

Transfusion-related adverse reactions: From institutional hemovigilance effort to National Hemovigilance program

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Abstract:

Aims: In this study we have evaluated the various adverse reactions related to transfusion occurring in our institution as a pilot institutional effort toward a hemovigilance program. This study will also help in understanding the problems faced by blood banks/Transfusion Medicine departments in implementing an effective hemovigilance program. **Materials and Methods:** All the adverse reactions related to transfusion of whole blood and its components in various clinical specialties were studied for a period of 1 year. Any transfusion-related adverse event was worked up in accordance with guidelines laid down by the Directorate General of Health Services (DGHS) and departmental standard operating procedures. **Results:** During the study period from November 1, 2011 to October 31, 2012, 45812 components were issued [30939 WB/PRBC; 12704 fresh frozen plasma (FFP); 2169 platelets]. Risk estimation per 1000 units of red cells (WB/PRBC) transfused was estimated to be: 0.8 for febrile nonhemolytic transfusion reaction (FNHTR), 0.7 for allergic reaction, 0.19 for acute hemolytic transfusion reaction (AChTR), 0.002 for anaphylactoid reactions, 0.1 for bacterial sepsis, and 0.06 for hypervolemia and hypocalcemia. 0.09 is the risk for delayed transfusion reaction and 0.03 is the risk for transfusion-related acute lung injury (TRALI). Risk estimate per 1,000 units of platelets transfused was estimated to be 1.38 for FNHTR, 1.18 for allergic reaction, and 1 in case of bacterial sepsis. Risk estimation per 1,000 units of FFP was estimated to be 0.15 for FNHTR and 0.2 for allergic reactions. **Conclusions:** Factors such as clerical checks at various levels, improvement in blood storage conditions outside blood banks, leukodepletion, better inventory management, careful donor screening, bedside monitoring of transfusion, and documentation of adverse events may decrease transfusion-related adverse events. Better coordination between transfusion specialists and various clinical specialties is the need of the hour and it will help in making the whole transfusion chain safe and effective. There is a need for a hemovigilance program at the national level so that true incidence and the spectrum of adverse events due to transfusion are known and policies formulated to minimize the risks associated with it.

Key words:

Indian hemovigilance, transfusion reactions, transfusion-related adverse events

Introduction

Safety from transfusion transmitted diseases has improved with advances of technology. The recent testing facilities have lowered the incidence of transfusion-transmitted diseases to the minimum; however, the incidence of adverse events due to human errors, ABO incompatibility, alloimmunization, bacterial contamination, and immunomodulation phenomena remain a matter of concern.

The term "hemovigilance" has come to be widely used over the past decade to describe the systematic surveillance of adverse transfusion reactions and events, encompassing the whole transfusion chain and aimed at improving the safety of the transfusion process, from donor to recipient, "vein to vein."^[1] Various hemovigilance programs have been developed and implemented in several countries including Canada, United Kingdom, and France, and they publish their annual reports of adverse events associated with blood transfusion. The aim of these

programs is to have a system of surveillance and thus lower the risks associated with transfusion.^[2-4]

Unfortunately, there has been no such program in India and the reporting of transfusion hazards is not mandatory. In addition, there is underreporting by the medical staff and thus most of the minor adverse events do not come to attention; therefore the exact incidence of various

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types of transfusion reactions is not known. Understanding the magnitude of the problem, a national hemovigilance program as an integral part of the pharmacovigilance program of India at a national level was launched on December 10, 2012. Initially, 60 medical colleges have been brought under the ambit of this program. The Medical Colleges enrolled under the hemovigilance program will collect data with respect to adverse reactions associated with blood transfusion and blood product administration using the Transfusion Reaction Reporting Form (TRRF). The information collected will be used to formulate recommendations and guidelines that will be communicated to various stakeholders.^[5]

In this study we have evaluated the various adverse reactions related to transfusion occurring in our institution as a pilot institutional effort toward hemovigilance. This will provide useful information and education to all concerned in transfusion medicine services as well as staff monitoring at bedside transfusion, toward minimizing the adverse reactions related to transfusion. This study will also help in understanding problems faced by blood banks/ Transfusion Medicine departments in implementing an effective hemovigilance program.

