ORIGINAL RESEARCH PAPER

Transfusion Medicine

ADVERSE EVENTS IN BLOOD DONORS: SPECTRUM AND REMEDY

KEY WORDS: Highlights: Retention, Vasovagal reaction, Donor Safety

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ABSTRACT

Introduction: Blood donation i.e. recruitment of new donors as well as the retention of existing donors forms an important backbone of any donation programme. Adverse events of any form can affect donor retention severely. This study aims to analyse the different types of adverse events with suggestions of the preventive measures. **Material And Methods:** Retrospective observational study conducted in allogeneic blood donors in Central India from January 2018 to May 2022. All the donor adverse events were recorded, retrieved and were categorised as vasovagal reactions, hematoma, extravasation, nerve injury. **Results:** Out of total 95483 blood donors during the study period, 89228 were males (93.45%) and 6255 were females (6.55%). The donations comprised 73216 (76.68%) voluntary donations in the blood center, 4756 replacement donations (5%) and 17511 units were donated in blood donation camps (18.32%). Overall, 1805 donors (1.89%) experienced adverse events with mean age of 36.0±6.3 years. Female donors who experienced adverse events were more than male donors (n = 1100 vs.750). Vasovagal reactions were seen in 974 (1.02%) donors (females = 772, males = 202). Hematoma developed in 506 donors and extravasation of blood and nerve injury were seen in 306 and 19 donors respectively. Replacement donors showed slightly more frequency of vasovagal reactions while hematoma and nerve injury were seen more commonly in donation camps. Extravasation happened more frequently in voluntary donors. **Conclusion:** Study of the blood donation adverse events vary among different countries. Proper measures are needed to maintain donor retention and recruit new donors.

INTRODUCTION

The importance of blood lies in the fact that it cannot be produced synthetically and, therefore, donation is required(1). Most blood donations in tertiary care setup are quite safe where the phlebotomists are trained, skilled and well equipped. The increasing need and demand for blood components constantly challenges almost all the blood centers to maintain a safe and adequate supply of blood(2). Even well-established blood donation programmes in several parts of the world not only have to work at a constant pace to bring in new donors but also ensure contact with existing donors (regular voluntary donors) to encourage them to donate again(3). Retention of blood donors hence is of equal importance as recruitment of new donors. Retention is defined as preventing donors from lapsing and eventually becoming inactive(4). Donor retention is directly linked with donor satisfaction and safety, which will otherwise decrease the rate of repeat donations. One of the key objectives of our National Blood Policy is to achieve 100% voluntary blood donation, the present national average being 61% (5). Motivation to donate blood can vary broadly in society. Some factors are altruistic reasons, for the well-being of the community i.e., voluntary donations, personal reasons/ replacement donations. The decision to donate blood and return for further donations depends largely on positive donation experience. Hence, blood banks must work to develop strategies and incentives to retain donors. Some important strategies that can be followed are shorter waiting time, more personal attention to decrease apprehension to donate, enhancing blood donor satisfaction, minimizing adverse reactions of donation and offering a convenient place to donate (3). The word of mouth of the donor who had a good donation experience is the strongest motivational tool for recruiting more voluntary donors. Many donors' motivational programs are run on a regular basis by NACO and SBTC to appreciate the organizations and repeat donors for their contribution to the society.

While blood donation is a safe procedure, a small percentage of donors may experience some adverse reactions or adverse events (AE)(6,7). AE analysis can help us to identify the blood donors who will be at risk of donor reactions (pre-donation counseling). Moreover, it can play a key role in adopting appropriate donor motivational strategies. This is particularly important to strengthen the voluntary blood donation program in our country (7). Various studies documented that 2–6% of donors experience an AE, with 0.08–0.3% who experience syncope(8,9). The reactions or adverse events can be immediate or chronic in nature. Few studies documented that on an average approximate 1% reactions occur before donation, 26% AE occur during or immediately after donation, 61% occur at the refreshment table and 12 % occur offsite usually within 1 hour (10). The present study aims to analyze the spectrum and prevalence of adverse reactions in blood donors in a tertiary hospital-based blood bank in Gwalior and to suggest remedy for the same with a final aim to provide safe and adverse free donation to obtain donor satisfaction.

