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Donor Haemovigilance: A South Indian experience

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ABSTRACT

Background: Blood Donation from healthy screened donors is a well-tolerated procedure. However a small percentage may experience adverse donor reactions. Donor haemovigilance aims at identifying and documenting these reactions for donor safety.

Materials and Methods: This prospective cross-sectional study conducted at the Department of Transfusion Medicine & Immunohaematology, Govt. Medical College, Kozhikode, Kerala for a one year study period from January 1st 2018 to December 31st 2018 included all adverse donor reactions and donor determinants in vasovagal reactions in allogenic whole blood donors. Donors were assessed as per the Standard Operating Procedure (S.O.P) based on national guidelines. 350ml collection bags were used. Vasovagal reactions were also graded as per the Blood Donation Reactions Inventory scale (B.D.R.I).

Results: During the 1 year study period, 1.79% of 27,800 donors experienced adverse reactions. The most common symptoms were pre-syncopal 1.33% with syncope forming only 0.3% and local reactions 0.16%. Correlation with donor characteristics using Pearsons chi square test showed significance for female gender, first timers and lack of adequate sleep (<5 hrs). In our study there was no association with age (S.O.P guidelines) or food intake <4hrs.

Conclusion: Our study reinforces the safety of blood donation with a very low prevalence of adverse reactions. Proper donor counseling and examination noting donor characteristics like adequate sleep, food intake and alleviation of fears and doubts of first timers can play a major role in further reducing the reaction rate and ensuring repeat donors, the need of the hour.

1. Introduction

In a healthy individual, blood donation is generally a well-tolerated procedure. Blood banks in our country follow their own Standard Operating Procedure (S.O.P) based on standard national guidelines like the Drugs & Cosmetics Act / National Blood Transfusion Counsel guidelines, in selecting donors to ensure that the procedure stays safe and uneventful. However, a small percentage may experience adverse events ranging from small hematomas and pre-faint reactions to systemic vasovagal reactions.[1,2] The incidence varies in different parts of the world and can vary from 0.3-4%.[3,4] With an ever-increasing need for blood and components, blood banks have an important role to play in ensuring donor comfort and minimizing any factors that can lead to adverse reactions during donation. This will promote regular and repeat donors which is the mainstay of ensuring adequate supply of safe blood. Maintaining a regular pool of repeated voluntary donors is also one of the main aims of our National Blood Transfusion policy.

During blood donation there are a number of documented adverse reactions that even a healthy donor can face.[5] It ranges from local events like hematoma to systemic events like vasovagal reactions. A vasovagal reaction

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is a general feeling of discomfort and weakness with anxiety, dizziness and nausea which may progress to loss of consciousness, vomiting, convulsions or even loss of sphincter control in some.[6] Donation while dehydrated / an empty stomach / inadequate sleep/ first time donors/ young age etc are all documented causes whereas in some donors the pain during venepuncture, sight of blood or even an adverse reaction in another donor might trigger a reaction.[7] Hence anticipation and early detection of such adverse reactions, close monitoring and selective deferral is of utmost importance in donor retention. An idea about the determinants of such reactions in the Indian population will also be helpful in this context.

There are a number of scales proposed under various Haemovigilance programs for classification of Donor reactions. The Blood Donation Reactions Inventory (B.D.R.I) scale is a standardized measure of subjective physiological reactions immediately after blood donation and individual scores can be used to predict chances of repeat donation as well.[8,9] The present study aims at applying this scale to the blood donor population at Govt. Medical College Kozhikode for assessing the prevalence and degree of donor reactions.

2. Materials and Methods

This was a prospective cross sectional study on adverse donor reactions and donor determinants in vasovagal reactions in allogenic whole blood donors during a study period of 12 months at the Department of Transfusion Medicine & Immunohaematology, Government Medical College, Kozhikode, Kerala, India. Inclusion and exclusion criteria for donors were in accordance with the departmental Standard Operating Procedure (SOP) which is based on National Blood Transfusion Counsel (NBTC) standards and rules laid down in Drugs and Cosmetics Act, Ministry of Health and Family Welfare, Government of India.

Donors approaching the Blood bank first met a counselor, who briefed them about the benefits of blood donation, answered queries posted by the donors, and also adviced them about post donation care. This aimed at providing a friendly and comfortable environment to the blood donors to help alleviate anxiety, if any. A thorough medical history taking and examination including hemoglobin level assessment was done by trained doctors.

The actual process of blood collection was done using 350 ml collection bags under aseptic precautions and the donors were given refreshment post donation and observed for a period of 30minutes post donation. An adverse donor reaction was defined as the symptoms or signs of donor discomfort of sufficient severity such that either the donor called for attention of the staff or they were noticed by the staff during or after donation. Pain at the time of venepuncture was excluded.[10] Delayed donor reactions occurring after the donor left the blood bank and notified later were also documented by trained staff.

