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A STUDY OF FRESH FROZEN PLASMA AND ITS UTILIZATION IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Background; Fresh frozen plasma (FFP) is a life-saving blood product. It is particularly critical in developing countries like India. Often the demand for FFP cannot be matched by the supply. The World Health Organization (WHO) reports that 87.5% of developing countries struggle to collect even half the FFP their populations require. Understanding current FFP usage patterns and trends can help predict future needs and identify areas where more efficient use could help preserve this valuable resource. This knowledge can also improve clinical decision-making, optimize blood bank resource allocation, and streamline FFP inventory management[1,2].

Materials and method: This study was undertaken in the Department of Pathology, Yenepoya Medical College, Derelakatte, Mangaluru. It is a cross-sectional study that includes systematic sampling data collection (from August 2022 – December 2023). 355 patients receiving FFP from the Yenepoya Blood Centre were included in the study. Data such as age, gender and indication for the transfusion was collected from hospital records while taking care of patient privacy. Pre and post transfusion PT, aPTT and INR values were collected from the hospital database.

Results: Our study found that fresh frozen plasma (FFP) is most commonly used to correct abnormal coagulation profiles. This highlights its critical role in managing bleeding risks during surgery. FFP was also used for chronic kidney disease, postpartum hemorrhage, dialysis support, and in cases of increased INR or low platelet counts. General medicine department requested FFP most frequently, followed by obstetrics/gynecology and nephrology, demonstrating its use across various specialties. The study showed that FFP effectively reduced prothrombin time, aPTT and INR levels, which is crucial for patients with coagulopathies and bleeding risks. These findings emphasize the importance of using FFP judiciously based on clear indications to ensure patient safety and optimal outcomes. However, further research is needed to understand the long-term effects of FFP and refine guidelines for its best use in clinical practice.

Conclusion: By examining departmental requests, we were able to identify trends in the number of FFP units used and the corresponding clinical indications and effects of transfusion. The paired t-test revealed a statistically significant difference ($p < 0.001$) in PT, aPTT, and INR values before and after FFP transfusion, indicating substantial improvements in these coagulation parameters.

Keywords: *FFP, Coagulation, Bleeding, Haematological Parameters.*

INTRODUCTION

Over the last few centuries, medicine has made great advancements in understanding the circulatory system. Every year, approximately a total of 118.5 million blood donations are gathered globally, with 60% coming from low- and middle-income countries, which have around 84% of the global population. High-income nations exhibit markedly higher rates of blood donation, averaging more than 6.3 times that of low-income countries.[1,2]

The impact of FFP is assessed by measuring the patient's coagulation profile before and after transfusion via changes in parameters such as PT, aPTT, and INR. These measurements help clinicians evaluate the therapeutic response and guide further management decisions[3].

Administering 1 mL of FFP per kg of body mass raises coagulation factor levels by approximately 1 IU/dL.This increment in factor levels contributes to correcting abnormal coagulation profiles, such as prolongations in PT, aPTT, and INR. By addressing deficiencies and enhancing coagulation factor levels, FFP administration helps restore balance and harmony within the coagulation cascade, promoting effective clot formation and reducing the risk of bleeding complications. Monitoring changes in coagulation parameters post-transfusion allows clinicians to gauge the effectiveness of FFP therapy and adjust treatment strategies accordingly, ensuring optimal patient care[3,4].

The application of FFP in clinical settings has shown different patterns and irregularities among various healthcare specialties, and medical professionals. Indiscriminate utilization of FFP can lead to adverse effects and complications. Analyzing the utilization trends and indications for FFP was crucial for blood banks to effectively manage procurement, allocation, and distribution processes[5-7].

As such, our study aimed to address this gap by investigating the purposes for transfusion of FFP and evaluating their efficacy in modulating coagulation profiles. By studying how FFP impacts coagulation profiles, our goal was to expand the understanding of FFP transfusion practices, providing insights to assist clinicians and blood bank personnel in making well-informed decisions about its use.

