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HAEMOVIGILANCE: THE BLOOD TRANSFUSION PROCEDURE

Akhileshar P. Mishr*[1], Himanshu Bhardwaj[1], Saurabh Bhardwaj [2]
[1]Assistant Professor, Institute of Pharmaceutical Sciences, J.S. University, Shikohabad (UP)
[2]Lecturer, Department of Pharmaceutical Sciences, J.S. University, Shikohabad (U.P.)
[2]Assistant Professor, Anand College of Pharmacy, Agra
*Corresponding Author: amakhii578@gmail.com

Abstracts:
Haemovigilance is regarded to be the series of monitoring measures that embody the complete transfusions procedure ranging from monitoring of blood to the prevention of blood-related disease. The time period hemovigilance originated from the term "pharmacovigilance", which contains operations and strategies to acquire intelligence precious in overseeing pharmaceutical goods, mainly adverse drug responses in humans, and to scientifically determine such data. This system is additionally an elemental phase of quality control in a blood system, bringing about corrective and preventive measures, and for the perpetual development of the high-quality and protection of blood products and the transfusion process. This follows the reporting device which consists of the enhancement of affected person safety. It additionally consists of mastering from disasters that end result in sure system modifications and hence prevents the related errors. It additionally consists of all key events and organizes numerous operations among blood banks, transfusion facilities, and health centre caregivers. The majority of affluent countries now use Haemovigilance to track adverse responses and occurrences related with blood donation and transfusion. This review focused the mild on haemovigilance: the blood transfusion procedure.
Keywords: Blood Safety, Blood Transfusion, Haemovigilance, Pharmacovigilance, Quality Management System

Introduction

Haemovigilance (Hv) encompasses a set of surveillance procedures covering the whole transfusion chain, aimed at collection and assessing information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence or recurrence. Haemovigilance consists of reporting all complications related to transfusion. It is an event which carries potential advantages as well as risks to the recipient. Any adverse event that results in a patient during or after transfusion of blood and blood products and for which no other cause can be found is called as a transfusion reaction. Transfusion of blood and blood components is often required with the objective of improving the blood counts and clinical condition of the patient[1-2].

Haemovigilance is described as an assembly of surveillance strategies covering the complete transfusion sequence from the collection of blood and its components to the follow up of its recipients, designed to collect and appraise information on unexpected or undesirable reactions resulting from the therapeutic use of blood products, and to avoid their occurrence and recurrence. Haemovigilance is an organized system that incorporates monitoring, identification, reporting, investigating and analysis of adverse episode nearmisses and reactions pertinent to transfusion and manufacturing blood products. This system is also an elemental part of quality control in a blood

system, bringing about corrective and preventive measures, and for the perpetual advancement of the quality and safety of blood products and the transfusion process[3].

The word 'haemovigilance' (hemovigilance in French) was coined in France in 1991 in analogy to the already existing term 'pharmacovigilance'. It is derived from the Greek word '*haema*' = blood and the Latin word '*vigilans*'= watchful. In the 19th century, Henri Leacock and James Blundell pioneered inter-human transfusion as a live saving therapy for severe blood loss. Due to matching and anti-coagulation blood transfusion became less dangerous in the 20th century and an accepted therapy also for less vital indications. At the end of the 1980s, the transmission of infections by blood created the need for a greater awareness on the safety of blood and pioneer work on haemovigilance started in France in 1991 with the setup of monitoring systems by Blood Transfusion Committees, resulting in a national haemovigilance network in 1994[4-5].

International haemovigilance

According to the WHO global database on blood safety and availability, up to 49% of reporting countries had a haemovigilance system in place in 2018. Alongside the establishment of national haemovigilance systems, there is a need for international regulation, information exchange and collaboration.

In the Europe Union (EU) a legal framework is laid down in the European Blood Directive, Directive 2002/98/ EC of the European parliament and the Council, and additional implementing acts. In the European blood legislation standards for quality and safety of blood are set, covering the collection, testing, processing, storage and distribution of blood and blood components. A requirement is formulated for member states to ensure serious adverse reactions and events are notified to the competent authority, and to submit an annual report on the notifications to the European Commission. Annual summaries of this reporting are available on the European Commission website. Several EU member states set up their haemovigilance systems in response to the legislation, demonstrating a positive regulatory effect. In 2014 the Rapid Alert system for Blood and Blood Components (RAB) was launched, a communication and information dissemination tool for the exchange of urgent information between national competent authorities. The WHO Blood Transfusion Safety programme aims to improve blood safety worldwide through education, advocacy and technical support. The WHO has defined strategies for the development of haemovigilance systems in the Guide to establishing a national haemovigilance system. This document provides policy and technical guidance to countries which are planning to implement a haemovigilance system and presents templates for the notification of adverse events, and for periodic and annual reporting. The WHO collects data on the functioning and results of national haemovigilance programs, the results of which are published in the Global Database on Blood Safety. The WHO, in collaboration with the Italian National Transplant Center, initiated the Notify project. The Notify Library is an open access database of adverse events associated with Medical Products of Human Origin (MPOH) and contains didactic cases, including relevant references, of adverse occurrences summarized and commented on by international experts. The collected cases encompass blood and blood components, as well as organs, tissues and cells[6].

