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Efficacies and Cost Evaluation of Double Dose Plateletpheresis in Additive Solution by Blood Cell Separator Between Continuous and Intermittent Flow System

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ABSTRACT

Introduction: *Blood Collection Unit of Maharat Nokhon Ratchasima Hospital, Thailand, have intention to increase efficiency of Single Donor Platelets (SDP). The SDP donor pre-count found highly for select to be double dose plateletpheresis (DDP). By two principle (intermittent with the Universal Platelet Protocol (UPP) and continuous flow) of platetetpheresis systems in this study.*

Objective: *This study aimed to compare efficacies and cost evaluation of DDP in Platelet Additive Solution (PAS).*

Materials and Methods: *Intermittent flow systems: Hemonetics MCS plus / UPP®, HAEMONETICS Braintree, MA,U.S.A.(I) and continuous flow system: Trima Accel®version 7.0, Terumo BCT, Lakewood, USA(II) were plateletphereis with the same donor (platelet pre count >280,000 cells / μL). Data of pre and post hematological characteristics of donors, completed process, quantity and quality of DDP, satisfaction's questionnaire, including margin cost were record. The data analysis test by T-test.*

Results: *DDP donor (N=30) found no statistically significant in hematological pre and post donated (p>0.05). Post donation found I has hematological characteristics less than II significantly (p<0.05). The duration process found statistically significant (p<0.05). DDP quantity found; I and II can collect platelet yield average $6.2x10^{11}$ and $6.5x10^{11}$ cells, respectively. Residual white blood cells (rWBC) found I less than II (p<0.05). pH and swirling phenomenon were not different (p>0.05). A,B and O blood group were low titer 66.6%, 100% and 91%, respectively. DDP with PAS found 100% low titer. The overall satisfaction rate; II higher than I (p<0.05). Percentage of the adverse reaction found numb lips, pain in phlebotomy site and dizziness; 90%,1.3% and 0.5%, respectively. The economic impacts found II system has positive profit from margin cost (+7,440 to 9,756 THB).*

Discussion and Conclusion: *The DDP donated by II have higher platelet yields than I. DDP in PAS useful for ABO identical platelets and provide without blood group specificity (100% low titer). PAS will increase patient safety by reduce the allergic reaction and febrile non hemolytic transfusion reaction. The percentage of collection efficiency (%CE) >60%, I=71.2%,II=73.6%. The PC prepared from a large amount of WB (>150,000 units in 2017-2019). DDP in PAS should be run in routine to allocate budgets to be worthwhile.*

Keywords

Platelet pheresis, Single donor platelet, Platelet additive solution.

Introduction

Platelets essential for the initial of hemostasis. Apheresis platelets collected from one donor and admire ~4-6 pooled units. Associate in apheresis platelet concentrate contains 200-400 mL of plasma. they will be collected as a random unit or be obtained for a particular recipient from a volunteer blood donor [5,6]. Apheresis platelets can storage for 5 to 7 days and the incubated storage is offered at the hospital. Platelet units should be maintained at temperature and agitated throughout storage.

Indications

1. To stop injury because of blood disorder. the edge of blood disorder at that injury could occur can vary counting on the patient's clinical condition. In general, spontaneous injury doesn't occur till the platelet count below 5,000 – 10,000/μL.
The counseled "trigger" for prophylactic thrombocyte transfusions in patients undergoing therapy or haematogenic somatic cell transplantation is <10,000/μL. different synchronal clinical conditions could increase this threshold.

2. In a very injury patient a platelet count higher than 50,000 ought to be maintained. in a very surgical patient, the required platelet count is varies counting on the procedure. For many surgeries 30,000-50,000/μL are going to be adequate. In high risk procedures, such as neurologic or ophthalmologic surgeries, 100,000/μL is suggested [8].

3. Abnormal platelet function is also inborn, or because of medications, sepsis, malignancy, tissue trauma, obstetric complications, additional corporeal circulation, or organ failure like liver or nephropathy. Spontaneous injury could then occur at higher platelet counts [9].

