

VALIDATION OF DOUBLE DOSE POOLED PLATELET PRODUCTS FOR PATHOGEN INACTIVATION WITH THE INTERCEPT BLOOD SYSTEM™ AND STORAGE FOR UP TO 7 DAYS

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BACKGROUND

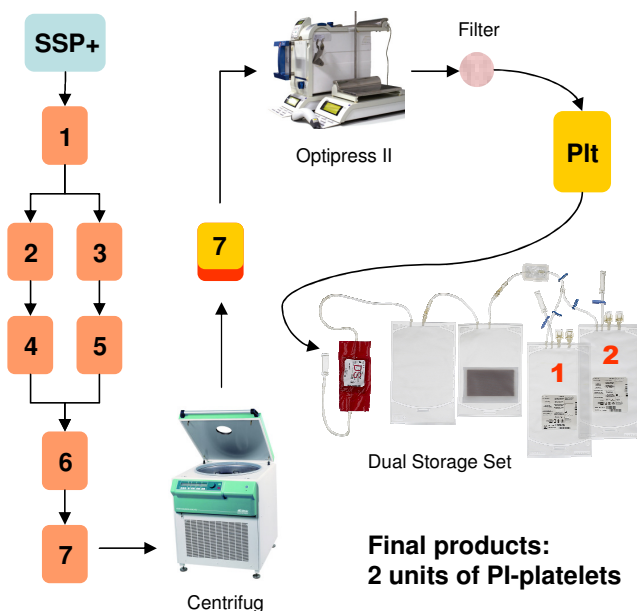
The INTERCEPT Blood System™ for platelets allows for pathogen inactivation in apheresis and buffy coat-derived platelet components. Production of buffy coats can be cost saving and makes platelet production less dependent on apheresis donors. The newly introduced dual-storage bag set enables for the production of two pathogen-inactivated platelet components from a pool of 7 buffy coats.

AIM

The objective of this study was to analyze the feasibility of pooling 7 buffy coats to produce a double dose platelet product suitable for the INTERCEPT™ process and their compliance with the acceptance criteria for manufacturing (local and EU guidelines) and for support of patients according to clinical practice guidelines and standard platelet infusion methods in Sweden. The quality of the produced split units was determined over the storage period of 7 days.

METHODS

Buffy coats were produced from whole blood (450 ± 45 mL) using the Optipress II device (Fenwal). Seven ABO-matched buffy coats were pooled with 300 mL of SSP+ additive solution (MacoPharma). Twelve buffy coat pools were evaluated before and after INTERCEPT™ treatment and in vitro parameters (volume, platelet count, glucose, lactate, swirling, pH value, O₂ consumption and CO₂ production) were analyzed at days 1 or 2, 4 or 5, and 7 of storage.



RESULTS

The mean volume of buffy coat pools ($n=12$) was 601 ± 6 mL. Target values for the resulting pooled platelet products were $5.5\text{--}7 \times 10^{11}$ platelets in a volume of 370–420 mL SSP+ with 32–47% plasma. Red blood cell (RBC) threshold was at $<4 \times 10^6/\text{mL}$ and maximum residual white blood cell (WBC) concentration at $1 \times 10^6/\text{unit}$.

After sampling, the volumes for all products were below 420 mL. Before INTERCEPT™ treatment, the mean volume was 404 ± 8 mL with $5.65 \pm 0.61 \times 10^{11}$ platelets. The products contained $1.2 \pm 0.4 \times 10^6$ RBC/mL and $0.11 \pm 0.1 \times 10^6$ WBC/unit.

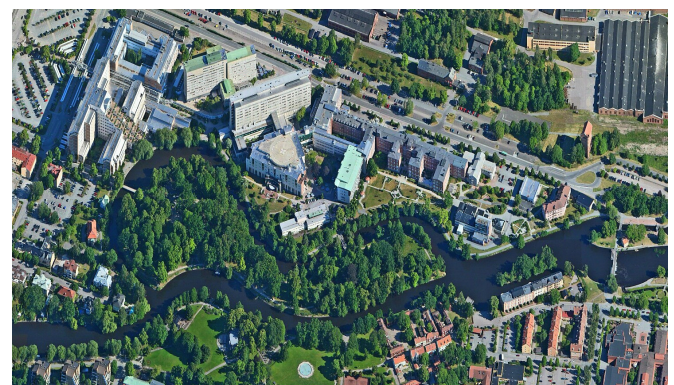
The products were split directly after treatment. The resulting platelet components had a mean platelet dose of 2.56×10^{11} on day 1/2 (in 192 ± 5 mL) and 2.43 and 2.44×10^{11} platelets on day 4/5 and 7 respectively, reflecting a total loss of about 5% during storage.

The mean pH value was 6.9 on day 1/2, 7 on day 4/5 and 6.8 on day 7 of storage. Lactate concentration increased from 9.1 to 12 and 15.8 mM/mL and glucose content decreased from 5.2 to 3.7 and 1.9 mM/mL from day 1/2 to day 4/5 and 7 respectively.

Over the 7 days of storage, the mean pO₂ level was 21.4, 21.7 and 21.2 kPa and the mean pCO₂ level was 4.3, 2.5 and 3.1 kPa on day 1/2, 4/5 and 7 respectively.

CONCLUSIONS

Production of pools of 7 whole blood-derived buffy coats for treatment of double dose platelet components is feasible with only minor losses. All pools produced in this study met the guard bands for the INTERCEPT™ treatment. Pathogen inactivation with the dual-storage bag set allows for the production of two components for transfusion which are in accordance with the local and EU guidelines. Analyses of the in vitro parameters show that these products are suitable for transfusion even after storage for up to 7 days.



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