Research Article

Evaluation of Adverse Donor Reactions Reported in the Blood Banks of Kerala

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ABSTRACT

The present study was designed to evaluate the donor reactions reported in the blood banks across the state of Kerala. For that the haemovigilance data for a period two years was collected from 19 blood banks of aforesaid region and a retrospective review of all the donor reactions in the specified period of time was done. The results showed that the total number of donations were 246092 (94.34%) and the donors rejected were 14752 (5.66%) 1174 (0.48%) had an adverse reaction of which 999 (0.41%) were vasovagal related and 175 (0.07%) were needle injuries. Form this study, it was concluded that donor safety is an important prerequisite to promote the voluntary blood donation. Assessment of adverse events helps to identify the blood donors at the risk of adverse events. It also helpful to apply the proper motivational strategies, pre donation counseling, provide the care during and after donation, develop and implement the guidelines and hemovigilance system. Strict adherence to the rules is an essential aspect to ensure the donor safety.

Keywords: Blood donors, Adverse donor reactions, Haemovigilance.

INTRODUCTION

Although, blood donation is a safer procedure, there is a possibility for the development of adverse reactions in the donors. These reactions may be local or systemic, mild or severe [1-3]. It may occur during or at the end of the procedure of blood collection[4].

Mostly, local reactions occur because of issues concerned with venous access. Usually, they are haematomas caused by extravasation form the veins due to imprecise placement of needle during venipuncture, swelling, pain and hyperaemia may develop at the site of extravasation. Generally, these are ordinary complications that do not require any treatment. However, local phlebitis and thrombophlebitis are some serious but very rare complications of this category.

In case of systemic reactions, it can be grouped in to mild and severe. Mostly, systemic reactions are vaso-vagal reactions triggered by the pain of venipuncture, by the donor observing his or her own blood or by the donor observing another donor unwell, by the anxiety and state of tension of undergoing the donation, etc. It is characterized by the appearance of pallor, sweating, dizziness, gastrointestinal disorders, nausea, hypotension, and bradycardia. Prompt therapeutic intervention is necessary to avoid the development of vasovagal syncope which may end in convulsive syncope. Systemic reactions can occur during apheresis procedure also. Utilization of anticoagulants such as acid-citrate-dextrose (ACD) during this procedure for the collection of blood components can cause hypocalcemia because of chelation. This hypocalcemia leads to the episodes of paraesthesia of the lips, oral cavity and limbs. Generally, these symptoms get normalized after the interruption of apheresis procedure. But, sometimes, therapeutic intervention may need in the form of administration of calcium gluconate. Tremor, muscle spasms, hypotension, tachycardia, arrhythmia, convulsions and tetany are some rare complications associated with apheresis procedure. Moreover, overdose of ACD may leads to acute intoxication rarely [3].

The present study was designed to assess the frequency and type of adverse events in donors. The outcome of this study would provide a good platform for further researches.

METHODS

In the present study, a retrospective evaluation of all the donor reactions reported by 19 leading blood banks belong to both Govt. and private sectors across the state of Kerala was done. For the collection of data, a standard pro forma was designed based on the suggestions of an expert team of doctors in the transfusion medicine department. With the help of this pro forma, haemovigilance data for the period of two years from 01/01/2014 to 31/12/2015 was collected from the blood banks under study and analyzed by estimating the frequencies and proportions with 95% confidence interval.

RESULTS

Initially, a total number of 246092 (94.34%) blood donations and 14752 (5.66%) donor rejections were found during the study period (Table 1).

Table 1: Total events regarding with donation of blood during the study period

Events	Count	Percentage
Number of donations	246092	94.34
Number of donors rejected	14752	5.66
Total	260844	100

Among 246092 donations, this study found a total of 1174 (0.48%) complications, of which 999 (0.41%) were vasovagal related reactions and 175 (0.07%) were needle injuries. It indicates, the overall rate of complications was 477/100000 [95% confidence interval (CI): 434-520/100000 (Table 2).

Table 2: Distribution of donor reactions

Donor reactions	No. of reactions	Percentage	Percentage on total reactions
Vasovagal	999	0.41	85
Needle injury	175	0.07	15
Total	1174	0.48	100

Complications related to vasovagal reactions occurred with a rate of 408/100000 donations (95% CI: 382 - 433). Among them, mild reactions contributes to 377/100000 (95% CI: 353 – 401), moderate 24/100000 (95% CI: 18 – 30) and severe contributes to 7/100000 (95% CI: 3 – 10) the results are shown in table 3.

Table 3: Frequency of vasovagal reactions

Vasovagal reactions	Count	Percentage of total reactions	Rate per 100000 (CI: 95%)	Percentage of total donation
Mild	924	78.61	377 (353 – 401)	0.38
Moderate	59	05.03	24 (18 - 30)	0.02
Severe	16	1.36	7 (3 - 10)	0.01
Total	999	85.00	408 (382 - 433)	0.41

Regarding with needle injuries, the results showed that the overall local complications caused by insertion of needle occurred with a rate of 72/100000 donations (95% CI: 61 – 82). Most of the complications were vessel injuries with haematoma (49/100000 donations, 95% CI: 40 – 57). The extravasations occurred with a rate of 18/100000 donations (95% CI: 13 – 23). The nerve injuries accounts for 5/100000 donations (95% CI: 2 – 8). The results are shown in table 4. Out of 1174 reactions, only one serious delayed reaction was reported which amounts to 0.01% of the total events (Table 5).

