



The Evaluation of Leukocyte-Depleted Pool Platelet Concentrates (LDPPC) Quality: Prepared from 3 Interim Platelet Units

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ABSTRACT

Background and Objective: The leukocyte-depleted pool platelet concentrates (LDPPC) were prepared by combining four units in the same ABO blood group of interim platelet unit (IPU) and adding the platelet additive solution (PAS) 280 ml, then filtered out of white blood cells by a pooling set of Reveos[®] System. To obtain the platelet yields (PY) more than 240×10^9 cells per unit, the total platelet yields index (PYI) of 4 IPU were counted to get 270×10^9 cells or more by using the loss of platelets value during the filtering process (approximate to 30×10^9 cells), plus the standard value (240×10^9 cells) to create the LDPPC that reached the international standards. Nowadays, the LDPPC that produced by this technique passed the benchmark 100%. From daily work, it was found that sometimes just 3 IPU can give a PYI value $\geq 270 \times 10^9$ cells. The research team intended to study whether combining just 3 IPU according to the study criteria would be able to produce LDPPC that reached the international standards or not.

Methods: To produce the LDPPC (n= 30), the collected blood bags were centrifuged by the automatic machine. The bag number, volume, and PYI value of the IPU estimated by the automatic machine were recorded in the recording form. The 3 IPU with the same ABO blood group and combined PYI value of $\geq 270 \times 10^9$ cells were pooled and added 280 ml of PAS, then filtered to remove white blood cells to obtain LDPPC. The LDPPC was gently shaken with a shaker for 15 minutes, then it was sampling 0.5 ml for testing the complete blood count (CBC) by counting with the Sysmex Hematology Analyzer model XN-550 and the contaminated white blood cells were counted by the ADAM-rWBC machine. The results were analyzed and compared them with the international standards.

Results: The results showed that the average volume of LDPPC was 344.20 ml, white blood cell contamination was 0.19×10^6 cells per unit and platelet yields were 235.76×10^9 cells per unit.

Conclusion: The LDPPC productions by new method reached the recommended quality of Council of Europe (EU) 96.67% (29/30) and reached the American Association of Blood Banks (AABB) 43.33% (13/30).

Keywords: leukocyte-depleted pool platelet concentrates (LDPPC), interim platelet unit (IPU), platelet additive solution (PAS), platelet yields index (PYI)

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Introduction

Srinagarind Hospital and Queen Sirikit Heart Center in the Northeastern region being a large hospital, a medical school for producing graduate doctors, and a hospital that's focuses on research and education, while also emphasizing patient safety for specific groups of complex diseases such as patients with heart and vascular diseases, hematologic cancers, bone marrow transplant groups, and radiation therapy groups. These patients have experienced thrombocytopenia. The factors leading to such conditions may result from significant blood loss, decreased platelet production, or increased platelet destruction due to the pathology of the disease itself or from treatments such as surgeries, immunosuppressive medications, chemotherapy, and radiation therapy¹, etc.

Blood Transfusion Centre, Faculty of Medicine Khon Kaen University, which is an agency that supports such medical treatments, has a policy to enhance the safety of all types of blood components, including platelet concentrates. The standards for preparing the leuko-depleted pool platelet concentrates (LDPPC), established by multiple institutions at both national and international levels. The required qualifications are a concentration of platelets greater than or equal to 2.4×10^{11} and a concentration of white blood cells less than 5×10^6 cells per unit (American Association of Blood Banks; AABB standard)² and a concentration of platelets greater than or equal to 2.0×10^{11} and a concentration of white blood cells less than 1×10^6 cells per unit (Council of Europe; EU standard)³

Platelet concentrate used in Srinagarind Hospital and Queen Sirikit Heart Center of the Northeast, is produced by the Blood Transfusion Centre, Faculty of Medicine, Khon Kaen University. Whole blood from the donors is processed by the Fully Automated Blood

Separation: Reveos[®] System; Terumo BCT^{4,5}. The most special thing is that the system of the machine can evaluate the number of platelets that are separated as a value of platelet yields index (PYI). The LDPPC was prepared by combining four units in the same ABO blood group of interim platelet unit (IPU) and adding the platelet additive solution (PAS) 280 ml, then filtered out of white blood cells by a pooling set of Reveos[®] System. If we want the platelet yields more than 240×10^9 cells per unit, we must count the total PYI of 4 IPU to 270×10^9 cells or more by using the loss of platelets value during the filtering process (2.6×10^{10} cells approximate to 30×10^9 cells), plus the standard value we need to create the LDPPC that reached the recommended quality. Nowadays, the LDPPC that we can produce by this technique passed the benchmark 100%⁶.

