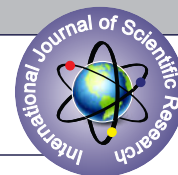


“A STUDY OF ACUTE ADVERSE BLOOD TRANSFUSION REACTIONS IN A TERTIARY CARE HOSPITAL OF WESTERN INDIA: A RETROSPECTIVE STUDY”



Pathology

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ABSTRACT

Background: Blood transfusions are life saving but can also be associated with adverse effects. Therefore, appropriate use and careful monitoring are essential for the early detection and management of these effects to ensure patient safety. **Aims And Objectives:** To determine the frequency and types of acute adverse transfusion reactions (ATRs), and its association with the type of blood or blood product during the study period. **Methods:** All acute ATRs occurring within the study period were studied according to the blood center standard operating procedure. Adverse transfusion events related to blood units were analyzed and classified based on clinical features and laboratory tests. Descriptive statistics were used to represent the acute ATRs. **Results:** Acute ATRs reported during study period were 60 (0.13%) in 44,954 units of blood and blood components transfused. Acute ATRs reported were febrile non hemolytic transfusion reaction (FNHTR) 35 (58.33%), and allergic reaction 21 (35%) followed by non-ABO hemolytic transfusion reaction (non-ABO HTR) 2 (3.33%), transfusion associated hypotension 1 (1.66%) and isolated hypertension 1 (1.66%). **Conclusion:** The most common acute ATRs were FNHTR followed by allergic reaction.

KEYWORDS

Acute adverse transfusion reactions, Febrile non hemolytic transfusion reactions, Red cell concentrate

INTRODUCTION:

The practice of blood transfusion has evolved remarkably over the past four centuries. The first recorded attempts at transfusion date back to the 17th century, when Jean-Baptiste Denys in France transfused animal blood into humans, often with fatal outcomes.^[1] The first successful human blood transfusion was performed in 1818 by British Obstetrician Dr. James Blundell, who used syringe to treat a case of postpartum hemorrhage after prior experiments on animal.^[1] This landmark event marked the beginning of therapeutic blood transfusion in clinical practice. The modern era began in 1901 with Karl Landsteiner's discovery of the ABO blood group system, which explained previous incompatibility reactions and earned him Nobel prize in 1930.^[2] Subsequent identification of Rh system in 1940 by Landsteiner and Weiner further improved transfusion safety.^[1,3] Advances in anticoagulant solutions and blood storage led to development of blood banks. In 1937, Bernard Fantus established the first hospital blood bank in the United States.^[4] The development of blood banks led to transforming transfusion into widely accessible therapy. In 1940, Edwin Cohn developed cold ethanol fractionation, the process of breaking down plasma into components and products. Albumin, gamma globulin and fibrinogen are isolated for clinical use.^[4] In 1941 Isidor Ravdin effectively treated the Pearl Harbor attack victims with Cohn's albumin for shock.^[4] Development of the refrigerated centrifuge in 1953 expedited blood component therapy.^[4]

With advancement of component therapy, transfusion medicine transitioned from whole blood transfusion to targeted use of packed red blood cells, fresh frozen plasma, platelet concentrates and cryoprecipitates, emphasizing transfusion safety. Today, blood transfusion plays a fundamental role in modern medicine, supporting trauma care, surgery, hematology, obstetrics, critical care and oncology. Globally, the World Health Organization estimates 118.5 million blood donations annually, emphasizing the scale of transfusion practice.^[5]

Despite blood component therapy and advances in donor screening, transfusion still carries risks. A blood transfusion reaction is defined as any untoward occurring during or after transfusion of blood and blood components.^[6] Blood transfusion reactions can be acute or delayed. Reactions occurring within 24 hours of transfusion are termed acute adverse transfusion reactions (ATR). Acute ATR are further divided into two groups: (1) Immune mediated include, hemolytic transfusion reaction (HTR), febrile non hemolytic transfusion reaction (FNHTR), allergic reaction, anaphylaxis and transfusion related acute lung injury (TRALI) and (2) Non immune mediated which include, transfusion

associated circulatory overload (TACO), transfusion associated dyspnoea (TAD), transfusion associated hypotension (TAH), metabolic complications and transfusion transmitted bacterial infections (TTBI).^[7]

