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Evaluation of Adverse Donor Reactions Reported In Kerala

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ABSTRACT

To describe the various adverse donor reactions and determine the frequency of their occurrence in whole blood donors. A retrospective review of all the no of donor Reactions reports of 19 blood banks of Kerala from 01/01/2014 to 31/12/2015 was done. 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. Donor safety is an essential prerequisite to increase voluntary blood donation. AE analysis helps in identifying the blood donors at risk of AE, applying appropriate motivational strategies, pre-donation counseling, care during and after donation, developing guidelines and hemovigilance programme in countries with limited resources. Strict adherence to the rules is essential to ensure donor safety. Also it would have detrimental effects on return of donors for subsequent donations and rate of complications resulting in long-term morbidity and disablement is not negligible.

Keywords: Blood Donors, Blood Donations, Adverse Reactions

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INTRODUCTION

The real challenges for Blood Banks are to meet the increasing demand for blood & blood components by maintaining a safe and adequate supply of blood from a decreasing pool of eligible donors as well as to reduce the frequency of adverse events associated with blood donation which can decrease the rate of repeat donations. Blood donors normally tolerate the donation very well, but occasionally adverse reactions of variable severity may occur during or at the end of the collection.

The adverse reactions that occur in donors can be divided into local reactions and systemic reactions.

Local reactions occur predominantly because of problems related to venous access. They are usually haematomas due to extravasation from the veins, caused by incorrect placement of the needle during the venipuncture. Pain, hyperaemia and swelling may develop at the site of the extravasation. Other local events include pain due to slight trauma to the subcutaneous nerve endings. In most cases, however, these are banal complications that do not require any treatment. Local phlebitis and thrombophlebitis are more serious complications than the foregoing, but are very rare.[1]. Hematomas (9-10%), thrombosis, infection, physical damage to anatomic structures such as median nerve are the few commonly noted problems. Pseudo aneurysm is a rare complication. Very rarely injuries to tendons or muscles are possible. Transection of nerve particularly median nerve could be possible with an incidence of 1 in 6300. These generally present with numbness and tingling, excessive or radiating pain, with occasional loss of strength. Because peripheral nerves can regenerate and heal, total recovery occurs in over 90% but it can take a prolonged time. Allergic reactions can be seen to ethylene oxide used to sterilize disposable sets or latex-related reactions are also possible.[2]

The systemic reactions, in contrast to the local reactions, can be divided into mild or severe. In most cases, they are vasovagal reactions that can be triggered by the pain of the venipuncture, by the donor seeing his or her own blood, by the donor seeing another donor unwell, by the anxiety and state of tension of undergoing the donation, etc[3-6]. The systemic reactions are characterized by the appearance of pallor, sweating, dizziness, gastrointestinal disorders, nausea, hypotension, and bradycardia. Therapeutic intervention must be swift, otherwise this clinical picture, typical of a vasovagal reaction, will progress into an episode of syncope, of variable severity, which may or may not be complicated by the onset of tonic-clonic muscle spasms (convulsive syncope), accompanied by vomiting and loss of sphincter control.[1] Among 2-6% donors experiencing

adverse events, syncopal reaction with loss of consciousness are said to be seen in 0.08-0.3% of cases. Other factors which are generally said to predispose a donor to any untoward event are young age, female sex, donating blood for the first time, low weight & Caucasian race. Syncope related falls are not uncommon and can cause injuries. Vasovagal reactions occur in 2% to 5% of blood donors with 0.34% to 0.8% of donations progressing to syncope. The syncope occurs before donation (1%), during or immediately after donation (26%), at refreshment table (61%) and offsite (12%) and usually within 1 hour. 6% of whole blood donors with syncope have emesis and 46% of reactions include clonic movements, tetany or twitching and 5% have incontinence (usually urinary) [7].

Systemic reactions can occur during apheresis procedures, which require the use of anticoagulants such as acid-citrate-dextrose (ACD) for the collection of the blood component. This anticoagulant can cause hypocalcaemia, because of chelation. The lowered concentration of calcium ions leads to episodes of paraesthesia of the lips, oral cavity and limbs. These symptoms resolve after interruption of the apheresis procedure, although it may sometimes be necessary to use a therapeutic intervention, such as the administration of calcium gluconate. Much more rarely, tremor, muscle spasms, hypotension, tachycardia, arrhythmia, convulsions and tetany develop. There are rare reports of acute intoxication due to overdoses of ACD[8].

