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TRANSFUSION
CLINIQUE ET BIOLOGIQUE

ELSEVIER
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Transfusion Clinique et Biologique xxx (2015) xxx–xxx

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 donator 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/m^2): 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.

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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http://dx.doi.org/10.1016/j.tracli.2015.04.002
1246-7820/

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 vagaux, 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.

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 1). 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).

Please cite this article in press as: Riga A, et al. Blood donors' – Serious adverse reactions (SAR) 2010–2014 EFS Châteauroux, France. Transfusion Clinique et Biologique (2015), http://dx.doi.org/10.1016/j.tracli.2015.04.002

Table 1
Characteristics of the 74 donors experiencing vasovagal syncope (VVS) according to the moment of appearance in time: before, during and/or after the blood donation.

Characteristics of donors	Period 1 *n*: 16	Period 2 *n*: 38	Period 3 *n*: 20
Type of blood collection	14 WB, 2 PL	27 WB, 7 PL, 4 PT	19 WB, 1 PL
Place of blood collection			
Site	0	9	1
Mobile	16	29	19
Age	31 years (18–48)	39 years (18–64)	42 years (19–65)
Sex	14 M, 2 W	19 M, 19 W	5 M, 15 W
Weight	72 kg (53–95)	70 kg (55–90)	65 kg (52–80)
Height	1.73 m (1.56–1.95)	1.69 m (1.51–1.83)	1.63 m (1.5–1.7)
BMI	24 (18–29)	24 (19–32)	24.4 (19–32)
Day of the week	30% Thursday	23% Friday	30% Wednesday
Season	40% Spring	34% Summer	35% Autumn
AM/PM	50%/50%	43%/57%	40%/60%
Rank SAR	2: 87%; 3: 13%	2: 85%; 3: 15%	2: 90%; 3: 10%
Activity	40% unemployed	26% unemployed	35% unemployed
Type somatic	62% Mesomorph	79% Mesomorph	75% Mesomorph
Ethnic	100% Caucasian	100% Caucasian	100% Caucasian
First blood donation	62%	37%	30%
Volume	76.8 ml (0–200)	409 ml (34–730)	473 ml (411–805)
Volume/Total blood volume			
Whole blood	100% < 13%	100% < 13%	100% < 13%
Plasma	100% < 16%	100% < 16%	100% < 16%
Blood pressure			
Systolic	119 mmHg (90–130)	120 mmHg (110–150)	121 mmHg (100–120)
Diastolic	71 mmHg (60–90)	70 mmHg (70–90)	70 mmHg (60–80)
Duration of blood donation	1.5 mn (0–4)	18.4 mn (5–85)	9.5 mn (5–55)
Hemoglobin	14.4 g/dl (12.5–16)	14.3 g/dl (12–16.4)	13.6 g/dl (12.5–14.7)
Donor with previous serious side effects (SAR)	1	1	0
Medical treatment			
Yes	1	9	7
No	15	29	13
Stop of subsequent blood donation after SAR	87% (14/16)	71% (27/38)	40% (8/20)

WB: whole blood; PL: plasma; PT: platelets; M: men; W: women; BMI: body mass index; SAR: serious adverse reactions. Period 1: VVS < 5 min according to the beginning of the blood donation. Period 2: VVS > 5 min after the beginning of the blood donation or within 5 minutes following the end of the donation. Period 3: VVS beyond 5 minutes after the end of the donation.

Fifty-two percent (38/74) (27 whole blood, 7 plasma, 4 platelets) of VVS took place during blood donation (time > 5 min) or within 5 minutes after the end of the blood donation (period 2). There were as many men (19) as women (19). In 37% (14/38), it was a first donation and in 76%, the VVS took place in a mobile blood collection. This resulted in a final stop of all donations in 71% (27/38).

