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Research Article

Double Speed Transfusion in Burkina Faso: Results of the Elisa 4th Generation Tests Versus Determine™ HIV½ of Blood Donors Presumed to be Seroconverting at National Blood Transfusion Center

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Abstract

Conflicting results are often observed at blood donors who used 4th generation Elisa and the Determine™ HIV½ tests. This study aims to assess both techniques and determine the most reliable test for blood transfusion.

This study was conducted at the National Blood Transfusion Center-Ouagadougou. This was a prospective study with descriptive purpose of the results of the two HIV diagnostic techniques over a period of five months from January 1 to May 31, 2014. It covered a total of 10028 samples of which 30 were discordant. A recall of 30 donors with discordant results to the Determine™ HIV ½ have given 4 positive and 26 negative results. Considering the results of the second Determine™ HIV ½ test, we finally retain the following results.

Among 10028 samples analyzed, 110 were positive for the 4th generation ELISA. Of these 110 positives, the 3rd generation DETERMINE™ HIV test yielded 80 positives and 30 negatives. Recall of the 30 donors with the discordant results two months later gave 4 positive and 26 negative results to the 3rd generation DETERMINE™ HIV test. The Determine™ 3rd Generation Test gives 0.04% false negative in blood donors. The 4th generation ELISA gives 0.3% false positive in blood donors.

Considering the results of the second DETERMINE HIV½ 3rd generation test, we do not recommend the use of the DETERMINE™ HIV™ 3rd Generation Test alone for HIV screening in blood donors.

Keywords: Evaluation; Determine™ HIV ½, Elisa 4th Generation; Discordant; Seroconversion; Blood Donors

Introduction

The risk of transmission of infectious agents during blood transfusion remains a serious public health problem in developing countries. The high prevalence of transmissible diseases in these countries is associated with a high risk of transfusing patients with infected blood.

Studies around the world have shown that the prevalence of HIV, hepatitis B, C and other transmissible diseases through transfusion are often lower in regular blood donors [1].

In Burkina Faso, as in most sub-Saharan African countries, donors of first-aid blood account for more than two-thirds of the pockets collected in blood banks [1].

These donors are recruited during socio-cultural ceremonies in the cities and in the countryside and various methods are put in place to retain these occasional donors in order to promote regular donations [2-4].

This represents a real problem because these first donations could end up in the "window of serological silence", defined as the early phase of the infection during which the antibodies of the infection are not detectable. It clearly appears the existence of a residual risk resulting in infectious donations collected during this "window of serological silence". Then there is the problem of only using tests that detect only the antibodies in the blood transfusion.

The detection of these infectious agents, in particular HIV, has seen the emergence of more and more sensitive screening tests. Thus, from the 3rd generation ELISA, we switched to the 4th generation ELISA which has the advantage of detecting both P24 antigens and antibodies. This evolution makes it possible to shorten the "window of serological silence". Also discordant results are very often seen in blood donors following the simultaneous use of these two (02) techniques making the donor and the medical staff embarrassed.

In Burkina Faso, the Regional center of Blood Transfusion (RCBT) and their coverage areas use the highly sensitive 4th generation ELISA which considerably reduces the serological window. Whereas, the other non-RCBT structures use the 3rd Generation Rapid Diagnostic Tests (RDT).

The technique of serological diagnosis varies according to the locality so that patients are not transfused in the same way, hence the notion of double-rate transfusion.

It is in this framework that we have undertaken to evaluate these two techniques (ELISA 4th generation and TDR) in order to determine the most reliable method compatible with the conditions of practicing it in disadvantaged countries.

The aims of study is to contribute to improve HIV screening in blood donors at the regional center of blood transfusion in Ouagadougou. Specially we want to compare the first conflicting results within the two techniques to the obtained results 2 months later through the Determine™ HIV1/2 test only.

Materials and Methods

The Ouagadougou RCBT served as a sampling place for the conservation and manipulation of our samples.

This is a cross-sectional study of samples taken over a period of (5) months from January 1 to May 31, 2014.

The study was performed on a total of 10028 blood donations from which we obtained 30 discordant results from volunteer blood donors. These are 30 doubly positive samples of 4th generation Elisa (Genscreen ULTRA HIV Ag-Ab) Architect and negative Determine™ HIV1/2. With the discordant results obtained first after screening using an algorithm combining two Elisa 4th generation, and a Determine™ HIV ½, these donors were recalled after a minimum of two months, and after completing a form of consent they are subject to a second sample. Thus, a sample was assumed in the serological window if it was positive for 4th generation Elisa and negative for the Determine™ HIV test. The obtaining of informed consent preceded the collection. The information collected was kept confidential.

