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Original Article

Pathology Section

Adverse Reactions to Blood Components- A Twelve-Year Retrospective Study- A Step towards Prevention

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ABSTRACT

Introduction: The transfusion of blood and blood components is a life-saving procedure in clinical practice. However, it is associated with risks that can range from trivial self-limited Allergic Reactions (AR) to life endangering anaphylactic or haemolytic transfusion reactions.

Aim: To analyse the pattern and incidence of transfusion related adverse events and to develop preventive strategies.

Materials and Methods: This was a retrospective, observational study conducted at Department of Pathology, PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India, on data of Adverse Transfusion Reactions (ATR) reported to the blood bank over a period of 12 years from January 2006 to December 2018. The ATRs were analysed with respect to gender, type of blood component, and nature of the reaction. The data collected were tabulated and the analysis was done using percentages.

Results: A total of 1,60,914 units of Whole Blood (WB) and blood components were issued during the study period. A 271 adverse reactions (129 reactions in females and 142 reactions in males) were documented constituting 0.168% of the total products issued, majority were due to packed red cells (0.29%). The incidence of AR was the maximum, accounting for 63.1% of the reactions (n=171, 75 in females and 96 in males) followed by Febrile Non Haemolytic Transfusion Reactions (FNHTR) which were 33.57% (n=91, 42 in males and 49 in females). There were four cases of Transfusion Associated Acute Lung Injury (TRALI), all in males, accounting for 1.48% of the reactions, three cases of anaphylactoid reactions (2 in females and 1 in male) accounting for 1.11% of the total reactions and two cases of haemolytic transfusion reaction (0.73%).

Conclusion: The frequency of adverse reactions in the present study is 0.168% (271 out of 1, 60,914 units), majority were due to packed red cells (0.29%). No adverse reactions due to bacterial contamination occurred during the study period. It is important to ensure education of nursing staff, interns, and residents regarding the correct procedure of blood transfusion, identification of adverse reactions and appropriate remedial measures for the same.

Keywords: Adverse transfusion reactions, Allergic reaction, Febrile non haemolytic transfusion reaction, Haemovigilance

INTRODUCTION

The transfusion of blood and blood components is a lifesaving procedure in clinical practice. However, it is associated with risks that can range from trivial self-limited AR to life-endangering anaphylactic or haemolytic transfusion reactions. Hence, monitoring of every transfusion for adverse reactions becomes an integral part of any transfusion service. An ATR is an undesirable event that occurs during or after blood or blood components transfusion. The severity and nature of ATR depend on the patient's susceptibility and the blood component transfused [1]. Knowledge about different types of ATRs helps in identifying the reaction and formulating protocols and remedies for prevention and treatment respectively of such adverse events. With the advent of new testing facilities, the risk of Transfusion-Transmitted Infections (TTI) has been lowered. Still, ATRs due to clerical errors, incompatibility, and alloimmunisation remains a hazard despite several precautionary and preventive strategies. Therefore, continuous monitoring of transfusion-associated adverse reactions and implementation of preventive strategies at each step becomes essential to ensure patient safety [2,3].

Haemovigilance is a set of surveillance procedures covering the entire transfusion chain from collection of blood to follow-up of the recipient for any untoward effects of blood transfusion [4]. Haemovigilance aims to detect and analyse all the ATRs to identify and correct the cause and to prevent its recurrence. One of the significant positive outcomes of this program has been the steady increase in the number of centres reporting to the Haemovigilance Program-India (HvPI) since the launch of the program [5,6]. The blood bank is a registered member of HvPI since 2016 and regularly participates in recipient and donor reaction reporting.

Chavan SK et al., in their study had found that AR were the commonest (55.6%) followed by FNHTR (33.3%), while Bassi R et al., and Prakash P et al., had found FNHTR to be more frequent than AR [2,4,7]. Bassi R et al., and Prakash P et al., had reported packed red cell concentrates to be responsible for the majority of the reactions [4,7]. The overall incidence of adverse reactions varies from 0.2-3.3%. Literature review showed that the incidence reported could be low because of underreporting. This study was conducted to evaluate the pattern and frequency of ATRs in hospitalised patients in various clinical specialties at the teaching hospital in Tamil Nadu over a period of 12 years and developed strategies to prevent them.

MATERIALS AND METHODS

This retrospective observational study was conducted at the Department of Pathology in PSG Institute of Medical Sciences and Research, Coimbatore, Tamil Nadu, India. The ATRs reported to the blood bank during the period of twelve years from Jan 2006 to December 2018 were retrospectively reviewed over a period of one year after obtaining approval from the Institutional Human Ethics Committee (19/080 dated 16.04.2019).

