

Haemovigilance Study in a Tertiary Care Hospital in Western Odisha

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Abstract: Blood transfusion is a routine, life-saving medical intervention which is generally regarded as safe when done appropriately, but it is not absolutely free from adverse reaction. The aim of the study was to analyze the Adverse Transfusion Reaction (ATRs) as a part of Haemovigilance Programme of India at VIMSAR, Burla. This study was prospective and observational. All blood transfusions and adverse reaction which occurred due to transfusion at V S S Institute of Medical Science and Research (VIMSAR), Burla, between June 2018 and November 2018 were studied. The reactions were reported in a pre-designed transfusion reaction (TR) reporting form for blood and blood products as per the Haemovigilance software, PvPI. ATRs were also analyzed with respect to types of blood products. Total blood components issued by our blood bank to various departments and total ATRs during the study period were 13145 and 121 respectively. Majority of the reactions occurred with whole blood (0.71%), followed by packed red cells (0.17%). The most common ATR observed was allergy (80.16%) followed by febrile Non hemolytic TR (19.83%). Most of the ATRs were acute reactions. The study emphasizes the different reaction accompanied with blood transfusion, and how it can be minimised by proper laboratory technique so that quality and safety of transfusion therapy can be improvised.

Keywords: ATR, FNHTR, TR, Haemovigilance.

INTRODUCTION

Haemovigilance is “a set of surveillance procedures, from the collection of blood and its components to the follow up of recipients, in order to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of blood/blood products, so that their occurrence or recurrence can be prevented” [1, 2].

Haemovigilance Program of India was launched at the National level on December 10, 2012, as a fundamental component of the Pharmacovigilance Program of India to track adverse transfusion events and to know the pattern, introduce best practices and interventions for improving the patient safety and care while improving the overall health care [3]. The incidence of transfusion transmitted disease has lowered with recent testing facilities; however, the incidence of adverse events due to human errors, ABO incompatibility, alloimmunisation, bacterial contamination remains a matter of concern [4].

VSS Institute of Medical Science And Research (VIMSAR) is a tertiary care hospital situated in western part of Odisha which is having high prevalence of Sickle cell anaemia and Thalasemia (61.9%) [5]. This Institute is having a Transfusion Medicine Dept with Red Cross Blood Bank attached to

it and it is primarily involved with collection of blood, separation of blood components, issue of blood to patients requiring Blood Transfusion and also monitoring adverse reactions occurring due to transfusion. Various components of blood that are being transfused at VIMSAR are Whole blood, Packed RBC, Fresh frozen plasma and Platelet. A lot of patients coming to VIMSAR require frequent blood transfusion because of anaemia due to sickle cell disease, Thalasemia, any surgery or procedure along with other medical conditions. Hence, this study was conducted with the primary objective to find any unexpected and undesirable effect following therapeutic use of blood and blood products and to evaluate the types and frequency of ATRs in hospitalized patients who needed blood transfusion at a tertiary care centre, a pilot effort towards Haemovigilance from the institution.

MATERIALS AND METHODS

The study was both prospective and observational.

STUDY PERIOD

June 2018 – November 2018.

PLACE OF STUDY

The study was conducted after obtaining approval from ethical committee at various departments of VIMSAR, Burla.

Inclusion Criteria: All the patients who have received blood transfusion

Exclusion Criteria: Nil

All patients who have been issued blood from blood bank for transfusion in indoor were followed up and any type of adverse events related to blood transfusion like allergic reactions (urticaria, itching), Febrile Nonhemolytic Transfusion Reactions(FNHTR), Anaphylactoid reactions (bronchospasm, hypotension) and pulmonary embolism (severe respiratory distress, froth from mouth, collapse) were observed in recipients and were recorded and analyzed as per departmental standard operating procedures [6]. All data were recorded in the pre-designed Transfusion Reaction Reporting Form (TRRF) for Blood & Blood Components & Plasma Products obtained from website of National Institute Of Biological [3].

Investigations of transfusion related adverse reaction:

- The patient's name and identification number both on the vial and requisition form were rechecked to rule out the possibility of wrong sampling or bedside transposition.
- Verification of the patient's clinical records and his/her red cell ABO and Rh typing records at the bedside and in the department.
- Relevant clinical history of the patient regarding the indications of blood/component transfusion(s) and similar episodes of adverse reactions in the past during transfusion was recorded.
- Nature of transfusion reactions: These included the clinical signs and symptoms like fever, chills, hypotension, rigors, dark-coloured urine, rashes, respiratory discomfort and any other untoward events which developed during the course of transfusion or following transfusion and their duration and management. Basing on this information transfusion reaction were classified into whether immediate or delayed in onset and with or without any evidence of haemolysis. Adverse events occurring within 24 hours were considered as acute transfusion reactions.
- Evidences for any concomitant medication.

