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Predictive Tools in the Care of Blood Donors: Prevention of Vasovagal Syndrome

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Abstract

Prediction in healthcare is essential in order to promote safe and quality care. Taking adequate care of blood donors, who perform an altruistic act towards society, is paramount. Therefore, the use of tools which allow to predict the risk of Vasovagal Syndrome during the act of blood donation is necessary. The objective of this study is to design a predictive engine of an expert system to determine the risk of Vasovagal Syndrome through the use of deductive methodology. Five clusters of predictors of this syndrome were obtained by applying grouping tables of the variables established by logical formulation in such a way that after combinatorial variables, 5 values were obtained for the determination of risk using a Lickert scale. With these results we could design the predictive engine that will allow the development of a computational tool to improve the quality of care of blood donors.

Keywords: Blood donation, Syncope Vasovagal, Adverse effects

Introduction

The Spanish National Transplant Organization (ONT) defines donation as "an altruistic gesture, considered the greatest act of kindness among human beings." [23] including blood donation, among the various types of donation.

This type of donation guarantees the transfer of an essential element for life: blood, with three essential functions within the whole organism: transport, regulation and protection[22].

The World Health Organization (WHO) advocates a blood donation with an altruistic social base, since this practice is not the same in all territories[19].

The concept of unpaid blood donation expressed by the Council of Europe is: "*The donation is considered voluntary and unpaid when the person donates blood, plasma or cellular components altruistically and does not receive financial compensation, either monetary, or in another form that could be considered a substitute for money, including a free time at work that is greater than reasonable for the movement and donation*"[3].

The principles of blood donation are: freedom, gratuity, anonymity, solidarity and responsibility[21].

Blood donation is an act in which the principle of beneficence has a dual purpose: not to cause harm to the donor or the recipient of the blood[10].

Although blood donation is a safe procedure, and despite all the benefits it provides to recipients, the process of donation can entail potential adverse effects (AEs) to the donor. The ability to predict these AEs would warn healthcare professionals in advance, and allow them to undertake preventive measures or treat them quicker in the event of their occurrence.

The International Society of Blood Transfusion and Hemovigilance Network ISBT / EHN standardized blood donation-related AEs in 2008. This study included category B, "complications with generalized symptoms" such as vasovagal reactions[20].

Blood donation-related complications or AEs are defined as "*any unexpected event that arises in the donation process and that puts the integrity, stability and / or health of the donor at risk, causing disability and / or illness*."[14].

In a retrospective study conducted at the Blood Bank Department of the Ignacio Chavez National Institute of Cardiology during the years 2006 and 2009, a total of 1789 AEs were reported among 31,176 donors. The most frequent AEs included dizziness (91.5%) followed by 43.2% pallor (43.2%) and, less commonly: diaphoresis, syncope, vomiting, seizures, tingling, chills, dyspnea and sphincter relaxation[15].

In another study conducted in Italy in 2008, AEs among a total of 89,332 donations were analyzed. A total of 523 AEs (0,59% of all donations) and 978 symptoms were identified. A total of 15% of reported symptoms were related to venipuncture (mainly bruising) and 77% were vasovagal reactions[8].

According to Múnera, "*the most frequently reported symptoms include weakness, diaphoresis, cold skin and pallor which, in most cases, are due to vasovagal reactions due to the psychological stress of the situation or to neurological factors*"[16]

According to the 2013 Hemovigilance Report of the Spanish Ministry of Health, Social Services and Equality, a total of 9090 incidents among a total of 1,698,097 donations were notified during 2012. Among these, 88% of them were due to vasovagal reactions and 12% to local symptoms [9]

Previous studies report vasovagal reactions as the most frequent blood donation-related AEs.

Vasovagal reactions are caused by a neurogenic reflex that causes hypotension due to vasodilation and an inadequate chronotropic response. It is the most common cause of syncope[4; 12]. These reactions are subdivided into severe and moderate with an overall prevalence which ranges from 1.4% to 5-7% among different series[2; 17].

