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RESEARCH ARTICLE
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AUDIT OF REQUESTS AND USAGE OF FRESH FROZEN PLASMA IN A TERTIARY CARE HOSPITAL

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ABSTRACT:

Background: Fresh Frozen Plasma (FFP) is a vital blood component used for hemostasis in cases of clotting factor deficiencies, coagulopathy, or ongoing bleeding. Even with stringent guidelines, its usage is often inappropriate, leading to increased costs and risks. This study audits FFP utilization in a tertiary care hospital to assess adherence to established guidelines and identify areas for improvement.

Method: A retrospective study was conducted over one year at a tertiary care hospital in Maharashtra. Data was collected for patients for whom FFP units were requested and transfused. Records reviewed included patient demographics, indications for FFP use, coagulation profiles, and departmental requests. Compliance with College of American Pathologists (CAP) guidelines was evaluated, and statistical analyses were performed.

Results: In this study a total of 381 patients were studied. The majority of FFP use was for surgical procedures (51.97%) and bleeding (23.88%) patients. The Cardiothoracic& Vascular Surgery department received maximum FFP units (35.43%). PT results were available for 60% of cases, with 25% showing deranged PT, indicating potential overuse in cases with normal PT values.

Conclusion: The audit reveals a significant discrepancy between FFP requests and issuance, highlighting potential over-requesting and stringent issuance criteria. Most FFP were used appropriately for surgery and bleeding, though there were instances of its use without clear indications. Regular audits and adherence to guidelines are crucial for optimizing FFP use and improving transfusion practices.

Keywords: *Fresh Frozen Plasma, transfusion guidelines, coagulation, audit, blood component utilization*

INTRODUCTION:

When whole blood (WB) component preparation was first introduced in 1960, both the efficacy and economics of using blood have been improved dramatically. Through this procedure, packed red blood cells (PRBC), random donor platelets (RDP), and fresh frozen plasma (FFP) can be extracted from a single unit of whole blood. [1]FFP is a blood component obtained from one unit of human blood that is centrifuged, separated, and then frozen at -80°C or lower within 6 hours of collection. [2]

All coagulation factors, including factor V and factor VIII, are present in it along with plasma proteins. Although stringent guidelines govern its use, FFP is often used indiscriminately in current clinical practice. [3]It is primarily used to achieve hemostasis in cases of clotting factor deficiencies, coagulopathy, or ongoing bleeding from various causes. [4] The inappropriate use of blood components might result in negative side effects, higher risk of transfusion-transmitted diseases and higher healthcare expenses. Allergies, anaphylaxis, acute lung injury from transfusions, and hemolysis caused by antibodies against blood group antigens—specifically A and B—are among these adverse consequences. Coagulation studies should be done to follow guidelines for the use of FFP for surgical or traumatic hemorrhage. [5]

Although the specific indications outlined by the College of American Pathologists (CAP) and the British Committee for Standards in Hematology (BCSH), global studies show a high rate of inappropriate FFP utilization. [6] Auditing blood and blood component transfusions based on established guidelines is essential for evaluating an institution's transfusion practices. This approach helps identify improper use of blood components and facilitates the implementation of corrective actions. [7] Although guidelines for FFP use exist, there are significant gaps in the literature, such as inconsistent guideline application, limited regional data, and insufficient outcome-based analyses. This study seeks to address these gaps through targeted audits, aiming to improve guideline compliance, reduce unnecessary transfusions, and enhance overall transfusion practices in a tertiary healthcare centre.

METHODOLOGY:

This was a retrospective study, conducted at the Blood Centre Division of Pathology Department of MGM’s Medical College & Hospital Chhatrapati Sambhajinagar, Maharashtra. This study was conducted from January 2019 to December 2019. Patients who got FFP transfusions from multiple departments and for whom FFP requests were submitted were included in the study. Patients who got FFP transfusions during the study period were identified by reviewing the department's component issue data.

The patients' coagulation profiles and physical and electronic medical records were examined. Records include the department that requested the FFP, the patient's presenting issues, the reason for the request, the date and quantity of transfusions, the patient's coagulation profile, any reasons of coagulopathy that were looked into, and the patient's ultimate result. The standards that were applied were the CAP guidelines. Usage that did not follow these guidelines was considered inappropriate. Bar charts were used to display the tabulated results.

