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ABSTRACT N. CO37

MALATTIE EMORRAGICHE CONGENITE E ACQUISITE

ASSESSMENT OF CLOTTING FACTOR ACTIVITY AND STERILITY IN THAWED FRESH FROZEN PLASMA SUPPLIED TO HELICOPTER EMERGENCY MEDICAL SERVICES FOR PREHOSPITAL TRANSFUSION.

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Background: Administration of thawed fresh-frozen plasma (FFP) in the pre-hospital setting during helicopter transport for critically injured patients significantly improves survival rates, especially for those at risk of hemorrhagic shock. It also lowers 30-day mortality rates and reduces the need for subsequent blood transfusions. The Immunohematology and Transfusion Medicine Department at Hospital Papa Giovanni XXIII in Bergamo is distinguished as the first institution in Italy to provide thawed FFP, along with packed red blood cells (RBC), to the Helicopter Emergency Medical Service (HEMS) of Bergamo, ensuring that blood products meet the highest quality standards.

Aim: This study aims to evaluate the preservation of thawed FFP quality and safety characteristics during air transport in routine conditions practice.

Methods: For HEMS use, a blood bank-validated protocol outlines the packing and storage of blood products. This includes two units of 0 Rh-negative packed RBC and two units of AB thawed FFP with a 5-day shelf life. The units are maintained at 4±2◦C in a golden hour cold box (Crēdo ProMed, Pelican BioThermal). To ensure product viability, the RBC and thawed plasma units are exchanged for fresh stock every 72 hours, and the box itself is replaced daily by a new preconditioned one. Continuous monitoring of the internal bag temperature is performed. As part of the quality assessment, coagulation factor VIII (FVIII), FV, and FVII activity, as well as fibrinogen levels, were measured after four days of storage using a STAR Compact Max 3 analyzer (Stago, Italy). Data on total protein levels and sterility, as detected by the BacT/ALERT microbial detection system, were also collected to identify both aerobic and anaerobic bacteria. To compare FVIII levels, 1,855 plasma units designated for quality control (QC) were tested before freezing and following one month of storage at −30◦°C.

Results: The median FVIII levels in the 1,855 FFP used for QC, measured on fresh samples before storage, were 116% (IQR, 100-145) for plasma obtained from apheresis and 111% (IQR, 93-138) for whole blood-derived plasma. After one month of storage at -30°, the median FVIII levels were 103% (IQR 87-124) for plasma from apheresis, and 99% (IQR 81-122) for whole blood-derived plasma. A total of 101 units of thawed FFP stored in the golden hour box was analyzed. In these units, the median levels of FVIII after 96 hours of storage were 73% (IQR, 61-87), with 59 units retaining median FVIII levels above 70%, 38 units above 50%, and only four units exhibiting levels below 50% (34-48). Median levels for FV, FVII, and fibrinogen were 87% (IQR, 71-95), 74% (IQR, 65-88), and 261 mg/dL (IQR, 234-296), respectively. In these plasma units, we observed reductions in FVIII levels of 34.24% and 26.27% compared to the QC plasmas before storage, and after one month of storage at -30°C, respectively. Importantly, sterility was consistently maintained across all units, and serum levels of albumin and immunoglobulins showed no significant change during the storage.

Conclusions: Our data show that thawed FFP retains levels of both stable (FVII and fibrinogen) and labile (FVIII and FV) that meet established reference standards during 96 hours of storage at 2-6°C in the golden hour box, along with other essential proteins.

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