https://doi.org/ 10.33472/AFJBS.6.Si2.2024.1797-1805

African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper Open Access

RETROSPECTIVE EVALUATION OF INDICATIONS AND STUDYING THEIR RELEVANCE IN FFP TRANSFUSIONS DONE AT A TERTIARY CARE CENTRE OVER A PERIOD OF 4 YEARS

Dr. TRSN Lakshmi, Dr. J. Bhagya Lakshmi, Dr. K. Lakshmi, Dr. V. Sivasankara Naik*, Dr. K. Sreedhar Babu, Blood Centre, Government General hospital, Ananthapuram.

1,2,5- Assistant Professors, Department of Pathology, GMC, Ananthapuram

3- Associate Professor, GMC, Ananthapuram

(* Corresponding Author - Professor and HOD, Pathology, GMC, Ananthapuram)

Article History

Volume 6,Issue Si2, 2024

Received:13 Mar 2024

Accepted : 16 Apr 2024

doi: 10.33472/AFJBS.6.Si2.2024. 1797-1805

Abstract:

Introduction: Fresh Frozen Plasma (FFP) is a frozen plasma product that contains all clotting factors, especially the labile factors V and VIII: useful for clotting deficiencies other than Hemophilia A, VWD and hypofibrinogenemia. It is generally used in therapeutic plasmapheresis procedures as a replacement fluid to maintain intravascular volume.

Objective: To evaluate the utilization of FFPs in relevance to their indications.

Materials and Methods: Retrospective evaluation of FFPs issued in the Govt. General hospital, Ananthapuram from November 2019 to October 2023 to different departments for various indications.

Results: During the four-year period from 2019 to 2023, a total of 1644 units of FFP were received by 756 patients for various indications into different departments. The department with the highest number of units of request was surgery with a total of 481 but according to the number of patients, department of Paediatrics stood before all accounting for 27.8%. Most common indication was for Surgery either prophylactic or therapeutic from surgery department, most relevant and appropriate request was from labour room of OBG department for APH/PPH while the most inappropriate request was found to be for Malnutrition/Anemia.

Conclusion: Educational interventions and regular audits are necessary to prevent inappropriate usage of FFP in transfusions.

Key words: FFP, Fresh Frozen Plasma, Transfusions

Introduction:

Fresh Frozen Plasma (FFP) is a frozen plasma product that contains all clotting factors, especially the labile factors V and VIII: useful for clotting deficiencies other than Hemophilia A, VWD and hypofibrinogenemia[1]. It is prepared from whole blood, freezing various plasma factors or from the plasma collected through a single donor.

It is generally used in therapeutic plasmapheresis procedures as a replacement fluid to maintain intravascular volume and oncotic pressure[1]. However, there are risks of transmission of infectious diseases, additive effect contributing to citrate toxicity and sensitization to plasma proteins and therefore the use of FFP should be reserved for treatment of TTP cases and related disorders.

Inappropriate requests for plasma transfusions, expose patients to risks of transfusion, reduce the availability of FFP which can be allocated to the production of plasma derivates to needs of many other patients[2].

Present study therefore aimed to evaluate the indications for which FFPs were requested in our hospital and check their relevance with the transfusion guidelines provided by various National and International systems for FFP. AABB[3] provided guidelines are taken in the present study. There are many other guidelines available such as The College of American Pathologists (CAP), The British Committee for Standards in Haematology (BCSH) and National guidelines like Directorate General of Health Services from the Ministry of Health services , Government of India.

Table- Indication guidelines for FFP transfusion as per AABB[3]

S.No	Indications
1	Management of preoperative or bleeding patients who require replacement of multiple plasma coagulation factors(Ex: Liver disorders, DIC)
2	Patients undergoing massive transfusion who have clinically significant coagulation deficiencies.
3	Patients taking Warfarin who are bleeding or need to undergo an invasive procedure before Vit K could reverse the Warfarin effect or who need only transient reversal of Warfarin effect
4	Transfusion of plasma exchange in patients with TTP
5	Management of patients with selected coagulation factor deficiencies, congenital or acquired, for which no specific coagulation concentrates are available.
6	Management of patients with rare specific plasma protein deficiencies, such as CI inhibitor, when recombinant products are unavailable.
	Contraindications
1	When coagulopathy can be corrected with specific therapy
2	When blood volume can be replaced with other components/volume expanders

Objective: To evaluate the utilization of FFPs in relevance to their indications.

Materials and Methods:

This was a retrospective study done with the available records taken from Blood Centre in Govt general hospital, Ananthapuram from November 2019 to October 2023. Number of patients who requested FFPs were noted along with the total number units. Records showing issues of FFPs along with other blood components like packed cells/whole blood/platelets for same patients were excluded from the study.

