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Original Article

Incidence and Risk Factors of Adverse Transfusion Reactions in a Tertiary Care Hospital: A Prospective Study

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ABSTRACT

Background: Adverse transfusion reactions (ATRs) remain a significant quality and safety concern in transfusion medicine. Systematic haemovigilance is essential to monitor their incidence, spectrum, and associated risk factors. This study aimed to determine the incidence, types, and predictors of ATRs in a tertiary care hospital.
Methods: A prospective observational study was conducted from October 2023 to September 2024, encompassing 12,505 transfusions. All transfusion events were actively monitored for adverse reactions. Data were analysed to determine reaction incidence, type, severity, and potential risk factors using univariate and multivariate logistic regression.
Results: A total of 23 ATRs were observed, yielding an overall incidence of 0.18% (1.84 per 1,000 transfusions). The most frequent reactions were allergic (60.9%) and febrile non-haemolytic transfusion reactions (34.8%), followed by a single case of acute haemolytic transfusion reaction (4.3%). No cases of transfusion-associated circulatory overload (TACO) or transfusion-related acute lung injury (TRALI) were recorded. All reactions were mild to moderate and completely resolved with symptomatic management. Logistic regression identified single donor platelet (SDP) and fresh frozen plasma (FFP) transfusions as the components most frequently associated with reactions, while age ≥60 years and prior transfusion history showed non-significant trends toward increased risk.
Conclusion: The incidence of ATRs in this tertiary care centre was low, with no severe or fatal outcomes. Allergic and febrile reactions predominated. Continued haemovigilance, component-specific monitoring, and timely intervention remain essential to sustaining transfusion safety.

Keywords*: Adverse transfusion reactions; Haemovigilance; Blood components; Risk factors; Transfusion safety.*

INTRODUCTION

Blood transfusion is a vital therapeutic intervention in modern medicine, often serving as a lifesaving procedure in surgical, medical, and emergency care settings. However, despite stringent donor screening and component preparation protocols, transfusion is not without risk. Adverse transfusion reactions (ATRs) can range from mild febrile or allergic responses to severe, life-threatening complications such as acute haemolytic reactions, transfusion-related acute lung injury (TRALI), and anaphylaxis. Monitoring these reactions through structured hemovigilance systems is essential for improving transfusion safety and clinical outcomes [1–3].

In India, institutional and regional hemovigilance studies have reported varying ATR incidence rates, typically ranging between 0.5% and 3% of all transfusions, with febrile non-haemolytic transfusion reactions (FNHTRs) and allergic reactions being the most frequently documented [1–5]. Saha et al. observed that systematic recording over a seven-year period provided valuable epidemiological insights and highlighted trends in reaction types and implicated blood

components [4]. Similarly, Sidhu et al. emphasised the importance of early detection, timely reporting, and robust documentation in reducing underreporting and improving patient safety [5].

Global studies have echoed similar findings, though the prevalence and pattern of ATRs vary depending on local transfusion practices, patient profiles, and the maturity of hemovigilance systems [6]. For example, in Ethiopian hospital settings, Regassa reported a comparable ATR spectrum, but with a higher proportion of reactions linked to limited premedication practices and delays in recognition [6]. Within India, Chavan et al. documented that sustained training, adherence to transfusion protocols, and proactive monitoring can significantly minimise the incidence of preventable reactions [7].

Despite these insights, there remains a paucity of prospective data from North Indian tertiary care hospitals, particularly from Haryana, where transfusion volumes are high and patient populations are diverse. The present prospective study was undertaken at MMIMSR, Ambala, to determine the incidence and spectrum of ATRs and to identify associated risk factors over a 12-month period.

AIMS AND OBJECTIVES

Aim:

This study aimed to determine the incidence and identify the risk factors associated with adverse transfusion reactions (ATRs) in patients receiving blood or blood components at a tertiary care hospital in North India.

