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## **STUDY OF ADVERSE REACTION IN ALLOGENEIC WHOLE BLOOD DONOR, AT PARUL SEVASHRAM HOSPITAL, VADODARA**

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### **ABSTRACT**

#### **Background and Objective:**

Blood Bank should ensure the well-being of whole blood donors, maintain donor confidence, and sustain a safe and effective blood supply for patients in need. The objective of monitoring and addressing adverse reactions in whole blood donors is to ensure the safety and well-being of donors during and after donation process.

#### **Methods:**

An observational - retrospective study was conducted among donors registered at Parul Sevashram Hospital Blood bank. ADR of whole blood was identified by using post donation report from. Advance software of MS excel is used for data collection and Analysis.

#### **Results:**

Total registered donors are 6001 during Month January 2022 to March 2023. Out of that **49 (0.80%)** donors are register for ADR. Total **41** donors come under category of replacement donor and **8** donor register as voluntary donors. The commonest ADR was hematoma, perspiration,

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giddiness, Gabhraman, vomiting and Nausea. Some rare ADR also observed which are hypersensitivity, unconsciousness, Injury due to lack of attention.

**Conclusion:**

Whole blood donation is generally considered safe and adverse reactions are relatively rare. The overall cause adverse reactions can vary depending on factors such as the donor population, the donation process, lack of awareness, the vigilance of ADR reporting systems.

**Keywords: Blood donation, Adverse reaction, Hematoma**

**INTRODUCTION:**

Blood donors are the pillars of a blood transfusion facility. Ensuring the safety of blood donors is of highest importance as is ensuring safe blood to the recipient. Since blood donors are selfless volunteers, they should be as protected from negative reactions as possible. The incidence of negative reactions can account for the fact that many first-time donors do not return for donation. The physical and mental experience of a blood donor has an impact on the blood donor return rate. It is important to make an effort to keep a sufficient number of repeat contributors. If donors feel confident, they will have a positive experience, they will be encouraged to give frequent blood donation. This can be accomplished by way of preventing adverse reactions in the donor [1]. According to WHO, the safest blood donors are voluntary, non-remunerated and from low-risk populations. By 2020, WHO wants all nations to exclusively rely on uncompensated voluntary blood donations [2]. Although there are few

risks associated with donating blood and donors are thoroughly checked for any restrictions before giving, occasionally unpleasant side effects occur during or after the procedure [3]. A donor's unfavourable response is described as a symptom or sign of discomfort in the donor that is severe enough to either require the donor to summon the blood bank's attention or of the blood bank staff or was noticed by the staff [2, 3].

Donor complications that may arise during the donation process is whether caused by psychologic factors or by neurophysiologic response to blood donation, the symptoms may include dimness, perspiration, giddiness, pallor, loss of consciousness, convulsions, and involuntary passage of stool or urine. The detail classification is classified as local, generalized complication, various allergic reactions, serious complication and others reactions [4].

The main aim of this study is describing the various adverse reactions and determine the

incidence of their occurrence in whole blood donors.

### **METHODS:**

This retrospective study was conducted from January 2022 to March 2023. We used the non-probability, feasibility-sampling method and recruited a total of 6001 allogeneic blood donors. The study was approved by the ethical and research committee of Parul University Vadodara Gujarat. A structural questionnaire was used to collect donor demographic information, such as name, age, gender, phone number, and kind of donor (replacement or Volunteer), linguistic heritage, and level of education. The predetermined inclusion criteria, which took into account factors like age ( $\geq 18$  years), body weight ( $> 50$  kg), haemoglobin levels ( $\geq 12.5$  g/dl, pulse (50–100 beats/min), and blood pressure (120/80 mmHg), were used to the selection of all donors. Every participant was questioned regarding their medical and donation background. The study deferred and eliminated donors having a history of jaundice, intravenous drug misuse, non-marital sexual intercourse, tattoos, or recent

blood transfusions or surgery. Every donor written informed consent after being questioned. Trained phlebotomists extracted about 350 to 450 ml of blood. Following the blood donation, all donors were held for 20 minutes while any potential negative outcomes were monitored. If there were any delayed adverse reactions, all donors were requested to report back within 24 hours & telephonic follow-up is also taken. Blood donors' frequencies of various adverse responses were collected. It's been also observed relationship between age and unfavourable reactions in blood donors.

### **OBSERVATIONS AND RESULTS:**

The current study was performed at blood bank of Parul Sevashram Hospital. A retrospective data of 6001 registered donor were analysed to see adverse reaction among voluntary (n= 1025) and replacement donor (n=5025). Physical examination result obtained are as follows: Mean weight =66.48 kg, Mean age =27.26 yr & Mean Haemoglobin =15.5g/dl, Mean Pulse count: 76.12, and mean blood pressure : 122.51 mm/Hg.

