Adverse reactions in blood and apheresis donors: experience from two Italian transfusion centres

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Background. Blood and apheresis donations are widely considered to be safe with a low incidence of adverse reactions and injuries; however, data reported in the medical literature on the prevalence of adverse events in donors and studies on the predictive risk factors for donor reactions are limited and contradictory.

Methods. From January 2002 to December 2006 we recorded every adverse reaction verified during 240,596 consecutive blood and apheresis donations (183,855 homologous whole blood donations, 6,669 autologous whole blood donations, 38,647 plasmapheresis, 2,641 plateletpheresis and 8,784 multicomponent donations) at the Italian Transfusion Centres of Verona and Ragusa,.

Results. Using a special, pre-arranged form within the quality system, a total of 686 adverse reactions (related to 0.28% of all donations) were recorded. Vasovagal reactions, mostly of mild intensity, were the most commonly observed adverse reactions, with a frequency of 0.20% (487/240,596). The frequency of the vasovagal reactions varied according to the different types of donation, being 0.19% (346/183,855) for homologous whole blood donations, 0.24% (16/6,669) for autologous whole blood donations, 0.16% (63/38,647) for plasmapheresis, 0.68% (18/2,641) for plateletpheresis and 0.49 (43/8,784) for multicomponent donations. Citrate toxicity was reported in 0.38% (189/50,072) of apheresis donations. Severe adverse reactions were very rare, as they occurred in 0.004% of the donations (10/240,596).

Conclusions. In conclusion, the results of our 5-year survey document that apheresis and blood donation are safe procedures for the donor with a low incidence of adverse reactions; the adverse reactions that did occur were mostly mild and resolved rapidly.

Key words: blood donation, apheresis, adverse events.

Introduction

Although apheresis and blood donation are generally considered to be safe procedures, the incidence of adverse effects in donors has not been determined in large, multicentre series of donations[1-9]. Moreover, data are lacking on the incidence of adverse effects of donations made with modern apheresis instruments[10-17].

In order to assess the rate of adverse reactions in a large number of Italian donors, we analysed all adverse events among blood and apheresis donors recorded at the Transfusion Centres of Verona and Ragusa between January 2002 and December 2006.

Patients and methods

This is a retrospective, multicentre study of all adverse reactions related to 240,596 consecutive homologous and autologous donations made between January 2002 and December 2006 at the Italian Transfusion Centres of Verona and Ragusa. The types

of donations made during the study period were homologous whole blood, autologous whole blood, plasmapheresis, plateletpheresis and multicomponent (plasma-platelets and platelets-red blood cells) donations.

All donations were collected using a 16-gauge needle inserted into a vein in the antecubital fossa. The minimum weight required for homologous whole blood and apheresis donations was 50 kg. For homologous whole blood donation, we collected 450 mLof whole blood from each donor. For autologous whole blood donation, we collected 350 mLof whole blood. Plasmapheresis (600 mL) was performed using a Haemonetics MCS+ or PCS+ machine (Haemonetics, UK) with a single-needle procedure. Plateletpheresis (approximately 500-600 mL) and multicomponent donations (approximately 540 mL) were performed using a Trima Accell cell separator (Gambro, USA) or a Haemonetics MCS+ machine with a single-needle procedure.

All adverse events were recorded by the staff in a specifically designed form. The adverse events occurring during or after the donation were classified as vasovagal reactions, citrate toxicity or other severe events (cardiopulmonary). Vasovagal reactions were divided into mild (pallor, weakness, dizziness, sweating, nausea and/or vomiting, hypotension, light-headedness, hyperventilation, irregular breathing and bradycardia), moderate (the above symptoms accompanied by transient unconsciousness) or severe (long-lasting loss of consciousness, convulsions, tetany and incontinence) reactions, while citrate toxicity was divided into mild/moderate (paraesthesias, flushed sensation, nausea and/or vomiting) or severe (tetany or seizure and cardiac arrhythmia). Our collecting staff underwent a training programme on the recognition, classification and treatment of adverse reactions, in order to standardise the recording of data.