METHODOLOGY

The demographic data (except identifying details like name/address/phone number),blood group data and other laboratory parameters, clinical diagnosis, and indication for transfusion of 355 in-patients to whom blood/blood components are issued from the blood bank attached to the Yenepoya Medical College Hospital were collected on a daily basis for a period of two years. Pre and post transfusion PT, APTT and INR data was collected whenever available. The data collected was analyzed to identify trends in the indications for transfusion, the components transfused, the clinical diagnoses and in variations of PT, APTT and INR. The data was analyzed to find any correlation between the use of fresh frozen plasma and the various clinical departments requesting them and the indications for transfusion.

RESULTS

SOCIO-DEMOGRAPHIC DETAILS

In our research, 355 study participants were included. The mean age of the study population was 54.75 +/- 16.8 years, with ages ranging from 20 to 85 years (Table 6). The study included 53.5% females and 46.5% males. In our study, 52.9% of the participants were aged between 30 and 59 years, with the majority falling within the 40 to 49-year age bracket.

Table 1 : SOCIO DEMOGRAPHIC FEATURES

Age (in years)		Gender		
		Females	Males	Tota(1
20-29	Number	21 (5.9%)	0	21 (5.9%)
30-39		33 (9.3%)	23 (6.5%)	56 (15.8%)
40-49		39 (11%)	35 (9.9%)	74 (20.8%)
50-59		35 (9.9%)	23 (6.5%)	58 (16.3%)
60-69		28 (7.9%)	28 (7.9%)	56 (15.8%)
70-79		23 (6.5%)	37 (10.4%)	60 (16.9%)
80-89		11 (3.1%)	19 (5.4%)	30 (8.5%)
Total		190 (53.5%)	165 (46.5%)	355 (100%)

In the present study a total of 355 individuals were considered. It may be observed from Table No. 7 That 188 (52.9%) of the individuals were in the age group of 30 to 59 years. The mean age of the study participants was found to be 54.7±16.8 years.

TABLE 2 : MEAN AGE OF THE STUDY PARTICIPANTS

	N	Minimum	Maximum	Mean	Std. Deviation
Age(in years)	355	20	85	54.75	16.848

DEPARTMENT WISE DISTRIBUTION OF FFP USAGE

In the current study, the assessment of FFP transfusion requests by the department revealed that the General Medicine department accounted for the highest proportion, with 23.9% of the total requests. The Obstetrics and Gynecology (OBG) department followed, representing 14.9%, while the Nephrology department contributed 12.1% of the requests. Other significant contributors included the Medical Intensive Care Unit (MICU) at 10.7% and the Oncology department at 10.4%, reflecting a diverse range of clinical needs across multiple specialties (Figure 10).

TYPES OF REQUESTS FOR FFP

The analysis of the types of requests for FFP showed that the majority, 56.1%, were urgent, indicating a high demand for immediate transfusion needs. Planned requests constituted 43.7%, reflecting a significant portion of FFP use for scheduled and non-emergency situations.

INDICATIONS FOR FFP USE

In our research, the analysis of FFP transfusion indications revealed that 40% of the cases were attributed to an abnormal / deranged coagulation profile (DCP), representing the most common reason for FFP use. Surgical procedures accounted for 36.9% of transfusions, making it the second most frequent indication. Bleeding was the reason for FFP administration in 10.7% of cases. Other indications included dialysis at 4.8%, chronic kidney disease (CKD) at 2.5%, and postpartum hemorrhage (PPH) at 1.7%. Less common reasons for FFP transfusion included increased INR and low platelet counts, each constituting 0.6%, and plasmapheresis at 1.1%. The least frequent indications, each contributing 0.3%, were abnormal uterine bleeding (AUB), poisoning, and thrombocytopenia. These findings highlighted the diverse clinical contexts in which FFP was utilized, with a significant focus on coagulation-related issues and surgical needs.

Within the study period for the total number of study participants, 570 units of FFP was issued for a total of 355 patients.

EFFECT OF FFP IN COAGULATION PROFILE

COMPARISON OF PRE AND POST TRANSFUSION PT

Table No. 8 depicts the pre and post-test PT values. The mean pre transfusion PT and post transfusion PT value is found to be 27.9 ± 9.5 and 13.0 ± 1.1 respectively. Using Paired t test statistically very high significant difference is observed in the pre and post transfusion PT ($p<0.001$).

