

TRANSFUSION MEDICINE

Evaluation of Serologic Markers for Transfusion Transmitted Infectious Diseases For Allogeneic Blood Donors in Puerto Rico

HILDABELÍS MARTÍNEZ-DÍAZ, MD; AISLINN C. FRYE-MALDONADO, MD;
CONSUELO CLIMENT-PERÍS, MD; ROMÁN VÉLEZ-ROSARIO, MD

ABSTRACT. The purpose of this project is to assess the prevalence of serologic markers for transfusion transmitted infectious diseases in allogeneic blood donors of the American Red Cross Blood Services (ARCBS) in Puerto Rico. Four hundred records were randomly selected from a population of 7718 first time volunteer donors from the ARCBS in P.R. covering the period from Jan. 1st to Jun. 30th, 1991. Variables obtained were: age, sex, presence of hepatitis B surface antigen (HBsAg), hepatitis B anti-core antibody (anti-HBc), hepatitis C virus antibody (anti-HCV), HIV 1/2 antibody, HTLV I/II antibody, RPR reactivity and

ALT. The prevalence of serologic markers in our study is consistently higher than that found in similar studies in the U.S. population, except for HBsAg and HCV. This could be explained with the use of data from only first time volunteer donors since the prevalence is higher in this group than in repeat donors. None of the donors in this sample were positive for HBsAg probably due to the small sample. The prevalence of anti-HCV in this study is within the values found for the U.S. population. *Key Words:* Serologic, Markers, Allogeneic, Blood, Puerto Rico

There are many infectious agents that can be transmitted via blood transfusions. The most important of these are viral agents. Transfusion-transmitted viral hepatitis can be caused by various agents: hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis D virus (HDV), cytomegalovirus (CMV) and Epstein-Barr virus (EBV). HAV is usually transmitted via the fecal-oral route. Transmission via blood transfusion has been documented. HDV is a defective virus that requires prior infection or co-infection with HBV in order to cause disease. On the other hand, CMV and EBV are commonly present in donor blood but they rarely induce clinically significant disease in immunocompetent recipients.

Retroviral infections are very important risk factors in blood transfusions. HIV-1 and HIV-2 cause AIDS.

HTLV-I may also cause post-transfusion infection and it has various manifestations: Adult T-cell Leukemia/Lymphoma (ATL), Tropical Spastic Paraparesis (TSP), and HTLV-I Associated Myelopathy (HAM)(6). A closely related virus, HTLV-II, has also been associated to blood transfusion.

Other infectious agents associated to blood transfusions are *Treponema pallidum*, *Babesia microti*, *Borrelia burgdorferi*, *plasmodia* (*P. falciparum*, *P. malariae*, *P. ovale*, *P. vivax*), *Toxoplasma gondii*, *Trypanosoma cruzi*, *Brugia malayi*, *Loa loa*, *Wuchereria bancrofti* and *B19 parvovirus*. Bacterial contamination of blood and its components is rare, but has been reported elsewhere. Gram-negatives are among the bacterial agents that contaminate blood. Cases of contamination by *Salmonella sp.*, *Serratia marcescens*, *Pseudomonas cepacia*, *staphylococci*, *Yersinia enterocolitica* and *Enterobacter cloacae* have also been reported. Multiple infections can be transmitted via blood transfusion. For instance, by 1990 the American Red Cross detected an average of 8 carriers of HIV per 100,000 otherwise acceptable blood donors, while in 1985, when testing for HIV antibodies began, an

From the Department of Pathology, Transfusion Medicine Section, Medical Sciences Campus, University of Puerto Rico

Address correspondence to: Hildabelis Martínez-Díaz, MD, Department of Pathology, Transfusion Medicine Section, PO Box 365067, San Juan, PR, 00936. Medical Sciences Campus.

average of 35 per 100,000 was detected (1). In order to make the blood supply safer, many blood tests have been implemented by blood banks. The Rapid Plasma Reagin test (RPR) that detects syphilis infection, was implemented in the 1920's (10). The test for hepatitis B surface antigen was implemented in the early 1970's. Anti-HIV test was established as a standard test for donor blood in 1985. Both ALT levels and Anti-HBc test are used as surrogate tests for NANBH since 1986. Testing to detect antibodies against HTLV-I or HTLV-II began on 1989. The most recent test implemented for donor blood was the Anti-HCV test, implemented on 1990. All these tests have been useful in diminishing the risks of infections through blood transfusions.

