ISSN- O: 2458 - 868X, ISSN –P: 2458 - 8687

International Journal of Medical Science and Innovative Research (IJMSIR)

IJMSIR : A Medical Publication Hub

Available Online at: www.ijmsir.com

Volume – 2, Issue –6, November – December - 2017, Page No. : 198 - 201

Current Hemovigilance Status in a Tertiary Care Hospital in a Nortern Region

Dr. Vijay Sawhney, Head of Department Immunohaematology and Blood Transfusion Medicine

Dr. Lubna, Post Graduate Department Immunohaematology and Blood Transfusion Medicine

Dr. Kajal, Post Graduate Department Immunohaematology and Blood Transfusion Medicine

Correspondence Author: Dr. Vijay Sawhney, Head of Department Immunohaematology and Blood Transfusion Medicine

Conflicts of Interest: Nil.

Abstract

Introduction: Hemovigilance is defined as a set of surveillance procedures covering whole transfusion chain from the collection of blood and its component to the follow of its recipients, intended to collect and access information on unexpected or undesirable effects resulting from the therapeuticuse of labile blood products, and to prevent their occurrence and recurrence. Thus, the ultimate goal of a hemovigilance system is to improve the safety of blood transfusion Aim and Objective: The main aim and objective of this study is safety of transfusion and pattern of reactions. Results: Out of 28828 transfusions, 0.22% reactions were reported.

Keywords: Heamovigilance, blood, transfusion.

Heamovigilance

Introduction: Heamovigilance is a Safety concept. It is an important part of quality control in transfusion medicine which involves organized scheme of monitoring, identifying, reporting, investigating, and analyzing adverse events and adverse reaction associated with blood transfusion and manufacturing blood products [1]. It covers the whole transfusion chain from donation, its component preparation to follow up of recipients. The work on heamovigilance started in France in the year 1990 wherein the haemovigilance is centralized and is rendered mandatory by law on January 24, 1994 while as in UK it is a National voluntary scheme between professionals (Serious Hazards of Transfusion) [2]. The concept later spreaded globally as a hybrid. in most developed countries to monitor the adverse events and incidents associated with transfusion. Currently, on a global scale an International Hemovigilance Network (IHN) is functional, which evolved from the European Hemovigilance Network established in 1998[3]. On 10th December 2012 Indian Pharmacopoeia commission started Heamovigilance Program of India under its Pharmacovigilance Program of India in collaboration with National institute of Biological, Noida, Uttar Pradesh, under Ministry of Health and Family welfare, Government of India[1]. Pharmacovigilance (PV) was officially introduced in December 1961 with the publication of a letter (case report) in the Lancet by W. McBride, the Australian doctor who first suspected a causal link between serious fetal deformities (phocomelia) and thalidomide, a drug used during pregnancy [4]. Similarly, as a reaction to the human immunodeficiency virus scandal in the 1980s/early 1990s, a complete surveillance system for blood transfusion was initiated in France, there and then also the word ‘haemovigilance’ (hémovigilance) was coined (from the Greek word ‘haema’ = blood and the Latin word ‘vigilans’ = paying particular attention to)[5]. Primary objective is to track adverse reactions/events and incidences associated with blood transfusion and blood product administration and to

help identify trends, recommend best practices and interventions required to improve patient care and safety. The European Blood Directive gives some definitions:

- **Serious adverse event:** any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity

- **Serious adverse reaction:** an unintended response in donor or in patient associated with the collection or transfusion of blood and blood components that is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalization or morbidity.

Aims and Objectives

To study the rate of reaction, pattern of reactions and the Haemovigillance reporting.

Identify the factors responsible for under reporting of transfusion reactions and find out the ways to improve reporting.

Brief description about the history of haemovigilance and the need of haemovigilance program.

Materials and Methods

It is a prospective, during the study period of 1 year from June 2016 to May 2017 total 28828 units of whole blood and blood components were issued by our blood bank to various clinical departments and total of 65 reactions were reported.

Results

Out of these 28828 units of whole blood and its components issued, the reaction rate was 0.22 %. The most common type of reaction reported was febrile non hemolytic transfusion reaction reported in 32 cases (49.3%) followed by allergic transfusion reaction in 25 cases (38.4%) in which Anaphylaxis was seen in 1 case. Delayed Hemolytic transfusion reaction was seen in 3 cases (4.6%) in which 1 of the patient undergoing dialysis was found to be Anti- Kell antibody positive and other patient was anti C positive. Fluid overload was seen in 3 cases (4.6%) and sepsis in 1 case due to platelet transfusion. The organism obtained on anaerobic blood culture of the patient was staphylococcus epidermidis which was same as that of the platelet unit culture. Also, most of the reactions were seen associated with whole blood 46%, followed by packed cells 35%, 12.3% with FFP and 6.1% with random donor platelets. The reactions were seen mostly in the age group of 17 years to 60 years with 58% of reactions in females and 42% of reactions in males. The reaction rate was seen more in patients with prior transfusion history (63%) than in the patients with first time transfusion.

