ADVERSE REACTIONS OF BLOOD DONATION: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT: BACKGROUND: Voluntary donors normally tolerate blood donation very well as the history and preliminary examination is clear without any hidden history or facts related to the health status of the donor, occasionally, adverse reactions of variable severity may occur during or at the end of the collection. **AIM:** Aim of this study is to estimate and possibly avoid the cause of unwanted reactions. **MATERIALS AND METHODS:** This study is conducted over a period of three years, from January 2011 to December 2013. The donor population consisted of 43492 donors (37724 male and 5768 female). The minimum age is 18 years and the maximum age for donation considered in this study was 58 years. **RESULTS:** Overall a total of 408 adverse reaction events were reported in relation to the total of 43492 donations for an overall adverse reaction rate of 0.93 % and an incidence of 1 every 107 donations. Of the 408 adverse reactions to blood donations 328 were observed in males while 80 were observed in females. Based on the type of blood donor reaction 231 males and 65 females reported giddiness. 52 males and 16 females reported nausea, 19 males and 7 females had an episode of vomiting, 24 males and 8 females reported cramps, one male reported of chills and one male reported anxiety. **CONCLUSIONS:** Although the number of donors who developed disturbances during or at the end of blood donation was very low and was mostly mild type which resolved rapidly, it is nevertheless desirable to reduce risks to a minimum by following a set of advices provided for preventing problems associated with blood donation.

KEYWORDS: Adverse reactions, Blood donation, efficient venepuncture, Vaso-vagal attack, Syncope.

INTRODUCTION: 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 early systemic and delayed systemic reactions.

1. Local reactions occur predominantly because of problems related to venous access. They are usually hematomas due to extra-vasation from the veins, caused by incorrect placement of the needle during the venepuncture. Pain, hyperemia 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 are very rare, which take longer time to subside.
2. The early systemic reactions, in contrast to the local reactions, can be divided into mild or severe. In most cases, they are vasovagal reactions than can be triggered by the pain of the venepuncture, 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. The early systemic

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reactions are characterized by the appearance of pallor, sweating, agitation, dizziness, cold feeling, sense of weakness, gastrointestinal disorders, nausea, hypotension, and bradycardia¹⁻⁴. 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, loss of consciousness, convulsive syncope accompanied by vomiting and loss of sphincter control^{1,4,5-7}.

3. Delayed systemic reactions are defined as adverse reactions occurring between 1 hour and 12 hours of blood donation which are characterized by pallor, sweating, nausea and vomiting, hypotension, bradycardia. Few of the triggering factors are smoking, alcohol intake, strenuous exercise after blood donation, lack of sleep etc.

AIM: The aim of this study is to estimate the frequency and type of adverse events, distinguishing mild disturbances from more severe reactions, and to measure the time for the donor to recover a state of well-being. In this way it is possible to monitor and improve the blood donation centres. A set of rules can be created to govern the behavior of the staff and improve the quality of the interventions and set advices or precautions for preventing problems associated with blood donations.

Our study identified a group of donors predisposed to the development of adverse reactions and enabled us to prevent problems in these subjects at subsequent donations.

MATERIALS AND METHODS: In this study a total of 43492 whole blood donations during the study period. Of the total 43492 donations 37724 were male donors and 5768 were female donors. Male donors were 86.74 % and female donors formed 13.26 % of the total donations. The minimum age is 18 years and the maximum age for donation considered in this study was 58 years. The donors included in this study were selected for complying with requisites established by the Drugs and Cosmetics Act and Standards for Blood Banks/ Blood centres and Transfusion Services put forth by National Accreditation Board of Hospitals and Healthcare Providers, New Delhi, India.

All the donations done are whole blood donations. A data collection form which was at par with the standards of Drugs and Cosmetic Act, National Accreditation Board of Hospitals and Healthcare Providers was used. The data collection form had donor demographic data, present health status, past history of any immunization or illness in the last 12 months, previous adverse reactions etc. In our study, the important factors were listed out and grouped into 6 groups from the questionnaire which our blood bank use before giving fitness for blood donation.

