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HAEMOVIGILANCE AND TRANSFUSION SAFETY

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ABSTRACT

Background: Blood transfusion play an important role in improving the health and save lives. Haemovigilance system is an important programme which ensures the transfusion safety. It is a process continuously involed in the collection and analysis of data regarding with transfusion related adverse events or reactions with the aim of identifying their causes and outcomes and prevent their occurrence or recurrence. Thus improving the quality and safety of transfusion therapy is the ultimate object of haemovigilance system. **Method:** Previously published articles relating haemovigilance and its transfusion safety have been collected and reviewed. **Observation:** Haemovigilance is a continuous process of data collection and analysis of transfusion –related adverse reactions in order to investigate their causes and outcomes, and prevent their further incidence. The well established haemovigilance systems of various countries have provided insight into various measures based on their data. Such systems would definitely improve blood safety. Haemovigilance is thus a tool to improve the quality of the blood transfusion chain, primarily focusing on safety. Haemovigilance will aid in preventing undesired reactions to blood donation and during the course of the transfusion chain.

KEYWORDS: Haemovigilance, Transfusion safety.

INTRODUCTION

Haemovigilance is the set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence. A Hemovigilance program as an integral part of pharmacovigilance program of India at a national level has been launched on December 10, 2012 with a road map of 5 years, i.e., year 2012–17, with four phases, i.e, initiation phase, expansion and phase, expansion and maintenance phase, and optimization phase.[1,2]

ORIGIN OF HAEMOVIGILANCE

Haemovigilance, the term derived by amalgamation of greek word ‘haema’ means blood and a latin word, ’vigil’ means watchful. The concept of haemovigilance first came into existence in france in 1990, almost with the same ideas and vision of pharmacovigilance. The initial work on haemovigilance was initiated in france in 1994 by creating a monitoring system ‘blood transfusion committee and establishing a national haemovigilance system. later in 1995, a resolution was published by European council with the aim of improving the public confidence in safe blood supply. Hence the haemovigilance system came under the governance of legal authorities. Later in 1998, the European haemovigilance network (EHN) was organized. Nowadays, a global system, ‘international haemovigilance network’(IHN) is in functioning. The objective of IHN is to organize and maintain a body concerned with the safety of blood and its components, transfusion medicines and haemovigilance throughout the world. The IHN is working along with ‘international society of blood transfusion’ (ISBT) to ensure a better service.[3]

Heamovigilance Program of India

Indian pharmacopoeia commission in collaboration with national institute of biologicals, Noida, uttar Pradesh has launched a HvPI on 10th December 2012 across the country under its PvPI, under ministry of health and family welfare., government of india. This programme has been implemented under the broad ambit of PvPI with dedicated budgetary during 12th five year plan (2012-2017)and divided into three phases initiation phase, expansion and consolidation phase, expansion and maintainence phase for establishment of haemovigilance programe.[2,3] This is an independent programe primarily restricted to voluntary reporting of

serious adverse reaction in recipients. Fundamental aim of this programe is to trail adverse reactions and episodes related to blood transfusion and blood product and administration and to help determine the tendency, recommend best practices or policies and inteventions required to improve patient care and safety.[2,3]

Haemovigilance In Developing Countries

Haemovigilance programe as an integral part of the PvPI at a national level was launched on December 10,2012. WHO has taken some initiatives in order to support and consolidate the haemovigilance programe in resource poor countries. The goal of these initiatives is to strengthen and expand national systems for data collection and management, risk assessment, surveillance and vigilance for policy decisions and programme planning for safe blood transfusion. WHO has developed norms, standerds, recommendations, guidelines, materials tools and training materials which will be useful for countries in developing haemovigilance systems. This will help in assessment, monitoring, and evaluation of national blood programme. WHO has also established a mechanism of collecting and reporting data of blood transfusion services from 194 WHO member states based on 20 key quantitative blood safety indicators and using a comprehensive data collection tool. In 2007, WHO organized a "global consultation on universal access to safe blood transfusion". The international experts and participants of this consultation gave recommendations to WHO on developing qualitysystems throughout the blood transfusion chain. In November 2012, WHO organized a global consultation jointly collaborated with IHN and ISBT and laid down recommendations on recent development on haemovigilance.[1,3]

Haemovigilance Definition

Based on the reports of WHO, ISBT and IHN, the haemovigilance is defined as a set of surveillance procedures covering the whole transfusion chain from collection of blood and its components up to the follow-up of its recipients intended to collect and assess information on undesirable or unexpected effects resulting from the use of blood products and to prevent their occurrence or recurrence. The European blood directive gives various definitions regarding with haemovigilance. It defines the serious adverse reaction as an unintended reaction occur in donor or recipient associated with the collection or transfusion of blood or its components that leads to fatal, life threating, disabling or incapacitating state or which result in or prolongs, hospitalization or morbidity. Guide on the preparation, use and quality assurance of blood components, recommendations of haemovigilance.[3]

Scoring for severity: 0-no sign, 1:immediate symptoms without vital risk amd complete resolution, 2:immediate symptoms with vital risk, 3: prolonged morbidity 4: death of the patient.

Scoring for imputabilty: 0: no relationship, 1: possible,2: likely 3: sure clinical and biological symptoms.

Immediate reaction: haemolysis, non-hemolytic febrile transfusion reaction, allergic reactions- rash, erythema, urticarial, anaphylaxis, transfusion related acute lung injury.

