Revista da Sociedade Brasileira de Medicina Tropical 47(2):179-185, Mar-Apr, 2014
http://dx.doi.org/10.1590/0037-8682-0032-2014

Major Article

Syphilis seroprevalence estimates of Santa Catarina blood donors in 2010

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ABSTRACT

Introduction: Knowledge of blood donor characteristics is essential to better guide clinical and serological screening for hemotherapy. The objective of this study was to determine the syphilis seroprevalence and the associated factors of blood donors in the State of Santa Catarina, Brazil. **Methods:** This population-based study from the State of Santa Catarina used information obtained from blood donation records. We analyzed 83,396 blood donor records generated from donors who were considered eligible to donate between January and August 2010. The aim of the study was to estimate the syphilis seroprevalence and its relationship with educational level, age, gender, geographical region and having donated blood in the past 12 months. We used descriptive analyses and a Poisson regression to calculate the prevalence ratios for the variables of interest. **Results:** We found a 0.14% overall seroprevalence and significant differences among the following: first-time blood donors (0.19%) versus repeat donors (0.03% to 0.08%); low educational levels (0.30%) versus medium and high educational levels (0.08% to 0.19%); and donors who did not report their residence (0.88%) or age (6.94%) versus those who did. Increased syphilis seroprevalence was also significantly associated with increased age. **Conclusion:** High syphilis seroprevalence was associated with lower educational level, age, first-time donation and the failure to provide age or residence information.

Keywords: Seroprevalence. Syphilis. Blood donors. Risk factors. Brazil.

INTRODUCTION

Syphilis is a chronic infectious disease caused by the spirochete bacterium *Treponema pallidum (T. pallidum)* and is characterized by alternating symptomatic and asymptomatic periods and possibly long latency periods[1]. Although its treatment is accessible in Brazil, its incidence remains a serious public health problem[2]. According to the World Health Organization (WHO), approximately 340 million new cases of curable sexually transmitted diseases emerged worldwide in recent years, including 12 million syphilis cases[3]. In Brazil, 843,300 new cases were reported in 2003[4].

Syphilis transmission can occur through sexual intercourse, blood transfusion and vertical transmission. Cases of infection through blood transfusions are rare due to the serological screening of blood donation candidates and because of the limited survival of *T. pallidum* in collected blood, whereby it is rapidly destroyed within a few minutes of exposure to drying, heat or air. Further, *T. pallidum* loses its viability after approximately seven days of storage at refrigerated temperatures[5]. Serological screening for syphilis and other infectious diseases is an important blood safety measure to avoid transfusion-transmitted infections. However, this procedure does not guarantee complete elimination of transmission risk because of the difficulty in detecting serologic markers in the early infection phase. To further reduce the risk of infection, a donor selection that effectively screens for behavioral risks is also necessary[6].

In 2004, the Brazilian Ministry of Health determined that all units of collected blood had to be serologically screened for the following infections: syphilis, hepatitis B, hepatitis C, Chagas disease, human immunodeficiency virus (HIV), malaria and type I and II human T-cell lymphotropic virus (HTLV)[7]. Serological syphilis screening can be accomplished with high-sensitivity treponemal and non-treponemal tests. The Venereal Disease Research Laboratory (VDRL) test is the most common non-treponemal test used in blood bank routines, followed by a subsequent treponemal test, such as the fluorescent treponemal antibody-absorption (FTA-ABS), treponemal protein hemagglutination test (TPHA) or enzyme immunoassay (EIA) test[8].

The syphilis prevalence in the Chinese blood donor population displayed an increasing trend over a five-year period from 2006 to 2010[9]. In Germany, the syphilis prevalence from 2008 to 2010 ranged from 31.0-42.1/100,000 donations and also increased during those years[10]. In Brazil, there is a wide variation in the reported syphilis prevalence, such as 2.1% and 0.2% prevalences in Guarapuava (Paraná), a 0.49% prevalence in Amazonas, a 0.3% prevalence in Cruz Alta (Rio Grande do Sul) and a 1.1% prevalence in São Paulo[8,11-13].

