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The Impact of Policies to Restrict the Use of Plasma Containing Products and Apheresis Platelets from Female Donors to Mitigate Transfusion Related Acute Lung Injury (TRALI) in Brazil

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Abstract

Background and Objectives—Although the incidence of TRALI is unknown in Brazil, some blood centers have adopted strategies to prevent TRALI. We evaluated the impact of three policies to mitigate TRALI on the supply of blood products: to divert the production of whole blood-derived plasma from female donors; to defer all female donors from apheresis platelet collections, and to defer only multiparous female donors from apheresis platelet collections.

Materials and Methods—Data from allogeneic whole blood and apheresis platelet donations from April 2008 to December 2009 were collected in three Brazilian blood centers and the impact of the aforementioned strategies was evaluated.

Results—Of 544,814 allogeneic blood donations, 30.8% of whole blood plasma and 24.1% of apheresis platelet donations would be reduced if only male donor plasma was issued for transfusion and all female donors were deferred from apheresis donation, respectively. If only multiparous donors were deferred from apheresis donation, there would be a 5% decrease of all apheresis platelet collections.

Conclusion—Restricting the use of whole blood derived plasma to male-only donors and deferring all female apheresis platelet donors would impact two out of three Brazilian blood centers. A deferral policy on multiparous apheresis platelet donors may be acceptable as a temporary measure, but may cause more stress on a system that is already working at its limit.

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Conflict of interest statement

The authors declare that they have no conflicts of interest relevant to the manuscript submitted to Transfusion and Apheresis Science.

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Keywords

TRALI; multiparous donors; apheresis platelets; leukocyte antibodies; Brazil; transfusion reactions

Introduction

Transfusion related acute lung injury (TRALI) is an adverse transfusion event with a mortality rate of 5 to 25%, and has become the leading cause of transfusion associated death in the USA [1, 2]. Two theories have been postulated to explain the complication. The “one-hit” theory advocates that anti-leukocyte and/or anti-neutrophil antibodies (anti-HLA and anti-HNA) circulating in the blood of sensitized donors are attracted to the pulmonary endothelium antigens of recipients or to the recipients’ granulocytes and can activate an inflammatory process[3]. HLA and HNA sensitization can occur mainly as a consequence of pregnancy and blood transfusions, as confirmed by studies describing the increased association between the number of pregnancies and the presence of anti-HLA and anti-HNA antibodies in donors’ blood [4]. The “two-hit” theory proposes the association between an underlying health condition of the recipient and the infusion of active substances or cytokines produced during blood storage or antibodies triggering the inflammatory response and leading to respiratory distress symptoms that usually require immediate medical treatment [5–7].

The UK Serious Hazards of Transfusion (SHOT) Hemovigilance Program showed the results of a 10-year investigation of 195 TRALI suspected cases [8]. In this study, the TRALI risk was higher with the infusion of plasma and platelets, and all donors of antibody-positive implicated plasma and platelets were female. During the years of the study, the UK National Blood Services proposed the indefinite deferral of women after pregnancy and transfusion of male-only plasma-containing products [9]. The provision of male-only plasma in the United Kingdom appears to have been an effective strategy to reduce TRALI [8]. Alternative policy strategies include those recommended by the AABB that suggested that blood centers implement interventions that minimize the preparation of high plasma-volume components from donors known to be leukocyte alloimmunized or at increased risk of leukocyte alloimmunization [10].

The incidence of TRALI is unknown in Brazil. However, the “Brazilian General Coordinating Agency for Blood and Derivatives” in association with blood banks and the “Brazilian Association of Haematology and Haemotherapy” held an expert meeting to discuss strategies to mitigate the occurrence of TRALI in the country [11]. One of the suggestions was to divert the use of plasma from female blood donors who had been pregnant three or more times to the production of fractionated derivatives and to defer these multiparous donors from apheresis platelet donation. Meanwhile, some blood centers, based on international experience, opted to distribute plasma-containing products collected from male-only donors. Considering that Brazilian blood centers do not routinely screen donors and patients for leukocyte antibodies and do not have an established guideline issued by the Ministry of Health for TRALI reduction measures, these strategies are under consideration.

We evaluated the impact on the available supply of plasma and apheresis platelets from three different policies to mitigate TRALI: to distribute plasma-containing products collected from male-only donors, to defer all female donors from apheresis platelet collection, and to defer only multiparous female donors from apheresis platelet collection. One of these strategies may be introduced if TRALI is identified as a major concern in our country.

