Doadores de sangue inaptos no estado de Roraima, Amazônia brasileira: Razões para inaptidão e soroprevalência de patógenos transmitidos por transfusão

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Deferred blood donors in the state of Roraima, Brazilian Amazon: Reasons for unsuitability and seroprevalence of transfusion-transmitted pathogens

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Abstract

BACKGROUND: Deferred blood donors are not targeted by any health policy. **OBJECTIVES:** To describe sociodemographic characteristics of unsuitable blood donors, the causes of unsuitability and compare the prevalence rates of transfusion-transmitted infections in deferred and eligible blood donors. **METHODS:** A cross-sectional survey was conducted to obtain sociodemographic data and blood samples; 8,159 donors were screened; (21.1% rejected, 78.9% approved). A sample of 212 deferred donors was established. **RESULTS:** Most rejected donors were female, young adults, with high school or university education, self-declared white, born in the North region and single. Main reasons for unsuitability were low hemoglobin concentration, potential exposure to malaria and risky sexual behaviour. The comparison of seropositivity rates in deferred and eligible blood donors generated the following prevalence ratios (PR) and respective 95% confidence intervals (CI): HIV, PR = 6.75 (1.46 – 31.05), p = 0.046; syphilis, PR = 1.47 (0.46 – 4.64), p = 0.463; anti-HBc, PR = 2.84 (1.24 – 6.50); p = 0.023; anti-HCV, PR = 4.67 (1.06 - 20.58), p=0,080; Chagas disease, PR = 60.75 (5.53 – 667.43), p = 0.003. **CONCLUSIONS:** Treating anemia in women and controlling malaria in Roraima will reduce the pool of rejected donors in the state.

KEY WORDS: Transfusion-transmitted diseases – Seroprevalence – Roraima – Blood donation

INTRODUCTION

In Brazil, blood donation is mandatorily voluntary and unpaid, and collection is done exclusively through a system of public blood banks managed by federative states, within the Unified Health System. [1,2] At blood banks, donated blood is tested for the presence of antibodies against blood antigens of transfusion importance and submitted to serological tests to detect the most prevalent transfusion-transmitted pathogens (HIV, HTLV I/II, HBV, HCV, Chagas disease, and syphilis) in addition to undergoing nucleic acid tests (NATs) to detect HIV, HBV, HCV, and malaria.[1,2,3] After these analyses, donated blood is fractionated to produce red blood cell concentrate, plasma and platelet concentrate. Other blood products include human albumin and immunoglobulins.

Since the 1980s, Brazil has prohibited paid blood donation, in addition to testing donated blood for the diseases mentioned above.[1,2] In the pre-testing era, the presence of blood-borne diseases among the population of paid donors has led to the occurrence of several cases of transfusion-transmitted infections.[4,5,6]

The window period of serological tests allow blood contaminated with transfusion-transmitted pathogens to present a negative test.[7] This requires questionnaires on sexual behaviour and investigation of other possible exposures to pathogens in the population of candidates for blood donation, which may characterize the potential donor as deferred.[1,2,8] Candidates deferred for donation are dismissed without performing serological tests, so the frequency of infection by blood-borne pathogens in this population is unknown. Knowing the seropositivity rates for transfusion-transmitted pathogens among deferred donors could improve donor selection strategies. NATs are also capable of detecting infections by these

agents before seroconversion, reducing the window period and increasing the safety of transfusions.[9]

Among the conditions that lead to ineligibility to donate blood in Brazil are factors related to sexual behaviour, chronic diseases, as well as simpler conditions such as low blood hemoglobin concentration, use of some medications and weight below 50 kg. There is a wide range of conditions that make donation not possible, both temporarily and permanently, which are described in the laws that regulates hemotherapy in Brazil.[1,2,10] In regions where malaria is endemic, such as the states belonging to the Brazilian Amazon, many donors may be deferred based on the criterion of having visited areas of active malaria transmission, which reduces substantially the pool of potential donors in the population.[8] The incidence of malaria in Roraima is increasing, strongly impacted by the interaction between gold mining and indigenous populations.[11]