4. Family donor or HLA matched , indicated for the patients who became refractory to random donor platelet transfusions because of alloimmunization [10].

5. In many transfusions; platelet might not be indicated unless there's important significant . In response thrombocytopenias (e.g. ITP) transfusion increments poor and protoplasm survival is brief. protoplasm transfusions is also contraindicated in patients with thrombotic thrombocytopenic purpura (TTP) unless there's clinically important hurt.

6. In paediatric patients, the standard therapeutic dose is 1 unit of platelet per 10 kilograms of body weight , or 5 mL/kg. A 50,000/μL rise is expected.

Table 1: Therapeutic effect [4].

Expected Platelet Increment			
	1unit 1.0 x 10^{11}	4units 4.0 x 10^{11}	6units 6.0x 0^{11}
50 lb/23 kg	22,000/ μL	88,000/μL	132,000/μL
100 lb/45 kg	11,000	45,000	66,000
150 lb/68 kg	7,400	30,000	44,000
200 lb/91 kg	5,500	22,000	33,000

*In a patient with a normal sized spleen and without platelet antibodies.

The survival of transfused platelets averages 3 to 5 days but will decrease if a consumptive process is present. Correction of a prolonged bleeding time in platelet dysfunction will depend on whether a condition exists that will affect the transfused platelets as well (e.g., anti-platelet agents, uremia) [14].

Single donor platelets (SDP) are platelets prepared from a single donor using plateletpheresis; by using a specific collection kit used with the automatic blood cell separator. In which the product that receives one-unit equivalent to platelet concentrates derived from 6-8 blood donors. The apheresis machine current be able to collect platelets in more than one unit quantity. Such as double dose plateletpheresis (DDP) or triple dose plateletpheresis (TDP) from a single donation among the only donors that passed the selection criteria for plateletpheresis. Therefore, its useful in increasing the amount of reserve platelets in the blood collection, blood components stocking, reducing the risk of transmitted infections and it can also reduce production costs [1-3].

Platelet Additive Solution (PAS) is an electrolyte solution to maintain platelets instead of plasma. PAS used in Europe first trial in 1995 and approved for use in Europe in 2007 and PAS has just been registered in Thailand and has been inspected by the Food and Drug Administration (FDA) in 2015. From this research, it was found that the use of Single Donor Platelet in PAS by plateletpheresis was the development of new technology that increases patient safety and can reduce allergic reaction [7].

It is also found that PAS effective for maintain the platelet medium's pH higher than 6.0, therefore preventing platelet degradation. PAS makes it possible for ABO blood platelet to be misaligned to the patient, thus increasing the options Blood Donation Unit at Maharat Nakhon Ratchasima Hospital trying to increase the number of platelet stocking [11,12].

But sometimes there is still a shortage or insufficiency because the platelets have a short shelf life (5 days) and must be stored at 22-24°C with gentle agitation. The plateletpheresis will increase the safety of both patients and platelet donors and increase the number of reserve platelets in the blood collection. It is also a management to improve the service system of the department. And reduce the budget for the cost of platelet preparation for patients appropriately and efficiently.

Objective

- To assess the effectiveness of the Double Dose Plateletpheresis in Platelet Additive Solution (DDP in PAS) preparation of the different principle between continuous and intermittent flow systems.
- To calculate the cost and compare between both system.

Materials and Methods

This research study Certified Ethics in People (Document no. 129/2019) by conducting a study on 30 platelet donors. There were 2 platelet donations, with both systems having a 21-day period of platelet donation. Research period from 29 November 2019 - 5 February 2020 with the following criteria, procedures and methods.

Inclusion criteria

Target group

Plateletpheresis donors who regularly donate at Blood Collection Unit of Maharat Nakhon Ratchasima Hospital. All of them have been screened by interviewing and using standard questionnaires

according to the blood donor selection criteria of the National Blood Service Center, Thai Red Cross. The qualifications of the plateletpheresis donor must have the same qualifications as the general blood donors and with additional requirements as follows;

- Be a donor who has previously donated platelets between the age of 21 years to 60 years.
- Body weigh more than 60 kilograms.
- No risk or no history according to blood born pathogen or blood infectious.
- No history of medication affecting platelet function, such as aspirin, etc.
- With a platelet count of not less than 280,000 cells / µL
- With veins in the arms, clearly and fairly large.
- Be able to donate 2 times, with the 1st and 2nd times 21 days apart.

