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Adverse Reactions in whole blood donors at a tertiary care center, Gwalior

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Abstract
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 collection. However, adverse reactions in donors have a negative impact on donor return which makes the donor recruitment and retention difficult.
Aims and Objects
The aim of the study was to estimate the frequency and type of adverse reactions occurring during whole blood donation and to assess the practices which would help to minimize them.
Materials and methods
This retrospective, two years, single-centre study was conducted from January 2016 to December 2017 at blood bank, G. R. Medical College, Gwalior, India. All whole blood donations made at the centre were analyzed. All adverse reactions occurring during or at the end of donation were noted using a standardized format.
Results
Overall 664 adverse reactions were reported in relation to 38797 donations, resulting in an overall adverse reaction rate of 1.66 %. Presyncopal symptoms, in other words systemic vasovagal reactions of mild intensity were the most commonly observed adverse reactions and accounted for approximately 86.96% followed by severe systemic reactions 9.32% and local reactions 3.73% among all adverse reactions noted.
Conclusion
The incidence of adverse reactions associated with whole blood donation in this study was 1.66% while national and international figures vary from 0.6% to 4.5% or more. The young age donors, first time donors, female donors and replacement donors are at higher risk of contracting adverse reactions.

Key Words: Adverse reactions, Blood donation, Blood donors, Vasovagal reactions, Syncope

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I. Introduction

Blood donation is considered to be one of the most valuable contributions of an individual to the community. Blood transfusion is vital and fundamental in medical practice since there is no efficient substitute to human blood when needed. The collection of whole blood is usually restricted to healthy donors, so ensuring the safety of blood donors is an essential factor to encourage them to donate and ensure their return in the near future [1]. According to WHO, the safest blood donors are voluntary, non-remunerated and from low-risk populations. WHO has set the goal for all countries to obtain all blood supplies from voluntary unpaid donors by 2020 [2]. Although, blood donation has relatively low risk rate and donors undergo meticulous screening for any contraindications prior donation, some adverse events arise occasionally during or after the process [3]. Donor adverse reaction has been defined as symptom or sign of donor discomfort that is severe enough to either warrant the donor calling for attention of the blood bank staff or was noticed by the staff [1]. Studies have shown the rate of adverse events/reactions vary from 0.59% to 33%. [4, 5, 6]. However, this may be because of the lack of a common standard to define the adverse event and the difference in the donor selection criteria. Results of single center studies in India concluded upon the rate of reactions varying between 0.6-2.33% [7, 8], however, serious adverse reactions leading to loss of consciousness are rarely encountered (reported in only 0.08–0.3% of the donor population) [9]. It is vital that blood donors (particularly voluntary donors) are retained and encouraged to become regular donors as a way of increasing the availability of donor units in blood banks. This laudable innovation has however been observed to be significantly hampered by the occurrence of adverse reactions in blood donors following donation. [10]. A previous study by Newman BH *et al* 2006 [11] has shown

that donor reaction had the most negative impact on the blood donor return rate (85% reduction). Some donor characteristics including young age, low weight, first-time donation status, female gender, and Caucasian race have been variously reported to reliably predict for the development of adverse reactions in potential blood donors [12, 13]. Another study, predictors of adverse events among young blood donors were more prevalent in those with lower weight, first time donors and females [14]. France CR *et al* 2010 reported that higher rate of reactions was associated with a significantly lower likelihood of repeat donation. [15].

The adverse reactions that occur in donors can be divided into local reactions and systemic reactions. Local reactions occur predominantly because of problems related to venous access. They are usually hematomas, pain, hyperemia and swelling may develop at the site of extravasation. Other local events include pain due to slight trauma to the subcutaneous nerve endings. In most cases these are non fatal complications that do not require any treatment. Local phlebitis and thrombophlebitis are more serious complications than the foregoing, but are very rare [3, 16].

The systemic reactions in contrast to the local reactions can be divided into mild or severe. In most cases, they are vasovagal reactions that can be triggered by the pain of venepuncture, 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 characterized by the appearance of pallor, sweating, dizziness, abdominal cramps, nausea, hypotension and bradycardia, etc. Therapeutic intervention must be swift, otherwise this clinical picture typical of vasovagal reaction will progress to 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 [3, 16].

The aim of this study was to estimate the frequency and type of adverse events occurring in whole blood donors, its management and prevention at our blood bank, G. R. Medical College Gwalior, India.

