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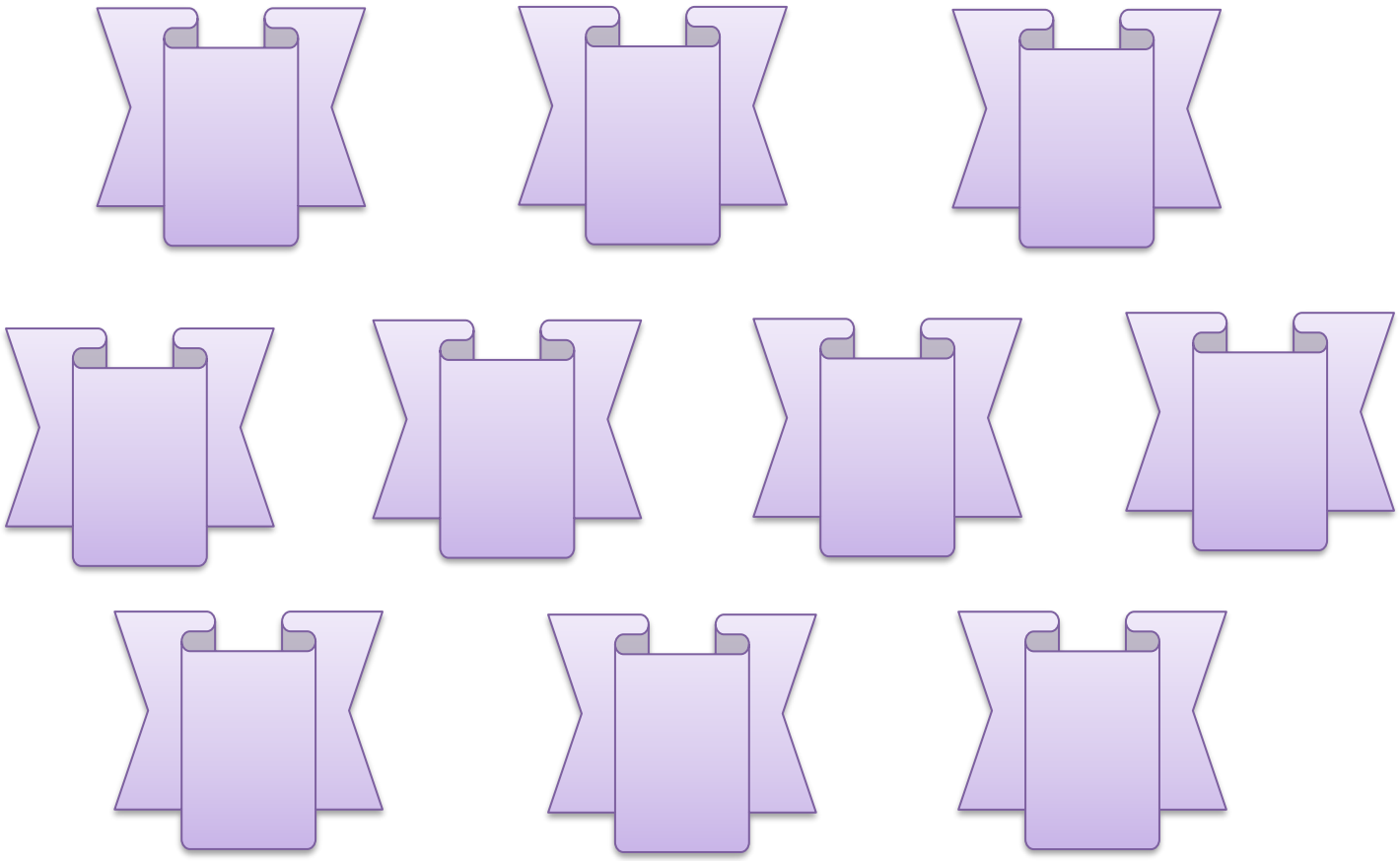

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Original Article

A Retrospective Audit of Fresh Frozen Plasma Usage in a Tertiary Care Hospital in South India

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ABSTRACT

Aim of the Work: To audit the usage of fresh frozen plasma [FFP] for one year and assess our pattern of usage and misuse. FFP is often requested blood component, but it is inappropriately used despite existing guidelines. The present study was done to improve the quality and to ensure the appropriate use of FFP in patients.

Materials and Methods: A one-year retrospective study was conducted in a Medical College Hospital blood bank during the period of January 2022 and December 2022 by a team from Department of Pathology. Case records and requisition forms of all the patients who received FFP were reviewed. FFP usage was classified as appropriate or inappropriate based on the guidelines by the CAP [College of American Pathologists] and The British Committee for Standards in Haematology.

