Comparison of Double RBC Collection by Blood Cell Separators

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Background: *The problem of red blood cell (RBC) shortage occurs because of the expanding demand for blood utilization and the difficulties in donor recruitment and retention. Resources can be maximized by using current technology to collect two units of RBC from the same donor during a single collection session.*

Objective: *To evaluate the performance, collection efficiency (CE), production cost, and donor satisfactions of two commercially available blood cell separators (BCS) for double dose red cell (DDRC) collection. Donor safety, clinical effectiveness, and patient safety were studied.*

Material and Method: *Thirty-one repeated male donors from the blood bank, Department of Pathology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University were recruited for DDRC collection by two BCSs, the Alyx™, Fresenius Kabi, NC, USA, and the MCS®+, Haemonetics Corporation, Scotland. The donation intervals were at least 16 weeks. The target RBC volume was 360 mL (180 mL x 2 units). Pre- and post-donation hematologic parameters were monitored and quality tests for DDRC were performed. Donor reactions (DR) were observed and donor satisfaction questionnaires were collected after donations. Eighty-six units of RBC were transfused to 33 patients. Transfusion reactions (TR) were observed, and hematocrit (Hct) increments were determined pre-transfusion and 24 hours post-transfusion.*

Results: *The Alyx™ was faster for collecting and filtrating RBC ($p<0.001$) and had better CE ($p<0.001$). All DDRC from both BCSs met all the quality standards, required by both the American Association of Blood Banks (AABB) and the Food and Drugs Administration (FDA), which were hemoglobin (Hb) >42.5 g, Hct 50 to 70% and the residual white blood cells (WBC) $<5x10^6$. The Alyx™ processed less whole blood (WB) volume but provided DDRC with higher RBC yield, Hb content, and RBC volume than that of MCS®+ ($p<0.001$). However, the MCS®+ had one advantage over the Alyx™ whereby the DDRC collected by the MCS®+ were washed to reduce the risk of plasma associated TR. No serious DR from either BCS was observed. All donors had Hb >10 g/dL and Hct >30% after collection, as required by AABB. Serum ferritin reduction and iron depletion found in DDRC donors were not different from WB donors. All donors were satisfied with the DDRC collection process and would like to donate again. There was no evidence of acute or delayed TR in the patients. Hct increased significantly in 69.70% of the patients.*

Conclusion: *DDRC collection can be performed safely and efficiently from both BCS. The quality of DDRC from both BCSs met the AABB and FDA standards. Donor safety, transfusion safety, and effectiveness were observed. Even though the production cost of DDRC was slightly higher than that of whole blood derived filtered RBC, DDRC was better in terms of quality, risk reduction for infectious agents, and RBC alloimmunization. Production of DDRC can also be helpful supplying special RBC such as group O, Rh D negative, and phenotyped RBC.*

Keywords: *Double dose RBC collection, Two units RBC, Apheresis*

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Red blood cell (RBC) shortages have been observed, as a result of the continuously expanding demand, over utilization and difficulties in the recruitment and retention of blood donors, more stringent donor criteria and economic and sociological changes[1-4]. In Thailand, the shortages often occur because of the high prevalence of thalassemic patients who need regular RBC transfusion, especially during summer vacation. The prevalence of α-thalassemia, β-thalassemia, and Hemoglobin (Hb) E are 20 to 30%, 3 to 9%, and 13%, respectively[5]. The patients who live upcountry may lose time and travel costs to the hospital and cannot be transfused because of the RBC shortage. In addition, most of multitransfused patients usually develop multiple RBC antibodies and it is more difficult to find compatible RBCs for these patients.

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To overcome these problems, maximizing donor resources by multicomponent collection from the same donor during one apheresis session has been implemented[4,6]. The automated instruments provide more units of standardized products, especially the group O RBCs and rare blood group RBCs and allow predictable collection with consistent volumes and yields[7,8]. Currently, the different instruments vary in terms of techniques, principles, processing speed, and efficiency. The aims of the present study were to evaluate the performance of blood cell separators (BCS) for double dose red cell (DDRC) collection, compare the quality and unit costs of DDRC, study donor safety and satisfaction, and study the clinical effectiveness of DDRC products.