The first group consisted of gender, first donation, periodic/ regular donation or occasional donation.

The second group consisted of effective venepuncture and difficult venepuncture.

The third group consisted of age of the donor, hemoglobin of the blood donor.

The fourth group consisted of Time and season of blood collection.

The fifth group consisted of time gap between the food intake and blood collection.

The sixth group consisted of symptoms such as – agitation, pallor, sweating, feeling of weakness, dizziness, nausea, vomiting.

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RESULTS: We have recorded a total of 43492 whole blood donations during the study period of three years, from January 2011 to December 2013. Of the total 43492 donations 37724 were male donors and 5768 were female donors. Male donors were 86.74 % and female donors formed 13.26 % of the total donations. (CHART 1)

Overall a total of 408 adverse reaction events were reported in relation to the total of 43492 donations for an overall adverse reaction rate of 0.93 % and an incidence of 1 every 107 donations.

- 1) Of the 408 adverse reactions to blood donations 328 were observed on males while 80 were observed in females. (CHART 2).

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CHART 3: PERCENTAGE OF REACTIONS ON Y-AXIS, TYPE OF DONOR ON X- AXIS

When the type of donor was considered of all the adverse reactions 60% of the reactions were observed in first time donors and 25% of reactions were observed in occasional donors while 15% of the adverse reactions were seen in repeat donors. (CHART 3)

- 2) For the type of venepuncture 308 reactions were seen in 43244 donors where there was effective venepuncture and 90 donor reactions were seen in 248 donors who had a difficult venepuncture (CHART 4 & 5).

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CHART 5: SHOWING REACTIONS INEFFECTIVE VENEPUNCTURE AND INDIFFICULT VENEPUNCTURE-YEAR WISE

- 3) When Age wise plotting of the adverse reactions was done, 54% of the adverse reactions were seen in the donors of age group 18-28years. 8% of the reactions were seen in 28-38 years age group, 10% of reactions were seen in the age group of 38-48 years. Second highest percentage of donor reactions was seen in the age group of 48-58years accounting to 28% of the reactions. (CHART 6).

CHART 6: SHOWING PERCENTAGE OF AGE WISE REACTIONS

- 4) With respect to hemoglobin levels 48% of the total reactions were seen in donors with hemoglobin levels of 12.5 gm. % -13.0 gm. %. 27% of reactions were seen in donors with hemoglobin levels between 13.1gm % -13.5gm %, 13% of reactions were seen in donors with hemoglobin range of 13.6gm % -14gm%, 7% of reactions were seen in donors with hemoglobin levels in range of 14.1gm%-14.5 gm. % and only 5 % of the total reactions occurred on donors with hemoglobin levels more than 14.5 gm.%. (CHART 7).

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CHART 7: NUMBER OF DONORS ON Y- AXIS, HEMOGLOBIN LEVELS ON X- AXIS

- 5) On plotting the results according to quarter by dividing the year into four quarters of three months each, there was an increase in average donor reactions during the second quarter (Q2) that is in the month of April, May and June. (CHART 8)

CHART 8: NUMBER OF DONOR REACTIONS ON Y- AXIS, SEASON QUARTERS ON X-AXIS

- 6) When the duration between blood donation and time since last meal were studied 46% of the total reactions occurred in the donors who donated blood within 0-1 hour since their last meal, 21% of the reactions were seen when the time between blood donation and their last meal was 1-2 hours, 5% and 10% of the total reactions were seen in the time gap of 2-3 and 3-4 hours respectively, while the third highest number reactions accounting to 18% of total reactions were seen when the duration between last meal and blood donation was more than 4 hours. (CHART 9)

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CHART 9: PERCENTAGE OF REACTIONS ON Y- AXIS, TIME INTERVAL ON X- AXIS

