Severe adverse reactions to blood transfusion in patients: a survey of cases reported between 2006 and 2009

Reacțiile adverse severe transfuzionale la pacienți: analiza cazurilor raportate între 2006 şi 2009

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Abstract

Adverse reactions to blood transfusion are an important part of blood component therapy and their management is necessary in order to ensure transfusion security. Haemovigilance schemes have been developed in Romania since 2006. ***Materials and methods.*** *31 severe adverse transfusion reactions were examined in patients with blood component therapy in 19 clinics between 2006 and 2009. Transfusion accident report forms as well as the patients' pre- and post-transfusion blood samples were analyzed. Immunohematological, bacteriological and biochemical tests based upon an algorithm established according to the type of the suspected reaction were carried out.* ***Results and discussions.*** *Each patient was administrated an average of 3.5 blood components and the global incidence of adverse reactions was of 1 to 4473. Upon evaluating the distribution of reactions according to the type of component, it followed that 64% of them were due to erythrocyte components. Regarding the type of reaction, 93.5% were immune reactions while, as far as severity was concerned, 71% were minor reactions. No deaths were reported.* ***Conclusions.*** *Hospital physicians should be aware of the importance of haemovigilance schemes in order to be able to promptly recognize adverse reactions, adequately manage them, avoid them when possible and report them. The best method of transfusion risk management is based upon the quality system consolidation at all stages of the transfusion process.*

Keywords: *adverse reactions to transfusion, haemovigilance, imputability, transfusion security.*

Rezumat

Reacțiile adverse transfuzionale sunt o parte importantă a terapiei cu componente sanguine şi gestionarea lor este necesară pentru asigurarea securității transfuzionale. Activitatea de hemovigilență a început în Romania din 2006. ***Material şi metodă.*** *Au fost analizate 31 reacții adverse transfuzionale la pacienți trataţi cu componente sanguine în 19 clinici, între anii 2006-2009. S-au analizat formularele de declarare a accidentului transfuzional şi eşantioanele pre şi posttransfuzional de la pacienți. S-au efectuat testări de imunohematologie, bacteriologie şi biochimie pe baza unui algoritm ales în funcție de tipul de reacție suspectat.* ***Rezultate şi discuții.*** *Fiecare pacient a primit în medie 3,5 componente sanguine iar incidența globală a reacțiilor adverse a fost de 1 la 4473. Evaluînd repartiția reacțiilor pe tip de compononent, preparatele eritrocitare au fost la originea a*

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64% din reacţii. În ceea ce priveşte tipul de reacţie, 93,5% au fost reacţii de tip imun iar în privinţa gravităţii, 71% au fost reacţii minore, neexistând nici un deces. ***Concluzii.*** *Medicii din spitale trebuie să cunoască importanţa activităţii de hemovigilenţă pentru a putea să recunoască la timp reacţiile adverse, să le trateze corespunzător, să le evite cînd este posibil şi să le declare. Cea mai bună metodă de gestionare a riscului transfuzional se bazează pe consolidarea sistemului calităţii în toate etapele procesului transfuzional.*

Cuvinte cheie. *Reacţii adverse transfuzionale, hemovigilenţă, imputabilitate, securitate transfuzională.*

Introduction

In recent years, thanks to technological and scientific progress, the immunological and infectious risks associated to blood transfusion therapy have considerably decreased; however, risk reduction remains one of the specialists' permanent concerns (1-3). Haemovigilance is now part of the transfusion quality and security system. The concept was taken by the National System of Blood Transfusion from the European legislation and is provided by law 282/2005 as supplemented by specific enforcement norms (4, 5). The Blood Transfusion Regional Center in Tirgu-Mures (BTRC), as a regional coordinator of haemovigilance, has, among others, the responsibility of analyzing transfusion adverse reaction cases reported by the belonging hospitals, in order to elaborate strategies for blood transfusion risk management. The results of these surveys were included in the annual haemovigilance report, which is a most useful source of information in point of transfusion security improvement (6).

Materials and methods

The present study represents a part of a detailed retrospective analysis of transfusion severe adverse reactions in transfused patients in clinics and hospitals from Mureş district. 31 cases reported by 19 clinics to which BTRC Tirgu-Mures distributes blood components on a daily basis were analyzed over a four year period.

These reactions were first signaled in 2006 by disseminating the transfusion accident statement form, together with the incriminated product, the pre transfusion sample and a post transfusion blood sample from the patient. BTRC Tirgu-Mures introduced the statement form in 2005. It contains information about the patient: personal data, the reporting medical unit, transfusion history, basal disease, clinical signs that suggest a transfusion reaction, data about the incriminated product. The examination of transfusion reactions was carried out according to a protocol that included laboratory investigations according to the suspected type of reaction: visual inspection, immunohematological control (ABO Rh typing, irregular antibody detections, Coombs Direct test, compatibility tests – the technique of agglutination in DiaMed gel), bacteriological control (inseminations - automatic BacT/Alert system), hematological control (Hb, Ht, blood test – Celltak analyzer), biochemical control (Bi, LDH typing etc - Vitros system) (6).

Results

During the reported interval, 61 217 standard and aphaeresis blood donations were performed in BTRC Tirgu-Mures. Upon processing, 138 669 blood components resulted (*Table 1*) which were distributed to the clinics and administered to 42 214 patients, with each patient receiving an average of 3.3 blood components.

Over this period 31 adverse transfusion reactions were reported in transfused patients (*Table 2*). The global incidence of adverse reactions was of 1 to 4 473 components.

