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Adverse Events and Risk Factors in Nepalese Blood Donors

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ABSTRACT

Background: The occurrence and fear of adverse events during blood donation is one major deterrent for new and old donors. Mostly, adverse events are regarded as symptoms in donors and clinical monitoring of donors is not usually practiced.

Methods: The general characteristics, past donation experiences, and measurements of heart rate and blood pressures were recorded in voluntary blood donors in the settings of blood donation camps organized in communities and hospital blood banks. Adverse events were recorded as subjective experiences and clinically detected presyncope or syncope.

Results: A total of 1150 donors participated in the study (79.2% males, 73% between 21 to 40 years, 62.4% overweight or obese); 9% experienced adverse effects and 4.8% had clinical presyncope and/or syncope. Among 693 repeat donors, 2.9% had experienced adverse events in past donation. Adverse events symptoms were more common in young, females, donors with previous adverse experience, long hours without meal, and in blood camps (p values <0.05). Less sleep hours, number of past donations, and amount of blood removed did not cause significant differences in the rate of adverse events. Subjective and clinical adverse effects were not significantly correlated.

Conclusions: Rate of adverse reactions is high in Nepalese blood donors. Young, female, and fasting donors should be closely monitored, especially in blood camps outside designated centers.

Keywords: Adverse events; blood donation; blood donation camps; high risk.

INTRODUCTION

A country's blood supply is said to be adequate if the rate of donation is 15 per 1000 people per year.[1] Generally, about one-third of the population is eligible to donate.[2] There is global discrepancy in the rate of blood donation, usually very low and inadequate in low- to middle-income countries.[3]

Blood donation is essentially an instance of acute blood loss. This poses challenge, especially to the blood pressure homeostasis. As a result, vasovagal reactions, experienced as syncopal symptoms, are known to occur in some donors. The rate of occurrence of adverse events (AEs) among donors is reported from 0.08 to 13% in different studies and vasovagal reactions are the commonest types of AE.[4-6] Occurrence of AEs is one major deterrent for people to donate blood for the first time or repeat.[7,8]

Generally, adverse events are reported on the basis of subjective symptoms. Monitoring physiological parameters are desirable but not in practice. In Nepalese donors, adverse events have not been explored much.

METHODS

This was a observational study that was conducted in different blood donation camps and hospital blood banks in Kathmandu, from June 2023 to September 2024. The subjective adverse events experienced by the blood donors and the changes in heart rate (HR) and blood pressure (BP) in response to removal of blood were recorded in order to identify health risk situations at the earliest. Ethical approval was obtained from the Research and Institutional Review Committee of Nepal Medical College (Ref. No. 56-079/080). Informed written consent was obtained from all donor participants.

Donors were selected according to the blood donor eligibility criteria practiced by the Nepal Red Cross Society: age 18-60 years, weight above 45 Kg, have

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hemoglobin above 12 gm/dL (clinically judged), have blood pressure 110-160/70-96 mmHg, not pregnant or lactating, at least 8 days since the start of recent menstruation, not recently taking any medicines, and not had a surgery within 2 years.[9]

The minimum sample size was 1095, calculated by using the Epi-Info version 7.2.5; taking confidence interval of 95%, allowable margin of error 2% and a design effect 1.5. Adverse events prevalence rate of 7.8% (rounded to 8%) was considered referring to a previous study conducted in Nepalese donors.[10] Donors were selected purposively; every blood donor was approached and those willing and consenting to participate were recruited.

Information about donor characteristics such as age, sex, blood group types, duration of last sleep, last meal, number of past donations, and occurrence of AEs in past donations were recorded by conversation with the donor. Height and weight were recorded using wall-mounted measuring tape and a digital weight scale, respectively. Body mass index (BMI) was categorized as recommended for Asia Pacific population.[11] Heart rate, beats per minute (HR, bpm) was measured manually from the radial artery of the non-donating hand. Blood pressure (BP) was measured manually using the auscultatory method. The BP cuff was firmly placed around the non-donating arm throughout and after the blood donation up to the five minutes of observation period. After the initial (pre-donation screening) measurement, donor was seated in donation bed and phlebotomy was performed with necessary precautions. HR and BP were recorded during (about two minutes from start), immediately after (0 min), two minutes after, and five minutes after blood donation.