Vasovagal reactions are the most common hypotensive reactions after blood donation. Psychological reactions along with hypovolemia predispose to syncope. Youth and the first donation are risk factors for blood donation-related AEs[7; 13].

Younger age, weight and the first episode of blood donation are the most relevant risk factors for blood donation-related AEs. In addition, long periods of fasting (between 4 and 23 hours), fear, stress and nervousness are predictors of donation-triggered AEs [2; 5; 15; 17].

Studies by Newman et al [18], Kamel et al [13]and Múnera et al [16], suggest that women are more likely to suffer AEs after donation than men. In the study by Newman et al, ethnicity (African vs Caucasians) did not impact the risk of donation-related AEs ($p = 0.30$), but age < 30 years ($p <0.002$) and weight < 150 pounds (68.04 kg) ($p <0.0001$) predicted for higher risk of blood donation-r elated AEs[18]. In another study by Kamel et al, Hispanic donors were more likely to suffer AEs than Caucasians[13].

The occurrence of adverse reactions during blood donation can lead to a negative psychological effect on potential donors. Most of whom could rely on the experience of others as an argument to refuse to donate blood[16].
Blood donation produces a series of rapidly reverted changes in the donor. These changes do not generally lead to significant changes on circulating blood volume due to the rapid start-up of the regulatory mechanisms that adequately maintain the hemodynamic equilibrium. These changes include: decrease in blood pressure, cardiac output and oxygen transport; increase in heart rate and body temperature by approximately 2ºC.
Replenishment of plasma and platelets are the first to occur within the first 24-48 hours after donation. Red blood cell recovery may delay for around 3 weeks[1]. Other variables such as temperature and cardiac output are normalized after 48 hours[11].
In addition to the described AEs, another complication that may be observed in blood donors is iron deficiency, which may manifest within 45-60 days from donation, and may lead to donation-related iron deficiency anemia[6].
The blood donation services have the responsibility of developing strategies to prevent and rapidly detect the presence of AEs in donors who come to their facilities.
Temporary or permanent rejection criteria may apply when evaluating potential donors as established by the Royal Decree 1088/2005 of September 16.
According to the aforementioned Royal Decree, the total extracted blood volume in each donation is 500 ml. Of these, 450 ml are destined to donation and 50 ml to perform infectious assessments, and hematimetry tests among others, marking the average time of the donation be 20-30 minutes.
The aims of this study include:
To validate the previously described variables in the appearance of the Vasovagal Syndrome in blood donation.
To design a predictive model to determine the risk of suffering a Vasovagal Syndrome in the act of blood donation.

Methods

This study was conducted at the University of Alcalá (Spain) from January 2016 to January 2017 within the MISKC research group (Management About Information and Standard Knowledge of Care)
In the first phase of the study, a bibliographical search was carried out in PubMed, Scopus and Web of Science databases, using the terms MeSH Blood donation, adverse effects and Syncope vasovagal, and the term AND. Included articles were limited to those published after the year 2000. Articles published prior to 2000 could be included if considered of significant relevance. All selected articles included the search terms within their title or abstract.
In order to evaluate the study objectives, a logical formulation through bi-value logic was developed. Risk factors of donation-related vasovagal syndrome described in the included articles were selected as variables for this assay. A total of 12 risk variables were identified, and used to develop logical reasoning techniques for risk assessment to design deductive matrices, within the scope of deductive research.

Results

First, selected variables were defined that affect the risk of suffering a Vasovagal Syndrome in blood donation and that will allow creating the expert system designed to predict the risk of suffering vasovagal syndrome in this group.
These variables were:

SEX (a): Female / Male. Woman have the greatest potential risk to suffer a vasovagal reaction.
AGE (b): Donors under the age of 30 are the most likely to suffer vasovagal reactions. Ages under 18 or over 65 exclude from blood donation.
RACE (c): Hispanic race is associated with greater risk of suffering a vasovagal reaction compared to Caucasian or black.
WEIGHT (d): Donors whose weight is less than 68 Kg are more prone to this type of reactions. Weight less than 50 Kg excludes from blood donation.
SYSTOLIC ARTERIAL PRESSURE (e): Systolic arterial pressures below 100 mmHg may predispose to vasovagal reaction.
DIASTOLIC ARTERIAL PRESSURE (f): Diastolic arterial pressures below 60 mmHg may predispose to vasovagal reaction.
CAPILLARY HEMOGLOBIN (g): Hemoglobin below 13 gr / dl in women and 14 gr / dl. in men is a risk in the appearance of a vasovagal reaction.
FIRST DONATION (h): The first donation may increase the possibility of suffering a vasovagal reaction.
FASTING TIME (i): Fasting periods greater than 5 hours predispose to the appearance of vasovagal reaction.
ANXIETY (j): High levels of anxiety are favorable for the appearance of vasovagal reactions.
ENVIRONMENTAL TEMPERATURE (k): Environmental temperature during donation of more than 27 º C increases the possibility of suffering a vasovagal reaction.
Subsequently, the variables were related to group them according to the relationships between them obtaining a total of 5 sets of variables. These are:

VARIABLES RELATED TO GENETICS. (G)
Sex (a)
Race (c).
VARIABLES RELATED TO HUMAN BIOLOGY. (B)
Systolic blood pressure (e).
Diastolic blood pressure (f).
Capillary hemoglobin (g).
VARIABLES RELATED TO TEMPORALITY. (T)
Age (b).
Weight (d).
VARIABLES RELATED TO THE CONTEXT. (C)
First donation (h).
Fasting time (i).
Ambient temperature (k).
VARIABLES RELATED TO PSYCHOLOGY (j)
Anxiety (j).

These variables may or may not be present at the time of blood donation. In the event that the variable negatively affects the process, that is to say that it can produce vasovagal reactions, it will be scroed by a 1 and in case it is not 0. The relationship is detailed in figure 1.

Variable		Vasovagal reaction	¬Vasovagal reaction
Gender	Men	0	1
	Woman	1	0
Age	> 30 years	0	1
	< 30 years	1	0
Race	Hispanic	1	0
	Caucasian	0	1
	Black	0	1
Weight	> 68 Kg	1	0
	< 68 Kg	0	1
Systolic Arterial Pressure	> 100 mmHg	0	1
	< 100 mmHg	1	0
Diastolic Arterial Pressure	> 60 mmHg	0	1
	< 60 mmHg	1	0
Capillary Hemoglobin	Right	1	0
	Wrong	0	1
First donation	yes	1	0
	no	0	1
Fasting Time	> 5 hours	0	1
	< 5 hours	1	0
Anxiety	yes	1	0
	no	0	1
Environmental temperature	> 27º C	0	1
	< 27º C	1	0

Figure 1– Variables relationship

Subsequently, a total of 5 deductive matrices including the established variables, and a logical formulation corresponding to each of these results were developed. The genetic variable is taken as an example. (figure 2)

GENETICS (G)

gender (a) — race (c)

	a=1	a=0
c=1	2	1
c=0	1	0

	women	men
hispanic	high risk	medium risk
not hispanic	medium risk	low risk

Mathematical formulation
$a \wedge c \rightarrow g(2)$
$a \wedge \neg c \rightarrow g(1)$
$\neg a \wedge c \rightarrow g(1)$
$\neg a \wedge \neg c \rightarrow g(0)$
Legend: not (¬), and (∧), it implies (→)

Numerical value	Nominal value
2	high risk
1	medium risk
0	low risk

Figure 2– Genetic variable example

After this step, a combinatorial table (figure 3) with variables in which a total of 12 values were obtained to determine the risk. These values were grouped in pairs to obtain a Lickert type scale of risk measurement as shown below.

