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Journal of Hematology & Transfusion

Research Article

The Incidence of Adverse Reaction and Its Predictors among Ethiopian Whole Blood Donors: A Retrospective Cohort Study

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Submitted: 19 July 2022
Accepted: 31 July 2022
Published: 02 August 2022
ISSN: 2333-6684

Keywords
- Volunteer donors
- Whole blood
- Incidence
- Adverse reactions
- Ethiopia

Abstract

Background: Blood donations are generally well tolerated but they are not completely without risk. Adverse reactions are complications of blood donations with significant donor discomfort and negative effect on donor satisfaction and return for donation. Published evidence from Ethiopia on this area is scanty.

Objective: This study assessed the incidence of adverse reaction and its predictors.

Methods: A cohort study was conducted using national data of volunteer whole blood donors. We analyzed the data by SPSS 26. We performed modified binary logistic regression to identify predictors of adverse reaction.

Results: We included 6019 donors in the analysis. The incidence of adverse reactions was 3% (95% CI: 2.56%-3.42%). A female had 83% lower chance; a young donor (<23 years old) had 69% lower risk compared to ≥ 23 years old; a donor who donated at mobile donation site had 94% lower chance of having adverse reaction. A donor who donated 450ml had 3 times higher chance compared to that who donated 350ml; first-time donor had at least 34% lower risk of having adverse reactions.

Conclusions: Interventions to reduce adverse reactions should consider sex, age, donation site, the volume of blood donated and donation history of the donors.

ABBREVIATIONS

ARR: Adjusted Relative Risk; **BCA**: Blood Collecting Agency; **CI**: Confidence Interval; **CRR**: Crude Relative Risk; **NGO**: Non-Governmental Organization; **RR**: Relative Risk; **SD**: Standard Deviation; **AR**: Adverse Reactions

BACKGROUND

According to the World Health Organization (WHO) guidelines, blood shall be collected from voluntary and non-remunerated donors (1). National blood transfusion services (NBTS) have the responsibility to collect blood only from donors who are unlikely to jeopardize their own health by blood donation (2). Blood donations are generally well tolerated, but they are not completely without risk. Adverse reactions are among the most common complications of blood donations (2-6).

Adverse reactions are systemic reactions and defined as symptoms or signs of donor discomfort that are severe enough to either warrant the donor calling for the attention of the blood bank staff or was noticed by the staff. These include increased perspiration, shallow respiration, dizziness, sweating, pallor, nausea, vomiting, unconsciousness (fainting/syncope), rigidity/tremor of extremities (convulsions), and loss of bladder or bowel control (3,7,8). Moderate adverse reactions have been observed in up to 1.4% to 7% of donors; however, serious reactions are rarely encountered (only 0.08% to 0.5%) (4,7,9-11). Adverse reactions have significant implications not only for the welfare of donors but also on the retention of donors and security of the blood supply (7,9,12). Donors who had adverse reactions may never attempt to donate again or take a longer time to return (11,13-18).

Some donor characteristics including young age, low weight(low blood volume), previous donation history, gender, (7,18) and pre-donation anxiety (19) have been variously reported to reliably predict the development of adverse reactions

in potential blood donors. In view of the negative influence of adverse reactions on donor retention and attainment of sufficient blood availability by maximizing donor retention, the interest to assess the incidence and predictors of adverse reactions among volunteer whole blood donors was felt. Both small and large scale studies of a similar kind are limited though the number of volunteer blood donors is still inadequate in our setup.

MATERIALS AND METHODS

Study design, population and data extraction

A retrospective record-based cohort study with both descriptive and analytic components was conducted on all volunteer whole blood donors who donated blood during 11th September 2012 – 5th September 2013 at National Blood Bank, Addis Ababa. National Blood Transfusion Services was established in 1969 by Ethiopian Red Cross Society and transferred to Ethiopian Federal Ministry of Health in 2004. Its mission is to ensure the availability of safe and adequate supply of blood and blood products to all transfusing health facilities in Ethiopia. In Ethiopia, any healthy person aged from 18-65 years and weighing not less than 45 kilograms may become a donor. A donor should weigh at least 45 kg to donate 350ml and 50 kg to donate 450ml (2,20).

