



## Retrospective Evaluation of Adverse Reactions Associated with Blood Transfusions Reported in the Blood Banks of Kerala

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### Abstract

A retrospective review of all the adverse transfusion reactions reported from 01/01/2014 to 31/12/2015 by the 19 blood banks of Kerala was done with the aim to assess the frequency and type of transfusion reactions occurring in patients receiving blood transfusion. During the study period a total of 455201 units of blood products were issued from the subjected blood banks for transfusion. RBC is the major product (39.8%) issued for transfusion and under the hemovigilance system, totally 814 adverse reactions (0.18%) were reported during the study period. Among them, the most common type of reaction observed was febrile non-hemolytic transfusion reaction (FNHTR) 69.9% (n =569) followed by anaphylaxis, Post transfusion purpura (PTP), Transfusion associated dyspnoea (TAD) were also reported. No major reactions like transfusion related acute lung injury (TRALI), transfusion associated graft Vs host disease (TAGvHD), transfusion associated circulatory overload (TACO) and haemolysis were reported. No infections were also reported during the study period. From this study it was clear that the frequency of adverse transfusion reactions was 0.18%. Obivesoly, it may be due to an underestimation of the true incidence because of under reporting and it revealed that necessity of awareness development regarding with safe blood transfusion and the implementation of proper and effective haemovigilance system to provide better patient care.

**Keywords:** Adverse transfusion reaction, Blood transfusion, Haemovigilance.

### Introduction

Blood transfusion, a life saving measure has no alternative for critically ill patients. But unfortunately transfusion of blood or its components may cause adverse reactions.<sup>(1)</sup> Severity of these adverse transfusion reactions may differed based on the type of reaction and

also based on the susceptibility of transfusion receiver which may be minor to life threatening. Based on the onset, transfusion reactions are classified in to immediate and delayed type and based on the pathogenesis it is classified in to immune and non immune type.<sup>(2)</sup>

Haemovigilance is an important tool to improve the transfusion safety. It is an ultimate indicator of quality of a transfusion service. Haemovigilance can be defined as a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components up to the follow-up of its recipients intended to collect and assess information on undesirable or unexpected effects resulting from the use of blood products and to prevent their occurrence or recurrence.<sup>(3)</sup> Information obtain from haemovigilance system is beneficial to the activities concerned with rectifying and preventing the risks related with transfusion safety. It also concerned with the quality of blood and its components and their transfusion. Briefly, these informations are very helpful for bringing necessary changes in the policies for improving the transfusion safety.<sup>(4)</sup> Knowledge on different types of blood transfusion reactions definitely help not only in the early identification and management of these reactions, but also play an important role in the prevention of the same. Without a strict and proper haemovigilance system, it is difficult to determine the actual incidence of these reactions. Recently, the published records revealed that the incidence of febrile non-haemolytic transfusion reactions (FNHTRs), transmission of Cytomegalovirus and platelet refractoriness has decreased significantly, which may be the result of introduction of novel immuno-haematological techniques in antibody identification and wide utilization of leuko-reduced blood products.<sup>(5)</sup> The current risk of human immunodeficiency virus and hepatitis C virus transmission is approximately 1 in 4 million and 1 in 3 million units, respectively.<sup>(2)</sup> Since continuous monitoring and analysis of transfusion related adverse reactions results in proper management and better patient safety, the present study was conducted with the aim to identify the types and frequency of adverse transfusion reactions reported in the blood banks of Kerala.

## Materials and Methods

A standard pro forma was prepared under the guidance of an expert team of doctors in the field of transfusion medicine for the purpose of collecting haemovigilance data. In this study, haemovigilance data for the period of two years from 01/01/2014 to 31/12/2015 was collected from the blood banks with component facilities across the Kerala. Reports of 19 leading blood banks belong to both Govt. and private sectors were subjected to the study. A retrospective review of all the adverse transfusion reactions reported by these blood banks in the specified period was done. Analysis was done by using percentages and ratios.

## Results

In the present study, it was found that a total of 625605 units of blood products were prepared by the participated blood banks during the study period. Out of which 455201 units were transfused. The analysis of transfused blood components revealed that the RBC is the main product found a major place in transfusion during the study period. 181256 units (39.8%) of RBC was transfused over the specified period of time. Followed by fresh frozen plasma (FFP) 128177 units (28.2%), platelets 111254 units (24.4%), whole blood 16656 units (3.7%), cryoprecipitate 11581 units (2.5%), pooled platelets 6277 units (1.4%) were transfused (Table 1).

Regarding with the frequency of adverse transfusion reaction, it was found that totally 814 reactions (0.18%) were reported out of 455201 units of transfusion. Among them, febrile non-haemolytic transfusion reaction (FNHTR) is the major reaction, 569 (69.9%) out of 814 reactions reported was FNHTR. It constitutes 0.125% in total units of transfusion. The second major reaction reported was anaphylaxis. 143 reactions of anaphylaxis (17.6%) were reported. It constitutes 0.030% in total units of transfusion; followed by 60 reactions (07.4%) of post transfusion purpura (PTP), 42 reactions (05.2%) of transfusion associated dyspnoea (TAD) were

reported during the study period. They constitute 0.013% and 0.009% in total units of transfusion respectively (Table 2). No major reactions like transfusion related acute lung injury (TRALI), transfusion associated graft Vs host disease (TAGvHD), transfusion associated circulatory overload (TACO) and haemolysis were reported. No infections were also reported during the study period.

