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Original Article

PREVALENCE OF SEROLOGICAL INELIGIBILITY AMONG BLOOD DONORS OF A HEMOTHERAPY CENTER IN CAXIAS DO SUL, SOUTHERN BRAZIL

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ABSTRACT

Introduction: Blood donation should be voluntary, anonymous and altruistic, and the donor should not, directly or indirectly, receive any remuneration or benefit by virtue of donating blood. Like any other therapeutic method, transfusion procedures are not risk free and can expose the patient to a several complications. Serological screening is of great importance to ensure transfusion safety. The present study aimed to estimate the prevalence of serological ineligibility among blood donors from a Hemotherapy Center in Caxias do Sul (RS).

Method: An exploratory, descriptive and quantitative study was conducted on data from July 2010 to December 2015 collected at a Hemotherapy Center in Caxias do Sul (RS).

Results: During the study period, 14,267 blood donors attended the Hemotherapy Center, of which 9,332 (65.40%) were males and 4,935 (34.60%) were female. Considering only the suitable donors, 12,702 blood donations were performed, 144 (1.13%) presented positive serological tests. The most prevalent positive serology was for hepatitis B (anti-HBc) with 98 cases (0.77%), followed by syphilis with 19 cases (0.15%); Chagas disease, with 10 (0.08%); hepatitis C, with nine (0.07%); and HIV and HTLV, with four (0.03%) reactive samples each.

Conclusion: The results presented are important for health surveillance and make it possible to take measures to ensure safe blood stocks.

Keywords: *Serology; blood donors; communicable diseases*

Blood donation should be voluntary, anonymous, and altruistic; moreover, the donor should not, directly or indirectly, receive any remuneration, according to the current Brazilian legislation¹. Hemotherapy is a therapeutic treatment consisting of blood transfusion or transfusion of blood products². Blood donation should be performed by specialized professionals and must strictly fulfill several criteria to ensure blood transfusion safety. For example, donors must comply with certain mandatory requirements set forth by law, such as being from 16 to 69 years, 11 months, and 29 days of age, and providing written formal consent from the legal guardians of donor candidates aged 16 and 17 years for every blood donation. The maximum age threshold for first donation is 60 years, 11 months, and 29 days of age. The maximum frequency allowed is four blood donations per year for men and three donations per year for women, and the minimum interval between donations should be 2 months for men and 3 months for women. Additionally, donor candidate must weight at least 50 kg and have good health. Besides meeting these requirements, donor candidates must be assessed throughout the different stages of blood donation, including pre-screening, clinical screening, and serological screening. Blood donation in Brazil is regulated by Ordinance No.

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158, dated of February 4, 2016, which determines the Sanitation Regulation for Hemotherapy Centers, which develop activities related to transfusion procedures and to the production cycle of human blood and blood components^{1,3}.

The blood transfusion cycle starts with blood collection from donor candidates and continues with pre-screening, clinical screening, and laboratory screening. Reducing the possibility of transmitting infectious agents through blood transfusion requires measures to ensure its safety⁴. The current legislation establishes that all country's Hemotherapy Centers must perform serological tests to detect markers of hepatitis B (anti-HBc/HbsAg), hepatitis C (anti-HCV), syphilis (Venereal Disease Research Laboratory, VDRL), AIDS (anti-HIV 1 and 2/Western blot), HTLV (anti-HTLV I and II), and Chagas disease (immunoenzymatic assay, EIA)¹.

A study of 60,211 blood donations performed in the Caxias do Sul Blood Bank, southern Brazil, from 2001 to 2005 found that 1,485 (2.50%) of these donations were discarded due to serological ineligibility, with the most prevalent marker being anti-HBc (1.67%), followed by VDRL (0.65%)⁵. The disposal of these ineligible blood bags during screening leads to substantial but necessary costs to achieve transfusion safety. Therefore, serological screening of blood donors is extremely important to prevent the dissemination of blood transmitted infectious microorganisms.

The present study aimed to investigate the prevalence of serological markers of hepatitis B, hepatitis C, AIDS, HTLV I/II, syphilis, and Chagas disease among blood donors attending a Hemotherapy Center in Caxias do Sul, southern Brazil, from July 2010 to December 2015.

METHODS

An exploratory, descriptive and quantitative study was conducted at a Hemotherapy Center in Caxias do Sul, southern Brazil. Firstly, the institution's database was searched for data on donor candidates with positive screening for the selected markers from July 2010 to December 2015. Subsequently, data were organized using Microsoft Office Excel 2007 for the creation of graphs and tables.

