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Original Research Article.

An Observational Study of Adverse Reactions Associated with Allogenic Whole Blood Donation in Normal Healthy Blood Donors: Experience of Tertiary Health Care Centre in Udaipur (Raj.)

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ABSTRACT

Background: Blood donors are the backbone of a Blood Transfusion Service. Donor retention is directly linked to donor services and donor care. Haemovigilance pays more attention to adverse events in patients receiving blood transfusions than to adverse events occurring in blood donors. Occurrence of any unexpected, undesirable and unintended event before, during or after donation of blood to the donor is called Adverse Donor Reaction (ADR). The aim of this study to evaluated the frequency and type of adverse reactions occurring in allogeneic whole blood donors during or immediately after blood donation.

Material & Methods: This is a observational study done on 170 blood donors at blood bank and camps attended during study period (July 2017 to October 2019) in Blood Bank RNT Medical College Udaipur (Rajasthan) using both qualitative and quantitative methods for data collection. The eligible donors were given a unique donation number and the same was entered in the donor form; relevant entries were made in the donor register and the donor's signature obtained in the register also. Adverse reactions, when observed, were managed appropriately and the donors monitored until recovery. The adverse events were recorded in the blood donor card.

Results: Our study shows that majority of blood donors were residing in urban location (55.9%) followed by rural location (44.1%). Most common Adverse Donor Reaction observed was Vasovagal Reactions in both blood bank (57.1%) and camps (57%). Next common adverse reaction was Nausea & Vomiting (23%) in camp donors while in blood bank donors next most common reaction was Haematoma (14%). The mean difference between Pre and Post Systolic Blood Pressure, Diastolic Blood Pressure and Pulse rate of Blood Donors were statistically significant p value <0.001.

Conclusion: Donation-related vasovagal syncopal reactions are a multifactorial process determined largely by weight, age, first-time donor status and total blood volume. Our study reinforces the fact that blood donation is a very safe procedure, which could be made even more event-free by following certain friendly, reassuring practices and by ensuring strict pre-donation screening procedures.

Keywords: Blood Donor, Vasovagal Syncope, Adverse Drug Reaction, Blood Camp.

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INTRODUCTION

Blood is essential for transporting oxygen, nutrients, and other substances to tissues throughout the body. Donated blood can be lifesaving for individuals who have lost blood because of accidents or surgery, as well as for people who have become severely anaemic or have dangerously low platelet counts because of certain medical conditions and/or treatments. Blood is the most precious and unique gift that one human being can give to another. The lifesaving fluid cannot be created artificially. Blood donors are the backbone of a Blood Transfusion Service. Donor retention is directly linked to donor services and donor care. Most donors tolerate giving blood very well but occasionally adverse reactions may occur.[1]

Blood donors are altruistic volunteers; they should be protected as much as possible from adverse reactions. As among repeat donors, adverse reactions are associated with decreased intentions to donate in future. Blood donor pool can be increased by motivation, recruitment and retention of donors. Whatever the minor reaction is, it has significant implications on the behaviour of the donor. These implications may be the self-deferral or unwillingness for the return blood donation in the future.[1]

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. It also places an ethical responsibility on health care givers (the users of blood) to avoid wastage and unnecessary use of blood transfusion.[2]

Haemovigilance pays more attention to adverse events in patients receiving blood transfusions than to adverse events occurring in blood donors. Adverse event analysis helps in identifying the blood donors at risk of donor reactions and adopting appropriate donor motivational strategies, pre-donation counselling, and care during and after donation, developing guidelines and hemovigilance programme in countries with limited resources.[3]

The donation of blood involves insertion of a needle into a blood vessel of the arm followed by a loss of 10% of the total blood volume within a few minutes. Worldwide this procedure is performed daily thousands of times, predominantly without complications, except for mild transient discomfort. However, complications do occur.

Occurrence of any unexpected, undesirable and unintended event before, during or after donation of blood to the donor is called Adverse Donor Reaction (ADR).[4] The aim of this study to evaluated the frequency and type of adverse reactions occurring in allogeneic whole blood donors during or immediately after blood donation.

