ISSN (P) : 2589-9120 / (O) : 2589-9139
PubMed-National Library of Medicine - ID: 101773527

International Journal of Medical Science and Applied Research (IJMSAR)

Available Online at: https://www.ijmsar.com

Volume – 5, Issue – 1, January – 2022, Page No. : 42 – 48

A Retrospective Analysis of Transfusion Related Adverse Reactions at a Tertiary Care Centre In South India: An Initiative towards Hemovigilance

[1]Dr. Ashwini, MBBS, 3rd Year Post Graduate, Department of Pathology, Kempegowda Institute of Medical Sciences and Research Centre, Bangalore, Karnataka, India

[2]Dr. Suja Ajoy Kumar, M.D, DNB, Associate Professor, Blood Bank Officer, Department of Pathology, Kempegowda Institute of Medical Sciences and Research Centre, Bangalore, Karnataka, India

Citation of this Article: Dr. Ashwini, Dr. Suja Ajoy Kumar, "A Retrospective Analysis of Transfusion Related Adverse Reactions at a Tertiary Care Centre In South India: An Initiative towards Hemovigilance,'' IJMSAR – January – 2022, Vol. – 5, Issue - 1, P. No. 42-48.

Corresponding Author: Dr. Ashwini, MBBS, 3rd Year Post Graduate, Department of Pathology, Kempegowda Institute of Medical Sciences and Research Centre, Bangalore, Karnataka, India

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background

Transfusion of blood and blood products is not without risks and it can lead to complications [1]. The goal of hemovigilance is to improve the safety and quality of blood transfusion services.

Objectives

To analyze the incidence and nature of adverse transfusion associated events reported to the blood bank.

Methods

This retrospective study included all adverse transfusion reactions reported to the blood bank of KIMS Bengaluru from January 2017 to December 2020.

Results

A total of 35,451 units of blood and blood products were issued. Out of which,45 adverse transfusion reactions have been reported accounting for only 0.13%. Febrile Non-Hemolytic Transfusion Reactions (FNHTR) were most common reported in 48.8%(22/45) of cases followed by Allergic reactions seen in 42.2%(19/45) of cases. These reactions were commonly associated with PRBC transfusion. No delayed transfusion reactions or mortality were observed. The result of this study is on par with other studies conducted in various institutions.

Conclusion

The study reflects the quality of blood transfusion services in our institution. The incidence of FNHTR

and allergic reactions can be further reduced by the use of leukoreduction. Hemovigilance aids for quality assurance in blood bank . It acts as a platform for fact finding rather than fault finding in analysis of Adverse Transfusion Reactions.

Keywords

Transfusion Reactions, Hemovigilance

Introduction

Blood transfusion has an important role in the modern practice of medicine and without it many surgical procedures would become impossible. Although it has undoubted benefits, some adverse effects do occur inspite of all relevant laboratory tests, which are called Blood Transfusion Reactions / Adverse Transfusion Reactions (ATR). The severity of these reaction varies from being mild to severe, which at times can be fatal [10].

Hemovigilance program of India (HvPI) was launched on 10th December 2012 under Pharmacovigilance program of India. Hemovigilance isa set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components till the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile products, and to prevent their occurrence and recurrence.

The primary aim of the centralized Hemovigilance Programme is to improve transfusion safety and quality by collecting, collating and analysing information on a common set of adverse reactions due to the transfusion of blood and blood products[1]. The committee has approved Transfusion Reaction Reporting Form, Guidance document, standardized definitions of transfusion reactions, and the Hemo-vigil software for online reporting of transfusion reactions. It provides a platform to investigate the cause and clinical outcome and avert their occurrence [9].

The objective of this study is to analyze the incidence and nature of adverse transfusion associated events reported to our blood bank.

Materials and Methods

This is a retrospective study conducted in blood bank of Kempegowda Institute of Medical sciences, Bengaluru for a period of 4 years (January 2017 – December 2020). After approval from the Institutional Ethical Committee, the incidence of adverse reactions due to transfusion of blood and its products, and the type of reaction were obtained from transfusion reaction report form. The workup of transfusion reaction was done according to the guidelines provided by National Institute of Biologicals, Ministry of Health and Family Welfare.

Transfusion Reaction Work - UP

- Clerical checks.
- Inspection of bag for gross evidence of hemolysis, clot, discolouration.

