



ISSN NO. 2320-5407

Journal homepage: <http://www.journalijar.com>

INTERNATIONAL JOURNAL
OF ADVANCED RESEARCH

RESEARCH ARTICLE

Study of adverse events and predisposing factors in whole blood donors – at a tertiary care hospital

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Manuscript Info

Manuscript History:

Received: 12 February 2014
Final Accepted: 25 March 2014
Published Online: April 2014

Key words:

Adverse events, donors, vasovagal reactions

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Abstract

Lack of awareness and community motivation, compounded with fragmented blood transfusion services in our country, often leads to shortage of blood. Donor recruitment and retention are essential for ensuring adequate blood supply. However, adverse events (AEs) in donors have a negative impact on donor return.

Aims and Objectives:

To assess the frequency of AEs in whole blood donors and analyze the predisposing factors for AEs.

Material and Methods:

The study was conducted on whole blood donors over a period of 12 months from December 2012 to December 2013. All whole blood donations made at the centre were analyzed. All adverse events occurring during or at the end of donation were noted using a standardized format.

Results:

Overall 84 adverse events were reported in relation to 7668 donations, resulting in an overall adverse event rate of 1.09 %. Presyncopal symptoms, in other words vasovagal reactions of mild intensity, were the most commonly observed adverse reactions and accounted for approximately 48.80 % of all adverse reactions noted. Vasovagal reactions showed a significant association with young age, lower weight, first time donation status, female gender. Hematoma the second commonest AE was noted in donors 11(13.09%). Hematoma formation occurred significantly more when less trained staff performed phlebotomy.

Discussion and Conclusion:

Only 1.09% of blood donations were complicated by adverse events and most of these events were presyncopal symptoms. Our study confirms the fact that blood donation is a very safe procedure which could be made even more event-free by following certain friendly, reassuring and tactful practices. In conclusion, blood centres have an obligation to constantly monitor risks of blood donation and to make a concerted and committed effort to achieve the lowest possible rate of complication.

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Introduction:

Lack of awareness and motivation in the community, compounded with fragmented blood transfusion service in our country, often leads to shortage of blood and blood components. Generally, two strategies are adopted to meet the public demand of blood and its components – recruitment of new donors and retention of already recruited donors.

Replacement donors, who still form a high proportion of all whole blood donors in developing countries, can be retained as future voluntary donors if found non-reactive for transfusion transmissible infection. Adverse events (AEs) in blood donors can adversely affect donor recruitment and retention.

Blood donors normally tolerate the donation very well, but occasionally adverse reactions of variable severity may occur during or at the end of the collection. The adverse reactions that occur in donors can be divided into local reactions and systemic reactions.

1. Local reactions occur predominantly because of problems related to venous access. They are usually hematomas due to extravasations from the veins, caused by incorrect placement of the needle during the venipuncture. Pain, hyperemia and swelling may develop at the site of the extravasation. Other local events include pain due to slight trauma to the subcutaneous nerve endings. In most cases, however, these are banal complications that do not require any treatment. Local phlebitis and thrombophlebitis are more serious complications than the foregoing, but are very rare.
2. The systemic reactions, in contrast to the local reactions, can be divided into mild or severe. In most cases, they are vasovagal reactions than can be triggered by the pain of the venipuncture, by the donor seeing his or her own blood, by the donor seeing another donor unwell, by the anxiety and state of tension of undergoing the donation, etc. The systemic reactions are characterised by the appearance of pallor, sweating, dizziness, gastrointestinal disorders, nausea, hypotension, and bradycardia. Therapeutic intervention must be swift, otherwise this clinical picture, typical of a vasovagal reaction will progress into an episode of syncope of variable severity, which may or may not be complicated by the onset of tonic-clonic muscle spasms (convulsive syncope), accompanied by vomiting and loss of sphincter control.

