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Adverse Donor Reactions in Whole Blood and Blood Component Donors of a Tertiary Care Hospital of Punjab, India.

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ABSTRACT

Blood donation is safe and uncomplicated; occasionally donors experience adverse reactions (ARs) during or after donation. ARs can deter voluntary donors for future donations. To find out the prevalence of ARs in whole blood and blood component donors & the factors determining them. 15000 healthy whole blood / blood component donors were observed for ARs. Chi-square test, Yates statistics applied. 95% of blood donors were male. The maximum donors were in the age group of 20-29yrs. (47%). There were higher donations in the camps (59%). 85% of the blood donors were above 60 kg of weight and were repeat donors. Overall prevalence of ARs was 6.07% in which mild reactions were 4.63%. 45% of the reactions were found in the age of 20-29yrs followed by below 19 yrs (32%). Prevalence of ARs in the females was double (12%) than males (6%). Donors below 60 kg and first time donors (13%) had more ARs. Donors donating in camps had slightly higher ARs (7%). No ARs were noted in platelet apheresis donors.Young age, female sex, low body weight, prior donation status and donation place determine ARs. Careful handling of these factors can reduce ARs.

Keywords: Whole Blood Donor, Blood Component Donor, Adverse donor reactions, Outdoor blood donation camps, Repeat donors, First time donors.

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INTRODUCTION

Blood transfusion services is a vital part of modern health care system. Its aim is to provide safe and adequate blood and blood products to the patient. Voluntary non-remunerated blood donors from low-risk populations are the cornerstone of safe and adequate supply of blood & blood components. Family/ replacement donors provide more than 45% of the blood collected in India. These are associated with higher prevalence of transfusion-transmissible infections. In our country comprehensive laboratory tests are not possible, it is best to switch over to 100% voluntary donations. Adverse reactions (ARs) to blood donation can deter voluntary donors from becoming regular donors. Prevalence of donor reactions ranged from 3.8% to 36% on the basis of solicited information from the donors. Predictive factors for vasovagal reactions are young age, low weight, anxious donor, epidemic fainting, history of previous reaction, inattentive or non-communicative phlebotomist, fatigue, empty stomach for more than 5 hours, summer season and low systolic blood pressure.

METHODS

15,000 blood donors who donated blood in the blood bank and at outdoor camps were included in the study which was from Jan 2008 to Dec 2008. Criteria for the selection of whole blood & blood component donors was in accordance with the rules laid down by the Directorate General Health Services, Ministry of Health and Family Welfare, Govt. of India [1] and as per Drug and Cosmetic Act of India 1940 and Rules 1945 amended in 1999. Any healthy adult, both male and female, can donate blood. Men can donate safely once in every three months while women can donate every four months. The amount of blood withdrawn was 450ml. Good health of the donor was fully ensured.

The universally accepted criteria for donor selection are:

1. Age between 18-60 years.
2. Haemoglobin > 12.5 g/dl
3. Pulse rate-between 60 and 100/ minute with no irregularities
4. Blood pressure – Systolic 100-180 mm Hg and Diastolic 60-100 mm Hg.
5. Afebrile
6. Body weight > 45 Kg.
7. Normal S. Protein & complete blood count (for platelet apheresis donors)
8. The donor should be in a healthy state of mind and body. They should fulfil the following criteria.

    - Past one year – not been treated for Rabies or received Hepatitis B immune globulin.
    - Past six months – not had a tattoo, ear or skin piercing or acupuncture, not received blood or blood products, no serious illness or major surgery, no contact with a person with hepatitis or jaundice.
    - Past three months – not donated blood or been treated for Malaria.
    - Past one month – had any immunizations.
    - Past 48 hours – not taken any antibiotics or any other medications.
    - Past 24 hours – not taken alcoholic beverages.

- Past 72 hours – not taken aspirin
- Present – not suffering from cough, influenza, sore throat or common cold.
- Women should not be pregnant or breast feeding her child.
- Women donor should not donate during her menstrual cycles.
- Free from Diabetes, not suffering from chest pain, heart disease or high BP, cancer, blood clotting problem or blood disease, unexplained fever, weight loss, fatigue, night sweats, enlarged lymph nodes in armpits, neck or groin, white patches in the mouth etc.
- Never had TB, bronchial asthma or allergic disorder, liver disease, kidney disease, fits or fainting, blue or purple spots on the skin or mucous membranes, received human pituitary- growth hormones, etc.

