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RESEARCH ARTICLE

AN AUDIT OF FRESH FROZEN PLASMA USAGE IN CHILDREN IN A TERTIARY CARE HOSPITAL IN WESTERN INDIA

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ABSTRACT

Introduction: Fresh frozen plasma (FFP) is a blood component which is being used as a rational replacement therapy for various clinical conditions. Many of the times FFP being used irrationally and associated with a variety of hazards. Because of ease of availability and gap in the knowledge of medical professionals blood products are being used liberally and sometimes inappropriately. **Methodology:** Prospective cross sectional observational study was done over a period of 1 year in a tertiary hospital, in the western part of India. 100 events of FFP therapy was studied in neonates (< 1month) and pediatric (1month-16years)age groups. Indications and reactions to transfusion of FFP were studied in both the groups and its indication was compared with BCHS guidelines for terming it as appropriate or inappropriate. **Results:** Out of total 100 events of transfusions majority of the transfusions was in age group of 1 to 5 yrs (44%), most common indication being sepsis. In the pediatric age group 58% of the transfusions were done in ICU, We found that overall 36 % FFP transfusions were Inappropriate. Use of FFP for volume expansion was the most frequent form of inappropriate use followed by cases of bleeding without derangement of coagulation tests. Increasing awareness among the clinicians and strict protocol in management may have helped to reduce the percentage of inappropriate transfusions. Overall 3.0% had transfusion reactions, commonest being had FNHTR. **Conclusion:** Regular audit of blood and its component usage is essential to assess the blood utilization pattern and set ideal policies in all the medical specialties to make it appropriate, ensure availability and save patients from its hazards.

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INTRODUCTION

Blood is a valuable but limited biological resource and no synthetic alternative has been discovered till date. Safety in collecting, testing and processing of blood and blood product brought revolutionary changes in the field of transfusion medicine (Street *et al*., 2012; McClelland, 2007; Madjdpour *et al*., 2006). Blood safety has considerably improved in the developed countries and gradually improving in the developing countries like India. Blood component therapy is extensively used in diverse fields of medicine like hematology, emergency medicine, oncology, neonatal, pediatric and adult intensive care units, surgery, gynecology, etc. Blood components include packed red blood cells (PRBC), platelet concentrate, fresh frozen plasma (FFP), cryoprecipitate, granulocytes, immunoglobulins (IG) and clotting factors. Blood components are proven to be superior over the whole blood in the present era. However blood component therapy is a double edged sword as it is associated with many hazards like transmissible infections, hemolytic and non-hemolytic transfusion reactions, transfusion related acute lung injury (TRALI), and transfusion associated graft versus host disease (TAGVHD) etc (Madjdpour *et al*., 2006; World Health Organization, 2001). Above transfusion hazards pose a significant concern in using this valuable biological product. Though advances in infectious disease testing continue to improve the safety of blood supply, viral, bacterial and parasitic diseases can still be transmitted by transfusion and novel agents may appear at any time. Thus, infectious complications of transfusion remain an important area of concern in transfusion medicine. According to world health organization(WHO), appropriate use of blood products is defined as "the transfusion of safe blood products only to treat a condition leading to significant morbidity or mortality that cannot be prevented or managed effectively by other means (World Health Organization, 2002; Vermeulen, 2010)". There are two crucial factors that determine the safety and effectiveness of transfusions. First is the accessibility and adequacy of supply of safe blood and blood products to meet the national needs; and second, the appropriate clinical use of blood and blood products. However, on studying the clinical use of blood between different hospitals, different clinical specialties and different clinicians, it was evident that there is

substantial disparities on the pattern of blood use from every region of the world[5]. The wide variation in the transfusion practice was due to the absence of consensus on the most appropriate criteria for blood transfusion therapy; the differences on blood component therapy guidelines; and the mixed effectiveness of the strategies in changing transfusion practice (Verma, 2008; Roseff, 2002). There by it deserves a huge demand for a study to review the appropriateness of use of blood products. Five percent (5%) of all transfusions should be audited on a quarterly basis as a requirement (Choudhury, 2001). There is a need for continuous evaluation of blood transfusions and audit of the use of blood products as therapy. Hence this study was planned to look at the clinical profile and usage of FFP in children admitted to urban tertiary hospital. This study will also look at the appropriateness of indications of use of the FFP as compared to standard guidelines laid down by British committee for standards in hematology (BCSH) (Committee, 2004) blood transfusion task force.

