HIV Seroconversion in blood donors from the coordinating blood bank in the State of Pará

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Background: *Transfusion of Human immunodeficiency virus (HIV) infected blood is probably the most effective means of transmission of this disease. Despite intense efforts and investment to ensure safety, transmission of HIV still remains a real possibility in the transfusion service due to the fact that routine laboratory tests in most Brazilian government blood banks rely on the detection of antibodies. This leaves an immunological window period of from 16 to 22 days, which could be minimized to approximately 9 to 11 days if nucleic acid amplification tests were employed in screening.*

Objective: *To analyze the profile of blood donors who seroconverted to HIV positive from 2008 to 2010 in the coordinating blood bank of the State of Pará in respect to gender, age, marital status and educational level.*

Methods: *HIV seroconversion cases of blood donors who donated on more than one occasion at the coordinating blood bank of the State of Pará were investigated. Records from 2008 and 2010 were analyzed in respect to gender, marital status, schooling and age.*

Results: *Among the 157,432 donations in this period, 45 HIV seroconversions were confirmed. Of these, 95.56% were men, of which 86.67% were single, 53.33% had completed high school and 40% were between 23 and 29 years old.*

Conclusions: *In order to improve the quality of blood and reduce the residual risk of HIV transmission in blood banks, it is necessary to know the profiles of donors who most frequently seroconvert and use nucleic acid amplification tests as routine screening.*

Keywords: *Blood donors; HIV seropositivity; HIV; Blood donors; Risk factors*

Introduction

Blood donation is an altruistic, unpaid voluntary act. However, many people who currently 'donate' are in fact more interested in quick, free of charge serologic testing, as blood tests naturally precede the donation process. This is a dangerous habit for the patients who require donated blood. Thus, transfusion safety consists in a series of steps which aim to guarantee that the blood product is, as far as possible, risk free. This implies a careful selection of donors and rigorous screening to identify donors who may be in an 'immunological window period'. The process of reducing risk also requires screening using progressively more sensitive tests and the use of a self exclusion option which allows loyal donors concerned about the possibility of being a virus carrier, to have the opportunity to confidentially exclude themselves from the donation process.[1,2]

With the computerization of blood banks tracking the donation process better and the growing number of frequent donors, cases of seroconversion have become more evident.[3] Resolution nº 153 of the Collegiate Directorate (RDC), in force at the time this study, defines the term seroconversion as a positive result for a certain type of test of a donor who in a previous donation had presented non-reactive serology.[4]

The careful selection of blood donors to detect anti-HIV 1 and 2 antibodies is generally performed by immunoenzymatic tests.[5,6] Examples of such tests are ELISA (enzyme linked immunosorbent assay), a 3rd generation test which detects antibodies (IgM and IgG) within about 22 days after exposure to a virus and 4th generation tests which also detects the viral antigen p24 that appears around seven days before the antibodies show up and thus reduces the immunological window period to approximately 16 days. On the other hand, the introduction of nucleic acid amplification testing (NAT) as screening would reduce the immunological window period to between 9 and 11 days.[7] This reduction of the immunological window period had a considerable impact in the United States, as the widespread use of NAT in 95% to 99% of blood donations reduced the risk of transfusion-

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transmitted HIV from 1:650,000 donations to something around 1:1,100,000.[8-10] In Germany, studies show that the risk of transfusion-transmitted HIV decreased from 1:2,770,000 donations to 1:5,540,000[11] after the introduction of NAT.

Given the relevance of this topic, the aim of this work was to evaluate the profile of blood donors who seroconverted from 2008 to 2010 in the coordinating blood bank of the state of Pará in respect to gender, age, marital status and education level and to check whether the donor delayed to return to the blood bank for the donation in which seroconversion was detected. For this analysis, the intervals between previous donations were taken into account for the donor.

Methods

Type of research and selection of cases

This research is classified as a descriptive, retrospective and cross-sectional study of HIV seroconversion cases of blood donors who donated on more than one occasion at the coordinating blood bank of the State of Pará. Records from 2008 and 2010 were analyzed. The definition of HIV seroconversion is the situation in which the donor presented reactive results for one or both of the screening serologic tests (ELISA) confirmed by the western blot test after this same donor had presented, in previous donations, non-reactive ELISA results for HIV. Only cases confirmed by the western blot test were included in this study to avoid possible false positive cases.

A control group of 100 randomly chosen donors was formed and its participants were evaluated using the same criteria.

Data collection

According to the RDC N° 153, blood donors are tested for HIV-1 and HIV-2 using two specific tests. Both tests employ the immunoenzymatic methodology and are manufactured by Abbot/Murex; a 3rd generation test that only detects IgM and IgG antibodies and a 4th generation test that also detects the p24 antigen. The serologic examinations were performed at the Blood-Borne Disease Screening Management Center of the Fundação HEMOPA. The reactive samples were sent to the Molecular Biology Management Center, where the western blot test was performed for confirmation.

