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Haemovigilance in Iran (First Report)

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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, Haemovgilance, 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

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blood banking personnel. D) Providing medical and scientific analysis of adverse reaction reports. E) Preparing clinical transfusion and hospital practice guidelines. F) Training the audit and risk management functions of hospitals in relation to transfusion. G) Designing online networks. H) Establishing a haemovigilance committee in the Ministry of health [5-10].

In 1997 five European countries established a system, today known as the International Haemovigilance Network, to gather information and improve patient's safety [7-9].

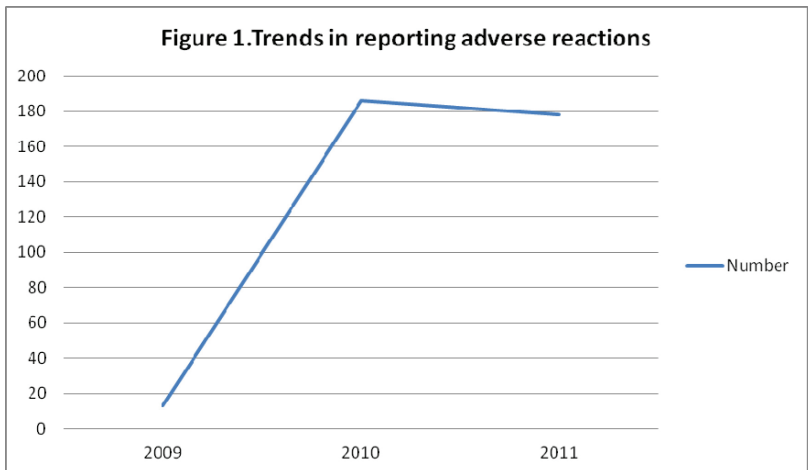
In Iran, blood is voluntarily donated without any financial incentive, and distributed by the Iranian Blood Transfusion Organization to public and private hospitals. Iranian Ministry of Health has ordered the Iranian Blood Transfusion Organization (IBTO) to implement haemovigilance in all hospitals in 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 trainedduring 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 [16]. T-test was used to compare means and Chi-square to compare proportions.

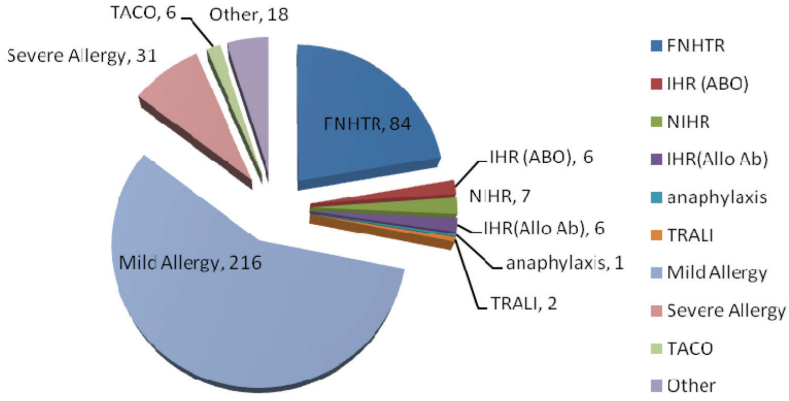
Results

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



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Figure 2.Incidence of Reactions



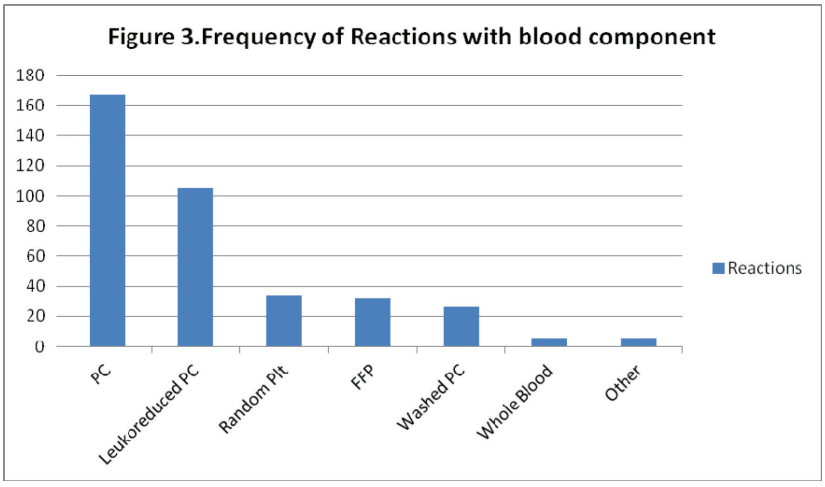
immune hemolysis transfusion reactions (n=7), transfusion associated circulatory overload (TACO n=6), transfusion related acute lung injury (TRALI n=2) and anaphylaxis (n=1), all represented very low to minimal risks for patients. However, there were 4 instances of incorrect blood component transfusions (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 intervalbetween 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

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checking are important ways to decrease blood transfusion complications [21-24]. The reactions were more common in males compared to females in most countries wihch is different from our findings. Most women are multiparous, which causes the presence of circulating antibody leading to reaction [22-25]. The percentage of adverse reactions by blood products were similar in all reports with packed cells [24-26] 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 [27-28]. Hypotension is the earliest symptom and TRALI manifestation is the latest, but most of them are observed before 60 minute similar to our study [18, 28]. 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 [16-19, 28]. Transfusion must be performed in centers with expert physicians to recognize and treat severe adverse reactions [2, 17, 28]. We did not have any report in the categories of infection, and delay reactions, but other countries have report 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 [17-19]. In most developed countries haemovigilance networks have been implemented to better analyze the blood transfusion-related morbidity and mortality [23-28]. National haemovigilance networks help to increase reports of incidents and implementing corrective measures [17-20]. 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.

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