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Study of Acute Transfusion Reactions in a tertiary care hospital

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Introduction: Blood transfusion is an effective way of correcting the hematological needs of patients, but adverse effects do occur during or after transfusion. These adverse events associated with the transfusion of whole blood or one of its components are known as transfusion reactions. **Aim**: To study the frequency and type of Acute Transfusion Reactions (ATRs) occurred in patients receiving blood transfusions. **Materials and Methods:** This retrospective observational study was done to know acute transfusion reactions reported to Bharati Vidyapeeth (Deemed to be University) Medical College and Hospital, Blood Bank, Sangli over a period of 5 years (January 2015-December 2019).All ATRs related to whole blood and blood components were analyzed and classified on the basis of their clinical features and laboratory tests. **Results:** ATRs during or after blood transfusion reported during the five year period were 77 (0.21%) out of 35,593 units of blood /blood components transfused. ATRs reported were febrile non hemolytic transfusion reactions (FNHTR) 46 (59.74%), allergic Reactions 29 (37.66%), anaphylactic reactions 2 (2.59%) in order of frequency. **Conclusion**: The majority of ATRs were FNHTRs followed by allergic reactions.

Keywords: Acute transfusion reactions, Blood component, FNHTR, Hemovigilance, Whole blood

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To Browse

Introduction

Blood transfusion is the term used to describe the therapeutic use of whole blood and blood products. Modern-day blood transfusion therapy is a relatively safe procedure because of the discovery of blood groups by Karl Landsteiner in 1901 [1]. Transfusions even though are lifesaving in critically ill patients and having clinical benefits in their treatments, also carries considerable risk to The patient [2]. So consider it as a double-edged weapon it should be used judiciously. The inherent risks embedded in transfusion varies in severity from minor to life-threatening [3]. One of the risks involved in transfusion is the risk of getting the non-infectious complications of blood transfusion [4]. These non-infectious complications are known as adverse transfusion reactions and classified into Acute Transfusion Reactions (manifesting within 24 hrs) and delayed trans-

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Fusion reactions (manifesting after 24 hrs).

A transfusion reaction is defined as any untoward event occurring during or after the transfusion of blood or blood components [5]. ATRs remain a matter of concern as the incidence of acute blood transfusion reactions is estimated to be 0.2-10% and is responsible for mortality in 1 per 250,000. Causes of ATRs include human errors, ABO incompatibility, alloimmunization, bacterial contamination, and immunomodulation phenomenon. A reaction can present with non-specific, often overlapping symptoms. The signs and symptoms of an acute transfusion reaction range from itching, urticaria (hives), fever, and chills. Respiratory distress, high-grade fever, hypotension, and red-colored urine indicate a more serious reaction [6]. Close observation at the start of the transfusion of each blood unit is, therefore, essential [7]. Access to adequate and safe blood transfusion facilities is an integral part of the basic health care delivery system [8]. The goal of hemovigilance is to improve the safety and quality of blood transfusion services as acute transfusion reactions are non-predictable.

Hemovigilance is defined as a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components to follow-up of its recipients, intended to collect and access its information on unexpected or undesirable effects resulting from therapeutic use of labile blood products and to prevent their occurrence and recurrence [9].

Observing the standard blood transfusion protocols in pre-transfusion, during transfusion, and post-transfusion period can help to prevent transfusion reactions. Hence the blood replacement therapy demands a considerable degree of expertise for maximum recipient protection [10]. Thorough knowledge can help in preventing the occurrence of ATR and dealing with possible unwanted events in clinical management [11]. A complete analysis of adverse events is the most important objective of a hemovigilance system [12]. Identification of the adverse reactions will help in haemovigilance to reduce their incidence and to make blood transfusion procedure safe [13]. For this purpose, it is essential to establish a system for monitoring, recording, and reporting adverse reactions caused by blood transfusion in the hospital.

The present study was conducted in Bharati hospital Blood Bank to know the frequency and type of acute Transfusion reactions (ATRs) observed in the patients who have received the blood transfusion.

Materials and Methods

Setting:

Duration of Study: 3 months (1-month data collection, 2-month data analysis)

Study Design: Retrospective analytical Study

Sampling Method: Purposive

Sample size: Medical records of 77 ATRs reported to the Blood Bank of Bharati Hospital, Sangli

Inclusion Criteria: ATRs occurred in all patients who had received a blood transfusion at our hospital within a 5 year period from 1 January 2015 to 31 December 2019 within 24 hours of Blood or blood components transfused.

