



TO TRACK ADVERSE REACTIONS, EVENTS AND INCIDENCE ASSOCIATED WITH BLOOD AND BLOOD PRODUCT TRANSFUSION

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ABSTRACT

Haemovigilance is defined as a set of surveillance procedures covering whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and assess the information. The major aim of this study is to track adverse reactions/ events and incidence associated with blood and blood product transfusion unexpected or undesirable effects resulting from therapeutic or liable blood products. To identify hazards , risks and to provide information as to where the system is breaking down. To analyze any incidents and errors that may impact on the safety of blood products. To promote, enable and maintain a high level of ethical medical and scientific standards in blood transfusion science and medicine. which shows that the transfusion was majorly done in patients between the age group of 20-30 (29.00%) followed by 30-40 years (22.00%). The age group with the least blood transfusion was found as 40-50years (15.00%), 10-20 years (6.00%) and 0-9 years (8.00%). In our study it was observed that the PRBC administration for the patients with normal Hb levels were due to dialysis and anemic conditions. PRBC are administered in surgery cases even if they have Hb levels greater than 10 gm/dl. Pharmacist should involve in the development of local educational and training materials which is required by staff involved in transfusion procedures. Staff training should be maintained and updated with evidence of training and competency documented assessment of training should be undertaken in accordance with local and national guidelines.

KEYWORDS: *Blood transfusion, Haemovigilance, Adverse reactions, procedure.*



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Received on: 21-02-2019

Revised and Accepted on:

DOI: <http://dx.doi.org/10.22376/ijpbs/lpr.2019.9.3.P48-60>

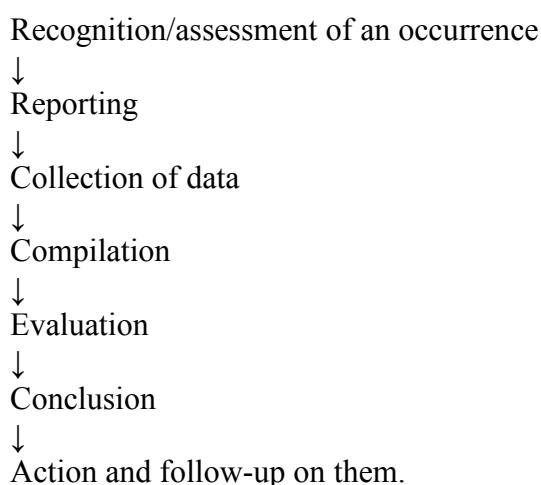
INTRODUCTION

"Haemovigilance is required to identify and prevent occurrence or recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all the activities of the transfusion chain from donor to recipient." Haemovigilance is defined as a set of surveillance procedures covering whole transfusion chain from the collection of blood and its components to the follow up of its recipients, intended to collect and assess the information on unexpected or undesirable effects resulting from therapeutic or liable blood products¹. The information gained from the investigations and analyses facilitate corrective and preventive actions to be taken to minimize the potential risks associated with safety and quality in blood processing and transfusion for donors, patients and staff. Such information is also key to introduce required changes in the applicable policies, improve standards, systems and processes, assist in the formulation of guidelines, and increase the safety and quality of the entire process from donation to transfusion. The haemovigilance system should involve all relevant stakeholders, and should be coordinated between the blood transfusion service, hospital clinical staff and transfusion laboratories, hospital transfusion committees, regulatory agency and national health authorities. Extension of the haemovigilance system to regional and global sharing of information will further enhance the process of learning for improvement. Hence there is a need for a haemovigilance system which can assure patient safety and promote public health. The ultimate purpose of haemovigilance is to prevent the repetition of adverse events and reactions. Blood transfusion is not without risk. Although the risks of HIV and hepatitis transmission have diminished, haemovigilance programs highlight that other significant transfusion hazards remain. Sepsis from bacterial contamination is the most common residual infectious hazard in developed countries, and events due to a clerical error are problematic. Unnecessary transfusions should be avoided. The involvement of healthcare professionals in haemovigilance programs are considered to be vital in ensuring the safe blood transfusion for better patient health outcome benefits². The system should cover monitoring, identification, reporting, investigating and assay of adverse events near-misses and reactions accompanying to transfusion and manufacturing. A abreast absence is an error or

deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient. This concerns the follow up of whole blood and labile blood components for transfusion: red cell concentrate, FFP and platelets³. Blood is an expensive and limited resource, over the last 20 years there has been a progressive increase in demands of this products, mainly as a result of the advances in onco-hematological therapy and the increase in major surgery. Blood transfusion is a cornerstone of modern medical practice, which is an essential component in the medical management of patients in almost every field of clinical practice. Medical practitioner who order the blood for their patients are faced with the challenge of managing blood transfusion in evidence based approach and balancing the expected clinical benefit with medical and legal risk inherent in blood transfusion. The decision to transfuse blood or blood products must be based on clinical assessment of clinical and laboratory indications that transfusion is necessary to save life or to prevent significant morbidity. Haemovigilance is a relatively recent development in transfusion safety. It is defined as surveillance procedures covering the whole transfusion chain, from collection of blood and its components to follow-up of recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence or recurrence (International Haemovigilance Network [IHN], 2012). The aims are to identify trends in adverse reactions and events, thereby to inform transfusion policy, to target areas for improvement in practice, to stimulate research, to raise awareness of transfusion hazards, to be an early warning of new complications and to improve the safety of transfusion for patients. The clinical risk of transfusions is perceived predominantly as the risk of acquiring infectious diseases. In reality, over the last 20 years, the incidence of transfusion-related transmission of diseases has decreased significantly, thanks to ever greater attention given to the stages of selecting donors and screening the units collected. The real transfusion process, mostly carried out in hospital wards and operating theatres, tends to be less considered, but now needs to be monitored to increase the safety of the whole process. Errors related to the identification of the patient, of the sample test-tube and of the blood component expose patients to risk and, in some cases, increase the risk of mortality⁵. From the

monitoring of adverse reactions due to transfusions, reported by countries in which a haemovigilance system has been active for some time, it can be deduced that immunological adverse events, transfusion-related acute lung injury (TRALI) and errors in the transfusion process are much more likely than infections transmitted by transfusion of blood components ^{1,2}. The ultimate purpose of haemovigilance, defined as the surveillance of unexpected or adverse reactions in donors and recipients and as epidemiological surveillance in donors, is to prevent the repetition of adverse events and reactions ³. In fact, the information obtained from haemovigilance systems can contribute to improving the safety of blood collection and transfusion by: a) supplying the medical community with a valid source of information about the risks related to transfusion; b) indicating corrective measures to prevent the repetition of some accidents or dysfunctions of the transfusion process, including particularly significant ones, such as samples taken from the

wrong person, mistaken identification of the sample, errors in the request form, and blood transfused to the wrong person; c) alerting the hospital wards and Transfusion Structures (TS) about adverse events that could involve several patients, such as those related to the transmission of infectious diseases and to the collection and processing of the blood. The collection and analysis of data on undesired effects of transfusion rely on a close collaboration between the TS, which supply the blood components, and the hospital wards. This collaboration is essential, in order to ensure complete investigations of every unfavourable event. The Committee for the Good Use of Blood, by involving all the professional figures “dealing with blood”, could represent the context in which to spread the culture of haemovigilance, making collaboration between TS and hospital wards more possible. In practicing the Haemovigilance Programme it involves different steps of quality improvement process:-



The outline of this process is similar at all levels where haemovigilance applied wards, hospitals, blood centers, competent authorities, manufacturers, etc. and the primary actors in this process are Physicians, Pharmacists, Nurses, medical technicians etc.

The major aim of this study is to track adverse reactions/ events and incidence associated with blood and blood product transfusion. Our objective is to define strategies for developing haemovigilance system, including the harmonized reporting of transfusion related adverse reactions and events. To collect analyses and utilizing national data of unexpected events or reactions in blood and blood products for continuous learning and improvement in the safety of blood donors, blood products and patients. To identify hazards and

risks, and to provide information as to where the system is breaking down. To analyze any incidents and errors that may impact on the safety of blood products. To promote, enable and maintain a high level of ethical medical and scientific standards in blood transfusion science and medicine. To help to identify trends, recommend best practices and interventions required to improve patient care and safety, while reducing overall cost of the healthcare system.

Methodology

This is a prospective observational study aimed in monitoring the adverse transfusion reaction in the patient receiving blood & blood components. The study was approved by the institutional ethical committee to conduct the study in a 150 bedded

secondary care hospital (Varma Hospitals, Bhimavaram) for a time period of 8 consecutive months from January 2013 to August 2013. Patient those who were transfused with blood products were included in our study, a good of 165 critically ill patients admitted between January to August 2013. We collected the transfusion cases from all units including general, cardiac, orthopedic, burns, pulmonology, dialysis unit, neurology, ICCU, gynecology, etc. Blood request forms of the patient were analyzed and various parameters during the transfusion were studied, all details were noted on a transfusion reaction / request form which includes all details of blood and components recipients including patient demographics, transfusion details (date, time, duration, stopping time, components transfused, units transfused past history), evaluation

details (clerical error, peripheral blood film, patient urine details report & blood bag culture), ATR information (reaction type, time of reaction), vital signs (before, during & after transfusion), laboratory investigations. Transfusion reactions occurring during or after transfusion were evaluated based on the clinical features experienced by the recipient and laboratory parameters, these reactions were classified by standards and recognized definitions⁶.

