Original Article

Retrospective evaluation of adverse transfusion reactions following blood product transfusion from a tertiary care hospital: A preliminary step towards hemovigilance

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Abstract:

Background: The goal of hemovigilance is to increase the safety and quality of blood transfusion. Identification of the adverse reactions will help in taking appropriate steps to reduce their incidence and make blood transfusion process as safe as possible. **Aims:** To determine the frequency and type of transfusion reactions (TRs) occurring in patients, reported to the blood bank at our institute. **Materials and Methods:** A retrospective review of all TRs reported to the blood bank at the All India Institute of Medical Sciences, between December 2007 and April 2012 was done. All the TRs were evaluated in the blood bank and classified using standard definitions. **Results:** During the study period a total of 380,658 bloods and blood components were issued by our blood bank. Out of the total 196 adverse reactions reported under the hemovigilance system, the most common type of reaction observed was allergic 55.1% (n = 108), followed by febrile non-hemolytic transfusion reaction (FNHTR) 35.7% (n = 70). Other less frequently observed reactions were Anaphylactoid reactions 5.1% (n = 10), Acute non-immune HTRs 2.6% (n = 5), Circulatory overload 0.5% (n = 1), Transfusion related acute lung injury 0.5% (n = 1), Delayed HTRs 0.5% (n = 1). Not a single case of bacterial contamination was observed. **Conclusion:** The frequency of TRs in our patients was found to be 0.05% (196 out of 380,658). This can be an underestimation of the true incidence because of under reporting. It should be the responsibility of the blood transfusion consultant to create awareness amongst their clinical counterpart about safe transfusion practices so that proper hemovigilance system can be achieved to provide better patient care.

Key words:

Adverse transfusion reactions, blood transfusion, hemovigilance

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Introduction

Transfusion of blood products is a double-edged sword, which should be used judiciously. Though blood transfusion can be life-saving, it can also lead to certain adverse reactions which can be fatal. There has been a concern and debate in the medical literature regarding the appropriate use of blood and blood products.[1] There is limited high-quality evidence of the benefits and harms of different blood product transfusion practices that exist throughout the world.[2] Knowledge about various types of blood transfusion reactions (TRs) will help not only in their early identification and management, but also in taking adequate measures to prevent the same. The true incidence of these reactions is difficult to determine because of lack of a proper and strict hemovigilance system throughout the country. With the introduction of newer immunohematological techniques in antibody identification and wider use of leuko-reduced blood products the incidence of febrile non-hemolytic transfusion reactions (FNHTRs), Cytomegalovirus transmission and platelet refractoriness has decreased.[3] The improvements in donor screening for infectious diseases has led to a decrease in the risk of infectious complications. But the risks of non-infectious complications have become more apparent.[4] Often, prevailing disease condition in the transfusion recipient makes the definite diagnosis of TRs even more difficult.[5] About 0.5-3% of all transfusion results in some adverse events, but most are minor without any significant consequence.[6,7]

Hence the present study was done with the primary objective to determine the frequency and types of adverse TRs occurring in hospitalized patients who required blood product transfusion at a tertiary care hospital in North India.

Materials and Methods

A retrospective review of all the TRs that were reported to the blood bank at the All India Institute of Medical Sciences (AIIMS), New Delhi, over a period of 4 years and 5 months (from December

2007 till April 2012) was done. All the reactions were clinically evaluated by the treating physician and reported to the blood bank in a pre-designed performa as per the guidelines laid down by the Directorate General of Health Services Technical Manual, Ministry of Health, Government of India [Annexure 1]. As a part of transfusion reaction work up and evaluation, the following information is collected:

