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MEDICAL PROFESSIONAL RESPONSIBILITY IN VIH CONTAGION AFTER BLOOD TRANSFUSIONS

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SUMMARY

In Spain a million and a half blood transfusions by year are carried out, that supposes between 2 and 10 cases of infection of VIH by year. The present state of science invites to do something more with tests to detect other virological and immunological markers, in order to identify seronegative carriers and thus avoid HIV transmission by them. We must consider the possibility to incur in professional responsibilities if we do not report adequate of this risk or if we do not provide patients all the cares that require, according to the state of the science so called *lex artis*.

Keywords: HIV Infection, lex-artis, seronegative carriers, transmission.

RESUMEN

En España se realizan un millón y medio de transfusiones de sangre al año, lo que supone un riesgo de entre 2 y 10 casos de infección de VIH a través de las mismas. El estado actual de la ciencia invita a hacer algo más pudiéndose ampliar los estudios de marcadores víricos e inmunológicos, para identificar a portadores seronegativos y así tratar de evitar la transmisión del virus de inmunodeficiencia humana a través de ellos. Debemos considerar la posibilidad de incurrir en responsabilidades profesionales si no informamos adecuadamente de este riesgo o si no proporcionamos a los pacientes todos los cuidados que requieren, según el estado actual de la ciencia, lo que denominamos *lex artis*.

Palabras Clave: Infección por VIH, transmisión, lex-artis, portadores seronegativos.

INTRODUCTION

In 1981 began the history of the illness that subsequently was called AIDS (acquired immune deficiency syndrome) or SIDA (Sindrome de immunodeficiencia adquirida) from there many legal medicine and ethical problems have been presented around this illness [1-6] There are a lot of ethics, legal and legal-medicine bibliography, fundamentally about the information, but there is a important legal-medicine problem that still remains without resolving. The history is repeated [7, 8].

The World Medical Association established guidelines to orient the professional responsibilities in the AIDS with a provisional statement in October of 1987 and the Statement on professional Responsibility of the doctors in the processing of patients with SIDA adopted by the 40 World Medical Assembly of Vienna, Austria, in September of 1988 [1,2].

The control of the donations was not obligatory in all the Spanish territory until February of 1987, in spite of the fact that from the middle of 1985 the media to perform the analysis were already available and existing a general conviction, vouched by the international experience, on the convenience of establishing the HIV detection in blood donations. Around 1500 patients were infected in Spain during that period and there was juridical sentences even in criminal law[8].

In conclusion, would be able to consider that not to do the control of donations since the moment in which the scientific community it shares extensively that is necessary, since is considered that they are efficient and that should be done, since the scientific knowledge exists or analysis were already available and existing a general conviction, vouched by the international experience, on the convenience of establishing the HIV detection in blood donations can constitute an imprudence in criminal law in Spain.

The HIV screening in the blood units is still performed today with indirect techniques, on the basis of specific demonstration of antibodies, producing a known risk of contagion evaluated around 1/150.000 and 1/750.000 depending on different epidemiological circumstances[9-11]. Several countries have jumped the alarm by cases of HIV contagion after blood transfusions before the general ignorance of the risk, having created social states of alarm that in many of those cases have been closed in false with information not of the every wise.

In Spain a million and a half blood transfusions by year are carried out, that supposes between 2 and 10 cases of infection by year. Cases of contagion have been already described and judicial sentences exist in both directions[8, 11-13].

The science knows that some individuals infected are not positive in anti-HIV antibody detection tests. Already since 1986 individuals with VIH infection have been described that not present positive serological diagnosis of HIV infection[12,14-18].

Investigators have thought the higher sensitivity of EIA tests using synthetic peptides justifies its generalization for sample screening in blood banks, have been tried second and third generation ELISA assays for the serodiagnosis trying to shortening of the diagnostic window and study in order to determine the most sensitive method for the early detection of HIV infection, polymerase chain reaction (PCR) and serology[12,14-18].

There are a lot of circumstances in which patients infected by VIH have negative serology, and it is important to apply the PCR technique together with tests to detect other virological and immunological markers, in order to identify seronegative carriers and thus avoid HIV transmission by them[9-11] (Table 1).

Table 1. Cause of PCR positive with False negative antibody test results:

Window period
Replacement transfusions
Bone marrow transplantation
Laboratory contamination
Hypogammaglobulinemia
Early treated with antiretroviral therapy
Dysfunction of immune function, no production of antibody, defect virus,...

