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Original Research Article

Prospective observational study for appropriateness of blood and blood components therapy in children up to 16 years of age admitted in a tertiary care hospital

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ABSTRACT

Background: Blood component therapy is a rational replacement therapy of proven clinical value and efficacy, but it is a double-edged sword as it is associated with many hazards of transfusion reaction. Because of ease of availability and gap in the knowledge of medical professional's blood products are being used very liberally leading to huge mismatch in the demand and supply of life saving blood product.
Methods: Prospective cross-sectional observational study was done over a period of 1 year in a tertiary hospital, in western part of India. 225 events of blood component therapy were studied in neonates (<1month) and pediatric (1month-16years) age groups. Indications and reactions to blood components therapy were studied in both the groups. Each component therapy was considered as one event and its indication was compared with standard guidelines for terming it as appropriate or inappropriate.
Results: Out of total 225 events of transfusions, most commonly used was PRBC (48.9%) followed by FFP (24.9%), platelet (16.0%), IVIG (9.8%) and whole blood (0.4%). Authors found that overall 17.3% of the component therapy were inappropriate(neonates 10.2% and 7.1% in the rest). Most commonly misused blood product was FFP (37.5%) followed by IVIG (22.7%), platelets (16.7%) and PRBC (6.4%).
Conclusions: 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.

Keywords: Appropriateness, Audit, Blood components, Transfusion

INTRODUCTION

Blood and blood components are a valuable and limited health-care resource. 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.[1,2]

However, blood component therapy is a double-edged sword as it is associated with many hazards. Guidelines for blood transfusion exist, but variability in their application, particularly in children, remains unsolved. Pediatric transfusion practices and their associated complications remain poorly described.

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.[3,4] 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. Inappropriate use of blood and its components have a significant impact on the health care system.

There is a need for continuous evaluation of blood transfusions and audit of the use of blood products as therapy. Hence this study has been planned to look at the clinical profile, usage and appropriateness of blood products in children admitted to urban tertiary hospital in the western part of the India (Pune).

METHODS

The aim of this study is to prospectively evaluate the usage, indications, adverse effects and appropriateness of blood and blood component therapy in children under 16 years of age in a tertiary care hospital setting.

It was a prospective, cross sectional observational study carried out at Jehangir Hospital, Pune (Urban tertiary care centre) for November 2015 to October 2016 (1 year). 225 events of blood or blood component transfusion taking place in children aged 0 to 16 years admitted in Jehangir hospital.

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

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

me=0.0285 (margin of error)

Statistical analysis

The data on categorical variables is presented as n (% of cases). The data on continuous variables is 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 is 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 is 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.

Inclusion criteria

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

Exclusion criteria

- Transfusions which are started or given outside Jehangir Hospital.

In present study 225 events of blood component 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 1 year (Nov 2015-Oct 2016). Total patients studied were 70 in which 21 were newborns and 49 pediatrics patients. The informed consent of parents/relatives was taken before enrolling them in the study. The indication for the blood component therapy and the clinical diagnosis, pre and post transfusion parameters for the specific type of blood component transfused were noted down. History of previous transfusions, chronic underlying disease status or details of chronic transfusion therapy were noted down. All the particulars of the blood/ blood components were noted (like bag no, grouping, cross matching confirmation, date of packing and date of expiry). Time taken for the issue of the blood component from the time of order is noted down in minutes as time for issue and time taken from the time of issue to completion of blood component is termed as time for transfusion. Blood component therapy was monitored throughout the transfusion and observed for any transfusion reactions. Transfusion recipient was monitored clinically and the outcome of the patient after receiving blood for which he/ she received blood/ component were also documented.

The entire study group was divided into 2 age groups, neonatal (aged less than 1month) and pediatric (aged from 1month to 16 years). Neonates were subcategorized as per gestational age and birth weight. Blood components like packed red blood cells (PRBC), platelets, fresh frozen plasma (FFP), immunoglobulin's (IG) and whole blood were studied in both the groups. Each component transfusion was considered as one event and its indication was compared with British committee for standards in hematology (BCHS) and American association of blood bank (AABB) guidelines for terming it as appropriate or inappropriate.[5,6] For IVIG therapy, guidelines set by United States Food and Drug Administration (US-FDA) were used for terming it as appropriate/ inappropriate.[7]

RESULTS

Of the 225 blood components studied, 67(29.8%) transfusions were done in neonates and 158 (70.2%) in pediatric population in which 33.3% transfusions were in the age group of 1 month to 5 years and 36.9% were between 6 years to 16 years. Total patients studied were 70 in which 21 were newborns and 49 pediatrics patients (Figure 1). The male to female ratio in the entire study group was 3.5:1.0.

