

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 managers¹

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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 ($0.019\text{--}0.044 \times 10^6$ 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 ($0.66\text{--}0.77 \times 10^{11}$ 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.

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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'érythraphère 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.

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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 $450 \text{ ml} \pm 10\%$) 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 ATSCB filters (Pall, Glen Cove, NY, USA).

2.5. Platelet additive solutions (PAS)

Two platelet additive solutions were used by some French blood centres to suspend platelet concentrates with a final volume of residual plasma ranging from 30 to 44%. The composition is identical for these two solutions, which are known as PAS-II [6]. Their commercial names are T-Sol (Baxter, Maurepas, France) and SSP (MacoPharma, Tourcoing, France).

2.6. Data collection

A national computerized Data Collection System was implemented in 2001, in order to collate the quality control (QC) results obtained in the French blood centres. An intranet application has been designed to collect and to integrate the regional data from each blood centre into a unique Oracle database. A process code attributed to each sample allows an analysis according to the preparation process, namely filter or apheresis separator, temperature of filtration and prefiltration storage time. Current QC programs are based on statistical control sampling according to ISO Standards (ISO 2859-1) and correspond, in 2006, to an average of around 1% of all produced RCC units, between 7 and 16% of all SDP units depending on the type of cell separator, between 5 and 10% of all PPC units depending on the year.

2.7. Laboratory analyses

Haemoglobin content and platelet count were determined by using standard haematology automat analysers. Residual leukocyte counting was performed by flow cytometry, according to the validated method used routinely in each blood centre. The flow cytometric counting methods were from BD Biosciences (Facsalibur and Facsan flow cytometers) and Beckman Coulter (Epics XL flowcytometer). According to French regulation, WBC counting was performed within 24 hours after leucoreduction. Since 2004, each year, an interlaboratory comparison assay involving the 21 flow cytometers employed for counting residual WBC is carried out to evaluate the performance of each French blood centre. The recently reported results [7] show a satisfying reproducibility of the results reflected by an interlaboratory coefficient of variation varying between 13.2 and 16.2% for RCC samples with 4.6 and 2.1 WBC/ μ l respectively, and 10.8 and 11.6% for SDP samples with 4.1 and 1.9 WBC/ μ l, respectively.

Measurements of pH were performed at 22 °C by using standard pHmeters or blood gas analysers.

2.8. Statistics

Haemoglobin and platelet content data are expressed as mean \pm S.D. Leucoreduction data are expressed as the median residual WBC count and the percentage of nonconforming (NC) units. The coefficient of variation (CV = S.D./mean) was also used as an indicator of component uniformity.

Another parameter, “*P*-upper”, is used to assess the performance of the leucoreduction process. “*P*-upper” is the upper limit of the 95% confidence interval of the nonconformance rate. It is calculated from the observed nonconformance rate using the nonparametric approach described by Dumont et al. [8]. The calculated value of “*P*-upper” allows us to state that there is a 95% probability that the percentage of nonconforming units in the whole production is less than “*P*-upper”.

The Wilcoxon test (two groups) was used for comparing quantitative variables. The χ^2 test was used to compare proportions. A *p* value less than 0.05 indicated statistical significance.

3. Results

3.1. Results for leucoreduced red cell concentrates

For 2006, Table 1 shows the haemoglobin content depending on the preparation process. The mean haemoglobin content was always higher than 50 g per unit. However, the distribution of haemoglobin values remained large, with an overall coefficient of variation of 13%. For apheresis RCC, the variability was decreased with a mean coefficient of variation of 6.6%, confirming the first results obtained in 2005 [6]. Overall, less than 1% of the tested RCC units had an haemoglobin content less than 40 g.

3.2. Results for leucoreduced single donor platelet concentrates (SDP)

As shown in Fig. 1, for one given apheresis separator, the mean platelet content of SDP remained quite constant throughout the years. In 2006, the mean platelet count ($\times 10^{11}$ platelets per SDP) were 5.8 \rightarrow Spectra, 5.5 \rightarrow Trima, Trima, 5.4 \rightarrow Amicus, 4.4 \rightarrow MCS3P and 4.3 \rightarrow MCS+.

