Evaluation of Two HIV Rapid Diagnostic Tests in a Context of Strains' Genetic Diversity in Mali

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Abstract

The rapid diagnostic tests used in most resource-limited countries offer little specificity in the differentiation of HIV-1, HIV-2, and HIV-1 + 2. World Health Organization (WHO) does periodically evaluate rapid tests in use in the South Countries. Despite the prequalification from WHO, it is necessary at local level to conduct comparative studies between the available tests. To do this in Mali, we conducted a cross-sectional study at the University Teaching Hospital Gabriel Touré and the Research and Training Center (SEREFO) of Bamako on 172 samples from retrospective and prospective studies. The goal of this project was to compare the following rapid tests: “HIV TRI-DOT” and OnSite HIV1/2 Ab Plus Combo Rapid Test for screening HIV-1 and HIV-2 to “ImmunoComb II BiSpot” (gold standard). The sensibility and specificity of “HIV TRI-DOT” for HIV-1 detection were 100% each [95% confidence interval (CI): 87.13–100 and 95.31–100]. Its performance for HIV-2 detection was 95.24% (95% CI: 84.21–98.68) (sensibility) and 100% (95% CI: 72.25–100) (specificity). The positive and negative predictive values were, respectively, 100% (95% CI: 91.24–100) and 83.33% (95% CI: 55.20–95.30). The sensibility and specificity of OnSite HIV1/2 Ab Plus Combo Rapid Test assay performance were 100% (95% CI: 87.13–100 and 95.31–100). Overall, OnSite HIV ½ Ab Combo Rapid Test proved to be a good test for warm countries and does not require refrigeration in these settings. Blood and its products can be used to perform the test, unlike “ImmunoComb II BiSpot” and “HIV TRI-DOT,” which must be kept cold and cannot be done with whole blood.

Keywords: HIV, rapid diagnostic test, West Africa, Mali

Introduction

HIV INFECTION AFFECTS the host immune system and can lead to the AIDS.

According to World Health Organization (WHO) report published in December 2015, 36.9 million people were living with HIV/AIDS worldwide.¹ Sub-Saharan African countries are heavily impacted with 25.8 million people infected, 69.91% of all cases worldwide.¹

In Mali, the fifth demographic and health surveys (EDS MV) conducted in 2012 reported a decline in the prevalence rate from 1.3% to 1.1%, which made it a low prevalence country with a tendency to stabilization.²

Although HIV-2 is responsible of one to two million infections worldwide in 2011,^{3–5} the overall urban prevalence was 2.50% in Cote d'Ivoire, 7.90% in Guinea-Bissau, 1.90% in Gambia, 1.40% in Cape Verde, 1.30% in Burkina Faso, 1.80% in Mali, and <0.80% in the remaining countries.^{6–9} HIV diagnosis is recognized as the first barrier in controlling the disease and achieving the three 90 goals “90-90-90” of UNAIDS.¹⁰ Indeed, the goal is to have (1) 90% of the HIV-infected population to know about their HIV status, (2) 90% of those who know their status to be on antiretroviral therapy (ART), and (3) finally, 90% of patients receiving ART to have a suppressed viral load (undetectable HIV RNA <50 copies/mL) by 2020.¹¹ This is particularly important as the

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management of patients depends on the infecting strains. A lack of specificity of HIV-2 rapid serological or Elisa tests has been shown, because of the many nonspecific cross-reactivity with HIV-1.^{12–14} This cross-reactivity leads to misinterpretation of the mono HIV-2 infection and the double-HIV 1+2 infections, with important consequences on biological and treatment monitoring of patients.

