Original Article

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Reporting Adverse Transfusion Reactions in a Teritary Care Centre, Kerala, India

Transfusion Medicine Section

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ABSTRACT

Introduction: Therapeutic use of blood and its components has increased in most tertiary care centres and also it carries its own advantages and risks.

Aim: To determine the frequency and type of Transfusion Reactions (TR) occurring in patients admitted to our hospital.

Materials and Methods: A retrospective review of all TR reported to the blood bank were analysed, between April 2016 to March 2017 was done. TR were evaluated and classified using standard definitions. Retrospective study was conducted in Department of Transfusion Medicine, Government Medical College, Thiruvananthapuram, Kerala, India.

Results: During the study period a total 52,925 units of blood and components were issued and transfused. Total of 110 (0.21%) adverse reactions were reported to blood bank. Among the TR most common was Febrile Non Haemolytic Transfusion Reactions (FNHTR) 58 (52.7%) followed by allergic reactions 43 (39.1%). 80% of TR were associated with Packed Red Blood Cell (PRBC) transfusion, 11.8% by Fresh Frozen Plasma (FFP), 6.4% by Platelet Concentrate (PC) and 1.8% by Platelet Rich Plasma (PRP) transfusion.

Conclusions: Not a single case of Delayed Haemolytic Transfusion Reactions (DHTR) was reported in our centre, which might have underreported. Establishing proper haemovigilance system to evaluate the critical transfusion events will improve the patient's safety and quality of blood transfusion.

Keywords: Allergic reactions, Blood transfusion, Fresh frozen plasma, Febrile non haemolytic transfusion reactions, Haemovigilance, Non-immune transfusion reactions

INTRODUCTION

Major developments have occurred in the past few years in the field of blood transfusion services like component separation as it reduced the usage of whole blood. Also, attained other achievements by introducing apheresis technology (erythrocytapheresis, plateletpheresis, plasmapheresis) and nucleic acid testing [1]. Following the transfusion guidelines, using clear indication, reduces unnecessary transfusions and can be lifesaving [2].

Even after the introduction of newer technology, the incidence of adverse events due to clerical errors, ABO incompatibility, alloimmunization (Minor Blood group system, Human Leukocyte Antigen, Human Platelet Antigen), bacterial contamination, and immunomodulation remains challenging [3]. Knowledge of possible causes of transfusion reaction occurrence and participation in haemovigilance program will help to manage and prevent the reaction in future [4-6].

Most common transfusion reaction reported are acute haemolytic reaction, FNHTR, allergic reaction, circulatory volume overload, bacterial contamination and hypotension [1]. The incidence of acute TR are reported to be 0.2% to10% [7-9] and it is also responsible for death in approximately 1 per 250,000 [8].

Since adverse transfusion events identification, documentation, and reporting related to blood transfusion are grossly inadequate; this study was initiated to analyse and report proper haemovigilance which will help us to improve quality of patient's care.

MATERIALS AND METHODS

The study was conducted in the Department of Transfusion Medicine, Government Medical College, Trivandrum, Kerala, India. Retrospective review of all TR that were reported in our Blood Bank for a period of one year (1st April 2016 to 31st March 2017) was done. Due permission was obtained from the Department of Transfusion Medicine for data collection. All the TR were reported to the blood bank and adverse TR form filled by physician was sent to blood bank along with the patient's blood sample (clotted and ethylenediaminetetraacetic acid). The TR workup was done in blood bank and reported to concerned doctor. Once there was TR, patient pre-transfusion data was collected which includes patient's hospital number, blood group of the patient, type of blood component transfused, donor number and his blood group, date and time of starting transfusion and patient's vital signs. Post-transfusion data included date and time of stopping transfusion, volume transfused, type of reaction noted and patient's vital signs. Routine evaluation for TR begin from checking clerical errors (patient's blood sample and blood bags were checked), post reaction blood sample was inspected for any evidence of hemolysis and compared with a pre reaction sample.