National Haemovigilance Programme of India,

Indian Pharmacopoeia Commission in collaboration with National Institute of Biologicals, NOIDA,

Uttar Pradesh has launched a Haemovigilance Programme of India (HvPI) on 10th Dec 2012 across the country under its Pharmacovigilance Programme of India (PvPI). Primary objective is to track adverse reactions / events and incidences associated with blood transfusion and blood product administration (Haemovigilance) and to help identify trends, recommend best practices and interventions required to improve patient care and safety. In order to collect and collate the data pertaining to all over the country, a software—Haemo-Vigil‖ has been developed. Programme has already enrolled 117 Medical College and Hospitals in India. National Institute of Biologicals is the Coordinating Centre, for HvPI to collate & analyze data with respect to Biologicals & Haemovigilance. A Core Group & Advisory Committee in this regard has already been constituted and first meeting of advisory committee was held on 29th Nov, 2012 to finalize Haemovigilance Transfusion Reaction Reporting Form (TRRF) & Guidance Document. The ultimate goal of this Haemovigilance programme of India is to be a part of the International Haemovigilance Network (IHN) which presently has 28 countries as its member and provides a global forum for sharing best practices and benchmarking of Haemovigilance data[7].

Advantages of Haemovigilance

1) For Blood donors:

- ❖ Donor safety has been enhanced by lowering problems in the blood transfusion procedure.
- ❖ It instills trust in volunteer blood donors.

2) Service for blood transfusion:

- ❖ On an early basis, any relevant flaws can be identified.
- ❖ By presenting the findings of safety, the development process will be accelerated.

3) The hospital-affiliated blood bank and health-care facility:

- ❖ Errors will be decreased and reported as a result of system faults being detected
- ❖ Adverse occurrences must be reported precisely and continuously
- ❖ To guarantee safety, development plans will be devised.

4) Hv systems can improve patient health safety by:

- ❖ Exact forecasting of present concerns affecting the individual.
- ❖ Providing the primary causes of problems as well as methods for correcting and repairing them.
- ❖ Providing evidence-based policy suggestions for improved policy changes.

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Objectives of HvPI [8]

To collect, combine and analyze the data of reactions associated with transfusion of blood and its components. (The term blood and its components include homologus and autologous whole blood, red blood cells, fresh frozen plasma, plasma derivatives, platelets, cryoprecipitate etc.). It should be well integrated between the blood transfusion service, hospital staff and transfusion laboratories, transfusion committees, regulatory authorities, and national health agencies. The core group of advisory committee has already formulated a guidance document on transfusion reaction reporting with the main objective of obtaining information which can be used to improve the transfusion safety.

1. A national reporting system which can be regarded as a measure of advance public policy relating to patient safety.
2. Reporting can determine hazards and risks, and provide information as to where the system is at fault.
3. This can help to reduce the probability of injury to future patients.
4. Prompt reporting facilitates effective risk management.
5. To promote awareness among the healthcare professionals to participate in this programme.
6. To develop evidence based recommendations and assist the Central Drugs Standards Control Organization (CDSCO) in regulatory decision making regarding with transfusion safety.
7. To communicate relevant information to stake holders.
8. To create national and international contacts.

Role of Authorities [9]:

Competent authorities are essential for the success of haemovigilance system. They play an important role in legislation, inspection, budget designing and ultimately surveying either directly or by delegation. Thus each and every haemovigilance system, whatever form it exists requires the role of competent authorities. Manufacturers of equipments, reagents and disposable materials for blood centres and hospitals should establish the post marketing survey procedures for the collection and processing of data related directly and indirectly with blood transfusion. Blood banks are the consumers of equipments, reagents and disposable materials but they provide services associated with transfusion and also importantly they produce various types of labile blood components. Transfusion committee has a prime role in the designing of guidelines, training administration, ensuring the peer review, reports supervision, taking preventive or corrective actions and auditing concerned with haemovigilance. Physicians and paramedical staffs are also playing an important role in haemovigilance. Thus on one side, they are consumer

and on other side they are producers and play an important role in haemovigilance.

Procedure[9]:

Hemovigilance is a "quality process" that seeks to improve the quality and increase the safety of blood transfusion. At each and every step of the process it has both an "input"(= transfusion of a patient or intent to do so) and an "output" (= corrective and/or preventive actions and follow-up on them). As is the case for the majority of processes, the hemovigilance process has different steps and interfaces as well as critical elements. Taking into account that hemovigilance covers and surveys all parts of the blood transfusion chain (equally concerning those relating to both donors and recipients), the procedure is very similar for both branches and hereafter, the general process is described in relation to the recipient of labile blood components.

In practice and generally speaking, the different steps of this quality process are:

- Recognition / assessment of an occurrence (deviating from the "norm")
- Reporting (according to established criteria and using a standard reporting form).
- Collection of data (following written instructions).
- Compilation (using a predefined matrix).
- Evaluation (according to agreed techniques) conclusions (fedback to those concerned and published).
- Actions (corrective and/or preventive) and follow-up on them.

