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Review Article

HAEMOVIGILANCE AND ITS SIGNIFICANCE IN TRANSFUSION SAFETY

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ABSTRACT

Blood transfusion plays an important role in improving the health and saves lives. Haemovigilance system is an important programme which ensures the transfusion safety. It is a process continuously involved in the collection and analysis of data regarding with transfusion related adverse events/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.

Keywords: Haemovigilance, Transfusion safety.

INTRODUCTION

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 (shortcuts) 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.[1] Hence, the haemovigilance system was developed with the ultimate goal of improving the safety of blood transfusion.[2]

Origin of Haemovigilance

The term 'haemovigilance' (he'movigilance in French) was coined in France in 1991[1, 3] in analogy to the already existing term 'Pharmacovigilance'.[4] The term 'haemovigilance' has Latin and Greek roots (Haema-blood; vigilance-paying special attention to).[3, 4, 5] As a safety concept, the haemovigilance was introduced in 1990s. 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.[2]

Haemovigilance Definition

Based on the reports of World health organization (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.[1, 5] WHO published the guidelines for 'adverse event reporting and learning system' in 2005. It clearly tells about the basic role of patient safety reporting system in the improvement of patient safety and suggests that the learning from the failures of health care system. It also instructs that the effectiveness of an advent reporting system is measured not only by accurate collection and analysis of data, but by its use to make recommendations that improve the patient safety. According to this guideline, an adverse event is defined as any undesirable or unintended occurrence before, during or after transfusion of blood or its components that may lead to death or life threatening or disabling condition of patient or which results in, or prolongs, hospitalization or morbidity.[4, 5] The "European blood directive" gives various definitions regarding with haemovigilance. It defines the serious adverse reaction as an unintended reactions occur in donor or recipient associated with the collection or transfusion of blood or its components that leads to fatal, life threatening, disabling or incapacitating state or which results in or prolongs, hospitalization or morbidity. Some of the definitions were obtained from other areas such as pharmacovigilance etc. The definition about the types of blood components is based on the council of Europe: Guide on preparation, use and quality assurance of blood components, Recommendation No. R (95) 15, Part C: Blood components. Some other aspects are based on the guidelines of EHN and the council of Europe: Guide on the preparation, use and quality assurance of blood components, Recommendation No. R (95) 15, chapter 31 of haemovigilance.

Scoring For Severity: 0 – No sign; 1 – Immediate symptoms without vital risk and complete resolution; 2 – Immediate symptoms with vital risk; 3 – Prolonged morbidity; 4 – Death of the patient.

Scoring For Imputability: 0 – No relationship; 1 – Possible; 2 – Likely; 3 – Sure Clinical and biological symptoms.

Immediate Reaction: haemolysis, non-hemolytic febrile transfusion reaction [NHFTR]; allergic reactions - rash, erythema, urticaria, anaphylaxis, transfusion related acute lung injury (TRALI).

Delayed Reaction After Transfusion: hemolysis, graft-versus-host disease (GvHD), post-transfusion purpura (PTP), Microbiological / viral transmission, allo-immunization (against antigens of RBC, WBC, PLT), incorrect blood component transfused (IBCT) and others.[5]

Haemovigilance: The Current Status

At present, the haemovigilance system has been implemented in most of the developed countries to monitor the adverse event related with donation and transfusion of blood.[4] Depending upon the country, this system is governed by either regulator (example: France, Germany and Switzerland) medical societies (example: UK and Netherland), public health authorities (example: Canada) or blood manufacturers (example: Japan, Singapore and South Africa).[3] In India, on 10th December 2012, the haemovigilance programme of India (HvPI) was implemented throughout the country under the Pharmacovigilance programme of India (PvPI). The Indian pharmacopoeia commission in collaboration with National institute of biological, Noida, U.P has launched this programme.[4] Haemovigilance monitor every step of transfusion process from donor to recipient (from vein to vein). It covers the whole chain of transfusion with various objects such as monitoring of prevalence and incidence of infectious markers in blood donors, compiling the data of adverse reactions/events including transfusion errors and product related side effects either suspected or confirmed and providing alert/warning procedures, thereby covers the

whole transfusion chain and the respective activities.

Recommendations For A Better Haemovigilance System

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.

Role of Industry

Manufacturers of equipments, reagents and disposable materials for blood centers and hospitals should establish the post marketing survey procedures for the collection and processing of data related directly and indirectly with blood transfusion.

Role of Blood Centres and Organizations

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. Thus on one side, they are consumer and on other side they are producers and play an important role in haemovigilance.

Role of Clinical Segment

Hospital 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.

Role of Authorities

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.

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

- 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
- Actions either corrective or/and preventive and follow-up on them.

As a quality process, the hemovigilance needs to be deeply embedded into the Quality Management Systems (QMS) of various establishments such as blood centers, manufacturing units, and hospitals. In order to ensure the final result (the efficient and safe blood transfusion to patient) there should be no exception to these rules, at any stage of blood transfusion chain.

Problems Concerned With The Implementation Of Haemovigilance

Concerned with haemovigilance, several problems exist at different levels, includes institutional, regional, national and international. In fact, these problems could not be solved. Generally, there is a deficit in relation with common definitions, terminology, standardized reporting formalities and uniform matrix. In Europe also there are still various organizational problems, funding shortages, unclear mandates, undefined responsibilities, low sensitivity, insufficient training and hesitation to move forward by implementing strong actions. In several countries across Europe haemovigilance is really established and working. But a national haemovigilance system is not in place in every European country.

Solution And Future

A strong network in haemovigilance will be vital and also common definitions, standards, forms, exchangeability of information, rapid alerts and early warnings are also playing important role. Mechanisms of corrective and preventive actions at community level will need to be developed. The players in the blood transfusion chain will see their respective roles 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 haemovigilance, especially at the community level.[5]

CONCLUSION

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. However this has to be strengthened further by improved information management or better progress in standardization from one region to the other. Haemovigilance is the ultimate quality indicator of a transfusion service. There is a continuous need to work on hemovigilance. Even though the laws and tools are in place, there is still the need of establishing the right awareness system in order to ensure that the procedure will be followed so that haemovigilance will aid in preventing undesired reactions to blood donation and during the course of the transfusion chain. The information gained from the haemovigilance facilitates corrective and preventive actions to minimize the potential risks associated with safety and quality in blood processing and transfusion to donors, patients and staff. Such information is also important for introducing required changes in the applicable policies, improving the standards, systems and processes, formulation of guidelines as well as increasing the safety and quality of the entire process from donation to transfusion.

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