Original Article

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Evaluation of Adverse Reactions among Blood Donors in South Gujarat: A Cohort Study under the Haemovigilance Programme of India

Transfusion Medicine Section

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ABSTRACT

Introduction: Blood donation is vital part of any blood transfusion services in healthcare. There are various Adverse Donor Reactions (ADRs) associated with blood donation. These reactions affect blood donation and, in terms supply of blood. Understanding the prevalence and nature of ADRs is crucial for improving the overall donor experience, so that the present study was done to estimate the incidence of ADRs among blood donors, along with typing such donors with reactions according to the National Blood Donor Vigilance Programme (Haemovigilance Program of India - HvPI).

Aim: The present study was conducted to find out the incidences and types of ADRs among whole blood and apheresis donors.

Materials and Methods: The present prospective observational cohort study was conducted at a blood centre attached to Tertiary Care Government hospital of South Gujarat, India, from February 2021 to December 2024, according to guidelines given by the Department of Biologicals, Government of India, under the National Haemovigilance Programme. During the present study analysis of ADRs among whole blood donors and apheresis donors, along with effect of gender, site of donation, and type of donation on ADRs. The analysis was done using two-tailed Chi-square test and odds ratios at 95% confidence interval.

Results: Among total of 34,202 blood donations during the study period, the overall incidence of ADRs was 168 (0.49%). Majority of ADRs were Vasovagal Reactions (VVR), constituting 96.42% of all types. Most ADRs (56.54%, i.e., 95 out of 168 ADRs) occurred in donors aged 18-30 years, with first-time donors exhibiting a higher prevalence of 52.38%. Notably, ADRs were more frequent in females than in males (0.74% vs. 0.48%). Outdoor donation camps showed a higher rate of ADRs compared to in-house donations (0.51% vs. 0.38%), although these findings were not statistically significant (p-value >0.05 at 95% confidence interval).

Conclusion: The present study highlighted the importance of age, gender, donation type, and donation site in relation to ADRs. Effective donor counselling and observation, especially for first-time donors, are crucial in minimising ADRs and enhancing donor safety. Understanding the factors influencing ADRs can be helpful to improve donor recruitment and retention, ultimately contributing to a safer and more sustainable blood donation system.

Keywords: Adverse donor reactions, Blood donation, Vasovagal reactions

INTRODUCTION

Blood donation by healthy volunteers assures the availability of safe blood components for transfusion, which is a central tenet of modern healthcare system. There are different categories of blood donors, include Voluntary Non-Remunerated Blood Donor (VNRBD), family replacement blood donors, paid/professional blood donors, forced blood donors, directed blood donors, autologous blood donors, and apheresis blood donors [1].

Blood donor pool can be increased through motivation, recruitment, and retention of donors. Donor retention is directly linked to donor services and care. Blood donation experience should be pleasant for donors to ensure repeated donation. This is important for managing the inventory of blood and blood components required to meet the increasing demands[2].

While blood donation is generally considered a safe procedure, ADRs of varying severity may occur during or after donation [3]. Whatever their minor nature, these reactions have significant implications on the behaviour. These implications may include self-deferral or an unwillingness towards blood donation in the future[4]. It is generally believed that fear is the main cause of these reactions, with the highest percentage appears with first-time blood donors, decreasing with every following blood donation. These reactions can range from mild discomfort to severe complications, necessitating a comprehensive examination of their prevalence, types, and underlying risk factors. The ADRs can be reduced by diligently following the screening protocols in a diligent manner and by making the donor feel comfortable[5].

Blood centres have a dual responsibility to provide an adequate supply of blood and blood components to the communities they serve and to protect the safety of their volunteer donors [6]. Adverse event analysis helps identify blood donors at risk of developing donor reactions, allowing for the adoption of appropriate motivational strategies, predonation counselling, and the provision of care during and after donation. Additionally, it aids in developing guidelines and haemovigilance programs in countries with limited resources [7-8].

Understanding the prevalence and types of ADRs is crucial for improving the overall donor experience and bolstering public confidence in the process. Furthermore, this knowledge is vital for formulating evidence-based strategies to minimise such reactions, thereby safeguarding both donors and recipients.

The primary objective of the present study was to estimate the incidence of ADRs among blood donors while categorising these reactions according to the National Blood Donor Vigilance Programme (Haemovigilance Program of India - HvPI).

MATERIALS AND METHODS

The present prospective observational cohort study was done at a blood centre attached to the Immunohaematology and Blood Transfusion department of the Government Hospital and Medical College of South Gujarat, India. The study involved whole blood and apheresis donors who donated blood from February 2021 to December 2024 during an outdoor blood donation camp and in-house at blood centre (IEC No: GMCS/STU/ETHICS/Approval/682/22, Dated: 22/03/2022).