Material and Method

Donors

All of the 31 donors were repeated donors for whole blood (WB) collection and plateletpheresis at the blood bank, department of pathology, Ramathibodi Hospital. The study was approved by the Ethics Clearance Committee of Human Rights Related to Research Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital, Mahidol University. All donors met the eligibility requirements of American Associated of Blood Bank (AABB), Food and Drug Administration (FDA), and the Council of Europe (EU) for WB donation and passed the requirements of AABB for DDRC collection[9] as shown in Table 1. The target RBC volume was set at 360 mL (180 mL x 2 units).

Collection protocol

Prior to the first donation, the donors were informed to donate DDRC twice by both BCS with the minimal donation interval (DI) of 16 weeks. They were allowed to choose the BCS for the first DDRC collection, and then each donor donated the second DDRC collection by the other BCS. For the first donation, 15 donors chose the Alyx™ and 16 donors chose the MCS®+. The donors were asked to donate the third DDRC collection in order to be monitored for their serum ferritin levels (SFL).

Table 1. Screening criteria for double RBC collection

Sex	Weight (kg)	Height (cm)	Hb	Absolute red cell volume
Male	59-67	≥155	≥13.3 g/dL	180 mL x2
	68-78	≥155	≥13.3 g/dL	200 mL x2
	≥79	≥155	≥13.3 g/dL	210 mL x2
Female	68-78	≥165	≥13.3 g/dL	180 mL x2
	≥79	≥165	≥13.3 g/dL	200 mL x2

RBC = red blood cell; Hb = hemoglobin

Serum ferritin levels

Before and after each donation, sera were separated and stored at -30°C for SFL at the immunology laboratory. The sera were thawed on the day of the assay and SFL was measured using a Chemiluminescent Microparticle Immunoassay (CMIA) by the automated immunochemistry analyzer, Architect system (Abbott Laboratories, Longford, Ireland). According to the World Health Organization (WHO) guidelines, the SFL of less than 15 ng/mL was indicative of depleted iron stores[10].

Production cost

The production cost of DDRC was calculated from labor cost, investment cost, and cost of disposable kits and blood processing laboratory tests. Then, the cost for one unit of DDRC was compared to the cost of WB derived filtered RBC.

Clinical effectiveness

The study included 33 thalassemic patients. Twelve patients had splenectomy. The Alyx™ DDRC was transfused into 22 patients. Thirteen of them received blood for the first time while the other nine patients received blood for the second time. The MCS®+ DDRC were transfused into 21 patients. Nine of them received blood for the first time, while the other 12 patients received blood for the second time. Hematocrit (Hct) were determined before and 24 hour after transfusion. Transfusion reactions were observed by nurses during and after transfusion.

Statistical analysis

SPSS for Windows, version 18.0 (IBM SPSS Inc., Chicago, IL) was used for the statistical analysis. The results were expressed as mean ± standard deviation (SD) and 95% confidence interval. A p-value of <0.05 was considered as statistically significant. Normal distribution was tested by the Kolmogorov-Smirnov test. If normality was rejected, the results were expressed as median and interquartile range (IQR). Statistical comparisons were made with the paired t-test and unpaired t-test. The donor satisfaction questionnaires were tested by the McNemar test. The instrument satisfaction and donor reaction were tested by Wilcoxon Matched-Paris signed-ranks test. The results of the questionnaires were expressed as percentages.

The raw data of SFL was transformed by logarithm base 10, and a normal distribution curve was obtained. The SFL were expressed as geometric mean ± SD and compared by unpaired t-test and paired t-test. The paired t-test and unpaired t-test were also used for both dependent and independent data for the clinical effectiveness study.

Results

No female donors were eligible for DDRC collection because their weight and height did not pass the criteria. Forty-five male donors were initially enrolled, but only 31 donors were included in the present study. Four donors did not come back to donate for the second time. The other ten donors did come back but did not want to donate DDRC. They donated WB and apheresis platelet instead. The median of DI using Alyx™ and MCS®+ was 18 and 19 weeks, respectively.

Donor characteristics

The donor ages ranged from 25 to 57 years old. The DI ranged from 17 to 30 weeks. The donor mean weight was 76.81±14.10 kg for Alyx™ and 77.32±13.96 kg for MCS®+. The median and range of donor height were 168 and 160 to 181 cm. The weight and height of each donor were not statistically significant at the time of donation. There were no significant differences of the first and second pre-donation hematologic parameters of the same donors between both BCS.