With regard to the number of units transfused, it was found that febrile reaction was seen in 13 out of 10000 units, anaphylactic/hypersensitivity reaction was seen in 3 out of 10000 units, PTP was seen in 1 out of 10000, TAD is 9 in 100000 units of transfusion. It was also noted that all the patients were recovered from the transfusion reactions.

**Table 1:** Distribution of blood products issued for transfusion during the study period

Blood Products	Units (Transfused)	Percentage (%)
RBC	181256	39.8
FFP	128177	28.2
Platelets	111254	24.4
Whole blood	16656	3.7
Cryoprecipitate	11581	2.5
Pooled platelet	6277	1.4
Total	455201	100

FFP- Fresh frozen plasma

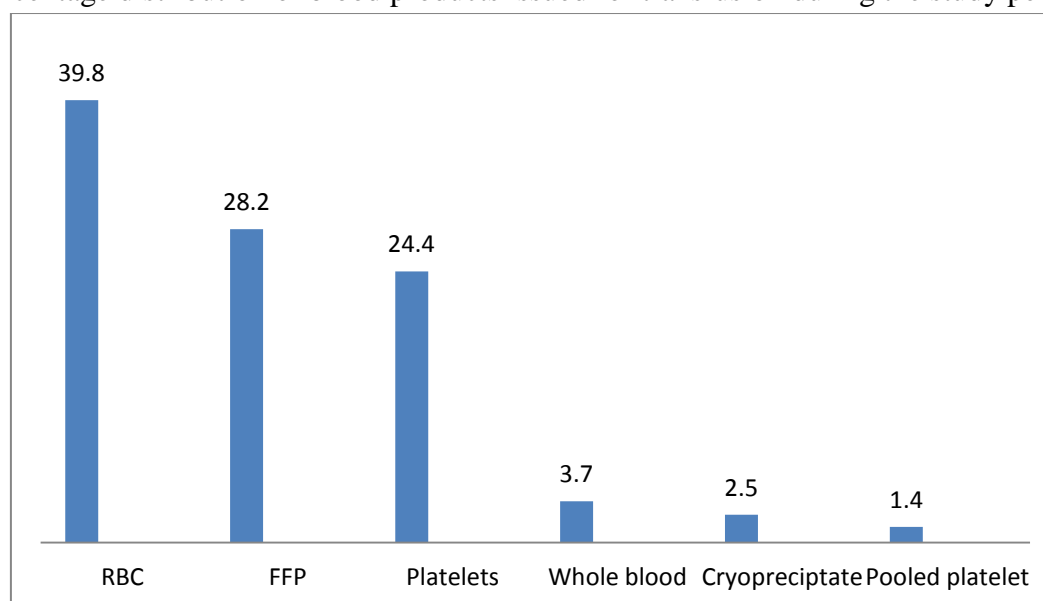
**Table 2:** Adverse transfusion reactions reported during the study period

Adverse transfusion reaction	Number reactions reported	Percentage (%) of reported reactions	Percentage (%) among total units of transfusion
FNHTR	569	69.9	0.125
Anaphylaxis	143	17.6	0.030
PTP	60	07.4	0.013
TAD	42	05.1	0.009
Total	814	100	0.177

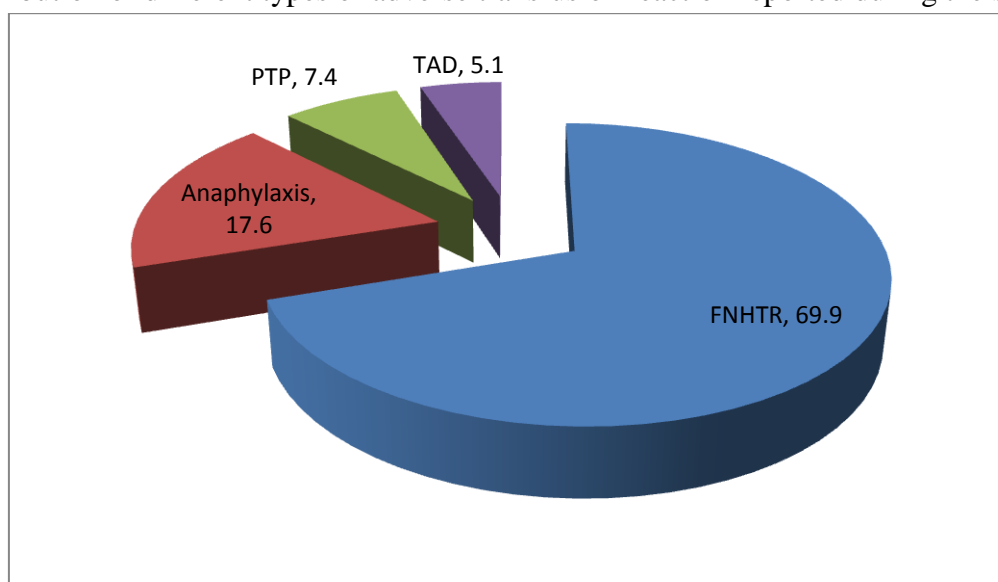
FNHTR - Febrile non-haemolytic transfusion reaction; PTP - Post transfusion purpura;