Nature of adverse event

There are many types of transfusion reactions which can be subdivided in several ways according to their occurrence, pathogenesis and/or symptoms. ATR were categorized into the following types:

- ❖ Allergic reactions
- ❖ Febrile non - hemolytic transfusion reaction
- ❖ Hemolytic transfusion reaction (Acute or delayed)
- ❖ Near miss events
- ❖ Transfusion related acute circulatory overload
- ❖ Transfusion related acute lung injury
- ❖ Anaphylaxis
- ❖ Component or equipment related events
- ❖ Incorrect blood component/product transfused
- ❖ Post-transfusion purpura
- ❖ Transfusion associated graft versus host disease
- ❖ Transfusion - transmitted infection

Adverse reaction in recipient

Adverse event should be described according to its severity and imputability, for describing the severity of an ATR in a recipient a grading system according to an internationally accepted scale is

| | |
|--|-------------|
| GRADE: | 0 - No Sign |
| 1 - Immediate signs without risk factors | |
| 2 - Immediate signs with vital risk | |
| 3 - Long term morbidity | |
| 4 - Death | |

Imputability scores

Were incorporated into the haemovigilance reporting i.e. The likelihood that an adverse reaction in a recipient can be attributed to the Blood component transfused is of importance in order to determine whether blood component may be involved or not.

Not Assessable (NA)

used which is the imputability score⁷. Reporting transfusion incidents using uniform registration forms on a voluntary basis was done, where the severity of transfusion reaction were graded in 0 - 4 as follows.

When there is insufficient data for imputability assessment.

Excluded

When there is conclusive evidence beyond reasonable doubt full attributing the event to alternative causes.

Unlikely

When the evidence is clearly in favor of attributing the event causes other than transfusion.

Possible

When the evidence is clearly indeterminate for attributing the event either to the transfusion or alternative causes.

Likely, probable

When the evidence is clearly in favor of attributing event to the transfusion.

Certain

When there is conclusive evidence beyond reasonable doubt attributing the event to the transfusion.

Source of data

Patient Case Sheets, Blood Bank Profile Form, Patient and their Representatives, Physician, Nurses.

STATISTICAL ANALYSIS

The parameters monitored were entered on Microsoft excel 2007 and applied descriptive statistics variables included in the transfusion reaction form. The incidence rate of ATRs was calculated as the total number of particular ATR per total number of transfusions (denominator). The tables and graphs were drawn for each variable in form and also calculated percentages for each table.

RESULTS AND DISCUSSIONS

Haemovigilance is not only the concern with tracing and reporting transfusion related adverse events but also optimize the utilization of blood products. ATRs reporting information is an independent interpretation from a more experienced person in transfusion medicine. Among the study population (n=100) 44 (44.00%) were male and 56 (56.00%) were female (table 1 & fig 1). Transfusion were more frequently done in males when compared with females, as male population are more prone to cardiac problems and accidental surgeries than the female. Age wise distribution among the study population was mentioned in the (table 2 & figure 2), which shows that the transfusion was majorly done in patients between the age group of 20-30 (29.00%) followed by 30-40 years (22.00%). The age group with the least blood transfusion was found as 40-50years (15.00%), 10-20 years (6.00%) and 0-9 years (8.00%). Indication for blood and blood product transfusion varies, where the patient admitted in different departments

and the patient illness was represented in the (table 3 & figure 3) which shows that among the study population, transfusion was done more in Anemia (50.00%) and renal (3.00%) with chronic kidney disease. Transfusion of whole blood component (94.00%) was at its inimitability followed by PRBC (2.00%), platelets (3.00%), and FFP (1.00%) In our study, it is observed that there is no any Transfusion done with cryoprecipitate (Table 4 & Figure 4). Study conducted by Dushyant SG et al 2009 showed that the whole blood was transfused to the maximum number in hospital than any other which is same with our study also, where this may be due to the increased requirement for whole blood in patients with coronary artery disease and fractures due to road traffic accident. According to the circular of information for the use of human blood and blood components 2009 jointly prepared by the American association of blood banks (the American Red Cross, America's blood centers and the armed services blood program), no any transfusion should take place more than 4 hours. In our study, (Table 5 & figure 5) about 67 patient (67.00%) undergone transfusion according to the AABP guideline, while the remaining 33 patients (33.00%) are violating the guideline which is due to various reasons; this violation might be due to considering the aspect of patient health condition. Packed RBC transfusion is done based on the Hb levels, while administering PRBC it is essentially required to follow the Hb levels. The most recent guidelines for perioperative component therapy published by the American society of anesthesiologists in 1996 indicate that RBC transfusion will almost always be necessary when the Hb level falls below 6 gm/dl and is rarely necessary when Hb level is above 10 gm/dl. If the Hb levels falls within the 6-10 gm/dl range then the need for RBC transfusion should be based on the patient's risk for complications of inadequate oxygenation⁸. In our study it was observed that the PRBC administration for the patients with normal Hb levels were due to dialysis and anemic conditions. PRBC are administered in surgery cases even if they have Hb levels greater than 10 gm/dl. (Table 6 and figure 6) shows the incidence of ATR among the incidence of ATR, among the study population and among the transfusion whole blood (28.72%). Previous research conducted by Safoorah k et al 2010 concluded that packed cells majorly contributed in transfusion reactions than others, where in our study packed cells contribute next to the whole blood transfusion reactions. In our study, setting various medical conditions for transfusion

