

Pattern of Donor Adverse Reactions in Blood Donation in a Tertiary Care Hospital in Bangalore, India

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ABSTRACT

Introduction: Blood is one of the unique and precious gift that one person can give to another person. Most donors tolerate blood donation well, but sometimes donors can develop adverse reactions.

Aim: To analyse the pattern of donor adverse reactions in blood donation in a tertiary care hospital in Bangalore, India.

Materials and Methods: It was an ambispective cross-sectional study. Donors who developed adverse reactions over a period of three years from January 2018 to December 2020 (January 2018 to December 2019- retrospective and January 2020 to December 2020- prospective) in a tertiary care hospital in Bangalore were studied. The parameters analysed were the type of adverse reaction (systemic and local), the reaction in first-time donors or repeated donors, and the gender of the donor. Stata 2016 version was used

in the analysis of data. Adverse Donor Reaction (ADR) is reported as a percentage and 95% confidence interval. The percentage of ADR in males and females was compared using the Chi-square test.

Results: The population studied consisted of 37,007 whole blood donors, with 35347 (95.51%) males and 1660 (4.48%) females. Among 37,007 donors, 316 donors 316/37007 (0.85%) had adverse reactions out of which, 287 were males and 29 females. There were 238 first-time donors and 78 repeat donors. The Vasovagal Reaction (VVR) was the most common 307 donors (97.15%) systemic ADR seen. Local reactions were seen in 9 donors (2.84%).

Conclusion: The number of donors who developed ADRs was low still it is desirable to reduce risks. The ADRs can be reduced by diligently following the screening protocols and carrying out the venipuncture precisely.

Keywords: Adverse donor reaction, Giddiness, Local reaction, Systemic reaction, Vomiting

INTRODUCTION

Blood is one of the unique and precious gift that one person can give to another person. Voluntary blood donors are important assets for blood banks. Most donors tolerate donating without any adverse incident, but sometimes donors can develop adverse reactions. These adverse reactions can happen while donating or after donation. A donor's adverse reaction is any untoward event or complication experienced by the donor before, during, or after the blood donation process [1-3].

The ADR, a rare event, has the most negative impact on the blood donor return rate. Improving the donor return rate and alleviating some adverse events are important. First-time blood donation, younger age groups, and females have a stronger association with ADRs. ADR can be acute (immediate) or delayed (after a single donation), or chronic in response to the long-term donation. It can also be classified as systemic or local reactions. Acute reactions appear due to anxiety about painful venipuncture or due to blood volume deficit during donation. The VVR is the most common type of acute and systemic reaction during or immediately after blood donation. Haematomas, thrombophlebitis, infection, and physical damage to nerves, tendons, or muscles are other adverse effects. Numbness, tingling, and radiating pain could be the presenting signs of nerve damage. Regular voluntary donors can develop iron deficiency [1-5].

Donor vigilance is regular monitoring of adverse reactions in the blood bank to improve the quality and safety of blood donors. This study was done to analyse the pattern of donor adverse reactions in blood donation in blood transfusion services.

MATERIALS AND METHODS

Donors who developed adverse reactions (retrospectively from January 2018 to December 2019 and prospectively from January

2020 to December 2020) in a tertiary care hospital in Bangalore over a period of three years studied. Approval for the study was obtained from the Institutional ethics committee (IEC 399/2019).

Inclusion and Exclusion Criteria: After sufficient predonation counseling and screening, donors within the age group of 18-60 years were selected. Donors who were not willing to donate voluntarily and fear needle pricking were excluded from the study.

Procedure

Donors were selected with a help of a donor questionnaire with a consent form by rules laid down by the Drugs and Cosmetics Act, Ministry of Health and Family Welfare, Government of India [1,2,6,7]. Donors' signatures were also taken on the donor record register as proof of the accuracy and reliability of the records and data. All the donor records were maintained and stored in both electronic and file forms. The parameters analysed were the type of adverse reaction (systemic and local), the reaction in first-time or repeat donation, and the gender of the donor.

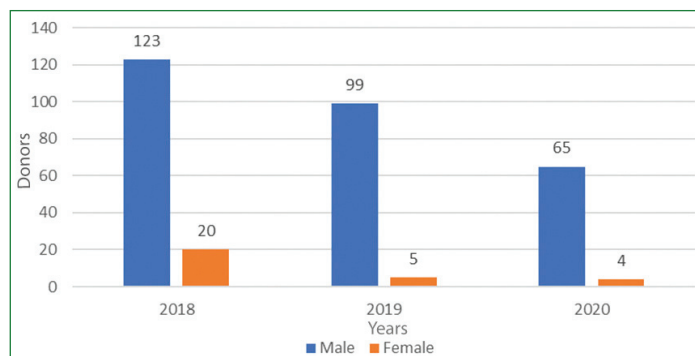
STATISTICAL ANALYSIS

Stata 2016 version was used in the analysis of data. ADR is reported as a percentage and 95% confidence interval. The percentage of ADR in males and females was compared using the Chi-square test.

