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COMPARISION OF ACTIVITY OF COAGULATION FACTORS (VIII) & FIBRINOGEN IN FRESH FROZEN PLASMA AND FROZEN PLASMA: AN INSTITUTIONAL STUDY

Pathology

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ABSTRACT

Aim: To compare the level of plasma Factor (VIII) & Fibrinogen in FFP & plasma frozen 8 hours after collection of blood but within 24 hours.
Material & method: By Semi-automated method using Coagulometer Analyzer of Transasia Company, level of Factor(VIII) & Fibrinogen were compared in FFP & Plasma prepared 8 hours after phlebotomy, but within 24 hours.
Result: When blood was collected from a donor & stored for about 24 hours & thereafter, plasma was extracted from it, it showed significant decrease of Factor(VIII) level, but the decrease of Fibrinogen level was not significant.
Discussion: The result shows that, there is not much variation in the level of Coagulation Factors mainly Fibrinogen in FFP & Frozen Plasma after 24 hours. Therefore frozen Plasma can be a substitute for FFP in selected cases.

KEYWORDS

Factor (VIII), Fibrinogen, FFP, Frozen plasma within 24 hours (FP_{24})

INTRODUCTION:

Plasma is a component of blood but contains apart from cellular elements, Coagulation factors & Plasma proteins. It also contains water, electrolyte, albumin, immunoglobulin etc1. Plasma can be obtained for therapeutic use by processing donated whole blood or through an Apheresis Procedure[2]. It needs to be stored in frozen form to preserve the clotting factor activity.

Plasma can be of different types like Fresh Frozen Plasma (FFP), plasma frozen within 24 hours (FP_{24}), single donor plasma, cryoprecipitate reduced plasma, and pathogen inactivated plasma and Thawed plasma[4]. Fresh frozen plasma means the plasma which is prepared within 8 hours of phlebotomy. FP_{24} hours is the plasma which is prepared from the plasma within 24 hours of collection of blood.

Now many countries are preparing FP_{24} as it is easy to prepare in a blood bank with a limited workforce.

As per Drugs & Cosmetic Acts (1945), 1% or 4 units per month of any component prepared & stored should satisfy specific quality control parameters[5]. The Fresh frozen plasma is issued to treat Coagulopathy due to multiple factor deficiency or in therapeutic plasma exchange. National Blood Transfusion Council (NBTC) and International organizations like AABB & European Committee on blood transfusion have laid down the Quality Control parameters for FFP & FP_{24}. But assessment of various factors for quality control is expensive. So most blood banks rely on PT & APTT levels as screening approach to assess the quality of FFP & FP_{24}.

The usual practice is estimation of PT and APTT for measuring the quality parameters of FP_{24} & FFP. However as per guideline, checking of labile factor should be a routine procedure[5,6]. It helps in improving the method of preparation & storage of blood components.

As per standard protocol, while preparing FFP, plasma is separated & frozen at -60^{0}C /-80^{0}C within 6-8 hours of whole blood collection. On an average FFP contains 1IU/ml of all the clotting factors, 200-450 mg/dl of fibrinogen and 0.7IU/ml of factor VIII. But frozen plasma is the plasma which is separated and frozen between 8 hours & 24 hours after phlebotomy.

This study was designed to compare the level of Coagulation factors specially Fibrinogen & Factor (VIII) in FFP & Fp_{24}.

MATERIALS & METHODS:

The current study was a prospective study conducted over a period of one year from Jan 2019 to Jan 2020 in the department of Transfusion Medicine & Immunohematology of VSSIMSAR, Burla which is a tertiary care hospital. It caters to the need of blood transfusion for the patients of western Odisha & adjacent districts of other bordering states.

The Blood was collected by phlebotomy from eligible donors in 350ml blood bags containing anticoagulant CPDA1 solution. The flow of blood was constant & rapid. Total time of one unit collection was within 8 minutes.. Then components from the whole blood were prepared like FFP, RDP & Packed cell in the component Laboratory using cytocentrifuge machines of Thermofischer Company. Heavy spin (5000x g for 5 minutes) & light spin (2000x g for 3 mts.) were applied.

Inclusion Criteria: FFP& FP_{24} prepared from whole blood donation in the blood bank.

Exclusion criteria: FFP & FP_{24} which were discarded due to various reasons.

LABORATORY ANALYSIS:

Most of the blood banks in India rely upon PT & APTT for quality control of FFP & FP_{24}. Coagulation machine of Trans Asia Company installed in the blood bank was used for estimation of factor (VIII) and Fibrinogen in FFP and FP_{24}. For estimation of Factor (VIII), Factor (viii) deficient plasma, Actime-PTT and Cacl2 were used, where as for estimation of Fibrinogen , Vernal Owrens buffer & Thrombic reagent were used. But in our study, estimation of Factor (VIII) & Fibrinogen had been done for the purpose of quality control. All the tests were done by Coagulation analyzer ERBA ECL 412 & the procedure followed was as per instruction of the manufacturer. The results were interpreted using a reference supplied by the manufacturer. Positive & negative controls were used only when test was run..

RESULT:

A total no. of 50 units of FFP were compared with 50 units of FP_{24} in terms of Fibrinogen level & activity of Factor (VIII). As fibrinogen is a stable Coagulation Factor & Factor (VIII) is a labile Coagulation factor, longer storage of whole blood before processing would result in decrease in Factor (VIII). In our study we found decrease in (40%) activity of factor (VIII), but fibrinogen activity was not decreased.

The comparison between the result of heavy spin & light spin is also not significant.

Comparison of coagulation factors in plasma prepared 8 hours and 24 hours after whole blood donation, with reference range.

FACTORS	Whole blood storage time		Reference Range
	<8h (n=50)	24h (n=50)	
Factor VIII	1.2 IU/ml (0.6-01,64)	0.72 IU/ml (0.45-1.2)	0.5 IU/ml-1.75 IU/ml
Fibrinogen	280 mg/dl	276 mg/dl	200-400 mg/dl

DISCUSSION:

As per DGHS criteria, the ideal quantitative amount of all coagulation factors should be 1U/ml. As per quality control criteria, the level of fibrinogen should be 200-400 mg per one unit of FFP prepared in a

450ml. whole blood & the level of Factor (VIII) should be 0.7 1U/ml.

In our study the, loss of Factor(VIII) after storage was significant, as same result reported by Alakesh et al, Sheffield et al, Smith et al. Agus et al and , Cardigan et al etc. The decline of of Fibrinogen level was reported to be 1.4% which was not significant, the same finding has been observed by Alhumaidan et al & Sheffield et al.

When plasma was prepared by utilizing heavy spin & light spin & then level of fibrinogen & Factor (VIII) were estimated, no statistically significant variation was found.

The indication of plasma transfusion is where there is abnormal coagulation screening tests or in clinical conditions of internal / external bleeding. The common clinical conditions of Coagulopathy are Liver diseases, Vitamin K antagonist Coagulopathy, D.I.C & dilutional Coagulopathy. The loss of Coagulation Factors observed is unlikely to be clinically significant. Therefore both FP_{24} & FFP can be given in same clinical conditions.

Further, heavy spin or light spin doesn't make any difference as far as level of Fibrinogen & Factor (VIII) in FP_{24} & FFP is concerned.

CONCLUSION:

Therefore, in the blood banks where, staff constraint is there and when outdoor VBD camps are organized in far off places away from the blood bank, Plasma can be prepared even after 8 hours of collection without much decline in Labile coagulation factor to meet the demand for Plasma in needy patients.

CONFLICT OF INTEREST:

There are no conflicts of interest.

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