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Donors Hemovigilance: An Institutional study

Medical Science

KEYWORDS : Blood Donation, Blood Donors, Adverse Events, Haemovigilance.

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ABSTRACT

Introduction: Although blood donation is considered to be a safe procedure, around 2 % to 3% of voluntary blood donors experience adverse events of varying severity that needs to be addressed adequately in order to ensure safe transfusion services. We undertook this study in order to estimate the frequency and type of adverse events & to suggest remedial measures to minimize them.

Materials and Methods:

Voluntary donors was selected as per guidelines laid down in Drugs & Cosmetics Act, Ministry of Health & Family Welfare, Government of India. 350 ml of blood was collected from donors weighing between 45 -55 kg and 450 ml from those weighing more than 55 kg. Minimum eligible haemoglobin (Hb) level was considered to be 12.5 gm%. Hb screening was done by copper sulphate (CuSo4) method. Donors were closely observed during and after donation for any adverse events (AE).

Results:

In the 2 year study period from January 2014 to December 2015. 25,000 whole blood donations were collected, of which 20,000 were voluntary and 5000 were replacement donors. AE's were recorded in 350 donors. Of the 350 AE's, 280 were pre-syncopal or vasovagal reaction. Syncopal minor reactions observed in 40 cases characterized by transient loss of consciousness, lasting for few seconds. Haematoma formation was observed in 20 donors. Minor events such as tingling, numbers, soreness of arm, local allergy, etc were observed in 7 donors. There were 3 major events one each of convulsion, loss of bladder sphincter control and accidental arterial puncture were noted. Appropriate statistical analysis were done.

Conclusion:

AE analysis helps in identifying the donors at risk and adopting environmentally appropriate measures to reduce risk and improve donor satisfaction in order to ensure regular supply of blood and blood products and there by maintain an effective hospital transfusion service.

Introduction:

"Safe Blood starts with a safe donor". In India there is wide gap in the demand & supply of blood. Regular voluntary non remunerated blood donors considered to the safest source of blood supply globally. Recruitment and retention of such donors is one of the biggest challenges for the transfusion fraternity in a rural, resource constrain setup like us. Increasing demands along with limited altruism in the population are of great concern. Methods for promotion of voluntary blood donation, programmes for recognizing and felicitating voluntary donors and non monetary incentives like health checks etc. can go a long way in this regard.

Starting from the point that the blood donor is the prerequisite for blood transfusion, his/her needs must be the focus of all activities. Without blood, it is not possible to consider the question of blood safety and quality. Without the blood donor, it is not feasible to develop transfusion medicine.

The safety of the entire transfusion chain, i.e. from the donor to the recipients needs monitoring. This can only be achieved by careful observation and analysis of adverse events, hence haemovigilance, which is defined as " a set of surveillance procedures, from the collection of blood and its components to the follow-up of recipients to collect and assessment information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence or recurrence".

Blood transfusion services world over exclusively depend on healthy voluntary donors to ensure an adequate supply of safe and quality blood to meet the needs of the patients they serve. To motivate voluntary donations initially and to retain them, it is important that the experience of blood donation should be, as pleasant, safe and convenient as possible. Therefore "Donor Care" has become an important critical factor for ensuring a constant supply of safe blood and promote safe transfusion practices.

However, lack of proper donor care can lead to loss of even regular donors which will be invariably associated with negative publicity and promote misunderstanding and misappreciation regarding blood donation.

In India haemovigilance, is not fully developed. Only few institutional reports are available regarding blood donor haemovigilance. Hence we under took the study to estimate the adverse events (AE) in blood donors in order to promote donors safety and contribute towards the initiation of a institutional haemovigilance system.

The aim of our study is to identify the various donor adverse events during blood donation and initiate suitable measures in order to minimize such complications which will lead to the sharing of the best practices, clear identification of responsibilities and action taken with regard to AEs without any fear of severe repercussion against the concerned staff as our endeavor will be provide adequate training towards the development of the institutional blood donor haemovigilance programme.