- 7) Based on the type of blood donor reaction 231 males and 65 females reported giddiness. 52 males and 16 females reported nausea, 19 males and 7 females had an episode of vomiting, 24 males and 8 females reported cramps, one male reported of chills and one male reported anxiety. (CHART 10)

CHART 10: NUMBER OF DONOR REACTIONS ON Y- AXIS, TYPE OF REACTION ON X-AXIS

DISCUSSION: MULTIVARIATE OBSERVATIONAL ANALYSIS: The analysis of the groups of “first-time donors”, “occasional donors” and “periodic donors”, with regards to the variables agitation and sweating, pallor, giddiness, cold feeling, nausea and vomiting, syncope which together reflect a state of anxiety, was conducted in order to study the level of association with these three groups of donors.

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The analysis of the first-time donors showed that there was a significant degree of association, 60 % (244/408) of the first time donors had adverse reactions.

The analysis of occasional donors (subjects who donate blood only when needed) showed 25% (102/408) of adverse reactions, which indicate moderate association. The analysis of periodic donors (subjects who donate blood every 3 months or 4 months agitation and sweating, showed very less significant association, only 15% (62/408) of the adverse reactions. These findings demonstrate a greater tendency to develop an anxiety syndrome, is much more pronounced in first time donors; this can be explained by large number of first donors showing adverse reactions (244/408).

There was not a well-defined pathophysiological cause for the vasovagal reactions, but rather a set of neuropsychological factors that the subjects had developed during their life, starting from the first donation/since first donation.

A logistic analysis was used to determine whether there was a connection between the development of pallor and a difficult venepuncture. The donors who developed pallor were divided into two groups: those in whom the venepuncture had been traumatic and those in whom the venepuncture had been efficient. The logistic regression analysis showed that the group of donors, in whom the venepuncture was difficult, had a statistically higher probability of developing pallor (36%) when compared to effective venepuncture (0.7%).

From these data, it can be concluded that a traumatic venepuncture, compared to an easy one, is a strong determinant of a vasovagal reaction. It can, therefore, be stated that a painful stimulus caused by venepuncture can lead to a vasovagal reaction. Sweating, in fact, causes a further decrease in blood pressure because of vasodilatation, with sequestration of the blood in splanchnic organs and stasis in the lower limbs, due to gravity.

This results in a slight and temporary deficit in blood flow to the brain. Dizziness follows on from hypoxia and causes a sense of ill- being or vasovagal reaction, which sometimes evolves into syncope in the absence of swift intervention. Therefore as shown in the analysis, adverse reactions of blood donation are a chain of reactions, which starts gradually with a banal vaso-vagal stimulus and then evolves inexorably into syncope, if not adequately treated.⁷⁻¹²

An analysis between age of the donor and adverse reaction was made, 54% of the adverse reactions were seen in the donors of age group 18-28years. 8% of the reactions were seen in 28-38 years age group, 25.7% of reactions were seen in the age group of 38-48 years. 28 % of donor reactions were seen in the age group of 48-58 years.

With respect to hemoglobin levels, 48% of the total reactions were seen in donors with hemoglobin levels of 12.5 gm. % -13.0 gm. %, 27% of reactions were seen in donors with hemoglobin levels between 13.1 gm.% -13.5 gm. %, 13% of reactions were seen in donors with hemoglobin range of 13.6 gm. % -14 gm. %, 7% of reactions were seen in donors with hemoglobin levels in range of 14.1 gm. % -14.5 gm. % and only 5 % of the total reactions occurred on donors with hemoglobin levels more than 14.5 gm. %.

The analysis shows adverse reactions are more common in the donors who have hemoglobin level in and around the prescribed standards of blood donation (standard Hb level for accepting subject as donor 12.5 gm. %).

When the duration between blood donation and time since last meal were studied 46% of the total reactions occurred in the donors who donated blood within 0-1 hour since their last meal, which can be due to sudden shift of the fluid to the vascular compartment during bleeding, the most

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common adverse reaction being nausea/vomiting, while the third highest number reactions accounting to 18% of total reactions were seen when the duration between last meal and blood donation was more than 4 hours is due to hypoglycemia.