Material and Methods

The US National Institutes of Health funded International Retrovirus Epidemiology Donor Study-II (REDS-II) includes three large blood centers in Brazil (Fundação Pró-Sangue in São Paulo, Fundação Hemominas in Belo Horizonte and Fundação Hemope in Recife). Donor and donation data from each blood center are captured in São Paulo and then transferred to a coordinating center in the US, as described previously [12].

We performed a cross-sectional analysis to determine the contribution of donations from females to whole blood and apheresis platelet availability at the three previously described centers from April 1, 2008 to December 31, 2009. Donor socio-demographic and blood type data were compiled and tabulated. Socio-demographic data included: sex, age, education status (less than 8 years of school, completed 8 years, up to 11 years and college or above), race (black, white, mixed or other), type of donation (community versus replacement), donor status (repeat versus first time), number of pregnancies and blood type. Multiparous donors were defined as those who disclosed three or more pregnancies in the pre-donation interview. Within the female donor group, we tabulated the distribution of blood donations from multiparous and non-multiparous (no pregnancy, one pregnancy or two pregnancies), and estimated the impact on the availability of plasma, random and apheresis platelets, under each possible TRALI mitigation strategy.

During the study period, candidates for donation were required to be between 18 and 65 year of age, weigh at least 50 kilograms, have a hematocrit 38% (haemoglobin 12.5 g/dL) for females and a hematocrit 39% (haemoglobin 13g/dL) for males. Women are allowed to donate whole blood up to three times per year while men can donate four times per year. Donors go through the usual steps of blood pressure and pulse assessment, hematocrit check, and medical and risk history. The interviews are confidential, face-to-face, and performed by physicians or trained nurses and technologists. During the pre-donation interview, all the females are asked if they have a history of pregnancy. In the case they answer YES, they are asked how many times they have been pregnant. All answers are entered into the blood bank computer system at the time of the interview.

In São Paulo and Belo Horizonte, citrate-phosphate-dextrose-adenine (CPDA-1) is used as anticoagulant-preservative solution and in Recife, saline-adenine-glucose-mannitol (SAG-M). All collected units are sent to processing and are separated into at least two blood components: red cells and plasma. Plasma-rich platelets is the method employed at all three blood centers to produce random platelets. The rate of whole blood donations fractionated into random platelets varied from 45.6% in São Paulo, 64.6% in Recife to 77.5% in Belo Horizonte. During the study, 80.4%, 49.5% and 39.6% of the plasma fractionated from whole blood donations was distributed to transfusion in Belo Horizonte, Recife and São Paulo, respectively. The remaining plasma was diverted to protein fractionation (16.1%, 48% and 39.2%, respectively) and to cryoprecipitate production (3.4%, 2.5% and 9.2%, respectively).

Donors are allowed to give apheresis platelets once a week, up to four times per month, if the donor has a platelet count equal or higher than $150,000/\text{mm}^3$ at each donation. Apheresis platelets are collected using the Trima Accel in São Paulo and the Fresenius Kabi in Belo Horizonte and Recife.

Statistical Analysis

The number and percentage of each type of donation (whole blood vs. apheresis platelets) from both men and women, donations from non-multiparous and multiparous women were

tabulated by center and donation procedure. Socio-demographic characteristics were tabulated. All data analyses were conducted using SASTM software 9.2 (SAS Institute, 2008).

Results

During the 21 month period of study, after excluding autologous donors, duplicate records, and donations with missing collection type there was a total of 544,814 allogeneic whole blood and apheresis donations collected from all donors for the three REDS-II blood centers in Brazil. Female donors contributed 165,414 (30.8%) of the whole blood donations (20.1% from Recife; 26.3% from Belo Horizonte; 49.7% from São Paulo). Pregnancy information was missing for 13,129 (2.4%) of questionnaires, mostly (79%) from Recife. There were 8,623 apheresis platelet collections, 1,706 (19.8%) in Recife, 1,808 (21%) in Belo Horizonte and 5,109 (59.2%) in São Paulo. Blood donations among women with none, one, two or three and more pregnancies represented 55%, 15.6%, 14.4% and 15% of all female whole blood donations, respectively. Among women who donated apheresis platelets, female donors with none, one, two or three and more pregnancies contributed to 48.7%, 14%, 16.6% and 20.7%, respectively (Table 1).

