Haemovigilance in Iran (First Report)
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Submitted: 10-05-2011, Accepted: 23-07-2011

Abstract
Haemovigilance is a system with standard program to cover the entire transfusion chain, monitor, evaluate and analyse the data to improve patients’ safety. We report the implemented haemovigilance system in hospitals and transfusion reactions (TR) in Iran.

Methods and Materials: This was a prospective descriptive study. The national reporting system for transfusion incidents was introduced in January 2009. In the period 2009-2011, 47 hospitals in a mandatory manner reported transfusion incidents among patients to the blood bank in a mandatory manner. All incidents were anonymously recorded in a standardized report form and registered in 10 categories.

Results: A total of 377 transfusion incidents were reported and categorized as: incorrect blood component transfused (n = 4), Febrile non hemolytic transfusion reaction (FNHTR) (n=84), Immune hemolytic transfusion reactions (n =12), nonimmune hemolytic transfusion reactions (n = 7), allergic reactions (n = 247), transfusion-related acute lung injury (n = 2). There were no reports in the categories of infections, post-transfusion purpura, transfusion-acquired viral infection, and transfusion-related graft versus host disease.

Conclusion: Haemovigilance is a tool for quality improvement and better surveillance on patient safety. The safety and quality of blood transfusions can be improved if we follow the transfusion chain, prevent and treat transfusion reactions and report adverse reactions to change the protocols.

Key Words: Adverse reaction, Blood Safety, Haemovigilance, Risk

Introduction
Haemovigilance is a “quality process” to improve the quality and increase the safety of blood transfusion 1. It covers and follows all activities of the blood transfusion chain from donors to recipients 2. Haemovigilance improves safety and quality of blood transfusion and also patient’s safety in clinical governance. Haemovigilance has been implemented in many countries with numerous significant differences in field of blood transfusion (political, historical, cultural, religious), different definitions, goals, organizational schemes and reports systems 3,4. As a result there is no simple and universal concept for Haemovigilance [4]. The development of Haemovigilance is according to: A) Global trend to develop national surveillance systems to improve quality and safety of blood transfusions. B) Increased quality of reporting and follow-up of adverse reactions to blood components. C) Supporting training programs for physicians, nurses, health care workers and

In 1997 five European countries established a system, today known as the International Haemovigilance Network, to gather information and improve patient’s safety.

In Iran, blood is voluntarily donated without any financial incentive, and distributed by the Iranian Blood Transfusion Organization to public and private hospitals. Iranian Ministry of Health has ordered the Iranian Blood Transfusion Organization (IBTO) to implement haemovigilance in all hospitals in Iran to improve patients’ safety. This is the results of related activities from 2009 to 2011.

Materials and Methods

This was a prospective, descriptive study. To reach a national approach in haemovigilance, the haemovigilance advisory committee has been established on the basis of following principles: redesigning the blood requisition, transfusion reaction report and also emergency request of blood form to facilitate better data collection, defining the scope of haemovigilance report which consists of blood collection, safety and usage, donor and recipient reactions, and provisional analysis of data. The committee prepared national guidelines for blood components and established educational courses for physicians, nurses, health care workers and blood banking personnel in hospitals. Events were validated at the hospitals to ensure that they were transfusion related and imputability scores were allocated. During the study’s period 4573 nurses, 318 physicians, and 123 blood bank personnel in 47 hospitals were trained during over 227 training courses on haemovigilance. All adverse reactions reports became mandatory if the system was implemented in a hospital. In the period from 1 January 2009- to December 2011, 47 hospitals reported transfusion incidents among patients to the blood bank in a mandatory manner. All incidents were recorded in a standardized report. Reports that were not consistent with the definition were excluded from the analysis. Data were analyzed by SPSS software. T-test was used to compare means and Chi-square to compare proportions.

Results

A total of 377 transfusion reactions were reported and most of them were acute incidents. Mean ± SD of age was 35.74 ± 23.85 years (Range 1-100). One hundred and ninety seven (52.5%) of cases were female and 180 (47.75%) were male. M/F ratio was 0.91. Figure 1 shows the trend in reporting transfusion reactions from 2009 to 2011. Figure 2 indicates the relative proportions of adverse events reported (n=377) to the Iranian National Haemovigilance department from 2009 to 2011. There was a majority of mild allergic reactions (n=216), with some serious allergic reactions (n=31). Febrile non hemolytic transfusion reactions (FNHTR) (n=84) were the next common incidence. Hemolytic transfusion reactions (Acute HTR n=10; Delayed HTR n=2), non
immune hemolysis transfusion reactions (n=7),
transfusion associated circulatory overload (TACO
n=6), transfusion related acute lung injury (TRALI
n=2) and anaphylaxis (n=1), all represented very
low to minimal risks for patients. However, there
were 4 instances of incorrect blood component
transfusions (IBCT) reported. In two cases the
reaction occurred due to blood banking error and
the other 2 cases were due to nursing error. There
were no reports in the categories of infection, post-
transfusion purpura, transfusion-acquired viral
infection, and transfusion-related graft versus host
disease.