Inclusion criteria: Data of all the adverse reactions reported to the blood bank with information on the nature of adverse reactions of the given time period were included in the study.

Exclusion criteria: Data about those adverse reactions reported with incomplete information regarding the nature of adverse reaction

and when the blood bags were not returned for post-transfusion workup were excluded from the study.

Study Procedure

The total number of blood and blood components issued from the blood bank was obtained from the issue register. A Transfusion Reaction Reporting Form (TRRF) was provided at the time of issue of blood components as per the Standard Operating Procedure (SOP) [Annexure 1]. After the transfusion is over, the TRRF has to be completed and submitted to the blood bank whether there is a transfusion reaction or not. In case of an ATR, blood bag along with IV set used for transfusion, 2 mL of patient's blood collected from a different vein in an Ethylene Diamine Tetra-acetic Acid (EDTA) tube and a post-transfusion urine sample were received in the blood bank for post-transfusion workup.

The documented transfusion reactions were worked up by the blood bank laboratory technician according to the protocol. Patient details were rechecked to rule out clerical errors. Blood and Intravenous (IV) sets used for blood transfusion were checked for any clot or haemolysis. Reconfirmation of ABO and Rh typing of the patient and the issued component and repeat compatibility testing of pre and post-transfusion blood samples were performed. Direct antiglobulin test on the post-transfusion sample was done. Blood bags and the patient's blood samples were sent to the microbiology laboratory for culture in case of febrile reactions. Urine samples were sent to the clinical pathology laboratory to test for haemoglobinuria.

The ATRs were categorised as per the standards defined by the American Association of Blood Banks (AABB) [1]. The data on ATRs was collected with respect to gender, type of blood component and nature of the reaction.

STATISTICAL ANALYSIS

The data collected were tabulated and the analysis was done using frequency (n) and percentage (%) calculations.

RESULTS

A total of 1, 60,914 units of WB and blood components were issued during the study period. The components issued included Packed Red Blood Cells (PRBCs), Platelet Concentrates (PLT), Fresh Frozen Plasma (FFP), and Cryoprecipitate (CRYO). There were 271 documented transfusion reactions, accounting for about 0.168% [Table/Fig-1]. A total of 129 reactions occurred in females and 142 reactions occurred in males.

Adverse reactions occurred in 156 of 53,775 (0.29%) PRBC transfusions, 51 of 34,092 (0.15%) PLT transfusions, 51 of 53,481 (0.095%) FFP transfusions, 11 of 15,659 (0.07%) WB transfusions and 2 of the 3905 (0.051%) CRYO transfusions. A 57.4% of the reactions were seen with PRBCs, 19% each with PLTs and FFP, 4% with WB and 0.7% with CRYO transfusions [Table/Fig-2]. This study encountered no adverse reactions with Single Donor Platelets (SDP).

Out of the 271 adverse events reported, the incidence of AR was the maximum, accounting for 63.1% of the reactions (n=171) followed by FNHTR which were 33.57% (n=91). There were four cases of Transfusion-Associated Acute Lung Injury (TRALI) accounting for 1.48% of the reactions, three cases of anaphylactoid reactions accounting for 1.11%, and two cases of haemolytic transfusion reaction constituting 0.73% of the total reactions [Table/Fig-1,2].

In case of AR, patients manifested with symptoms like rash, itching, facial puffiness, or lip oedema, rash being the commonest presentation. The majority of the ARs occurred with PRBC transfusions constituting 42.1% (n=72). A total of 75 of the AR were reported in females and 96 occurred in males.

Year of Transfusion	FNHTR n(%)	Allergic reactions (AR) n(%)	TRALI n (%)	Anaphylactoid Reactions n (%)	Haemolytic Transfusion Reaction n (%)	Total n (%)
2006	8 (0.052%)	7 (0.066%)	-	-	-	15 (0.119%)
2007	-	6 (0.04%)	-	-	-	6 (0.04)
2008	8 (0.086%)	19 (0.13%)	-	-	-	27 (0.216%)
2009	9 (0.068%)	20 (0.15%)	-	-	-	29 (0.218%)
2010	2 (0.014%)	21 (0.151%)	-	-	-	23 (0.165%)
2011	5 (0.04%)	8 (0.06%)	-	1 (0.009%)	-	14 (0.109%)
2012	6 (0.05%)	8 (0.06%)	-	-	-	14 (0.11%)
2013	2 (0.014%)	12 (0.087%)	-	-	-	14 (0.101%)
2014	12 (0.09%)	10 (0.07%)	1 (0.007%)	-	-	23 (0.167%)
2015	12 (0.08%)	14 (0.104%)	-	-	-	26 (0.188%)
2016	8 (0.05%)	11 (0.08%)	2 (0.014%)	-	-	21 (0.144%)
2017	4 (0.021%)	17 (0.09%)	1 (0.005%)	-	-	22 (0.116%)
2018	15 (0.089%)	18 (0.11%)	-	2 (0.01%)	2 (0.73%)	37 (0.209%)
Total	91	171	4	3	2	271

