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Original Research Article

An audit on usage of fresh frozen plasma in a tertiary care hospital in north western part of India

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ABSTRACT

Background: Every blood Component carries inherent risk of adverse transfusion reactions and transmission of transfusion transmitted disease (TTD). The adverse transfusion reactions are unpredictable and makes transfusion services puzzled, FFP being the most common one, it is therefore necessary that appropriate and rational use of FFP is done to make transfusion safer in terms of patient safety. The objective of the study was to assess the utilisation of FFP in a tertiary care Hospital.
Methods: We conducted a retrospective study on 256 patient who received FFP transfusion at our tertiary care hospital over a period of 6 months .The usage was classified as appropriate or inappropriate based on the guidelines for FFP usage by British committee for standards in haematology, 2004 and college of American pathologist, 1994.
Results: There were 256 patients in the study period who received 1370 units of FFP transfusions. The male: Female ratio was 162 M & 94 F. Most of the patients belonged to 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.
Conclusions: The study emphasize on the need to incurate rational use of blood components which is FFP in present case for evolving safe transfusion practices in the country. This study highlights no adherence to guidelines among clinicians which is mainly due to lack of knowledge of appropriate usage.

Keywords: Audit, Fresh frozen plasma, Transfusion

INTRODUCTION

Blood transfusions are an important part of medical management in the modern Health Care System. Blood and blood products are collected from healthy donors after conducting an appropriate selection procedure and special clinical lab tests. The Blood components that are available mostly include Red cell concentrates, platelet concentrates, FFP & Cryoprecipitate. FFP is a component of one unit of human blood that has been centrifuged, separated & frozen solid @-18 degree Celsius within 8 hrs of collection.[1-3] It contains plasma proteins and all the coagulation factors, including the labile factor V & VIII. FFP transfusions are among the most "high risk" of all blood component transfusion in relation to transfusion reactions.[1,3] Transfusion of FFP is indicated in specific clinical situations associated with coagulation disorders. In other situations, the use of FFP has not been shown to be of benefit, or safer and satisfactory alternative therapies are available. Inappropriate or excessive use of FFP is associated with transfusion Hazards. The most serious immediate adverse reaction is TRALI.[2]

Others include TTI, anaphylactic reactions, Risk of volume overload and immune haemolytic transfusion reactions.[2] In addition irrational use may lead to shortage of this valuable blood component. Hence, FFP should be used only when clearly indicated as per guidelines published by NHMRC/ASBT, CAP, BCSH.[1,3] Nevertheless, studies from all over the world report a high frequency of inappropriate utilisation of FFP.[4-26] Clinical transfusion audit helps to identify current pattern of usage and areas of improvement. We observed an increasing trend of FFP transfusion in our institution over past 3-4 years.

Hence, a Retrospective audit was conducted at the dept. of transfusion medicine with the primary objective of assessing the appropriateness of FFP transfusion and evaluating the adequacy of monitoring of FFP transfusion events.

METHODS

We did a retrospective study from 1 January to 30 June, 2017 on FFP usage in the dept. of transfusion medicine in Santokbha Durlabhji Memorial Hospital, Jaipur after approval of the institutional ethics committee. All the patients receiving FFP transfusion from various departments aged 18 and above were included in the study . Paediatrics & neonatal patients, Patients below 18 years of age and the patients whom data was missing were excluded from the study.

The component issue records available in the department were scrutinized to identify the patients who had received FFP transfusion during the study period. Thus 256 patients included in the study.

Defining study criteria

Demographic data

It was evaluated as the % of entry in areas like Age, Gender, blood group, Provisional Diagnosis, Type of Request (Urgent or Planned) and clinical specialties prescribing the FFP transfusion were included in the Blood request form.

Data for assessment of transfusion

Clinical Diagnosis, indications for FFP transfusions, presence or absence of bleeding, History of Anticoagulant therapy, invasive or surgical procedure performed, Pre and Post-transfusion PT & INR. These were collected from the medical record department of the hospital and in the case record file.

Indications for transfusion and dosage

Appropriateness was Defined based on compliance to FFP transfusion guidelines based on the British committee for standards in Haematology (BCSH) and college of American Pathologists (CAP).[1,3]

***Fresh frozen plasma transfusion guidelines based on the British Committee for Standards in Hematology, 2004 and College of American Pathologist, 1994.*[1,3]**

Multiple coagulation factor deficiencies/DIC who have significant coagulopathy associated with bleeding or going for an invasive procedure. Surgical/ traumatic bleeding/massive transfusion – FFP transfusion to be guided by coagulation profile. Inherited deficiencies of single clotting factors for which virus safe specific factor concentrate is not available. Liver diseases with significant coagulopathy* with bleeding or going for an invasive procedure/ surgery. Bleeding patients of hemorrhagic disease of the newborn and neonates with coagulopathy who are bleeding or who have to undergo invasive procedures. TTP. Reversal of warfarin effect, only in cases of bleeding or prior to an invasive procedure.