Adverse responses to donation can be 1) Acute : immediate or delayed (after single donation).It can be Mild or Serious. 2) Chronic: in response to long term donation. Acute reactions most frequently arise from anxiety about painful venipuncture or susceptibility to blood volume deficit during or after donation. The most common type of reaction is a vasodepressor reaction associated with changes in pulse and blood pressure. Long term effects: Among whole blood donors major concern is iron depletion leading to anemia. Over 200 mg of iron is lost with each donation.[9]

59% of donors having no reaction returned to donate within 1 year. For donors with mild reaction the return was reduced to 26% and for more severe reactions it was 14%[6, 7]. The interval from blood donation to subsequent presentation is a useful indicator of donor behavior. Adverse consequences of donation are generally well understood such that donors can be adequately protected. Efforts to decrease reactions will be rewarded because donors who have reactions or suffer long term consequences are less likely to return for further donation[10].

Grading of donor reactions are classified as follows depending on the GRADE SYMPTOMS[11]

I(MILD)- Pallor, perspiration, sighing/yawnin g, hyperventilatio n, feeling of warmth/air hunger, dizziness/light headedness, nausea with or without vomiting

II(MODERAT E)- Bradycardia, shallow respirations, hypotension(systolic 15 min) III(SEVERE)- Rigidity or tremor of extremities, variable color (pale to cyanotic), incontinence of urine, convulsions .

The adverse events as suggested by American Red Cross Hemovigilance were classified as Major/Minor according to the Severity rating.[12]

The aim of this study was to estimate the frequency and type of adverse events on donors. This survey helps in identifying a group of donors predisposed to the development of adverse reactions and enables to prevent problems in these subjects at subsequent donations.

MATERIALS AND METHOD

In Kerala there are 171 no of blood banks[13]. After evaluation by an expert team of doctors in Transfusion medicines a standardized proforma was prepared and distributed to 22 leading blood banks who have component facilities too across Kerala requiring Haemovigilance data for 2014 and 2015. It includes 4 govt medical and colleges 2 General hospitals in the Govt sector out of which 2 medical colleges were not responded. 2 institutes were selected and only 1 responded for both 2014 and 2015 data and the other institute responded only for 2015 data(This data was not considered). In the pvt sector 2 medical colleges and 12 in the corporate sector were selected and they all responded. The data from 19 blood banks were analyzed in this study. A retrospective review of all the donor reactions that were reported by the 19 blood banks in Kerala over a period of 2 years (2014 and 2015) was done. The results of the number of donor reactions reported by the blood banks in the pre-designed proforma was evaluated based on the incidence of reactions. Analysis was done by estimating frequencies and proportions with 95% confidence interval. The number of adverse events of acute or delayed were also analyzed for seriousness.

RESULTS AND DISCUSSION

The total number of donations were 246092(94.34%) and the Donors rejected were 14752(5.66%)[Table-1 and Figure-1]

