

## Study of Haemovigilance in A Tertiary Care Teaching Hospital Inandhrapradesh

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### Abstract

**Introduction:** Haemovigilance is a set of surveillance procedures covering the whole transfusion from collection of blood and its components to the follow up of its recipients. Haemovigilance programme of India was launched on 10<sup>th</sup> December 2012.

**Objective:** To identify and prevent occurrence or recurrence of transfusion related unwanted events and to increase the safety, efficacy and efficiency of blood transfusion.

**Materials And Methods:** Transfusion reactions reported over a period of 3 months (march, april, may 2016) were reviewed and analysed.

**Results:** A total of 2445 units of whole blood and components were transfused in this period. In this 1330 units of whole blood, 950 units of packed cells, 65 units of platelet rich plasma and 100 units of fresh frozen plasma were transfused. Acute transfusion reactions (ATR) encountered were 16 (0.65%). Out of which ATRs with whole blood were (n= 7, p=0.13), with packed cells were (n= 2, p=0.19), with platelets were (n= 4, p=0.18) and with frozen plasma were (n=3, p=0.53). Allergic reactions were most common ATRs seen with whole blood transfusions. Febrile reactions were the second most ATRs. Least number of ATRs are seen with packed cells. Obstetrics and gynaecology department received most of blood transfusions (58.27%), while paediatric department stood second (8.6%).

**Conclusion:** The overall incidence of ATRs in this hospital is 0.65%. Though there are no leucoreduction facilities, the ATRs are less due to strict aseptic compatibility testing.

**Keywords:** Haemovigilance, Acute transfusion reactions, Febrile reactions, Allergy, Whole blood transfusion.

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### I. Introduction

Blood transfusion is lifesaving in critically ill patients. Blood transfusion typically uses sources of someone else's (allogenic or homologous transfusion) or one's own (autologous transfusion). Before transfusion ABO compatibility and Rh compatibility is tested<sup>[1]</sup>. Donated blood is then separated into components like RBC, plasma, platelets, albumin, clotting factor concentrate, cryoprecipitate, fibrinogen, immunoglobulins and packed cells. In this institute only packed cells, platelets rich plasma, fresh frozen plasma and whole blood are available for transfusion.

Haemovigilance is a tool to improve the quality of blood transfusion chain, primarily focusing on safety<sup>[2]</sup>. Haemovigilance systems have shown that blood transfusion is relatively safe and majority of adverse reactions are preventable. Haemovigilance is used for surveillance of alternatives for allogenic blood transfusions<sup>[3]</sup>.

Initiation of software development for Haemovigilance programme in India (HVPI) was started on 15<sup>th</sup> November, 2012. Haemovigilance software was uplinked on national institute of biology on 24<sup>th</sup> January. There are about 2545 licensed blood banks out of which 981 (38.5%) are in public sector and remaining 1564 are in private hospital or managed by charitable or voluntary organizations<sup>[4]</sup>. The average annual blood collection is around 7-8 million units in our country<sup>[6]</sup>. There are 134 centers for HVPI, out of which 35 are at north zone, 23 at west zone, 18 at east zone and 58 at south zone. Targets for HVPI are initiation phase 2012-13, expansion and consolidation phase 2013-15 and expansion and maintenance phase 2015-17.

### II. Materials And Methods

The study was conducted in the department of pharmacology and blood bank of Rajiv Gandhi Institute of Medical Sciences (RIMS), Kadapa, Andhrapradesh. The Institutional Ethics committee of RIMS, Kadapa during

its meeting held on 15<sup>th</sup> march 2015 heard the presentation and gave approval. A prospective observational study was done for 3 months ie on march, april, may 2016 during which acute transfusion reactions occurring in various departments in RIMS were reviewed and analysed<sup>[7]</sup>.

Before a recipient receives a transfusion, compatibility testing between donor and recipient blood is done. The first step before a transfusion is given is to type and screen the recipient's blood. Typing of recipient's blood determines the ABO and Rh status. The sample is then screened for any alloantibodies that may react with donor blood. It takes about 45 minutes to complete .

A positive screen warrants an antibody panel/investigation to determine if it is clinically significant. An antibody panel consists of commercially prepared group O red cell suspensions from donors that have been phenotyped for antigens that correspond to commonly encountered and clinically significant alloantibodies<sup>[8]</sup>. Donor cells may have heterozygous (e.g. K+k-), homozygous (K+k+) expression or no expression of various antigens (K-k-). The phenotypes of all the donor cells being tested are shown in a chart. The patient's serum is tested against the various donor cells. Based on the reactions of the patient's serum against the donor cells, a pattern will emerge to confirm the presence of one or more antibodies. Not all antibodies are clinically significant (i.e. cause transfusion reactions, HDN, etc.). Once the patient has developed a clinically significant antibody it is vital that the patient receive antigen-negative red blood cells to prevent future transfusion reactions. A direct antiglobulin test ([Coombs test](#)) is also performed as part of the antibody investigation.

