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KEY WORDS: Blood Donors, Blood Donation, Adverse Donor Reactions, Vasovagal Reactions, Pre and Post Donation Counselling.

ASSESSING THE COMPLICATIONS ASSOCIATED WITH BLOOD DONATIONS IN A BLOOD CENTRE AT TERTIARY CARE HOSPITAL OF NORTH INDIA: A RETROSPECTIVE DATA ANALYSIS

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ABSTRACT

Introduction: The blood donors are the backbone of this system. Though blood donation is relatively safe, there can be complications associated with it which can be an important reason why the donors fail to return for repeat blood donations. This emphasizes the need of looking into the frequency of the complications and the factors influencing them, so that they can be minimized. **Aims and Objectives:** To assess the prevalence of complications (adverse reactions) related to blood donations over a period of ten years in a Blood Centre of a tertiary care hospital of Himachal Pradesh and come up with suggestions for minimizing discomfort to blood donors. Material and methods: It was an institutional based study with secondary data analysis of "Donor Adverse Reaction Register" available at the Blood Centre, Department of Immunohaematology and Blood transfusion, Dr Rajendra Prasad Government Medical college Kangra at Tanda (Himachal Pradesh). **Results:** Overall prevalence of adverse reactions was found to be 0.2% (184/90,270). Out of which local reaction was found in 0.005%, vasovagal reaction with loss of consciousness (<60sec) in 0.19% and vasovagal reaction without loss of consciousness in 0.008% of the blood donors. **Conclusion:** The best practice for reducing prevalence of post blood donation complications is to provide a friendly, warm and comfortable atmosphere for the blood donors, ensure good structured pre and post donation counselling and proper pre donation hydration and to engage particularly anxious donors in conversation during donation.

INTRODUCTION

Blood has an essential role in patient management within health care systems. Despite the advances in the field of medicine for treating many conditions with synthetic and semi synthetic products, the importance of biological blood products can't be undermined.

Blood is an important resuscitative tool and saves many lives at the times of need. A well organised Blood Transfusion Service is a vital component of any health care delivery system. The blood donors are the backbone of this system. Though blood donation is relatively safe, there can be complications associated with it which can be an important reason why the donors fail to return for repeat blood donations. This emphasizes the need of looking into the frequency of the complications and the factors influencing them, so that they can be minimized. Vasovagal reactions (VVRs) constitute the majority of complications associated with blood donations. These may manifest with mild to moderate symptoms like weakness, nausea, sweating, fainting etc or with severe symptoms like total loss of consciousness, seizures etc. Other complications include venous hematomas, arterial punctures, neurological deficits etc. These complications have been reported to have an association with the donor related factors like age, sex, height, weight of the donor, type of blood donation, history of previous donation, etc [1-3].

Complications associated with blood donation significantly lower odds of subsequent donations [4]. Physicians may encounter blood donors with adverse events and should be familiar with their prognosis and treatment [5].

There is already a paucity of published literature regarding complications among blood donors especially in hilly terrains like in the area this institute is situated. Hence, this study has been planned to assess the prevalence of complications (adverse reactions) related to blood donations over a period of ten years in a Blood Centre of a tertiary care hospital of Himachal Pradesh and come up with suggestions for minimizing discomfort to blood donors.

MATERIALS AND METHODS

It was an institutional based study with secondary data analysis of "Donor Adverse Reaction Register" available at the Blood Centre, Department of Immunohaematology and Blood transfusion, Dr Rajendra Prasad Government Medical college Kangra at Tanda (Himachal Pradesh). It was carried out during the month of December 2025 and all the blood donors entered in the register (January 2016 to December 2025) were taken into the consideration. The information related to demography (age and gender), donor status (voluntary donor, family donor, replacement donor), donation status (first time or repeat donation), data capture (on site, call back by donor and call back by blood centre), donation site (in house, in blood centre and outdoor blood donation camp) and type of adverse reaction (local and systemic reaction) were recorded. The classification of adverse reactions was based on the "Guidance Document for Reporting Blood Donor Adverse Reactions" under National blood donor vigilance programme 2022 by National Institute of Biologicals.

Ethical clearance for the study was obtained from the Institutional Ethics Committee of Dr Rajendra Prasad Government Medical College (Dr RPGMC) Kangra at Tanda, Himachal Pradesh India. Only the relevant data was taken from the register and the privacy of the participants was respected and confidentiality was maintained up to full extent.

