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EDITOR
B. O. OSOTIMEHIN

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A. O. UWAIFO

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Quality assessment of platelet concentrate prepared at a tertiary centre in Nigeria.

FA Fasola, MA Okunade and UMA Abjah

Department of Haematology, University College Hospital, Ibadan, Nigeria

Summary

The need for platelet transfusion has increased at the University College Hospital (U.C.H) Ibadan, Nigeria because of improved patient care and use of intensive therapeutic regimen associated with bone marrow aplasia. Therefore there is a need to assess the quality of the platelet concentrate prepared in our environment with a view to improving the quality of services available, consequently this study was carried out. Fifty platelet concentrates were assessed for pH, swirling index, volume, platelet count, WBC count and red cell count. All the concentrate preparations were within acceptable pH value of 7.25. The average volume was 18.52mls/bag. The average platelet count per concentrate was $41.7 \pm 39.5 \times 10^9/L$. Thirty-five percent (35%) of the platelet concentrates had a value $> 55 \times 10^9/L$. White blood cell count (WBC) $< 12 \times 10^9/L$ was seen 49% of the platelet concentrates prepared. Forty percent (40%) of the platelet concentrate had a red blood cell count (RBC count) $> 12 \times 10^9/L$ with 30% not having red cell contamination. Swirling test was positive in 72% of the platelet concentrate units. The results from this study point to the need to improve the quality of the platelet concentrates being prepared in our blood bank in order to get maximum therapeutic values. There is also a need for regular quality control of the platelet concentrate being prepared in our blood bank.

Keywords: Platelet, quality, blood bank, UCH.

Résumé

La nécessité de transfusion des plaquettes sanguines a augmenté au centre Hospitalier Universitaire (UCH) Ibadan, Nigeria due à l'amélioration des soins aux patients et l'utilisation des régime thérapeutiques intenses à l'anémie aplastique de la moelle épinière. Cependant, il ya un besoin de contrôler la qualité de la plaquette sanguine préparée dans notre environnement dans la vue d'améliorer la qualité des services utilisés. Raison pour laquelle cette étude avait été effectuée cinquante concentrés de plaquette avaient en leur PH l'index d'équilibre, volume. Le taux de plaquettes, le taux de globule blanc et rouges déterminés. Toutes les préparations de plaquettes avaient un pH acceptable de 7.25. le volume moyen était de 18.52 ml/sachet. Le taux moyen de concentré des plaquettes sanguines était de $41.7 \pm 39.5 \times 10^9/L$. Le taux de globules blanc était $12 \times 10^9/L$ obtenu dans 47% des concentrés de plaquettes sanguines préparés. Quarante pour cent (40%) des concentrés de plaquette sanguines avait un taux de globules rouges $> 12 \times 10^9/L$ avec 30% n'ayant pas de contamination de globules rouges. Cette étude d'équilibre était positive dans 72% du concentrés de plaquette sanguine préparés. Les résultats de cette étude montre la nécessité d'améliorer la qualité des concentrés; de plaquettes sanguines préparés dans les banques de sang afin d'obtenir des valeurs thérapeutiques maximales. Il ya aussi la nécessité d'un contrôle régulier des concentrés de plaquette sanguines préparés dans nos banques de sang.

Introduction

Platelet transfusion is used with the aim of correcting haemostatic defects due to thrombocytopenia or certain qualitative platelet dysfunction. Duke 1910 [1] first used fresh whole blood transfusion to raise platelet count and stop haemorrhage in thrombocytopenic patients. This early observation formed the basis of the therapeutic use of platelet concentrates. Platelet concentrates are prepared either from fractionation of whole blood donations or by selective harvesting by automated apheresis [2,3]. The relatively short life span of platelets as compared with red cells make the supply of platelet concentrates a major logistic problem [4]. Any deviation from the usual efficacy of harvesting platelets should be investigated and corrected as this could affect the potential clinical effectiveness of the platelet concentrate.

The need for platelet transfusion has increased at the University College Hospital (UCH) Ibadan because of increase demand for platelet concentrate. Apart from the fact that it is a referral center for haematological disease; it is one of the very few places in Nigeria where platelet concentrate is prepared.

There is therefore a need to assess the quality of the platelet concentrate prepared in our environment with a view of improving the quality of the service available.

Methods

Whole blood was collected into a CPD-A₁ donor double bags from fifty healthy blood donors aged 18-65 years. The units of blood were screened for Hepatitis B surface antigen and antibodies to Human immunodeficiency viruses I and II.

Platelet rich plasma (PRP) were prepared from the whole blood by centrifugation at 1500g for 10 minutes within 6 hours of donation. The PRP were then transferred into a transfer pack (satellite bag) where it was centrifuged at 4500g for 7 minutes. The supernatant platelet poor plasma (PPP) were then transferred back into the red cell concentrate. The platelet concentrates in the satellite bag were left undisturbed for one hour after the PPP has been decanted. The bag containing platelet concentrate was subsequently kneaded to break-up the platelet clump and put on a rotator operated at 6 revolutions per minute in an air-conditioned room at 20-24°C. The platelet concentrates were assessed for pH, swirling index, platelet concentrate volume, platelet count, white cell count (WBC), and red cell count (RCC). The mean of the variables and their 95% confidence interval were determined.