Procedure parameters

The procedure parameters and the calculated collection efficiency (CE) were shown in Table 2. The DDRC collection time (CT) and filtration time (FT) by Alyx™ was significantly lower than the MCS®+. Moreover, the volume of WB processed and SAG-M additive solution used by Alyx™ were significantly lower than those of the MCS®+. However, the volume of ACD-A infused into the donors was much lower with MCS®+ collection even though ACD-A was used as a priming solution in MCS®+ while 0.9% NSS was used as a priming solution in Alyx™. The CE by the Alyx™ was significantly higher than the MCS®+.

Product characteristics

The characteristics per unit of RBC (total volume, RBC volume, Hb content, and RBC yield) collected by the Alyx™ were significantly higher than that of the MCS®+ as shown in Table 3. On the other hand, the Hct of RBC collected by MCS®+ was significantly higher than that of the Alyx™ even though the Hb content was significantly lower. The products from both BCS met the requirements of AABB and EU. All units had Hb >42.5 g, RBC volume >128 mL, and residual white blood cells (WBC) $\leq 1x10^6$.

Product costs

The production cost in Thai Baht were compared between of DDRC and four types of WB derived pre-storage and post-storage filtered RBC, which were three pre-storage inline filtered RBC from top and bottom system (Haemonetics Corporation, Massachusetts, USA), WB filtration (Terumo BCT, Tokyo, Japan and Haemonetics Corporation, Massachusetts, USA) and post-storage filtered RBC (Terumo BCT, Tokyo, Japan).

Donor safety

No serious donor reaction and complaint were observed. The donors' feedbacks were collected for

Table 2. Procedure parameters

Parameters	Instruments		*p*-value
	Alyx™ (mean ± SD)	MCS®+ (mean ± SD)	
Procedure time (minute)	34.03±5.71	47.16±3.01	<0.001
Collection time	27.55±5.85	36.94±2.53	<0.001
Filtration time	6.48±0.43	10.22±1.23	<0.001
Whole blood processed (mL)	893.23±63.14	1,015.35±71.48	<0.001
ACD-A prime (mL)	0	15	
ACD-A used (mL)	122.35±6.87	71.39±4.16	<0.001
SAG-M addition (mL/unit)	80.56±3.84	92.21±3.43	<0.001
Collection efficiency (%)	85.23±3.69	69.00±4.08	<0.001

ACD = acid-citrate-dextrose; SAG-M = saline-adenine-glucose-mannitol
Statistically significant difference $p<0.05$

Table 3. Product characteristics per unit

Parameters	Instruments		*p*-value
	Alyx™ (mean ± SD)	MCS®+ (mean ± SD)	
Volume (mL)	259.06±6.25	230.80±10.04	<0.001
Hb content (g)	51.38±3.39	47.46±3.88	<0.001
RBC volume (mL)	157.44±6.77	145.74±8.29	<0.001
Hct (%)	60.06±2.39	62.16±1.83	<0.001
RBC yield ($x10^{12}$)	1.83±0.16	1.716±0.17	<0.001
Residual WBCs ($x10^6$)	0.14±0.14	0.14±0.10	0.850

Hct = hematocrit; WBCs = white blood cells
Statistically significant difference $p<0.05$

any discomforts (perioral tingling, pain at the needle site, and dizziness) during and after the collection. There were no significant differences in discomfort between both BCS.

All of the post-donation parameters (Hb, Hct, RBC, and WBC count) with the exception of platelet counts, showed significantly lower level than those of pre-donation level. However, only the differential values of Hb, Hct, and RBC count were significantly lower after collection. According to AABB standard, the post-donation Hb and Hct of DDRC donors shall not be less than 10 g/dL and 30%, respectively. All of the DDRC donors in our study passed the AABB standard.

Donors SFL before and after DDRC collection were compared as geometric mean ± SD. We can compare 31 donors' SFL before and after the first donation, but only 27 donors' SFL before and after the second donation because four donors did not come back after the second donation. There were no significant difference of SFL ($p = 0.13$) between the first and second pre-donation. Similarly, there were no significant difference of SFL ($p = 0.41$) between the first and second post-donation. Table 4 showed the SFL reduction after DDRC collection from the same group of donors by each instrument. There were no significant difference of SFL reduction for both BCS ($p = 0.69$ and 0.95, respectively). Donor SFL before DDRC collection were shown in Table 5. It was found that 3/31 donors (9.68%), 4/31 donors (12.90%) and 2/27 donors (7.41%) had iron depletion (IRD) before the first, second, and third DDRC collection, respectively.