The discordant patients were recalled, and after the samples on dry tube, the samples are centrifuged at 3000 rpm for 5 minutes. Serum from each tube was collected and aliquote into 02 cryotubes, then stored at -20°C and thawed on the day of use.

Results

Results of the tests carried out on blood donations

Among 10028 samples analyzed, 110 were positive for the 4th generation ELISA. Of these 110 positives, the 3rd generation DETERMINE™ HIV test yielded 80 positives and 30 negatives. Recall of the 30 donors with the discordant results two months later gave 4 positive and 26 negative results to the 3rd generation DETERMINE™ HIV test (Figure 1).

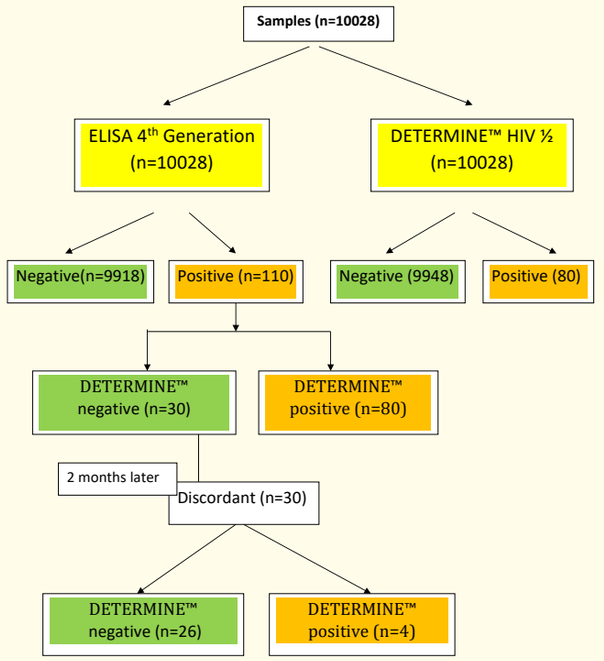

Figure 1: Tests results by Elisa 4th Generation and Determine™ HIV ½.

Socio demographic characteristics of discordant donors

In our study, the average age was 26, with extremes of 19 to 52 years. Among of 30 discordant donors 27 donors were male versus 3 female and between 18 and 35 years old and 3 were between 36 - 55 years of age. The majority of donors is pupils and students (Table 1).

	Number	Percentage (%)
Sex		
Male	27	90
Female	3	10
Total	30	100
Age (years)		
15 - 35	27	90
36 - 55	3	10
Total	30	100
Profession		
Pupils/Students	22	73,3
Civil servants	4	13,3
Traders	1	3,3
Others	3	10
Total	30	100

Table 1: Assessment of discordant donors according to the socio demographic characteristics.

Evolution of the results of discordant donors

Among the discordant donors we initially observed 30 positive donors to ELISA test (Genscreen ULTRA HIV Ag-Ab) Architect but negative to DETERMINE™ HIV ½.

Results of tests performed two months later on discordant donors are shown below. Four (4) blood donors became positive to DETERMINE™ HIV ½ 2 months later (Table 2).

Results	Number	Percentage (%)
Positive	4	13
Négative	26	87
Total	30	100

Table 2: Results of the DETERMINE™ HIV ½ test in discordant donors two months later.

Discussion

The duration of our collection was spread over 5 months from January 1st to May 31st, 2014. The number of samples analyzed by the RCBT during our collection period is 10028. The number of negative results obtained at Elisa was 9918 samples against 110 positives giving a prevalence of 0.011% (110/10028). Of the 110 devices, 80 were declared definitively positive by the RCBT because they were also positive for the DETERMINE™ HIV ½ test, or a prevalence of 0.008% (80/10028).

The recall of the 30 discordant donors two months later gave 4 positive results against 26 negative DETERMINE™ HIV ½ results. Considering the results of this recall as true positives and true negatives of our study, the false rate negative for the 3rd generation DETERMINE™ HIV-3 test in the first blood donor tests i (4/10028). This result increases the prevalence of HIV among blood donors by 0.0004 (4/10028).

This prevalence increased from 0.008 (80/10028) to 0.0084 (84/10028). Also, 0.0026 (26/10028) samples were found to be false positive in the 4th generation ELISA. In Burkina Faso, where only large transfusion centers use 4th generation Elisa tests, other health facilities using only the DETERMINE™ HIV ½ test, this result reveals a high transfusion risk and confirms the significant part of the blood pathway in HIV transmission following the use of the DETERMINE™ HIV ½ 3rd generation test alone.