[Table/Fig-1]: Year-wise distribution of adverse transfusion reactions.
FNHTR: Febrile non haemolytic transfusion reactions; TRALI: Transfusion associated acute lung injury

Type of reaction	Whole blood (WB) n (%)	PRBC n (%)	Platelet (PLT) n (%)	FFP n (%)	CRYO n (%)	Total n (%) (N=271)
FNHTR	4 (4.44)	79 (86.5)	4 (4.44)	4 (4.44)	-	91 (33.57)
Allergic reaction	7 (4.09)	72 (42.1)	45 (26.3)	45 (26.3)	2 (1.16)	171 (63.1)
Anaphylactoid	-	-	2 (75)	1 (25)	-	3 (1.11)
TRALI	-	3 (75)	-	1 (25)	-	4 (1.48)
Haemolytic transfusion reactions	-	2 (100)	-	-	-	2 (0.73)

[Table/Fig-2]: Incidence of Adverse Transfusion Reactions (ATRs) with Whole Blood (WB) and blood products.
FNHTR: Febrile Non Haemolytic Transfusion Reactions; TRALI: Transfusion associated acute lung injury; PRBC: Packed red blood cells, FFP: Fresh frozen plasma; CRYO: Cryoprecipitate

Patients presented with fever (change of ≥1°C from pretransfusion value) and/or chills and rigor in the case of FNHTR. A 42 out of the 91 reactions occurred in males and 49 of the reactions occurred in females. The incidence of FNHTR was 0.056% and was 0.02% with use of WB, 0.14% with PRBCs, 0.007% with FFP and 0.0117 with PLT.

A total of four cases of TRALI were reported, accounting for about 1.5% of the total reactions. All four reactions developed in males. Patients presented with chills, tachycardia, respiratory difficulty, headache, chest pain, and abdominal pain. Three out of the 271 reactions were of the anaphylactoid type, accounting for about 1.11% of the total reactions. Two out of the three reactions occurred in females. One reaction occurred due to FFP and two reactions occurred due to platelet transfusions.

There was one case of immune haemolytic transfusion reaction which occurred due to clerical error (wrong blood issue). The error was identified soon after starting transfusion. There was no mortality associated with the reaction.

The single case of non immune haemolytic transfusion reaction occurred in a 56-day-old infant who was transfused with 40 mL of blood group A^+ PRBCs (group identical). The transfusion

was uneventful. However, one hour after transfusion, the baby passed black urine. Post-transfusion urine sample demonstrated haemoglobinuria. Direct antiglobulin test done on pre and post-transfusion samples was negative, thus ruling out immune mediated haemolysis. Workup for other non immune causes for haemolysis was done. The donor was recalled and a Glucose-6-Phosphate Dehydrogenase (G6PD) assay and sickling test were done both of which were negative. The microbiological culture of donor blood was sterile. Hence, the reaction reported was categorised as possibly a non immune haemolytic transfusion reaction. The authors of the present study, were not able to understand the underlying pathogenesis of this reaction.

During the study period of twelve years, there were no reactions that could be attributed to bacterial contamination of blood products.

DISCUSSION

The reporting of adverse events is important in knowing the actual incidence of transfusion reactions. The risk of developing an ATR following transfusion is relatively low. Reporting of these adverse reactions depends on the awareness of clinicians and nursing staff to identify these events and to ascertain whether the adverse event is attributable completely to transfusion. The true incidence of ATR is hence difficult to obtain because of underreporting especially when reactions are mild and non specific [8,9]. The overall frequency of transfusion reactions in the present study was 0.168% (271 out of 1, 60,914). This rate is very similar to another study by Pahuja S et al., where the incidence of transfusion reaction was 0.19% (314 out of 1,60,973) and also to that of Bhattacharya P et al., where the incidence was 0.18% [10,11].