Objectives:

1. To estimate the incidence and classify the types and severity of ATRs during the study period (October 2023 to September 2024) at MMIMSR, Ambala.
2. To evaluate demographic, clinical, and transfusion-related factors associated with the occurrence of ATRs.
3. To assess the time of onset, clinical course, outcomes, and propose strategies to reduce ATR incidence through improved transfusion practices and hemovigilance.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective observational study conducted in the Department of Transfusion Medicine at Maharishi Markandeshwar Institute of Medical Sciences and Research (MMIMSR), Ambala, Haryana, India. The study period extended over 12 months, from October 2023 to September 2024. MMIMSR is a tertiary care teaching hospital catering to a wide range of clinical specialities and performing approximately 20–25 blood transfusions daily.

Study Population

All patients receiving blood or blood components (whole blood, packed red blood cells [PRBCs], platelet concentrates, fresh frozen plasma [FFP], or cryoprecipitate) during the study period were eligible for inclusion.

Inclusion Criteria

- Patients of all ages and both sexes who received transfusion(s) during the study period.
- Transfusions carried out in both inpatient and outpatient settings.

Exclusion Criteria

- Patients with incomplete transfusion records.
- Transfusion reactions attributable to causes unrelated to transfusion (e.g., unrelated febrile illness).

Data Collection

Data were collected prospectively using standard hemovigilance reporting forms as per the National Haemovigilance Programme of India (HvPI) guidelines. All transfusions were monitored at the bedside by nursing staff and clinicians during and up to 24 hours post-transfusion. In the event of a suspected ATR, transfusion was stopped immediately, and the reaction was evaluated by the transfusion medicine team following institutional protocol.

Variables Recorded

For each transfusion, the following information was documented:

- Patient demographics (age, sex)
- Clinical diagnosis and comorbidities
- Type and number of blood components transfused
- Indication for transfusion
- History of previous transfusions
- Storage duration of the component

- Transfusion-related premedication (if any)
- Onset time, type, and severity of ATR
- Clinical management and outcome of the reaction

Definitions and Classification

ATRs were defined and classified according to standard criteria outlined by the International Society of Blood Transfusion (ISBT) and HvPI guidelines, including:

- Febrile Non-Haemolytic Transfusion Reaction (FNHTR)
- Allergic reactions
- Acute Haemolytic Transfusion Reaction (AHTR)
- Transfusion-Related Acute Lung Injury (TRALI)
- Transfusion-Associated Circulatory Overload (TACO)
- Other less common reactions (e.g., hypotensive reactions, sepsis)

Statistical Analysis

Data were entered into Microsoft Excel and analysed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to calculate incidence rates (number of ATRs per 100 transfusions). Categorical variables were compared using the Chi-square test or Fisher's exact test, and continuous variables were analysed using Student's t-test or Mann–Whitney U test, as appropriate. Logistic regression analysis was performed to identify independent risk factors associated with ATRs. A p-value of <0.05 was considered statistically significant.

RESULTS

1.Baseline Transfusion Activity and Patient Profile

A total of 12,505 transfusions were administered during the study period (October 2023 to September 2024). Packed red blood cells (PRBCs) constituted nearly half of all transfusions, followed by fresh frozen plasma (FFP) and platelet concentrates. Among platelets, random donor platelets (RDPs) predominated, while single donor platelets (SDPs) formed a smaller proportion. Cryoprecipitate use was minimal.

The mean age of transfusion recipients was 43.1 ± 18.5 years, with a male-to-female ratio of approximately 1.4:1. The principal indications for transfusion included surgical or traumatic blood loss, chronic anemia, malignancy, and obstetric causes. About one-third of recipients had a history of previous transfusion, and premedication was administered in nearly 30 % of cases. The average storage duration of PRBC units was 13 ± 5.5 days.

Table 1 summarises the baseline characteristics of transfusion episodes and recipients.