Methodology:

Ours is the licenciated, 900 bedded, tertiary care, teaching hospital based blood bank attached to a post graduate medical institute with the facilities for blood and blood components collection, preparation, storage & distribution.

In the 2 year study period from January 2014 to December 2015. 25,000 whole blood donations were collected, of which 20,000 were voluntary and 5,000 were replacement donors. Voluntary donors were selected as per guidelines laid down in Drugs & Cosmetics Act, 1940, Ministry of Health & Family Welfare, Government of India. Prior informed donor consent were obtained and donor confidentiality were ensured. The study was approved by institutional ethics committee.

Pre-donation counseling and medical examination was done and those who did not qualify were deferred. Donors were closely observed during and after donation for any AEs. AEs were defined as the symptoms or signs of donor discomfort of sufficient severity such that either the donors requested for medical assistances of the staff or the AEs were observed by the staff themselves. AEs were subdivided by systemic and local events as per the American Red Cross Hemovigilance Programmes.

The blood collection was done by qualified phlebotomist who followed standard collection procedures and used common definitions to recognize, manage, and document AE following blood collection. On recovery, a report form was filled by the donor listing out in detailed symptoms and its duration along with relevant personal details. For delayed AEs the donors were requested to contact the designated departmental staff along with a duly filled-up reaction form. All AEs that occurred at the collection sites and any delayed AEs reported were reviewed by the authors and brought to the notice of the hospital transfusion committee as a part of local institutional haemo-vigilance program. Autologous and insufficient collections were excluded from our study.

Data was collected and recorded in a dichotomous form (presents/absent). The statistical analysis of the data, regarding both the descriptive statistics and the inferential analysis, was conducted using the SPSS, Minitab and OpenStat software packages. Chi-square test was used to assess the overall difference of frequency distribution of reactions among subgroups. Multivariate logistic regression analysis, was done taking into consideration the relative importance of all the parameters, regarding the occurrence various AEs.

The donors having AEs was monitored for 15-20 minutes in the post donation period. Next the donors were re-examined by the doctors and if found satisfactory they were advised to leave the donation site after voluntarily signing a declaration form stating their current comfortable status with an advice to inform the staff of their well-being the following day. However none of the donors reported the psycho-physical disturbances in following day.

According to SOP, all vasovagal reactions were divided into three categories – mild, moderate, severe. During or after blood donation, if blood donors presented with anxiety, tachypnea, tachycardia, pallor sweating, dizziness, nausea / vomiting, cold or clammy skin, it was categorized into mild category. If they presented with signs and symptoms of transient loss of consciousness and those who presented with mild reaction but for more than 15 minutes, they were categorized into moderate category. Donors presenting with convulsion and / or incontinence (fecal / urine) were placed severe category.

Results:

In the 2 year study period from January 2014 to December 2015 . 25,000 whole blood donations were collected, of which 20,000 were voluntary and 5,000 were replacement donors. AE's were recorded in 350 donors. Of the 350 AE's, 280 were pre-syncopal or vasovagal reaction. Syncopal minor reactions observed in 40 characterized by transient loss of consciousness, lasting for few seconds. Haematoma formation was observed in 20 donors. Minor events such as tingling, numbness, soreness of arm, local allergy, etc were observed in 7 donors. Table 1: shows no. of blood collection along with donor categories. Table 2 : Adverse Events in Male & Females donors . Table 3: Age wise distribution of 1st time and repeat donors pre-syncopal & syncopal adverse events. Table 4: Gender wise distribution of donors having pre-syncopal & syncopal adverse events.

In our study we observed 0.28 % accidental arterial puncture leading to hematoma. The arterial puncture usually occurs with the initial skin puncture but, in rare instances, it occurs after needle adjustment. Inexperienced phlebotomists are more likely to cause this injury than phlebotomists with five or more years of experience.

The overall percentage of AEs (pre-synopal, syncopal,minor & major) was 1.4%.The percentage of pre-syncopal was 1.1% with female preponderance. This AEs was mostly in camps during hot and humid summer seasons. The percentage of Major donor reactions was 0.012% .