While blood donation is a safe procedure, a small percentage of donors may experience an AE. The most frequent AE is usually a mild vasovagal reaction, but for the donor it is an unpleasant experience, and acts as a deterrent for repeat donation. It has been documented in various studies that 2–6% of donors experience an AE, but only 0.08–0.3% have a syncopal reaction where there is loss of consciousness.⁽²⁻⁴⁾

Method & Material:

The study was conducted on whole blood donors over a period of 12 months from December 2012 to December 2013. We had analyzed the data of adverse reaction which is maintained by A. D. Gorwala Blood bank. Criteria for the selection of whole blood donors were in accordance with the rules laid down in Drugs and Cosmetics Act, Ministry of Health and Family Welfare, Government of India. Blood collection was performed in the A. D. Gorwala blood bank of the Shree Krishna Hospital, Karamsad and in blood donation camps.

Blood was collected using a 16 gauge needle from the antecubital vein under proper aseptic technique. 350 ml of blood was collected from donors weighing between 45 - 55 kg and 450 ml from those weighing more than 55 kg. Minimum haemoglobin level was 12.5 g%. Haemoglobin screening was done by HemoCue Hb 301or CuSO₄ method. Pre-donation medical examination was done in all donors.

Donors were observed before, during, and after blood donation for any AEs. Post-phlebotomy observation was defined as the time until the donor left the donor site, which was usually 30 min after donation.

Results:

7668 donors had donated blood at A D GORWALA BLOOD BANK from December 2012 to December 2013, where 3879(50.58) were IN HOUSE and 3789(49.42) were IN CAMP donors,

Table- 1 Frequency of adverse donor reactions occurring in Camp and in house blood donations.

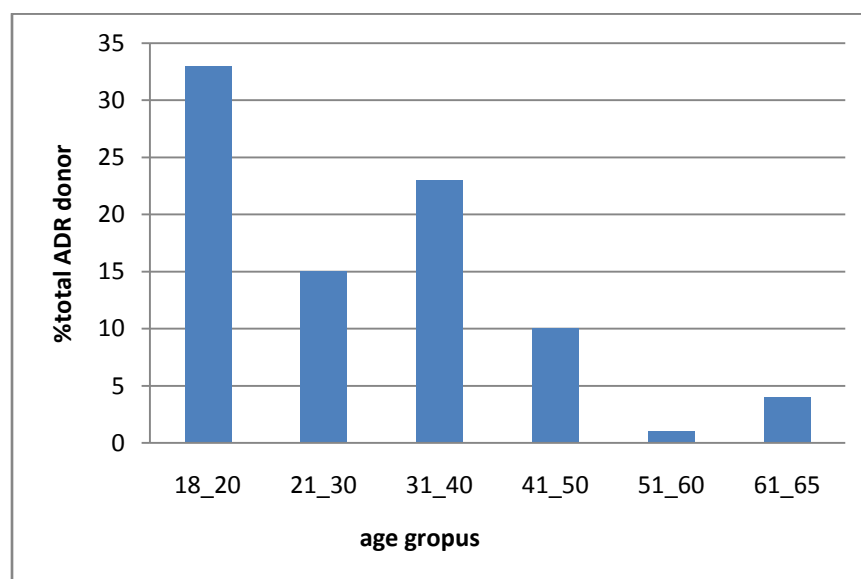
Blood donations	Total numbers of donors	Number of donors affected	Percentage
In camp	3789	52	1.37 %

In house	3879	32	0.82 %
Total	7668	84	1.09 %

Table 1 shows total 84 (1.09%) adverse donor reactions were noted during blood donation. 52(1.37%) adverse reactions were noted in camp and 32 (0.82%) during in house donations.