MATERIALS & METHODS

This is an observational study done on 170 blood donors at blood bank and camps attended during study period (July 2017 to October 2019) in Blood Bank RNT Medical College Udaipur (Rajasthan) using both qualitative and quantitative methods for data collection.

Inclusion Criteria

All donors meeting the donor selection criteria as per

Exclusion Criteria

All deferred donors according to guidelines

Donor Selection Procedure

Donors were selected as per the Drugs & Cosmetic rules (1945) of the Government of India and the National Aids Control Organisation (NACO) guidelines for donor eligibility and deferral were followed.

Donors were greeted warmly at the reception and those in the age group of 18-60 years were registered. Donors were first requested to answer the donor questionnaire and informed consent for donation and testing of collected blood was obtained in writing. Donor's medical history was elicited by the Medical officer and some donors were deferred based on their responses to the donor questionnaire and medical history.

Donors not deferred on the basis of medical history were subjected to a body weight check. Donors weighing < 45 kg were deferred and those weighing above 45 kg underwent haemoglobin estimation by the Copper sulphate (Specific gravity 1.053) method. Donors with Hb values <12.5 g/ dl were deferred while those with Hb values >12.5 g/dl were subjected to physical examination by the Medical officer.

Donors with:

- Pulse rate 60 -100 beats/min and regular rhythm,
- Blood pressure in the range of 100/60 to 140/100 mm Hg,
- Respiratory rate between16 to 20 per minute,
- Body temperature between 98.4 to 99.5°F and with no skin lesions at the venepuncture site (cubital fossa) were certified to be fit for blood donation by the Medical Officer. In any case, the Medical Officer's decision was final.

The eligible donors were given a unique donation number and the same was entered in the donor form; relevant entries were made in the donor register and the donor's signature obtained in the register also. The donation number was entered on the blood bag along with the date of collection.

Standard 350ml blood bags (Polymed, Mitra and HLL) with 49ml of anticoagulant (CPDA1) were used. Blood bags chosen were either single / double / triple/quadruple. The donors were informed that irrespective of the blood bag used only 350 ml of blood will be collected.

Blood Collection Process

The donor was led to the donation couch and after verifying the donor identity as per the entries on the donor form and blood bag, the donor was made to lie down on the donor couch. The donor couch with a head-up tilt and facility to raise the foot end was used in the Blood bank and a flat couch was used at out-door blood collection sites. The donor arm was scrubbed with a suitable disinfectant (Povidone iodine or isopropyl alcohol) after applying the BP cuff. The BP cuff was inflated to about 60 mm Hg and the donor was made to squeeze a soft rubber ball (placed in the palm of the limb to be venipunctured) so that the veins would become prominent. The blood bag was placed in the Blood Collection Monitor. The antecubital vein was identified and the phlebotomy performed aseptically with the blood bag needle (16 G).

Once the blood started flowing down the tubing, the BP cuff pressure was reduced and the donor was instructed to squeeze the soft ball intermittently and gently to increase the rate of flow. The donor was distracted from the blood collection process by keeping him engaged in a conversation with the phlebotomist.

Once 350ml of blood got collected (in 7 to 10 min) as shown by the display on the blood collection monitor, the squeeze ball was removed from the donor's palm and the BP cuff completely deflated and removed.

A plastic clip was applied to the tubing of the blood bag to stop the blood flow. The needle was then removed, a sterile cotton ball was placed over the venipunctured site and the donor asked to flex his / her elbow with the arm slightly raised. The donor was instructed not to get up from the donor couch until instructed.

After collecting blood samples in pilot tubes and uniform mixing, the blood bags were sealed using a di-electric tube sealer and placed in the transport box (at camp sites).

Once the blood stopped oozing from the venipunctured site, a medicated Band-Aid was applied. After about 10 min of observation, the donors were instructed to get down from the couch and led to refreshment area. The donors were given snacks and drinks and were instructed to remain there for at least fifteen minutes. The donors were given post donation instructions, thanked for the donation and were given a certificate of appreciation. The donors were instructed to report to the Blood Bank Medical officer if they experienced any adverse reaction like dizziness, fainting, convulsions, hematoma, bruise, sore-arm or fatigue, either on-site or off-site.