Results: Totally 10,760 units were issued for 3,020 patients [1,450 males and 1,570 females, mean age 33 years, range Newborn-65 years] in one year. “Acute DIC with high INR” was the most common indication for appropriate FFP transfusion while the use of FFP for “Raised PT/INR without bleeding” was the most common indication for inappropriate transfusion of FFP.

Conclusion: This study showed that 6564[61%] cases was appropriately transfused while remaining 4196[39%] cases was transfused without any supporting evidence. This highlights the importance of knowledge about the appropriate and inappropriate usage among clinicians. So, the interventions needed are education about appropriateness of the FFP indication, regular transfusion audits and training the medical staff at regular intervals.

Keywords: Fresh Frozen Plasma; Audit; Appropriate; Inappropriate; Plasma Guidelines.

INTRODUCTION

Fresh plasma is separated from the whole blood within 6-8 hours of blood collection and frozen solid at -300 °C or lower. Fresh frozen plasma [FFP] contains all coagulation factors [1]. FFP uses are becoming more frequent in the management of bleeding or complex coagulopathies [2]. It is a source of coagulation factors, including labile factors V and VIII. [3, 4] The College of American Pathologists [5] and the British Committee for Standards in Haematology [6] have published guidelines to highlight these issues and minimize misuse. The problems with use of FFP include anaphylactic reactions, excessive intravascular volume [transfusion associated circulatory overload [TACO], as well as transfusion related acute lung injury [TRALI] and disease transmission. Risks of transfusion transmitted infections are similar to that of whole blood and red blood cells. But many studies from around the world still report a high frequency of inappropriate usage of FFP [7, 8].

Our institution is a large 2000 bedded general hospital in south India with a broad range of medical, surgical, and super specialties. Our transfusion service noted that FFP usage in the hospital is high. Although guidelines for FFP usage are available, inappropriate usage continues to be a significant problem. Furthermore, excessive inappropriate usage can lead to shortage of FFP in regular times of need when the blood donation camps are infrequent, so we decided to study on the institute's appropriate and inappropriate usage of FFP. The present study was done to ensure the appropriate use of FFP in patients and to introduce the measures to improve the same. The differences in outcome of patients depending on usage or indication was not compared in this study.

THE AIM OF THE WORK

The aim of this work is to evaluate and identify the usage behaviour and misuse of fresh frozen plasma [FFP] over the course of year among the clinicians of various departments.

MATERIALS AND METHODS

Our study is a cross-sectional retrospective observational study conducted in the Blood Bank of Government Medical College Hospital in South India during the period of January 2022 to December 2022 by a team from the Department of Pathology. The case records of all patients who received FFP were reviewed. The following data was collected: demographic data including age and gender of the patient, provisional clinical diagnosis, indications for FFP, department of the requesting clinician, date of transfusion, number of units transfused, and the coagulation profile of the patient. The audit was done using FFP transfusion guidelines based on the College of American Pathologists [CAP] and British Committee for Standards in Hematology [BCSH] [5, 6] [Table 1]. Fresh frozen plasma infusion of 10–15 mL/kg body weight of the patient was considered an adequate dose. Requisition for FFP and transfusion was based on the decision of the clinicians.

The FFP transfusion usage was categorized as: i. Appropriate: if both the indication for transfusion and the dose transfused were appropriate. ii. Inappropriate: if the indication and/or the dose were inappropriate or if the record did not provide the details required to decide the appropriateness of the transfusions as per the indications and/or the transfusion dose.

Table [1]: Hospital FFP transfusion guidelines based on College of American pathologists [1994] [5] and British committee for standards in haematology [2004] [6]

No.	Indication
1	Multiple coagulation factor deficiencies / DIC who have significant coagulopathy* associated with bleeding or planned for an invasive procedure
2	Surgical/ traumatic bleeding/ massive transfusion – FFP transfusion to be guided by coagulation profile
3	Inherited deficiencies of single clotting factors, for which virus safe specific factor concentrate is unavailable
4	Liver diseases with significant coagulopathy* with bleeding or planned for invasive procedures
5	Bleeding patients with haemorrhagic disease of the newborn and neonates with coagulopathy who are either bleeding or have to undergo invasive procedures
6	For plasma exchange in cases of Thrombotic thrombocytopenic purpura [TTP]
7	Reversal of warfarin effect, only in cases of bleeding or prior to an invasive procedure
	*Significant coagulopathy: at least one of the following. 1. Prothrombin time [PT] >1.5 times the midpoint of normal range. 2. Activated partial thromboplastin time [aPTT] >1.5 times the top of the normal range. 3. Coagulation assay of <25% activity

RESULTS

A total of 10,760 units were issued for 3,020 patients in 3,200 episodes, which included 1,450 [49%] males and 1,570 [51%] females. The patient age range was from newborn to 65 years, with a mean age of 33 years

The greatest number of FFP transfusion requests were prescribed by the specialty of General Medicine [2,238 [20.8%]], followed by Obstetrics and Gynaecology [2,130 [19.8%]] and then by Plastic Surgery for burns cases [1,571 [14.6%]] [Table 2].