II. Materials and Methods

The present two years study was conducted at blood bank, G. R. Medical College Gwalior which is a Tertiary Health Care Centre from January 2016 to December 2017. All adverse reactions related to all whole blood donations were recorded. All donations were collected as per Departmental SOPs. Strict asepsis was maintained by cleaning the site of venipuncture sequentially using betadine and alcohol. The minimum weight required for donation was 50 kg and the lowest acceptable haemoglobin concentration was set at 12.0 g/dl. A warm, friendly and comfortable atmosphere for donors is provided at our department. Those donors who complain of adverse reactions like giddiness, light headedness, pallor are managed by stopping the donation immediately and raising the legs of donor (anti shock position) as pallor, sweating, agitation are harbingers of severe vasovagal reaction which could be prevented by taking corrective measures right at the onset of symptoms. Donors are given refreshment and retained in donor's rest room for at least 30 minutes before being sent away.

The classification scheme employed for recording the adverse events was as suggested by the American Red Cross Hemovigilance Program that classifies complications into defined categories with severity ratings (minor/major) for certain types of reaction [7, 17].

The data of adverse reactions related to whole blood donations was collected, retrieved, tabulated, summarized and compared statistically by frequency distribution and percentage proportion. Chi square (X2) test was applied to know the significant (*p* value) ratio of difference statistically.

III. Results

A total of 38,797 donors were donated blood within the study period, comprising of 35349 (91.11%) males and 3448 (8.89%) females *(p<0.001)*, the mean age of the donors was 33.22 ± 7.63 years (range of 18–60 years). The average weight of the donor in the study was 68.2 ± 10.2 Kg. There were 36859 (95%) voluntary and 1938 (5%) *(p<0.001)* were replacement donors in this study.

Overall prevalence of donors adverse reaction rate in the study was 1.66% (n=644 /38,797), statistically significant *(p<0.001*). Prevalence rate of adverse reaction among male versus females donors was 1.59% (n= 561/35349): 2.41% (n= 83/3448) while among voluntary versus relative donors it was 1.60% (n=590/36859); 2.78 % (n=54/36859) respectively *(p<0.001*).

Incidence of adverse reactions was higher among female donors 2.41% *(p<0.001)* , replacement donors 2.78% (*p<0.*001), donors <30 years 2.09% (*p<0.*001) and first time donors 1.84% *(p<0.001)* compared to the male donors 1.59 %, voluntary donors 1.60%, ≥30 years old 1.39% and previous donors (0.99%) respectively. However, parameters like weight, Hb g/dl and blood pressure of donors have no statistically significant correlation with adverse reactions in the present study. (Table 1)

Table1. Incidence of adverse reactions with donor characteristics

	Sample	Adverse reaction n (%)	No adverse reaction n (%)
Total	38,797	644 (1.66)	38153(98.34)
		χ^2=93.47,p-value: 0.000001*	
Gender			
Male	35349	561(1.59)	34788(98.41)
Female	3448	83(2.41)	3365 (97.59)
		χ^2=1 12.67 p-value : 0.000373 *	
Type of donation			
Voluntary	36859	590(1.60)	36269 (98.40)
Replacement	1938	54 (2.78)	1884 (97.22)
		χ^2=15.71, p-value :0.000074*	
Age of the Donor			
< 30 Years	18,402	383 (2.09)	18019 (97.91)
≥30 Years	20375	264 (1.39)	20111 (98.61)
		χ^2=27, p-value:0.000001*	
Donation History			
First time	30426	561(1.84)	29865 (98.16)
Previous History	8371	83 (0.99)	8288 (99.01)
		χ^2=29.11, p-value : 0.000001*	
Weight of donor			
< 70 Kg	19472	320 (1.64)	19152 (98.36)
≥ 70 Kg	19325	324 (1.67)	19001 (98.33)
		χ^2=0.05 , p-value :0.816857	
Hemoglobin Hb g/dl			
12-14	25480	430 (1.68)	25050 (98.32)
14.1 and above	13317	214 (1.60)	13103 (98.40)
		χ^2=0.34, p-value : 0.557296	
Blood Pressure			
Normal/Pre-hypertensive	29806	480 (1.61)	29326 (98.39)
Hypertensive	8991	164(1.82)	8827 (98.18)
		χ^2 =1.87 , p-value : 0.171763	

n= frequency,%=percentage, χ^2**=chi square,** *p*= *p*- value

In the present study, adverse reactions to blood donations were observed in 644 donors; constituted of mild systemic complication 86.96% (560/644), severe systemic reaction 9.32% (60/644) and local adverse reactions 3.73% (24/644) (figure 1). Most commonly encountered adverse reaction was dizziness 33.54% followed by pallor 30.12%, nausea/vomiting 15.84%, chills 3.11%, hypotension 3.11%, nervousness 2.79%, hematoma 2.79%, syncope 2.48%, headache 1.55%, respiratory problem 1.55%, emesis 1.24%, diaphoresis 0.93%, allergic 0.62% and numbness/tingling 0.31%.(Table 2)