Indeed, misdiagnosis leads to inappropriate therapeutic choices, which may cause an early virological failure and promote selection of HIV drug resistance. A proper diagnostic that allows differentiation of HIV type is crucial. The rapid diagnostic tests (RDTs) used in a resource-limited country, in general, have low specificity in the differentiation of HIV-1 from HIV-2 or HIV-1+2.¹⁵ WHO periodically evaluates HIV RDTs in use in the developing countries. But, it is still necessary at local levels for countries to conduct their own regular comparative studies of the tests before their widespread use. We conducted this study to provide a wide range of RDTs for HIV testing in Mali and facilitate choices in case of stockouts. Indeed, the tests we evaluated as per the manufacturers have, respectively, a sensitivity of 99.50% and 100% and a specificity of 99.99% and 100%, for, respectively, “HIV TRI-DOT” and OnSite HIV1/2 Ab Plus Combo Rapid Test.^{16,17} So, it was important to initiate a study comparing these RDTs with a validated diagnostic algorithm (ImmunoComb II BiSpot with 100% of sensitivity and 99.40% of specificity¹⁸) in Mali. The aim of this study was, therefore, to assess the performance of HIV TRI-DOT[®] and OnSite HIV-1/2 Ab Plus Combo Rapid Tests in Mali.

Materials and Methods

We conducted a cross-sectional study from July to September 2015. The study included children and adult patients recruited during their routine HIV screening at the Biomedical analysis laboratory of the University Teaching Hospital Gabriel Toure, and samples of previous studies were stored at the Training and Research Center on HIV and Tuberculosis “SEREFO” bio-banks. The study included 172 samples from patients of public HIV care centers and the University Hospital Gabriel Touré. A total of 115 samples have been tested for the three rapid tests (OnSite HIV1/2 Ab Plus Combo Rapid Test, ImmunoComb II BiSpot, and HIV TRI-DOT). DetermineTM and ImmunoComb II BiSpot previously tested 57 samples were used. Those HIV-2-positive samples were collected during routine screening in Segou (third region of Mali). We only had to test them for HIV TRI-DOT.

The screening algorithm

We first used the national algorithm of the Mali HIV National Control Program for diagnostics in the hospitals, to which was added HIV TRIDOT. A total of 115 prospectively collected plasma samples were tested with OnSite HIV-1/2 Ab Plus Combo Rapid Test and then confirmed by ImmunoComb II BiSpot. With the retrospective bio-banks, the plasma samples (57) were tested with the Determine HIV-1/2 and ImmunoComb II BiSpot.

In this study, we compared each tests with ImmunoComb II BiSpot (chosen as gold standard). ImmunoComb II BiSpot has a sensitivity of 100% and a specificity of 99.40% as previously described.¹⁸ All samples were tested for HIV TRIDOT. This study was submitted to the hospital medical

board members and their authorization was received. The tests were performed in the laboratory at around 25°C.

Informed or assent consents were obtained from all participants at the University Teaching Hospital Gabriel Toure. Anonymity and confidentiality were guaranteed on all information obtained from patients.

Results

Female gender was the most prevalent with 53.05% (61/115) of our participants, with a gender ratio M/F of 0.88 for women. The age group of 25–29 years old was the most represented with 14.78%. This group was followed by the 35–39 years old group with 13.91%, then the 30–39 years group with 13.04%. All patients were aged between 2 and 61 years. The average age of patients included was 29.48 ± 13.38 years.

HIV-1 prevalence in samples from Gabriel Touré University Teaching Hospital patients was 23.48% (27/115). HIV-1 was the most represented with 99.13% (114/115).

ImmunoComb II BiSpot showed 43.02% (74/172) of positivity. By contrast, HIV TRI-DOT test showed lower sensitivity with 39.53% (68/172) positives and 2.32% (4/172) of indeterminate result (Table 1a). We found a sensitivity for HIV TRI-DOT test of 97.14% (68/70) and a specificity of 100% (98/98). The positive predictive value was 100% (68/68), whereas the negative predictive value was 98.00% (98/100). The overall diagnostic accuracy of the tests was 98.81% (166/168) (Table 1b). There were no discordant results between the two tests.

ImmunoComb II BiSpot and HIV TRI-DOT showed, respectively, 22.80% (26/114) of positives and 77.80% (88/114) of negatives and there was no indeterminate result (Table 2a).

