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Original Research Article

Study of Adverse Donor Reactions in Whole Blood Donors in a Tertiary Care Hospital

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ABSTRACT

Aim: To estimate the frequency, severity & association of adverse events occurring in whole blood donors. And to assess the predisposing risk factors of these adverse events

Materials & Methods: The present study is a one year hospital based cross-sectional study & the donors who developed adverse reactions were categorized with respect to: age, sex, hemoglobin, type of donor, & place of donation.

Results: During this one year study period, a total of 35256 donors donated blood, out of which 1928 (5.5 %) donors experienced donation related adverse effects. Reaction rate among male & female donors were 5.3% (1730/23928) & 8.5 % (198/2328) respectively. Most of the donors 90.6 % (1746/ 1828) who experienced adverse donor reactions belong to the younger age groups. Age & gender had a significant effect on rate of reaction ($p < 0.0001$). Higher rate of adverse reactions 7.9 % (562/7050) was observed in donors with hemoglobin in the range of 12.5 – 13.4 g/dl. Also Significantly higher ($p < 0.01$) rate of adverse reactions was observed among 1st time donors 8.7% (1376/15866), replacement donors 6.6% (1048/15864) & donors who donated blood in outside donation camps 6.1% (426/7052).

Summary & Conclusion: Donation related adverse reactions are multifactorial determined by age, sex, hemoglobin, type & status of donor, & place of donation. 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.

Key Words: Blood Donor, Adverse Donor Reactions, Donor Safety.

INTRODUCTION

Blood is the most precious and unique gift that one human being can give to another. It is life saving fluid that cannot be created artificially, but is only collected from donors which are the precious resources. [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. [2,3] Blood-donor pool can be increased by motivation, recruitment and retention of donors. Donor retention is directly linked with the donor services and donor care.

Blood donation is generally considered to be a safe procedure, but occasionally adverse reactions of varying severity may occur during or after donation. [4] 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. [5,6]

Blood centers have a dual responsibility to provide an adequate supply of blood & blood components to the communities they serve and to protect the safety of their volunteer donors. [7] It also places an ethical responsibility on health care givers (the users of blood) to avoid wastage & unnecessary use of blood transfusion. [8]

Hemovigilance 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 counseling, and care during and after donation, developing guidelines and hemovigilance programme in countries with limited resources. [9,10]

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. [11]

Occurrence of any unexpected, undesirable and unintended event before, during or after donation of blood to the donor is called Adverse Donor Reaction (ADR). [12]

Adverse events are an inevitable part of whole blood donation. The adverse reactions that occur in donors can be divided into Local and Systemic reactions. [13,14]

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, Thrombophelebitis & 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. [13,14]

The reactions usually develop suddenly during or immediately after phlebotomy & can generally be divided into 3 categories: a) mild b) moderate & c) severe. [15]

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:

Immediate Reactions: Events that occur in the refreshment area or within premises of a Blood Collection Service (usually within half an hour) are classified as 'Immediate reactions.

Delayed Reactions: Donors who experience any of the mentioned signs and symptoms any time after they have left the Blood Collection Service or Center (usually after half an hour) are classified as delayed reactions.

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

AIMS AND OBJECTIVES

Aim: To estimate the frequency, severity & association of adverse events occurring in whole blood donors. And to assess the predisposing risk factors of these adverse events

MATERIALS AND METHODS

The present study " Study of Adverse Donor Reactions In Whole Blood Donors In A Tertiary Care Hospital" is a one year cross sectional done in the Post Graduate Department of

Immunohematology and Transfusion Medicine GMC, Jammu from Nov 2013 to Oct 2014. 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 [16] & NACO, Ministry of Health and Family Welfare. Govt. of India; [17] 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 [18] & 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 counseling.