There were only 3 major events - one each of convulsion, loss of bladder sphincter control and accidental arterial puncture (0.28 %) . Thus our study confirms that blood donation is a very safe procedure which could be made more event free by following, certain friendly, reassuring and tactful practices.

Discussion:

The term hemovigilance is derived from the Greek word 'hema'= blood and the Latin word 'vigilans = watchful [1]. Hemovigilance is defined as a set of surveillance procedure covering whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence [1]. Thus, the ultimate goal of a hemovigilance system is to improve the safety of blood transfusion.

Approximately one-third of whole-blood donors have an adverse physical event during or after whole-blood donation of 500 ml[3]. In most cases, it is a minor event; but if the donor feels it is significant, the donor might visit a physician. The incidence of seeking outside medical care for an adverse event is at least 1 in 3,400 blood donation or 0.033 percent[4]. Therefore, physicians should be familiar with the recognition, treatment and prognosis of blood donation complications. Prevention of adverse events, where possible, is important to minimize the number of blood donor injuries, but adverse events are an inevitable part of whole-blood donation [3].

The safety of the entire transfusion chain, i,e. from the donor to the recipient needs monitoring. This can only be achieved by careful observation and analysis of AEs. Hence haemovigilance, is of great relevance particularly in donor motivation and retention in a rural and resource constrained set-up like us.

On of the salient, universal feature of transfusion service remains first, 'know your donor' and second, test your donor'. For India we need a dedicated, least expensive non remunerated voluntary blood donation programme based on effective donor recruitment and retention strategies. Retention of blood donors depends largely on their satisfaction with the transfusion services. A warm welcome by qualified personnel who pay attention to the donor's well-being is essential. The blood donors who feel at home in the blood center will come again and bring their family members and friends. A safe and pleasant first time donation experience with good donor care promotes repeat donation.

The ever increasing demand for blood and blood products

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poses to be a major challenge for blood bankers to maintain the safe and adequate blood supply from a limited pool of eligible donors particularly with regard to the rural Indian scenario were most of the donors are semi literate, first time donors having numerous misplaced apprehensions regarding voluntary blood donation. Often, even regular donors stop donating and are called "lapsed donors". This may be because of medical reasons, dissatisfaction with the transfusion services due to poor donor care or not getting timely help when they need blood, inconvenient time or place to donate and etc. The reasons for the lapse should be established and as far as possible rectified. Awards, letters of appreciation and encouragement refreshment, ceremonies, parties, newsletters, are all valuable materials and methods which can be utilized for promoting blood donation. For the purposes of recruitment and retention of blood donors, development of donor data-base is essential, and donor notification and referral for counseling, as well as monitoring of transfusion transmitted infections in the donor population should be an integral part of the quality system in the blood services.

A typical venipuncture or collection failure rate is approximately 2 to 4 percent. To reduce the risk of hypovolemia and vasovagal reactions, an AABB standard required that the blood collection volume should not exceed 10.5ml/kg of donor weight. In the American Red Cross, the current collection volume consists of 481 ml in the tubing, for a total of 525 ml. This limitation on collection volume reduces the risk of hypotensive reactions and ensures compliance for the lowest acceptable allogeneic blood donor weight, which is 50 kg (110 Ib). In some Asian countries, the collection volume is much lower. For instance, in Japan, there are two whole-blood collection volumes, 200ml and 400 ml.

Sazama et al described 12 donation-related deaths reported to the FDA between 1976 and 1985. Of the 12 donors, 8 were plasma donors from the plasma industry and one was a white-blood cell donor. Of the three whole-blood donors, two donors had a myocardial infarction and one had a pheochromocytoma.

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. All this is added to the fall in blood pressure caused by the removal of blood during the donation (450 ml). The result is a slight and temporary deficit in blood flow to the brain. Dizziness follows on from hypoxia and causes a sense of ill-being or a vasovagal reaction, which sometimes evolves into syncope in the absence of a swift therapeutic intervention [6]. Therefore, there is a chain reaction, which starts gradually with a vaso-vagal stimulus and then evolves into syncope, if not adequately treated. This fact highlights the importance of adequate training of the blood bank personnel regarding the Basic Life support (BLS) system[6]. In order to attend such problems all medical and paramedical staff of our blood bank are trained regarding BLS.

