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Case Report

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Gender Influence on Changes of Coagulation Factors in Fresh Frozen Plasma at Kisii Teaching and Referral Hospital

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Abstract

Background: *Fresh frozen plasma is a critical substitute therapy in management of bleeding. Increased risk of venous thrombosis has been described to be associated with high plasma levels of several coagulation factors.*

Objective: *The objective was to evaluate gender influence on changes of coagulation factors in fresh frozen plasma at Kisii Teaching and Referral Hospital.*

Methodology: *This study was a longitudinal study involving time series analysis of fresh frozen plasma stored at -18°C for five weeks. A sample of 180 ml plasma was obtained from the blood centrifuged at 4000rpm which was aliquoted into three parts each containing 60ml. The first aliquot was used to assess the changes in coagulation factors in FFP at baseline during the first week of sample collection, the second aliquot was used to assess the changes in coagulation factors in FFP storage at -18°C temp after three weeks of storage, the third aliquot was used to assess the changes in coagulation factors in FFP storage at -18°C temp after five weeks of storage. Coagulation factor analysis was performed using Erba Mannheim ECL 105 coagulation analyzer, India factor results recorded. Thawing for subsequent coagulation factor analysis and serial testing of stored cryoprecipitate and fresh frozen plasma was done using Stericox Plasma Thawing Bath at 37°C, for 45 mins before before analyzing the samples. Standard storage conditions for the aliquots were monitored and maintained to ensure homogeneity.*

Results: *The findings showed no significant association between gender and FFP with p-values for three sampled weeks of the study with [0.333, 0.345 and 0.940] respectively greater than 0.05 standard alpha values. This means that, the coagulation factors in FFP were not affected by the gender of the blood donor.*

Conclusion: *There was no influence of gender on coagulation factors in fresh frozen plasma during storage at -18°C for 5 weeks at Kisii Teaching and Referral Hospital, Kisii County.*

1. Introduction

Fresh frozen plasma is the fluid portion of a unit of whole blood centrifuged, separated, and frozen solid at minus 18 °C [0 °F] or colder within eight hours of collection from whole blood donation or via apheresis device [1]. Fresh frozen plasma is stored at -18ºC or below and thawed in a water bath at 30 to 37ºC for 20 to 30 minutes or in an FDA-cleared device as quickly as 2 to 3 minutes before being administered and administered immediately after thawing. Thawed fresh frozen plasma is stored at 1 to 6ºC if not given immediately after thawing and discarded if not used in 24 hours. Coagulation factors are proteins withinside the blood that assist to manage bleeding [1]. The factors are generally enzymes [serine proteases] which act by cleaving downstream proteins. Coagulation system is a highly regulated cascade which involves intrinsic and extrinsic pathways leading to blood clot formation [1]. The clotting factors includes Factor I[fibrinogen], Factor II [prothrombin], Factor III [tissue thromboplastin or tissue factor], Factor IV [ionized calcium], Factor V [labile factor or proaccelerin], Factor VII [stable factor or proconvertin], and Factor VIII [antihemophilic factor], Factor IX [plasma thromboplastin component or the Christmas factor], Factor X [Stuart-Prower factor], Factor XI [plasma thromboplastin antecedent], Factor XII

[Hageman factor], and Factor XIII [fibrin-stabilizing factor] [2]. Several physiological and pathological variables affect coagulation factor levels [3].

The activity of clotting factors, predominantly factor VIII and factor V, decline gradually once thawed [4]. Fresh Frozen Plasma has specific indications which are limited to the treatment of deficiencies of coagulation proteins for which specific factor concentrates are undesirable or unavailable [5]. FFP is indicated in the replacement of isolated factor deficiencies and reversal of warfarin effect, treatment of thrombotic thrombocytopenic purpura, for antithrombin III deficiency, treatment of immunodeficiencies, treatment of conditions in which there are low blood clotting factors or low levels of other blood proteins and replacement fluid in plasma exchange. Fresh frozen plasma contains all of the clotting factors [5].