Demographic data showed that female donations were more frequent among young donors (63% aged under 35 years old), had high school or higher educational level (67.6% had completed 11 years and above of study), 47.7% were white, 10.7% black, and 39.5% mixed, and community (70.2%) and repeat (59.6%) donors (Table 2). Multiparous donors were more likely to be older (80.3% versus 37% overall female donors above 35 years) and had lower educational level (53.3% completed less than 11 years of education versus 22.3% of overall female donors). There was no difference regarding the type of donation, with 69% versus 70.2% community donations from multiparous versus non-multiparous donors. However, multiparous females were more likely to be repeat donors than were overall donors (65.5% versus 59.6%).

The ABO blood type of the plasma donations was not different among the multiparous and non-multiparous groups, as expected. If we diverted plasma from all female whole blood donors to fractionation, the decrease in the overall plasma availability for all centers combined would be 27.9%, 28.1%, 27.9% and 28.6% for A, AB, B and O blood types, respectively.

Finally, considering the three main objectives of the study, we found that if we diverted all female-donor plasma from transfusion, the reduction in available plasma would be around 30%; if we deferred all female donors from apheresis platelet collection a shortage of 24% of the availability of this component would result; and if we deferred only multiparous female donors from donating apheresis platelets, a 5% decrease in platelet inventory would result.

Discussion

This is the first study that evaluates more than half a million blood donations in Brazil, and reports on the contribution of female donors on blood collection and the impact on blood availability of introducing restrictive female donation criteria. We found that female donors contributed almost one third of all blood donations during the study period. Considering only apheresis platelets, female donors provided almost one fourth of these collections and multiparous donors contributed about 5% of all apheresis platelets collected.

Regional differences regarding female donor contributions across the three centers, especially when comparing the Northeast (Recife) versus the Southeast centers (São Paulo and Belo Horizonte) were evident. Recife showed a lower proportion of female donations,

and this may be explained by the lower socioeconomic characteristics of the state and region that can affect women's health and eligibility to donate blood. Higher rates of deferral have already been described in Recife, especially due to a low haemoglobin level [13]. In addition, Recife has not been prioritizing campaigns focusing on recruiting more female donors.

We also found that multiparous women were older, which is an expected finding; and had a lower educational level, which is consistent with a lower use of birth control methods [14, 15]. Multiparous females were more likely to be repeat donors than non-multiparous females, and this is likely attributable to a combined age and pregnancy effect. Multiparous and non-multiparous females were mostly community donors (69%), perhaps reflecting the successful strategy to convert replacement to community donors during the last decades in Brazil[14].

Answering the three main questions proposed at the beginning of this manuscript, we found that if we transfused only male donors' plasma containing products, it would impair only the blood center of Belo Horizonte, as they issue around 80% of their collected plasma for transfusion. São Paulo and Recife distribute about half of all the plasma collected for transfusion, so this may not cause a major availability issue for these centers. We speculate if other blood centers in Brazil have a similar profile as Belo Horizonte, they could face the same issue. Another interesting approach would be to analyse the indications for plasma transfusion, considering that plasma used for transfusion ranged from 40 to almost 80% among the three blood centers. Regarding whole blood random platelets, the restrictive policy of transfusing only male donors' plasma containing products would also affect random platelet availability in Belo Horizonte, as they pool platelets from three quarters of the whole blood collections. In São Paulo and Recife it would not damage their inventory as they fractionate platelets from 45.6% and 64.6% of their whole blood collections, respectively. On the other hand, if we deferred all female donors from donating apheresis platelets, this component availability would be strikingly decreased in São Paulo, a large urbanized and developed area that attracts patients from all over the country searching for health care and treatment. We have been noticing a higher demand for apheresis platelets in São Paulo for oncological and haematological patients, and, if the delivery of this blood component is compromised through restrictive criteria, certainly the care of these patients will be jeopardized. Belo Horizonte and Recife would not face the same difficulties, as currently apheresis platelets have a limited role in their daily platelet transfusion practice. However, we should also consider that platelets have a short shelf life and the number of donations is seasonal, which may contribute to periods of shortage and reduced platelets availability[15]. Finally, if we deferred only multiparous females from donating apheresis platelets it would cause a minor decrease in our inventory, and potentially, incentives to increase donor recruitment would quite easily compensate for this loss.