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Received 10 February 2014
Accepted 7 April 2014

Knowing the blood donor's epidemiological profile is essential to better guide clinical and serological screening methods. The objective of this study was to determine the syphilis seroprevalence in blood donors from the State of Santa Catarina, its distribution across different geographical regions and its association with socioeconomic factors.

METHODS

In 2011, there were approximately 2.4 million blood donations in the Brazil public health sector, with the Southern region accounting for almost 57% of all donations[14]. This retrospective study of the Santa Catarina blood donor population assessed people aged 16-65 between January and August of 2010. The study used secondary data obtained during the blood donation process. Additionally, we analyzed those individuals considered eligible to donate after a clinical examination. The data were extracted from the computerized Center for Haemotherapy of the State of Santa Catarina (*Centro de Hematologia e Hemoterapia Hemoterapia de Santa Catarina* - HEMOSC) database, Brazil.

In the blood bank, the donor candidates underwent clinical examinations, which included verification of their weight, height, blood pressure and signs of anemia, followed by an interview regarding transfusion risk factors that included sexual behavior questions. Specifically, we asked the donors if they had ever been diagnosed with sexually transmitted diseases, if they had ever paid for sex, how many sexual partners they had in the last year, if they were having sex with the same sex partner or if they had an imprisoned partner or a partner who had many sexual partners. A confidential exclusion option was offered immediately after the blood donation. The candidates considered eligible to donate were referred for the collection of approximately 500ml of blood and the collection of blood samples for serological tests.

The dependent variable in the study was the syphilis prevalence. The total number of infected donor candidates was adjusted for those with reactive VDRL test results who did not return for subsequent testing. The confirmation rate, using another VDRL and a treponemal test (FTA-ABS and EIA) in the VDRL screen-positive donors, was estimated from a multinomial regression whose outcome categories included the following: 1) a screen test that was confirmed positive, 2) a screen test that was confirmed negative, 3) an indeterminate test result and 4) an unknown test result (i.e., the donor did not return for follow-up testing). A screen-positive VDRL test was considered confirmed if the subsequent VDRL and/or a treponemal test also produced a positive result. As the main objectives of syphilis screening in blood donors are to evaluate risky sexual behavior, either past or present, and to prevent transfusion of the blood donated from such donors, donor candidates with a VDRL titer of 1:1 or higher were considered screen-positive and were referred for further testing. The syphilis stage and its clinical management were beyond the scope of the blood bank serological investigations, but all infected donors were referred to medical services for further clinical investigation and treatment if necessary.

The VDRL screening test that was used was VDRL Bras, which was supplied by Laborclin (Pinhais/PR, Brazil). Additionally, the FTA-ABS test was produced by WAMA Diagnostica (São Paulo, Brazil), and the EIA test was supplied by Abbott (Abbott Park-II, USA).

The independent variables included gender (male or female), age (16-25, 26-35, 36-45 and 46-65 years), education level (complete or incomplete primary or secondary school), residence region (from the seven major geographical regions of the state: Florianópolis, Extremo Oeste, Meio Oeste, Planalto Norte, Sul, Vale do Itajaí and Planalto Serrano) and previous blood donation status (never, within previous 12 months or more than 12 months ago). This model allowed for an estimation of the syphilis infection probability among those donors who did not return for follow-up testing, despite a reactive screening test result.

The donors who did not provide their residential postal (zip) code were included in the analysis in the *not informed* category.

The provided descriptive statistics included the syphilis seroprevalence and its 95% confidence intervals, along with its variation according to the examined independent variables. Both univariate and multivariate Poisson regression analyses were used to assess the significance of the risk factors and the magnitude of their impact via prevalence ratios. Stata software, version 11, was used for all statistical analyses.

Privacy and confidentiality of the blood donor records were assured by omitting any personal information that could be used for individual donor identification.

Ethical considerations

The study was approved by the HEMOSC Ethics Committee (number 004/10), in accordance with the Declaration of Helsinki. The research was also approved by the HEMOSC Ethics Committee (nº 004/12).

RESULTS

In the first eight months of 2010, 83,396 blood donation candidates in Santa Catarina were considered eligible for donation after a clinical examination.