In principle, the outline of this process is similar at each level where hemovigilance applies: wards, hospitals, blood centers, competent authorities, manufacturers, etc., and the main participants involved in this process are physicians, pharmacists, nurses, medical technicians, etc. It is paramount to ensure ascending and descending, predefined and established communication channels between the different levels.

In order to make this process work at each of the different levels, at different sites, and with many different people involved, it is essential that close and constructive cooperation is established between the different participants. For this reason it is important to settle the organizational aspects, to define the respective responsibilities and mandates, to increase sensitivity in a "no blame environment," to have clear written procedures and to offer adequate and continuous training.

As a quality process, hemovigilance needs to be deeply and solidly embedded into the Quality Management Systems (QMS) of the different establishments: in the blood centers, in the manufacturing companies, and also in the hospitals. In order to guarantee the final result (safe and efficient blood transfusion to the patient) there should be NO exception to this rule, at no stage and for none of the activities of the blood transfusion chain.

Recommendations for a Better Haemovigilance System [10]:

Some pre requisites are needed for establishing and maintaining a fully functional haemovigilance system. They are

- Legal framework
- Continuous and guaranteed budgeting and finance facility
- Central evaluation centre setup
- Commonly agreed definitions

- Standardized reporting system
- Development of rapid alert/early warning system
- Established culture of professionalism
- Functional hospital transfusion committees
- Introducing the preventive or corrective procedures
- Creating the international cooperation

Different category of participants such as blood centres, hospitals, competent authorities etc are present in this system. However, these key participants should be ready to work in a constructive and coordinated manner to fulfill the overall objectives of haemovigilance system.

Problems and Solutions

The main problems concerned with Hv are found at different subsequent levels. Usually, there is a deficit within the common definition, terminology, and standardized reporting formalities with a uniform matrix. In Europe there are still numerous organizational problems arose due to a shortage in funding, mandates unclear, undefined responsibilities, low sensitivity with insufficient training, and hesitation to move forward by executing strong actions[10]. In several European countries, HvPs are well established and working but few countries lack the HvPs. Although regulations and laws are in place, there is a concern about underreporting undesired reactions to blood and blood products. This is still a common problem in Brazil, which shows reporting rates much lower than in countries such as France and the United Kingdom where the systems are consolidated[12]. There are numerous opportunities for error during this process if procedures are not strictly followed due to untoward occurrences associated with the collection, testing, processing, storage, and distribution of blood or blood components that might lead to death or life-threatening. Reports from the UK (2005) indicate that nearly 60% of adverse events associated with transfusion are a result of 'wrong blood to the wrong patient. The majority of these errors are the result of failure to follow procedures, or inadequate or unclear procedures[13].

Hemovigilance has become mandatory and therefore an obligatory element of blood safety and quality. The trend is towards comprehensive national systems, designed in order to favour international cooperation and the exchange of information. Common definitions, standards, forms, exchangeability of information, rapid alerts and early warnings, etc., will require a strong effort to make them suitable for Community purposes. Mechanisms of corrective and preventive actions at Community level will need to be developed. It would also make good sense to rely on existing European initiatives that have proven to be functional and have generated results, not least because they are working "bottom-up" and therefore have valuable input from experts in the field. The players in the blood transfusion chain will see their respective roles valued and their input into the system will quickly grow in importance. The problem of current vigilance systems interfering with blood transfusion needs to be resolved: spinning of or bridging and bundling will be crucial issues when it comes to modern, advanced hemovigilance, especially at the Community level.

Conclusions:

Haemovigilance programme is a vital a part of quality management in blood chain. There's never-ending process have to be compelled to work on haemovigilance and additional establishment for a right procedure to be followed. The knowledge gained from the haemovigilance and analyses

facilitate corrective and preventive actions to be taken to attenuate the potential risks related to safety and quality in blood process and transfusion for donors, patients and employees. Such info is additional key to introduce needed changes within the applicable policies, improve standards, systems and processes, assist within the formulation of tips, and increase the security and quality of the complete method from donation to transfusion. Developing tips, audit and haemovigilance systems in countries with restricted resources may be achieved additional without delay through a stepwise implementation.

Future prospective:

The significance of hemovigilance has been recognized broadly in a kind of short time, but the degree of its achievement varies significantly between countries. The cooperation of transnational associations has significantly contributed to the elevation, achievement, and knowledge in this field. Thanks to ambition taken, the safety of transfusion practice has been bettered in numerous parts, primarily related to the hazards of adverse events in donors of blood elements. In similar with changing transfusion practice, the hemovigilance process has also developed. In addition to the reduction of being hazards and the early discovery of coming up hazards, hemovigilance has also embraced the principles of patient blood care. Exploration in hemovigilance is more gradually focused on specific orders of cases, specific blood factors and approaches of their specific, rare responses, and transfusion efficacity and effectiveness. A visionary approach and use of big data can play an important part in achieving these aims. Another and sustained exertions should be made to help underreporting of events and to amend data community through clear descriptions and grading systems.

Conflict of interest:

Nil

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