1. Patient's identification (Name, Age, Sex, Registration number, Ward and bed number).
2. Clerical error checked by reconfirming and matching the implicated blood product and details of the patient transfused.
3. Returned bag along with transfusion set is checked for visible clots or hemolysis.
4. Patients post-transfusion sample is checked for hemolysis and compared with pre-transfusion sample. In case of suspected hemolytic reaction, further investigations done (In the department of Laboratory medicine) are:
   - Quantitative estimation of plasma hemoglobin: Crosby and Furths modification method (Benzidine method), Reference range <4 mg%.
   - Serum Haptoglobulin: Photometric method.
   - Hemoglobinuria: gross visual examination and urine haemoglobin by dipsticks (Siemens Uristix).
   - Serum unconjugated bilirubin and serum lactate dehydrogenase (LDH): Blood sample should be collected within 1 h after the occurrence of reaction. Serum Bilirubin is estimated by Jendrassik-Grof method and Serum LDH by pyruvate/lactate reduction method (Normal range 6-1,200 U/l) in the department of laboratory medicine.
   - Peripheral blood smear examination for the presence of schistocytes and spherocytes.
5. Compatibility testing is repeated on pre- and post-transfusion sample. Direct antiglobulin testing (DAT) (using polyspecific Antihuman globulin and monoclonal anti C3, Bio-Rad) and antibody screening (three Panel, R1R1/R2R2/rr, ID-Diacell I-II-III Bio-Rad) are also repeated.
6. Bacteriological testing is done by sending the blood from bag to the microbiology department in a bottle culture method.

TRs occurring during or after transfusion were evaluated. On the basis of reporting by the treating physician of signs and symptoms accompanied by the blood bank workup, the reactions were classified in accordance with the standards and recognized definitions defined by American association of blood banks (AABB).[8] Any transfusion-related adverse events occurring within 24 h were considered as acute TRs while those occurring after, were considered as delayed reactions. Febrile non-hemolytic transfusion reaction (FNHTR) was defined as "a body temperature rise of >1°C occurring in association with transfusion and without any other explanation". Rigors and other symptoms in the absence of fever were also included as FNHTR.[8] Allergic reactions comprised urticaria or erythematous itchy or non-itchy lesions, not accompanied by fever or other adverse findings. Anaphylactic reactions were categorized as those having systemic symptoms including hypotension and/or loss of consciousness and/or shock.[8] Transfusion related acute lung injury (TRALI) was considered as reaction with acute respiratory insufficiency and/or X-ray findings consistent with bilateral pulmonary edema but with no other evidence of cardiac failure or a cause for respiratory failure. Hemolytic reactions were diagnosed based on the clinical and/or laboratory evidence of hemolysis and DAT testing. Bacterial contamination was defined by a positive culture of the blood product transfused. Volume overload referred to respiratory distress leading to pulmonary edema on chest X-ray.[8]

Results

From December 2007 to April 2012, 3,80,658 units of blood and blood components were transfused to the patients admitted at AIIMS. The number of different blood products transfused is given in Table 1 and the various indications of blood product transfusions, implicated in adverse TRs, have been depicted in Figure 1. The total number of TRs reported to our blood bank during the study period was 196 (0.05%), of which, 120 (54.3%) were seen in males and 76 (45.7%) in females. Mean age was 34.1 years (range 0.1-85 years). The signs and symptoms encountered are shown in Figure 2. The mean volume of blood product transfused, when the reactions were noted, was 150 ml. 195 out of 196 reactions were of immediate/acute type with the mean time at which reaction was noted, being 38 min (range 5-450 min). One delayed type of reaction was noted 27 h 30 min after initiation of transfusion. Of all the TRs that were reported, 42.8% occurred with packed red blood cells (PRBC), while platelet rich plasma (PRP) and fresh frozen plasma (FFP) transfusions were responsible in 37.7% and 19.3%, respectively. Overall 0.05% of PRBCs, 0.06% of platelets and 0.02% of FFP issued from the blood bank during the study period were involved in causing TRs. Table 2 depicts the number of TRs according to the type of blood component involved. Figures 3-5 show relative frequency of adverse reactions by PRBC, random donor platelets(RDP), FFP, respectively. Among these, the commonest was allergic reaction in 108 subjects (55.1%),

