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Evaluation of Adverse Events Associated With Allogenic Whole Blood Donation Observed At a Tertiary Care Center in Bikaner, Rajasthan (India)

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Introduction

Background: Although the blood donation process is usually safe and uncomplicated, occasionally adverse events of variable severity may occur during or after the phlebotomy. Adverse events have negative impact on donor recruitment and retention. To assess the frequency and type of adverse events in our center, we analyzed all adverse events among blood donors.

Method: Blood bank based cross-sectional analysis of adverse events during and immediately after allogenic whole blood donations, was carried out during the period of one year from July 2015 to June 2016, among a total of 26,649 blood donors. The blood donors were monitored and compared for common adverse events like vasovagal reaction (VVR), hematoma, nausea, vomiting etc. The data were statistically analyzed and chi square test was applied using PRIMER software.

Result: Total of 802 (3.01%) adverse events were observed in blood donors. VVRs with mild intensity (with or without transient syncope) were the most commonly observed adverse events (2.16%), especially in first time donors (1.37%); followed by hematoma (0.65%), nausea (0.14%) and vomiting (0.06%). The incidence of adverse events was found significantly higher among first-time-donors compared with those having H/o previous donation (P=0.0001). The association of incidence of adverse donor events was found statistically insignificant (P>0.05) with sex and type of donation (replacement and voluntary).

Conclusion: Knowledge about incidence rates and patterns of adverse donor events enables to train and prepare personnel in the phlebotomy area to respond quickly to those reactions and efficiently reduce the chances of such untoward events among blood donors, ultimately improving blood donor return rate.

Keywords: Phlebotomy, adverse events, blood donors, donor safety, donor retention.

Introduction

Although the blood donation process is usually safe and uncomplicated, occasionally adverse events (AEs) of variable severity may occur during or after the phlebotomy. Adverse events have negative impact on donor recruitment and retention.

Concerning adverse events, the vasovagal ones have been mainly evaluated in previous studies, but donors' arm injuries such as bruises and haematomas, traumatic injuries,[1,2] arterial puncture phlebotomy[3] and neurologic needle injuries[4] have also been documented.[5]

Our blood bank is the second largest government blood bank in the state of Rajasthan and the annual whole blood collection of this blood bank is around 30,000. The purpose of this study was firstly to find the incidence of

various adverse reactions among allogenic whole blood donors during or immediately after blood donation in a blood bank of a tertiary care hospital in Bikaner (Rajasthan) and their association with factors like gender, type of blood donation (volunteer/family or replacement donors) and frequency of blood donation (first-time or repeat donors).

Material and Methods

The present study was conducted at the Department of Immuno-Hematology and Transfusion Medicine at S.P. Medical College & A.G. Hospitals, Bikaner (Rajasthan), India. The blood donors who donated whole blood at our blood bank and outdoor camps were included in the study. Blood bank based cross-sectional analysis of adverse events during and immediately after whole blood donations, was done during the period of one year from July 2015 to June 2016, among a total of 26,649 blood donors.

Physicians qualified and experienced in blood banking, performed the brief physical examination and selection of blood donors according to the guidelines for selection of blood donors laid down by Ministry of Health and Family Welfare, Government of India in Drug and Cosmetic Rules. A trained nurse performs the phlebotomy in the donor room itself with a 16-G needle as the donor laid in a supine position on the donor couch. The blood is collected in blood bags made by HLL and Mitra manufacturers with 350 ml collection capacity.

When blood donation was completed, the donors remained laid for 5-10 min and if they felt well, they were allowed to sit up and given light refreshment, being under careful supervision for 15-20 min at least. If they felt well, they were allowed to leave the blood bank/camp site with instructions regarding post-donation complications and safety. The blood donors were monitored during and immediately after the blood donation and compared for common adverse events like vasovagal reaction, hematoma formation at venepuncture site, nausea, vomiting etc. The data were analyzed using PRIMER software.

Results

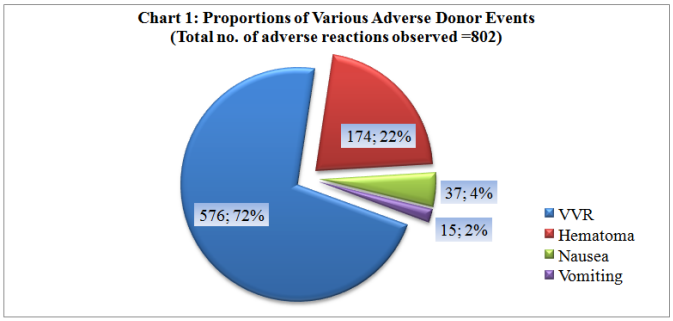
During the study period, a total of 33,520 volunteers reported for the blood donation either at our blood bank or at outdoor blood donation camps. Amongst them, 6,872 individuals were deferred from blood donation because of various reasons and 26,649 volunteers were accepted for the blood donation based on donor selection criteria. The deferred volunteers also included individuals who were (or looked so) anxious, restless, sleepless, stressed out, women under menstruation and having H/o fainting episodes; because of being at risk of adverse donor reactions. These criteria were based on our physicians' experience and are included in the European and AABB (American Association of Blood Banks) guidelines about blood donor general appearance and lead to increased rate of adverse donor reactions. Among 26,649 donors, the distribution of blood donors, based on sex, frequency of donation and type of donation, is given below in Table (1).