Table 1. Baseline characteristics of transfusion episodes and recipients during the study period

Variable	Value
Total transfusions, n (%)	**12,505 (100.0)**
PRBC	5,773 (46.1)
Platelets (total)	3,148 (25.2)
RDP	2,850 (22.8)
SDP	298 (2.4)
FFP	3,533 (28.2)
Cryoprecipitate	51 (0.4)
Unique recipients, n (approx.)	~5,700
Mean age (years) ± SD	43.1 ± 18.5
Sex, n (%)	Male 58 %; Female 42 %
Indications, n (%)	Surgery/trauma 28 %; Obstetric 18 %; Malignancy 22 %; Anemia/chronic 26 %; Other 6 %
Prior transfusions, n (%)	34 %
Premedication, n (%)	30 %

2.Incidence of Adverse Transfusion Reactions

During the study period, 23 adverse transfusion reactions (ATRs) were documented among 12,505 transfusions, yielding an overall incidence of 0.18 % (or 1.84 per 1,000 transfusions).

Component-wise analysis showed that fresh frozen plasma (FFP) had the highest ATR rate (2.83 per 1,000 transfusions), followed by single donor platelets (SDP, 6.71 per 1,000), while random donor platelets (RDP), packed red blood cells (PRBCs), and cryoprecipitate demonstrated lower incidences. No reactions were reported with cryoprecipitate transfusions.

Table 2 presents the distribution of ATRs by blood component, and Figure 1 illustrates the component-wise incidence.

Table 2. Incidence of adverse transfusion reactions by blood component

Blood Component	Transfusions (n)	ATRs (n)	Incidence (%)	Incidence per 1,000 (95 % CI)
PRBC	5,773	8	0.139	1.39 (0.6 – 2.7)
Platelets (total)	3,148	5	0.159	1.59 (0.5 – 3.7)
RDP	2,850	3	0.105	1.05 (0.2 – 3.0)
SDP	298	2	0.671	6.71 (0.8 – 24.2)
FFP	3,533	10	0.283	2.83 (1.4 – 5.2)
Cryoprecipitate	51	0	0.000	0.00
Total	**12,505**	**23**	**0.184**	**1.84 (1.2 – 2.8)**

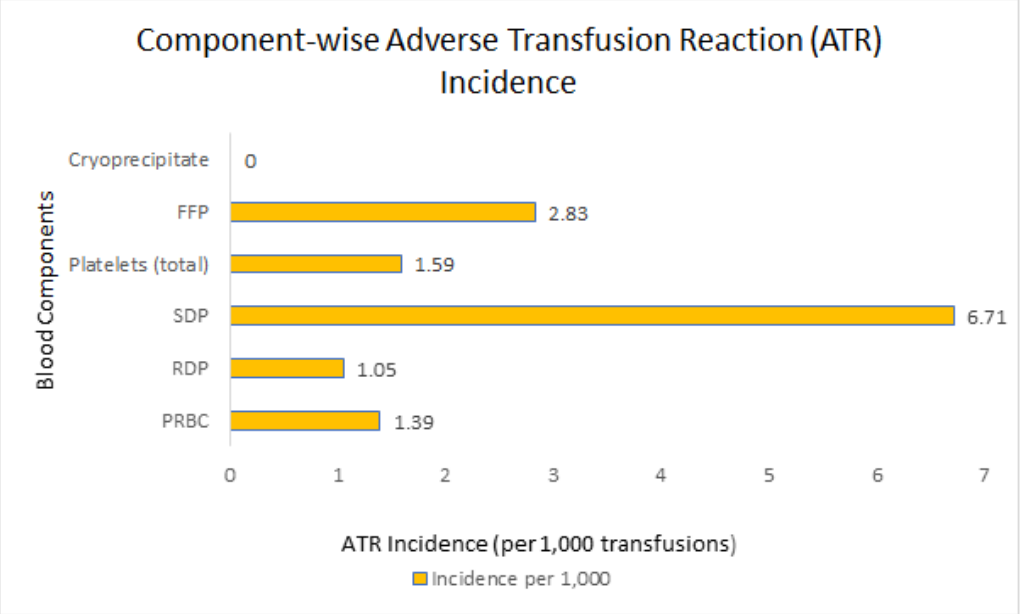

Figure1. Component-wise Adverse Transfusion Reaction (ATR) Incidence

Among all components, the incidence of adverse transfusion reactions was highest with single donor platelets (6.71 per 1,000 transfusions), followed by fresh frozen plasma (2.83 per 1,000), while reactions to PRBCs, RDPs, and cryoprecipitate were comparatively infrequent.