An analysis with the type of blood donor reaction 231 males and 65 females reported giddiness. 52 males and 16 females reported nausea, 19 males and 7 females had an episode of vomiting, 24 males and 8 females reported cramps, one male reported of chills and one male reported anxiety. This analysis shows the commonest reaction encountered is giddiness.

In our study of three years, there was no major adverse reaction occurred which needed hospitalization of the donor.

All this is in agreement with the literature, in which it is described that an anxiogenic stimulus, represented by the strong emotion of giving blood or the donor's sight of his or her own blood, evokes fear and anxiety.

From a purely psychological point of view, this phenomenon can be likened to what is technically defined, in psychology, as a "simple phobia", which is nothing other than a learned behavior associated with an anxiogenic stimulus.^{3,13,14}

This type of behavior, usually not conscious, is maintained by a set of dramatic or catastrophic thoughts and by unpredictable complications or consequences that can occur during the donation. Vasovagal reactions often occur in these subjects immediately after the needle insertion, or even later, once the donation has been completed.

It can be said that, irrespectively of whether the venepuncture is traumatic or non-traumatic, the donor attributes this part of giving blood a particular weight. Indeed, for many people, one of the uncertainties about giving blood derives from the psychological impact of needle insertion.

CONCLUSION: Although the number of donors who developed disturbances in relation to donating blood was very low, it is nevertheless desirable to reduce risks to a minimum, working not only with the maximum environmental safety, but also with complete medical assistance. Thus, a series of innovations have been introduced to facilitate not only the work of the staff, but also safe donation by the volunteer blood donors. The remedies and specific areas of care are the following:

- Shorten the waiting time.
- Do not allow the donor to remain standing for long time before donation.
- Allow the donor a light breakfast, excluding sugar, milk and milk products, in particular in subjects predisposed to develop some form of distress ²
- Ensure a comfortable room temperature and humidity.
- Identify those subjects who are particularly anxious and ensure them the greatest comfort and the most assiduous attention by the staff.
- If necessary, reduce the amount of blood collected, within the limits allowed by law (range 350 ml +/- 10 % or 450 ml +/- 10 %).
- Engage the donors during donation, particularly anxious donors in conversation, in order to distract their attention from what is happening during the donation.
- Carry out the venepuncture precisely and cleanly.
- Avoid traumatic needle insertion with invasive and painful maneuvers.
- Identify the best venous access, by inspecting both forearms.

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- If the first venepuncture is unsuccessful, allow the donor to rest and reassure him or her, before attempting a new venipuncture.
- Do not let the donor leave the donor site too quickly.
- Do not let the donors drink very hot or very cold drinks during the recovery phase, make the donor have the refreshment drink in the refreshment room for 10 to 15 minutes.
- Monitor very carefully young, bradycardic donors, whose blood pressures tend to be low.
- Do not take blood from donors, who have carried out very intensive sporting activities in the preceding 24 hours.
- Do not accept the donor who smoked in the preceding 2 hours or who had alcohol in the preceding 24 hours.
- Give great care to those donors who take antihypertensive drugs, particularly β -blockers
- Do not allow donors to eat solid foods during the donation ^{10, 11}.
- React swiftly to the initial symptom of pallor, by putting the subject in the Trendelenburg position.
- Reassure the donor.
- Loosen any tight clothing such as tie, belt etc. in order to facilitate normal respiration.
- If necessary, administer vasopressors.
- If the donor has low blood pressure, infuse fluids (physiological saline, Ringer's lactate solution, balanced solutions).
- Monitor the donor and retain him or her at the donor site until there has been an adequate hemodynamic recovery,
- If recovery is very slow, corticosteroids can be administered as a continuous infusion in a solution
- If the pulse is very weak and the heart rate slow, atropine can be administered
- If the clinical situation evolves into an episode of syncope, ensure that the airways are patent.

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