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Plasma Transfusion in Patients With Cirrhosis in China: A Retrospective Multicenter Cohort Study☆,☆☆

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ABSTRACT

Patients with cirrhosis used to be associated with frequent use of blood components because of their complex disorder of hemostasis and bleeding complications. Recent findings have indicated that patients with cirrhosis have a state of "rebalanced" or even procoagulant hemostasis and have questioned the prophylactic use of plasma. To evaluate the current status of plasma use in patients with cirrhosis, we conducted a retrospective survey in 11 tertiary-care hospitals in China from September 1 to October 31, 2013. All patients admitted with cirrhosis during the study period were included in the study. The survey collected information including patients' diagnostic and demographic data, clinical course including bleeding complications and invasive procedures, laboratory results, and plasma transfusion data. Among 1595 patients with cirrhosis admitted to the 11 hospitals, 236 (14.8%) patients received 1 or more plasma transfusions during the study period. The number of plasma transfusions is defined as the number of transfusion orders. A total of 1037 plasma transfusions were administered to these patients, with a mean of 4.4 transfusions per transfused patient, ranging from 1 to 22 transfusions per transfused patient. Most plasma transfusions (760/1037; 73.3%) were given to patients without bleeding, for treatment of coagulopathy either without planned invasive procedures (70.4%) or before invasive procedures (2.9%). The median dose of plasma transfusion was 3.8 mL/kg. The rate of plasma transfusion of participating hospitals varied from 5.3% to 31.8%. It is encouraging to see that in one teaching hospital, 85.7% plasma transfusions were given to patients with bleeding indication, showing a promising sign in appropriate transfusion. Prophylaxis or empirical plasma transfusion is still a common problem in managing patients with liver cirrhosis. Wide variations are found in plasma transfusion practice among hospitals. Effective measures to control and reduce empirical correction of abnormal coagulation tests through transfusing plasma should be strengthened urgently.

Abbreviations: HBV, hepatitis B virus; PT, prothrombin time; APTT, activated partial thromboplastin time; Hb, hemoglobin; PLT, platelets; CRA, clinical research associates; QC, quality control; IQR, interquartile ranges; INR, international normalized ratio; HCV, hepatitis C virus; ICU, intensive care unit; TRALI, transfusion related acute lung injury; TACO, transfusion associated circulatory overload.

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Cirrhosis is a significant cause of mortality and morbidity worldwide, with more than 1 million deaths in 2010 [1,2]. In China, cirrhosis is a common reason for hospital admission, accounting for 10.7% to 51.1% of all the in-patients suffering from liver diseases [3,4]. Unlike more developed countries where the main causes of liver cirrhosis are alcohol consumption, infection with hepatitis C virus, and, increasingly, nonalcoholic liver disease [1,5], chronic hepatitis B virus (HBV) infection is the main primary cause of adult liver cirrhosis in China [6], with most studies reporting a prevalence of 60% or higher [7,8]. Although cirrhosis mortality has declined, which may be related to a reduction in HBV prevalence, liver cirrhosis is still an important health and economic burden.

Plasma transfusion for the purpose of supplementing procoagulation factors has been a common practice in cirrhosis patient management for either treating bleeding or prophylaxis before invasive procedure or surgery [9]. Nevertheless, growing evidence demonstrates that patients with cirrhosis are deficient in both procoagulation and anticoagulation factors, so conventional coagulation tests (ie, prothrombin time [PT] and activated partial thromboplastin time [APTT]) are poor predictors of bleeding risk in these patients. Moreover, stable patients with cirrhosis have a state of "rebalanced" or even procoagulant hemostasis rather than hypocoagulable status as reflected by prolonged PT, APTT, and bleeding complications [10]. Also, prophylactic transfusion of plasma is not recommended because there is little evidence that prophylactic transfusion helps to prevent procedure-related bleeding and it may even do harm to patients [11]. In other words, plasma transfusion may not be a requisite for most stable patients with cirrhosis. Since the new concept of "rebalanced" hemostasis of liver disease has been proposed for several years [12], we attempted to find out if any improvement of plasma transfusion practice has been achieved, by conducting a multicenter survey on the detailed pattern of plasma utilization in patients with cirrhosis. Specifically, this study aimed at collecting data on the indications and the dose used for plasma transfusion in patients with cirrhosis, and the variations in practice between hospitals.

Materials and Methods

Hospitals and Patients

Eleven tertiary-care Chinese hospitals (all have >1000 hospital beds) participated in this study. Geographical diversity was achieved by selecting hospitals from different representative regions of China. Five hospitals are teaching hospitals affiliated to universities, 3 of which have designated digestive disease centers.

All patients 16 years or older admitted with a diagnosis of liver cirrhosis during a 2-month study period between September 1 and October 31, 2013 were eligible for inclusion. Patients were excluded if the data reviewers found insufficient evidence to confirm the diagnosis of liver cirrhosis. *Cirrhosis* was defined as either biopsy-proven or based on clinical findings including esophageal varices, ascites, or hepatic encephalopathy.

Study Design

A standard data collection form was used to review medical records retrospectively for all patients admitted with cirrhosis during the study period. A pilot study was first conducted in 3 hospitals in August of 2013, to develop a data collection form. The data collection form collected information on patient demographics, body weight, diagnosis, severity of cirrhosis (ie, Child-Pugh score), laboratory results of hemostasis, hemoglobin, platelets count and hepatic function, clinical information including hospital course, bleeding and medical/surgical procedures, and plasma transfusion information. Plasma transfusion in China uses both fresh-frozen plasma and frozen plasma; both are available in most hospitals and often used interchangeably depending on availability. For this study, we did not make a distinction between these 2 types of plasma. One transfusion event is defined as one transfusion order. *Coagulopathy* was defined as international normalized ratio (INR) value greater than 1.5. *Gastrointestinal hemorrhage* was defined as a significant bleeding observed with the clinical manifestation of hematemesis, or repeated occurrence of hematochezia or melena. Mucocutaneous bleeding, such as light blood staining of oral, or the occurrence of ecchymosis was considered as minor hemorrhage. Study data were collected for a maximum of 28 days after admission or until transfer, discharge or death, whichever came first.

Data Collection and Handling

Data were collected by trained clinical research associates through the hospital electronic medical record system and the hospital blood bank information system. Quality control of data collection was performed by double-data entry by additional clinical research associates and regular data review by central research staff from the Data Coordinating Center for data accuracy and completeness. After quality control, data were inputted into the Web-based database before being exported and electronically compiled into an Excel spreadsheet.

Patients' private identification information was not collected for this study. The protocol was approved by the Ethics Committee of Daping Hospital, the Third Military Medical University. The project was registered in the Chinese Clinical Trial Registry (ChiCTR-ONC-13003689).