The group of donors who became HIV seropositive and the control group were analyzed in respect to gender, age, marital status and education level. The seroconverters were also checked to see whether there was a delay for them to return to the blood bank for the donation in which the seroconversion was detected, by comparing the interval of the previous seronegative donation.

Data analysis

The data obtained in respect to gender, age, marital status and education level were analyzed using the G-test of Independence. The intervals of time between donations with negative serology (N-N) and the period elapsed between the last seronegative donation and the seropositive donation, that is, when seroconversion was evidenced, were analyzed using the paired t- test.

The Chi-square test for trend was used to verify if there was a significant increase in the number of cases of seroconversion in the analyzed period.

All statistics tests were performed using the BioEstat 5.0 Program and the level of significance was set for an alpha error of 5% (p-value ≤ 0.05).

Results

Donor profile and serologic inaptitude

In the study period 158,270 donations were considered healthy (suitable) according to the clinical screening; 122,509 (77.4%) were from men and 35,761 (22.6%) were from women. In regards to the type of donor, 35,046 (22.14%) were from first-time and 123,224 (77.86%) were from repeat donors. The majority of donations (n = 93,633; 59.16%) were spontaneous, 63,168 (39.91%) were replacement donations with the remainder were specific and autologous blood donations.

Of the suitable donors, 157,432 donated and 1316 (0.84%) were found to be serologically unsuitable, that is, were reactive or inconclusive for HIV-1 and HIV-2. Of these 512 seropositive donors (39%) were donating for the first time and 804 (61%) were repeat donors. In 2008 a frequency of 1.05% of HIV seropositive or inconclusive blood bags were identified; this was reduced to 0.89% in 2009 and to 0.56% in 2010.

Profile of seroconverted donors

Among the group of repeat donors, 45 seroconverters were confirmed by western blot, of which 43 (95.56%) were male while only 2 (4.44%) were female. In the control group, a predominance of men was also observed (n = 71) compared to 29 women. There was a higher number of single individuals in both the seroconverted group and the control group. Moreover, it was also observed that in the control group, most donors were between 23 to 29 years old. HIV seroconversion was also more often confirmed within this age group. Additionally, most seroconverted donors and members of the control group had completed high school.

The majority of the seroconverted donors donated spontaneously (n = 43; 95.56%), but two made replacement donations (4.44%). On the other hand, all donations of the control group were spontaneous.

Table 1 - Profile of seroconverted donors and controls

Variable		Seroconverted Group (n=45) %	Control Group (n=100) %	p-value
Gender	Female	4.44	29	≤ 0.05
	Male	95.56	71	
Marital status	Married	11.11	34	≤ 0.05
	Single	86.67	64	
	Other	2.22	2	
Schooling	Incomplete elementary school	8.89	6	> 0.05
	Concluded elementary school	15.56	15	
	Incomplete high school	4.44	9	
	Concluded high school	53.33	5	
	Incomplete undergraduate studies	15.56	7	
	Concluded undergraduate studies	2.22	7	
Age	18 - 22 years old	11.11	13	> 0.05
	23 - 29 years old	40	36	
	30 - 39 years old	33.34	27	
	40 - 49 years old	13.33	18	
	50 - 59 years old	2.22	6	

Table 2 - Evaluation of suitable donations (n = 158,270)

Suitable donors by clinical screening - n (%)		
Gender	Female	35,761 (22.6)
	Male	122,509 (77.4)
Type of Donor	1st time donor	35,046 (22.14)
	Repeat donor	123,224 (77.86)
Type of donation	Spontaneous donation	93,633 (59.16)
	Replacement donation	63,168 (39.91)

Table 3 - Relationship between confirmed seroconversion cases and donations received per year

Years	Total donations	HIV Seropositive/inconclusive n (%)	Confirmed cases of seroconversion n (%)
2008	53,508	561 (1.05)	9 (0.017)
2009	52,855	468 (0.89)	21 (0.040)
2010	51,069	287 (0.56)	15 (0.029)

The HIV seroconverted donors had made on average 7 (2-24) donations, within an average period of 71.5 months (8-149) from the 1st to the last donation where seroconversion was evidenced. The average time interval between two seronegative donations (N-N) was 12.7 months (2.3-80) and the mean time between the last seronegative donation and the donation identified as seropositive was 20.4 months (3-107). In reference to the number of cases of seroconversion throughout the analyzed period, no statistically significant increase in the number of cases was observed (p-value = 0.2205).