The records were thoroughly analyzed for demographic data like age, sex, department from which they were requested along with the clinical diagnosis, blood group and indication written for the requirement of FFP on the requisition form. Number of units requested along with the parameters of Hemoglobin, Platelets were also noted along with coagulation studies of PT, APTT, INR wherever available.

Results:

There was a total of 756 patients who requested a total of 1644 units of FFP altogether during the period of 4 years between 2019 November and October 2023 as per the records.

Gender wise analysis showed that number of female patients who requested FFPs was more in comparison with the males, total number of issues showed similar female predominance in requisitions.

Most common blood group observed according to the records was O group in the FFP recipients followed by B group.

Table 1- Gender wise FFP issue table

S.No	Gender	No. Of Patients	No. Of FFPs
1	Female	404	866
2	Male	352	778
	Total	756	1644

Most transfusion requests (number of patients) were seen in the paediatric age group (0 to 10) accounting for 25.3% (192/756). overall pediatric patients who requested FFPs were more as per the records studied. The number of units requested was more in the age group of 30-40 accounting for 22.5% of the total of 1644 units requested.

Table 2- Age wise FFP issue table

S.No	Age group	No. Of Patients	Units
1	0-9	192	192
2	10-19	48	52

3	20-29	132	236
4	30-39	132	370
5	40-49	72	216
6	50-59	72	184
7	60-70	48	190
8	>70	60	204
	Total	756	1644

Number of patients requesting FFPs was seen the most from the department of Paediatrics accounting for 27.8% with 210 patients, followed by the department of OBG with 18.8%, least percentage of patients was seen from Orthopaedics accounting for 5%.

Table 3- Department wise requisition list of FFP

S.No	Department	No. of patients	Percentage
1	Paediatric	210	27.8%
2	Gynaecology	142	18.8%
3	General medicine	102	13.5%
4	AMC	99	13%
5	Surgery	165	21.9%
6	Orthopaedics	38	5%
	Total	756	

Analyzing the data of total number of units requested from various departments, highest was seen from surgery with 481 units out of 1644, followed by the department of medicine with 281 units and next in line was the department of OBG with 265 units. Acute medical care unit requested around 220 units, department of paediatrics requested 210 units. There were requisition forms from various departments with incomplete data with neither clinical diagnosis nor history without mentioning the indication, those were kept under separate category of No diagnosis which accounted for about 7% with 116 units.

Most common indication for which FFPs were requested was for surgery irrespective of the coagulation profile either prophylactic or therapeutic followed by bleeding irrespective of INR either from the department of OBG or Medicine.

Bleeding cases requiring coagulation factor replacements were found to be appropriate as per the guidelines in the present study from both OBG and surgical departments, but there were cases which had no coagulation abnormalities for which FFPs were requested with questionable indication.

FFPs requested for deranged coagulation profile specially in cases of Liver disorders were found to be appropriate along with the FFPs requested for leukemic patients in cases of DIC.

Next in line of requests was from the emergency departments for snake bites and various other reasons of hypovolemic replacements.

Indications mentioned in the paediatric requisition forms were malnutrition/ TTP requesting a therapeutic plasma exchange. FFP Requests for TTP as therapeutic plasma exchange were found to be appropriate.

Orthopaedic requests were mostly for the indication of amputations and other replacement surgeries which were kept under separate category in the present study.

Hypovolemic replacements with alternate options for transfusions, malnutrition cases, category of No diagnosis written were taken as inappropriate for FFP transfusion in the present study which together accounted for 22.2%.

During the 4-year period of 1644 units issued to different departments, there were 78 units of FFP either returned or not taken by the respective departments after thawing for miscellaneous reasons. Thus, the FFPs were gone into waste, therefore counted in the inappropriate section accounting for 4.7%. Overall, the inappropriate issue percentage in the present study was found to be 26.9%.

Though not all the cases of snakebite requested for FFPs, there might have been some cases not needing FFP if had tested properly and provided all the required data like coagulation profile as a point of interest in the present study.

Table 4- Indications mentioned in the records:

S.No	Department	Clinical diagnosis	Indication	No. of units
1	Gynecology	Pregnancy/Onset of Labour	Bleeding/Anemia	265
2	Medicine	Liver disorders/Leukemic cases	Deranged coagulation profile, DIC	281
3	AMC	Snake bite/Accidents	Hypovolemic replacements	220
4	Surgery	Surgery	Prophylactic/Therapeutic	481
5	Orthopaedics	Amputations/replacements	Amputations/replacements	71
6	Paediatrics	LBW/Malnutrition/TCP/TTP	TTP/TCP/Anemia	210
7	Various	No diagnosis written	Anemia/Nil	116

Discussion:

Plasma can be manufactured into various components from whole blood. It is labelled as FFP if frozen within 8 hours of collection. Frozen plasma can be stored for 1 year at -18 degrees and up to 7 years at or below -65 degrees with FDA approval. FFP contains maximum levels of both stable and labile clotting factors of about 1 International unit per milliliter. It is thawed at a temperature of 30-37 degrees, once thawed should be used within 24 hours with temperature being maintained at 1 to 6 degrees[1].