Materials and Methods

The current study was done at the Post Graduate Department of Immunohematology and Blood Transfusion Medicine Government Medical College (GMC), Jammu. All the adverse reactions related to transfusion of whole blood and its components between November 1, 2011 and October 31, 2012 in various clinical specialties were studied. Any transfusion-related adverse reaction was worked up in accordance with guidelines laid down by the Directorate General of Health services (DGHS) technical manual, Ministry of Health, Government of India and departmental standard operating procedures. Transfusion reaction was defined as any unfavorable transfusion-related event occurring in a patient during or after transfusion of blood/blood component. The diagnosis of various types of reactions was based on clerical checks, clinical history and examination of patient, and various investigations done at the department of Transfusion Medicine and other departments such as Pathology, Microbiology, and Radiology, as described in Table 1.

Investigation of transfusion-related adverse reactions

Clerical check

The patient's name and identification number were rechecked to rule out the possibility of wrong sampling or bedside transposition. This was followed by verification of the patient's clinical records and his/her ABO and Rh typing records at the bedside and in the department. The implicated unit's identity was verified by checking

its number and ABO/Rh type and confirming if it was issued to the intended recipient.

Clinical history and examination of patient

Clinical history of the patient regarding the indications of transfusion(s) and similar adverse reactions in the past was recorded; each patient was also asked about any history of pregnancy and drug intake. To ascertain the nature of the reaction, clinical signs and symptoms (i.e., fever, chills, hypotension, rigors, cola-colored urine, rashes, respiratory discomfort, and any other untoward events developed during the course of transfusion or following transfusion) and their duration and management were recorded. Circumstantial evidences for thermal, oncotic, and osmotic injury were looked for by reviewing the mode of storage of the issued unit after it was released from the blood bank and whether any medication was given to the patient along with blood transfusion.

Investigations at department of transfusion medicine

1. Gross examination.
 - a. Blood bag and transfusion set examined for any discoloration, clot, and hemolysis.
 - b. The patient's supernatant plasma observed for evidence of hemolysis by appearance of pink or reddish tinge.
2. Serological testing on pre- and posttransfusion samples.
 - a. ABO and Rh typing of the patient by both forward and reverse.
 - b. ABO-Rh type of the implicated blood component.
 - c. Compatibility done by an immediate-spin, indirect antiglobulin test (IAT) and enhancement-technique low ionic strength solution (LISS) with the patient's pre- and posttransfusion sample.

Investigations outside department of transfusion medicine

1. Bacterial culture from the blood bag and patient's blood were done at the Department of Microbiology.
2. Other supportive laboratory investigations in suspected cases of hemolytic transfusion reaction: Estimation of plasma hemoglobin (using peroxidase method), urine for hemoglobinuria by visual examination and hemoglobin estimation, peripheral blood smears examination, estimation of hemoglobin and bilirubin.
3. In nonhemolytic transfusion, reactions investigations were done according to their clinical presentations, namely: Chest x-ray for transfusion-related acute lung injury (TRALI), or serum calcium levels for hypocalcemia.

The risk of adverse reaction was calculated per 1,000 transfusions of that component, i.e., {Total no. of implicated reactions/total no. of components Transfused} × 1000. Different ratios were calculated, the significance limit was set at .05 and the chi square test was used to find statistical significance.

