Open Access Original Article

Donor Hemovigilance: An Essential but Neglected Surveillance Procedure; A Single Center Study in Pakistan

Urooj Irfan[1]
Aiman Mahmood Minhas[2]
Hasan Raza Hashmi[3]
Maryam Ramzan[4]
Shamaila Razzaq[5]
Ayisha Imran[6]

Chughtai Institute of Pathology

Address for Correspondence
Dr Urooj Irfan
Chughtai Institute of Pathology
urooj.zae@gmail.com

Abstract

Objective: The goal of this study is to identify the adverse reactions occurring during donation phase and the post-donation phase in whole blood donors.

Methodology: This study was performed at the Department of Hematology, Chughtai Institute of Pathology, Lahore from May 2022 till April 2023. All healthy donors fulfilling blood donation criteria according to AABB were included in the study. All donations were monitored and reactions occurring during pre-donation, donation and post-donation phases were noted. Data was analyzed by using SPSS 23.00. Mean ± SD was calculated for continuous variable. Frequency and percentage were calculated for categorical variables. Chi-square test was used to ascertain significance of categorical variables while Kruskal-Wallis was used for continuous variables. Wilcoxon Signed Ranks Test was used to compare the pre and post donation vital signs. A p-value of <0.05 was taken as significant.

Results: A total of 399 donors with mean age of 26.21 years, 335 (84.0%) male and 64 (16.0%) females were included in the study. A significant association of donor´s weight was seen with the occurrence of adverse reactions with a significant p-value. However, no significance with age, gender, or number of donations made was seen with the occurrence of any complication.

Conclusion: We conclude from our study that blood donation is a safe procedure however we need to come up with strategies to make donors more comfortable and make donation a pleasant experience for them so that a regular and persistent chain of blood donation can be continued.

Key Words: Hemovigilance, blood donor, blood transfusion.

Introduction

Hemovigilance is a very important element of blood safety which monitors any adverse reactions and incidents during blood donation and transfusion for both donors and recipients. Unfortunately, many a times patients do not receive save blood products due to shortage of blood donors especially in the under developed nations. Many times, donor experience unpleasant event during donation like vasovagal syncope, nausea, hematoma, prolonged bleeding etc. It makes people afraid of blood donation. Hemovigilance is now an important tool in transfusion medicine worldwide. It helps to detect any complications in transfusion process and helps health care professionals to make innovations to reduce these complications. Safe blood donation process plays a vital role to build trust between blood donors and blood centers. This encourages voluntary blood donation in society.

Authorship Contribution: [1] Conceived and planned the idea of the study, [6]final approval of the version to be published, [2,4]Collecting the data, [3]Manuscript drafting, analysis, [5]drafting the work or revising it critically for important intellectual content.

Funding Source: none
Conflict of Interest: none
Received: Nov 05, 2024
Accepted: April 16, 2025

According to WHO, provision of safe blood must be an integral part of nation health policy and voluntary unpaid donation should be encouraged.[1] In Pakistan, it is estimated that 80% of donations are by family members of patient whereas only 20% of donations are by voluntary donors. This is attributed to lack of awareness about blood donation and presence of myths related to adverse effects of donation among the general population.[2]

The concept of hemovigilance first emerged in 1990s and over the last 3 decades it has evolved from surveillance of adverse reactions in patients, to a well-defined system that monitors the entire transfusion chain and improves its safety.[3] The aim of hemovigilance is to identify, monitor and prevent adverse effects in both donors and recipients. Donor hemovigilance includes systematic reporting of unexpected adverse effects and complications during donation process.[4]

Donor hemovigilance includes monitoring blood donor from the pre-donation phase to post-donation phase. It is emphasized in order to improve the donor comfort and safety so that they can be motivated to become a regular nonremunerated voluntary blood donor.[4] This will ensure

regular blood transfusion and maintenance of regular supply of safe blood and its product for patients.

Therefore, the purpose of this study is to identify any adverse reaction in blood donors (pre-donation to the post-donation phase) so that the improvements can be suggested in hemovigilance system thereby encouraging more donations.

Methodology

This observational cross-sectional study was performed at the Department of Hematology, Chughtai Institute of Pathology, Lahore from May 2022 till April 2023, for a period of 01 year, after taking approval from Institutional Review Board (IRB), vide reference number CIP/IRB/1117. After a thorough literature search, we calculated a sample size of 399 using WHO calculator, keeping the margin of error at 5%, a confidence level at 95%, and prevalence of blood donors in our country as reference.[5] Sampling was done using a non-probability consecutive sampling technique.

