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Study of Adverse Events in Voluntary Blood Donors in A Tertiary Care Hospital In Tamil Nadu

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ABSTRACT
Blood donation is safe process. Blood donation centres follow strict procedures to ensure safety and well-being of their donors. Blood donors are the backbone of health care delivery system. Blood donation has to be carried out with proper aspectic precautions and was to be carried out by experienced phlebotomists to retain them as repeat donors. The primary objective of this study was to assess the nature and prevalence of adverse reactions observed in donors giving whole blood. The retrospective investigation was carried out at the Department of Blood Transfusion Medicine, Madurai Medical College, Tamil Nadu, spanning from July 2021 to June 2022. All whole blood donations were collected as per departmental SOPs. Adverse reactions were divided into two groups namely local and generalised. All whole blood donations were analyzed and all adverse events occurred during or at end of donations were noted. A total of 102 adverse events were recorded in association with 18,932 donations, resulting in an overall adverse event rate of 0.538%. The most frequently observed adverse reactions were mild syncope (vasovagal syndrome), accounting for approximately 42 out of 102 adverse reactions (41.17%). A total of 18,932 donors where seen within the study period, comprising of 16,850 (89%) males and 2082 (11%) females. About 0.56% of male donors and 0.34% of female donors developed adverse reactions. About 71 donors had generalised reaction and 31 donors had local reactions during this study. Throughout the study period, no serious adverse reactions were observed and none of the reactions led to deferral of donors from repeat donation. Our findings reinforce the notion that blood donation is a highly safe procedure and with reassuring and cautious practices, it can be conducted without any significant adverse effects. Creating a friendly, warm and comfortable atmosphere for donors contributes to the safety of the donation process, motivating them to consider repeat donations in the future.

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Key Words
Adverse donor reaction, blood donations, generalized reactions, local reactions

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INTRODUCTION

Blood donors are the backbone of health care delivery system. There is a huge need for blood and its components in this fast developing world. Indeed without blood complex surgeries, damage control surgeries in trauma, transplantation of organ, postpartum hemorrhage, patients on chemotherapy for cancer treatment would not be possible.

At present, there is no clinically equivalent suitable for whole blood and its components. It needs to be procured from non-remunerated voluntary blood donors only. Only 1% of the population donate blood comparing to 1.5-2% of population needs blood. Indeed, it is the paramount responsibility of the Blood Center to prioritize donor safety and ensure their well-being throughout the donation process[1].

By implementing stringent safety measures, maintaining high-quality standards and providing a conducive environment for donors, the Blood Center can foster a sense of trust and confidence in the donors. This, in turn, will encourage donors to make repeat donations, contributing significantly to the ongoing availability of life-saving blood products and meeting the healthcare needs of the community[2].

A variety of adverse reactions and injuries can do occur during donations. Most donors tolerate withdrawal of 350-450 ml of blood without incidences. However, 4% of Donors may experience some form of reactions. Most of them were mild vasovagal reactions[3].

Knowing about donor reactions, elaborate donor counselling and reassurance helps in motivating donors to ensure their repeated donations.

Aim and objective: The objective of this current investigation was to assess the nature and incidence of adverse reactions in voluntary blood donors.

MATERIALS AND METHODS

This retrospective study was conducted at the Department of Immunohematology and Blood Transfusion in Madurai Medical College, Tamilnadu, from July 2021 to June 2022. Blood donations were collected in accordance with departmental SOPs (Standard Operating Procedures) and NBTC (National Blood Transfusion Council) norms. Each donor was provided with a standard questionnaire from TANSACS (Tamil Nadu State AIDS Control Society) to be filled out and the significance of each question was communicated to the donor.

Accordingly the donor selected based on two important things:

- Medical history
- Preliminary health check

Similarly, the history of diseases such as Hepatitis, sexually transmitted diseases, recent vaccination, active tuberculosis, malaria, HIV/AIDS, lung diseases, recent history of blood transfusions or surgery and unexplained weight loss in the donor can be harmful for the recipient if he/she receives his/her blood.