Process of Observation

Throughout the above mentioned process – from donor registration through blood collection, refreshment and until the

donors leave the blood bank / camp site – donors were closely observed for the following signs and symptoms of an adverse reaction : anxiety, increased rate of respiration, pallor, sweating, dizziness, continuous yawning, nausea or vomiting, fainting, slow pulse rate, convulsions, abnormal movements and hematomas . Emergency drugs and Oxygen cylinder were kept ready for use in case of any emergencies.

Management of Adverse Reactions

Adverse reactions, when observed, were managed appropriately and the donors monitored until recovery. The adverse events were recorded in the blood donor card. These donors were reassured and held under observation for another 30 minutes before they were allowed to leave the blood bank / camp site. In case of any adverse reaction off-site, the donors were instructed to report to the Blood Bank Medical officer.

Data Analysis

Data was coded and entered on Microsoft excel sheet and analysis done on SPSS version 16. Binary coding was done for the components of skills observed on the checklist. The results were presented in tables showing proportions of the distribution of characteristics. Mean along with SD was ascertained for the vital parameters of donors pre and post donation. Chi square test was applied to compare characteristics, difference was ascertained as significant when p value was < 0.05.

RESULTS

Our study showed that majority of blood donors were residing in urban location (55.9%) followed by rural location (44.1%). Mostly donors were male (90.6%) followed by female (9.4%) and belonged to age group of 18-22 years followed by 23-27 years group (16.5%) (table 1).

In our study group maximum Blood Donors were Graduate (54.1%) followed by Secondary (27.1%), Higher Secondary (12.9%) and only 5.9% blood donors were Illiterate (table 1).

mostly blood donors were self-employed (27%) then nearly 1/5th donors were students (21.8%), farmers (19.4%) and in service (22.4%) (table 1).

Majority of Blood Donors had donated blood for the first time 78.2% and only 21.8% blood donors already had experience of donating blood previously (table 1).

Table 1: Distribution of Blood Donors according to Area of residence

Parameters	No. of Donor (N=170)	Percentage %
Type of residence		
Rural	75	44.1
Urban	95	55.9
Gender		
Female	16	9.4
Male	154	90.6
Age groups (yrs)		
18-22 Years	48	28.2
23-27 Years	28	16.5
28-32 Years	26	15.3
33-37 Years	25	14.7
38-42 Years	11	6.5
43-47 Years	15	8.8
48-52 Years	15	8.8
53-60 Years	2	1.2
Education		
Illiterate	10	5.9
Secondary	46	27.1
Higher secondary	22	12.9
Graduate and above	92	54.1
Occupation		
Farmer	33	19.4
Housewife	5	2.9
Labourer	10	5.9
Self employed	47	27.6
Service	38	22.4
Student	37	21.8
Type of donor		
First Time Donor	133	78.2
Repeat Donor	37	21.8

Table 2: Distribution of type of Adverse Reactions according to location of blood donation

Type of Adverse Reaction	Location of Blood Donation			
	Blood bank	Camp	Grand Total	P Value
	N (%)	N (%)	N (%)	
CS	1(1.4)	1(1)	2(1.2)	0.505
HMT	14(20)	19(19)	33(19.4)	
NV	13(18.6)	23(23)	36(21.2)	
TET	2(2.9)	0(0)	2(1.2)	
VVR	40(57.1)	57(57)	97(57.1)	
Total	**70(100)**	**100(100)**	**170(100)**	

Table 3: Distribution of type of adverse reaction according to type of blood donor

Type of Adverse Reaction	First Time Donor	Repeat Donor	Grand Total	P value
CS	1(0.8)	1(2.7)	2(1.2)	
HMT	18(13.5)	15(40.5)	33(19.4)	
NV	25(18.8)	11(29.7)	36(21.2)	<0.001
TET	2(1.5)	0(0)	2(1.2)	
VVR	87(65.4)	10(27)	97(57.1)	
Total	**133(100)**	**37(100)**	**170(100)**	