Data Analysis: Data collected was coded and entered in Microsoft-excel spreadsheet and was analysed using SPSS version 24. Continuous variables were expressed as mean and range, while categorical data were presented as frequencies and percentages. Statistical associations were assessed using the Chi-square test, with p-values less than 0.05 considered significant.

RESULTS

Out of total 90,270 donors, 184 (0.2%) donors had adverse reactions. Of the 184 donors experiencing adverse reactions, 152 (82.6%) were male and 32 (17.4%) were female (Figure 1). The majority of these donors (70.2%) fell within the 18–30 age bracket, with a total age range of 18–51 years (Figure 2).

Regarding data capture, the vast majority of reactions were identified onsite (98.4%; n=181), while 1.6% (n=3) were

identified via "call back by donor" (Figure 3). No reactions were captured via "call back by blood centre" (due to staffing limitations).

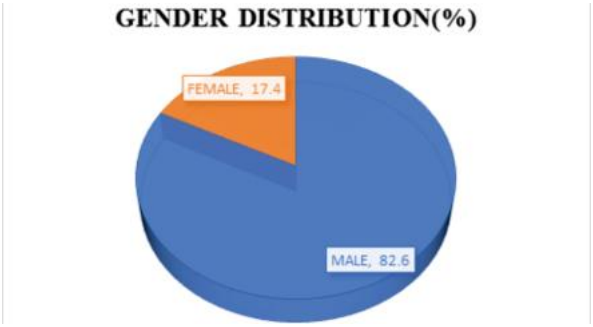

Figure 1 : Gender Distribution of Donors with Complications.

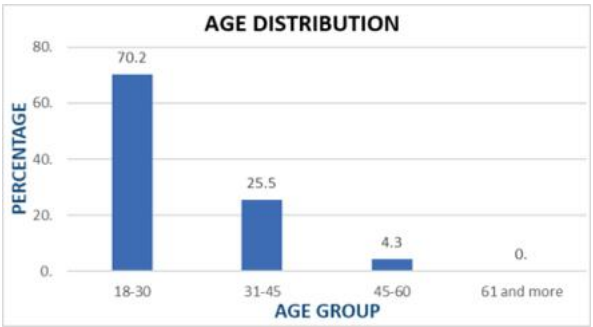

Figure 2 : Age Distribution of Donors with Complications.

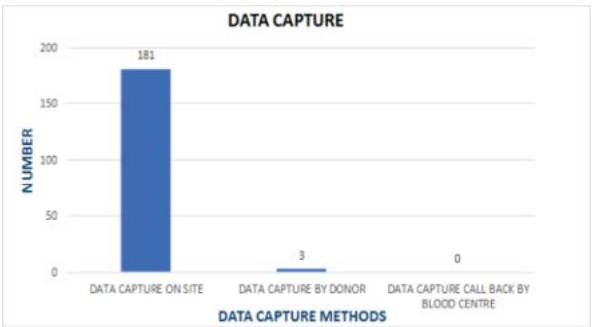

Figure 3: Distribution of Donors Based on Data Capture Method.

Overall prevalence of adverse reactions was found to be 0.2% (184/90,270). Out of which local reaction was found in 0.005%, vasovagal reaction with loss of consciousness (<60sec) in 0.19% and vasovagal reaction without loss of consciousness in 0.008% of the blood donors (Table 1). Within the VVR with loss of consciousness group (0.19%), the vast majority (170/172) regained consciousness in under 60 seconds. One instance (0.5%) involved a loss of consciousness exceeding 60 seconds, and one instance (0.5%) resulted in a VVR-related injury. Systemic reactions were significantly more common than local reactions ($p < 0.05$).

Table 1: Prevalence of Adverse Reactions in Blood Donors.

ADVERSE REACTION	PREVALENCE (%)
Local	0.005
VVR with LOC (<60sec)	0.19
VVR without LOC	0.008
Overall	0.2

Higher rate of overall occurrence of adverse reactions was observed among first time donor as compared to repeat donor, among voluntary donor as compared to replacement and family donor and among in house blood centre donation as compared to outdoor blood donation camp, and was statistically highly significant (P<0.0001) (Table 2).