In this study, males were affected more than females (52.788% and 47.211%) similar to the study carried out by Bhattacharya P et al., and Kumar P et al., where the incidence was lower among females (34.2% and 45.7%) [11,12] [Table/Fig-3]. Prakash P et al., observed no significant sex predilection with 48.48% in males and 51.1% in females [7]. However, a high incidence of ATR in females was observed in a study done in Sikkim by Sharma DK et al., [8]. AR (63.1%) were the commonest in the present study and occurred more with PRBC transfusions. These are due to the interaction between recipient Immunoglobulin (Ig)E and donor antigens or the release of leukotrienes in the stored blood [7]. AR may present with rash, pruritis, urticaria, localised angioedema, periorbital pruritis, and/or conjunctival oedema [13]. Rash with pruritis was the commonest manifestation in the present study. The incidence of AR varies from 0.028-3%. Here in this study, the overall incidence of AR was 0.106% and it was 0.133% with PRBCs, 0.131% with PLTs, 0.0822% with FFP, 0.051% with CRYO, and 0.0422% with WB. Similar results were obtained in the studies by Chavan SK et al., and Kumar P et al., [2,12]. Mild reactions can be treated with antihistamines and the transfusion can be continued once the symptom subsides. Patients with a history of AR can be premedicated with antihistaminics before transfusion [14,15].

Reactions	Bhattacharya P et al., [11] %	Kumar P et al., [12] %	Venkatacha-lapathy TS [17] %	Bassi R et al., [4] %	Present study %
Allergic reaction	34	55.1	50	24	63.1
FNHTR	41	35.7	43.75	73	33.5
Haemolytic transfusion reaction	8.56	2.6	-	1	0.73
TRALI	0.95	0.5	-	-	1.48
Anaphylactic reaction	3.8	5.1	-	-	1.11

[Table/Fig-3]: Comparison of various studies with the incidence of adverse reactions [4,11,12,17].

FNHTR was the second commonest reaction in the present study constituting 33.7% while other studies report FNHTR to be the commonest ATR. The incidence of FNHTR was 0.056%-0.02% with WB, 0.14% with PRBCs, 0.007% with FFP and 0.0117% with PLTs. The reported incidence of FNHTR varies from 0.036 to 0.114% in other studies [11,16,17]. The frequency of FNHTR varies among different studies throughout the country. The possible explanation for this variation could be underreporting and administration of antipyretics before transfusion. It has been reported to be associated more with PRBCs than platelets [2,7]. FNHTRs are the result of antibodies to donor leucocyte antigens present in the recipient. The febrile reactions can also be due to cytokines released from WBCs in the stored blood. The risk of febrile reactions is proven to be lower with prestorage leukoreduction [4]. In a comparative study, the incidence of FNHTR was 0.12% in non leukoreduced and 0.08% in prestorage leukoreduced blood [18]. In blood bank of present study institute, leukoreduction is done only in selected cases such as for patients requiring repeated transfusions as in the case of hereditary haemolytic anaemias, prospective transplant recipients, and those with a documented history of previous FNHTR to a blood component. Even then, the incidence of FNHTR in this study is less (0.056) when compared to the incidence of 0.114% FNHTR with non leukoreduced red blood cells reported by Bhattacharya P et al., [11]. Hence, introduction of prestorage leukoreduction in the blood bank on a regular basis may possibly aid in lowering the risk still further.

Anaphylactoid reactions accounted for 1.1% (3 out of the 269 reactions) of the total reactions as compared to 5.5% in a study by Kumar P et al., [12]. In the current study, all three recipients who developed anaphylactoid reactions presented with rash and hypotension. Platelets were found to be responsible for 75% of the reactions (2 out of 3 reactions)- this was similar to the observations of Kumar P et al., where the incidence of anaphylactoid reactions due to platelets was 50% [12].

The TRALI is a rare, but life-threatening complication of transfusion where the patient experiences respiratory distress within 2 -6 hours following transfusions. Symptoms include fever, hypotension, chills, cyanosis, non productive cough, dyspnea, and sometimes severe hypoxia [13]. In this study, the incidence of TRALI was 0.0024%. Bhattacharya P et al., reported an overall risk of 0.04% for TRALI [11]. The incidence of TRALI reported in various studies from the Western literature ranged from 0.014-0.08% per unit transfused [19].