If there is no antibody present, an immediate spin crossmatch or computer assisted crossmatch is performed where the recipient serum and donor red blood cells are incubated. In the immediate spin method, two drops of patient serum are tested against a drop of 3-5% suspension of donor cells in a test tube and spun in a serofuge. Agglutination or hemolysis (i.e., positive Coombs test) in the test tube is a positive reaction and the unit should not be transfused.

If an antibody is suspected, potential donor units must first be screened for the corresponding antigen by phenotyping them<sup>[8]</sup>. Antigen negative units are then tested against the patient plasma using an antiglobulin/indirect crossmatch technique at 37 degrees Celsius to enhance reactivity and make the test easier to read. From the whole blood ,packed cells, platelets and fresh frozen plasma are separated. Strict aseptic precautions are followed.

ATRs like allergic reactions (urticaria, itching), (FNHTR) febrile nonhaemolytic transfusion reactions (fever), anaphylactoid reactions (bronchospasm, hypotension) and pulmonary embolism (severe respiratory distress, froth from mouth, collapse) were monitored in recipients of transfusion<sup>[9]</sup>.

### III. Data analysis

The data collected for this study were analysed for frequency, percentage, mean and standard deviation. Statistical software used was Microsoft excel 2007 and IBM SPSS statistics version 20. The chi square test was used where ever applicable and p value <0.05 was considered significant.

The following parameters were calculated and tabulated.

- 1) Percentage of component /whole blood transfused. (TABLE-1)
- 2) Risk of acute transfusion reactions with a particular component /whole blood<sup>[10]</sup>. (TABLE-1)
- 3) Risk of particular reaction with a particular component/whole blood. (TABLE-2)
- 4) Percentage of particular reaction in relation to total number transfusion. (TABLE-3)
- 5) Percentage of particular reaction in relation to total number of acute transfusion reactions. (TABLE-4)
- 6) Percentage of units received by various clinical departments in the hospital. (TABLE-5)
- 7) Demographic data. (TABLE-6)

### IV. Results

**Table -1**

Type of transfusion	Total number of units transfused (n=2445)	Percentage of units transfused	Total number of acute transfusion reactions. (n=16)
Whole blood	1330	54.39%	7
Packed cells	950	38.8%	2
Platelet rich plasma	65	2.6%	4
Fresh frozen plasma	100	4.08%	3

**Table-2**

Type of transfusion reaction	Whole blood (n=1330)	Packed cells (n=950)	Platelet rich plasma (n=65)	Fresh frozen plasma (n=100)	Total (n=2445)
Allergic reaction	4	1	2	1	8
Febrile nonhaemolytic transfusion reaction	2	1	2	1	6
Anaphylactoid reaction	1	Not	Not reported	1	2

		reported			
Pulmonary embolism	Not reported	Not reported	Not reported	Not reported	Nil

**Table-3**

Type of transfusion reaction	Number of transfusion reactions	Percentage of transfusion reactions in relation to total no of transfusions(n=2445)
Allergy	8	0.33%
Febrile nonhaemolytic transfusion reaction	6	0.25%
Anaphylactoid reaction	2	0.08%
Pulmonary embolism	0	Nil

**Table-4**

Type of transfusion reaction	Number of transfusion reactions	Percentage of transfusion reactions in relation to total no of transfusion reactions(n=16)
Allergy	8	50%
Febrile nonhaemolytic transfusion reaction	6	37.5%
Anaphylactoid reaction	2	12.5%
Pulmonary embolism	0	Nil

**Table-5**

Type of clinical department	Number of units recieved	Percentage of units received
Obstetrics and gynaecology	1424	58.27%
Paediatrics	212	8.6%
Surgical	133	5.4%
Medical	102	4.17%
Others	574	23.47%

**Table-6**

Demographic characteristics of transfusion recipients reporting acute transfusion reactions

Gender	10(62.5%)
Males	6(37.5%)
Females	
Age	6-72 years
Mean age males	35±12.4years
Mean age females	32±18.6years
Blood group	4
A+	4
B+	3
AB+	5
O+	