Subjective adverse effects were recorded by asking the donors frequently if they felt any difficulties at any time. Donors were also instructed beforehand to report any difficulties or unpleasant sensations as soon as they were experienced. Syncope was defined as a condition of systolic blood pressure less than 70 mmHg and heart rate less than 50 bpm. Presyncope was defined as a condition of fall in systolic BP by 30 mmHg or more with a concomitant fall in HR by 10 bpm or more; or a fall in HR by 30 bpm or more with a concomitant fall in systolic BP by 10 mmHg or more.[12] Amount of blood withdrawn was indicated by the type of collecting bag: single bag (350 mL) or multiple bags (450 mL).

Primary data was entered into MS Excel, checked for errors and completeness, and coded. HR and BP changes were calculated and identified for the purpose of clinical adverse events (syncope/presyncope). The data was then transferred to SPSS (version 16.0) for further analysis. Donors' subgroups were formed according to different characteristics and the rates of the adverse events were compared among groups by Chi square. A p value less than 0.05 was taken as statistically significant.

RESULTS

The study was completed in a total of 1150 donors. Majority of donors were males, of age between 21 and 40 years, and in the BMI category of overweight or obese (Table 1). Among the 693 repeat donors, 20 (about 3%) had experienced some adverse effects in previous donations. About three percent donors had not taken a meal (breakfast or lunch) for at least four hours. About 13% had less than 7 hours in last sleep. Regarding amount of blood withdrawn, blood was collected in single bag in about 58% of donors. In two donors, blood collection was stopped soon (in about a minute, less than 100 mL collection) due to complaints of symptoms and they were excluded in some analyses.

Table 1. Donors' general and blood donation related characteristics. (N=1150)

Characteristics	Subgroups	Number	Percentage of total
Age groups (Mean = 29.6±8.56)	Up to 20 years	162	14.1
	21 to 30 years	544	47.3
	31 to 40 years	296	25.7
	41 years and above	148	12.9
Sex	Male	911	79.2
	Female	239	20.8
Body mass index (BMI) categories	Normal (BMI < 23)	376	32.7
	Overweight or obese (BMI ≥ 23)	774	67.3
Duration of last sleep (Mean = 7.62±1.04)	Less than 7 hours	148	12.9
	7 to 9 hours	947	82.3
	More than 9 hours	55	4.8

Table 1. Donors' general and blood donation related characteristics. (N=1150)

Characteristics	Subgroups	Number	Percentage of total
Number of past donations	None (new donors)	457	39.7
	1-5 times	445	38.7
	6 or more times	248	21.6
Adverse events in past donations (N=693)	No	673	97.1
	Yes	20	2.9
Last meal within 4 hours	No	33	2.9
	Yes	1117	97.1
Amount of blood withdrawn	Single bag (350 mL)	671	58.3
	Multiple bags (450 mL)	477	41.5
	Stopped (< 100 mL)	2	0.2

From the time of blood withdrawal and up to five minutes of observation, 104 donors (9%) reported of experiencing difficulties such as headache, dizziness, light-headedness, sweating, and numbness in limbs. By measuring HR and BP changes, AEs were detected in 55 donors (4.8%).

The rate of occurrence of different AEs in donors were compared with respect to different donor characteristics (Table 2). Age seemed to be a significant factor only in relation to subjective AEs. More percentage of younger donors complained of subjective adverse experiences ($p<0.05$). In donors who had experienced AEs in the past, subjective as well as clinical AEs were significantly more common. Place of blood donation also had significant effects, but in opposite manners. Subjective AEs were experienced more commonly in blood camps organized in communities as compared to donating in hospital blood bank. Conversely, presyncope and/or syncope was more commonly observed in hospital or blood bank settings compared to community blood donation camps. All types of AEs were significantly more common in donors who had not had meal (breakfast or lunch) within the past four hours.