The swirling index / platelet shimmering effect was assessed by assessing the degree of light scattering on swaying of the platelet concentrate bag in front of a bright light from a bulb. The degree of light reflection was assessed visually (subjectively) with the naked eye [5]. Those platelet concentrate bags which did not reflect light were scored negative, while those that reflected light were scored positive or intermediate depending on the degree of light reflections [6].

The volume of the platelet concentrate was determined by withdrawing it into a syringe at the time the platelet concentrate was to be administered to the patient

Platelet count, leucocyte count and Red cell count were done using the manual method as described by Dacie and Lewis [7]. The reagents were controlled using specimen from 10 normal individuals.

Results

The mean pH was 7.25 ± 0.15 with the least pH reading being 6.82 and the highest pH value was 7.42. The swirling index was positive in 36 (72%) of the platelet concentrate intermediate in 8 (16%) and negative in 6 platelet concentrates. The mean volume of the platelet concentrate was 18.52 mls with the minimum being 10 and maximum volume was 30mls.

The platelet count $<55 \times 10^9 / L$ was present in 68% of the concentrates while 32% had a platelet count $> 55 \times 10^9 / L$. Twenty three (48.9%) of the units of platelets concentrate had white blood cell count less than $12 \times 10^8 / L$ while, 27(51%) had WBC $>12 \times 10^8 / L$. Red cell contamination was absent in 15 (30%) of the units of the platelet concentrate with 20 (40%) having red cell count between $1 - 12 \times 10^9 / L$. The remaining 15 (30%) had red cell count $>12 \times 10^8 / L$.

Discussion

Blood transfusion practice has been made easy with the introduction of blood fractionation technology. The production of blood components through this technological advances has the added benefit of using a limited natural resource more effectively by providing a needed therapeutic material to several patients from a single donation [8].

Platelet concentrate which is one of the major blood components used in thrombocytopenic patients has been prepared in UCH Ibadan, for the past 3 decades. An average of 150 units of random donor platelets are prepared per year. This value does not reflect the demand of the hospital as the request being made by the clinician exceeds the production.

Patients who benefit from this product are mainly those on cytotoxic chemotherapy, irradiation, those with dilutional thrombocytopenia and disseminated intravascular coagulation. The current improvement in patient care with the use of more aggressive chemotherapy has made a demand on the use of good quality platelet concentrate in order to get the best result in our patients management.

The mean platelet count of $41 \times 10^9 / L$ seen in the platelet concentrate (PC) prepared in the blood bank does not meet the FDA regulation and AABB standard. With 32% of the PC meeting the required $55 \times 10^9 / L$ necessary to raise platelet count by $5,000 - 10,000 / mm^3$, there is a need to review the operational procedure for maximum therapeutic value. The procedure required for review include centrifugation conditions, quality control of machine and quality control of plasma volume in platelet rich plasma (PRP) [3]. The averagely lower platelet count in the negroes compared to their Caucasian counterpart might play a role in the lower mean platelet count recorded in the platelet concentrate [9]. Nevertheless too short a centrifugation time for the g force might not allow adequate separation of PRP from other cells while too long centrifugation sediments the platelet into the buffy coat [3] There is a need to monitor the rotation per minute of each machine with a tachometer and also check the dial time with a stop watch.

A positive swirling phenomenon seen in 72% of the platelet concentrate is rather impressive keeping in-view the mean platelet count. The evaluation of this phenomenon is a useful and inexpensive test for quality control [6]. The mean pH of 7.25 with a range of 6.0-7.4 is within the acceptable limit of FDA regulation [10]. This translates into a good platelet

survival on storage and good post-transfusion recovery. The clause to this good survival on storage is the platelet concentrate volume of 10 - 30 ml. The volume of the PC is adequate for PC to be transfused immediately after preparation but detrimental to storage (considering the low mean platelet concentrate volume) [5]. Notwithstanding, the plasma volume required is determined by the storage time. The buffer in plasma should be in sufficient quantity to prevent a fall in pH resulting from the metabolic activity of the platelets. It is therefore advisable to transfuse these platelet concentrate to patients as soon as it is prepared. The advantage of this early transfusion is that freshly prepared platelet concentrate will have large platelet with large volume and are therefore haemostatically active [11].

White blood cell count $> 1.2 \times 10^9 / L$ seen in 51% of platelet concentrates suggests a need to pay attention to the leucocyte contamination of the PC. The high leucocyte contamination is implicated in febrile transfusion reaction, in alloimmunization phenomenon/platelet refractoriness and immunosuppression, also in transmission of viral infections [12,13]. It may also cause impaired platelet viability / function on storage which will further reduce the already low mean platelet count of the concentrate.

The high red cell contamination will also increase the rate of alloimmunization with immune haemolysis and rhesus (D) sensitization [14,15]. Therefore strict adherence to ABO and Rhesus (D) blood group compatibility should be advocated for the patients using this concentrate.

The result of this study suggest that there is a need for a well designed quality assessment program to ensure compliance with regulatory and accreditation requirement. This will afford an opportunity to monitor the clinical services been rendered, reduce the risks of litigation and improve patients care.

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