On Pre & Post- Transfusion Samples

- Repeat blood grouping
- Repeat crossmatching
- Direct antiglobulin test

On Post-Transfusion Sample

- Plasma hemoglobin estimation
- Urine examination (hemoglobinuria)
- LFT (serum total and unconjugated bilirubin)
- Peripheral blood smear examination (to look for schistocytes and spherocytes)
- Blood culture of blood bag and patient

Chest X-ray of patient in suspected cases of TRALI

The adverse transfusion reactions were classified based on the criteria provided by Directorate

General of Health Services, Government of India as shown in Table 1.

Table 1: Categories of Adverse Transfusion Reactions.

Type of reaction	Acute (onset within < 24 hours)	Delayed (onset within days or months)
Immune mediated	Hemolytic Febrile nonhemolytic Allergic Anaphylactic Transfusion-related acute lung injury (TRALI)	Hemolytic reaction Alloimmunization Graft -vs.- host disease Post transfusion purpura
Nonimmune mediated	Transfusion associated circulatory overload (TACO) Hyperkalemia Bacterial contamination Physical or chemical damage to RBCs	Iron overload Malaria and infections

Results

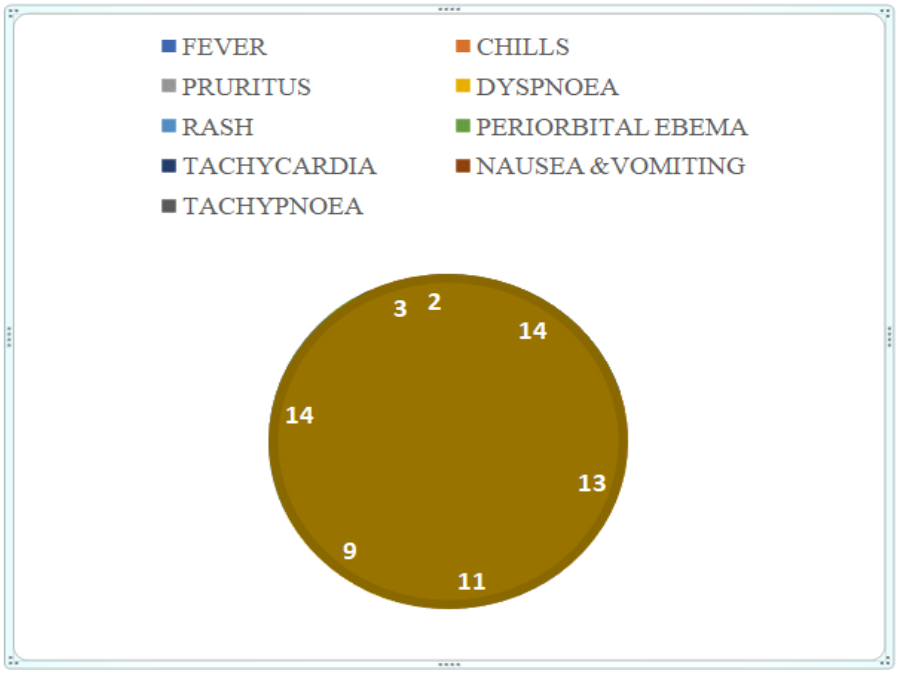
A total of 35,451 units of blood and blood products were issued.45 adverse transfusion reactions have been reported accounting for 0.13%.The age of the patients who had ATRs ranged from 1.5 years to 72 years with female preponderance of 53% (24/45 cases). Incidence of ATRs was high in recipients with O positive blood group in 21 cases (44%) followed by B positive in 10 cases (22.2%), A positive in 9 cases (20%), B negative in 3 cases (6.6%), one case in AB positive & A negative blood groups each (4.4%). The demographic characteristics of Adverse Transfusion Reaction (ATR) are tabulated in Table 2.

ATRs were more common with PRBC transfusion accounting for 93% of cases.

Table 2: Distribution of demographic characteristics of ATR (n = 45)

Parameters	Frequency of ATR
Gender	
Male	21 (47%)
Female	24 (53%)
Age in years	
Range	1.5 – 72 yrs
Mean age	
Blood group	
A positive	9 (20%)
B positive	10 (22.2%)
AB positive	1 (2.2%)
O positive	21 (44%)
A negative	1 (2.2%)
B negative	3 (6.6%)

Fig 1: Signs and Symptoms of Transfusion Reactions.



The most common adverse transfusion reaction observed in our study was FNHTR [48.8% (22/45)]. Allergic reactions were second common [42.2% (19/45)].

Fig 2: Different Types of Transfusion Reactions

Anaphylaxis was seen in 2.2%(1/45) of cases. Transfusion Related Acute Lung Injury (TRALI) was seen in 2.2%(1/45) of cases. Two cases (4.4%) presented with nonspecific signs and symptoms. No hemolytic transfusion reactions, delayed transfusion reactions or mortality were observed our study.

