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Original Research Article

Study of Adverse Donor Reactions in Whole Blood Donors in a Tertiary Care Hospital, Srinagar, North India

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Abstract:

Aim: To estimate the frequency of adverse reactions occurring in whole blood donors and to assess the predisposing risk factors of these adverse reactions.

Materials & Methods: The present study is a hospital based observational study carried in the department of blood transfusion and Immunohematology from Jan 2015 to Dec 2022. The donors who developed adverse reactions or adverse events were categorized with respect to: age, sex, hemoglobin, type & status of donor.

Results: During this seven-year study period, a total of 76188 donors donated blood, out of which 5.5 % (4190/76188) donors experienced donation related adverse effects. Reaction rate among male & female donors were 5.3 % (3970 /75011) & 18.7 % (220 /1177) respectively. Most of the donors who experienced adverse effects or adverse reactions [6.1 % (2248/ 37332)] belong to the younger age groups. Age & gender had a significant effect on rate of reaction ($p < 0.001$). Higher rate of adverse reactions [8.3 % (1236/ 14842)] were observed in donors with hemoglobin in the range of 12.5 – 13.4 g/dl. Also Significantly higher ($p < 0.001$) rate of adverse reactions were observed among 1st time donors [8.9 % (2428/27292)] & replacement donors [7.8 % (1804/ 23145)].

Summary & Conclusion: Donation related adverse reactions or adverse effects are multifactorial determined by age, sex, hemoglobin, type & status of donor. Our study reinforces that blood donation is a safe procedure which could be made even more event free by analyzing adverse events, identifying the donors at risk of donor reactions and adopting appropriate donor motivational strategies, pre-donation counseling, and care during and after donation, strict adherence to guidelines in donor examination & selection.

Keywords: Blood Donor, Adverse Donor Reactions, Donor Safety.

Introduction

Blood donation is generally considered to be a safe procedure, but occasionally adverse reactions of varying severity may occur during or after donation [1]. Whatever the minor reaction is, it has significant implications on the behavior of

the donor. These implications may be the self-deferral or unwillingness for the return blood donation in the future [2,3]. One of the key components to run a successful health care system is to establish a well-organized blood transfusion service (BTS). The basic requirement to setup a well-organized BTS is the recruitment and retention of blood donors. The blood donors are selfless volunteers, and they need to be protected as much as possible, from adverse reactions. As among repeat donors, adverse reactions are associated with decreased intentions to donate in future [4,5]. A dual responsibility has been put on blood centers to provide an adequate supply of blood & blood components to the communities they serve and to protect the well-being and safety of their volunteer blood donors [6]. Hemovigilance which is more concerned to adverse events in patients receiving blood transfusions and pays less attention to adverse events occurring in blood donors. Hence, adverse event analysis in blood donor population helps in identifying the donors at risk of developing adverse 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 [7,8].

The donation of blood process involves insertion of a needle into a blood vessel of the arm followed by a loss of almost 10 % of the total blood volume within a few minutes. Worldwide this procedure is done routinely thousands of times, principally without any complications, except for mild transient discomfort. However, complications do occur [9]**.** Occurrence of any unexpected, undesirable and unintended event before, during or after donation of blood to the donor is called Adverse Donor Reaction (ADR) or Adverse Event [AE] [10].

The adverse reactions that occur in donors can be divided into Local and Systemic reactions [11,12]**.**

Local reactions occur predominantly because of problems related to needle injury & are mainly characterized by extravasations of blood & pain. They include hematoma formation, difficulty with blood flow, accidental puncture to the artery, delayed bleeding, nerve irritation, nerve injury, tendon injury, painful arm, thrombophlebitis & local allergy.

Systemic reactions. In most cases, they are vasovagal generated by the autonomic nervous system and further stimulated by psychological factors, and the volume of blood removed relative to the donor's total blood volume. The reactions are more common in young donors, low weight donors, female donors, and first-time donors. Non-syncopal reactions are 25 times more common than syncopal reactions [11,12]. The reactions usually develop suddenly during or immediately after phlebotomy & can generally be divided into 3 categories: a) mild b) moderate & c) severe [13].