Table 4: Mean and SD of vital parameters before and after blood donation

Vital Parameters	Pre Donation Mean±SD	Post Donation Mean±SD	P value
SBP	121.4±6.4	115.4±7.3	<0.001
DBP	74.3±6.6	70.4±6.6	<0.001
PULSE	70.2±2.5	72.6±2.2	<0.001

**paired 't' test

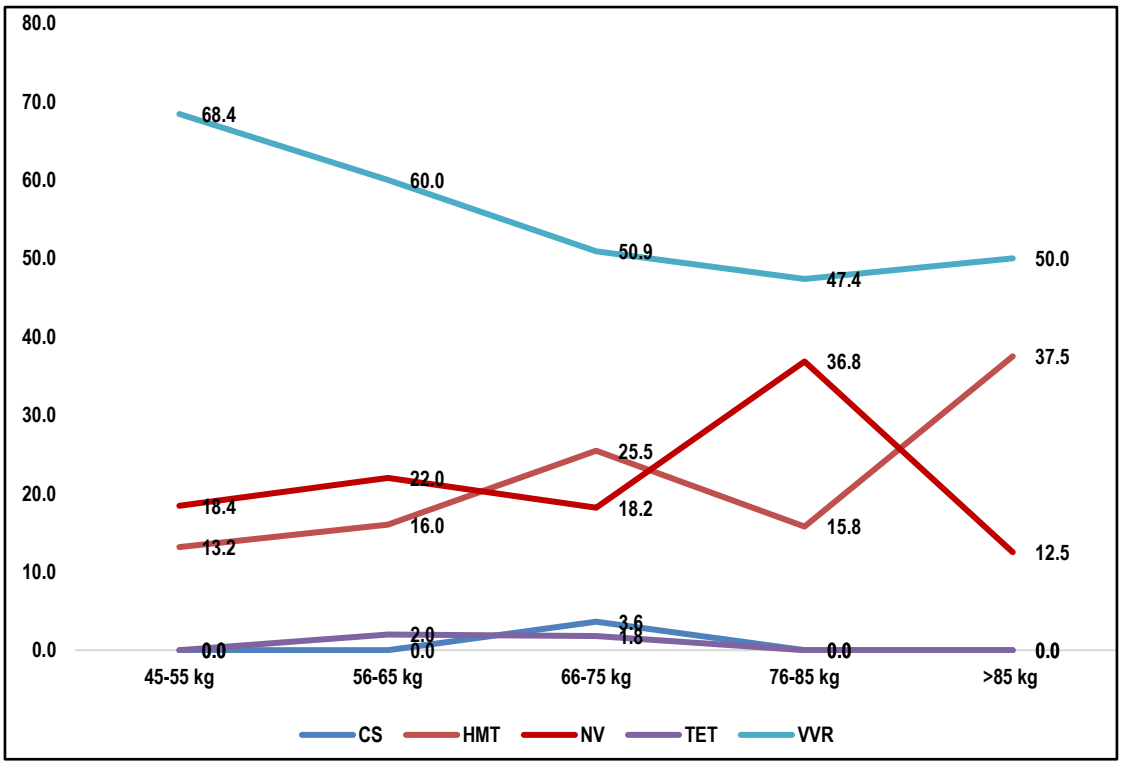

Figure 1: Percent Distribution of type of adverse donor reaction according to weight of blood donors

Most common Adverse Donor Reaction observed was Vasovagal Reactions in both blood bank (57.1%) and camps (57%). Next common adverse reaction was Nausea & Vomiting (23%) in camp donors while in blood bank donors next most common reaction was Haematoma (14%). There is no statistically significant association between type of adverse reaction with location of blood donation (p-value=0.505) (table 2). Our study showed that no statistically significant association between weight group with type of adverse reaction (p-value=0.632) (figure 1).

VVR (65.4%) was the most common adverse blood donor reaction in first time donors while HMT (40.5%) was the most common adverse blood donor reaction in repeat donors. There is a statistically significant association between type of adverse reaction with type of donor (p-value<0.001) (table 3).

