

Research Article

Adverse blood transfusion reactions at tertiary care hospital

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Received: 22 April 2016

Accepted: 25 May 2016

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ABSTRACT

Background: The goal of hemovigilance is to increase the safety and quality of blood transfusion. It is necessary to recognize and prompt response to adverse transfusion reactions, which will help in taking appropriate steps to reduce their incidence and make blood transfusion process as safe as possible. The aim of the study was to determine the frequency and type of transfusion reactions (TRs) occurring in patients, reported to the blood bank at our institute.

Methods: A retrospective review of all TRs reported to the blood bank Krishna Hospital, between January 2011 and July 2013 was done. All the TRs were evaluated in the blood bank and classified using standard definitions.

Results: During the study period a total 13126 units of blood and components were issued by our blood bank and total of 45 (0.3%) adverse reactions were reported to blood bank. The most common reaction observed was allergic reaction 25(55.6%) followed by FNHTR 15 (33.3%).

Conclusions: Not a single case of anaphylactic reactions, TRALI, acute immune hemolytic transfusion reaction, and Sepsis was observed. This can be an underestimation of the true incidence because of under reporting which can be improved by proper hemovigilance system to provide better patient care.

Keywords: Adverse transfusion reaction, FNHTR, Hemovigilance, Haemolytic transfusion reaction

INTRODUCTION

Blood transfusions when used with caution and clear indications are useful and life saving. A transfusion reaction is defined as any untoward event which occurs during or after transfusion of blood or blood components.¹

Transfusion therapy changed from a hazardous proposition to a relatively safe procedure with the discovery of blood group antigens in 1901, by Karl Landsteiner. Safety of blood transfusion improved further with advancement of technology. The incidence of transfusion-transmitted diseases has lowered with recent testing facilities; however, the incidence of adverse events due to human errors, ABO incompatibility, alloimmunization, bacterial contamination, and immunomodulation phenomenon remain a matter of concern.

In spite of precautions and preventive measures unfavourable reactions continue to occur which may be serious and even prove fatal in some cases. Hence the blood replacement therapy demands a considerable degree of expertise for maximum recipient protection. Knowledge of possible undesirable effects will be useful to prevent their occurrence and help in clinical management.² Hemovigilance is aimed to detect and analyze all untoward effects of blood transfusion in order to correct their cause and prevent recurrence. A centralized Hemovigilance programme to assure patient safety and promote public health has been launched for first time in the country on 10th December 2012 in 90 medical colleges in first phase.³

In present study we have aimed to detect and investigate transfusion-related adverse events as a pilot institutional efforts toward hemovigilance.

METHODS

Present study is carried out at Krishna Hospital and Medical Research Centre Blood Bank, Karad. Retrospective review of all transfusion reactions that were reported to the Krishna Hospital Blood Bank from January 2011 to July 2013 was done. All the adverse events related to transfusion of blood and blood components were reported to the blood bank in a predesigned "transfusion adverse reaction reporting form" by the treating physician. In blood bank TR is investigated as outlined in the department's standard operating procedures prepared accordance with the guidelines laid down by Transfusion Medicine Technical Manual (DGHS) Second Edition 2003.⁴ The results of investigations with interpretation are documented in predesigned "Post transfusion reaction Work-Up" form. During issue of each unit of blood and blood components a compatibility card was dispatched containing written guidelines regarding bedside monitoring of transfusion event and the procedure of reporting of transfusion-related adverse events to blood bank.

Investigation of transfusion-related adverse events.

- Patient's identification (name, age, sex, hospital no., ward, unit) were rechecked both on the vial and compatibility card to rule out possibility of wrong sampling or bedside transposition.
- Details of patients record & blood unit transfused are checked to rule out any clerical error.
- Returned blood bag along with transfusion set inspected for signs of deterioration i.e. clot, discoloration, hemolysis or foul smell.
- ABO and Rh typing on patient's pre & post transfusion samples and reconfirmation of ABO and Rh type of blood unit transfused.
- Compatibility testing was repeated with pre & post transfusion patients samples.
- Patients post transfusion blood sample was checked for:
 - Haemolysis
 - Serum bilirubin (direct & indirect)
 - Peripheral smear examination was done for signs of haemolysis.
- Patients post transfusion urine sample was examined for haematuria and haemoglobinuria.
- DAT & irregular antibody screening was done on patients pre & post transfusion samples.

