

An Institutional Hemovigilance Effort at a Tertiary Care Centre

Kirti Rathod¹, Krishna Patel², Mustafa Ranapurwala³

¹Associate Professor, ²MSc Student, ³Assistant Professor, Department of Pathology, PS Medical College & Shree Krishna Hospital, HM Patel Centre for Medical Care & Education, Karamsad, Anand, Gujarat, INDIA.

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*Correspondence to:

Dr Kirti Rathod
Dept. of Pathology
PS Medical College
Karamsad, Gujarat,
kirtimr@charutarhealth.org

ABSTRACT

Aims: This study was designed to analyze the incidence and spectrum of adverse effects of blood transfusion.

Materials & Methods: Blood Transfusion Reactions were analyzed during the period from October 2009 to October 2014 and classified on the basis of their clinical features and laboratory tests. During the study period 55,152 blood and blood components were issued.

Results: A total of 51 (0.10%) adverse transfusion reactions were observed; 23 (45.10%) were seen in males, 28 (54.90%) in females. 47 out of 51 (92.15%) reactions occurred with red cell concentrates (RCC), while 3 cases (5.88 %) followed platelet transfusion and a single TR (1.96%) was observed due to a fresh frozen plasma (FFP). Febrile non hemolytic transfusion reaction [76.47% ($n = 39$)] and allergic reactions [5.88 % ($n = 3$)] were common types of transfusion reactions, followed by Acute hemolytic transfusion reaction [1.96% ($n = 1$)].

Conclusion: Hence, utilization on newer technologies and a hemovigilance system should be stressed on to help in decreasing transfusion reactions in patients.

KEYWORDS: Adverse events of transfusion, Acute haemolytic transfusion reaction, Febrile non hemolytic transfusion reaction, Hemovigilance.

INTRODUCTION

Transfusion of blood products is a double-edged sword, which should be used judiciously. Though blood transfusion is life-saving on numerous occasions, however, it can also lead to certain adverse reactions which can be fatal. There has been a rising concern and debate in the medical literature regarding the appropriate use of blood and blood products.¹ The improvements in donor screening for infectious diseases and newer testing modalities have lowered the incidence of transfusion-transmitted diseases to a 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 true incidence of transfusion 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 leuco-reduced blood products the incidence of febrile non-hemolytic transfusion reactions (FNHTRs), Cytomegalovirus transmission and platelet refractoriness has decreased.² But the risks of non - infectious complications have

become more apparent.³ Often, the condition of the prevailing disease in the transfusion recipient makes the definite diagnosis of TRs even more difficult.⁴ About 0.5-3% of all transfusion results in some adverse events, but most are minor without any significant consequence.^{5,6}

The present study was undertaken 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 (Shree Krishna Hospital) at Karamsad, Gujarat, India.

MATERIALS AND METHODS

A retrospective study was carried out at the A.D Gorwala blood bank of the Shree Krishna Hospital, Karamsad; on the incidence of the different adverse events related transfusion of blood and blood product over a period of 5 years (October 2009 to October 2014). All the adverse events related to transfusion of blood and blood components in various clinical specialties at the Shree Krishna Hospital, Karamsad were recorded, and later analyzed and classified on the basis of their clinical

features and laboratory tests. Each transfusion-related adverse event was worked up as outlined in the department's standard operating procedures prepared in accordance with the guidelines laid down by the Directorate General of Health Services (DGHS) Technical Manual, Ministry of Health and Family Welfare, Government of India.

When the patients developed symptoms or findings suggestive of blood transfusion reaction, transfusion was discontinued immediately and the following was done and records appropriately maintained.^{7,8}

a. Samples sent: Post-transfusion patient blood sample in plain and EDTA vacuette, along with implicated blood unit and attached transfusion set is sent to the Blood Bank. The patient's first urine sample after receiving transfusion is also sent to the Blood Bank.

b. Labels checked: The label on the blood container and all other records are checked to detect if there has been error in identifying the patient or the blood unit.

c. Look for hemolysis: The patient's post-reaction serum or plasma is inspected for evidence of hemolysis, comparing with pre-transfusion sample.

d. Blood grouping: ABO and Rh (D) blood grouping is done on pre- and post-transfusion samples and from the blood in the blood bag. If the results match, labeling / technical error is ruled out.