The VDRL syphilis screening confirmation rates were 50% and 58% for the indeterminate and positive test results, respectively (**Figure 1**); however, the estimated confirmation rate among the cases without follow-up testing was lower (38%).

Based on confirmed cases only, the overall syphilis prevalence was 0.14%. Additionally, the prevalence was higher among women (0.16%) than among men (0.12%); however, this difference was not statistically significant (**Table 1**).

Increased syphilis infection risk was also significantly associated with increased age ($p = 0.002$), with an average risk increase of 38% and with 95% confidence intervals between 12% and 69%. Additionally, the prevalence was almost 7% among the donor candidates who did not report their age (**Table 1**).

Donor candidates with incomplete primary school education had a syphilis seroprevalence that was significantly higher (0.3%) than that of donor candidates in the other education

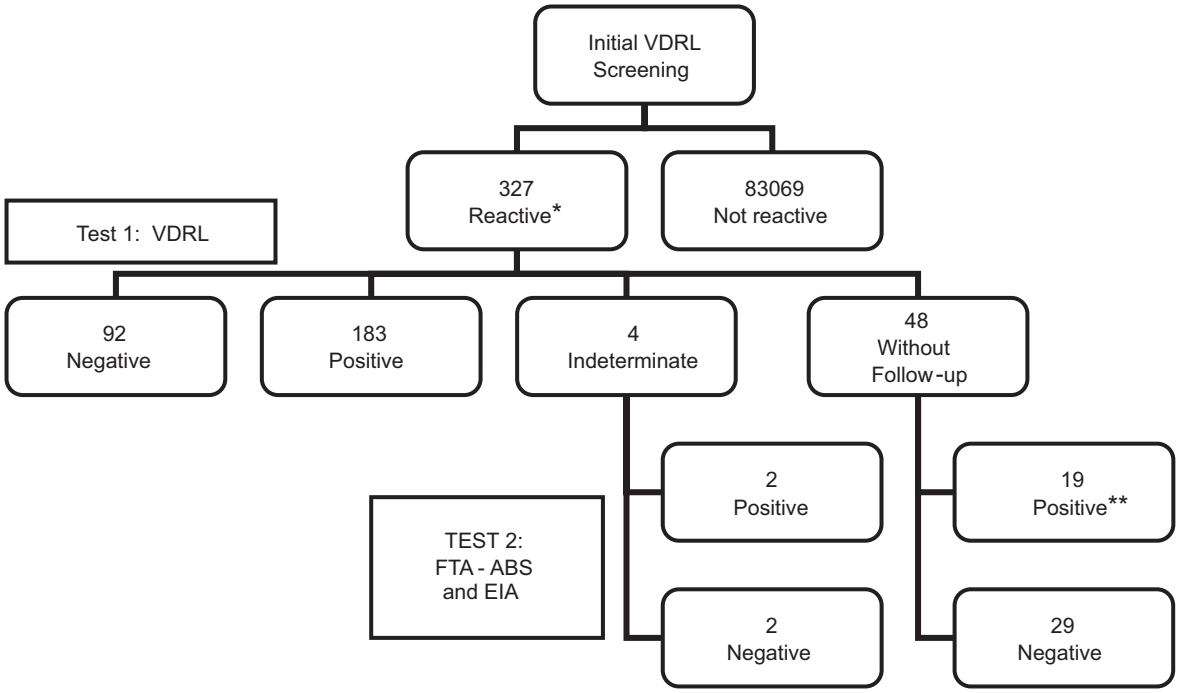

FIGURE 1 - Syphilis serological testing flow chart.
VDRL: Venereal Disease Research Laboratory; FTA-ABS: fluorescent treponemal antibody-absorption; EIA: enzyme Immunoassay. *titer>1:1. **Estimated by multinomial regression

level groups. Additionally, the seroprevalence among first-time donors was significantly higher in comparison with that of repeat donors (**Table 1**).

Although the seroprevalence variation across the geographical regions (**Table 1**) of the state was not statistically significant (p = 0.51), its amplitude ranged from 0.09% in the Planalto Serrano region to 0.29% in the Meio Oeste region. Moreover, higher values were observed among those donor candidates who did not report their zip codes (0.88%).