Similar to the study conducted by Anne et al[7] in our study also minor complications (presyncope, small hematoma) are the main AEs observed [7]. This may be medically inconsequential but their significance lies in the fact that they hamper donor retention and prevent donor recruitment in the long run.

In our study there were only 3 major events - one each of convulsion, loss of bladder sphincter control and accidental arterial puncture (0.28 %) . All such event were handled by our trained medical and paramedical blood bank staff. This highlights the importance of conducting regular refresher courses for our staffs in order to update their knowledge and skills regarding the management of rare AEs of blood donation.

Our study observed that AE during blood donation were higher in younger and first time donors . statically significant association between age and number of donations (1st time & repeat donors) lesser the age more the adverse effects in both first time & repeat donors.

The same has been confirmed by Harkin R et al [8] and Eder et al [9] in their studies. The mechanisms responsible for the increased susceptibility to systemic (syncopal type) complications following blood donation in young donors, however, are not clearly defined. Central thalamic pathways and peripheral adventricular baroreceptor sensitivity may play a central role, and the age-dependent differences in responses to physical and emotional stress may underlie the observed differences in young donors compared with older donors [11]. A psychological predisposing factor regarding AE among young, anxious, first time donors have been observed by several authors and the phenomenon of "epidemic fainting" or clusters of adverse reactions among donors who witness a AE have also been noted but poorly documented and studied [11].

Similar to studies conducted by Hanson SA et al [12] we have tried several interventions such as (eg, having the donor drink 1 glass of water shortly before donation, or using applied muscle tension, distraction, or behavior modification) to reduce AE but no single intervention have been successful to meet the situation. Reducing the relative proportion of blood loss by requiring a higher donor weight or by reducing the collection volume have also been used as additional precautions with no significant benefit. The same have also been observed by Danic B et al [13]. Wiltbank TB et al [14] have suggested to explore the feasibility of automated collection procedures with concurrent intravascular fluid administration to minimize the incidence of AE.

India had no national haemovigilance system in place till last year, although the implementation of haemovigilance programme is included in the National Blood Policy. Only few institutional efforts at haemovigilance have been reported in but that does not constitute a system [1]. Hence, we had made efforts to develop our system of handling donor AEs and there by contribute to the conceptualization and effective implementation of local, institutional haemovigilance system under the national guidelines and international regulations.

During our study we have realized that there are no uniform 'Standard Operating Procedure' to refer and adhere events and reactions. Hence we undertook the preparation of standardized protocols to successfully handle AEs and there by contribute towards the local hemo-viligance system keeping in mind the best interest of the blood donors.

Since the blood banking system of today relies upon the selfless and philanthropic act of the voluntary non-remunerative blood donors, it is the moral and social responsibility of the blood banks to strive to reduce any kind of discomfort, that the donor may be subjected to [2]. Blood centers around the world are exploring techniques to reduce the rate of complications in blood donation. There is an urgent need to learn from the experience of the other centers across the world and enhance the protocols that are being used locally so as to expedite the process of identification

of best strategies to minimize discomfort [2].

Guidelines, standard operating procedures, monitoring indicators and work evaluation methods are tools of quality management and quality assurance in blood transfusion [1]. Vulnerability and capacity assessment (VCA) is a process recommended to meet the challenge of the strategic work plan, reflecting goals, strategies and priorities [1]. Promotion of regional cooperation and maintaining links with international organizations are other important activities of national blood transfusion service directed towards sustaining the development effort.

On the threshold of the new millennium and in view of the existing international conflicts, national and civil disturbance, war and other major social and economic upheavals, the development of programs for the recruitment and retention of voluntary non-remunerated blood donors is a challenge which calls for further support and reassurance [1].

Proper and effective utilization and of mass media communication facilities including the solicitation of the services of well known social, cultural, sport and political personalities regarding the promotion of voluntary blood donation with emphasis on regular donor recruitment and retention will be helpful in improving the blood transfusion services with proper donor care and comfort [1].