Major component transfused was PRBC. (48.9%) followed by FFP (24.9%), platelet (16.0%) and IVIG (9.8%) and 1 case (0.4%) had exchange transfusion with whole blood. Thirty nine out of 225 (17.3%) transfusions were inappropriate in which majority 23(10.2%) of the inappropriate transfusions were done in neonates and 16(7.1%) in pediatric population. Most commonly misused blood product was FFP (37.5%) followed by IVIG (22.7%), platelets (16.7%) and PRBC (6.4%) with P-value<0.001 which was statistically significant (Table 1).

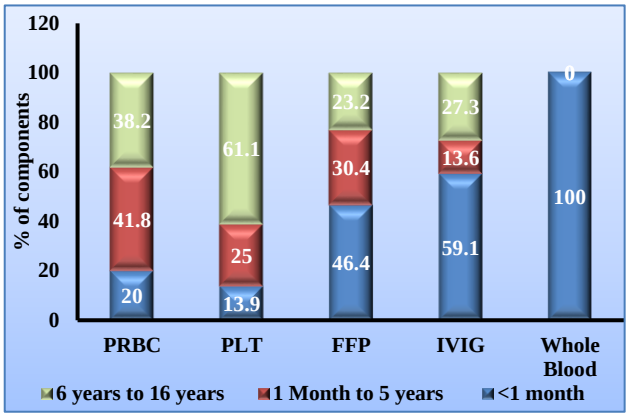

Figure 1: Distribution of blood components administered as per age and type of component therapy (n=225).

Table 1: Distribution of the appropriateness of the blood component administered (n=225).

	Neonatal		Pediatric		All	
Component	**Appropriate**	**Inappropriate**	**Appropriate**	**Inappropriate**	**Appropriate**	**Inappropriate**
PRBC (n=110)	20 (90.9)	2 (9.1)	83 (94.3)	5 (5.7)	103 (93.6)	7 (6.4)
PLT (n=36)	3 (60.0)	2 (40.0)	27 (87.1)	4 (12.9)	30 (83.3)	6 (16.7)
FFP (n=56)	12 (46.2)	14 (53.8)	23 (76.7)	7 (23.3)	35 (62.5)	21 (37.5)
IVIG (n=22)	8 (61.5)	5 (38.5)	9 (100.0)	0	17 (77.3)	5 (22.7)
Whole blood (n=1)	1 (100.0)	0	0	0	1 (100.0)	0
Total	44 (19.5%)	23 (10.2%)	142 (63.5%)	16 (7.1%)	186 (82.6%)	39 (17.3%)

P-value=0.001 (statistically significant). P-value by Chi-Square test.

In present study, out of 225 components studied, 3.1% had a transfusion reaction. 1.8% were to PRBC's, 8.3% to platelet transfusions, 9.1% to IV IG therapy and none of the FFP's had a reaction. One neonate had severe hypersensitivity reaction to inappropriately given IV IG therapy which required aggressive resuscitation and mechanical ventilation, one more neonate had mild hypersensitivity reaction to inappropriately given IV IG. Two children with PRBC transfusions had febrile non-hemolytic reaction (FNHR), 2 children with platelet transfusions developed mild hypersensitivity reaction and another 1 had FNHR. Out of the 7 who had reactions, 4 had history of reaction in the past and 3 had reaction for the first time. Out of 7 reactions, 5 reactions were seen with aplastic anemia and oncology patients. The distribution of incidence of reactions due to blood component therapy differs significantly across various type of components of blood transfusion and was statistically significant.

Authors studied time taken for the issue of the blood component and time taken for completion of the transfusion from the time of issue. Transfusion time were within the standard timings set down as per the guidelines for the completion of the transfusion and exceptions were negligible.

DISCUSSION

Indiscriminate use of blood components is on a rise due to easy availability of sophisticated blood banking services.[8] It is important for the medical professionals to fulfill 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.[9] Till date most of the studies on transfusion practices are done in adults and children together.