MATERIALS AND METHODS

Study design: Prospective, cross sectional observational study

Study site: Jehangir Hospital, Pune (Urban tertiary care centre).

Study population: Children in the age group 0 to 16 years admitted for various clinical conditions in Jehangir hospital.

Sample size: 100 events of FFP component transfusion taking place in children aged 0 to 16 years admitted in Jehangir hospital.

Sample Size Calculation: Sample size was determined by using the effect sizes from the previously published studies and with the help of following formula:

$$n = z2\,\frac{pq}{(me)^2}$$

p = 0.05 (Approximate hospital based prevalence of requirement of FFP among the children aged 0 – 16 years),
Sampling Technique:- Convenience sampling.

Study duration: November 2016 to Oct 2017 (1year)

Inclusion Criteria

- Parental consent to participate in the study
- FFP component transfusion in children of age group 0 to 16 years admitted for various clinical conditions in pediatric department, Jehangir hospital.

Exclusion Criteria

- Parents not willing to participate in this study.
- Transfusions which are started or given outside our hospital.

MATERIALS AND METHODS

In our study 100 events of FFP therapy was studied in children up to 16 years of age from the department of general pediatrics, neonatal intensive care unit (NICU), pediatric intensive care unit (PICU), pediatric surgery, pediatric orthopedics and oncology day care unit of Jehangir hospital over a period of 12 months (Nov 2016 to Oct 2017). The clinical profile of the patient that is demographic data, history, examination, diagnosis and lab parameters were noted down in the set proforma. Other relevant investigations were also recorded depending on clinical situation which may be hematological, microbiological, biochemical, or radiological (x-ray, USG, CT scan, MRI scan) etc. The informed consent of parents/relatives was taken before enrolling them in the study . The indication for FFP transfusion and the clinical scenario and diagnosis , pre and post transfusion parameters were noted down. All the particulars like bag no, grouping, cross matching confirmation, date of packing and date of expiry were noted . The recipients were monitored throughout the transfusion and observed for any transfusion reactions. If there were any transfusion reactions - it was noted and recorded in the set proforma. Transfusion recipient was monitored clinically for vitals (HR, RR, BP, Spo2)**,** perfusion (CFT, distal pulse**)** looked for signs and symptoms of transfusion reactions if any (fever, chills, rashes, breathlessness). The outcome of the patient after receiving FFP for which he/ she received FFP were also documented. The entire study group was divided into 2 groups, neonatal (aged < 1month) and pediatric (aged from 1month to 16 years). Indication for the FFP transfusion was noted down and compared with the standard guidelines set by BCHS [10] for its appropriateness. As per World Health Organization(WHO), appropriate use of blood products is defined as "the transfusion of safe blood products only to treat a condition leading to significant morbidity or mortality that cannot be prevented or managed effectively by other means"[5,6]

Statistical analysis

Statistical methods used: The data on categorical variables is presented as n (% of cases). The data on continuous variables was presented as Median along with Min – Max across various groups of transfusion therapy. The statistical significance of difference of categorical variables across several groups of transfusion therapy was tested using Chi-Square test. The statistical significance of inter-group difference of median values of time to issue, time to BT and time to completion of therapy was tested using Kruskal-Wallis H test. P-values less than 0.05 are considered to be statistically significant. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data was statistically analyzed using Statistical Package for Social Sciences (SPSS ver 16.0, Inc. Chicago) for MS Windows.