Investigation of Transfusion Reaction

- Patient's identification (name, age, sex, hospital id number, Date of birth, ward, unit) were rechecked both on the patient sample tube and compatibility report to rule out possibility of clerical errors, wrong sampling or bedside sampling error.
- Patient details were cross checked for any clerical errors with blood unit which was transfused.
- Blood bag which was returned was checked for clot, discoloration, haemolysis or foul smell.
- Investigation started from beginning, ABO and Rh typing on patient's pre and post transfusion samples and in sample of blood bag which transfused.
- Compatibility testing was repeated for donor blood sample with pre and post transfusion patient samples.
- Post transfusion blood sample of patient was checked for haemolysis, serum bilirubin, Peripheral smear examination and

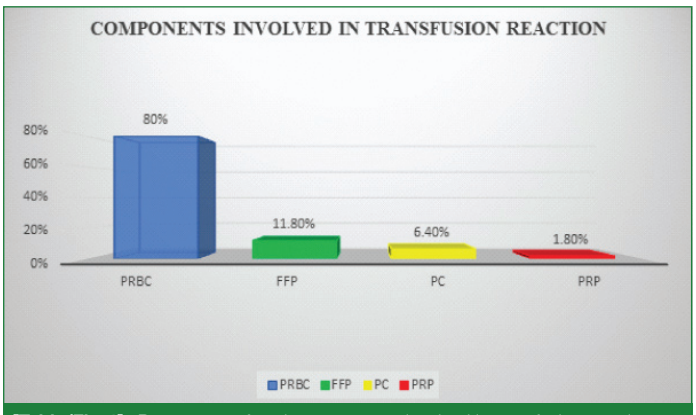
post transfusion urine sample was examined for hematuria and hemoglobinuria. Bag sample was sent for culture to rule out contamination of micro-organisms.

- Direct Coombs Test (DCT) and irregular antibody screening was done on patients pre and post transfusion samples.

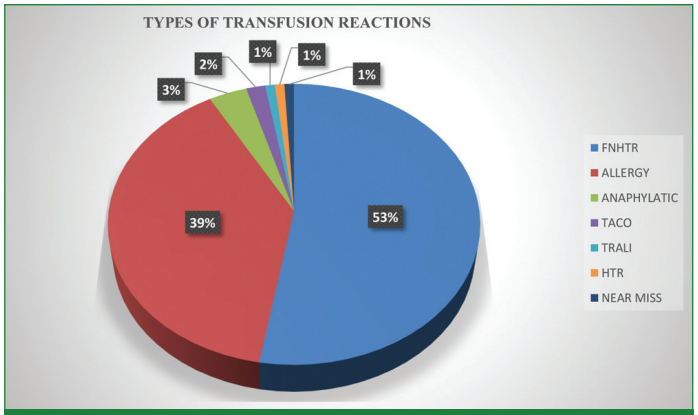
- FNHTR is defined as increase in body temperature 1°C or more occurring during or after transfusion of blood components without any other explanation [10].
- Allergic reactions are associated with allergens or antibodies present in the transfused unit.
- Diagnosis of Immune haemolytic reactions based on the clinical and/or laboratory evidence of haemolysis and positive DCT.
- Non immune haemolysis due to mechanical destruction of red cells suspected when the patient had haemolysis and negative DCT.
- Bacterial contamination is defined as the contamination of the blood product detected by a positive culture of the blood product resulting in infection to the recipient.
- Volume overload is manifested by respiratory distress leading to pulmonary oedema on chest X-ray.
- Isolated hypotension is marked by sudden hypotension after starting transfusion.
- Serious Hazards of Transfusion (SHOT) guidelines define Transfusion-Related Acute Lung Injury (TRALI) as acute dyspnoea with hypoxia, and bilateral pulmonary infiltrates during or within six hours of transfusion and not due to circulatory overload or other likely cause.