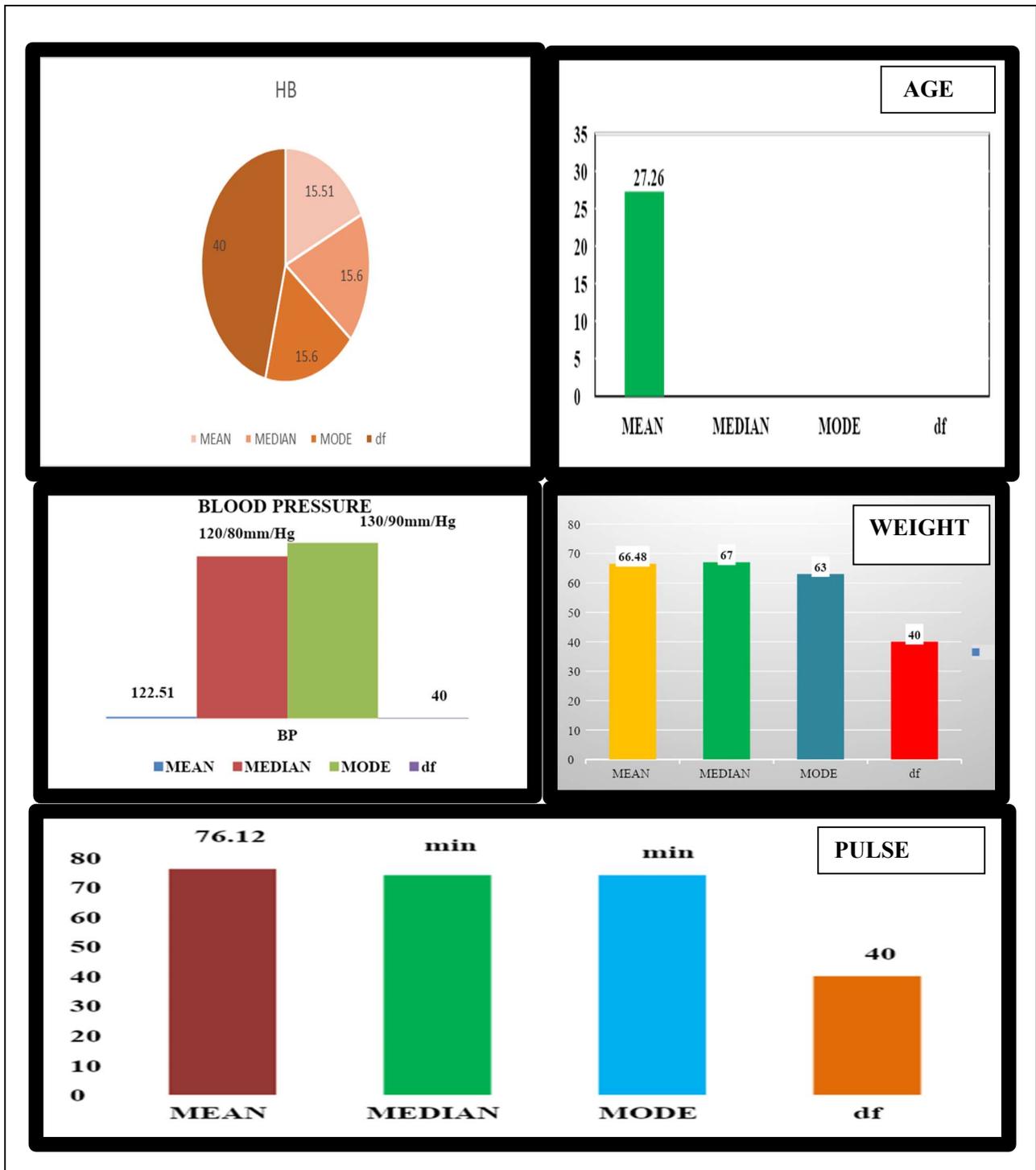


Figure 1: Average results of donors physically examination

As per data recorded total adverse events register was n=49 (0.79%) out of 6001 register donor, out of that n=41 (84%)

adverse reaction occurred among replacement donors and n=8(16%) were seen in voluntary donors.