RESULTS

Blood and blood products are considered drugs by the food and drug administration (FDA) (Hillyer *et al*., 2003). Indiscriminate use of blood components is on a rise due to easy availability of sophisticated blood banking services () [12]. It is important for the medical professionals to fulfil the demands for this life saving product and at the same time, evaluate and access the existing trends of blood ordering. The importance of an internal audit and education program emphasize proper selection of blood components for patients and avoiding their overuse[13]. Till date most of the studies on transfusion practices are done in adults and children together. As a fact the supply of blood and blood components are finite, a high rate of inappropriate use has been reported around the world.

Table 1. Distribution of FFPs administered as per age (n=100)

	Neonate		Pediatric			
	<1 month (n=26)		1 month to 5 years (n=44)		6 years to 16 years (n=30)	
Component	n	%	n	%	n	%
FFP (n=56)	26	26	44	44	30	30

Values are n (% Components studied)

Comments

Of the 100 FFP studied, 26 transfusions were done in neonate less than 1 month and 74 FFPs were transfused in children less than 16 years in which majority of the transfusions were done in children less than 5 years (44).

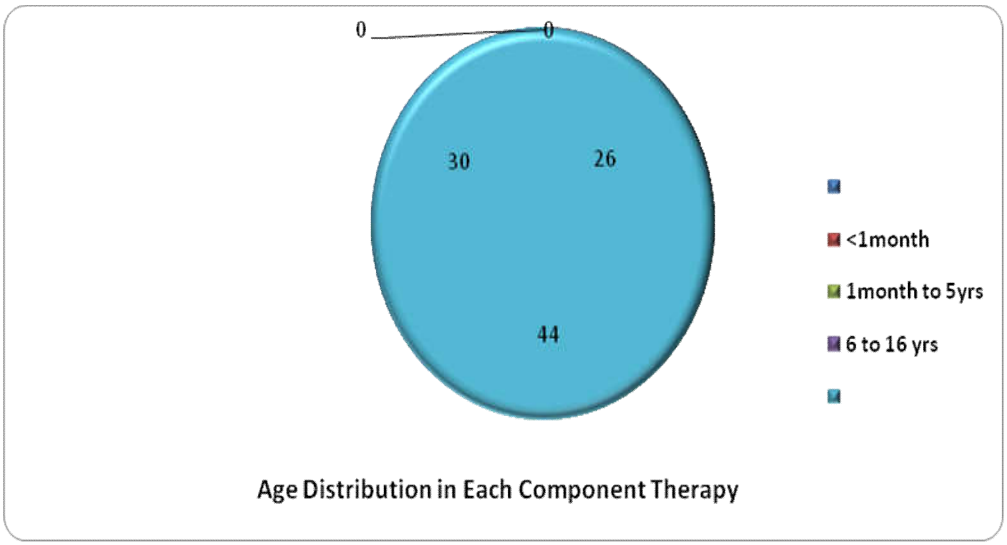

Figure 2. Distribution of FFPs administered as per age and type of component therapy (n=100).

Table 2. Distribution of FFPs administered as per Gender (n=100).

	Male (n=62)		Female (n=38)	
Component	N	%	N	%
FFP (n=56)	40	71.4	16	28.6

Of the 100 FFPs studied, 62 transfusions (62%) were done in males and 38 transfusions (38%) were done in females. The male to female ratio in the entire study group was 1.6;1

