

## A study of incidence and type of acute transfusion reaction encountered in patients during blood transfusion- an observational study in tertiary care hospital

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### Abstract:

**Background and Aims:** Blood transfusion is a vital, life-saving intervention, yet it poses risks of acute transfusion reactions (ATRs), which may range from mild to fatal. Despite their potential impact, there is limited Indian data on ATR incidence and patterns. This study aimed to evaluate the frequency, types, and clinical features of ATRs to enhance hemovigilance and transfusion safety at a tertiary care center.

**Methodology:** An ambispective observational study was conducted at the blood bank of Inlaks and Budhrani Hospital, Pune, from January 2019 to December 2023. All ATRs occurring within 24 hours of transfusion were analyzed. Data were collected from patient records, and reactions were classified per AABB guidelines. Vital parameters, symptom onset, and transfusion volume were recorded and statistically analyzed using SPSS v21.

**Results:** Out of 24,373 transfusions, 73 ATRs were reported (0.3% incidence). Most patients were male (60.3%) with a mean age of 54 years. PRBCs caused 75.3% of ATRs, followed by FFP (17.8%) and platelets (6.8%). Febrile non-hemolytic transfusion reactions (FNHTR) were most common (57.5%), followed by allergic reactions (37.2%). FFP reactions occurred faster and with smaller volumes compared to PRBCs and platelets. No Rh mismatches or hemolysis were detected.

**Conclusion:** ATRs were mostly mild but require vigilant monitoring. PRBCs remain the leading cause, though FFP poses a higher early-onset risk. Strengthening hemovigilance systems, staff training, and implementing preventive strategies are essential to improving transfusion safety and minimizing adverse outcomes.

**Keywords:** Blood Transfusion, Febrile Non-Hemolytic Transfusion Reactions, Allergic Reaction, Haemovigilance.

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### Introduction

Over the past few centuries, medicine has made great strides in understanding blood circulation [1]. Any basic healthcare delivery infrastructure must include access to adequate safe blood transfusion facilities. Since the early 20th century, blood transfusions have been extensively and excessively employed in medical practice to treat various illnesses [2]. "Blood transfusion" refers to the therapeutic use of whole blood and blood components. Karl Landsteiner's discovery of blood groups in 1901 made modern blood transfusion treatment a relatively safe procedure [3].

Overall, transfusion of blood components serves as a valuable method for managing temporary deficiencies in red blood cells (RBCs), platelets (PLTs), and clotting factors. The primary goals of transfusion are to address chronic anemia, coagulation disorders, severe bleeding conditions,

and inadequate red cell production. In specific clinical scenarios or during recovery from critical illnesses, transfusion may be the only life-saving option [4].

Hence, blood transfusion can be a life-saving procedure, but errors in the transfusion procedure can be fatal, either immediately (acute transfusion reaction) or years later (delayed transfusion reaction) through the spread of infectious pathogens [5]. An efficient way to lower transfusion-related adverse events is by careful patient and donor selection, pragmatic pretransfusion assessments of risk against the benefit to the possible recipient, and strict quality control. Continuous monitoring of transfusion-related complications can also improve patient care and safety.

Hemovigilance plays a vital role in India's national pharmacovigilance program, initiated on December 10, 2012. It is a systematic, centralized approach for collecting, managing, and analyzing data related to adverse reactions from blood transfusions and blood product administration. The goal is to enhance transfusion safety by generating evidence-based guidelines and implementing preventive strategies to minimize risks [6].

Acute transfusion reactions (ATRs) are adverse events that occur following the administration of whole blood or its components, ranging from mild to potentially life-threatening. These reactions can be immune-mediated—triggered by a response to donor blood cell antigens—or non-immune in origin, resulting from infections, circulatory overload, or iron overload (transfusion siderosis). ATRs affect approximately 0.2–10% of transfusion recipients and are linked to one death in every 250,000 transfusions. Contributing factors include human error, ABO mismatches, alloimmunization, bacterial contamination, and immunomodulatory responses [7]. Common symptoms include fever, chills, hives (urticaria), and itching, which often resolve with minimal intervention. However, more severe manifestations such as respiratory distress, high-grade fever, low blood pressure (hypotension), and reddish urine (haemoglobinuria) may signal serious complications requiring prompt medical attention [7, 8].