FFP transfusion guidelines, CAP, 1994.[8]

1) When a patient's clinical course or history point to a coagulopathy brought on by acquired or congenital deficiencies in coagulation factors, together with ongoing bleeding or the requirement for invasive operations, the diagnosis must be backed by a minimum of one of the following criteria:

a) A prothrombin time (PT) greater than 1.5 times the standard range's midpoint.
b) A partial thromboplastin time (PTT) that is activated that is more than 1.5 times the upper bound of the normal range.
c) The coagulation test demonstrating a factor activity of less than 25%.

2) In cases of massive transfusion, where more than one blood volume is supplied in a matter of hours, and there is continuous bleeding along with the symptoms described in (1) of coagulation insufficiency.
3) To neutralize the effects of warfarin when acute hemostasis—especially if PT is longer than 18 seconds or INR is higher than 1.6—is required because of active bleeding, before urgent surgery, or before an invasive operation.
4) Prophylactic administration for patients with documented acquired or congenital coagulation factor deficits prior to surgery or an invasive procedure.
5) To correct deficits in protein C, protein S, heparin cofactor II, or antithrombin.
6) For plasma exchange in the management of hemolytic uremic syndrome and thrombotic thrombocytopenic purpura.

RESULTS:

Table-1: Distribution according to Gender in the study group

Gender	No of cases	Percentage	P-value
Female	159	41.73%	0.001
Male	222	58.27%	
Total	381	100.00%	

Among the study group, females comprised 41.73% of the cases, while males accounted for 58.27%. The P-value of 0.001 indicates a statistically significant gender disparity in the distribution of FFP transfusion events.

Table-2: Distribution according to Indications in the study group

Indication	No of cases	Percentage
Surgery	198	51.97%
Bleeding	91	23.88%
Deranged PT	39	10.24%
Warfarin toxicity	1	0.26%
Thrombocytopenia	1	0.26%
Trauma	2	0.52%
Dialysis	5	1.31%
Exchange Transfusion	3	0.79%
Sepsis	1	0.26%
Not known	40	10.50%

The distribution of indications in the study group is as follows: Surgery 51.97%, Bleeding 23.88%, Deranged PT 10.24%, Warfarin toxicity 0.26%, Thrombocytopenia 0.26%, Trauma 0.52%, Dialysis 1.31%, Exchange TX 0.79%, Sepsis 0.26%. The diagnoses were not mentioned on the requisition forms in 10.50% cases.

Table-3: Distribution according to department

Department	No of cases	Percentage
Medicine	66	17.32%

Surgery	68	17.85%
Obstetrics & Gynaecology(OBGY)	31	8.14%
Pediatrics	45	11.81%
Medical Intensive Care Unit	2	0.52%
Pediatric &Neonatal Intensive Care Unit	15	3.94%
Cardio Vascular &Thoracic Surgery	135	35.43%
Nephrology	3	0.79%
Hematology	7	1.84%
TB/Chest	3	0.79%
Orthopedics	3	0.79%
Other	3	0.79%

In the distribution of FFP transfusions by department, the largest number of cases was recorded in the Cardiovascular & Thoracic Surgery department, comprising 35.43%. The Surgery and Medicine departments followed, with 17.85% and 17.32% of cases, respectively. Pediatrics accounted for 11.81%, while OBGY had 8.14%. The Medical Intensive Care Unit had 0.52%, Pediatric & Neonatal Intensive Care Unit 3.94%, and Nephrology, Hematology, TB/Chest, Orthopedics, and other departments each had 0.79%, 1.84%, and 0.79% of cases.

Table-4: Distribution according to Prothrombin Time in the study group

Prothrombin time (PT)	**No of cases**	**Percentage**
PT available	231	60.62%
Deranged PT	97	25.45%
Normal PT	134	35.17%

In the study group, the distribution of FFP transfusions according to PT revealed that Prothrombin Time values were available in 231 patients (60.62%). Among the PT values available, 25.45 % were deranged, while 35.17% were normal.

DISCUSSION:

The indiscriminate use of blood and blood components is often due to their easy availability and inadequate clinician knowledge of recommended usage guidelines. Regular Blood Centre audits are essential to identify misuse and serve as a quality control measure. Increased inappropriate use of these components depletes limited resources, drives up healthcare costs, and elevates the risk of transfusion-transmitted infections (TTIs). [9]

The present study was performed at the tertiary care hospital over a period of 12 months. In this study overall 381 participants were enrolled. The gender distribution of the present study shows a notable difference, there were 159 females, accounting for 41.73% of the cases, while males constituted 222 cases, making up 58.27% of the total. **(Table 1)Shasi V. et al. [8]**included a total of 3,020 patients, in which 1,450 (49%) males and 1,570 (51%) females.