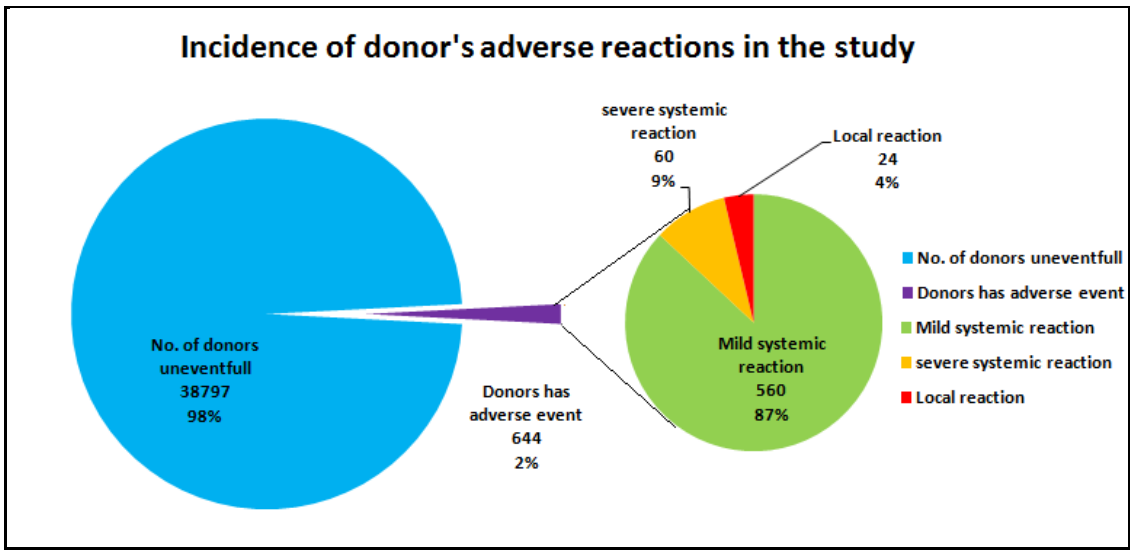

Figure1. Incidence of donor's adverse reaction in the study

Table 2. Frequency of various types of adverse reactions occurring in the donor population

Type	Number	Percentage
Systemic Complications		
Mild	**560**	**86.96**
Chills	20	3.1
Nausea/Vomiting	102	15.84
Pallor	194	30.12
Dizziness	216	33.54
Nervousness	18	2.79
Headache	10	1.55
Severe	**60**	**9.32**
Hypotension	20	3.11
Syncope	16	2.48
Respiratory Problem	10	1.55
Diaphoresis	6	0.93
Emesis	8	1.24
Local complications	**24**	**3.73**
Hematoma	18	2.79
Numbness/ Tingling	2	0.31
Allergic	4	0.62

IV. Discussion

There was a male dominated donor pool (91.11%) in the present study as similarly reported in our previous study (96.16%) [18]. Majority of the studies within India have also described a large number of male donors compared to female donors [19, 20], which are comparable with countries like Bahrain, Kuwait, Yemen, Qatar etc. While, in countries like Australia and Finland males and females donate their blood in almost same proportion [21].

In present study, average age of donors was 33.22 ± 7.63 years, similarly reported by Dogra A *et al* 2014 [3] 32 ± 9 years while younger age of donors was reported by John C A *et al* 2017: 30.64 ± 7.23 years [23], Agrawal RK *et al* 2016 : 28.2 ± 5.5 years [22] and Almutairi H *et al* 2017: 26.5±7.9 years [24]. The average weight of the donors in the study was 68.2 ± 10.2 Kg while in the study of Agrawal RK *et al* 2016 [23], it was 73.1 kg (SD: 11.3). Voluntary donors in the study were 95% which is very close to the target of 100 % voluntary blood donation , a goal set by WHO by the year 2020 [25].

We observed that women donors were at a significantly higher risk of complications (*p<0.001)* compared to their male counterparts which are in agreement with earlier studies [1, 9, 12, 26, 27] while no significant difference between them was observed by Almutairi H *et al* 2017 in their study [24] . Also, the rate of complications is decreasing with increasing age (*p<0.001)* and it is in agreement with the earlier studies [1, 4, 9 12, 27, 28, 29]. In our study replacement donors are more prone to adverse reaction in comparison with voluntary donors (*p<0.001)* which is in agreement with the earlier studies [1, 30]. In our study, first time donor is on high risk than those donated previously (*p<0.001)* which is in agreement with the study of Almutairi H *et al* 2017 [24]. This is thought to occur as a result of the "opponent-affective theory" which states that repeated exposure to adverse stimuli gradually decreases the intensity of response to such stimuli [30]. It is, therefore, likely that the repeated blood donations enabled the voluntary donors to become well acclimatized to the routines of donation, as against family replacement donors who may only donate at irregular intervals [22]. However, this study didn't reveal a significant relationship of adverse event with weight, haemoglobin and blood pressure of the donor while other studies reported that it has inverse relationship with weight [1] and has direct relationship with haemoglobin [24].

