

Research Article

Ensuring Donor Safety: Incidence and Characteristics of Adverse Reactions in Blood Donors

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ABSTRACT

Background: Blood donation is generally safe, however, donor adverse reactions may occur during or after donation and can affect donor safety, satisfaction and willingness to donate again.

Aim and Objectives: To estimate the frequency and pattern of donor adverse reactions and assess their distribution according to age, sex, and donation history at Government Medical College & Associated Hospital, Udhampur.

Materials and Methods: This retrospective observational study was conducted at the Blood Centre, Government Medical College & Associated Hospital, Udhampur, over two years. Records of 5,700 blood donors were included. Categorical variables were summarized as frequencies and percentages, and associations between donor characteristics and adverse reactions were assessed using the chi-square test or Fisher's exact test, as appropriate.

Results: Donor adverse reactions were documented in 75 of 5,700 donors, giving an overall reaction rate of 1.32%. Vasovagal reactions accounted for 45 (60.0%) events, followed by hematoma in 18 (24.0%), bruising in 6 (8.0%), bleeding at the venipuncture site in 3 (4.0%), and other reactions in 3 (4.0%). Reaction rates were highest among donors aged 18-25 years (2.19%), female donors (2.63%), and first-time donors (2.34%). The associations with age group ($p=0.016$), sex ($p=0.004$), and donation history ($p<0.001$) were statistically significant.

Conclusion: Donor adverse reactions were uncommon, with vasovagal reactions accounting for the majority of documented events. Higher reaction rates among younger, female, and first-time donors support focused preventive measures, careful observation, and systematic donor haemovigilance.

Keywords: Blood Donors, Donor Adverse Reactions, Vasovagal Reactions, Donor Haemovigilance, Donor Safety.

INTRODUCTION

Blood donation is an essential component of health-care delivery, supporting the management of surgical patients, trauma, malignancy, haematological disorders, and many other clinical conditions. Because human blood cannot be fully replaced by artificial substitutes for routine transfusion needs, maintaining a safe and adequate blood supply remains a major public-health responsibility. Sustainable transfusion services depend not only on donor recruitment and appropriate screening, but also on protecting donor health and ensuring a safe donation experience that encourages continued participation [1].

Although blood donation is generally safe, a small proportion of donors experience adverse reactions during or after donation. These may be localized reactions, such as hematoma, bruising, bleeding, nerve injury, or other venipuncture related complications and systemic reactions, most commonly vasovagal symptoms such as dizziness, nausea, sweating, pallor, weakness, and syncope. Reported frequencies vary across donor populations and settings because of differences in donor characteristics, collection practices, definitions, observation periods, and the intensity of adverse event surveillance [2,3].

Indian studies have reported considerable variation in the frequency of donor adverse reactions. Dogra et al. evaluated 29,524 whole-blood donations in the Jammu region and documented 108 adverse events, corresponding to an overall rate of 0.365%; presyncopal or mild vasovagal reactions were the most frequent events [4]. In contrast, Agnihotri et al. reported an overall adverse-event rate of 2.5% among 37,896 whole-blood donors in North India, with vasovagal reactions and hematomas accounting for most events [5]. Such variation reinforces the importance of standardized definitions, systematic documentation, and periodic local surveillance. Several donor characteristics have been associated with a greater likelihood of donation related reactions. Younger age, lower body weight or estimated blood volume, female sex, and first-time donation have repeatedly been associated with vasovagal reactions in donor populations [3,6]. Philip et al. examined the influence of age, sex, donation status, weight, total blood volume, and collection volume on vasovagal reactions [6]. The National Blood Donor Vigilance Programme of India has further demonstrated the value of systematic donor haemovigilance in identifying groups that may require closer observation and preventive measures [3].

Donor adverse reactions are relevant not only because of their immediate clinical consequences, but also because an unpleasant donation experience may influence future donor behaviour. Wiersum-Osselton et al. reported reduced subsequent return after vasovagal and needle-related complications, particularly among first-time donors [7]. Newman et al. similarly demonstrated that adverse events following whole-blood donation can negatively affect donor return [8]. Preventing and appropriately managing donor reactions is therefore important both for individual donor safety and for maintaining a stable donor pool.