MATERIAL AND METHOD

This retrospective observational study was conducted in allogeneic blood donors coming in the Blood Center of a tertiary care hospital in Central India. The study period was from January 2018 to May 2022. Criteria for the selection of whole blood donors and the donor questionnaire & consent form were in accordance with the rules laid down in the Drugs and Cosmetics Act, Ministry of Health and Family Welfare, Government of India(11). The study was approved by the local ethical committee . All the donor records were maintained and stored in both the electronic and the file. Adverse events pertaining to whole blood donation were recorded and retrieved subsequently. The adverse events were categorized as:

1. Vasovagal reactions - Reflex of the involuntary nervous system that causes decreased heart rate and pooling of blood in legs, thus reducing the amount of blood being supplied to the brain. When the brain is deprived of oxygen, a fainting episode (syncope) is probable. Symptoms are dizziness, sweating, nausea and may precede fainting. Severity of symptoms can be -

A. Mild- Symptoms lasting less than 15 minutes without fainting (loss of consciousness) or seizure.

B. Moderate- Symptoms lasting at least 15 minutes but less than 1 hour without fainting (loss of consciousness) or convulsions.
C. Severe- A donor who faints experiencing loss of consciousness for any length of time with or without convulsions (seizures) or pre-faint symptoms that persist for more than 1 hour.
2. Bruise or haematoma- It is bleeding or a collection of blood under the skin. It is formed when blood leaks from the vein into the surrounding tissues.
- 5 centimeters in diameter or greater
- less than 5 centimeters in diameter, but associated with persistent pain or symptoms of nerve injury or irritation.
3. Extravasation - Occurs when a large volume of blood or fluid leaks under pressure, out of the vein wall into the surrounding tissue and forearm.
4. Nerve Injury - Direct nerve injury or trauma occuring when the needle cuts or damages the nerve or the sheath of the nerve. Indirect nerve injury, trauma or irritation is caused by pressure from a bruise/haematoma or swelling pushing against the nerve.

Data were analyzed using the Statistical Package for Social Sciences version 20.0 (SPSS Inc., Chicago, IL, USA) computer software. Descriptive statistics were employed to represent the frequency of adverse reactions in donors (as percentages). Rates of adverse reactions across gender groups, by reaction severity and type of blood donation were compared using the Chi-square test; *P value* was statistically significant at <0.05

RESULTS

Data of total 95483 blood donors was retrieved, out of which 89228 were males (93.45%) and 6255 were females (6.55%). The donations comprised 73216 (76.68%) voluntary donations in the blood center, 4756 replacement donations (5%) by relatives and friends of admitted patients and 17511 units were donated in blood donation camps (18.32%). Among all these whole blood donors, 1805 (1.89%) experienced adverse events during or immediately after the process of blood donation. The mean age of donors who experienced adverse events was 36.0±6.3 years. Female donors who experienced adverse events were more than male donors (n = 1100 vs.750). Female donors experienced more vasovagal reactions while male donors presented with hematoma and extravasation more frequently(figure 1). However, no statistically significant association was found between gender and type of adverse event (p value = 0.733887664).

Vasovagal reactions were seen in 974 (1.02%) donors (females = 772, males = 202). Most of the cases of vasovagal reactions were mild (93.12%, n= 907) with only 48 moderate (4.9%) and 19 severe (1.9%) vasovagal reactions. Females clearly experienced more vasovagal reactions as compared to males, however, association of gender with severity was not found to be statistically significant (p value = 0.929279)(figure 2). Hematoma developed in 506 donors and extravasation of blood and nerve injury were seen in 306 and 19 donors respectively. Arterial prick, cardiac arrest, and seizures were not observed. Replacement donors showed slightly more frequency of vasovagal reactions while hematoma and nerve injury were seen more commonly in donation camps. Extravasation happened more frequently in voluntary donors. The association between type of donation and adverse event was not statistically significant (P value = 0.169679425)(figure 3).Type of blood donation did not show significant association with severity of vasovagal reactions (P value =0.871453763). While analyzing gender association with adverse events in voluntary blood donation, vasovagal reactions were significantly higher in females as compared to hematoma and extravasation in males (p value= 0.00251611)(figure 4). Similar results were seen in replacement blood donation (p value =0.04085015). Although blood donation camps showed a similar trend in vasovagal reaction and hematoma, extravasation was significantly higher in females (p value = 0.040229)(figure 5).