A univariate Poisson analysis (**Table 2**) revealed an increased syphilis infection risk among older donors, first-time donors, those with less education, those that lived in the Meio Oeste and Planalto Serrano regions and those who did not provide their residence or age information. The strong association observed between a non-response and infection risk reinforces the need to treat a non-response as a special category in the multivariate regression. The increase in syphilis infection risk with age and among first-time donors remained significant in the multivariate model, while the highest educational level had a protective effect. The geographic variation was no longer statistically significant after adjusting for other variables in the multivariate model.

DISCUSSION

The predominant demographic profile of the Santa Catarina blood donors in 2010 was composed of men younger than 36 years who completed at least 9 years of school and lived in the state capital. Similar demographic blood donor population profiles have also been reported in other studies[6,15].

The present study found a low (0.14%) syphilis prevalence in the donor population compared with the values observed in other Brazilian states[8,12,13]. A similar result was noted in the neighboring State of Parana, which reported a 0.2% prevalence in VDRL reactive donors[11]. However, the largest blood bank in the State of São Paulo had a 1.7% prevalence in 2007[6]. Other Latin American countries have also observed a wide syphilis prevalence variation, from a 0.5% prevalence in Uruguay to a 5% prevalence in Paraguay[16]. The lower syphilis seroprevalence among the Santa Catarina blood donors may be the result of less risky sexual behavior in the general population and better blood donor selection. Among the former, it is worth mentioning that the implementation of obligatory syphilis screening of pregnant women in 1993 consequently reduced the vertical transmission of this infection[17].

Although the syphilis prevalence was not statistically significant between men and women, the former had a one-third higher risk. This difference may be related to riskier sexual behavior among men and a shorter interval between donations in this group, which resulted in a greater number of donations over the same period[12,18]. Anemia related to postmenstrual periods are known to decrease the blood donation frequency in women[12].

In the present study, the 0.12% syphilis prevalence of female donors and the 0.07% syphilis prevalence in the Vale do Itajaí region were significantly lower than the 0.43% prevalence

TABLE 1 - Seroprevalence and 95% confidence intervals for syphilis markers in the blood donors with regard to sex, age, repeat donation, educational level and residence region. HEMOSC, Florianópolis, 2010 (N= 83,396).

		Initially reactive VDRL (screening)			Subsequent VDRL or treponemal test reactive		
Variable	Percentage	n	prevalence (%)	95% CI	n	prevalence (%)	95% CI
Gender							
female	42.2	83	0.24	0.18-0.29	55	0.16	0.12-0.20
male	57.8	105	0.22	0.18-0.26	58	0.12	0.09-0.15
Age (years)							
16-25	33.1	56	0.20	0.15-0.26	32	0.12	0.07-0.15
26-35	32.3	56	0.21	0.15-0.26	38	0.14	0.09-0.18
36-45	19.7	44	0.27	0.19-0.35	22	0.13	0.08-0.19
46-65	13.7	31	0.27	0.18-0.37	21	0.18	0.11-0.26
not informed	1.2	140	13.50	11.42-15.58	72	6.94	5.39-8.49
Education							
1st incomplete degree	11.8	268	0.54	0.48-0.61	148	0.30	0.25-0.35
1st complete degree	16.8	31	0.14	0.09-0.18	19	0.08	0.05-0.12
2nd full degree	37.9	28	0.24	0.15-0.33	18	0.16	0.08-0.23
completed high school	13.8	26	0.27	0.16-0.37	16	0.16	0.08-0.24
not informed	19.7	43	0.31	0.21-0.40	26	0.19	0.11-0.26
Repeat donation							
no (first-time donor)	59.2	268	0.54	0.48-0.61	92	0.19	0.14-0.22
yes, within the last 12 months	27.1	31	0.14	0.08-0.18	7	0.03	0.0-0.05
yes, >12 months ago	13.7	28	0.24	0.15-0.33	9	0.08	0.03-0.13
Regions							
Florianópolis	19.9	34	0.20	0.14-0.27	26	0.16	0.09-0.22
Planalto Norte	19.4	28	0.17	0.11-0.24	15	0.09	0.05-0.14
Extremo Oeste	13.9	27	0.23	0.15-0.32	17	0.15	0.08-0.22
Meio Oeste	2.9	7	0.29	0.08-0.51	7	0.29	0.07-0.51
Sul	13.4	25	0.22	0.14-0.31	14	0.12	0.06-0.19
Vale do Itajaí	14.0	28	0.24	0.15-0.33	16	0.14	0.07-0.20
Planalto Serrano	5.6	21	0.45	0.26-0.64	11	0.23	0.09-0.37
not informed	10.8	157	1.74	1.47-2.01	79	0.88	0.68-1.07

