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Original Article

Blood Donors Hemovigilance in Public Sector Tertiary Care Hospitals of Peshawar

Safia Nawaz[1*], Ayaz Ayub[1], Bilal Ahmad[1] and Tahira Nawaz[2]

[1]Institute of Public Health & Social Sciences, Khyber Medical University, Peshawar, Pakistan
[2]Department of Biochemistry, University of Peshawar, Peshawar, Pakistan

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Corresponding Author:
Safia Nawaz
Institute of Public Health & Social Sciences, Khyber Medical University, Peshawar, Pakistan
maahgulk@gmail.com

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ABSTRACT

Hemovigilance of blood donors is an integral part of blood transfusion system, conferring to lessen the blood donation complications and enhancing the safety of blood donors. **Objective:** To determine the prevalence, severity, and associated factors of acute hemovigilance reactions in the blood donors of public sector tertiary care hospital bank banks in Peshawar. **Methods:** A multi-centered, cross-sectional approach was applied on blood donors` population selected via random proportionate sampling, visiting 6 Public sector tertiary care hospitals in Peshawar. Adverse reactions were reported on national guidelines reporting form during and after the blood donation. **Results:** Out of 420 blood donors selected via random proportionate sampling of total blood donors` population, prevalence of acute adverse hemovigilance reaction was 8.57% while no adverse reactions occurred in 91.43% of the blood donors. The most frequent hemovigilance reaction was vasovagal reactions (5.2%). All the reactions were of mild to moderate severity with no life threatening hemovigilance reactions. **Conclusions:** The overall prevalence rate was 8.57% of all healthy blood donors` which strengthens the fact that adverse reactions are avoidable complication of blood donations among the voluntary and replacement blood donors, and can be prevented with centralized hemovigilance data base for a sustainable base of voluntary blood donors.

INTRODUCTION

Hemovigilance has become an essential component of Blood Transfusion service (BTS) worldwide and has substantially contributed to the health systems of developed countries [1]. Blood Transfusion System in Pakistan is disintegrated and principally depends upon the replacement blood donors [2, 3]. Hemovigilance is proficient only in few blood bank facilities in Pakistan [4]. Approximately 3 million blood donors donate blood which is not enough to replenish the demand of drying blood banks in the country [5, 6]. The Blood Transfusion Services in the country were built upon the provincial legislations of Blood safety acts during 1997 till 2017 [7]. Pakistan became member of international hemovigilance network in 2013 February [5, 8]. The Khyber Pakhtunkhwa provincial assembly promulgated the Blood Transfusion Safety Authority Act XXV, on 20th October 2016, by establishing Khyber Pakhtunkhwa blood transfusion authority (KPBTA) with a principal focus on donor hemovigilance (section 18.1 & 18.2) [9-11]. The blood donor adverse reactions are categorized as localized or widespread. The localized reactions are majorly due to leakage of blood from veins after inaccurate venipuncture causing hematoma formation, nerve injury, pain, swelling and redness on the site of blood leakage [12-14]. The vasovagal reactions include dizziness, nausea, sweating, pallor, abdominal discomfort, low blood pressure, vomiting and decrease heartbeat. Whereas, systemic reactions may also lead to syncope or fall thus requiring prompt medical attention and

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management [15]. The main objective of this study was to determine the prevalence, severity, and associated factors of acute hemovigilance reactions in the blood donors of public sector tertiary care hospital bank banks in Peshawar. The acute adverse blood donation reactions have been studied extensively across the globe as depicted in Table 1.

Table1: Adverse blood donation reactions across the globe

S. no	Author	Year	Country	Prevalence/ Incidence of hemovigilance reactions
1.	Land et al., [16].	2012-2017	United States of America	20.8 to 24.3/1000
2.	Notes et al., [4].	2009	Italy	1.2%
3.	Zeiler et al., [17]	2011	Germany	0.63%
4.	Newman et al., [18]	2003	United States of America	7.8%
5.	Inaba et al., [19]	2013	Japan	5.2%
6.	Wiersum-Osselton et al., [14]	2014	Netherlands	3.9 -3.5%
7.	Charoonruangrit [20]	2013	Thailand	24.06%
8.	Kamel et al., [21]	2010	United States of America	41/10000
9.	Agnihotri et al., [22]	2012	Bangalore, India	2.5%
10.	Patidar et al., [23]	2013	North India	18%
11.	Mahbub-ul-Alam et al., [24]	2007	Bangladesh	4.98%
12.	Sultan et al., [25]	2016	Karachi, Pakistan	1.3%
13.	Rohra et al., [26]	2010	Karachi, Pakistan.	8.2%
14.	Amanat et al., [27]	2015	Islamabad, Pakistan.	3%
15.	Shabber et al., [28]	2016	Islamabad, Pakistan.	0.7%