Discussion

A National Blood Donor Vigilance Program started on 14 June 2015 on World Blood Donor's day under the Heamovigilance Program of India to improve the safety of blood donors. A software Heamovigil has been developed to collect and analyze data related to heamovigilance all over the country in which National institute of biologics is acting as the coordinating centre.

The information obtained from haemovigilance systems can contribute to improving the safety of blood collection and transfusion by, the top 10 conclusions and results obtained are,[6]

- Haemovigilance systems have shown that blood transfusion is relatively safe compared with the use of medicinal drugs and that at least in Europe blood components have reached a high safety standard.
- The majority of the serious adverse reactions and events occur in the hospital.
- The majority of preventable adverse reactions are due to clerical errors.

- Some adverse reactions such as anaphylactic reactions often are not avoidable and therefore have to be considered as an inherent risk of blood transfusion.
- Well-functioning haemovigilance systems have not only indicated how safety should be improved, but also documented the success of various measures.
- The type of organisation of a haemovigilance system is of relative value, and different systems may have the same outcome.
- International collaboration has been extremely useful.
- Haemovigilance systems may be used for the vigilance and surveillance of alternatives for allogeneic blood transfusion such as cell savers.
- Haemovigilance systems and officers may be used to improve the quality of aspects of blood transfusion other than safety, such as appropriate use.
- Haemovigilance systems will be of benefit also for vigilance and surveillance of the treatment with other human products such as cells, tissues and organs.

Conclusion

The Transfusion medicine department of Government medical college, Jammu has been enrolled under the Heamovigilance Program and is being actively followed with monthly submission of all the transfusion reactions reported from various clinical departments of GMC, Jammu. The reactions reported to the blood bank are thoroughly investigated as per the SOPs of the department, classified as per the given standards and submitted via Hemovigil software to the NCC under its own separate user id. However, the blood banks from other districts of the same division are lagging behind as the reactions are not either reported to the blood bank or no official records are kept. Also the clinicians do not fill the transfusion reaction reporting forms properly leading to insufficient information about the transfusion reaction and other medical history of the patient. A detailed analysis of some of the transfusion incident reports revealed complex deviations and/or failures of the procedures in place in the hospital, allowing the implementation of corrective and preventive measures.

Heamovigillance Program of India is an essential component of quality control in blood transfusion system putting forward preventive measures and advancement of quality and safety of blood products and transfusion process. The spectrum of reporting varies, the program is being actively followed at the tertiary care level however needs much attention at the other levels of health care. The staff working at district level in blood banks and clinical departments need to be educated about the importance of the program and its need for the enhancement of safety of blood transfusion and a good co ordination should be maintained between the hospital clinical staff and transfusion laboratories. The attention on Donor heamovigilance should also be emphasized as it is equally important with respect to the donor as well as the recipient.

Blood product	Issuance	Reactions	%age
Whole blood	12973	30	46.2
Packed cells	11531	23	35.4
FFP	2883	8	12.3
Platelets	1441	4	6.1

References

[1]. Mukherjee S, Maiti R. Haemovigilance: A Current Update in Indian Perspective. *Journal of Clinical and Diagnostic Research : JCDR*. 2016;10 (11):EE05-EE09. doi:10.7860/JCDR/2016/21029.8868.

[2]. Transfusion Alternatives in Transfusion Medicine Volume HYPERLINK "http://onlinelibrary.wiley.com/doi/10.1111/tatm.2003.5.issue-1/issuetoc" HYPERLINK "http://onlinelibrary.wiley.com/doi/10.1111/tatm.2003.5.issue-1/issuetoc" 5, Issue 1, Version of Record online: 28 JUN 2008.

[3]. Boparai JK, Singh S. Hemovigilance: A new beginning in India. *International Journal of Applied and Basic Medical Research*. 2015;5(3):200-202. doi:10.4103/2229-516X.165379.

[4]. Suke SG, Kosta P, Negi H. Role of Pharmacovigilance in India: An overview. *Online Journal of Public Health Informatics*. 2015;7(2):e223. doi:10.5210/ojphi.v7i2.5595.

[5]. De Vries, R. R. P. (2009), Haemovigilance: recent achievements and developments in the near future. ISBT Science Series, 4: 60-62. doi:10.1111/j.1751-2824.2009.01227.x

[6]. De Vries, R. R. P., Faber, J.-C., Strengers, P. F. W. and Members of the Board of the International Haemovigilance Network (2011), Haemovigilance: an effective tool for improving transfusion practice. Vox Sanguinis, 100: 60–67. doi:10.1111/j.1423-0410.2010.01442.x