*Significant coagulopathy is defined as at least one of the followings: PT>1.5 times the midpoint of normal range, aPTT>1,5 times the top of the normal range, Coagulation assay of <25% activity. DIC: Disseminated intravascular coagulation, FFP: Fresh frozen plasma, TTP: Thrombotic thrombocytopenic purpura, PT: Prothrombin, aPTT: Activated partial thromboplastin time.

Adverse reactions

Any adverse reactions due to FFP administration were noted.

RESULTS

Table 1: Patient demographics.

Total no. of patients	256
Males (%)	162 (63.28)
Females (%)	94 (36.71)
Total No. of FFP units transfused	1370
Mean weight of patients (min-max)	56 Kg. (38-98)
Mean age of patients (min-max)	27 years (18-65)
<20, n (%)	23 (8.98)
20-45, n (%)	170 (66.4)
>45, n (%)	63 (24.6)
Blood Group, n (%)	
O	40 (15.62)
B	107 (41.79)
A	86 (33.59)
Ab	25 (9.76)
Commonest diagnosis	Liver disease (41.75%)

Patient demographics

Total 256 patients including 162 males and 94 females received 1370 units of plasma (100-280ml) from 1560 requisitions. Blood group wise majority patients were of 'B' Blood group. Major users of plasma were Gastroenterology (41.75%) against Cardiothoracic Surgery (15.32%). Mean age of the patients was 27 years.

Table 2: Department wise distribution of FFP transfusion.

Department	No. of FFP transfusion %)
Gastroenterology	572(41.75)
Cardiothoracic surgery	210(15.32)
General Medicine	200(14..59)
General Surgery	138(10.07)
Neurology	101(7..37)
Nephrology	72(5.25)
Oncology	33(2.40)
Obs. and Gynaecology	28(2.04)
Others	16(1.16)

Table 3: Appropriate and inappropriate use of FFP according to speciality.

Clinical Speciality	Total Transfusions (%)	Appropriate Transfusions (%)	Inappropriate Transfusions (%)
Gastroenterology	572 (41.75)	502 (87.76)	70 (12.23)
Cardiothoracic surgery	210 (15.32)	95 (45.23)	115 (54.76)
General Medicine	200 (14.59)	114 (57)	86 (43)
General Surgery	138 (10..07)	112 (81.15)	26 (18.84)
Neurology	101 (7.37)	95 (94.05)	06 (5.94)
Nephrology	72 (5.25)	39 (54.16)	33 (45.83)
Oncology	33 (2.40)	00 (00)	33 (100)
Obs.& Gynaecology	28 (2.04)	03 (10.71)	25 (89.28)
Others	16 (1.16)	06 (37.5)	10 (62.5)
Total	1370 (100)	966 (70.51)	404 (29.48)

Table 4: Commonest indications for appropriateness and inappropriateness.

Speciality	Commonest Indication of	Commonest Indication for
	Appropriate transfusion	Inappropriate transfusion
Gastroenterology	Decompensated liver disease with bleeding and deranged coagulative parameters.	Mildly elevated PT with no evidence of bleeding in various disorders
Cardiac surgery	Warfarin reversal before emergency value replacement surgeries for RHD and raised PT/INR along with vitamin K	Coronary artery bypass graft with Normal INR and No evidence of Bleeding
General surgery	Massive blood loss	Post OP correction of mildly elevated PT
General medicine	DIC with bleeding	Correction of mildly elevated PT

Indications and dosage of plasma administration

The patients enrolled in the study were diagnosed with multiple disorders. Most common indication was liver disease. The median dose of FFP administered was 10.3 ml/kg.

The FFP transfusion episodes were divided as

Appropriate:

If both the indications and dose transfused were appropriate as per BCSH / CAP guidelines.[1,3]

Inappropriate:

If the indication or dose were inappropriate.

Adverse reactions and mortality

Overall, 0.24% of plasma units transfused were related with adverse reaction. Mostly were Mild Allergic and pruritic. There were no cases of TRALI. No deaths were reported due to transfusion.

DISCUSSION

Over the past several decades, the indications for FFP transfusion have changed dramatically various guidelines and protocols are available for guiding the FFP transfusions. Indications for FFP transfusion given by BCSH are very limited and very specific. However, these guidelines are not followed strictly in clinical practice.