Donor satisfaction

There were no significant differences of mean donor satisfaction scores between these two BCS in all questions, except for the question of donation experience on each BCS. The satisfaction for Alyx™ was slightly higher than MCS®+.

Table 4. Comparison of serum ferritin reduction after DDRC collection

Decreased ferritin level (mean ± SD)		*p*-value
Alyx™	MCS®+	
27.70±1.91 (first)	24.78±1.70 (second)	0.69
23.92±1.99 (second)	24.36±1.70 (first)	0.95

DDRC = double dose red cell
Statistically significant difference $p<0.05$

Table 5. Serum ferritin levels before DDRC collection

Ferritin level	Before DDRC collection		
	1st donation (n = 31)	2nd donation (n = 31)	3rd donation* (n = 27)
Normal (≥15 ng/mL)	28	27	25
Iron depletion (<15 ng/mL)	3	4	2

* Only 27/31 DDRC donors came to donate for the third time

Clinical effectiveness of DDRC

Thirty-three thalassemic patients (β-thalassemia/Hb E and β-thalassemia major) received 43 DDRC (86 units of RBC) from 31 donors. The patient median age was 14 years old (range 8-20). All patients received two units of RBC at the same transfusion sessions. The successful transfusion was indicated by the increased Hct within 24 hours after transfusion.

No matter what patients received DDRC from either Alyx™ or MCS®+, all patients had significantly higher post-transfusion Hct ($p<0.001$). The transfused

Table 6. Comparison of the hematocrit increments after DDRC transfusion

Patients	No. of patients	Hematocrit increment (%)		*p*-value
		Alyx™ DDRC (mean ± SD)	MCS®+ DDRC (mean ± SD)	
Patient group I	10	7.61±2.47	6.40±1.92	0.24
DDRC from the same donor	4	7.93±2.69	7.50±1.39	0.74
DDRC from the different donor	6	7.40±2.55	5.67±1.97	0.22
Patient group II	23	7.27±1.70	6.80±2.71	0.62
Total	33	7.42±2.04	6.61±2.32	0.23

Statistically significant difference $p<0.05$

patients were classified into two groups. Group I patients (n = 10) received DDRC from both BCS. Group II patients (n = 23) received DDRC from either Alyx™ or MCS®+. The percentage of Hct increment in both groups from either the same or different donors were not statistically significant as shown in Table 6. However, the percentages of Hct increment in patients who received Alyx™ DDRC was always higher those of MCS®+. No patient had transfusion reactions.

Nevertheless, there were 10 patients whose Hct increment less than 6%, which is lower than the predicted post-transfusion Hct after receiving DDRC from both BCS.

Discussion

Thirty-one eligible male donors were enrolled into the present study. We cannot include any female donors because most of Thai women have smaller stature than international screening criteria and they often have menstruation, which stops them from donating. The AABB and FDA required the DI of greater than16 weeks. The DI range in the present study was 17 to 30 weeks because some donors lived in the periphery or outside of Bangkok and did not want to travel very often for DDRC collection. We reduced the bias that could affect the result of procedure parameter and product quality by collecting DDRC from the same group of donors by both BCS. Considering for donor safety, we collected absolute RBC volume at the lowest target volume (180 mL x 2 units).

There were significant differences in all procedure parameters between both BCS which was similar to the previous report by Picker et al[3]. It can be explained by the fact that MCS®+ used the discontinuous flow (DCF) principle to collect WB and filled up the centrifuge bowl. Therefore, MCS®+ needed more extracorporeal blood volume. Alyx™ used the continuous flow principle, which the WB was gradually drawn into the reservoir and the centrifuge chamber. Thus, the Alyx™ processed WB was less than MCS®+. Therefore, the CE of MCS®+ was lower and it was considered as a limitation of MCS®+. ACD volume used in Alyx™ was significantly more than that of MCS®+ because the ACD ratio of Alyx™ was less than that of MCS®+. However, the donor reactions observed were not statistically significant between both BCS.

The shorter donation time (DT) was critically important for DDRC donor recruitment and retention[2,3] because the donor usually chose to donate with the BCS that had shorter DT. Our result was similar to the earlier study by Picker et al[3], that Alyx™ was faster than MCS®+. The CT of MCS®+ was significantly longer due to the DCF technique. It was observed in our study that the FT of Alyx™ was significantly shorter than MCS®+ as previously reported by Radojska et al[11]. The Alyx™ performed filtration automatically under pressure immediately after collection while MCS®+ used gravity for RBC filtration from a height of 1.3 meters.