We then analysed donors' age, weight, sex, donation status and blood pressure in order to discover possible risk factors associated with severe reaction during or after donations.

Results

We recorded a total of 240,596 donations during the study period (183,855 [76.4%] homologous blood, 6,669 [2.8%] autologous whole blood blood, 38,647 [16.1%] plasmapheresis, 2,641 [1.1%] plateletpheresis and 8,784 [3.6%] multicomponent donations).

Figure 1 shows the different type of donations made during the study period.

Table I shows the adverse-effect rates for each type of donation. Overall, 686 adverse events were reported in relation to the 240,596 donations for an overall adverse-event rate of 0.28 percent and an incidence of 1 every 350 donations.

Vasovagal reactions, mostly of mild intensity, were the most commonly observed adverse reactions, with a frequency of 0.20% (487/240,596). The frequency of vasovagal reactions according to the different types of donation was 0.19% (346/183,855) for homologous whole blood donations, 0.24% (16/6,669) for autologous whole blood donations, 0.16% (63/38,647) for plasmapheresis, 0.68% (18/2,641) for plateletpheresis and 0.49 (43/8,784) for

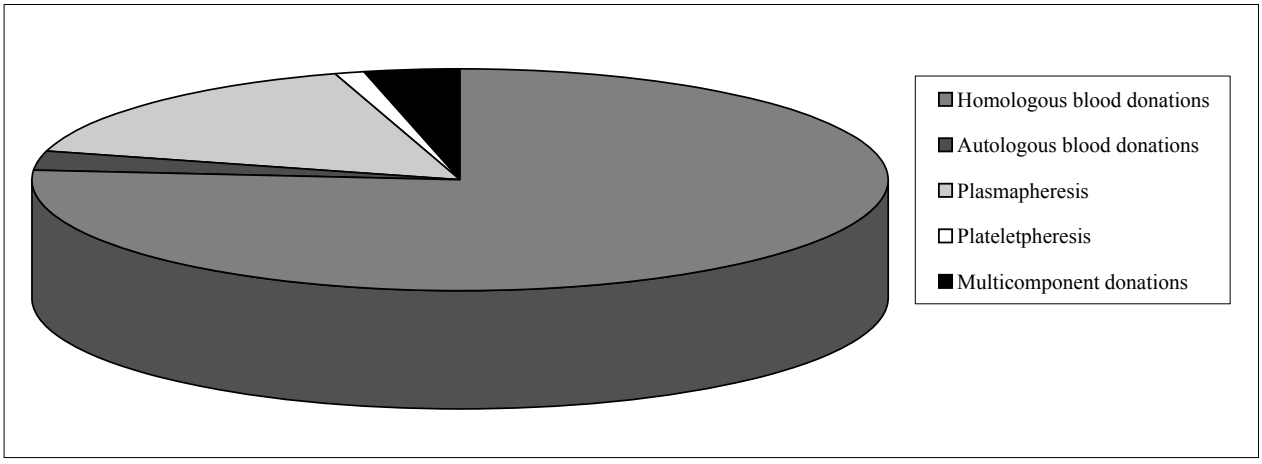

Figure 1 - Type of donations during the study period

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Table I - Adverse reactions occurring during apheresis donations

Adverse reactions	Donations (n = 240,596)*				
	Homologous WBD (n = 183,855)	**Autologous WBD** (n = 6,669)	**Plasmapheresis** (n = 38,647)	**Plateletpheresis** (n = 2,641)	**Multicomponent** (n = 8,784)
Vasovagal reactions					
Total	346 (0.19%)	16 (0.24%)	63 (0.16%)	18 (0.68%)	43 (0.24%)
Citrate toxicity					
Total	- -	- -	189 (0.38%)**	189 (0.38%)**	189 (0.38%)**
Severe adverse events	6 (0.003%)	3 (0.04%)	- -	- -	1 (0.01%)

Abbreviations: WBD, whole blood donations. Results are expressed as number (percentage). *Donations during the period January 2002 – December 2006. **Pooled incidence (all apheresis procedures = 50,072).

multicomponent donations. Citrate toxicity was reported in association with 0.38% (189/50,072) of apheresis donations.