Changes in plasma coagulation factors during blood storage entail a gradual reduction in biologic activity [6]. Coagulation factor VIII and V activity experiences rapid loss during the storage period due to their lability [6]. By storage of 35 days, whole blood in CPD-Adenine, factor VIII 16–20% and factor V falls to 15–21% activity. There is only slight decline observed in factor X and II during the same storage time. Other factors except for factor VII are virtually unchanged. Factor VII reduces slightly but otherwise can be activated in the cold [6]. Factor VIII reduces in fresh frozen plasma that is stored for a year, and this is reduced by more rapid freezing to lower temperatures. Coagulation factors are properly maintained in platelets concentrates, with the exception of the labile factors. However, factor V falls more rapidly with room temperature storage and agitation while decline is lessened in factor VIII [6]. Low coagulation factor levels can cause blood clotting to fail which leads to unexplained bleeding episodes. Healthcare practitioner can determine the cause of the bleeding and the best treatment by measuring coagulation factors [7].

Changes occurring in coagulation factors in stored fresh frozen plasma have not been analyzed to evaluate its association with gender and thus, this study aimed at evaluating gender influence on changes of Coagulation factors in fresh frozen plasma at Kisii Teaching and Referral Hospital.

2. Methodology

2.1 Study site

This study was conducted at Kisii Teaching and referral hospital [KTRH] laboratory department. KTRH is located within Kisii town at the southern end of the western Kenyan highlands at an altitude of 1,660m above sea level. Coordinates for the town are 0°41'S 34°46'E / 0.683°S 34.767°E

2.2 Sample size

The study involved 108 eligible volunteer blood donors at Kisii Satellite Blood Transfusion Center, who met the donor suitability criteria following the World Health Organization guidelines.

2.3 Study design

This study was a longitudinal study involving time series analysis of fresh frozen plasma stored at -18°C for up to five weeks. Four hundred- and fifty-ml blood was collected into tetra blood bags containing citrate-phosphate-adenine anticoagulant-preservative [CPDA-1] as an anti-coagulant preservative for subsequent processing into fresh frozen plasma for storage at -18°C. The collected blood was centrifuged at 4000 RPM for 9 minutes within 5 - 8 hours after collection in a separate sanitized room where about 180ml plasma was formed as supernatant which then was separated and collected. The 180ml plasma obtained through centrifugation was aliquoted in three parts each containing 60ml. The first aliquot was used to assess the changes in coagulation factors in fresh frozen plasma at room temp at baseline during week one of collection [baseline], the second aliquot was used to assess the changes in coagulation factors in fresh frozen plasma storage at -18°C temp after three weeks of storage, the third aliquot was used to assess the changes in coagulation factors in fresh frozen plasma storage at -18°C temp after five weeks of storage. Coagulation factor analysis was performed using Erba Mannheim ECL 105 coagulation analyzer, India at KTRH Hematology laboratory. Thawing for subsequent coagulation factor analysis and serial testing of stored fresh frozen plasma was done using Stericox Plasma Thawing Bath, an equipment designed for rapid and uniform thawing of fresh frozen plasma [FFP] bags at 37°C, for 45 mins before the samples are analyzed by Erba Mannheim ECL 105 coagulation analyzer, India and results recorded to assess the coagulation factors changes and levels in fresh frozen plasma. Standard storage conditions for the aliquots were observed and maintained to ensure their coagulation factor levels homogeneity.

3. Data management and statistical analysis

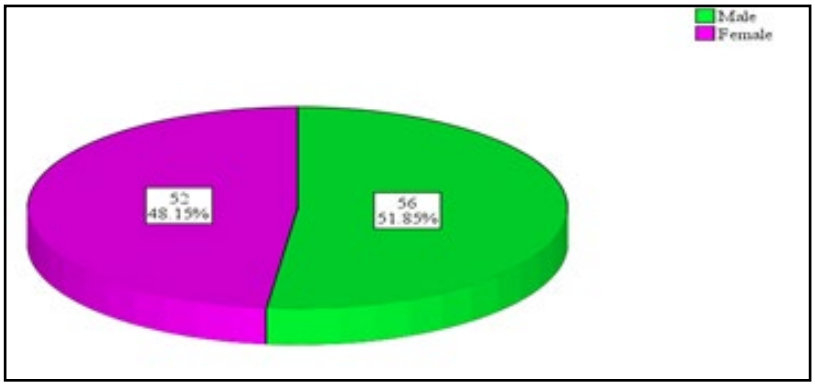
The data was recorded as numbers [value measured]. Statistical analysis was descriptive statistics. The raw data collected was entered in Microsoft office Excel spreadsheet before being transferred to SPSS software version 25.0. The findings were presented in tables and graphs.