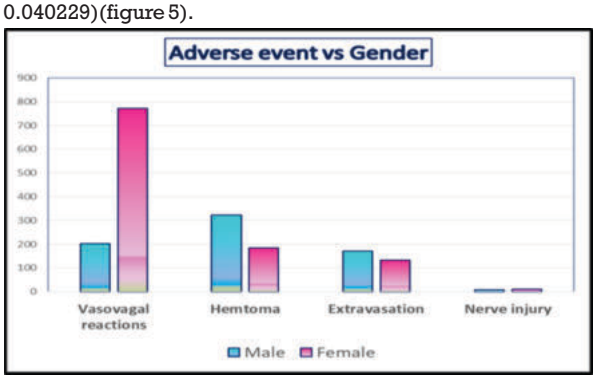

Figure 1: Comparison of frequeny of adverse events among males and females(p value=0.733)

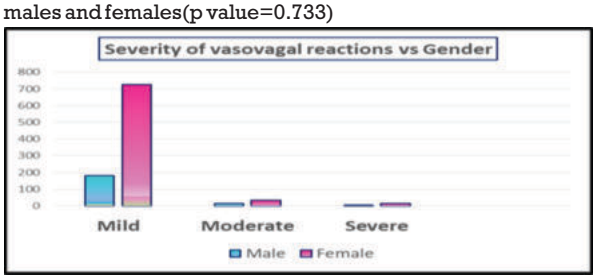

Figure 2: Comparison of vasovagal reaction verses gender (p value=0.92)

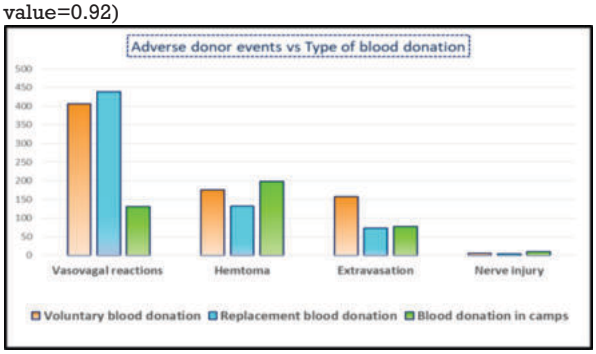

Figure 3: Frequency of adverse events among the different categories of blood donation (p value=0.169)

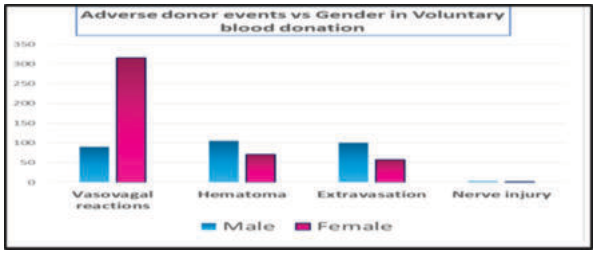

Figure 4: Frequency of adverse donor events among males and females in voluntary blood donation (p value= 0.002)

Figure 5: Adverse donor events among males and females in blood donation camps (p value= 0.04)

Table 1: Frequency of different types of adverse events

	Male	Female	Total	
Population	89228	6255	95483	
Adverse donor events(overall)				
Vasovagal reactions				
Mild	182	725	907	P value = 0.929279
Moderate	15	33	48	
Severe	5	14	19	
Total Vasovagal reactions	202	772	974	
Hematoma	322	184	506	
Extravasation	172	134	306	

Nerve injury	9	10	19	
Total Adverse events	705	1100	1805	
Voluntary blood donation				
Vasovagal reactions	90	316	406	P value = 0.0025
Hematoma	105	71	176	
Extravasation	100	57	157	
Nerve injury	3	2	5	
Total	298	446	744	
Replacement blood donation				
Vasovagal reactions	102	336	438	P value = 0.0408
Hematoma	100	32	132	
Extravasation	60	12	72	
Nerve injury	1	3	4	
Total	263	383	646	
Donation in blood camps				
Vasovagal reactions	10	120	130	P value = 0.0402
Hematoma	117	81	198	
Extravasation	12	65	77	
Nerve injury	5	5	10	
Total	144	271	415	

DISCUSSION:

Blood centers are constantly under pressure due to the two main responsibilities. These are maintaining adequate flow of blood components to the hospital and to ensure the safety of the donors. The most common complications of blood donation (like syncope, small haematomas), are medically inconsequential. Their significance lies in the fact that any adverse event, even a minor one will definitely reduce the likelihood of repeat donation (11, 12). In the medical literature there is broad variation in the frequency of adverse events during donations (13-15).

