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

Collince Odiwuor Ogolla1* and Rodgers Norman Demba2

1Department of Applied health science, School of Health Science, Kisii University, Kenya.
2Department of Medical Laboratory Science, School of Medicine, Maseno University, Kenya.

*Corresponding Author
Collince Odiwuor Ogolla, Department of Applied health science, School of Health Science, Kisii University. P.O Box 408-40200, Kenya.

Submitted: 2023, Apr 15; Accepted: 2023, May 19; Published: 2023, Jun 08

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 -18°C or below and thawed in a water bath at 30 to 37°C 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 6°C if not given immediately after thawing and discarded if not used in 24 hours. Coagulation factors are proteins withinide 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...
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.

<table>
<thead>
<tr>
<th>Time</th>
<th>n</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFPW1</td>
<td>27/108</td>
<td>114.03</td>
<td>19.49</td>
<td>62.60</td>
<td>152.60</td>
</tr>
<tr>
<td>FFPW3</td>
<td>87/108</td>
<td>105.70</td>
<td>19.42</td>
<td>54.80</td>
<td>144.20</td>
</tr>
<tr>
<td>FFPW5</td>
<td>89/108</td>
<td>95.30</td>
<td>18.62</td>
<td>48.50</td>
<td>133.70</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Gender</th>
<th>Chi-square Test</th>
<th>Degree of Freedom</th>
<th>Chi-square value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>48</td>
<td>6</td>
<td>6.872</td>
<td>0.333</td>
</tr>
<tr>
<td>Female</td>
<td>47</td>
<td>6</td>
<td>4.35%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Total</td>
<td>95.30</td>
<td>0.006</td>
<td>0.940</td>
<td></td>
</tr>
</tbody>
</table>

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.

Acknowledgements
Special appreciation to my mentors and supervisors of this research project, Dr. Benson Nyanchongi [PhD] and Dr. Rodgers Norman Demba [PhD]. Special thanks to lecturers in the department of biomedical science for the skills and knowledge gained. Special thanks to KTRH, Kisii University and NACOSTI for the opportunity they gave me to carry out this study. My special thanks also go to my family, parents [Hellen Ogolla and Joseph Ogolla] and siblings without whom this incredible experience would not have been possible.

References