Discussion

Adverse reactions are unprecedented risks associated with blood transfusion. Few factors convey that the number of transfusion reactions reported to the blood bank might not be a true reflection of the actual. Due to lack of awareness, underreporting of actual number of cases do occur [12].

First hemovigilance surveillance system was implemented in France in 1994 as a part of mandatory reporting as required by updated French regulation. Serious hazards of transfusion (SHOT) were established in United Kingdom after 1996 as voluntary reporting [13]. It has gained popularity since the time of inception. Now, haemovigilance is considered as a quality indicator and practised worldwide as an essential component of quality assurance in blood transfusion [9].

Haemovigilance acts as a systematic surveillance of adverse reactions and events related to blood transfusion. It aims to accumulate data on the relative risks of blood transfusion that can be for betterment of hospital transfusion practice, support development of national guidelines and local protocols, inform blood safety policy decisions at the national level, enlighten clinicians who use blood, and patients who receive it.

The estimated frequency of adverse reactions ranges from 0.2% to 10%. The mortality rate is 2 in 2,00,000[9,11]. In our study, the incidence of transfusion reactions was 0.13% which correlated and varied with

various studies done in different parts of the country.The prevalence of transfusion reactions was found to be 0.05%, 0.18%, 0.28% in studies done by Kumar et al., Bhattacharya et al., and Sidhu et al., respectively[2,5,7].The lower incidence could be attributed to underreporting of transfusion reactions to the blood bank.

In our study ATR were more in females (53%) compared to males (47%) similar to study done by Pai. S and Sinha et al.[8,13]. However, Kumar et al. found males to be more affected than females in their study[2]. The most common adverse transfusion reaction observed in our study was FNHTR accounting for 48.8% (22/45) of ATR. FNHTR is defined as an increase in temperature of ≥1◦C from the baseline value[6]. These reactions are caused by release of cytokines from leukocytes during storage of bloodand reaction of alloantibodies in recipient with transfused white cells leading to release of pyrogens. They presented with fever and chills. This is in concordance to the study done by Kumar et al. and Sharma et al.[2,3].The incidence of FNHTR was high with PRBC transfusion concurring with study done by Krishnamurthy AV et al[9]. The main reason is PRBC being a nonleuko-depleted component. Blood banks should be encouraged to prepare leuko-filtered products and setting up plateletpheresis for good quality platelets.

The overall incidence of FNHTR in the current study was found to be 0.062%.Similarly study done by Khalid et al. showed that febrile non-hemolytic reaction (0.03%) was the most frequent transfusion reaction followed by allergic reactions (0.02%)[15]. Studies by Kumar et al. and Bhattacharya et al. showed incidence of 0.04% and 0.114% of FNHTR, respectively[2,5].

Allergic reactions were second common accounting for 42.2% (19/45) of cases similar to study done byBhattacharya et al.,Sidhu et al., Pai.S and Krishnamurthy AV et al[5,7,8,9]. The cases presented with pruritus, rash, chills and periorbital edema. They occur due to interaction between plasma proteins of the donor and corresponding IgE antibodies in recipient's plasma resulting in histamine release and denovo synthesis of platelet activating factor and leukotrienes. Another significant contributing factor is assumed to be the remnant plasma kept in PRBC (to decrease viscosity of blood) causing immune reactions.

The overall incidence of allergic reaction in the present study was found to be 0.053%.Studies by Kumar et al., Sidhu et al.,and Domen and Hoeltgefound an incidence of allergic reactions to be0.028%, 0.11%, and 0.02%, respectively[2,7,14].

Anaphylactic reaction was seen in one case accounting for 2.2% (1/45) of ATR. However, Bhattacharya et al showed higher incidence of 3.8%[5]. Anaphylactoid reactions tend to occur in patients with IgA deficiency, with the presence of anti-IgA antibodies in their plasma following exposure [16].

The overall incidence of anaphylactic reaction in our study was found to be 0.003%. Kumar et al., Sidhu et al., and Domen et al. found incidence of anaphylactic reactions to be 0.11%, 0.003% and 0.003% respectively in their studies [2,7,14].

Transfusion Related Acute Lung Injury was seen in one case accounting for 2.2% (1/45) of ATR.Clinical reports of TRALI describe a sudden deterioration in lung function related to blood transfusion. These changes occur rapidly and normally begin within two hours and always within six hours of the subsequently implicated transfusion. Chest Xrays show nodular shadowing typically in the "bat's wing"

pattern of acute respiratory distress syndrome (ARDS).In Study done by Dutta et al.TRALI constituted 0.26% of ATR[17].In a study by Bisht et al. TRALI constituted 0.26% of adverse transfusion reactions from 2013 to 2016, 0.23% in 2016, and 0.27% of adverse transfusion reactions in 2017[18].