Table 1: Details of blood products transfused during study period

Year	RBC	PRP	FFP	Total
2007 Dec	1522	1011	857	3390
2008	33071	24903	17402	75376
2009	35373	26624	18639	80636
2010	35775	31822	30372	97969
2011	38218	31224	21584	91026
2012 Jan-April	13358	11846	7057	32261
Total	157317	127430	95911	380658
% of total	41.3	33.4	25.1	100

RBC=Red blood cell; PRP=Platelet rich plasma; FFP=Fresh frozen plasma

Table 2: Different types of transfusion reactions according to type of blood component

Transfusion reactions	PRBC	PRP	FFP	Total
FNHTR (%)	64 (91.4)	6 (8.6)	0	70
Allergic reactions (%)	12 (11.1)	68 (63.0)	28 (25.9)	108
Non-immune hemolysis (%)	5 (100.0)	0	0	5
Ac HTR	0	0	0	0
TACO (%)	1 (100)	0	0	1
Anaphylactoid reactions (%)	0	0	10 (100)	10
TRALI (%)	1 (100)	0	0	1
DHTR (%)	1 (100)	0	0	1
Total	84	74	38	196

PRBC=Packed red blood cell; PRP=Platelet rich plasma; FFP = Fresh frozen plasma; FNHTR=Febrile nonhemolytic transfusion reaction; HTR = Hemolytic transfusion reactions; TACO = Transfusion associated circulatory overload; TRALI = Transfusion related acute lung injury; DHTR = Delayed hemolytic transfusion reactions; (% indicates frequency of reaction by caused by that product)

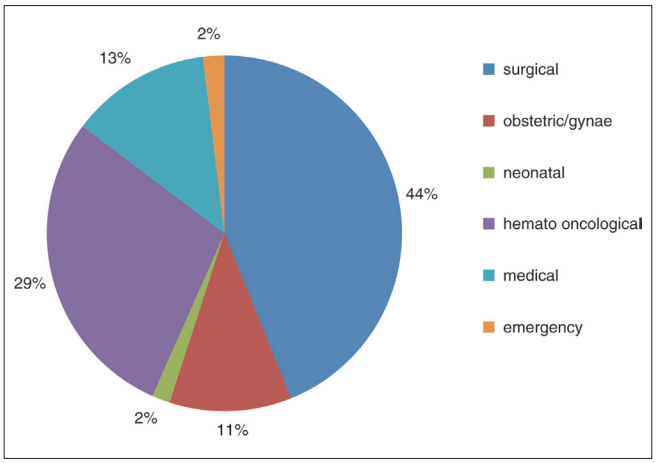

Figure 1: Indications of transfusion in patients with adverse transfusion reactions