All healthy donors fulfilling blood donation criteria according to AABB were included in the study. All apheresis donors and donors falling under donor defer criteria (underweight, donation in last 3 months, active infection, drugs intake) were excluded from the study. Written consent was obtained before enrolling all donors, and their confidentiality was ensured at all levels.

A donor reaction reporting form was designed containing demographic data of the donor, past medical and surgical history, previous blood donation history, reactions occurring phases of donation. Vitals were monitored throughout these phases and recorded. All donors were telephonically called and were inquired about any adverse reaction occurring after 24 hours.

Data was entered in excel sheet and was analyzed by using Statistical Package for the social sciences (SPSS) version 23.00. Mean ± SD was calculated for continuous variables like age, weight and sleeping hours etc. Frequencies and percentages were calculated for categorical variables like gender and types of complications etc. Shapiro-Wilk test was used to check the normality of data. Chi-square test was used to ascertain significance of categorical variables like gender and no. of (times) donations made while Kruskal-Wallis was used for continuous variables like age and weight. Wilcoxon Signed Ranks Test was used to compare the pre and post donation vital signs. A p-value of <0.05 was taken as significant.

Results

The study included 399 blood donors. Their demographic characteristics are presented in Table I. Out of 399, 226 (56.6%) donors were regular donors while 173 (43.4%) were donating blood for the very first time.

Table I: Demographic Characteristics of the patients. (n=399)

Parameters	
Gender (n, %) Male Female	335 (84.0%) 64 (16.0%)
Age (Mean±SD)	26.2±4.7
Weight (Mean±SD)	81.14±10.2

Pre-donation information of the donors such as hours of sleep, last meal taken as well as pre- and post-donation vitals such as blood pressure, pulse and temperature are summarized in Table II.

Table II: Pre and post-donation donor vitals. (n=399)

Pre-donation	Parameter	Mean ± SD
	Sleep (hours)	6.42±1.27
	Last meal taken (Hours)	3.02±1.24
	Systolic BP	116.5±8.4
	Diastolic BP	76.8±5.4
	Pulse	80.3±7.8
	Temperature	98.0±0.0
Post-donation	Systolic BP	113.7±11.1
	Diastolic BP	76.1±5.4
	Pulse	80.6±7.3
	Temperature	98.0±0.0

The number of donors encountering adverse reactions is summarized in Table III. Adverse reactions included complications encountered during donation, within 24 hours of donation, and after 24 hours of donation.

Table III: Donors encountering adverse reactions.

Timeline	No. of Donors, n (%)
During donation	70 (17.5%)
Within 24 hours	13 (3.25%)
After 24 hours	15 (3.75%)

Various adverse reactions included allergies, anaphylactic reactions, bruises, hematomas, arterial puncture, failed phlebotomy, hypotension, tachycardia, tachypnea, pale extremities and conjunctivas, dizziness, heart sinking, sweating, nausea, vomiting, headache, loss of consciousness and fits/convulsions. Frequency of the

various adverse reactions encountered is shown in Figure – I-III.

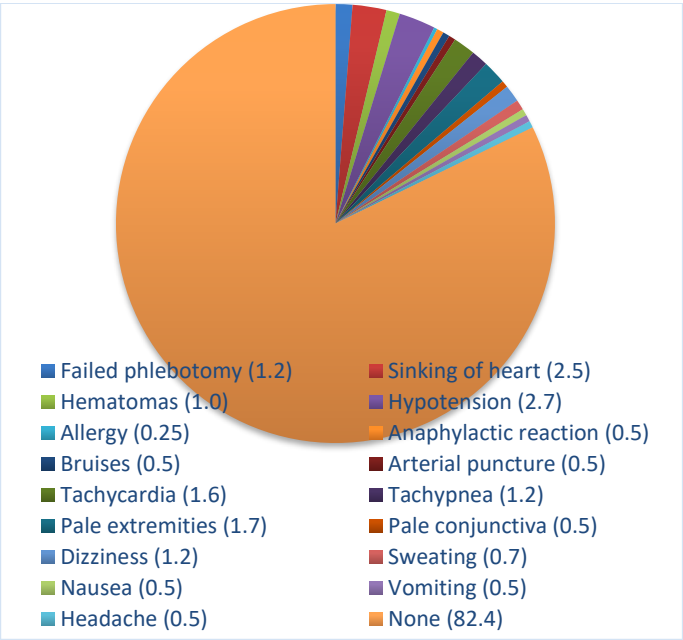

Figure I: Summary of complications encountered during donation. (n=399)