The mean difference between Pre and Post Systolic Blood Pressure, Diastolic Blood Pressure and Pulse rate of Blood Donors were statistically significant p value <0.001 (table 4).

DISCUSSION

The frequency of the various adverse reactions like vasovagal reaction, convulsive syncope, tetany, hematoma, nausea and vomiting in whole blood donors has been studied and the percentage of adverse reactions in the study population has been compared with that of other studies and has been found to be less than in other studies. The influence of factors like body weight, age, sex, donation status in the causation of adverse reactions has also been noted in the study.

The incidence of vasovagal reactions was 0.16% in the present study as compared to 1.13% in the study by Ogata et al.[5] The other findings like higher reaction rates in first time donors and at a particular time of the year were also similar between the two studies. According to Ogata et al[5], there was no significant sex difference; in the present study also, there was no significant sex difference noticed. Convulsive syncope occurred in 0.03% of blood donors and was more common in men in a study conducted by Lin JT et al.[6] In the present study also, convulsive syncope was found only in men and at a rate of 1.2% .The probable reason for the difference may be that marked individual variation may exist in the susceptibility of the central nervous system to ischemia as proposed by Lin JT et al.[6]

Adverse reaction rates in first time and repeat donors were 1.7% and 0.19% respectively in the study conducted by Kasprisin et al.[7] In the present study reaction rates observed were- 0.22% in first time donors and 0.06% in repeat donors.

Trouern Trend JJ et al.[8] have observed that blood donation adverse reaction rates were higher in young donors, first time donors and low weight donors and the same has been recorded in the study by Franchini et al.[9] The results of the present study are in agreement with the above studies.

Incidence of bruising was 0.35% in males and 0.98% in females and this did not affect the donor return rate according to Ranasinghe E et al.[10] In the present study bruising was not at all reported by the donors. Newman BH et al.[11] observed that vasovagal reaction rate was inversely proportional to body weight in first time blood donors. The observations made in the present study are similar. In the study by Shehata N et al.[12], the highest rate of mild reactions was shown to occur in donors less than 20 years of age. In the present study also, the mild reactions were found to occur more frequently in donors aged 18 to 22 years.

Vasovagal reaction rate was 0.87% according to Zervou EK et al.[13] and the possible reason for the lower incidence of reactions in donors than in other studies was attributed to the fact that physicians were responsible for the selection of donors. The same holds good for the present study. Hematoma is an occasional side effect of phlebotomy according to Ohnishi H[14] and the 0.05% of hematoma occurrence in the present study is in concordance with the above study. The lower adverse reaction rates in the present study as compared to other studies could be due to proper donor selection, screening criteria and the utmost care taken by the blood bank personnel in ensuring donor safety.

CONCLUSION

Preventive strategies to avoid adverse reactions in blood donors should include:

- Proper elicitation of donor history like time since last meal, nature of their occupation & whether they had a good sleep on the day prior to donation should be done.
- Proper and stringent donor screening and examination procedures should be followed in adherence to guidelines to rule out unfit donors before donation.
- Providing a comfortable couch at camp sites, proper phlebotomy techniques by an experienced phlebotomist reduce frequency of adverse reactions.
- Ensuring adequate ventilation and a comfortable environment (preferably 24°C) helps reduce adverse events.
- Predonation hydration with water or other fluid ingestion, audio-visual distraction, and muscle tensing have been shown to reduce reactions and is an effective mechanism to limit the complications with generalised symptoms.
- Blood donation complex should be located near to emergency centre in the hospital to tackle emergencies without delay caused by transportation.
- Maintaining a good relationship with the donor, distraction of donors mind just before and at the time of blood donation has anxiolytic effect.
- Continuous monitoring of the donors during and after donation so that adverse donor reaction sequelae can be minimized.
- Using height and weight to determine acceptability of light donors under 19 yrs. instead of weight alone, could reduce reactions by deferring young donors with blood volumes of less than 3500 ml.
- Automated donor screening, and interview programs could be developed to rapidly determine donor accept ability and select alternative collection volumes.

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