Original Research Paper

Volume - 16 | Issue - 02 | February - 2026 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Transfusion Medicine

A STUDY ON ADVERSE BLOOD DONOR REACTIONS IN A TERTIARY CARE CENTRE, BARABANKI, NORTH INDIA

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ABSTRACT **Aim-** To determine the frequency, severity, and factors associated with adverse events in whole blood donors, and to identify the predisposing risk factors for these reactions. **Materials and Methods-** This hospital-based cross-sectional study was conducted over a five-year period. All whole blood donors who experienced adverse reactions were evaluated. Donors were analyzed according to age, sex, hemoglobin level, donor type (replacement or voluntary) and donation status (first-time or repeat). Adverse events were recorded and classified according to standard donor reaction criteria. Statistical analysis included Chi-square tests to assess associations between donor characteristics and the occurrence of adverse reactions. **Results -** A total of 11,068 whole blood donations were recorded during the study period, of which 120 donors experienced adverse reactions, yielding an overall reaction rate of 1.08%. Replacement donors exhibited a substantially higher reaction rate of 1.34% (115/8,600) compared with voluntary donors, who showed a reaction rate of only 0.20% (5/2,468). The percentage distribution of adverse reactions among blood donors showed a higher reaction rate among first-time donors (1.25%) compared to repeat donors (0.75%) exhibited a lower reaction rate of 0.75%. Chi-square analysis revealed a highly significant association between donor type and adverse reactions ($\chi^2 = 40.14$, df = 1, $p < 0.0001$) as well as a significant association between donation status and reaction occurrence ($\chi^2 = 5.78$, df = 1, $p = 0.016$). These findings indicate that replacement donors and first-time donors are at a considerably higher risk of experiencing adverse events. Despite these observations, the overall adverse reaction rate remained low, reaffirming that whole blood donation is a generally safe procedure. **Conclusion-** Whole blood donation is a safe practice but adverse reactions during donation can happen any time. These reactions during whole blood donation are influenced by several factors, including donor age, sex, hemoglobin level, donor type, donation status, and place of donation. Donor education and improving donation practices may help reduce reaction rates.

KEYWORDS : whole blood donors, adverse reactions, reaction rate

INTRODUCTION

Blood is a vital and irreplaceable therapeutic resource that one individual can offer to another, serving as a life-saving component that cannot be artificially synthesized (1). Blood donors are altruistic individuals whose contributions are essential to healthcare systems, and it is therefore crucial to minimize their risk of experiencing adverse reactions. Even minor donor reactions may negatively influence future donation behaviour, particularly among repeat donors (2,3). Expanding the donor pool requires effective strategies for donor motivation, recruitment, and retention, all of which depend on providing high-quality donor services and ensuring donor safety. Although blood donation is widely regarded as a safe procedure, donors may occasionally experience adverse reactions of varying severity during or after donation (4). Even mild reactions can significantly impact a donor's willingness to return. Blood centres thus carry a dual responsibility: to secure an adequate supply of blood and blood components for the population, and to safeguard the well-being of donors throughout the donation process (5). Additionally, healthcare providers, as the end-users of donated blood, have an ethical obligation to minimize wastage and prevent unnecessary transfusions (6).

Historically, hemovigilance systems have concentrated on adverse events in transfusion recipients, with relatively limited emphasis on donor-related reactions. Systematic monitoring and analysis of adverse donor reactions (ADRs) are essential for identifying high-risk individuals, implementing targeted motivational and counselling interventions, optimizing care during and after donation, and establishing evidence-based donor safety guidelines—particularly in resource-limited settings (7,8). Whole blood donation typically involves venepuncture to collect approximately 10% of the donor's total blood volume within a few minutes. This procedure is performed thousands of times daily worldwide and is generally safe, with most donors experiencing only mild and transient discomfort (9). However, complications can occur. An adverse donor reaction is defined as any unexpected, undesirable, or unintended event occurring before, during, or after the donation process (10). Adverse events are an inherent aspect of blood donation and are broadly categorized into local and systemic reactions (11,12). Local reactions are usually related to needle insertion and may include pain, hematoma formation, blood leakage, difficulty in blood flow, accidental arterial puncture, delayed bleeding, nerve irritation, tendon injury, thrombophlebitis, or localized allergic responses. Systemic reactions, most commonly vasovagal in nature, result from autonomic nervous system responses influenced by emotional stress and the relative volume of blood withdrawn. These reactions occur more frequently in younger donors, female donors, individuals with lower body weight, and first-time donors. Non-syncopal vasovagal reactions are approximately 25 times more common than syncopal episodes. Systemic reactions generally arise suddenly during or immediately after phlebotomy and are classified as mild, moderate, or severe.