METHODS

This was an analytical cross-sectional study conducted at the blood banks of Tertiary Care Hospitals in Peshawar. This study was conducted in 3 months interval from April 2021 till June 2021. The Quantitative research approach was adopted. It was a multicenter study, executed at the 6 Public Sector Tertiary care hospitals blood banks affiliated under the Regional Blood Center Peshawar. Khyber Medical University Advanced Study and Research Board (AS&RB) endorsed the study, Agreement of Helsinki Declaration (World Medical Association) [29] was maintained throughout the study [30, 31]. The target population in this study were the blood donors visiting the blood banks of tertiary care hospitals in Peshawar. The sampling technique was Random Proportionate Sampling. The total blood donor population recorded in these hospital blood banks were 66,624. The total sample frame was 420 which was collected proportionately from the 6 public sector tertiary care hospitals working under Blood Transfusion Authority Khyber Pakhtunkhwa. The sample calculation for a finite blood donor population through standard formula for sample size calculation was used. The selection criteria for blood donors were adopted according to the National guidelines in transfusion medicine [32], which includes: Age >18years, Weight >50kg, Hemoglobin levels>12.5g/dl, Blood pressure levels (systolic blood pressure not more than 140mmHg, diastolic blood pressure not more than 100mmHg). The general inclusion criteria included the willingness to participate in the study, after 1st 20min immediately post donation and 23hrs 40mins on telephonic interview after leaving the hospital blood bank through informed consent questionnaire duly signed by all the participants. For consideration of any potential blood donor deferral the National Guidelines for Quality Control in Transfusion Medicine deferral lists were followed [32]. Each donor was observed for development of adverse hemovigilance reactions during or after the blood donation of 1 pint or 500ml for at least 20 mins according to the national guidelines for quality control in transfusion medicine by trained staff of the hospital blood banks. The types of adverse hemovigilance reactions observed within 24 hrs. were noted through telephonic interviews for documentation on national transfusion medicine guideline adverse reaction reporting form. The blood donors were then classified into 3 age categories 10 years apart as: Category A (18-29 years), Category B (30-39 years), and Category C (40-49 years). The weight of blood donors was categorized into two groups: Group A (60-80kg), Group B (80-100kg and above). The hemoglobin levels were divided into two categories as: Category 1 (12-15gm/dl) and Category 2 (15-≥18gm/dl). The systolic blood pressure levels were categorized into 2 groups as: Group A (systolic blood pressure <100-119mmHg) and Group B (systolic blood pressure 120-139 mmHg). The adverse hemovigilance reactions were divided into 2 categories depending upon the onset of adverse symptoms in blood donors into: a) Acute immediate adverse hemovigilance reactions occurring within 20 mins after blood donation and b) Acute delayed adverse hemovigilance reactions occurring in 23hr 40min of blood donation. SPSS version 23.0 was used for the data analysis.

RESULTS

A total of 420 blood donors were enrolled in the study. A total of 97.61 % blood donors enrolled in the study were males while 2.38% of the blood donors were female. The mean age was 27.47±7.21 years. The mean weight(kg) of the blood donor was recorded as 76.78 ± 7.461 kg. A total of 208 (49.52%) blood donors were having different categories of occupation, while 212 (50.48%) were not working in any sort