In our study, the overall prevalence of donor's adverse reaction rate was 1.66%. This is in agreement with the study by John CA *et al* 2017 [22] of 1.60%. It was higher than some other studies [6, 7] in which they reported 0.6-0.8% and lesser than several other studies [1, 4, 14, 17, 23] where they reported >2.2 % complications (Table 3). However, this may be because the significant differences in the definitions, the mechanism for identification of the complication, difference in the donor selection criteria and lack of a common standard to define the adverse event.

Table 3 Comparison of frequency of adverse donor reactions reported in different studies

S.No	Study	Year	adverse donor reaction reported
1.	Crocco et al	2007–2009	2.2 %
2.	Gonçalez TT et al	2007-2009	2.3%
3	Agnihotri N et al	2002–2003	2.5 %
4.	John C A et. al	2015	1.6 %
5.	Pathak C et al	2007–2009	0.6 %
6.	Sorensen BS et al	2008	0.8%
7.	Agrawal et al	2011-2014	3.2%
8.	Eder AF et al	2009	4.35%
9.	Present study	2016-17	1.66 %

Vasovagal reactions, a systemic complication of mild intensity (with variable signs and symptom like chills, nausea/ vomiting , dizziness, pallor, nervousness and headache) was the most commonly observed and accounted for approximately (560/644) 86.96 %, constituted over all incidence (1.44%), which are nearly in accordance with the studies by Pathak C *et al* 2011 (70%) [7], and Crocco *et al* in 2009 (71%) [17]. These symptoms are self limiting and donor recovered with conventional methods of management at donation premises.

Local complications which constituted (24/644) 3.73% of total adverse reaction and over all incidence in the study was 0.06% comprise of; hematomas (18/644) 2.79%, allergic (4/644) 0.62% and numbness/tingling (2/644) 0.31% cases. 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 hematomas, numbness/tingling and some time excessive or radiating pain, The time to recover from these complications can range from less than 3 days to more than 6 months, reported by Newman BH *et al* 1996 [31]. In our study, symptoms are mild and donor recovered within a week with or without treatment. Localized allergic reaction in the study was due to allergy with the antiseptic solutions applied to the venipuncture site.

Syncopal reactions, a systemic complication of severe intensity was observed (60/644) 9.32% of total adverse reaction and it's over all incidence was (60/38797) 0.15% in the study while low incidence was reported by Pathak C *et al* 2011(0.005%), Crocco I *et al* 2009 (0.004%) and Popovsky MA *et al* 1995 (0.0005%). In our study, we have not encountered any severe episode of syncope, where hospitalization of the donor or administration of intravenous fluids to the donor is required. The volume collected from donor in the study was 350 and 450 ml (400± 50) according to the weight of donor which represents only about less than 10% of the total blood volume in a subject. 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 [32]. Studies have observed a significant effect of offering fluids and snacks before starting the donation on the development of adverse events [33–34].

Management of donor adverse reaction if happen is a vital for blood bankers because it affects the voluntary blood donation [10]. Study by Newman BH *et al* 2006 [11] has shown that donor reaction had the most negative impact on the blood donor return rate (85% reduction).

V. Limitations of the study

This study had some limitations. Delayed adverse reactions associated with blood donation that usually occur after leaving the blood donation center were not fully investigated because poor turnout of donors to report the adverse reaction. In addition, although the blood donor center has policies and procedures regarding the recognition, handling and managing of such adverse events, a clear distinction between the severities of adverse reactions may not be perfectly established. In other words, categorizing these is subjective to the assessment of technicians, nurses and medical officer on duty.

VI. Conclusion

The incidence of adverse reactions associated with whole blood donation in this study is 1.66% while national and international figures vary from 0.6% to 4.5% or more. These adverse events are higher among young age donors, first time donors, female donors and replacement donors. However, this study didn't reveal a significant relationship of adverse event with weight, haemoglobin and blood pressure of the donor. The severity of the adverse reaction in the study ranges between mild and severe with no severe/fatal episode where hospitalization of the donor or administration of intravenous fluids to the donor is required.

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Donors Consent

The written informed consent from the donors has been taken before starting the project.

Ethical Approval

All author(s) hereby declare that all procedures of project have been examined and approved by the appropriate ethics committee of Gajra Raja Medical College, Gwalior, India and research has therefore been performed in accordance with the ethical standards laid down in the 1964 declaration of Helsinki.

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Competing Interests

Authors have declared that there are no competing interests.

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