

A RETROSPECTIVE STUDY ON HAEMOVIGILANCE IN A TERTIARY CARE HOSPITAL, MYSURU**Dr. Basavanna P. L.*, Kadeejath Sayitha, Leenu Lakshmi and Vanitha A. S.**

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ABSTRACT

Background and Objectives: Blood transfusion plays an important role in improving the health and saves lives. However, it should be done in proper way as it can also cause adverse reactions ranging in severity from minor to life threatening events. Haemovigilance programme of India (HvPI) is very essential programme as it aims to ensure the transfusion safety by monitoring every step of transfusion process from donor to recipient. Such adverse reaction caused during transfusion are termed as Adverse transfusion reactions (ATRs). An identification of adverse transfusion reactions (ATRs) and it's spontaneous reporting will help us to take appropriate steps to reduce their incidence and in its management which ultimately makes blood transfusion safer. This study is aimed to determine the frequency and type of ATRs in blood recipients. **Materials And Methods:** A retrospective review of all transfusion reactions reported to the Blood Bank at Mysore Medical College and Research Institute, KR Hospital, Mysore between 2018 and 2019 was done. All the transfusion reactions were evaluated by the blood transfusion officer and classified using standard definitions. **Result:** During the period of 2 years, 2018-2019, a total of 46 blood transfusion reactions were reported. Among the haemocomponent receptors who had a transfusion reactions, the majority of the patients were female (74%) than male (26%). Majority of the reactions were associated with packed red blood cells (93.5%). As for the reporting unit, higher number of notification came from from obstetrics and surgical wards (58.7%) followed by medicinal unit (26%). Most reported transfusion reaction were febrile non haemolytic transfusion (FNHTR) reaction followed by allergic reactions. **Conclusion:** This study allowed for a better assessment and understanding of transfusion reactions, which will help to improve the quality of blood transfusion and provide greater safety of patients undergoing transfusion. Rational use of blood, improving storage conditions, bedside monitoring of transfusion and documentation of adverse events will help in improving transfusion safety. This can be ensured by creating awareness among health professionals and also the patients. Patient's should be educated about the adverse events which can occur during transfusion and also be encouraged to report such reactions if occurred. Awareness about haemovigilance programme can be generated through haemovigilance news letters, scientific publications, and by organising continuing medical education (CME).

KEYWORDS: Adverse transfusion reactions, Hemovigilance, Whole blood transfusion.**INTRODUCTION**

Blood transfusion is a regular and indispensable life-saving procedure with many clinical benefits. It is generally considered as a safe procedure when done properly. In conditions such as anemia and in many chronic diseases such as heart failure and CKD, blood transfusion serves as supportive treatment. Even though it is considered as safe and life saving in many condition, it can lead to a series of adverse events. So transfusion of blood products is a double-edged sword and should be used judiciously so that adverse events can be avoided.^[1] The risk of transmission of infectious diseases associated with blood transfusion can be reduced by proper screening of donor and by transfusion transmissible testing procedures.

An adverse transfusion reaction (ATR) is an unfavorable reaction which is associated with the administration of whole blood or one of its component. These reactions may differ in severity, from minor to life threatening, depending on the type of reaction and the patient's susceptibility. On the basis of onset of the reaction, these reactions are classified as immediate or delayed reactions. Depending on the pathogenesis of the reaction, it can be classified as immune or non immune type. The reactions which occur within minutes to 24 h of the transfusion are known as acute reactions. Acute reactions are cell and plasma-related reactions. These can be immediate hemolytic transfusion reaction, febrile nonhemolytic transfusion reaction (FNHTR), urticarial, anaphylactic, transfusion-related acute lung injury

(TRALI), transfusion-related sepsis, transfusion-associated circulatory overload (TACO), nonhemolytic hemolysis, air embolism and hypothermia. Delayed reactions usually occur after 24 hrs of the transfusion. Delayed reactions are due to secondary anamnestic response. These reactions can be delayed hemolytic transfusion reaction, alloimmunization against red blood cell (RBC) and human leukocyte antigens, graft versus host disease, post transfusion purpura, immunomodulation and iron overload. Knowledge of these ATRs helps us in easy identification and also guide us in its management. It also alerts us to prevent its occurrence by taking required precautions.^[2]

This study was carried out with the objective of analysing the frequency and the type of adverse transfusion reactions (ATRs) reported in the blood bank of Mysore medical college and research institute, KR hospital, Mysore during the period of 2 yrs from 2018-2019.