It is important to make a preliminary health check of the donor before donation in order to make an assessment of their health status and not solely depend upon what the donor tells in his/her medical history. We make sure the following parameters were checked for each donor who comes to donate blood:

- General appearance
- Age
- Weight
- Blood pressure
- Pulse
- Temperature
- Physical assessment

Hemoglobin estimation: The blood collection done in an area which is very well ventilated, pleasant, convenient, well lit and air conditioned, so that the donors feel comfortable and relaxed. Donor reactions are rare but do occur at times either during donation or after donation. The donor clinic staff should be well-trained to promptly recognize and treat adverse reactions and immediately inform the concerned blood center physician. Adverse reactions in donors can be categorized into three types:

- **Mild reactions:** These are common and generally include symptoms like fainting (vasovagal syncope), dizziness and nausea. These reactions are usually short-lived and resolve on their own or with minimal intervention
- **Moderate reactions:** These reactions may involve more significant symptoms such as excessive vomiting, persistent dizziness, or mild allergic reactions. Immediate medical attention and appropriate intervention may be required to manage these reactions effectively
- **Severe reactions:** These reactions are rare but can be life-threatening. They may include severe allergic reactions (anaphylaxis) or convulsions. Immediate and advanced medical intervention is essential in such cases

Before donation, a staff member will verify the donor's name and identification number to ensure accurate identification. Then, a well-trained phlebotomist will carefully examine both arms of the donor to select a suitable large vein in the antecubital area. The donor will be asked to lie down on a donor

couch and the phlebotomist will apply a sphygmomanometer or blood pressure apparatus just above the cubital fossa.

The blood pressure cuff is inflated to a pressure of 60-70 mm Hg. This process helps to dilate the veins and make them more visible and accessible for blood collection. Once the vein is adequately dilated, the phlebotomist will proceed with the blood donation process, ensuring a smooth and efficient procedure for the donor. Proper vein selection and use of the blood pressure cuff contribute to a successful and comfortable donation experience for the donor. Having the donor make a fist usually helps to bring the vein into prominence. One of the crucial step and recommended procedure is to disinfect the donor arm/phlebotomy site and it takes about 1 mi. The disinfectant contains 2% chlorhexidine gluconate with 70% isopropyl alcohol. By observing hand antiseptics and wipe the area to be cleaned in such a way that the antiseptic soaked cotton swab should move from the central area of the selected vein to peripheral areas in a circular manner. We will let the solution to be in contact with the skin for at least 30 seconds, then phlebotomy done

About 2-5% of voluntary blood donors experience some form of reaction like sweating, pain to serious reactions like convulsions and loss of consciousness. These reactions occur most commonly in young donors, low weight, first time or female donors. Donors who experience an adverse event are less likely to return.

Mild reactions during blood donation may manifest as sweating, anxiety, cold skin with a decrease in blood pressure, rapid and thready pulse, dizziness, nausea, vomiting, hematoma, twitching and muscle spasms. Syncope, or fainting, may occur due to an idiopathic cause or upon seeing blood and it is advisable to move the affected donors to a separate room to prevent other donors from becoming apprehensive.

To manage these reactions, it is essential to raise the donors' legs above the level of the head to improve blood flow to the brain, loosen tight clothing to enhance comfort and closely monitor vital signs. In case of vomiting, the donor's head should be turned to one side and a suitable receptacle should be provided to avoid aspiration. Prompt and appropriate measures taken by trained staff ensure the well-being and safety of blood donors during and after the donation process.

A moderate reaction during blood donation may involve any of the mild reactions mentioned earlier, along with the loss of consciousness. In such cases, the donor may experience a decrease in pulse rate, hyperventilation and a significant fall in systolic blood pressure to 60 mm Hg or below. These moderate reactions require immediate attention and intervention to ensure the donor's well-being and safety. Trained medical staff should be prepared to respond quickly to such situations by providing appropriate care and taking necessary measures to stabilize the donor's condition. Timely management is crucial to prevent any further complications and to ensure a successful blood donation process.