RESULTS

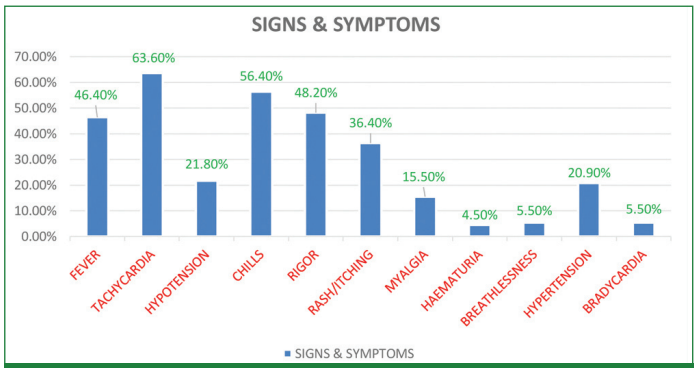
Totally 52,925 units of blood and blood products were transfused to the patients admitted in Government Medical College Trivandrum, Kerala, India. The total number of TR reported in our blood bank was 110 (0.21%), during the study period. Of which 28 (25.5%) were seen in males and 82 (74.5%) in females. Whole human Blood (WB), Packed Red Blood Cells (PRBC), Platelet Concentrate (PC), Platelet Rich Plasma (PRP), Fresh Frozen Plasma (FFP), cryoprecipitate and single donor plasma were blood components issued from our center. [Table/Fig-1] shows percentage of each component involved in TR. Not a single WB, cryoprecipitate or single donor plasma was involved in TR. Most common component involved was PRBC (80%). [Table/Fig-2] shows various types of TR encountered during the study period. FNHTR (n=58, 52.7%) was most common type of TR noted followed by allergic reactions (n=43, 39.1%) and others (n=9, 8.2%). [Table/Fig-3] shows signs and symptoms of TR. FNHTR was commonly associated with tachycardia, chills and rigor. Allergic TR was commonly associated with hypotension and rash/itching. [Table/Fig-4] shows type of TR according to type of components transfused.



[Table/Fig-1]: Percentage of each components involved in transfusion reactions.



[Table/Fig-2]: Types of transfusion reactions.



[Table/Fig-3]: Signs and symptoms of tranfusion reactions.

Type of Reactions	PRBC	FFP	PC	PRP	TOTAL
FNHTR	57 (51.8%)	0	1 (0.9%)	0	58 (52.7%)
Allergy	27 (24.5%)	9 (8.2%)	6 (5.5%)	1 (0.9%)	43 (39.1%)
Anaphylactic	0	3 (2.7%)	0	1 (0.9%)	04 (3.6%)
TACO	2 (1.8%)	0	0	0	02 (1.8%)
TRALI	1 (0.9%)	0	0	0	1 (0.9%)
HTR	1 (0.9%)	0	0	0	1 (0.9%)
MIS ID.	1 (0.9%)	0	0	0	1 (0.9%)

[Table/Fig-4]: Transfusion reactions according to Type of components transfused. *FNHTR: Febrile Non Haemolytic Transfusion Reactions; TACO: Transfusion Associated Circulatory Overload; TRALI: Transfusion Related Acute Lung Injury; HTR: Haemolytic Transfusion Reaction; MIS ID.: Mis identification

DISCUSSION

A total of 110 (0.21%) of TR were reported in total of 52,925 transfusions. In our study, only acute TR were reported. Delayed TR was not reported which might be due to those TR unnoticed/undiagnosed. Incidence of acute TR in Our Centre was 0.21% of total blood components transfused. Chakravarty-Vartak U et al., reported 50 (0.16%) TR out of 30,470 units issued over the period of two years [11]. Similarly, Noor Haslina MN et al., Henderson and Pinder et al., Climent-Peris et al., and Bhattacharya P et al., reported the overall low incidence of immediate TR which were 0.21%, 0.2%, 0.34% and 0.35% respectively [12-15].

An 80% of TR occurred with PRBC transfusion, 11.80% with FFP, 6.40% with PC and 1.80% with PRP transfusions. Chavan SK et al., reported 57.77% TR with WB and 42.22% with PRBC in their study. No TR was reported with PRP and FFP transfusions [3].

