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RESEARCH

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Prevalência de inaptidão sorológica dos doadores de sangue no hemocentro regional de Montes Claros, Minas Gerais

Prevalence of serological inability of blood donors in regional blood center of Montes Claros, Minas Gerais

Prevalencia de imposibilidad serológico de donantes de sangre en hemocentro regional de Montes Claros, Minas Gerais

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ABSTRACT

Objective: to estimate the prevalence of disability serological of blood donors at the Regional Blood Center of Montes Claros, in the period 2009 to 2013. **Methods**: this is a transversal study, exploratory, through retrospective data collection, involving 2.101 donors unfit serologically. The study was approved by the CEP of Hemominas Foundation 381/2014. Results: of the 82.743 candidates suitable for blood collection, 2.101 (2.5%) had reactive serologic tests, but only 1.434 (1.9%) confirmed the result through the 2nd sample collection. Among the diseases investigated, there was the following distribution prevalence of hepatitis B (anti-HBc) donors with 0.77% about the total of suitable, syphilis (0.41%), Chagas (0.40%), and others showed values below 0.08%. **Conclusion**: we concluded that in comparison with other studies, it was found that the prevalence of disability in our blood bank serological is similar, showing that the measures taken are safe.

Descriptors: serology; blood donors; transmissible diseases.

RESUMO

Objetivo: estimar a prevalência da inaptidão sorológica dos doadores de sangue no Hemocentro Regional de Montes Claros, no período de 2009 a 2013. **Métodos:** trata-se de um estudo transversal, de caráter exploratório, através da coleta de dados retrospectivos, que envolveu 2.101 doadores inaptos sorologicamente. O estudo foi aprovado pelo CEP da Fundação Hemominas nº381/2014. **Resultados:** do total de 82.743 candidatos aptos para a coleta de sangue, 2.101(2,5%) apresentaram testes sorológicos reativos, porém apenas 1.434 (1,9%) confirmaram o resultado através da coleta de 2ª amostra. Dentre as doenças pesquisadas, houve a seguinte distribuição de prevalência: hepatite B (anti-HBc) com 0,77% doadores em relação ao total dos aptos; sífilis (0,41%); Chagas (0,40%); e demais apresentaram valores abaixo de 0,08%. **Conclusão:** concluímos que em comparação com outros estudos, verificou-se que a prevalência de inaptidão sorológica em nosso hemocentro é semelhante, mostrando que as medidas adotadas são seguras.

Descritores: sorologia; doadores de sangue; doenças transmissíveis.

RESUMEN

Objetivo: estimar la prevalencia de la discapacidad serológica de donantes de sangre en el Centro Regional de Sangre de Montes Claros, en el período de 2009 a 2013. **Métodos:** estudio transversal, exploratorio, retrospectivo, involucrando 2.101 donantes no aptos serológicamente. El estudio fue aprobado por el CEP de Fundación Hemominas 381/2014. **Resultados:** de los 82.743 candidatos adecuados para la recogida de sangre, 2.101 (2,5%) tenían pruebas serológicas reactivas, pero sólo 1.434 (1,9%) confirmaron el resultado a través de la segunda toma de muestras. Entre las enfermedades investigadas, hubo la siguiente prevalencia de distribución: hepatitis B (anti-HBc) con 0,77% de donantes en relación al total de adecuados, sífilis (0,41%), Chagas (0,40%) y otros mostraron valores por debajo de 0,08%. **Conclusión:** en comparación con otros estudios, se encontró que la prevalencia de la discapacidad serológica en banco de sangre es similar, lo que demuestra que las medidas adoptadas son seguras.

Descriptores: serología; donantes de sangre; enfermedades transmisibles.

INTRODUCTION

Blood transfusion is important for meeting the needs of patients in cases of emergency (severe accidents) and treating patients with chronic, serious illnesses that require transfusions regularly as in the case of sickle cell anemia, thalassemia, clotting factor deficiencies (hemophilia and Von Willebrand disease, for example), myelodysplastic syndrome, bone marrow aplasia, among others.[1] Then, it has shown to be an effective therapy and widely used in the treatment of various diseases.[2]

The transmission of infectious diseases by blood is known from the beginning of the twentieth century, even before there are the first blood banks. However, the onset of AIDS in 1981, and the evidence that the disease was transmitted by blood caused a revolution in world Blood Therapy services.[3]