The sensitivity and specificity of the HIV TRI-DOT test were 100% (26/26 and 88/88, respectively) for the detection of anti-HIV-1 antibodies. The positive and negative predictive

TABLE 1. TEST RESULTS OF IMMUNOCOMB II BiSPOT TESTS AND HIV TRI-DOT (A); HIV TRIDOT PERFORMANCE RELATIVE TO IMMUNOCOMB II BiSPOT TEST (B)

(a)			
HIV status (N = 172)	ImmunoComb II Bispot % (n)	HIV TRI-DOT% (n)	p
Positive	43.02 (74)	39.53 (68)	.696
Negative	56.97 (98)	58.13 (100)	.892
Indeterminate	00.00 (0)	2.32 (4)	
Total	100.00 (172)	100.00 (172)	
(b)			
Parameter	HIV TRI-DOT	95% CI	
Sensitivity (%)	97.14	90.17–99.21	
Specificity (%)	100	96.23–100	
Positive predictive value (%)	100	94.65–100	
Negative predictive value (%)	98.00	93.00–99.45	
Diagnostic accuracy (%)	98.81	95.76–99.67	

CI, confidence interval.

TABLE 2. TEST RESULTS OF IMMUNOCOMB II BiSPOT AND HIV TRI-DOT TEST (A); HIV TRI-DOT PERFORMANCE RELATIVE TO IMMUNOCOMB II BiSPOT TEST FOR HIV-1 ANTIBODIES DETECTION (B); DISTRIBUTION OF BIOBANK SAMPLES IN TERMS OF IMMUNOCOMB II BiSPOT AND HIV TRI-DOT TEST SCORES (C); HIV TRI-DOT PERFORMANCE RELATIVE TO IMMUNOCOMB II BiSPOT TEST FOR HIV-2 ANTIBODIES DETECTION HIV TRI-DOT PERFORMANCE RELATIVE TO IMMUNOCOMB II BiSPOT TEST FOR HIV-2 ANTIBODIES DETECTION (D)

(a)			
HIV-1 status (N = 114)	ImmunoComb II Bispot % (n)	HIV TRI-DOT % (n)	p
Positive	22.80 (26)	22.80 (26)	1.000
Negative	77.20 (88)	77.20 (88)	1.000
Indeterminate	00.00 (0)	00.00 (0)	
Total	100.00 (114)	100.00 (114)	
(b)			
Parameter	HIV TRI-DOT	95% CI	
Sensitivity (%)	100	87.13–100	
Specificity (%)	100	95.31–100	
Positive predictive value (%)	100	87.13–100	
Negative predictive value (%)	100	95.31–100	
Diagnostic accuracy (%)	100	96.44–100	
(c)			
HIV-2 status (N = 57)	ImmunoComb II Bispot % (n)	HIV TRI-DOT % (n)	p
Positive	82.24 (47)	70.17 (40)	.151
Negative	17.54 (10)	21.05 (12)	.816
Indeterminate	00.00 (0)	7.01 (4)	
Total	100.00 (57)	100.00 (56)	
(d)			
Parameter	HIV-TRI-DOT	95% CI	
Sensitivity	95.24	84.21–98.68	
Specificity (%)	100	72.25–100	
Positive predictive value (%)	100	91.24–100	
Negative predictive value (%)	83.33	55.20–95.30	
Diagnostic accuracy (%)	96.15	87.02–98.94	

values were 100% each. The diagnostic accuracy was 100% (114/114) (Table 2b).

ImmunoComb II BiSpot showed 82.24% (47/57) of positive results and 17.54% (10/57) negative results. We found with HIV TRI-DOT test, 70.17% (40/57) of positive, 21.05% (12/57) of negative, and 7.01% (4/57) were undetermined (Table 2c).

The sensitivity of HIV TRI-DOT test was 95.24% (40/42) with a specificity of 100% (10/10) for the anti-HIV-2 antibody detection. The positive predictive value was 100% (40/40), whereas the negative predictive value was 83.33% (10/12). The diagnostic accuracy was 96.15% (50/52) and the Cohen κ was 0.885 (Table 2d).

For ImmunoComb II BiSpot and OnSite HIV ½ Ab Plus Combo Rapid Test, we found 23.47% (27/115) of positives

and 76.52% (88/115) negatives. There were no discordant results between the two rapid tests (Table 3a).