Regarding product characteristics, the unit volume, RBC yield and volumes of Alyx™ DDRC were significantly more than those of MCS®+ even though the targets were set at the same volume. After filtration, the RBC volume in each unit was less than the set target due to the loss of RBC in the dead space of filters, which were about 45 mL for MCS®+ and 38 mL for Alyx™. Therefore, the new set target volume should be 200 mL x 2 units and 210 mL x 2 units for Alyx™ and MCS®+ respectively in order to achieve the final target of 180 mL x 2 units DDRC. If we used these new set target volumes to screen the donors in the present study, we would have only 25 qualified donors (80.65%). The remaining six donors (19.35%) would not meet the screening criteria because their weights were less than 68 kg.

The Hb content in DDRC by MCS®+ was significantly lower than that by Alyx™. However, the Hct in DDRC by MCS®+ was significantly higher because less volume of SAG-M was added to MCS®+

DDRC. Moreover, the procedure of MCS®+ included RBC wash with 0.9% NSS, which might lower the amount of fluid in the product. The advantage of MCS®+ over Alyx™ was that the final products were washed RBC, which could reduce the incidence of transfusion related acute lung injury (TRALI), especially from multiparous female donors.

The residual WBC in DDRC showed no significant difference, but it was observed that Alyx™ had slightly higher residual WBC as reported by previous studies[3,11]. This could be due to pressure filtration. After filtration, air pressure released from the final product bags to filters might cause an artificial reflux from filters that contained high WBC back into the final product bags. It could be avoided by placing a clamp together with an additional air bag between the storage bag and the filter[3,11]. In addition, skill in burping of the final products should be done with attention to avoid this reflux. The quality of filtered RBC from both BCS had no significant difference in terms of hemolysis rate, supernatant Hb, supernatant K+, ATP content, pH, glucose, and lactate on the collection day as previously described[3,11].

The production cost of DDRC was not much different than WB derived filtered RBC. The DDRC reduced the labor cost of component preparation and processing. Moreover, the reagent cost for infectious marker screening and quality control reduced because they were the cost of two units RBC in DDRC, compared to the same cost for only one unit of WB derived RBC. The workload for paperwork was also reduced. The only higher cost of DDRC was the higher price of the disposable kits[7].

There were no significant differences for donor reactions during and after collections by both BCS. No vasovagal reaction was observed. This was probably because all donors were repeated donors. Nine of them (29%) were plateletpheresis and 22 of them (71%) were regular WB donors. The common donor reaction observed in our study was perioral tingling from citrate toxicity, which was similar to the previous studies[3,12-16] and it was resolved immediately by oral calcium administration.

Considering donor safety, post-donation levels of Hb, Hct, and RBC were slightly lower in donors collected by Alyx™ because the CE of Alyx™ was better than MCS®+, but no donor had Hct and Hb less than AABB standard[17].

The donors' iron status was monitored in our study by SFL[10,18] in order to prevent IRD. The donor may have normal Hb even though they have depleted iron store. According to WHO guidelines, donor with SFL less than 15 ng/mL is considered to have IRD[19]. As DDRC collection removed approximately twice the amount of RBCs as compared to WB donation, the DI recommendations for the DDRC was more than four months[20]. Shi and Ness reported that iron loss from DDRC collection was 320 to 420 mg[12]. There was ample documentation that SFL dropped significantly after donation and remained depressed at 30 days compared to baseline levels, but was still within the lower end of normal range[20]. Five donors had SFL dropped below 15 ng/mL, which was considered to have IRD. Even though iron supplements were given to all donors, most of them did not take it regularly and that might cause IRD in regular blood donors. The IRD in DDRC donors prior to collection in the present study was similar to the previous report of iron stores in Thai WB donors by Tardtong et al, which showed that the IRD occurred gradually with the increased frequency of WB donations[21]. Moreover, IRD in blood donors might have been caused by many other factors including diet and menstruation. Therefore, the type of donation, WB or apheresis, was not really the explanation for iron deficiency and IRD[15,21].

