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

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Running Title: HIV Rapid Diagnosis Test Assessment in Bamako

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 pre-qualification of 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 sensitivity and specificity of “HIV TRI-DOT” for HIV-1 detection were 100 % each [IC 95: 87, 13-100 and 95,31-100]. Its performance for HIV-2 detection was 95.24% [IC 95: 84,21-98,68] (sensitivity) and 100% [IC 95: 72,25-100] (specificity). The positive and negative predictive values were respectively 100% [IC 95: 91,24-100] and 83.33% [IC 95: 55.20-95,30]. The sensitivity and specificity of OnSite HIV1/2 Ab Plus Combo Rapid Test assay performance were 100% [IC 95: 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

Human Immunodeficiency Virus (HIV) infection affect the host immune system and can lead to the Acquired Immunodeficiency Syndrome (AIDS).

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

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 the HIV-2 is responsible of one to two millions infections worldwide in 2011 (3–5). The overall urban prevalence in Côte d'Ivoire was 2.50%, in Guinea-Bissau 7.90%, 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 (6–10). HIV diagnosis is recognized as the first barrier in controlling the disease and achieving the three 90 goals "90-90-90" of UNAIDS (11). Indeed, these goals ambition 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 ART and 3) finally, 90% of patients receiving ART to have a suppressed viral load (undetectable HIV RNA < 50 copies/mL) by 2020 (12). This is particularly important as the management of patients depends on the infecting strains. It has been shown a lack of specificity of HIV-2 rapid serological or Elisa tests, because of the many non-specific cross-reactivity with HIV-1 (13–15). 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 choice, which may cause an early virological failure and promote selection of HIV drug resistance. A proper diagnostic that allow differentiation of HIV type is crucial. The rapid diagnostic tests (RDTs) used in resource-limited country in general have low specificity in the differentiation of HIV-1 from HIV-2 or HIV-1 + 2 (16). WHO periodically evaluate HIV RDTs in use in the developing countries. However, it is still necessary at local levels for countries to conduct their own regular comparative studies of the tests before their widespread in the countries. We conducted this study to provide a wide range of RDTs for HIV testing in Mali. Then facilitate choices in case of stock outs. 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 (17,18). 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 specificity) (19) 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.

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 in at the Biomedical analysis laboratory of the University Teaching Hospital Gabriel Toure and samples of previous studies stored at the Training and Research Center on HIV and Tuberculosis “SEREFO” bio-banks. . Inform consents or assents were obtained from all participants. Anonymity and confidentiality were guarantee on all information obtained from patients.

Sample collection

We collected 172 fresh and frozen serum from patients living with HIV (**figure1**). They have been collected in HIV care services and University Hospital Gabriel Toure of Bamako.

Hundred and fifteen (115) fresh serum samples collected from patients have been tested with three rapid tests (OnSite HIV 1/2 Ab Plus Combo Rapid Test, ImmunoComb II BiSpot and HIV TRI-DOT).

We also used frozen HIV-2 serum previously collected during routine screening in Segou (3rd region of Mali) and stored six months ago in minus twenty. Those samples (57 samples) have been already tested with Determine™ and ImmunoComb II BiSpot. We only retested them with HIV TRI-DOT (*We have a shortage of OnSite HIV 1/2 Ab Plus Combo Rapid Test*).

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 prospective collected serum samples were tested with OnSite HIV-1/2 Ab Plus Combo Rapid Test and then confirmed by ImmunoComb II BiSpot. While with the retrospective bio-banks, the serum samples (57) have been 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). I

ImmunoComb II BiSpot has a sensitivity of 100% and a specificity of 99.40% as previously described (19). All samples were tested for HIV TRIDOT. This study was submitted to the hospital medical board members and received their authorization. The tests were performed in the laboratory at room, around 25 degrees Celsius.

Results

Female gender was the most prevalent with 53.05% (61/115) of our participants, with a sex ratio M/F of 0.88 for women. The age group of 25 to 39 years old was the most represented with 41.74% (**Table 1**).

The prevalence of HIV in our 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 and HIV TRI-DOT showed respectively 22.80% (26/114) of positives, 77.80% (88/114) of negatives and there was indeterminate result (**Table 2a**). The sensitivity and specificity of the HIV TRI-DOT test 100% (26/26 and 88/88 respectively) for the detection of anti-HIV-1 antibodies. The positive and negative predictive values were 100% each. The diagnostic accuracy was 100% (114/114) (**Table 2b**).