e. Cross-matching: Pre and post transfusion samples (in case of whole blood and red cell concentrate) of the patient are re-cross matched with the pre transfusion samples of donor. If the results match, labeling / technical error is ruled out.

f. Direct Coomb's test (DCT): Perform DCT on the post transfusion sample of the patient and on pre transfusion blood sample of the patient for comparison. DAT demonstrates sensitization of patient's red cells by immune antibodies (IgG) or by complement. Positive post-transfusion DCT is indicative of hemolytic blood transfusion reaction. False negative result may occur if

blood sample is drawn several hours later, after the cells have already been destroyed.

g. InDirect Coomb's test (ICT): Perform ICT on the post transfusion sample of the patient, which demonstrates the presence of atypical or unexpected antibodies in patient serum.

h. Serum bilirubin: Determination of serum bilirubin concentration is done, preferably 5 to 7 hours after the transfusion. Increased indirect bilirubin indicates intravascular hemolysis.

i. Urine examination: Examine the first post transfusion urine sample of the patient for evidence of hemoglobin or bilirubin using dipsticks.

j. Gram stain and culture of post-transfusion recipient samples may also be considered when suspicion of transfusion-associated sepsis is a possibility.

k. Grams stain and Culture the contents of the bag. After performing the aforementioned diagnostic work up, the adverse reaction was then classified in to the following types of transfusion reactions.⁸

- a. Hemolytic Transfusion reactions
- b. Non-hemolytic febrile transfusion reactions
- c. Non-hemolytic non-febrile transfusion reactions
- d. Allergic transfusion reactions
- e. Anaphylactic reactions

RESULTS

A total of 55,152 units of blood and blood components were transfused to the patients admitted at Shree Krishna Hospital during the five years of the retrospective study. The transfusion protocols at the Shree Krishna Hospital dictate the use of only blood components and utilization of whole blood only when indicated; hence, majority of the patients receive blood components. The transfusion needs were met by the A D Gorwala Blood Bank, situated within the hospital. The details of the blood products transfused during the study period have been outlined in Table 1.

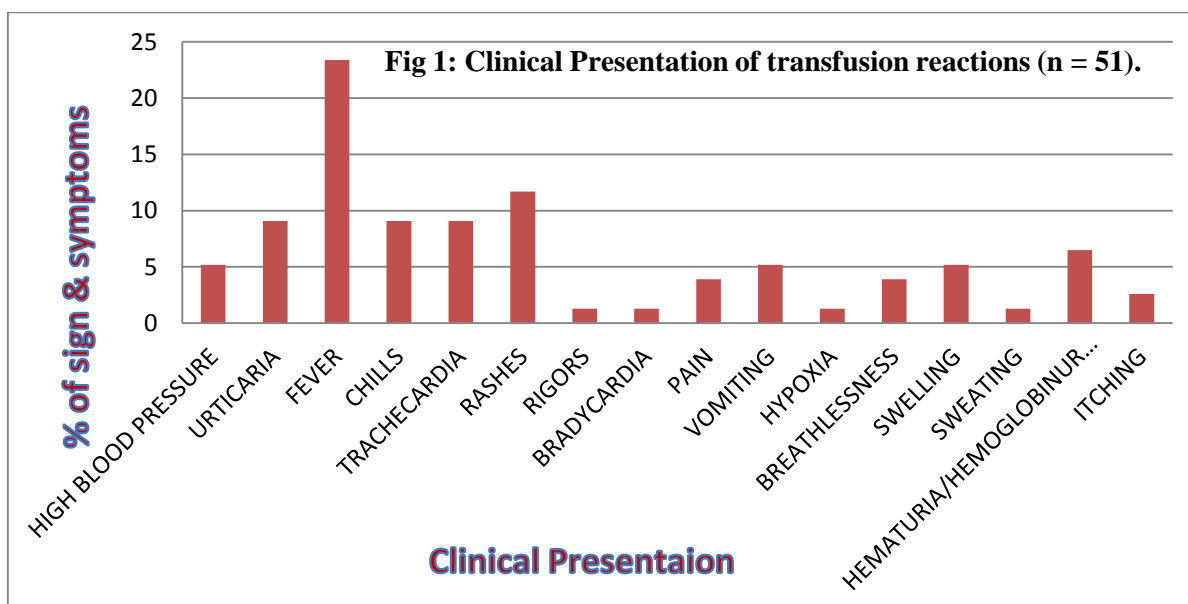


Table 1: Frequency distribution of blood product usage (n = 55152)