Haemolytic transfusion reactions accounted for 0.74% of all the reactions which is similar to that reported by Bassi R et al., [4]. Bhattacharya P et al., had reported six out of nine haemolytic reactions in their study to be non immune in nature [11]. In his article, the cause was attributed to the storage of RBCs in unmonitored refrigerators in the wards. Bacterial contamination remains an important cause of transfusion-related morbidity and mortality.

Sources of bacteria are believed to arise from the donor either from the venipuncture site, unsuspected bacteremia, or during component preparation [20]. Bhattacharya P et al., reported five cases of suspected bacteremia [11]. In the present study, any transfusion reactions that could be attributed to bacterial contamination were not observed. Strict aseptic precautions are taken during venesection and collection of blood from donors. The blood bank uses a sterile docking system for component separation. In addition, the authors ask donors to call the blood bank if they have fever, diarrhoea, or any signs of infection in the twenty-four hours after donating blood. As a quality check, once a month, 1% of the random platelet units collected are sent for bacterial culture.

The current protocol emphasises the need for recording and notifying the ATRs. It is worthwhile that identification and implementation of all possible preventive strategies become mandatory.

Although leukoreduction was performed in the blood bank, it is only for those patients who are likely to require regular blood transfusions as well as patients waiting for transplants. Likewise,

the use of washed red cells is already in practice for patients who have had recurrent severe allergic transfusion reactions. Preventive administration of drugs such as antihistaminics and antipyretics for AR and FNHTR is proven to be beneficial [21]. However, the use should be limited to those who have recurrent reactions. The transfusion reaction reports are to be provided to the patients stating the nature of reactions and preventive premedication that can be administered in future transfusions.

Periodic auditing of the transfusion process using a standardised procedure right from the issue of blood from the blood bank and unequivocal identification of patient and blood products to the return of transfusion reaction reporting form should be initiated. This is especially important in a teaching hospital.

The study results represent the true incidence of adverse reactions in the present population since the institute's blood bank follows stringent protocols in ensuring reporting of adverse reactions by making the submission of TRRFs mandatory for all transfusions. The study period of twelve years also contributes to finding the true incidence of these reactions.

Limitation(s)

The limitation of the study is that there is a possibility that delayed transfusion reactions if any were not reported back to the blood bank.

CONCLUSION(S)

The frequency of adverse reactions in the current study is 0.168% (271 out of 1, 60,914 units), the majority were due to packed red cells. The most common were AR followed by FNHTR. TRALI and anaphylactoid reactions were rare. There was one each of immune and non immune haemolytic transfusion reactions. No adverse reactions due to bacterial contamination were reported. FNHTR can be minimised further by prestorage leukoreduction. The authors hereby propose for documentation of the previous history of adverse reactions in the request form to be made mandatory so that leucodepletion and washing of red cells can be planned accordingly, educating the ward staff, interns, and residents about preventive strategies and periodic auditing of transfusion process. A future study is recommended on the occurrence of adverse reactions after implementation of the above measures to analyse the effectiveness of these preventive strategies.

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ANNEXURE 1

TRANSFUSION REACTION FORM

Date .....

Please return to : BLOOD BANK,
PSG HOSPITALS, Peelamedu, Coimbatore 641 004

A. TO BE FILLED BY BLOOD BANK

UNIT No..... PRODUCT .....

Hospital No ..... Ward No .....

Recipient's Name ..... Group .....

Donor's Name ..... Group .....

Cross matched by ..... Date & Time .....

Issued by .....Date & Time .....

Received by .....Date & Time .....

.....

B. TO BE FILLED BY M.O. INCHARGE

Time at which Transfusion started .....

Time at which Transfusion completed .....

Quantity given .....

	Before Transfusion	During Transfusion	After Transfusion
1. Temperature			
2. Pulse			
3. Blood Pressure			

4. Other signs and symptoms :

(a)	Chills ... Yes/No	(e)	Haemoglobinuria	...	Yes/No
(b)	Regor ... Yes/No	(f)	Pulmonary Oedema	...	Yes/No
(c)	Rash / Itching ... Yes/No	(g)	Jaundice	...	Yes/No
(d)	Pain-Back ... Yes/No	(h)	Any other signs	...	Yes/No
	Head ... Yes/No				
	Chest ... Yes/No				
	Elsewhere ... Yes/No				

NOTE : In the event of a severe reaction occuring, stop transfusion, the blood bank should be informed immediately and the remains of the unit used with transfusion set in-situ returned to the blood bank, together with the post transfusion samples of the patient's blood collected into (a) dry sterile vial (plain) (b) vial with anto coagulant solution.

Name & Signature of M.O. I/C. Ward