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RESEARCH ARTICLE

A regional hemovigilance study of transfusion-related adverse events at a tertiary care hospital

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ABSTRACT

Background: Blood transfusion is a routine, life-saving medical intervention which is generally regarded as safe when done appropriately. Hemovigilance is systemic surveillance of adverse transfusion reactions (ATRs). **Aims and Objective:** The aim of the study was to analyze the ATRs as a part of Haemovigilance Programme of India under the broad ambit of Pharmacovigilance Programme of India (PvPI). **Materials and Methods**: A retrospective review of all ATRs reported to the department of immuno haematology and blood transfusion, Victoria Hospital attached to Bangalore Medical College and Research Institute (BMC and RI), Bengaluru, between December 2012 and November 2017 was done. All the reactions were reported in a pre-designed transfusion reaction (TR) reporting form for blood and blood products as per the haemovigilance, PvPI. TR workup was done for all TRs. The frequency and distribution of ATRs year wise over a period of 5 years were assessed. ATRs were also analyzed with respect to age, gender, and types of blood products implicated in ATRs. **Results:** Total blood components issued by our blood bank to various departments and total ATRs during the study period were 48,576 and 89 respectively. ATRs were experienced by all age groups with a male preponderance (56.18%). Majority of the reactions occurred with whole blood (0.46%) followed by packed red cells (0.19%). The most common ATR observed was febrile nonhemolytic TR (88.76%) followed by anaphylaxis (2.25%). Most of the ATRs were acute reactions and transfusion siderosis being the only delayed reaction. **Conclusion:** The study emphasizes the continuous need to implement hemovigilance to improve the quality and safety of transfusion therapy.

KEY WORDS: Hemovigilance; Adverse Transfusion Reaction; Blood Transfusion

INTRODUCTION

Blood transfusion is a life-saving procedure in the clinical scenario and considered as safe when it is done appropriately. Sometimes, however, blood transfusion is associated with significant clinical risks. These risks can be broadly classified as infectious or non-infectious complications.[1]

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Approximately 0.5–3% of all blood transfusion results in few adverse transfusion-related events without any major consequence.[2,3] Several strategies have been put in place to minimize the risks of transfusion and ensure the optimally proper use of blood products.

Knowing about different types of blood transfusion reactions (TRs) will be useful in early identification and management, and hence appropriate measures can be taken to prevent the same. The incidence of febrile non-hemolytic TRs (FNHTRs), cytomegalovirus transmission and platelet refractoriness have declined due to the advancement in recent immuno-hematological procedures in antibody finding and also use of leukoreduced blood components.[4]

Hemovigilance term was introduced in France in the 1990's. Since its inception, this system has become an integral part of transfusion practices internationally. The basic idea of this program is to track adverse TRs (ATRs) and it will be helpful to introduce best practices/policies and hence there is a need to improve patient care and safety.[5] Due to the underreporting of the minor adverse events by the medical staff, the actual prevalence of these ATRs is not known.

Hemovigilance Programme of India was introduced on December 10, 2012 by Indian Pharmacopoeia Commission in association with National Institute of Biologicals. The aim of the program is 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.[6]

Hence, this study was conducted with the primary objective to evaluate the types and frequency of ATRs in hospitalized patients who needed blood transfusion at a tertiary care center, a pilot effort toward hemovigilance from the institution.

MATERIALS AND METHODS

A retrospective observational study of all TRs reported during December 10, 2012–November 30, 2017, to the blood bank at Victoria hospital, Bangalore Medical College and Research Institute (BMC and RI), Bengaluru. The study was conducted after obtaining ethics committee approval, all the adverse events related to blood transfusion reported to the department of immuno hematology and blood transfusion (IHBT) ware recorded and analyzed as per departmental standard operating procedures.

Data were recorded in the pre-designed TR reporting form for all blood TRs which ware evaluated by the treating physician and reported to the blood bank as per the guidelines laid down by Indian Pharmacopoeia Commission - National Institute of Biologicals, Ministry of Health and Family Welfare - Government of India, Hemovigilance, Pharmacovigilance Programme of India. As a part of hemovigilance workup plan, the following data were collected.