Table1: Distribution on donations and donors rejected

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

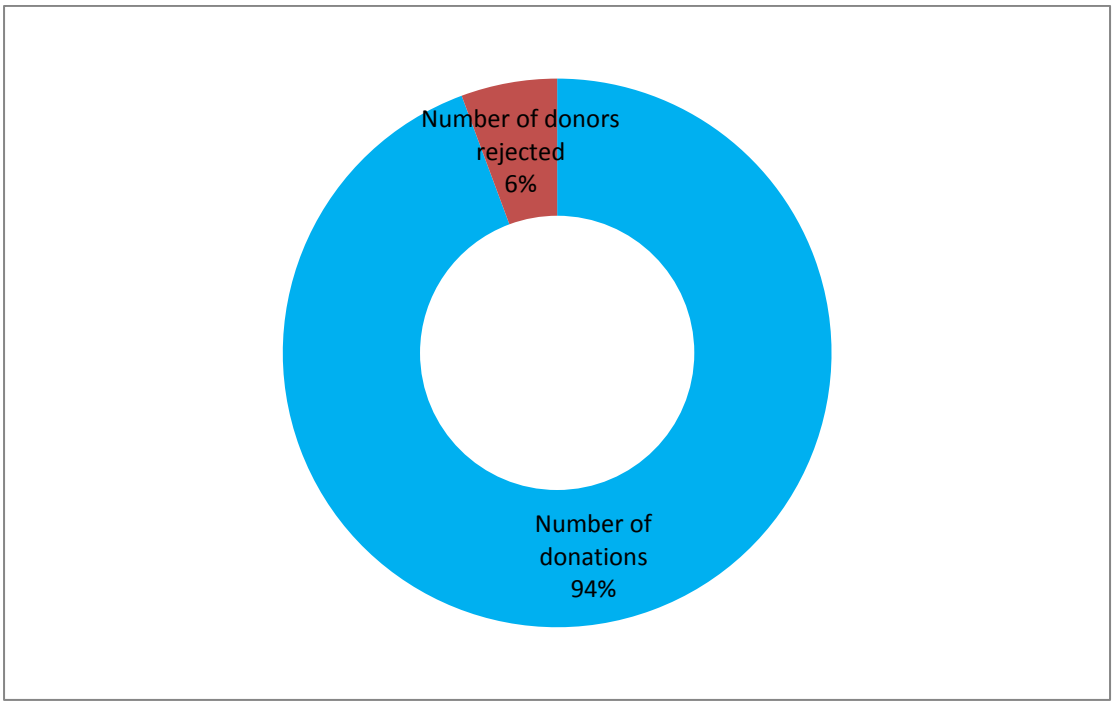

Figure 1: Distribution of donations and rejections

In this survey, 1174 number of complications among 246092 donations were observed. 1174(0.48%) had an adverse reaction of which 999(0.41%) were vasovagal related and 175(0.07%) were needle injuries. The overall rate of complications was 477/100000[95% confidence interval (CI): 434-520/100000]. [Table-2]

Table 2: Distribution of Reactions

Reactions	No of reactions	Percentage on total donations	Percentage on total reactions
vasovagal	999	0.41	85
Needle injury	175	0.07	15
total	1174	0.48	100

Vasovagal reactions

Complications related to vasovagal reactions occurred with a rate of 408/100000 donations (95% CI: 382-433) (Table 3). Most of the complications were vasovagal reactions. Mild reaction 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).[Table 3 and Figure 2]

Needle injuries

Local complications caused by insertion of the needle, occurred with a rate of 71/100 000 donations (95% CI: 61–82). Most of the complications were vessel injuries with hematoma (49/100000 donations, 95% CI: 40-57) and extravasations (18/100000, 95%CI: 13-23). The remainder consisted of nerve injuries (5/100000 donations, 95% CI: 2–8). [Table 4 and figure 2]

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

Table 4: Frequency of needle injury

Needle injuries	Count	Percentage of total	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