Observation for reaction

All donors were examined before, observed during and after blood donation for any signs or symptoms suggestive of any adverse reactions.

Adverse Reactions Based On the Site of Reaction

Systemic Reactions

General- Fatigue, tetany.

Cardiovascular- vasovagal reaction, vasovagal reaction with syncope, angina, MI, stroke

Systemic reactions can occur during apheresis procedure which require use of ACD for collection of blood component. This anticoagulant can cause hypocalcemia because of chelation. This lowered concentration of calcium ions leads to episode of paraesthesia of lips, oral cavity and limbs.

Local Reaction

Bruising, hematomas, arm soreness, arterial venepuncture, nerve injury, local irritation/allergy to adhesive material/antiseptic solution, local infection, thrombophlebitis [2].

Adverse Reactions based on the Severity of Reactions

Mild Reaction

Nervousness, anxiety, complaints of feeling warm, nausea and vomiting, sweating, pallor, increased or thready pulse, increased respiration, decreased blood pressure.

Moderate Reactions

Features of mild reactions, plus loss of consciousness, decreased pulse rate, rapid shallow respiration and hyperventilation, systolic pressure may drop to 60 mm Hg.

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Severe Reactions

Convulsion in association with mild or moderate reactions constitutes severe reactions. Convulsions or seizures can be caused by cerebral ischemia associated with vasovagal syncope; by marked hyperventilation; or by epilepsy. True convulsions are rare.

Donors were observed for 15 minutes after the donation and before leaving were advised to:-

- Drink fluids more than usual in the next few hours.
- Not to remain hungry and not to smoke in the next few hours.
- If feeling fainting sensation or dizziness, the donors were advised to lie down or sit with his head between the knees. If symptoms persist he should ask for help, return to the blood bank or consult a doctor.
- Avoid strenuous exercise or lifting heavy weight with the arm from which the blood was collected, for the next 24 hours.
- Not to donate blood for the next 3 months in males and 4 months in females.

Donor was further advised to report for any delayed reaction like arms soreness, stiffness or marked discoloration of the arm with venipuncture, in person / phone.

Statistical analysis was done by using Chi-square test and Yates statistics.

RESULTS

The present study was undertaken to quantify the prevalence of ARs in voluntary and replacement blood donors of Rajindra Hospital, Patiala. This study was carried out on 15,000 whole blood & blood components donors both voluntary and replacement, who came to donate blood in-house as well as at outdoor blood donation camps held by various organizations all over the state of Punjab. Blood bank team visited all blood donation camps in and around the state of Punjab.

The maximum number of donors were in the age group of 20-29 years i.e. 7062 (47.08%) donors followed by the 30-39 years of age group i.e. 3825 (25.5%) donors, and minimum in 60 years & above i.e. 22 (0.15%) P=0.01. The majority of donors were males,14392 (95.95%). Half of the total donors both males 47% (6753 out of 14392) and females 51% (309 out of 608), were in the 20-29 yrs age group. Maximum number of donors in camps 4206 (48%) and indoor 2856 (46%) were seen in the age group of 20-29 years. 70% of camp donations came from donors below 29 years of age. 50% of indoor donations came from donors below 29 years of age (P=0.05). Majority of the donors were repeat donors 12849 (85.66%) while first time donors were 2151 (14.34%). Maximum first time donors were in the age group of 10-19 years (1498) followed by 20-29 years (621) while maximum repeat donors were seen in the age group of 20-29 years (6441) followed by the 30-39 years (3801).

Majority of the donors (12786) were above 60 kg [85.63% males (12324 out of14392) and 76.04% females(462 out of 608)] while remaining donors were in 45-60 kg category.

8275(57%) males & 572(94%) females donated blood in outdoor camps. 6117(43%) males and 36 (6%) females donated blood indoors. Majority of the males 12464 (97%) and females 385 (3%) were repeat donors. 6951 repeat donors donated blood in camps and 1896 donors were first time donors in the camps. 5902 repeat donors donated blood indoors while 251 were first time donors who donated blood indoors. Blood component / Apheresis donors were in the age group of 19 – 40 years. Out of total 15,000 donors, 98 donors (.65%) were of plateletapheresis. No ARs (0%) were seen in blood component donors. Table 1 shows 45% of the total reactions were present in the age group of 20-29 years followed by 10-19 years age group with 32% of reactions. In total 77% reactions were seen in donors below 29 years of age which was a significant finding.