were monitored in which the ATR reported among them were also observed (table 10 and figure 10). The transfusion among cardiac patients was reported highly with ATR (29.88%) than others followed by renal (51.85). (Table 11 and figure 11) The cases indicated for transfusion in our study setting were more among the cardiac and renal problems, so the reactions are also contributed more than the others⁹. Safoorh k et al 2010 found that maximum number of ATRs reported with PRBC but in our study, whole blood transfusion reported ATR including febrile and circulatory related symptoms following with pain, GIT, Allergic and others. In FFP majority of symptoms related to allergic and other symptoms. PRBC transfusion reaction outstands at febrile then allergic followed by circulatory, pain restlessness. Transfusion of older blood especially in PRBC shows more ATRs when compared to fresh one (Koch CG et al 2008) which may be due to decreased half-life of transfused red cells and/or product undergone any changes during storage. Platelet transfusion reaction majorly occupied with febrile, circulatory, pain type of reaction and then glossitis occupied at the terminal position. Respiratory related symptoms were not observed during the study period and finally our observation reports that minor reaction occurred are resolvable which can be treated with antihistamine, hydrocortisone, paracetamol, etc. Severity score of adverse transfusion reaction are constructive i.e. maximum ATRs observed as Grade I (96.29%) were resolvable, as the recipients may require treatment but lack of such would not result in permanent damage or body function impairment. Patient with grade 2 severity requires hospitalization or prolongation of hospitalization directly attributable to the event; and/or the adverse

events resulted in persistent or significant disability or incapacity; or the event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function. In our study no reports on transfusion related life-threatening (Grade 2, 3, 4) (table 9 and figure 9). Imputability score implies the chances of ATR developed by particular blood or blood components transfused, which is classified into 6 categories (Not assessable, Excluded, Unlikely, Possible, Probable/likely, certain).table With improper laboratory investigations ATRs were confirmed as possible (51.85) and probable (37.03%), number of cases reported unlikely (11.11%) and no cases were excluded (Not Assessable)(table 8). So imputability score does not strengthen the strict adherence of healthcare providers regarding transfusion guidelines¹⁰. Managing the ATRs is also required essentially,(table 7 and figure 7)which is by administering the drugs for developed reaction. In our study, drugs consumed individually for developed ATR is represented in which shows the antihistaminic, anti-inflammatory and antipyretic agents use in excess than the others, as by study conducted by Jim Faed 2002, these are the commonly developed reactions with transfusion and drugs used for managing them. Pharmacists play an integral role within selected practice setting promoting standardization of care. In a similar manner, pharmacists are playing an active role in a blood management Programme in many institutes at least as it relates to the use of pharmacologic alternatives (Walton T 2005). Clinical pharmacist who plays an important role in providing pharmaceutical care can also monitor blood related product transfusion which definitely reduces the transfusion related reactions.

Table 1
Gender wise Distribution

| Gender | No. of individuals | % |
|--------|--------------------|-----|
| Male | 44 | 44% |
| Female | 56 | 56% |

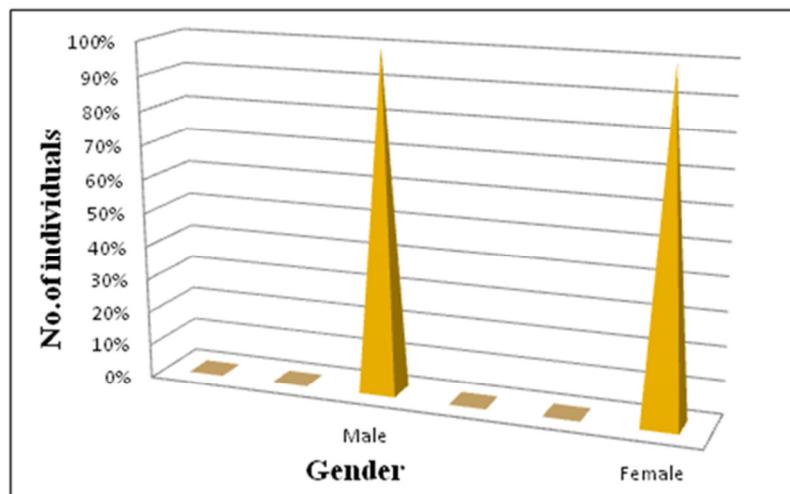


Figure 1
Gender wise distribution

Table 2
Age wise distribution

| Age in(year) | No. of subjects | Percentage |
|--------------|-----------------|------------|
| 00-10 | 8 | 8 |
| 10-20 | 6 | 6 |
| 20-30 | 29 | 29 |
| 30-40 | 22 | 22 |
| 40-50 | 15 | 15 |
| 50-60 | 10 | 10 |
| 60-70 | 09 | 09 |
| 70-80 | 00 | 00 |
| 80-90 | 00 | 00 |
| 90-100 | 00 | 00 |