Socio-demographic aspects

In our study, the average age was 26; with extremes of 19 to 52 years, against 18 to 56 years for Zohoun., *et al.* [5] and 18 to 55 years for Orkuma., *et al* [6]. The majority age group of 18 to 35 years accounted for 90% of the cases. This bracket is essentially young, more available and willing to donate blood. Male donors are the most represented with 90% against 10% of female donors. The sex ratio is 9.

In the general population of donors, Nagalo., et al. found 84% males versus 16% females with a sex ratio of 5.30 [1,7]. This may be due to the fear that many women have for blood donation. Also, there are many restrictions to blood donation for women (menstruation, breastfeeding or pregnancy).

Our study population consisted mainly of students with 73% of patients. This predominance could be explained by the collection strategy in high schools and universities. Civil servants accounted for 12%, 5% were traders, 10% were unemployed. Essomba., *et al*. in Cameroon found respectively 22.1% of pupils and students, 29.1% of civil servants and 25.7% of unemployed [8]. These differences could be explained by the fact that in our study all the donors were volunteers, compared to 4.1% of volunteer donors and 95.8% of family donors for Essomba., *et al* [8].

Comparison of the tests results

The 4th generation ELISA test detects both anti-HIV ½ antibodies and P24 antigen. All 30 discordant samples in the study were doubly positive on the 4th generation ELISA. On the other hand, the DETERMINE™ HIV ½ test detects only anti-HIV ½ antibodies and obtained firstly a negative result on all 30 discordant samples of the study.

Indeed, the 4th generation ELISA tests have been developed to ensure the safety of donations of blood. They meet the criteria for a screening test designed to improve sensitivity, especially concerning seroconversion samples. Thus, they allow the exclusion of as many infected blood as possible, even if this process rejects certain seronegative donations.

In the field of blood transfusion, the risk of HIV transmission comes exclusively from donations from individuals during the window period or the presence of antibodies when the virus is undetectable in the first-infected individual [9].

The recall 2 months later of 30 donors with discordant results gave four positive results in the DETERMINE™ HIV ½ test. In our 0.0004% (4/10028) study, samples were found to be false DETERMINE™ HIV ½ negative in the first tests. Several factors could be at the root of the high number of false negatives.

The genetic diversity of HIV results in variability of antigens with antibodies that show less affinity for antigens and pose screening problems [10]. Indeed, all screening kits are produced on the basis of subtype B sequences [11], yet HIV-1 non-B subtype is responsible for more than 90% of the pandemic in Africa [4,7].

Thus, during infection with a non-B subtype, the antibodies produced are less well recognized, particularly during the early phases of infection, when the affinity of the antibodies is the lowest [12]. In blood donors at NBTC shows that up to 30.7% will immediately donate their blood to check for possible contamination in case of exposure to HIV risk [13]. This attitude could be a source of false negatives if screening is only realized on the DETERMINE™ HIV ½ test.

Also in blood donors, the rate of donations occurring during the serological window can reach 0.58/1000 [10]. Thus the use of tests detecting only antibodies such as the DETERMINE™ HIV ½ test poses a real screening problem for donors.

Contradictions in the results between 4th generation Elisa and Determine™ can be explained by the performance of combined tests detecting p24 antigen and anti HIV½ antibodies compared to conventional tests such as DETERMINE™ HIV½ detecting only antibodies anti-HIV½. The first, by reducing the serological window

allows an earlier detection of infected donations thus ensuring, by their eviction, a better transfusion safety [6]. Basavaraju., *et al.* in Kenya showed that the risk of transfusion was zero for 12435 donations with the 4th generation Elisa test [12].

The use of the highly sensitive Elisa 4th generation clearly appears to be a good technique for reducing the risk of transmission of HIV.

Conclusions

This study recalls once again the significant part of the blood pathway in HIV transmission linked to the use of tests detecting only the antibodies in blood transfusion, despite the correct practice of the techniques. In a total of 10028 samples analyzed, 30 samples were discordant. Recall of 30 discordant donors after 2 months gave 4 positive and 26 negative DETERMINE™ HIV½ results.

This explains the high number of discordant results between the DETERMINE™ HIV™ test and the 4th generation ELISA. This shows that the use of the DETERMINE™ HIV½ test is inadequate in the prevention of HIV transmission in blood transfusion or the notion of double-rate transfusion depending on whether the patient is under the coverage area of the RCBT or out of RCBT.

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