The number of blood components used in
patients with adverse reactions are shown in figure
3. The number of reported transfusion reactions
following packed cell usage were 167 (44.29%),
followed by leukoreduced packed cell 105 (27.85%)
and random platelet of 34 (9.01%). We did not find
any sex related significant difference in complications.
The Mean±SD of the time interval between
complications and blood component transfusion
was 52±28 minute. The highest number of reports
was from Tehran (24.40%), and Esfahan (22.55%).
The mean ± SD interval between complication
date and confirmation date by haemovigilance
department was 5.63±9.85 days. Death occurred in
4 patients. Two cases were due to ABO mismatch
after packed cell transfusion, 1 case was due to
TRALI after random platelet transfusion and the last
case was due to underlying disease. We diagnosed
Bombay blood group following hypotension and
chills after blood injection in 2 cases.

Discussion
Centralized national haemovigilance system
was implemented in Iran in 2009. Despite all
quality management systems in clinical governance
for health care centers and hospitals, the adverse
reaction in the blood transfusion chain was still
present 11–14. An organized and problem oriented
system for haemovigilance can detect all transfusion
events. Reporting of all incidents can improve
the knowledge of health workers, prevent similar
accidents and also prompt immediate treatment
of reaction to increase patient safety 14–19. During
the study period, 377 transfusion reactions were
reported by 47 hospitals in Iran. The most common
reactions were mild allergic reactions followed by
FNHTR. In Australia, the proportions of serious
adverse events reported (n=294) for the 2008/09
period were febrile reactions (n=154) followed
by allergic reactions (n=87), and few serious
anaphylactic / anaphylactoid reactions (n=8) 16. In
Japan from a total of 1,727 adverse reactions and
infectious diseases related to transfusion 1,544
cases were non-hemolytic adverse reactions, 149
were suspected transfusion-transmitted infections,
and 22 were hemolytic adverse reactions 19. SHOT
has reported a total of 2464 cases with transfusion
reactions in 2010 17. There has been an increase in
the total number of reports submitted in Australia,
Japan; and UK 16–20. Our study shows some increase
in the number of incident reports. SHOT reports a
29% overall reduction in the number of incorrect
blood component transfused which was similar
to other studies 17. Using a wrist band and double
Checking are important ways to decrease blood transfusion complications. The reactions were more common in males compared to females in most countries which is different from our findings. Most women are multiparous, which causes the presence of circulating antibody leading to reaction. The percentage of adverse reactions by blood products were similar in all reports with packed cells being the most common which is similar with our findings. The time interval from the transfusion to the onset of adverse reactions depends on the reaction in most reports. Hypotension is the earliest symptom and TRALI manifestation is the latest, but most of them are observed before 60 minutes similar to our study. In our study the proportion of death due to blood transfusion errors in comparison to total incident was similar to other reports. All deaths occurred in hospitals. Transfusion must be performed in centers with expert physicians to recognize and treat severe adverse reactions. We did not have any report in the categories of infection, and delay reactions, but other countries have reported them. As a result, we need continuous improvement in training and education to increase awareness among hospital staff to report all incidents. Transfusion medicine must be a part of the core curriculum for students, residents and all health workers in training. In most developed countries haemovigilance networks have been implemented to better analyze the blood transfusion-related morbidity and mortality. National haemovigilance networks help to increase reports of incidents and implementing corrective measures. Implementing a network system is an essential tool to improve haemovigilance in Iran. Also we need to increase IT system capabilities in all fields.

**Conclusion**

Haemovigilance is an important system to improve the quality and safety of blood transfusion. Blood banking committees in hospitals should actively get involved in haemovigilance systems to facilitate reporting of the adverse reactions. Regular follow up after implementation of the system promotes data reporting, collation and analysis.

**Acknowledgement**

We thank the ministry of health for helping to conduct this project, as well as all health care workers in participating hospitals and the IBTO personnel.

**References**

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