Some of the most severe complications seen in relation to blood donation are accidents in donors who lose consciousness after leaving the donation site. So adverse donor reactions are further grouped into: acute reactions, delayed reactions [14].

Acute Reactions: Events that occur in the refreshment area or within premises of a blood collection center, usually within half an hour (onset within less than 24 hours) are classified as 'Acute reactions.

Delayed Reactions: Donors who experience any of the mentioned signs and symptoms any time after they have left the blood collection center (usually after days or even months) are classified as delayed reactions.

Serious systemic reactions after blood donation including medical emergencies such as angina, myocardial infarction, & cerebrovascular accident can occur which are quite rare & these reactions may not be related to donation but may be co-incidental.

Aim: To estimate the frequency of adverse reactions occurring in whole blood donors and to assess the predisposing risk factors of these adverse reactions.

Materials and Methods:

The present study is a hospital based observational study done in the Post Graduate Department of Blood Transfusion & Immunohematology - Sheri Kashmir Institute of Medical Science (SKIMS), Soura Srinagar from Jan 2015 to Dec 2021. Blood donors included in the study were screened by the medical officer on duty. A preexisting blood donor questionnaire & consent form was filled by each donor or by the donor clinic staff. Preliminary physical examination for relevant parameters like age, pulse, BP, weight, temperature, haemoglobin, etc, by the concerned doctor was taken & the donors were selected fit for donation. Strict adherence to Departmental SOP & National Guidelines under Drugs & Cosmetics Act 1945 [15] & NACO, Ministry of Health and Family Welfare. Govt. of India [16]; was maintained while screening the blood donors. Donors who did not qualify the guidelines were excluded.

Blood collection (phlebotomy) procedure was performed as per Transfusion Medicine Technical Manual, DGHS 2003; 2nd Edition [14] & the Departmental SOP (standard operating procedure). Donors were closely observed during and after donation for any Adverse Reaction.

In case of any ADR, the patient was promptly treated symptomatically by the trained staff of the Department. On completion of the blood donation, the donors were given light refreshment and discharged with post-donation counselling.

Those donors who developed reactions were categorized with respect to: Age, Sex, Hemoglobin, Type of donor (Voluntary / Replacement) and Donor status (1st time donor / Repeat donor)

The adverse donor reactions were managed in accordance with guidelines laid down by Transfusion Medicine Technical Manual, DGHS 2003; 2nd Edition [14], NACO Ministry of Health and Family Welfare. Govt. of India [16] & the Departmental SOP.

Observations and Results:

A total of 76188 donors donated blood during this seven-year study period, out of which 4190 (5.5 %) donors suffered complications or adverse reactions. The observed reaction rate among male population was 5.3 % (3970/75011) and among female population was 18.7 % (220/1177) and the association came to be highly significant ($p<0.001$). Table 1

The blood donors were divided into five main age groups. It was observed that most of the donors who experienced adverse donor reactions belong to the younger age groups. 6.1 % (2248/37332) and 5.3 % (1534/28953) adverse reactions were observed in the age group of 18- 27 years & 28-37 years respectively. Reaction rate was lowest in the age group of 58-65 years [2.2 % (10/457)] which is statistically significant ($P<0.001$). Table2

According to the Hb status, higher rate of adverse reactions 8.3 % (1236/14842) was observed in donors with Hb in the range of 12.5 – 13.4 g/dl as compared to 4.1 % (936/23278) donors with Hb ≥ 14.5 g/dl, which is statistically significant ($P<0.001$). Table 3

Higher rate 7.8 % (1804/23145) of adverse reactions was also observed among Replacement Donors as compared to Voluntary Donors 4.5% (2386/53043), & the association came to be highly significant $P<0.001$. Table 4

Adverse donor reaction rate was observed to be higher among 1st time Donors 8.9% (2428/27292) as compared to Repeat Donors 3.6 % (1762/48896) & is statistically highly significant $P<0.001$. Table 5

Table 1: Frequency of adverse donor reactions with respect to Gender

Gender	No. of Donor with Reactions N (%)	No. of Donors without Reaction N (%)	Total N (%)
Males	3970 (5.3)	71041 (94.7)	75011 100)
Females	220 (18.7)	957 (81.3)	1177 (100)
Total	4190 (5.5)	71998 (94.5)	76188 (100)