Inclusion criteria: All the donors eligible for blood donation as per as per the Drugs and Cosmetics (Second Amendment) Rules, 2020 and who have given consent.

Exclusion criteria: Donors who were unfit for blood donation as per the Drugs and Cosmetics (Second Amendment) Rules, 2020 and not given consent.

Sample size calculation: The sample size for calling 300 donors "telephonically" was derived following incidence of approximately 2% of delayed ADRs, with a confidence interval of 99.99% using a random sampling technique.

Study Procedure

All the donors were selected and screened for blood donation as per the Drugs and Cosmetics (Second Amendment) Rules, 2020 [9]. Blood donors for whole blood donation were tested for haemoglobin estimation level by Copper Sulphate ($CuSO_4$) method or rapid haemoglobin estimation method as per the Standard Operative Procedure (SOP) of the blood centre. Short physical examination-including pulse, Blood Pressure (BP), and respiratory rate-along with a general examination for donor fitness for blood donation, were done as per the Drugs and Cosmetics (Second Amendment) Rules, 2020. For apheresis donors, in addition to the above, Complete Blood Count (CBC) was done before donation as per the SOP.

Documentation for adverse donor reactions occurring at the collection site was done using the ADR form as per the SOP. Analysis of the ADRs was done according to guidelines given by the Department of Biologicals, Government of India, under the national haemovigilance programme [10].

Data collection involved interviews conducted at the time of obtaining written consent from donors, with subsequent information was collected through telephonic interviews on two occasions. The first call was made 48 hours after blood donation to check for any immediate adverse reactions. Second call occurred two weeks later to inquire about any delayed adverse reactions. During both calls, questions like delayed bleeding, pain, swelling, and inflammation were asked to rule out any reactions. In the present study, 300 blood donors were followed up after 48 hours and after two weeks post donation by telephonic interview.

Additional donors were called upon to cover missing follow-up if needed. Informed consent to call the donors on two occasions was taken from donor who wished to participate in the present study regarding the two follow-up calls.

The ADR reporting form was prepared following guidelines by the national executive committee of the HvPI. Data were collected from the blood centre and submitted to donor Vigil software prepared and hosted by the official website of the National Institute of Biologicals.

STATISTICAL ANALYSIS

The statistical analysis was done using two-tailed Chi-square test and Odds Ratio, with a 95% confidence interval. A p-value of <0.05 was used to reject the null hypothesis. Statistical software used for the present study was an online website-based calculator (openepi.com).

RESULTS

In the present study, total of 34,202 donations were included. [Table/Fig-1] shows the distribution by gender and donor type.

Variables	Numbers (n)	Percentage (%)
Total blood donors	34,202	100
Total male donors	33,529	98.03
Total female donors	673	01.97
Total voluntary donors	29,269	85.57
Total replacement donors	4,933	14.42

[Table/Fig-1]: Distribution of total blood donors.

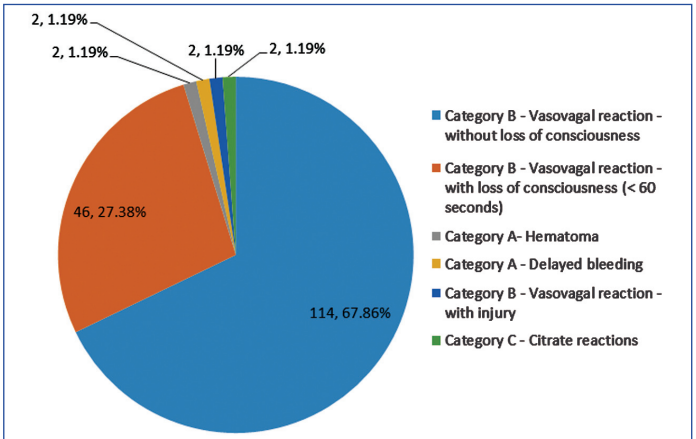
The ADRs were seen in 168 (0.49%) donors during the study period. Amongest 168 ADRs, 163 (97.02%) adverse reactions were seen in males, and 5 (2.98%) adverse reactions were seen in females. This difference in the rate was not significant statistically with a p-value of 0.35 (two tailed Chi-square test at 95% confidence interval), along with odds ratio for female donor was 1.532. Among the 168 ADRs, 2 apheresis blood donors had reaction related to apheresis.