Conclusion:

AE analysis helps in identifying the donors at risk and adopting environmentally appropriate measures to reduce risk and improve donor satisfaction in order to ensure regular supply of blood and blood products and there by maintain an effective hospital transforming hostility into sympathy, prejudice into acceptance, apathy into interest and ignorance into knowledge.

Donor Categories	Collection in camp	Collection in blood bank
Voluntary Donors	20000	------
Replacement Donors		50000
Total	20000 (80%)	50000 (20%) =25,000

Table 1: Total no. of blood collection along with donor categories

Adverse Events	Total	Male %	Female %	
Pre-syncopal	280	80 (22.85)	200 (57.14)	$X^2 = 20.19$ df=2 *P*=0.000004
Syncopal and major reactions (loss of sphincter control, agitation, nausea & vomiting arterial puncture)	43	12 (3.4)	31 (8.8)	
Minor reactions (haemotoma cold feeling, perioral paraesthesia, pins and needles, sweating, pallor dizziness)	27	19 (5.4)	8 (2.28)	
Total	350			

Table 2 : Adverse Events in Male & Females donors

Age in years	1st time donors	Repeat Donors	$X^2 = 11.26$ df=2 *P*=0.003
20	50	25	
>19	70	35	
>18	140	30	

Table 3: Age wise distribution of 1st time and repeat donors pre-syncopal & syncopal adverse events.

Age	Total	Male	Female	$X^2 = 18.66$ df=2 *P*=0.00009
20	70	10	30	
>19	100	40	60	
>18	180	30	150	

Table 4: Gender wise distribution of donors having pre-syncopal & syncopal adverse events.

References:

1. Newman BH, Pichette S, Pichette D, Dzaka E. Adverse effect in blood donors after whole-blood donation: a study of 1,000 blood donors interviewed 3 weeks after whole blood donation. Transfusion 2003;43:598-603.
2. Tomasulo P, Anderson AJ, Paluso MB, Gutchenritter MA. Aster RH. A study of criteria for blood donor deferral Transfusion 1980;20:511-18.
3. Newman B. Blood donor suitability and allogenic whole blood donation. Transfusion Medicine Reviews 2001;15:234-44.
4. Newman BH. Donor reactions and injuries from whole blood donation. Transfusion Medicine Reviews 1997;11:64-75.
5. Sazama K, Reports of 355 transfusion-associated deaths: 1976 through 1985. Transfusion 1990;30:583-90.
6. Ogata H, linuma N, Nagashima K, Akabane T. Vasovagal reactions in blood donors. Transfusion 1980;20:679-83.
7. Anne F. Eder, MD, PhD, Christopher D. Hillyer, MD, Beth A.Dy, BS. Adverse Reactions to Allogeneic Whole Blood Donation by 16 – and 17-year-olds: JAMA, 2008;299: 2279-2286.
8. Harkin R, Lessig M. Reaction incidence among teen-aged first time and repeat whole blood and apheresis donors [abstract] in: abstracts of the AABB annual meeting, October 20-23, 2007, Anaheim, California. Transfusion. 2007;47(3 suppl):105A.
9. Eder AF, Dy BA, Kennedy JA, Notari EP, et al. The American Red Cross Donor Hemovigilance program, complications of donation reported in 2006. Transfusion. In press.
10. Maisel WH, Stevenson WG. Syncope-getting to the heart of the matter. N Engl J Med. 2002;347 (12):931-933.
11. Beynton MH, Taylor ES. Complications arising in donors in a mass blood procurement project. Am J Med Sci.1945;209:421-436.
12. Hanson SA, France CR. Predonation water ingestion attenuates negative reactions to blood donation. Transfusion 2004;44:924-28.
13. Danic B, Gouezec H, Bigant E, et al. Incidents of blood donation. Transfus Clin Biol 2005; 12: 153-9.
14. Wiltbank TB, Giordano GF. The safety profile of automated collections: an analysis of more than 1 million collections. Transfusion. 2007; 14(6): 1002-1005.