The Ministry of Health states that for every donation, serological tests must be carried out for the following pathogens: HIV1 and HIV2, HTLV I and HTLV II, HCV, HBV, T. cruzi, Treponema pallidum, Plasmodium in endemic areas of malaria and CMV for immunosuppressed patients.[4] These tests are laboratory screening procedures that define if a unit can be approved for transfusion, being released only those whose tests were negative for all markers required.[5] According to the legislation, ordinance 1353 of June 13th 2011, redefined the by ordinance 2,712, of November 12th 2013, it is mandatory to carry out highly sensitive laboratory tests in every donation.[6-7] Thus, candidates for blood donation undergo clinical and serological screening to minimize the risk of disease transmission via transfusion.[8]

The country´s blood banks adopt measures as questionnaires about the general medical condition and exposure to sources of infection (hemodialysis, intravenous drug use, promiscuity); performing rigorous tests in all donated blood for tracing transmissible diseases. The presence of risk factors and seropositivity for blood transmissible diseases involve the immediate disposal of blood bags.[9-10] In this context, it is estimated that the serological discard rate in the national blood banks ranges from 10% to 20%, being higher than in developed countries, mainly due to the high percentage of people who donate for the first time and which have a prevalence of infection close to the general population.[11]

The transmission of pathogens through transfusion needs basically that the donor has the circulating agent in his blood, the serological screening tests are unable to detect it and the host being susceptible. Furthermore, the tropism of certain infectious agents from the blood component determines the contamination of various blood components (red blood cells, platelet concentrates, leukocyte concentrates and plasma). In the transfusion, one of the limitations is the immunological window, which allows contaminated blood transfusion.[8]

In Brazil, until June 2014, it was reported in the System Born informatio– - SINAN NET, 70,677 cases of infection

by the human immunodeficiency virus (HIV) among adults and 773 in children.[12] As to transmission among the older than 13 years old, sexually prevails. In women, 86.8% of the cases recorded in 2012 resulted from heterosexual sexual contact with HIV-infected people. Among men, 43.5% of the cases given by heterosexual contact, 24.5% by homosexual and 7.7% by bisexual. The rest occurred through blood and vertical transmission. Although the number of cases in males still is higher among heterosexuals, the epidemic in the country is concentrated (in population groups with behaviors that expose them to a greater risk of HIV infection, such as men who have sex with men, sex workers and drug users).[13]

The hepatitis B virus (HBV) is the only DNA virus that causes hepatitis in humans, belonging to the *hepadnaviral* family. Its main forms of transmission are a transfusion of blood or blood products, sex, perinatal transmission, intravenous drug use, organ and tissue transplantation, skin lesions or needle stick injuries. Therefore, infection with hepatitis B is a major public health problem.[9,14]

From data of blood banks, it is estimated six million people worldwide living with HBV.[10] The tests required for the detection of hepatitis B are: - detection surface antigen of hepatitis B virus (HBV) - HBsAg; and antibodies detecting against HBV capsid anti-HBc (IgG or IgM + IgG).[9]

With the identification of hepatitis C virus (HCV), studies have shown that this agent was also responsible for 90% of parenterally acquired hepatitis and at least 50% of the sporadic hepatitis non-A, non-B. For hepatitis C, the law measures the detection of antibody to HCV or combined detection of HCV antibody + antigen and detection of nucleic acid (NTA) of HCV.[9]

The human T-lymphotropic virus (HTLV) was the first isolated human retrovirus in 1980. In 1982, the second retrovirus with 60% homology with HTLV-I was isolated and named HTLV-II. Both the HTLV-I and II determine chronic infections with low viral replication rates, Adult T-cell leukemia/lymphoma (ATL) and remains most of the time in the incorporated provirus form the genomic DNA of the host lymphocytes.[15-16] In Brazil, most of the data to investigate the prevalence of HTLV has been obtained from research conducted with donors of blood through transfusion services.[16]

Studies with blood donors in several Brazilian capitals showed that Salvador is characterized as the most endemic region for HTLV-I, with a registered seroprevalence around 1.35%, followed by Recife and Rio de Janeiro with 0.33%, Belo Horizonte with 0.32% and this value was much higher than the 0.025% observed in the United States.[16]

Chagas disease is a tissue and hematologic infection caused by the flagellate protozoan Trypanosoma cruzi, whose natural vectors are insects of the order Hemiptera, and Triatoma infestations most important vector of the disease, described in 1909 by Carlos Chagas. Chagas disease is endemic only on the American continent and has 16 million to 18 million people infected with approximately 300,000 new cases per year, a significant cause of mortality of young adults, reducing in 13 years the expectation of life.[17] Today, legislation stipulates that the detection is through anti-T cruzi enzyme immunoassay antibody (IEE) or chemiluminescence (QLM).[18-19]