A donor experiencing convulsions during blood donation defines a severe reaction. While true convulsions are very uncommon, if they occur, it is of utmost importance to prevent the donor from injuring themselves during the episode. One preventive measure is to place a tongue depressor between the donor's teeth to avoid any potential biting of the tongue. Additionally, immediate medical attention and intervention are crucial in such cases and trained medical staff should be prepared to respond swiftly to ensure the safety and well-being of the donor. Prompt management and appropriate care are essential in handling severe reactions to ensure the donor's health and prevent any further complications. Ensuring adequate airway and checking the pulse frequently, loosen tight clothing. Prolonged recovery means the presyncopal symptoms with or without LOC, that do not resolve within 30 minutes. And accidental puncture of artery is a very rare complication in which there is very fast flow of bright red blood. If it occurs it is important to stop donation immediately. And applying hard pressure for minimum of 15-30 min.

Adverse reactions also divided into two groups namely local and generalized. All blood donations were analyzed and all adverse events occurred during or post donations were noted.

RESULTS

Total voluntary non remunerated blood donors during the study period between july 2021 to june 2022 at Department of Immunohematology and Blood transfusion at Madurai medical college were 18932.

Among them the total donors 16,850 (89%) males and 2082 (11%) females (Fig. 1).

Adverse reaction were noted in 102 donors, resulting in overall adverse event rate of 0.538% (Fig. 2).

About 95 (0.56%) of male donors and 7 (0.34%) of female donors developed adverse reactions (Fig. 3).

As per the classification of adverse reactions 98 out of 102 donors had mild adverse reaction, 3 donors out of 102 had moderate adverse reaction like loss of consciousness and severe adverse reactions were none (Fig. 4).

Syncope (vasovagal syndrome), characterized by mild intensity, was the most frequently observed adverse reaction, accounting for approximately 42 out of 102 (41.17%) of all adverse reactions reported in the study (Fig. 5).

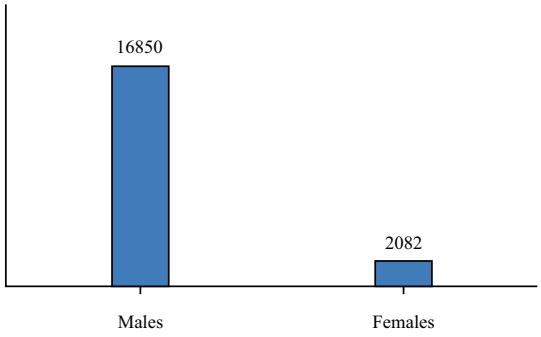

Fig. 1: Total donations sex wise (N = 18932)

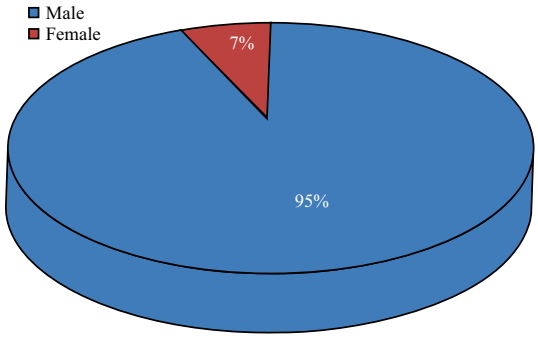

Fig. 2: Sex wise adverse reaction (N = 102)

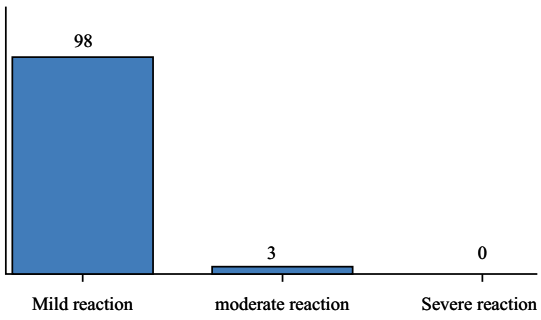

Fig. 3: Adverse reactions (N = 102)

About 82/102 (80.39%) of first time donors and 20/102 (19.6%) of repeated donors developed adverse reaction.

