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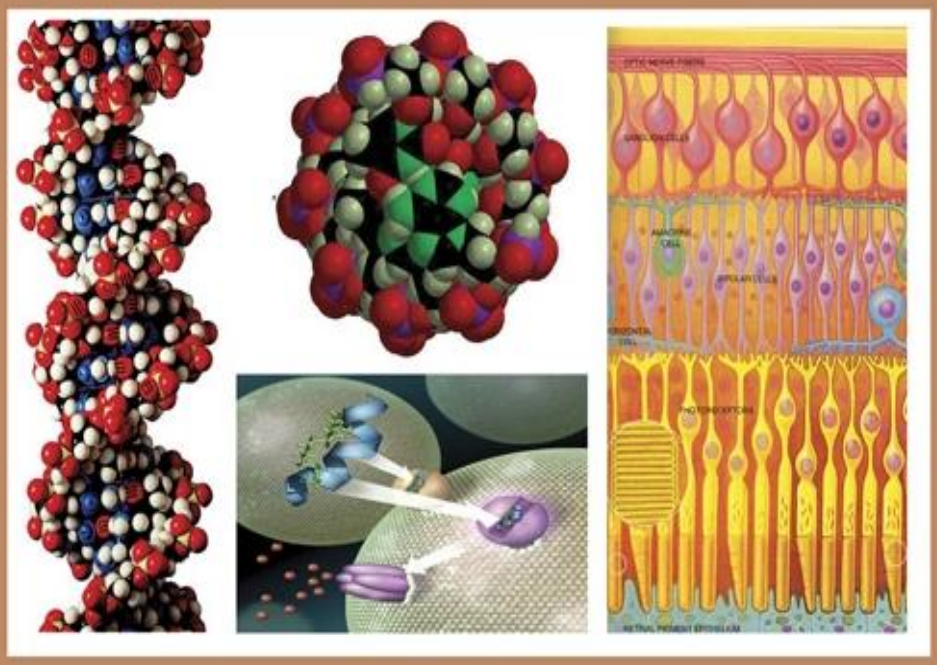

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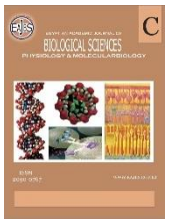

Quality Control of Fresh Frozen Plasma in Hospital Blood Bank Using pH, Volume, Residual Cells Count, PT, and PTT

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ABSTRACT

Background: Quality control of blood and its derivatives is essential for the safety of patients. Fresh frozen Plasma (FFP) is obtained by separating fresh whole blood and stored at -25 Cº or below. According to the European guideline in quality controls, the FFP should be checked before being transfused to patients. This study was designed to examine volume, pH, residual red blood cells (RBCs), white blood cells (WBCs), platelets (PLTs), PT, and APTT before freezing as a part of FFP quality control.**Materials and Methods:** A cross-sectional study included 100 FFP bags conducted in a hospital blood bank in Khartoum state - Sudan. Residual cells (RBCs, WBC, and platelet) were counted by Sysmex KX-21 Analyzer also Prothrombin time (PT) and partial thromboplastin time (PTT), which were performed using Día Lab Coagulometer. The pH of the bags was measured by a pH meter in addition to the Plasma volume.**Result:** The FFP residual cells RBCs and WBCs showed decreased count from the international standard P-value=0.00, while the platelets count was within the reference value. The pH was slightly acidic with an average value of 6.95, and the mean volume of the FFP bags (120 ml) was below the international standard range P-value = 0.00. PT and PTT within international standards.**Conclusion:** This study demonstrated that the prepared FFP bags do not meet international criteria for residual cells, volume, and pH. In contrast, PT and PTT are within the internationally recommended range.

INTRODUCTION

Blood and Blood derivatives transfusion is a relatively common medical procedure for treating many disorders. Fresh Frozen Plasma (FFP) is separated from whole blood by initial high-speed centrifugation (4,158 r, 14 min, -22C°) sealed in triple or quadruple plastic blood bags. FFP should be stored at or below -25 and thawed in a water bath over 20 to 30 minutes before use. It can also be stored at - 30 ºC for up to a year or at -65 C° for up to 7 years (Basu D . and Kulkarni R. 2014). Fresh frozen Plasma contains all coagulation factors except platelets (labile and stable coagulation factors). It also contains fibrinogen (400 to 900 mg/unit), albumin, protein C, protein S, antithrombin, tissue factor pathway inhibitor, and fibrinolytic and complement factors (Quek J., *et al.,* 2019). It is frequently used to treat minor to major coagulation factor deficiency. Other indications for treatment with FFP are disseminated intravascular coagulation (DIC), liver disease patients, and reversal of therapy with vitamin K antagonists (Keir A.K., Stanworth S.J.*et al.,* 2016).

After the blood separation, FFP should not be contaminated with other parts of blood, such as free erythrocytes and leukocytes. It should not have a leakage, clots, or abnormal color. There is a potential risk of transfusion of contaminated FFP, such as the transmission of viral or bacterial infections. Alloimmunization can happen to patients when FFP is contaminated with red blood cells. Also, hemolysis of the patient's red cell can occur due to the formation of Anti-A and anti-B when ABO- fresh frozen Plasma is incompatible. For that, checking FFP units before transfusion is essential as a part of quality control(Sheila M. , Lorna M. W. 2006).Quality analysis of FFP aims to transfuse safe FFP to patients after applying all standard quality control guidelines, quality assurance, and quality management (Pooja Y. Modi *et al.,* 2021).The standard guidelines for FFP include tests of 4 bags monthly for FactorVIII, Fibrinogen, Prothrombin Time (PT), and Activated partial prothrombin time(APTT) (Saran R.K., 2003).