HEMOSC: *Centro de Hematologia e Hemoterapia de Santa Catarina;* VDRL: Venereal Disease Research Laboratory; CI: confidence intervals.

among pregnant women in the City of Itajaí in the second half of the 2010 decade[19]. This result was expected because the female blood donors were screened for risky sexual behavior during the blood donation candidate interview in the present study, whereas no such screening was performed in the other study that included all pregnant women.

Regarding the donation type, first-time donors had a higher seroprevalence than repeat donors. Community and repeat blood donors are considered a low-risk population for blood-borne diseases, as they are repeatedly screened and therefore less likely to be infected[20]. Rising donor awareness of behavioral risks for sexually transmitted diseases is undoubtedly a key tool for further reducing the disease transmission risk by blood transfusion[21-23].

Although the younger donors participated more than the older donors, the highest syphilis seroprevalence was noted in the 45- to 65-year-old age group (0.18%). Syphilis in this age group may have been acquired decades ago because older individuals could have been exposed for longer time periods and during a period when the syphilis prevalence was higher than

TABLE 2 - The State of Santa Catarina blood donor univariate and multivariate Poisson regression results with their respective confidence intervals (95%) and prevalence ratios. HEMOSC, 2010.

		Univariate	Multivariate
Risk factors	n	PR (95% CI)	PR (95% CI)
Gender			
female	47,611	1	1
male	34,748	0.93 (0.59-1.46)	0.91 (0.58-1.43)
Age (years)			
16-25	27,635	1	1
26-35	26,930	1.35 (0.72-2.53)	1.68 (0.88-3.20)
36-45	16,389	2.29 (1.23-4.29)*	2.61 (1.36-5.02)
46-65	11,405	2.41 (1.23-4.73)*	2.62 (1.28-5.38)
not informed	1,033	69.46 (39.66-121.64)*	-----
Educational level			
incomplete primary school	9,809	1	1
completed primary school	14,018	0.95 (0.49-1.84)	1.16 (0.59-2.29)
incomplete high school	31,678	0.59 (0.32-1.10)	0.82 (0.43-1.58)
high school degree	11,481	0.19 (0.06-0.61)*	0.23 (0.07-0.78)*
refused to answer	1,027	1.02 (0.20-5.14)	0.93 (0.18-4.72)
not informed	15,379	2.21 (1.25-3.91)*	0.60 (0.25-1.45)
Repeat donation			
no (first-time donor)	49,332	1	1
yes, within the last 12 months	22,607	0.17 (0.09-0.35*	0.24 (0.11-0.49)*
yes, >12 months ago	11,453	0.42 (0.22-0.79)*	0.58 (0.30-1.15)
Regions			
Florianópolis	16,593	1	1
Planalto Norte	16,195	1.14 (0.52-2.49)	0.99 (0.45-2.18)
Extremo Oeste	11,600	1.42 (0.64-3.17)	1.08 (0.48-2.42)
Meio Oeste	2,406	2.88 (1.01-8.17)*	2.32 (0.81-6.63)
Sul	11,216	1.14 (0.48-2.69)	0.84 (0.35-2.00)
Vale do Itajaí	11,668	1.23 (0.53-2.82)	0.75 (0.32-1.76)
Planalto Serrano	4,698	2.51 (1.04-6.04)*	2.11 (0.87-5.11)
not informed	9,016	8.11 (4.33-15.18)*	1.06 (0.44-2.57)