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of occupation. The mean hemoglobin level was observed as 14.91 ± 0.7 gm/dl. The prevalence of acute adverse hemovigilance reaction was observed to be 8.57% while no adverse reactions were present in 91.43% of the blood donors. About 91.67% of the blood donors had no adverse hemovigilance reactions, 3.81% of the blood donors had experienced mild severity adverse reactions, 4.52% blood donors had experienced moderate adverse reactions. However, no severe and life threatening adverse hemovigilance reactions were observed. The most frequent acute immediate adverse hemovigilance reaction observed was systemic vasovagal reactions with or without loss of consciousness (5.2%), whereas nausea/vomiting (1%), weakness/hypotension (1.2%), and localized reactions such as hematoma and delayed bleeding (1.2%) as demonstrated in Table 2 as:

Table 2: Frequency of Acute immediate hemovigilance reactions among blood donors

Acute immediate adverse hemovigilance reactions (<20min)	Frequency (%)
No adverse reactions	384 (91.4)
Vasovagal reactions/syncope/faint	22(5.2)
Nausea /vomiting	4(1.0)
Hypotension/weakness	5(1.2)
Hematoma/delayed bleeding	5(1.2)
Total	420(100)

The most frequent delayed hemovigilance(adverse) reactions observed in blood donors was weakness, hypotension, and dizziness after blood donation. However no Systemic anaphylactoid reaction was observed during the blood donation process. the next frequent reactions noted in blood donors 23hr 40min post donation were localized reactions such as hematoma and delayed bleeding while delayed syncope/vasovagal reactions were the least frequent among blood donors as shown in Table 3 as:

Table 3: Frequency of Acute delayed hemovigilance reactions

Acute Delayed Hemovigilance Reactions Among Blood Donors (23hr 40min)	Frequency (%)
No adverse reaction	389 (92.6)
Delayed Vasovagal reactions/faint/nausea/vomiting	7(1.7)
Hematoma /delayed bleeding	9(2.1)
hypotension/dizziness/weakness	15(3.6)
Total	420(100)

Chi square test of association was applied to determine the significance of association as shown in Figure 1, a significant association of low weight categories (p=0.003 at 95% confidence interval and 0.05% margin of error) and lower hemoglobin levels (p=0.003 at 95% confidence interval and 0.05% margin of error) development of adverse hemovigilance reactions was found.

Table 4: Association of blood donors `demographic factors with development of acute hemovigilance reactions

Demographic Variables	Categories	Number (%)	Percentage of Adverse Reactions	p-value
Gender	Male	410(97.61%)	8.09%	0.191
	Female	10 (2.38%)	0.476%	
Occupation	Yes	208(49.52%)	4.076%	0.773
	No	212(50.47%)	4.52%	
Age	18-29 yrs.	271(64.52%)	5.47%	0.974
	30-39 yrs.	111(26.42%)	2.38%	
	40-49 yrs.	38(9.04%)	0.714%	
Weight	60-80 Kg	289	9.11%	0.003
	80-≥100Kg	95	0.26%	
Blood Pressure Level (Systolic)	<100119mmHg	150(35.71%)	4.04%	0.147
	120-139mmHg	270(64.28%)	4.52%	
Hemoglobin Level	12-15gm/dl	259	8.59%	0.003
	15-≥18gm/dl	125	0.78%	

DISCUSSION

The voluntary blood donations are the key force to maintain a sustainable blood donation supply to meet the blood demands of a country, which could be achieved through strict vigilance of adverse donation reactions at hospital blood bank. The overall prevalence of adverse reactions in, healthy allogenic blood donors visiting the Public Sector tertiary care hospital blood banks in Peshawar is 8.57%. This is the first baseline data from Khyber Pakhtunkhwa regarding blood donors from the Northwest frontier region inclusive of blood donors visiting from Afghanistan. The result of this study is in concurrence with a study steered at Karachi that reported vasovagal adverse donation reactions prevalence rate of 8.2% in healthy replacement blood donors [26]. In another study from Karachi by Sultan *et al.*, concluded an adverse reactions rate of 1.3% in allogenic healthy blood donors [25]. A relatively lower adverse donation reactions rate of 0.7% were reported in a study executed in a Tertiary care hospital in Islamabad [28]. The prevalence rate reported in this state are in accord with adverse donation reactions rate 24.06% in Thailand donors' surveillance program [20]. Whereas, a slightly higher prevalence rate 4.9% was observed in Bangladesh [24]. A relatively lower prevalence rate of 2.5% and 2.04% was recorded in a study in two studies in India [22]. A study from Italian blood transfusion centers enshrined a prevalence rate of 1.2% [14], while in Japan, only 2.8% blood donors experienced adverse hemovigilance reactions [19]. Meanwhile in Germany a prevalence rate of 0.63% was detected in elderly blood donors [17]. These variations in prevalence rates mainly attributes to the difference in demographic characteristics of blood donors. The most predominant acute hemovigilance adverse reaction observed in our study was vasovagal systemic reactions (5.2%) inclusive of syncope/faint occurring on site to blood