TR workup was done for all the TRs. The following data were documented, namely patient's central registration number, name, unit number, hospital number, tube number, patient's vital signs, date and time of starting transfusion, and any history of the previous transfusion received. Repeat blood grouping and typing with pre-transfusion patients sample, post-transfusion sample, pilot sample, and bag sample ware done. Cross-matching was done with a pre-transfusion sample of patients and pilot sample. Cross-matching with post-transfusion and bag sample was also done. Hemolysis was analyzed in pre-transfusion blood sample, post-transfusion blood sample, and blood bag sample. Urine analysis was done for red blood cell, white blood cell, epithelial cells and bacteria. Direct Coomb's test was done with post-transfusion blood sample of the patient.

STATISTICAL ANALYSIS

Data collected were tabulated and continuous data were expressed as mean (standard deviation) and categorical data were expressed as percentages/proportions.

RESULTS

Blood Components Distribution

During the study period, 48,576 units of whole blood and its components were issued to various departments in the Victoria hospital during the 5-year study period 201-2017. These comprised whole blood 4610 (9.49%), packed red blood cells 33239 (68.43%), fresh frozen plasma (FFP) 7714 (15.88%), and platelet concentrates 3013 (6.20%) in Figure 1. The TRs reported to the department of IHBT during the study period were 89/48,576 (0.18%). The number of TR's for each blood component is depicted in Figure 2. The percentage of TRs encountered in each year of the study period is represented in Figure 3.

Age and Gender Distribution of TRs

ATRs were observed in all age group patients with majority (33.7%) of the reactions being observed in the age group

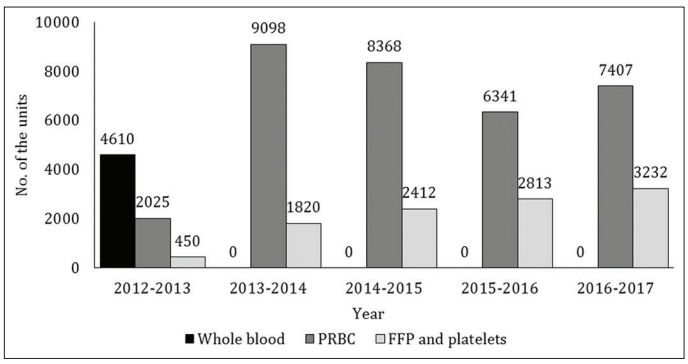

Figure 1: Year-wise distribution of blood components

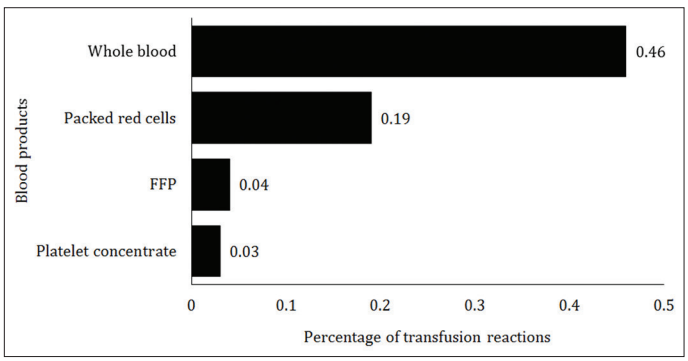

Figure 2: Percentage of transfusion reaction to each blood component during the study period