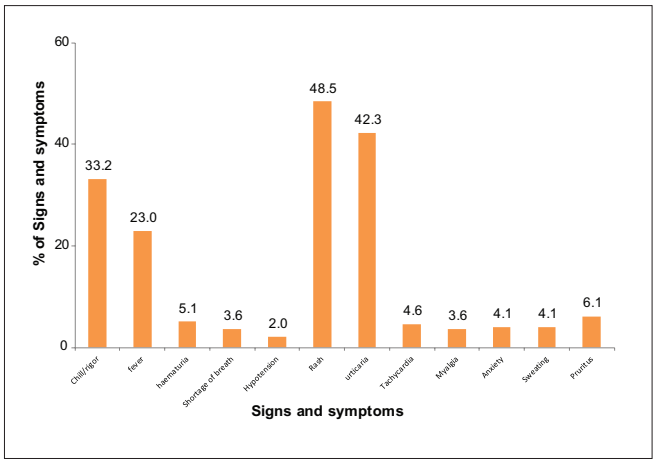

Figure 2: Signs and symptoms of transfusion reactions

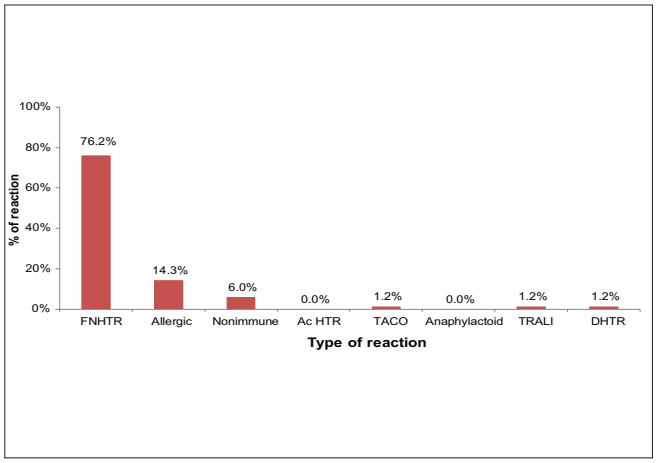

Figure 3: Relative frequency of adverse reactions by packed red blood cell

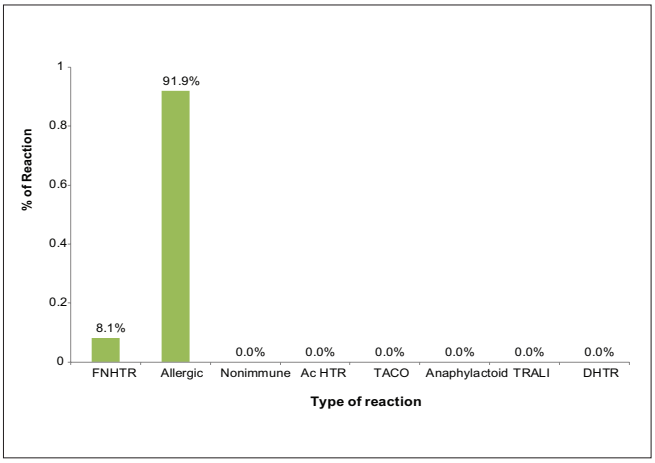

Figure 4: Relative frequency of adverse reactions by random donor platelets

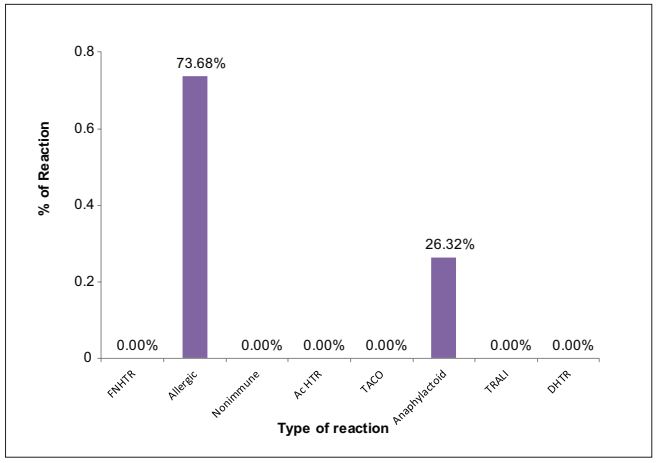

Figure 5: Relative frequency of adverse reactions by fresh frozen plasma

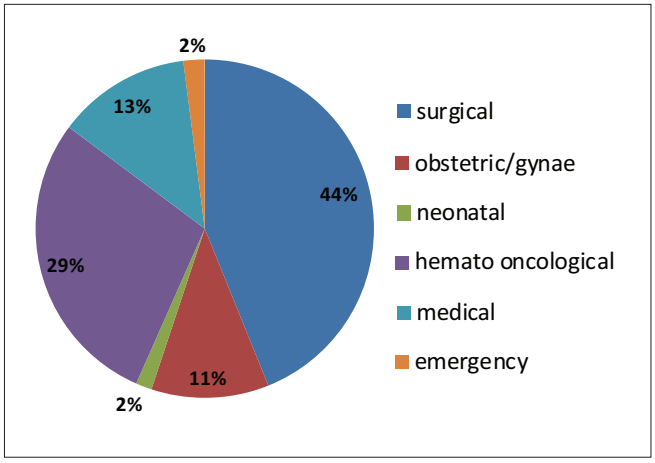

Figure 6: Categorization of adverse reaction according to departments

followed by FNHTR in 70 patients (35.7%). Categorization of TRs according to departments where the transfusion reaction occurred has been depicted in Figure 6. In all of the reactions that were notified, cultures from the blood left in blood bag were performed and all were found to be negative.