YEAR	WHOLE BLOOD	Red Cell Concentrate	Platelet Concentrate	Fresh Frozen Plasma	Cryo precipitate	TOTAL
2009(Oct-Dec)	5	902	120	120	5	1152
2010	20	6072	2460	1910	75	10537
2011	26	6349	2555	1702	77	10709
2012	4	7020	2415	1065	80	10584
2013	34	7000	3056	3925	265	14280
2014 (Jan-Oct)	1	4364	1280	2119	126	7890
TOTAL	90	31707	11886	10841	628	55152

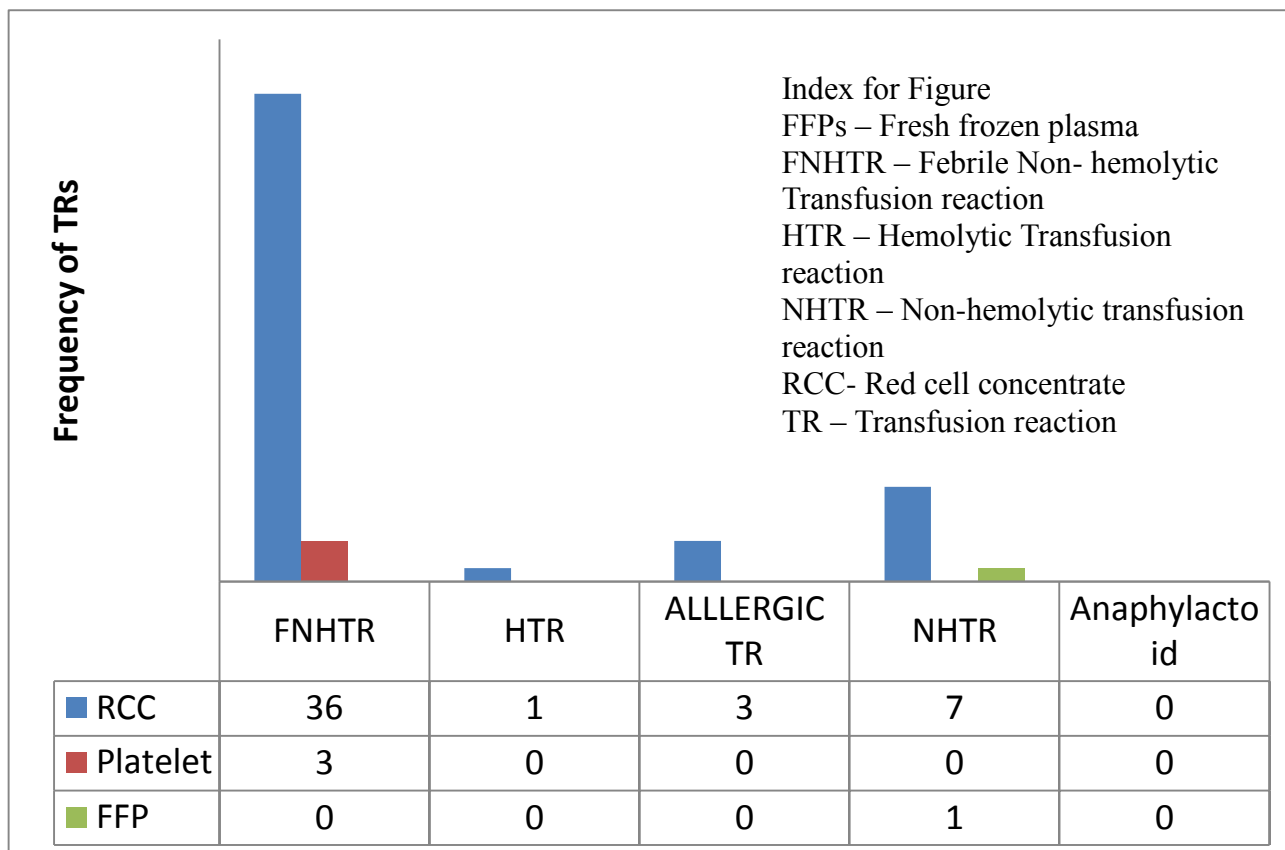


Fig 2: Different types of transfusion reaction according to type of blood component.

