



Original Article

# Donor Hemovigilance Programme in managing Blood Transfusion Needs: Complications of Whole Blood Donation

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## Keywords:

Blood transfusion services;  
Adverse events;  
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## ABSTRACT

**Background:** Hemovigilance like quality systems and audits have become an integral part of Blood Transfusion Services in the developed countries and has contributed greatly to its development. Hemovigilance begins with donors and must enable the collection of information on reactions occurring during the donation of blood, selections of donors and to prevent such incidents. The aim of study was to help identify the trends of adverse events, occurring in blood donors at a tertiary-care hospital, to recommend best practices to improve donor care and safety

**Materials and Methods:** This record-based study was conducted on all adverse events related to allogenic whole blood donations performed over 24 months. All whole blood donations were analyzed. All adverse events occurring during or at the end of the donation were noted using a standardized format and analyzed determining significance at  $p < 0.05$ .

**Results:** Overall rate was 0.3% with vasovagal reactions constituting 82%, and 18% mild syncopal reactions ( $p < 0.001$ ). Immediate vasovagal reaction with injury was very rare (0.007%). Vasovagal reactions showed a significant association with young age, female gender, first time donation status. Mean age of persons recording adverse effects was  $30.23 \pm 7.49$  years as compared to those without adverse effects,  $31.14 \pm 8.56$  years.

**Conclusion:** Donor safety is an essential prerequisite to increase voluntary blood donation. AE analysis helps in identifying the blood donors at risk of AE, applying appropriate motivational strategies, pre-donation counseling, care during and after donation, developing guidelines and hemovigilance programme in countries with limited resources.

## INTRODUCTION

Hemovigilance like quality systems and audits have become an integral part of Blood Transfusion Service (BTS) in the developed countries and have contributed greatly to the

development of Blood Transfusion Services. The goal of hemovigilance is to identify and prevent occurrence / recurrence of transfusion related unwanted events, in order to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of blood transfusion chain from donors to recipients. However, developing countries are still grappling with donor recruitment, retention and efforts towards sufficiency and safety of blood supply.

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Tools to help improve the safety of blood supply include –

1. Clinical (Transfusion) guidelines
2. Audit systems to monitor adherence to the guidelines as well as effects of guidelines.
3. Hemovigilance programme which monitors the entire blood supply chain, develop measures and solutions to the problems anywhere along the chain that can threaten the safety of component supply and monitors the implementation of these corrective actions.

Hemovigilance begins with donors and donations of blood and must enable the collection of information on reactions occurring during the donation of blood, selections of donors and to prevent the occurrence or recurrence of such incidents.

Whole blood donation is generally considered to be safe and uncomplicated procedure but occasionally donors experience adverse reactions of variable severity during or at the end of collection. Despite complications rates of blood donations being relatively low, donor complications are an important problem, not only for donors but also for the transfusion medicine in general, as some complications may negatively affect donor recruitment and retention.

There have been innumerable studies and articles in the literature on the recording and management of adverse events related to transfusion of blood component to the patients, data on donor adverse events is primarily from western studies.<sup>1-10</sup> In order to estimate the frequency and type of adverse events occurring in whole blood donors at a tertiary-care hospital, to disseminate the findings, to develop evidence-based medicine and to introduce new and/or existing policies for monitoring blood safety and to bring uniformity in hemovigilance system, this record-based study was conducted.

## MATERIALS AND METHODS

Record-based study was conducted on all adverse events related to allogenic whole blood donations performed over 24 months from January 2010 to December 2011. Criteria for the selection of whole blood donors were in accordance with rules laid down in Drugs and Cosmetic Act, Ministry Of Health and Family Welfare, Govt. of India.<sup>11</sup> Blood donors must be 18 to 65 years old and in good health. All donations were performed using 16 gauze needles from vein in the antecubital area after maintaining strict asepsis of venipuncture site.

It is important to react swiftly to initial complaints of giddiness, light headedness, pallor by donor by stopping the donation immediately and raising the legs and lowering of head end of donor couch (Anti-shock position) as pallor,

sweating, giddiness are harbingers of severe vasovagal reactions which could be prevented by taking corrective measures right at the onset of symptoms.