This study delves into the spectrum of acute transfusion reactions (ATRs), which can range from mild to life-threatening events. ATRs encompass allergic reactions, febrile non-hemolytic transfusion reactions (FNHTR), transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), and anaphylaxis. These reactions typically manifest during or within 24 hours of a transfusion. While some, like FNHTR, are relatively minor, others such as TRALI or blood sepsis (BS) can be fatal [9].

On a thorough literature search, we noticed a dearth of Indian studies that assessed the incidence and the most common type of ATRs occurring. Hence, we planned this study to observe and analyze the ATRs encountered in the blood bank of our institute. Through this study, we aimed to add crucial evidence that would help us plan and establish a vigilant system for monitoring, recording, and reporting adverse reactions caused by blood transfusion in the hospital.

**Methodology:** This ambispective observational study was conducted at the FDA-approved Blood

Bank of Inlaks and Budhrani Hospital, Pune — a 364-bed tertiary care center serving a diverse patient population. The research aimed to analyze all ATRs reported over a five-year period (January 2019 – December 2023). ATR cases were examined retrospectively (2019–2022) and prospectively (2023). For sample size estimation, a prevalence of 5.1% based on existing Indian data was assumed, yielding a minimum required sample of 19 ATR cases.

The study included all patients who developed transfusion reactions within 24 hours of receiving blood or its components at the hospital, irrespective of age or gender. Exclusion criteria included delayed transfusion reactions and transfusions performed using blood from external sources.

Data collection involved detailed patient demographics, transfusion-related parameters, and clinical signs and symptoms. Transfusion reactions were classified per AABB guidelines into types such as FNHTR, allergic reactions, haemolytic reactions, bacterial contamination, and TRALI. Laboratory investigations included blood grouping, direct Coombs test, serum bilirubin levels, urine analysis, and culture studies when indicated.

The data was entered into Microsoft Excel version 16.75.2 and analysed using SPSS software 21 version with the help of a professional statistician. Frequencies and percentages were provided for categorical variables and mean and SD, minimum, and maximum were provided for all the continuous variables. Bar graphs and Line charts were made for a graphical representation of the data. The appropriate tests for comparison were chosen based on the normality of the data using Shapiro-Wilk test. This comprehensive evaluation aimed to strengthen hemovigilance, improve transfusion safety, and contribute to better clinical practices in transfusion medicine.

## Results

During the five-year study period from January 1, 2019, to December 31, 2023, a total of 24,373 transfusions were performed at our tertiary care centre. Among these, 73 ATRs were reported within 24 hours of transfusion, resulting in an overall ATR incidence of 0.3%. The mean age of affected patients was  $53.99 \pm 19.3$  years, with the youngest being 12 years old and the oldest 93 years. The age distribution has been depicted in Figure 1. It was seen that 44 patients (60.3%) who had encountered an ATR were males and 29 patients were females (39.7%).

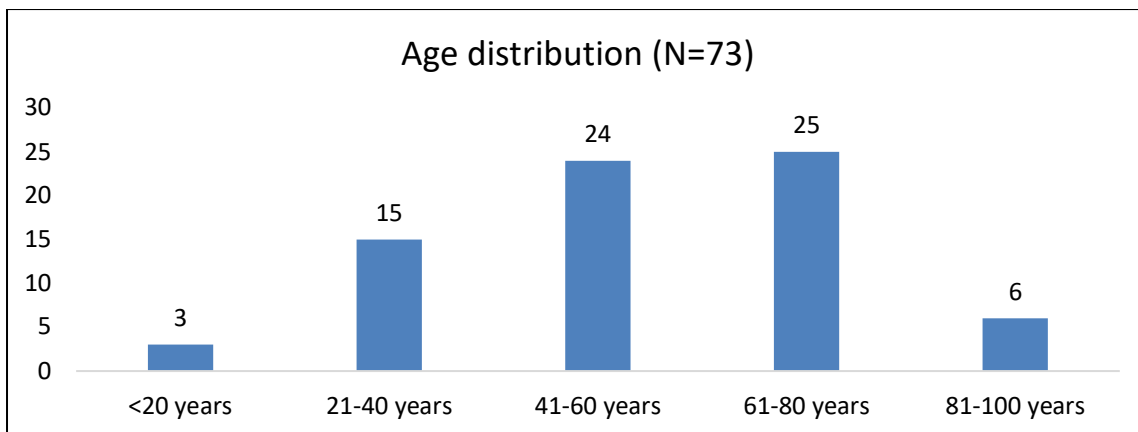


Figure 1: Age distribution.