Exclusion Criteria: patients who received blood from outside blood banks.

Data Collection Procedure:

The retrospective study was done after receiving approval from the Institutional Ethical Committee, with approval letter BV (DU) MC&H /Sangli/IEC/384/2020

A total of 77 ATRs are noted during the study period amongst 35,593 units of blood transfused from Bharati blood bank in Bharati Hospital Sangli. Details of all ATRs were recorded.

The predesigned "transfusion adverse reaction reporting form" was filled by the treating physician and reported to the Blood Bank was studied in detail and entered in the excel chart.

All transfusion reactions that were reported during the period of five years (January 2015- December 2019) were investigated and analyzed as per the departmental protocol which was prepared in accordance with the guidelines by Transfusion Medicine Technical Manual (DGHS) Second Edition 2003 [14].

The transfusion record contains the patient's identification, type of transfusion component, date of issue, date of transfusion, start time, completed time, the reaction occurred, type of reaction allergic or pyrogenic or hemolytic and remark if any. After noting this following protocol was followed.

Patient identification (name, age, sex, hospital no, ward, unit) were rechecked both on the vial and

Compatibility card 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.

The compatibility card with the remaining blood bag and blood transfusion set was inspected for signs of deterioration i.e. clot, discoloration, hemolysis, or foul smell.

Post transfusion blood sample from the vein of the opposite side and urine sample was asked to send to the blood bank for further investigations. -2ml of a blood sample in EDTA, 3ml of a blood sample in the plain along with the first void urine sample after blood transfusion. ABO and Rh typing on patient's pre and post-transfusion samples and reconfirmation of ABO and Rh type of blood unit transfused

Compatibility testing was repeated with pre and post-transfusion patients samples.

The patient's post-transfusion blood sample was checked for:

- Hemolysis
- Serum bilirubin (direct and indirect)
- A peripheral smear examination was done for signs of hemolysis.
- The patients' post-transfusion urine sample was examined for haematuria and hemoglobinuria.
- Direct Coombs Test (DCT) and irregular antibody screening were done on patients' pre and post-transfusion samples.
- Sample from the blood unit was sent to the microbiology department for culture.
- Renal Function Test
- Febrile non- hemolytic reaction (FNHTRs) was defined as a temperature increase of more than 1-degree Cabove 37'Cand/or chills associated with blood transfusion without any other explanation.
- Allergic reactions were associated with cutaneous or systemic manifestations.
- Immune hemolytic reactions were diagnosed based on the clinical /laboratory evidence of hemolysis and positive direct agglutination test (DAT). Non-immune hemolytic reactions due to mechanical destruction of RBCs were suspected when the patient had hemolysis but negative DAT.
- Transfusion-related acute lung injury (TRALI) was characterized by hypoxemia, respiratory failure, hypotension, and fever in the absence of cardiac failure.

Results

ATRs during or after blood transfusion reported to the blood bank in 77 patients (0.18%) out of 35,593 units of blood transfused. As per the gender distribution of ATR cases are 30 (38.96 %) males and 47 (61.03%) females (Table 1).

Table-1: Gender-wise distribution of ATRs (n=77).

Total ATRs	Number of male	%	Number of Female	%
77	30	38.96 %	47	61.03 %

The age of the study patients ranged between1day to 80 years. As per the gender distribution 47 (61.03%) ATRs were seen in females. The females in the age group of 21–40 years were found to have more (24 i.e. 51.06 %) ATRs (Table 2)

Table-2: The distribution of ATRs based on age and gender (n=77).

Age (Years)	Male (n=30)	%	Female (n=47)	%
0-20	10	33.33	10	21.27
21-40	09	30	24	51.06
41-60	08	26.66	06	12.76
61-80	03	10	06	12.76
Total	30		47	

The incidence of Febrile Non-Hemolytic Transfusion Reactions (FNHTR) was reported in 46 (59.74%) patients, allergic reactions in 29 (37.66%) patients, anaphylactic reactions in 02(2.5%) patients in order of frequency (Table 3).

Table-3: The distribution of type of ATRs (n=77).