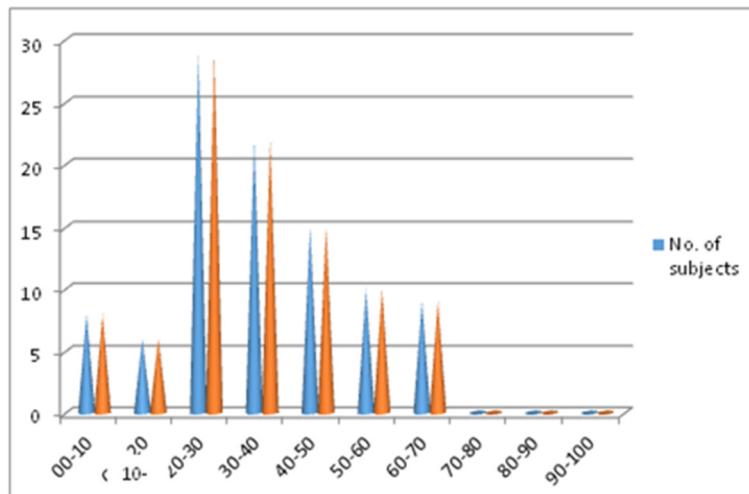


Figure 2
Age wise distribution

Table 3
Indication for transfusion

| Indications | Cases | Percentage |
|-------------|-------|------------|
| Cardiac | 00 | 00 |
| Accidental | 8 | 8 |
| Burns | 1 | 1 |

| | | |
|-------------------------|----|----|
| Renal | 3 | 3 |
| Anemia | 50 | 50 |
| Gynecology | 28 | 28 |
| Orthopedic | 00 | 00 |
| Low platelet Count | 3 | 3 |
| Respiratory | 00 | 00 |
| Fever | 00 | 00 |
| Cerebrovascular illness | 2 | 2 |
| GIT | 3 | 3 |
| Others | 2 | 2 |

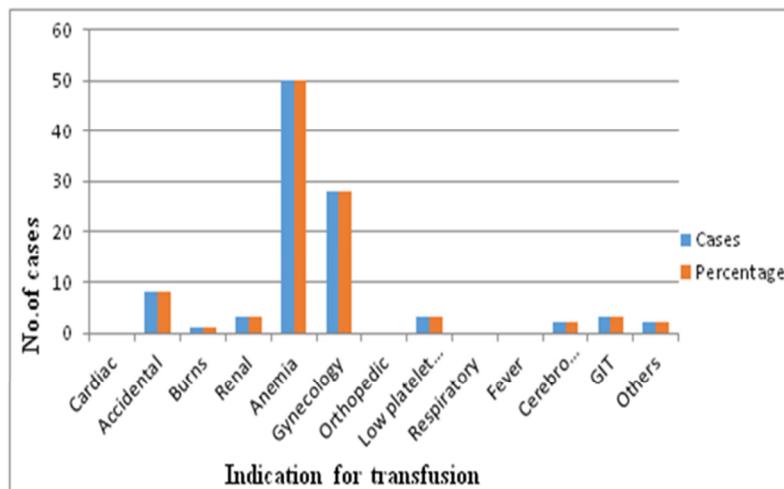


Figure 3
Indication for Transfusion

Table 4
Blood component transfused

| Components | Cases | Percentage |
|-----------------|-------|------------|
| Whole blood | 94 | 94 |
| PRBC | 2 | 2 |
| FFP | 1 | 1 |
| Platelet | 3 | 3 |
| Cryoprecipitate | 0 | 0 |

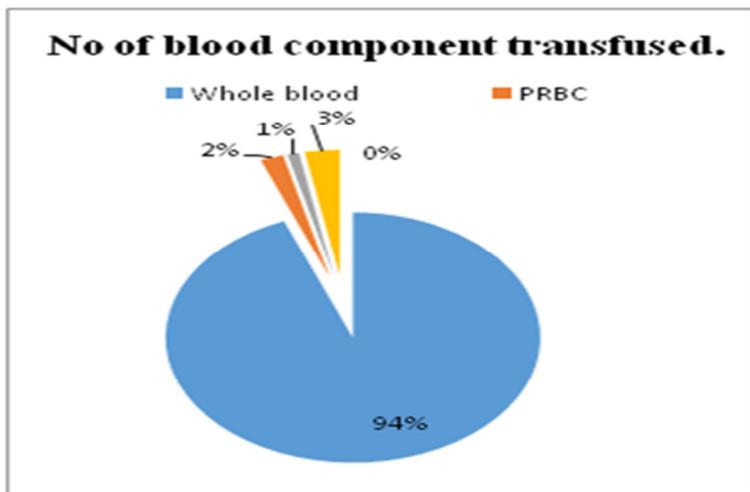


Figure 4
Blood component transfused.