## Adverse Events (AE)

Donor adverse reactions were classified into local symptoms, generalized symptoms, complications related to Apheresis and others into 13 categories<sup>12</sup>. In order to create database, data was collected on the form designed as per guidelines by American Red Cross Hemovigilance Programme.<sup>1</sup>

Presyncopal symptoms included pallor, sweating or lightheadedness without loss of consciousness.

Syncopal type of complications were classified as:

**Minor** - transient loss of consciousness lasting for < 1 minute

**Major** - prolonged loss of consciousness for >1 minute or complicated by loss of bladder/ bowel control, seizures or convulsions

Local adverse events- hematomas which can be small (<25.8 mm<sup>2</sup>) or large (>25.8 mm<sup>2</sup>), bruises, infiltration, allergic reactions and a tingling / burning sensations.

Once the donor recovered from AE, a detailed report was filled by phlebotomist. For delayed reactions, the donor was advised to be in touch with designated staff of blood transfusion services.

This study was approved by the Institutional Ethics Committee.

**Statistical Analysis:** The data has been summarized through frequency distributions and contingency tables along with suitable graphs. Statistical analysis was performed with Mann-Whitney and Chi-square/Fisher's Exact test using SPSS version 15.0 software determining significance at  $p < 0.05$ .

## RESULTS

During the 24 months period, blood centre at a Tertiary-care hospital performed 14,600 donations of which 13,015 (89.14%) were whole blood donations (350ml/450ml) while 1585 (10.86%) were SDP donations.

The 5907 (45.39%) donations were made by first time donors and 7108 (54.61%) by repeat donors ( $p$  value <0.001). There were 247 (1.90%) voluntary donors and 12,768 (98.10%) replacement donors ( $p$  value <0.001).

Out of 13,015 whole blood donations 12,169 (96.96%) were made by male donors and 396 (3.04%) by female donors. ( $p$

**Table 1: Age and Sex Wise Comparison of Donations And Adverse Events**

Age Range (yrs)	DONATIONS			ADVERSE EVENTS			AE% Vs Donation
	Females	Males	Total	Females	Males	Total	
18-25	75(1.85)	3979(98.15)	4054(31.15)	1	11	12(30.77)	0.30
26-35	124(2.33)	5204(97.67)	5328(40.94)	0	16	16(41.02)	0.30
36-45	133(4.95)	2552(95.05)	2685(20.63)	0	10	10(25.65)	0.37
46-55	55(6.54)	786(93.46)	841(6.46)	1	0	1(2.56)	0.12
56-65	9(8.41)*	98(91.59)	107(0.82)	0	0	0	0
<b>Grand Total</b>	<b>396 (3.04)</b>	<b>12619(96.96)*</b>	<b>13015(100)</b>	<b>2(0.50)*</b>	<b>37(0.29)</b>	<b>39(100)</b>	<b>0.30</b>

Note - Figures in parentheses indicate percentages, \*p value<0.001, † odd ratio =1.726 (0.422, 7.063)

value<0.001) (Table 1).

Mean age of donors was 31.14±8.56 years with a range of 18 to 65 years. Mean age of male donors was 31.02 ± 8.49 years and female donors 35.02±9.74 years (p value<0.001, Mann-Whitney test)

No. of donations in various age groups is significantly associated with gender. Hence, in the age group categorization, highest donations (5328, 40.94%) was made in the age range of 26-35 years followed by 18-25 years age group (4054, 31.15%) and 36-45 years age groups (2685, 20.63%). The age group 46-55 and 56-65 years had the lowest donations as 6.46% (841) and 0.82% (107) respectively. In the different age groups, males were the predominant donors ranging from 91.40% to 98.15% while the maximum females (9.08%) were in the age group of 55-65 year. (p value<0.001; Table 1).

Out of 13,015 whole blood donations, donor adverse events were noted in 39 donors amounting to an overall incidence of 0.30%. Out of the female donors, 0.50% females developed adverse events while 0.29% of male donors developed adverse events (p value=0.448), Odds Ratio in favor of females recording adverse event is 1.726 (0.422, 7.063; Table 1).

