

Quality Control of Fresh Frozen Plasma using Fibrinogen, Factor VIII, PT and aPTT as Measure: A Retrospective Study in a Tertiary Care Hospital in South Gujarat

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ABSTRACT

Introduction: Quality control of blood and its components ensures the availability of high quality product with maximum efficacy and minimal risk to recipients. As per standard guidelines, for quality assurance of FFP, 1% of all the units prepared or 4 units per month are tested for stable coagulation factors: Factor VIII, Fibrinogen levels, PT and aPTT levels. Current research aims to study the quality control of fresh frozen plasma using fibrinogen, Factor VIII, PT and aPTT as measure in a tertiary care hospital in south Gujarat.

Material and Methods: The retrospective data was collected from archives of blood bank from the period of 1st January 2017 to 31st December 2020 in new civil hospital, Surat. Out of total 35116 units collected, 35013 were processed for component separation. 0.6% of Fresh Frozen plasma (212/35013) was tested for total volume, fibrinogen content, factor VIII, PT and aPTT levels for quality control with the help of semi-automated coagulometer.

Result: 93.86% of FFP samples tested had factor VIII levels above 0.7 IU/mL and 98.58% of samples had fibrinogen content >200mg/dl. 99.055 of FFP samples had INR >0.8 and 76% of FFP tested had aPTT in the normal range.

Conclusion: It is concluded that quality of FFP being prepared at present blood bank meets the standard guidelines. Regular quality evaluation and maintenance of records is essential for effective standards and keeping check on any deficiency

Keywords: Components, Volume, Plasma, Quality Analysis

INTRODUCTION

Plasma separated from whole blood, frozen within 6-8 hours of collection and stored at -30°C or below is defined as fresh frozen plasma (FFP).¹ Usually 175- 250 mL of FFP is separated from standard donation of whole blood (450mL), containing 70-80 units/dl of factor VIII, factor IX, von Willebrand factor and other plasma clotting factors.² FFP is a constituent of blood needed to reconstitute the clotting properties of the patient's blood (by virtue of the properties of the various coagulation proteins) and very occasionally to restore the plasma volume of the patient. Therapeutically, transfusion of the FFP procedure is commonly used during severe bleeding episodes, or prophylactically in invasive surgery for non-bleeding patients. These coagulopathies may include liver diseases; vitamin K related coagulopathies, dilutional coagulopathy or disseminated intravascular coagulation (DIC).³ The efficient quality management of blood component including FFP is effective in blood bank

routine activity management and eventually betterment of patients. The demand for FFP is increasing in day to day practice, and its quality management is of utmost importance. Quality analysis of FFP depends on the concepts of quality control, quality assurance and quality management which aim at providing right blood to the right person at right place and time.⁴ Quality control of blood and its components ensures the availability of high quality product with maximum efficacy and minimal risk to recipients. As per standard guidelines, for quality assurance of FFP, 1% of all the units prepared or 4 units per month are tested for Factor VIII - ≥ 0.7 Units/mL and Fibrinogen levels 200- 400mg, Prothrombin time (PT), and Activated partial prothrombin time (Aptt).² These can be measured in a blood bank with the help of coagulometer by clotting assay.

Current research aims to study the quality control of fresh frozen plasma using fibrinogen, Factor VIII, PT and aPTT as measure in a tertiary care hospital in south Gujarat.

MATERIAL AND METHODS

Routine monthly quality check as per standard guidelines was carried out in the blood bank. The retrospective data was collected from archives of blood bank from the period of 1st January 2017 to 31st December 2020. During this period, total of 35116 units of blood were collected from healthy, screened donors (more than 45 kg) in sterile single, double, triple or quadruple blood bags with anticoagulant CPDA 1 after taking written consent. Out of these 35116 units, 35013 units (99.70%) collected in double triple or quadruple bags were processed for separation of components in a refrigerated centrifuge (Cryofuge 6000i, Heraeus, Germany). After holding time of 2-4 hours, units were centrifuged at 4000

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rpm for 10 minutes at 4°C for separation into Packed red blood cells (PRBCs) and fresh frozen plasma (FFP); 2 spin centrifugation at 1500 rpm for 10 minutes at 22°C followed by 2750 rpm for 10 minutes at 22°C for separation into FFP, PRBCs and Platelet concentrate. 212 of 35013 units of Fresh Frozen plasma were tested for total volume, fibrinogen content, factor VIII, and PT and aPTT levels for quality control, by semi-automated coagulometer (Coastat-1, Tulip Diagnostics India), as per standard guidelines given in ‘Technical Manual of Transfusion Medicine’, by Directorate General of Health Services Ministry of Health and Family Welfare, India, 2nd edition, 2003.