In recent years, the state of Roraima has been receiving massive waves of migration from Venezuela. Venezuelans come to Brazil in search of better living and working conditions, Roraima being the gateway and destination for a large proportion of migrants. In a context of poverty and unemployment, some Venezuelan women have found prostitution to be the only way to survive in Brazil.[12] The new sex trade networks in the state capital, Boa Vista, could potentially amplify the transmission of sexual transmitted infections (STIs)[13] and increase the proportion of blood donors rejected in the state of Roraima. It should be emphasized that, regardless of this migratory process, the incidence of STIs has increased substantially in Brazil.[14] In addition, the movement of people across the Brazil-Venezuela border, especially in Indian Lands, harms malaria control.[15] The present study aimed to describe a sample of donors deferred by the Hemotherapy and

Hematology Center of Roraima (Hemoraima), including the reasons for unsuitability and frequency of transfusion-transmitted infections.

POPULATION AND METHODS

Setting. The state of Roraima, in the extreme north of Brazil, is in the Brazilian Amazon, bordering Venezuela and Guyana. It is virtually isolated by road and can be accessed by air. The state has 652,713 inhabitants distributed over 224,300 Km^2, which gives it a very low population density of 2.91 inhabitants/Km^2; 46% of its territory is represented by Indian Lands, mainly the Yanomami Indian Land and the Raposa Serra do Sol Indian Land. The human development index is 0.699 and the capital, Boa Vista (2°49′12″ N, 60°40′19″W), has 470,169 inhabitants.[16]

Study design, sampling, recruitment strategy and statistical analysis. A cross-sectional survey was conducted with a sample of deferred blood donors at the Hemoraima, in order to obtain sociodemographic data and blood samples for serological testing for HIV, *Treponema pallidum* (syphilis), hepatitis B and C, HTLV, and *Trypanosoma cruzi* infection (Chagas disease). During the period from June to October 2024, 8,159 donors were screened at Hemoraima, of which 1,719 (21.1%) were rejected for various reasons and 6,440 (78.9%) were approved. A random sample of 212 deferred donors was established, based on the following parameters: expected frequency = 10%, margin of error = 2.5% and confidence level = 80%. Prevalence ratios and their respective 95% confidence intervals (CIs) were calculated based on the prevalence of transfusion-transmitted infections among deferred and eligible donors. The statistical significance of the associations was verified using Fisher's exact test, with a significance level set at $p<0.05$.

Classification of donors as eligible and deferred. Regarding social and behavioural characteristics, candidates for blood donation are considered deferred if they have risky sexual behaviour (e.g. have multiple sexual partners, have had non-habitual sexual intercourse without using a condom, have had sexual intercourse with sex workers, with injectable drug addicts, with people who have had hepatitis, with people living with HIV, with transfused persons or with ex-convicts), reside in or have visited a malaria-endemic region less than one month ago, use marijuana or have had a tattoo, piercing, permanent makeup or acupuncture less than six months ago. Medical conditions that prevent donation include low blood hemoglobin concentration/hemorrhage, high or low blood pressure, weight less than 50 kg, serious illness less than 1 month, flu-like illness, major surgery in the last 6 months, dental treatment in the last 72 hours, minor surgery in the last 3 months or heart rate above 110 bpm. Have received vaccines against rabies, meningitis, influenza, tuberculosis (BCG), measles-mumps-rubella or measles alone in the last 4 weeks also prevents donation. Among previous infectious diseases that make de donor unsuitable are toxoplasmosis, malaria, syphilis, Chagas disease, HIV/AIDS, hepatitis, dengue, rubella, brucellosis and mononucleosis. Other conditions include have had received blood/components transfusion less than 1 years, chronic kidney disease/renal replacement therapy, diabetes, hyper or hypothyroidism, autoimmune diseases, hematological diseases/hemoglobinopathies, alcoholism and use of antibiotics in the last 5 days. Blood hemoglobin concentration was measured in the screening of potential donors with the non-invasive OrSense Hemoglobin Analyzer (OrSense Ltd, Tel Aviv, Israel).