- Sample from blood unit was sent to microbiology department for culture.
- Patient's clinical features reveal the diagnosis of Febrile non-hemolytic transfusion reactions (FNHTR), allergic and anaphylactoid reactions.
- Definition of FNHTR as given in American Association of Blood Banks technical Manual 16th ed. "A body temperature rise of $>1^{\circ}\text{C}$ or more occurring in association with transfusion and without any other explanation" such reactions are often associated with rigors and chills. Rigors and other symptoms in the absence of fever are also included as FNHTR because of a presumed common mechanism.⁵

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

Institutional ethical clearance was obtained before starting the study.

Statistical methods

Statistical analysis was carried out after the raw data entered into MS Excel and analyzed into frequency percentage distribution.

RESULTS

From January 2011 to July 2013, total 13126 units of blood & blood products were transfused to the patients admitted at Krishna Hospital, Karad. The number of different blood and blood components transfused is given in Table 1.

The total number of transfusion reactions were reported to our blood bank was 45 (0.34%), during the study period. Of which 13 (28.9%) were seen in males & 32 (71.1%) in females. Mean age of patients were 40 years and range was 5-75 years.

Of all the TRs that were reported to our blood bank during the study period, 57.77% transfusion reactions occurred with Whole blood and 42.22% with packed red blood cells (PCV). While not a single transfusion reaction was reported with platelet rich plasma (PRP) and fresh frozen plasma (FFP) transfusions. Table 2 depicts the number of TRs according to the type of blood components transfused in patient.

Among these commonest was allergic reactions in 25(55.6%) patients followed by FNHTR in 15 (33.3%) patients and non-immune haemolysis in 5 (11.1%) patients. Out of total 25 allergic reactions, the common clinical signs and symptoms were chills & rigors in 56% (14 out of 25) and purities in 48% (12 out of 25).

Allergic reaction was seen in 0.15% of total 4441 units of PCV transfused and 0.30% of total 5911 whole blood transfused. Categorization of TRs according to

departments where the transfusion reaction occurred has been depicted in (Figure 3).

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

Year	Whole blood	PCV	Platelet concentrate	FFP	Total
2011	2400	1632	395	521	4948
2012	2295	1645	559	635	5134
2013 Jan-July	1216	1164	279	385	3044
Total	5911(45.03%)	4441 (33.83%)	1233(9.39%)	1541(11.74%)	13126

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

	Whole blood	PCV	Platelet conc.	FFP	Total
FNHTR	6 (23%)	9 (47.36%)	0	0	15 (33.3%)
Allergic reactions	18 (69.23%)	7 (36.84%)	0	0	25 (55.6%)
Acute Non –immune hemolysi	2 (7.7%)	3 (15.78%)	0	0	5 (11.1%)
TACO	0	0	0	0	0
Anaphylactoid	0	0	0	0	0
TRALI	0	0	0	0	0
DHTR	0	0	0	0	0
Total	26 (57.77%)	19 (42.22)%	0	0	45 (100%)

Table 3: Estimated risk of various types of transfusion reactions per 1,000 units of blood components transfused.

	Whole blood	PCV	Platelet conc.	FFP
FNHTR	3.04	2.0	NR	NR
Allergic reactions	1.05	1.57	NR	NR
Acute non -immune hemolysis	0.33	0.67	NR	NR
TACO	NR	NR	NR	NR
Anaphylactoid	NR	NR	NR	NR
TRALI	NR	NR	NR	NR
DHTR	NR	NR	NR	NR
Total	NR	NR	NR	NR

Note: Not reported in this series because the particular type of reaction was not observed with particular blood component.