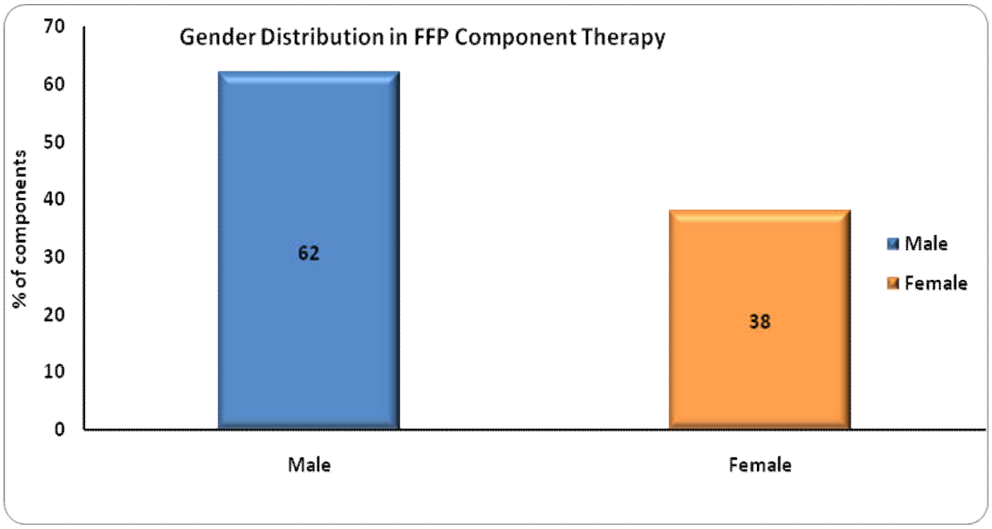

Figure 2. Distribution of FFPs administered as per gender (n=100)

Table 3. Indications of neonatal FFP component therapy and its appropriateness (n=26)

Indications	No.of components	Appropriate	Inappropriate
Sepsis with bleeding	10	10 (100.0)	0
Sepsis without bleeding	14	0	14 (100.0)
Surgical	2	2 (100.0)	0
Total(n=26)	26	12 (46.1)	14 (53.9)

Values are n (% Components studied).

Comments:

Out of 26 neonatal FFP transfusions , 14 (53.9%) were done for sepsis without bleeding and all of them were inappropriate & 10 FFP's transfused for sepsis with bleeding & were appropriate. 2 FFP's were transfused for surgical indications and were appropriate.

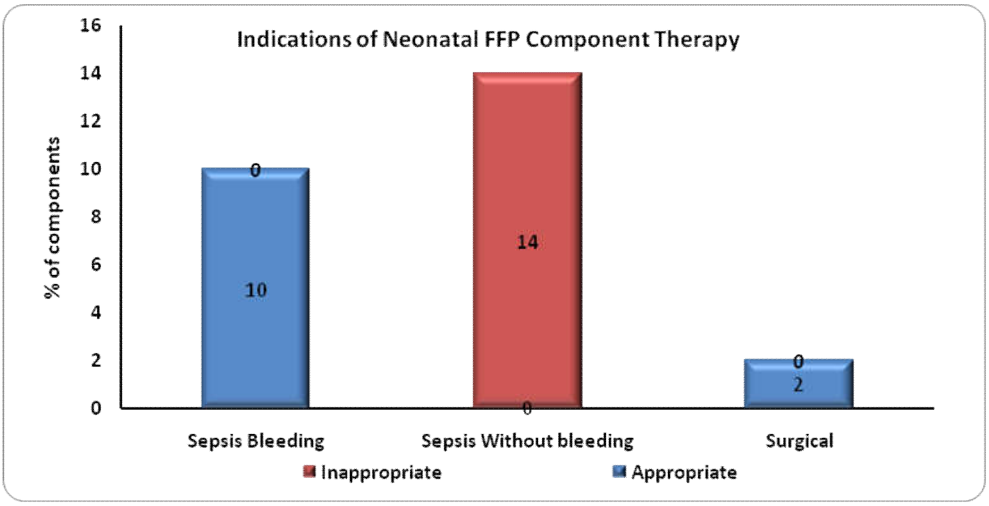

Figure 3. Indications of neonatal FFP component therapy and its appropriateness (n=26)

Table 4. Indications of pediatric FFP component therapy and its appropriateness (n=74)