Serological tests. The serological tests performed on the sample of deferred donors and on the population of eligible donors were as follows: ARCHITECT HIV

Ag/Ab Combo (a chemiluminescent microparticle immunoassay [CMIA], ARCHITECT anti-HCV (CMIA), ARCHITECT Syphilis TP (CMIA), ARCHITECT rHTLV-I/II (a CMIA test that screens for proviral DNA), ARCHITECT Chagas (a CMIA for the qualitative detection of antibodies to *Trypanosoma cruzi*), ARCHITECT Anti-HBc II, and ARCHITECT HBsAg (all provided by Abbott Laboratories, Lake Bluff, Illinois, USA).

Ethics. The study was approved by the Ethics Committee on Research of the Federal University of Roraima, protocol CAAE 75834223.9.0000.5302.

RESULTS

Sociodemographic characteristics and reasons for ineligibility to donate. Table 1 shows that most rejected donors were female, with a predominance of young adults with high school or university education and self-declared white, born in the North region and single. As presented in Table 2, the main reasons for deferred for blood donation were low blood hemoglobin concentration, potential exposure to malaria and risky sexual behaviour, in addition to the presence of tattoos and piercings.

Prevalence of transfusion-transmitted infections among eligible and deferred donors. As presented in Table 3, the sample of rejected donors showed an overall seropositivity rate, for any pathogen, significantly higher than the population of donors approved in the social and medical questionnaire. Analyzing the pathogens individually, the seropositivity rates and the number of seropositive individuals among refused donors were 0.94% (n=2) for anti-HIV, 1.4% (n=3) for syphilis, 2.8% (n=6) for anti-HBC, 0% (n=0) for HBsAg, 0.94% (n=2) for anti-HCV, 0% (n=0) for HTLV I/II and 0.94% (n=2) for Chagas disease. Among the 6,440

eligible donors, the seropositivity rates and the number of seropositive individuals were 0.14% (n=9) for anti-HIV, 0.96% (n=62) for syphilis, 0.99% (n=64) for anti-HBC, 0.09% (n=6) for HBsAg, 0.2% (n=13) for anti-HCV, 0.03% (n=2) for HTLV I/II and 0.02% (n=1) for Chagas disease. The comparison of seropositivity rates in deferred and eligible blood donors generated the following prevalence ratios (PR) and respective 95% confidence intervals (CI): HIV, PR = 6.75 (1.46 – 31.05), p=0.046; syphilis, PR = 1.47 (0.46 – 4.64), p = 0.463, p=0.006; anti-HBC, PR = 2.84 (1.24 – 6.50); p=0.023; anti-HCV, PR = 4.67 (1.06 - 20.58), p=0,080; Chagas disease, PR = 60.75 (5.53 – 667.43), p=0.003. For HBsAg and HTLV I/II the PRs were undefined.

DISCUSSION

The present study aimed to characterize blood donors deferred by a blood bank in the Brazilian Amazon. The sociodemographic characteristics of the rejected donors indicate a predominance of women, which can be explained by the fact that the main cause of unsuitability was low blood hemoglobin concentration. Regarding age, it was demonstrated that many unsuitable donors are young adults, a fact related to the frequency of some characteristics considered incompatible with donation, such as risky sexual behaviour and the presence of tattoos and piercings. The age distribution of unsuitable donors can be related to the finding that most of the unsuitable donors have a good level of education, with high school or university education and are single. This study demonstrated that the three main causes of ineligibility to donate blood in the state of Roraima are low blood hemoglobin concentration, potential exposure to malaria and risky sexual behaviour. Anemia, which for the purposes of donor refusal is characterized by a hemoglobin concentration of less than 12.5 g/dL for women and 13 g/dL for men, is the main