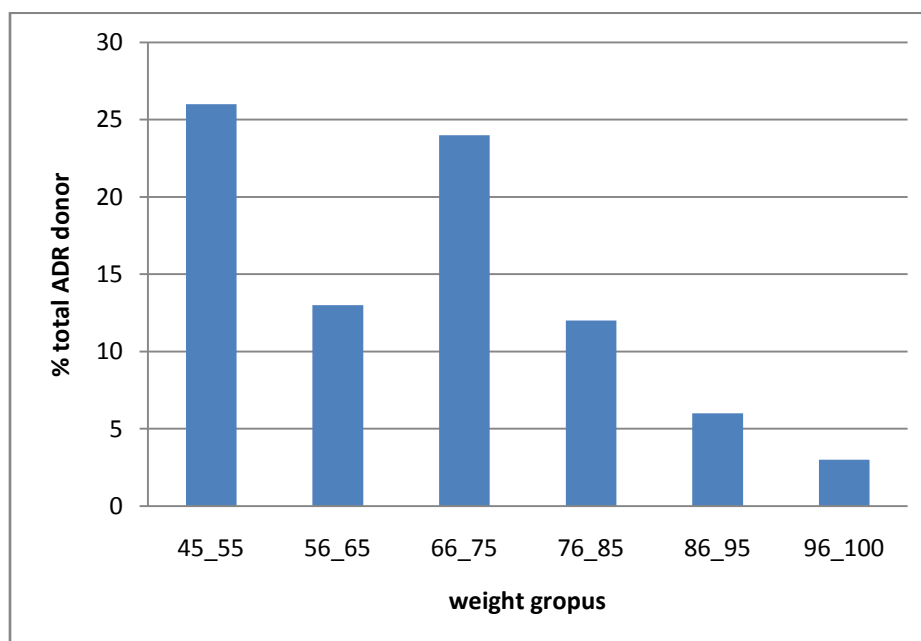
Figure-1 Age wise distribution of the various adverse donor reactions.

(n = 84)



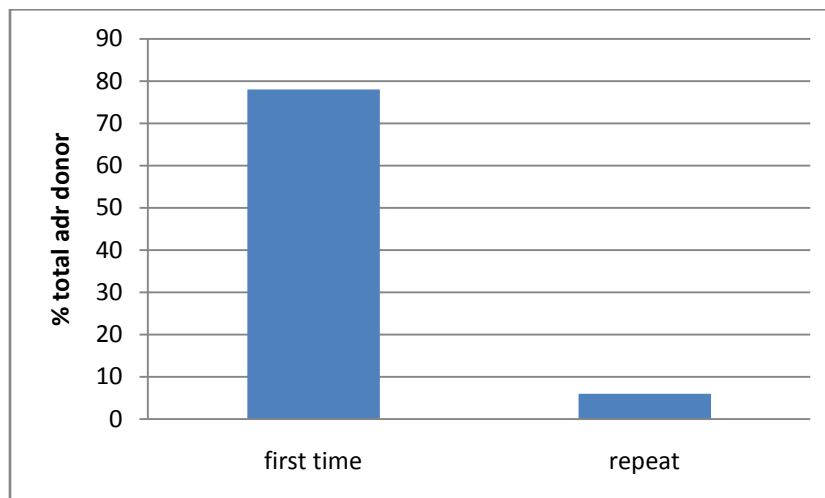
Most common donors that experienced adverse donor reactions belonged to the age groups of 18-20 years (39.3%) followed by donors in the age group of 31-40 years (27.4%).

Figure-2 Weight wise distribution of adverse donor reactions. (n = 84)



Most common donors that experienced adverse donor reactions belonged to the weight groups of 45-55 kg wt (31.0%) followed by donors in the weight group of 66-75 kg wt (28.6%)

Figure-3 Incidence of adverse donor reactions in first time and repeat donors.



Total 84 adverse donor reactions, 78 ADR was noted in first time blood donation and 6 ADR was noted in repeat time blood donation shown in fig.3

Table-2 Incidence of adverse donor reactions in male and female donors

Gender	Number of total blood donation	Number of donors affected	Percentage
Male	7343	76	1.03%
Female	325	8	2.46%
Total	7668	84	1.09%

Total 84 adverse donor reactions, 76(1.03%) ADR was noted in male blood donors and 8 (2.46%) ADR was noted in female blood donors.