		j(1)											
		C(3)			C(2)			C(1)			C(0)		
		G(2)	G(1)	G(0)	G(2)	G(1)	G(0)	G(2)	G(1)	G(0)	G(2)	G(1)	G(0)
B(3)	T(2)	11	10	9	10	9	8	9	8	7	8	7	6
	T(1)	10	9	8	9	8	7	8	7	6	7	6	5
	T(0)	9	8	7	8	7	6	7	6	5	6	5	4
B(2)	T(2)	10	9	8	9	8	7	8	7	6	7	6	5
	T(1)	9	8	7	8	7	6	7	6	5	6	5	4
	T(0)	8	7	6	7	6	5	6	5	4	5	4	3
B(1)	T(2)	9	8	7	8	7	6	7	6	5	6	5	4
	T(1)	8	7	6	7	6	5	6	5	4	5	4	3
	T(0)	7	6	5	6	5	4	5	4	3	4	3	2
B(0)	T(2)	8	7	6	7	6	5	6	5	4	5	4	3
	T(1)	7	6	5	6	5	4	5	4	3	4	3	2
	T(0)	6	5	4	5	4	3	4	3	2	3	2	1

		j(0)											
		C(3)			C(2)			C(1)			C(0)		
		G(2)	G(1)	G(0)	G(2)	G(1)	G(0)	G(2)	G(1)	G(0)	G(2)	G(1)	G(0)
B(3)	T(2)	10	9	8	9	8	7	8	7	6	7	6	5
	T(1)	9	8	7	8	7	6	7	6	5	6	5	4
	T(0)	8	7	6	7	6	5	6	5	4	5	4	3
B(2)	T(2)	9	8	7	8	7	6	7	6	5	6	5	4
	T(1)	8	7	6	7	6	5	6	5	4	5	4	3
	T(0)	7	6	5	6	5	4	5	4	3	4	3	2
B(1)	T(2)	8	7	6	7	6	5	6	5	4	5	4	3
	T(1)	7	6	5	6	5	4	5	4	3	4	3	2
	T(0)	6	5	4	5	4	3	4	3	2	3	2	1
B(0)	T(2)	7	6	5	6	5	4	5	4	3	4	3	2
	T(1)	6	5	4	5	4	3	4	3	2	3	2	1
	T(0)	5	4	3	4	3	2	3	2	1	2	1	0

Numerical value	Nominal value
0	very low risk
1	low risk
2	medium risk
3	medium-high risk
4	high risk
5	very high risk

Figure 3– Variables value

Finally, the formulation of the combination of all the variables was carried out. This shows in the example the formulation of the combination that produces more and less risk in blood donation. In this way obtaining a result of 5 implies a greater risk of suffering a vasovagal syndrome in the act of blood donation. (figure 4)

Mathematical formulation
$j(1) \wedge c(3) \wedge g(2) \wedge b(3) \wedge t(2) \rightarrow 5$
$j(0) \wedge c(0) \wedge g(0) \wedge b(0) \wedge t(0) \rightarrow 0$
Legend: and (∧), it implies (→)

Figure 4– logical formulations

Discussion

To date, published studies evaluating the risk of blood-donation related vasovagal syndrome include analytical and descriptive studies of potential risk factors, but there is no study which uses deductive research in this field.

Current evidence suggests there are only protective actions against a possible risk. Such is the case of the study by Fisher et al in which the relative risk of vasovagal syndrome could be reduced by providing different amounts of water to donors prior to donation. However, this study does not establish the different magnitude of risk of donors depending on their individual characteristics.

Other studies have designed applications aimed at registering adverse effects in blood donations, including vasovagal syndrome. This tool would be destined to the epidemiological evaluation of this problem, but not to its prediction and, therefore, to its prevention.

Currently, the results of this study are being evaluated by a group of transdisciplinary experts among nurses and mathematicians. After this validation, the program development will proceed according to the IEEE std requirements specification. 830-1998 for its subsequent computational development.

This study has been the result of interest of the JUB SOLUTIONS company which has signed a collaboration agreement, financed for the creation of this tool in computer format.

Conclusions

In the present study, we have managed to evaluate the variables affecting blood donors during the act of blood donation and created the inference engine for the future application, which allows this measurement and prevent the appearance of a syndrome vasovagal in the act of blood donation calculating the risk of its occurrence.

Similarly, it has been possible to establish a predictive model based on a Lickert-type scale on risk measurement.

Caring for donors and preventing the appearance of negative events during the process of blood donation, will create a climate of safety for them by having blood donations repeated periodically, thus maintaining their reserves and benefiting the Patients who need transfusions improving their care in this way.