Table 1: Showing categories of transfusion reaction and relevant investigations

Type of reaction	Clinical features	Lab investigations
AcHTR	Chills, fever, hemoglobinuria, DIC, shock	Clerical checks, DAT, visual inspection, serum bilirubin, urine Hb, blood film examination
FNHTR	Chills, rigors, increase in temperature	DAT (to rule out hemolytic reaction), blood film examination
Urticarial reaction	Urticaria, pruritus, rash	DAT to rule out any hemolytic reaction
Anaphylactic reaction	Urticaria, severe hypotension, shock	DAT to rule out any hemolytic reaction
Delayed hemolytic transfusion reaction	Posttransfusion jaundice, fall in Hb after 24 h	DAT, posttransfusion incompatibility
TRALI	Respiratory distress	Chest x-ray

AcHTR: Acute hemolytic transfusion reaction, FNHTR: Febrile non hemolytic transfusion reaction, TRALI: Transfusion related acute lung injury, DIC: Disseminated intravascular coagulation, DAT: Direct antiglobulin test

Results

During the study period from November 1, 2011 to October 31, 2012, 45812 components were issued [30939 WB/PRBC; 12704 fresh frozen plasma (FFP); 2169 platelets]. A total of 84 adverse reactions due to transfusion were observed during the study period. Table 2 describes different types of transfusion reactions observed in the study.

Transfusion reactions were categorized into 2 major categories:

1. Acute (onset within 24 h).
2. Delayed (onset after 24 h).

Acute transfusion reactions

Acute transfusion reactions were defined as those adverse reactions which occurred within 24 h of blood/component transfusion. They comprised about 95% of the reactions. A total of 80 were acute events, out of total 84 transfusion reactions.

Acute Hemolytic Transfusion Reaction (AcHTR) (N = 6)

Patient profile: Six patients had AcHTR. Four were males and 2 were females. Mean age 44.6 ± 9.66 years (range 32-63 years). Out of these six reactions, 2 were from Gynecology and Obstetrics, 2 from Surgery, and 1 each from Medicine and Medical Oncology.

Clinical features: Clinical signs and symptoms as observed in AcHTR, according to decreasing order of frequency were: Lumbar pain 83.3% (N = 5), hemoglobinuria 83.3% (N = 5), hypotension 66.6% (N = 4), rigors 66.6% (N = 4), jaundice 66.6% (N = 4), fever 50% (N = 3), pallor 33.3% (N = 2), vomiting 16.6% (N = 1). Acute renal failure occurred in 2 of the patients and 1 of the patients had a fatal outcome.

Immune mediated hemolysis occurred in 2 patients: A major ABO mismatch blood transfusion occurred in a 35-year-old Gynecology and Obstetrics patient. She was blood group O+ve and was transfused with A+ve blood due to a clerical error at a blood bank. Another major ABO mismatch blood transfusion occurred in a Gynecology and Obstetrics patient. Only one sample was received for both grouping and crossmatching as the patient was in shock. The patient's sample got mixed up when being labeled in the labor room. A+ve blood was transfused to B+ve patients.

Nonimmune hemolysis (pseudohemolytic reaction): Nonimmune hemolysis was seen in 4 patients. All the four implicated units were damaged due to thermal injury. They were stored outside the blood bank past the permissible limit, resulting in hemolysis due to exposure to extreme weather conditions. One of these patients of nonimmune hemolysis died due to acute renal failure. Three of the patients had uneventful recovery following hemoglobinuria.

Component characteristics: All the implicated units were red cells (WB/PRBC). The storage time of the implicated unit was 16.5 ± 4.24 days in the blood bank refrigerator. The time interval between the beginning of transfusion ranged 1-22 h with a mean value of 10.16 ± 6.8 h. The mean volume of blood transfused before reaction was observed as 97.5 ± 63.28 mL, the range being 10-190 mL.

Acute nonhemolytic transfusion reaction

Out of 84 reactions, 74 (88%) were nonhemolytic transfusion reaction. Nonhemolytic transfusion reactions were further classified according to their clinical signs and symptoms and laboratory investigations.

