

Original article

Blood donors – Serious adverse reactions (SAR) 2010–2014 EFS Châteauroux, France

Effets indésirables graves donneurs (EIGD) 2010–2014, EFS Châteauroux

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Abstract

Background. – In 2013, the national French incidence of serious adverse reactions (SAR) was 155.7 per 100,000 donations and 82% of SAR were grade 2 (French classification of SAR related to blood donors)

Aims. – The purpose of our study was to describe the profile of blood donor candidate which had a SAR in our center.

Methods. – The study contains all the SAR superior to grade 1 occurred on the site EFS Châteauroux (site and mobile blood collection) from January 2010 to October 31, 2014. We analyzed 37 parameters from the e-fit files (e-site French blood vigilance) and In-log software.

Results. – We identified 82 SAR for 72,553 blood donations (incidence: 113.02 SAR per 100,000 donations). Forty-one men and 41 women, middle age 39 years (18–66). Average height: 1.68 m (1.49–1.85); average weight: 68 kg (50–98); body mass index (kg/m²): 24.13 (18.6–31.9). All donors were Caucasian and 30% unemployed. We found 74 vasovagal syncope (VVS), 5 hematomas, 2 arterial injuries and an adverse reaction to citrate. In 90%, the SAR was immediate and of grade 2 in 85% of cases. Thirty-seven percent of SAR were first donation in connection with whole blood in 87% of cases. Regarding the seniority of donors, the number of average donations (whole blood, plasma, platelets) was 16.5. An SAR determined the stop of blood donation in 65% of cases with nearly 80% stoppage if it was a first donation. Seventy-three percent of SAR as a VVS took place during blood collection or within 5 minutes following the end of the donation. Sixty-one percent were men. Forty-four percent of cases were a first donation and 83% occurred in mobile blood collection. Average age was 36 years. The result was a permanent stop of all type of donations in 76% of cases. Twenty-seven percent of SAR as a VVS took place beyond 5 minutes after the end of the donation. Seventy-five percent were women. Thirty percent of cases were a first donation and 95% of SAR occurred in mobile blood collection. Average age was 42 years. The result was a permanent stop of all type of donations in 40% of cases.

Conclusions. – When the SAR as a VVS occurs during or within 5 minutes following the end of the donation, it leads to a permanent stop of any type of donation in 76% of cases.

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Keywords: Blood donors; Vasovagal syncope; Adverse reactions; Donation time course; Donor vigilance

Résumé

Introduction. – En 2013, l'incidence nationale était de 155,7 EIGD pour 100 000 dons dont 82 % étaient de grade 2. Le but de notre étude était de décrire le profil du candidat au don du sang ayant eu un EIGD dans notre centre.

Matériel et méthode. – L'étude contient tous les EIGD supérieurs au grade 1 survenus sur le site de Châteauroux (collecte mobile, collecte en site fixe) de janvier 2010 au 31 octobre 2014. Nous avons analysé 37 paramètres à partir des fiches *e-fit* et du logiciel *In-log*.

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Résultats. – Nous avons recensés 82 EIGD pour 72 553 dons (incidence de 113,02 EIGD pour 100 000 dons). Quarante et un hommes et 41 femmes, d'âge moyen : 39 ans (18–66). Nous avons trouvé 74 malaises vagues, 5 hématomes, 2 blessures artérielles et une réaction au citrate. Dans 90 %, l'EIGD était immédiat et de grade 2 dans 85 % des cas. Dans 37 % des cas, il s'agissait d'un premier don, en rapport avec du sang total dans 87 %. L'apparition d'un EIGD entraînait un arrêt définitif de tout don dans 65 % des cas avec près de 80 % s'il s'agissait d'un premier don. Soixante-treize pour cent des EIGD sous la forme d'un malaise vagal avaient lieu pendant le prélèvement ou dans les 5 minutes qui suivaient son arrêt. Soixante et un pour cent étaient des hommes. Dans 44 %, il s'agissait d'un premier don. Cela entraînait un arrêt définitif de tout don dans 76 %. Vingt-sept pour cent des EIGD sous la forme d'un malaise vagal avaient lieu au-delà de 5 min après la fin du prélèvement. Soixante-quinze pour cent étaient des femmes. Dans 30 %, il s'agissait d'un premier don. Cela entraînait un arrêt définitif de tout don dans 30 %.