Baseline donor data and history of donor reaction were extracted from existing databases. Type of blood collection center (fixed site or mobile site), donor's age, sex, occupation, previous donation experience, the volume of blood donated (350ml vs 450ml), ABO blood group, Rh factor, and weight were extracted data. The adverse reaction assessed in this study were the reaction that occurred during or immediately after donation, but before the donor leaves the donation site. Donors were observed for at least 10 minutes after donation to check occurrence of donor adverse reaction. Adverse reactions were identified by observation and recording of reactions by the collection staff or report of discomfort by the donor.

Data analysis

Data were imported into SPSS version 26 statistical software from Microsoft Excel for cleaning and analysis. All analyses were performed by SPSS 26. Descriptive analyses such as frequency distributions and percentage were computed. Bivariate and multivariable modified binary logistic regressions were performed to assess the association between donors' adverse reaction and baseline characteristics. Before modeling, binary logistic regression model assumptions were checked.

During modeling, multivariable logistic regression was preceded by bi-variate logistic regression. P-value of less than 0.20 and clinical importance of variables were considered to identify candidates for multivariable analysis. Before running multivariable logistic regression, multicollinearity among candidate variables was checked in linear regression with collinearity diagnostics. Variance inflation factor (VIF) > 5 was considered as the presence of collinearity, but the maximum VIF detected was 2.174 and thus, there was not any collinearity. The interaction/effect modification between each pair of independent variables was also assessed using Breslow-Day test in cross-tabs. A significant interaction between age (categorical) and volume, occupation and volume, and previous donation experience and sex were detected. Finally, multiple logistic regression was performed to identify the independent predictors of adverse reaction. Interaction terms between baseline characteristics were also included in the regression, but there was not any significant interaction detected in multiple regression. The strength of association was reported by adjusted relative risk (ARR) and its 95% confidence interval (CI). P-value < 0.05 was considered as statistically significant for all independent variables in the final model. Model fitness was assessed by the Hosmer-Lemeshow test (p-value = 0.199) and the overall percentage of correct classification (97.1%) at the last step.

RESULTS

The incidence of adverse reactions and its predictors

Six thousand and nineteen voluntary blood donors donated blood during the study period. The incidence of adverse reactions was nearly 3% (180/6019). Bivariate binary logistic regression showed that sex, age, weight, blood group B, donation site, the volume of blood donated, donation experience and occupation (student, civil servant) were associated with adverse reaction at p-value < 0.05 whereas Rh factor was not associated with adverse reaction (Table 1).

In multivariable analysis, sex, age, donation site, the volume of blood donated and donation experience were factors significantly associated with adverse reaction at p-value < 0.05. A female donor had at least 83% lower risk [ARR = 0.166, 95%CI (0.067, 0.412)] of having adverse reaction. A young (< 23 years old) donor had at least 69% lower risk [ARR = 0.308, 95%CI (0.108, 0.878)] of having adverse reaction compared to a donor whose age is 23 and above years. A first-time donor had at least 34% lower risk [ARR = 0.658, 95%CI (0.469, 0.925)] of having adverse reaction. The risk of having adverse reaction for one who donated at mobile donation site was at least 94% lower [ARR = 0.057, 95%CI (0.020, 0.160)]. With regard to the volume of blood donated, one who donated 450ml had nearly 3 times higher risk [ARR = 2.734, 95%CI (1.859,4.021)] of having adverse reaction compared to who donated 350ml (Table 2).

DISCUSSION

This study investigated the incidence of adverse reactions and associated factors. The incidence of adverse reaction determined was 3%. Sex, age, donation site, the volume of blood donated, and previous donation history (experience) were factors found significantly associated with the occurrence of adverse reactions.