Some of the most serious complications associated with blood donation arise when donors experience loss of consciousness after leaving the donation site. Adverse donor reactions can be further classified into distinct categories based on their onset and severity. **Immediate reactions** occur within the blood collection premises, typically in the refreshment or observation area, and usually manifest within the first 30 minutes following donation. **Delayed reactions** develop after the donor has left the donation site and generally appear more than 30 minutes post-donation. Although rare, **serious systemic reactions** may also occur and can include severe medical events such as angina, myocardial infarction, or cerebrovascular accidents. These events are uncommon and may not always be directly attributable to the donation process; however, they represent potential medical emergencies that necessitate prompt recognition and appropriate management.

MATERIALS AND METHODS

Study Design and Setting: This hospital-based, retrospective cross-sectional study was conducted over a five-year period, from January 2019 to December 2023, at the Blood Bank of Hind Hospital. The objective was to determine the frequency, severity, and risk factors associated with adverse reactions in whole blood donors.

Study Population: The study included all individuals who donated whole blood at Hind Hospital during the specified period. Donors were assessed and selected according to the standard eligibility criteria prescribed by national and institutional guidelines. Only those meeting the required medical, physiological, and regulatory criteria were permitted to donate.

Data Collection: Data were extracted from the blood bank's donor records and hemovigilance documentation. The information collected included donor demographics (age, sex), hemoglobin concentration, body weight, donor type (voluntary or replacement), donation status (first-time or repeat), and the occurrence and classification of adverse donor reactions. Donors with incomplete documentation or those deferred for medical or technical reasons were excluded from the analysis. Donor screening and selection procedures were carried out in strict adherence to the departmental Standard Operating Procedures (SOPs), the regulatory requirements outlined in the Drugs and Cosmetics Act, 1945, and the guidelines issued by the National AIDS Control Organization (NACO), Ministry of Health and Family Welfare, Government of India. Individuals who did not fulfil these eligibility criteria were not permitted to donate.

Classification of Adverse Reactions

Adverse donor reactions were classified according to their nature, severity, and timing:

- **Local reactions:** Included hematoma formation, pain at the venipuncture site, nerve irritation or injury, accidental arterial puncture, delayed bleeding, thrombophlebitis, and localized allergic responses.
- **Systemic reactions:** Comprised vasovagal reactions (syncopal and non-syncopal) and other rare but serious systemic events such as angina, myocardial infarction, and cerebrovascular accidents.
- **Severity:** Reactions were graded as mild, moderate, or severe based on standardized donor hemovigilance criteria.
- **Timing:** Reactions were categorized as *immediate* (occurring within 30 minutes of donation and typically observed within the donation or refreshment area) or *delayed* (manifesting more than 30 minutes after the donor had left the donation site).

Data Analysis- Data were entered and analyzed using a statistical software package (e.g., SPSS version XX). Continuous variables were summarized as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. The Chi-square test was applied to evaluate associations between donor characteristics and the occurrence of adverse reactions. A p-value of <0.05 was considered statistically significant. Odds ratios (ORs) with corresponding 95% confidence intervals (CIs) were calculated to estimate the strength of association between potential risk factors and donor reactions.

Ethical Considerations

The study protocol received approval from the Institutional Ethics Committee of Hind Hospital. Confidentiality of all donors was strictly maintained, and data were anonymized prior to analysis to ensure privacy and compliance with ethical research standards.