RESULTS

The population studied consisted of 37,007 whole blood donors with 18,588 (50.2%) voluntary donors and 18,419 (49.7%) replacement donors. Out of the total 35,347 (96% of the total) were males, and 1660 (4% of the total) were females. Adverse reactions were divided into local and systemic reactions. Donors who manifested adverse reactions were managed appropriately and were kept under observation in the blood bank until their vital parameters returned to normal.

Of the total donors, 316 (0.9%) donors had adverse reactions. The prevalence of ADR of 0.9% estimated with a 95% confidence interval was reported. Adverse reactions were seen in 287 (0.81%) male donors and 29 (1.7%) female donors. The proportion of female donors 29/1660 (1.746%) who experienced ADR is significantly higher (p -value<0.001) as compared to male donors 287/35347 (0.8119%). The adverse reactions were seen more in the year 2018 compared to 2019 and 2020. In the year 2020, the total number of donors were significantly low due to the Coronavirus Disease 2019 (COVID-19) pandemic and the ADRs are seen as falsely low. (The total numbers of donors in 2018, 2019 and 2020 were 12822, 13328, and 10857, respectively). Year-wise distribution of ADR is shown in [Table/Fig-1].



[Table/Fig-1]: Year-wise distribution of Adverse Donor Reactions (ADR).

Of donors who had adverse reactions, the adverse reaction occurred predominantly in the 18-30 years age group. The demographic data of donors who developed adverse reactions are shown in [Table/Fig-2].

Age group (in years)	Male (n)	Female (n)	Total
18-30	221	22	243
31-40	52	7	59
41-50	13	0	13
51-60	1	0	1
Total	287	29	316

[Table/Fig-2]: Demographic data of donors who developed adverse reactions.

Among 316 donors who developed adverse reactions, 238 were first-time donors and 78 were repeat donors. Year-wise distribution of first-time and repeat donors who developed adverse reactions is shown in [Table/Fig-3].

Year	First-time donors		Repeat donors		Total
	Males	Females	Males	Females	
2018	97	19	25	2	143
2019	74	4	26	1	105
2020	41	3	24	0	68
Total	212	26	75	3	316

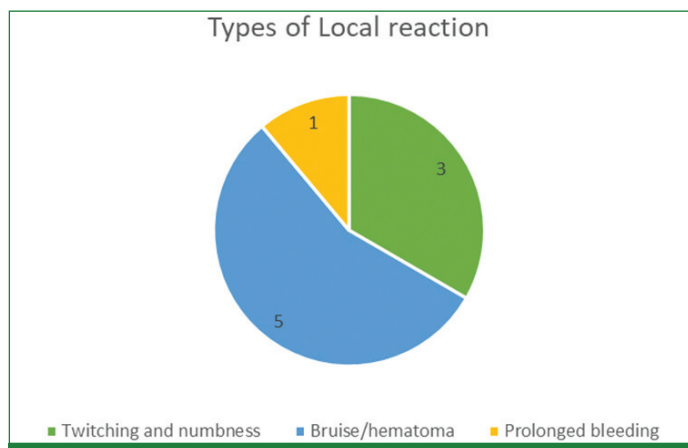
[Table/Fig-3]: Year-wise distribution of first-time and repeat donors who developed adverse reactions.

The VVR was the most common systemic reaction, developing in 307 (97.15%) of the total adverse reaction. The most common VVR was giddiness followed by vomiting, nausea, and sweating, where 70.25% of the donors had giddiness after donation. One donor had giddiness superseded by loss of consciousness, postdonation. One donor had hyperventilation before the donation and the donation was deferred. [Table/Fig-4] shows types of systemic ADR.

A 9 (2.8%) of donors had a local reaction. Three of the donors had twitching and numbness. One donor had prolonged bleeding. Five donors developed a haematoma, thrombophobe (Benzyl nicotinate and heparin) ointment was applied in the area around the venipuncture site and the donor was reassured. One donor had hyperventilation before the donation and the donation was deferred. The types of local reactions are shown in [Table/Fig-5].

Systemic adverse reactions					
	Predonation	During donation	After donation		
Type of reaction	Anxious and hyperventilation	Giddiness	Giddiness and vomiting	Giddiness and nausea	Giddiness and sweating
Numbers of donors	1 (0.31%)	222 (70.25%)	19 (6.01%)	4 (1.265%)	9 (2.848%)

[Table/Fig-4]: Shows types of systemic Adverse Donor Reaction (ADR).



[Table/Fig-5]: Shows the types of local reactions.

DISCUSSION

Blood donation is normally a safe procedure, but sometimes adverse reactions can occur during or after donation. The ideal donor comes voluntarily without expecting remuneration for blood donation and it is important to care for these donors [1-3]. The adverse reactions that occur in donors can be divided into local reactions and systemic reactions. The systemic reactions can be mild to severe. The most common systemic adverse reaction is a VVR.