Platelet donors who pass the blood donation selection criteria according to the standard of the National Blood Service Center, Thai Red Cross Society will get the invitation and sign in the consent form. And their information identifies clearly.

Criteria for donor rejection from the research

- The positive of an infectious marker infection must refrain from donating blood and platelets. Repeat blood tests and send to the consultation unit.
- The antibody screening positive results.
- High blood lipid levels/ lipemic and abnormal plasma color.
- Body weight over 100 kilograms.
- MCV<75 fL.

Before and after separating platelets from each automatic machine, the blood test will perform the following checks;

- Collect blood samples before donating to test of the infectious markers.
- Complete blood count (CBC) test before and after the donation with the automated hematology analyzer.
- Record all information of whole procedure of the operation of automatic apheresis separator.
- After removing the needles from the donor, the T-PAS + solution are added to the donor platelets.
- Leave DDP in PAS bag in a platelet agitation cabinet at a temperature of 22-24°C for at least 2 hours
- Automated hematology analyzes to CBC in DDP product.
- Check the swirling phenomenon on days 2 and 5.
- Measure pH on days 2 and 5 with the Blood Gas Analyzer
- Determine the amount of residual white blood cell (rWBC) using rWBC analyzer.
- Check the antibody titer of anti-A and Anti-B before and after adding T-PAS+.
- Do the satisfaction questionnaire of platelet donors.
- Gather information on medical supplies, platelet collection kits to calculate the cost per preparation and calculate per standard dose.

Consent to donate platelets using 2 systems, which are
Intermittent flow systems: Hemonetics MCS plus / UPP®, HAEMONETICS
Braintree, MA, U.S.A. Using the principle of extracting whole blood from the donor and spinning to separate the platelet rich plasma (PRP). Then return to other blood components to donor as one cycle. Donors have to collect the platelet rich plasma approximately 9-11 cycles. And the last round (super surge) will spin and store as a Platelet concentrate. And with the principles of the UPP (Universal Platelet Protocol). There is a development to increase procedures to control the amount of blood that is outside the body, not more than 15 percent of the total blood volume in donors. To increasing the safety for donors. In this research study Use the Conc PLT & PLS Set wFilter and UPP.A2 Protocol card to obtain DDP in PAS.

The continuous flow system: Trima Accel®version 7.0, Terumo BCT, Lakewood, USA. Uses the principle of pulling blood into centrifuge. Platelet separation with continuous pulling and returning alternately until the process is completed. There is no separate collection like intermittent flow system.

Data analysis

Platelet yield calculation
Platelet yield (10^{11}) = Platelet product count (x 10^3/µL) x Blood volume process (mL) x Conversation factor (1000)

Collection efficiency (% CE)

$$\text{Collection efficiency (\% CE)} = \frac{\text{Platelet yield x } (10^{11}) \text{ x } 100}{\text{Mean PLT count } (10^9/\text{L}) \text{ x (Blood volume processed -anticoagulant used (mL)}}$$

Statistical analysis

Analyzed by the program Stata version 12 by analyzing the t-test. The data are taken to mean and standard deviation (SD) to compare platelet yield, rWBC, pH, distance. The processing time, the efficiency of the automatic blood cell separator (% CE), of anti-A and anti-B were tested before and after adding T-PAS + to assess whether the use of T-PAS + results in to change The titre of an antibody using a paired t-test p value ≤ 0.05 are considered statistically significant differences.

Limitation

- Because platelet donations are a routine and platelet donors are healthy. The donor is safe by choosing to use donation machine; to have security for donors. Reduce the side effects of donations by donor preparation and prevention before donations and during donations. It is also a donation within the medical concern. Lifesaving equipment used to monitor donors. And there are staff members that are adequately trained in helping platelet donors.
- Blood sampling for infectious markers and CBC uses approximately 30 mL. the donation of platelets in the plasma is about 150-200 mL. All procedures are in accordance with the procedure of donating platelets from SDP.