Syphilis is a chronic infectious disease caused by Treponema pallidum. In some countries, like Brazil, it is considered one of the major public health problems, similar to other emerging infectious diseases in the country.[20]

According to the World Health Organization, it is estimated about 12 million new cases of people infected each year with some disease related to sex, among which syphilis has great representation.[21] Currently, the search for syphilis is done with specific and non-specific tests, and most laboratories have opted for Venereal Disease Research Laboratory (VDRL) and enzyme-linked immunosorbent assay (ELISA) for being easy to perform. According to the law, the test should be by detecting the anti-teponemal or non-treponemal antibody.[6]

In the last two decades, there has been more concern with ensuring transfusion safety. In parallel, an aging population, violence and accidents, associated with technical and scientific advances in the medical field have brought an increase in demand for transfusions, not always accompanied by an increase in the number of blood donors. For the safety of blood products to be used in transfusions, strict quality parameters should be followed.[1] There must be functional systems that minimize the likelihood that one infected unit of the stock components available for transfusion to ensure that the blood and its components are as safe as possible.[22]

Laboratory screening for blood transmissible diseases is one of the most powerful tools in ensuring safety blood transfusion. However, alone, it is no guarantee of safe blood components. All procedures involving blood donation should be carried out in a structured and standardized form to minimize transfusion risks.[23] Hence the importance of fulfilling efficiently the chemotherapeutic cycle, which begins with the collection and selection of donors, followed by serological and immuno-hematological screening, processing and fractionation of collected units, dispensation, transfusion, and post-transfusion evaluation.[11]

The lack of epidemiological data in Brazil, and more specifically in the North of Minas Gerais Region is a stimulus for this study, seeking greater knowledge about characteristics of this population, through data collection on infectious diseases of the donors of the Regional Blood Center Montes Claros-MG hills that is a reference to the North of Minas Gerais.

This study aimed to determine the frequency of the prevalence of serological markers of hepatitis B and C, HIV, HTLV I / II, syphilis and Chagas disease among blood donors attending the Montes Claros Regional Blood Center from 2003 to 2013 and associate seroprevalence sociodemographic characteristics of these donors.

METHODS

This is a cross-sectional, descriptive and quantitative study. The study population was candidates for blood donation at the Blood Center Regional Montes Claros-MG, in the period 2009-2013, which showed reactive serologic tests and confirmed the inability serologic by collecting the second sample n=1,434.

Secondary data from the Blood Center Blood Bank System were collected, coming from the standard procedure of screening and questionnaire completion prior to blood collection and also the results of serological tests for Chagas disease, HTLV I and HTLV II, AIDS, syphilis, Hepatitis B and C and adult T-cell leukemia/lymphoma recommended by the Ministry of Health. Thus, the variables in this study are part of a computerized database donors control (FDOA). This study also has the variables of gender (male and female), age group (18-29 years old and ≥30 years old), marital status (married, single or other) and type of donation (first time and repeat).

Statistical analysis were performed using the Statistical Package for Social Sciences - SPSS version 11.0 for Windows. Descriptive analyzes were performed with the presentation of absolute and relative frequencies and measures of central tendency and association analyzed with Chi-square and Fisher exact.

The study was approved by CEP Hemominas Foundation # 381/2014.

RESULTS

The Montes Claros Regional Blood Center is the main blood donation center of Northern Minas Gerais assisting 29 transfusion agencies, was one of the first cities in the state of Minas Gerais to house a Hematology core of Hemominas Foundation. It is a regional reference in the care of patients with hemoglobinopathies, coagulopathy and transfusion procedures for patients in outpatient conditions. It has about 2,500 registered patients, 77% of patients with sickle cell anemia.

In 2012, the blood center received around 22,173 candidates for blood donation, from the area and underlying regions of Montes Claros. Due to the loyalty of work carried out, 16,746 were eligible for donation, with a percentage of 29.6% new and 70.4% loyal donors, that is, repetition. This information and the approach found in a study in the hospital Santo Ãngelo - RS, between 2005 and 2010, where the total of candidates for donation was 24,862, and of these 18,295 (73.6%) were eligible and 6,567 unsuitable (625 by serologic screening and 5,942 by hematological screening).[24]

In this study conducted from 2009 to 2013, a total of 1,434 (1.9%) donors confirmed the result by the second sample and obtained reactive results, that is they were unfit for positive serology, being included and distributed according to gender, age, marital status, and type of donation as shown in Table 1.