The present study was undertaken to determine the frequency and pattern of documented donor adverse reactions at the

Blood Centre, Government Medical College & Associated Hospital, Udhampur, and to examine their distribution according to age, sex, and donation history. By describing the local reaction profile and the donor groups in whom reactions were more frequently recorded, the study aimed to inform practical measures for strengthening donor care and haemovigilance.

MATERIALS AND METHODS

Study design: Retrospective observational study.

Study population: Blood donors who donated at the Blood Centre, Government Medical College & Associated Hospital, Udhampur, during the study period.

Sample size: Records of 5,700 blood donors were included in the analysis.

Duration of study: Two years.

Study setting: Blood Centre, Government Medical College & Associated Hospital, Udhampur, Jammu.

Inclusion criteria:

1. Blood donor records pertaining to donations performed during the study period.
2. Records containing documentation of adverse reactions observed during or after blood donation.

Exclusion criteria:

1. Missing or incomplete donor records.
2. Duplicate records in the database.

Statistical analysis:

Data extracted from donor records were entered into Microsoft Excel and analysed using statistical software. Categorical variables, including age group, sex, donor status, and type of adverse reaction, were summarized as frequencies and percentages. Associations between donor characteristics and the occurrence of adverse reactions were examined using the chi-square test or Fisher's exact test, as appropriate. A two-sided p value <0.05 was considered statistically significant.

RESULTS

Table 1. Distribution of blood donors according to demographic characteristics

Variable	Category	Number (n)	Percentage (%)
Age (years)	18–25	1,140	20
	26–35	1,710	30
	36–45	1,425	25
	46–55	855	15
	>55	570	10

Sex	Male	5,130	90
	Female	570	10
Donor status	First-time donor	1,710	30
	Repeat donor	3,990	70
Total donors		5,700	100

Table 2. Frequency and types of adverse blood donor reactions

Type of reaction	Number (n)	Percentage of all donors (%)	Percentage of reactions (%)
Vasovagal reaction	45	0.79	60
Hematoma	18	0.32	24
Bruising	6	0.11	8
Bleeding at venipuncture site	3	0.05	4
Other reactions	3	0.05	4
Total adverse reactions	75	1.32	100
No recorded adverse reaction	5,625	98.68	—
Total donors	5,700	100	—

Table 3. Association between donor characteristics and adverse reactions

Variable	Category	Donors (n)	Donors with reaction (n)	Reaction rate (%)	p-value
Age	18–25 years	1,140	25	2.19	0.016
	26–35 years	1,710	25	1.46	
	36–45 years	1,425	15	1.05	
	46–55 years	855	7	0.82	
	>55 years	570	3	0.53	
Sex	Male	5,130	60	1.17	0.004
	Female	570	15	2.63	
Donor status	First-time donor	1,710	40	2.34	<0.001
	Repeat donor	3,990	35	0.88	

Table 4. Distribution of systemic and local adverse reactions

Reaction category	Type of reaction	Number (n)	Percentage among reactions (%)
Systemic	Vasovagal reaction	45	60
Systemic subtotal		45	60
Local	Hematoma	18	24
	Bruising	6	8
	Bleeding at venipuncture site	3	4
Local subtotal		27	36
Other	Other documented reactions	3	4
Total		75	100

Table 5. Comparison of adverse reaction rates by donor status and gender

Comparison	Group	Donors (n)	Adverse reactions (n)	Reaction rate (%)	p-value
Donor status	First-time donors	1,710	40	2.34	<0.001
	Repeat donors	3,990	35	0.88	