Reaction percentage within the age groups were highest (0.37%) in 36-45 years followed by 26-35 years and 18-25 years age groups (0.30% each) while the lowest in 46-55 years age groups as 0.12%. There was no adverse event in 56-65 years age group (Table 1). The mean age of persons recording adverse events is 30.23 ± 7.49 years as compared to those without adverse events, 31.14 ± 8.56 years (p value=0.507, Mann-Whitney test).

We tried to analyze the incidence of adverse events within the particular ABO Rh group donations and found that highest percentage of adverse events (0.87%) was in 'O' Negative donors followed by 'B' Negative donors (0.33%) while there were no adverse events in 'A' negative and 'AB' Negative donors. The type of blood groups reporting adverse events are not associated with gender and age (Fisher's Exact Test p value=0.772 & 0.836 respectively).

Frequency of AE within various blood groups AE was highest in 'B' Positive followed 'O' Positive, 'A' Positive, 'AB' Positive, 'O' Negative, 'B' Negative. There was no adverse events in female Rh Negative donors (fig. 1).

Of all the adverse events, 59% (23/39) adverse events were observed in first-time donors while 41% (16/39) were in repeat donors. The frequency of adverse events in first-time donors in different age groups is shown in figure 2 (p value=0.113). The number of adverse events in first time/repeat donors is not significantly associated with age distribution (p value=0.134, Fisher's Exact test).

Majority of adverse events (82%, 32/39) were systemic, generalized symptoms (i.e. mild vasovagal reactions) while 18% (7/39) donors showed moderate vasovagal reactions (p value<0.001). They affected 0.3% of the donors (39/13015). Immediate vasovagal reaction with injury was very rare; 0.007% (01/13015). Forty four percent (17/39) donors with adverse events were able to complete the donation. Eighty two percent (32/39) of all adverse reactions occurred in phlebotomy room. None of the donor with adverse event necessitated the hospitalization.

## DISCUSSION

The aim of this study was to estimate the frequency and type of adverse events occurring in whole blood donors so that appropriate actions can be taken through appropriate educational processes to prevent occurrence and recurrences of these incidences and sufficient and safe blood supply can be maintained by ensuring safety and well-being of the 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.<sup>6,7,9</sup>

Donation-related adverse events were recorded according to standardized criteria. However, a classification of complications has been implemented in accordance with Standards for Surveillance of Complications Related to Blood Donations.<sup>12</sup>

In our study, 0.3 % of all whole blood donations were

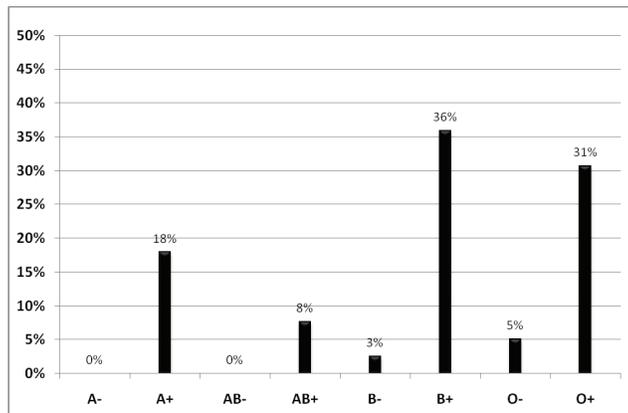


Figure 1: Group Wise Adverse Events

complicated by an adverse event. This is in accordance with various studies conducted all over the world in which the rate of adverse events associated with donations ranged from 0.3% to 3.8%<sup>2-10,13,14</sup> Variations may result due to differences in donor demography, behavior of collection staff and methodology used to obtain information regarding adverse events from donor.