4. Ethical considerations

Institutional ethical clearance was obtained from Baraton ethical review committee - [UEAB/ISERC/02/05/2022] and research permit obtained from National Commission for Science and Technology [NACOSTI] - NACOSTI/P/22/17542.

5. Results

The study involved 108 participants who included both male and female. From the analysis, most of the study participants 56 [51.85%] were male blood donors and 52 [48.15%] of blood donors being female. The analysis implies that, majority of the respondents in the study were dominantly male as compared to female as illustrated in the figure below.



Assessing the changes in coagulation factors in FFP during storage at minus 18°C for 5 weeks at KTRH was achieved by the use of Friedman analysis and findings were as illustrated below.

Time	n	Mean	Std. Deviation	Minimum	Maximum
FFPW1	27/108	114.03	19.49	62.60	152.60
FFPW3	87/108	105.70	19.42	54.80	144.20
FFPW5	89/108	95.30	18.62	48.50	133.70

Fresh Frozen Plasma in Week One (FFPW1), Fresh Frozen Plasma in Week three (FFPW3), Fresh Frozen Plasma in Week five (FFPW5)

Table 1.0: Descriptive Statistics for Coagulation Factors in Fresh Frozen Plasma

The mean of Fresh Frozen Plasma for the first week was 114.03 with a standard deviation of 19.49. This means that most of the fresh frozen plasma factors in week one did not vary widely, but were clustered around the mean FFPW1 of the 108 blood donors: the mean FFPW3 and FFPW5 was 105.70 and 95.30 respectively as reported in Table 4.5 above. This reveals existence of a small and significant difference in means for the fresh frozen plasma factors for the five-week time period, hence, for the variables stated above, there was normality in distribution

			Gender		Chi-square Test		
			Male	Female	Degree of Freedom	Chi-square value	P-value
W1FFP	Normal	Count	48	47	6	6.872	0.333
		% of Total	44.4%	43.5%			
	Abnormal	Count	8	5			
		% of Total	7.4%	4.6%			
W3FFP	Normal	Count	46	45	4	0.892	0.345
		% of Total	42.6%	41.7%			
	Abnormal	Count	10	7			
		% of Total	9.3%	6.5%			
W5FPP	Normal	Count	29	22	4	0.006	0.940
		% of Total	26.9%	20.4%			
	Abnormal	Count	27	30			
		% of Total	25.0%	27.8%			

Table 1.1: Chi-square Test for Influence of Gender on Coagulation Factors in FFP

The chi-square analysis results showed no association between gender and FFP. For the first week for the FFP for the male, 48 [44.4%] were normal and only 8 [7.4%] were abnormal, for the female, 47 [43.5%] were normal and 5 [4.6%] were abnormal. For week 5 of the study considering male, 29 [26.9%] were normal and 27 [25.0%] were abnormal and for the female, 22 [20.4%] were normal and 30 [27.8%] were abnormal. The chi-square test indicated by the p-values for three sampled weeks of the study with [0.333, 0.345 and 0.940] respectively greater than 0.05 standard alpha values. This means that, the coagulation factors in FFP were not affected by the gender of the blood donor.

6. Discussion

The chi-square analysis results showed no association between gender and FFP which was indicated by the p-values for three sampled weeks of the study with [0.333, 0.345 and 0.940]

respectively greater than 0.05 standard alpha values. This means that, the coagulation factors in FFP were not affected by the gender of the blood donor. The results of this study mirrored the findings of [8].

7. Conclusion

There was no influence of gender of the blood donor on changes in coagulation factors in fresh frozen plasma at Kisii Teaching and Referral Hospital.

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