Twenty-seven percent (20/74) (19 whole blood, 1 plasma) of the VVS took place at least 5 minutes after the end of blood donation (period 3). Seven of twenty VVS took place outside the site. There were more women (15) than men (5). In 30% (6/20), it was a first donation and 95% took place in a mobile blood collection. This resulted in a final stop of all donations in 40% (8/20).

In all, 52% (39/74) of donors who have had a VVS had a complete blood donation.

The statistical variability of the characteristics of donors who have had a VVS depending on the occurring moment of it compared to the period of blood donation revealed that men have more VVS than women during the 1st and 2nd period ($P < 0.05$). VVS occurring during the period 1 were most often in mobile blood collection ($P < 0.05$). Donors who had a VVS during

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period 1 and 2 in relation to the period 3 were the most likely those who abandoned blood donation ($P < 0.05$).

5. Discussion

Our retrospective study has the advantage of a number SAR in the range of the national average, which is a guarantee of a good representation of the population studied. We have shown few serious SAR: 15% grade 3 and no grade 4.

Our classification regarding the VVS depending on the moment of appearance compared to the period of blood donation follows the pathophysiological mechanism. In fact, there are two periods well defined in the pathophysiology: an immediate before blood donation period and one late post-blood donation period. The immediate before blood donation period goes to 4–5 minutes after stopping the blood donation, in connection with a neurocardiogenic mechanism and the late post-blood donation period (>4–5 minutes) after the end of blood donation in relation to orthostatic position and hypovolemia [4,5].

In our study, we distinguished these two periods, but by breaking the first one in 2 parts in an attempt to determinate the potential differences. We found the same results as Bravo et al. [5], with the major difference we observe that when the VVS occurs during or within 5 minutes after blood donation, it causes a stop of any future blood donation in 76% of cases.

These results have, to our knowledge, never been described in the literature and show how the VVS can be a further obstacle to blood donation. The spectacular character of a VVS when the blood donation just started and the fact that most of these vagal reactions took place on a mobile blood collection is probably a decisive factor for stopping further blood donation (fear of another vagal faintness). This last criterion was already highlighted by Bravo et al. [5]. Donors experiencing a late VVS (5 minutes after the end of blood donation) have less total cessation of further blood donations.

Nevertheless, it must still be noted that in our study, 52% of donors who have had a VVS achieved a complete blood donation.

We have not highlighted any faintness variability in relation to prescribed blood volumes (420 ml/450 ml/480 ml in the whole blood chart, and in the plasma chart). Therefore, regardless of the charts, the blood volume initially requested does not determine the VVS which is related to the characteristics of each donor and other psychological and hormonal components.

Indeed, we have shown that more women than men had VVS in the post-blood donation period. This has been demonstrated by Tomasulo et al. [4]. In this study, the duration of the VVS was also higher among women than men (we do not have this data in our study). The regulation of blood pressure is different depending on sex [6,7]. Regulation of orthostatic position and its tolerance is less efficient in women, explaining that they are more susceptible to VVS in late post-donation [8]. Estrogens decrease the renin-angiotensin system unlike testosterone that reinforces it [9]. This phenomenon explains our results and allows to understand why men have a better adaptation to orthostatic problems.

Several studies have demonstrated the interest of drinking 15–20 minutes before the blood donation (mineral water, juice, etc.) and muscle tension manoeuvres during the blood donation which can improve the venous circulation [6,10–12], this being a research point to consider in the future.

6. Conclusions

In our study, most of serious adverse reactions were of grade 2. The VVS represented 90% of the SAR. When these vagal reactions occurred during blood collection or within 5 minutes following the stop of blood donation, this meant the total abandonment of any subsequent blood donation in 76% of cases. It is therefore imperative to find and implement preventive measures adapted to the pathophysiological mechanism.

Disclosure of interest

The authors have not supplied their declaration of conflict of interest.

Acknowledgements

Dr. Riga and Dr. Sapey contributed equally to the study. Dr. Bacanu contributed at the elaboration of the study. Dr. Py and Dr. Dehaut reviewed the manuscript.

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