ATRs remain a significant concern, with an estimated incidence ranging from 0.2% to 10%, and a mortality rate of approximately 1 in 250,000 transfusions.^[6] Continuous monitoring of patient for transfusion related complications can promote patient care and safety. The recognition and reporting of adverse transfusion reactions led to establishment of hemovigilance systems. Hemovigilance is a set of surveillance procedures covering the whole transfusion chain from the collection of blood, separation into its components to follow-up of its recipients for unexpected or undesirable effects, and to prevent their occurrence and recurrence. It is an important tool for improving safe blood transfusion practices in a country.^[8] The hemovigilance system was first introduced in France in 1993, followed by worldwide acceptance. India launched its National Hemovigilance Programme (HvPI) on 10th December 2012.^[9]

Despite global progress, the true incidence of ATRs remain underreported in developing countries due to lack of awareness, incomplete reporting and limited resources.

AIM AND OBJECTIVE:

To determine the frequency and types of acute adverse transfusion reactions, and association of acute ATRs with the type of blood or blood product reported during the study period.

MATERIALS AND METHODS:

This retrospective study was conducted after obtaining approval from the Institutional Human Ethics Committee (IHEC). The acute adverse transfusion reaction reported in Blood Centre, GMERS Medical College and Hospital, Gotri, Vadodara, Gujarat, India between 1st January 2012 to 30th April 2025 were studied. All acute ATRs that occurred in patients who received blood or blood products in the Institute were included in the study. Incomplete records and patients who received blood from outside blood centers were excluded from the study.

The acute ATRs were investigated and analyzed in accordance with the guidelines laid by Transfusion Medicine Technical Manual (DGHS) Third Edition 2023.

As a protocol 'Blood Transfusion Reaction Report' is issued with every

unit of blood product dispatched. Patient's sample and blood unit segment from which cross-matching and/or grouping is done is preserved for one week.

In case of suspected blood transfusion, duly filled report is sent to the Blood Centre with blood bag, blood transfusion set, 2 ml of blood sample in ethylene diamine tetra acetic acid (EDTA), 3 ml of blood sample in the plain vacuette, and the first voided urine sample after blood transfusion. The blood sample is taken from the vein of the opposite arm. 'Blood Transfusion Reaction Report' contains patient's identification, type of blood product transfused, date and time of issue, date and time of starting transfusion, date and time transfusion completed/stopped, volume transfused, signs and symptoms of the suspected reaction, pre-transfusion vitals and vitals at the time of reaction.

Upon receiving the 'Blood Transfusion Reaction Report', clerical check for patient identification [name, age, sex, Medical Record Department (MRD) number, ward, unit], blood unit number identification, and blood group identification is done. Patient identification is done to rule out the possibility of wrong sampling or bedside transposition. Details of patient records and blood unit transfused are checked to rule out any clerical error.

'Suspected blood transfusion reaction investigation report' is filled for each case of suspected blood transfusion reaction. The report contains the patient details, transfusion details, signs and symptoms, and clerical check.

The investigations carried out at the Blood Center include visual inspection of the received blood unit for clot, discoloration or signs of hemolysis. ABO and Rh typing on patient's pre- and post-transfusion samples and reconfirmation of ABO and Rh type of blood unit transfused is done. Compatibility testing, where applicable is repeated with pre- and post-transfusion patient's sample. Direct Coomb's test (DCT) and indirect Coomb's test (ICT) are done on patient's pre- and post-transfusion samples.

Routine and microscopic examination of patients' post-transfusion urine is done. Urine is especially examined for hematuria. Serum bilirubin (direct and indirect) is done in Department of Biochemistry. Sample from the blood bag is sent to Microbiology Department for culture.