Discussion

HIV-infected blood transfusions, due to the amount of inoculum, are the most efficient manner of transmission.[9,12] In recent years there has been a dramatic reduction in the transfusional transmission of this virus as a result of a much more rigorous clinical selection of donors aiming at eliminating those who have risky behavior, the use of more sensitive laboratory assays that reduce the immunological window and the establishment of testing and counseling centers that confidentially provide HIV serologic examinations free of charge, thus reducing the number of people who go to blood banks as donors but who are in fact interested in the examination results.[13,14] However, some risk still remains, even though it is residual, as the currently available laboratory tests have reduced the immunological window period, but not eliminated it completely.

Therefore, it is important to remember the importance of loyal donors, as repeat donors are constantly made aware of their role. At each donation they are submitted to clinical and serological screening; if identified as HIV seropositive they are permanently excluded from the system.[5,13-15]

A larger number of single and male participants have been observed among seroconverted donors (p-value ≤ 0.05), showing, in general, that men are more exposed to risk factors. On the other hand, the predominance of young adults between 23 and 29 years old, who concluded high school education in the seroconverted group was not statistically relevant when compared to the control group (p-value > 0.05).

These findings corroborate with others in the literature, in which the observation of HIV seroconversion in young, male, single donors who had concluded high school were more prevalent.[16,17] Minga et al. performed extensive analysis of the profiles of 241 donors who became HIV seropositive between 1997 and 2005 after donating blood; 61% were male with an average age of 28 years old. On studying risky behavior in blood donors, a similar profile was observed by Silvani et al.[18] The group of single or divorced male donors with ages ranging from 25 to 35 years old was considered the highest risk. Such findings suggest that educational campaigns specifically aimed at this group of donors may raise awareness on the issue of transmission by blood transfusions.

The average time between the last donation with negative serology and that with positive serology of seroconverters was 20.4 months, longer than that reported by Minga et al. (7 months); thus there was a significant delay

between the last seronegative donation and the first seropositive (p-value ≤ 0.05). The same was reported by Schreiber et al.[19] This delay may be a consequence of signs and symptoms related to primary infection by HIV. It is known that around 2 to 6 weeks after being exposed to HIV, 40% to 90% of individuals develop a clinical syndrome associated with acute infection.[9,19] Another possible cause is that donors, conscious of their exposure to risk, decide not to donate. However, the lack of knowledge or a mistaken concept about the course of HIV infection, associated to denial, influence their decision to return to donate. Some people believe that if their behavior does not result in symptoms of the disease, it means they are not infected by HIV. Furthermore, some donors who suffered the clinical effects of contamination still do not associate this with HIV infection.[19]

According to the RDC No. 153, in confirmed cases of seroconversion it is recommended that a test to detect the genome of the infectious agent is made both for the sample where seroconversion was detected and for the individual's donation preceding seroconversion.

NAT is still not available for HIV at the Fundação HEMOPA where this study was carried out. Thus, this possibility of transfusional HIV transmission has to be investigated by the Transfusion Surveillance Service, the institution responsible to investigate the destination of the blood components of donors according to the guidelines of ANVISA.[7] After confirmation of seroconversion using the ELISA test for HIV, a check of stored blood bags of that donor must be made. If blood components of this donation had been supplied to other transfusion services, they must be informed and consequently they become responsible to check possible transmission of infection to transfused patients.

In general, in 97-98% of individuals, the antibodies become detectable in a period of 30 to 90 days after infection. However, for 2-3% of infected individuals, antibodies are produced in concentrations detectable by standard techniques between 3 to 12 months after infection, that is, there is an immunological window period involving a previous donation in both cases with the possibility of transfusional transmission of HIV.[9]

Hence, the introduction of routine NAT is fundamental to reduce this window and consequently the residual risk of HIV transmission.[15,20,21] Despite the high costs of this technology, not employing NAT is to deny universal access to safer transfusions.[22,23] Studies on the possibility of introducing this technology are underway at HEMOPA.

All things considered, it is also important to state that the utilization of direct tests (antigen p24, NAT) should not lead to the exclusion of research on anti-HIV IgG antibodies (ELISA) which are present during chronic phases of the disease when blood viral levels are not detectable but in a phase that is still potentially infectious.[9]

Conclusions

Blood transfusion carries a risk in itself, whether immediate or delayed. Thus, in order to improve the quality of the transfused blood and reduce the residual risk of HIV transmission, it is necessary to know the profile of seroconverters, to introduce NAT into the laboratory routine of Brazilian blood banks, to carry out continuous improvements in the process of screening for risk factors, develop inactivation processes of pathogens and create new alternatives for the use of blood components, such as blood substitutes.

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