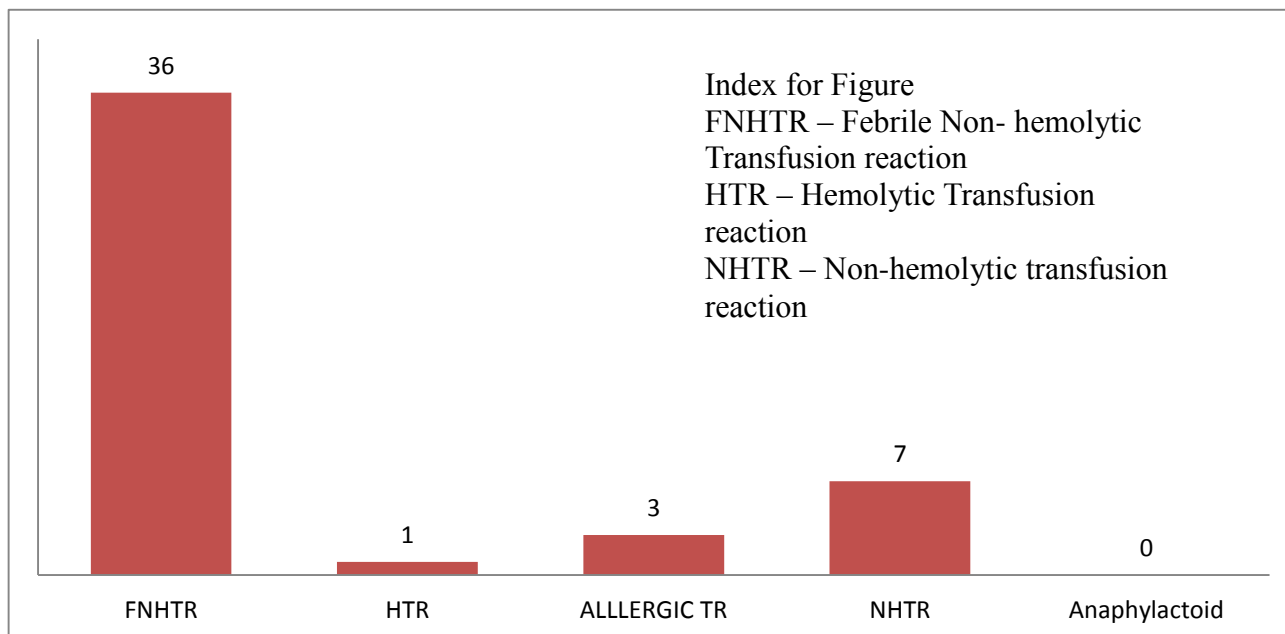


Fig 3: Frequency Distribution of adverse reaction by Red Cell Concentrates (n = 47)

Clinical Presentation of reactions

A total of 51(0.09%) blood transfusion reactions were encountered in the same period of which 23 (45.10%) were seen in males while 28 (54.90 %) were reported in females. The patients had developed numerous signs and symptoms like high blood pressure, urticaria, Fever, Chills, Tachycardia, Rashes, Rigors, Pain, Vomiting, etc. with varying frequency as shown in Figure 1.

Components related to transfusions

Amongst all the transfusion reactions reported, 47 out of 51 (92.15) occurred with red cell concentrate (RCC), while a single transfusion reaction(1.96) was observed due to a fresh frozen plasma (FFP) and 3 cases(5.88) followed platelet concentrate transfusion. Overall 0.09% of RCC, 0.006% of platelets and 0.002% of FFPs issued from the blood bank during the study period were involved in causing TRs. Figure 2 depicts the number of transfusion reactions according to the type of blood component involved.

Types of Transfusion Reactions – Red Cell Concentrate:

The relative frequency of adverse reactions by red cell concentrate were as follows; FNHTR 36 out of 47, HTR 1 out of 47, Allergic TR 3 out of 47 and NHTR 7 out of 47 . The frequency of acute HTR were found to be 0.003 per 1000 RBC's (1 out of 31,707), while that of acute FNHTR was found to be 1.14 per 1000 RBCs(36 out of 31707). The frequency of the 3 allergic reactions was calculated to be 0.09 per 1000 RBCs and for the 7 NHTRs to be 0.22 per 1000 RBCs.