Table2: Distribution of Donor Adverse Reactions Based on Donor Status and Donation Site.

PARAMETER	NUMBER (%)	p value
First time donor	136(73.9)	<0.0001
Repeat donor	48(26.1)	
Voluntary donor	159(86.4)	<0.0001
Replacement donor	12(6.5)	
Family donor	13(7.1)	
In house blood centre donation	116(63.1)	<0.0001
Outdoor blood donation camp	68(36.9)	

Table 3: Summary of Local and Systemic Adverse Events

Type of reaction	Presenting features	Number (%)	P value
Local reaction	Hematoma	3(1.6)	<0.05
	Bruise	2(1.1)	
Systemic reaction	VVR without LOC (nausea/vomiting/anxiety)	7(3.8)	<0.05
	VVR with LOC <60sec (fainting)	170(92.4)	
	VVR with LOC>60sec	1(0.5)	
	VVR with injury	1(0.5)	
	VVR without injury	183(99.5)	

Among distribution of adverse reaction, systemic reactions were much commoner than local reactions. Vasovagal reactions associated with fainting was the most common among systemic reaction (Table 3). These differences were found to be statistically significant ($p<0.05$).

Table 4: Distribution of Adverse Donor Reactions Stratified by Demographic and Donation Characteristics.

PARAMETERS		ADVERSE REACTIONS (184)		
		Local (5), N(%)	VVR with LOC(172), N(%)	VVR without LOC(7), N(%)
Gender	Male (152)	5(2.7)	141(76.6)	6(3.4)
	Female (32)	0(0)	31(16.8)	1(0.5)
Age (yrs)	18-30 (129)	3(1.6)	123(66.9)	3(1.6)
	31-60 (55)	2(1.1)	49(26.6)	4(2.2)
Donation	First (136)	3(1.6)	130(70.6)	3(1.6)
	Repeat (48)	2(1.1)	42(22.9)	4(2.2)
Site of donation	In house (116)	2(1.1)	109(59.3)	5(2.7)
	Outdoor (68)	3(1.6)	63(34.2)	2(1.1)

Vasovagal reaction was found to be more common as compared to local reaction. Local reaction and vasovagal reaction was found to be more common among males as compared to females ($p>0.05$, no significant association found) (Table 4). Local reaction and vasovagal reaction with loss of consciousness was found to be more common among younger age groups whereas vasovagal reaction without loss of consciousness was found to be more among older age groups ($p>0.05$, no significant association found) (Table 4).Local reaction and vasovagal reaction was found to be more common among first time donor whereas vasovagal reaction without loss of consciousness was found to be more among repeat donor ($p>0.05$, no significant association found) (Table 4). Although first-time donors had a higher total number of reactions, there was no statistically significant association ($p > 0.05$) between donor status and the specific type of adverse event (local vs VVR). This suggests that while first-time status is a predictor of whether a reaction will occur, it does not significantly influence the clinical manifestation of that reaction once it is triggered.

DISCUSSION

Blood centres have a dual responsibility to provide an adequate supply of blood components to the needy ones in the communities they serve and to ensure the safety and well-being of their blood donors [6]

Local reactions are mainly caused by blood donation-related neurological needle injuries which are commonly

experienced by donors after the donation in the form of haematomas, numbness/tingling, excessive or radiating pain, loss of arm/hand strength. The time to recover from these complications can range from less than 3 days to more than 6 months [6].

Vasovagal reactions (VVRs) are caused by a reflex of the parasympathetic nervous system, mediated by the vagus nerve, which causes the heart to slow down and at the same time, affects the nerves to the blood vessels in the legs permitting them to dilate, leading to lesser blood flow to the brain, thus causing vasovagal syncope (if severe). In the blood donors, they are hypothesized to occur on the sight of blood or due to anxiety and stress levels associated with blood donation. They manifest with symptoms like nausea, dizziness, light headedness, sweating, fainting, loss of consciousness, convulsions etc [7].

In our study the overall prevalence of donation related complication was found to be 0.2 %, out of which local reaction was found in 0.005%, vasovagal reaction (VVR) with loss of consciousness (<60sec) in 0.19% and vasovagal reaction without loss of consciousness in 0.008% of the blood donors.While the overall prevalence of complications was low (0.2%), the occurrence of one VVR-related injury (0.5% of reactions) underscores the necessity of the immediate onsite interventions practiced at our center, such as raising the foot end and close observation. The low incidence of prolonged LOC (>60 sec) further supports the efficacy of the immediate resuscitative measures described.