About 71/102 (69.6%) of generalised reaction and 31/102 (30.39%) of local reactions were noted during this study (Fig. 6).

DISCUSSIONS

The aim of studying adverse reactions in voluntary blood donors is to understand and monitor the potential risks and complications associated with blood donation. By investigating these reactions, researchers and healthcare professionals can identify ways to improve donor safety and enhance the overall blood donation process.

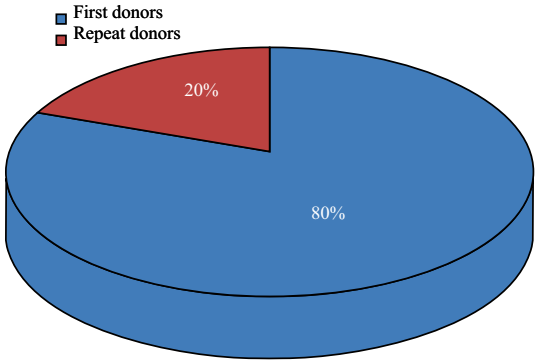

Fig. 4: Donor reactions (N = 102)

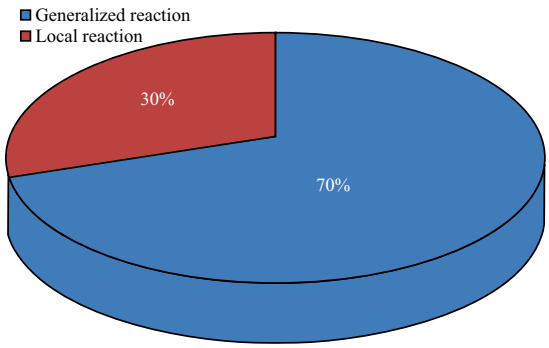

Fig. 5: Type of adverse reaction (N = 102)

The national blood requirement is partly influenced by the capacity of the country's healthcare system and its population coverage[4]. With social and economic development, as well as improved healthcare coverage, there have been significant shifts in the clinical demand for blood in both developed and developing countries.

In developed countries, the demand for blood is driven by advanced health systems, complex medical and surgical procedures, trauma care, management of blood disorders and the growing elderly population[5]. Despite recent reports showing a decline in blood collection and utilization in developed countries, the demand for blood and blood products remains high in developing and underdeveloped countries.

According to the World Health Organization (WHO), a blood donation rate of 1% of the population is considered the minimum requirement to meet a nation's basic blood needs, with higher requirements for countries with advanced healthcare systems[6]. However, this hypothesis lacks evidence-based support or accessible statistical models to validate its accuracy.

For India, based on the above norm, the demand for blood would be around 13.1 million blood units (1% of a population of 1.3 billion). However, studies and reports have indicated varying levels of annual blood collection in India. In 2007, the total collection was reported as 4 million units, falling significantly short of the estimated need of 10 million units[7].

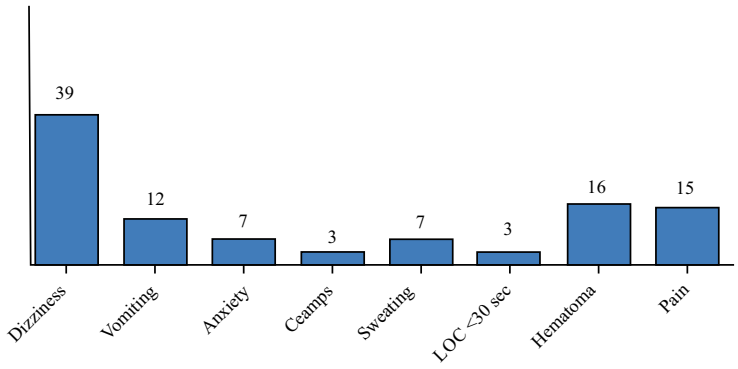

Fig. 6: Adverse reaction (102)

In 2011, reports showed that Indian blood banks collected approximately 5.5 million blood units, while the annual requirement was estimated to be around 9 to 9.5 million units, indicating a significant mismatch between demand and availability[6]. Another study highlighted that India has 2,433 blood banks with the capacity to collect 9 million units annually but the actual collection was only 7 million units[8].