Clerical errors including misidentification of the patient or the recipient and technical errors including errors in blood grouping of donor or patient's blood or errors in cross matching were the most serious risks leading to acute ABO incompatible hemolytic reactions. In our study, not a single case of acute ABO incompatible hemolytic reactions was reported.

In our study, delayed transfusion reactions were not experienced possibly due to nonreporting, due to loss of follow-up, under diagnosis since the recipients get discharged.

Lastly, underreporting of ATR by medical staff could have underestimated the number of ATRs in our study.

Conclusion

Febrile Non-Hemolytic Transfusion Reactions (FNHTR) were most common in our study followed by Allergic reactions. The incidence of FNHTR and allergic reactions can be further reduced by the use of leukoreduction (i.e. prior removal of buffy coat or transfusion through leucocyte depletion filters).

In our study the incidence of adverse reactions post-transfusion is 0.13%. This can be an underestimation of true incidence. This can be prevented by proper implementation of hemovigilance in our institution. Proper training of staff for identification, reporting, investigation and analysis of Adverse Transfusion Reactions will increase the incidence of reporting.

Hemovigilance aids quality assurance in blood banking and acts as a platform for fact finding rather than fault finding in analysis of Adverse Transfusion Reactions. It directs towards continual improvement of the quality and safety of blood products and the transfusion process by bringing corrective and preventive actions.

References

1. IPC-NIB Guidance Document for Reporting Serious Adverse Reactions in Blood Transfusion Service National Institute of Biological, Ministry of Health and Family Welfare, Government of India; 2012. Paper T1–31
2. 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(02):109–115.
3. Sharma DK, Datta S, Gupta A. Study of acute transfusion reactions in a teaching hospital of Sikkim: A hemovigilance initiative. Indian J Pharmacol. 2015;47(4):370-374.
4. Callum J L, Pinkerton P H. Toronto, Ontario: Sunny brook and Women's College Health Sciences Centre; 2005. Transfusion reactions; pp. 34–65.
5. 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(2):164-170.
6. Mangwana S. Prevention of adverse reactions: Journey from blood safety to transfusion safety. Int J Blood Transfus Immunohematol 2019.

7. Sidhu M, Meenia R, Yasmeen I, Akhtar N (2015) A study of transfusion related adverse events at a tertiary care centre in North India: an initiative towards hemovigilance. Int J Adv Med 2:206–210
8. Pai S. Surveillance of Transfusion Related Adverse Reactions in a Tertiary Care Centre in Bangalore: A 4-Year Hemovigilance Initiative. Indian J Hematol Blood Transfus. 2020 Oct;36(4):733-739.
9. Krishnamurthy AV, Mathialagan J, Raghavan ATMV, Srinivasan S. Analysis of Patternsof Adverse Transfusion Reactions and Management: A Novel Initiative toward Hemovigilance in a Teaching Hospital of South India. J Lab Physicians. 2020;12(2):133-140.
10. Makroo RN. Blood transfusion reactions: Principles and practice of transfusion medicine. 2nd ed., kongposh publication: 2018
11. Venkatachalapathy TS. A prospective audit of blood transfusion reactions in tertiary care hospital for the use of blood and blood components. J Blood Disord Transfus 2012;3:118
12. Narvios AB, Lichtiger B, Neumann JL. Underreporting of minor transfusion reactions in cancer patients. MedGenMed 2004;6:17.
13. Sinha RTK, Rai P, Dey A. A study of transfusion related adverse events at a tertiary care center in Central India: A retrospective evaluation. J Med Sci Health 2016;2(3):6-12.
14. Domen RE, Hoeltge GA. Allergic transfusion reactions: An evaluation of 273 consecutive reactions. Arch Pathol Lab Med 2003;127:316-20.
15. 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.
16. Pilli GS (2012) Transfusion reactions. In: Pilli GS (ed) Blood banking and transfusion medicine, 1st edn. KLE University, Belgaum, pp 54–68.
17. Dutta A, Banerjee A, Chaudhry S. Hemovigilance in India: Corrective Action towards Safety of Blood Transfusion. J Prev Med Holistic Health 2020;6(2):66-71.
18. Bisht A, Marwaha N, Kaur R, Gupta D, Chhabra R. Haemovigilance Programme of India: Comparative analysis of transfusion reactions reported over a 5-year period through two reporting formats and key recommendations for blood safety. 2020;14:103-16.