3.Spectrum and Severity of Adverse Transfusion Reactions

A total of 23 adverse transfusion reactions (ATRs) were recorded during the study period. The majority of these were allergic reactions (60.9%), followed by febrile non-haemolytic transfusion reactions (FNHTRs; 34.8%). A single case of acute haemolytic transfusion reaction (AHTR; 4.3%) was observed, while no episodes of transfusion-associated circulatory overload (TACO) or transfusion-related acute lung injury (TRALI) were reported.

Most ATRs were mild in severity (82.6%), with moderate reactions in 13.0% of cases. Only one event (4.3%) was classified as severe, corresponding to the AHTR case. All reactions were promptly recognised and managed according to institutional haemovigilance protocols, and no fatalities occurred.

The distribution of ATRs by type(figure2) and severity is presented in Table 3.

Table 3. Spectrum and severity of adverse transfusion reactions (n = 23)

Type of ATR	n (%)	Mild	Moderate	Severe
Febrile non-haemolytic transfusion reaction (FNHTR)	8 (34.8)	7	1	0
Allergic reaction / urticaria	14 (60.9)	12	2	0
Acute haemolytic transfusion reaction (AHTR)	1 (4.3)	0	0	1
Transfusion-associated circulatory overload (TACO)	0 (0.0)	0	0	0
Transfusion-related acute lung injury (TRALI)	0 (0.0)	0	0	0
Total	**23 (100.0)**	**19 (82.6)**	**3 (13.0)**	**1 (4.3)**

Allergic manifestations typically presented within the first hour of transfusion and responded promptly to antihistamines. FNHTRs were characterised by isolated fever or chills in the absence of haemolysis and resolved following symptomatic management and observation. The single case of AHTR occurred during a PRBC transfusion and was managed by immediate discontinuation of the transfusion, supportive therapy, and close clinical monitoring, leading to full recovery.
Overall, the spectrum of ATRs observed in this study demonstrated a predominance of mild allergic and febrile reactions, with a very low incidence of severe or life-threatening events.