Table 1: frequency distribution donor unsuitable for seropositivity in the 2009-2013 period.

Category	Unfit
Gender	
Male	789 (55.0%)
Female	645 (45.0%)
Age group	
18-29	281 (19.6%)
≥30	1153 (80.4%)
Marital Status	
Married	724 (50.5%)
Single	508 (35.4%)
Other	202 (14.1%)
Type of Donation	
First time	1069 (74.5%)
Repetition	365 (25.5%)

The male was the one with the highest prevalence of gender. It is observed that the most affected age group corresponded to those who were 30 years old. Regarding marital status, there was a prevalence among married. It also became evident an increase among first-time donors.

A study in the Blood Bank of Uberaba-MG found the prevalence of male donors (73%) and in age, there was slightly higher than for people over 30 years old[25], corroborating the findings of this work. In research on first-time blood donors in Recife, there was also a prevalence of males (73%) and about 48% were married or had a stable relationship.[26] In another study, the public blood bank of Natal-RN again was detected the predominance of the male gender, age over 29 years old and regarding marital status, indices were similar between married (48.1%) and single (47.9%).[27] A similar situation to that found in Santa Cruz do Sul-RS, in which the total number of surveyed individuals, both married as singles accounted for 46.4%.[28] A research of Rohr et al.[24] although performed with unsuitable in clinical screening, profiling the candidates matches this work as the gender (most male) and the fact of being a spontaneous donor. However, it differed with the age, since most were between 18 and 23 years old. Different from these research, Belato et al..[29] research revealed that 50% of donors were women, and 50% were men.

Regarding the prevalence of male gender, a study of Anvisa[30] found that more men seek the blood donation service. Probably, this is the reason for the number of unfit men beeing higher than womens.[24,31-32]

Table 2 describes the prevalence of unsuitable donations by serology. From these data, it was found a significant increase in the percentage of the virus for hepatitis

B-anti-HBc marker (0.77%), followed by syphilis-related diseases (0.41%) and Chagas (0.40%).

Alves et al.[9] study showed that 1.97% of unsuitable donors, from 1995 to 2009, had positive serology for HBV. Moraes-Souza study[25] showed non-negative serology for Chagas of 0.31% and study of Melo et al..[33], made in Pernambuco reported that 39.70% of donors had reagent serology for Chagas, and of these, 60.30% were for inconclusive serology. In another study of 218,989 donors considered suitable by serology, 0.2% were ineligible because positive for Chagas disease.[34]

Table 2: prevalence of unsuitable donations by serology at the Regional Blood Center of Montes Claros, in 2009-2013.

Disease	Prevalence by the total of donors	Prevalence by the number of unsuitable donors
Syphilis	0,41%	343 (23.9%)
HbSAg	0,08%	65 (4.5%)
HBC	0,77%	637 (44.4%)
HCV	0,06%	52 (3.6%)
CHAGAS	0,40%	326 (22.7%)
HIV1	0,07%	64 (4.5%)
HIV2	0,05%	43 (3.0%)
HTLV	0,06%	49 (3.4%)
Total of donors	**82743**	**1434**

The association between gender, age, type of donation, marital status for the group of communicable diseases (syphilis, anti-HBc, HCV, HIV/I and HIV/II), is shown in Table 3.

Table 3: distribution of age, gender, type of donation and marital status about disability by diseases transmitted by transfusion.

Group		Gender M F	P*	Age 18-29 >30	P*	Type of Donation First time R	P*	Marital status Married Single Other	P
Syphilis	**Pos**	203 140	0.082	60 283	0.276	216 127	0.000	167 113 63	0.031
	Neg	586 505		221 870		853 238		557 395 139	
HBC	**Pos**	368 269	0.062	141 496	0.032	533 104	0.000	326 239 72	0,020
	Neg	421 376		140 657		536 261		398 269 130	
HCV	**Pos**	25 27	0.323	14 38	0211	28 24	0.001	18 25 9	0.063
	Neg	764 618		267 1115		1041 341		706 483 193	
HIV1	**Pos**	34 30	0.798	28 36	0000	38 26	0.004	23 34 7	0.010
	Neg	755 615		253 1117		1031 339		701 474 192	
HIV2	**Pos**	22 21	0.642	10 33	0558	19 24	0.000	21 15 7	0.914
	Neg	767 624		271 1120		1050 341		703 493 195	

* Chi-square test

** Fisher's exact test

It was found that with regard to age, there was no statistically significant difference with the marker for HIV/I (p=0.000) and with the anti-HBc marker (p=0.032).

