# Adverse reactions in whole blood donors: an Indian scenario

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**Background**. Whole blood donation is generally considered to be a safe procedure, but occasionally adverse reactions of varying severity may occur during or at the end of the collection. The aim of the study was to estimate the frequency and type of adverse events occurring during blood donation and to assess the practices which would help to minimise them.

**Materials and methods**. This retrospective single-centre study was conducted from June 2007 to November 2009 at a regional blood transfusion centre. All whole blood donations made at the centre were analysed. All adverse events occurring during or at the end of donation were noted using a standardised format.

**Results**. Overall 113 adverse events were reported in relation to 19,045 donations, resulting in an overall adverse event rate of 0.6%, that is, an incidence of 1 in every 166 donations. Presyncopal symptoms, in other words vasovagal reactions of mild intensity, were the most commonly observed adverse reactions and accounted for approximately 70% of all adverse reactions noted.

**Conclusions**. Only 0.6% of blood donations were complicated by adverse events and most of these events were presyncopal symptoms. Our study reinforces 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.

**Key words**: blood donation, adverse events, vasovagal reaction.

## Introduction

Whole blood donation is generally considered to be a safe procedure, but occasionally adverse reactions of varying severity may occur during or at the end of the collection. The unremitting need and increasing demand for blood components constantly challenges blood centres to maintain a safe and adequate supply of blood from a decreasing pool of eligible donors, at the same time reducing the frequency of adverse events associated with blood donation which would otherwise decrease the rate of repeat donations. The aim of this study was to estimate the frequency and type of adverse events occurring in whole blood donors at our Regional Blood Transfusion Centre from June 2007 to November 2009 and to assess the practices which would help to minimise them.

## Materials and methods

This is a retrospective, single-centre study of all adverse reactions related to all the consecutive whole blood donations made between June 2007 and November 2009. All donations were collected using a 16 gauge needle inserted into a vein in the antecubital area. Strict asepsis was maintained by cleaning the site of venipuncture sequentially using savlon, betadine and alcohol. The minimum weight required for donation was 45 kg and the lowest acceptable haemoglobin concentration was set at 12.5 g/dL. For whole blood donation 350 mL of whole blood were collected from donors weighing between 45 and 55 kg while donors weighing more than 55 kg donated 450 mL of whole blood. As part of our study we assessed certain practices which could help to minimise 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 the donation, in order to distract their attention. It is also very important to react swiftly to initial complaints of giddiness, light headedness, 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 and retained in the recovery room for at least 30 minutes before being sent away.

The classification scheme employed for recording the adverse events was suggested by the American Red Cross Hemovigilance Program that classifies complications into defined categories with severity ratings (minor/major) for certain types of reaction[1,2]. Presyncopal symptoms include pallor, sweating or light-headedness without loss of consciousness. Syncopal types of complications are classified as minor if there is a transient loss of consciousness lasting less than one minute, while prolonged loss of consciousness for more than a minute or complicated by loss of bowel/bladder control, seizures or convulsions is said to be a major syncopal complication. Local adverse events include haematomas which can be small (<25.8 $mm^2$) or large (>25.8 $mm^2$), bruises, infiltration, allergic reactions, and a tingling/burning sensation.

## Results

We recorded a total of 19,045 whole blood donations (350 mL/450 mL) during the study period of which 18,635 were made by males and 441 by females. The donations were made by 16,745 first-time donors and 2,331 repeat donors. There were 1,778 voluntary donors and 17,298 replacement donors. Overall 113 adverse events were reported in relation to the 19,045 donations, resulting in an overall adverse event rate of 0.6%, that is, an incidence of 1 in every 166 donations.

Presyncopal symptoms, in other words vasovagal reactions of mild intensity were the most commonly observed adverse reactions and accounted for approximately 70% of all adverse reactions noted. They affected 0.4% of the donors (79/19,045). Major syncopal complications/severe adverse reactions were very rare, as they occurred in relation to 0.005% (01/19,045) of all donations; none necessitated hospitalisation of the donor. The frequency distribution of the various types of adverse reactions that occurred in donors during the study period is presented in Table I.

**Table I** - Frequency of various types of adverse reactions occurring in the donor population

| Type of adverse reaction | Number of donors affected | Percentage |
|---|---|---|
| ***Systemic complications*** | | |
| Presyncopal symptoms | 79 | 0.4% |
| Syncopal complications (minor) | 9 | 0.05% |
| Syncopal complications (major) | 1 | 0.005% |
| ***Local complications*** | | |
| Haematoma | 14 | 0.07% |
| Numbness/tingling/ soreness of arm | 10 | 0.05% |

## Discussion

Blood centres 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 (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[3,4]. 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[5-7]. The aim of this study was to assess the frequency of various types of adverse reactions associated with blood donation and to assess the measures that would help prevent or reduce the occurrence of these incidents.

Donation-related adverse events were recorded according to standardised criteria as suggested by The American Red Cross Hemovigilance Program[1]. In our study, 0.6% percent of all whole blood donations were

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% [2,3,8-10]. Presyncopal symptoms, which include giddiness, sweating or light-headedness without loss of consciousness, accounted for approximately 70% of all adverse events (69.9%, 79/19,045). This is in accordance with the results of a study conducted by Crocco *et al*. in 2009, who found that vasovagal reactions of mild intensity constituted 71% of all adverse incidents reported.

As regards local reactions, haematoma was found to be the most common adverse event (0.07%, 14/19,045). Local reactions are mainly caused by blood donation-related neurological needle injuries which are commonly experienced by the donors after the donation in the form of haematomas, numbness/tingling, excessive or radiating pain, loss of arm/hand strength. The time to recover from these complications can range from less than 3 days to more than 6 months[11]. 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 authors[2,8,9], we found a very low incidence of severe reactions (major syncopal reactions 0.005%, 1/19,045) with no episodes necessitating hospitalisation of the donor or administration of intravenous fluids. It is worth noting that the maximum volume of blood withdrawn during the donation (450 mL ± 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[12].

As part of our study we also assessed certain practices which could help to minimise 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 0.6% of whole blood donations were complicated by adverse events and most of these events were presyncopal 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 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 complications.

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Received: 10 January 2010 - Revision accepted: 8 July 2010
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