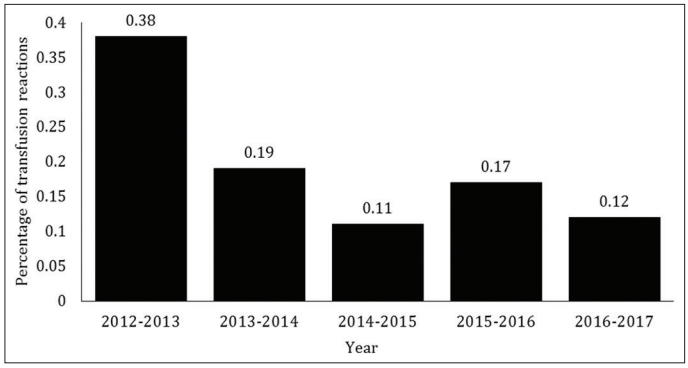

Figure 3: Year-wise distribution of transfusion reactions

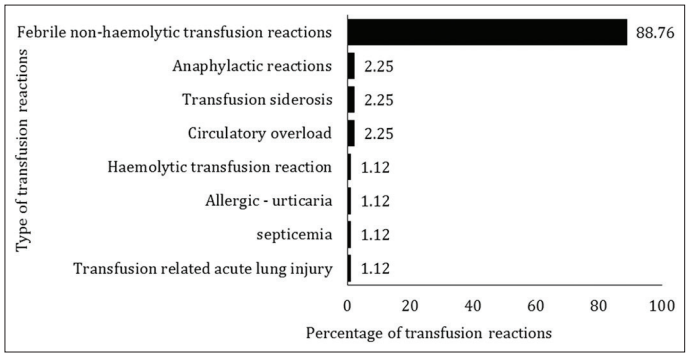

Figure 4: Types of adverse transfusion reactions (acute and delayed)

Table 1: Distribution of TRs according to age and gender wise

Age (years)	TRs	Gender	Number of TRs (%)
1–15	21	Male	13 (61.9)
		Female	8 (38.1)
16–25	12	Male	8 (66.6)
		Female	4 (33.3)
26–40	16	Male	7 (43.7)
		Female	9 (56.2)
41–60	10	Male	4 (40)
		Female	6 (60)
>60	30	Male	18 (60)
		Female	12 (40)

TRs: Transfusion reactions

of >60 years followed by 1–15 years (23.6%), 26–40 years (17.9%), 16–25 years (13.5%) and with least being in the age group 41–60 years (11.2%). There were 50 (56.2%) males and 39 (43.8%) females who had experienced TRs [Table 1].

TRs

Of the total ATRs reported (89) all were acute reactions to the blood products except transfusion siderosis which was a delayed reaction encountered in only 02/89 (02.25%) of overall reactions. The acute ATRs were FNHTR (*n* = 79/89 [88.76%]), anaphylactic reactions (*n* = 02/89 [02.25%]), circulatory overload (*n* = 02/89 [02.25%]), allergic urticarial (*n* = 1/89 [1.12%]), hemolytic (*n* = 1/89 [1.12%]), isolated hypotension (*n* = 01/15 [0.018%]), transfusion-related acute lung injury (*n* = 1/89 [1.12%]) and septicemia (*n* = 1/89 [1.12%]) [Figures 1-4].

DISCUSSION

The term hemovigilance was derived by a combination of Greek word "hema" (blood) and a Latin word, "vigil" (watchful). Hemovigilance Programme of India was initiated to monitor the ATRs related with blood products in the year 2012. In this study, data regarding various ATRs were collected from the blood bank and analyzed using a pre-defined protocol on the basis of clinical history and laboratory workup. In this study, the frequency of ATRs was found to be 0.18% (89 of 48,576) which is similar to a study by Bhattacharya *et al.*,[10] wherein the incidence of ATR was also 0.18% (105 reactions out of 56,503 units of blood and its components were transfused). The total ATRs recorded were not actual number due to the after underreporting some reactions such as allergic or FNHTR which might have been managed without notifying to the blood bank.[8] Underreporting of ATRs has been found by Narvios *et al.*[9] In this study, males were more affected than females which are analogous with the study findings of Kumar *et al.*[11] and Bisht *et al.*[6]

The highest incidence of TRs was found to be of FNHTR. this finding was in concordance with the study done by Khalid *et al.*,[12] which reported the febrile non-hemolytic reaction (0.03%) was the most frequent ATR and it was followed by allergic reactions (0.02%). In a study by Bisht *et al.*,[6] the incidence of FNHTR was 40.8%. The incidence of anaphylactic reactions in the present study is more compared to studies by Sidhu *et al.*,[13] Kumar *et al.*,[11] and Domen *et al.*[14] in which the incidence was 0.11%, 0.003%, and 0.003%, respectively. The foremost cause of ATRs was non-immune cause of hemolysis. The blood products have been deteriorated by improper storage and inappropriate method of transfusion. Hence, it is better to educate the medical and nursing staff to reduce this risk. Hence, the blood bank has circulated instructions to all wards and operation theaters with "dos and don'ts." The western literature shows 0.014–0.08% risk of transfusion-related acute lung injury (TRALI)[9] and the low incidence may be because of failure of recognition of the condition. Most of the times, TRALI is confused with other conditions such as hypervolemia, adult respiratory distress syndrome, and congestive cardiac failure.[15,16]