Table 5
Duration of transfusion among the study population.

| Transfusion duration (hrs.) | Whole blood | Platelet | FFP | PRBC | TOTAL % |
|-----------------------------|-------------|----------|-----|------|---------|
| < 4 | 64 | 00 | 1 | 2 | 67 |
| >4 | 30 | 3 | 00 | 00 | 33 |

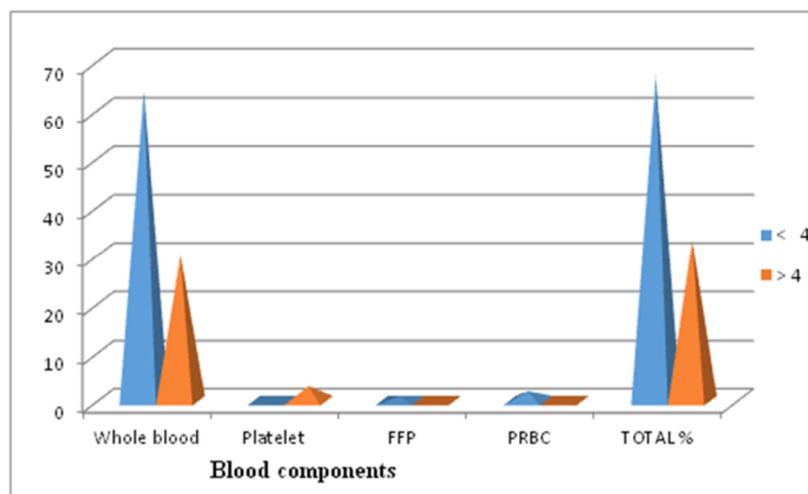


Figure 5
Transfusion duration based on time intervals.

Table 6
ATR's reported among the study population.

| Transfusion component | All transfusion | Transfusion with reaction % |
|-----------------------|-----------------|-----------------------------|
| Whole blood | 94 | 28.72 |
| PRBC | 2 | 00 |
| FFP | 1 | 00 |
| Platelet | 3 | 00 |

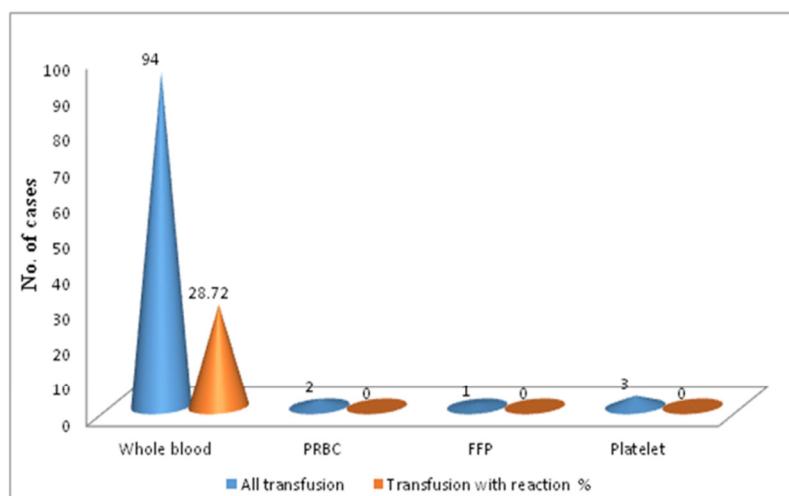


Figure 6
ATRs reported among the study population.

Table 7
ATR's observed in various medical condition.

| Transfusion Indications | ATR reported | Percentage |
|--------------------------|--------------|------------|
| Cardiac | 00 | 00 |
| Accidental | 3 | 11.11 |
| Burns | 00 | 00 |
| Renal | 1 | 3.70 |
| Anemia | 14 | 51.85 |
| Gynecology | 7 | 25.92 |
| Orthopedic | 00 | 00 |
| Low platelet Count | 00 | 00 |
| Respiratory | 00 | 00 |
| Fever | 00 | 00 |
| Cerebro vascular illness | 1 | 3.70 |
| GIT | 1 | 3.70 |
| Others | 00 | 00 |