All donors were provided with the donor performa in both English and local language. It included donor characteristics like age, sex, donor status (first time/repeated), height, weight, and details like previous history of adverse reaction (if repeat donor), food/fluid intake and sleep. All local and systemic adverse reactions were recorded and those reactions of systemic / vasovagal nature were classified as per the Blood Donation Reactions Inventory Scale (B.D.R.I). It consisted of 11 items, each corresponding to a reaction or feeling regarding the latest blood donation. The symptoms recorded were 1) Faintness (feeling faint or losing consciousness), 2) Dizziness, 3) Weakness, 4) Facial flush, 5) Visual disturbance, 6) Difficulty in hearing, 7) Light headedness, 8) Rapid/Pounding heartbeat, 9) Sweating, 10) Rapid/difficult breathing and 11) Nausea / Upset stomach. Each item if present was graded from 0-5 using the 6-point Likert scale ranging from 0 ('not at all') to 5 ('to an extreme degree'). Donors were encouraged to mark any reaction felt and the grade to which it was felt, obtaining help from Doctors if required. The responses were summed to the final score producing values between 0 and 55. Higher values signified greater reaction intensity. A statistical analysis using Pearson chi-square test was also carried out to find out the significance between various donor characteristics analyzed and chance of developing vasovagal reactions. P value <0.05 was considered significant.

Abbreviated B.D.R.I scales with 6 (1, 2, 3, 5, 7 and 11 points) and 4 (1, 2, 3 and 7) item variants have also been proposed, but the present study was based on the 11 point scale.

3. Results

During the study period from 1^{st} January 2018 to 31^{st} December 2018; 27800 allogenic whole blood donations were made in our blood bank from the 36215 registries. Deferred donors were those who did not meet the criteria for healthy donors as per the Standard Operating Procedure. Voluntary Donors were 21684 and Replacement donors 6116.

Of 27800 donors, 10286 (37%) were in the age group of 18-30yr, 8896 (32%) were 31-40yr, 6950 (25%) were between 41-50yrs and the rest 1668 (6%) were in the age group of 51-60yrs. Most of our donors; 13622 (49%) were educated upto or less than 12^{th} Std, 10008 (36%) were pursing or completed graduation and only 4170 (15%) were postgraduates.

Female donors were notably less than males accounting for only 2.5% (695donors) of total donations. The average height in males was 168.2cms and among females it was 160.1cms, while the average weight in males was 73.5kgs and in females it was 56.8kgs.

Repeat donors were more, accounting for 64% (17792) compared to 36% (10008) first time donors. Among the Repeat donors only 21 gave history of adverse donor reactions in previous donations- 16 had history of tiredness, 2 syncope and 3 had hematoma/ thrombophelebitis. None of the repeat Donors admitted fear of donating blood, but among first timers, fear / apprehension / doubts were recorded at 22% (2202 donors).

As per the SOP, donors without food intake before 4hrs of donation were temporarily deferred from donating. Hence all our accepted donors had food before the procedure, with most having between 2-4 hrs (69%- 19182 donors), 0 -2 hrs (31%- 8618 donors). The average hours of sleep on day prior to donation was more than 5 hrs in 87% (24186 donors) and less than 5 hrs for 13% (3614 donors).

A total of 498 cases of adverse reactions were recorded from the 27800 Donations, accounting for 1.79% of the total bleeding. Of these, 43 were hematomas/ bruises (1-5cms) and 1 a case of thrombophelebitis which reported on the third day after donation, making local reactions form only 8.84% of total adverse reactions and 0.16% of total bleed.

Adverse reactions of systemic/vasovagal nature, which formed the remaining 454 cases (91.16% of total adverse reactions and 1.63% of total bleeding) were classified (Figure 1) and graded (Table 1) as per the B.D.R.I scale. These were classified into 11 points as given in the scale, and was also graded from 0-5 based on intensity (0- Not at all, 1- Slight degree, 2- Moderate degree, 3- Strong degree, 4- Very strong degree, 5-Extreme degree) as per the oral interview of the donors who experienced the adverse reactions, by the Medical Officer who explained the differences between the terms.

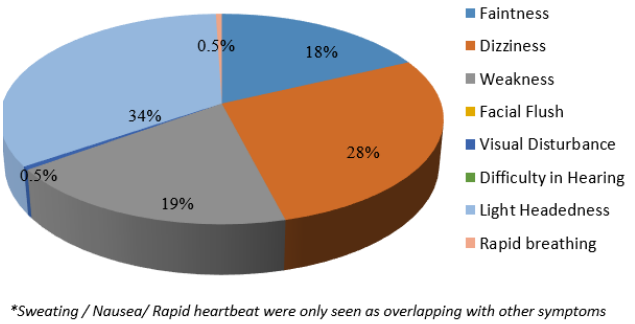

Figure 1: Types of systemic adverse donor reactions

The predominant vasovagal symptom reported was Light headedness (34%) followed by Dizziness (28%), Weakness (19%) and Faintness (18%). Visual disturbance and Rapid breathing was seen in 0.5% each.