The mean age of those who experienced ADRs was 30.58 years. In the present study, total adverse reaction in donors aged 18-30 years were higher, accounting for 56.54% (95/168), compared to older age group donors.

The majority of donors had category B ADRs, with VVR predominant (96.42%). Among these, 114 donors experienced VVR without loss of consciousness, 46 donors had VVR with loss of consciousness (<60 Sec) and two had an injury along with VVR. Among category A type of ADRs, local complications in the form of haematoma were observed in 2 donors, and delayed bleeding occurred in 2 donors out of the total 34,202 donation. In category C, reactions related to apheresis procedures, citrate reactions (numbness/tingling/vibrations on lip, fingers, and muscle twitching) were seen in 2 aphaeresis donors, as shown in [Table/Fig-2,3].

ADRs in different categories		Frequency (n)	Percentage (%)
Category A-Haematoma		2	1.19
Category A-Delayed bleeding		2	1.19
Category B-Vasovagal reaction	Without loss of consciousness	114	67.85
	With loss of consciousness (<60 seconds)	46	27.38
	With injury	2	1.19
Category C-Citrate reactions		2	1.19

[Table/Fig-2]: Category-wise distribution of adverse donor reaction.



[Table/Fig-3]: ADRs frequency in different categories.

A total of 27,236 donations were done at camps, with 141 (0.51%) incidences of donor reactions, and 27,095 donations without any reactions. At blood centre, 6,966 blood donations were done with 27 (0.38%) cases of donor reactions and 6,939 donations without any reactions. There was a statistically significant association between the site of donation and donor reactions (two-tailed Chi-square test a p-value >0.05 at a 95% confidence interval), and odds ratio was 1.337 [Table/Fig-4].

Variables		Donor reaction		Total	p-value
		Present	Absent		
Gender	Male	163 (0.48%)	33366	33529	0.35(95% CI)
	Female	05 (0.74%)	668	673	
Site of donation	Camp	141 (0.51%)	27095	27236	0.16 (95% CI)
	At centre (In-house)	27 (0.38%)	6939	6966	
Donation type	Voluntary	155 (0.52%)	29114	29269	0.01 (95% CI)
	Replacement	13 (0.26%)	4920	4933	

[Table/Fig-4]: Association of ADRs with different variables.

Among voluntary donors, there were 155 cases (0.52%) of donor reactions out of 29,269 donors, while 29,114 did not experience a reaction. For replacement donors, 13 individuals (0.26%) had a donor reaction out of 4,933, while 4,920 did not. (Two-tailed Chi-square test yielded a p-value of 0.01 at 95% confidence interval). This p-value suggests an association between the type of donation and the occurrence of donor reactions. In other words, the likelihood of a reaction significantly differed between voluntary and replacement donors. The reason for this difference may be better donor screening for all in-house replacement donors, with an odds ratio of 0.50 for replacement donors.

Among 168 donors with ADR, 88 (52.38%) were first-time donors, while 80 (47.61%) were repeat blood donors with a history of previous donation.

DISCUSSION

The incidence of ADRs in the present study was 0.49% (168/34,202). A nationwide study by Bisht A et al., [11] reported a 0.24% incidence of adverse reactions in blood donors, while a study by Pathak C et al., [12] showed a 0.6% incidence. These two studies showed similar incidence of ADRs as that of present study. Research by Tondon R et al., [13] reported ADRs at 1.6% from 2007 to 2009. These studies had higher incidence of ADRs than the present study, The present study had underreported ADRs due to various constraints at camp site.

It was observed in the total adverse reactions in donors aged 18-30 years were higher, accounting for 56.54% (95/168), compared to older age group donors. The study by Bisht A et al., [11] showed an ADRs rate of 69% in the younger age group of 18-30 years. Newman BH showed vasovagal reactions were higher in donors who were less than 30 years old [14]. The VVR rate was 8.2% in Caucasian high school students, stating that these young donors may be donating for the first time, contributing to a higher incidence [15]. American haemovigilance Program showed young donors (<20 years old) had a significantly higher reaction rate than older donors [16]. Agnihotri N et al., observed the highest reaction rate (2.72%) in donors aged 18-24 years, which was significantly higher than the overall prevalence of 1.6% [7]. A study from France postulated that baroreceptor sensitivity is decreased in healthy young individuals when they are physically or psychologically stressed. With increasing age, the body becomes more stable haemodynamically. Also, the younger donors may be more apprehensive about the pain of phlebotomy and may thus be more prone to adverse reactions [7]. The present study aligns with these findings [17].