The following algorithm based on 'Transfusion Medicine Technical Manual', third edition, is used to classify blood transfusion reaction.^[7]



(BP: Blood pressure, RR: Respiratory rate, HR: Heart rate, UCT: Unclassifiable complication of transfusion)

Flowchart 1: Differential Diagnosis Of Adverse Transfusion Reactions^[7]

RESULTS:

During the study period spanning over 12 years, a total of 44,954 units of blood and blood components were issued. The distribution of type of blood and blood product issued is shown in Table 1.

Table 1: Distribution Of Type Of Blood And Blood Products Issued

Units transfused	WHB	RCC	FFP	PC	CRYO
Number	4467	24,964	9253	6250	20
Percentage (Total=44954)	9.9%	55.53%	20.58%	13.9%	0.04%

60 acute adverse transfusion reactions (ATRs) (0.13%) were reported to the blood center during the study period. Table 2 shows the gender-wise distribution of acute ATR.

Table 2: Gender-wise Distribution Of Acute Adverse Transfusion Reactions

Adverse Transfusion Reaction	Number	%
Males	16	26.22
Females	44	73.33

Table 3 shows gender distribution of acute adverse transfusion reactions in different age groups.

Table 3: Age Group And Gender-wise Distribution Of Acute Adverse Transfusion Reactions

Age group (years)	Male (n=16)		Female (n=44)	
	Number	%	Number	%
0-20	2	12.5	5	11.11
21-40	6	37.5	23	52.27
41-60	7	43.75	8	17.77
61-80	1	6.25	8	17.77

Table 4 shows distribution of types of acute adverse blood transfusion reactions.

Table 4: Distribution Of Types Of Acute Adverse Transfusion Reactions

Type Of Reactions	Total number	%
ABO Hemolytic transfusion reactions (ABO HTR)	0	0
Non-ABO Hemolytic transfusion reactions (Non-ABO HTR)	2	3.33
Febrile non hemolytic reaction (FNHTR)	35	58.33
Allergic reactions	21	35
Anaphylactic reactions	0	0
Transfusion related acute lung injury (TRALI)	0	0
Transfusion associated circulatory overload (TACO)	0	0
Transfusion associated hypotension (TAH)	1	1.66
Isolated hyperventilation	1	1.66

Table 5 shows blood or blood products associated with acute adverse transfusion reactions.

Table 5: Distributions Of Blood And Blood Components Associated With Acute Adverse Transfusion Reactions

Type Of Adverse Transfusion Reaction	WHB	RCC	FFP	PC	CRYO
ABO Hemolytic transfusion reactions (ABO HTR)	0	0	0	0	0
Non-ABO Hemolytic transfusion reactions (Non-ABO HTR)	0	2	0	0	0
Febrile non hemolytic reaction (FNHTR)	8	27	0	0	0
Allergic reactions	7	11	1	2	0
Anaphylactic reactions	0	0	0	0	0
Transfusion related acute lung injury (TRALI)	0	0	0	0	0
Transfusion associated circulatory overload (TACO)	0	0	0	0	0
Transfusion associated hypotension (TAH)	0	1	0	0	0
Isolated hypertension	0	1	0	0	0

DISCUSSION:

Acute adverse transfusion reactions (ATRs) remain an important cause of morbidity and mortality in transfusion medicine despite advances in donor screening and blood component therapy.

The frequency of acute transfusion events in present study was 0.13% (60 out of 44,954 units transfused). Similar findings were reported by Sidra Izhaz et al, with frequency of acute adverse transfusion reaction of 0.71% (30 out of 4185) and Riti Tushar Kanti Sinha et al, reporting the frequency of acute adverse transfusion reaction of 0.27% (15 out of 8121).^[10,11]

In the present study on acute ATR, it was found that females were more affected 44 (73.33%) than males 16 (26.22%). Similar findings were reported by Riti Tushar Kanti Sinha et al, where females were more affected [11 (73.3%)] than males [4 (26.7%)] and Afroz et al, where females were more affected [59 (62.1%)] than males [36 (37.9%)].^[11,12]

