



A Study on Adverse Transfusion Reactions in a Secondary Care Hospital of Rural India

**Bogireddy Sahithi^{1*}, Polamada Prathyusha¹, Kandibedala Chandana Sree¹,
Ramagoni Alekya¹, Goruntla Narayana¹ and N. Hariharanadha Sarma²**

¹Department of Pharmacy Practice, Raghavendra Institute of Pharmaceutical Education and Research (RIPER) - Autonomous, Anantapur, Andhra Pradesh, 515721, India.

²Department of Pathology, Rural Development Trust Hospital, Bathalapalli, Anantapur, Andhra Pradesh, India.

Authors' contributions

This work was carried out in collaboration among all authors. Author BS designed the study, performed the data analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors PP, KCS, RA, and GN helps in hypothesis framing, literature review, design, data collection, data entry, and managed the analyses of the study. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i35A31884

Editor(s):

(1) Dr. Aurora Martínez Romero, Juarez University, Mexico.

Reviewers:

(1) Lucia Stanciakova, Comenius University, Slovakia.

(2) Monica Tarcea, University of Medicine, Pharmacy, Science and Technology of Târgu Mureș, Romania.

Complete Peer review History: <http://www.sdiarticle4.com/review-history/70741>

Original Research Article

Received 28 April 2021

Accepted 02 July 2021

Published 05 July 2021

ABSTRACT

Aims: The study aims to assess the incidence, causality, and severity of adverse transfusion reactions in patients transfused with blood or blood components at a secondary care referral hospital.

Study Design: A prospective observational study was conducted in the secondary care referral hospital located in rural settings of Anantapur district, Andhra Pradesh, India. The study was conducted for a period of six months from May 2019 to October 2019

Methodology: All the patients transfused with blood or blood components in the hospital located in Andhra Pradesh during those six months study period were included. The transfusion reactions were reported to the blood bank in the Adverse Transfusion Reaction Report Form (ATRRF). Descriptive statistics were used to represent the adverse transfusion reactions.

Results: From 2549 transfusions, 30 adverse transfusion reactions were reported (1.17%). Most of the reactions reported were febrile non-hemolytic transfusion reactions FNHTRs (73.3%) followed by allergic reactions (20.0%). Transfusion reactions were predominant in females 21 (70.0%) than

*Corresponding author: E-mail: smileysaketha8@gmail.com;

males 9 (30.0%). Most of the reactions were confirmed/definite (46.6%) in causality assessment and moderate (63.3%) in severity assessment. The incidence of adverse transfusion reactions was found to be 1.17%.

Conclusion: The study concludes that there was a low incidence of adverse transfusion reactions indicating probably underreporting in the healthcare system. This would be due to lack of knowledge regarding importance of surveillance and reporting of adverse transfusion reactions by blood or blood components. There was a need to conduct continuous educational programs (CEP) on hemovigilance system towards healthcare providers to improve the reporting practice. The study provides insights about type of adverse transfusion reactions and their causality and severity. This data helps in motivating the healthcare staff to report ATRs and also to develop strategies to handle preventable ATRs.

Keywords: Adverse transfusion reactions (ATRs); blood transfusion; hemovigilance; causality; and severity assessment.

1. INTRODUCTION

Transfusion of blood or blood components is essential to improve the clinical condition of the patient [1]. Even though blood transfusion was considered a life-saving intervention, it was associated with a wide range of complications from minor fever to severe anaphylactic reaction [2]. Haemovigilance is “systematic surveillance of adverse reactions and adverse events related to transfusion” intending to improve transfusion safety [3]. The hemovigilance system involves identifying, monitoring, reporting, investigating, and analyzing Adverse Transfusion Reactions (ATR) of Blood and Blood components [4].

This approach was developed by the French Blood Agency in 1994 with the implementation of Blood Transfusion Committees and setting a National Hemovigilance System [4]. This system is essential for quality control, prompting preventive measures, and advancing the quality and safety of blood products [5].

Indian Pharmacopoeia Commission, in collaboration with the National Institute of Biologicals, Noida, Uttar Pradesh, has launched a Hemovigilance Programme of India (HvPI) on 10th December 2012 under its Pharmacovigilance Programme of India (PVPI), under the Ministry of Health and Family Welfare, Government of India [6]. About 3,027 transfusions were reported through hemovigil software in a period of 3 years from 2013 to 2016 [7].