Table 3 : PRE AND POST TRANSFUSION PT

	Mean	n	Std. Deviation	t test	P value
Pre transfusion PT	27.986	355	9.5833	29.15	<0.001
Post transfusion PT	13.005	355	1.1232		

COMPARISON OF PRE AND POST TRANSFUSION APTT

The mean pre and post-transfusion APTT values are presented in Table No.9. The mean pre-transfusion APTT and post-transfusion APTT value is found to be 85.1 ± 33.0 and 24.3 ± 7.6 respectively. Using Paired t test statistically very high significant difference is observed in the pre and post transfusion APTT ($p<0.001$).

Table 4 : COMPARISON OF PRE AND POST TRANSFUSION APTT

	Mean	n	Std. Deviation	t test	P value
Pre-transfusion APTT	85.112	355	33.0653	34.030	<0.001
Post-transfusion APTT	24.324	355	7.6304		

COMPARISON OF PRE AND POST-TRANSFUSION INR

In Table No. 10, the mean pre and post-transfusion INR values are presented. It may be observed from the table that the mean pre-transfusion INR and post-transfusion INR value is found to be 3.46 ± 0.6 and 1.63 ± 0.52 respectively. Hence on using Paired t test statistically very high significant difference is observed in the pre and post transfusion INR ($p<0.001$).

Table 5 : COMPARISON OF PRE AND POST-TRANSFUSION INR

	Mean	N	Std. Deviation	t test	P value
Pre transfusion INR	3.4645	355	.68508	42.960	<0.001
Post transfusion INR	1.6359	355	.52394		

DISCUSSION

This study aimed to analyze FFP usage to better understand its precise indications, necessity, and effects on the coagulation profile. The major benefit of this study is that it can provide evidence-based guidelines for more rational and judicious use of FFP, potentially improving patient outcomes and optimizing resource utilization in healthcare settings. Research on the specific indications for FFP and its impact on coagulation, especially among the Indian population, is currently limited.

In our research, 355 study participants were included. The mean age of the study population was 54.75 +/- 16.8 years, with ages ranging from 20 to 85 years. The study included 53.5% females and 46.5% males. In our study, 52.9% of the participants were aged between 30 and 59 years, with the majority falling within the 40 to 49 year age bracket. The blood analysis revealed that the majority of patients in the study had O-positive blood type (81.4%), followed by B Positive (7.3%) and A Positive (5.1%), with the least common being AB Negative (0.3%). In our study of 355 patients, approximately 570 units of FFP were administered. About 50.7% of the patients required only a single unit of FFP, while 45% needed two units. For five patients, each received eight units of FFP. Additionally, 2.3% of the participants required three units of FFP. The average utilization rate of FFP in our study was 1.60 per person.

The review of exact clinical diagnoses for which FFP was utilized revealed that CKD was the leading indication, accounting for 16.1% of the cases. Anemia was also a common reason, contributing to 14.4% of FFP transfusions. Surgical procedures were associated with 13.5% of FFP usage, reflecting a significant portion of cases. Other notable diagnoses included leukemia (6.2%), carcinoma (5.6%), and liver cirrhosis (5.4%). The study also showed that 7.9% of the cases involved FFP use for patients undergoing lower segment cesarean section, and 4.5% for thrombocytopenia. Bleeding disorders, including PPH, represented a smaller yet significant fraction of the cases, with PPH alone accounting for 2.5%. Various other conditions such as fractures, hepatitis, and complications from conditions like dengue, diabetes, and gastrointestinal issues collectively made up the remaining percentage. This distribution highlighted the diverse clinical scenarios necessitating FFP transfusions, emphasizing its critical role in managing a wide range of medical conditions.