The overall percentage of reactions was 6.07% with mild reactions commonest (4.63%) . No donor in this study had severe adverse reaction. Amongst the reactions: 76% were Mild, 11% Hematoma, 9% Moderate, 4% Bruise. Table 2 shows that mild reactions were most common across all age groups in this study. ($P<0.005$). Table- 3 shows that females had twice more chances of experiencing adverse reactions than males ($p <0.001$). Table 4 shows that the maximum donors experienced mild reactions in both weight categories followed by local reactions. Table-5 shows that first time donors had more reactions ($P<0.001$). Table-6 shows that adverse reactions were more in camps. Table-7 shows that there were no adverse reactions in blood components / apheresis donors.

Table 1: Distribution of the donor reactions according to their age group

Age Group (years)	Numbers of Reaction Present (%)	Numbers of Reaction absent (%)
10-19	292 (32)	1756 (12)
20-29	406 (45)	6656 (47)
30-39	158 (17)	3667 (26)
40-49	46 (5)	1677 (12)
50-59	8 (1)	312 (2)
60 & above	0 (0)	22 (0.5)
Total	910 (6.07)	14090 (93.93)

Table 2: Adverse reactions and Donors distribution according to age & type of reaction

Type of reaction	10-19 yrs	20-29 yrs	30-39 yrs	40-49 yrs	50-59 yrs	>60 yrs
Bruise Hematoma	5	20	7	3	0	0
Mild	63	29	3	2	0	0
Moderate	213	321	120	35	6	0
Severe	12	38	27	8	1	0
	0	0	0	0	0	0

Table 3: Adverse reactions and Donor Distribution according to gender

	Male(%)	Female(%)	Total
Reaction Present	864 (6)	73 (12)	937
Reaction absent	13528 (94)	535 (88)	14063

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Table 4: Distribution of the donors according to weight and type of adverse reaction

Type of reaction	45-60 Kg	Above 60 Kg	
Local	24	106	X^2=0.176 df=2
Mild	116	579	P=0.91,
Moderate	15	71	Yates=0.065
Total	155	756	

Table 5: Donors Distribution according to donation status and adverse reaction

	First timer (%)	Repeater (%)	Total
Adverse Reaction present	280 (13)	642 (5)	922
Adverse Reaction absent	1871 (87)	12207 (95)	14078
Total	2151 (100)	12849 (100)	15000

Table 6: Adverse Reactions and Donor Distribution according to place of donation

	Camp	Indoor	Total	Chi-square
Reaction present	619 (7)	246 (4)	865	X2= 270.06
Reaction absent	8228 (93)	5907 (96)	14135	Df=1
Total	8847 (100)	6153 (100)	15000	P<0.05 S.
				Yates= 268.66

Table 7: Adverse Reactions in Whole Blood Donor and Apheresis Donors

Age	Total Donors	Whole Blood Donors	Adverse Reactions in Whole Blood Donors (%age)	Apheresis Donors	Adverse Reactions in Apheresis Donors
< 19 yrs.	1981	1975	291 (14)	6	0
20-29 yrs.	7031	6979	409 (5)	52	0
30-39 yrs.	4055	4023	155 (3)	32	0
40-49 yrs.	1846	1836	46 (2)	8	0

DISCUSSION

In this study out of the total donors, 95.95% males. National Family Health Survey-2 (NFHS-2)[3] report conducted in 1998-99 revealed that in India, haemoglobin levels were tested for 88% of women. Overall, 52% of women have some degree of anaemia. This high prevalence of anaemia in Indian women leads to higher deferral of women wanting to donate blood and hence leads to less number of women donating blood.

60.73% donors were young donors below 30 years of age both in house and outdoor camps taken together. Young donors below the age of 30 years at the outdoor camps were 68%, while indoor donors were 50%. The percentage of donors below 60 kg of weight was 14.76% and above 60 kg was 85.24%. The total donations were higher in camps (58.98%) as compared to indoor facility (41.02%). In this study 85.66% donors were repeat donors while 14.34% donors were first time donors.

The overall prevalence of reactions in the present study was 6.07% in which mild reactions were 4.63%, followed by moderate reactions 0.57%, hematoma 0.64% and bruise 0.23%. Amongst the reactions: 76% were Mild, 11% Hematoma, 9% Moderate, 4% Bruise.

