Hemovigilance: A new beginning in India

Jaspreet Kaur Boparai, Surjit Singh

Department of Pharmacology, Gian Sagar Medical College and Hospital, District Patiala, Punjab, 1Department of Pharmacology, AllIMS Jodhpur, Rajasthan, India

Abstract

Hemovigilance plays an essential role in ensuring patient safety with regard to blood transfusions. The data generated through the hemovigilance system helps in framing important changes in the whole blood transfusion process which are useful for better patient safety. This article briefly describes the history of hemovigilance, why the need of hemovigilance was felt and also illustrates about the Hemovigilance Program of India.

Key words: Blood transfusion reactions, hemovigilance, pharmacovigilance

Submission: 25‑03‑2015  Accepted: 15‑7‑2015

Introduction

The word “Hemovigilance” is derived from the Greek word “haema” which means blood and the Latin word “vigilans” which means watchful.[1] Hemovigilance as defined by Faber is “a set of surveillance procedures covering the whole transfusion chain (from the donation of blood and its components to the follow-up of recipients of transfusion), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent the occurrence or recurrence of such incidents.”[2]

The need for safe blood transfusion was felt as early as 1980’s and 1990’s when many hemophilia patients in the UK, France, Canada, Japan, and USA contracted HCV and HIV from blood transfusions and factor concentrates.[3] This heartbreaking example in history emphasized the need for hemovigilance. The work on hemovigilance was first initiated in France in 1991, with the setup of monitoring systems by Blood Transfusion Committees followed by the inception of Centre National d’Hemovigilance in 1992.[4] A complete French Hemovigilance System was in place by 1994, followed by the Serious Hazards of Transfusion launched by the UK. A similar voluntary scheme called the Transfusion Transmitted Injuries Surveillance System was introduced by the Public Health Agency of Canada.[3] Currently, on a global scale an International Hemovigilance Network (IHN) is functional, which evolved from the European Hemovigilance Network established in 1998. To further augment the safety of blood transfusion an international database - International Surveillance of Transfusion Associated Reactions and Events has been formed to share hemovigilance data across the globe.[3]

Blood transfusion safety systems may be managed either by regulators (e.g. France, Germany, and Switzerland), blood manufacturers (e.g. Japan, Singapore, and South Africa), medical societies (e.g. Netherlands, UK) or public health authorities (e.g. Canada).[6]

Hemovigilance has evolved from pharmacovigilance, which aims to collect and assess information related to medicinal products, most importantly adverse drug reactions in
human beings. Pharmacovigilance in transfusion medicine deals with plasma derivatives: Clotting factor concentrates immunoglobulins, albumin, and other fractionated products. Hemovigilance, as the name suggests, is responsible for blood components: Whole blood, erythrocytes concentrates, thrombocytes concentrates, and fresh frozen plasma.\[7\]

The information obtained through hemovigilance is imperative to make necessary changes in transfusion policies, for amendments in transfusion practices in hospitals and blood services, to enhance transfusion standards, to help in formulating transfusion guidelines and to improve quality and safety of entire transfusion process. The ultimate goal is to improve the overall safety of blood transfusion by detecting and analyzing all untoward effects of blood transfusion to correct their cause and to prevent recurrence.

As per the Ministry of Health and Family Welfare, Government of India, there are 2545 authorized blood banks in India which emphasise the need of a centralized hemovigilance system in India.\[8\]

**The Hemovigilance Program of India**

Hemovigilance Program of India was launched at the national level on December 10, 2012, as a fundamental component of the Pharmacovigilance Program of India (PvPI). The hemovigilance program is functional through a core group and an advisory committee, which coordinate the activities of hemovigilance between medical colleges and the National Coordinating Centre and also provide an expert opinion for analysis of the information generated. The advisory committee also provides insights helpful in linking Hemovigilance Program of India with the IHN. The Transfusion Reaction Reporting Form (TRRF) and the software (Hemovigil) for reporting were also designed under the guidance of the advisory committee.\[9\] Hemovigil software was uplinked on National Institute of Biologicals (NIB) website on January 24, 2013, and can be assessed from http://nib.gov.in/haephp/haemovigilance_login.php. The TRRF can be downloaded from these websites: www.nib.gov.in, www.ipc.gov.in and www.cdsco.nic.in.