Where as in a study by Vijayvergiya G et al [8], donation related complications were found to be 1.09% with the most frequently encountered complication VVRs (65.48%), followed by hematomas (30.08%) and arterial puncture (4.42%), respectively. In another study by Meena M et al [7] donation related complications, even mild ones, were found to be 0.99% of the total donations. VVRs were the most frequently encountered of all the complications (64.9%) followed by venous hematomas (32.4%) and arterial puncture respectively (2.7%). In a study done in Italy, the total complication rate was reported to be 0.28% and VVRs constituted 71% of the total complications, post blood donation [9]. In study by Pathak C et al [6] 0.6% percent of all whole blood donations were blood complicated by an adverse event. Presyncopal symptoms, which include giddiness, sweating or light-headedness without loss of consciousness, accounted for approximately 70% and haematoma for 0.07%.

In our study local reaction and vasovagal reaction was found to be more common among males as compared to females but no significant association (p>0.05) was found whereas in a study by Vijayvergiya G et al [8], the incidence was higher in females than males (1.64% versus 0.69%), however, this gender predilection was not statistically significant (p=0.665) in their study. In a study by Agarwal et al [4] female donors experienced about 4 times as many complications with generalized symptoms (female: 6.50%, male: 1.74%) and twice as many complications with localized symptoms (female: 1.71%, male: 0.92%) as their male counterparts. The frequency of post donation complications was observed to be 3 times higher for females (8.7%) compared to males (2.8%).

In our study most (70.2%) of the donors with adverse effects were between age 18-30 years and overall mean age was 28.8 years. The local reaction and vasovagal reaction with loss of conciousness was found to be more common among younger age groups (18-30 years) whereas vasovagal reaction without loss of consciousness was found to be more among older age groups but no significant association (p>0.05) was found. In a study by Agarwal et al [4] the higher rate of complication was also observed for younger donors with 4.6% of the donors below the age of 20 experiencing one of the complications. The rate of complications steadily declined with age both for male and for female donors, and a strong correlation (r = 0.97) was seen between the age of the donor and the probability of complication and the average age of donors who experienced reactions was 27.6 years (SD: 8.4) in their study.

In our study higher rate of adverse reactions was observed among first time donor as compared to repeat donor (P<0.0001). Local reaction and vasovagal reaction with loss of consciousness was found to be more common among first time donor whereas vasovagal reaction without loss of consciousness was found to be more among repeat donor but no significant association (p>0.05) was found whereas in a study by Vijayvergiya G et al [8] a higher incidence of VVRs was seen among the donors who had a history of previous blood donation.

Also, in our study higher rate of adverse reactions was observed among voluntary donor as compared to replacement but no significant association (p>0.05) was found but in study by Vijayvergiya G et al[8] the incidence was higher in the replacement donors, which was not found to be statistically significant (p= 0.162).

While gender was not a statistically significant factor for the type of reaction in our study (p > 0.05), the higher absolute number of reactions in males (n=151) reflects the skewed donor demographic of this region rather than a higher biological risk. This aligns with other Indian studies where the male donor pool is significantly larger, emphasizing that donor experience and status (first-time vs. repeat) may be more predictive of adverse events than gender alone.

Other complications like arm injuries, thrombophlebitis, iron deficiency, nerve damage and its sequel etc have been found in many other studies [5,10]. However, none of the donors had any neurological deficits due to inadvertent neural damage and no deaths related to blood donation were reported in our study.

As a routine practice blood donors are routinely counselled pre and post donation about the care and precautions to be taken, the possibility of adverse reactions and that were encouraged to contact the department in case of any discomfort (call back by donor). The onsite data capture regarding post donation adverse reactions and data capture by call back by donor was found to be in 98.4% (181/184) and 1.6% (3/184) of the donors respectively. The data capture by call back by blood centre itself was not feasible as a routine feature as there was no dedicated staff for calling up the donors. Specifically, the reliance on onsite data capture and donor-initiated "call backs" (1.6%) likely introduced detection bias. This potentially explains why the prevalence in this study (0.2%) is lower than reported in literature where more active follow-up was utilized.