Table 2: Classification of transfusion reactions in 84 patients

Types of reactions	Number of patients	Percentage (%)
Acute transfusion reaction	80	95.23
AcHTR	6	7.14
Immune hemolytic transfusion reaction	2	33.3
Nonimmune transfusion reaction	4	66.6
Acute nonhemolytic transfusion reaction	74	88.09
FNHTR	31	37
Allergic reaction	30	35.7
Bacterial sepsis	5	6
Anaphylactoid reaction	2	2.3
Hypervolemia	3	3.5
Hypocalcemia	2	2.3
TRALI	1	1.19
Delayed transfusion reaction	3	3.5
Delayed hemolytic transfusion reaction	3	3.5
Unclassified	1	1.19

Febrile Nonhemolytic Transfusion Reaction (FNHTR) (N = 31)

Age and gender profile: A total of 31 patients had FNHTR. Twenty were males and 11 were females. The mean age of male patients was 48.4 ± 12.46 years (range 21-77 years). The mean age of female patients was 44.72 ± 13.93 years (range 23-72 years).

History of previous transfusion reaction: Fifteen out of 20 males and 6 out of 11 females were multitransfused. Past history of FNHTR was noted in 6 patients.

Obstetric History: Nine out of 11 females had a positive history of pregnancy or during the transfusion.

Clinical specialties where FNHTR was observed: Out of 31 reactions, 35% (N = 11) were from Medical Oncology, 32% (N = 10) from Medicine, 19% (N = 6) from Surgery, and 13% (N = 4) from Gynecology and Obstetrics.

Clinical signs and symptoms in decreasing order of occurrence: Fever N = 31; rigors N = 23; chills N = 19; myalgia N = 7; vomiting N = 6; hypotension N = 4; cough N = 1.

Component characteristics: Twenty-six patients developed FNHTR after transfusion of PRBCs or W/B. The mean age of storage of red blood cells (RBCs) was 16 ± 6.54 days. Three patients had a reaction after platelet transfusion and 9 platelets were transferred to these 3 patients. Two patients developed FNHTR after FFP transfusion; a total of 8 FFPs had been transfused to these patients.

Outcome: After conservative treatment, recovery was seen in all the patients. Patients recovered within 1-6 h.

Allergic reaction (N = 30)

Age and gender distribution: Allergic reactions were noted in 30 patients including 18 males and 12 females. The mean age for males was 49.6 ± 14.3 years (range 10-73 years) and for females was 46.08 ± 15.4 years (range 21-71 years).

Clinical signs and symptoms: In order of occurrence, these were as follows: Rash (N = 25); pruritis (N = 12); wheals (N = 8); cough (N = 5); periorbital edema (N = 2); vomiting (N = 1).

History of previous transfusion and obstetrical history: A total of 22 patients had a history of transfusion in the past (13 out of 18 males and 9 out of 12 females). Eight out of 12 females had history of pregnancy prior to or during the transfusion event. A total of 22 out of 30 patients with allergic reactions had history of prior sensitization. The chi-square test was applied and this difference was significant; the *P* value was 0.025.

Component characteristics: Out of the 30 allergic reactions, 23 were due to WB/PRBCs and the mean age of product was 18.08 ± 4.3 days. Mean volume of blood transfused was 104 ± 90.8 mL. Four allergic reactions were from platelets transfused and 3 from FFP transfusion. All of these patients had uneventful recoveries. Tables 3 and 4 show relation of age of blood component and previous sensitization with incidence of transfusion reaction.

Anaphylactic/anaphalactoid reactions (N = 2)

Both patients were males. Both the reactions were reported from medicine. Immunoglobulin A (IgA) levels in one of the patient was significantly decreased. Patients presented with symptoms of rash, hypotension, pallor/cyanosis, cough, periorbital edema.

Component characteristics: Both the implicated units were W/B. The storage periods of implicated unit were 7 days and 20 days. The mean volume of blood transfused was 15 mL (range 10-20 mL).