We encountered FNHTR (53%) as a most common TR followed by allergic TR (39%), Anaphylactic reaction (3%), Transfusion Associated Circulatory Overload (TACO) (2%), TRALI (1%) and non-immune haemolytic transfusion reactions (1%) were also been reported. In contrast, Chavan SK et al., reported that allergic (55.6%) is common than FNHTR (33.3%) [3]. Kumar P et al., also reported allergic reaction (55.1%) as commonest followed by FNHTR (35.7%) [16].

Lubart et al., found FNHTR to be most common TR (72%) as in the study by Ibrahim UN et al., in pregnant patients (47.7%) [17]. In a Study by Bassi R et al., noted that FNHTR with maximum of 73%,

Allergic Reactions 24%, Bacterial sepsis 1%, Hypotension due to ACE inhibitors 1%, Acute Haemolytic TR (AHTR) 1% [18].

Other than FNHTR and Allergic TR, we also had 4 (3.6%) Anaphylactic reaction, 2 (1.8%) TACO, 1 (0.9%) TRALI, 1 (0.9%) HTR and 1 (0.9%) case of misidentification of patient id [Table/Fig-4] Similarly, study by Chakravarty-Vartak U et al., reported 1.1% had severe transfusion reaction in his study population i.e. 0.08% TRALI/possible TRALI, 0.02% anaphylactic, and 0.02% hypotensive reactions [19].

Mean age in our study was 37.78 years (range 4-90). 30-40 years was common age group in our study (antenatal mother). Study by Chakravarty-Vartak et al noticed most common age group was pediatric and young adults. Maximum number (28%) was in the age group of 11-20 years, and almost half of them were thalassemia patients who had a history of repeated transfusions. The second most common group was 21-30 years [11].

In our study 7 cases (6.4%) of TR occurred within 15 minutes of initiation of transfusion, 30 cases (27.3%) between 16-60 minutes, 37 cases (33.6%) between 61-120 minutes, 29 cases (26.4%) between 121 -180 minutes, 5 cases (4.5%) between 181 – 240 and 2 cases (1.8%) between 241-300 minutes. Another study by Bassi R et al., evaluated ATR with period of which blood and blood components kept unmonitored from the time of issue of blood bags from blood bank, reported that 91 (0.43 %) patients of 21,047 WB/PRBC transfusion, 8 (0.50 %) patients of 1584 PC transfusion, 1 (0.04 %) patient of 2468 FFP transfusions had ATR and their time interval between issue and transfusion was 15 minutes to 7 hours, 15 to 25 minutes, 20 minutes respectively [18]. We did not encounter ABO mismatch or bacterial contamination among the cases reported, similar to the findings observed in the study by Kumar P et al., [16]. In a study by Bhattacharya P et al., bacterial contamination was suspected in four cases transfused with packed red cells [15].

In our study, we noticed fever, tachycardia, chills and rigor were the most common signs reported in TR. Chakravarty-Vartak U et al., noticed hypotension as common manifestation of several TR namely AHTR, bacterial contamination, TRALI and anaphylaxis [11]. PRBC was the most common component involved in TR. No reactions were reported with WB, cryoprecipitate or single donor plasma transfusions. Majority of TR occurred in female patients might be due to alloimmunization by multiple gravida and previous blood transfusions.

LIMITATION

Since it was a retrospective study, the clinical data was collected from previously filled TR forms only, thus exact incidence of TR was difficult to acquire.

CONCLUSION

Adverse reaction following blood transfusion is a common complication which should be kept in mind and blood transfusion should be prescribed only if indicated. Most common TR noted was FNHTR followed by allergic reaction. Most of the reactions were noted in patients with a history of repeated transfusion. This can be reduced by using leukocyte-reduced blood products. DHTR were not reported, thus, clinicians need to be educated about the same. Here, haemovigilance plays an important role. Haemovigilance system should be well coordinated between blood transfusion service, hospital clinical staff and transfusion laboratories, hospital transfusion committee, regulatory agency, and national health authorities.

To have a well-organized haemovigilance system in developing countries like India, a comprehensive approach is required.