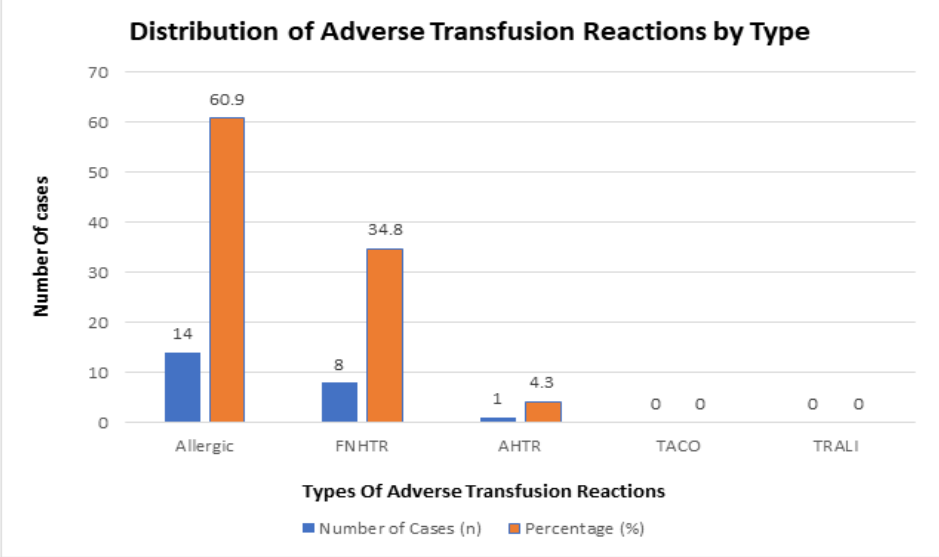

Figure2. Distribution of Adverse Transfusion Reactions by Type

4.Time to Onset and Clinical Course

The median time to onset of adverse transfusion reactions (ATRs) was 45 minutes (interquartile range: 25–70 minutes) from the initiation of transfusion. The majority of reactions (78.3%) occurred during transfusion, whereas the remaining 21.7% manifested within 24 hours after completion of transfusion.

Allergic reactions and febrile non-haemolytic transfusion reactions (FNHTRs) typically presented early, most often within the first hour of transfusion, whereas the single case of acute haemolytic transfusion reaction (AHTR) developed within the first 15 minutes of transfusion initiation.

The clinical manifestations were generally mild and transient, including fever, chills, pruritus, urticaria, and flushing. These were managed effectively with symptomatic treatment, including antihistamines, antipyretics, and temporary cessation of transfusion when indicated. No cases of hypotension, respiratory distress, or hypoxia were documented.
All patients recovered completely, with no progression to severe systemic complications. None of the reactions resulted in mortality. The median duration of symptoms was approximately 3.5 hours (interquartile range: 2–6 hours), and none required prolonged hospitalisation.

5.Risk Factor Analysis

To identify variables associated with the occurrence of adverse transfusion reactions (ATRs), both univariate and multivariate logistic regression analyses were performed, incorporating key demographic and transfusion-related factors.
In the univariate model, advanced age (≥60 years), prior transfusion history, and transfusion of fresh frozen plasma (FFP) or single donor platelets (SDP) were associated with higher odds of developing ATRs compared with packed red blood cell (PRBC) transfusions. Female sex exhibited a modest, non-significant increase in risk.

On multivariate analysis, SDP transfusion (AOR = 4.21; 95 % CI: 0.90–19.72; p = 0.06) and FFP transfusion (AOR = 1.84; 95 % CI: 0.78–4.34; p = 0.16) emerged as the strongest predictors of ATRs, although neither reached statistical significance. Age ≥60 years and previous transfusion exposure demonstrated borderline associations with increased risk, while sex and premedication use were not significantly related to ATR occurrence.

These findings suggest that component type, particularly SDP and FFP, may play a more critical role in ATR susceptibility than patient-specific factors such as age or sex.

Table 4. Univariate and multivariate logistic regression analysis of factors associated with adverse transfusion reactions (ATRs)

Variable	ATR incidence (%)	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Sex					
Male	0.15	1.00 (reference)	—	1.00 (reference)	—
Female	0.22	1.45 (0.65–3.24)	0.36	1.31 (0.57–3.04)	0.52
Age group					
<60 years	0.16	1.00 (reference)	—	1.00 (reference)	—
≥60 years	0.27	1.68 (0.78–3.65)	0.18	1.52 (0.68–3.42)	0.30
Prior transfusion history					
No	0.14	1.00 (reference)	—	1.00 (reference)	—
Yes	0.25	1.74 (0.82–3.72)	0.14	1.48 (0.68–3.21)	0.32
Component type					
PRBC	0.14	1.00 (reference)	—	1.00 (reference)	—
Platelets (RDP)	0.10	0.72 (0.20–2.50)	0.61	0.65 (0.17–2.36)	0.50
Platelets (SDP)	0.67	4.95 (1.08–22.73)	0.04*	4.21 (0.90–19.72)	0.06
FFP	0.28	2.05 (0.91–4.62)	0.08	1.84 (0.78–4.34)	0.16
Cryoprecipitate	0.00	—	—	—	—
Premedication					
Not used	0.18	1.00 (reference)	—	1.00 (reference)	—
Used	0.19	1.04 (0.48–2.26)	0.91	0.98 (0.44–2.18)	0.96

*Significant at $p < 0.05$

Abbreviations: PRBC, packed red blood cells; RDP, random donor platelets; SDP, single donor platelets; FFP, fresh frozen plasma; OR, odds ratio; CI, confidence interval.