Table 2. Comparison of rate of adverse events among donors with different characteristics. (Chi square test)

Characteristics	Subgroups	Adverse Symptoms		Clinical adverse event	
		No (%)	Yes (%)	No (%)	Yes (%)
Age groups	Up to 20 years	143 (88.3)	19 (11.7)	154 (95.1)	8 (4.9)
	21 to 30 years	486 (89.3)	58 (10.7)	519 (95.4)	25 (4.6)
	31 to 40 years	279 (94.3)	17 (5.7)	283 (95.6)	13 (4.4)
	41 years and above	138 (93.2)	10 (6.8)	139 (93.9)	9 (6.1)
	X^2 (p)	8.012 (0.046)*		0.698 (0.874)	
Sex	Male	851 (93.4)	60 (6.6)	864 (94.8)	47 (5.2)
	Female	195 (81.6)	44 (18.4)	231 (95.2)	8 (3.3)
	X^2 (p)	32.179 (<0.001)***		1.365 (0.243)	
Weight-to-height ratio	Normal BMI	593 (89.8)	67 (10.2)	635 (96.2)	25 (3.8)
	Overweight/obese	453 (92.4)	37 (7.6)	460 (93.9)	30 (6.1)
	X^2 (p)	2.312 (0.128)		3.366 (0.067)	
Duration of last sleep	< 7 hours	128 (86.5)	20 (13.5)	137 (92.6)	11 (7.4)
	7-9 hours	866 (91.4)	81 (8.6)	907 (95.8)	40 (4.2)
	>9 hours	52 (94.5)	3 (5.5)	51 (92.7)	4 (7.3)
	X^2 (p)	4.733 (0.094)		3.680 (0.159)	
Number of past donations	New	406 (88.8)	51 (11.2)	434 (95.0)	23 (5.0)
	1 to 5 times	409 (91.9)	36 (8.1)	424 (95.3)	21 (4.7)
	6 or more times	231 (93.1)	17 (6.9)	237 (95.6)	11 (4.4)
	X^2 (p)	4.424 (0.109)		0.132 (0.936)	
Adverse events experienced in past donations (**n=693**)	No	624 (92.7)	49 (7.3)	644 (95.7)	29 (4.3)
	Yes	16 (80.0)	4 (20.0)	17 (85.0)	3 (15.0)
	X^2 (p)	4.449 (0.035)*		5.040 (0.025)*	

Table 2. Comparison of rate of adverse events among donors with different characteristics. (Chi square test)

Characteristics	Subgroups	Adverse Symptoms		Clinical adverse event	
		No (%)	Yes (%)	No (%)	Yes (%)
Had meal within 4 hours	No	26 (78.8)	7 (21.2)	29 (87.9)	4 (12.1)
	Yes	1020 (91.3)	97 (8.7)	1066 (95.4)	51 (4.6)
	X^2 (p)	6.116 (0.013)**		4.018 (0.045)*	
Place of donation	Blood camp	520 (86.8)	79 (13.2)	585 (97.7)	14 (2.3)
	Blood bank	526 (95.5)	25 (4.5)	510 (92.6)	41 (7.4)
	X^2 (p)	26.115 (<0.001)***		16.417 (<0.001)***	
Amount of blood withdrawn (**n=1148**)	350 mL	605 (90.2)	66 (9.8)	640 (95.4)	31 (4.6)
	450 mL	439 (92.0)	38 (8.0)	454 (95.2)	23 (4.8)
	X^2 (p)	1.183 (0.277)		0.025 (0.874)	

Amount of previous sleep hours, number of past donations, and amount of blood withdrawn did not relate to significant differences in either type of AEs. In overweight or obese donors, there was higher rate of detection of presyncope/syncope but the difference was of borderline significance (p = 0.067).

The Phi coefficient of correlation between the symptomatic and clinical types of AEs was found to be 0.029 (p = 0.329), suggesting no significant correlation between them.

DISCUSSION

The prevalence of symptomatic and clinical adverse events and their correlating factors were explored in a total of 1150 voluntary blood donors in an observational study conducted in different blood bank and community blood camps in Kathmandu. The criteria of eligibility for blood donation are universally similar, and apply to both males and females. In this study, about 21% of donors were females. The proportion of female donors have been reported to be variable in various populations, ranging from less than 3% to more than a third of total number of blood donors.[6,13-16] Most other characteristics of the donor population are comparable to other studies.