Results

Total of 30 platelet donors randomized to donate platelets using two systems; continuous and intermittent flow. Donors age between 38 to 47 years old. Donor body weight were 75 ± 12 kilograms,

respectively. Height of donor between 163 to 176 cms (Table 2). And sex were 25 males and 5 females (Table 3).

Table 2: General information of platelet donor's characteristic (N=30).

Characteristics	Mean ± SD
Age (yrs)	42 ± 5
Weight (kgs)	75 ± 12
Height (cm)	169 ± 7

Table 3: Sex of platelet donors.

SEX	N
Male	25
Female	5
Total	30

The comparison of hematologic parameter of platelet donor information of pre-donation and post-donation found; hematological values before and after platelet donation of platelet donations from both systems; platelet count, Hct. Hemoglobin, WBC count, RBC count and MCV found no statistic significant (P<0.05) (Table 4). The hematological value after platelet donations in donors using the intermittent flow method is less than that from continuous flow method after completed plateletapheresis. The statistically significant (p <0.05) in the platelet count, Hct. Hemoglobin, WBC count, RBC count. The platelet post donation by intermittent system decrease from 233.8 ± 24.9 x10^3/ul to 190.6 ± 25.8 x10^3/ul, same as Hct. Hemoglobin, WBC count, RBC count was showed in table 4.

Table 4: The comparison of hematologic parameter of blood donor information of pre-donation and post-donation.

Parameter		Mean ± SD		p-value
		Continuous flow	Intermittent flow	
Platelet count (x10^3/ul)	Pre-donation	330.7 ± 39.2	324.9 ± 37.2	0.28
	Post-donation	233.8 ± 24.9	190.6 ± 25.8	<0.0001
Hematocrit (%)	Pre-donation	43.2 ± 3.5	42.7 ± 2.7	0.29
	Post-donation	41.3 ± 3.3	39.6 ± 2.8	0.01
Hemoglobin (g/dL)	Pre-donation	14.4 ± 1.2	14.2 ± 0.9	0.33
	Post-donation	13.8 ± 1.1	13.2 ± 0.9	0.02
WBC count (x10^3/ul)	Pre-donation	7.2 ± 1.8	7.0 ± 1.5	0.26
	Post-donation	8.3 ± 1.8	7.1 ± 1.5	0.002
RBC count (10^3/ul)	Pre-donation	5.0 ± 0.6	5.2 ± 0.7	0.18
	Post-donation	4.8 ± 0.5	4.2 ± 0.5	0.26
MCV (fL)	Pre-donation	86.2 ± 6.4	84.5 ± 5.8	0.14
	Post-donation	86.4 ± 6.4	84.5 ± 5.7	0.13

The comparison about apheresis parameter found; whole blood volume process, ACD-A anticoagulant consumption, platelet donation duration, the efficiency of the device (CE%) and collection rate (Mean ± SD) were 3,490.9 ± 372.2 ml, 379.4 ± 35.3 ml, 65.8 ± 8.0 minutes, 73.6 ± 8.8% and 0.1 ± 0.0x10^{11} per minute, respectively (Table 5). Differences were statistically significant (p <0.05) found in whole blood volume process, ACD-A anticoagulant consumption, platelet donation duration.

Table 5: The comparison about apheresis parameter between two apheresis systems.