Hemolytic transfusion reactions are the most common non-infectious complications. Ten million units of RBCs were given to 30 million patients in 10 years. So, the risk of hemolytic transfusion reactions is 1:55,000 per unit [8]. The

occurrence of transfusion reactions has been increasing day by day, which poses a burden on the health and economy of individual patients. Thorough knowledge of the incidence and ATR profile can help prevent and treat adverse transfusion reactions of blood or blood components. For this purpose, the study aims to assess the incidence, causality, and severity of adverse transfusion reactions in patients transfused with blood or blood components at a secondary care referral hospital.

2. MATERIALS AND METHODS

A prospective observational study was performed over a period of six months, from May 2019 to October 2019, in a secondary care referral hospital located in rural settings of Anantapur district, Andhra Pradesh, India. All the patients transfused with blood or blood components during the study period were considered for inclusion. After transfusion of blood or blood products, all reactions were reported to the respective blood bank in the Adverse Transfusion Reaction Report Form (ATRRF).

The data collection form comprises IP admission number, age, gender, current diagnosis, treatment drugs, type of blood component transfused (number, frequency, volume), laboratory investigations, reaction observed (onset time, duration, and characteristics), history of the patient, and management of the transfusion reaction.

1.1 Investigation of Adverse Transfusion Reactions

1. The patient's name and identification number were checked in the blood request form and blood bag to rule out manual administration errors.

2. The identifiers were rechecked before transfusion of the blood or blood components.
3. A Blood bag along with the transfusion set was observed for any deterioration before transfusion.
4. Records of ABO compatibility and Rh typing were checked before transfusion.
5. Compatibility tests and cross-matching were repeated both on pre-transfusion and post-transfusion samples.
6. Medical and medication history of the patient, including transfusions and transfusion reactions, were considered.
7. In case of sepsis or other infections patient's post-transfusion sample and blood bag were cultured.
8. In the case of non-hemolytic transfusion reactions, lab tests were done based on the symptoms.
9. Post-transfusion sample was checked for hemolysis; bilirubin levels and antibody screening were done.
10. The observed reactions were assessed for causality and severity based on the scales developed by the World Health Organization.

1.2 Data Analysis

Data analysis was performed using Epi-Info 7 statistical software given by the Centre for Disease Control, USA. Descriptive statistics like proportion, frequency, mean, and standard deviation were used to represent the adverse transfusion reactions.

3. RESULTS AND DISCUSSION

During the study period, 2549 blood and blood components were transfused. Among them, 30

adverse transfusion reactions were reported. The majority of the reactions were seen in adults, i.e., 43.3%, and mainly observed in females 21 (70%), as shown in Table 1.

Among all transfusion reactions reported, 26 (86.6%) occurred in Packed Red Blood Cells transfusions, and 4 (13.3%) occurred in platelet transfusions. Though the blood transfusions are done for the blood group of O+Ve(899) and B+Ve(874) were almost nearer, the reactions were primarily observed in B+Ve(17) than in O+ve(3).

Table 2 presents the types of reactions observed during the blood transfusions. Most of the reactions were of Febrile Non-Hemolytic Transfusion Reactions (FNHTRs) 22(73.33%) followed by allergic reactions 4 (13.33%). Only a single case of tachycardia and respiratory distress has been reported.

Table 3 presents the details of the causality assessment done for the adverse transfusion reactions observed. Out of 30 reactions, 14 (46.6%) were confirmed, 4 (13.3%) were excluded, 2(6.66%) were unlikely, 3 (10%) were likely, 3 (10%) were probable, 4 (13.2%) were inconclusive.

Table 4 presents the details of the severity assessment done for the adverse transfusion reactions observed. Out of 30 reactions, 19 (63.3%) were moderate, 8 (26.6%) were mild, 4 (13.3%) were severe.

The reactions were primarily observed in transfusions done for the patients with anemia (9); Thalassemia (7); During labor (4), and aplastic anemia (4), followed by pancytopenia (2); surgery (2); pure red cell aplasia (1) and dengue (1). Most of the symptoms the patients experienced include fever, chills, and itching.

Table 1. Age and gender-wise distribution of blood transfusion reactions

Age	Gender		No. of transfusion reactions
	Male	Female	
Neonates (<1month)	0	0	0
Infants (1 month - 2 years)	0	0	0
Young child (2-6 years)	0	1	1(3.3%)
Child (6-12 years)	2	2	4(13.3%)
Adolescents (12-18 years)	5	5	10(33.3%)
Adults (19-55 years)	3	10	13(43.3%)
Geriatrics (>55 years)	0	1	1(3.3%)

Table 2. Types of Adverse Transfusion Reactions

Type of reactions	Number of reactions	Percentage of reactions
FNHTRs*	22	73.3
Allergic reactions	6	20.0
Tachycardia	1	3.33
Respiratory distress	1	3.33