Those donors who developed reactions were categorized with respect to:

a). Age
b). Sex
c). Hemoglobin
d). Type of donor
1.Voluntary /
2.Replacement
e) Donor status
1. 1st time donor/
2. Repeat donor
f). Place of donation
1. In blood bank
2. In outside camp

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

OBSERVATIONS & RESULTS

The present study is a hospital based cross-sectional study & the donors who developed adverse reactions were categorized with respect to: age, sex, hemoglobin, type of donor & place of donation

During this one year study period, a total of 35256 donors donated blood, out of which 1928 (5.5 %) donors suffered adverse reactions.

The reaction rate observed among male population was 5.3 % (1730/32928) and among female population was 8.5 % (198/2328) and the association came to be highly significant (p<0.0001).

Table 1

Gender	No. of Donor with Reactions N (%)	No. of Donors without Reaction N (%)	Total N (%)
Males	1730 (5.3)	31198 (94.7)	32928(100)
Females	198 (8.5)	2130 (91.5)	2328 (100)
Total	1928 (5.5)	33328 (94.5)	35256 (100)

Chi Square-44.46, p <0.0001 (Highly significant)

The donors were divided into five main age groups (Table 2): Most of the reactions 53.9 % (1038/1928) & 36.7 % (708/1928) were in the age group of 18- 27 years & 28-37 years respectively. 8.8 % (170/1928) donors suffered adverse reactions in the age group of 38-47 years, 0.5 % (10/1928) donors in the age group of 48-57 years and 0.1% (02/1928) donors in the age group of 58-65 years. So it was observed that most of the donors who experienced adverse donor reactions belong to the younger age groups.

Table2

Age groups	Male		Female		Total	
	Number of donors	Adverse reactions	Number of donors	Adverse reactions	Number of donors	Total Adverse reactions (%)
18-27	15760 (44.7)	926 (53.5)	1164 (3.3)	112(56.6)	16924 (48)	1038 (53.9)
28-37	13116 (37.2)	654 (37.9)	774 (2.1)	54 (27.2)	13890 (39.4)	708 (36.7)
38-47	3172 (9)	138 (7.9	326 (01)	32 (16.2)	3524 (10)	170 (8.8)
48-57	668 (1.9)	10 (0.6)	38 (0.1)	0 (0)	706 (02)	10 (0.5)
58-65	212 (0.6)	2 (0.2)	0 (0)	0 (0)	212(0.6)	02 (0.1)
Total	32928 (93.4)	1730	2328 (6.6)	198	35256 (100)	1928

According to the Hb status, higher rate of adverse reactions 7.9 % (562/7050) were observed in donors with Hb in the range of 12.5 – 13.4 g/dl as compared to 04% (446/11284) donors with Hb ≥ 14.5 g/dl , which is statistically significant (P<0.0001).

Table 3

Hemoglobin Level (g/dl)	Donors with reaction N (%)	Donors without reaction N(%)	Total no of donors N (%)
12.5 – 13.4	562 (7.9)	6488 (92.1)	7050 (100)
13.5 – 14.4	976 (5.7)	15948 (94.3)	16924(100)
≥ 14.5	446 (04)	10836 (96)	11282 (100)
Total	1928 (5.5)	33328 (94.5)	35256 (100)

Chi=133.1 P<0.0001 (Highly significant)

Higher rate 6.6% (1048/15864) of adverse reactions was also observed among Replacement Donors as compared to Voluntary Donors 4.5% (880/19392), & the association came to be highly significant P<0.0001.

Table 4.

Type of Donor	Donors with reaction N(%)	Donors without reaction N(%)	Total Donors N(%)
Replacement donors	1048 (6.6)	14816 (93.4)	15864 (100)
Voluntary donors	880 (4.5)	18512 (95.5)	19392 (100)
Total	1928 (5.5)	33328 (94.5)	35256 (100)

Chi 72.2 p< 0.0001 (Highly significant)

Adverse donor reaction rate was observed to be higher among 1st time Donors 8.7% (1376/15866) as compared to Repeat Donors 2.8% (552/19390), & is statistically highly significant P<0.0001.