Bacterial sepsis (N = 5)

Bacterial sepsis was suspected in 5 patients with transfusion reaction. These have been described in Table 5.

Patient profile: Out of 5 patients, 3 were males and 2 were females. The age range was 4-52 years with the mean age of 31.4 ± 16.3 years.

Table 3: Days of storage versus reaction units

No. of days stored in blood bank	No. of W/B, PRBC	Percentage (%)
0-7	3	11.5
8-14	5	19.23
>14	18	69.23

Table 4: History of previous sensitization and allergic reaction

Type of transfusion reaction	Previously sensitized	Not sensitized	Total
Allergic reactions	22	8	30
Other transfusion reaction	26	28	54
Total	48	36	84

Chi-square: 5.0, *P* value: .025

Table 5: Transfusion details and investigations of patient with bacterial sepsis

Age/Sex	Blood/component	Age of the stored unit	Storage outside blood bank	Bacterial culture of the patient and the blood component	Outcome
4/M	PCV	22	7	Pos. Both were +ve for <i>K. pneumoniae</i>	Recovered
43/M	Platelets	5	2	Pos. Both for macrofungal spores	Died
52/M	Platelets	5	5	Pos. Both for coliforms	Recovered
31/F	W/B	17	11	Pos. Both +ve for coliforms	Recovered
27/F	W/B	27	8	Pos. Both +ve for <i>Yersinia enterocolitica</i>	Recovered

PCV: PRBC → Racked red blood cells

Component characteristic: Of the 5 implicated units, 2 were WB, 2 were platelets, and 1 was PRBC. The age of storage ranged 17-27 days for red cell units with a mean of 22 days ± 7. Both the implicate platelet units were 5 days old. The mean time interval between the issue of the unit and the beginning of transfusion was 7.4 ± 8.4 h.

Clinical Signs and Symptoms: Fever *N* = 4; rigors *N* = 3; hypotension *N* = 2; breathlessness *N* = 1. No cases of septicemia associated with FFP transfusion were reported.

Hypervolemia (N = 3)

It was observed in 3 patients. First patient was a 3-day-old neonate who developed sudden-onset acute respiratory distress and cyanosis while undergoing exchange transfusion. The second patient was 43 years old who received 5 units of whole blood while undergoing laparotomy for hemoperitoneum. On the table he developed frothing in tube fall in saturation and galloping heart sounds on auscultation. Oxygen and diuretics helped in recovery of the patient. The third patient was a 67-year-old chronic kidney disease patient with decreased urinary output. He received 2 whole blood transfusions before being taken up for dialysis to raise his hemoglobin level. He developed shortness of breath and cyanosis. He was managed with diuretics and oxygen and showed recovery within 24 h.

Hypocalcemia (N = 2)

Hypocalcemia was observed in 2 neonatal patients; both were admitted with neonatal intensive care unit. These were observed on the second and fifth days of their life when they were undergoing exchange transfusion for neonatal jaundice. Both had bradycardia and twitching while the exchange was ongoing. On estimation of calcium levels, it was found that both of them had hypocalcemia. They were started on 10% calcium gluconate. They had uneventful recovery.

Transfusion-associated acute lung injury (N = 1)

This was seen in 1 patient who was admitted to the medicine ward for motor neuron disease. Patient complained of sudden onset of shortness of breath and cyanosis after 1 unit of whole blood transfusion. X-ray was done that showed bilateral pulmonary edema consistent with TRALI; no other cause of noncardiogenic pulmonary edema was seen. The patient did not recover and died within 7 h of transfusion. As all the investigations required to meet the criteria of TRALI could not be done, it was a possible case of TRALI.

Delayed hemolytic transfusion reaction (N = 3)

All 3 were thalassemia major patients and they presented with history of increase frequency of transfusion and jaundice after

transfusion. All the 3 patients were classified as identified as delayed hemolytic transfusion reaction as the symptoms were seen 24 h after transfusion.