In routine hospital practices, FFP is usually utilized to stabilize hemostasis in cases of clotting factor deficiency, coagulopathy, ongoing bleeding cases whereas the actual indications according to many available guidelines are very limited. Many studies done all over the world have reported such inappropriate transfusions[4].

Unnecessary or excessive transfusion of FFP units have serious impact on patients' health safety which may lead to transfusion transmissible infections, TRALI, volume overload and the most common adverse effect is allergic reactions[9].

Transfusion audits are required to evaluate the usage of components and redefine the appropriateness for optimal utilization of the resources like FFP in the ever-increasing demand in countries like India.

In the present study, maximum number of FFP issues requested were from the surgical department for either prophylactic or therapeutic indications accounting for 29.2% followed by cases of bleeding irrespective of INR from OBG and department of Medicine accounting for 19.5%.

The highest numbers of FFP were issued by the Medicine department, followed by the General Surgery department in Sandhya Krupal et al study, in case of Shah et al, ICU was the highest in requests.

Various studies noted that the commonest indication observed for FFP transfusion was surgical bleeding and observed that after regular audits, there had been decrease in the proportion of FFPs requested by the clinical departments specially for Prophylactic usage in cases of surgeries. Manish Raturi et al showed bleeding with coagulopathy to be the commonest indication in their study with most common inappropriate indication being protein energy malnutrition.

The highest number of FFP was supplied to patients with active bleeding and least to patients undergoing therapeutic plasma exchange in Sandhya Krupal et al study. Kumar S et al separately categorized the common indications under appropriate and inappropriate transfusion sections with DIC being the commonest among the appropriate section.

Kumar S et al study showed drastic decrease in the percentage of inappropriate usage of FFP from 51.8% before educational interventions to 29.5% after audit. The percentage after audit is in correlation with the present study. Other studies like Prinja N etal showed 39.57%, Selvi et al showed 29.8%, Sandhya Krupal et al showed 20.31% whereas Bhagwat et al study and Manish Raturi et al showed a percentage 0f 53.4 and 56 of inappropriate FFP usage respectively.

Shah SN et al study showed a percentage of 33.56 for inappropriate usage of FFP but the study excluded all the emergency FFP transfusions from it.

The present study could not effectively evaluate the appropriate usage because of poor documentation which might improve if regular audits and follow ups are conducted with clinical departments and perform a prospective study.

Table- Various studies with their Inappropriate issue percentage

S.No	Name of the study	Percentage
1	Present	26.9%
2	Kumar S et al	29.5%(after audit)
3	Shah SN et al	33.56%
4	Sandhya Krupal Variganji et al	20.31%
5	Selvi et al	29.8%
6	Prinja N etal	39.57%
7	Bhagwat et al	53.4%
8	Manish Raturi et al	56%

Limitations:

Lack of follow up of the patients who requested FFPs as the present study was a retrospective one because of which the effective estimation of appropriateness with respect to dose could not be done.

Single centered study.

Poor documentation was another drawback.

Conclusion:

There is a need for individual institutional guidelines based on the existing national and international guidelines for effective utilization of blood and blood components and also educational interventions with regular audits are necessary to prevent inappropriate usage of FFP in transfusions.

Conflicts of interests- Nil

Ethical committee approval- Taken.

Author details:

Dr.TRSN Lakshmi- Assistant professor, Department of Pathology, Govt Medical college, Ananthapuram

Dr.J.Bhagya Lakshmi- Assistant professor, Department of Pathology, Govt Medical college, Ananthapuram

Dr.K.Lakshmi- Associate professor, Department of Pathology , Govt Medical college, Ananthapuram

Dr.V.Sivasankara Naik- Professor & HOD, Department of Pathology , Govt Medical college, Ananthapuram
Dr.K.Sreedhar Babu- Assistant professor, Department of Pathology , Govt Medical college, Ananthapuram

Annexure-Abbreviations

FFP	Fresh Frozen Plasma
OBG	Obstetrics and Gynaecology
INR	International normalized ratio
TRALI	Transfusion related acute lung injury
FDA	Food and Drug Administration
DIC	Disseminated Intravascular coagulation
TCP	Thrombocytopenia
TTP	Thrombotic thrombocytopenic purpura
APH	Antepartum hemorrhage
PPH	Postpartum hemorrhage
VWD	Von Willebrand disease

References:

