), body temperature (BT), type of pelvic fracture based on AO/OTA classification, transfusion of PRBCs, fresh frozen plasma (FFP), platelet concentrate (PC), hemoglobin (Hb), platelets (PLTs), base excess (BE), lactate, prothrombin time/international normalized ratio (PT/INR), activated partial thromboplastin time (aPTT), D-dimer, Fbg, and extravasation of computed tomography (CT) contrast medium. An unstable pelvic fracture was defined as AO/OTA classification B1/B2/B3, C1/C2/C3. Blood samples were collected on admission to the emergency department (ED) and before resuscitation.

2.2. Blood samples

Blood samples were collected at the time of arrival at the ED and before the administration of fluids. Whole blood was collected, with sodium citrate as an anticoagulant, in a conventional blood collection tube (NIPRO, Osaka, Japan). Several hemostatic markers, including the Fbg level, were measured within an hour after collection.

2.3. Statistical analysis

All variables were expressed as medians and interquartile ranges (i.e., 1st to 3rd quartile) or numbers (%). Comparisons between the two groups were made using the Mann-Whitney *U* test for continuous variables and the chi-square test for categorical variables. Multiple logistic regression was used to analyze the independent predictors for MT. We evaluated sBP, Hb, lactate, BE, and Fbg levels as predictors for MT. These variables have been previously used as parameters in some MT prediction scoring systems [16-18].

Receiver operating characteristic (ROC) curves of variables with statistical significance in the logistic regression analysis were constructed to predict MT. Cut-off values were defined based on the Youden Index. The optimal cut-off values are defined as the point that results in both the highest sensitivity and specificity on ROC curve to predict the need for massive transfusion. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics [19]. A probability value <0.05 was considered statistically significant.

3. Results

3.1. Patient characteristics

The patient characteristics and outcomes are shown in Table 1. Patients in the MT group had significantly higher ISS and extravasation than did those in the non-MT group. In contrast, patients in the MT group had significantly lower RTS, TRISS Ps, sBP, Hb, lactate, BE, and Fbg levels. A significantly higher number of patients in the MT group received blood transfusions (PRBCs, FFP, PLT).

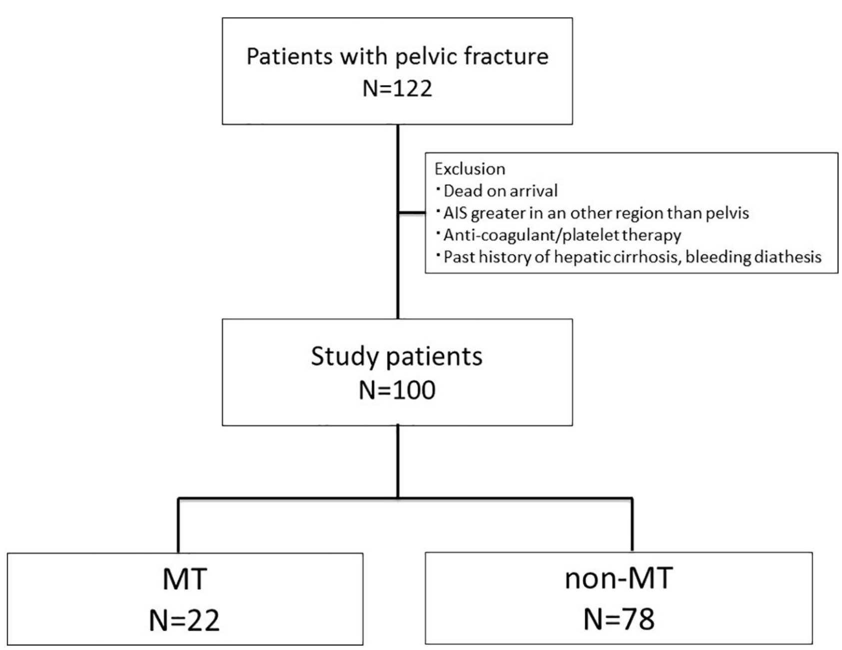

Fig. 1. Flow chart of the study selection. We excluded 22 patients using exclusion criteria. A total of 100 patients with pelvic fracture were enrolled. Massive transfusion (MT) was defined as the transfusion of 10 units of packed red blood cells due to bleeding within 24 h of admission. We divided the patients into two groups: non-MT and MT. There were 22 patients (11 males and 11 females) in the MT group, and 78 patients (43 males and 35 females) in the non-MT group.