Table-3 Type of Adverse donor reactions (n =84)

Type of adverse donor reactions	No. of donors affected	Percentage
Mild vasovagal reactions	41	48.80%
Moderate vasovagal reactions	25	29.76%
Severe vasovagal reactions	1	1.19%
Hematoma	11	13.09%
Difficulty with blood flow	6	7.16%

Total	84	100%
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Mild vasovagal reaction (48.80%) was the commonest adverse donor reaction experienced followed by moderate vasovagal reactions (29.76%) and hematoma (13.09%) formation, out of the total 84 ADRs noted.

Discussion:

Blood centers have a dual responsibility to provide an adequate supply of blood components to the communities they serve and to ensure the safety and well-being of their donors. The most common systemic and phlebotomy-related complications of blood donation (mild vasovagal reactions, haematoma), 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.

Although whole blood donation is considered to be safe, reports in the medical literature about the frequency of adverse events during donations show broad heterogeneity. ⁽⁴⁻⁶⁾

In our study, 1.09% percent of all whole blood donations were complicated by an adverse event. This is an 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% .^(7,8) Vasovagal reactions constituted 79.75% of all AEs and mostly mild in nature. This is correlates with study conducted by Naveen Agnihotri et al. ⁽⁹⁾

Highest reaction prevalence (39.3%) was seen in donors 18–20 years of age and was significantly higher. A study by France ⁽¹⁰⁾ 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. This is correlates with study conducted by Vasovagal reactions in whole blood donors at three REDS-II blood centers in Brazil by Thelma T. Gonçalves et al. ⁽¹⁰⁾

Frequency of reactions of the donor decreased as weight of the donor increased from 45 kg to more than 80 kg, an observation similar to that reported by Kasprisin et al. Newman ^(7,8) showed that reaction rate was inversely proportional to the weight of the donor while Boynton and Taylor reported that reactions were twice that expected in donors weighing less than 120 lbs. ⁽⁹⁾

As regards local reactions, haematoma was found to be the most common adverse event (13.09%). Since these complications are mostly experienced by the donor some time after the donation and we recorded only adverse events occurring during the donation period and stay in the recovery room, the rate of local adverse incidents observed in our study was very low.

Finally, like other author, we found a very low incidence of severe reactions (major syncopal reactions 1.19%) with no episodes necessitating hospitalization of the donor or administration of intravenous fluids. It is worth noting that the maximum volume of blood withdrawn during the donation (450 mL $\pm$ 10%) represents only about 10% of the total blood volume in a subject weighing 70 kg. Since at least 800–1,500 mL of blood, i.e. 15–20% of the total blood volume would have to be lost in order to be in at least class I risk of hypovolaemia, blood donors are unlikely to experience severe vasovagal reactions. ⁽¹⁰⁾

As part of our study we also assessed certain practices which could help to minimize the adverse incidents associated with blood donation. It is always advisable to provide a friendly, warm and comfortable atmosphere for the donor and to engage particularly anxious donors in conversation during donation, in order to distract their attention. It is also very important to react swiftly to initial complaints of giddiness, light-headedness, or pallor by the donor by stopping the donation immediately and raising the legs of the donor (anti-shock position) as pallor, sweating, agitation are harbingers of a severe vasovagal reaction which could be prevented by taking corrective measures right at the onset of symptoms. Donors are given refreshment, retained in the recovery room for at least 30 minutes before being sent away. In brief, donors are provided a hospitable environment that ensures safe donation in order to motivate them to make repeat donations in the future.

Only 1.09% of whole blood donations were complicated by adverse events and most of these events were mild vasovagal symptoms. Thus our study confirms the fact that blood donation is a very safe procedure which could be made even more event-free by following certain friendly, reassuring and tactful practices. In conclusion, blood centers have an obligation to constantly monitor risks of blood donation and to make a concerted and committed effort to achieve the lowest possible rate of complications.

Donor safety is an essential prerequisite to increase voluntary blood donation. AE 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.

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