Parameter	Mean ± SD	p-value	p-value
	Continuous flow	Intermittent flow	
Whole blood processed (mL)	3,490.9 ± 372.2	3,970.6 ± 413.9	<0.0001
ACD-A used (mL)	379.4 ± 35.3	546.8 ± 58.2	<0.0001
Processing time (min)	65.8 ± 8.0	98.9 ± 13.3	<0.0001
CE (%)	73.6 ± 8.8	71.2 ± 6.5	0.11
Collection rate (PLTsx1111/min)	0.1 ± 0.0	0.1 ± 0.0	0.12

The results of the quality and quantity of platelets obtained from the platelet donations from both methods showed that; the volume of the platelets is approximately the same, with the 499 ml. The number of platelets yield is approximately 6.2 to 6.5x10^{11} cells per unit. The equivalent to a platelet unit of 11.3 to 11.6 units per donation set (also known as a platelet double dose). Residual leukocytes (rWBC) are approximately 0.1-0.3x10^6 cells per unit, with the pH and swirling phenomenon of days 2 and 5 changing after collection; statistically significant (p <0.05). Leukocytes are approximately 0.1-0.3x10^6 cells per unit, with the pH and swirling phenomenon of days 2 and 5 changing after collection. Statistically significant (p <0.05). Leukocytes are approximately 0.1-0.3x10^6 cells per unit, with the pH and swirling phenomenon of days 2 and 5 changing after collection, statistically significant (p <0.05) (Table 6).

Table 6: Quality and quantity of platelets obtained from the platelet donations from two systems.

Parameter		Mean ± SD		p-value
		Continuous flow	Intermittent flow	
Total platelet volume (mL)		498.6 ± 16.7	499.0 ± 0.0	0.45
Platelet yield (x10^{11})		6.5 ± 0.8	6.2 ± 0.5	0.14
rWBC (x10^6)		0.3 ± 0.2	0.1 ± 0.1	0.00357
Unit of DDP in PAS (U)		11.6 ± 1.6	11.3 ± 1.0	0.22
pH	Day 2	7.1 ± 0.1	7.1 ± 0.1	Day 2 and Day 5
	Day5	6.7 ± 0.1	6.7 ± 0.1	<0.0001
Swirling phenomenon	Day 2	5+	5+	Day 2 and Day 5
	Day 5	3+	3+	<0.0001

The titration check on plasma donor anti-A and B And in the donated platelets, adding T-PAS + solution found that ; among blood donors A, B, and O, there were low tier = 66.6%, 100% and 91% respectively, while platelets in T-PAS + solution were low titer 100% for all platelet donors (Table 7).

The results of satisfaction assessment of platelet donors are divided into 5 parts as follows; satisfaction with the tools for donating platelets, time of donation of platelets, information providing of service personnel and the overall of service found that; time of

platelet donation between 2 devices with statistical differences ($p < 0.05$). Other parts were similar level as table 8.

Table 7: Titration levels of anti-A and B in platelet donors and in platelets collected with PAS solution.

Parameter	%	
	Donor sample (low titer)	PAS platelet (low titer)
Group A	66.6	100
Group B	100	100
Group O	91	100

Table 8: Platelet donor satisfaction mean scores.

Parameter	Mean ± SD		p-value
	Continuous flow	Intermittent flow	
Instrument satisfac-tion	4.6 ± 0.7	4.6 ± 0.5	0.26
Donation time	4.6 ± 0.5	4.1 ± 0.8	0.0013
Process satisfaction	4.6 ± 0.5	4.4 ± 0.8	0.12
Information providing	4.8 ± 0.4	4.8 ± 0.3	0.13
Overall satisfaction	4.8 ± 0.4	4.4 ± 0.7	0.013

The adverse reactions during the platelet donation; 90 % of numb reactions in the lips were observed during platelet donation (54/60). The pain at the phlebotomy site was 1.3% (8/60) and dizziness was 0.5% (3/60). The details are shown in the table 9.

Table 9: Donor reaction during processing and after DDP.

Parameter	N (during/after)		%
	Continuous flow	Intermittent flow	
Numb lips	19/2	24/9	90
Pain at phlebotomy site	4/0	3/1	1.3
Dizziness	0/0	1/2	0.5

The economic impact found; intermittent flow system chargeable higher than continuous flow system. And DDP in PAS can calculate into two therapeutic doses. The chargeable will be double of SDP. In other hand, DDP in PAS from two systems have a positive cost when compare with SDP margin.

Table 10: Economic impacts.