COMMON INDICATIONS FOR FFP TRANSFUSION ACROSS VARIOUS STUDIES

Table 6 : Common indications for FFP transfusion across various studies

No	Study	Year of Study	The two most common indications mentioned
1	Choudary et al [63]	2005	CLD, DIC
2	Maheshwari et al [64]	2018	DIC, Massive transfusion
3	Jyoti et al [65]	2016	Massive transfusion, Surgery
4	Kulkarni et al [66]	2012	DIC, Surgical bleeding
5	Prinja et al [67]	2017	DCP, Bleeding
6	Shinagare et al [68]	2010	DIC, Bleeding
7	Shah et al [69]	2020	Bleeding, RTA
8	Trupti et al [70]	2017	DCP, Therapeutic plasma exchange
9	Sangeetha et al [71]	2012	Surgery, Bleeding
10	Simon et al [77]	2017	Bleeding, Pre-procedural prophylaxis
11	Makroo et al [78]	2007	Bleeding, Liver disease
12	Sandhya et al [79]	2020	Bleeding, DCP
13	Sreelakshmi et al [80]	2021	DCP, Bleeding
14	Manish et al [81]	2017	Liver disease, DIC
15	Romana Akbar et al [82]	2016	Bleeding, Neonatal sepsis prophylaxis
16	Ramya et al [83]	2020	Bleeding, DCP
17	G Ene et al [84]	2022	Surgery, Bleeding
18	Sufana et al [93]	2019	Bleeding, Surgery prophylaxis
19	Puri et al [93]	2019	Surgery, Thrombocytopenia
20	Sasi et al [94]	2023	DIC, Liver diseases
21	**Our study**	**2024**	**DCP, Surgery, Bleeding, CKD**

EFFECT OF FFP IN COAGULATION PROFILE

Our analysis showed that the mean pre-transfusion PT was 27.9 seconds, which decreased significantly to a mean post-transfusion PT of 13.0 seconds, indicating a 53.4% reduction. The paired t-test demonstrated a statistically very high significant difference between pre-and post-transfusion PT values ($p<0.001$), confirming the efficacy of FFP in significantly reducing PT. This substantial improvement underscored the effectiveness of FFP in correcting coagulopathy and enhancing coagulation function.

The present study indicated that the mean pre-transfusion aPTT was 85.1 seconds, which was significantly reduced to a mean post-transfusion aPTT of 24.3 seconds, reflecting a 71.4% decrease. The paired t-test confirmed a statistically very

high significant difference in aPTT values before and after transfusion ($p<0.001$). This substantial reduction in aPTT demonstrated the critical role of FFP in effectively normalizing prolonged aPTT, thereby improving coagulation profiles in patients.

Our study also revealed that the mean pre-transfusion INR was 3.46, which decreased significantly to a mean post-transfusion INR of 1.63, indicating a 52.9% reduction. This marked decrease in INR highlighted the efficacy of FFP in significantly lowering elevated INR levels, thereby improving coagulation and reducing the risk of bleeding complications in patients.

LIMITATIONS:
The study does not differentiate between appropriate and inappropriate use of FFP.

CONCLUSION

Blood transfusions pose safety and cost concerns, requiring proper justification. Fresh frozen plasma, initially used for volume replacement since 1941, is now mainly used for managing excessive bleeding or in patients with abnormal coagulation tests undergoing invasive procedures. The main uses include treatment for bleeding, warfarin reversal, and coagulation factor deficiencies, but if not judiciously used can lead to risks like allergic reactions and volume overload. Our study aimed to evaluate FFP usage trends, indications, and coagulation effects to improve its clinical application in tertiary care hospital settings.

Our research revealed that the predominant indication for FFP transfusion was to manage abnormal coagulation profiles, which emerged as the most common reason for its use. This was followed closely by surgical procedures, highlighting the significant role of FFP in perioperative care where managing bleeding risks is crucial. Other notable indications included treatment for chronic kidney disease and postpartum hemorrhage, as well as support for dialysis and cases of increased INR or low platelet counts. The distribution of FFP requests varied across departments, with General Medicine leading in the number of requests, followed by Obstetrics and Gynecology, and Nephrology, highlighting the diverse clinical settings where FFP is vital.

The effectiveness of FFP in reducing prolonged prothrombin time and normalizing aPTT levels was evident, demonstrating its critical impact on enhancing coagulation function and managing coagulopathy-related conditions. Our analysis also underscored the significant reduction in INR post-transfusion, which is crucial for patients at risk of bleeding or clotting disorders. This marked improvement in coagulation parameters post-FFP transfusion validates the efficacy of FFP in reducing elevated INR levels and preventing bleeding complications. The study's findings emphasize the importance of precise indications and judicious use of FFP to ensure patient safety and optimize treatment outcomes. However, further research is needed to explore the long-term impacts of FFP use and to refine guidelines for its appropriate and effective application in clinical practice.

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