A total of 2445 units of whole blood and components were transfused in the study period, out of which a total of 16(0.65%) acute transfusion reactions(ATR) were encountered. Table -6 depicts the demographic characteristics of recipients reported with transfusion reactions. The age of recipients reporting ATR is 6-72 years, with mean age of males being 35±12.4 years and mean age of females being 32±10.6 years. There is male preponderance (62.5%) in the frequency of transfusion reactions compared to females (37.5%). However this difference is not significant ( $p > 0.05$ ). Transfusion with whole blood was most commonly associated with ATR ( $P = 0.13$ ) followed by platelet rich plasma ( $p = 0.18$ ). Allergic reactions were most commonly encountered ATR ( $p = 0.16$ )<sup>[11]</sup>. This is followed by febrile nonhaemolytic transfusion reactions ( $p = 0.25$ ). There was no case of pulmonary embolism during the period of study. TABLE-2, shows relative frequency of ATRs. TABLE-3 depicts percentage of ATRs compared to total number of transfusions, whereas TABLE-4 shows percentage of ATRs in relation to total number of transfusion reactions. The percentage of transfusions done in individual clinical departments was depicted in TABLE-5.

## V. Discussion

The concept of haemovigilance was first initiated by French. Haemovigilance system is designed to detect, gather and analyse unexpected or undesirable effects associated with transfusion. It is thus not only an avenue to analyse blood transfusion incidents but also a tool to measure the effects of new processes or corrective action implemented to remedy their causes and prevent their recurrence. Noninfectious adverse transfusion reactions such as acute haemolytic transfusion reactions, FNHTRs, anaphylactoid reactions, transfusion related acute lung injury and allergic reactions are recognized as predominant constituent

factors of transfusion related morbidity and mortality<sup>[12]</sup>. ATRs are those immune or nonimmune adverse reactions that occur within 24 hours of transfusion. The estimated frequency of ATR varies from 0.2% to 10% and mortality is approximately 1 in 2,50,000. In this study frequency of ATRs was observed to be 0.65% which is comparable to that carried out in Sikkim where the incidence is 0.92%. In other study conducted in Punjab the incidence of ATRs was 1.09%. Two larger studies done in New Delhi and Chandigarh however showed a relative lower frequency of ATRs (0.05% and 0.018% respectively). A study in Switzerland and at Quebec reported ATRs at the rates of 0.042% and 0.035% respectively<sup>[13]</sup>.

The frequency of ATRs was more in males than females though it was not statistically significant. A skewed incidence of transfusion reactions towards females was seen in studies done in Saudi Arabia (54.3%) and Zimbabwe (61.6%)<sup>[14]</sup>.

The most common ATRs observed was allergic reaction (50% of ATRs) which presented most commonly as urticaria and/or itching. There is no significant difference observed between number of allergic reactions and type of transfusions ( $p > 0.05$ ). Allergic reactions can occur up to 2% of transfusions as a result of recipient immunoglobulin E and donor antigen interaction triggering the release of histamine, leucotrienes and platelet activating factor. Clinically allergic reactions have been discerned from the more severe anaphylactoid reactions by the absence of clinical manifestations such as bronchospasm and/or hypotension. Similar to the findings of this study, allergic reactions were most common ATRs in a study done in Delhi (55.1%) and Iran (49.2%)<sup>[15]</sup>. Overall incidence of allergic reaction in a study in Delhi was 0.02% whereas it was 0.33% in our study. It was 0.6% in a study done in Sikkim.

FNHTR, which is defined as an otherwise unexplained rise in temperature of at least 1° during or shortly after transfusion, comprise of 37.5% of the total ATRs (0.25% of total transfusion). In a study in Sikkim it was 28% of total ATRs and 0.26% of total transfusions<sup>[16]</sup>. Two FNHTRs were seen with whole blood and platelet transfusions. The association was nonsignificant ( $p > 0.05$ ). A study done in Sikkim showed significant association of FNHTR with packed cell transfusion ( $p < 0.05$ )<sup>[17]</sup>. In a study done in AIIMS, the frequency of FNHTRs with packed red blood cells was found to be 0.04% which is low compared to this study. Leukocyte depleted red blood cells have shown to reduce the incidence of FNHTRs<sup>[18]</sup>. The risk of FNHTR with transfusion of nonleukoreduced whole blood and packed cells was estimated to be 0.114% in a study done in Chandigarh<sup>[19]</sup>. There was no case of pulmonary embolism during the three months of the study. In a study done in Sikkim the incidence of pulmonary embolism was 0.09% compared to all total transfusions<sup>[20]</sup>.

## VI. Conclusion

The overall incidence of ATRs in this institution is more compared to higher institutions like AIIMS but less compared to studies done in north eastern states like Sikkim. There was no significant association among the types of transfusion and ATRs ( $p > 0.05$ ). The use of leukoreduced whole blood and packed cells possibly reduce ATRs in general and FNHTRs in particular.

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