cause of ineligibility to donate blood globally.[17] A previous study conducted at Hemoraima demonstrated that the frequency of ineligibility due to low hemoglobin concentration was 23.9%[18] and, therefore, this situation persists to the present day. This finding is also related to the high prevalence of iron deficiency in the population and it should also be considered that in women, menstrual losses associated with abnormal uterine bleeding are an important cause of anemia. Recent studies have documented a higher prevalence of low hemoglobin concentration in female donors when compared to male donors. [19,20]

In the present study, one-fifth of donors were rejected due to potential exposure to malaria. In a previous study carried out in Roraima 5 years ago, a different pattern of causes of deferral for donation was observed, in which potential exposure to malaria accounted for only 1.5% of deferral.[18] The incidence of malaria in Roraima has increased, influenced by the vulnerability associated with the interaction of gold mining with Indian societies[21], so that all municipalities in the state currently have active transmission[22] and it should also be considered that a proportion of the reported cases are imported from Venezuela.[23] In Roraima, a large proportion of the territory is part of the Yanomami and Raposa Serra do Sol Indian Lands, which have extensive borders with Venezuela and Guyana. The expansion of illegal gold mining in these regions is related to the increasing incidence of malaria in the state. Of the 15 municipalities in the state of Roraima, seven were classified in 2023 as high risk for malaria (incidence > 50 cases/1000 inhabitants/year).[22] Having visited any of these municipalities in the 30 days prior to donation is a reason for ineligibility, so malaria has played an increasing role in refusing blood donors in Roraima. It is important to note that the blood of all approved donors is also subjected to a malaria NAT test.[24]

The third main reason for refusal to donate was risky sexual behaviour. In the previous study carried out at Hemoraima, this was the second most frequent cause, ahead of malaria.[18] New patterns of sexual behaviour have been observed with an increase in the number of sexual partners, and this may be related to the fact that many rejected donors are young people.[25,26] In the present study, the fact that risky sexual behaviour was identified in a group of unfit donors could be related to the relatively higher seroprevalence rates for some transfusion-transmitted pathogens, which are also STIs, such as HIV and HBV. However, although one of the two HIV-positive unsuitable donors was rejected for risky sexual behaviour, among the six unsuitable donors who were positive for hepatitis B, only one was in this rejection category, so the other five were rejected for other reasons (three had been in an area of active malaria transmission). The study's main limitation was the need to sample deferred donors, so that wide confidence intervals were generated when the prevalence rates of transfusion-transmitted diseases were compared. In this sense, although the HIV, HBV, and Chagas disease seropositivity rates were significantly higher among rejected candidates, the wide confidence intervals mean that this data needs to be interpreted with caution. Concerning HCV, there was a tendency towards greater seropositivity among refused donors, although without statistical significance at the 5% level.

In the present study, the seroprevalence of Chagas disease was higher among rejected donors when compared to approved donors. One of these two Chagas disease-seropositive donors was deferred because he had hepatitis after 10 years old and the other because he had malaria in the last 12 months, not having been deferred because they presented Chagas disease previously. It is possible that serological cross-reactions with leishmaniasis occur and that the greater

exposure to malaria among rejected donors is associated to greater exposure to leishmaniasis. The identification of false-positive individuals for Chagas disease due to serological cross-reactions with *Leishmania* antigens has been a cause for concern, especially in areas where both diseases are endemic. [27] It should be noted that, although 95% (4,169/4,404) of reports of acute Chagas disease in Brazil between 2008 and 2023 came from the Amazon region, only 5 cases were reported in the state of Roraima.