Year (2015-2019)	Total ATRs	%
FNHTR (Febrile non- haemolytic reaction)	46	59.74
Allergic reactions	29	37.66
Acute Non –immune hemolysis	0	0
TACO (Transfusion associated circulatory overload)	0	0
Anaphylactic reactions	02	2.59
TRALI (Transfusion-related acute lung injury)	0	0
Total	77	100

The number of blood component units transfusion done were 14,017 RBCs, 3294 whole blood (WB), 7602 platelets, 10256 fresh frozen plasma (FFP), 72 Cryoprecipitate and 352 single donor platelet (SDP.) Of all the reported ATRs, (i.e77ATRs) 38 (49.35%) occurred with transfusion of packed red

Blood cells (PRBC,)15 (20.77%) occurred with whole blood (WB), 13 (16.88%) with Fresh Frozen Plasma (FFP) and 10 (12.98%) with platelets Transfusions in order of frequency. Not a single case of ATRs was reported after the transfusion of cryoprecipitate and single donor platelet. (Table 4)

Table-4: Type of transfusion reactions according to a type of component transfused (n=77).

Type of components transfused and quantity	FNHTR (Febrile non-hemolytic reaction)	Allergic reactions	Acute Non – immune hemolysis	TACO (Transfusion-associated circulatory overload)	Anaphylactic Reaction	TRALI (Transfusion-related acute lung injury	DHTR	Total
Whole blood (WB) 3294	08	07	00	00	01	00	00	16
Packed cell RBC (PRBC) 14,017	21	16	00	00	01	00	00	38
Platelet concentrate 7602	07	03	00	00	00	00	00	10
Fresh Frozen Plasma (FFP) 10256	10	03	00	00	00	00	00	13
Cryoprecipitate 72	00	00	00	00	00	00	00	00
SDP 352	00	00	00	00	00	00	00	00
Total 35593	46	29	00	00	02	00	00	77

Categorization of ATRs

All the cases in the present study were acute transfusion reactions.

FNHTRA total of 46 (59.74%) patients had signs and symptoms of FNHTR. The age group of patients with FNHTR ranged from 1 month to 80 years. Out of 46 patients, 29 patients received transfusion with WB/PRBCs, 7 received with Platelet concentrate, and 10 received FFP transfusion. Fever was the most common presenting symptom (50.9%) followed by chills and rigors in (40.9%)of patients.

Allergic reactions were observed in 29 (37.66 %) patients. Age range from 22days to 62years. Of the 29 patients, 23 patients had WB/PRBCs transfusion and 03were transfused with Platelet concentrate and 03 had FFP transfusion. The most common presentation of allergic reactions was urticaria (17.2%), followed by a rash (13.6%).

Anaphylactic reactions were seen in 2 (2.59%) patients. Both were females, age 30 years, and 22 years and they were transfused with RBCs.

Discussion

ATRs are unprecedented risks associated with allogenic blood transfusions. Clinical reporting is the only source of information about the incidence of transfusion reactions. Identification of the acute blood transfusion reactions will help in taking appropriate steps for haemovigilance. An ideal Hemovigilance system is designed to detect, gather, and analyze unexpected or undesirable effects associated with transfusion [15]. In India, the haemovigilance program was launched on 10th December 2012.

In the present study, all the reactions reported were acute. The frequency of acute transfusion events in the present study was 0.21% (77 out of 35,593). 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 [1] and in another study by Pahuja et al the incidence of adverse transfusion reaction was 0.19% (314 out of 1,60,973 units of blood and blood component transfused) [12]. This rate is similar to other published results, varying from 0.22%to 0.42% transfusion events.

In the present study of ATRs, it was found females were more affected 47 (61.03%) than males 30 (38. 96%) similar to the study by Sidhu et al [16] and same with another study by Sharma DK the frequency of ATRs was more in females (59.4%) than in males (40.6%) [8]. However, Kumar et al. [13] in their study found males to be more affected than females. In the present study transfusion reactions noted in female patients in the age group of 21-40 years were maximum 24, (i.e. 51.06%) than their male counterparts.(9, i.e. 30%).