The current study is undertaken to analyse the pattern of adverse reactions, including the incidence of ADR in male, and female populations, the type of reaction (systemic or local and the reaction in first-time and repeat donors.

A total of 38,917 donors over a period of three years were studied. An average of 12962 donors per year was donated. Most of the donors were voluntary donors 20,498 (52.6%), while replacement donors accounted for 18,419 (47.3%). Most of the donors were males (90.8%) and females account for (9.1%) of the donors. Out of 38,917, adverse reactions were found in 316 donors (0.9%). This correlates with the results of various studies where the ADR ranges from 0.3% to 3.8% [3-5]. A study done by Kandukuri MK et al., showed adverse reactions were seen in 0.9% of donors of which 80% were males. Based on the type of blood donor reaction, 231 males and 65 females reported giddiness [8].

ADRs were seen more in first-time donors (75%-238 donors) than the repeat donors (25%-78 donors). A similar study was conducted by Rajvanshi R et al., in which total of 35,027 donations were recorded in three years amongst which, 11,586 were replacement donors and 23,441 were voluntary donors. Male donors were 33,867 and female donors were 1,160. A study done by Rajvanshi R et al., in Gujarat showed in 0.9% (315) donors and ADR was seen more in the first-time (0.84%) compared to the repeat donors (0.46%) [9]. In a study done by Newman BH et al., ADR was found to be higher (47%) among first-time blood donors than a lower 36% among repeat donors [10]. Donors in the age group of 18-20 years had more ADRs than donors of age over 30. This finding is comparable with a study at Government Medical College, in Jammu by Ryhan R et al., [11]. It showed that ADRs were seen more in the younger group (18-37 years) [11]. ADRs were seen more in females than in males supported by a study done by Sreekumar PK et al., [12]. One more study done by Sreekumar PK et al., showed that 84% of ADR is due to VVR [13]. VVRs showed a significant association with

young age, female gender, and first-time donation status reported by Mangwana S [13].

Nausea and vomiting (8%) were the second most common adverse reaction. It is comparable to a study done by Sultan S et al., and Jain S et al., where nausea and vomiting were seen in 133 and 11 donors, respectively [14,15].

The haematoma was found to be common in the local donor adverse reaction. Two donors had a haematoma and one had prolonged bleeding in the study. Tiwari AK et al., study showed that haematoma was more commonly observed in repeat donors as compared to first-time donors (4% vs. 2%) [16].

No delayed donor reactions were recorded in the present study similarly there is no delayed donor reaction in a study by Daanish AB et al., [17].

The distribution of adverse reactions in the present study compared with other studies is shown in [Table/Fig-6] [8,9,13,17,18,19].

Author name	Place of study	Year	Type of adverse reaction	Percentage of Adverse reaction
Kandukuri MK et al., [8]	Andhra Pradesh	2014	Giddiness, nausea, vomiting, cramps, chills, and anxiety	0.93%
Kumari S [18]	Punjab	2015	Giddiness, sweating, nausea, pallor, vomiting, loss of consciousness	0.7%
Almutairi H et al., [19]	Saudi Arabia	2017	Syncope, nausea, vomiting, convulsions, chills.	1.1
Sreekumar PK et al., [13]	Kerala	2018	Vasovagal reactions (VVR)	0.41%
Rajvanshi R et al., [9]	Gujarat	2019	Syncope, haematoma	0.9%
Daanish AB et al., [17]	Dhaka	2019	VVRs, syncope, vomiting haematoma	3.8
Present study	Karnataka	2023	Giddiness, nausea, vomiting, sweating, haematoma	0.9%

[Table/Fig-6]: The distribution of adverse reactions in the present study compared with other studies [8,9,13,18,20,21].

Management of Adverse Donor Reactions (ADR): In cases where adverse reactions happened during donation, and blood donation was stopped immediately, donors were reassured, and their vitals were checked. The VVR was managed by lowering the head end and loosening the tight clothing thus maintaining adequate airway and elevating the legs. In one donor, where there was a loss of consciousness, the donor was made to lie down in a lateral position to prevent any aspiration. All donors who had VVRs recovered within 10-15 minutes after the donation. The donors who developed an adverse reaction after donation were made to lie down on the donor couch, vitals were checked, and refreshments provided. For donors who developed a haematoma, thrombophobe (Benzyl nicotinate and heparin) ointment was applied in the area around the venipuncture site and the donor was reassured.

Limitation(s)

The donor's adverse reaction which had developed outside the blood transfusion services and hospital campus, later after reaching

the workplace or residence was not documented and included in the study. Also, local reactions like haematoma which happened to see or hear over the phone, after a few days of blood donation were not documented.

CONCLUSION(S)

The number of donors who developed ADRs in relation to donors donating blood was low still it is desirable to reduce risks to a minimum. The ADRs can be reduced by following the screening protocols in a diligent manner, making the donor feel comfortable and carrying out the venipuncture precisely and cleanly. Traumatic needle insertion with invasive and painful maneuvers should be avoided. By reducing the adverse reactions during and after donation, the donor return rate can be improved.

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