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Short Communication

Adverse Drug Reactions Associated with Blood and its Transfusion: A Brief Report

Pramod Kumar, Ismeet Kaur* and V Kalaiselvan

Department of Pharmacovigilance , PvPI, Govt. of India

***Corresponding Author**: Ismeet Kaur, Department of Pharmacovigilance , PvPI, Govt. of India.

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Abstract

Indian Pharmacopoeia Commission has started Haemovigilance Program of India (HvPI) in 2012 under the umbrella of Pharmacovigilance Program of India (PvPI) in collaboration with National Institute of Biologicals (NIB), Noida, Uttar Pradesh, under Ministry of Health and Family welfare, Government of India with a primary objective to track adverse reactions/events and incidences associated with blood transfusion and blood product administration and to identify trends, recommend best practices and interventions required to improve patient care and safety.

Keywords: *Adverse Drug Reactions; Blood; Transfusion*

Introduction

WHO defines "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 [1]. This aims to identify trends in adverse reactions and events, thereby to inform transfusion policy, to target areas for improvement in practice, to stimulate research, to raise awareness of transfusion hazards, to be an early warning of new complications and to improve safety of transfusion for patients [2]. The World Health Organization (WHO) Global forum (November 2012) in association with the International Society of Blood Transfusion (ISBT) and the International Haemovigilance Network had representation from 46 countries to identify the challenges included in blood transfusion services [3,4].

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Haemovigilance is a relatively recent development in transfusion safety. The aims are to identify trends in adverse reactions and events, thereby to inform transfusion policy, to target areas for improvement in practice, to stimulate research, to raise awareness of transfusion hazards, to be an early warning of new complications and to improve safety of transfusion for patients. As transfusion is a complex multistep process involving members of several different professional groups, nurses, doctors, pharmacists, laboratory scientists as well as the donors and recipients. The many steps result in several risk points. At each of these steps mistakes may be made that put patients' lives at risk [6]. This article is aimed to analyze all the transfusion reactions received at NCC-PvPI and to bring the awareness towards the haemovigilance.

Methodology

The present study has been carried out as retrospective analysis at Indian Pharmacopoeia Commission (IPC) functioning as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) to evaluate the Individual Case Safety Reports (ICSRs) related to blood and its transfusion which were received during July 2011 to October 2017 in VigiFlow™ web-based software [7]. The reported cases were analysed for the information like; patient age and gender, seriousness criteria; outcome of reaction and system organ class effected. The coding of reactions and drugs were performed as per WHO-ART and WHO-DD respectively.

Results

The total numbers of ICSRs reported in the given period for blood products were 406 out of which 236 (58%) were observed in females; 86 (21%) ICSRs were found be serious; Age criteria were assessed and majority of 302 (74.5%) ICSRs were reported among adults. Among all the ICSRs majority of reactions are observed to be recovered (83%) and less than 1% of reactions were found to be fatal (0.5%). Further details on same were mentioned in table 1 and 2. Among all the ICSRs majority of reactions are observed with general disorders and administration (47.3%) followed by skin and subcutaneous tissue reactions (24%) and immune system disorders (16.3%) and was further detailed in table 3.

Category	Number of ICSRs	Percentage (%)
Gender		
Female	236	58
Male	170	42
Age Group		
Child [SP1] [A2]	66	16
Adult [A3]	302	74.5
Elderly [A4]	38	9.5

Table 1: *Demographic characteristic of the study population.*

Number of ICSRs	Percentage (%)	Category
Outcome assessment		
Recovered	338	83
Recovering	34	8
Not Recovered	16	4
Unknown	18	4.5
Fatal	02	0.5
Seriousness		
Serious	86	21
Non-Serious	320	79

Table 2: *Details of Seriousness and Outcome of the reaction.*

S. no	Reaction	Count	Percentage
1	Blood and lymphatic system disorders (Haemolysis)	3	0.7
2	Cardiac disorders (palpitations 2, tachycardia 3)	5	1.2
3	Gastrointestinal disorders (vomiting 10, abdominal pain 5, nausea 2)	17	4.2
4	General disorders and administration site conditions (chills 86, pyrexia 95, chest pain 9, Oedema 2)	192	47.3
5	Immune system disorders (anaphylactic reaction 36, hypersensitivity 30)	66	16.3
6	Injury, poisoning and procedural complications (transfusion reaction)	14	3.4
7	Investigations (abnormalities in liver function, bilirubin, urine)	11	2.7
8	Musculoskeletal and connective tissue disorders (back pain 2, myalgia 2)	4	1.0
9	Nervous system disorders (dizziness 3, headache 1, tremors 2)	6	1.5
10	Psychiatric disorders (restlessness 4, anxiety 2)	6	1.5
11	Renal and urinary disorders (Haematuria)	6	1.5
12	Reproductive system and breast disorders (vaginal pruritus)	1	0.2
13	Respiratory, thoracic and mediastinal disorders (Dyspnoea 14, respiratory depression 1, cough 2)	17	4.2
14	Skin and subcutaneous tissue disorders (rash 50, pruritus 31, urticaria 16)	97	23.9
15	Vascular disorders (hypotension)	7	1.7

Table 3: *Represents the system organ class assessment.*

Discussion

The database shown that majority of reactions was observed in female gender and adult population which is in much similar to the study conducted by Bolton-Maggs [4]. Though majority of reactions were recovered some reactions are not recovered and also leads to additional treatment for the reaction. From the analysis we have observed that majority of reactions are from general disorders and administration site conditions which included reactions such as (chills, pyrexia and pain) followed by skin and subcutaneous tissue disorders which included reactions such as (rash, pruritus and urticaria).

As of now not even 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 continuous efforts taken towards bringing awareness on reporting of adverse events, 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 [8]. However in India the same scenarios are reflected but soon with the proper interventions which are taking place the achievement of complete management will be done.

In order to have a well-organized haemovigilance system in developing countries like India, a comprehensive approach is required. A streamlined mechanism for data collection using standardized tools at hospital level and good coordination at the national level can bring up effective hemovigilance system in a country. A functional hospital transfusion committee can act as backbone for this by developing policies for transfusion practices, appropriate documentation, reporting and investigation of transfusion reaction. Thus it incorporates required modifications in the relevant policies, improve standards, assists in the formulation of guidelines, and reinforce the safety and quality of the whole chain from donation to transfusion [9].

It is expected that all the information provided by haemovigilance may contribute to improving the safety of blood transfusion by providing the medical community with a reliable source of information about untoward effects of blood transfusion and indicating corrective measures required to prevent the recurrence of some accidents or dysfunctions in the transfusion process along with warning hospitals and blood transfusion services about adverse events that could involve more individuals than a single recipient.

Conclusion

Haemovigilance program scrutinizes, expedite remedial and preventive actions to be taken to minimize or reduce the potential risks related to safety and quality in blood processing and transfusion for donors, patients and medical staff. In resource constrained countries, a stepwise implementation of the policies would be required in order to establish and develop haemovigilance systems in a substantial manner. Haemovigilance will also have a major impact on optimal blood usage. It is expected that existing haemovigilance systems in hospitals will contribute in the near future also to the surveillance of optimal blood use.

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