Sex	Male	5,130	60	1.17	0.004
	Female	570	15	2.63	

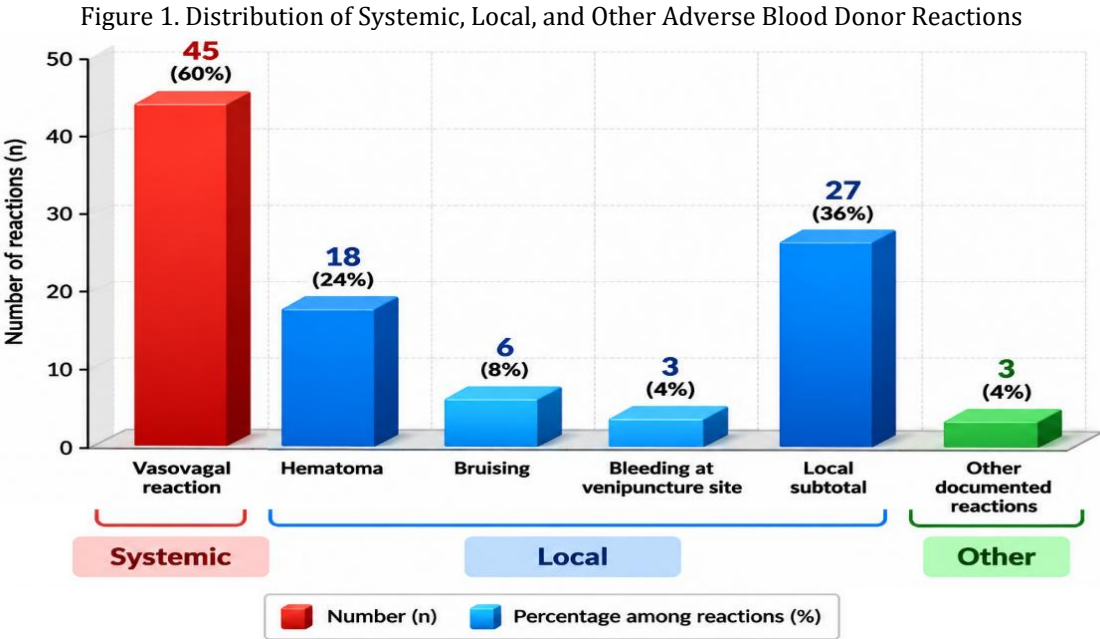
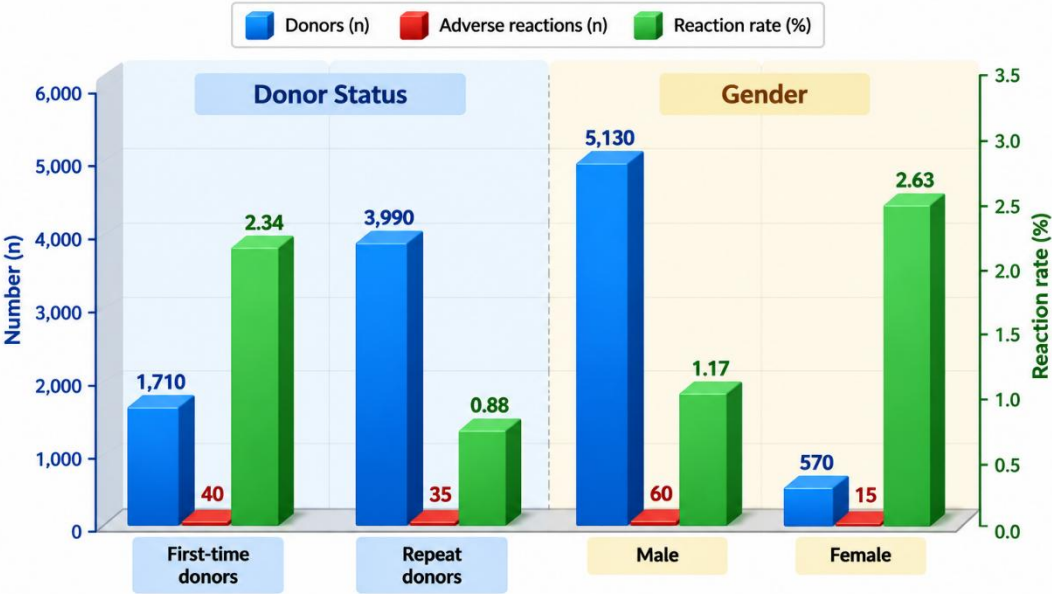