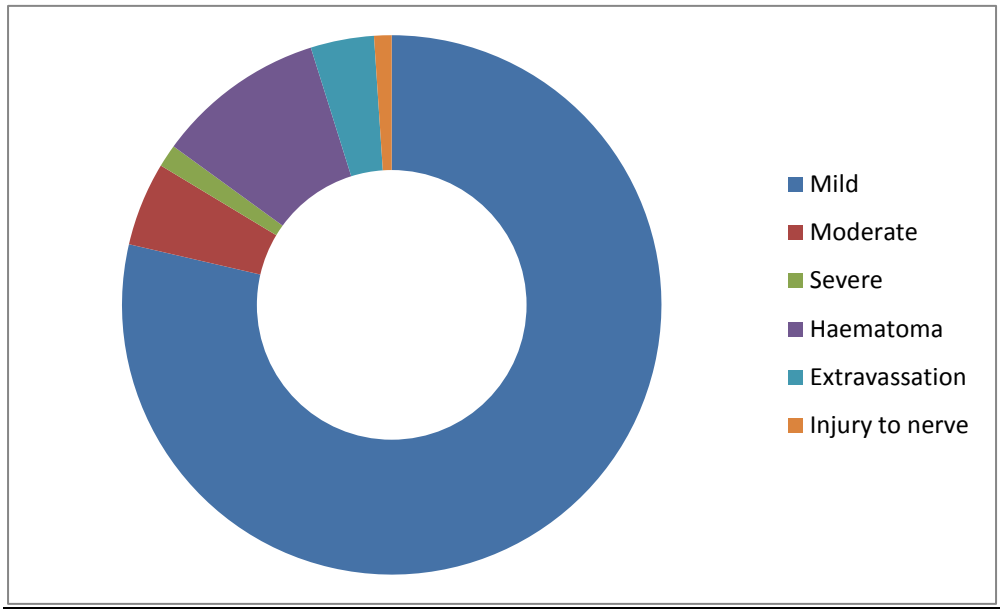

Figure 2: Adverse events to blood donation

Out of the 1174 reactions only one Serious delayed reaction was reported which amounts to 0.01% of the total events. [Table 5 and Figure 3]

Table 5: Distribution according to total events

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

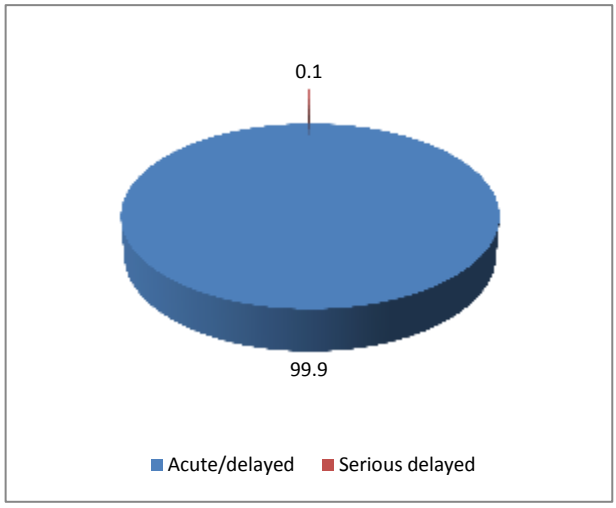

Figure 3: Distribution according to total events in percentage

DISCUSSION

We found the overall rate of complications related to blood donation to be 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. In our study the percentage of mild vasovagal reaction was 78.61%of the total reactions (0.37% of total donations) and moderate reactions were 5.03%(0.24% of total donations).1.36%(0.007% of total donations) was the severe reaction. Mangwana S et al[12] in his study found Mild vasovagal reactions, which include giddiness, sweating or light headedness without loss of consciousness, accounted for 82% of all adverse events (0.24% of total donations) while moderate vasovagal reactions accounted for 18% of all adverse events (0.05% of total donations) They found a very low incidence (0.007% of total donations) of vasovagal reaction-immediate with injury but not necessitating hospitalization of the donor or administration of intravenous fluid which is in accordance with results of other authors[1,14,15]who categorized such adverse events as severe reactions (major syncopal reactions). In a survey by Abhishek et al, they identified 564 complications among 27719 donations. The overall rate of complications was 2035/100000[95% confidence interval (CI): 1870– 2210/100000].Complications related to vasovagal reactions occurred with a rate of 1151/100000 donations (95% CI: 1023–1279)[2]. Common Adverse events noted in the study conducted by Smita Mahapatra et al [16] are vasovagal reactions and haematoma constituting 2.44% Crocco A and D'Elia D in their study found only 1.2% of all the volunteers suffered some kind of adverse reaction: 59 (1.08% of the subjects) had mild reactions (agitation, sweating, pallor, cold feeling, sense of weakness, nausea), and only 4 had more severe disorders, including vomiting, loss of consciousness, and convulsive syncope[1]. In

the regional survey by Sorensen et al, they identified 340 complications of any type among 41 274 donations, corresponding to a rate of 824/100,000 donations [95% confidence interval (CI): 741-916]. All complications were either needle injuries or vasovagal reactions. In the nationwide register, a total of 752 moderate and severe complications were recorded among 2,575,264 donations, corresponding to a rate of 29/100,000 donations (95% CI: 27-31) [17] The rate of vasovagal reactions found in this study was lower than reported in some other studies The pattern may be explained by the possible under-reporting of late complications, in particular mild vasovagal reactions. Late events could be underreported, in particular, mild complications, such as mild vasovagal reactions. In contrast, the registration of moderate and severe complications is more likely to have been complete.