Since the SFL had a wide range, they were transformed to log base 10 before comparing the level. It was found that there was no significant difference of SFL reduction in the same group of donors between both BCS, no matter which BCS was chosen to be the first one to collect DDRC in those donors. Tardtong et al reported that the mean SFL in regular WB male donors who donated WB four times per year was 27.70±19.89 ng/mL (range from 8-47)[21]. The mean SFL of male DDRC donors in our study after two donations (4 units of RBC) was 51.27±41.86 ng/mL (range from 9-93), which was not lower than WB donors. It was shown that the DDRC collection was as safe as WB donations.

Among five DDRC donors who had IRD, two donors had IRD throughout the study, one donor had IRD after the second donations and the other two donors had IRD after the first donation but turn to have normal SFL after the second donation. Three donors had IRD prior to the first collection. They were regular WB donors for over 10 years (4 times/year), which corresponded to the data reported by Tardtong et al that IRD occurred gradually with the increased number of donation[21].

Even though there was no significant difference in terms of willingness to return to donate on the same BCS, the donors would like to donate

DDRC by Alyx™ more than MCS®+ because of shorter DT. However, 6% of donors would not want to donate by Alyx™ because of the high noise emission from the instrument and discomfort during the draw and return phase due to variations in blood flow. At the end of the study, five donors did not come back to donate DDRC again. Two donors became WB donors at their nearby hospitals, the other two donors did not like the longer DI and the last one got sick and stopped donating blood.

According to transfusion guideline, a dose of one unit of RBC will increase the Hct by approximately 3% or Hb by 1 g/dL[22,23]. We found that all of the thalassemic patients had post-transfusion Hct levels increased significantly. Ten patients (4 patients with splenectomy and 6 patients without splenectomy) had post-transfusion Hct level increased less than 6% which was less than the predicted Hct increment after receiving DDRC. This might be explained by the variation of laboratory tests because some patients (5/10) had 24-hour post-transfusion samples collected and tested at their nearby hospitals. The other five patients whose samples were collected in our hospital might have their individual unexplained problems that affected post-transfusion Hct levels.

It was observed in our study that there was no significant difference of Hct increment in patients who received DDRC either from the same or different donors and in patients who received DDRC from different BCS. Therefore, there was no significant difference for the clinical effectiveness of DDRC from both BCS.

No acute and delayed type of transfusion reaction was observed after DDRC transfusion in the present study. However, the sample size of the patients was rather small. It was reported by previous studies[2,7,12,24] that the benefits of transfusing DDRC to the same recipients were reduction of allogeneic exposure (infectious agents and RBC antigens) and immunomodulatory effects. In addition, the expected outcome of DDRC transfusion should be better than WB derived RBC because of more predictable increase of Hb or Hct due to the defined amount of RBC in DDRC and less collection injury from anticoagulant by apheresis.

Currently, DDRC collection may not be suitable to replace WB derived RBC as routine collections because the technology still need experienced operators and some donors are reluctant to spend longer CT for DDRC collections. However, DDRC collections should be implemented for collecting RBC from donors who have rare blood groups or group O. Maximization of resources are needed so that the shortage of RBC will not occur, especially in the country like Thailand, which thalassemic patients with multiple antibodies need regular and long-term blood transfusion.

Conclusion

Blood shortages have occurred continuously because of expanding demand of blood utilization and more difficulties in donor recruitment and retention. The DDRC collections are one of the effective ways to maximize resources.

It was observed that BCS, Alyx™, and MCS®+, were capable of safely and efficiently collecting DDRC. The Alyx™ was faster for collecting and filtrating RBC and had better CE. All DDRC from BCS and met all the standards required by AABB and FDA, which were Hb content, Hct, and residual WBC. The Alyx™ processed less WB volume but provided DDRC with higher RBC yield, Hb content, and RBC volume than that of MCS®+. However, the MCS®+ DDRC products were washed RBC which could reduce the risk of plasma associated TR in patients.

No serious donor reaction was observed from BCS. None of the donors had Hb and Hct below the AABB standard after donations. Serum ferritin reduction and iron depletion found in DDRC donors were not different from WB donors. All donors were satisfied with collection processes and would like to donate again. There was no evidence of acute and delayed TR in patients. Even though the production cost of DDRC was slightly higher than that of WB derived filtered RBC, the DDRC were better in terms of quality, risk reduction for infectious agents and RBC alloimmunization. The DDRC by apheresis is unlikely to replace WB donations for routine blood collection, but it can be helpful for blood center and hospital blood bank to optimize RBC collection for sufficient blood supply, especially on production of two units of RBC for special purposes such as group O, Rh D negative and phenotyped RBC in patients with multiple antibodies.