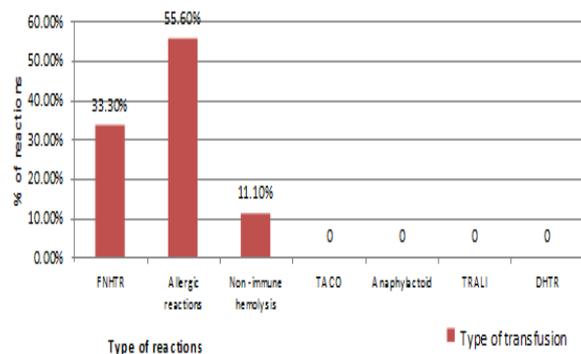


Figure 1: Type of transfusion reactions.

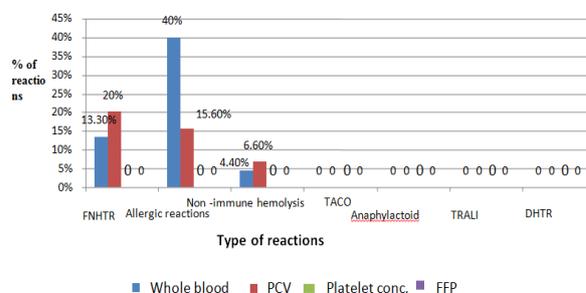


Figure 2: Type of transfusion reactions according to type of components

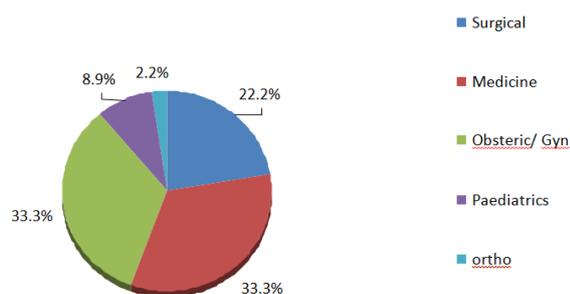


Figure 3: Categorization of adverse reactions according to departments.

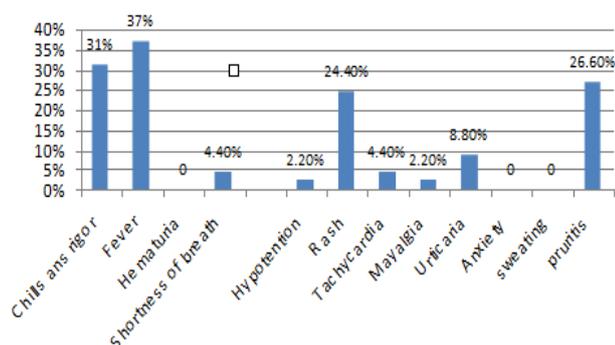


Figure 4: Signs and symptoms.

Estimation of risk for various transfusion reactions

The total 13,126 blood units transfused during the study period of which 10,352 were PCV and whole blood, 1,233 were platelets and 1,541 were fresh frozen plasma and cryoprecipitates. The risk of transfusion reaction was expressed per 1,000 units of blood component transfused (Table 3). FNHTRs: 15 out of 45 (33.3%) TRs were found to be FNHTRs. The most common signs and symptoms of these reactions were fever in 37% ($n = 17$), chills and rigors in 31% ($n = 14$). Acute non-immune hemolytic TRs (HTR): 5 of 45 (11.1%) recipients had acute non-immune hemolytic transfusion reaction. Of these five reactions, one was reported from surgical and four from Medicine unit. Clinical signs and symptoms as observed in these patients were jaundice in 100% ($n = 5$), hematuria and hemoglobinuria in 20% ($n = 1$), chill/rigors in 80% ($n = 4$), fever in 60% ($n = 3$) and tachycardia in 20% ($n = 1$). Frequency of adverse reactions by whole blood, Packed red cells, random donor platelets (RDP), FFP, respectively shown in Table 2.