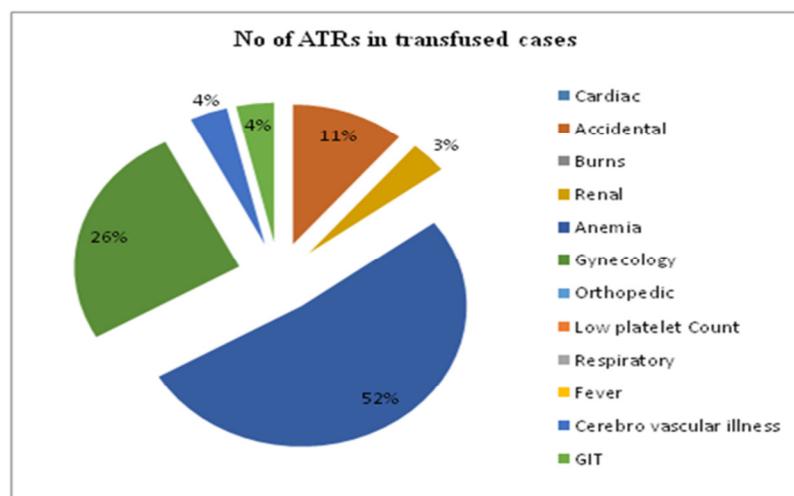


Figure 7
ATR's observed in various medical conditions.

Table 8
Nature of adverse events.

| Component | Allergic | Febrile | AHTR | TACO | Others |
|-------------|----------|---------|------|------|--------|
| Whole blood | 25 | 2 | 0 | 0 | 0 |
| PRBC | 0 | 0 | 0 | 0 | 0 |
| FFP | 0 | 0 | 0 | 0 | 0 |
| Platelet | 0 | 0 | 0 | 0 | 0 |

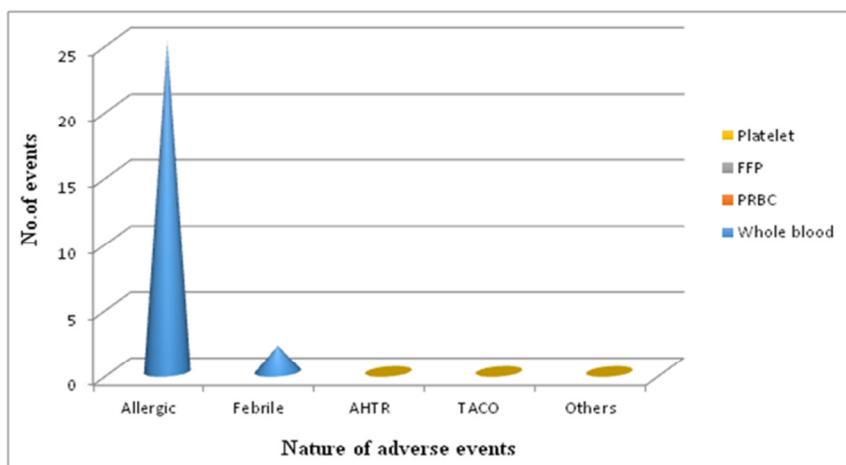


Figure 8
Nature of adverse events.

Table 9
Severity of the ATR's monitored

| Component | Grade I | Grade II | Grade III | Grade IV |
|-------------|---------|----------|-----------|----------|
| Whole blood | 26 | 1 | 0 | 0 |
| PRBC | 0 | 0 | 0 | 0 |
| Platelet | 0 | 0 | 0 | 0 |
| FFP | 0 | 0 | 0 | 0 |

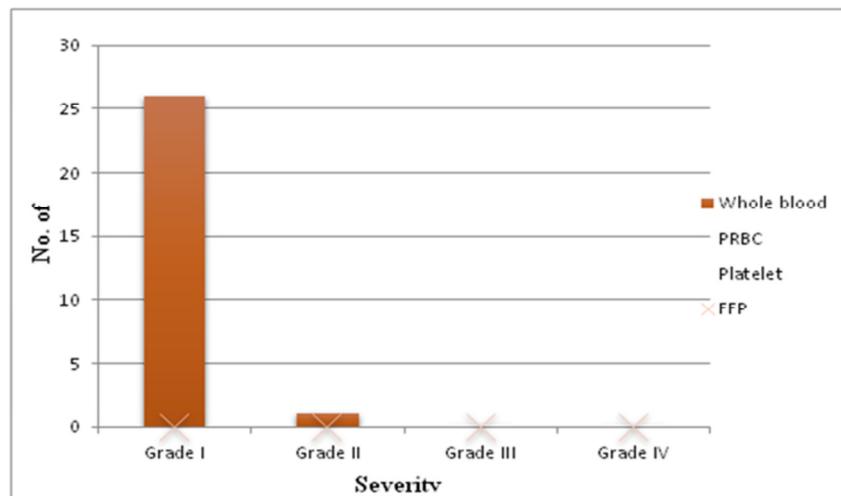


Figure 9
Severity of the ATR's monitored

Table 10
Immutability Score of the ATRs monitored.