The observations show that pre-syncopal reactions (81.9% of systemic adverse reactions and 1.33% of total bleeding) accounted more than actual fainting/syncope (18.1% of systemic adverse reactions and o.3% of total bleeding). There was also an overlap of symptoms - The 7 donors with rapid pulse also had lightheadedness. All the donors who experienced both nausea (25 donors) as well as sweating (31donors) had symptoms of either light-headedness/ dizziness/ fainting. The lowest percentage was for visual disturbance and rapid breathing, both complained by just two patients each. Two symptoms present in the BDRI scale but were not seen in any of the donors included facial flush and difficulty in hearing.

Table 1: Adverse Donor Reactions- Grade

Symptom	0	1	2	3	4	5
1.Faintness (feeling faint or losing consciousness)	0	0	36	31	14	1
2.Dizziness	0	0	16	61	47	3
3.Weakness	0	0	49	37	0	0
4.Facial Flush	0	0	0	0	0	0
5.Visual disturbance	0	0	2	0	0	0
6.Difficulty Hearing	0	0	0	0	0	0
7.Light headedness	0	0	65	79	11	0
8.Rapid/ Pounding Heartbeat	0	0	7	0	0	0
9.Sweating	0	0	0	0	31	0
10.Rapid/ Difficult breathing	0	0	0	2	0	0
11.Nausea / Upset Stomach	0	0	0	12	13	0

Comparing the symptoms with 5 donor characteristics namely Age, Sex, First time/ Repeat, Food intake and Sleep the observations are as follows-

Light headedness- At 34%, this was the commonest systemic symptom experienced by 155 donors. All grades improved with foot end elevation and oral fluids. None of the cases required any medication. The number of donors in the four age groups of the study were 60: 53: 39: 3, in increasing order of age. 128 were males and 27 females. As the proportion of Male: Females in the blood bank during the study period was 27105 males to 695 females, 0.47% of males and 3.9% females experienced the symptom. 143 (92%) of the 155 donors were first-timers. All had had food 2-4hrs prior and 82 donors (53%) had slept <5hrs.

Dizziness- Seen in 127 donors (28%), age group division being 42: 50: 27: 8. All were males, and first time donors. 56 donors (44% of those with dizziness) had food between 2-4hrs and the rest 71 (66%) had food between 0-2 hrs. All gave history of sleep more than 5hrs, with 18% waking up earlier than usual.

Weakness- Experienced by 19% (86 donors), and described by most as the inability to stand up and feeling drained. The donors in the four age groups of the study were 23: 34: 29:0 in increasing order of age. Among the 86 donors who complained of weakness only one was female. The proportion between first timers and repeat donors was 48:38. Food intake was between 2-4hrs in 28 donors (33%)

and sleep <5hrs was seen only in 10 (12%). Here again we noticed disturbance of usual sleep pattern / travel in 28%.

Faintness- The symptom observed in 82 donors (18%). One Donor experienced grade 5 and needed ionotropes and I/V fluid administration for recovery. Grade 4 required administration of IV fluids while Grade 2 and 3 improved with oral fluids and foot end elevation. The age distribution in increasing order was 27: 27: 19: 9 donors. All the donors were males. 67 (82%) were first timers, all had had food between 2-4hrs and in 36 donors (47%) sleep was <5 hrs. Though not in the questionnaire, 31% gave history of waking up earlier / disturbance of usual sleep / travel of > 1hr to reach Blood Bank on the day of donation.

Others- Visual disturbance was complained by two first time male donors, one in 18-30yr age group and the other 31-40. Both had food between 2-4hrs of blood donation and sleep was <5hrs. Rapid breathing was seen in one male and one female donor, both first timers in the 18-30 yr age group with food intake 2-4hrs prior and slept >5hrs.

Sweating, seen in 31 donors was a part of the vasovagal response occurring with other symptoms. Nausea / upset stomach seen in 25 donors, also occurred as part of other systemic vasovagal responses and not in isolation. Rapid heartbeat, visual disturbance and increased breathing were also noted. The symptoms which were not recorded in any of the donors were facial flush and difficulty in hearing.

Table 2 shows the Summary of the Systemic Adverse reactions observed with the Donor characteristics studied..

The Probability of developing vasovagal symptoms (systemic adverse reactions) was also analyzed for the following donor characteristics using the Pearsons chi-square test.