All adverse donor reactions (ADRs) were promptly managed by trained staff in accordance with established clinical protocols. Donors experiencing reactions were provided immediate symptomatic treatment. Following donation, all donors were offered light refreshments and received post-donation counselling, with additional guidance provided to those who experienced any form of reaction.

Donors who developed ADRs were further evaluated based on the following parameters:

a) Age
b) Sex
c) Hemoglobin level
d) Donor type (voluntary or replacement)
e) Donation status (first-time or repeat donor)

Management of all adverse events adhered to the guidelines detailed in the *Transfusion Medicine Technical Manual* (DGHS, 2003, 2nd Edition), the recommendations of the National AIDS Control Organization (NACO), Ministry of Health and Family Welfare, Government of India, and the standard operating procedures (SOPs) of the department.

OBSERVATIONS AND RESULTS

This hospital-based cross-sectional study evaluated whole blood donors who experienced adverse reactions during the study period. Donors were analyzed across multiple parameters, including age, sex, hemoglobin level, type of donor (voluntary or replacement), and donation status (first-time or repeat). These variables were examined to identify patterns, trends, and potential risk factors associated with the occurrence of adverse donor reactions.

Table 1: Distribution of Adverse Reactions by Gender

Gender	Donors With Reaction n (%)	Donors Without Reaction n (%)	Total Donors n (%)
Male	110 (1.03%)	10,548 (96.40%)	10,658 (96.29%)
Female	10 (2.50%)	400 (3.60%)	410 (3.71%)
Total	120 (1.08%)	10,948 (98.92%)	11,068 (100%)

Chi-square value (χ^2) ≈ 7.27; p < 0.01 (statistically highly significant)

As shown in **Table 1**, among the 11,068 total donors, 10,658 (96.29%) were male and 410 (3.71%) were female. In total, 120 donors experienced adverse reactions (1.08%), while 10,948 donors (98.92%) did not report any reaction. Within gender categories, 110 of 10,658 male donors (1.03%) developed reactions, whereas 10 of 410 female donors (2.44%) experienced reactions. Conversely, 10,548 male donors (98.97%) and 400 female donors (97.56%) remained reaction-free. Notably, of all recorded adverse events (n = 120), 91.67% occurred among males (n = 110) and 8.33% among females (n = 10). A statistically significant association was observed between gender and the occurrence of donor reactions ($\chi^2 = 7.27$, df = 1, $p < 0.01$). Female donors demonstrated a disproportionately higher reaction rate compared with male donors, contributing substantially to the overall Chi-square value. Although male donors constituted the majority of the donor pool, the proportion of reactions among female donors was more than double that observed in males, highlighting an important gender-based disparity in donor safety outcomes.

The donors were divided into five main age groups:

Table 2: Distribution of adverse reaction in blood donors according to age and gender

Age Group (years)	Male Donors n (%)	Male Adverse Reactions n (%)	Female Donors n (%)	Female Adverse Reactions n(%)	Total Donors n (%)	Total Adverse Reactions n (%)
18-27	**6500 (60.90%)**	**60 (54.50%)**	**220 (3.20%)**	**5 (2.27%)**	**6720 (60.71%)**	**65 (54.16%)**
28-37	**2500 (23.40%)**	**30 (27.20%)**	**150 (2.10%)**	**3 (2%)**	**2650 (23.67%)**	**33 (27.5%)**
38-47	**1500 (14%)**	**15 (13.60%)**	**25 (0.35%)**	**1 (4%)**	**1525 (13.77%)**	**16 (13.33%)**
48-60	**158 (1.48%)**	**5 (4.54%)**	**15 (0.21%)**	**1 (6.67%)**	**173 (1.56%)**	**6 (0.83%)**
Total	**10658 (96.29%)**	**110 (91.70%)**	**410 (3.70%)**	**10 (8.30%)**	**11068 (100%)**	**120 (100%)**