- Thermal, oncotic and osmotic injury were also looked for by reviewing storage conditions, intravenous blood transfusion set.
- Laboratory investigations in the Department of Transfusion Medicine:
 - a. Coomb's test for suspecting immune mediated haemolysis.
 - b. Blood bag and transfusion set were examined for any abnormal findings namely discoloration, clot, and haemolysis.
 - c. ABO and Rh typing of the patient.
 - d. Bacterial culture: Bacterial culture from the blood bag(s) and patient's blood was taken in suspected cases of bacterial sepsis and sent to the Department of Microbiology.
 - e. Urine for hemoglobinuria by gross visual examination

Febrile Nonhemolytic Transfusion reaction (FNHTR) and allergic and Anaphylactoid reactions were diagnosed by their clinical features namely fever, rigors, chills, and rashes which had no primary causes for their manifestation. Definition of FNHTR as given in American Association of Blood Banks technical Manual 16th ed. "A body temperature rise of >1°C or more occurring in association with transfusion and without any other explanation" such reactions are often associated with rigor and chills [7].

Simple allergic reaction was differentiated from Anaphylactoid reaction by the absence of systemic manifestations such as bronchospasm, hypotension as seen in Anaphylactoid reaction [8].

STATISTICAL ANALYSIS

Data were collected, analysed and were expressed as percentages/proportion.

RESULTS

From June 2018 to November 2018, total 13145 units of blood & blood products were transfused to the patients admitted at VIMSAR, Burla. The number of different blood and blood components transfused is shown in Table-1. As evident from Table-1 maximum number of whole blood has been transfused (56.68%) followed by Packed Red Blood Cell (20.85%) followed by fresh frozen plasma (13.9%) and platelet (8.46%).Table-2 depicts the number of Transfusion Reactions(TR) observed in different type of blood components transfused in patient. The total number of transfusion reactions were reported to our blood bank was 121(0.92%), during the study period. Of all the Transfusion Reactions (TRs) that were reported to our blood bank during the study period, 76.85% transfusion reactions occurred with Whole blood, followed by packed red blood cells (19.01%) and fresh frozen plasma (3.3%). Among these commonest was allergic reactions in 97(80.16%) patients followed by FNHTR in 24(19.83%) patients.

Table-1: Details of blood products transfused during study period

whole blood	Packed Red Blood Cell	Fresh Frozen Plasma	Platelet	Total
7451(56.68%)	2742(20.85%)	1839(13.9%)	1113(8.46%)	13145

Table-2: Type of transfusion reactions according to type of components transfused

Type of reaction	Whole blood	PRBC	FFP	Platelet	Total
Fnhtr(febrile non haemolytic transfusion reaction)	17(14.04%)	6(4.95%)	1(0.82%)	0	24(19.83%)
Allergy	76(62.8%)	17(14.04%)	3(2.47%)	1(0.82%)	97(80.16%)
Taco(transfusion associated cardiac overload)	0	0	0	0	0
TRALI(Transfusion related Acute Lung Injury)	0	0	0	0	0
Anaphylactoid	0	0	0	0	0
Total	93(76.85%)	23(19.01%)	4(3.3%)	1(0.82%)	121

DISCUSSION

The present study is information about various Transfusion Reactions observed from the patients who were being transfused blood for various illnesses. All these reactions were evaluated on the basis of clinical history and laboratory investigations using a predefined protocol. In this study, the frequency of Transfusion Reactions was found to be 0.92% (121 out of 13145). Commonest TR was allergic transfusion reactions 97(80.16%) and occurred more with whole blood than PRBC followed by fresh frozen plasma and platelet (62.8% with whole blood, 14.04% with PRBC, 2.47% with FFP and 0.82% with Platelet). FNHTR was found in 24(19.83%) patients, which was more with whole blood 17(14.04%) than with PRBC 6(4.95%) than with FFP 1(0.82%). It suggests that PRBC is relatively safer than whole blood transfusion. Although bacterial contamination remains an important cause of transfusion related morbidity and mortality, in the present study not a single transfusion reaction occurred due to bacterial sepsis which may be due to good laboratory practice. Sources of bacteria are believed to arise from donor either from venipuncture site or from unsuspected bacteraemia and during component preparation [9]. In previous studies it was found that the incidence of transfusion-associated bacterial contamination (TABC) varies from 0.0002 to 0.003 for PRBC and 0.01 to 0.44 for platelets per 1,000 units of blood component transfused [4, 9]. The incidence of TRALI is rare in the Indian subcontinent. However, it is generally agreed that TRALI is under diagnosed. Although the incidence of TRALI reported in various studies ranged from 0.014% to 0.08% per units transfused [10, 11], no cases of TRAIL was observed in our study. This may be due to poor awareness, lack of recognition of the condition, or confusion with other conditions like adult respiratory distress syndrome (ARDS), hypervolemia, and congestive heart failure.

CONCLUSION

In our study majority of Transfusion Reactions observed are allergic type followed by FNHTR. TRALI, TAGvHD, and DHTRs were not observed, possibly due to good laboratory practice or may be due to underreporting, which can be improved by Haemovigilance system. Acute transfusion reactions are

responsible for causing most serious adverse reactions or events. Awareness about various clinical features of acute transfusion reactions with an ability to assess the serious reactions in time can lead to a better prognosis. Frequency of FNHTR and allergic reactions can be reduced by insisting maximum use of components and to restrict use whole blood only in indicated cases. Also use of leukocyte depleted and irradiated blood products will help to minimize the allergic TRs. Observation and monitoring are required throughout the transfusion episode, at best for first 15 min. There should be a standard operating procedure containing the details for documentation, reporting, evaluation, and follow-up of all adverse reaction.

CONFLICT OF INTEREST: None

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