As part of our study, we tried to analyze the various patterns and found that highest adverse events occurred in the age group of 26-35 years (0.37%). Young age, female gender and first time donation status were associated with significantly higher reaction prevalence.<sup>5,14</sup> There was significant drop in reaction prevalence after the age of 36 years. Mean age of donors recording adverse events is  $30.23 \pm 7.49$  years compared with mean age of donors without adverse events  $31.14 \pm 8.56$  years ( $p$  value = 0.507). A study by France postulated that baroreceptor sensitivity is decreased in healthy young individuals when they are physically or psychologically stressed.<sup>15</sup> With increasing age, body becomes more stable hemodynamically. Also the young donors were more apprehensive to the pain of phlebotomy.

Female donors showed 0.50% incidence of adverse events against 0.29% incidence in male donors. Female donors, both voluntary & replacement, had significantly higher prevalence similar to other studies.<sup>14</sup> Repeat donation status lowered the chance of adverse events as compared to first time donations but the number of adverse events in first time / repeat donors did not show any association with age distribution ( $p$  value = 0.134).

Amongst different blood group donations 'O' negative donors showed the highest incidence of AE 0.87% with no adverse events in 'A' negative and 'AB' negative donors.

The most common systemic and phlebotomy related complications (i.e. Pre-syncope, small hematoma), 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 chances of donor retention

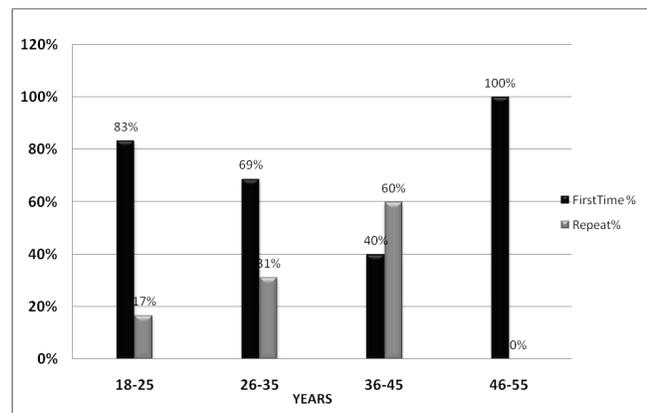


Figure 2: AE in First Time and Repeat Donors

or repeat donation. In addition, minor complications may be an indirect measure of more serious complications, although this is difficult to assess because of infrequent occurrence.

Mild vasovagal reactions, which include giddiness, sweating or light headedness without loss of consciousness, accounted for 82% of all adverse events (0.24% of total donations) while moderate vasovagal reactions accounted for 18% of all adverse events (0.05% of total donations) which is consistent with data from previous studies.<sup>2,13</sup>

We found a very low incidence (0.007% of total donations) of vasovagal reaction- immediate with injury but not necessitating hospitalization of the donor or administration of intravenous fluid which is in accordance with results of other authors<sup>2,3,13</sup> who categorized such adverse events as severe reactions (major syncopal reactions).

Donor safety is an essential prerequisite to increase voluntary blood donation. One of the key objectives of our national blood policy is to achieve 100% voluntary blood donation,<sup>16</sup> The present national average being 61%. Adverse events analysis helps in identifying the blood donors at risk of donor reactions, applying appropriate motivational strategies, pre-donation counseling, care during and after donation, developing guidelines and hemovigilance programme in countries with limited resources if a step-up approach is used. As per WHO Global Database Report on Blood Safety,<sup>17</sup> the national hemovigilance system is present in 42 (40%) of the 105 reporting countries with 24 countries (23%) being in process of development of such a system. 39 (37%) countries do not have a national hemovigilance system. Among the Asian countries a well established hemovigilance system is lacking and there is paucity of data on hemovigilance except in Japan.<sup>18</sup> In India, a national blood system has been launched on December 10, 2012.<sup>19</sup> This programme is an integral part of Pharmacovigilance programme of India.

## CONCLUSION

In order to have a well organized hemovigilance system

in developing countries like India, a comprehensive approach is required. A streamlined mechanism for data collection using standardized tools at hospital level and good coordination at national level can bring up effective hemovigilance system in a country. The data from a well functioning hemovigilance system can be used as quality indicator for monitoring blood safety and also contribute significantly to evidence-based medicine as well as help to introduce new and /or access the existing blood policies. There is need to strengthen and to bring uniformity in the hemovigilance system globally.

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