The sensitivity and specificity of the Ab Combo OnSite HIV ½ Ab Plus Rapid were both 100% (27/27 and 88/88, respectively) for the detection of HIV antibodies. The test positive and negative predictive values were 100% each. Its overall diagnostic accuracy was 100% (115/115) (Table 3b).

For ImmunoComb II BiSpot and OnSite HIV ½ Ab Plus Combo Rapid, we found, respectively, 22.60% of positive

TABLE 3. DISTRIBUTION OF SURVEYED PATIENTS IN TERMS OF ONSITE HIV ½ AB PLUS RAPID TEST AND IMMUNOCOMB II BiSPOT TEST SCORES (A); ONSITE HIV ½ AB PLUS RAPID TEST PERFORMANCE RELATIVE TO IMMUNOCOMB II BiSPOT (B); DISTRIBUTION OF SURVEYED PATIENTS IN TERMS OF ONSITE HIV ½ AB PLUS RAPID TEST AND IMMUNOCOMB II BiSPOT TEST SCORES FOR HIV-1 ANTIBODIES DETECTION (C); ONSITE HIV ½ AB PLUS RAPID TEST PERFORMANCE RELATIVE TO IMMUNOCOMB II BiSPOT TEST FOR HIV-1 ANTIBODIES DETECTION (D)

(a)			
HIV-1 status (N = 115)	ImmunoComb II Bispot % (n)	Onsite HIV1/2 Ab Plus Combo Rapid Test % (n)	p
Positive	23.47 (27)	23.47 (27)	1.000
Negative	76.52 (88)	76.52 (88)	1.000
Indeterminate	00.00 (0)	00.00 (0)	
Total	100.00 (115)	100.00 (115)	
(b)			
Parameter	OnSite HIV ½ Ab Plus Combo Rapid Test	95% CI	
Sensitivity (%)	100	87.54–100	
Specificity (%)	100	95.82–100	
Positive predictive value (%)	100	87.54–100	
Negative predictive value (%)	100	95.82–100	
Diagnostic accuracy (%)	100	96.77–100	
(c)			
HIV-1 status (N = 114)	ImmunoComb II Bispot % (n)	OnSite HIV ½ Ab Plus Combo Rapid Test % (n)	p
Positive	22.80 (26)	22.80 (26)	1.000
Negative	77.20 (88)	77.20 (88)	1.000
Indeterminate	00.00 (0)	00.00 (0)	
Total	100.00 (114)	100.00 (114)	
(d)			
Parameter	OnSite HIV ½ Ab Plus Combo Rapid Test	95% CI	
Sensitivity (%)	100	87.13–100	
Specificity (%)	100	95.31–100	
Positive predictive value (%)	100	87.13–100	
Negative predictive value (%)	100	95.31–100	
Diagnostic accuracy (%)	100	96.44–100	

and 77.20% of negative test. There were no discordant results between the two tests (Table 3c). The sensitivity and specificity of OnSite HIV ½ Ab Plus Combo Rapid test were, respectively, 100% (26/26 and 88/88) for the detection of anti-HIV-1 antibodies. The positive and negative predictive values were 100%. The diagnostic accuracy was 100% (114/114) (Table 3d).

Discussion

We performed chi square test to determine whether the difference between compared result is significant. The significant difference has a p value $<.05$. Female gender was the most represented in this study with 53.05% of all cases (61/115). These results are similar to those of Traoré and Coulibaly who found, respectively, 56.20% ($p>.05$) in the Infectious Diseases Unit of the University Hospital of Point G in Bamako in 2014¹⁹ and 67.00% ($p>.05$) at INRSP (Institut National de la Recherche en Sante Publique: National Institute of Public Health) in Bamako Mali in 2006.²⁰

Study participants were aged from 2 to 61 years old. The most represented age range was 25–39 years with 41.73% (48/115). This result is comparable with that of Diawara and Touré who found, respectively, 35.50% for the range 26–33 years in Bamako, Mali in 2007²¹ and 29.30% for the range 30–39 at Gabriel Touré Hospital in Bamako, Mali in 2008.²²