What is already known on this topic?

The previous studies focused on comparing the performance of the BCS for DDRC collection and DDRC quality that were able to perform safely and efficiently collecting the high quality DDRC.

What this study adds?

In addition to evaluating the performance of the BCS for DDRC collection and the DDRC quality,

this studies also evaluated the donor safety by focusing on the serum ferritin levels and the clinical effectiveness by the Hct increment.

Potential conflicts of interest

None.

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การเปรียบเทียบการเก็บ double RBC โดยเครื่องแยกเม็ดโลหิตอัตโนมัติ

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ภูมิหลัง: ปัญหาการขาดแคลนโลหิตมีแนวโน้มจะเพิ่มขึ้นจากการรักษาโรคที่ใช้โลหิตมากขึ้น และเกณฑ์การคัดเลือกผู้บริจาคโลหิตที่เข้มงวดมากขึ้น ทำให้โอกาสได้ผู้บริจาคโลหิตเพิ่มขึ้นมีไม่มาก การใช้ประโยชน์สูงสุดจากทรัพยากรที่มีอยู่โดยใช้เทคโนโลยีล่าสุดเพื่อเก็บเม็ดโลหิตแดงครั้งละ 2 ถุง จากผู้บริจาคโลหิตคนเดียวในการบริจาคครั้งเดียว อาจจะเป็นวิธีที่ทำให้สามารถได้โลหิตที่มากขึ้นและเพียงพอ

วัตถุประสงค์: เพื่อประเมินการทำงานของเครื่องแยกเม็ดโลหิตแดงอัตโนมัติ 2 ชนิด ที่มีใช้อยู่ในปัจจุบัน โดยประเมินประสิทธิภาพในการเก็บต้นทุนในการทำคุณภาพของเม็ดโลหิตแดงที่เก็บได้ ศึกษาความพึงพอใจของผู้บริจาคต่อเครื่อง ความปลอดภัยของผู้บริจาคและผลการศึกษาจากการให้โลหิตแก่ผู้ป่วย

วัสดุและวิธีการ: ผู้บริจาคโลหิตในการศึกษาครั้งนี้ ถูกคัดเลือกจากผู้บริจาคผู้ชายจำนวน 31 คน ที่บริจาค whole blood เป็นประจำที่คลังเลือด ภาควิชาพยาธิวิทยา คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล ผู้บริจาคแต่ละคนบริจาคเม็ดโลหิตแดง 2 ถุง โดยเครื่องแยกเม็ดโลหิตอัตโนมัติ 2 เครื่อง ได้แก่ เครื่อง Alyx™ (Fresenius Kabi, NC, USA) และ MCS®+ (Haemonetics Corporation, Scotland) โดยระยะห่างของการบริจาคครั้งที่ 1 และ 2 ในผู้บริจาคคนเดียวกันไม่น้อยกว่า 16 สัปดาห์ จำนวนเม็ดโลหิตแดงที่เก็บแต่ละครั้งคือ 360 มิลลิลิตร (180 มิลลิลิตร x 2 ยูนิต) เม็ดโลหิตแดงที่เก็บได้ได้รับการตรวจคุณภาพทุกถุง ผู้บริจาคทุกคนได้รับการตรวจเลือดเพื่อความปลอดภัยโดยหาค่าทางโลหิตวิทยาก่อนและหลังบริจาคทุกครั้ง หากมีปฏิกิริยาต่อการรับบริจาคโลหิตจะถูกบันทึกไว้ ความพึงพอใจต่อการบริจาคแต่ละครั้งถูกประเมินโดยผู้บริจาคด้วยการตอบแบบสอบถามหลังการบริจาค เม็ดโลหิตแดงจำนวน 86 ถุง ที่เก็บได้ถูกนำไปให้แก่ผู้ป่วย 33 คน หากมีปฏิกิริยาจากการรับโลหิตจะถูกบันทึกไว้ ผู้ป่วยถูกเจาะเลือดก่อนและหลังได้รับโลหิต 24 ชั่วโมง เพื่อหาค่าฮีมาโทคริต สำหรับประเมิน clinical effectiveness ของเม็ดโลหิตแดงที่เก็บได้