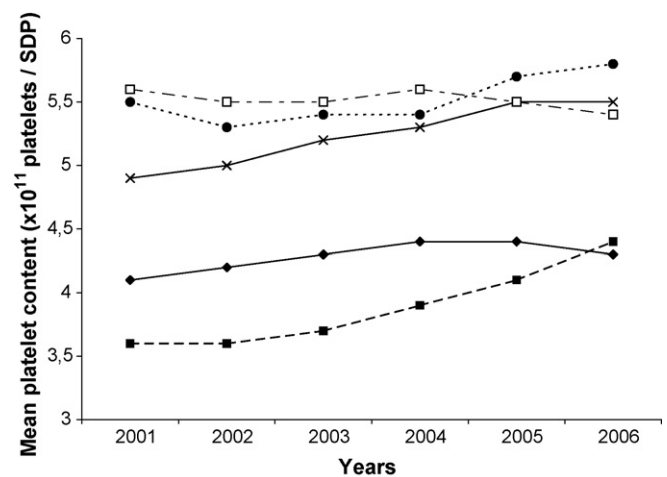


Fig. 1. Mean platelet content of leucoreduced SDP according to the separator (2001 to 2006): —■— MCS3P, —◆— MCS+, —×— Trima,●.... Spectra, ---□--- Amicus.

Table 1
RCC haemoglobin content according to the preparation process (2006)

Process	Whole blood filtration	RCC filtration	Apheresis	Overall
Number of tested units	9348	4957	1086	15391
Haemoglobin/RCC (mean \pm S.D.) (g/unit)	57.6 \pm 6.8	50.8 \pm 5.8	51.2 \pm 3.4	55.0 \pm 7.1
Coefficient of variation (%)	11.8	11.2	6.6	12.9
Number of NC units (< 40 g/unit)	24	98	0	122
% of NC units	0.3	2.0	0	0.8

NC: nonconforming.

Table 2
Residual WBC content and percent of nonconforming SDP (2001–2006)

Year	2001	2002	2003	2004	2005	2006
Number of tested SDP	16727	20111	19584	18257	16238	15581
Median WBC residual count ($\times 10^6$ WBC/SDP)	0.042	0.040	0.046	0.042	0.039	0.031
Number of NC SDP	219	332	291	187	174	159
% of NC SDP	1.3	1.7	1.5	1.0	1.1	1.0
<i>P</i> -upper (%)	1.5	1.8	1.6	1.2	1.2	1.2

NC: nonconforming.

Table 3
Residual WBC content and percent of NC SDP according to the separator (2006)

Separator	MCS+	MCS3P	Spectra	Trima	Amicus
Number of tested SDP	4792	501	1376	5627	3285
Median WBC residual count ($\times 10^6$ WBC/SDP)	0.019	0.037	0.039	0.044	0.029
Number of NC SDP	38	5	10	48	58
% of NC SDP	0.8	1.0	0.7	0.9	1.8
<i>P</i> -upper (%)	1.0	2.1	1.2	1.1	2.2

NC: nonconforming.

Table 2 summarizes the leucoreduction data from 2001 to 2006. The overall estimated frequencies of nonconforming units (*P*-upper) for leucoreduced SDP were less than 3%, confirming that the productions of leucoreduced SDP meet the French standard for leucoreduction.

Table 3 compares, for 2006, the leucoreduction performances of each type of apheresis separator. While the median residual WBC count remained satisfying ($< 0.045 \times 10^6$ WBC/SDP), the frequency of nonconforming units were significantly different between separators. The percentage of units exceeding 1×10^6 leukocytes per unit was significantly higher with

Amicus than with the other separators (1.8% versus 0.8%, $p < 0.0001$ in 2006).

Since 2004, some blood centres started to introduce platelet additive solutions for SDP preparation.