1. Harmening D. Modern blood banking & transfusion practices. 7th ed. Philadelphia, Pa: F.A. Davis Company; 2019.
2. National Health and Medical Research Council (NHMRC) ASoBTA. Clinical Practice Guidelines on the Use of Blood Components (red blood cells, platelets, fresh frozen plasma and cryoprecipitate) 2002.
3. American association for the advancement of blood and biotherapies: Circular of information for the use of Human blood and Blood Components, American Association of Blood Banks: December 2021.
4. Kumar S, Kushwaha N, Tomar A, Philip J, Biswas AK. A retrospective audit to evaluate the appropriateness and rationalization of Fresh Frozen Plasma usage in a tertiary care hospital. Medical Journal Armed Forces India. 2021 Jul;
5. Cable Ritchard, Carlson Brian. 2nd ed. American Red Cross; 2007. Practice Guidelines for Blood Transfusion.
6. Prinja N., Sharma S., Narain R. Fresh frozen plasma utilization pattern in tertiary care hospital of North Western India. *Int J Res Med Sci.* 2017;5(12):5372–5375.
7. Bhagwat S, Sharma J. A Retrospective Audit of Appropriateness and Monitoring of Fresh Frozen Plasma Transfusions in A Tertiary Care Hospital. International Journal of Contemporary Medical Research [Internet]. 2017;4:2454–7379.
8. Selvi NT, Revathishree R, Chandana A, Khan DM, Abilash SC. Study of Appropriateness of FFP transfusions in a tertiary care centre. IP Arch Cytol Histopathology Res 2021;6(1):12-14.

9. Shah SN, Sidhu M, Gupta V. Audit of fresh frozen plasma usage, prospective study: a report from department of immunohematology and transfusion medicine, government medical college Jammu, Jammu and Kashmir, India. Int J Res Med Sci 2020;8:1371-4
10. Krupal, V & Inuganti, Renuka & Chitturi, Ramya & Lakshmi, Kasula & B, Garima. (2020). Utilisation of Fresh Frozen Plasma in a Tertiary Care Hospital. National Journal of Laboratory Medicine. 9. 10.7860/NJLM/2020/44306:2398.
11. Raturi Manish & Shastry, Shamee & Murugesan, Mohandoss & Baliga, Poornima. (2017). Clinical Use of Fresh Frozen Plasma in a Tertiary Care Hospital from India. Journal of Transfusion Medicine. 2017. 77-83.
12. Kandasamy D., Kumar A., Joshua D.J. Outcome of audit and education on blood transfusion practice in obstetrics setting. *Hematol Transfus Cell Therapy.* 2020 doi: 10.1016/j.htct.2020.08.014. ISSN 2531-1379.
13. Bolton-maggs P., Beattie C., Cardigan R., Kallis Y., Stanworth S.J., Green L. Corrigendum to: British Society of Haematology Guidelines on the spectrum of fresh frozen plasma and cryoprecipitate products: their handling and use in various patient groups in the absence of major bleeding British. *J Haematol.* 2018;181(1):54–67.
14. Apfelroth S. Standard terminology for plasma products. Transfusion. 2003;43:983.
15. Lundberg G.D. Guidelines P. Practice parameter for the use of fresh-frozen plasma. *J Am Med Assoc.* 1994;271(3)
16. Wong M.P., Droubatchevskaia N., Chipperfield K.M., Wadsworth L.D., Ferguson D.J. Guidelines for frozen plasma transfusion. *B C Med J.* 2007;49(6):311–319.
17. Chaudhary R, Singh H, Verma A, Ray V. Evaluation of fresh frozen plasma usage at a Tertiary care Hospital in North India. ANZ J Surg. 2005;75:573-6.
18. Shinagare S.A., Angarkar N.N., Desai S.R., Naniwadekar M.R. An audit of fresh frozen plasma usage and effect of fresh frozen plasma on the pre-transfusion international normalized ratio. *Asian J Transfus Sci.* 2010;4(2):128–132.
19. Pahuja S., Sethi N., Singh S., Sharma S., Jain M., Kushwaha S. Concurrent audit of fresh frozen plasma: experience of a tertiary care hospital. *Hematology.* 2012;17(5):306–310.
20. Hasrat K., Jon B., Murat Y., et al. Fresh-frozen plasma and platelet transfusions are associated with development of acute lung injury in critically ill medical patients. *Chest.* 2007;131(5):1308–1314. doi: 10.1378/chest.06-3048. [Internet]. The American College of Chest Physicians.
21. Narick C., Triulzi D.J., Yazer M.H. Transfusion-associated circulatory overload after plasma transfusion. *Transfusion.* 2012;52(1):160–165.
22. Stanworth S.J. The evidence-based use of FFP and cryoprecipitate for abnormalities of coagulation tests and clinical coagulopathy. *Hematology Am Soc Hematol Educ Program.* 2007:179–186