VALIDATION OF INTERCEPT BLOOD SYSTEM FOR PLASMA AT THE BLOOD TRANSFUSION SERVICE ZURICH

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Background: In Switzerland, quarantine stored fresh frozen plasma (qFFP) and S/D-plasma (Octaplas®, Octapharma) are currently available for transfusion. Regarding transfusion transmitted disease (TTD) risk, pathogen inactivated products provide potential advantages. Amotosalen/UVA treatment (INTERCEPT®, Cerus) is the only authority approved pathogen inactivation (pi) procedure that can be incorporated into the local FFP production process omitting quarantine storage. We describe the validation of the INTERCEPT procedure for FFP at the Blood Transfusion Service Zurich (ZHBSD).
Methods: 12 INTERCEPT preparations (lot 1) were performed on FFP units reflecting blood group (BG) distribution of qFFP sold in 2011 (2xAB, 2xB, 4xA and 4x0). BG B and AB plasma was prepared by apheresis and 0 and A plasma was recovered from whole blood donations. Half of the plasma was processed within 8h after donation (short term, st) and the other half 15 to18 hours (long term, lt) after donation. Within 1h following INTERCEPT treatment, FFP was shock frozen at -30°C. 14 additional preparations of BG 0 FFP (lot 2) were carried out (4x st, 10x lt) to evaluate FVIII preservation as a function of processing delay after donation. Process entry requirements, product specifications and Fibrinogen (Fbg) were measured. FVIII and Fbg recovery rates (RR) after INTERCEPT treatment were calculated.
Results: At study entry, the volumes of plasma preparations ranged from 643-650mL (spec. 385-650mL), max. erythrocyte contamination was 0.8x10e6/mL (spec. <4x10e6/mL), and max. leucocyte contamination was 0.07x10e6/650mL (spec. <3x10e6/650mL). Residual platelets did not exceed 0.11x10e9/L (spec. <50x10e9/L). Following INTERCEPT treatment, mean RR of FVIII and Fbg were 73% (62-83%) and 82% (73-92%) respectively. FVIII concentration of final piFFP of lot 1 (n=12, st and lt processing delay) was st: 0.75IU/mL (0.52-1.08) and lt: 0.60 IU/mL(0.47-0.73), resp. The second lot of exclusive BG 0 plasma (n=14) revealed FVIII st: 0.61IU/mL (0.56-0.66, n=4) and FVIII lt: 0.45IU/ml (0.35-0.54, n=10). Fbg concentration of final products was 2.0g/L (range 1.6-2.8, n=12) and revealed no dependency on processing delay of the plasma. Residual amotosalen was below the limit of 2µM for all units assessed.
Conclusions: Whole blood donation and apheresis donation provide donor plasma quality meeting the requirements for INTERCEPT treatment. FVIII recovery after INTERCEPT treatment is satisfactory and fulfills expectations. All piFFP units met specifications except some piFFP units of BG 0, which were processed 15-18h after donation. These met FVIII requirement (≥0.5 IU/mL) only borderline. Since FVIII concentration in BG 0 plasma is on average ca 20% below FVIII concentration of Non-BG 0 plasma, processing delay of BG 0 plasma might be critical.