Types of Transfusion Reactions – Platelet concentrate:

All the three transfusion reactions encountered post platelet transfusions were of the FNHTR type which brings down the frequency to 0.25 per 1000 PCs (3 out of 11,886 PCs).

Types of Transfusion Reactions – Fresh Frozen Plasma:

The single incident of transfusion reaction encountered post FFP transfusion was a NHTR type of TR [0.09 per 1000 FFPs (1 out of 10,841 FFPs)]

Types of Transfusion Reactions – Fresh Frozen Plasma:

None of the cryoprecipitate transfusions were associated with a transfusion reaction.

DISCUSSION

In the present study, information about various adverse transfusion reactions was collected from cases reported to the A.D Gorwala 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 transfusion reactions was found to be 0.09% (51 out of 48152). In a similar study by Bhattacharya et al., incidence of adverse transfusion reaction was 0.18% (105 reactions out of 56503 units of blood and blood component transfused).⁹ However, the total number of adverse reactions may not be the actual indicator mainly because of under reporting, especially

of minor transfusion reactions. Under reporting of minor transfusion reactions also observed by Narviolet al.¹⁰

In all the hemolytic transfusion reactions reported, hemolytic reaction was confirmed by hemoglobinuria, hematuria, and rise of serum unconjugated bilirubin. The frequency of acute hemolytic reactions observed in different studies ranges from 0.2 to 0.7 per 1,000 red cell units transfused.^{11,12} In the present study, the frequency of acute hemolytic transfusion reaction were found to be 0.003 per 1000 RBC's (1 out of 31707). The major causes encountered by the different studies were improper storage conditions and inappropriate rate or method of transfusion that leads to deterioration of blood products and hence, hemolysis. However, in the present study, the reason for the hemolytic reaction was a transfusion in a patient positive for irregular antibodies where a least incompatible blood bag was transfused as the transfusion was deemed mandatory by the treating clinician. The low percentage of the hemolytic transfusion reaction in the present study are due to a well sensitized nursing staff and medical residents by the routine practice of circulating instructions to various wards and OTs with “dos and don'ts” during the monthly hospital blood transfusion committee meetings.¹³

There are a lot of variations in the frequency of febrile non-hemolytic transfusion reactions among different studies throughout the world. This can be attributed to the variations in reporting system, frequent use of antipyretics and anti-histaminic, and pre-transfusion condition of the patient. Also, febrile non-hemolytic transfusion reactions are associated with platelets more than RCC.¹⁴ Leucoreduction has also been associated with a reduction in the incidence of febrile non-hemolytic transfusion reactions; as described in a few studies where the overall risk of febrile non-hemolytic transfusion reactions has reduced 0.12% in non-leuco-reduced to versus 0.08% in leuco-reduced blood products.¹⁴ In our study, the frequency of febrile non-hemolytic transfusion reactions with the use red cell concentrate is 0.12% (39 out of 31707 RCC transfused) while febrile non-hemolytic transfusion reactions incidence with platelet concentrates was 0.25 per 1000 platelet concentrates which is in concordance to the literature search done.¹⁵

The overall incidence of allergic reactions has been found to be (0.05%) and anaphylactic reaction was not encountered in the present study. The blood product most commonly implicated in allergic reaction was red cell concentrate (0.09%) (3 out of 31707). 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 (0.03%), 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%.³

This variation in the incidence reporting is primarily due to variations in the definitions for allergic reaction; from presence of only hives or urticarial lesions 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.¹⁹ 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 strong and compliant hemovigilance system. There lays 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, which should be very vigilant and investigate the root cause to rectify it.

CONCLUSION

The hemovigilance system plays a very important role in improving blood safety. The preliminary hemovigilance data highlight the importance of establishing functional hospital transfusion committees at institute level and at the same time developing a national hemovigilance program for policy making in transfusion services. An encouraging environment for reporting of adverse events and near-misses in a supportive, nonblaming learning culture is required to have an effective hemovigilance system. Vigilance in hospital transfusion practice and analysis of these data are of paramount importance to improve transfusion safety.

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