On review of literature, authors found that there are few studies on appropriateness of blood component therapy in the pediatric age group and there are very few which are prospective. In present study 67 (29.8%) transfusions were done in neonates and 158 (70.2%) in pediatric population in which 75 (33.3%) transfusions were in the

age group of 1 month to 5 years and 83 (36.9%) were between 6 years to 16 years. Total patients studied were 70 in which 21 were newborns and 49 pediatrics patients (Figure 1).

Bahadur S et al have reported an audit of pediatric transfusion practices in a tertiary care hospital, New Delhi.[10] A total of 2,145 units of hematological components were transfused to children, including 1,181 (55%) units of red cells, 566 (26.4%) units of platelets, 118 (5.5%) units of whole blood and 280(13%) units of FFP. They found that RBC's (55%) were the most commonly used blood component in children.

Alcantara et al reported in their study on blood transfusion in tertiary care hospital in Philippines that packed red blood cells (841) were the most frequently utilized, followed by whole blood (127), platelet concentrates (91) and fresh frozen plasma (16).[11]

PRBCs was the most commonly used blood product in all the above-mentioned studies which was similar to present study result.

Out of the 225 components studied ,39 (17.3%) transfusions were inappropriate out of which 23(10.2%) inappropriate transfusions were done in neonates and 16(7.1%) in pediatric population (Table 4). 7(6.4%) of PRBC's, 6(16.7%) of platelets, 21(37.5 %) of FFP and 5(22.7%) of IVIG transfusions were inappropriate and could have been avoided (Table 1). Thus, most commonly misused blood product in the study group was FFP followed by IV IG, platelets and PRBC. Overall, the distribution of appropriateness of blood transfusion differs significantly across various type of component therapy and it was statistically significant.

Geetanjali et al in their study on appropriateness of blood component transfusion in children in a tertiary care teaching hospital, Chandigarh also found that FFP was most inappropriately used component.[12]

Martí-Carvajal et al in a cross-sectional study in Venezuela, also found that FFP and cryoprecipitate had a high rate of inappropriate use, overall prevalence of inappropriate use of blood products was 39.2% (158/404).[13] Inappropriate use of blood products was as follows: cryoprecipitate (71.5%), FFP (62.7%), platelets (47.4%), PRC (24%) and WB (17%).

Out of all neonatal transfusions, authors found that maximum blood component requirement was in preterm babies with weight less than 2.5kg and the commonest indication was prematurity with sepsis (Table 2).

Table 2: Distribution of blood components administered in neonates according to their gestational age (n=67).

	Gestational age (Weeks)							
	<28 Weeks Extremely preterm (EPT)		28-31 Weeks Very preterm (VPT)		32-36 Weeks Preterm (PT)		>37 Weeks Term	
Component	n	%	n	%	n	%	n	%
PRBC (n=22)	4	18.2	16	72.8	1	4.5	1	4.5
Platelets (n=5)	0	0.	5	100.0	0	0.0	0	0.0
FFP (n=26)	4	15.4	19	73.0	1	3.9	2	7.7
IVIG (n=13)	2	15.4	9	69.2	1	7.7	1	7.7
Whole blood (n=1)	0	0.0	1	100.0	0	0.0	0	0.0
Total (n=67)	10	14.9	50	74.6	3	4.5	4	6.0

Values are n (% components studied)

Ayede et al study on blood component therapy in neonates found that blood component requirement was highest in preterm babies compared to term babies.[14] Up to 82% of the transfusions done in neonates were in preterms and weight range was between 0.8kg to 3.6 kg with a mean weight of 1.64 kg. Majority were in the LBW babies. These findings were similar to present study.

Out of 22 neonatal PRBC's transfusions done for correction of anemia, 2 (9.1%) transfusions were done for pre-transfusion Hb <7g%, 20(90.9%) transfusions were done for Hb between 7-10g% and no transfusions were done for Hb >10g%. Seven transfusions were given for ventilated babies, 8 were on oxygen support, 5 were off oxygen and stable and 2 transfusions were done for surgical indications.

The distribution of incidence of reactions due to present blood transfusion differs significantly across various type of components of blood transfusion and was statistically significant. Pedrosa AK et al study on blood transfusion reaction in children also found that a total of 57 reactions were reported among the 1,226 patients.[15]

Prevalence of reactions was up to 3.8% and most allergic reactions were seen with platelet concentrate (68.4%). It is similar to present study results.