RESULTS

Total of 35116 units of blood were collected from healthy, screened donors, out of which 35013 units were processed for preparation of FFP from the period of 1 January 2017 to 31 December 2020. 212 out of 35013 units (0.6%) were tested for quality analysis parameters, i.e., total volume, Factor VIII and Fibrinogen levels, PT and aPTT. Mean volume was 224.96 ± 38.52 ml with range of 130- 368 mL which was well within the normal acceptable range. Mean fibrinogen levels were 343.30 ± 110.79 mg/dl with a range of 155-718.9 mg/dl; the cut off criteria for quality control is ≥ 200mg/dl (Figure 1).

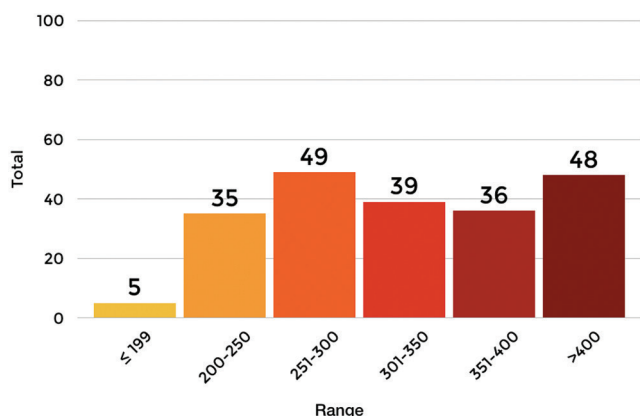


Figure-1: Bar chart showing Fibrinogen distribution in the FFP tested.

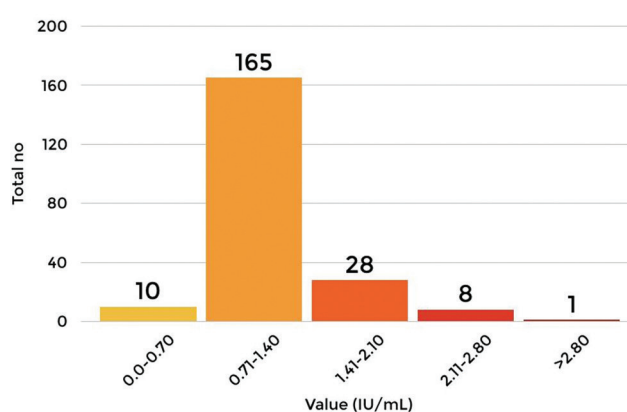


Figure-2: Bar chart showing Factor VIII distribution in the FFP tested.

Mean factor VIII levels were 1.18±0.62 IU/mL with range of 0.40 – 2.80 IU/MI, the cut off criteria for the purpose of quality control is ≥ 0.7 U/mL (Figure 2).

Mean PT level is 13.31 +/- 1.48 seconds with range of 9-16.7 seconds. Normal range of INR is 0.8-1.1. Out of 212 FFP tested only 2 are INR <0. 8 (0.94%) and 210 out of 212 (99.05%) are in normal INR range.

Mean aPTT level is 31.30 +/- 4.39 seconds with range of 22-48.1 seconds.

199 out of 212 (93.86%) of FFP samples tested had factor VIII levels above 0.7IU/mL and 209 out of 212 (98.58%) FFP tested had fibrinogen content between >200mg/dl. 210 out of 212 FFP tested (99.05%) had normal PT INR range (Table 1).

DISCUSSION

Plasma is the aqueous component of blood in which many different cellular elements and macromolecules are suspended, but it is the proteins that have been the focus of interest for transfusion medicine, including specifically albumin, coagulation factors, and immunoglobulins.⁵ Fresh frozen plasma is plasma separated from whole blood within 6-8 hours and rapidly frozen and stored at temperature below -30° C.