Statistical Results: Chi-square value: 400.1 df: 1 p-value: < .001

Table 2: Frequency of adverse donor reactions with respect to Age

Age groups	No. of Donor with Reactions N (%)	No. of Donors without Reaction N (%)	Total (%)
18-27	2248 (6.1)	35084 (93.9)	37332 (49)
28-37	1534 (5.3)	27419 (94.7)	28953 (38)
38-47	340 (4.3)	7583 (95.7)	7923 (10.4)
48-57	58 (3.8)	1465 (96.2)	1523 (02)
58-65	10 (2.2)	447 (97.8)	457 (0.6)
Total	4190 (5.5)	71998 (94.5)	76188 (100%)

Statistical Results: Chi-square value: .621 df: 4 p-value: < .001

Table 3: Frequency of adverse donor reactions with respect to Hemoglobin

Hemoglobin Level (g/dl)	Donors with reaction N (%)	Donors without reaction N (%)	Total no of donors N (%)
12.5 – 13.4	1236 (8.3)	13606 (91.7)	14842 (100)
13.5 – 14.4	2018 (5.3)	36050 (94.7)	38068 (100)
≥ 14.5	936 (4.1)	22342 (95.9)	23278 (100)
Total	4190 (5.5)	71998 (94.5)	76188 (100)

Statistical Results: Chi-square value: 329.2 df: 2 p-value: < .001

Table 4: Frequency of adverse donor reactions with respect to Type of Donor

Type of Donor	Donors with reaction N (%)	Donors without reaction N (%)	Total Donors N (%)
Replacement donors	1804 (7.8)	21341 (92.2)	23145 (100)
Voluntary donors	2386 (4.5)	50657 (95.5)	53043 (100%)
Total	4190 (5.5)	71998 (94.5)	76188 (100%)

Statistical Results: Chi-square value: 336.8 df: 1 p-value: < .001

Table 5: Frequency of adverse donor reactions with respect to Status of Donor

Donor Status	Donors with reactions N (%)	Donors without reactions N (%)	Total N (%)
1st time donor	2428 (8.9)	24864 (91.1)	27292 (100)
Repeat donor	1762 (3.6)	47134 (96.4)	48896 (100)
Total	4190 (5.5)	71998 (94.5)	76188 (100)

Statistical Results: Chi-square value: 944.1 df: 1 p-value: < .001

Discussion

A dual responsibility been put on blood centers to provide an adequate supply of blood & blood components to the communities they serve & to ensure the well-being &safety of their volunteer blood donors. Medically the most common systemic & phlebotomy related complications of blood donation (i.e., presyncope, small haematomas) are inconsequential although they are uncomfortable for the donor. The significance of these minor complications,

however, lies primarily in the observation that any complication, even a minor one, reduces the likelihood of repeat donation [1,6,17] & increases the possibility that a short-term yield in donations incurs the ultimate expense of deterring future blood donation by these donors. Whole blood donation is considered to be safe, although, reports in literature about the frequency of complications during blood donation show broad heterogeneity [1,18,19,20,21].

The present study revealed that out of 76188 donors who donated blood during the study year, 4190 (5.5 %) donors had post donation adverse effects. Comparable results were observed by Mahbub-ul-Alam M et al, 2007 (4.9 %) [22]. Higher rates of adverse reactions were observed by David T 1961 (15.2 %); Majlessi F 2008 (13.4 %); Rohra DK 2010 (13.5%) & Chowdhary F) S et al, 2011 (8.7 %) [23,24,25,26]. Lower rates were observed by Pathak C et al., 2011(0.6%); Mangwana S 2013 (0.3 %); Rathod K, Choudhary M 2014 (1.09 %); Patel PA et al., 2012 (1.48 %); Tomasulo P et al 2009 (1.43%); Gupta S et al 2011 (2.33 %); Agnihotri N et al 2012 (2.5%); & Abhishekh et al 2013 (2 %) [1,7,8,27,28,29,30,31]. This variation in results among different studies from our study could be due to different selection, classification & grading criteria of adverse donor reaction.