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References

[1] A.E. Ample I, La donacíon de sangre. In salud EVdedl. Administración de Sangre y Hemoderivados., *Copedio de Medicina Transfusional. Valencia. EVES.* (2004), 131.
[2] K. Amrein, A. Valentin, G. Lanzer, and C. Drexler, Adverse events and safety issues in blood donation--a comprehensive review, *Blood Rev* **26** (2012), 33-42.
[3] S.E.d.T.S.y.T. Celular, Guía sobre la transfusión de componentes sanguíneos y derivados plasmáticos, (2005).
[4] B. Danic, H. Gouezec, E. Bigant, and T. Thomas, Incidents of blood donation], *Transfus Clin Biol* **12** (2005),153-159.
[5] B. Danic and C. Lefort, Serious adverse effects of blood collection], *Transfus Clin Biol* **17** (2010), 301-305.
[6] C. Finch, Regulators of iron balance in humans, *Blood* **84** (1994), 1697-1702.
[7] S.A. Fisher, D. Allen, C. Doree, J. Naylor, E. Di Angelantonio, and D.J. Roberts, Interventions to reduce vasovagal reactions in blood donors: a systematic review and meta-analysis, *Transfus Med* **26** (2016), 15-33.
[8] G. Garozzo, I. Crocco, B. Giussani, A. Martinucci, S. Monacelli, and V. Randi, Adverse reactions to blood donations: the READ project, *Blood Transfus* **8** (2010), 49-62.
[9] U.d. Hemovigilancia, Hemovigilancia 2013. Madrid., (2013).
[10] B.H.A. Hernandez Diaz P, La ética y la ciencia en la donación de sangre voluntaria, *UNIV DIAG* (2000), 24-30.
[11] V.J. Hill D, Effect of plasma donation and blood donation on aerobic and anaerobic responses in exhaustive, several intensity exercise, *Applied Physiology, Nutrition and Metabolism* **28** (2013), 551-557.
[12] C.T. JE., Síncope., *Biomédica* (2015), 66-85.
[13] H. Kamel, P. Tomasulo, M. Bravo, T. Wiltbank, R.Cusick, R.C. James, and B. Custer, Delayed adverse reactions to blood donation, *Transfusion* **50** (2010), 556-565.
[14] C.R.L. Luna Mendoza L, Oropeza Uribe Y., Diseño y validación de un instrumento para el registro de reacciones adversas a la donación de sangre y sus componentes., *Revista Mexicana de Enfermeria Cardiológica* **21** (2013), 50-56.
[15] R.S.L. Luna Mendoza L, Cruz Rodriguez L., Incidencia de las reacciones adversas a la donación de sangre 2006 a 2009., *Enfermería Neurológica* **12** (2010), 76-80.
[16] R.S. Muñera MI, Zapata CM., Reacciones adversas inmediatas a la donación: frecuencis y caracterización, Banco de Sangre de la Clínica Cardiovascular Santa María, Medellín, 1999, *Biomédica* (2001), 224-227.
[17] B.H. Newman, Donor reactions and injuries from whole blood donation, *Transfus Med Rev* **11** (1997), 64-75.
[18] B.H. Newman, S. Pichette, D. Pichette, and E. Dzaka, Adverse effects in blood donors after whole-blood donation: a study of 1000 blood donors interviewed 3 weeks after whole-blood donation, *Transfusion* **43** (2003), 598-603.
[19] W.H. Organization, http://www.who.int/mediacentre/factsheets/fs279/es/. (2017).
[20] P.M. R., Hemovigilancia del donador, *Rev Mex Med Transf* **4** (2011), 111-115.
[21] F.N.d.D.d. Sangre, http://www.donantesdesangre.net/menu.htm. (2017).
[22] R.G.S. Tortora GJ, Principios de Anatomía y Fisiología, **Mosby/Doyma Libros, S.A.** (1996).
[23] O.N.d. Trasplantes, http://www.ont.es/home/Paginas/default.aspx. (2017).

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