DISCUSSION

In the present study information about various TRs was collected from cases reported to the blood bank. All these then evaluated on the basis of clinical history and laboratory investigations using a predefined protocol. The total no. of adverse reactions may not be the actual indicator due to underreporting. Underreporting of minor

TRs has also been found by Narvios et al.⁶ The most important concerns are the dependence on the awareness of physicians and other health care workers to (1) look for adverse effects and their reporting, (2) determine whether the effects could have been caused by transfusion.

The accurate figures for the number of recipients transfused was difficult to obtain, so the risk estimate was calculated based on the number of units transfused. In this study, the frequency of TRs was found to be 0.3% (45 out of 13126). Similar study by Bhattacharya et al, the frequency of TRs was 0.18% (105 out of 56503 units of blood transfused) and Study by Kumar P et al, 0.05% (196 out of 3,80,658 units of blood transfused).^{7,8}

Overall risks for acute hemolytic reactions which were observed in different studies ranges from 0.02 to 0.07 per 1,000 red cell units transfused.⁹⁻¹¹ In the present study frequency of acute immune hemolytic reaction is nil. Acute non-immune hemolytic reactions occurs in 5 (11.1%) patients. Improper storage conditions in unmonitored refrigerators outside the department led to deterioration of red cell units. Hence awareness among the bedside staff is essential to reduce this risk. A leaflet about handling and storage of blood and components for the clinicians & other staff has been developed by the department and is issued to all wards as a ready reference.

In the present study commonest was allergic transfusion reactions i.e. total 25 (55.6%) and occurred more with whole blood than PCV. Definitions of allergic reactions vary greatly in literature and there are a few data on incidence of allergic reactions on well-designed studies in the general patient population reported a 3% rate of mild allergic reactions from Mayo Clinic.¹² This mild allergic reaction was defined as hive or localized urticaria. Incidence in other studies varies from 0.2% to 3%.^{11,13,14} Higher incidence of allergic reactions 3-4.8% reported in studies with platelet transfusion in hemato-oncology patients. In the present study it was 0.3% with whole blood and 0.15 % with red cells.^{11,15}

Our study revealed FNHTR 15 (33.3%) that frequency of FNHTR is more with PCV followed by whole blood. No TR is reported with PLC and FFP transfusion. Bacterial contamination remains an important cause of transfusion-related morbidity and mortality. Sources of bacteria are believed to arise from donor either from venipuncture site or from unsuspected bacteremia and during component preparation.¹³ 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.^{14,15} In present study not a single transfusion reaction occurs due to bacterial sepsis.

The incidence of TRALI is rare in the Indian subcontinent where most donors are male (95% in the

present study). The incidence of TRALI reported in various studies from Western literature ranged from 0.014% to 0.08% per units transfused. However, it is generally agreed that TRALI is under diagnosed.¹⁶ This is likely because of poor awareness, lack of recognition of the condition, and/or because TRALI is easily confused with other conditions, e.g., adult respiratory distress syndrome (ARDS), hypervolemia, and congestive heart failure. This case has reported in study by Fedrowicz et al.¹⁷

The overall risk estimates of DHTR cited in various studies vary from 0.007 to 0.6907 per 1,000 red cell units transfused.⁹⁻¹¹ In the present study in the institute, not a single incidence of DHTR was reported. The data on overall incidence of DHTR vary in different studies because DHTR is difficult to diagnose and most often, it is asymptomatic or may even be similar to the clinical signs and symptoms of the patient so that it remains under diagnosed and underreported. No incidence of DHTR in our study, it seems to be due to underreporting. TRALLY & TACO were not observed in a single case. In our study there was no reporting of infectious complications with any blood or blood components transfused.