This program is being implemented under the ambit of the PvPI. It is launched by the NIB in collaboration with the Indian Pharmacopoeia Commission (IPC). Currently, 154 centers have been enrolled in this program.\[10\] The data from the medical colleges (Department of Transfusion Medicine or the blood bank) in case of any adverse reaction related to blood transfusion or blood product administration is collected. Information obtained is filled in the TRRF and forwarded to the National Coordinating Centre at NIB through Hemovigil software. The recommendations based on the collected data will be forwarded to the National Coordinating Centre IPC for further transmission to Drugs Controller General (India), Central Drugs Standard Control Organization.\[11\] The safety regulatory guidelines will be formulated and modified from time to time by CDSCO based on the inputs from TRRF, which will be implemented by health care professionals and blood banks for the benefit of patients. This data communication process has been illustrated in Figure 1.

About 765 adverse reports were submitted via hemovigil software by centers to NIB. Of 735 reports submitted between February to November 2013, 364 (49.7%) were febrile nonhemolytic transfusion reactions and 167 (22.8%) were allergic reactions. The type and number of reaction reports generated under the Hemovigilance Program of India have been shown in Figure 2.\[12\] Not a single case of transfusion-related acute lung injury were reported which may be a result of under-diagnosis as well as under-reporting. Despite being active, there is overall under-reporting of adverse reactions associated with blood transfusion. WHO identified that the fragmented blood transfusion systems, lack of government commitment, lack of understanding among clinicians, lack of culture of reporting, fear of punishment, lack of expertise and regulatory framework on hemovigilance, lack of computerized management system might be challenges for the implementation of hemovigilance program in the world.\[13\]

**Conclusion**

Hemovigilance is an essential component of quality management in a blood system and is needed for the continual enhancement of quality and safety of blood products and transfusion process.
by monitoring and safeguarding the adverse events associated with the use of blood products.

Financial support and sponsorship Nil.

Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. de Vries RR, Faber JC, Strengers PF; Board of the International Haemovigilance Network. Haemovigilance: An effective tool for improving transfusion practice. Vox Sang 2011;100:60-7.

2. Faber JC. Haemovigilance procedure in transfusion medicine. Hematol J 2004;5 Suppl 3:S74-82.

3. Tutu EK. A review of international blood safety and quality regulations: Key implications for blood organizations and hospital blood transfusion practice. Can J Med Lab Sci 2011;73:6-12.

4. Salmi R. Epidemiological support of hemovigilance. Transfus Clin Biol 1994;6:421-4.

5. Jain A, Kaur R. Hemovigilance and blood safety. Asian J Transfus Sci 2012;6:137-8.

6. Kuenhert M, Goldsmith J, Williams A, Bowman J, Glynn S, Klein H, et al. Biovigilance in the United States: Efforts to bridge a critical gap in patient safety and donor health. USA: Department of Health and Human Services; 2009. p. 16-8. Available from: http://www.hhs.gov/ash/bloodsafety/biovigilance/ash_to_acbsa_oct_2009.pdf. [Last accessed on 2015 Mar 24].

7. Strengers PF. Haemovigilance – Why? 102-109. Available from: http://www.ztm.si/uploads/publication/990/1009.pdf. [Last accessed on 2015 Mar 24].

8. Cdsco.nic.in. Central Drugs Standard Control Organization; c2014-15. Available from: http://www.cdsco.nic.in/html/BloodList.html. [Last updated on 2014 Sep 30; Last cited on 2015 Mar 24].

9. Bisht A, Singh S, Marwaha N. Hemovigilance program-India. Asian J Transfus Sci 2013;7:73-4.

10. nib.gov.in. National Institute of Biologicals, Ministry of Health and Family Welfare, Government of India. Available from: http://www.nib.gov.in/haemovigilance1.html. [Last updated on 2015 Feb 10; Last cited on 2015 Mar 24].

11. Prasad JP, Gopinath SV, Bisht A. Haemovigilance Newsletter. Vol. 1. January-June, 2013. p. 1-16

12. Marwaha N, Singh S, Bisht A. ISBT Science Series. Vol. 9. Hoboken, NJ: Wiley Publishers. 2014. p. 178-83.

13. Global Consultation on Haemovigilance. 20-22 November 2012, Dubai, United Arab Emirates. Jointly Organized by WHO HQ/ Geneva, Sharjah Blood Transfusion and Research Center and the Government of the United Arab Emirates, in Collaboration with the International Haemovigilance Network and the International Society of Blood Transfusion. 2012. Available from: http://www.who.int/bloodsafety/haemovigilance/haemovigilance-report.pdf. [Last accessed on 2015 Mar 24].