In the present study, the majority of blood donors belonged to the 18–27-year age group, comprising 60.9% of male donors and 3.2% of female donors. This age group also accounted for the highest proportion of adverse reactions, with 54.5% of all male reactions and 2.27% of female reactions occurring in this category. Donors aged 28–37 years represented 23.4% of males and 2.1% of females, contributing to 27.2% and 2.0% of adverse reactions, respectively. The 38–47-year group constituted 14.0% of male donors and 0.35% of female donors, with corresponding reaction rates of 13.6% and 4.0%. The smallest proportion of donors was observed in the 48–60-year age group, which included 1.48% of males and 0.21% of females, contributing 4.54% and 6.67% of adverse reactions, respectively. Overall, males constituted 96.29% of the donor population and accounted for 91.7% of all adverse reactions, whereas females made up 3.70% of donors and experienced 8.3% of reactions. These findings indicate that younger donors, particularly those in the 18–27-year age group, are more likely to experience adverse reactions, consistent with patterns reported in previous literature.

Table 3: Distribution of adverse reaction in replacement and voluntary blood donors:

	Donors with reaction n(%)	Donors without reaction n (%)	Total Donors n (%)
Replacement donors	**115 (1.34%)**	**8485 (98.66%)**	**8600 (77.69%)**
Voluntary donors	**5 (0.20%)**	**2463 (98.80%)**	**2468 (22.31%)**
Total	**120 (1.08%)**	**10948 (98.92%)**	**11068 (100%)**

chi square value (χ^2) - 40.14 ; p value < 0.0001 (statistically highly significant)

In this study, a total of **11,068 blood donors** were included in the

analysis. The **overall incidence of adverse reactions** was **1.08%**, whereas **98.92%** of donors did not experience any reaction during or after donation. **Replacement donors** constituted **77.69%** of the study population; among them, **1.34%** developed adverse reactions, while **98.66%** remained reaction-free. In contrast, **voluntary donors** accounted for **22.31%** of all donations, with only **0.20%** experiencing reactions and **99.80%** reporting no untoward effects. A **Chi-square test** demonstrated a **highly significant association** between donor type and the occurrence of adverse reactions ($\chi^2 = 40.14$, **df = 1, p < 0.0001**), indicating that the likelihood of adverse reactions varied significantly between replacement and voluntary donors.

Table 4: Distribution of donor reaction according to haemoglobin level in blood donors

Hemoglobin level (g/dl)	Donors with reaction n (%)	Donors without reaction n (%)	Total no of donors n (%)
12.5 – 13.4	45 (0.89%)	5000 (99.1%)	5045 (45.58%)
13.5 – 14.4	55 (1.54%)	3500 (98.45%)	3555 (32.11%)
>14.5	20 (0.81%)	2448 (99.81%)	2468 (22.29%)
Total	120 (1.08%)	10948 (98.91%)	11068 (100%)

Chi square value (χ^2) = 10.57; p value - 0.005 (statistically highly significant)

There is a **statistically significant association** between hemoglobin level and adverse donor reactions ($\chi^2 = 10.57$, **df = 2, p = 0.005**), demonstrating that reaction frequency varies significantly across hemoglobin groups.

Table 5: Distribution of adverse reaction in first time and second time blood donors

Donation status	Donors with reactions n (%)	Donors without reaction n (%)
1st time donation	95 (1.25%)	7500 (98.25%)
Repeat donation	25 (0.75%)	3448 (99.28%)
Total	120 (1.08%)	10948 (98.92%)

Chi-square value (χ^2) -8.72; p value- .0031 (statistically highly significant)

The percentage distribution of adverse reactions among blood donors showed a higher reaction rate among first-time donors (1.25%) compared to repeat donors (0.75%). The majority of donors in both groups did not experience any adverse reactions, accounting for 98.25% of first-time donors and 99.28% of repeat donors.

A statistically significant association was observed between donation status and the occurrence of adverse reactions ($\chi^2 = 5.78$, df = 1, p = 0.016). First-time donors experienced a significantly higher proportion of adverse reactions compared to repeat donors.