The patients who encountered ATR were transfused either PRBC, FFP or platelets. The distribution is as follows. Fifty-five (75.3%) ATRs were seen with PRBC, followed by 13 (17.8%) in FFP and 5 (6.8%) in platelets. All the cross-matchings (100%) were conducted by the blood bank staff.

The vital parameters were assessed before and after the transfusion, illustrated in Table 1. Two patients were on ventilation, so their respiratory cycle couldn't be assessed. Post-transfusion, blood pressure and temperature showed no significant change ( $p > 0.05$ ), but pulse and respiratory rates increased significantly ( $p < 0.05$ ), likely due to acute transfusion reactions.

Table 1: Examination of vital parameters. \*Represents  $p < 0.05$  on Paired T-test and Significant increase in post-transfusion group

Vitals Parameters (N=73)	Pre-transfusion findings	Post-transfusion findings	P-value
Systolic blood pressure (SBP) in mmHg	128.76 ± 21.8	136.3 ± 26.9	0.06
Diastolic blood pressure (DBP) in mmHg	75.2 ± 11.1	79.1 ± 14.3	0.06
Temperature in F	96.9 ± 7.8	98.3 ± 8.1	0.2
Pulse rate in beats/min	91.4 ± 14.5	103.6 ± 24.4	0.0003*
Respiratory rate in cycles/minute	21.7 ± 3.3	23.4 ± 5.6	0.02*

We closely monitored the patients who experienced ATR in the prospective portion of the research study to evaluate the signs and symptoms of ATR. Medical filing was closely observed for the

retrospective portion. Most observed symptom was chills and rigors (39 patients) followed by fever (33 patients), highlighted in Figure 2.

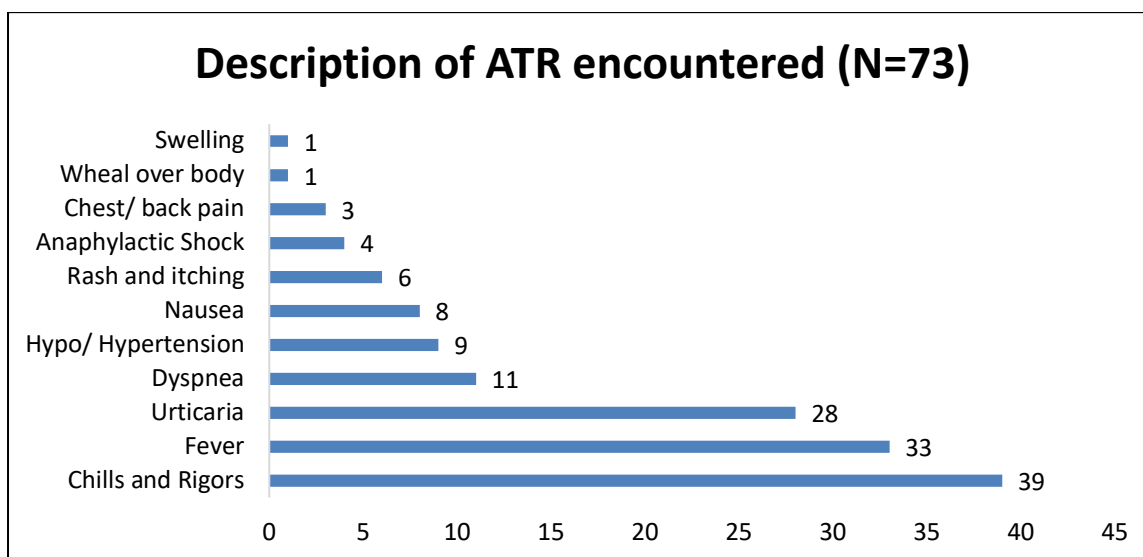
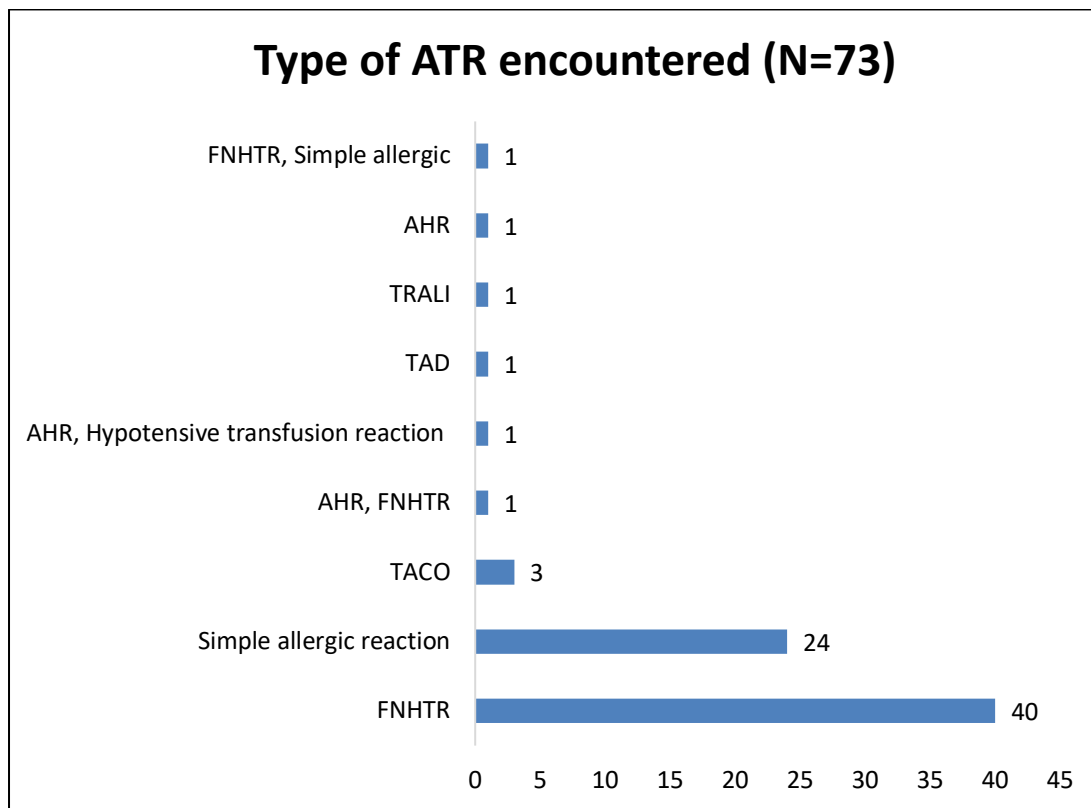