1. MATERIALS AND METHODOLOGY

This is a retrospective study conducted in the blood bank of Krishna Rajendra hospital, Mysore., that used data

2. RESULT

(a) Distribution Of Transfusion Reaction Events Based On Gender

Table 1: Distribution of transfusion reactions based on gender.

Gender	NUMBER OF PATIENTS	PERCENTAGE
Male	12	26.0%
Female	34	74.0%
Total	46	100%

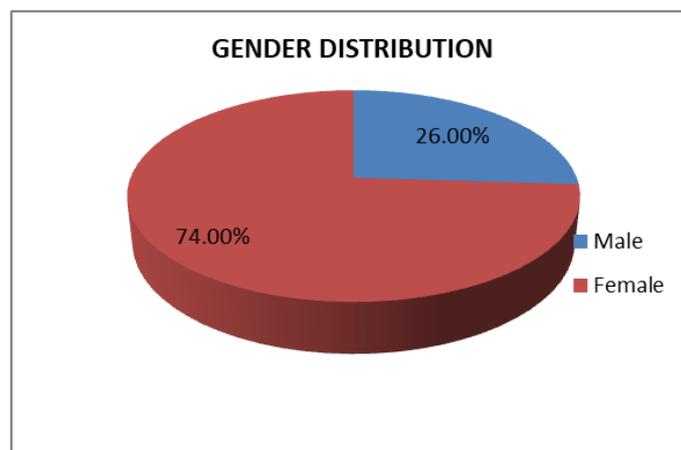


Figure 1: Distribution of transfusion reactions based on gender.

(b) Distribution of transfusion reaction based on age group.

Table 2: Distribution of transfusion reactions based on age group.

AGE GROUP	NO OF PATIENTS	PERCENTAGE
Pediatrics	4	8.7%
Adults	26	56.5%
Geriatrics	16	34.8%
Total	46	100%

collected between 2018 and 2019. Krishna Rajendra Hospital (K R- Hospital) and Cheluvamba Hospitals are both Tertiary Referral Centers and Teaching Hospitals attached to the Mysore Medical College and research institute.. The study duration was from September 2020 to March 2020. The study sample was composed of 46 transfusion reaction sheets.

Ethical approval was obtained from the institutional ethical committee of Mysore medical college and research institute and associated hospital, Mysuru.

Inclusion Criteria

All haemovigilance notification sheets that were properly filled in with reports of transfusion reactions confirmed by a blood transfusion officer.

Exclusion Criteria

Late incidents or notification for which reported signs and symptoms were not related to immediate transfusion reaction were excluded.

(c) Distribution Of Transfusion Reactions According To Reporting Unit

Table 3: Distribution of transfusion reaction according to reporting unit.

REPORTING UNIT	NO OF PATIENTS	PERCENTAGE
Surgical and Obstetrics	27	58.7%
Medical clinic	12	26.0%
Oncology	4	8.7%
Others	3	6.5%
TOTAL	46	100%

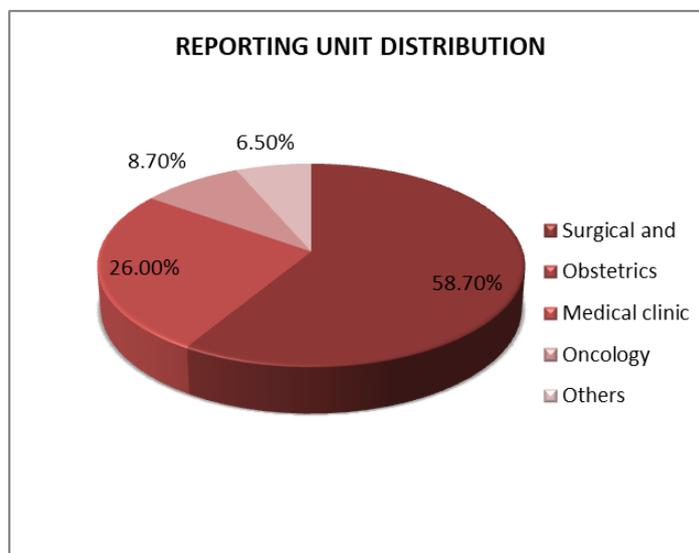


Figure 2: Distribution of transfusion reactions based on reporting unit.