The purpose of this project is to assess the prevalence of serologic markers for transfusion transmitted infectious diseases in allogeneic blood donors of the American Red Cross Blood Services in Puerto Rico. Special attention will be given to associations existing among the different serologic markers. Prevalence differences by sex or age group will be explored. The prevalence of serologic markers determined in this study will be compared to the prevalence of these markers in the United States.

Materials and Methods

A retrospective study was conducted obtaining the data from the records at the American Red Cross Blood Services in Puerto Rico. The period covered is from January 1st, 1991 until June 30th, 1991. The population of volunteer first time donors during this period of time consisted of 7718 donors. In order to facilitate the study effort, it was decided to select a sample from this population. The sample size needed in order to obtain results with a 95% level of confidence from a population of 8000 is 367 (12). It was decided to round this number to 400 and this is the actual size of the sample. The sample was selected at random, selecting every 19th observation from the population list. The male to female ratio of the sample was 1.8 to 1 and the age range was from 18 to 67 years old with a mean of 31.74 years old and a mode of 20 years old.

Variables obtained from the records were: age and sex of the donor, presence of hepatitis B surface antigen, hepatitis B anticore antibody, HIV1\2 antibody, HTLVIII antibody, hepatitis C virus antibody, RPR reactivity and ALT-SGPT activity.

The data was entered and analyzed in a computer using EPIINFO, a program for epidemiologic and statistical analysis. Tests of statistical significance were included. Information concerning the prevalence of these markers in the United States was obtained from previous studies.

Results

Of 400 donors, 143 (35.75%) were females and 257 (64.25%) were males. Among the 143 females: none was positive for HIV1\2, HBsAg or RPR; one (0.7%) was positive for HTLVIII and another one for HCV; two (1.4%) were positive for ALT; and 8 (5.6%) were positive for Anti-HBc. Of the 257 males: none was positive for HBsAg or HTLVIII; three (1.2%) were positive for HCV; four (1.6%) were positive for RPR; five (1.9%) were positive for HIV1\2; eighteen (7%) were positive for ALT; and 20 (7.8%) were positive for Anti-HBc. Upon confirmation only one male was found positive for HIV1\2 (0.4%)

The sample was divided in 3 age sub-groups (18-34 y/o, 35-51 y/o and 52-67y/o) in order to obtain the frequencies of positive markers in each one of them and evaluate if there is any difference between them in terms of markers frequencies. The first age sub-group (18-34 y/o) had 269 (67.25%) of the donors, the second one (35-52 y/o) had 105 (26.25%) and the third one (52-67 y/o) had 26 (6.50%). Among the 269 donors within the first sub-group: one (0.4%) was positive for HTLVIII; two (0.7%) were positive for HCV, both of them males; four (1.5%) were positive for HIV1\2; the same frequency was found for RPR; thirteen (4.8%) were positive for ALT, all of them males. Upon confirmation only one donor (0.4%) was positive for HIV1\2. Of the 105 donors within the second age sub-group: none was positive for HTLVIII or RPR; one (1%) was positive for HIV1\2; two (1.9%) were positive for HCV, one of them a female and the other one a male; seven (6.7%) were positive for ALT, two of them females and the other five males; and twelve (11.4%) were positive for Anti-HBc, two of them females and ten males. Upon confirmation the HIV1\2 positive donor was found negative. Among the third age sub-group: none was positive for HIV1\2, HCV, HTLVIII, RPR or ALT; and one (3.8%) was positive for Anti-HBc and it was a female.

For the retroviral markers, five (1.25%) of 400 were HIV1\2 positive and one (0.25%) was positive for HTLVIII, but only one of the HIV1\2 positive was found positive upon confirmation (0.25%). For the hepatitis markers, none was positive for HBsAg, four (1%) were positive for HCV, and 28 (7%) were positive for Anti-HBc. There were four (1%) donors positive for RPR and 20 (5%) positive for ALT.

Discussion

Studies have shown a prevalence of 0.1% for HBsAg among the blood donors in the United States (10). In this

study none of the donors selected in the sample was positive for HBsAg, but this could be due to the relatively small size of the sample.