Figure 2: Description of ATR encountered.

The 73 ATRs encountered were described by the study team based on the signs and symptoms, as depicted in **Figure 3**. Some patients experienced more than one type of acute transfusion reaction

(ATR) following the transfusion of blood or blood components. The most frequently observed ATR was FNHTR, seen in 43 patients, followed by allergic reactions in 25 patients.



**Figure 3: Type of ATR encountered. [FNHTR: Febrile non-haemolytic transfusion reaction; AHR: Acute haemolytic reaction; TRALI: Transfusion-related acute lung injury; TACO: Transfusion associated circulatory overload; TAD: Transfusion associated dyspnea]**

The time interval between the start of transfusion and the onset of reaction was calculated, revealing a mean time-gap of 96.5 minutes (SD = 70.8), with a median of 90 minutes. The interquartile range (IQR) was 105 minutes, ranging from a minimum of 5 minutes to a maximum of 295 minutes.

A significantly longer time-gap for ATR onset was observed with PRBC transfusion (120.5 ± 69.8 minutes) compared to platelets (47 ± 45.1 minutes) and FFP (29.2 ± 24.9 minutes) (p<0.0001 on Kruskal Wallis test). Post-hoc analysis showed no significant difference between FFP and platelet transfusions (**Figure 4**).

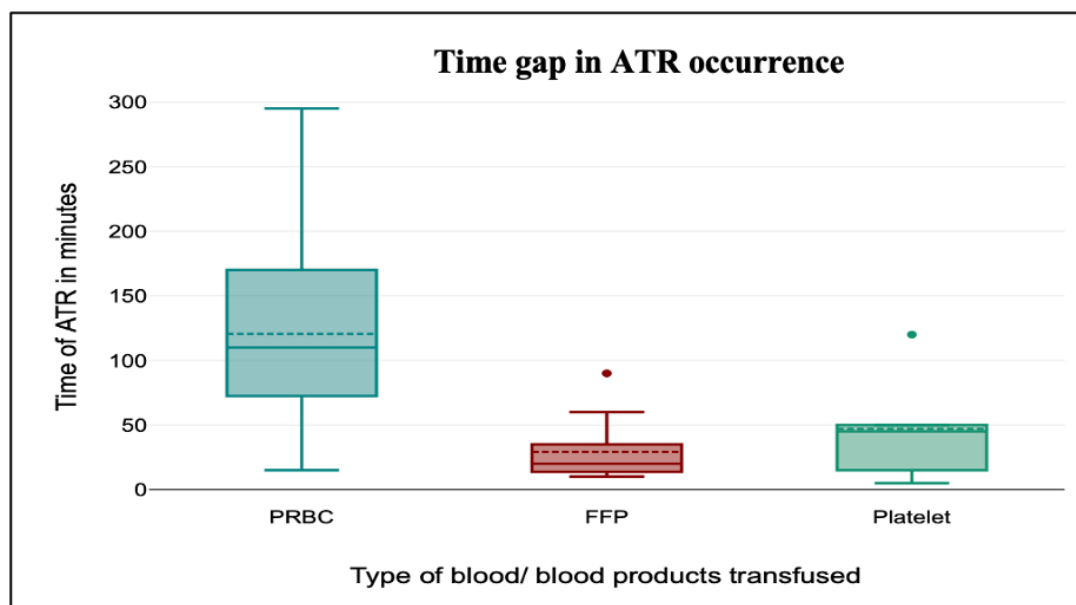


Figure 4: Time gap in ATR occurrence.

Additionally, a significantly lower volume was transfused before ATR onset in patients receiving FFP (35 [17.5–82] mL) compared to those receiving platelets (200 [125–200] mL) and PRBC (145.5 [100–200] mL) ( $p < 0.0001$ , Kruskal-Wallis test). This indicates that ATRs can occur even with small volumes of FFP.

After the occurrence of ATRs, fresh blood samples were sent to the blood bank in 72 patients, while one patient's sample was not submitted. Urine samples were received from 59 patients; 14 patients, mostly with chronic kidney disease (CKD), did not have urine samples sent. Pre-transfusion, 67 patients were Rh-positive and 6 were Rh-negative. Post-transfusion, 66 remained Rh-positive and 6 Rh-

negative, with one patient's sample unavailable. Thus, no Rh mismatches were found. Among transfused units, 63 were Rh-positive and 6 Rh-negative; 4 bags were not returned for verification. No hemolysis or abnormalities (e.g., clots/turbidity) were observed in 69 bags; 4 were not returned. Post-transfusion Direct Antiglobulin Test (DAT) was negative in 69 patients and positive in 3; one sample was not collected. Additionally, there was no growth seen after culture.