Future Recommendations

In future proper awareness about DHTR should be created among treating physician's and other hospital staffs who are involved in the patient management. So that DHTR's can be detected earlier and the patient management can be improved. Active participation in the haemovigilance program will be helpful to understand the transfusion related adverse reactions. In our study most TR were associated with PRBC transfusions, so by implementing leucoreduction filters the incidence of TR can be reduced.

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REFERENCES

[1] Pahuja S, Puri V, Mahajan G, Gupta P, Jain M. Reporting adverse transfusion reactions: A retrospective study from tertiary care hospital from New Delhi, India. Asian J Transfus Sci. 2017;11:6-12.
[2] Training Module For Laboratory Technologists: NACO: 1995.
[3] Chavan SK, Patil G, Rajopadhye P. Adverse blood transfusion reactions at tertiary care hospital. Int J Res Med Sci. 2016;4:2402-07.
[4] Zarin bharucha. Model standard operating procedures for blood transfusion service. Introduction to transfusion medicine: first edition 1990.
[5] Serious Transfusion Incident Report; 2008-2009. (file:///C:/Users/n/Downloads/DH_STIR_report_web%20-%20PDF.pdf)
[6] Bisht A, Shing S, Marwaha N. Hemovigilence Programme India. Asian J Transfus Sci. 2013;7:73-74.
[7] Kleinman S, Chan P, Robillard P. Risks associated with transfusion of cellular blood components in Canada. Transfus Med Rev. 2003;17:120-62.
[8] Bain BJ. Bloody easy, blood transfusions, blood alternatives and transfusion reactions: A guide to transfusion medicine. J Clin Pathol. 2005;58(6):672.
[9] Robillard P, Nawej KI, Jochem K. The Quebec haemovigilance system: Description and results from the first two years. Transfus Apher Sci. 2004;31:111-122.
[10] Mazzei CA, Popovsky MA, Kopko PM. Noninfectious complications of blood transfusion. American Association of Blood Banks; 2008:715-51.
[11] Chakravarty-Vartak U, Shewale R, Vartak S, Faizal F, Majethia N. Adverse reactions of blood transfusion: A study in a tertiary care hospital. Int J Sci Study. 2016;4(2):90-94.
[12] Noor Haslina MN, Mohd Fakhri MA, Saw TH, Salamah AS. An audit on acute transfusion reaction in North Eastern Malaysia. Scholarly J. Med. 2012;2(5):60-62.
[13] Henderson RA, Pinder L. Acute transfusion reactions. Auckland Regional Blood Centre. N Z Med J. 1990;103(900):509-11.
[14] Climent-Peris C, Velez-Rosario R. Immediate transfusion reactions. P R Health Sci J. 2001;20:229-35.
[15] Bhattacharya P, Marwaha N, Dhawan HK, Roy P, Sharma RR. Transfusion-related adverse events at the tertiary care center in North India: An institutional hemovigilance effort. Asian J Transfus Sci. 2011;5:164-70.
[16] Kumar P, Thapliyal R, Coshic P, Chatterjee K. Retrospective evaluation of adverse transfusion reactions following blood product transfusion from a tertiary care hospital: A preliminary step towards hemovigilance. Asian J Transfus Sci. 2013;7:109-05.
[17] Ibrahim UN, Garba N, Tilde IM. Acute blood transfusion reactions in pregnancy, an observational study from North Eastrn Nigeria. J Blood Disord Transf. 2013;4:1-3.
[18] Bassi R, Aggarwal S, Bhardwaj K, Thakur KK. Patterns of adverse transfusion reactions in a tertiary care centre of North India: A step towards hemovigilance. Indian J Hematol Blood Transfus. 2016;33(2):248-53.
[19] Hendrickson JE, Roubinian NH, Chowdhury D, Brambilla D, Murphy EL, Wu Y, et al. Incidence of transfusion reactions: a multicenter study utilizing systematic active surveillance and expert adjudication. Transfusion. 2016;56(10):2587-96.

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