RESULTS

From July 2010 to December 2015, 14,267 donor candidates attended the Hemotherapy Center in Caxias do Sul, southern Brazil, of which 9,332 (65.40%) were male and 4,935 (34.60%) were female. Of the total number of candidates, 14,242 underwent clinical screening to ensure recipient's safety, of which 13,217 (92.80%) were considered clinically eligible for blood donation and 1,025 (7.20%) were considered ineligible.

Eligible candidates had their blood collected, 12,702 of which donated a full blood bag and had their blood samples screened for serological markers. Of the 12,702 donations, 12,558 were released for transfusion (serologically eligible) and 144 (1.13%) were discarded (serologically ineligible). The most prevalent positive serology was for hepatitis B (anti-HBc and HbsAg), with 98 cases (0.77%); followed by syphilis (VDRL), with 19 cases (0.15%); Chagas disease (EIA), with 10 cases (0.08%); hepatitis C (anti-HCV), with nine cases (0.07%); and HIV (anti-HIV 1 and 2/Western Blot) and HTLV (anti-HTLV I and II), with four (0.03%) positive samples each (table 1). The findings presented in Figure 1 showed that, during the study period, the prevalence of hepatitis B among blood donors significantly increased over the years.

Table 1: Annual distribution of positive results for serological markers in an Hemotherapy Center.

Positive serological screening	2010 794 (100%)	2011 1778 (100%)	2012 2027 (100%)	2013 2718 (100%)	2014 2782 (100%)	2015 2606 (100%)	TOTAL n (%)
Chagas disease (EIA)	0 (0.0%)	3 (0.17%)	4 (0.20%)	2 (0.07%)	0 (0.0%)	1 (0.04%)	10 (0.08%)
Anti-HBc / HbsAg	2 (0.25%)	3 (0.17%)	15 (0.74%)	22 (0.80%)	22 (0.80%)	34 (1.30%)	98 (0.77%)
Anti-HCV	0 (0.0%)	3 (0.17%)	4 (0.20%)	0 (0.0%)	0 (0.0%)	2 (0.08%)	9 (0.07%)
Anti-HIV 1 and 2/Western Blot	0 (0.0%)	3 (0.17%)	0 (0.0%)	1 (0.04%)	0 (0.0%)	0 (0.0%)	4 (0.03%)
Anti-HTLV I/II	0 (0.0%)	0 (0.0%)	1 (0.05%)	1 (0.04%)	0 (0.0%)	2 (0.08%)	4 (0.03%)
VDRL	0 (0.0%)	1 (0.05%)	1 (0.05%)	3 (0.11%)	5 (0.18%)	9 (0.34%)	19 (0.15%)
Total	2 (0.25%)	13 (0.73%)	25 (1.23%)	29 (1.06%)	27 (0.97%)	48 (1.84%)	144 (1.13%)

EIA: Immunoenzymatic assay; **Anti-HBc:** Detects the presence of the antibody against chorion (a protein that is present in the nucleus of the hepatitis B virus); **HbsAg:** Detects surface antigens of the hepatitis B virus; **Anti-HCV:** Detects the presence of antibodies against the hepatitis C virus; **Anti-HIV1 and 2:** Detects the presence of antibodies against the HIV 1 and 2 viruses; **Anti-HTLV I/II:** Detects the presence of antibodies against the HTLV I/II viruses; **VDRL:** Venereal Disease Research Laboratory. A non-treponemal test to detect syphilis.

DISCUSSION

Pretransfusion stages, such as donor's recruitment and selection, along with serological screening tests, reduce the possibility of transfusion transmission of infectious microorganisms but is not free of risk for recipients. During the study period, there was a higher prevalence of male donor candidates in the Hemotherapy Center in Caxias do Sul, southern Brazil, from July 2010 to December 2015. The lower prevalence of female candidates may be explained by the fact that some women do not reach the minimum weight for donating blood or by the occurrence of anemia in women during reproductive age and after the menstrual period, thus compromising attendance of women to the Hemotherapy Center⁴. Moreover, the higher prevalence in the male gender may be explained by the fact that current legislation establishes a maximum frequency of four donations per year for men and three donations per year for women¹. Our results are consistent with those of a study that found a higher prevalence of male donors in the Caxias do Sul Blood Bank (69.10%)⁵. In another

study conducted in Maringá, southern Brazil, with 93,490 donor candidates, the percentage of male donors was 61.54%⁶. Similarly, males accounted for 57.00% of blood donations performed in Porto Alegre, southern Brazil, from 2013 to 2014⁷.