Two out of 22 (9%) PRBC's were transfused for Hb between 7-10g% were inappropriate. One 30 weeks preterm neonate at 27 days of life was recovering from RDS and sepsis received PRBC for correction of mild anemia with Hb 9.9g% and another one was stable preterm neonate (28 week) off oxygen with anemia of prematurity with Hb of 9.2g% received a PRBC transfusion inappropriately. None of the neonates had reaction to PRBC (Table 3).

Out of 5 platelet transfusions 2 (40%) were inappropriate. 1 was done in sick PT with count of >50,000 and 1 was in stable term neonate without bleeding with platelet count between 20,000 -50,000 (Table 4). None of the neonates had reaction to platelets.

Out of 26 neonatal FFP transfusions, 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. None had reaction to FFP transfusions.

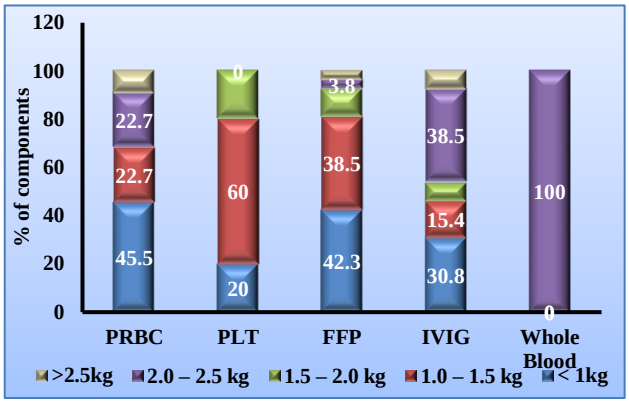

Figure 2: Distribution of blood components administered in neonates according to their birth weight (n=67).

Table 3: Indications of neonatal PRBC therapy and its appropriateness (n=22).

Indications; Anemia with	Number of components	Appropriate	Inappropriate
Respiratory distress on ventilator	7	7 (100.0)	0
Oxygen support	8	7 (87.5)	1
Off oxygen; stable	5	4 (80.0)	1
Surgical	2	2 (100.0)	0
Total	22	20 (91)	02 (9)

Values are n (% components studied)

Table 4: Indications of neonatal platelets component therapy and its appropriateness (n=5).

Indications	No. of components	Appropriate	Inappropriate
Sick preterm neonate not bleeding	2	1 (50.0)	1 (50.0)
Stable term neonate not bleeding	1	0	1 (100.0)
DIC without bleeding	1	1 (100.0)	0
Preterm neonate with bleeding	1	1 (100.0)	0
Total	5	3 (60.0)	02 (40.0)

Values are n (% components studied)

Table 5: Distribution of blood components administered in the critically ill children and its appropriateness (n=86).

Component	No. of blood component	% of blood component	Inappropriate
PRBC	36	41.8	04
Platelet	21	24.4	04
FFP	24	27.9	07
IVIG	05	5.9	00
Total	86	100.0	15

Values are n (% components studied)

Thirteen IV IG's were transfused in the neonates, 5 transfusions were done in sepsis, 4 in sepsis with DIC, 1 in ABO incompatibility, 3 in Rh incompatibility. Out of these, 5 were inappropriate, 4 had sepsis and 1 had ABO incompatibility. Five of these were inappropriate, out of which 4 had sepsis and 1 had ABO incompatibility. Two IV IG transfusions had hypersensitivity reaction, out of which one received it for moderate sepsis, and had a severe life-threatening hypersensitivity reaction requiring-aggressive resuscitation and mechanical

ventilation and another mild hypersensitivity reaction was seen in a baby who received IV IG inappropriately for ABO incompatibility. These cases highlight the importance of using blood products rationally and prudently.

In present study, of 86 blood components studied in critically ill children, 36 (41.8%) were PRBC's, 21 (24.4%) were platelets, 24 (27.9%) were FFP's and 05 (5.9%) were IVIG transfusion. Overall 17.4% of the transfusions in critically ill were inappropriate. Out of 36 PRBC transfusions in critically ill children, 18(50%) transfusions were done with pre-transfusion Hb of <7 in which one with hemoglobin of 5.5g% had nutritional anemia and hence it was inappropriate. Remaining 18 (50%) transfusions were done with Hb of 7g-10g%, in which 3 were inappropriate, 2 were in children with sepsis, 1 child had pneumonia. 4/ 36(11.1%) PRBCs, 4/21(19%) platelets, 7/24 FFP's (29.1%) were inappropriate (Table 5).