The prevalence for RPR reactivity in the U.S. is less than 0.1% (10). In this study a prevalence of 1% was found for this marker. The reason for this could be a higher prevalence of syphilis in the general population of Puerto Rico compared to that in the U.S. or a higher rate of false positives. Fang et. al.(1) found a prevalence of 0.008% for HIV in their study. In this study the prevalence of HIV was found to be 1.25% when screening tests were used, but once confirmed results are used the prevalence is 0.25%. This difference in prevalence could be due to the fact that P.R. is one of the countries with highest prevalence of HIV in its general population. On the edition of December 21, 1990 of the Morbidity and Mortality Weekly Report (14) a seroprevalence of 0.066% is reported for HTLVIII. The seroprevalence found in this study was higher, 0.25%.

In the study realized by Stevens et. al.(15) a prevalence of 4.3% was found for elevated ALT levels, but when the hispanic donors were taken into consideration separately, the prevalence was 5.6%. Our study found a prevalence of 5.0% for elevated ALT levels. This prevalence is almost an intermediate value between the prevalence for the general population of donors and the prevalence for the hispanic population of donors in the U.S..

Stevens et.al. found that male donors tended to have higher ALT levels than female donors. This is consistent with the findings of this study, where the prevalence of elevated ALT is higher for males than for females. Stevens et.al. found a 3% prevalence for anti-HBc for the complete sample, but a 6.1% prevalence for the hispanic group. In this study the seroprevalence for anti-HBc was 7%, which is similar to the value for the hispanic donors in the U.S.. In their study the prevalence was slightly higher in males than in females, but the difference was minimal, 0.4%. In this study the difference in prevalence of anti-HBc between male and females was higher, 2.2%, being the male donors' prevalence higher than the females'. Their study also found a 0.9% to 1.4% overall prevalence of anti-HCV, which is consistent with earlier studies. The prevalence in the hispanic group was 7.1% in their study. The prevalence for anti-HCV in this study was 1%, which is consistent with the overall prevalence and lower than the hispanics. Anti-HCV prevalence in Stevens et.al. study differed little between male and female donors, 0.3%. This study also differed little between gender's prevalence, 0.5%.

The prevalence of anti-HCV increased from 0.74% in the first age sub-group (18-67 y/o) to 1.9% in the second sub-group (35-51 y/o). Then it decreased to 0% in the

third sub-group (52-67 y/o). The seroprevalence of anti-HBc increased from 5.58% in the first age sub-group to 11.43% in the second. Then it decreased to 3.85% in the last age sub-group. The ALT seroprevalence increased from the first to the second age sub-group (4.83% to 6.67%). The prevalence of HIV1\2 decreased from the first to the second age sub-group (0.4% to 0.0%). The prevalence of HTLVIII and RPR were only representative of one age sub-group, so comparisons could not be made.

Conclusions

From this study it can be concluded that the puertorrican population of first time volunteer blood donors has a higher prevalence of serologic markers than the U.S. population. This higher prevalence could be explained, at least partially, with the use of data from only first-time volunteer blood donors. In previous studies it has been found that the prevalence of serological markers for first-time donors is higher than for repeat donors. "The lower prevalence in repeat donors is largely due to the fact that seropositive donors are not allowed to donate again and are gradually screened out of the donor pool."(8).

The purpose of this study, however, not to explain these differences. In order to explain them, additional data would be required, the gathering of which could violate the anonymity of the donor. What we intend to do is to establish reference epidemiologic values that can be used in future evaluations as new and more specific and sensitive tests become available.

Resumen

El propósito de este estudio es determinar la prevalencia de marcadores serológicos para enfermedades infecciosas transmitidas por transfusión en donantes allogeneicos de la Cruz Roja Americana, Servicios de Sangre, en Puerto Rico. Cuatrocientos expedientes se seleccionaron aleatoriamente, de una población de 7718 donantes voluntarios por primera vez en el periodo de enero 1^{ro} a junio 30 de 1991. Las variables evaluadas fueron: edad, sexo, presencia de antígeno de superficie de hepatitis B, anticuerpo hacia antígeno "core" de hepatitis B, anticuerpo hacia HIV 1/2, anticuerpo hacia HTLV I/II, anticuerpo hacia virus de hepatitis C, reactividad en RPR y nivel de ALT. La prevalencia de estos marcadores en la población evaluada fue consistentemente mas alta que la encontrada en estudios similares en E.U. excepto para HbsAg y anti HCV. Una posible explicación para estos hallazgos podría ser el uso de donantes por primera vez cuya prevalencia

de marcadores es mas alta que en donantes habituales. Ningún donante resultó positivo para HbsAg probablemente debido al pequeño tamaño de la muestra. La prevalencia de anti-HCV fue similar a la de los Estados Unidos.

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