

SUMMARY of SAFETY and EFFECTIVENESS

Seven Day Platelets Storage Using Platelets Collected with COBE Spectra Apheresis Systems and the Trima Automated Blood Component Collection System

BACKGROUND:

Fatal and non-fatal septic reactions from bacterially contaminated blood products are the highest risk disease associated with transfusion. One approach to reduce this risk is implementation of a bacterial screening scheme for 100% of the platelet inventory. Increasing the allowable shelf life of room temperature stored platelets from 5 to 7 days has been proposed as a means to recover costs associated with such a program and relieve platelet inventory pressures. In vitro and in vivo studies were conducted by Gambro BCT to evaluate 7 day platelet storage. The objectives of the in vitro study conducted at Gambro BCT were to describe the changes associated with classically measured platelet in vitro characteristics for apheresis platelets stored in the COBE® ELP™ platelet storage bag, and to verify the allowable storage configuration determined by volume, platelet concentration, and total platelets within a storage bag. The in vivo studies evaluate the effectiveness of platelets stored in plasma for seven days in the ELP bag as demonstrated by recovery and survival of radiolabeled, autologous platelets. Seven day platelets are compared to the current standard of 5 day stored platelets using a paired, double radioisotope labeling technique. In vitro platelet characteristics over 7 days of storage are also described. Both the in vitro and the in vivo data contribute to the verification of the allowable storage configuration for the ELP bag.

METHODS:

Apheresis platelets were collected from volunteer subjects with the COBE Spectra™ LRS® Turbo™ version 7 or Trima® Automated Blood Collection Systems. Platelet concentration and volume per bag were controlled to examine a wide combination of these variables. Platelets were stored in one ELP bag at 22°C with horizontal agitation in a temperature-controlled platelet incubator for 7 to 8 days.

In vitro biochemical and functional tests were conducted on the stored platelets. The clinical study evaluated in vivo recovery and survival of radiolabeled aliquots taken on days 5 and 7. Standard subject pre and post apheresis parameters were taken.

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SUMMARY of RESULTS:

No bacterial growth was detected in any platelet product as indicated by negative culture results of aliquots taken on days 3, 5, 7, and/or 8 of storage.

The data presented in these studies show, as expected, a gradual and continuing decline in platelet in vitro characteristics over storage through day 7 except for the capacity to utilize oxygen which was stable over 7 days. Glucose consumption and lactate generation were stable throughout storage at all investigational sites and consistent with data reported by others. Thus, we conclude the capacity for oxidative phosphorylation was maintained for the platelets, and there was no Pasteur shift associated with these products. Metabolic function of the platelets was maintained, and $\text{pH}_{22^{\circ}\text{C}}$ was consistently greater than 6.2. Excursions of $\text{pH}_{22^{\circ}\text{C}}$ over 7.4 were observed. We conclude from the data reported in these studies that the platelets are not adversely effected by what some believe to be high pH during storage.

There were small reductions in day 7 compared to day 5 in vivo recovery and survival of 14% and 17%, respectively. These changes, while statistically significant, are in line with current standard of care platelet transfusion products, as discussed further in the in vivo report.

These data support that extension of platelet storage in plasma in the ELP bag maintains platelet function adequate for transfusion. Because of the known risks associated with bacterially contaminated platelets, any such extension of shelf life must be coupled with a 100% screening for bacterial contamination using a marketed device and recommended method prior to transfusion.

These data also support the effective storage range for platelets in plasma kept in the ELP bag under standard conditions for up to and including 7 days is:

<p>100-400 mL/bag, $1.0 - 2.1 \times 10^6$ platelets/μL, maximum 5.1×10^{11} platelets per bag</p>
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