Local reactions like hematoma, nerve injury and thrombophlebitis are caused by blood donation-related neurological needle injuries. Recovery time for these complications ranged from less than three days to more than six months. . Accidental arterial venipuncture is very uncommon (1 in 100,000), and donors with arterial punctures do well if pressure is applied for an extended period of time. Neurologic needle injuries occur approximately once in every 6,300 donations.[17.] Local complications caused by insertion of the needle in our study occurred with a rate of 71/100 000. Abhishek Dr et al reported the local complications caused by insertion of the needle, occurred with a rate of 884/100 000 donations (95% CI: 772–996) Most of the complications were vessel injuries with hematoma (779/100000 donations, 95% CI: 673–885) and extravasations (76/100000, 95%CI: 43-109). The remainder consisted of nerve injuries (29/100000 donations, 95% CI: 9–49).[2] When all categories of nerve injuries were considered, the rate was lower than previously reported. The variation in the nerve injury that may leads to permanent injury or some degree of disablement is less frequent to report and may be due to improper reporting back from the donors and proper follow up.

Thrombophlebitis has a low incidence (1 in 50,000 to 1 in 100,000), and infection at the phlebotomy site is rare. Both are easily treated and have little impact on the donor's health.[18]

The figures we got in the study are in accordance with various studies conducted all over the World in which rate of adverse events associated with donations ranged from 0.3% to 3.8%.[3,14, 15,19 -23] Comparison among international data on blood donation related complications is difficult, because the classification of complications and the quantification of severity vary substantially. A common classification will improve the possibility of direct comparisons, and thereby will hopefully facilitate further studies and initiatives within this area.

In our study the total number of donations were 246092(94.34%) and the Donors rejected were 14752(5.66%). The candidates ready for donations were rejected during the predonation counseling or medical check up. The pre-donation counseling and medical checkup have rejected 5.66% of the candidates who were ready for donation. The criteria of blood donation with respect to age, weight, temperature, pulse, certain diseases and other conditions for deferment of blood donations, strict adherence to the requirements of GMPs and standard operating procedures in the Part XIIB of Schedule-F of the Drugs and Cosmetics Rules definitely play a vital role to reduce the number of donor reactions and thereby avoid risky donations. The comfort of donors also is very important and is further ensured by the general requirements such as well lighted, ventilated air conditioned blood collection room, refreshment-cum-rest room, refreshment, equipments such as donor bed, chairs, etc.[24]

The donor's physical experience has a significant impact on the willingness to return and donate blood. The blood donor return rate is dependent on the type of adverse effect[3.] The interval between donations is directly related to the severity of donor reaction and is prolonged in several types of donors who have experienced. Donor safety is an essential perquisite to increase voluntary blood donation. One of the key objectives of our national blood policy is to achieve 100% voluntary blood donation. The present national average being 61%. The most common events relating to the donors are medically considered inconsequential. But these can very well decrease the likelihood of repeat donations.[25,26]

CONCLUSION

Blood donation is considered as safe procedure, if the adverse reactions can be reduced with appropriate donor selection, proper counseling, accompanying donor during procedure at post donation phase. Strict adherence to the rules is essential to ensure donor safety. These actions reduce donor reactions, reduce severity of reaction and help the donors to be repeated donors in spite of having adverse reactions. Adverse events analysis helps in identifying the blood donors at risk of donor reactions, applying appropriate motivational strategies, pre-donation counseling, care during and after donation, developing guidelines and hemovigilance programme in countries with limited resources if a step-up approach is used. Resident doctors, technicians and nurses understand the importance of reporting all major and minor events to the transfusion service. Attainment towards the goal of safe transfusion can be achieved only by establishing a hemovigilance system.

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