In conclusion, the current policy of classifying potential blood donors as unfit contributes to the safety of blood transfusion. Female donors with hemoglobin levels close to the lower limit of normal or low could have their clinical condition clarified and be advised to seek a health unity to have the cause of this clinical condition evaluated, receive treatment and become eligible donors in the future. [28] Better control of malaria in the state of Roraima will also contribute to reducing the rate of ineligibility for blood donation.

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AUTHORS' CONTRIBUTION

DRR recruited patients, organised the dataset and designed the study; FG supervised the study; FACC was responsible for the epidemiological design, data analysis and preparation of the manuscript.

DISCLOSURE

The authors declare that they have no competing interests in this work.

Table 1. Sociodemographic characteristics of deferred blood donors in the Hemotherapy and Hematology Center of Roraima (Hemoraima), Boa Vista, Roraima, 2024

Gender	N	%
Female	136	64
Male	76	36
Age group (years)		
18-19	7	3.3
20-29	73	34.4
30-39	69	32.6
40-49	44	20.8
50-59	18	8.5
60-69	1	0.5
Education		
Elementary	9	4.3
High school	96	45.3
University	96	45.3
Unknown	11	5.2
Ethnicity		
Yellow	17	8.0

White	172	81.1
Indian	2	0.9
Brown	5	2.4
Black	9	4.3
Unknown	7	3.3
Brazilian region where was born		
North	152	71.7
Northeast	45	21.2
South	1	0.5
Southeast	8	3.8
Central-West	0	0
Stranger	4	1.9
Unknown	2	0.9
Marital status		
Single	131	61.8
Married	43	20.3
Other	24	11.3
Divorced	6	2.8
Unknown	8	3.8

Table 2. Causes of non-suitability for blood donation in candidates for donation in the Hemotherapy and Hematology Center of Roraima (Hemoraima), Boa Vista, Roraima, 2024.

Condition impairing blood donation	**Male**	**Female**	**N**	**%**
Low blood hemoglobin concentration	2	57	59	27,8
Potential exposition to malaria	22	19	41	19,3
Sexual behavior	21	17	38	17,9
Not listed	4	12	16	7,6
Tatoo/piercings	0	11	11	5,2
Use of medicines	5	4	9	4,3
Vaccines	6	1	7	3,3
Hyper- or hypotension	3	4	7	3,3
Any definitive condition	5	0	5	2,4
Autoimmune diseases	2	2	4	1,9
Tireoid diseases	1	2	3	1,4
Flu	1	2	3	1,4
Low body weight	0	2	2	0,9
Hematological disease	2	0	2	0,9
Hepatitis after 10 years-old	2	0	2	0,9
Surgery	0	1	1	0,5
Tachicardia	0	1	1	0,5
Transfused less than on year	0	1	1	0,5

Total	76	136	212	100

Table 3. Comparison of seropositivity rates for different transfusion-transmitted pathogens in suitable and unsuitable blood donors in the Hemotherapy and Hematology Center of Roraima (Hemoraima), Boa Vista, Roraima, 2024.

	Eligible (n=6,440)		Deferred (n=212)			
	Positive (n)	Positive (%)	Positive (n)	Positive (%)	PR* (95% CI**)	p-value***
Chagas disease	1	0.02	2	0.94	60.75 (5.53 – 667.43)	0.003
HTLV I/II	2	0.03	0	0	Undefined	NP
HCV	13	0.2	2	0.94	4.67 (1.06 – 20.58)	0.080
Syphilis	62	0.96	3	1.4	1.47 (0.46 – 4.64)	0.463
HBsAg	6	0.09	0	0	Undefined	NP
HIV	9	0.14	2	0.94	6.75 (1.46 – 31.05)	0.046
Anti-HBc	64	0.99	6	2.8	2.84 (1.24 – 6.50)	0.023
Any test	157	2.4%	15	7.1%	2.90 (1.73 – 4.84)	< 0.001

*Prevalence Ratio; **Confidence Interval; ***Assessed through Fisher's Exact Test

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