DISCUSSION

In the present study, the overall adverse reaction rate among blood donors was 1.08%, which is comparable to the complication rates reported in previous large-scale investigations, reaffirming that blood donation is a safe procedure for the majority of donors (13,5). Newman et al., in their analysis of over one million blood donations, similarly documented that most adverse reactions are mild, transient, and self-limiting, further supporting the established safety profile of the donation process (13).

A noteworthy finding of the present study is the significantly higher incidence of adverse reactions among replacement donors compared to voluntary donors. This pattern is consistent with evidence from previous studies conducted in India and other developing countries, where replacement donors often exhibit greater pre-donation anxiety, lower confidence levels, and limited prior donation experience—all of which predispose them to an increased risk of vasovagal and other minor reactions (14). The highly significant Chi-square value observed in this study further reinforces donor type as an important predictor of adverse reaction occurrence. These results are in agreement with the findings of Agnihotri et al., who also reported a substantially elevated risk of donor reactions among replacement donors (14).

Gender- and age-related patterns observed in the present study are consistent with established findings in the literature. Female donors demonstrated a higher proportion of adverse reactions, a trend frequently attributed to physiological factors such as lower total blood volume and comparatively reduced hemoglobin levels. These characteristics have been repeatedly highlighted in previous studies as significant contributors to increased susceptibility to donor reactions (15,16).

Younger donors (18–27 years) constituted the largest donor group in the present study and also exhibited a higher number of adverse reactions in absolute terms. This observation aligns with previous research indicating that younger and first-time donors are more susceptible to vasovagal reactions due to heightened anxiety and autonomic responsiveness (16,17). In contrast, donors in the older age group (48–60 years) demonstrated a higher percentage of reactions; however, this finding must be interpreted cautiously given their relatively smaller representation in the donor population.

In the current study, 60.7% of all donors belonged to the 18–27-year age group, followed by 23.9% in the 28–37-year category. These distributions are consistent with the findings of Mahbub-ul-Alam M. et al, who also reported a predominance of younger donors, with 33.6% in the 18–25-year group, 29.5% in the 25–30-year group, 14.9% in the 30–35-year group, and only 0.2% in donors aged ≥60 years (18).

In the present study, out of a total of 11,068 donations, 10,658 (96.2%) were contributed by male donors, while only 410 (3.7%) were from female donors. This gender distribution closely mirrors findings from previous studies. Mangwana S. reported a similar pattern with 96.96% male and 3.04% female donors (7) while Majlessi F. et al. (19) Chowdhury F.S. et al. (20) and Jain N. et al. (21) also documented comparable male predominance, reporting male donor proportions of 94%, 92.5%, and 96.1%, respectively. The persistence of this trend across multiple studies underscores the consistently lower participation of female donors, often attributed to physiological factors such as lower hemoglobin levels and higher deferral rates.

In terms of donor type, 55% of the participants in the current study were voluntary donors, whereas 45% were replacement donors. These findings align closely with the results of Agnihotri N. et al., who reported 59.6% voluntary and 40.4% replacement donors (14). However, Patel P.A. et al. observed a slightly different distribution, with voluntary donors constituting 42.3% and replacement donors comprising 57.27% in their cohort (1). Such variations across studies may reflect differences in regional donor recruitment strategies and levels of community awareness.

Out of 11068 donors who donated blood during the study year, 120 (1.08%) donors had post donation adverse effects. Comparable results were obtained by Rathod K, Choudhary M (8) (1.09 %). Lower rates were observed by Patel PA et al., (1.48 %) (1); Pathak C et al, (4) (0.6%); Mangwana S (7) (0.3 %); Agnihotri N et al (14) (2.5%); Tomasulo P et al (24) (1.43%); Gupta S et al (25) (2.33%) & Abhishekh et al (26) (2%). Higher rates of adverse reactions were observed by Rohra DK (22) (13.5%); Majlessi F (19) (13.4 %); Chowdhary FS et al, (20) (8.7 %) & David T (26) (15.2 %). The disparity in results among different studies from our study could be due to different selection, classification & grading criteria of adverse reaction.