Out of 108 allergic reactions, the common clinical signs and symptoms were rash in 88.8% (80 out of 90), pruritus in 33.3% ($n = 30$) and urticaria in 30% ($n = 27$). Allergic reaction was seen in 0.046% of total 1,57,317 units of PRBC transfused and 0.006% of total 1,27,430 PRPs transfused.

FNHTRs: 70 out of 196 (35.7%) TRs were found to be FNHTRs. The most common signs and symptoms of these reactions were chills and rigors in 78.3% (n = 54), fever in 54.2% (n = 38), myalgia in 8.4% (n = 6) and anxiety in 9.6% (n = 7).

Acute non-immune hemolytic TRs (HTR): 5 of 196 (2.6%) recipients had acute HTR. Of these five reactions, two were reported from oncology (one each from surgical and hemato-oncology), three from obstetrics unit. Clinical signs and symptoms as observed in these patients were hematuria and hemoglobinuria in 80% (n = 4), chill/rigors in 50% (n = 3), jaundice in 60% (n = 3) and fever in 20% (n = 1). Intra operative passage of cola colored urine was observed in two anaesthetized patients after 100-150 ml transfusion, after which the transfusion was stopped and reported.

Anaphylactoid reactions: 5.1% (10 out of 196) reactions were due to anaphylaxis to the transfused product. Of the 10 patients, seven were hemato-oncology patients, while three from the nephrology ward. All these patients were multiple-transfused patients due to reigning clinical conditions. Clinical signs and symptoms in these reactions were rash in 70% (7 out of 10), hypotension in 40% (4 out of 10), respiratory distress in 70% (7 of 10), and urticaria in 40% (4 of 10). PRP was found to be responsible for 50% of these reactions.

TRALI: This single case was reported from the Pediatric Oncology Department. A 14 year old girl with acute leukemia who was asymptomatic before transfusion developed acute respiratory distress and circulating shock manifesting as tachypnoea, tachycardia, hypoxia and hypotension with bilateral wheeze after she was transfused PRBC. Her post-transfusion chest skiagram revealed bilateral fluffy infiltrates without cardiomegaly. She was successfully resuscitated with face mask oxygen and bronchodilators.

Transfusion associated circulatory overload (TACO): This was a single case reported in a 7-year-old child admitted in hemato-oncology ward with severe anemia, diagnosed with hypoplastic anemia. He received multiple previous transfusions from other hospitals and was referred to AIIMS. He was transfused three units of PRBC in 1 day after which he developed sudden onset, acute respiratory distress, tachycardia and S3 gallop on auscultation. The child responded to diuretics and symptomatic management.

Delayed hemolytic transfusion reactions (DHTR): A single case of DHTR was reported in a 55-year-old female admitted for adnexal mass surgery in gynecological ward. She was transfused with eight units of FFP and three units of PRBC both intra and post-operative for blood loss during surgery. She had a previous transfusion history, 4 weeks back for low hemoglobin outside the institute. On the 2nd day of the transfusion, the patient complained of flushing and sweating. She passed orange to red colored urine. Her post-transfusion serum unconjugated bilirubin was 13 mg/dl which rose to 18 mg/dl within 2 days. Levels of plasma hemoglobin, serum LDH confirmed hemolysis. The patient's condition improved after 7 days and was discharged with no complications. Post-transfusion work up however did not point towards any mismatch error, DAT and antibody screen was negative on pre- and post-transfusion sample. The patient was lost to follow-up.