Conclusion. – Lorsque l'EIGD sous la forme d'un malaise vagal se produit pendant le prélèvement ou dans les 5 minutes qui suivent son arrêt, il entraîne un arrêt définitif de tout don dans 76 % des cas.

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Mots clés : Donneurs de sang ; Malaise vagal ; Mauvaise réaction ; Moment du don ; Vigilance donneur

1. Introduction

In 2013, the national French incidence regarding blood donor serious adverse reactions (SAR) was 155.7 per 100,000 donations and 82% were of grade 2 [1]. The aim of our study was to describe the profile of a candidate to blood donation which had a SAR in our center in a period of 5 years, between 2010 and 2014.

2. Material and method

This is a retrospective study containing all the SAR superior to grade 1 occurred on the site EFS Châteauroux (site and mobile blood collection) from January 2010 to October 31, 2014. We analyzed numerous parameters from the e-fit files (e-site French blood vigilance) [2], computer files (In-log Software Version 5.65) and the paper report form for SAR. The following parameters were studied and listed: date of the SAR, donation number on SAR, type on SAR, site of SAR (site blood collection/mobile blood collection), occurrence of the SAR (immediate/late), E-fit files classification (grade 2, 3 or 4 and accountability), day of the week, time of year (winter, spring, summer, autumn), time of blood donation (morning/afternoon), date of birth, place of birth, age, sex, height, weight, BMI (body mass index), marital status (single/married), socioprofessional category (SPC), active/unemployed/retired, somatic type (endomorph, mesomorph, ectomorph), status of the donor (first donation/known donor), number of previous donations, type of donation (whole blood, plasma, platelets), blood pressure before donation, total blood volume (VST) (liters), calculation of VST “rule of 5 – Gilcher” [3], blood volume withdraw (ml), blood volume withdraw compared to total blood volume (VST) (< 13% whole blood/< 16% plasma), theoretical volume (mL) according charts (whole blood chart 01.07.2012; plasma chart: 13/09/2010), duration of blood donation (minutes), hemoglobin level before blood donation, drug treatment the day of blood donation, prior SAR (number and type), comments/miscellaneous, immediate and late consequences (stop of the blood donation or continuing the blood donation).

3. Statistical analysis

We studied, using χ^2 and Student tests, the statistical variability of each characteristic of the donors who have had a vasovagal syncope (VVS) in relation with the occurring time of the faintness (during/after donation, immediately or later).

4. Results

We identified 82 serious adverse reactions for 72,553 blood donations (incidence: 113.02 SAR per 100,000 donations) occurred on the site EFS Châteauroux over a period of 5 years, between 1st January 2010 and 31 October 2014.

The proportion comprised as many men (41) as women (41), with these average characteristics: age 39 years (18–66), height: 1.68 m (1.49 to 1.85), weight 68 kg (50–98), BMI: 24.13 (18.6 to 31.9).

All were Caucasian, 30% of them unemployed. We accounted 74 VVS, 5 hematomas, 2 arterial injuries and one reaction to citrate.

The characteristics of the donors who had a VVS and their classification according to the moment of the faintness are revealed by Table 1.

In 90% of cases, the SAR was immediate and of grade 2 in 85% of cases. In 37% of cases (31/82), it was a first donation in connection with whole blood in 87% of cases (27/31). In other cases, the average number of previous donations (whole blood, plasma, platelets) was 16.5 donations. The appearance of a SAR stopped the donation in 65% of cases (53/82) with nearly 80% (25/31) in case of the first donation.

We studied in a precise manner the VVS considering the fact that they represented more than 90% of SAR in our study. We have identified different groups according to the occurring moment of the vagal faintness in connection to the start of blood donation.

Twenty-one percent (16/74) of SAR (14 whole blood, 2 plasma) in the form of a VVS took place within <5 minutes after the start of blood donation (period I). In 86% (14/16), the donor was a man, in 62% (10/16) a first donation and in 100% of cases a mobile blood collection. This resulted in a final stop of any donation in 87% of cases (14/16).

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