Prevalence of donor reactions was 36% in a study by Newman BH et al 1997.[4] Mild reactions included vasovagal reactions, which is the most common systemic reaction, occurring in 2% to 3% of donors[5,6].

A study on faint and prefaint reactions in whole blood donors: an analysis of pre-donation measurements and their predictive value suggests that the overall reaction prevalence was 1.43%.[7] The maximum number of reactions were found in the age group of 20-29 years (45%) followed by the age group of 10-19 years (32%) the combined prevalence of reactions in both age groups was 77% which is in accordance with the literature.[5] Youth was predictor of reaction.[5] Donors under 30 years (1.15% versus 0.71%) had a significantly greater possibility to have a reaction (P < 0.001) [8] .

The prevalence of reactions in the present study in female donors was 12% as compared to 6% in males (p<0.001). Literature quotes overall higher donor reaction rate (16.7%) in17 years old Caucasian females than male donors (7.3%) at equivalent donor weights. Females were at significantly higher risk (odds ratio [OR] = 2.8, p<0.0003) compared to males[9]. Newman BH et al (2003) [2] concluded that men were half as likely as women to have an AE (23% AE vs. 48% AE, p <0.0001).

In the present study 7% of donors below 60 kg of weight experienced adverse reactions while 6% of donors weighing above 60 kg experienced adverse reactions. Solicitation of information from the general donor population increased the vasovagal reaction detection rate by 2.5 times (from 2.6% to 6.5%), and it is suggested that the vasovagal reaction rate might be as high as 27% in first time donors who weighed between 110 and 139 pounds[2]. Newman suggested that body weight is a very important determinant of vasovagal reaction rates in first time donor, but previous successful blood donation appears to mitigate the effect of body weight on vasovagal reaction rates[2]. Donors who had reaction were of lower weight (mean, 153.7 Ib.) than those who did not (mean, 166.4 Ib). [5]

In the present study first time donors experiencing adverse reactions was 13% as compared to 5% in repeat donors (P=0.01). Literature also quotes higher frequency of ARs in first time donors (1.7%) than repeat donors (0.19%). [5] Stewart KR (2006) [10] showed multilevel logistic regression analysis demonstrated that a one-standard deviation increase in Social skills Inventory score was associated with a significant reduction in the likelihood of donor reaction in the first sample [odd ratio (OR), 0.86; 95% confidence interval (CI), 0.76-0.96] and with a marginally significant reduction in the likelihood of donor reaction in the second sample (OR 0.90; 95%. C1, 0.79-1.02). The high school population had a much higher vasovagal reaction rate than the general donor population (8.0% Vs 2.6%). The vasovagal reaction was same in first time blood donors in both population, but the trend was not as well defined in repeat blood donors.[9] Repeat blood donors had fewer adverse effects (AEs) than first time blood donors (36% AE vs. 47%).[2]

First time donors (1.7% versus 0.68%) had a significantly greater possibility to have a reaction (P<0.001). 7% of donors donating blood in camps had adverse reactions while 4% of indoor donors had adverse reactions (p <0.05)[9].

The greatest number of AR occurred during or after donation of whole blood, with there being fewer after donations of other blood components. This finding is explained by the greater number of donors, both periodic donors and first-time donors, recruited to give whole blood; plasma and other blood components were almost always donated by periodic donors.[11]

In the present study, negligible donor ARs (0%) were seen in platelet apheresis donors because these were mostly periodic donors.

Donor reactions can significantly affect the return rate of donors for repeat donation [12]. Donors who had major reactions had longer times to return than donors with minor or no reactions. The adjusted odds rations (AORs) of returning for donors with major reactions was 0.32 (95% confidence interval [CI], 0.28-0.37) and with minor reactions 0.59 (95% CI, 0.56-0.62) when compared to donors who did not have reactions [13]. Donor recruitment is critical to the success of safe and adequate blood and its products to meet patients need.

Several interventions e.g. having the donor drink 16 oz water shortly before donation [14], or using applied muscle tension, distraction, or behavior modification [15], have been demonstrated to marginally reduce donor complication rates, but no single measure has been shown to prevent a majority of systemic reactions or to prevent the rare but more serious complications, such as syncope-related injury after whole blood donation. Reducing the relative proportion of blood loss by requiring a higher donor weight or by reducing the collection volume has also been proposed as safety measures.

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