Lacroix et al, highlighted that in the TRIPICU trial comparison was done between restrictive strategy of transfusion (7g%) with liberal strategy of transfusion (9.5g%) in critically ill children.[16] The authors conclude that for stable critically ill children in the PICU a haemoglobin threshold of 7g% can be used for PRBC transfusion. This was shown to decrease transfusion requirements without increasing adverse outcomes.

Out of 21 platelet transfusions, four were inappropriate which were prophylactic transfusions done in sepsis with DIC without bleeding with counts of 3 children between 20,000-50,000 and one >50,000 (Table 5). Out of 24 FFP's transfused, 7 were inappropriate- 4 in sepsis and DIC without bleeding, 1 in acute liver failure without bleeding and 1 in pneumonia with ARDS on mechanical ventilation with poor perfusion without any bleeding.

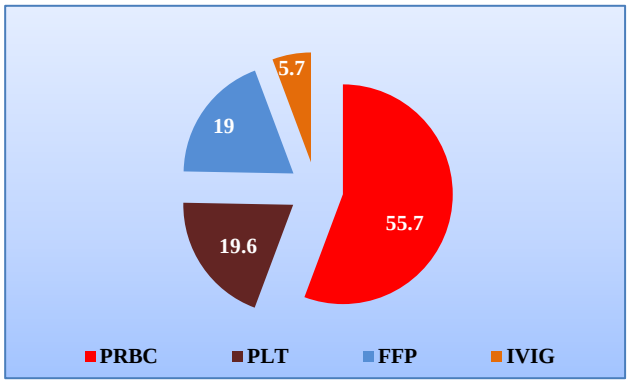

Figure 3: Distribution of blood components administered in the pediatric age group (n=158).

Out of 88 pediatric PRBC's transfusion (Figure 3), 30(62.5%) transfusions were done with pre-transfusion Hb<7g%, 55(62.5%) were between 7-10g% Hb and 3(3.4%) with Hb >10g%. 24(27.3 %) components were transfused for children with thalassemia, rest 64 transfusion were done for anemia with varied diagnosis. Out of these, 5(5.7%) of the pediatric PRBC's were inappropriate for the reason that there Hb was in the range of 7-10g%, they were neither in failure nor they required any respiratory support. One child with Hb of 5.5gm% with minimum oxygen support and not in failure was termed inappropriate because etiology was nutritional. Two of the PRBC's transfusions had reactions, 1 was in oncology group and 1 was in child with aplastic anemia. Both were mild FNHR and required just supportive care.

In a study by Wade et al, audit on rational use of blood components found 35.5% PRBC transfusions inappropriate in pediatric patients.[17] Makroo et al found 21.4% of PRBC transfusions to be inappropriate.[18] Earlier studies by Hume et al and Mozes et al found 5.9% and 49.6% of PRBC transfusions to be inappropriate respectively.[19,20]

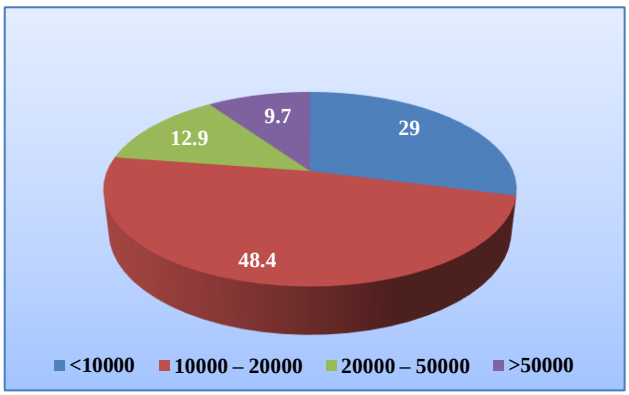

Figure 4: Pediatric platelet therapy according to pre-transfusion platelet levels (n=31).