In Europe, the quality control (QC) for FFP was checked for volume (must be ± 10% of the stated volume) before freezing. It also tests the residual cells- RBCs and WBCs which should be less than 6.0 X 10^9 per litre and 0.1 X 10^9 per litre, respectively (Directorate for the Quality of Medicines & Health Care of the Council of Europe 2010). Most blood bank centers in Sudan do not check the quality of fresh frozen Plasma they make. The present study aimed to evaluate the quality control of prepared fresh frozen Plasma (FFP) by checking the volume, pH, number of residual cells (Red, White, and platelets), as well as PT (Prothrombin Time) and PTT (Partial Thromboplastin Time).

MATERIALS AND METHODS

A cross-sectional study was conducted on 100 FFP bags in a blood Bank center in Khartoum State- Sudan. FFP bags were collected after centrifugation of fresh whole blood (450 ± 50 ml) for 8 hours in triple bags containing 63 mL of Citrate Phosphatase Dextrose Adenine-1 (CPDA-1) as described in a previous protocol(Basu D . and Kulkarni R. 2014). Ethical clearance was obtained from the institutional ethics committee.

All bags were tested for viral infection (Hepatitis B, C, and HIV). Each unit of FFP was weighted using a sensitive balance (Scientific-x Denver Instrument, variance-1000g). Then the volume was determined according to the following equation (Umesh D. and Arumugam P. 2018).

Collected Vol. ml = [Weight of bag + Plasma (gm)] – [Weight of the empty bag (gm)] / Specific gravity of Plasma

From each selected FFP bag, 5 ml of Plasma was taken from each bag and divided into two plain containers. One for counting residual cells (RBCs, WBC, and platelet count) using Sysmex KX-21 Analyzer and the second for estimation of Prothrombin time (PT) and partial thromboplastin time (PTT), which were performed using Technoclon (TC) kit and Dia Lab Coagulometer Analyzer™. The pH of the bags was measured by a pH meter. Data were collected and analyzed using SPSS program version 23. The results were compared with international reference using a one-sample *t*-test with 95% confidence intervals, and *P*-values less than 0.05 were considered significant.

RESULTS

The independent *t*-test showed a significant decrease in FFP volume ranging (90-136 ml) compared to the international standard (150-250 ml), *P*-value = 0.00. Also, the pH was significantly different from the international standard, and the tested FFP was slightly acidic, ranging from (6.8-7.1) with a *P*-value = 0.00. in contrast, the study showed no significant difference in the mean of PT and PTT (*P*-value= 0.299, 0.079 respectively), as shown in (Table 1).

The count of residual cells in tested FFP bags showed an increased number of RBCs and WBCs compared to the international standard (*P*-value = 0.00). In contrast, the platelets count did not show

significant statistical differences p-value =0.493 (Table 2).

Table 1: The tested FFP bags compared to international standards

Analyzed parameters	International standerd	Mean of Tested bags	*P*-value
Volume	150-250ml	120	0.00
pH	7.2-7.4	6.98	0.00
PT	11-16 Sec	15.3	0.299
APTT	26- 40 Sec	37.1	0.079

Table 2: Residual cells in tested FFP bags compared to the standard range.

Blood cell type	(Cell count range) mean	International standerd Range	P-value
RBCs $\times/10^{12}$cells/L	(0.0-6) 1.12	< 0.6	0.000
WBCs $\times$ 10^9 cells /L	(0.0-0.9) 0.24	< 0.1	0.000
PLTs $\times 10^9$ cells /L	(0.0-3.1) 2.61	< 5.0	0.493

DISCUSSION

Quality control of blood and its components ensures the availability of products with high-quality, maximum efficacy and minimal risk to recipients. The recommendation of the international guideline in the quality control for FFP is to collect fewer residual cells (WBCs, RBCs, and PLTs) (Wilsher C., *et al.*,2018). This study included 100 FFP bags in a hospital blood Bank in Khartoum state, Sudan. The quality of these bags was assessed by measuring total plasma volume, pH, PT, PTT, and residual cells.

The mean volume of 100 FFP tested was 120 mL with a range of 90-136mL. The study found a significant difference in bag volume compared to the internationally recommended volume (Uwamungu S., *et al.,* 2014 and Gunjan Bala *et al.,* 2019), studied the volume of 41 FFP units, and their result showed the mean volume was 217 mL with a range of 192-235 mL, which differed from our result. This difference may be due to the plasma separation process, based only on manual adjustment of the plasma volume with a plasma extractor. At the same time, the used bags do not contain red cell filters to ensure that most of the plasma volume has been appropriately collected.

Also, the pH of the tested bags was significantly different from the normal international plasma range, and this finding was inconsistent with other studies Uwamungu S., *et al.,* 2014 and Pták J., *et al.,*2000).

On the other hand, the analyzed PT and PTT values were within the standard, acceptable range, which was consistent with other published results by Pooja Y. and Modi *et al.* (2021).in south Gujarat.

The study also showed an increase in WBCs and RBCs count from the international reference range. This might be due to the triple plastic bags used in whole blood collection, which do not contain white and red blood cell filters during plasma separation, which is less costly than the bags with filters. Another cause could be an error in the centrifugal force used in the cold blood bank centrifuge. In addition, the result revealed that the number of PLTs count in the examined bags was within the standard reference value. The results justify the further development of the plasma separation process and demonstrate the importance of using triple bags with red and white cell filters to minimize the number of residual blood cells in the fresh frozen Plasma prepared in the future.

Conclusion

The study concluded that the plasma volume of FFP was less than international blood bank standards. The residual cells (RBCs and WBCs) were slightly increased

than the normal range, while the platelet was within the international range.

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