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Original Contribution

Analysis of risk classification for massive transfusion in severe trauma using the gray zone approach☆,☆☆,★

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ABSTRACT

Background: The Traumatic Bleeding Severity Score (TBSS) was developed to predict the need for massive transfusion (MT). The aim of this study is evaluation of clinical thresholds for activation of a MT protocol using the gray zone approach based on TBSS.
Methods: This is a single-center retrospective study of trauma patients, admitted from 2010 to 2013. The TBSS on admission was calculated, and the accuracy of predicting MT was analyzed using area under the receiver operating characteristic curve. Risk classification for MT was made using sensitivity/specificity. The gray zone (indeterminate risk) was defined from a sensitivity of 95% to a specificity of 95%, patients were separated into MT and non-MT groups, and their clinical characteristics were compared.
Results: A total of 264 patients were enrolled, with an area under the TBSS curve of 0.967 (95% confidence interval, 0.94-0.99). A TBSS of 10 points or less resulted in a sensitivity of 96.5% with 146 patients in this group, and 3.4% (5/146) of them received MT. A TBSS of 17 points or higher had a specificity of 97.8%, which included 72 patients, and 94.4% (68/72) of them received MT. Forty-six patients had a TBSS from 11 to 16 points (gray zone), and 26.1% (12/46) of them received MT. Comparing the MT group (12/46) and non-MT group (34/46), coagulopathy and extravasation on computed tomographic scan were more prevalent in the MT group.
Conclusion: The TBSS is highly accurate in predicting the need for MT, and a risk classification for needing MT was created based on TBSS.

1. Background

Massive hemorrhage is a major cause of early trauma death [1-3]. In severely injured trauma patients, trauma-induced coagulopathy commonly occurs [4], and resuscitation with only large volumes of crystalloid or red blood cells causes dilution coagulopathy [5]. Trauma resuscitation with red blood cells, fresh frozen plasma, platelet concentrates, and clotting factors is recommended [3,6]. Previous studies suggest that packed red blood cells/fresh frozen plasma/platelet concentrates in a ratio of 1:1:1 or packed red blood cells/fresh frozen plasma greater than or equal to 1:1.5 improves the outcome [7,8], and administration of fresh frozen plasma and platelet concentrates in an appropriate ratio is recommended in trauma resuscitation [9], although the optimal ratio of various blood products is still unclear. In recent years, approximately 85% of major trauma centers in the United States have instituted massive transfusion (MT) protocols to direct the appropriate transfusion of blood products [10].

Severely injured trauma patients with hemorrhagic shock, large hemoperitoneum, or coagulopathy often need MTs, based on existing literature [3]. However, in the care of some patients despite suffering hemorrhage, such normotensive patients, those with minimal hemoperitoneum, or a patient receiving anticoagulants, we may not be able to clearly decide whether to activate an MT protocol. These patients constitute a "gray zone" in the decision process.

A number of scoring systems to predict the need for MT have been developed to apply specific criteria [11-17]. The Traumatic Bleeding Severity Score (TBSS) (Fig. 1) is one such scoring system, developed to predict the need for MT in severely injured trauma patients. The TBSS has a strong predictive value and is calculated using only 5 clinical variables, including the patient's age, systolic blood pressure, results of the Focused Assessment with Sonography for Trauma scan, the presence/severity of a pelvic fracture, and the serum lactate level [17].

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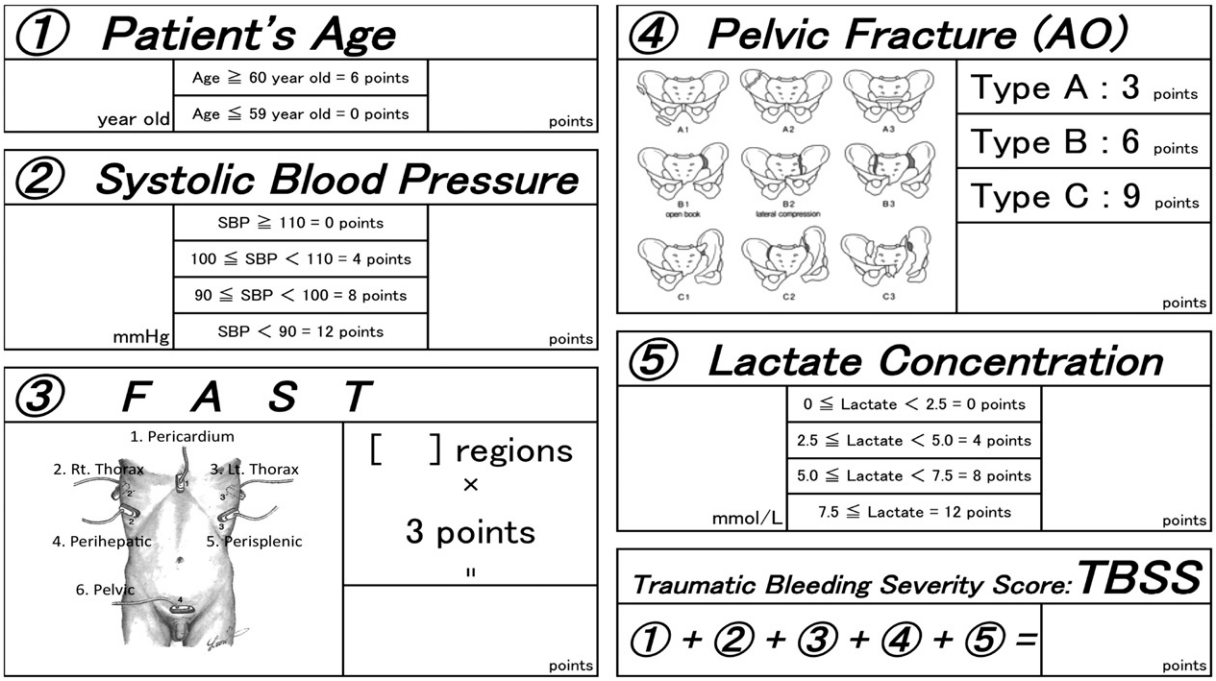