Table 1: Primary distribution table of blood donors.

Characteristics	No. of donors	% of total donors
Sex		
Male donors	26,348	(99.99%)
Female donors	301	(0.01%)
Frequency of donation		
First time donors	7,994	(30%)
Donors having H/o past donation(s)	18,655	(70%)
Type of donation		
Voluntary/Family donors	24,650	(92.5%)
Replacement donors	1,999	(7.5%)
Total no. of donors	**26,649**	**(100%)**

802 (3.01%) adverse events were observed among these total 26,649 blood donors during or after the phlebotomy, while the donors were there within the blood bank premises only. Vasovagal reactions with mild intensity (with or without transient loss of consciousness)

were most commonly observed (2.16 %; 576/26,649), followed by hematoma (0.65%; 174/26,649), nausea (0.14%; 37/26,649) and vomiting (0.06%; 15/26,649). Chart (1) below, depicts proportions of various adverse donor events in the form of an exploded pie.



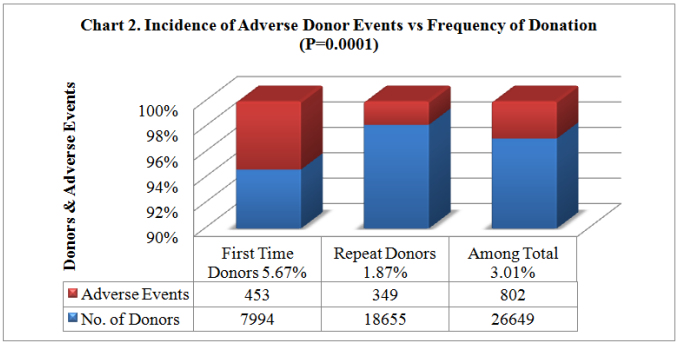
None of the blood donors were reported to have any severe complications or prolonged loss of consciousness (>60 sec). All the donors with adverse reactions were restored in the blood bank/camp site only, and their admission to the hospital was not required.

Incidence rates of adverse events among male and female donors were observed to be 3.02% (797 cases among 26,348 males) and 1.67% (5 cases among 301 females) respectively. The incidence rates of overall adverse donor events; and VVR and hematoma per se, compared with male versus female donors, were found statistically insignificant (Chi square test; P>0.05). Gender wise distribution of various adverse events among blood donors during or immediately after the blood donation is shown in Table (2).

Table 2. Distribution of various adverse donor events, as per sex.

Events	Among male donors	Among female donors	Total (% Incidence)
Whole blood donations	26,348	301	26,649
Vasovagal reactions	573	3	576 (2.16%)
Hematoma	173	1	174 (0.65%)
Nausea	36	1	37 (0.14%)
Vomiting	15	0	15 (0.06%)
Grand Total	**797**	**5**	**802 (3.01%)**

The incidence of adverse events was significantly higher among first-time-donors compared with those having H/o previous donation (Chi square=274.946; dof=1; P=0.0001), as illustrated by 100% stacked columns in Chart (2).



Incidence of VVRs was observed as significantly higher among first time donors (365/7,994; 4.56%) compared with that among those having H/o previous donation (211/18,655; 1.13%) (Chi square=310.587; dof=1; P=0.0001). When incidence of Hematomas was compared among first time donors (59/7994; 0.74%) and among repeat donors (113/18655; 0.61%), found to be insignificant (Chi square=1.328; dof=1; P=0.249). These comparisons explain that main difference in the incidence of adverse events among first time and repeat donors was due to VVRs.

Incidence of adverse events was found to be higher among replacement donors who donated blood for their relatives or friends (67/1999; 3.35%) as compared among voluntary/family donors who donated either in the blood donation camps or donated for their first degree relatives at the blood bank (735/24650; 2.98%). This difference was found statistically insignificant (Chi square=0.745; dof=1; P=0.388).