For the type of donation, there was no difference with syphilis (p=0.000), anti-HBc (p=0.000), HCV (p=0.001), HIV/I (p=0.004) and HIV/II (p=0.000). Marital status with syphilis (p=0.031), anti-HBc (p=0.020) and HIV/I (p=0.010). The other parameters were not statistically significant.

The prevalence of disability serological hepatitis B virus (HBV) in this study was 0.77%, and the hepatitis C virus (HCV) was 0.06% about the total of suitable donors, demonstrating a greater prevalence of hepatitis B in the northern region of Minas Gerais. On average, in Brazil, this prevalence is around 8%. In the southern states is about of 0.3% to 1.7% in São Paulo and Rio de Janeiro from 1.0 to 2.1%, which shows the similarity of this study to other described before.[13] In a study performed in the Blood Bank of Uberaba - MG, the prevalence was 5.6% compared to HBV, and males predominated, age older or equal to 30 years old, marital status as married.[9] In another study, it was found that 0.37% of donors are unsuitable by HCV.[35]

However, in the Northeast and the Amazon region, the prevalence is around 2.8% to 10.3%. In this sense, it confirms the heterogeneity of our country.[13] In England, the prevalence of viral hepatitis in blood donors is low and decreasing: 0:39:100,000 donations for the hepatitis B virus (HBV) and 0:17:100,000 donations for hepatitis C (HCV). These rates are much lower than the rates reported in the United States (1:63.000 HBV; 1:103,000 HCV) and France (1:112,000 HBV; 1: 217,000 HCV). In Brazil, the prevalence of viral hepatitis rates in blood banks are not negligible for markers of hepatitis B and C: 0.3% - 1.5% for HBsAg; 3.7% - 11.1% for anti-HBc and 0.9% - 2.6% anti-HCV.[36]

For this study, the prevalence of syphilis was 0.41% which reinforces similar findings in the study of Borelli et al..[37] at the Blood Center of Maringá, Paraná. On the other hand, the positivity rate for the pathology in Guarapuava (PR) was 2.1%, so a higher rate than that reported in the current study. Research in other states of blood centers also showed a high positivity rate for syphilis testing, as well as in the Brazilian states of Amazonas, São Paulo and Sergipe.[37]

Regarding the prevalence of syphilis, which in this study was 0.41% and hepatitis B (0.77%), together have demonstrated a high disability rate serologic, corroborating studies by Rodriguez et al.,[38] Salles et al.,[39] Carrazone et al.,[22] and data obtained from the National Health Surveillance Agency.[40]

The prevalence of hepatitis B and syphilis as the main pathologies associated with serological screening may be linked to the fact that currently the population has a cumulative effect of behavioral risks. These mainly involve unprotected sex, since these diseases are mainly transmitted through sexual intercourse, the use of illicit injectable drugs and other exposures to blood and blood products.[1]

Analyzing the rate of Chagas disease in this study (0.40%), it was relatively low compared with rates of 1.1% and 1.9% in other studies.[41-42] This analysis shows that currently there was a significant decrease in transmission of Chagas disease in Brazil, estimated at between three and twenty occurrences in the context of more than 4 million annual transfusions.[43]

This decrease may be explained by a different proportion of rural migrants in urban areas between the 70 and 80, or perhaps for the better management of the disease and reducing transmission.[44]

In tests of association between the diseases (syphilis, HIV, and HTLV) and marital status, in participants with negative serology, the proportion of married couples is higher than in those with positive serology.

CONCLUSION

The rate of unsuitable serological blood banks in Brazil ranges from 10 to 20%.[39] Currently, ANVISA recommends that the suitable serological rate is less than 8.3%. The results of the serological prevalence of unsuitable from this study are with values below the national parameters. Thus, it is concluded that epidemiological surveillance is an essential tool for determining the risk of infection and profile of infected patients, enabling the implementation of prevention and maintenance measures of reduced serum values, requiring a collection of constant epidemiological information to improve the research and reporting process.

The acquisition of new customers has been one of the biggest challenges for the institution. It requires a constant educational program, to increase the number of spontaneous and regular donors, but if not careful; it can increase the incidence of seropositivity in a first blood donor.

One effective measure is to conduct educational campaigns and quality information to the public about blood donation. With this awareness, a voluntary and altruistic donation will increase, and consequently a better profile of donors, improving safety on donation.

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