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Original Article

To study the effects of gamma irradiation on single donor apheresis platelet units by measurement of cellular counts, functional indicators and a panel of biochemical parameters, in order to assess pre-transfusion platelet quantity and quality during the shelf life of the product

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ABSTRACT

Background: The occurrence of transfusion associated graft versus host disease can be prevented by gamma irradiation of blood components. This study was undertaken to assess the effects of gamma irradiation on single donor platelet (SDP) concentrate units.
Method: SDPs were collected by a continuous flow apheresis technique ($n = 400$). The SDPs from each donor were divided into two parts, one gamma-irradiated with 25 Gy and the other used as a non-irradiated control. Swirling and morphological features, cellular counts, biochemical parameters including blood gas analysis, and platelet activation levels (CD62P: p-selectin) by flow cytometry were analyzed on Day 1 and on Day 5.
Results: Swirling and morphology were maintained in all products, in both the groups throughout the shelf life. No significant change was seen in both groups, on the first and fifth day, as far as pO_2, pCO_2, Na^+, K^+, HCO_3^- & Ca^{2+} were concerned. However, lactate increased and glucose decreased significantly in irradiated products over 5-day storage period. A small but significant decrease in pH and platelet count was found in the irradiated PCs after 5-day storage. The mean proportion of platelets expressing CD62P over 5-day storage increased significantly.
Conclusion: After an overall assessment of all our in vitro parameter results and observations, a few of which were significant, while most were not significant, we concluded that a well-preserved quality of gamma irradiated apheresis platelets is maintained throughout

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the entire 5-day shelf life of the platelet product, with minimal difference compared to non-irradiated platelets.

Introduction

Transfusion associated graft versus host disease (TA-GVHD) is a rare but a highly lethal complication of cellular blood transfusion. It is defined as a delayed immune transfusion reaction caused due to an immunologic attack by viable donor lymphocytes contained in the transfused blood component against the transfusion recipient.[1] According to UK haemovigilance system severe hazards of transfusion (SHOT), TA-GVHD accounts for 0.2% of complications associated with transfusion of blood products.[2] The occurrence of TA-GVHD can be prevented by gamma irradiation of cellular blood components with a minimum of 25 Gray (Gy) delivered to the central portion of the product and a minimum of 15 Gy dose elsewhere. It acts by inhibiting the proliferation of T-lymphocytes.[1]

The transfusion of irradiated blood components is mainly indicated for transfusion in infant or foetal patient populations (in case of intra-uterine and exchange transfusions), in patients with malignancies or compromised immune systems, individuals receiving cellular blood components from blood relatives and also in patients receiving HLA-matched products, e.g. haematopoietic stem cell transplant recipients.[3]

The exact number of residual leucocytes (T-lymphocytes) in leuco-reduced blood products that can cause TA-GVHD is unknown.[4] Hence, it is important to irradiate blood components including platelet concentrate (PC) units, whose demands are growing day by day and for which a large number of PCs are produced by apheresis procedures.[5] Until now, only a few relevant studies on the influence of gamma radiation on single donor platelet concentrate units (SDPs) obtained by plateletpheresis have been performed, which show conflicting results with regard to in vivo and in vitro platelet characteristics.[5–10]

Even though some of the earlier studies attempted to evaluate various quantitative and qualitative aspects of platelets as well as their in vivo properties (by radiolabelling studies) in random donor platelet (RDPs) concentrate units and SDPs,[5–18] the sample size chosen was too small to reach to a conclusion with certainty.

This study was undertaken to assess the effects of gamma irradiation on single donor apheresis platelet units by measurement of its cellular counts, functional indicators and a panel of biochemical parameters, in order to assess pre-transfusion platelet quantity and quality during the entire approved shelf life of the product (i.e. 5 days), so as to unfold any significant deleterious effects occurring due to irradiation.

Material and methods

Study design

This was a prospective, analytical study carried out in the Department of Immunohaematology and Blood Transfusion, over a period of 2 years from December 2012 to December 2014. The study was carried out after taking prior approval from the Institutional Ethical Committee and informed consent from the plateletpheresis donors.

Donor selection

Platelets were collected by standard apheresis procedures from four hundred (400) healthy voluntary donors, who met the Food and Drug Administration (FDA),[19] Directorate General of Health Services (DGHS) India,[20] and American Association of Blood Banks Guidelines and recommendations for plateletpheresis.[21] It was ensured that none of the subjects were receiving medications known to affect platelet function or kinetics.

Platelet collection

For the study, SDP units were collected on a continuous-flow cell separator, Fenwal Amicus with software version 3.5 (Baxter Healthcare, Deerfield, IL, USA) using the single needle plateletpheresis kit (PL 2410). Acid-citrate-dextrose (ACD-A) was used as anticoagulant agent. The instrument was programmed to collect 3×10^{11} platelets in a volume of 300 ml. On the basis of the entered donor parameters (such as sex, weight, height, haematocrit and pre-procedure platelet count) and the ratio of whole blood to ACD, the instrument calculated the total blood volume to be processed. Contaminating white blood cells were removed by the in-built leucoreduction system of the cell separator.

Storage

After completion of the procedure, each platelet suspension was equally divided into the two integral attached polyolefin containers. This was done with the help of an electronic weighing scale and a tube sealer. A 10 ml representative sample was collected from each of the two bags to analyze the baseline values of the parameters to be measured in the study. The product bags were stored as per laid down guidelines in a platelet agitator/incubator (Terumo Penpol, India) at 22–24 °C with continuous agitation, at a frequency of 60 horizontal agitations/min.

Gamma irradiation

One part of the product was then subjected to gamma irradiation of 25 Gray (Gy) with a ^{137}Cs source blood irradiator (Gammacell 3000 Elan, Nordion, Canada), as per manufacturer's directions. The irradiation instrument canister was loaded with single platelet concentrate unit at one time. An irradiation indicator (Rad-Sure type 25Gy, International Specialty Products, Wayne, NJ) was applied to each unit and