"Acute disseminated intravascular coagulation [DIC] with high international normalized ratio [INR]" was the most common indication for appropriate FFP transfusion [Table 3], while the use of FFP for "Raised PT/INR [prothrombin time-international normalized ratio] without bleeding" was the most common indication for inappropriate transfusion of FFP [Table 4].

FFP was transfused inappropriately in hypo-proteinemia and in cases with no evidence of bleeding and/or deranged coagulation parameters.

In this study, 6564 [61%] of the cases were grouped under the appropriate usage of fresh frozen plasma [Table 3], and 4196 [39%] of the cases under inappropriate usage [Table 4].

Table [2]: FFP usage in units among various departments

S.NO	Department	FFP usage in units [N=10,760]
1	General Medicine	2,238 [20.8%]
2	Obstetrics and gynaecology	2,130 [19.8%]
3	Plastic Surgery	1,571 [14.6%]
4	Neonatal Intensive Care Unit and Paediatrics	1,378 [12.8%]
5	General Surgery	1,206 [11.2%]
6	Neurosurgery	807 [7.5%]
7	Accident and Emergency	699 [6.5%]
8	Oncology	484 [4.5%]
9	Cardiology	129 [1.2%]
10	Orthopaedics	118 [1.1%]

Table [3]: Percentage of various appropriate FFP requests in our hospital

S.NO	Reasons	Department	Number of request [percentage]
1	DIC with high INR	General Medicine	3150 [29.3%]
2	Liver disease	Obstetrics and gynaecology	1780 [16.5%]
3	Factor deficiency	Plastic Surgery	790 [7.3%]
4	Raised PT/INR with bleeding	Neonatal Intensive Care Unit and Paediatrics	662 [6.2%]
5	Therapeutic plasma exchange	General Surgery	130 [1.2%]
6	Reversal of warfarin effects	Neurosurgery	30 [0.28%]
7	In massive transfusion	Accident and Emergency	22 [0.2%]
	Total appropriate requests		6564 [61%]

Table [4]: Percentage of various Inappropriate FFP requests in our hospital

S.NO	Reasons	Department	Number of request [percentage]
1	DIC/ Raised INR without bleeding	Obstetrics and gynaecology	1150 [10.7%]
2	Hypoproteinaemia	General Surgery	720 [6.6%]
3	Mild prolongation of coagulation results- PT/ APTT <1.5 times of normal range	Neonatal Intensive Care Unit and Paediatrics	530 [4.9%]
4	During haemorrhage with normal INR	Neurosurgery	470 [4.7%]
5	Surgery related with normal INR	Plastic Surgery	500 [4.6%]
6	Hypovolemia	Accident and Emergency	490 [4.4%]
7	Prophylactically without bleeding	Oncology	176 [1.6%]
8	Acute bleeding without coagulation test	General Medicine	160 [1.5%]
	Total Inappropriate requests		4196 [39%]

DISCUSSION

Appropriate usage of FFP is very important, so that it is not wasted and available for more needy patients. Inappropriate use also leads to increased risk of transfusion related complications. Many studies have shown a high incidence of inappropriate use of FFP [7-12] in spite of many formulated guidelines for its use. [4, 5]. So, evaluation of FFP usage is very important for improving the use of this blood component.

Various published articles show a high proportion of inappropriate usage, which ranges from 30.2–73% [Table 5]. The appropriateness of FFP in our study was found to be 6564 [61%] of 10,760 units. This was concordant with the study by **Makroo *et al.*** [12], which showed 573 [69.8%] of 2,915 units of FFP among affecting 2,202 [75.54%] units of FFP were appropriately indicated, while 248 [30.2%] of FFP requests were inappropriately indicated. A study done by **Chaudhary *et al.*** [11] with a total of 595 units issued to 112 patients found that among the 112 patients, 33 [29.5%] had appropriate FFP transfusions [205 units] for indications, which was significantly less than that of our study. In a similar study by **Chang *et al.*** [3], 932 units of FFP were used during the study period for 359 transfusion episodes, and only 98 [27%] episodes were deemed appropriate.

Kulkarni [9] in his study done during two years, 1884 units of FFP were used for 945 patients, of which only 454 [48%] requests were appropriate and 491 [52%] were inappropriate requests. Two other studies [8, 10] also found that the appropriateness in FFP usage was 39.7% and 40% respectively. The most common appropriate indication for FFP usage in this study is disseminated intravascular coagulopathy [DIC] with bleeding [3150 [29.3%]], which is comparable to a study by **Kulkarni** [9] with 27.3%.