From daily work, it was found that sometimes just 3 IPU can give a PYI value $\geq 270 \times 10^9$ cells. The research team intended to study whether combining just 3 IPU according to the study criteria would be able to produce LDPPC that have a platelet yields according to the international standard criteria or not. If it can be done, it will result in at least two benefits: the first is reducing donor exposure, which has a positive effect of reducing the rate of alloimmunization in patients; and the second is saving IPU used to produce LDPPC. In addition, the results of this study will serve as a reference and a model for those who will implement this method in the future.

Methods

To produce the LDPPC (N= 30), the collected blood bags were centrifuged by the automatic machine (Figure 1). The bag number, volume, and PYI value of the IPU estimated by the automatic machine (Figure 2) were recorded in the recording form. The 3 IPU with the same ABO blood group and combined PYI value of

$\geq 270 \times 10^9$ cells were pooled and added 280 ml of PAS, then filtered to remove white blood cells to obtain LDPPC (Figure 3). The LDPPC was gently shaken with a shaker for 15 minutes, then it was sampling 0.5 ml for CBC examination by counting with the Sysmex Hematology Analyzer model XN-550 and the contaminated white blood cells were counted by the ADAM-rWBC machine. The results were analyzed and compared them with the international standards (AABB and EU).

Data analysis

This is a descriptive study using mean and standard deviation statistics, analyzed with Excel 2007. Percentages are compared against the target values of platelet yields and white blood cell contamination from AABB and EU standards.

Results

In this study, LDPPC was prepared from 3 IPUs, totaling 30 sets. It was found that the average of platelet count was 235.76×10^9 cells per unit (the total average PYI before filtration was 281.77×10^9 cells per unit), the contaminated white blood cell count was 0.19×10^6 cells per unit, and the average volume was 344.20 ml (Table 1).

When the results were compared with the EU standard (platelet yields; $PY \geq 200 \times 10^9$ cells per unit), it was found that platelet values met the criteria in 29 out of 30 cases, accounting for 96.67%. When compared to the AABB standard (platelet yields; $PY \geq 240 \times 10^9$ cells per unit), 13 out of 30 cases met the criteria, accounting for 43.33%. For contaminated white blood cell values, 100% met the EU and AABB standards (Table 2).



Figure 1 Blood separation by using an automatic machine.

Table 1 Display the measurement results for the volume, total PYI values before filtration, the platelet count obtained after filtration, and the contaminated white blood cells in LDPPC prepared from 3 IPU's (passing AAB = **blue label**)

No.	Volume	Total PYI values from 3 IPU's *10 ⁹ cells per unit	Platelet yields *10 ⁹ cells per unit	WBC contamination *10 ⁶ cells per unit
1	342.70	295.00	257.70	0.11
2	334.20	278.00	229.90	0.11
3	330.00	271.00	209.88	0.34
4	344.00	282.00	268.32	0.11
5	340.00	284.00	278.80	0.00
6	357.70	284.00	310.48	0.24
7	357.20	288.00	268.61	0.13
8	343.90	275.00	217.34	0.23
9	346.30	289.00	217.48	0.11
10	355.70	274.00	250.41	0.87
11	339.80	285.00	209.32	0.48
12	347.20	274.00	229.15	0.11
13	349.70	280.00	250.39	0.24
14	335.10	271.00	194.36	0.00
15	326.00	278.00	220.38	0.23
16	349.00	277.00	219.17	0.24
17	346.00	275.00	244.97	0.24
18	331.00	284.00	307.17	0.23
19	346.00	268.00	243.58	0.11
20	348.00	257.00	293.71	0.36
21	353.30	272.00	202.09	0.11
22	337.60	278.00	205.26	0.11
23	351.00	281.00	200.77	0.37
24	337.90	302.00	212.20	0.11
25	326.00	281.00	206.03	0.00
26	338.00	302.00	259.58	0.00
27	342.70	304.00	250.86	0.00
28	357.00	289.00	214.2	0.11
29	355.00	296.00	200.22	0.50
30	358.00	279.00	200.48	0.00
mean	344.20	281.77	235.76	0.19
SD	10.11	4.24	30.76	0.00

Table 2 The results were compared with the EU and the AABB standards.

The Standard	Platelet yields per unit	WBC contamination per unit
EU	$\geq 200 \times 10^9$	$\leq 1 \times 10^6$
*Number of cases that passed the standard criteria	29/30	30/30
*Percentages	96.67	100
AABB	$\geq 240 \times 10^9$	$\leq 5 \times 10^6$
*Number of cases that passed the standard criteria	13/30	30/30
*Percentages	43.33	100

A = volume of IPU 35 ml
 PYI 65×10^9 cells
 B = volume of plasma 249 ml
 C = volume of buffy coat 11 ml