Figure 2. Comparison of Adverse Blood Donor Reaction Rates According to Donor Status and Gender



A total of 5,700 blood donors were included. The largest age group was 26–35 years (1,710; 30.0%), followed by 36–45 years (1,425; 25.0%), 18–25 years (1,140; 20.0%), 46–55 years (855; 15.0%), and >55 years (570; 10.0%). Most donors were male (5,130; 90.0%), while 570 (10.0%) were female. Repeat donors accounted for 3,990 (70.0%) donations and first-time donors for 1,710 (30.0%) (Table 1). Donor adverse reactions were documented in 75 of 5,700 donors, giving an overall reaction

rate of 1.32%; 5,625 donors (98.68%) had no recorded reaction. Vasovagal reactions were the most frequent event, occurring in 45 donors (60.0% of all reactions; 0.79% of all donors). Hematoma was the next most frequent reaction (18; 24.0%), followed by bruising (6; 8.0%), bleeding at the venipuncture site (3; 4.0%), and other documented reactions (3; 4.0%) (Table 2). Reaction rates declined progressively with increasing age: 25 of 1,140 donors aged 18–25 years (2.19%), 25 of 1,710 aged 26–35 years

(1.46%), 15 of 1,425 aged 36–45 years (1.05%), 7 of 855 aged 46–55 years (0.82%), and 3 of 570 aged >55 years (0.53%). The association between age group and occurrence of a donor adverse reaction was statistically significant ($p=0.016$) (Table 3).

Among 5,130 male donors, 60 experienced an adverse reaction (1.17%), compared with 15 of 570 female donors (2.63%). The recorded reaction rate was therefore higher among female donors, and the association between sex and adverse reaction occurrence was statistically significant ($p=0.004$) (Table 3).

Adverse reactions were documented in 40 of 1,710 first-time donors (2.34%) and 35 of 3,990 repeat donors (0.88%). The higher reaction rate among first-time donors was statistically significant ($p<0.001$) (Tables 3 and 5).

Of the 75 documented adverse reactions, 45 (60.0%) were systemic and all were vasovagal reactions. Local reactions accounted for 27 (36.0%) events, comprising 18 hematomas, 6 cases of bruising, and 3 episodes of bleeding at the venipuncture site. Three additional events (4.0%) were classified as other documented reactions (Table 4).

DISCUSSION

In this two-year retrospective analysis of 5,700 blood donors at Government Medical College & Associated Hospital, Udhampur, donor adverse reactions were documented in 1.32% of donors. Vasovagal reactions accounted for the majority of events, while local venipuncture related reactions constituted more than one-third of the documented reactions. A clear age-related pattern was observed, and reaction rates were significantly higher among female and first-time donors. Taken together, these findings identify readily recognizable donor groups in whom closer observation and targeted preventive measures may be particularly useful.

The overall reaction rate of 1.32% lies within the broad range reported in the literature but differs from previous Indian estimates. Dogra et al., in an earlier study from the Jammu region, reported 108 adverse events among 29,524 donations (0.365%) [4], whereas Agnihotri et al. reported an overall adverse-event rate of 2.5% among 37,896 whole-blood donors in North India [5]. National donor-haemovigilance data from India reported 2.45 donor adverse reactions per 1,000 donations during the initial two years of programme implementation [3]. These differences should

not be interpreted simply as differences in donor safety. Reported frequencies are strongly influenced by reaction definitions, active versus passive surveillance, duration of observation, donor characteristics, and completeness of documentation. The present rate therefore adds useful local data while also emphasizing the need for standardized donor-haemovigilance practices.