Out of 31 platelet transfusions in the pediatric age group, 15 were transfused prophylactically and 16 transfused for patients with severe thrombocytopenia and bleeding. 11 children on chemotherapy and 4 in sepsis with DIC were transfused prophylactically (Figure 4). Of the 16 therapeutic platelet transfusion in children with bleeding, 8 were in sepsis with DIC, 7 were done in aplastic anemia, 1 in HLH. 9 (29%) had pre-transfusion platelet counts of <10,000, 15 (48.4%) had pre-transfusion counts in the range of 10,000-20,000, 4 (12.9%) had counts between 20,000-50,000, 3 (9.7%) had counts of >50,000. Most of the pediatric platelet transfusions, (48.4%) were done with pre-transfusion counts in the range of 10,000-20,000. Out of these, 4 (12.9%) were inappropriate, 3 transfusions were done with counts in the range of 20,000-50,000 and 1 transfusion with count of >50,000 (Table 6). All the inappropriate transfusions were done prophylactically in patients with sepsis and DIC.

Table 6: Indications of pediatric platelet component therapy and its appropriateness (n=31).

	Indications	Number of components transfused	Appropriate	Inappropriate	Reaction
Prophylactic	Oncology patients on chemotherapy	11	11 (100.0)	0	1
	Sepsis with DIC	04	0	4 (33.4)	1
	Sepsis with DIC	08	08(100.0)	0	
With bleeding (Therapeutic)	Aplastic anemia (bone marrow-failure)	7	07 (100.0)	0	1
	HLH	1	01 (100.0)	0	0
	Total	31	27 (87.1)	4 (12.9)	3

Values are n (% components studied)

Table 7: Indications of pediatric FFP component therapy and its appropriateness (n=30).

	Indications	Number of units of FFP	Appropriate	Inappropriate
With bleeding	Sepsis and DIC	8	8 (100.0)	0
	ALF	4	4 (100.0)	0
	Pneumonia ARDS	3	3 (100.0)	0
	Aplastic Anemia	3	3 (100.0)	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
Without bleeding	Thrombotic thrombocytopenic purpura (TTP)	1	1 (100.0)	0
	Hemophagocytic lymphohistiocytic syndrome (HLH)	1	1 (100.0)	0
	Surgical	1	1 (100.0)	0
	Total	30	23 (76.7)	7 (23.3)

Values are n (% components studied)

Three pediatric platelets transfusions had reactions, 1 in child on chemotherapy, 1 in sepsis with DIC and 1 in aplastic anemia. All 3 reactions were mild and required just supportive care. Makroo et al study on use of blood components in critically ill patients in the medical intensive care unit of a tertiary care hospital reported that 19% of the platelet transfusions in critically ill patients were inappropriate.[18]

Out of 30 pediatric FFP transfusions, 18 FFP transfusions were done in children with significant bleeding and 12 FFPs were transfused without any clinical bleeding, in which seven (23.3%) were inappropriate and 5 were appropriately used for HUS, TTP and one used for major intracranial surgery with coagulopathy. 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 patients with acute liver failure (ALF), all without bleeding and none had reaction to FFP (Table 7).

In present study, rate of inappropriate FFP usage was 23.3%, which was comparatively less as compared to prior studies but FFP was the highest misused product in present study. Kakkar et al audit on transfusion practice of FFP and its appropriateness indicated that 60.3% FFP prescriptions were inappropriate.[21] Out of 9, IV IGs transfused, 3(33.3%) were transfused for Guillain Barre Syndrome (GBS) 3 (33.3%) for immune thrombocytopenic purpura (ITP), 2(22.3 %) for Kawasaki's disease, 1(11.1%) for auto immune hemolytic anemia (AIHA). All were appropriate, and none had reaction for IV IG in pediatric age group.

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 blood component therapy will help to reduce the misuse of the precious blood products.

Recommendations

There is an urgent need to generate awareness among treating doctors across all medicine specialties regarding appropriate transfusion practices and the inherent dangers of using this precious resource indiscriminately.

There should be standard written protocols for blood component therapy in all ICUs and wards. Regular audit of the blood component therapy should be carried out in all tertiary care hospitals to assess the usage of the blood components in the respective institute and then rectify the lacunae observed through various measures. There is a need for a multicenter study on assessing appropriateness of blood component therapy in pediatric age group in Indian setup for creating awareness and to bring out the evidence on the misuse of blood components.

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