Table 5.

Donor Status	Donors with reactionsN (%)	Donors without reactions N (%)	Total N (%)
1st time donor	1376 (8.7)	14490 (91.3)	15866 (100)
Repeat donor	552 (2.8)	18838 (97.2)	19390 (100)
Total	1928 (5.5)	33328 (94.5)	35256 (100)

Chi 572.9 p<0.0001 (Highly significant)

The rate of reactions was observed to be higher in outside donation camps 6.1% (426/7052) as compared to donations carried inside blood bank 5.3% (1500/28204), which is statistically significant (P<0.0001).

Table 6.

Place of Donation	Donors with reaction N (%)	Donors without reaction N (%)	Total Donors N (%)
In Blood Bank	1500 (5.3)	26704 (94.7)	28204 (100)
In Outdoor Camp	426 (6.1)	6623.9 (94)	7052 (100)
Total	1928 (5.5)	33328 (94.5)	35256 (100)

Chi 5.41 p <0.01 (Significant)

DISCUSSION

Blood centers have a dual responsibility to provide an adequate supply of blood & blood components to the communities they serve & to ensure the safety & well-being of their donors. The most common systemic & phlebotomy related complications of blood donation (i.e., presyncope, small haematomas), although uncomfortable for the donor are medically inconsequential. 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 [4,7,19] & increases the possibility that a short-term yield in donations incurs the ultimate expense of deterring future blood donation by these donors. Although whole blood donation is considered to be safe, reports in the medical literature about the frequency of adverse events during donation show broad heterogeneity. [4,20-23]

The present study of "Adverse Blood Donor Reactions In A Tertiary care Hospital" is a cross-sectional, hospital based study.

Majority of the donors 48 % were in the younger age group of 18 – 27 yrs followed by 39.4 % donors in the age group 28 – 37 yrs. Mahbub-ul-Alam M et al, 2007 [24] in their study also observed higher frequency of donors in age groups 18-25 yrs (33.6 %) , 25-30 yrs (29.5 %) , 30-35 yrs (14.9 %) & ≥ 60 yrs (only 0.2 %). Rohra D K et al, 2010 [25] & Agnihotri N et al, 2012 [26] also observed higher frequency of donors in younger age groups.

Our study revealed that out of 35256 donors, 93.4 % (32928) were male donors & only6.6 % (2328) were female donors. Similar studies by Mangwana S 2013; [9] Majlessi F et al, 2008; [27] Chowdhury FS et al, 2011; [28] Jain N et al, 2014 [29] showed almost same frequency of male (96.96 %, 94 %, 92.5%, 96.1 %) & female (3.04 %, 6 %, 7.5 %, 3.9 5) donors respectively.

There were 55 % voluntary blood donors & 45 % were replacement donors. Comparable results were obtained by Agnihotri N et al, 2012 [26] (VD 59.6 % & RD 40.4 %). Patel PA et al, 2012 [1] in their study observed a frequency of 42.3 % voluntary & 57.27 % replacement. However, it is still below the present national average of 61 % (Mangwana S 2013). [9]

Out of 35,256 donors who donated blood during the study year, 1928 (5.5 %) donors had post donation adverse effects. Comparable results were observed by Mahbub-ul-Alam M et al, 2007 [24] (4.9 %). Higher rates of adverse reactions were observed by Rohra DK 2010 [25] (13.5%); Majlessi F 2008 [27] (13.4 %); Chowdhary FS et al, 2011 [28] (8.7 %) & David T 1961 [30] (15.2 %). Lower rates were observed by Patel PA et al., 2012 [1] (1.48 %); Pathak C et al, 2011 [4] (0.6%); Mangwana S 2013 [9] (0.3 %); Rathod K, Choudhary M 2014 [10] (1.09 %); Agnihotri N et al 2012 [26] (2.5%); Tomasulo P et al 2009 [31] (1.43%); Gupta S et al 2011 [32] (2.33 %) & Abhishekh et al 2013 [33] (2 %). The disparity in results among different studies from our study could be due to different selection, classification & grading criteria of adverse reaction.