Discussion

In the present study, information about various adverse TRs was collected from cases reported to the institute's blood bank. These were then evaluated on the basis of clinical history and laboratory work-up using a pre-defined protocol. In the present study, the frequency of TRs was found to be 0.05% (196 out of 3,80,658). In a similar study by Bhattacharya *et al.*, incidence of adverse transfusion reaction was 0.18% (105 reactions out of 56,503 units of blood and blood component transfused).[9] However, the denominator used to calculate the frequency of TRs was not the actual number of recipients transfused mainly because some patients received multiple transfusions and a very small number of issued blood products could have been unused, not returned to the blood bank and discarded. Even the total number of adverse reactions may not be the actual indicator mainly because of under reporting. Under reporting of minor TRs has also been found by Narvios *et al.*[10]

In all the HTRs reported, hemolytic reaction was confirmed by hemoglobinuria, hematuria, rise of serum unconjugated bilirubin and serum LDH. All of these patients had received anti-human globulin negative (Gel method) blood products and pre- and post-transfusion antibody screening by R_1R_1/R_2R_2 (O_1 and O_2) cells were negative. However, in case of any sample being positive with the O_1 and O_2 cell panel, the antibody is further categorized by the 11-cell antigen panel in the blood bank special procedure laboratory. Direct antibody test (Immunoglobulin G and C3d) was negative in eight of the 11 HTRs (acute and delayed). These TRs were attributed to non-immune causes like thermal injury as a result of storage in the unmonitored domestic refrigerator in the ward or due to rapid transfusion through fine bored IV cannulas that was used to transfuse hypotonic intravenous fluids simultaneously. It has been observed that PRBC with a hematocrit of 75-80%, when transfused forcibly through 21-22G IV cannula may result in local hemolysis.[11] The other three HTR, with both pre- and post-transfusion DAT positivity were from the nephrology ward where multiple sessions of hemodialysis were done prior to transfusion. Also on enquiry, two patients had been on drugs like methyldopa, which can lead to DAT positivity. Hence, even in these patients, the DAT positivity was not suggestive of an immune cause of hemolysis. The frequency of acute hemolytic reactions observed in different studies ranges from 0.2 to 0.7 per 1,000 red cell units transfused.[12,13] In the present study, the frequency of acute HTR (non-immune) was found to be 0.03 per 1,000 RBCs (5 out of 1,57,317). The non-immune causes of hemolysis have emerged to be the foremost cause of HTRs in the present study. Improper storage conditions and inappropriate rate or method of transfusion leads to deterioration of blood products. Hence, it is prudent to educate the nursing staff and medical residents to reduce this risk. To reduce this risk, blood bank has circulated instructions to various wards and OTs with "dos and don'ts" [Annexure 2]. Blood bank is very regular and persistent to obtain appropriately filled transfusion reaction form for each adverse transfusion reaction reported.

Literature search revealed that the frequency of FNHTRs varies and are associated with platelets more than PRBC.[14] Also with the use of leuko-reduced blood products the overall risk of FNHTR has reduced 0.12% in non-leuko-reduced to versus 0.08% in leuko-reduced blood products.[15] In our study, the frequency of FNHTRs

has been found to be consistently low though increasing awareness and reporting about adverse reaction through hemovigilance system is balanced by the use of leuko-reduced blood products. There are a lot of variations in the frequency of FNHTRs among different studies throughout the world. This can be attributed to the variations in reporting system, frequent use of antipyretics and antihistaminics, and pre-transfusion condition of the patient. In our study, the frequency of FNHTRs with the use PRBC is 0.04% (64 out of 1,57,317 PRBC transfused).This is clearly less than the other studies, mostly because of the use of quadruple bags in collection and RBC filters. In our case, reaction from FFP was due to improper thawing in case of emergency and continuous pressure by the clinicians to issue FFP immediately. To reduce this risk, blood bank has devised a protocol to issue one FFP at a time and when the FFP has been partially transfused, then demand for the second unit of FFP is accepted and delivered. It is ensured that the FFP bags are thawed properly and have no visible floating flakes.