TAD - Transfusion associated dyspnoea

**Figure 1:** Percentage distribution of blood products issued for transfusion during the study period



FFP- Fresh frozen plasma

**Figure 2:** Distribution of different types of adverse transfusion reaction reported during the study period

FNHTR – Febrile non-haemolytic transfusion reaction; PTP - Post transfusion purpura;  
TAD - Transfusion associated dyspnoea

### Discussion

In the present study, it was found that a total of 455201 units of blood products were transfused during the study period. RBC is the major product (39.8%) employed for the transfusion. Other blood products such as FFP, Platelets, Whole blood, Cryoprecipitate and Pooled platelet were also utilized for transfusion. Out of 455201 units of transfusion 814 adverse transfusion reactions (0.18%) were reported. FNHTR (69.9%) is the major one among the reported adverse reaction. Anaphylaxis, PTP and TAD were also reported. Importantly, major reactions such as TRALI, TAGvHD, TACO and haemolysis were not reported. Infections also not reported. In case of previous literatures, report of the study conducted by Bhattacharya *et al.*, in 2011 indicated that the incidence of adverse transfusion reaction was exactly 0.18% (105 reactions out of 56,503 units of blood and blood components transfused). FNHTR (41%; n = 43) and allergic reactions (34%; n = 36) were the major reactions among the reported adverse reactions. 65% febrile reactions were observed in a study carried out in Nigeria<sup>(7)</sup> which was almost near to our observation. The incidence of 0.16% adverse transfusion reactions was observed in another one study and the most common reaction noted in that study was febrile

reaction followed by allergic reaction.<sup>(8)</sup> In another one study, the frequency of adverse transfusion reactions reported was 0.92%<sup>(9)</sup> which was comparable to that of a study carried out in Punjab, where the incidence of adverse transfusion reactions was 1.09%.<sup>(10)</sup> The incidence of adverse transfusion reactions reported in another one study was only 0.082%.<sup>(11)</sup> A study in Switzerland<sup>(12)</sup> and the Quebec haemovigilance system<sup>(13)</sup> reported transfusion reaction rates of 0.042% and 0.035% respectively.

Regarding with PTP, the literatures states that it is a rare delayed transfusion reaction where a patient develops dramatic, sudden and self-limiting thrombocytopenia (platelet counts  $<10 \times 10^9/L$  in 80% of cases), typically 7 to 10 days after a blood transfusion. It is caused by allo-immunization against platelet antigens, anti-HPA-1a being the most frequent antibody.<sup>(14)</sup> In our study, 60 numbers of PTP was reported out of 814 reactions and amount to 7.4%. 42 cases of TAD were found in our study reports which represent 5.1% of total reactions. It may be a misclassification. TAD is a type of transfusion reaction has respiratory features (TRRF) that do not fit definitive entities. TRRF including TADs are clinically significant and many TADs may have been transfusion associated circulatory

overload. Better information in transfusion reaction reports and refining transfusion reaction diagnostic criteria may helpful in less misclassification of TRRF<sup>(15)</sup>. Moreover, the denominator utilized for the calculation of frequency of transfusion reactions may not be the actual number of recipients of transfusion mainly because some patients might have received multiple transfusions and also a very small number of issued blood products could have been unused, not returned to the blood bank and discarded. Even the total number of adverse reactions reported may not be the actual indicator because of under reporting. The present study was focused on analyzing the type and frequency of adverse transfusion reactions reported and it was found that reactions such as FNHTR were mainly reported. These reactions are less harmful but major reactions such as TRALI may also occur. Preventive measures must be taken to avoid such reactions.

### Conclusion

During the study period, 814 adverse transfusion reactions were reported out of 455201 units of transfusion. RBC is major component issued for transfusion. FNHTR is the prime adverse reaction among the reported reactions followed by anaphylaxis, PTP, TAD were reported. No major reactions like TRALI, TAGvHD, TACO and haemolysis were reported. No infections were also reported during the study period. Obivesoly, it may not reflect the true incidence because of under reporting. The prevailing disease conditions in the transfusion recipient may also develop difficulties in the definite diagnosis of transfusion reactions. All these limitations can be overcome by implementing proper and effective haemovigilance system. Utilizing newer technologies, recruiting adequate skilled and dedicated staffs, reporting all adverse events, set up of full functional hospital transfusion committee and continuous education to the staffs of medical and paramedical department will definitely help in strengthening hemovigilance system and reducing

the incidence of adverse transfusion reactions to minimum.

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