The highest number of reactions was observed in Medicine and Obstetric /Gynac patients. FNHTR and allergic reactions were the commonest type of adverse events observed almost in all patient groups (incidence 33.3% and 55.6% respectively). DHTR, TRALI, and TAGvHD were not seen in our study it can be possibly due to under diagnosed and underreported. Hemovigilance data are highly valuable for initiating changes to improve blood safety. Over 12 years of reporting, the trends observed by SHOT, UK (serious hazards of transfusion) have revealed the outcome of an effective hemovigilance system. The number of events reported has risen, while the frequency of the most serious events, and the mortality directly related to transfusion, and has fallen.⁷

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.

CONCLUSION

In our study majority of TRs occurred with gynecological and medicinal cases followed by surgical and pediatric cases. Majority of the reactions observed are allergic type followed by FNHTR & non immune haemolysis. TRALI, TAGvHD, and DHTRs were rare; possibly due to underreporting. This can be an underestimation of the true incidence due to underreporting which can be improved by hemovigilance 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 on time can lead to a better prognosis. Observation and monitoring are required throughout the transfusion episode, more so for within first 15 min. There should be a standard operating procedure containing the details for documentation, reporting, evaluation, and follow-up of all adverse reactions.

ACKNOWLEDGEMENTS

Authors would like to thanks the blood bank technical staff for their support. Authors would also like to Thank Mr. M.R. Pawar, clerk for helping me in data collection.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Training Module For Laboratory Technologists: NACO:1995.
2. Introduction To Transfusion Medicine: Zarin Bharucha: First Edition 1990.
3. Bisht, Shing S, Marwaha N. Hemovigilance Programm- India. Asian J Transfus Sci. 2013;7:73-4.
4. Transfusion Medicine Technical Manual:Saran R.K.: Second Edition 2003.
5. Mazzei CA, Popovsky MA, Kopko PM. Noninfectious complications of blood transfusion. In: Roback JD, Combs MR, Grossman BJ, Hillyer CD, editors. Technical Manual. 16 th ed. Maryland: American Association of Blood Banks; 2008 p.715-51.
6. Narvios AB, Lichtiger B, Neumann JL. Underreporting of minor transfusion reactions in cancer patients. Med Gen Med. 2004;6:17.
7. 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.
8. 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;7:109-15.
9. Moore S, Taswell HF, Pineda AA. Delayed hemolytic transfusion reactions: Evidence of the need for an improved pretransfusion compatibility test. Am J Clin Path. 1980;74:94-7.
10. Lichtiger B, Thornton E. Hemolytic transfusion reactions in oncology patients: Experience in a large cancer center. J Clin Oncol. 1984;2:438-42.

11. Robillard P, Itaj kN. Incidence of adverse transfusion reactions in the Quebec Hemovigilance System. *Vox Sang.* 2002;83:120 (abstr suppl).
12. Moore SB. Anaphylactic transfusion reactions - A concise review. *Ir Med J.* 1985;78:54-6.
13. Uhlman EJ, Isgrigs E, Wallhermanfechtel M, Goodnough LT. Prestorage universal WBC reduction of RBC units does not affect the incidence of transfusion reactions. *Transfusion.* 2001;41:997-1000.
14. Kleinman S, Chan P, Robillard P. Risks associated with transfusion of cellular blood components in Canada. *Transfus Med Rev.* 2003;17:120-62.
15. Heddle NM, Klama LN, Griffith L, Roberts R, Shukla G, Kelton JG. A prospective study to identify the risk factors associated with acute reactions to platelet and red cell transfusions. *Transfusion.* 1993;33:794-7.
16. Kathryn E, Webert, Blajchman MA. Transfusion-related acute lung injury. *Transfusion Med Rev.* 2003;17:252-62.
17. Federowicz I, Barrett BB, Andersen JW, Urashima M, Popovsky MA, Anderson KC. Characterization of reactions after transfusion of cellular blood components that are white cell reduced before storage. *Transfusion.* 1996;36:21-8.

Cite this article as: Chavan SK, Patil G, Rajopadhye P. Adverse blood transfusion reactions at tertiary care hospital. *Int J Res Med Sci* 2016;4: 2402-7.