The overall incidence of allergic and anaphylactoid reactions has been found to be 0.028% and 0.003%, respectively, in the present study. The blood product most commonly implicated in allergic reaction was PRP 0.053% (68 out of 1,57,317) followed by PRBC. These results are consistent with study by Domen *et al.* who reported allergic and anaphylactoid reaction as 1 per 4124 (0.02%) and 1 per 2338 (0.003%), respectively.[15] In a concise review done by Moore *et al.* at Mayo's clinic, the rate of mild allergic reactions was estimated to be 3%.[16] Incidence in other studies varies from 0.2 to 3%.[4] The definitions for allergic reaction have varied from presence of only hives or urticaria, to presence of wheezing and angioedema as well in some studies.[17,18] Further work up of allergic and anaphylactoid reactions in the form of estimation of serum IgE and anti IgA could not be done. Our blood bank ensures single pricks during phlebotomy which reduces the allergic risk to the patient transfused.

TRALI is a rare, but important cause of transfusion-related mortality.[19] It is a great mimicker of a variety of clinical conditions and can be life threatening. In our study, TRALI occurred after PRBC transfusion to a 14-year-old child diagnosed as acute leukemia.[20] However, the donor sample could not be evaluated for anti-HLA or anti-HNA antibodies which may suggest susceptible host factors. Careful selection of donors can decrease incidence of TRALI.[21]

A single case of TACO was observed in a 7-year-old child with Hb <4 mg/dl who received three units of PRBC. In a study by Popovsky *et al.*, the incidence of circulatory overload was estimated to be 1 in 3,168 (0.03%) patients transfused with PRBC.[22] Rapid transfusion of blood products should be avoided and AABB recommends an infusion rate of 2-4 ml/min for RBCs and 'faster' rates for plasma and FFP.[8] However, patients with severe anemia (Hb <4-5 g/dl) are at increased risk of TACO because of already being in a hyperkinetic state, with the heart being intolerant to even slight increase in blood volume.[23]

Despite vigorous donor screening, bacterial contamination still remains an important cause of transfusion-related morbidity and mortality.[24] In various studies, incidence of bacterial contamination leading to TRs have been found to be 0.0002-0.003 for PRBC and 0.01-0.44 for platelets per 1,000 units of blood component transfused.[25] The sources of these bacteria are often from donor either from venepuncture site or breach in the aseptic technique during component preparation and storage. In our study, there were no infectious complications even with PRP transfusions. Strict aseptic measures are observed while collection as well as handling and storage. The quality control is ensured by checking 1% of the collected PRPs by the Bact-Alert system to ensure no bacterial contamination. The platelets are also leuko-reduced by using platelet filters and irradiated. This has reduced infectious TRs to a minimal number.

Resident doctors and nurses in the ward should understand the importance of reporting all major and minor transfusion events to the transfusion service, especially at night and in a very busy set up. Attainment towards the goal of safe transfusion can be achieved only by establishing a hemovigilance system. There lies a grave concern regarding the underreporting of adverse reactions due to clerical errors as it may question the knowledge, efficiency and service of the technologist as well as ability of the administration to run the system. Thus, the responsibility lies on the head of the transfusion system, who should be very vigilant and investigate the root cause to rectify it.

Conclusion

The frequency of TRs in our patients was found to be 0.05% (196 out of 3,80,658). Of these, majority of the adverse reactions was observed in elective surgery followed by multiple-transfused hemato-oncology patients groups. The majority of the types of reactions observed were allergic reactions followed by FNHTRs and HTRs. This can be an underestimation of the true incidence because of underreporting which can be improved by hemovigilance system. Emphasis should be given to adopt newer technologies with improvement in existing ones so that blood transfusion can be towards zero risk transfusion. Adequate skilled and dedicated manpower, reporting of all adverse events, fully functioning hospital transfusion committee with continuous medical education to medical and paramedical staff will definitely help in strengthening hemovigilance system and reducing the incidence of adverse TRs to minimum.