In a US study, Rios et al. [16] found a decrease of 22% of apheresis platelets in inventory if all female donors with previous pregnancy history were deferred from donating and 5% if only those with a positive anti-HLA test were deferred. Brazilian blood centers do not routinely screen donors and patients for HLA and/or HNA antibodies. Moreover, the association between the number of previous pregnancies and antibody positivity is unknown in Brazil. In line with what was described by Brazilian experts, one possible approach to mitigate TRALI would be the exclusion of multiparous female donors from donating platelets as they have the highest risk for HLA and HNA antibodies. However, even if the blood centers could meet transfusion needs after adopting either female donor deferral strategy, both strategies could reduce the willingness of women to donate blood [17], and therefore would impact negatively on the availability of other blood components. It might also send conflicting messages to the population as the Brazilian Ministry of Health has

been promoting the importance of female donors and trying to increase their participation as blood donors during the last few years through public awareness campaigns [18].

An International Forum in 2007 showed different approaches used to mitigate TRALI in 15 countries. As most of the blood centers that participated in the Forum did not have any regulatory guideline provided by national health agencies at the time, distinct procedures were reported on how to deal with the increased TRALI risk associated with female donors with and without a history of pregnancy. The main strategies reported were screening multiparous platelet apheresis donors for HLA and HNA antibodies, using solvent-detergent treated pooled plasma, using male-only plasma, preparing buffy coat pooled platelets from male and female donors but resuspending them in male plasma, and producing platelets with platelet additive solution (PAS) instead of plasma. However, there were also blood centers that reported they did not ask donors about their pregnancy history and did not avoid using plasma and platelets from female donors [19, 20]. Another publication has suggested the collection of multiple components by apheresis, avoiding TRALI by decreasing allogeneic exposure [21].

Our study has limitations. We analyzed three major blood centers located in large and distinct urbanized areas, with different socioeconomic and population profiles that may or may not reflect the characteristics of blood collection in other areas of Brazil. However, these centers together can enhance the generalizability of our findings. Also, we had missing pregnancy information, especially from Recife, which can be explained by the fact that this question on the pre-donation interview was not mandatory previously to REDS-II implementation. Pregnancy data also relies on the female donors' honesty, as they can abstain from declaring abortions, miscarriages and previous pregnancies. We, of course, cannot independently verify the pregnancy history. We have sought to reduce this donor bias by applying external quality control and requiring standards of procedures for inquiring about pregnancy history. Face-to-face interviews are required by law in Brazil and may limit full disclosure. For example, intentionally induced abortion is legal in Brazil for limited circumstances only. If the interview were digitalized and completed in private, the donors might feel comfortable in honestly answering questions that can be stigmatizing.

In conclusion, the policy of restricting the use of plasma containing products to male-only donors and to defer women from apheresis platelets donation will impact Belo Horizonte and São Paulo blood centers, respectively. A deferral policy on multiparous apheresis platelet donors may be acceptable as a temporary measure in the absence of reference centers to screen donors for HLA and HNA antibodies and/or the implementation of other techniques to treat plasma containing products, but may cause more stress on a system that already works at its blood availability limit. Data on TRALI incidence and morbidity/mortality in Brazil are very important to be able to understand the scope of the problem in relation to the possible interventions that would be feasible in Brazil. A continuous hemovigilance program to track the real incidence of TRALI in Brazil is warranted. Reference centers to detect anti-leucocytes antibody are needed either to support the diagnosis of TRALI or to screen potential donors who can cause TRALI. In the meantime blood centers may consider the implementation of different policies that reflect local blood collection and availability patterns.

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Abbreviations

TRALI	Transfusion Related Acute Lung Injury
USA	United States of America
SHOT	The United Kingdom Hemovigilance Scheme Serious Hazards of Transfusion
AABB	American Association of Blood Banks
REDS-II	Retrovirus Epidemiology Study II