1. Sex- In our study, the proportion of males developing adverse reactions was only 1.57% compared to females, where it was 4.17%.The chi-square statistic is 28.616, p value is <0.00001. This result is significant at p< 0.05 which suggests that as in our study finding, adverse reactions are significant with respect to sex.
2. Age- The proportions in the four age groups of the study in relation to total donors in that group was 1.5%: 1.85%: 1.6%: 1.2%. The chi-square statistic is 5.6993, p value 0.127193, and hence not significant at p<0.05.
3. Donor status-In our study the percentage of First timers developing ADR was 3.89%, which was higher than the total percentage of ADR and higher than repeat donors in whom the value was 0.37%. The chi-square statistic is 494.4665, p value<0.00001. This result is again significant at p< 0.05, making first time donors more prone to ADR compared to repeat donors.
4. Food intake- The percentage of donors with ADR having a meal 2-4hrs prior was 1.69% compared to 1.5% in those in the 0-2hr period. The chi-square statistic is 1.4428, p value 0.229679, making the result not significant at p value 0.05.
5. Sleep- The percentage of ADR in donors who slept <5hrs was 3.6% compared to 1.3% in donors who slept >5hrs. The chi-square statistic is 103.4442 and with a p value <0.00001, the result is significant.

Table 2: Systemic ADR and donor characteristics

Sex distribution	**ADR**	**No ADR**
Males	425	26680
Females	29	666
Age		
18-30yrs	155	10131
31-40yrs	165	8731
41-50yrs	114	6836
51-60yrs	20	1648
Donor status		
First Timer	389	9619
Repeat	65	17727
Food intake		
0-2hrs	129	8489
2-4hrs	325	18857
Sleep		
<5hrs	130	3484
>5hrs	324	23862

4. Discussion

During the study period of one year we had a total of 27800 allogenic whole blood donations in our Blood bank. Adverse reactions were experienced by 1.79% of donors with 1.63% donors having systemic/ vasovagal symptoms. Local reactions were recorded at 0.16%. Systemic symptoms of vasovagal nature formed the bulk of donor reactions, of which presyncopal was recorded at 1.33% and true syncope at 0.3%.

The overall rate of ADR[5–13] is slightly more compared to international studies like Garozzo et al[13] (0.59%) and Crocco et al[13] where the rate was 1.2%, and less than studies in Indian population like Agnihotri N[6] where it was 2.5%. However it falls within the usual prevalence of 0.3-4% in various studies.[5–13] Every study[11–14] showed vasovagal reactions to be more frequent than local complications (70-90%) similar to ours (91%). The finding of pre-syncopal symptoms higher than actual syncope / fainting was also comparable with other studies.[11–14] This also reinforces the safety of the procedure as most of the recorded adverse reactions are minor symptoms.

The association of adverse reactions and various donor characteristics are also well documented in various studies.

Our study analyzed the association of mainly 5 donor characteristics namely- Age, Sex, First time/ Repeat, Sleep and Food intake with the risk of developing vasovagal reactions. As only donors with minimum prescribed weight, height, normal vital signs and hemoglobin of 12.5g/dl were accepted as per the S.O.P, these donor characteristics were

not analyzed.

Our findings of reactions being common in females and first timers are also seen in other studies like Newman BH[2], Trouern,[12] J Philip.[14] Our study also found a significant association with sleep and disturbance of sleep pattern with chance of developing vasovagal reactions. This donor characteristic has not been studied much in the various studies on the subject.

Our study could not find correlation between age groups and food intake(<4 hrs, as food intake >4hrs were deferred as per S.O.P). Studies like Touern[12] and J Philip[14]however, could find association with age with increased reaction rates in younger age groups(<45yrs). In our study the donor were classified into 4 age groups which showed an almost equal distribution. Regarding Food intake, as per our S.O.P, only donors who have had food at least within 4 hrs of blood donation are accepted. This could be the reason that we could not find any association between food intake and vasovagal reactions as prolonged fasting was deferred. It also reinforces the importance of ensuring that donors have a proper meal and are well hydrated before donation.[15]

5. Conclusions

Our study with an adverse donor reaction rate of 1.79% and only 0.3% of syncopal reactions among total bleeding, reconfirms the safety of the procedure. Reporting of delayed adverse reactions however was low in our study in spite of counseling and providing phone number for callback. No delayed systemic reaction was reported by any donor, the only delayed reaction reported was a single case of thrombophelebitis.

Our study concludes that apart from proper donor screening and adherence to standard guidelines of donor selection, importance to factors like adequate sleep, food intake, hydration and having trained counselors for alleviating fears and offering post donation advice will go a long way in further reduction of reactions and maintaining a healthy and repeat donor population.

6. Source of Funding

None.

7. Conflict of Interest

None.

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