Parameter	Apheresis system		
	Continuous flow	Intermittent flow	
Dose	DDP	DDP	SDP
Cost per dose (THB.)	7,044	9,360	7,044
Kit	6,484	8,800	6,484
Test	560	560	560
Chargeable	8,400x2	8,400x2	8,400
Gap between margin cost	9,756	7,440	1,356

Discussion and Conclusion

According to studies of DDP in PAS platelet donors using both types of plateletpheresis by different operating principles for the machine; the general characteristics of platelet donors appropriate because the same donor had donation process in both systems. A hematological value before and after platelet donation in platelet donors donated by 2 systems; including platelet count, Hct. hemoglobin, WBC count, RBC count and MCV Before the platelet donation have no statistical differences ($p > 0.05$) were not found. After the platelet donation was completed, it was found that the hematological value after the platelet donation in the donors from the intermittent flow method was less than the continuous flow method, which was significantly lower ($p < 0.05$) in terms of Platelet count, Hct. Hemoglobin, WBC count, RBC count. Therefore, the platelet donors by intermittent flow may be responsible for accidents or injuries after platelet donations. Due to the loss of platelets in the body more than other methods. From a study report in Thailand previously reported found similar characteristics. The differentiation from this study, this time using the same donor That starts from the platelet pre count from the same person There was no statistical difference between the two platelet donations ($p > 0.05$). However, platelet donations in both methods have reported studies. In an average of 24 platelet donors, platelet post count amounts to more than 150,000 /cu.mm, not lower than the American Associated of Blood Banks (AABB) criteria. thrombocytopenia in donors and with normal protein and albumin levels.

The report confirms that the double dose donor groups can be re-donated after 7 days and the group who donated triple dose can be re-donated after 14 days. From this study, the donated platelets from both methods had the volume of platelets (mean ± SD) $6.5 \pm 0.8 \times 10^{11}$ and $6.2 \pm 0.5 \times 10^{11}$ cells per batch and the volume of platelets at the minimum level of 5.7×10^{11} cells per set. The data was found 92.7% (5/60) for DDP quantity more than minimum level.

In principle, ABO identical platelets are recommended for optimal increments in the counts in patients. However, practically, this is not always feasible due to the scarcity of group-specific platelets, especially SDP's, in times of urgent need. This is compounded by the fact that it has a short shelf life of 5 days, wherein strict adherence to the policy of transfusing ABO identical SDPs can lead to outdate and expiry of platelet [15]. Therefore, PAS for apheresis units and to remove most of the plasma and naturally occurring ABO antibodies so that we can provide SDPs without blood group specificity [16]. And many studies have suggested the SDP in PAS can be stored for longer period than 5 days. The additive solution would maintain in vitro parameters successfully for up to 9 days. In vivo studies, however, are required to confirm the in vitro results [13,17].

In term of %CE, the acceptable percentage for the apheresis system must be higher than 60%. Two system were accepted; Trima Accel® (73.6%) higher than the Haemonetics MCS plus / UPP®(71.2%).

The DDP donated by Trima Accel® have more platelets than those from the Haemonetics MCS plus / UPP®. Because of T-PAS + as a platelet preservative, PAS will increase patient safety. Reduce the allergic reaction and febrile non hemolytic transfusion reaction. It

also causes donors to lose less plasma on each donation. At the same time, it is expected that platelet function in platelets in PAS will be better than those in normal plasma. The research will confirm the expect results. Moreover, from the data on platelet concentrates (PC) preparation in Maharat Nakhon Ratchasima Hospital, at various types of PC are prepared in 2017-2019 as follows; random donor platelet (RDP) was 50,038 units, Leukocyte poor platelet concentrate (LPPC) was 46,023 units, LPPC in PAS was 979 units and Leukocyte depleted poor platelet concentrates (LDPC) was 427 units. The PC prepared from a large amount of WB. It costs a lot as well. Therefore, the DDP in PAS is useful for Blood Bank management; a blood supply policy should be established. To allocate budgets to be worthwhile.

The authors declare no conflits of interest.

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