From the distribution of cases according to their indications, it can be concluded that surgery was the predominant reason, comprising over half of the cases at 51.97%. Bleeding and deranged PT were also significant indications, representing 23.88% and 10.24% respectively. Less common indications included dialysis (1.31%), exchange transfusion (0.79%), and trauma (0.52%). Warfarin toxicity, thrombocytopenia, and sepsis each accounted for only 0.26% of cases. Notably, 10.50% of

cases had an unknown indication, highlighting a need for better diagnostic clarity in a notable portion of the study group. **(Table 2)**

The results of this study were in concordance with the study done by **Lingegowda JB et al.**[5]in their study, department-wise distribution of FFP shows that Surgery received the most FFP transfusions, accounting for 49.27% of cases. The Medicine department followed with 21.25%, while Gynecology received 18.35%. Orthopedics and Pediatrics received smaller proportions, at 6.76% and 4.34%, respectively. This distribution highlights the predominant use of FFP in surgical settings, with significant but smaller usage in other departments.

Gomathi G et al. [10]conducted a study involving 148 patients, finding an overall appropriateness rate of 90% for transfusions. Significant differences were noted in the mean number of transfusions per department, with Nephrology and Urology (2.08 ± 1.98) and Gastroenterology (2.75 ± 1.39, P<0.006) showing statistical significance. In contrast, no significant differences were observed in the mean number of transfusions for General Medicine, Cardiology, Orthopedics, Obstetrics and Gynecology, General Surgery, Pediatrics, and Neurology.

In current study, the departmentwise distribution of FFP showed that the Cardiovascular & Thoracic Surgery department received the highest proportion, at 35.43%, followed by Surgery (17.85%) and Medicine (17.32%). Pediatrics received 11.81%, and OBGY accounted for 8.14%. Smaller proportions were noted in PICU/NICU (3.94%) and MICU (0.52%), with minimal use in Nephrology, Hematology, TB/Chest, Orthopedics, and Other departments, each ranging from 0.79% to 1.84 %.**(Table3)**

YadavA et al. [2]indicates significant variability in the appropriateness of FFP transfusions across specialties. While Gastroenterology and Neurology exhibited high rates of appropriate transfusions, cardiothoracic surgery and Oncology had notable proportions of inappropriate use. Overall, 70.51% of FFP transfusions were deemed appropriate, but 29.48% were inappropriate, highlighting a need for improved compliance with transfusion guidelines.**Waheed U et al**. **[11]**found significant variability in the appropriateness of FFP transfusions across clinical units. The Thalassaemia centre had 100% appropriateness, while Oncology had all transfusions deemed inappropriate. Other units exhibited mixed results, with Paediatric units showing the highest appropriateness at 70% and NICU the lowest at 7%. Overall, 52% of FFP transfusions were appropriate, and 48% were inappropriate.

In present study, the distribution of FFP transfusions based on PT shows that PT values were available for 60.62%of cases. Among these, 25.45% had deranged PT, indicating abnormal clotting and a potential need for FFP. In contrast, 35.17% had normal PT values, suggesting that FFP was used in some cases without evident clotting abnormalities. The P-value of <0.0001 indicates a statistically significant finding highlighting the need for careful evaluation of PT results before FFP transfusion to ensure appropriate use.**(Table 4)Waheed U. et al.[11]**in their study demonstrated that, a total of 73 patients with known coagulation factor deficiencies or deranged coagulation profiles were identified. Of these, 46 were hemophilic, and 27 had other disorders affecting PT/APTT. **Emektar et al.(12)** indicate that FFP transfusion significantly improved coagulation parameters in patients. The median INR decreased from 6.2 to 2.5, PT from 71.5 seconds to 27.4 seconds, and PTT from 52.4 seconds to 36.3 seconds, demonstrating effective correction of coagulopathy.

The findings of this study highlight significant variability in FFP transfusion appropriateness across clinical departments, with many transfusions being inappropriate. The findings highlight the need for strict compliance with transfusion guidelines. Regular audits and clinician education is important to prevent misuse, preserve resources, and minimize transfusion-transmitted infection risks. These measures will ultimately improve patient outcomes and enhance the efficiency of blood transfusion services in healthcare settings.

CONCLUSION

In conclusion, the audit of FFP usage in our tertiary care hospital has provided valuable insights into the current practices and trends in Transfusion Medicine. Through a meticulous examination of the data, we have identified areas of improvement and highlighted successful protocols in place. The

findings underscore the importance of promoting evidence-based transfusion practices to optimize patient care and ensure judicious use of this critical blood component.

Limitations:
The duration of study is limited i.e.one year.

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