The disposal rate is related to the importance of serological screening to prevent infectious disease transmission through blood transfusion. Hepatitis B, an infection transmitted by blood transfusion, is considered a public health problem, because of the high rates of serological disposals due to positive serological results⁸. In the present study, the overall disposal rate due to positive serological results was 144 donations (1.13%), with markers for hepatitis B (anti-HBc) and syphilis (VDRL) being the most prevalent during the study period, as described in Table 1. These findings are in line with those of studies conducted in other Brazilian states and cities, as shown in Table 2. In Porto Alegre, Brazil, the most prevalent positive serology among blood donor candidates was for hepatitis B, with 1,774 (1.97%) cases in 2013 and 1,603 (1.82%) in 2014, followed

Table 2: Comparison of seroprevalence among blood donors in different Hemotherapy Centers in Brazil.

Serologically ineligible donors					
	City/state	Blood donations	N	%	Authors
Chagas Disease	Caxias do Sul/RS	12.702	10	0.08%	*
	Santa Maria/RS	25.207	246	0.98%	Cogo et al. ⁹
	Recife/PE	204.124	31	0.02%	Sabino et al. ¹⁰
	São Paulo/SP	49.541	19	0.04%	Ferreira et al. ¹¹
Hepatitis B	Caxias do Sul/RS	12.702	98	0.77%	*
	Alfenas/MG	25.034	347	1.39%	Diogo et al. ¹²
	Porto Alegre/RS	88.201	1,603	1.81%	Trevizan and Cavada ⁷
	Barra das Garças/MT	1.607	91	5.66%	Delmondes et al. ¹³
	Erechim/RS	2.108	119	5.60%	Sbeghen and Paraboni ¹⁴
Hepatitis C	Caxias do Sul/RS	12.702	9	0.07%	*
	Uberaba/MG	218.871	814	0.37%	Josahkian et al. ¹⁵
	Anápolis/GO	13.633	12	0.09%	Costa et al. ¹⁶
	Campo Mourão/PR	25.044	96	0.38%	Alves and Isolani ¹⁷
HIV	Caxias do Sul/RS	12.702	4	0.03%	*
	Cruz Alta/RS	280	15	5.4%	Martins et al. ¹⁸
	Maringá/PR	93.490	46	0.05%	Pereira and Bonafé ⁶
	Pernambuco	106.203	217	0.20%	Queiroz et al. ¹⁹
HTLV	Caxias do Sul/RS	12.702	4	0.03%	*
	Piauí/PI	233.927	400	0.17%	Oliveira et al. ²⁰
	Ceará	679.610	164	0.02%	Gomes and Eleutério ²¹
	Uberaba/MG	147.489	36	0.02%	Lima et al. ²²
Syphilis	Caxias do Sul/RS	12.702	19	0.15%	*
	Cruz Alta/RS	6.139	37	0.60%	Martins et al. ¹⁸
	Goiás	389.424	2,364	0.61%	Rodrigues ²³
	Montes Claros/MG	82.743	343	0.41%	Magalhães et al. ²⁴
	Porto Alegre/RS	88.201	819	0.92%	Trevizan and Cavada ⁷

*Data found in this study.

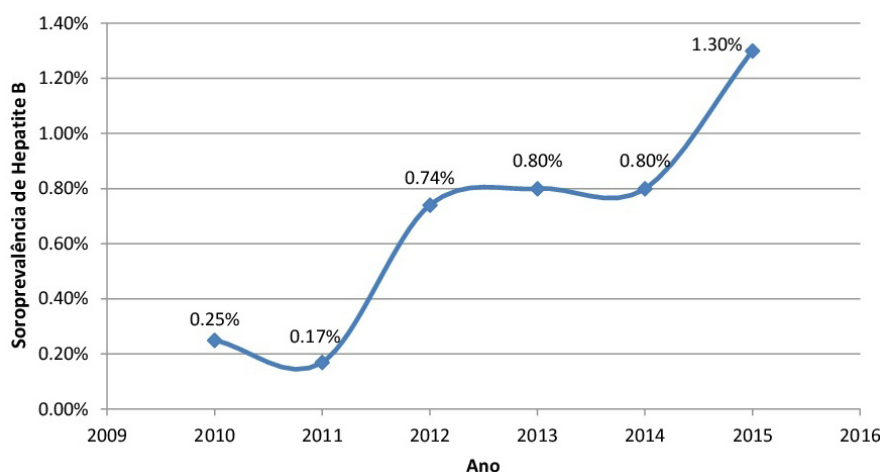


Figure 1: Annual prevalence of positive serology for hepatitis B markers.

by syphilis, with 702 (0.78%) and 819 (0.93%) cases respectively⁷. According to Ramos and Ferraz²⁵, the most prevalent cases of serological ineligibility in the blood center of Campo Mourão, southern Brazil was due to hepatitis B, with 275 (71.43%) donors, and syphilis, with 43 donors (11.17%), out of a total of 385 disposals after serological screening.