The overall rate of symptomatic or subjective adverse events observed in this study was 9%. The rate of AEs is diverse in different characteristic categories, with significantly higher rates in young donors (11.7% in donors up to 20 years' age), females (18.4%), with AE experienced in past donation (20%), not taken meal for long hours (21.2%), and in community blood camps (13.2%). The higher rate of AE in young donors, females, and past adverse experiences have been recognized in several other studies.[6,14-18] However, John et al (2017) have reported no significant difference in rates of AE in males and females in their study conducted on 3520 donors (females 12.24%) in a tertiary level Nigerian hospital.[14] Philip et al (2014), in their study comprising 88,201 donations in a single center in Maharashtra-India, have reported higher AE rates in donors of or above 45 years compared to donors less than 45 years, which is contrary to most other reports.[17]

We did not find significant difference in AE rate with respect to amount of blood withdrawn. The finding of Philip et al (2014) is similar, when comparing AE rate with respect to amount of blood volume collected – 350 mL or 450 mL.[17] Goncalez et al (2012) have reported that lower BMI is associated with higher rate of AE.[16] Our finding is suggestive of similar tendency of subjective AE but opposite with clinical AE, although the difference in the two donor groups in our study is not statistically significant. Agnihotri et al (2012) have reported significantly higher overall AE frequency in donors donating 350±35 mL blood compared to those donating 450±45 mL blood (3.97% vs 0.67%, P<0.0001).[6] This seems quite contrary to the general thought that AEs would be more common or severe in case of more amount of blood removed than when less amount is withdrawn. However, 350 mL blood had been collected from donors with body weight < 55 Kg and 450 mL blood from donors ≥ 55 Kg, although the authors claimed to have adjusted the blood volume collected as per donors' body weight. Therefore, the relation of AE rate to the amount of blood removed needs further exploration and verification.

In our study, the symptomatic AEs were more frequent in community blood donation camps than in hospital blood bank. Sandhya et al (2020) observed that of the total number of adverse events, 81% occurred in blood donation camps and 19% in blood banks.[19] where as Agnihotri et al (2012) have reported almost identical

rates of AEs when donating in blood donating camps (1.58%, n=20,671) and donating in hospital premises (1.59%, n=17,225).[6] A study on Nigerian population observed more AE in blood banks and argued that donors in blood camps get encouragement and support from the interactive and friendly environment.[15]

We observed significantly higher rate of AE in donors who had not taken meal within last four hours. Agnihotri et al did not observe significant relationship with time of taking last meal.[6] Agarwal et al (2016) observed that the rate of vasovagal reaction decreased significantly by introduction of pre-donation hydration.[18] An earlier study from Nepal observed that pre-hydration with plain water was associated with a significant fall in systolic blood pressure in donors.[10]

In this study, the overall rate of AEs, as clinically evidenced by significant falls in systolic blood pressure and heart rate, was 4.8%. Most studies on donor adverse events are based on symptoms instead of clinical measurements. Kumar et al (2010) observed that the occurrence of symptoms of vasovagal reactions was associated with significant falls in systolic blood pressure and pulse rate.[20] We did not find a significant correlation between clinical and symptomatic AEs. An attempt to define blood donor AE in terms of changes in blood pressure and/or heart rate or other clinical parameters is lacking. The definition of clinical AE in this study has been adopted from study by Lu et al (2003) for the diagnosis of postural hypotension and syncope in postural challenge tests.[12]

A small sample size is the main limitation of this study, which discourages the comparisons within subgroups and generalization of the findings. The use of clinical measurements with view of detecting symptomatic AEs in donors is a noble thought but the poor correlation between the two types of AEs did not support it.

CONCLUSIONS

Considering the high rate of adverse events in blood donors, we recommend close monitoring, especially the young and female donors. Information about fasting state and adverse experiences in previous donation should be added as part of donor screening to identify risk groups. Finally, donors should be encouraged to donate blood in designated centers.

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