ผลการศึกษา: พบว่า Alyx™ ใช้เวลาในการเก็บและกรองเม็ดโลหิตแดงน้อยกว่า MCS®+ อย่างมีนัยสำคัญ ($p<0.001$) นอกจากนี้ Alyx™ ยังมีประสิทธิภาพในการเก็บแยกดีกว่า MCS®+ อย่างมีนัยสำคัญ ($p<0.001$) เม็ดโลหิตแดงที่เก็บได้ทุกถุงมีคุณภาพตามมาตรฐานของ American Association of Blood Bank (AABB) และ Food and Drug Administration (FDA) ได้แก่ ปริมาณฮีโมโกลบินมากกว่า 42.5 กรัม ปริมาตรของเม็ดโลหิตแดง 50-70% และปริมาณเม็ดโลหิตขาวปนเปื้อนน้อยกว่า $5x10^6$ ตัว ถึงแม้ว่า Alyx™ จะใช้ปริมาณโลหิตหมุนเวียนในการเก็บเม็ดโลหิตแดงน้อยกว่า ($p<0.001$) แต่เม็ดโลหิตแดงที่เก็บโดย Alyx™ มีปริมาณฮีโมโกลบิน ปริมาตรของเม็ดโลหิตแดง และปริมาณของเม็ดโลหิตแดงมากกว่า MCS®+ อย่างมีนัยสำคัญ ($p<0.001$) อย่างไรก็ตาม MCS®+ มีข้อดีกว่าที่เม็ดโลหิตแดงที่เก็บได้เป็น washed RBC จึงลดความเสี่ยงในการเกิดปฏิกิริยาจากการรับโลหิต ไม่พบมีปฏิกิริยารุนแรงเกิดขึ้นจากการบริจาคไม่ว่าจะใช้เครื่องใด และผลการตรวจเลือดหลังการบริจาคพบว่า ไม่ว่าจะใช้เครื่องใด ไม่มีผู้บริจาคคนใดที่มีค่าของฮีมาโทคริตน้อยกว่า 30% และปริมาณฮีโมโกลบินน้อยกว่า 10 g/dL ซึ่งเป็นไปตามมาตรฐานของ AABB นอกจากนี้พบว่าการลดลงของค่า serum ferritin และการเกิด iron depletion ในผู้บริจาคเม็ดโลหิตแดง 2 ถุง ไม่มีความแตกต่างจากผู้ที่บริจาค whole blood ผู้บริจาคทุกคนพอใจในการบริจาคเม็ดโลหิตแดง 2 ถุง และต้องการกลับมาบริจาคอีก พบว่า 69.70% ของผู้ป่วยหลังจากรับเม็ดโลหิตแดงมีปริมาณของฮีมาโตคริตเพิ่มขึ้นอย่างมีนัยสำคัญ และไม่มีผู้ป่วยที่เกิดปฏิกิริยาจากการรับโลหิตทั้งแบบเฉียบพลันและไม่เฉียบพลัน

สรุป: ผลการศึกษาครั้งนี้พบว่าการบริจาคเม็ดโลหิตแดง 2 ถุง โดยวิธี Apheresis โดยใช้เครื่อง Alyx™ และ MCS®+ สามารถทำได้อย่างปลอดภัยและได้เม็ดโลหิตแดงที่มีคุณภาพตามมาตรฐานสากล AABB และ FDA ผู้บริจาคมีความปลอดภัยระหว่างบริจาคและผู้ป่วยมีความปลอดภัยและได้รับผลดีจากการรักษาหลังได้รับเม็ดโลหิตแดง ถึงแม้ว่าต้นทุนการผลิตโดยวิธีนี้จะแพงกว่าการเก็บเม็ดโลหิตแดงโดยบริจาคเป็น whole blood แต่ก็คุ้มกับต้นทุนที่สูงขึ้นไม่มาก เนื่องจากได้เม็ดโลหิตแดง 2 ถุง ที่มีคุณภาพที่ดีกว่า ลดความเสี่ยงต่อการติดโรค และ alloimmunization การบริจาคเม็ดโลหิตแดง 2 ถุง โดยวิธีนี้มีประโยชน์เนื่องจากสามารถเก็บเม็ดโลหิตแดงได้มากขึ้น 2 เท่า จากผู้บริจาคที่มีหมู่โลหิต O และหมู่โลหิตหายาก เช่น Rh D negative