Table 4 gives an analysis of the influence of additive solution on the pH of SDP. At Day 5, a significant lower pH was found for SDP suspended in additive solution than for SDP suspended in plasma (6.9 ± 0.3 versus 7.2 ± 0.3 ; $p < 0.0001$). Accordingly, the frequency of pH less than 6.4 was significantly higher with SDP in additive solution than with SDP in plasma (5.2% versus 1.1%; $p < 0.0001$).

3.3. Results for leucoreduced pooled platelet concentrates (PPC)

The Table 5 gives the results for the platelet content of PPC from 2001 to 2006. With time, the mean platelet content per PPC remained relatively constant varying from 3.6 to 3.9×10^{11} platelets per PPC. Platelet concentration did not change. Most interesting is the observation of a continuous increase in the mean platelet content by buffy coat. The temporary decrease in 2004 coincided with the introduction of additive solutions for platelets and the necessity to adjust the preparation process to this new suspension medium. The significant increase in 2006 is partly linked to the introduction

Table 4
pH of SDP at day five depending on the suspending medium (January 2006–April 2007)

	SDP in plasma	SDP in additive solution
Number of tested SDP	814	344
pH at Day 5 (mean \pm S.D.)	7.2 \pm 0.3	6.9 \pm 0.3 ^a
Number of NC units (pH < 6.4)	9	18
% of NC units (pH < 6.4)	1.1	5.2 ^a

NC: nonconforming.

^a Significantly different from SDP in plasma ($p < 0.0001$).

Table 5
PPC and buffy coat mean platelet content (2001–2006)

Year	2001	2002	2003	2004	2005	2006
Number of tested PPC	1918	2239	2940	2171	2076	2093
Platelet content (mean \pm S.D.) ($\times 10^{11}$ platelets/PPC)	3.7 \pm 1.0	3.6 \pm 0.8	3.7 \pm 0.8	3.7 \pm 0.8	3.9 \pm 0.7	3.9 \pm 0.7
Platelet concentration (mean \pm S.D.) ($\times 10^9$ platelets/ml)	1.3 \pm 0.3	1.4 \pm 0.3	1.4 \pm 0.3	1.3 \pm 0.3	1.3 \pm 0.2	1.3 \pm 0.3
Platelet content/buffy coat (mean \pm S.D.) ($\times 10^{11}$ platelets/buffy coat)	0.66 \pm 0.18	0.71 \pm 0.13	0.71 \pm 0.14	0.68 \pm 0.13	0.71 \pm 0.13	0.77 \pm 0.16

Table 6
Residual WBC content and percent of nonconforming PPC (2001–2006)

Year	2001	2002	2003	2004	2005	2006
Number of tested PPC	1918	2239	2940	2171	2076	2093
Median WBC residual count ($\times 10^6$ WBC/unit)	0.061	0.038	0.033	0.023	0.026	0.018
Number of NC units	41	21	21	9	25	29
% of NC units	2.1	0.9	0.7	0.4	1.2	1.4
<i>P</i> -upper (%)	2.8	1.4	1.0	0.7	1.7	1.9

NC: nonconforming.

Table 7
pH of PPC at day five depending on suspending medium (January 2006–April 2007)

	PPC in plasma	PPC in additive solution
Number of tested PPC	305	418
pH at Day 5 (mean \pm S.D.)	7.2 \pm 0.2	7.0 \pm 0.2 ^a
Number of NC units (pH < 6.4)	7	4
% of NC units (pH < 6.4)	2.3	1.0

NC: nonconforming.

^a Significantly different from PPC in plasma ($p < 0.0001$).

of the semiautomatic Orbisac technique (Gambro BCT, Lakewood, CO, USA) in three French blood centres [9].

For year 2001 to 2006, Table 6 summarizes the national results for leucoreduction. The median residual WBC count decreased through the years reaching 0.018×10^6 WBC/PPC in 2006. The estimated “*P*-upper” values varied from 2.8 to 0.7%, indicating that the overall national production of PPC complied with the requirement of at least 97% units meeting the standard.