Various studies have been done worldwide showing inappropriate use of FFP ranging from 21.3 to 83%.[4-26] chng et al. in 2003 reported 73% inappropriate FFP requests in their retrospective analysis in Singapore.[5] Shinagare et al. in 2010 reported 39.4% inappropriate FFP transfusions in India.[6] On the other hand, Mozes et al. in 1989 reported 83% rate of inappropriate FFP transfusions in Israel.[7] Our study revealed that out of total FFP requests, 29.48% were inappropriate.

Table 5: Use of FFP in various studies.

Study	Years	Place	Guidelines	Appropriate usage (%)
Chng et al.[5]	2003	Singapore	BCSH/CAP	27
Kakkar et al.[11]	2004	India	BCSH	39.7
Chaudhary et al.[17]	2005	India	BCSH	29.5
Hui et al.[14]	2005	China	NHMRC/ASBT	72
Makroo et al.[18]	2007	India	CAP	69.8
Shinagare et al.[6]	2010	India	NHMRC/ASBT	60.6
Kulkarni.[16]	2012	India	CAP/NHMRC/ASBT	48
Pahuja et al.[20]	2012	India	BCSH/CAP	21.8
Agarwal et al.[25]	2014	India	CAP	49.5
Vaidehi patel et al.[22]	2015	India	AABB	38
N. Jayanthi.[21]	2015	India	NHMRC	74
Lingegowda et al.[24]	2016	India	NHMRC/ASBT	59.3
Puri V et al.[26]	2016	India	BCSH/CAP	67
Current study	2017	India	BCSH/CAP	70.91
Shah SN et al.[23]	2018	India	DGHS	66.44

The appropriateness of FFP was found to be 70.91% which was concordant with the study by Makroo et al. in 2007 and Eagleton et al. in 2000 which showed 69.8% and 66% appropriateness respectively.[18,19] A similar study conducted by Hui et al. in 2005 shows 72% appropriateness. [14] A study by Jayanthi and Pitchai in 2015 shows that in 74% of cases, the indication for FFP use were inappropriate.[21] FFP usage was reported appropriate only in 29.5% by Chaudhary et al. in 2005 which was significantly less than that of our study.[17] Similar to our study, Pahuja et al. applied the criteria set by the BCSH and CAP, and only 22% of the FFP transfused episodes were deemed appropriate.[20] Kulkarni in 2012 and Vaidehi et al. in 2015 also found that the in appropriateness in FFP usage was more common (52 and 62% respectively).[16,22] The discrepancy between the results may be due to differences in transfusion guidelines used as reference and the number of centres included in the study and inclusion of algorithms may have caused the difference in FB uses affecting the final art of these studies.

A prospective study done by Kakkar et al. in 2004 showed that 60.3% of the FFP demands were inappropriate according to the BCSH guidelines.[11] Then, they performed a reaudit after education campaign , and the inappropriate usage of FFP showed a significant reduction by 26.6%. Whereas appropriateness of FFP usage was 67 & 66.44% in recent studies conducted by Puri V et al. & shah N et al. respectively which is similar with our study.[26,23]

Comparative analysis of FFP audits show varied indications of inappropriate use including volume expansion, bleeding with normal coagulation profile, or non-available coagulation profile leading cause of inappropriate use in our study was found to be in bleeding or non-bleeding patients with PT/INR non availability or within normal limits or mildly elevated. Luk et al. found maximum patients to be inappropriately transfused with FFP in the presence of normal coagulation profile.[8] However, Kakkar et al. in their prospective study from India have found Hypoproteinaemia state to be the most common cause of

inappropriate use whereas use of FFP for volume expansion has been quoted as the most common cause of inappropriate use by shinagare et al.[11,6]

Our study identified the generalised, and widespread irrational use of FFP in our hospital amongst specialities. Following which we conducted a one day CME on indications and guidelines on FFP usage and our Hospital Transfusion Committee gave guidelines and has a regular check for adherence to these guidelines. We also proposed to carry regular audits to have a check on rational use of not only FFP but all other blood components too. Awareness programmes regarding blood component usage in various clinical conditions are conducted for clinicians regularly. It is planned that requisition forms should carry appropriate indications to remind clinicians for appropriate uses. A computerised transfusion decision system will also help to bring down unnecessary transfusion. This will avoid shortage of FFP in times of need and reduce unwanted treatment cost.

Limitations: Our study is a single centred, retrospective study. The low number of cases is one of the limitations in our study. In addition, there is the possibility of having missing and faulty information in the record files of the patients in our study, which was conducted retrospectively.

CONCLUSION

Patients with a high pre transfusion INR are more likely to be benefited with FFP & show better improvement. FFP is a precious product, we purpose a preferential use of FFP for those patients who fulfil the guidelines & have a high pre transfusion INR. We feel that further studies on these lines are required to improve the utilisation of this important blood product. Regular evaluation may help to reduce inappropriate use & play a vital role in overseeing transfusion practices to ensure optimal use of blood and component therapy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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