The incidence of adverse reaction determined in this study was comparable to the finding of a study conducted in Nigeria (21). However, our finding was higher than most reports of previous studies. It was higher than the report of a study conducted in India (22) where a total of 2.04% adverse reaction was observed. It was also more than eight times higher than the finding of a study conducted in Bangladesh (4); five times higher than the finding of another study conducted in India (23); and almost 3 times higher than report of study conducted in Saudi Arabia (24). The finding was also much lower than the finding of a study conducted in Pakistan where a prevalence of at least 8.2% was reported (23).

Table 1: Incidence and crude association between adverse reaction and characteristics of blood donors, Addis Ababa, Ethiopia.

Donor characteristics		Total Donors	Adverse reaction	CRR (95%CI)	P-value
Sex	Male	3847	164 (4.26)	1	
	Female	2172	16 (0.74)	0.173 (0.103,0.289)	< 0.001
Age (years)	Young (< 23)	2375	26 (1.10)	0.259 (0.170,0.394)	< 0.001
	≥ 23	3644	154 (4.23)	1	
Weight (in Kg)*, Mean (SD) = 65.41 (11.82)				1.055 (1.044,1.066)	< 0.001
Blood group	O	2505	87 (3.47)	1	
	A	1713	47 (2.74)	0.790 (0.551,1.132)	0.199
	B	1428	33 (2.31)	0.665 (0.443,0.999)	0.049
	AB	373	13 (3.49)	1.004 (0.555,1.816)	0.991
Rh	Positive	5580	162 (2.90)	1	0.173
	Negative	439	18 (4.10)	1.412 (0.860,2.320)	
Donation site	Fixed	3121	176 (5.64)	1	<0.001
	Mobile	2898	4 (0.14)	0.024 (0.009,0.066)	
Volume	350ml	4296	42 (0.98)	1	<0.001
	450ml	1723	138 (8.01)	8.192 (5.774,11.624)	
Donation experience	Repeat donor	4260	109 (2.56)	1	0.003
	1st-time donor	1759	71 (4.04)	1.578 (1.164,2.138)	
Occupation†	Private/NGO worker	3674	123 (3.35)	1	
	Student	1982	24 (1.21)	0.362 (0.233,0.562)	<0.001
	Civil servant	277	26 (9.39)	2.804 (1.805,4.355)	<0.001
	Unemployed	36	3 (8.33)	2.489 (0.756,8.194)	0.134
	Others**	50	4 (8.00)	2.390 (0.850,6.721)	0.099

*continuous variables, †2 cells (20%) have expected count less than 5, ** daily laborer (2), driver (17), housewife (9), policeman/policewoman (6), religious leader (1), teacher (15)

Table 2: Adjusted association between adverse reaction and characteristics of blood donors, Addis Ababa, Ethiopia.

Donor characteristics		Coefficient of regression (B)		ARR (95%CI)	P-value
Sex	Female	-1.796		0.166(0.067,0.412)	< 0.001
	Male			1	
Age (years)	Young (< 23)	-1.177		0.308 (0.108,0.878)	0.028
	≥ 23			1	
Donation site	Mobile	-2.864		0.057 (0.020,0.160)	< 0.001
	Fixed center			1	
Volume	350ml			1	< 0.001
	450ml	1.006		2.734 (1.859,4.021)	
Donation experience	1st time donor	-0.418		0.658 (0.469,0.925)	0.016
	Repeat donor			1	
Age by volume†		1.039		2.825 (0.895,8.919)	0.077
Donation experience by sex†		1.082		2.950 (0.964,9.033)	0.058

†interaction term

In this analysis, a female donor had 83% reduced chance of having adverse reactions. One of the potential explanations for the lower prevalence among women would be the fact that women have fewer donations than men, due to menarche, pregnancy, and breastfeeding. However, this finding was different from the finding of studies conducted in Bangladesh, India, and Nigeria (4,21,25) where the female donor was found significantly more prone to develop adverse reactions. In our analysis, first-time donors had a 34% lower risk of having adverse reactions. This could be because first-time donors may be motivated about blood donation and thus, they are not in anxiety. It could also be because blood collecting professionals were more careful with first-time donors. But, this finding was different from the report of earlier studies where the first-time donor had increased risk of having donor reaction (21,24,25).