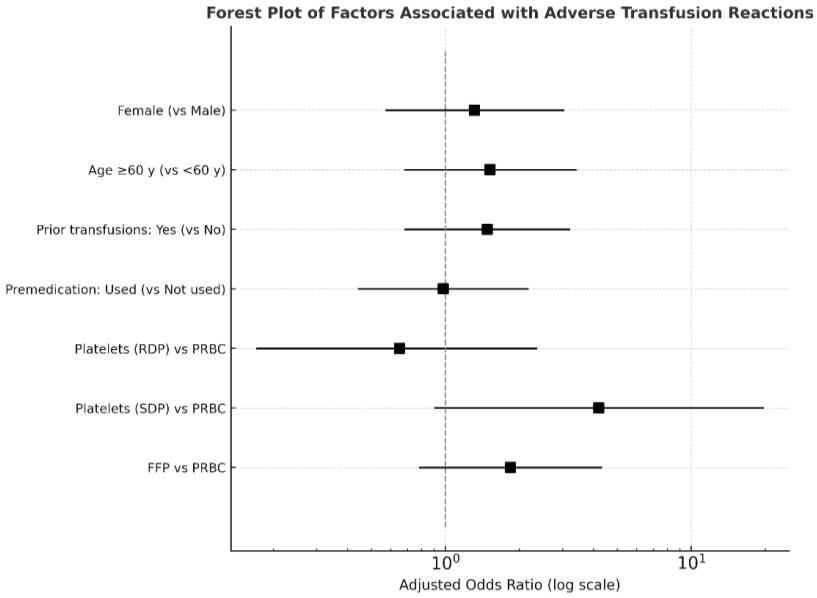

Figure3. Forest plot of factors associated with adverse transfusion reactions (ATRs).

Forest plot depicting adjusted odds ratios (AORs) and 95% confidence intervals for key predictors of adverse transfusion reactions. AORs were estimated using multivariate logistic regression. The vertical dashed line at OR = 1 represents the line of no effect. Higher odds of ATRs were observed with single donor platelet (SDP) and fresh frozen plasma (FFP) transfusions. Older age (≥60 years) and prior transfusion history showed non-significant trends toward increased risk. No significant associations were found for sex, premedication, or random donor platelets (RDP) compared with packed red blood cells (PRBC).

6.Outcomes

All patients who experienced adverse transfusion reactions (ATRs) were managed promptly and recovered completely without any long-term sequelae. The overall clinical course was favourable in all 23 cases, and there were no instances of mortality, anaphylaxis, or transfusion-related acute lung injury (TRALI).

The median duration of symptoms was approximately 3.5 hours (interquartile range: 2–6 hours). Most reactions subsided following temporary cessation of the transfusion and administration of symptomatic therapy, including antihistamines and antipyretics. No patient required intensive care support or prolonged hospitalisation as a consequence of the reaction. Febrile non-haemolytic transfusion reactions (FNHTRs) and mild allergic reactions responded rapidly to conservative measures, with no recurrence during subsequent transfusions. The single case of acute haemolytic transfusion reaction (AHTR) was managed according to institutional haemovigilance protocol, which included immediate discontinuation of the transfusion, intravenous hydration, and supportive management. The patient achieved full recovery without renal or haemodynamic complications.

All ATRs were duly reported to the National Haemovigilance Programme and documented in the institutional transfusion registry. Continuous clinical vigilance and prompt intervention contributed to favourable outcomes and prevented secondary complications.

