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Original article

National French observatory of the quality of blood components for transfusion

Observatoire national de la qualité des PSL préparés par l'EFS

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For the EFS group of blood component QC laboratory managers[1]

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Abstract

Purpose. – Since 1998, prestorage leucoreduction of cellular blood components (BC) is mandatory in France. The French Blood Service needs to follow the data on the quality of the BC prepared by blood centers. This article gives an overview of the quality control (QC) data from 2001 to 2006.
Material and methods. – QC data are submitted to a central data bank by each centre. The data are stratified according to preparation process for analysis of key performance criteria – residual leukocytes and haemoglobin or platelet content. BC preparation processes, methods for measuring haemoglobin and platelet content, and for counting residual leukocytes are those routinely employed by centers.
Results. – The preparation process of red cell concentrates (RCC) influences the haemoglobin content: 57.6 ± 6.8 g per unit versus 50.9 ± 5.4 g per unit for whole blood or RCC filtration, respectively. Apheresis RCC exhibits a reduced variability (51.2 ± 3.4 g per unit). For apheresis platelet concentrates, the median residual leukocyte count remains low for all separators ($0.019–0.044 \times 10^6$ leukocytes per unit, in 2006). However, the percentage of units exceeding 1×10^6 leukocytes per unit is significantly higher with one separator (1.8% versus 0.8%, in 2006). For pooled buffy-coat derived platelets, we observed a significant increase in platelet recovery throughout the years ($0.66–0.77 \times 10^{11}$ platelets per buffy-coat in 2001 and 2006, respectively).
Conclusion. – Our QC data show an overall compliance with the requirements for cellular BC. Our data bank is useful to inform on the performance of leucoreduced BC preparation processes carried out with market available devices.

Résumé

But de l'étude. – La déleucocytation systématique des produits sanguins labiles (PSL) cellulaires est obligatoire en France. L'Établissement français du sang doit suivre la qualité des PSL préparés dans les centres régionaux. Les données de contrôle qualité (CQ) de 2001 à 2006 sont analysées.
Méthodes. – Chaque centre envoie les données de CQ à une base de données nationale (BDN). L'analyse des paramètres clé – contenu en hémoglobine ou plaquettes, contamination leucocytaire résiduelle – est faite en fonction des techniques de préparation. Les techniques de préparation, les méthodes utilisées pour mesurer l'hémoglobine et le contenu plaquettaire, et pour compter les leucocytes résiduels sont celles utilisées en routine.
Résultats. – Les techniques de préparation des concentrés érythrocytaires (CGRD) influencent le contenu en hémoglobine : $57,6 \pm 6,8$ et $50,9 \pm 5,4$ g par unité en 2006 pour la filtration du sang total et du CGR, respectivement. L'érythraphérèse permet de réduire la variabilité ($51,2 \pm 3,4$ g par unité). Pour les concentrés plaquettaires d'aphérèse, la médiane des leucocytes résiduels reste basse pour tous les séparateurs

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(0,019 à 0,044 $\times$ 10^6 leucocytes par unité, en 2006). Le pourcentage d'unités non conformes est plus élevé avec un séparateur (1,8 % versus 0,8 %, en 2006). Pour les mélanges de concentrés de plaquettes, une amélioration de la récupération est observée : 0,66 plaquettes par couche-leuco-plaquettaire versus 0,77 $\times$ 10^{11} plaquettes par couche-leuco-plaquettaire en 2001 et 2006, respectivement.
Conclusion. – Les données de CQ montrent que les productions de PSL respectent les exigences réglementaires. La BDN est un outil de comparaison des techniques disponibles pour la préparation des PSL.

Keywords: Blood components; Quality control; Haemoglobin content; Platelet content; Residual leukocytes; Leucoreduction; Platelet additive solutions

Mots clés : Produits sanguins labiles ; Contrôle qualité ; Contenu en hémoglobine ; Contenu en plaquettes ; Leucocytes résiduels ; Déleucocytation ; Solutions de conservation pour les plaquettes

1. Introduction

Since April 1998, prestorage leucoreduction of all cellular blood components has been made mandatory in France to maximise the safety and quality of our blood supply.

In France, the standard for leukocyte (WBC) reduction of cellular blood components has been set at less than 1×10^6 WBC per unit with a 95% confidence that 97% of units will meet this standard [1–3].

Following centralization of the French regional transfusion services and creation of a unique French operator for blood transfusion in 2000, the Établissement français du sang (EFS), it was found necessary to have a national follow up of the quality of the blood components prepared by EFS.

A computerized data bank was built to collect regularly, from each blood centre, all the data obtained in the frame of their quality control (QC) testing programs. This system is fully working since 2001.

We present below, follow-up data on haemoglobin and platelet content and on leucoreduction performance for cellular blood components prepared in routine practice over year 2001 to 2006. In addition, we analyse the influence of preparation processes on the 2006 results.

Preliminary accounts of this work have been presented previously [4].

An extensive analysis of red cell concentrate (RCC) data from 2001 to 2005 having been recently published [5], the present article will essentially focused on QC data obtained for platelet concentrates, i.e., leucoreduced single donor apheresis platelet concentrates (SDP) and leucoreduced pooled platelet concentrates (PPC).

2. Study design and methods

2.1. Processes of blood component preparation and prestorage leucoreduction

Blood and blood components were collected and processed according to the French Good Blood Transfusion Practices. The processes for blood component preparation were those routinely employed by the French blood centres. More than two millions whole blood and 160,000 apheresis platelet concentrates were collected each year by the French blood centres. For PPC, the French production increased from about 25,000 (2001–2004) to 34,300 (in 2005) and 42,600 (in 2006) PPC per year.

The disposable filtration sets used for collecting whole blood included citrate-phosphate-dextrose (CPD) as the anticoagulant solution (63 ml for a blood volume of 450 ml $\pm$ 10%) and SAG-M as the RCC additive solution (100 ml). SDP were collected with acid-citrate-dextrose (ACD) as the anticoagulant solution.

2.2. Preparation of red cell concentrates (RCC)

Two processes were mainly used to prepare leucoreduced RCC, either whole blood filtration (concerning about 80% of the RCC national production) or RCC filtration with in-line RCC filters. The RCC filtration process allowed the preparation of buffy coat derived PPC. Whole blood filtration was carried out at room temperature. RCC filtration was performed at room temperature or at 4 °C after overnight refrigeration of the RCC units. Some blood centres filtered a small amount of RCC after sterile connection of a filter, however this practice was progressively abandoned contributing to 12% of the data in 2001, 1.7% in 2004 and 0% in 2006.

In 2005, blood centres started to collect RCC with two automated apheresis separators, the Trima (Gambro) and MCS+ (Haemonetics) cell separators.

2.3. Preparation of single donor platelets (SDP)

Five different apheresis cell separators were used in France to collect leucoreduced SDP: MCS+ and MCS3P (Haemonetics, Braintree, MA, USA), Amicus (Baxter, Deerfield, IL, USA), Trima and Spectra (Gambro BCT, Lakewood, CO, USA). Leucoreduction of SDP was achieved by filtration with integrated filters (MCS+ and MCS3P), or directly in process with the three other cell separators.

2.4. Preparation of pooled platelet concentrates (PPC)

All PPC were obtained by the buffy coat preparation method. Usually four to six buffy coats were pooled to prepare one PPC. For leucoreduction, filtration was performed with Sepacell PLX5 (Asahi Medical, Tokyo, Japan), or LRP or ATSBC filters (Pall, Glen Cove, NY, USA).