Table 4: Frequency of needle injury

Needle injuries	Count	Percentage of total reactions	Rate Per 100000 (CI: 95%)	Percentage of total donation
Haematoma	119	10.15	49 (40 - 57)	0.049
Extravassation	44	3.80	18 (13 - 23)	0.018
Injury to nerve	12	1.05	5 (2 - 8)	0.005
Total	175	15.00	71 (61 - 82)	0.071

Table 5: Distribution according to total events

Total events	Count	Percentage
Acute / Delayed	1173	99.99
Serious delayed	1	0.01
Total	1174	100

DISCUSSION

In the present study, it was found that the overall rate of complications associated with blood donation was low even when considering all mild complications. In this survey 1174 number of complications (0.48%) among 246092 donations were observed of which 999 (0.41%) were vasovagal related and 175 (0.07%) were needle injuries. It was identified that mild vasovagal reactions constitute 78.61% in total reactions observed (0.38% of total donations). 5.03% moderate reactions (0.02% of total donations), 1.36% severe reactions (0.01% total donation) were also found during the study period. Mangwana S., 2013 reported that 82% observed reactions were mild (0.24% of total donations), 18% of reactions were fall on moderate category (0.05% of total donations). The author reported very low incidence (0.007% of total donations) of severe reaction. The survey by Sorensen *et al.,* 2008 identified 340 complications

among 41274 donations, corresponding to a rate of 824/100,000 donations (95% CI: 741-916). All complications were either needle injuries or vasovagal reactions. In our study the total number of donations was 246092 (94.34%) and the donors rejected were 14752 (5.66%). The candidates ready for donations was rejected during the pre-donation counseling or in medical checkup. 5.6% of candidates were rejected in this basis. Local complications caused by insertion of the needle in our study occurred with a rate of 71/100000. The rate of vasovagal reactions found in this study was lower comparing with some other studies. It may be due to underreporting of late complications, in particular mild vasovagal reactions. But the figures found in this study were in accordance with various previous literatures. Obviously, the classification of complications and the quantification of severity vary substantially between the countries. So that the comparison between international data on blood donation related complications is difficult. Hence, a common classification approach in this area will facilitate the direct comparisons of data and better outcomes.

CONCLUSION

Adverse reactions associated with blood donations can be minimized by various routes such as selection of appropriate donor, proper counseling of patients, accompanying donor during the procedure and at post donation phase etc. Such activities make the blood donation as safe. Moreover, strict adherence to the concerned rules is essential to ensure the donor safety. Analyses of adverse events assist in identifying the blood donors at the risk of donor reactions, applying proper motivational strategies, organizing pre-donation counseling, providing care during and after donation, developing guidelines and haemovigilance programme. Of course, all these activities definitely reduce the donor reactions or minimize the severity of reactions and ensure the active participation of donors in the future. Importantly, medical and paramedical staffs should understand the significance of reporting all events both major and minor to the transfusion service. From this, it was clear that, a properly established haemovigilnace system only helps to achieve the goal of safe blood transfusion.

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REFERENCES

1. Chintamani Pathak, Meenu Pujani, Sangeeta Pahuja, Manjula Jain, Adverse reactions in whole blood donors: An Indian scenario, Blood transfusion, 9(1), 2011, 46-49. DOI 10.2450/2010.0002-10
2. Isabella Crocco, Massimo Franchini, Giovanni Garozzo, Anna Rosa Gandini, Giorgio Gandini, Pietro Bonomo, Giuseppe Aprili, Adverse reactions in blood and apheresis donors: Experience from two Italian transfusion centres. Blood Transfusion, 7(1), 2009, 35-38, DOI 10.2450/2008.0018-08
3. Antonio Crocco, Domenico D'Elia, Adverse reactions during voluntary donation of blood and/or blood components. A statistical-epidemiological study, Blood Transfusion 5(3), 2007, 143-152 DOI 10.2450/2007.0005-07
4. Sadia Sultan, Mohammad Amjad Baig, Syed Mohammed Irfan, Syed Ijlal Ahmed and Syeda Faiza Hasan, Adverse reactions in allogeneic blood donors: A tertiary care experience from a developing country, Oman Medical Journal 31(2), 2016, 124-128
5. Mangwana S, Donor hemovigilance programme in managing blood transfusion needs: Complications of whole blood donation, Journal of Pathology of Nepal 3(6), 2013, 459-463. DOI: http://dx.doi.org/10.3126/jpn.v3i6.8993
6. Sorensen BS, Johnsen SP, Jorgensen J, Complications related to blood donation: A population based study. Vox Sanguinis, 94(2), 2008, 132-137. DOI: 10.1111/j.1423-0410.2007.01000.x

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