In the present study, amongst females, most acute ATRs occurred in the 21–40 years reproductive age group (23 cases, 52.27%), followed by 41–60 years (8 cases, 17.77%), 61–80 years (8 cases, 17.77%) and 0–20 years (5 cases, 11.11%). Among the male patients' majority acute ATR were observed in the 41–60 years age group (7 cases, 43.75%), followed by 21–40 years (6 cases, 37.5%), 0–20 years (2 cases, 12.5%), and 61–80 years (1 case, 6.25%). In contrast, Afroz et al. reported that most common age group was > 60 year (37 cases, 38.9%) and followed by 26–45 years (29 cases, 30.5%)^[12]

In the present study, febrile non hemolytic transfusion reaction (FNHTR) (58.33%) and allergic reactions (35%) were the most common among all acute ATRs, consistent with various published literature as shown in Table 6.

Table 6: Comparison Of Types Of Acute Adverse Transfusion Reactions With Other Studies

Name of study	FNHTR	Allergic reaction	Anaphylactic reaction	Non ABO HTR	TAH	Isolated hypertension	TACO	TRALI
Goetkar YR et al ^[6]	59.74 %	37.66 %	2.59%	-	-	-	-	-
Rahim et al ^[13]	54.64 %	36.36 %	-	-	-	-	9%	-
Vaithy et al ^[14]	64.55 %	22.22 %	-	3.17%	9.5%	-	-	-
P. Vijaykumar et al ^[15]	72%	24%	-	-	-	-	2%	2%
Present study	58.33 %	35%	-	3.33%	1.6%	1.6%	-	-

FNHTR are associated with recipient's anti HLA antibodies and cytokine accumulation in stored blood components.^[16] Implementation of leukoreduction effectively decreases FNHTRs by removing donor leukocytes, the main source of cytokines.^[17] The comparatively higher frequency of FNHTR observed in our study is likely related to the non-implementation of universal leukoreduction in our blood center.

Allergic transfusion reaction is usually triggered when recipient mast cells and basophils, coated with IgE, encounter donor-derived proteins or allergens. This interaction stimulates release of vasoactive mediators, including histamine, complement fragments, prostaglandins, and leukotrienes, which increase vascular permeability and manifest clinically as urticaria, pruritus, and localized edema.^[18]

Hemolytic transfusion reactions are due to increased cell destructions produced by transfusion. Hemolytic reactions can be ABO or non-ABO. In the present study, we report 3.33% non-ABO hemolytic transfusion reaction. Vaithy et al also showed similar result.^[14] Non-ABO hemolytic transfusion reactions occur due to alloantibodies formed against minor red cell antigens (Kell, Kidd, or Duffy) following prior sensitization from transfusion or pregnancy, leading to immune-mediated destruction of transfused red cells.

Transfusion associated hypotension (TAH) defined as a drop of systolic blood pressure of more than or equal to 30 mm Hg occurring during or within one hour of completing transfusion and systolic pressure less than or equal to 80 mm Hg and all other transfusion reactions presenting with hypotension are excluded.^[7] TAH may be due to the release of bradykinin, which causes vasodilatation. In our study TAH was seen in 1.66% cases. 9.5% TAH was reported by Vaithy et al.^[18]

Isolated hypertension is transient rise in blood pressure due to anxiety, pain or stress during transfusion.

Transfusion-associated circulatory overload (TACO) is a non-immune

transfusion reaction caused by excessive or rapid transfusion leading to increased intravascular volume and hydrostatic pressure, resulting in pulmonary edema and circulatory overload within 6 hours of transfusion.^[7]

Transfusion-related acute lung injury (TRALI) is an immune-mediated and potentially life-threatening transfusion reaction characterized by acute non-cardiogenic pulmonary edema and severe hypoxemia occurring within 6 hours of transfusion, caused by donor anti-leukocyte (anti-HLA or anti-HNA) antibodies reacting with recipient neutrophils, leading to capillary leakage and lung injury.^[7]

In the present study TACO and TRALI were not reported. Similar findings were reported by Goetkar YR et al and Vaithy et al.^[6,14] Rahim et al however reported 9% TACO and P. Vijaykumar et al reported 2% cases each of TACO and TRALI.^[13,15]