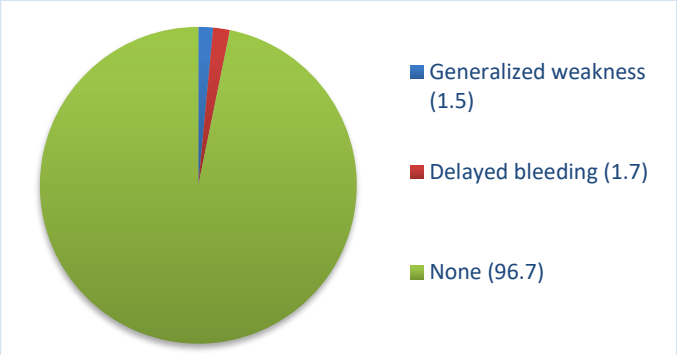

Figure II: Summary of complications within 24 hours of donation. (n=399)

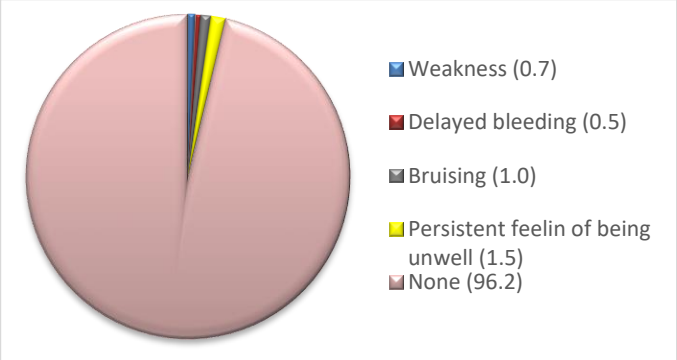

Figure III: Summary of complications after 24 hours of donation. (n=399)

Significance of adverse reactions to various demographic characteristics of the donors is shown in Table IV. No significant association with age, gender, weight or number of times donation made was seen with the occurrence of any complication.

Table IV: Significance of adverse reactions with donor demographics. (n=399)

Timeline	Association with	P value
During donation	Age	0.346
	Gender	0.508
	Weight	0.634
	No. of times donations made	0.384
Within 24 hours	Age	0.386
	Gender	0.659
	Weight	0.105
	No. of times donations made	0.158
After 24 hours	Age	0.269
	Gender	0.878
	Weight	0.828
	No. of times donation made	0.936

The comparison of pre-donation and post-donation vital signs is shown in Table V. The change in pulse rate before and after donation is not statistically significant (p=0.878) while there are significant increases in both diastolic (p=0.035) and systolic blood pressure (p<0.001) post-donation.

Table V: Comparison of Pre-Donation and Post-Donation Vital Signs.

	Mean±SD	95% CI of the Difference		p-Value
		Lower Bond	Upper Bond	
Pre-Donation pulse-Post donation Pulse	-0.296 ± 7.122	-0.997	0.405	0.878
Pre-Donation Diastolic BP-Post donation Diastolic BP	0.694 ± 6.074	0.096	1.292	0.035
Pre-Donation Systolic BP-Post donation Systolic BP	2.785 ± 11.550	1.648	3.921	<0.001

Discussion

Hemovigilance is a very important tool to provide safe blood transfusion to patients. However, only surveillance of transfusion process will do nothing if we do not take steps to bring change in our transfusion centers to provide safe donation. In our study young adults participated more enthusiastically in blood donation.

Hemovigilance gives a sense of satisfaction and emotional well being to donors that they are serving

people. According to Mughion et al, unpleasant sensations and personal fears of needle, pain, site of blood and fainting are some of the reasons which discourage non-donors from donating. These factors can be overcome by proper education of non-donors in order to encourage them to donate.[6] Likewise, Ahmed et al also found that the factors which discourage blood donation include objection from parents or guardians, rude behavior of healthcare staff, and fear of adverse effects. Such donors again need to be encouraged not to listen to these fabricated beliefs about blood donation.[7]

Our study found out that majority of the blood donors did not experience any adverse after blood donation thereby rendering blood donation to be a safe procedure. The adverse reactions that can occur during blood donation can be divided into local and systemic reactions. Local reactions include formation of hematoma, hemorrhage, bruising, and associated inflammation at the site of needle, while systemic reactions include symptoms like tachycardia, dizziness, hyperventilation.[8]

In a study conducted in India it was observed that immediate adverse effects occurred in only 1.6% of the donors. Delayed adverse effects were commonly encountered in female donors. Young donors experienced more bruising as compared to elder donors (age >50 years) who comparatively experienced more fatigue as compared to younger donors. Delayed adverse effects were lower among regular donors as compared to the first-time donors.[9] In our study, we observed that only 17.6% of donors experienced adverse effects during donation which included mainly hypotension and sinking of heart followed by hematoma formation due to poor phlebotomy technique. In our study majority of blood donors were males (84%) and female donors contributed less in donation (16%). A few common reasons among females for not participating in blood donations camps include fear of pain, fear of blood, fear of needle etc. No observation in our study indicated that females are more prone to experience adverse effects upon blood donation. No age-related adverse effects were reported in our study.