The analysis of the degrees of imputability (the probability that one adverse effect noticed in one transfused patient be attributed to the respective component) showed that the excluded and possible ones (degrees 0 and 1) were found in 51% of cases, the probable and certain ones (degrees 2 and 3) - in 17% of cases, while in 32% of cases there were not sufficient data to evaluate imputability.

Table 1. Blood components distributed by BTRC Tirgu Mures betwen 2006-2009

Blood components	Year			
	2006	**2007**	**2008**	**2009**
Red cells	14245	14143	13170	17042
Platelets	6848	5507	5954	6063
Fresh frozen plasma	11241	12236	12014	16711
Cryoprecipitate	1543	1003	589	360
TOTAL	33877	32889	31727	40176

Table 2. The distribution of adverse reactions depending on the level of imputability

Level of imputability	Number of adverse reactions			
	2006	**2007**	**2008**	**2009**
Indeterminate	3 (50%)	1 (20%)	4 (33,3%)	2 (25%)
0	1 (16,6%)	3 (60%)	3(25%)	1(12.5%)
1	2 (33,3%)	0	3 (25%)	3 (37,5%)
2	0	1 (20%)	1 (8,3%)	2 (25%)
3	0	0	1 (8,3%)	0

Table 3 . The distribution of adverse reactions by type of blood component

Blood components	Adverse reactions			
	2006	**2007**	**2008**	**2009**
Red cells	5	3	7	5
Platelets	1	0	2	1
Fresh frozen plasma	0	2	3	2
Cryoprecipitate	0	0	0	0
TOTAL	6	5	12	8

Upon evaluating the distribution of adverse reactions according to the type of blood component (*Table 3*) it can be noticed that red cells blood components are at the origin of 64% of the reported reactions.

The distribution based on the type of diagnosis after confirmation (*Figure 1*) shows a preponderance of immune reactions consisting in 51.6% allergic reactions / anaphylaxy, 29% non-hemolitic fever reactions and 12.9% cases in which immunological incompatibility was confirmed between the transfused component and the patient. Regarding immunological incompatibility, two cases showed acute hemolysis by ABO incompatibility due to an error in patient identification. Four of the allergy cases were anaphylactic shocks but the enquiry established possible imputability in only one case.

Discussion

Adverse reactions to blood transfusions are generally classified in immune or non-immunological, immediate or delayed, infectious or non-infectious, minor or serious (7-10). Physicians who use blood components are aware that these reactions do not always follow a clinical pattern and it is often difficult to eval-

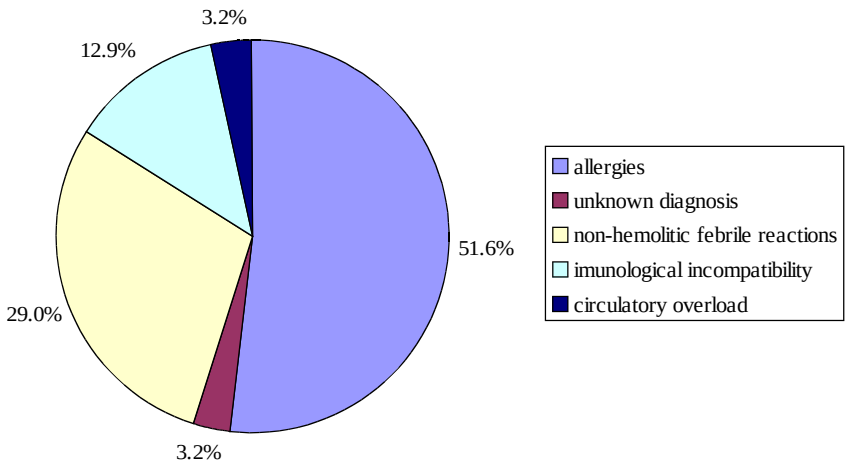

Figure 1. The distribution of adverse reactions depending on the type of diagnostic after confirmation

uate them so as to start adequate therapy in the respective patients (11-15).

Each year about 300 000 patients benefit from blood components therapy in Romania. Taking into consideration the diversity of the possible adverse reactions, we believe that there are more cases than actually reported, especially because there are very many hospitals where the haemovigilance system is still just beginning, while in others it hasn't been initiated as yet. A four year trend comparative analysis of reported cases shows a slight increasing tendency, which can be explained by the fact that, on the whole, hospitals have become aware of the necessity to report cases. However, there are still many situations that are neglected, especially regarding incidents related to the transfusion process, which are not reported at present, although the legislation clearly stipulates this obligation (16). Regarding the degree of imputability, mention should be made that a straightforward causal relation was established in only 16% of cases, which shows that medical staff has become more concerned in reporting such reactions.

The evaluation of health consequences of adverse reactions shows that in 77% of cases there were no serious consequences (non hemolytic febrile reactions, minor allergies), only 16% showed high risk (hemolysis, anaphylactic shock); no death was reported. All these observations are positive aspects of blood transfusion security. Compared to other countries, the high rate of immune reactions highlights the crucial importance of immunological risk related to blood component therapy, a risk that is difficult to manage due to genetic polymorphism as well (17 - 19).

Conclusions

Physicians in hospitals should be aware of the importance of haemovigilance schemes for the early detection of adverse reactions, in order to treat them properly or to avoid them when possible. Experience has demonstrated that the best method of preventing and managing adverse transfusion reactions is based on improving the quality system in point of transfusion process both in blood transfusion center and in medical care unit.

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