	Indications	Number of units of FFP	Appropriate	Inappropriate
With Bleeding	Dengue	20	20(100.0)	0
	Sepsis & DIC	15	15 (100.0)	0
	ALF	4	4 (100.0)	0
	Pneumonia ARDS	3	3 (100.0)	0
	Aplastic Anemia	3	3 (100.0)	0
Without Bleeding	Dengue	15	0	15(100.0)
	Pneumonia with ARDS	2	0	2(100.0)
	ALF	1	0	1 (100.0)
	Sepsis DIC	4	0	4(100.0)
	Hemolytic Uremic syndrome	2	2 (100.0)	0
	Thrombotic thrombocytopenic purpura(TTP)	1	1 (100.0)	0
	Hemophagocytic lymphohistiocytic syndrome (HLH)	1	1 (100.0)	0
	Surgical	3	3 (100.0)	0
	Total	74	52 (70.3)	22 (29.7)

Values are n (% Components studied).

Comments:

Out of 74 pediatric FFP transfusions, 22 (29.7%) were inappropriate. Of these 15 FFPs were transfused for Dengue patients who ever not bleeding, 4 transfusions were done in patients with sepsis -disseminated intravascular coagulation (DIC) without bleeding , 2 transfusions were done in patients with acute respiratory distress syndrome (ARDS)without bleeding and 1 transfusion was in patients with acute liver failure (ALF) without bleeding .No reactions were observed during FFP transfusion.

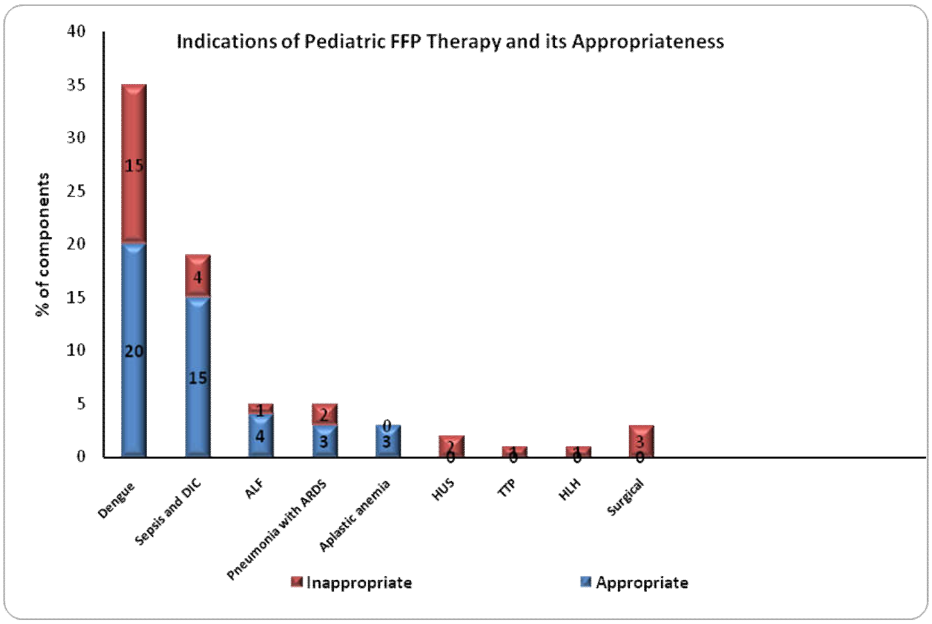

Figure 4. Indications of pediatric FFP therapy and its appropriateness (n=74)

Table 5. Distribution of the appropriateness of the FFP administered (n=100)

	Neonatal		Pediatric		All	
Component	Appropriate	Inappropriate	Appropriate	Inappropriate	Appropriate	Inappropriate
FFP (n=100)	12	14	52	22	64	36

P-value = 0.001 (Statistically Significant). P-value by Chi-Square test.

Out of the 100 components studied, 36 transfusions were inappropriate, 14 were in neonates & 22 transfusions were done in pediatric population. Overall, the distribution of appropriateness of blood transfusion differs significantly across various indication of component therapy (P-value<0.001) which was statistically significant.