We found overall 23.48% (27/115) prevalence of HIV type 1 at the University Teaching Hospital Gabriel Touré of Bamako. This prevalence is higher but not different than what was found by Traoré in Mali, which was a prevalence of 2.00% ($p>.05$) from the National blood transfusion Center of Bamako among blood donors in 2014²³ and comparable with that found by Coulibaly 44.00% ($p>.05$) at INRSP in 2006 on 100 samples.²⁰

HIV-1 was the most represented with 99.13% (114/115) of our study population. This result is higher than that found by Traoré and Diawara With, respectively, 93.30% ($p<.05$) in the Department of Infectious Diseases of the University Hospital of Point G in Bamako, Mali, in 2014¹³ and 88.70% ($p<.05$) in Bamako in Mali in 2007.²¹

The sensitivity of HIV TRI-DOT as compared with ImmunoComb II BiSpot was 97.14% (68/70). This sensitivity is lower than that found by Sudha *et al.* (99.50%) in India in 2005 and Kannangai *et al.* (99.50%) in India in 2000.^{24,25} This value is also lower than the WHO standard of 99.00%.²⁶ However, it is higher than reports from Mirawell single HIV test (94.00%) by Coulibaly on whole blood in INRSP Bamako in 2006.²⁰

We found a specificity of 100% in our study. This value is similar to Sudha *et al.*'s 99.99% ($p>.05$) report compared with ELISA and to Kannangai *et al.*'s 99.99% ($p>.05$) in India in 2000.^{18,19} Our number is also consistent with the WHO minimum standard of 99%.²⁶

In our study, we found four (2.32%) of HIV-2 samples with indeterminate HIV TRI-DOT result.

HIV TRI-DOT proved to be 100% sensitive in our study. This result is comparable with Kannangai *et al.*'s (99.50%) ($p>.05$) in India in 2000,¹⁸ and consistent again with the WHO minimum standard of 99.00%.²⁶ Its specificity of 100% (98/98) is comparable with that reported by Kannangai *et al.* of 99.50% ($p>.05$),²⁵ and is greater than the WHO minimum standard of 99.00%.²⁶

In our study, TRIDOT revealed a sensitivity of 95.24% (40/42) in the detection of anti-HIV antibodies. This result is similar to that of Gautheret-Dejean *et al.*'s who obtained 98.00% ($p>.05$) sensitivity for ImmunoComb II BiSpot for the detection of HIV-2 in Paris in 2015.²⁷

TRIDOT specificity was 100% (10/10) in HIV-2 antibody detection. These results are comparable with those obtained by Gautheret-Dejean *et al.* with 98.00% ($p>.05$) sensitivity for ImmunoComb II BiSpot for the detection of HIV-2 in 2015.²⁷ Compared with ImmunoComb II BiSpot, OnSite HIV ½ Ab Plus Combo Rapid Test showed a sensitivity and specificity of 100%, both with HIV-1 and HIV-2. These results are comparable with those obtained by the manufacturer in its assessment and also to those reported by ImmunoComb II BiSpot.¹⁸

We found four samples indeterminate with HIV TRI-DOT test. In Niger, in a rapid diagnosis test assessment study, indeterminate cases were also reported.²⁸ From our findings, we found that OneSite HIV ½ Ab Plus Combo Rapid Test has a good performance even in warm areas like ours.

Another more precise method would be desirable such as Western blot or Sequencing as gold standard. This is a limitation of our study.

This cross-sectional study shows the importance of periodical assessment of RDTs. In Mali, like in most of low-income countries, HIV RDTs are used based only on WHO periodic assessment. This study informed us that OneSide HIV1/2 Ab Plus Combo Rapid test, updated to our environmental conditions, and does not need cold storage conditions. This rapid diagnosis test evaluation will provide to the Malian health authority another rapid diagnosis test option and, therefore, not dependent on only one company, as HIV test kit shortage from manufacturers is quite frequent.

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Author Disclosure Statement

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