Table 1
Patient demographics and clinical characteristics

Variables	MT ($n = 22$)	non-MT ($n = 78$)	p-value
Age (years)	72 (59,77)	66 (45,81)	0.770 (n.s)
Sex (male/female)	50.0 (11/11)	55.1 (43/78)	0.811 (n.s)
ISS	29 (24,36)	16 (9,20)	<0.001
RTS	7.227 (4.093,7.840)	7.840 (7.840,7.840)	<0.001
TRISS Ps	0.758 (0.115, 0.878)	0.968 (0.938,0.990)	<0.001
sBP, mmHg	100 (84,115)	130 (115,148)	<0.001
HR, bpm	99 (69,113)	83 (74,95)	0.084 (n.s)
RR, bpm	25 (19,29)	20 (17,23)	<0.05
BT, °C	36.5 (35.6,36.9)	36.7 (36.2,37.1)	0.108 (n.s)
GCS	13 (3,14)	15 (14,15)	0.052 (n.s)
Unstable pelvic fracture (%)	86.4 (19/22)	61.5 (48/78)	<0.05
Hb, mg/dL	9.3 (6.6,11.4)	12.7 (10.9,13.8)	<0.001
PLT ($\times 10^4$)	124 (78,165)	191 (146,245)	<0.01
BE	−5.3 (−13.1,-3.4)	−0.4 (−2.0,1.0)	<0.001
Lactate, mmol/L	4.3 (2.8,7.9)	1.4 (1.0,2.3)	<0.001
PT-INR	1.25 (1.17,1.53)	1.02 (0.98,1.10)	<0.05
APTT	35.7 (28.2,64.9)	26.9 (23.9,30.6)	0.077 (n.s)
D-dimer	67.5 (41.4168.5)	46.7 (18.5,67.6)	<0.05
Fbg, mg/dL	149 (83.5178.8)	256 (205,313)	<0.001
Transfusion within 24 h			
PRBC, U	17 (10,25)	0 (0,4)	<0.001
FFP, U	24 (14,31)	0 (0,0)	<0.001
PC, U	10 (0,23)	0 (0,0)	<0.001
extravasation of CT contrast medium	77.2 (17/22)	14.1 (11/78)	<0.001

n.s: not significant; "n.s" was defined as p-value≧0.05; ISS: injury severity score; RTS: revised trauma score; TRISS Ps: probability of survival based on Trauma and Injury Severity Score; sBP: systolic blood pressure; HR: heart rate; RR: respiratory rate; BT: body temperature; GCS: Glasgow coma scale; Hb: haemogulobin; PLT: platelet; BE: base excess; PT-INR: prothrombin time-international normalized ratio; aPTT: activated partial thromboplastin time; Fbg: Fibrinogen; CT: computed tomography.
Data are shown as median (1st to 3rd quartile) or % (n).

3.2. Multiple logistic-regression analysis

Lower sBP and Fbg levels were independent predictors for MT (odds ratio (OR) 0.955, 95% confidence interval (CI) 0.915–0.997 and OR 0.955, 95% CI 0.928–0.982, respectively; Table 2).

3.3. Receiver operating curve (ROC) analysis

Fig. 2 shows the ROC curves for the prediction of MT based on sBP and Fbg levels. The results of area under the curve (AUC) and optimal cut-off values are shown in Table 3. The optimal cut-off values for sBP and Fbg levels were ≦109 mmHg (sensitivity 0.727%, specificity 0.823%) and 193.0 mg/dL (sensitivity 0.955%, specificity 0.829%), respectively.

Table 2
Results of multiple logistic regression analysis for predicting MT.

Variables	p-value	Odds ratio	95% CI
Systolic blood pressure, mmHg	0.0351	0.955	0.915–0.997
Fibrinogen, mg/dL	0.0014	0.955	0.928–0.982

CI: confidence interval.