Since 2004, some blood centres started to introduce platelet additive solutions in PPC preparation.

The Table 7 gives an analysis of the influence of additive solution on the pH of PPC. At day five, a significant lower pH was found for PPC suspended in additive solution than for PPC suspended in plasma (7.0 ± 0.2 versus 7.2 ± 0.2 ; $p < 0.0001$). The frequency of pH less than 6.4 was not significantly different with PPC in additive solution than with PPC in plasma.

4. Discussion

Our automated quality control Data Collection System offers the possibility to analyse a great amount of data. It helps

EFS management to keep abreast of the quality of the blood components, which are produced. Since a variety of preparation methods are currently available for the preparation of leucoreduced blood components, it can also be used to compare the performances of these different preparation processes.

The results presented in this paper show that the routine preparation processes employed by blood centres enable the overall productions of leucoreduced blood components to meet the French standard for leucoreduction [3]. However, differences between the processes can still be observed in the rate of leucoreduction failures as expressed by the percentage of blood components failing to respect the threshold of 1×10^6 WBC per unit. This reality and the continuous emergence of new technologies for blood component collection or preparation make necessary a regular monitoring of the leucoreduction processes. Relying on an accumulation of QC data, manufacturers have made significant progress to improve the reliability of whole blood and RCC filters since our first report on the quality of leucoreduced blood components in 1999 [10]. This advancement has allowed blood services to select filtration devices with the best technical characteristics and to warrant an adequate leucoreduction level for RCC. For platelet concentrates, care should still be taken to ascertain that no deviation would appear. Recently, our national quality monitoring allowed us to advice the removal of the LRP6 filter for filtration of PPC, following the observation of a high percentage of PPC units exceeding the 1×10^6 WBC per unit cut-off.

The standard for haemoglobin content (≥ 40 g per unit [3]) is reached for around 99% of units. However, the present data indicates that the haemoglobin content in the final RCC units may vary widely (from 29 to 82 g, in 2006), confirming the results detailed in our previous report [5]. Moreover, RCC preparation processes have an influence on haemoglobin content as shown in Table 1. Högman recommended to standardize the haemoglobin content of RCC units, mainly to

help transfusing physicians who are generally unaware of this haemoglobin content variation [11]. Although the French experience with routine apheresis leucoreduced RCC is recent, our data show that the automated apheresis techniques might result in a more standardized final component, since the 1086 leucoreduced apheresis RCC tested in 2006 had a mean haemoglobin content of 51.2 ± 3.4 g corresponding to a CV of 6.6%.

For SDP, the minimum permissible platelet content in France is 2×10^{11} platelets per SDP [3]. This level was reached for more than 99% of SDP, with only 0.3% of nonconforming SDP in 2005 and 2006 (data not shown).

For PPC, the mean platelet content and concentration remain constant throughout the years (Table 5). The most salient result is the constant increase in the mean platelet content by buffy coat, which reflects the sustained improvement in platelet recovery achieved by the French blood centres in their process of preparation of PPC with buffy coats.

Since 2004, blood centres started to use platelet additive solutions. The use of PAS has several advantages, mainly to decrease adverse reactions related to plasma and to provide more plasma for fractionation. There is already evidence that the incidence of allergic reactions is reduced [6,12]. However, the partial substitution of plasma by PAS II is accompanied by a slight, but significant, fall of pH during storage as shown in the present data. This prompts us to ask French regulators to facilitate the use in France of new available platelet storage solutions, which allow a better preservation of platelet during storage [13–16].

During the 2001–2006 period, the QC data management presented in this paper has been invaluable in providing useful information on the performance of different techniques for blood component processing with market available collection and preparation devices. This information was used to analyse supplier claims in the framework of our invitation to tender for collection disposable sets integrating leucoreduction filters. Since 2006, the national QC data management was strengthened to analyse the data on a monthly basis and to issue regularly a summary of the QC results over a mobile 13-month period. This should help in improving our ability to detect rapidly any quality deviation and in optimizing the organization of corrective measures with our suppliers.

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