(d) Distribution Of Blood Types Among Haemocomponent Receptors Who Had A Transfusion Reaction

Table: 4 Distribution of blood types among those who had reported transfusion reaction.

BLOOD TYPE	NUMBER OF PATIENTS	PERCENTAGE
O+	20	44%
A+	12	26%
A-	2	4.3%
B+	9	19.6%
B-	1	2.2%
AB+	2	4.3%
Total	46	100%

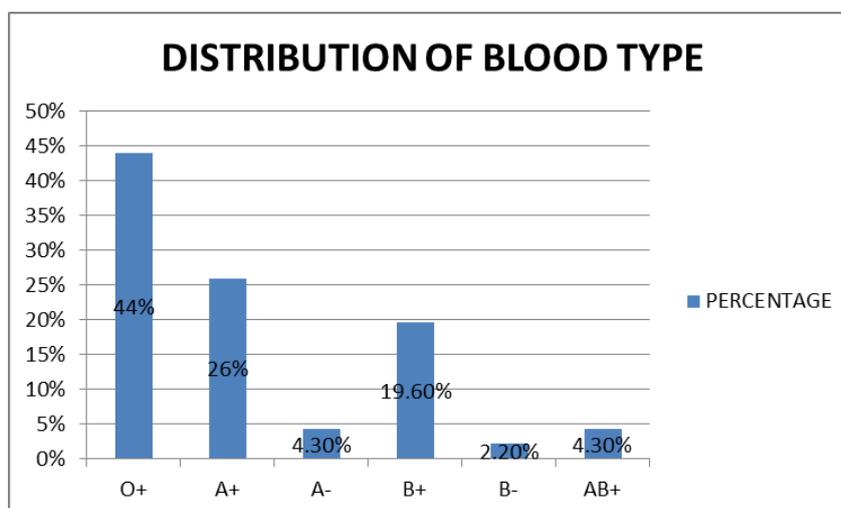


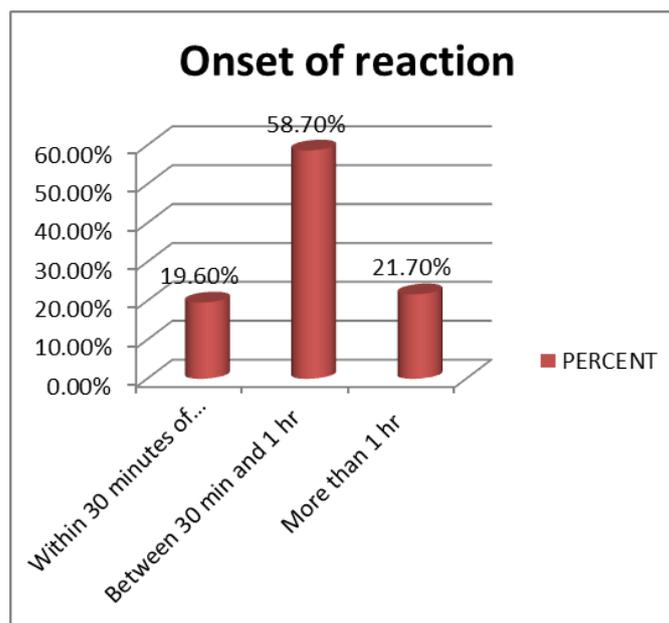
Figure 3: Distribution of blood types in the study population.