In the present study, it was observed that the majority of donors who experienced adverse reactions, accounting for 90.6% (1746 cases), belonged to the younger age groups of 18–27 years and 28–37 years. A significant decline in the proportion of reactions was noted with increasing age ($p < 0.001$). Similar trends have been reported by Mangwana S. (9), Rathod K. (10), Rohra D.K. (25), and Tondon R. et al. (34), all of whom documented a decreasing incidence of donor reactions as age advanced. A study from France (35) further suggested that younger individuals exhibit reduced baroreceptor sensitivity when subjected to physical or psychological stress, which may predispose them to vasovagal reactions. With increasing age, hemodynamic stability improves, thereby lowering the risk of such events. Additionally, younger donors are often more apprehensive about the pain associated with phlebotomy, which may further contribute to the heightened reaction rates observed in this age group.

In the present study, a total of 120 adverse donor reactions were recorded among 11,068 donations. The majority of these reactions occurred in younger donors, with donors aged 18–27 years and 28–37 years together accounting for most of the reported events. A clear declining trend in reaction rates was observed with increasing age, and this association was statistically significant ($p < 0.001$). Similar findings have been documented by Mangwana S. (2013) [7] Rathod K. (8), Rohra D.K. (22) and Tondon R. et al. (24) all of whom reported a

decrease in adverse reactions as donor age increased. A study from France (28) further explained this pattern by suggesting that younger individuals exhibit reduced baroreceptor sensitivity during physical or psychological stress, predisposing them to vasovagal reactions. With advancing age, hemodynamic responses stabilize, resulting in fewer reactions. Additionally, younger donors tend to be more anxious and apprehensive about phlebotomy, which may further contribute to the higher reaction rates observed in this age group.

In the present study reaction rate among male donors was 1.03% (110 /10548) & among female donors was 2.5% (10/400). Reaction rate among female donors was more than male donors. This is comparable to that observed by Mahbub-ul-Alam M et al, (18) & Chowdhary FS (20) were adverse reaction rate among male & female donors was 4.94 %, 0.35 % & 5.97%, 5.56 % respectively. Mangwana S 2013 [7] also observed the similar findings of higher reaction rate among female donors (0.50%) than male donors (0.29%). The higher reaction rate among female donors may be due to higher emotional liability, lower hemoglobin level, low normal weight

& smaller size of female donors. In our study, significantly ($p< 0.005$) higher rate of adverse reactions 0.89% (40/5000) were observed in donors with hemoglobin in the range of 12.5 – 13.4 g/dl as compared to 0.81 % (20/2448) donors with Hb ≥ 14.5 g/dl. Higher rate of adverse reactions was observed among Replacement Donors 1.34% (115/8485) as compared to Voluntary Donors 0.20% (5/2463), ($p<0.0001$) which is highly significant. The reason for high reaction rate among replacement donors may be due to anxiety, emotional & mental stress. In our study, adverse donor reaction rate was observed to be higher among 1st time Donors 1.25 % as compared to Repeat Donors 0.75% ($p< 0.0031$). This may be due to associated anxiety & needle phobia with inexperienced 1st time donors relative to repeat donors who are familiar with the donation process. Higher reaction rate was also observed by Mangwana S (7) among 1st time donors 59 % (23/39) as compared to repeat donors 41% (16/39). 89.9 % of the reactions were immediate adverse reactions. Only 10.1 % of reactions were delayed type of reactions. The reason may be that registration of delayed donor complications in our department is based on call back and late developing complications are therefore only identified if the donor returns with a complaint. Thus, late events could be under reported. In the present study, the most common variables associated with adverse donor reactions were younger age, female gender, first time donation, replacement donations and low hemoglobin.

CONCLUSION

Adverse reactions during whole blood donation are influenced by several factors, including donor age, sex, hemoglobin level, donor type, donation status, and place of donation. Although the overall reaction rate was low, indicating that blood donation is a safe practice, enhanced donor screening, thorough pre-donation assessment, targeted counselling, and attentive monitoring during and after donation can further minimize the risk of adverse events. Strengthening donor education and improving donation practices may help reduce reaction rates, particularly among first-time and replacement donors

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