Unclassified reaction (N = 1)

A 30-year-old male who was transfused with whole blood, after transfusion of 50 mL of blood developed urticaria, rash, and wheals all over his body. The rash did not subside after administration of antihistaminics and he patient was shifted to another hospital. Further workup could not be done on the patient. The patient had also received a dose of ceftriaxone 1 h prior to transfusion and it could not be determined what the exact cause of symptoms was as the patient was not available for further investigations. The symptoms could be attributed to allergic reaction due to blood or the antibiotic dose given.

Measurement of risk

The measurement of risk associated with blood transfusion depends upon case reporting of adverse events and laboratory workup of these adverse events.

The clinical case reporting had several limitations as a source of information about the incidence of transfusion reaction. The awareness of physicians and paramedical staff is very important. They have to look for adverse events and then report them and determine whether it could be due to transfusion or any other cause.

It is easier to identify a transfusion-related adverse event if it occurs within a short duration of transfusion. However, the longer the time after the transfusion that the event occurs, the less likely it is to be reported, especially if the adverse event was mild and nonspecific.

The risk estimate was calculated based on the number of units transfused; the risk of transfusions per 1,000 transfusions was calculated. Table 6 shows risk associated with different blood components.

Discussion

Blood transfusion is always associated with risks. An informed decision about transfusion has to be made based on the risk-to-benefit ratio associated with blood transfusion for a particular patient. This study was designed to assess the risk associated with allogenic blood transfusion and/or component transfusion in our institution.

Hemolytic transfusion reaction

The estimated risk for acute hemolytic reaction in present study was 0.19 per 1,000 red cell units transfused. Immune mediated hemolysis (2 out of 6) was due to major ABO mismatch. Four out of 6, that is, 66% cases of AchTR in our study were due to improper storage of blood outside blood banks leading to hemolysis. The risks for acute hemolytic reactions that were observed in different studies range from 0.02 to 0.07^[6-8] per 1,000 red cell units transfused. The cause for both immune hemolytic reactions was clerical errors, which can be decreased by designing administrative systems to analyze and prevent future occurrence of errors. Most of these errors are preventable, so a strategy for avoiding such errors is very important. Nonimmune hemolysis due to storage

Table 6: Estimated risk of various types of transfusion reactions per 1,000 units of blood/component transfused

Type of reaction	WB/PRBC	Platelets	FFP
AchTR	0.19	NR	NR
FNHTR	0.8	1.38	0.15
Allergic	0.74	1.8	0.23
Anaphylactic	0.06	NR	NR
TRALI	0.02	NR	NR
Hypervolemia	0.09	NR	NR
Hypocalcemia	0.06	NR	NR
Bacterial sepsis	0.1	1	NR

of blood outside the blood bank under improper conditions can be prevented by proper education of staff responsible for bedside storage and monitoring of transfusion. Three cases of delayed hemolytic reaction were reported and all of them were thalassemic children. There was an estimated risk of 0.09 of delayed hemolytic transfusion reaction per 1,000 red cell units transfused.

Febrile nonhemolytic transfusion reaction

The incidence of FNHTR in present study was 0.8 per 1,000 for WB/PRBC, 1.38 per 1,000 platelet transfusions, and 0.15 per 1,000 FFP transfusion. The rate of FNHTR in most of the studies is 0.5-1%.^[9] Since we are not doing universal leukoreduction, this may be the reason for the higher incidence of FNHTR as compared to the Western literature.

In our study, 26 WB/PRBC units were responsible for FNHTR. Out of these, 18 units (69%) were more than 14 days old; a similar difference in rate of reaction compared with duration of storage in the blood bank was found by Heddle *et al.*^[10] This association of increased febrile reaction with increased storage time could be due to the cytokines released during storage of components. All the reactions to platelets were due to random donor platelets (RDP). Twenty-one out of 31 patients (67.74%) were previously sensitized; due to either transfusion or pregnancy prior to reaction with the implicated unit, this difference was not statistically significant ($P = 0.13$). Leukocytes are usually responsible for causing FNHTR, and adopting universal prestorage leukoreduction will help in decreasing the number of cases of FNHTR. Moreover, proper inventory management and providing patients with relatively fresh blood will also decrease the incidence of FNHTR and allergic reactions.