In the present study, 1.89% donors experienced adverse events during or immediately after the process of blood donation. This was found to be in concordance with various studies conducted all over the world which mentioned the range of adverse events varying from 0.3% to 3.8% (2,16-20). Study by Ryhan R et al reported reaction rate to be 5.3% in their study(21). This variation can be attributed to the difference in the age groups of participants in different studies, the blood donor type (i.e., voluntary donations versus replacement donors), behavior of collection staff, use of donor chairs versus flat bed (7).

Vasovagal reactions were seen in 974 (1.02%) donors (53.9% of total AE) (females = 772, males = 202). Most of the cases of VVR were mild (93.12%, n= 907) with 48 moderate (4.9%) and 19 severe (1.9%) VVR. Studies from India reported VVR prevalence between 63.5% to 70.0% (2,7). Agnihotri et al reported 63.5% VVR and were mostly mild in nature (7). Young age, lower weight, female gender, and first-time donation status were associated with significantly higher reaction prevalence (7). In the present study, overall female donors clearly experienced more vasovagal reactions as compared to males. However, the severity was not found to be statistically significant (p value = 0.929279). Female donors, both voluntary and replacement, had significantly higher reaction rate almost twice as compared to male donors. However, female donors in blood donation camps showed strikingly higher VVR, which can be attributed to participation of younger females of weaker physical constitution in camps organized in educational institutes. Replacement donors showed slightly more frequency of VVR. Stress on account of their patients' health, can be a contributing factor. First time donation in an emergency and partial unwillingness for donation are also major contributors in such cases. Sight of blood, although completely psychological, is also a major reason for VVR in donors who may have held back their apprehension of blood in pre-donation counseling. Many studies have reported higher prevalence of vasovagal reactions among the female donors in various donation setup (4,9,16,17,22,23,24,25,26).

Hematomas were reported as the second commonest AE among the donors (7). Hematoma developed in 506(0.5%) donors and extravasation of blood and nerve injury were seen in 306(0.01%) and 19(0.01%) donors respectively in the present study. Pathak et al reported 0.07% events of hematoma post donation (2), Sultan S et al reported 2% events of needle injury post donation(6). Newman et al reported a very high frequency of bruises in 15.1% of donors (27) while Agnihotri et al determined hematoma as an adverse event in 35% of all reactions(7). Newman BH found that the underlying causes could be the faulty technique, untrained phlebotomists and failure to select an appropriate vein (27).

In our study, males developed hematomas more frequently, most likely due to restlessness and overexcitement. Prevailing obesity in males because of poor lifestyle choices causes difficulty in finding proper veins thus forming hematomas. This higher rate can not be attributed to improper technique as phlebotomists in our blood center have experience of years. However, a chaotic environment in some donation camps may have led to higher incidence of hematoma. As donor recruitment and availability of beds is decided by organizers in such camps, higher turnover of donors may lead to increased pressure on a small team of phlebotomists leading to few faulty pricks causing hematomas. Higher incidence of nerve injury in Blood camps can also be attributed to above mentioned reasons. Gender based incidences were however almost equal.

Extravasation was seen slightly more frequently in males in voluntary and replacement donation most likely due to learning attempts at phlebotomy by laboratory technology trainees. Reasons for a higher incidence of extravasation of blood in donation camps are more or less same as that for hematomas. However, due to rushed pre-donation counseling and improper history taking of female donors, some cases of mild thrombocytopenia and donors on some medications (blood thinners, hypolipidemics, antimalarial etc.) were overlooked. Some of the female donors might also have decreased skin elasticity thus leading to extravasation.

Proper communication with donation camp organizers before the camp should be established regarding availability of beds and crowd management. In order to maintain precise pricks and a comfortable donor experience, organization of a phlebotomy team sufficient for the expected number of donors and their training to spend at least 6-10 minutes per donor should also be ensured. An interactive pre-donation counseling must include a dialogue between the counselor and donor, which encourages potential donors to ask questions regarding blood donation (28, 29). Alleviating the donor`s apprehension and answering their queries lead to a comfortable donation experience thus reducing VVR. Complete clinical examination, proper history taking and comfortable donation room helps in reducing such incidences (30). VVR although are mostly mild, if managed promptly will ease the prevailing apprehension against blood donation in society.

CONCLUSION:

Study of the blood donation adverse events vary among different countries. Many of these reactions can be prevented by proper pre dontion counselling, efficient and stress free phlebotomists due to overcowding in camps, systemic organisation to provide a proper donation environment so that the donor can have good donation experience with an aim to maintain donor retention.

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