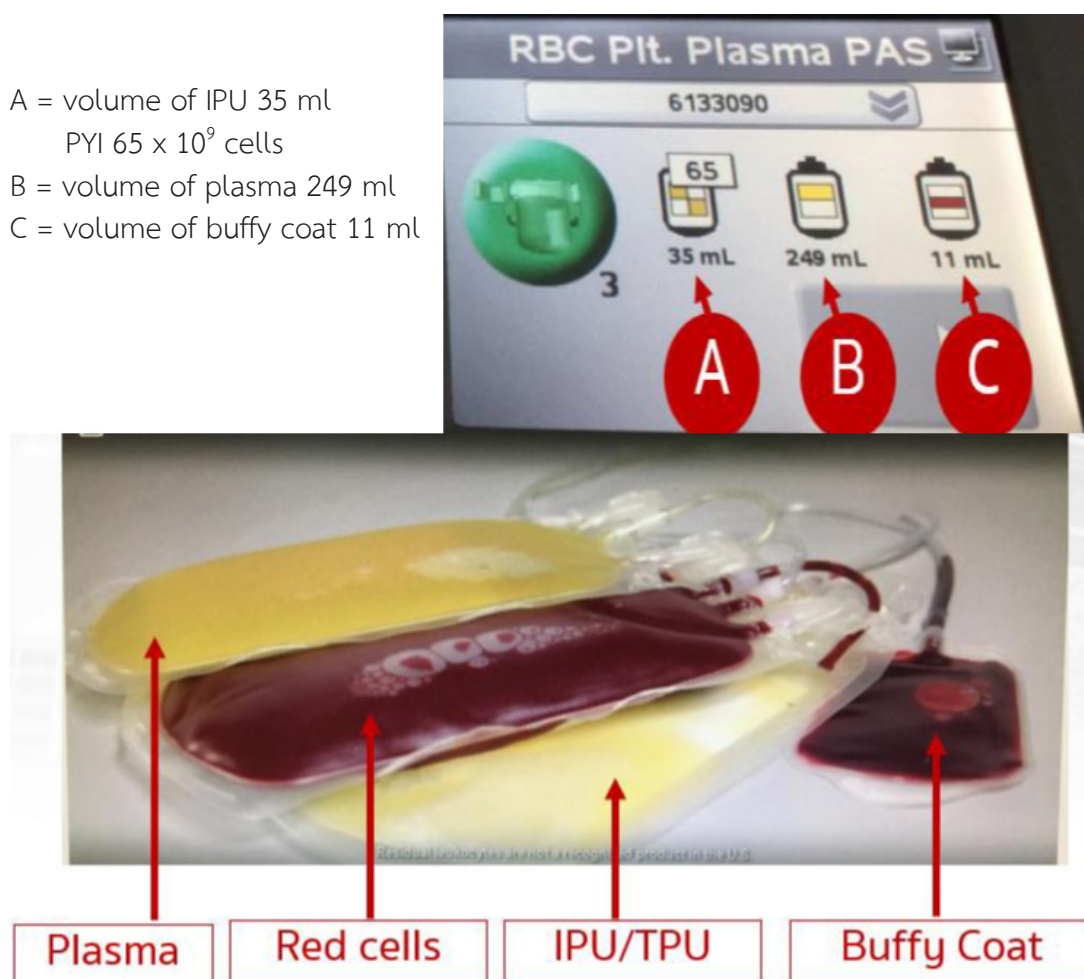
**Figure 2** Display the components of the blood obtained from the automatic centrifuge and show the values obtained on the machine screen.



Figure 3 Shows the process to prepare LDPPC from 3 IPU.

Discussion

From the results of the experiments, if we adhere to the AABB standard (platelet yields; $PY \geq 240 \times 10^9$ cells per unit), LDPPC from 3 IPU has an average platelet count of 235.76×10^9 cells per unit. Therefore, it should not be produced for patient use as it does not meet the threshold of 50% of the expected value. However, in the future, if the agency refers to the EU standard ($PY \geq 200 \times 10^9$ cells per unit), the platelet count meets the standard for 29 out of 30 cases, accounting for 96.67%, which is considered very high.

However, based on the actual working, sometimes even if we only have 3 IPU, we may need to produce the LDPPC for use if there is a real shortage, and the patients might need to

use platelets at that time. It depends on the discretion of the physician caring for the patient at that moment on how to decide administering platelets to patients who truly need them, even it's not as much as required, is still better than having nothing at all.

Limitations of the study: Since such research has never been conducted before, the data available for analysis may not be sufficient. However, using any blood products on patients safely and reliably for treatment requires adherence to at least one standard guideline. During times of blood shortages, which may result from disasters, wars, or emerging epidemics, preparing pooled platelets from 3 IPU is another option, that can help ensure we have enough of LDPPC for patients in need. Even if the products do not fully meet the

international standards of both institutions, as long as they meet the standard of one certified institution, the manufacturer can be confident and unhesitant in producing them for the benefit and safety of patients at that time.

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