It was observed that most of the donors who experienced adverse donor reactions belong to the younger age groups. 6.1 % (2248/37332) and 5.3 % (1534/28953) adverse reactions were observed in the age group of 18- 27 years & 28-37 years respectively. There was a significant decrease in the reaction rate as the age increased ($p< 1.001$). In their studies, Mangwana S2013; Rathod K 2014; Rohra DK 2010; Tondon R et al 2008; [7,18; 25,32]; also reported that the reaction rate decreased with increasing age of donors. A study from France [33] postulated that baroreceptor sensitivity is decreased in healthy young individuals when they are physically or psychologically stressed. However, hemodynamically, the body becomes more stable with increasing age. Also, the young blood donors become more apprehensive to the phlebotomy pain.

In the present study reaction rate among male donors was 5.3 % (3970/75011) & among female donors was 18.6 % (220/1177). This is comparable to that observed by Mahbub-ul-Alam M et al, 2007 & Chowdhary FS 2011 [22,26], were adverse reaction rate among male & female donors was 4.94 %, 0.35 % & 5.97%, 5.56 % respectively. Mangwana S 2013 [7] also observed the similar findings of higher reaction rate among female donors (0.50%) than male donors (0.29%). The higher reaction rate among female donors may be due to higher emotional liability, lower hemoglobin level, low normal weight & smaller size of female donors.

In our study, significantly ($p< 0.001$) higher rate of adverse reactions 8.3 % (1236/14842) were observed in donors with hemoglobin in the range of 12.5 – 13.4 g/dl as compared to 04.1 % (936/23278) donors with Hb ≥ 14.5 g/dl.

Higher rate of adverse reactions was observed among Replacement Donors 7.8 % (1804/23145) as compared to Voluntary Donors 4.5% (2386/53043) ($p<0.001$) which is statistically significant. The reason for high reaction rate among replacement donors may be due to anxiety, emotional & mental stress.

In our study, adverse donor reaction rate was observed to be higher among 1st time Donors 8.9 % (2428/27292) as compared to Repeat Donors 3.6 % (1762/48896) ($p< 0.001$). This may be due to associated anxiety & needle phobia with inexperienced 1st time donors relative to repeat donors who are familiar with the donation process. Higher reaction rate was also observed by Mangwana S 2013 [7] among 1st time donors 59 % (23/39) as compared to repeat donors 41% (16/39)

In the present study, the most common variables associated with adverse donor reactions were younger age, female gender, low hemoglobin, replacement donations & 1st time donation.

Summary & Conclusion

Donation related adverse reactions or adverse effects are multifactorial determined by age, sex, hemoglobin, type & status of donor. Our study reinforces that blood donation is a safe procedure which could be made even more event free by analyzing adverse events, identifying the donors at risk of donor reactions and adopting appropriate donor motivational strategies, pre-donation counseling, and care during and after donation, strict adherence to guidelines in donor examination & selection.

Complications of blood donation are mostly preventable. Therefore, in order to prevent these adverse events, while maintaining the health of the donors and in order to help encourage donors to become repeated donors the following points are suggested:

- Donor examination and selection criteria should be strictly following to rule out unfit donors.
- A good and cardial relation should be maintained between the blood donor and donor clinic staff.
- Blood donors should be continuously monitored during and after blood donation.
- Divert blood donors mind just before and during blood donation develops some anxiolytic effect on donor and helps to reduce the incidence of ADR as it on as Giving refreshment in the form of milk, fruit juice, snakes, tea or coffee etc before and after donation and taking some rest after donating blood may help to reduce ADR. Also, taking some rest and postponing donation for some time in donors who had some exercise or walked a long distance before donation helps to reduce incidence of ADR.
- Some entertainment source like a television set or some musical system should be installed at the donor reception and phlebotomy room to please and mentally relax the blood donors.
- Post donation advice should be properly conveyed to the donors by the doctor on duty or donor clinic staff and the donors are stressed to follow the advice strictly.
- Blood Donation Centre should be architected near the accidental or emergency block so that any adverse reaction or untoward event can be tackled without delay.
- Each and every ADR should be reported to the proper platform.

There is also a need for starting donor hemovigilance at national level so that risks & spectrum of various donation-related adverse events is known & strategies to improve safe blood transfusion are prepared.

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