The International Society of Blood Transfusion (ISBT) together with the International Hemovigilance Network (IHN) describe anaphylactic transfusion reactions as those presenting with skin and mucosal signs (pruritic rash, urticaria, lip or periorbital swelling, conjunctival edema) accompanied by airway compromise or marked hypotension, occurring during or shortly after a transfusion.^[19] Anaphylactic reactions are due to presence of allergen in donor blood, preformed IgE from donor, haptoglobin deficiency or IgA deficiency. Anaphylactic reactions are rare. Like in present study, Rahim et al, Vaithy et al and P. Vijaykumar et al too did not report any case of anaphylactic reaction. Goetkar YR et reported 2.59% cases of anaphylactic reaction.^[6]

Table 7: Comparison Of Acute Adverse Transfusion Reactions Associated With Blood Or Blood Products With Previous Studies

Study	WHB	RCC	FFP	PC
A Kushwaha et al ^[20]	3.03%	87.87%	6.06%	1.5%
Rashmi et al ^[21]	-	74%	18%	7%
Sharma DK et al ^[22]	40.6%	46.67%	12.5%	-
Sindhu M et al ^[23]	47.8%	36%	6.3%	10.8%
Present study	25%	70%	1.66%	3.33%

In the present study, the highest percentage of transfusion reactions was observed with red cell concentrates (RCC) at 70%, followed by whole human blood (WHB) at 25%, platelet concentrate (PC) at 3.33% and fresh frozen plasma (FFP) at 1.66%. A Kushwaha et al and Rashmi et al too reported a high incidence of acute ATR with RCC- 87.87% and 74% respectively. Sharma DK et al and Sindhu M et al reported high incidence of acute ATRs with WHB.^[22,23] This could be attributed to higher number of whole human blood transfusions included in the studies, as shown in Table 8. The percentage of reactions attributed to FFP in our study (1.66%) is lower than reported in other studies. Reactions to platelet concentrate range from 1.5% to 10.8%, with the present study showing 3.33%.

These differences may reflect variations in transfusion practices, component utilization, patient population, and monitoring protocols across institutions. Furthermore, regional differences in pre-storage leukoreduction practices, storage conditions, and patient comorbidities may also account for the observed variation.

Table 8: Number Of Blood/blood Products Issued

Study	WHB	RCC	FFP	PC	CRYO	CPP
A Kushwaha et al ^[20] (n=8925)	83 (0.9%)	6305 (70.6%)	2046 (22.9%)	270 (3.0%)	221 (2.5%)	-
Rashmi et al ^[21] (n=61069)	276 (0.5%)	39720 (65.0%)	8958 (14.7%)	12060 (19.7%)	41 (0.07%)	-
Sharma DK et al ^[22] (n=3455)	1467 (42.2%)	1042 (30.2%)	650 (18.9%)	246 (7.1%)	30 (0.9%)	20 (0.6%)
Sindhu M et al ^[23] (n=33,852)	5274 (15.5%)	17875 (52.7%)	8232 (24.3%)	2471 (7.2%)	-	-
Present study (n=44954)	4467 (9.9%)	24,964 (55.5%)	9253 (20.6%)	6250 (13.9%)	20 (0.04%)	-

CPP= Cryo Poor Plasma

Red cell or whole human blood account for the highest number of acute ATRs. The importance of vigilant monitoring during RCC/WHB transfusion and the standardization of hemovigilance protocols to reduce adverse events across all blood components cannot be overstated.

CONCLUSION:

This study presents the blood transfusion experience of a tertiary care hospital, focusing on of acute adverse transfusion reactions (ATRs) was 0.13%. The majority of reactions were associated with red cell concentrate (RCC) transfusions, with febrile non-hemolytic and allergic reactions being the most common. No cases of acute hemolytic reactions, TRALI, TACO, or anaphylaxis were seen during the study period. Although most reactions were mild, blood transfusion must be performed with strict adherence to standard procedures to reduce risks. Regular review of transfusion practices can help identify trends, improve preventive measures, and support safer patient care.

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