| Causality | Whole blood | PRBC | FFP | Platelet | Percentage |
|-----------------|-------------|------|-----|----------|------------|
| Unlikely | 3 | 0 | 0 | 0 | 11.11 |
| Possible | 14 | 0 | 0 | 0 | 51.85 |
| Likely/Probable | 10 | 0 | 0 | 0 | 37.03 |
| Certain | 0 | 0 | 0 | 0 | 0 |
| Excluded | 0 | 0 | 0 | 0 | 0 |

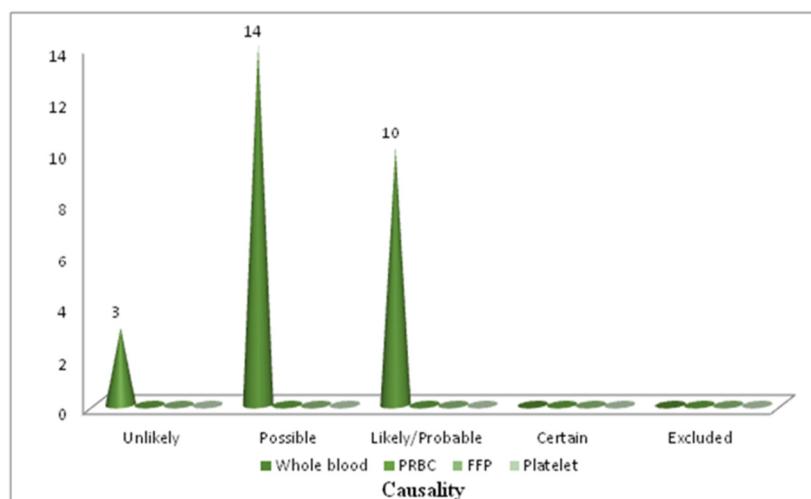


Figure 10
Immutability Score of the ATRs monitored.

Table 11
Management of ATR's

| Drug therapy | No of cases | Units administered |
|-------------------|-------------|--------------------|
| Antihistamine | 18 | 37 |
| Anti-inflammatory | 0 | 00 |
| Antipyretic | 1 | 1 |
| Antiemetic | 8 | 8 |
| Antacid | 0 | 0 |
| Anti-coagulant | 0 | 0 |
| Antihypertensive | 0 | 0 |

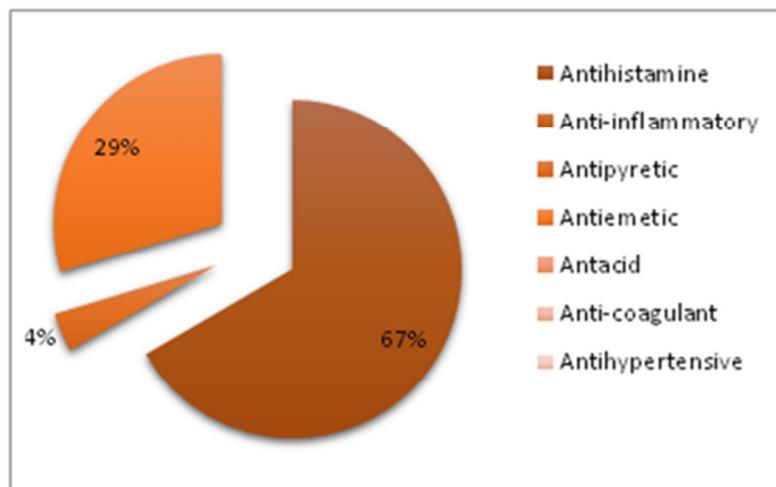


Figure 11
Management of ATR's

CONCLUSION

Conducting workshops and training programs for the professionals who are associated with blood transfusion regarding Haemovigilance system can improve the knowledge and prevent occurrence and reoccurrence of ATRs. For reducing patient harm, haemovigilance system should be effective on four danger points during transfusion process which includes medical decision to transfuse, collection of patient samples, in lab where samples are analyzed and during bedside administration of blood components. Maintaining coordination between various healthcare professionals associated with transfusion of blood products for identifying break down of system and tackling the problems related to ATRs may be beneficial for the patient. We believe that there is a need for strengthening the haemovigilance system in each setting of transfusion with national coverage that can be supportive in the detection of transfusion reaction as well as in the decision to take appropriate

preventive measures which further reduces the overall cost of treatment.

AUTHORS CONTRIBUTION STATEMENT

Susmitha Gadamsetti designed the study. Susmitha Gadamsetti and Ramesh collected the data from the hospital. All others read and approved the final manuscript.

ACKNOWLEDGEMENTS

We are thankful to Varma hospital and departments included for providing necessary facilities and support. All authors would like to thank Varma hospital for their constant support and encouragement.

CONFLICT OF INTEREST

Conflict of interest declared none.

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