We are in face of a situation in which the present state of science invites to do something more, being been able to offer in a wider manner HIV tests that can reduce the window period and other circumstances trying to minimize the risk of Transfusion-associated HIV infection [14,16-18] We must consider the possibility to incur in professional responsibilities if we do not report adequate of this risk.

The W.H.O estimated that blood transfusion saves millions of lives but is unfortunately an efficient route of transmission of HIV and other transfusion transmissible infections (TTIs). Today, a new generation of test kits for HIV are available (which are, for example, able to detect simultaneously HIV antigen and HIV antibody), biological technique are also important, enabling the early detection of infection. This is a crucial line of defence in blood safety. In addition, increasing numbers of HIV test kits are produced in developing countries. However, adequate data is lacking for many of these test kits which have varying capacities to detect different variants and strains of HIV[8,14,16-18].

The W.H.O. also estimated that 5-10% of the global HIV infections are caused by unsafe blood and blood products. Thus, it is vital that all donated blood be screened using high quality, appropriate diagnostic tests. Those donations identified as infectious must be properly discarded to safe guard the blood supply.

Recently Catalonia (Spain) has extended the execution of the techniques of molecular biology that reduce the risk. Test that are not obligatory in Spain although if are advised for the EU since 1999. The history is repeated.

Doctors in its professional exercise are obliged not only to cure patients, but to provide them all the cares that require, according to the state of the science so called lex artis. The medical responsibility should be based on clear fault that reveal an ignorance of responsibilities, according to the present state of the science.

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Comment of the reviewer Mario C. Salinas-Carmona, MD. Department of Immunology, Faculty of Medicine and University Hospital, Monterrey. Nuevo Leon, Mexico.

The paper deals with the remote but possible transmission of HIV by blood transfussion. Information or concern to use of blood derived products such as albumin, gamaglobulin, plasma, clotting fctors, etc is not provided. The paper focus the attention to a legal responsability because the risk of HIV transmission is not taken in consideration during blood transfussion in certain parts of Spain

Technology to minimize the mentioned risk is already available even though its cost is high in economic figures.

Comment of the reviewer Beatriz Cuevas Ruiz MD, PhD. Servicio de Hematología. Hospital General Yagüe. Burgos. España

The recommendations of the WHO in 1989 in the safety report "Global blood safety initiative: Consensus statement on accelerated strategies to reduce the risk of transmisión of VIH by blood transfusión", establishes that the transfusional security will only be achieved by means of the design of procedures of quality assurance that affect three points specially:

- **Safer donors.**
- **Blood components safer.**
- **Reduction of the number of units transfused.**

The first point implies the promotion of voluntary donors who were repeat donors, altruistic, anonymous donation; an exhaustive, oral and written information has to be given to the donor before each donation and the possibility of self-exclusion; also a confidential questionnaire will exist that allows the elimination of donors with risk practices. To obtain safer blood components supposes, as the application of techniques of NAT for the early detection of viral infections author points out. And the third point is achieved through campaigns to train clinical staff to reduce the inappropriate use of the blood components, to stimulate the predeposit autologous transfusion and to harness alternatives to the transfusion. Therefore we must stress these three points to diminish the transmission of infections by blood transfusion.

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Transfusion transmission of HIV, the virus that causes AIDS, has been almost completely eradicated; since blood banks began interviewing donors about at risk behaviours and a blood test became available in early 1985. The HIV/ AIDS pandemic have focused particular attention on the importance of preventing transfusion-transmitted infections. Between 5% and 10% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products In fact, the chances that someone who has received a transfusion with HIV blood will infected are estimated to be over 90 percent, but the risk can be reduced by minimizing unnecessary transfusions through the effective clinical use of blood and blood product and the appropriate use simple alternatives to transfusion which are safe. Transfusion medicine specialists are continually researching new technologies to further reduce the transmission of HIV.

Curiel et al. shows the rise of a molecular genetics technique, the polymerase chain reaction (PCR), technology essentially permits the detection of a single viral genome during the early phase of HIV infection, prior to positivity in a test for anti-HIV; PCR assays can define the actual presence of the virus in appropriate samples. There is still considerable concern about the potential for transmission of HIV from seronegative blood donors in the window period. Finally, they must consider the possibility to incur in professional responsibilities if the doctors in its professional exercise do not report the risk of transfusion-associated HIV infection.

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