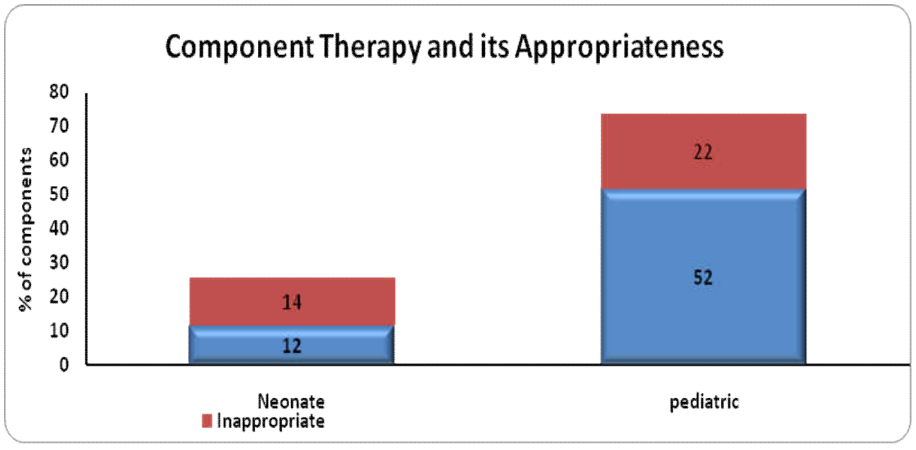

Figure 4. Distribution of the appropriateness of the FFP administered (n=100).

Table 6. Distribution of transfusion reactions following the FFP therapy (n=100)

Reactions During Current Transfusion					
Component	Yes		NO		% transfusion reaction
	Neonatal	Pediatric	Neonatal	Pediatric	
FFP	00	03	26	71	3.0
Total(n=100)	3		97		3.0

Values are n (% Components studied). P-value = 0.008 (Statistically Significant). P-value by Chi-Square test

Out of the 100 components studied, adverse reactions were observed during 3 transfusions all of them were FNHR, in Pediatric age group. No reactions were seen in neonatal age group. The distribution of incidence of reactions due to FFP transfusions were statistically significant (P-value<0.05).

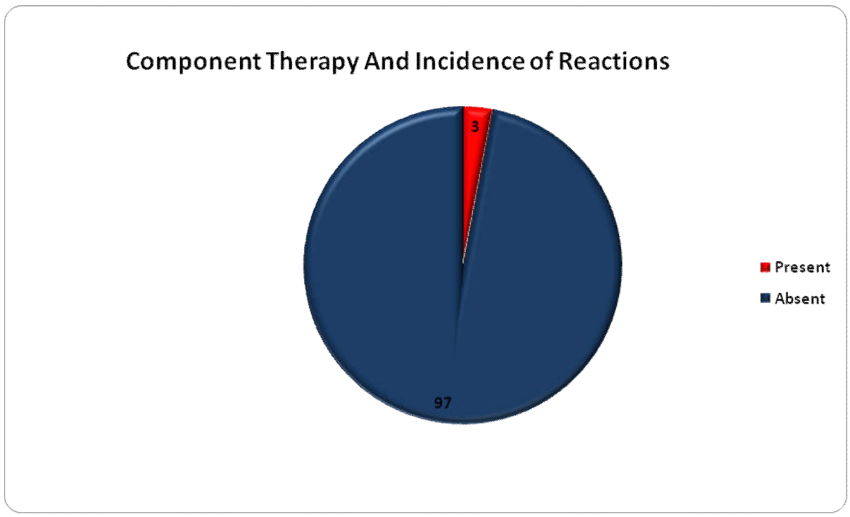

Figure 5. Distribution of transfusion reactions following the FFP therapy (n=100)

