



ASSESSMENT OF VOLUME AND ACTIVITY OF CLOTTING FACTORS IN FRESH FROZEN PLASMA PRODUCED FROM WHOLE BLOOD IN BLOOD BANK

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ABSTRACT

Introduction: Plasma is the aqueous component of blood, Fresh-frozen plasma (FFP) is one of the plasma products frequently used to treat minor to major coagulation factor deficiency. The present study assessed the quality of prepared (FFP) by measuring the whole volume of FFP, concentration of FV, FVIII and fibrinogen. **Materials and Methods:** This was descriptive cross sectional study done in two blood bank hospitals at Khartoum state–Sudan, during the period December 2014 to February 2015, in which a total of 100 triple blood bags collected from blood donors and fresh plasma was extracted. From each prepared plasma bags FV, FVIII and fibrinogen were measured on Dia Lab Coagulometer Analyzer™, also the volume of the prepared plasma bags have been determined. **Results and discussion:** The study revealed that the activity of FV= 111.3%, FVIII=184.3 % and Fibrinogen=349.5mg/dl which is agreed with the international reference value of FFP in quality control of blood banks, while the mean volume for the studied FFP was 118ml which is less than the international reference value.

KEYWORDS: Factor V, Factor VIII, fibrinogen, fresh frozen plasma.

INTRODUCTION

Plasma is the aqueous component of blood in which many different cellular elements and macromolecules were suspended; moreover it contains plasma proteins which is the focus of interest for transfusion medicine, including specifically albumin, coagulation factors, and immunoglobulin.^[1]

Fresh-frozen plasma (FFP) is frequently used to treat minor to major coagulation factor deficits.^[2] also it use in treatment of patients with disseminated intravascular coagulation, liver disease patients and reversal of therapy with vitamin K antagonists.^[3]

Labile factors Factor V and VIII (V,VIII) beside fibrinogen activity are most important indicators mentioned in the current quality requirement of FFP,^[4] due to the effect of storage time and temperature on theses coagulation factors.^[5]

The aim of this study is to measure the level of labile factors (FV, VIII) and fibrinogen in plasma prepared from whole blood of Sudanese donors and compares them with international reference value in order to assess

the quality control of prepared fresh frozen plasma (FFP) in blood bank.

MATERIAL AND METHODS

A total of 100 FFP samples were collected randomly from prepared FFP units in Ibn Sina Hospital, department of blood bank Mohammed Salih Idress Center during the period from December 2014 to February 2015, all bags were negative for viral infection (Hepatitis B, C & HIV). Ethical clearance was approved and obtained from the Research Unit at Ministry of Health Sudan.

The whole blood units (450±50ml) were collected in triple bags containing 63mL of Citrate Phosphatase Dextrose Adenine-1(CPDA-1) and centrifuged within 8 hours of collection. A semi-automated extractor was used to separate the plasma within 30minutes, FV, FVIII and fibrinogen were measured on Dia Lab Coagulometer Analyzer™. Tests were run as per the manufacturer's instructions which measured the clot formation of the sample during the test. Factor V was assessed using factor V deficient plasma and Thromboplastin reagent (Technoclone GmbH, Vienna, Austria), factor VIII was

assessed using factor VIII deficient plasma, calcium chloride and actin-aPTT reagent (Technoclone GmbH, Vienna, Austria). fibrinogen level was estimate use modified Claus procedure using Thrombin reagent (Technoclone GmbH, Vienna, Austria).

Data were analyzed using SPSS program version 23, FV, VIII and fibrinogen were compared to international reference using one sample T- test with 95% confidence intervals P value < 0.05 were considered as significant.

RESULT

The total volume of 100 FFP bags was measured and ranged from 90-140ml with mean $\pm$ SD 118ml $\pm$ 9.7ml and the number of bags in different volumes shown in figure 1. T-test showed a significant difference in the mean of plasma volume of the tested bags from normal reference volume (150-250ml) mean 200ml P value=0.000.

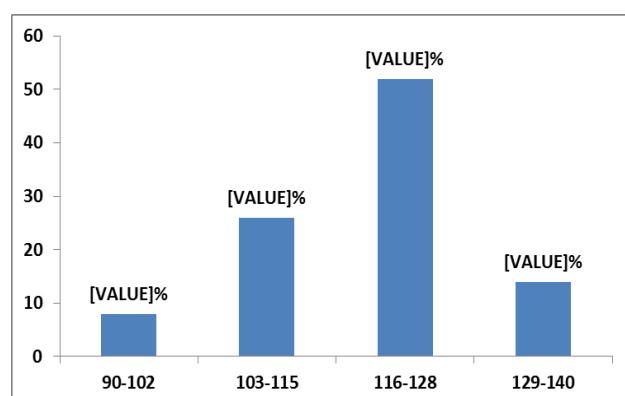


Figure 1:- Distribution of different volumes in ml for the studied FFP bags.

Factor five (FV) activity ranged from (26-175%) mean $120 \pm 89\%$, the bags FV activity distributed as in Figure 2. There was no significant difference between the activity of FV in our study and the blood bank reference range P value= 0.265 Table 2.

Factor VIII (FVIII) activity revealed range of activity from (60-264%) mean $184.3 \pm 60\%$, the bags FVIII activity distributed as in Figure 3. There was no significant difference between the activity of FVIII in our study and the reference range P value= 0.08 Table 2.