Discussion

The present study showed the incidence of adverse reactions among blood donors to be 3.01%. This percentage is in line with the ones reported by Agnihotri et al,[6] Newman et al[7] and Trouern-Trend et al[8]; but

lower than that observed by other authors such as Boynton & Taylor (8.9%)[9] and Newman (1997) (11-21%).[1]

Comparatively lower incidence rate in present study could be explained by the fact that the physical examination and selection of blood donors is performed by experienced physicians and therefore we take a better evaluation of blood donors who have predisposition to complications. But even lower incidence have been observed by some authors, like Pathak et al (0.6%),[10] Zervou et al (0.87%),[5] Crocco & D'Elia (1.20%)[11] and Damulak et al (2.05%),[12] may be because of differences in donor demographics, behaviour of collection staff, skill development refresher trainings of phlebotomists and reporting system to obtain information regarding adverse events.

We believe that negligible incidence of injuries due to fainting, compared with other studies, is the result of efficient pre-donation counseling and careful attendance during and immediately after the blood donation. First, a physician and a permanent trained nurse are present in the blood donation room who recognize the first mild symptoms of a reaction immediately and give the appropriate care to help to the donors, laying the donor with the mild early symptoms of fainting on a bed with head end at lower position. Second, after blood donation, while the donors have short refreshment, they are under close attendance by the personnel and only when the medical staff is sure that the donors feel well, allow them to leave blood bank/camp site. This process helps to prevent injuries in the case of fainting.

Female blood donors, in a study by Damulak et al,[12] had significantly higher rate (3.2%) of adverse effects than their male counterparts (1.4%) similar to higher adverse reactions among female donors (5.97% in females versus 4.94% in males) reported among subjects in a study by Mahbub-Ul Alam.[13] They concluded that this calls for keen observation, care and attention to female blood donors in particular, during and after donation to identify early signs of discomfort for immediate prevention and mitigation of evolving adverse effects.

In contrast to these studies, at our centre, although statistically insignificant (P>0.05), we found a higher rate of adverse events among male donors (3.02%) than that among female donors (1.67%); which could be explained by the fact that keen observation, care and attention have already been practicing while dealing with female blood donors; because of the fact that in our area, the prevalence of anemia is higher among female donors (26.4%) than male donors (1.1%).[14] Lower rate of adverse events among female donors might also be attributed to outnumbered male donors than female donors (99.99% versus 0.01%) in present study, which suggests studies with still larger sample sizes.

Our findings show that the first-time blood donors had a statistically significantly higher possibility to have an adverse reaction compared with the repeat donors. The difference in the incidence of hematomas between first-time and repeat donors was found statistically insignificant. But the difference in the incidence of VVRs does make a difference to overall higher incidence of adverse events among first-time donors when compared with repeat donors, as this difference was found to be statistically highly significant.

One reason of this could be that it is expected for the first-time donors to be more anxious than repeat blood donors, because the procedure of blood donation is unknown to them. The stress has direct emotional effect and may affect central neural activity stimulating peripheral vasodilatation.[15] In addition, studies have shown that stress affects peripheral ventricular baroreceptor sensitivity in young people.[16,17] Secondly, sometimes voluntary young donor are over-enthusiastic and careless,

who ignore the instructions of the phlebotomist, especially immediately after the donation. Suddenly getting up from the donor's couch just after the removal of needle might cause fainting in such donors. Therefore, during the first donation, the donor may experience a vasovagal reaction, and in most cases this experience will determine whether the donor will continue to give blood or not.

Association between adverse events and type of donation was found statistically insignificant in the present study (P>0.05). Most common reasons related to a reaction, some donors reported fasting, apprehension, anxiety, stress, tiredness, sleeplessness, full stomach or a combination of these factors; which the donors concealed during pre donation counseling. The donors who conceal some of these factors are mainly replacement donors, trying to give blood for their relatives or friends and highly motivated voluntary donors who desperately want to donate blood because of high level of influence of some spiritual master or socio-political leader.

Conclusion

Vaso vagal reaction of mild intensity (with transient syncope) was found to be the most common adverse event associated with blood donation which was significantly higher (P<0.05) among first-time-donors. But moderate and complicated adverse donors events are also not uncommon. Obtaining such data on incidence of adverse events enables to train and prepare personnel in the phlebotomy area to respond quickly to those reactions to improve safety and comfort of the donor. Also it helps in minimizing negative impact on donor recruitment and retention, thereby improving blood donor return rate. Such studies should be done with still larger sample sizes in all parts of the country, comparing more parameters that might have causative potential of adverse donor events.

Other than during and immediately after the phlebotomy, delayed adverse reactions might also occur among whole blood and apheresis blood donors as well. A simple and efficient reporting system should be developed and adopted at blood banks to know the real impact of immediate as well as delayed adverse reactions, so that effective measures could be worked out to reduce the burden of adverse donor events and thereby increasing the retention of donor pool.

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