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donation. the vasovagal reactions are the most frequent acute hemovigilance reactions to blood donation in nearly 1-5% of all the blood donors [12]. A similar rate of vasovagal adverse events of 8.2% was enshrined by Rohra *et al.*, in a study executed at two hospital blood banks in Karachi, Pakistan [26]. The difference may be due to the sample size as in our study random proportionate sample was taken from all the public sector tertiary care hospitals. The vasovagal reactions account for 60.67% of overall acute adverse hemovigilance reactions (8.57%, n=420) which are somehow similar to an Indian studies vasovagal reactions (VVR) prevalence rates of 63.5% and 70.0%, [33]. The delayed adverse reactions after leaving the hospital blood bank and experienced >20min post donation and within 24 hours are recorded as 7.4% with hypotension /weakness as the most frequent delayed adverse hemovigilance reactions (3.6%) among all the blood donors. These prevalence rates are similar to a study by Kamel *et al.*, observed the delayed adverse reactions to be 12% that occurred offsite; elaborating the importance of follow up in blood donors through effective donors' surveillance system [21]. The findings in our study suggests that low hemoglobin levels and adverse donation events are significantly associated p=0.003 at 95% confidence interval and 0.05% margin of error ,which also support the results from other studies that blood donation related adverse reactions is a multifactorial process mainly demonstrated by factors such as young age, female gender, low weight, and first time blood donation status [34, 35] As demonstrated by Newman *et al.*, [18], the occurrence of adverse reactions are more likely in lower weight groups as stated in accordance with previous findings [36], and likewise demonstrated in a study in United States [37], which supports the findings of this study for determining the association of adverse events to weight categories the p=0.003 at 95% confidence interval and 0.05% margin of error. The female participants in current study were only 2.38% which is much less as compared to Italy where 30% of blood donors are female [38]. The overall female voluntary blood donors are <1 % of the total blood donor population in Pakistan according to the previous researches [26, 39]. However, our study revealed that there is no association between the adverse hemovigilance reactions and gender. The main reasons behind this lesser female proportion attributes to the paucity of information, cultural norms and increase misperception regarding adverse health outcomes in female blood donors. Hematoma and delayed bleeding along with hypotension/weakness constituted the 2nd most common (1.2%) of the overall adverse hemovigilance reactions in our study. These results settle with a study 2% from Bangladesh [24]. The findings are lesser as compared with the results of an Indian study by Agnihotri *et al.*, [22] which enshrined that 35% of all the adverse donors' events were localized hematoma. Another study from US which also elaborated a 15.1 % of the bruise /hematoma in blood donors The defective phlebotomy technique related localized adverse hemovigilance reactions occur 1 in every 6300 blood donors [40]. Moreover, the severity of all the adverse hemovigilance events in blood donors were of mild to moderate intensity predominantly. This also compliments the findings of other native studies which did not record any life threatening or severe intensity adverse reactions in their study [25, 28].

CONCLUSIONS

The overall prevalence rate of acute hemovigilance reactions revealed in our study was 8.57% of all the healthy blood donors` population taken from the public sector tertiary care hospital blood banks. It was learnt that no severe intensity acute hemovigilance reactions were observed during and after the blood donation thus strengthening the fact that blood donation is a harmless process. The adverse reactions are avoidable complication of blood donation which can be prevented through active surveillance during and after the blood donation process. Delayed adverse reactions are also prevalent among the blood donors but the nonexistence of baseline centralized data on delayed adverse hemovigilance reactions is a major unresolved hinderance for a sustainable base of voluntary blood donors for future blood demands.

Authors Contribution

Conceptualization: SN, AA
Methodology: SN, AA, BA, TN
Formal Analysis: SN, BA, TN
Writing-review and editing: SN, AA, TN

All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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