4. Discussion

In the present study, we found that Fbg levels on admission could be an independent predictor of MT in patients with pelvic fractures. Fbg plays an important role in clot formation and is substantially diminished as a result of hyper-fibrinolysis. Therefore, low Fbg levels are associated with hemostatic impairment and induction of massive bleeding [20]. Several studies have indicated that a low Fbg level is a strong risk factor for poor outcomes in trauma patients [21,22]. Schochl et al. evaluated Fbg levels by whole-blood thromboelastometry on arrival at the ED and reported that Fbg level predicts the need for MT in trauma patients [21].

Previous studies have indicated that Fbg deficiency develops before other hemostatic abnormalities. Hiippala et al. reported that Fbg levels reach 100 mg/dL at 142% blood loss in animal models [23]. Hayakawa et al. reported that Fbg levels reached a critical level (150 mg/dL) earlier than any other routine coagulation parameters (such as platelet counts, PT, and aPTT) in patients with severe trauma [24]. Sawamura et al. reported that the optimal cut-off value of Fbg to predict massive bleeding and death was 190 mg/dL [8]. Moreover, Nakamura et al. reported that Fbg level on admission can be an independent predictor of MT after severe blunt trauma and that the optimal cut-off value is 190 mg/dL [25]. In the present study, the optimal cut-off value of Fbg was 193.0 mg/dL. This value is similar to those reported in previous studies.

Inaba et al. reported that Fbg levels were positively correlated with survival rates for trauma patients who required MT. They also concluded that a Fbg level < 100 mg/dL was a strong independent risk factor for death [22]. On the other hand, some guidelines have indicated that Fbg levels should be maintained at ≥150 mg/dL to maintain hemostatic functions [26,27]. The updated European trauma guidelines recommend maintaining Fbg levels at ≥150–200 mg/dL, which was increased from 100 mg/dL in previous guidelines [28].

Fbg levels might not have adequate sensitivity and specificity to predict MT as a single parameter. In various studies, HR, sBP, and GCS were reported as predictors in MT scoring systems [17,18]. Whereas vital signs can be identified easily and continuously, HR and SBP are highly variable. In the present study, Fbg level was identified as an independent predictor of MT need in multiple logistic analysis, indicating that future studies should consider incorporating Fbg levels when devising models for MT prediction. From these points, we concluded that the Fbg level on admission is one of the most important predictors for MT in patients with pelvic fractures.

The association between type of pelvic fracture and pelvic bleeding remains controversial. Several authors have reported that the Young-Burgess classification affects blood transfusion amount [29,30]. On the other hand, there have been some studies reporting that the Young-Burgess classification does not consistently correlate with a patient's need for urgent embolization [31,32]. There are also some reports that the AO/OTA classification has a significantly higher correlation with massive hemorrhage than does the Young-Burgess classification [33]. AO/OTA classification is based on a patient's stability, which is provided primarily by the posterior ligamentous complex. In this study, patients with unstable pelvic fractures according to the AO/OTA classification required MT significantly more frequently than did those with stable pelvic fractures.

In unstable pelvic fractures, as with any high-energy trauma, the development of TIC occurs in 25% to 40% of patients [10,11]. TIC leads to Fbg deficiency. Several factors have been identified as contributing to TIC, including the severity of the injury, hemorrhagic shock, hemodilution, clotting factor consumption, and impaired formation of thrombi. Additionally, bleeding and tissue hypoperfusion lead to the lethal triad of acidosis, hypothermia, and coagulopathy [34,35]. It is important to prevent this vicious circle in patients with pelvic fractures, especially unstable types.

This study has several limitations; the first is its small sample size. Second, this study was conducted in a single center and was