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Table 1

Number and percentage of pregnancies by site and donation procedure

	Number of Donations	Female Donations		Number of Female Donations with Pregnancy data	Number of pregnancies (% of Female donations) ^a						
		N	% of Total		2			3			
					0	1	2	0	1	2	
Site											
Recife	185,636	34,929	18.8	24,546	16525 (67.3%)	2471 (10.1%)	2836 (11.6%)	2714 (11.1%)			
Belo Horizonte	123,742	45,278	36.6	44,216	23370 (52.9%)	7503 (17.0%)	6683 (15.1%)	6660 (15.0%)			
São Paulo	235,436	87,288	37.1	85,604	44851 (52.4%)	14062 (16.4%)	12843 (15.0%)	13848 (16.2%)			
Donation Procedure											
Whole Blood	536,191	165,414	30.8	152,328	83754 (55.0%)	23750 (15.6%)	22023 (14.4%)	22801 (15.0%)			
Apheresis	8,623	2,081	24.1	2,038	992 (48.7%)	286 (14.0%)	339 (16.6%)	421 (20.7%)			
Total	544,814	167,495	30.7	154,366	84746 (54.9%)	24036 (15.6%)	22362 (14.5%)	23222 (15.0%)			

^aPercentages by Number of Pregnancies updated after removing those with missing pregnancy data.

Table 2

Number and percentage of pregnancies by socio-demographics and type of donors and donations

Donation Characteristics	Total Female Donations	Number of Pregnancies			
		0	1	2	3
Age					
age <25	42,589 (27.6)	37166 (43.9)	4180 (17.4)	943 (4.2)	300 (1.3)
age 25 – <35	54,711 (35.4)	31442 (37.1)	11445 (47.6)	7329 (32.8)	4,495 (19.4)
age 35 – <45	31,619 (20.5)	9752 (11.5)	5673 (23.6)	8091 (36.2)	8,103 (34.9)
age 45 – <55	19,057 (12.4)	4759 (5.6)	2193 (9.1)	4809 (21.5)	7,296 (31.4)
age 55	6,389 (4.1)	1627 (1.9)	544 (2.3)	1190 (5.3)	3,028 (14.0)
Education					
< 8 years	15,817 (10.3)	3343 (3.9)	1927 (8.0)	3503 (15.7)	7,044 (30.3)
Completed 8 years	18,451 (12.0)	6019 (7.1)	2998 (12.5)	4095 (18.3)	5339 (23.0)
11 years	87,569 (56.7)	54217 (64.0)	14509 (60.4)	10755 (48.1)	8088 (34.8)
College and above	32,305 (10.9)	21043 (24.8)	4574 (19.0)	3978 (17.8)	2,710 (11.7)
Race					
Black	16,443 (10.7)	9377 (11.1)	2699 (11.2)	2094 (9.4)	2,273 (9.8)
Mixture	60,980 (39.5)	32097 (37.9)	9613 (40.0)	9114 (40.8)	10,156 (43.7)
White	73,568 (47.7)	41082 (48.5)	11338 (47.2)	10777 (48.2)	10,371 (44.7)
Other/Yellow or Red	2,775 (1.8)	1826 (2.2)	307 (1.3)	313 (1.4)	329 (1.4)
Type of Donation					
Community	108,412 (70.2)	60449 (71.3)	16781 (69.8)	15168 (67.8)	16014 (69.0)
Replacement	45,954 (29.8)	24297 (28.7)	7255 (30.2)	7194 (32.2)	7208 (31.0)
Donor Status					
Repeat Donor	92,051 (59.6)	48010 (56.7)	14578 (60.7)	14261 (63.8)	15202 (65.5)
First Time Donor	62,315 (40.4)	36736 (43.3)	9458 (39.3)	8101 (36.2)	8020 (34.5)
Type of Blood					
A+	46,433 (30.1)	25845 (30.5)	7203 (30.0)	6580 (29.4)	6805 (29.3)
A–	6,459 (4.2)	3565 (4.2)	948 (3.9)	964 (4.3)	982 (4.2)

Donation Characteristics	Total Female Donations	Number of Pregnancies			
		2			3
		0	1	2	
AB+	4,996 (3.2)	2883 (3.4)	730 (3.0)	683 (3.1)	700 (3.0)
AB−	703 (0.46)	392 (0.46)	108 (0.45)	101 (0.45)	102 (0.44)
B+	16,126 (10.5)	8846 (10.4)	2555 (10.6)	2257 (10.1)	2468 (10.6)
B−	2,178 (1.4)	1161 (1.4)	356 (1.5)	342 (1.5)	319 (1.4)
O+	66,030 (42.8)	35859 (42.3)	10323 (42.9)	9668 (43.2)	10180 (43.8)
O−	10,364 (6.7)	5541 (6.5)	1654 (6.9)	1628 (7.3)	1541 (6.6)

^a All column totals for each variable do not always add up to 100% due to missing data.