Urine examination (done in 59 cases) showed pale yellow color in 53, absent albumin in 26, absent sugar in 48, no blood in 33, pus cells in 39, absent RBCs in 34, and epithelial cells present in 46 cases (Table 2).

Table 2: Variables assessed in Urine analysis.

Urine analysis Variable	Present	Absent	Trace	Numerous
Albumin	26	24	9	0
Sugar	11	48	0	0
Blood	20	33	6	0
PC	39	8	7	4
EC	46	6	7	0
RBC	14	34	4	7

### Discussion

Blood transfusion remains one of the most common hospital procedures but carries the risk of both fatal and non-fatal adverse reactions. ATRs are the most frequent complications associated with transfusion. Despite the low incidence, the morbidity can be significant and is often preventable. Preventive measures such as proper patient evaluation, donor screening, pre-medications, and component modification are essential, though some reactions may occur unpredictably. ATRs can prolong

hospital stay, increase treatment costs, and delay care, posing a burden on both patients and the healthcare system.

In this study, a total of 24,373 transfusions were conducted, during which 73 adverse transfusion reactions (ATRs) were recorded, yielding an overall incidence of 0.3%. Subgroup analysis showed 55 ATRs from 12,200 PRBC transfusions (0.45%), 13 from 6,317 FFP transfusions (0.2%), and 5 from 5,856 platelet transfusions (0.08%). These findings align with Gotekar Y et al. [10], who reported 77

ATRs in 35,593 transfusions over five years (0.21%), and Krishnamurthy AV et al. [11], who noted a 0.9% incidence (189 ATRs in 19,800 transfusions).

The mean age of patients in the present study with ATRs was  $53.99 \pm 19.3$  years, ranging from 12 to 93 years, with most cases (34.2%) in the 61–80 age group. Males accounted for 60.3% (44 patients). No significant change was observed in pre- and post-transfusion vitals, except pulse and respiratory rate. In comparison, Gotekar Y et al [10]. reported a mean age range of 1 day to 80 years among 77 ATR cases, with most male patients in the 0–20 age group and females in 21–40 years. Krishnamurthy AV et al [11]. found a mean age of  $52 \pm 22.5$  years; 61% were female, 38% male, and 1% transgender, with no significant gender difference ( $p = 0.09$ ). Gelaw Y et al [9]. observed that 60.7% of ATR cases were female, mostly from rural areas (67.2%) and married (76.3%), with a median age of 31 years (range 15–31).