*FNHTRs - Febrile Non-Hemolytic Transfusion Reactions

Table 3. Causality assessment of transfusion reactions based on the WHO scale

Causality	Number of transfusion reactions	Percentage of transfusion reactions
Confirmed	14	46.6%
Likely	3	10%
Probable	3	10%
Unlikely	2	6.66%
Excluded	4	13.3%
Inconclusive	4	13.3%

Table 4. Severity assessment of transfusion reactions

Severity	Number of transfusion reactions	Percentage of transfusion reactions
Mild	8	26.6%
Moderate	19	63.3%
Severe	4	13.3%

As the number of transfusion reactions has been increasing, which may endanger the health and economic burden on individual patients and the nation, monitoring the occurrence of transfusion reactions is necessary to prevent and for the early management of those reactions. To know the incidence of transfusion reactions, reporting is the only source of information. In our study, all the reactions reported were acute. No delayed reactions were reported, though recipients were advised to visit the hospital for follow-up.

The incidence of adverse transfusion reactions in our study was found to be 1.17%. The incidence obtained in our study may not be the true incidence due to underreporting of some mild reactions. Underreporting was also found in a study conducted by Surekha K et al., Incidence in our study was found to be 1.17% which was different from a study conducted by Surekha K et al. (0.3%), Bhattacharya et al. (0.18%), and Praveen Kumar et al., (0.05%) [8,9,10]. A hemovigilance study conducted in Portuguese among elderly people shown a high rate of adverse transfusion reactions compared to the current study [11].

In our study, transfusions were predominant in females (70%) than males (30%). These results

coincide with the study done by Vidya Shree M (females-53.8% & males- 46.1%). In our research, most of the reactions were confirmed (46.6%) in causality assessment which was different from observations of Vidya Shree M, where most of the reactions were probable [12].

Our study's principal reason for transfusions was anemia, which was found to be similar to the observations of study conducted by Vidya Shree Met al. Among all the transfusion reactions, most of the transfusion reactions have occurred in patients who received Packed Red Blood Cells (86.6%). These results coincide with the study done by Vidya Shree M and Praveen Kumar et al., [8,12]. The study findings were contrast with the results of the study conducted by Krishnamurthy AV et al, where the transfusion reaction is high among patients on whole blood transfusion [13].

Our observations revealed that transfusions were predominant in females than in males. These observations were similar to the observations of Dhruva Kumar Sharma. In our study, most of the reactions were FNHTRs which were different from the observations of studies conducted by Dhruva Kumar Sharma et al, and Borhany M et al. Their results have shown that most reactions

were allergic reactions (65.6%) and (46.8%) [14,15]. The higher incidence of reactions in our study was constituted by FNHTRs (73.3%), which were similar to the study carried out by Rajini Bassi et al (50.9%), Pahuja S et al (37.2%),and Pai S et al(51.4%) [16,17,18].

Our study has shown that B-Positive (56.5%) had a higher incidence of transfusion reactions among all blood groups than other groups, which are different from the study conducted by the Vikram Kumar Gente in which B-Negative had a higher incidence of transfusion reactions [2].

The study findings revealed that adults (19-55 Years) have a higher incidence of transfusion reactions compared to children. These findings contrast with the studies conducted by SaiyadaliAllisabanavar et al. and Praveen Kumar et al., where children (1-15 Years) showed a high rate of adverse transfusion reactions [6,8].

Out of all reactions reported, no reactions were found in Fresh Frozen Plasm (FFP). These results coincided with the study conducted by Surekha K et al., The most frequent clinical manifestation in our research was hyperthermia (73.8%). These results were similar to the study done by Joao Luiz Grandi et al., [9,19].

Our study was correlated with the study conducted by Venkatachalapathy TS, Praveen Kumar et al., RajiniBassi et al., their results also showed a higher incidence of FNHTRs. FNHTRs occur due to interaction between antibodies of recipient and antigens on leukocytes of the donor. The use of leuko-reduced blood products can control these reactions. Packed Red Blood Cells were more frequently involved in acute transfusion reactions. These results were correlated with the study done by Rajini Bassi et al. [8,13,20].

The limitations of our study were dependent on the reporting of transfusion reactions. Reporting was not done for some mild reactions and delayed reactions. In our study, risk factors that increase the incidence of transfusion reactions were not evaluated.

4. CONCLUSION

The study concludes that there was a low incidence of adverse transfusion reactions indicating probably underreporting in the healthcare system. This would be due to lack of

knowledge regarding importance of surveillance and reporting of adverse transfusion reactions by blood or blood components. There was a need to conduct continuous educational programs (CEP) on hemovigilance system towards healthcare providers to improve the reporting practice. The study provides insights about type of adverse transfusion reactions and their causality and severity. This data helps in motivating the healthcare staff to report ATRs and also to develop strategies to handle preventable ATRs.