Estimations suggest that the country's blood requirement ranges from 8.5 million to 10 million units per year, while the available supply falls short at approximately 7.4 million units per year[9]. These findings illustrate the critical need to bridge the gap between blood demand and supply in India's healthcare system.

The studies and reports of Newman[10] clearly indicate a significant disparity between the demand and supply of blood in India[11]. The estimations for blood requirements vary widely, reflecting the complexity of the healthcare system, which comprises public, private and not-for-profit sectors, with a large proportion of unregulated private entities. Additionally, factors such as changing epidemiological and demographic patterns, inequitable distribution of health services and a continuously growing population pose challenges in accurately forecasting blood needs in the country. As a result, addressing this imbalance and ensuring adequate and safe blood supply remains a critical area of concern in India's healthcare landscape.

The lack of accurate numbers and wide variations in set targets have significant implications on the planning process of blood distribution and access to blood across the country. Existing methods of estimating national blood requirements, particularly in developing countries like India, may not adequately reflect the dynamic nature of blood needs in the healthcare system or may be challenging to apply due to insufficient data availability[12].

To address this issue, there is a need for a comprehensive study to estimate blood requirements using a robust and sensitive methodology that considers various factors influencing blood demand beyond the current supply and utilization. Such a study would provide valuable insights into the conditions affecting blood requirement in India and enable better planning and allocation of blood resources to ensure equitable and efficient access to blood products across the nation[13-15].

Frequency and types of adverse reactions: Studying adverse reactions helps determine the frequency and types of reactions that occur during or after blood donation. This includes immediate adverse reactions, such as fainting, dizziness, or allergic reactions, as well as delayed reactions, such as infections or delayed hemolytic transfusion reactions. Understanding the prevalence and nature of these reactions allows for better preparedness and appropriate intervention strategies.

Risk factors and predictors: Research on adverse reactions can help identify the risk factors and predictors associated with specific reactions. For example, certain donor characteristics, such as age, weight and medical history, may increase the likelihood of experiencing adverse reactions. By identifying these risk factors, healthcare providers can better assess donor eligibility and implement preventive measures to minimize the occurrence of adverse reactions.

Mitigating measures: By studying adverse reactions, researchers can identify strategies to mitigate and prevent these reactions in blood donors. This may include implementing educational programs to inform donors about potential risks and providing guidance on post-donation care. Additionally, studies can assess the effectiveness of interventions, such as pre-donation hydration, to reduce adverse reactions.

Donor satisfaction and retention: Understanding adverse reactions and implementing measures to minimize them can enhance donor satisfaction and

retention. When donors experience adverse reactions, it can have negative implications on their overall donation experience. This may decrease their willingness to donate blood in the future. By addressing and reducing adverse reactions, blood donation centers can promote a positive donor experience, leading to increased donor retention and a more sustainable blood supply.

Continuous improvement of blood donation practices: Research on adverse reactions can contribute to the continuous improvement of blood donation practices. By analyzing data on adverse reactions, donation centers can identify trends and patterns, leading to modifications in procedures, donor screening protocols and collection techniques. This ensures that blood donation remains a safe and well-managed process for both donors and recipients.

CONCLUSION

Studying adverse reactions in voluntary blood donors is essential to ensure donor safety, identify risk factors, implement preventive measures, enhance donor satisfaction and continuously improve blood donation practices. This research serves as a foundation for ongoing efforts to maintain a safe and efficient blood supply system.

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