DISCUSSION

In this prospective study conducted over a one-year period (October 2023 to September 2024), the overall incidence of adverse transfusion reactions (ATRs) was 0.18 % (1.84 per 1,000 transfusions). This rate is markedly lower than that reported in several regional and international studies, such as Khalid et al. (1.2 %) [8] and Bassi et al. (1.4 %) [9]. The relatively low incidence in the present series likely reflects effective haemovigilance practices, use of screened blood components, and improved pre-transfusion compatibility procedures. Comparable low ATR rates have been described in Ethiopian [10, 11] and Bangladeshi [18] tertiary-care studies, supporting the impact of systematic transfusion safety programmes.

Component-specific analysis in the current study revealed that single donor platelets (SDP) and fresh frozen plasma (FFP) were associated with the highest reaction rates (6.71 and 2.83 per 1,000 transfusions, respectively), while packed red blood cells (PRBCs) and random donor platelets (RDPs) showed lower frequencies, and no reactions were observed with cryoprecipitate. This pattern is consistent with the observations of Temesgen and Fissehatsion [11] and Manasa et al. [12], who both noted platelet and plasma products as common sources of ATRs. The lower PRBC reaction rate may be attributable to the widespread adoption of pre-storage leukoreduction, a measure also emphasised by Krishnamurthy et al. [13] as reducing febrile reactions.

Regarding the type and severity of reactions, allergic manifestations (60.9 %) and febrile non-haemolytic transfusion reactions (34.8 %) predominated, together accounting for more than 95 % of all ATRs. A single case of acute haemolytic transfusion reaction (AHTR) was documented, and no cases of transfusion-associated circulatory overload (TACO) or transfusion-related acute lung injury (TRALI) occurred. This distribution mirrors that reported by Chakravarty-Vartak et al. [14] and Cho et al. [15], where FNHTRs and allergic reactions constituted the majority of events. Severe reactions were rare (4.3 %), comparable to the <5 % serious-event rate observed by Shantha et al. [16].

Risk-factor analysis indicated that the odds of ATRs were higher in recipients of SDP and FFP transfusions, while older age (≥ 60 years) and prior transfusion exposure showed non-significant upward trends. Female sex and premedication use were not significantly associated with reaction risk. These findings align directionally with those of Shantha et al. [16], Thurn et al. [17], and Afroz et al. [18], who identified platelet components, advanced age, and previous sensitisation as potential contributors to ATR susceptibility. Although none of the variables achieved statistical significance in the current cohort—likely owing to the small number of events—the trends underscore the need for continued vigilance in elderly and multiply transfused patients, and for careful monitoring of plasma and platelet recipients.

All ATRs in the present study were non-fatal and fully reversible. Most resolved with symptomatic management and transient interruption of transfusion, and no patient required intensive care or experienced long-term morbidity. Similar favourable outcomes have been reported by Cho et al. [15] and Krishnamurthy et al. [13], reflecting the effectiveness of timely recognition and standardised haemovigilance response protocols.

Overall, the findings reaffirm that while ATRs remain infrequent in well-regulated tertiary centres, a small but predictable subset of patients—particularly those receiving SDP or FFP—may be at relatively higher risk. Strengthening component-specific transfusion practices, optimising donor selection and storage conditions, and maintaining robust haemovigilance reporting can further enhance transfusion safety in high-volume hospital settings.

Limitations

The study was limited by its single-centre design and the small number of adverse reactions, which restricted the statistical power of multivariate analysis. Minor or delayed reactions may have been underreported, despite active surveillance. Larger, multicentric studies are needed to validate these findings and strengthen risk stratification models.

CONCLUSION

The present study found a low incidence of adverse transfusion reactions (0.18%) in a tertiary care hospital, reflecting effective haemovigilance and transfusion practices. Allergic reactions and FNHTRs were most frequent, and all events were mild to moderate, with complete recovery and no fatalities. Single donor platelet and fresh frozen plasma transfusions showed higher odds of reactions, while age and prior transfusions exhibited non-significant trends toward increased risk. Robust monitoring, adherence to transfusion protocols, and timely intervention ensured favourable outcomes. Ongoing surveillance and component-specific risk assessment remain essential to sustain transfusion safety.

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