Utilization of fresh frozen plasma in clinical practice has

Parameter	Mean	Range	QC criteria	Concordance (%)
Fibrinogen (mg/dl)	343.30 ± 110.79	155-718.9	>200	98.58
Factor VIII (IU/mL)	1.18±0.62	0.40-2.80	>0.7	93.86
PT (seconds)	13.31 +/- 1.48	9-16.7	-	-
INR	1.02 +/- 0.13	0.79-1.34	>0.8	99.05

Table-1: Values of different Parameters for Quality Control of Fresh Frozen Plasma

Study	Fibrinogen (mg/dl) (Mean±SD)	Total(%) fulfilling QC cut-off for fibrinogen	Factor VIII (IU/mL) (Mean±SD)	Total(%) fulfilling QC cut-off for factor VIII
Sultan et al	247.17±49.69	100	0.84± 0.15	95
Agus N et al	-	-	1.0	75
Dogra M et al	270.66 ± 69.64	-	1.17 ±0.29	-
Bala et al	304.31±53.68	100	0.8±0.086	97.5
Present study	343.30 ± 110.79	93.86	1.18±0.62	98.58

Table-2: Values of Fibrinogen and Factor VIII in various studies for Quality Control of Fresh Frozen Plasma.

been increased in recent years: Plasma for transfusion is most often used where there is abnormal coagulation screening tests, either therapeutically in the face of bleeding, or prophylactically in non-bleeding patients prior to invasive procedures or surgery. For safe and effective preparation of blood and its components, in house quality control plays a very important role. Quality concepts comprises of a triad of quality control, quality assurance, quality management and their maintenance.⁶ Quality control is the backbone of all laboratory services including blood bank. Quality testing and monitoring of blood components have led to development of safer and more potent components for transfusion practices. Factor VIII, fibrinogen levels, PT and aPTT are internal quality control parameters required for quality analysis of fresh frozen plasma as per standard guidelines.² The present study assessed the volume, levels of factor VIII, Fibrinogen, PT and aPTT in stored units of FFP after they were thawed for utilization. 212 of 35013units (0.006%) of FFP prepared in five years were evaluated and levels of the parameters were in concordance with standard guidelines.²

93.86% of units tested had factor VIII levels above 0.7 U/ML and 98.58% units had fibrinogen levels more than 200mg/dl as per reference standards.² 99.05% of units tested were of normal PT INR range (Table 1).

Similar study was done by Sultan et al in which 100 units were tested for internal quality control. The mean factor VIII and fibrinogen levels were found to be 84.24± 15.01 IU/mL and 247.17±49.69 mg/dl for FFP respectively (Table 2). Almost all donors have fibrinogen ≥150 mg/dl, while only five (5%) donors had factor VIII below the desired levels.⁷

In another study done by Agus N et al, 30 units of FFP prepared within 8 hours of collection were tested for factor VIII levels (Table 2). Mean was 1.0 IU/mL with a range of 0.66- 1.47 IU/ML.⁸

Dogra M et al also did a study on comparative analysis of activity of Factors V, VIII and level of fibrinogen in Fresh Frozen Plasma (Table 2). They studied 100 units of FFP in which levels of fibrinogen were 270.66 ±69.64 mg/dl and Factor VIII was 117.205±29.01 %.⁹

Thus, all the above mentioned studies have evaluated quality control parameters as done in the present study and results are in concordance as per standard reference parameters.

FFP is generally not used in developed countries due to the availability of recombinant or factor concentrates; however, in developing countries like India utilization of FFP is more for various inherited coagulation disorders and diseases leading to liver dysfunctions.

CONCLUSION

Internal quality control thus enhances the quality of blood products and helps in monitoring of quality standards of blood bank. Regular quality evaluation and maintenance of records helps to keep up the working standards and any deficiency can be checked and curtailed. It is concluded that quality of FFP being prepared at present blood bank meets the international standards of factor VIII > 0.7IU/mL (93.86% of units tested) and fibrinogen levels of > 200 mg/dl(98.58%

of units tested). Regular update of quality assessment with respect to standard guidelines is important for effective production of blood components. A study of quality parameters as done above is essential for establishment of good transfusion practices.

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