Fig. 1. The Traumatic Bleeding Severity Score. Abbreviations: SBP, systolic blood pressure (after rapid infusion of 1000-mL crystalloid); FAST, Focused Assessment with Sonography for Trauma; AO, Arbeitsgemeinschaft für Osteosynthesefragen/Orthopedic Trauma Association classification.

The TBSS is simple to calculate using a (no-cost) iOS application on smart phones [17]. The Trauma Associated Severe Hemorrhage (TASH) Score is widely used, with a high overall accuracy as reflected by an area under the receiver operating characteristic curve (AUC) of 0.89 [18]. The aims of this study are to compare the TBSS and TASH scores for predicting the need for MT in severely injured trauma patients and to further establish clinical thresholds for activation of an MT protocol using the gray zone approach for the TBSS.

2. Patients and methods

This study was conducted at a single institution that admits approximately 200 severely injured patients per year (Injury Severity Score [ISS], ≥16). The institutional review board approved this review of patient data before starting the study (approval no. 2413, dated September 25, 2013). This is a single-center retrospective study of severely injured patients (ISS, ≥16) admitted between January 2010 and May 2013. These patients were included in the original TBSS validation study [17], admitted from January 2010 to March 2012. Because of the trauma epidemiology in our patient population, nearly all patients in this study had blunt traumatic injuries. Patients with out-of-hospital cardiac arrest or isolated head trauma were excluded from this study.

The TBSS and TASH scores for each patient at the time of arrival to the emergency center were retrospectively calculated. Receiver operating characteristic curve analysis was then performed to test the accuracy of the TBSS and TASH scores to determine the need for MT.

2.1. Massive transfusion protocol

An *MT* is defined as administration of 10 units or more of packed red blood cells within 24 hours after injury. Patients admitted to the emergency department were treated according to the current MT protocol and received 10 units of type O+ packed red blood cells and 10 units of type AB+ fresh frozen plasma in the initial transfusion. This was followed by transfusions of type-specific blood products, which were repeated until the bleeding was controlled. Fibrinogen levels and platelet counts were monitored, and further transfusions of platelets and fresh frozen plasma were given as needed.

2.2. Statistical analysis

In this study, all statistical analyses were performed using MedCalc (Ostend, Belgium). The predictive performance of thresholds for the need for MT was evaluated by the sensitivity, specificity, positive predictive value, and negative predictive value within 95% confidence intervals. We defined the point of 95% specificity as the cut-off point of the high-risk group for MT and the point where the sensitivity is 95% as the cut-off point of the low-risk group for MT. The *gray zone* (indeterminate risk group) is defined as the range from the cut-off point of the low-risk group to the cut-off point of the high-risk group [19]. Massive transfusion predictors were identified by comparing clinical parameters in gray zone patients who underwent MT (MT group) with those who did not (non-MT group).

High accuracy was defined as AUC of more than 0.9, moderate accuracy was defined as AUC less than 0.9 but greater than 0.7, and low accuracy was defined as an AUC less than 0.7 [20].

Gray zone patients defined by the TBSS are divided into patients who received a MT (MT group) and patients who did not (non-MT group). The clinical characteristics compared between these 2 groups include age, sex, systolic blood pressure, heat rate, respiratory rate, Glasgow Coma Scale, hemoglobin, platelet count, prothorombin international normalized ratio (PT-INR), fibrin and fibrinogen degradation product, D-dimer, fibrinogen, presence of extravasation on computed tomographic (CT) scan, and preinjury use of anticoagulants.

3. Results

There were 599 severely injured patients (ISS, ≥16) admitted during the study period from January 2010 to May 2013, but 128 were out-of-hospital cardiac arrests and 207 were isolated head trauma patients and were excluded from further analysis. The remaining 264 severely injured trauma patients were enrolled in this study (Fig. 2). Of these 264 patients, 113 patients admitted from admitted from January 2010 to March 2012 were included in the original TBSS validation study [17]. An additional 151 patients admitted from April 2012 to May 2013 were included in the present study. The overall rate of MT in this study is 32.2% (85/264).