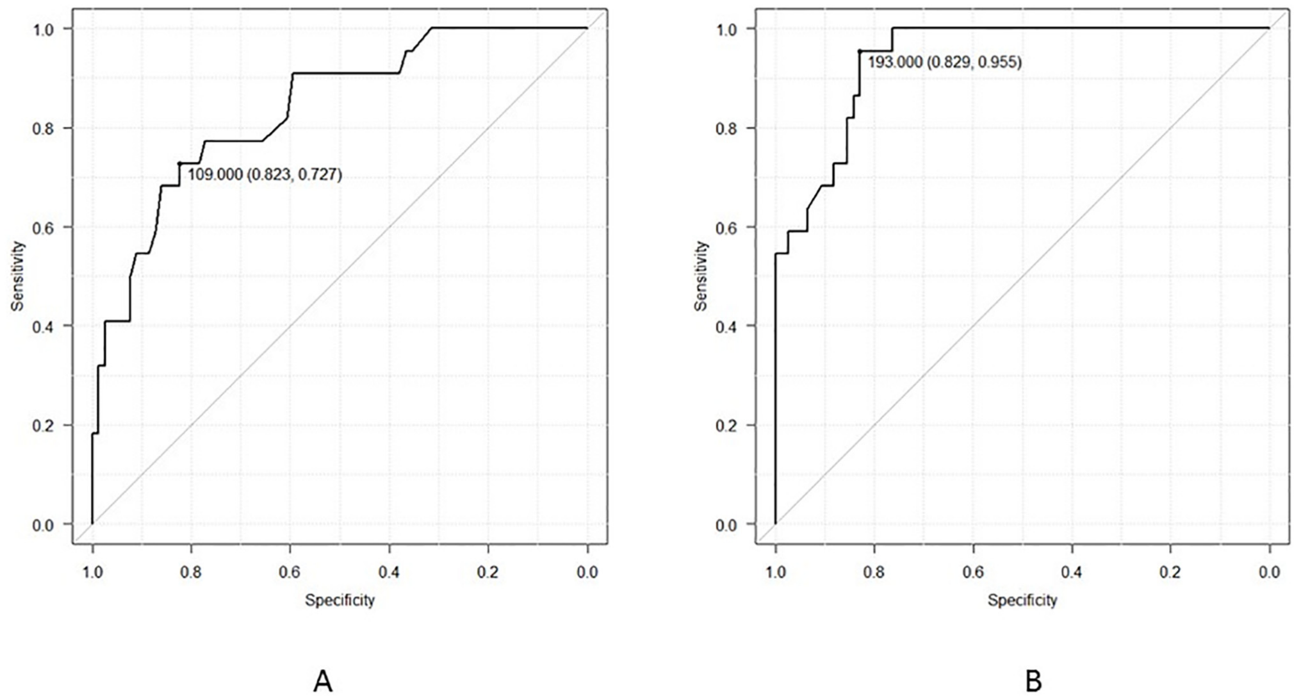

Fig. 2. Receiver operating characteristic curves for predicting massive transfusion based on systolic blood pressure (sBP) and fibrinogen (Fbg) in pelvic fracture. A: sBP The optimal cut-off values for sBP were ≦109 mmHg (sensitivity 0.727, specificity 0.823). B: Fbg The optimal cut-off values for Fbg levels were 193.0 mg/dL (sensitivity 0.955, specificity 0.829)

retrospective in nature. Therefore, a multi-center prospective study with a larger sample size is needed to validate the accuracy of this study. Third, our exclusion criteria included the effects of regions other than the pelvis; however, the possible contribution of other trauma regions could not be eliminated. Fourth, we did not consider the volume of prehospital infusion and transport time to our hospital. Prehospital infusion might potentially induce hemodilution, which leads to coagulopathy. Therefore, further studies are required to address these limitations.

5. Conclusion

In the present study, we evaluated the usefulness of coagulation biomarkers as predictors of the need for MT in patients with pelvic fractures. Patients with unstable pelvic fractures according to the AO/OTA classification required MT significantly more frequently than did those with stable pelvic fractures. We demonstrated that Fbg levels on admission can be an independent predictor of the requirement for MT in patients with pelvic fractures. Moreover, we found that the optimal cut-off value of Fbg for MT prediction was 193 mg/dL. Therefore, the use of Fbg levels on admission to predict MT could lead to more prompt and effective treatment of pelvic fractures.

Conflicts of interest and source of funding

The authors declare that they have no conflict of interest.
Compliance with ethical standards

Conflicts of Interest: The authors report no conflict of interest concerning the materials or methods used in the present study or the findings specified in the present paper.

Informed Consent: For this type of study, informed consent is not required.

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Table 3
Receiver operating characteristic curve analysis

Variables	AUC	95% CI	Optimal cut-off value	Sensitivity	Specificity
Systolic blood pressure, mmHg	0.838	0.744–0.932	109	72.7	82.3
Fibrinogen, mg/dL	0.944	0.902–0.985	192.0	95.5	82.9

AUC: area under the curve; CI: confidence interval.

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