The 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 2a**). 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), while the negative predictive value was 83.33% (10/12). The diagnostic accuracy was 96.15% (50/52) and the Cohen kappa 0.885 (**Table 2b**).

For ImmunoComb II BiSpot and OnSite HIV ½ Ab Plus Combo Rapid, we found respectively 22.60% of positive and 77.20% of negative test. There were no discordant results between the two tests (**Table 3a**). 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 3b**).

Discussion

We perform chi square test to determine if the difference between compared results is significant or not. The significant difference have a p value < 0.05 . Female gender was the most represented in this study with 53.05% (61/115). This result support the global burden of HIV in female. It is also similar to those of Traore D. and Coulibaly S. who found respectively 56.20% ($p > 0.05$) in the Infectious Diseases Unit of the University Hospital of Point G in Bamako in 2014 (20) and 67.00% ($p > 0.05$) at INRSP (Institut National de la Recherche en Santé Publique: National Institute of Public Health) in Bamako Mali in 2006 (21).

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 to Diawara A. and Toure N. who found respectively 35.50% for the range 26-33 years in Bamako, Mali in 2007 (22) and 29.30% for the range 30 to 39 at Gabriel Touré Hospital in Bamako, Mali in 2008 (23).

We found overall 23.48% (27/115) of prevalence HIV at the University Teaching Hospital Gabriel Touré of Bamako. This prevalence is high but not different from what was found by TRAORE H. in Mali. Which was a prevalence of 2.00% (130/6470, $p < 0.00001$) from the National blood transfusion Center of Bamako among blood donors in 2014 (24) and different from the one found by Coulibaly S. 44.00% (44/100; $p > 0.05$) at INRSP in 2006 on 100 samples (21) this difference is due to sampling. This prevalence is higher than 1.1% (national prevalence of Mali)(2).

HIV-1 was the most represented with 99.13% (114/115) of our study population. This result mean that HIV-1 is the most prevalent type in sub-Saharan Africa. It is higher than what was found by TRAORE D. and DIAWARA A. with respectively 93.30% (83/89; $p < 0.05$) in the Department of Infectious Diseases of the University Hospital of Point G in Bamako, Mali in 2014 (20) and 88.70% (55/62; $p < 0.05$) in Bamako in Mali in 2007 (22).

The sensitivity of HIV TRI-DOT as compared to ImmunoComb II BiSpot was 97.14% (68/70). This sensitivity is lower than what was found by Sudha T et Al. (99.50%) in India in 2005 and Kannagai R. et al. (99.50%) in India in 2000 (25,26). This value is also lower than the WHO standard of 99.00% (27). However, it is higher than reports from Mirawell single HIV test (94.00%) by Coulibaly S. on whole blood in INRSP Bamako in 2006 (21).

We found a specificity of 100% in our study. This value is similar of Sudha T. et al.'s 99.99% ($p > 0.05$) report compared to ELISA and like Kannagai R. et al.'s 99.99% ($p > 0.05$) in India in 2000 (18, 19). Our number is also consistent with the WHO minimum standard of 99% (27).

In our study, we found 4 (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 to Kannagai R. et al. (99.50%) ($p > 0.05$) in India in 2000 (18), and consistent again with the WHO minimum standard of 99.00% (27). Its specificity of 100% (98/98) is comparable to report from Kannagai R. et al. of 99.50% ($p > 0.05$) (26), and is greater than the WHO minimum standard of 99.00% (27).

In our study, TRIDOT revealed a sensitivity of 95.24% (40/42) in the detection of anti-HIV antibodies. This result is similar to the one of Gautheret-Dejean A. et al.'s who obtained 98.00% ($p > 0.05$) sensitivity for ImmunoComb II BiSpot for the detection of HIV-2 in Paris in 2015 (28). TRIDOT specificity was 100% (10/10) in HIV-2 antibody detection. These results are comparable to those obtained by Gautheret-Dejean A. et al. with 98.00% ($p > 0.05$) sensitivity for ImmunoComb II BiSpot for the detection of HIV-2 in 2015 (28). Compared to 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 to those obtained by the manufacturer in its assessment and also to those reported by ImmunoComb II BiSpot (19).