Fibrinogen level were ranged (243 - 562mg/dl) with mean 350 ± 55 mg/dl. Fibrinogen concentration in tested bags was distributed as in figure 4, also there was no significant difference obtained between fibrinogen level in our study and reference range P value=0.9 table 2.

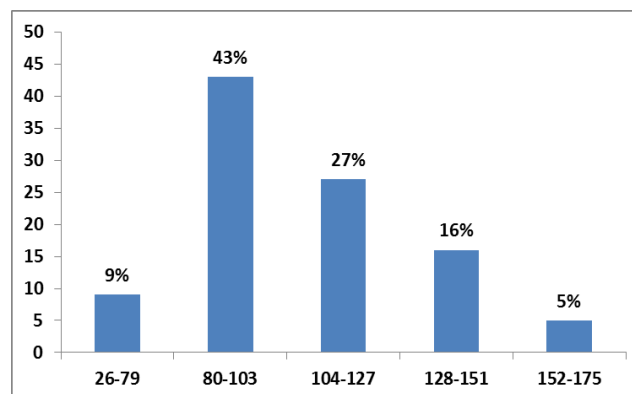


Figure 2: Frequencies of Factor V activity in the studied bags

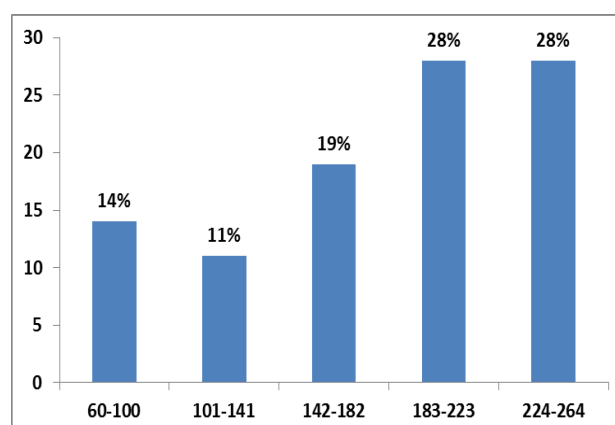


Figure 3: Frequencies of Factor VIII activity in the studied bags

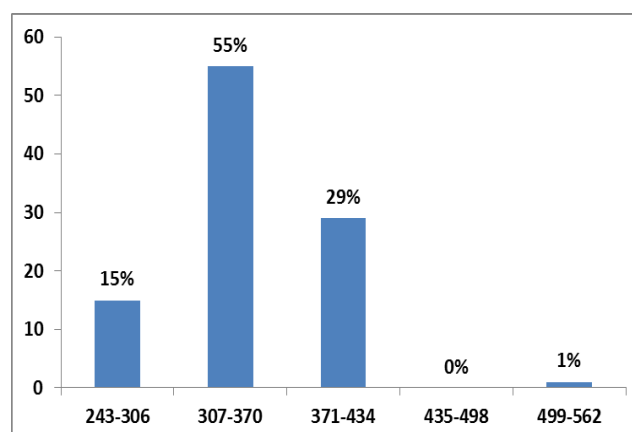


Figure 4: Frequencies of fibrinogen level in mg/dl among the studied bags

Table 2: Mean Values of tested parameters compared to reference range

Variable	Normal range	Sample Range	Mean $\pm$ SD	p-value
FV (%)	50 -200 %	26-175%	120 ± 89	0.265
FVIII (%)	50 -200 %	60-264%	184.3 ± 60	0.08
Fibrinogen mg/dl	150-400 mg/dl	243-562mg/dl	350 ± 55	0.9

DISCUSSION

Fresh frozen plasma (FFP) is indicated for the treatment and prevention of bleeding disorders due to deficit in minor or major coagulation factors, management of massive bleedings, liver disease, disseminated intravascular coagulation or reverse anticoagulant therapy.^[2] A hundred units of plasma were enrolled in this study to evaluate the quality of FFP by measuring factor V, VIII activity and fibrinogen concentration.

Our study revealed that the mean volume of plasma units were 118ml which is below the normal range of the guideline of council of Europe.^[6-8] (150-250ml) with P value =0.000, the decreased volume of all units might be due to the collection of low volume of whole blood at donation step (much bags less than 450ml) or due to imbalance centrifugation which have been observed at cold centrifuge through the process of plasma preparation in which turbid plasma was produced resulting in difficulty for plasma separation to the appropriate plasma volumes, further more using old plasma extractors devices and blood bags without red cell filters also resulting in low extracted plasma volumes.

Measurement of FV activity was 111% which is within the reference hematological range and these finding were agreed with other study done in Rwanda which find the activity of FV mean were 116.5%.^[5,9,10]

Factor VIII activity is the most valuable component in the quality control of FFP due to its potent therapeutic effects on coagulation factors deficiency treatment, our study revealed that the FVIII mean were 184.3%, which agreed the criteria of Council of Europe and hematological reference range.^[2,5]

Finally mean concentration of fibrinogen which obtained in this study were 349.5mg/dl which is according to reference hematological values, these finding is similar to those obtain by Uwamungu S.^[10-12]

CONCLUSION

We conclude that factor V, VIII and fibrinogen level were within the reference international value of FFP, but unfortunately the volumes of the FFP bags were less than international criteria.

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