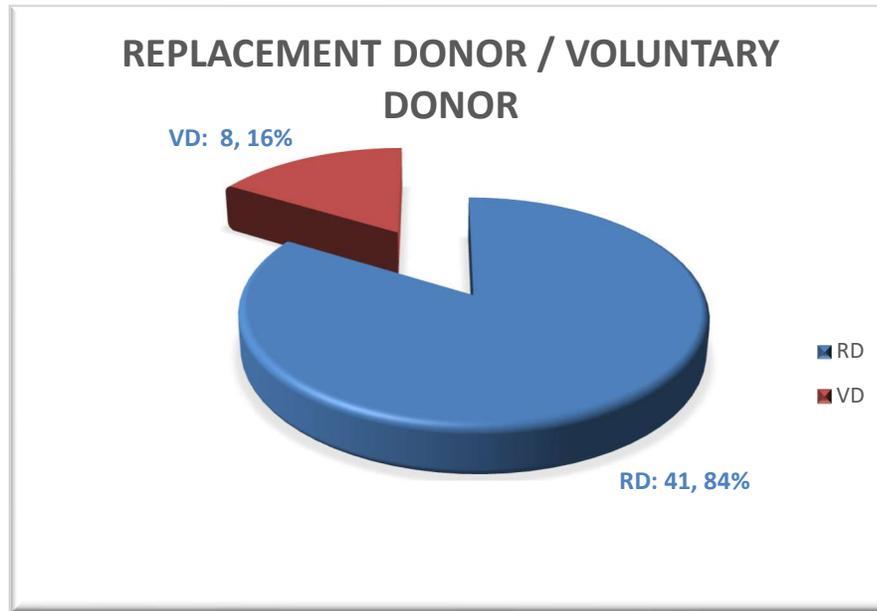


Figure 2: Percentage ratio of Replacement and Voluntary donation

The above graph represents most common adverse reaction among donors were perspiration and giddiness in n=23(0.38%), followed by nausea and vomiting in n=7(0.12%). n=3 (0.05%) developed gabhraman and unconsciousness, and n= 18

(0.30%) developed hematoma. Current study has observed common vasovagal reactions including perspiration, giddiness, gabhraman, nausea and vomiting. A few rare case of severe donor reaction observed which is unconsciousness.

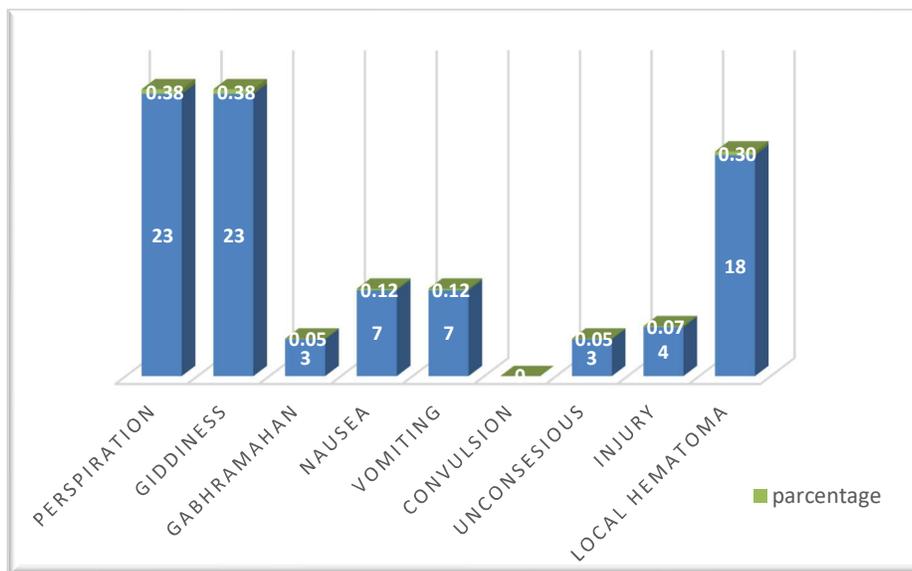


Figure 3: Different ADR in Whole Blood Donors

The below graph is representing category of ADR found among donors, Overall ADR observed among donors was around 0.79% (49/6001). Out of total reported ADR, only

donors found with VVR is n= 28 (57%), only with Hematoma is around n= 18, (37%), and ADR of VVR with hematoma is around n=3 (6%).