CONSENT

Before data collection, informed consent was obtained from the patients who received blood or blood component transfusions.

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

ACKNOWLEDGEMENTS

All authors would like to thank Dr. Praveen Kumar, Director, Rural Development Trust Hospital, for permitting to conduct the study successfully.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Khoyumthem P, Rachandra K, Goswami S, Lyngdoh LN, Sharma AB, Singh AM. Acute transfusion reactions in a tertiary hospital: A 2-year retrospective study. *JMS - J Med Soc.* 2018;32(1):47–50.
2. Gente V, Basavarajegowda A, Kulkarni R, Basu D. Recipient hemovigilance at a tertiary care hospital in Southern India: A cross-sectional study. *Int J Adv Med Heal Res.* 2018;5(2):66.
3. Boparai J, Singh S. Hemovigilance: A new beginning in India. *Int J Appl Basic Med Res.* 2015;5(3):200.
4. Jain A, Kaur R. Hemovigilance and blood safety. *Asian J TransfusSci.* 2012; 6(2):137–8.
5. Somagari DR, Sriram CS, Rachamalla CK V, Dutta UC, Chaliha T, Lahkar M, et al.

- Haemovigilance study at a tertiary care hospital the north-east of India. *ISBT Sci Ser.* 2015;10(2):61–4.
6. Allisabanavar S. regional hemovigilance study of transfusion-related adverse events at a tertiary care hospital. *Natl J Physiol Pharm Pharmacol.* 2018;8(9):1.
 7. Robert C, Karaszewska B, Schachter J, Rutkowski P, Mackiewicz A, Stroiakovski D, et al. Haematology fundamentals of biomedical science. P T [Internet]. 2012; 38(5):346–53.
 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(2):109–15.
 9. Chavan S, Patil G, Rajopadhye P. Adverse blood transfusion reactions at tertiary care hospital. *Int J Res Med Sci.* 2016;4(6):2402–7.
 10. Bhattacharya P, Marwaha N, Dhawan HK, Roy P, Sharma RR. Transfusion-related adverse events at the tertiary care centre in North India: An institutional hemovigilance effort. *Asian J Transfus Sci.* 2011;5: 164-70.
 11. Sobral PADS, Göttems LBD, Santana LA. Hemovigilance and patient safety: analysis of immediate transfusion reactions in elderly. *Rev Bras Enferm.* 2020 ;73:e20190735. DOI: 10.1590/0034-7167-2019-0735
 12. Vidya Shree M, Vithya T, Shankar Prasad, Shobha Rani RH. A study on blood and blood components transfusion, adverse reaction at a tertiary care teaching hospital, Bangalore. *J Blood DisordTransfus.* 2016;7:372. DOI: 10.4172/2155-9864.1000372
 13. Krishnamurthy AV, Mathialagan J, Raghavan ATMV, Srinivasan S. Analysis of patterns of adverse transfusion reactions and management: A novel initiative toward hemovigilance in a teaching hospital of South India. *J Lab Physicians.* 2020;12:133-140. DOI: 10.1055/s-0040-1716592
 14. 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):370-4. DOI: 10.4103/0253-7613.161257. PMID: 26285707; PMCID: PMC4527056.
 15. Borhany M, Anwar N, Tariq H, Fatima N, Arshad A, Naseer I, Shamsi T. Acute blood transfusion reactions in a tertiary care hospital in Pakistan - an initiative towards hemovigilance. *Transfus Med.* 2019 ;29:275-278. DOI: 10.1111/tme.12541.
 16. 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 Journal of Hematology & Blood Transfusion: an Official Journal of Indian Society of Hematology and Blood Transfusion.* 2017;33:248-253. DOI: 10.1007/s12288-016-0684-9
 17. 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. DOI: 10.4103/0973-6247.200779
 18. 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;36:733-739. DOI: 10.1007/s12288-020-01312-w
 19. Grandi JL, Grell MC, Areco KCN, Barbosa DA. Hemovigilance: The experience of transfusion reaction reporting in a Teaching Hospital. *Rev Esc Enferm USP.* 2018;52:e03331. DOI: <http://dx.doi.org/10.1590/S1980-220X2017010603331>
 20. Venkatachalapathy TS. A prospective audit of blood transfusion reactions in tertiary care hospital for the use of blood and blood components. *J Blood DisordTransfus.* 2012;3:118. DOI: 10.4172/2155-9864.1000118.

© 2021 Sahithi et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Peer-review history:

The peer review history for this paper can be accessed here:
<http://www.sdiarticle4.com/review-history/70741>