The present study showed more numbers of adverse reactions in females than in males (0.74%, 5/673 in females vs 0.48%, 163/33,529 in males, p=0.35). VVR in females accounted for 2.38% (4/168), and haematomas were at 0.59% (1/168), compared to 94.05% (158/168) and 1.19% (2/168) in males, respectively. Newman BH et al., (2003) concluded that men were half as likely as women to experience adverse effects (23% vs. 48%) [18]. The prevalence of reactions in the study by Dogra A et al., was 4.25% in female donors compared to 0.296% in male donors [19].

ADRs were higher in first-time donors than in repeat donors (88/168, 52.38% vs. 80/168, 47.61%) in the present study. Philip J et al., showed a correlation between vasovagal complications and whole blood donation among first-time donors [20]. First-time donors are usually more apprehensive and anxious about blood donation. First-time donors tend to be more conscious of any discomfort post-donation, like painful arms. A study by Bisht A et al., showed a minor difference in ADRs rate between 1st time and repeat donors, recorded as 0.25% to 0.21% of total donations [11]. The reaction rate among first-time donors was 2.21%, compared to 0.85% in repeat donors in a study conducted by Agnihotri N et al., [7].

Adverse reactions at outdoor camps were observed in 121 donors (72.02%) out of 168 reactions, which was higher compared to the 27 reactions (16.08%) that occurred during in-house donations in the present study. Vasovagal reactions at the camp were higher compared to in-house donations (0.51%, 139/27,236 vs. 0.33%, 23/6,966), although this was not statistically significant (p>0.05). Haematoma reactions at outdoor camps were also higher than in-house donations. Mahapatra S et al., concluded that 542 (2.07%) in-house donors experienced ADRs, while 402 (3.21%) at outdoor voluntary campsites. Rathod et al., showed that the frequency of reactions at outdoor camps was higher than in-house donations (2% vs. 1.37%) [21]. Agnihotri N et al., found that out of 948 adverse reactions, 425 (44.8%) were observed in the department, and 523 (55.2%) in the blood donation camps [7]. The present study was in agreement with other studies.

The present study revealed that Category B was the most common ADR reported, with 162 (96.42%) donors out of a total of 168. Category A had the second most number of ADR cases with 4 donors (2.38%), while Category C ADR was observed in 2 donors (1.19%). No ADR were reported for Categories D, E, or F as per HvPI. A study by Bisht A et al., [11] showed a similar distribution of ADRs, with 83.61% in Category B, 7.66% in Category A, 7.76% in Category F, and 0.5% each for Category C and D, with no ADRs for Category E.

The overall incidence of vasovagal reactions in this study was 0.47% (162/34,202), while haematomas and re-bleeding incidents were at 0.01% (4/34,202). Newman BH et al., showed vasovagal reactions occur in 5-10% of donors and haematoma in 0.9% to 2% [22]. Abhishekh B et al., reported VVRs as occurring in 2-5% and haematoma in 0.88% [23]. The overall ADR rate in the present study was 0.49% (168/34,202), with vasovagal reactions constituting 96.42% (162/168) and haematomas 2.38% (4/168) and rebleeding 1.2% (2/168) of all reactions. Agnihotri N et al.,'s analysis of onsite adverse reactions showed vasovagal reactions constituting 63.5% and haematomas 35% of all reactions [7].

Prompt attention should be taken promptly to attend donors with ADRs to prevent any injury from the fall. Proper advice should be given to such donors to manage such reactions occurring offsite. Blood centres should utilise information on donor adverse reactions should be utilised by blood centres in outstanding factors contributing to it and thus provide better donor care. The blood donor return rate is dependent on the type and incidence of adverse reactions, with various studies showing that donors who sustained donor reactions are more likely to return. A few modifications in behaviour of phlebotomist like paying attention to donors, keeping their minds occupied during donation, encouraging predonation hydration with water and salt-containing fluid or coffee, Low collection volumes, and advising muscle relaxation, can help minimise ADRs [24,25].

Limitation(s)

The present study design primarily focused on onsite reactions, and only 300 donors were contacted telephonically for delayed/off-site ADRs. Under reporting of the ADRs was also limitation.

CONCLUSION(S)

The spectrum of adverse reactions among donors of the present study was comparable to reports from other parts of country, with a preponderance of generalised reactions. This underscores the importance of adequate donor counselling and observation before and after blood donation, as well as the application of other measures that have been reported to reduce the frequency of ADRs, particularly vasovagal reactions.

Authors' contribution: AST, TSK: Data collection, data analysis and interpretation; AST: Manuscript preparation; CAU, JNP: Data analysis and interpretation, manuscript preparation; JNP: Study conception, study design.

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