HEMOSC: *Centro de Hematologia e Hemoterapia de Santa Catarina;* N: number; CI: confidence intervals ; ----- omitted because of collinearity. *p <0.05.

it is currently[24]. A study in São Paulo revealed a similar relationship between donor age and syphilis prevalence[25]. Additionally, the fact that syphilis infection is relatively simple to cure in its early stages might have resulted in more effective disease treatment in campaigns against sexually transmitted diseases, thus decreasing syphilis prevalence in younger generations[23]. It is also worth noting that the participation level increased to approximately 90% among the donor candidates under 40 years old in this study compared with the 80% participation level in the 1990-1999 decade[26].

The Meio Oeste region had the highest (0.29%) syphilis prevalence. In the southern region of the state, the prevalence was 0.18% in the first half of the 2010 decade[27]. These data emphasize the need for region-specific preventive actions.

In the state capital region, which had the highest number of donors, the 0.16% seroprevalence was close to the seroprevalence for the period between 1991 and 1996 (0.15%), demonstrating that there has been no progress in reducing the syphilis transmission rate in this population over the last ten years[23].

The limitations of this study include incomplete data with regard to donor residence (10.8%) and educational level (19.7%), along with the inevitable increase in the variation of rare events, such as syphilis infection, especially when data are broken down by region. The observed relationship between an age or residence non-response and increased syphilis infection risk suggests an information bias that limits the generalizability of the results, which merits further investigation. It is also important to note that the serological tests used did not differentiate recently infected donor candidates from those infected years ago or during clinical stages of the disease.

False-positive test results are common in the VDRL screening of low-risk populations, such as blood donors. In HEMOSC, the false-positive rate used to be over 60% but has been reduced to approximately one-quarter with the so-called reverse algorithm[28]. The rate was significantly associated with previous pregnancy, which was in agreement with other studies[29]. Although some other infections have been reported to increase the false-positive rate, these findings could not be confirmed with the HEMOSC donors[28]. False-negative test results are more likely to occur with treponemal tests compared with VDRL tests in the early phase (2-3 weeks) of infection, whereas the opposite is true for the later stages of infection[29]. Most non-treponemal tests are less sensitive in patients with primary syphilis than in those with secondary syphilis[30]. Both false-positive and false-negative test results may bias the prevalence estimates; however, they are often difficult to quantify in blood bank settings.

Despite the limitations, the study evaluated a large number of potential blood donors, which is essential for the study of rare events, and provided good coverage of geographical and socio-demographic risk factors. Furthermore, the statistical treatment of the non-responders to follow-up testing and of the independent variables (e.g., unknown residence and education level) in the multinomial regression analysis reduced the potential bias by providing estimates of the likely relative risk in these subgroups using a Poisson regression. The sociodemographic profile of the present study is similar to other such profiles found in the Brazilian literature, reinforcing the validity of these results and allowing generalization to other areas of the country with similar profiles[8,11,15,22,27]. Additionally, this study provides useful elements for assessing the risk of syphilis transmission by blood transfusion and for improving hemovigilance. Integrated with the epidemiological surveillance data, these study results may be important in tailoring specific preventive actions regarding syphilis transmission in the state regions[23]. For example, health professionals may be able to improve the prevention of sexually transmitted diseases (STD) in specific areas with a high syphilis prevalence among blood donor candidates as indicated by their zip codes. Additionally, STD transmission, anonymous testing and treatment facility information (e.g., those abbreviated as *DST* in Brazil) may be offered to individuals at higher risk for these infections. The high prevalence of syphilis, a disease with high prevention and treatment potential, reinforces the need for such integration. On a larger scale, such integration is becoming increasingly viable with the Retrovirus Epidemiology Donor Study-II (REDS-II) project, which systematically monitors blood bank data across the country[31]. In the absence of population-based syphilis prevalence studies, data from blood banks provide the best estimate of infection frequency in the general population.

ACKNOWLEDGMENTS

The authors would like to thank the HEMOSC staff and the blood donors for their cooperation in providing data. AMB and EK designed the study and analyzed the data. AP contributed essential reagents and data, and all authors wrote the paper.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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