Overall, vasovagal reactions and citrate toxicity were mostly of mild intensity. Severe adverse reactions were very rare, as they occurred in relation to 0.004% of the donations (10/240,596) and none necessitated hospitalisation of the donor. During preoperative autologous blood donation we recorded two episodes of atrial fibrillation in patients who had previously been successfully treated for this pathology; these episodes responded quickly to treatment. Figure 2 and table I summarize the adverse events occurring during the study period.

The results of the parameters analysed among the 10 donors who had severe reactions are reported in table II No statistically significant differences were observed between the characteristics of donors who had reactions and those of our historical group of normal donors[18].

Table II - Characteristics of the donors who had severe reactions (n = 10)

Parameters analysed	Donors (n = 10)
Age (years)*	29.6 (21-40)
Weight (kg)*	64.3 (57-80)
Sex	6 males /4 females
First donation	2/10
Blood pressure*	110.2 (95-130) 78.2 (70-85)

* median value (range)

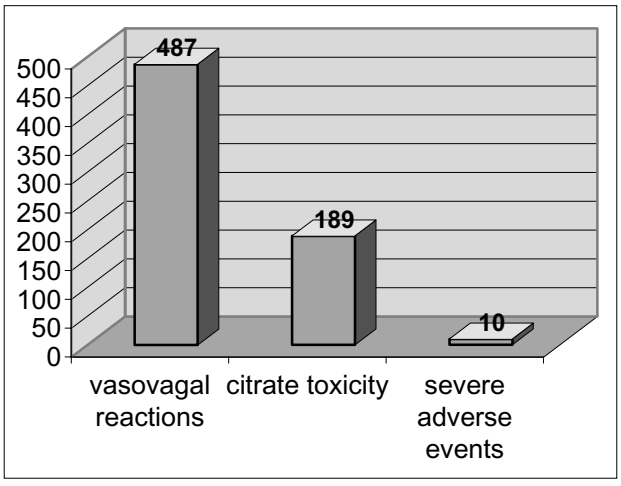

Figure 2 - Types of adverse reactions

Discussion

The aim of this study was to assess the frequency of and the predictive factors for adverse reactions during blood and apheresis donations. Although these procedures are considered to be safe, data reported in the medical literature about the frequency of adverse events during donations show a broad heterogeneity[2-4]. Furthermore, most reports come from multicentre studies with marked centre-to centre variation in adverse events rates[1]. Although our data were collected from two Italian centres, the incidences of adverse events were similar thus allowing analysis of a homogeneous set of data.

Donation-related adverse events were recorded according to standardised criteria. However, a classification of complications related to blood donations has recently been implemented in accordance with the Guidelines of the International Society of Blood Transfusion.

In our study, 0.3 percent of all donations (homologous and autologous blood, plasma and

platelet apheresis, multicomponent donations) were complicated by an adverse event. This incidenceis lower than that reported in a recent study conducted in the United States[19]. Seventy-one percent (487/686) of all adverse effects were vasovagal reactions of mild to moderate intensity and most of them (71.2%, 346/486) were observed during homologous blood donation. The low rate of vasovagal reactions (0.24%) observed during or after autologous donations is consistent with data from previous studies indicating that adverse reactions in autologous blood donations are not more frequent that during homologous blood donations[20,21]. As regards citrate toxicity, the overall incidence found in our study (0.38%, 189/50,072) is similar to that observed in earlier studies[10,11,15,16]. Finally, like other authors[3,22], we found a low incidence of severe reactions (0.004%, 10/240,596) with no episodes necessitating hospitalisation of the donor and no difference in reaction rates according to the type of donation. None of the parameters analysed (i.e., sex, age, body weight, donation status and blood pressure) was predictive of a severe reaction.

In summary, only 0.3 percent of our blood and apheresis donations were complicated by an adverse event, and most of the adverse events were mild vasovagal reactions. Thus, our study, conducted in two Italian Transfusion centres, underlines the safety of blood and apheresis donations and the very low incidence of adverse events associated with such donations.

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