Delayed reaction after transfusion: hemolysis, graft- versus- host disease, post transfusion purpura, microbiological or viral transmission, allo-immunization, incorrect blood component transfused and others.[3]

HAEMOVIGILANCE: The Current Status

At present, the haemovigilance system has been implemented in most of the developed countries to monitor the adverse events related with donation and transfusion of blood. Depending upon the country, this system is governed by either regulator, medical societies, public health authorities or blood manufactures. In India, on 10th December 2012, the haemovigilance programme of india was implemented throughout the country under the pharmacovigilance programme of India. Haemovigilance monitor every step of transfusion process from donor to recipient. It covers the whole chain of transfusion with various objects such as monitoring or prevalance and incidence of infectious markers in blood donors, compiling the data of adverse reactions or events including transfusion errors and product related side effects either suspected or confirmed and providing alert or warning procedures, thereby covers the whole transfusion chain and the respective activities.[3,4]

Scope of Haemovigilance, Its Essentiality And Terminology

The haemovigilance system should cover all measures and techniques throughout the whole transfusion sequence, from blood donation processing and transfusion to patients for the monitoring, reporting and investigation of adverse events and reactions and near misses pertinent to blood transfusion. It should be well integrated between the blood transfusion service, hospital staff and transfusion laboratories, transfusion committees, regulatory authorities, and national health agencies. an adverse effects that results in morbidity or

mortality of a recipient is called an adverse reaction and when it affects a donor it is called complication.[1,4]

Haemovigilance For Recipients

An internationally accepted scale is used to grade the 'severity' of an adverse reaction in recipients. The likelihood for adverse reaction or imputability can be attributed to the blood component transfused and it is also important to determine whether blood component has been involved or not. Criteria for 'severity' and' imputability' of transfusion reaction has been laid down by the ISBT.

Haemovigilance For Donors

Blood donor haemovigilance is also equally important as far as adverse reaction or event during whole blood or component donation is concerned. Adverse reaction in donor is called complication as the aetiology is different from those in the recipient. These adverse reaction may be due to donation, selection and management of donors, which may directly harm the donor or impact the quality of the product, which ultimately influence the recipient.

Importance of Transfusion Safety

Transfusion is a multistep process in which the members of different profession mainly doctors nurses laboratory scientists and also the donors and recipients of transfusion are participated. Due to the complexity and multi steps transfusion procedure leads to a chance for the development of several risk points. Mistakes here force the patients to life threatening state. Mistakes mostly arose from the omission of essential checks and perhaps an assumption that someone else is responsible for safety. Comparing with the risk of infection form transfusion, the risk of receiving the wrong blood was considerably higher. An error in the process such as at the point of blood sampling or in the laboratory or at bed side administration ended in wrong transfusion that creates a heavy risk at patient side. Hence, the haemovigilance system was developed with the ultimate goal of improving the safety of blood transfusion.[1,3]

Procedure

Haemovigilance is a quality process, it needs improvement in the quality and safety of blood transfusion. So that this process focusing on both input (transfusion of a patient or intent to do so) and output(corrective or preventive measures and follow up on them).

Various essential steps involved in the haemovigilance are:[4]

- Assessment or recognition of an occurrence
- Reporting by using established criteria and reporting form
- Collection of data
- Compilation by using predefined matrix
- Evaluation as per approved techniques
- Conclusions and feedback to those concerned and published
- Action either corrective or and preventive and follow-up on them

As a quality process, the haemovigilance needs to be deeply embedded into the quality management system of various establishments such as blood centres, manufacturing units, and hospitals. In order to ensure the efficient and safe blood transfusion to patient there should be no exception to these rules, at any stage of blood transfusion chain.

Objective For Reporting Adverse Reactions and Adverse Reaction In Transfusion

- Reporting for obtaining information is a tool which can be used to improve the product safety
- A national reporting system, therefore, can usefully be admired as a tool to advance public policy concerning patient safety.
- Reporting provides information as to where the system is breaking down, it can help to identify hazards and risks.
- This can advice target improvement efforts and system changes to reduce the likelihood of injury to future patients.
- Reporting of doubtable adverse reaction in a timely manner facilities effective risk management.
- ADR monitoring centres: these are medical colleges and institutes, blood banks, hospitals in india that are registered with the pharmacovigilance national co-ordinating centre for reporting the adverse reaction that occurs during blood transfusion or blood product administration.

Risk and Factors To Ades

Certain factors may access the likelihood of a transfusion related adverse effect and thee inclue

- Individual patient characteritics
- Blood components

- Equipments
- Unspecific medications and intravenous fluids

Recommendation For Better Haemovigilance Programe

- More trained personnel
- Better national blood quality and safety initiatives
- Reducing or minimizing technical and human errors
- Generate data standards
- Improve capacity of reporting

CONCLUSION

The information gained from the haemovigilance and analyses facilitate corrective and preventive actions to be taken to minimize the potential risks associated with safety and quality in blood processing and transfusion for donors, patients and staff. Such information is also key to introduce required changes in the applicable policies, improve standerds, system and processes, assist in the formulation of guidelines, and increase the safety and quality of the entire process from donation to transfusion. Developing guidelines, audit and haemovigilance systems in countries with limited resources can be achieved more readily through a stepwise implementation.

Conflict of Interest

The author declared no conflict of interest with respect to the authorship, research or publication of the article.

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