It was observed that most of the donors who experienced adverse donor reactions 90.6 % (1746) belong to the younger age groups, 18─27 years & 28-37years. There was a significant decrease in the reaction percentage as the age increased ($p< 1.001$). In their studies Mangwana S 2013; [9] Rathod K 2014; [10] Rohra DK 2010; [25] Tondon R et al 2008; [34] also reported that the reaction percentage decreased as the age of donors increased. A study from France [35] postulated that baroreceptor sensitivity is decreased in healthy young individuals when they are physically or psychologically stressed. With increasing age, the body becomes more stable hemodynamically. Also, the young donors were more apprehensive to the pain of phlebotomy.

In the present study reaction rate among male donors was 5.3% (1730/23928) & among female donors was 8.5 % (198/2328). Reaction rate among female donors was more than male donors. This is comparable to that observed by Mahbub-ul-Alam M et al, 2007 [24] & Chowdhary FS 2011 [28] were adverse reaction rate among male & female donors was 4.94 %, 0.35 % & 5.97%, 5.56 % respectively. Mangwana S 2013 [9] 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 7.9 % (562/7050) were observed in donors with hemoglobin in the range of 12.5 – 13.4 g/dl as compared to 04 % (446/11284) donors with Hb ≥ 14.5 g/dl.

Higher rate of adverse reactions was observed among Replacement Donors 6.6% (1048/15864) as compared to Voluntary Donors 4.5% (880/19392) ($p<0.001$) 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 8.7% as compared to Repeat Donors 2.8% ($p< 0.001$).

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 [9] among 1st time donors 59 % (23/39) as compared to repeat donors 41% (16/39)

In our present study, the rate of adverse reactions was observed to be higher in outdoor donation camps 6 % as compared to reactions 5.4 % in blood bank donations ($p<0.001$). Similarly, higher reaction rate was observed by Gupta S et al, 2013, [32] 81.4% reactions in outdoor camps as compared to 18.65% reactions in blood bank premises.

The reason for higher reaction rate in camps may be due to that blood is collected in outdoor camps around Jammu City in hot and humid environment during most of the months in the year. More adverse events were observed in the afternoons when there was more donor dehydration & clustering and crowding of donors. Hence more stress was given on pre-donation fluid intake in addition to post donation refreshment. Other reasons may be due to hasty medical examination missing some important aspects of donor recruitment & selection, inadequate post-donation rest or poor phlebotomy technique by less trained staff.

89.9 % of the reactions were immediate adverse reactions. Only 10.1 % of reactions were delayed type of reactions. The reason may be that registration of delayed donor complications in our department is based on call back and late-developing complications are therefore only identified if the donor returns with a complaint. Thus, late events could be under reported.

Subjects who suffered severe degree of ADR in the form of twitching & convulsions were managed in blood bank only & none required hospitalization.

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

SUMMARY & CONCLUSION

The present study "Study of Adverse Donor Reactions In Whole Blood Donors In A Tertiary Care Hospital" was done in the Post Graduate Department of Immunohematology and Transfusion Medicine GMC, Jammu from Nov 2013 to Oct 2014. It is a cross-sectional, hospital based study

The present work comprised of:

- Studying the frequency & severity of Adverse Blood Donor Reactions in both voluntary & replacement donors & to describe the spectrum of various causes & predisposing risk factors of Donor Reactions.
- During the one year study period, a total of 35,256 voluntary & replacement donors were selected as fit for allogeneic blood donation.
- Among the study group 93.4 % were male donors & 6.6 % were female donors. Blood donation among females is not common in our region because of the prevalent customs, fear and ignorance, lack of exposure & awareness & lack of opportunities

among them. Another reason is anemia which is in accordance to the overall prevailing prevalence of anemia among female population all over India as more than 50 % females in reproductive age group in India are anemic.