(e) Distribution of Hemocomponent Types Related To Transfusion Reaction**Table 5: Distribution of haemocomponent type among patients with transfusion reaction.**

HAEMOCOMPONENT TYPE	NUMBER OF PATIENTS	PERCENT
Packed red blood cells	43	93.5%
Others	3	6.5%
Total	46	100%

ONSET OF TRANSFUSION REACTION IN THE STUDY POPULATION**Table 6: Onset of transfusion reaction in study population.**

ONSET	NUMBER OF PATIENTS	PERCENT
Within 30 minutes of transfusion	9	19.6%
Between 30 min and 1 hr	27	58.7%
More than 1 hr	10	21.7%
Total	46	100%

**Figure 4: Onset of ATR in study population.****(f) Prevalence of adverse transfusion reaction in study population****Table 7: Prevalence of ATR in study population.**

ADVERSE TRANSFUSION REACTION	NUMBER OF PATIENTS	PERCENT
Patients with 1-2 adverse transfusion reaction	26	56.5%
Patients with more than 2 reactions.	20	43.5%
Total	46	100%

(g) Distribution Of Different Transfusion Reactions During Study Period**Table 8: Distribution of types of ATR in study population.**

Type of reactions	Number of patients	Percentage
Febrile non haemolytic transfusion reaction	27	58.7%
Allergic reactions	10	21.7%
Transfusion associated circulatory overload	4	8.7%
Febrile Haemolytic transfusion reaction	2	4.3%
Others	3	6.5%
Total	46	100%

(h) Distribution Of Clinical Manifestation Observed In Haemocomponent Receptors**Table 9: Distribution of signs and symptoms in the study population.**

SIGNS AND SYMPTOMS	NUMBER OF PATIENTS	PERCENT
Fever	42	34.1%
Chills and rigors	33	26.8%
Dyspnea	5	4.1%
Flushing	6	4.9%
Vomiting	6	4.9%
Tachycardia	4	3.2%
Hypotension	2	1.6%
Drowsiness	3	2.4%
Hypertension	4	3.2%
Rashes	8	6.5%
Urticaria	10	8.1%
Total	123	100%

In total 36,456 blood and blood components were issued from the blood bank of KR hospital, Mysore during a period of 2 years, from 2018-2019. During this period, 46 (0.13%) transfusion related reactions were reported. Among the patients who had reported transfusion reactions, 34 (74%) patients were male and 12 (26%) patients were female. The details are represented in table 1 and figure 1. Table 2 shows that most of the patients who had transfusion related reactions were in the age group of adult (n=26) followed by geriatrics group (n=16) and the least is in the pediatric group (n=4).

Overall, 58.7% (n=27) of the transfusion reactions were seen in the department of surgical and obstetrics. Further details about the departments showing transfusion reactions are depicted in table 3 and figure 2. Most of transfusions were done for preoperative and postoperative anemia and to control active bleeding. Among blood group, higher incidence of transfusion reactions were seen due to the transfusion of O+ (44%, n=20) blood group and the least was due to the transfusion of B – (2.2%, n=1) blood group. These details are shown in the table 4 and figure 3. 93.5% of transfusion reactions were associated with PRBC transfusion. Details are given in the table 5.

Among 46 patients with transfusion reactions, in 27 patients (58.7%) transfusion reaction occurred within 30 min and 1 hour. Further details about the onset of the reaction were depicted in table 6 and figure 4. Although, only 46 patients were presented with transfusion reaction, 123 reactions were seen. 20 patients (43.5%) were reported with more than 2 transfusion related reactions and 26 (56.5%) patients were reported with 1-2 transfusion related reactions. These details are shown in table 7.

In our study, febrile non haemolytic transfusions (FNHTR) were most commonly encountered (58.7%, n=27), followed by allergic reactions (21.7%, n=10). Further details about the type of transfusion reactions are represented in the table 8. Most commonly reported reactions were fever, chills and rigors. Hypotension and

drowsiness were also reported in very less patients. Table 9 shows complete information about the signs and symptoms seen in the patients.

3. DISCUSSION

Haemovigilance is required to ensure the quality of the blood transfusion and patient's safety. To strengthen the blood transfusion system, spontaneous transfusion reaction reporting is very necessary. It can be done by increasing awareness among the doctors, other health professionals & patients and their care takers and training them on reporting transfusion reactions.