Initially, during 2012–13 whole blood was implicated in most of the ATRs. In a study by Bisht *et al.*[6] whole blood was implicated in anaphylaxis (31.7%), FNHTR (14%), transfusion-associated circulatory overload (3.84%), and TRALI (10%). Hemovigilance data in the present study are highly valuable in initiating changes to improve transfusion safety such as shifting to 100% component preparation

and discontinue the use of whole blood transfusions, formulating guidelines for rational use of blood and its components. This study, therefore, serves as a basis for meaningful risk assessment and further research. It also sets the tone for improvement of the current reporting system as well as the preventative action required to minimize transfusion-related risks in resource-limited countries. The study also highlights the importance of rational use of blood and its components, improving storage conditions, bedside monitoring of transfusion, and documentation of adverse events and implementation of the hemovigilance system, thus helping to improve transfusion safety. Education and awareness campaigns for health-care professionals are required to improve both the quality and quantity of reports. Limitations of the study include inadequate reporting of ATRs that occurred due to blood products issued outside the institution.

CONCLUSION

The frequency of ATRs ware found to be less. FNHTR being the most common, majority of the reactions occurred with whole blood followed by packed red cells, FFP and least with platelet concentrate. There may be an underestimation of the true incidence due to the underreporting and that can be improved by hemovigilance system. Adequate manpower with continuous medical education will help in strengthening of hemovigilance system and which will reduce the incidence of ATRs.

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REFERENCES

1. Spiess BD. Blood transfusion: The silent epidemic. Ann Thorac Surg 2001;72:S1832-7.
2. Kicklighter EJ, Klein HG. Hemolytic transfusion reactions. In: Linden JV, Bianco C, editors. Blood Safety and Surveillance. New York: Marcel Dekker, Inc; 2001. p. 47-70.
3. Kleinman S, Chiavetta J, Hindieh F, Pi D, Ricketts M, Robillard P, *et al.* The Surveillance and Epidemiology of Transfusions Working Group Final Report. Ottawa; 1999. Available from: http://www.phac-aspc.gc.ca/hcai-iamss/tti-it/pdf/setrep0299_e.pdf. [Last accessed on 2017 Nov 13].
4. Sharma RR, Marwaha N. Leukoreduced blood components: Advantages and strategies for its implementation in developing countries. Asian J Transfus Sci 2010;4:3-8.
5. Faber JC. Worldwide overview of existing haemovigilance systems. Transfus Apher Sci 2004;31:99-110.
6. Bisht A, Singh S, Marwaha N. Hemovigilance program-India. Asian J Transfus Sci 2013;7:73-4.
7. Haemovigilance Programme; National Institute of Biologicals. Available from: http://nib.gov.in/Haemovigilance/TRRF_Form.pdf. [Last accessed on 2017 Nov 13].
8. Stainsby D, Jones H, Asher D, Atterbury C, Boncinelli A, Brant L, *et al.* Serious hazards of transfusion: A decade of hemovigilance in the UK. Transfus Med Rev 2006;20:273-82.
9. 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.
10. Narvios AB, Lichtiger B, Neumann JL. Underreporting of minor transfusion reactions in cancer patients. MedGenMed 2004;6:17.
11. 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.
12. Khalid S, Usman M, Khurshid M. Acute transfusion reactions encountered in patients at a tertiary care center. J Pak Med Assoc 2010;60:832-6.
13. Sidhu M, Meenia R, Yasmeen I, Akhtar N. A study of transfusion related adverse events at a tertiary care centre in North India: An initiative towards hemovigilance. Int J Adv Med 2015;2:206-10.
14. Domen RE, Hoeltge GA. Allergic transfusion reactions: An evaluation of 273 consecutive reactions. Arch Pathol Lab Med 2003;127:316-20.
15. Kathryn E, Blajchman MA. Transfusion- related acute lung injury. Transfus Med Rev 2003;17:252-62.
16. Sharma RR, Bhattacharya P, Thakral B, Saluja K, Marwaha N. Transfusion- related acute lung injury. Ind J Pathol Microbio 2009;52:561-3.

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