Since in outdoor blood donation camps and during mega blood donation camps the footfall is much higher in comparison to in house donations, it is possible that some entries of adverse donor reactions have been missed out or recorded sometime later after the camp and the actual number might be a little higher than available data.

Many findings of our study were found to be quite different from other studies done in India. The overall prevalence in our study (0.2%) was lower than that reported by Vijayvergiya et al [8] (1.09%) and Meena et al [7] (0.99%). This discrepancy might be attributed to our center's specific pre-donation protocols. Unlike some settings, our donors received mandatory 200ml hydration and standardized clinical examinations (blood pressure and hemoglobin) immediately prior to donation. These interventions were known to mitigate the vasovagal response by maintaining intravascular volume and reducing donor anxiety.

The high variance might also be due to the difference in nature of the study (design and methodology), differences in the definitions and classification used, mechanism for identification of the complications (systematic processes, tools and protocols to detect, classify and record), threshold of the observer (individual variation), procedure room environmental conditions and aura, heterogeneous study population (age, health and disease, socioeconomic and education levels) etc. In our study settings, comfortable temperature and good ambience of procedure room, dedicated trained staff nurse and counsellor and availability of safe drinking water and good hydration (200ml) prior to blood donation might be responsible for low prevalence and incidence of complications. Pre-donation clinical examination (weight, blood pressure, rate pulse and blood haemoglobin levels) also might have added to it. Whenever VVRs occurred at our blood donation site, blood donation was stopped immediately, foot end was raised, clothes of donors were loosened, head end was lowered down, cotton cloth cold compression was done, along with close observation, assurance and monitoring. The immediate management protocol at our center, lowering the head while elevating the foot end, directly counters the orthostatic hypotension associated with vasovagal syncope by promoting venous return to the brain. The use of cotton cloth cold compression and loosening of clothing further aids in thermal regulation and sympathetic calming. This rapid response likely prevented the progression of mild symptoms into severe, prolonged loss of consciousness, as evidenced by our data showing 92.4% of reactions were resolved within 60 seconds.

Generally, every possible measure should be taken in order to further reduce the rate of complications to encourage people to donate blood at a regular basis. This starts right from spreading awareness about the safety and importance of blood donations along with the discussion of the process with the donors, to alleviate their anxiety related to it. The donor should take adequate sleep a night before donation and should have a proper meal before donation [7]. It is always advisable to provide a friendly, warm and comfortable atmosphere for the donor and to engage particularly anxious donors in conversation during donation, in order to distract their attention. Strict screening should be done to check the general health status of the donors. The waiting room as well as the donation block can have a television set or light music in background to divert the donor's attention [7]. A good understanding of the psychology of the blood donor and the human physiology can help reduce adverse donor reaction and tackle these complications with good mitigation strategies.

Strength and limitation of study: Our study was a novel study which had not been conducted in the past under similar settings. It was a secondary data analysis done on the records available which might be subjected to incomplete data (as there was no feasibility of call back by blood centre as a routine procedure due to lack of dedicated staff) and which could have provided exhaustive information on many other factors responsible for post blood donation complications and influenced our results. Study with better study design and adequate sample size and routine call back by Blood Centre should be carried out in future for more reliable estimates.

CONCLUSION

In our study the overall prevalence of donation related complication was found to be 0.2%, out of which local reaction was found in 0.005%, vasovagal reaction (VVR) with loss of consciousness (<60sec) in 0.19% and vasovagal reaction without loss of consciousness in 0.008% of the blood donors. In conclusion, it is reaffirmed that the best practice is to provide a friendly, warm and comfortable atmosphere for the blood donors, ensure good structured pre and post donation counselling and proper pre donation hydration and to engage particularly anxious donors in conversation during donation, in order to distract their attention. Encouraging call back by donors in case of discomfort and spreading the message of nobility and altruism associated with act of blood donation and appreciation can strengthen donor confidence, promote a satisfying donation experience and enhance donor retention. While routine manual call-backs are hindered by staffing constraints, the implementation of automated SMS-based follow-up systems or digital donor portals should be explored. Such cost-effective tools could ensure more reliable data collection for delayed adverse events without increasing the workload of blood centre personnel.

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