Allergic reaction

In the present study, the risk of allergic reaction due to transfusion was 0.6 per 1,000 transfusions. The incidence of allergic reaction varies greatly in the literature, and there are a few studies on the incidence of allergic reaction in general patient population studies that estimated the risk due to allergic reaction to be around 3%.^[6] Tanz *et al.*^[11] in their study on leukoreduced components found the rate to be as low as 0.06%. The incidence of allergic reaction in a presensitized population is higher than that of an unsensitized patient population. In patients with previous history of allergic transfusion, reaction premedication can help in decreasing the incidence of allergic reaction.

Anaphylactic reaction

In the present study, the risk of anaphylactic reaction was 0.04 per 1,000 transfusions. Pineda *et al.*^[12] reported an incidence of .0021 per 1,000 units of transfusion of blood and its components. IgA levels was done in 1 of the patients and found to be very low. Selective deficiency of IgA is known to cause anaphylactic reactions.

Transfusion-related acute lung injury

The overall incidence of TRALI was 0.02 per 1,000 transfusions. The incidence of TRALI is very low in the Indian subcontinent as most of the donors, as many as 90%, are males. Mani *et al.*^[13] published a case of TRALI, which was also observed due to donation by a female donor from North India. Bhattacharya *et al.*^[14] in their study also described a case of TRALI. The incidence of TRALI reported in various studies from the Western literature ranged from .001 to .008 per 1,000 transfusions.^[15] TRALI is often underdiagnosed because of low suspicion of the condition and/or because TRALI is easily confused with other conditions that cause acute lung injury but are not related to transfusion.

Hypervolemia

Risks per 1,000 recipients for transfusion-associated hypervolemia present study were 0.06 per 1,000 transfusions. Popsky *et al.*^[16] in their study estimated the risk of hypervolemia to be 0.31 per 1,000 transfusions. The predisposing factors observed in this study were faulty transfusion administration techniques, i.e., rapid infusion of WB, which resulted in volume overload. In 1 of the patients, chronic kidney was a precipitating factor for acute volume overload.

Hypocalcemia

This is a known complication due to citrate toxicity. Premature newborns are more susceptible due to underdeveloped liver predisposing them to citrate toxicity. The risk of hypocalcemia was 0.04 per 1,000 transfusions. Bhattacharya *et al.*^[14] in their study found the risk of hypocalcemia to be 0.16 per 1,000 red cell units.

Bacterial sepsis

Bacterial contamination remains an important cause of transfusion-related morbidity and mortality. According to the United States Food and Drug Administration (FDA) estimates, bacterial sepsis accounted for 16% transfusion fatalities. Infection risk from platelet transfusion (1 per 1,000 platelet transfusions) was higher as compared with that from RBCs (0.1 per 1,000 WB/PRBC transfusion). This may be because of the fact that platelets are stored in room temperature, promoting the growth of microbes more easily as compared to red cell units; similar differences were found by Kuehnert *et al.*^[17] Overall, the risk of infection from bacterial contamination now may exceed that from viral agents. Predisposing factors, which might be responsible for bacterial contamination in this study, may be: Contaminated skin flora, asymptomatic donor bacteremia, and longer than permissible time taken to transfuse these components 6.6 h (range 2-11 h). The majority were reports in the summer months, suggesting sweating might be the cause for bacterial proliferation of donor skin flora. Careful selection of blood donors through proper medical history and aseptic skin preparation of venipuncture site is very important. Noting the color and character of blood before issuing may help in decreasing the incidence of bacterial sepsis due to transfusion.

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Conflicts of interest

There are no conflicts of interest.

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