The volume of blood donated was another factor significantly associated with the chance of developing adverse reaction. A participant who donated 450ml was three times at higher risk of developing adverse reaction than a participant who donated 350ml. A study conducted among first-time young donors (16-18 years) detected that collecting 350ml has a large and significant reduction in reaction rates among all females and most males except the higher weight subgroups (26). One who donated blood at mobile donation sites was also at much reduced (94% lower)

risk of developing adverse reactions. This could be because those who donated 350ml are more than 9 times more likely to donate at mobile sites, age and sex being constant. Younger age (< 23 years old) donors had 69% lower risk of having adverse reaction contrary to earlier studies that reported an increased risk of adverse reaction in younger age donors (21,24,27). This could also be because, in this study, younger donors are nearly 4 times more likely to donate at mobile sites, volume and sex being constant. Females are also 30% higher likely to donate at mobile sites, age and volume being constant. In the study conducted in India, age ≥ 45 years was found to be at higher risk of developing adverse reaction (25).

Blood group was not found associated with the occurrence of adverse reaction in this study contrary to the previous study that reported an increased risk of adverse reaction in a donor with blood group B (21). Weight was also not associated with adverse reactions in current study. This finding was different from earlier study conducted in Saudi Arabia which reported increased chance having adverse reactions among lower weight donors (< 75 kg) (24). It was also different from earlier study conducted in Pakistan that reported increased risk of developing adverse reaction with weight < 70 kg (27). Occupation and Rh were also not associated with adverse reactions in current study.

LIMITATIONS

This analysis has some limitations. There was no access to delayed adverse reactions (reactions occurring after the donor leaves the blood donation site). In addition, the research was unable to classify reactions into different levels (minor/mild and major/severe) which is important for interventions. This data is applicable to the reactions seen with whole blood donation, but not with automated collection methods.

CONCLUSIONS

The risk of adverse reactions related to blood donation was high in this study. Thus, attention towards donor's adverse reactions is warranted, as it would have detrimental effects on the return of donors for subsequent donations, and the rate of complications resulting in long-term morbidity and disability is not negligible. It is important to follow strict donor selection criteria and ensure careful monitoring during the donation process to avoid fatal consequences. A well-trained and experienced phlebotomist and pre-evaluation counseling of blood donors could further minimize the adverse reactions.

DECLARATIONS

Ethics approval and consent to participate

Ethical approval was obtained from Ethical Review Board of the Institute of Health, Jimma University. Permission was obtained from the Office of National Blood Bank Services to use the data for this study. All the information obtained from the donors' record was kept confidential by excluding personal identifiers. Information obtained was also used only for the purpose of the study.

Availability of data and materials

All datasets on which the conclusions of the paper rely were presented in the main manuscript.

Competing interests

The authors have declared that they have no competing interests.

Authors' contributions

HJ conceptualized the study, participated in its design and performed statistical analysis, and drafted the manuscript. LT participated in the design of the study and carried out data extraction. FA participated in the design of the study. All authors read and approved the final manuscript.

ACKNOWLEDGMENTS

The authors appreciate the National Blood Bank data officers for the permission given to use the data.

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Cite this article

Hebo HJ, Gebremeskel LT, Tesfamichael FA, Bedecha DY, Edaso AU (2022) The Incidence of Adverse Reaction and Its Predictors among Ethiopian Whole Blood Donors: A Retrospective Cohort Study. J Hematol Transfus 9(1): 1104.