This inappropriate use of blood and its components have a significant impact on the patients and the hospital staff in the form of health care cost, wastage of resources, depriving more needy patients and transmission of infection with unnecessary allergic reactions causing high mortality and morbidity in patients [13.] On review of literature, we found that there are few studies on appropriateness of FFP therapy in the pediatric age group and there are very few which are prospective. This made us conduct a prospective study on usage of FFP in pediatric age group to look into the transfusion practices in children admitted in Jehangir Hospital, Pune (a tertiary care hospital) and its level of appropriateness. Out of 100 FFP transfusions, 26 FFPs were transfused in neonatal age group , 14 (53.9%) transfusions were done for sepsis without bleeding and all 14 were inappropriate and 10 FFP's transfused for sepsis with bleeding were appropriate. 2 FFP's were transfused for surgical indications and were appropriate (Table 3) . none had reaction to FFP transfusions(Table 3 and 6). Out of 74 pediatric FFP transfusions, 52 FFP transfusions were done in children with significant bleeding and 22 FFPs were transfused without any clinical bleeding, in which 36% were inappropriate and 5 were appropriately used for HUS, TTP and one used for major intracranial surgery with coagulopathy (Table 3). 4 out of the 7 inappropriate transfusions were done in patients with sepsis and disseminated intravascular coagulation (DIC), 2 transfusions were done in patients with acute respiratory distress syndrome (ARDS), and 1 transfusion was done in patient with acute liver failure (ALF), all without bleeding and none had reaction to FFP.

Previous studies report inappropriate FFP usage ranging from 23-73%. Our results were inconsistent with the studies by Chang *et al*. (2003) and Chaudhary *et al*. (2005) who reported inappropriate FFP usage to be 73% and 70.5% respectively. Quareshi *et al*. (2015) found 19.34% FFPs were used inappropriately. Use of FFP for volume expansion was the most frequent form of inappropriate use followed by cases of bleeding without derangement of coagulation tests. Increasing awareness among the clinicians and strict protocol in management may have helped to reduce the percentage of inappropriate transfusions. Shalini Bahadur *et al*. (2015) study of blood transfusion in New Delhi stated that 76% of FFP transfusions were unjustified. Total 51 fresh frozen plasma (FFP) transfusions were given in 31 patients of which 28 (55%) were given because of deranged coagulogram without bleeds, 17 (33%) had bleeds and 6 (11.7%) received for other miscellaneous indications. Most appropriate indication of FFP usage was coagulopathy (42.57%). Kakkar *et al*. (2004) audit on transfusion practice of FFP and its appropriateness indicated that 60.3% FFP prescriptions were inappropriate. Geetanjali *et al*. (2015) in her retrospective study reported that 76% FFP transfusions were unjustified, total 51 fresh frozen plasma (FFP) transfusions were given in 31 patients of which 28 (55%) were given because of deranged coagulogram without bleeds, 17 (33%) had bleeds and 6 (11.7%) received for other miscellaneous indications. Marti-Carvazal *et al*. (2005) cross sectional study in Venezuela, also found that found 72% of FFP transfusions were inappropriate and Hume *et al*. (1991) in his retrospective study in 630 transfusion episodes found that 364 (57.7%) FFP were used inappropriately. In our study, rate of inappropriate FFP usage was 36%, which is comparatively less as compared to above mentioned studies (Jindal, 2015; Marti-Carvazal *et al*., 2005; Hume, 1991). Some of the common reasons behind the inappropriate usage is as follows - FFP being used as volume expander, to treat shock, or de-arranged lab parameters without clinical bleeding and for improving poor perfusion. In present study 23% of FFP transfusions were inappropriate. There is still need for improvement to completely nullify the inappropriate usage of FFP.

Conclusion

The decision to transfuse blood products has to be very cautious in each and every patient and it requires a lot of commitment on the part of health authorities, health care providers and clinicians. Regular audit and strict feasible guidelines on FFP transfusion will help to reduce the misuse of the precious blood products.

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