This study was a retrospective observational study carried out for a period of 6 month using all the required information about the blood and blood components issued from the blood bank of KR hospital Mysore in the period of 2 years from 2018-2019. In our study, all the transfusion reactions reported were acute type. The occurrence of transfusion related reactions were very minute compared with the number of transfusion events of whole blood and blood products. A total of 0.13% of the patients were reported with transfusion related reaction (46 patients with transfusion reactions were found in 36,456 transfusions). A study by **Gente VK et al**, showed a comparable result, in which 0.15% patients of total transfusion were reported with transfusion reactions⁽³⁾. In another study, the incidence of transfusion reactions was found to be 1.09%⁽⁴⁾.

Out of 46 Acute transfusion reactions (ATR), majority of reactions were reported in female (n=34, 74%) than male patients (n=12, 26%). In the study of **Sidhu et al**, female were more affected than male, similar to our study⁽⁴⁾. A contrast result was shown in the study of **Pahuja S et al**, in which the incidence of transfusion reaction was higher in male (n=170, 54%) than female (n=144, 46%)⁽⁵⁾. Among 46 patients, 26 patients (56.5%) reporting transfusion reaction were adult followed by geriatrics patients (n=16, 34.8%). Only 4 pediatric patients (8.7%) were presented with transfusion reaction.

Most of the transfusion reactions were seen in the department of surgical and obstetrics (n=27, 58.7%) followed by medicine department (n=12, 26%). Same result was shown in the study of **Gente VK et al**⁽³⁾. In another study, majority of the ATRs were notified from oncology department (n=45, 43%)⁽⁶⁾.

In this study, highest number of ATR was found in the blood group O [O+: n=20, (44%)], followed by A [A+ = 26% (n=12;) and A- =4.3% (4.3%)] . In the study of **Sinha RTK et al** , the higher incidence of ATR are associated with the transfusion of blood group A followed by B⁽⁷⁾. Among 46 patients, majority of the ATR was associated with PRBC transfusion (n=43, 93.5%). A similar result was shown in the study of **Vidyashree M et al and Gente VK et al**^{(8),(3)}.

On reviewing , it is found that 27 patients (58.7%) were affected with the ATR in between 30 min and 1 hour of the transfusion. 8 patients were presented with ATR within 30 min and 10 patients were presented in >1hr of the transfusion. A study by **Chakravarty-Vartak U et al** showed a different result from our study in which the higher number of ATR occurred within 30 min (n=26, 52%) followed by >1hr (n=15, 30%) and least occurred in between 30 min and 1 hr(n=9, 18%)⁽¹⁾. On reviewing signs and symptoms in patients with ATR, it is found that, 43.5% of the patients were observed with more than 2 signs and symptoms and rest were observed with 1 or 2 signs and symptoms.

Among 46 patients, majority of the patients were observed with febrile non haemolytic transfusion reaction (FNHTR-58.7%, n=27) followed by allergic reactions (n=10, 21.7%). A concordant result was seen in the study of **Prakash P et al**, which pointed out 54.55% (n=36) of FNHTR and 33.33% (n=22) of allergic reaction in their study⁽⁹⁾. **Bhattacharya P et al** also showed similar result as our study⁽⁶⁾. In our study majority of the patients were observed with fever, chills and rigors.

4. CONCLUSION

The frequency of ATR in our study population was 0.13% (n=46). Most commonly ATRs were reported in female patients and adult group in our study. Majority of the ATR were seen in surgical an obstetrics department (n=27, 58.7%). 44% of ATR were seen in the blood group of O+. 93.5% of the ATR were associated with the PRBC transfusion. Majority of the reactions were FNHTR (58.7%) followed by allergic reactions (21.7%). High incidence of fever, chills and rigors were seen in our study.

Hemovigilance programme is very important to ensure the safety of patients and to improve the quality of blood transfusion. Developing awareness about the importance of reporting ATRs among the doctors and other health professional can help in ensuring safety and improving patient's quality of life. Thus this study shows the

importance of rational use of blood and its component, bedside monitoring of transfusion and spontaneous reporting system.

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