Annexure 1

Transfusion reaction reporting form (For use in wards)
Main blood bank, AIIMS
Patient details
Name of patient:
Age/Sex:
C.R. No:
Diagnosis:
Indication for transfusion:
Date of transfusion:
Details of the transfused unit

Transfused product (PRBC/Leucodepleted PRBC/RDP/FFP/CRYO/SDP)

1. Unit No:
2. Date of collection:
3. Date of expiry:
4. Blood group:
5. Volume transfused:
6. Date and time of issue of the unit from the blood bank:
7. Date and time of starting transfusion: Duration for complete transfusion
8. Patient monitoring
9. Collection of sample for work up
10. Post-transfusion blood sample collected: Yes: No:

11. Post-transfusion urine sample collected: Yes: No:

Note: Post-transfusion blood sample should be collected within 1 h after the occurrence of reaction and the post transfusion urine sample should be collected within 6 h of the occurrence of reaction and visual observation of urine should be reported to blood bank.
Signature and Name of Medical Officer

Annexure 2

Dos and Don'ts of blood transfusion
DOs

- Check the patient identification with compatibility slip.
- Inspect the bag for color change, visual clots or froth; such bags are not to be transfused and must be returned back to the blood bank immediately.
- Check the expiry date of blood components (written on the bag).
- The transfusion of packed cells should be done within 30 min of issue, and fresh frozen plasma, platelet concentrate and single donor platelet should be transfused immediately after receiving them.
- If this is not possible, it should be returned to the blood bank with documented time and date immediately.
- Except in the massive transfusion setting, transfusion rates for blood should not exceed 2-4 ml/kg/h.
- From starting the infusion (puncturing the blood pack with the infusion set) to completion, infusion of packed red blood cells should take a maximum of 4 h.
- Each unit of plasma should be transfused to the uncompromised adult over 30-60 min. Patient should be examined clinically for evidence of volume overload.
- A single adult dose of aphaeresis platelets contains 230-300 ml. Each dose of apheresis platelets should be transfused over a period of 30-60 min.
- The only fluids that can be given concurrently through the same IV device as red cell transfusion are: Normal saline with plasma protein fractions and 4% albumin with ABO compatible plasma.
- The transfusion reaction form should be filled up for each transfusion and sent to the blood bank.
- Blood must be transfused preferably through fresh venflon of 16/18 gauge needle.
- Please fill up the transfusion reaction form completely so that the work up can be done.

DON'TS

- Medication/IV fluids (including warm saline) must not be added to the blood bag or to the transfusion lines.
- RBC transfusion must be started within 30 min of issue. If there is a delay then the bag should be returned to the blood bag immediately. Platelets and FFP should be transfused immediately. At no cost should any of the blood components be stored in the ward refrigerators.
- No fluid/medication should be added to the blood bag.
- Do not infuse the following fluids concurrently through the same IV device as the red cell transfusion:
- Electrolytes and colloids solutions containing calcium (e.g., Haemaccel, Gelofusion) shall never be given with blood cell component collected in an anticoagulant containing citrates as they may cause clotting of the infusion line.
- 5% Dextrose in water or Hypotonic Sodium solution may cause red cells to Haemolyse.
- Routine warming of blood is not indicated.
- Note: Patient who will benefit from warmed blood include adults and children receiving massive transfusion, infants requiring exchange transfusion and patients with clinically significant high titer cold agglutinins active in vitro at 37°C. In case warming is needed, a proper blood warmer should be used for the purpose.
- Red blood cells and plasma exposed to temperature over 40°C and below 2oC may cause severe transfusion reactions.
- Blood components must not be warmed by improvizations such as putting the pack into hot water, in a microwave, or on a radiator, as uncontrolled heating can damage the contents of the pack.
- Do not transfuse if IV cannula is blocked or infected.

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