In the present study, 98 (0.77%) of blood donors had positive serology for hepatitis B. In Erechim, southern Brazil, the rate of positive serology for hepatitis B was 5.6% out of a total of 2,108 blood donors¹⁴. In a survey of report forms of 25,034 blood donors from the Hemotherapy Center da Santa Casa de Alfenas (NHSCA), located in Alfenas, southeastern Brazil, Diogo et al.¹² found 347 (1.83%) positive results for the anti-HBc marker from January 2000 to December 2006. Data from the Fundação Hemoninas show that hepatitis B is the main cause of serological ineligibility among blood donors, accounting for 1.26% of ineligible donations in serological screening²⁶.

According to Hemoprod, the percentage of serological ineligibility due to hepatitis B among blood donors in Brazil was 1.47% in 2012, with each Brazilian region showing different seropositive rates. The northern region was the one with the highest prevalence of positive hepatitis B serology, with 3.77%, followed by the southern region, with 1.94%. In 2013, the prevalence of the HBs-Ag marker in Brazil ranged from 0.07% in the state of Espírito Santo to 0.43% in the state of Paraíba. The state of São Paulo had the lowest rate for anti-HBc (0.76%), whereas the highest rates were reported in the states of Rondônia (4.38%) and Acre (4.33%)²⁷.

According to data from the Epidemiological Bulletin of the Brazilian Ministry of Health, there were 38,007 confirmed cases of hepatitis B from 1999 to 2011 in the southern region. In 990 (6.60%)

of these cases, blood transfusion transmission was reported as the possible source/mechanism of infection²⁸. In an American study of 217,738 donors, the prevalence of positive hepatitis B donors was 121 (0.06%)²⁹. The high rates of hepatitis B and syphilis found in the present study may be explained by the current environmental risks, which mainly involve unprotected sex, since these two diseases may be sexually transmitted. Although there is a vaccine for hepatitis B, the number of individuals contaminated with HBV has increased, as shown in Figure 1. This may be explained by the fact that vaccination campaigns are not meeting population demands and that these individuals were infected before the hepatitis B vaccine was available.

Syphilis is a chronic sexually transmitted infection caused by the *Treponema pallidum* spirochete. The usual source of infection is contact with a cutaneous or mucosal lesion of a sexual partner contaminated with syphilis, but it can also be transmitted during pregnancy and via blood transfusion³⁰. In the present study, 19 (0.15%) donors were positive for syphilis. In Brazil, syphilis is the second leading cause of serological ineligibility among blood donors, with a prevalence of 0.67%. The northeastern region had the highest prevalence, with 0.97% of positive cases, followed by the southern region, with 0.67%. The prevalence ranges of syphilis from 0.13% in the state of Rondônia to 2.42% in the state of Maranhão, with Rondônia presenting the lowest positivity rate for syphilis but the highest prevalence for the anti-HBc marker²⁷.

Screening methods to detect syphilis include non-treponemal tests, such as the VDRL test, and diagnosis should be confirmed with treponemal tests such as the microhemagglutination assay for *Treponema pallidum* or the fluorescent treponemal

antibody-absorption test¹. A study assessing the prevalence of serological ineligibility due to syphilis in a Hemotherapy Center in Cruz Alta, southern Brazil, from 2003 to 2009 found 60 (0.03%) VDRL positive cases out of a total of 20,780 medical records³¹. According to Rodrigues, there were 389,424 blood donations in the Goiás Blood Center, midwestern Brazil, from January 2002 to December 2011, 2,364 (0.61%) of which were positive for the VDRL marker²³. In the state of Santa Catarina, the seroprevalence of syphilis was 81.3 per 100,000 inhabitants (0.08%) from January to December 2010³². In Montes Claros, southeastern Brazil, positive results for the VDRL marker was the most prevalent reason for serological ineligibility, with 243 (0.41%) cases out of a total of 82,743 blood donors²⁴.