FNHTR (Febrile Non-Hemolytic Transfusion Reactions)

Data on the incidence of FNHTR varies greatly in the literature. Possible reasons for this variation include differences in recording of symptoms by the bedside staff, case ascertainment, and the use of pre-transfusion medications to control fever [17,18]. In the present study incidence of FNHTR was 46 (59.74 %). The incidence of FNHTR may be high because PRBCs were not leuco depleted. Pre-storage WBC reduction significantly reduced the rate of FNHTRs to Packed Cells and packed red blood cells (PRBCs) [6]. The present study correlated well with the study done by Chowdhury et al. [2], Khalid et al. [4], and Bhattacharya et al. [1] which also showed the incidence of FNHTR from 37.2 to 62.5 % in their studies (Table 5). Allergic reactions: Allergic reactions were observed in 29 (37.66 %)patients in the present study compared with studies done in Delhi (55.1%) by Kumar et al [13] and Iran (49.2%) by Payendeh et al [17]. Allergic transfusion reactions accounted for 17% (273 of 1613) of the transfusion reactions in the previous studies [19-23].

Anaphylactic reactions: The incidence of anaphylactic reactions have been found to be 2 (2.59%) in the present study compared to (5.1%), by Kumar et al [13].

TACO (Transfusion-associated circulatory overload) in the present study not a single case of TACO was found but studies estimating the risks of hypervolemia due to transfusion reported as 0.31-0.42/1000 recipients of transfusion [23,24.25].

Table-5: Comparison of the present study with other studies with respect to the type of ATRs seen.

Name of study	FNHTR (%)	Allergic reactions (%)	AHTR (%)	Anaphylactic Reactions (%)
Chowdhury et al [2]	62.5	25	-	-
Khalid et al [4]	41.9	34.4	1.8	-
Bhattacharya et al [1]	41	34	8.56	–
Pahuja et al [12]	54.7	41.4	1.2	2.4
Kumar et al [13]	35.7	55.1	2.6	–
Payendeh et al [17]	37.2	49.2	–	-
Venkatachalapathy TS et al. [19]	43.75	50	–	-
Riti Tushar [21]	55.8	41.5	-	2.5
Present study	59.74%	37.66 %	00	2.59 %

TRALI (Transfusion-related acute lung injury)

The risk factors of severe transfusion-related diseases including TRALI and anaphylactic shock Depend on the patient's disease, number of transfusions, and history of adverse events [18]. Literature search has revealed case reports [26] and haemovigilance reports [27] of TRALI, but there was not a single case observed in the present study.

Table-6: Comparison of the present study with other studies conducted in relation to Transfusion reactions according to the type of components transfused.

Name of study	WB and PRBC (%)	Platelets (%)	FFP (%)
Bhattacharya et al [1]	82.8	11.4	5.7
Pahuja et al [12]	93.63	3.82	2.54
Kumar et al [13]	42.8	37.75	19.38
Payandeh et al [17]	45.7	20.3	30.51
Venkatachalapathy TS et al [19]	95.83	–	2.08
Haslina et al [20]	76.5	6.57	16.9
Sinha RTK [21]	68.83	12.98	18.18
Present Study (n=77)	54 (77.12%)	10 (1.2%)	13 (16.88 %)

In the present study, the highest percentage of reactions were seen with whole blood and packed red blood cells (PRBCs) which were 54 (77.21%).This rate is similar to other published results, varying from 42.8% to 95.83% [1,11,13,17,19,20,21]. Adverse transfusion reactions seen with Platelets were 10 (1.2%) which was similar (0.7%) to a study by Khalid S [4] and with FFP were 13 (16.88%) which was similar (19.38%) to study by Kumar et al [13].

So, to establish a good hemovigilance system and attainment towards the goal of safe transfusion, resident doctors and nurses in the hospital ward should be made aware of the importance of safe blood transfusion process. Reporting of all major and minor transfusion events and analysis to avoid ATRs.

Limitations

In this study, it was noted that only acute transfusion reactions were reported during the first 24 hours after transfusion. Underreporting of minor transfusion reactions by medical/nursing staff can be a possibility.

Conclusion

The majority of ATRs were FNHTRs followed by allergic reactions.

Recommendation: It is recommended that the blood bank staff should take the responsibility to educate and to give adequate knowledge to the medical and paramedical staff who work in the wards about the prevention of ATRs. To achieve proper hemovigilance a checklist before starting blood transfusion must be made mandatory.

What does the study add to the existing knowledge

Skilled, trained, and dedicated manpower working in the blood bank, and reporting of all adverse events can have a good haemovigilance system in reducing the incidence of ATRs to a minimum.

Author's contribution

Dr. Yashodhara Gotekar: Collection of data, preparation of a manuscript for introduction, material and methods, and preparation of a manuscript for discussion.

Dr. Amruta Khade: Corresponding and second author: Data analysis, preparation of results, a compilation of references, correspondence with the editor.

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