Vasovagal reactions represented 60.0% of all documented events in the present study, followed by hematoma (24.0%). This pattern is consistent with Indian experience, where vasovagal reactions have commonly constituted the largest reaction category [3-5]. Agnihotri et al. reported vasovagal reactions in 63.5% and hematomas in 35.0% of adverse events [5]. In contrast, a large national haemovigilance analysis from China reported 24,678 adverse reactions among 1,962,174 donations, approximately 12.6 reactions per 1,000 donations, with vasovagal reactions overwhelmingly predominating and local reactions forming a much smaller proportion [11]. Such variation in the relative contribution of systemic and local events is likely to reflect differences in case definitions, surveillance intensity, collection practices, and whether delayed or minor local reactions are actively captured. The appreciable proportion of local reactions in our study is operationally relevant because venipuncture related events may be amenable to careful technique, competency based staff training, and consistent post-phlebotomy care.

A notable finding was the progressive decline in adverse reaction rates with increasing age, from 2.19% among donors aged 18–25 years to 0.53% among those aged >55 years. Greater susceptibility among younger donors has been repeatedly described in donor haemovigilance studies [3,6,10]. Meher et al., in a randomized controlled trial involving whole-blood donors, also identified younger age as being associated with vasovagal reactions [12]. Although the present analysis does not establish age as an independent predictor, the consistent gradient across age groups supports closer observation of younger donors, particularly during their early donation experiences.

Female donors had a higher recorded reaction rate than male donors (2.63% versus 1.17%). The direction of this association is consistent with the National Blood Donor Vigilance Programme of India, which reported higher donor adverse-reaction rates among females

than males [3] and with other donor haemovigilance studies [6,11]. However, the present dataset did not include potentially relevant physiological variables such as body weight or estimated blood volume. The observed association with sex should therefore be interpreted as an unadjusted relationship rather than evidence of an independent effect. First time donors also had a substantially higher reaction rate than repeat donors (2.34% versus 0.88%). Similar associations have been reported in Indian national haemovigilance data and in studies evaluating vasovagal reactions among whole-blood donors [3,5,10,12]. Possible contributors include unfamiliarity with the donation procedure and donation related anxiety, although these factors were not directly measured in the present study. The finding nevertheless has immediate practical relevance: first-time donors can be identified before collection and may benefit from focused counselling, reassurance, appropriate hydration strategies, and closer observation during and immediately after donation.

The findings also have implications beyond the immediate management of a reaction. An adverse donation experience can influence a donor's willingness to return, and both vasovagal and needle-related complications have been associated with reduced subsequent donation [7,8]. Prevention is therefore relevant not only to immediate donor safety but also to donor retention. Practical measures should include careful donor selection, clear pre-donation information, attention to hydration where appropriate, early recognition of vasovagal symptoms, sound venipuncture technique, and adequate post-donation observation. In a randomized trial, Meher et al. found that preventive strategies, including water ingestion and applied muscle tension reduced vasovagal reactions with the combined approach showing the lowest incidence among the intervention groups [12]. Such interventions are particularly attractive because they can be incorporated into routine donor care with limited additional resources.

This study has several limitations. Its retrospective design relied on reactions documented in routine donor records and may therefore have underestimated minor or delayed events, particularly those occurring after donors left the collection site. As a single-centre study, the findings may not be directly generalizable to donor populations with different demographic or operational characteristics. In addition, the associations

with age, sex, and donation history were based on unadjusted analyses; potentially relevant variables such as body weight, estimated blood volume, pre-donation anxiety, and previous history of vasovagal reactions were not available for multivariable assessment. Nevertheless, the study provides real-world information from a peripheral tertiary-care setting and identifies practical donor groups and reaction patterns that can inform local surveillance and preventive practice.

CONCLUSION

Donor adverse reactions were uncommon in the present study, occurring in 1.32% of donors, but their prevention remains important for donor safety and retention. Vasovagal reactions were the predominant event, while local venipuncture-related reactions accounted for a substantial proportion of documented reactions. Younger, female, and first-time donors had higher recorded reaction rates, supporting focused counselling, careful observation, and preventive strategies in these groups. Consistent documentation and routine analysis of donor adverse reactions should remain integral to donor haemovigilance, allowing blood centres to identify local patterns, strengthen preventive practice, and support a safe and positive donation experience.

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