In another study in Germany, the most frequently reported adverse effects during donation included hematoma, pain and swelling at needle site, dizziness, nausea and vomiting.[10] The same was observed in our study as well.

In our study, reactions during donation phase were more as compared to immediate post donation reactions and reactions after 24 hours. This can be prevented by teaching phlebotomy staff to act more vigilantly and carefully while doing phleboyomy. There should be training courses for phlebotomist to educate them about hemovigilance.

In our study there was no significant difference between adverse effects experienced by first time donor and regular donor was observed in our study. However, Eder et al found out that first time donors experienced more vasovagal reactions as compared to regular donors.[11]

Goldman et al have stated that relationship between low body weight and systemic adverse reactions in donors.[12] However, Tondon et al suggests that blood volume drawn rather than the weight of the donor is responsible for adverse reactions.[13]

Conclusion

We conclude from our study that blood donation is a safe procedure however we need to come up with strategies to make donors more comfortable. We suggest proper training of phlebotomists so that their phlebotomy skills can be further polished to reduce local complications. We need to utilize social media and other electronic platforms to create awareness among general public about the benefits of blood donation especially among the younger age groups. Proper pre-donation and post-donation instructions in the form of brochures can help reduced complications. A calm and safe system of donation in blood centers can help encourage donors and thereby ensure regular donations by them.

References

1. Beyene GA. Voluntary blood donation knowledge, attitudes, and practices in Central Ethiopia. Int J Gen Med. 2020;13:67-76. https://doi.org/10.2147/IJGM.S246138
2. Waheed U. Knowledge, attitude and practices towards blood donation in Pakistan: a nationwide survey. Hematol Transfus Int J. 2015;1(4):00018. https://doi.org/10.15406/htij.2015.01.00018
3. Vuk T, Politis C, Laspina S, et al. Thirty years of hemovigilance - achievements and future perspectives. Transfus Clin Biol. 2023;30(1):166-172. https://doi.org/10.1016/j.tracli.2022.09.070
4. Mani A, Gupta D. Hemovigilance: an analysis of adverse effects of blood donation among blood donors in a tertiary-care center. Glob J Transfus Med. 2021;6(1):15-19. https://doi.org/10.4103/GJTM.GJTM_104_20

5. Nawaz S, Ayub A, Ahmad B, Nawaz T. Blood donors hemovigilance in public sector tertiary care hospitals of Peshawar. Pak J Health Sci. 2023;4(8):14-19. https://doi.org/10.54393/pjhs.v4i08.959
6. Guglielmetti Mugion R, Pasca MG, Di Pietro L, Renzi MF. Promoting the propensity for blood donation through the understanding of its determinants. BMC Health Serv Res. 2021;21(1):230. https://doi.org/10.1186/s12913-021-06134-8
7. Ahmed M, Saeed M, Waheed U, et al. Perception of blood donation among Pakistani youth. Pak Armed Forces Med J. 2020;70(Suppl-1):S134-S140. https://www.pafmj.org/PAFMJ/article/view/5564
8. Taheri Soodejani M, Haghdoost AA, Okhovati M, et al. Incidence of adverse reaction in blood donation: a systematic review. Am J Blood Res. 2020;10(5):145-150.
9. Tiwari AK, Aggarwal G, Dara RC, et al. Post-donation telephonic interview of blood donors providing an insight into delayed adverse reactions: first attempt in India. Transfus Apher Sci. 2017;56(2):141-146. https://doi.org/10.1016/j.transci.2016.10.009
10. Orru' S, Poetzsch K, Hoffelner M, et al. Blood donation-related adverse reactions: results of an online survey among donors in Germany (2018). Transfus Med Hemother. 2021;48(5):272-283. https://doi.org/10.1159/000516049
11. Eder AF, Hillyer CD, Notari EP, Benjamin RJ. Adverse reactions to allogeneic whole blood donation by 16- and 17-year-olds. JAMA. 2008;299(19):2279-2286. https://doi.org/10.1001/jama.299.19.2279
12. Goldman M, Fournier E, Cameron-Choi K, Steed T. Effect of changing the age criteria for blood donors. Vox Sang. 2007;92(4):368-372. https://doi.org/10.1111/j.1423-0410.2007.00897.x
13. Tondon R, Pandey P, Chaudhary R. Vasovagal reactions in 'at risk' donors: a univariate analysis of effect of age and weight on the grade of donor reactions. Transfus Apher Sci. 2008;39(2):95-99. https://doi.org/10.1016/j.transci.2008.07.010