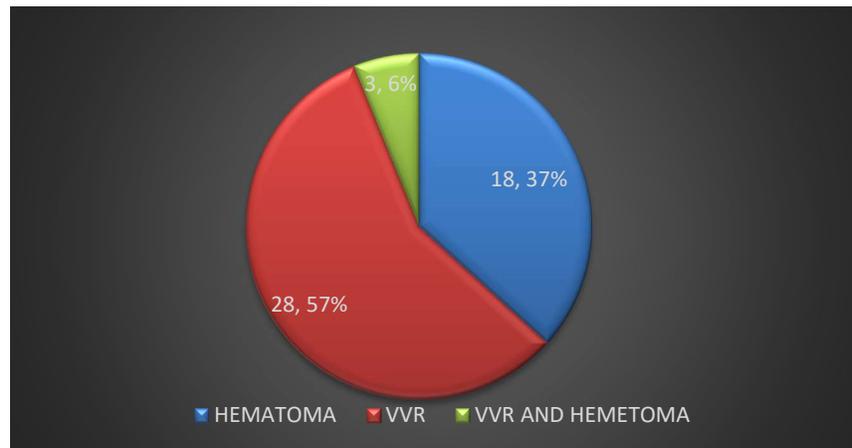


Figure: 4 Percentage distribution of different category of adverse reaction

## DISCUSSION:

Blood banks have a double responsibility: to meet the blood supply for the community and to ensure maximum blood donors' safety. The donor's physical experiences have a noticeable impact on donor return, and adverse incidents dictate the donor return rate [5]. Our study revealed adverse donor reactions in 0.79% of healthy allogeneic donors. Blood donation-related adverse effects are rather uncommon. Most donors have an asymptomatic unremarkable experience. Although the frequency of adverse reaction varies, they typically occur in just a few percent of donors. Blood donations centre a high priority on donor security and

have established protocols to minimise this event.

Vasovagal reaction and mild allergic reaction are instance of recurrent reactions that normally pass quickly and do not leave any lasting effects. Our results are in concurrence with a Pakistan study that reported adverse events in 1.3% of healthy blood donors [1]. Another local study from Bangalore, Pakistan revealed a prevalence of 2.04% [5]. A relatively high prevalence of 4.9% was reported in a study from Bangladesh that assessed randomly selected whole blood donor Compared to data from developed countries, our results are less parallel. An Italian study found an overall occurrence

1.2% [5]. A large study from Japan on 98,389 donors recorded a 2.8% positivity rate of adverse reactions [5]. However, a relatively low frequency of 0.63% adverse reactions was determined in a German study, conducted in elderly (66–71 years) voluntary blood donors.<sup>5</sup> This difference is accredited to difference in the age groups of our studies, and the blood donor type (i.e., voluntary donations versus replacement donors) as in our study included both replacement and voluntary donors. Regular voluntary donors are expected to have fewer adverse donor reactions. VVR were the most common adverse reaction of blood donors [1]. Donation related VVR is a multifactorial response primarily determined by young age, low weight, female gender, and first-time donor status.

We could not identify adverse reaction in gender or sex group because virtually all blood donors were male. Female blood donors constituted 30% of blood donations reported from Italy. However, the situation in India is even more disturbing, where the prevalence was < 1% as reported in studies.

Needle injuries can damage vasculature, may result in bruises, hematoma, arterial puncture, arteriovenous fistula, or pseudoaneurysm. Needle injuries were encountered (18%), which was high from other study. In over

study we seen that staff was changed, so the new staff or non-experiences staff not do proper phlebotomy. However, this study had disclosed very high frequency of bruises in 15.1% of donors [6]. While Agnihotri *et al.*, 2012 [7] determined hematoma as an adverse event in 35% of all reactions. Underlying etiology seems to be the faulty technique, untrained phlebotomists, and failure to select an appropriate vein. 8 Needle-associated nerve injuries occur in one of every 6300 donations. 24 Nerve injury was not observed in our donors.

Adverse occurrences only complicated 0.79 % of blood donors, and the majority of these problems were presyncope signs. Our study provides evidence that blood donation is a very safe activity that might be made even safer by adhering to a few kinds, supportive actions.

Whole blood donation procedures to collect blood have an impressive safety record, and most volunteer blood donors have uneventful donations and feel good about donating blood to help others. Still, blood donation is a procedure associated with risk of minor discomfort, pain and rare cases serious injury. Recent activity on donor hemovigilances and research programs identify possible ways to reduce the risk of complications after blood donation. Ongoing efforts and continued

vigilance are necessary to further improve safety for volunteer blood donors.

The blood donation return rate was most adversely affected by donor response. Donor reaction tiredness, and sore arm all seem to work in concert. Possibly, improving some circumstances could increase the return rate for blood donations.

Regardless of previous donation history, having a negative reaction greatly decreases the likelihood of making another donation. An increased incidence of bad reactions has not been linked to any significant positive or negative predictors of return following a reaction.

The reasons for the lack of blood donation include lacking knowledge, lack of education, misunderstandings, and false prediction about blood donation. This is a limitation of our study that delays the generalization of the results.

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