Chagas disease is known to be an endemic infection in some regions of South America and Brazil; therefore, serological screening of blood donors is essential, since this disease may be transmitted by blood transfusion. Chagas disease is an infection caused by the protozoan parasite *Trypanosoma cruzi* and transmitted by the infected stool of hematophagous triatomine insects. Other means of contamination include vertical transmission, oral transmission, and organ transplantation³³. Currently, screening for Chagas disease in Hemotherapy Centers is performed by detecting anti-*T. cruzi* antibodies using EIA or chemiluminescence¹. In the present study, positive serological results for Chagas disease were found in 10 donors (0.08%). In 2012, serological ineligibility rate for blood donation due to Chagas disease was 0.26%, according to data from the Annual Hemotherapy Production Bulletin. This bulletin also reports that the prevalence of Chagas disease in Brazil ranged from 0.02% in the state of Espírito Santo to 0.54% in the state of Rio de Janeiro²⁷. In an analysis of 25,207 blood donations performed in the Hematology Unit of Hospital Universitário de Santa Maria, southern Brazil, from January 2004 to December 2007, Cogo et al.⁹ found that 246 (0.98%) donors presented a positive or indeterminate serology for Chagas disease. The prevalence of positive serology for Chagas disease may be explained by the higher number of individuals who had not sought other health care services yet and whose disease had not been detected before, since it is usually asymptomatic, by the high rate of migration from rural to urban areas, and by improvements in housing, educational, and health conditions^{34,35}.

Serological screening for hepatitis C is performed by two tests: detection of anti-HCV antibodies or combined detection of anti-HCV antibodies and HCV antigens; and detection of HCV nucleic acid¹. In the present study, 9 (0.07%) donors were positive

for hepatitis C. In 2012, the ineligibility rate due to hepatitis C among blood donors was 0.27% in Brazil, ranging from 0.09% in the state of Tocantins to 0.65% in the state of Mato Grosso do Sul²⁷.

There were 18,307 confirmed cases of hepatitis C in the southern region from 1999 to 2011. In 3,910 (32.30%) of these cases, transfusion transmission was reported as the possible source/mechanism of infection²⁸. Josahkiane et al.¹⁵ assessed 218,871 blood donations carried out at Hemocentro Regional de Uberaba (HRU) from 1995 to 2008, 814 (0.40%) of which were ineligible because of positive serological test for HCV. The implementation of the nucleic acid amplification test in hemotherapy centers has been of great help in attempting to minimize risks arising from blood transfusions. This test is also mandatory for hepatitis C screening, thus reducing the window period to 6 or 7 days³⁶.

In the present study, the prevalence of positive serology for HIV 1 and 2 and HTLV I and II was 0.03%, which was the lowest prevalence among all the tested serologies. Currently, screening for HIV includes serological tests that detect the presence of the antibody against HIV or allow for the combined detection of antibody against HIV + HIV p24 antigens and molecular tests that aim to detect HIV nucleic acid¹. From 1980 to 2015, 207 HIV cases were reported to the Notifiable Diseases Information System (Sistema de Informação de Agravos de Notificação, SINAN) as the possible source/mechanism of transfusion infection³⁷. In 2012, 0.36% of blood donors were serologically ineligible due to HIV infection; in the southern region, this percentage was 0.28%²⁸. HTLV I and II are screened by detecting antibodies against HTLV I/II¹. In Brazil, the prevalence of serological ineligibility due to positive serology for HTLV was 0.17% in 2012, with the northeastern region showing the highest seropositive rate, with 0.28%, and the northern region showing the lowest rate, with 0.07%²⁷.

There is clearly a significant difference in the prevalence of positive serologies among blood donors from different Brazilian states. One should bear in mind that variations in results may be explained by several factors, such as differences in the methodologies used and good clinical screening, because when the latter is efficiently performed donors with possible positive serology are disqualified for blood donation. In the present study, hepatitis B and syphilis were the main causes of serological ineligibility among blood donors and may be related to present-day habits and behaviors, which lead to increased risk of contamination. Therefore, pre-transfusion measures covering recruitment of blood donors, clinical screening, and serological screening are of great help in attempting

to minimize risks arising from blood transfusions¹⁸. Considering that microorganisms causing diseases such hepatitis B, hepatitis C, HIV, HTLV, syphilis, and Chagas disease may be transmitted during transfusion and impair recipient's quality of life, further studies are necessary to evaluate the serological profile of blood donors. Screening to detect the presence of a given blood transmitted microorganism in blood bag will contribute to the adoption of more objective and early measures to reduce contamination during transfusion.

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Conflicts of interest

The authors declare no conflicts of interest

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