- Majority of the donors (87.4 %) belong to the younger age groups (18-27 yrs & 28 – 37 yrs). With increasing age, the number of donors decreased as there were only 0.6% donors in the age group of 58 – 65 yrs. This highlights the fact that a sizeable proportion of the youth in this region take part in blood donation & the major blood donor pool of our region consist of young donors because of the awareness & motivation of the young people regarding the importance of blood donation.
- Although our voluntary blood donation (55%) is more than replacement donation (45%), it is however, still below the present national average of 61%.
- As per the donation status, 45 % of the donors were 1st time donors & 55 % were Repeat blood donors. Maximum of the donors 80 % donated in the departmental blood bank & only 20 % donated in blood donation camps outside hospital premises, as per convenience of donors.
- Out of 35,256 donors who donated blood during the study year, 1928 (5.5 %) donors experienced donation related adverse effects.
- Reaction rate among male donors was 5.3% (1730/23928) & among female donors was 8.5 % (198/2328). 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.
- Most of the donors 90.6 % (1746/ 1828) who experienced adverse donor reactions belong to the younger age groups 18─27 years & 28-37 years. There was a significant decrease in the reaction rate as the age increased. The mechanism responsible may be that baroreceptor sensitivity is decreased in healthy young individuals when they are physically or psychologically stressed. With increasing age, the body becomes more stable hemodynamically. Also, the young donors were more apprehensive to the pain of phlebotomy.
- Higher rate of adverse reactions 7.9 % (562/7050) were observed in donors with hemoglobin in the range of 12.5 – 13.4 g/dl as compared to donors with Hb ≥ 14.5 g/dl, 04 % (446/11284).
- Significantly higher rate of adverse reactions was observed among Replacement Donors 6.6% (1048/15864) as compared to Voluntary Donors 4.5% (880/19392). The reason for high reaction rate among replacement donors may be due to anxiety, emotional & mental stress.
- Adverse donor reaction rate was higher among 1st time Donors 8.7% (1763/15866) as compared to Repeat Donors 2.8% (552/19390) ($p< 0.001$). 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. 1st time donors should be properly counseled & treated with compassionate care to make them repeat donors to increase the donor pool.
- Rate of reaction was higher in outside donation camps (6.1 %) as compared to donations in blood bank (5.3 %) ($p<0.001$). The reason for higher reaction rate in camps may be due to clustering and crowding of donors, hasty medical examination missing some important points regarding donor selection, hot and humid environment, donor dehydration, inadequate post-donation rest due to inadequate space or poor phlebotomy technique by less trained staff.
- 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:

- Strict adherence to guidelines in donor examination & selection to rule out the unfit donors before donation.
- Continuous monitoring of the donors during & after donation so that adverse donor reaction sequelae can be minimized.
- Maintaining a good relationship with the donor. Distraction of patient's mind just before and at the time of blood donation has anxiolytic effect that helps to reduce the incidence of ADR. Also the donor should be followed-up 24-48 hours after blood donation, if possible.
- Stress on the importance of pre & post-donation refreshment in the form of fruit juice & snacks and taking some rest after donating blood especially in women and first-time donors helps to reduce the incidence of ADR.
- Postponing blood donation for sometime in subjects who had walked a lot or exercised before blood donation
- Stressing on the importance of adherence to post donation advice given by the doctor incharge or by the donor clinic staff.
- Installation of some entertainment source like some musical system or a television set with entertaining channels at donor reception area and phlebotomy room of blood bank will help to reduce the incidence of ADR.
- Post donation advice should be clearly displayed in the phlebotomy room & donor rest room & should be properly conveyed to the donors.
- Architecting of Blood Donation Complex near to accidental or emergency centre in the hospital to tackle such emergencies without delay caused by transportation.
- Proper reporting of Adverse Donor Reactions
- 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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