In the current study, most ATRs occurred with PRBCs (75.3%), followed by FFP (17.8%). The mean time to ATR onset was longest for PRBCs ( $120.5 \pm 69.8$  minutes) and shortest for FFP ( $29.2 \pm 24.9$  minutes). Notably, even minimal FFP volumes (35 mL) triggered ATRs. These findings align with prior studies. Krishnamurthy AV et al [11]. reported 66% of ATRs with PRBCs and 19% with platelet concentrates, while Alfroz et al [12]. found 62.1% ATRs with PRBCs and 3.2% with FFP or platelets. Gelaw Y et al [9]. observed most ATRs with whole blood (94.8%) and fewer with other components. Choudhury et al [13]. also reported PRBCs as the most frequent trigger (61%). PRBCs are in high demand and may contain residual leukocytes, which can provoke reactions. Platelets and FFP, though less frequent, were associated with allergic reactions, possibly due to antibodies against human neutrophil antigens (HNA) or human leukocyte antigens (HLA), particularly class II. Leukoreduction may reduce overall ATR incidence, especially febrile reactions [14].

In the current study, most ATRs were associated with PRBCs (75.3%), followed by platelets (17.8%) and FFP (6.8%), with no reactions linked to whole blood. Bhattacharya et al [15]. noted a similar trend, with 52% for whole blood and 19% for PRBCs. In contrast, Alfroz et al [12]. found the highest ATRs with PRBCs (62.1%), while Venkatachalapathy [16] and Kumar et al [17]. showed a more balanced distribution among all components.

In the present study, FNHTR were the most commonly observed ATRs, accounting for 57.5% of cases, followed by allergic reactions in 34.2%. Less frequent events included hypotension and TRALI, each reported in 1.4% of cases, and acute haemolytic

reactions (AHR) and TACO, both seen in 4.1% of the cases.

Similar trends were observed in other studies. Tadasa E et al [18] noted that FNHTR (63.6%) and allergic (36.4%) were the only observed types of ATRs. Izhar S et al [19]. observed that FNHTR (46.66%), allergic reactions (33.33%), anaphylactic reactions (13.33%). Only single case of TACO and TRALI was documented. Krishnamurthy AV et al [11]. reported a higher incidence of FNHTR (64.5%) and a lower rate of allergic reactions (22.7%), with hypotension being significantly more frequent at 9.5% and AHR seen in 3.2% of cases. Overall, FNHTR and allergic reactions consistently remain the most frequent ATRs across studies, while severe reactions like AHR, TACO, and TRALI occur much less frequently but are clinically significant. FNHTR, or fever that seems otherwise inexplicable within the first four hours after transfusion. FNHTR is brought on by antibodies to donor leukocytes or cytokines released from leukocytes during storage. According to a literature search, the prevalence of FNHTR ranges from 17% to 54% [20].

One of the key limitations of this study was its relatively small sample size compared to similar research conducted in other countries. This may have influenced the detection and reporting of less frequent transfusion reactions such as TRALI and TACO. Additionally, reliance on clinical reporting as the primary source for identifying ATRs posed a challenge in determining their true incidence. Mild reactions may have gone unreported due to under recognition or underreporting by medical and nursing staff, as active surveillance was not implemented in this study.

To address these challenges, it is recommended that blood bank personnel take an active role in training medical and paramedical staff on the prevention and recognition of ATRs. Implementing a mandatory pre-transfusion checklist can enhance hemovigilance practices. Furthermore, establishing a robust hemovigilance system that encourages open, blame-free reporting of adverse events and near-misses is essential to improving transfusion safety and overall patient care.

### Conclusion

To enhance transfusion safety, monitoring ATR outcomes is essential. In this study, ATRs occurred in 0.3% of cases—mostly mild—with FNHTRs (57.5%) and allergic reactions (37.2%) being most common. PRBCs were the leading cause due to higher usage, while FFP triggered quicker reactions even in small volumes. These findings reflect effective donor screening, transfusion practices, and institutional vigilance. Strengthening local and national hemovigilance systems is crucial, along with identifying patients prone to ATRs. Greater awareness among medical staff and collaboration

between clinicians and transfusion specialists is needed to improve reporting and minimize ATRs through better technology and monitoring tools.

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