Yadav *et al.* [13] studied 256 patients who received 1370 units of FFP transfusions. Most patients belonged to the Gastroenterology Department [41.75%], followed by CTVS [15.32%]. 29.48% of FFP transfusions were reclassified as inappropriate either due to lack of indication or inappropriate doses.

Table [5]: Comparison of studies by different authors on appropriate usage of fresh frozen plasma

S.NO	Study	Appropriate usage	Inappropriate usage
1	WJ Chng et al [3]	27%	73%
2	Marti-carvajalet al [7]	51%	49%
3	Prathiba R. et al [8]	40%	60%
4	Kulkarni [9]	48%	52%
5	Kakkar N. et al [10]	39.7%	60.3%
6	Chaudhary R. et al [11]	29.5%	70.5%
7	Makroo RN. et al [12]	69.8%	30.2%
	Present study	61%	39%

FFP use is appropriate in DIC where there is activation of the coagulation system, leading to a generalised coagulopathy. But according to the CAP guidelines, FFP should be given only in the setting of bleeding in these patients. Many patients who receive FFP can be managed more effectively and safely with alternative modalities of treatments. The high rate of FFP use reflects the uncertainty among the treating physicians about the appropriate clinical indications for its usage. Another reason may be the mis-conception regarding its effectiveness as a haemostatic agent.

The use of blood and blood components has been indiscriminate due to easy availability as well as inadequate clinician knowledge of the recommended guidelines of components usage. Blood bank audits should be regularly performed to identify misuse and also as a part of quality control. The increased inappropriate use is affecting the limited resource, while impacting health care cost along with increased TTI risk [14, 17-19].

FFP transfusions. In addition, due to litigation atmosphere, precaution transfusions are also known to happen. Lack of awareness about blood component usage, especially FFP usage is the most common reason for this inappropriate use of FFP [14-17, 20, 21].

Admittedly, some of the patients with acute bleeding were given FFP prior to results of coagulation screening were available due to the urgency of the situation. But these cases were

very minimal and excluding these cases would not have an overall impact on the results of our study. Furthermore, the practice of FFP use before the availability of coagulation results should be discouraged. For surgical specialties, FFP was often requested for correction of only mild prolongation of clotting times.

The current study has therefore documented the usage of FFP to formulate policies and strategies, to minimize unnecessary transfusions and to ensure safe and rational use of FFP in these patients. After our study results, this issue was discussed in hospital committee meetings and the appropriate measures were decided to be taken to prevent the misuse of FFP. We decided to introduce certain modifications in our blood bank practice and planning to review after two years for its effectiveness: i] Request forms will be re-designed to include appropriate indications for FFP transfusion to serve as a reminder of the appropriate indications for doctors requesting for FFP, ii] FFP request forms should include the lab values of coagulation tests, iii] Awareness to clinicians, postgraduates, and interns about the guidelines of FFP usage, iv] Periodic audit of transfusion practices [every six months] examined by the Hospital Transfusion Committee to reduce the misuse of FFP, and v] Transfusion topics and guideline should be re-enforced regularly during various departments' continuing medical education [CME] programs.

For better inventory management, audit of FFP usage is important to monitor clinical transfusion practices.

The limitation of our study is, it is a retrospective single centred study involving low number of cases. In addition, there is the possibility of having missing and faulty information in the record files of the patients.

Conclusion: A transfusion audit is necessary to access the blood utilization pattern in any hospital and to ensure its appropriate use and is an important part of the quality assurance program that can provide necessary information for the improvement of transfusion practices. FFP misuse results in wastage and subjecting recipients to unnecessary risk. Despite availability of guidelines, inappropriate FFP use is a significant problem worldwide, both in developed and developing countries. Our audit provides further evidence that this is an on-going problem. Post auditing, we have decided to implement some measures that we think will have immediate as well as lasting effects. The audit will be repeated two to three years after the implementation of these measures. Our audit showed high number of inappropriate requests for FFP if the CAP and BCSH guidelines were to be followed. The percentage of inappropriate usage in our study was similar to those published from other series.

Training and supervising the medical staff at regular intervals should be done. Apart from that, regular screening of the requisition forms by the blood bank doctors is necessary.

Our study highlights the need for educating the clinicians to prescribe FFP and use only in required conditions as per guidelines and also recommend few measures like Hospitals should have locally agreed specialty specific guidelines for the use of FFP [eg. Local guidelines should address the use of FFP in liver patients, cardiac surgery, trauma, Intensive Care Units and Neonatal units] to improve the safe FFP practices in hospitals. Also, these guidelines should define appropriate dose [ml /Kg] of FFP and Clinicians who prescribe FFP should be familiar with the guidelines. Each clinical specialty using FFP should perform regular [annual] audits of compliance with local and national guidelines and all these will go a long way in ensuring the rational use of FFP in these patients.

To summarize, this audit shows that FFP continues to be frequently used in the absence of bleeding and/or evidence of abnormal coagulation.

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