We found 4 samples indeterminate with HIV TRI-DOT test. In Niger, in a rapid diagnosis test assessment study, indeterminate cases were also reported (29). 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.

Overall, RDTs with sensitivity and specificity values lower than 99% are not very good for Mali due the national prevalence of HIV.

This cross-sectional study shows the importance of RDTs periodically assessment. 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 is performant, updated to our environmental conditions and no need to have a cold storage conditions.

Based on our findings, we recommend the use of OneSide HIV1/2 Ab Plus Combo Rapid test in field in Mali. It require any advanced technologies in term of storage and using. This test will be a good support for fast track goal achievement in Mali.

Limitation:

In this study, HIV-2 samples have not been tested with OneSide HIV1/2 Ab plus Combo Rapid test because of its shortage.

We were not able to get fresh HIV-2 sample due to its low prevalence compare to HIV-1 that why we used frozen samples. Another limitation of this study the low number of HIV-1+2 sample.

We were not able to perform a molecular characterization of undetermined samples.

Conflict of Interest: the authors declared no conflict of interest

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Figure I : Study sample flow both fresh and frozen

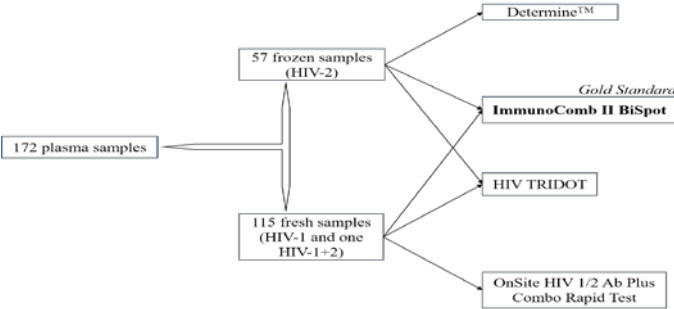


Table I: Characteristics of the study population

Characteristics	Frequencies	Percentages
Sex (Female)	61	53.05
Age range [25-39]	48	41.74
Average of age		29.48 13.38
Prevalence of HIV	27	23.48
Prevalence of HIV-1	114	99.13

Table II: Test results from ImmunoComb II BiSpot and HIV TRI-DOT for HIV-1 and HIV-2 (a); HIV TRI-DOT performance relative to ImmunoComb II Bispot test for HIV-1 and HIV-2 antibodies detection (b)

(a)				(b)		
HIV status	ImmunoComb II BiSpot % (n)	TRIDOT % (n)	P Value	Parameters	HIV TRIDOT %	Confidence Interval 95%
HIV-1 Positive	22.80 (26)	22.80 (26)	1.000	Sensitivity for HIV-1	100	87.113-100
HIV-1 Negative	77.20 (88)	77.20 (88)	1.000	Specificity for HIV-1	100	95.31-100
HIV-2 Positive	82.24 (47)	70.17 (40)	0.151	Positive Predictive Value for HIV-1	100	87.13-100
HIV-2 Negative	17.54 (10)	21.05 (12)	0.816	Negative Predictive Value for HIV-1	100	95.31-100
Undetermined	00.00 (00)	7.01 (4)	-	Diagnostic Accuracy for HIV-1	100	96.44-100
Total	100.00 (172)	100.00 (172)	-	Sensitivity for HIV-2	95.24	84.21-98.68
				Specificity for HIV-2	100	72.25-100
				Positive Predictive Value for HIV-2	100	91.24-100
				Negative Predictive Value for HIV-2	83.33	55.20-95.30
				Diagnostic Accuracy for HIV-2	96.15	87.02 -98.94

Table III: 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)

(a)				(b)		
HIV status	ImmunoComb II BiSpot % (n)	OneSite HIV ½ Ab Plus Combo Rapid Test % (n)	P Value	Parameters	OneSite HIV ½ Ab Plus Combo Rapid Test %	Confidence Interval 95%
HIV-1 Positive	22.80 (26)	22.80 (26)	1.000	Sensitivity for HIV-1	100	87.13-100
HIV-1 Negative	77.20 (88)	77.20 (88)	1.000	Specificity for HIV-1	100	95.31-100
HIV-1+2 Positive	100 (1)	100 (1)	-	Positive Predictive Value for HIV-1	100	87.13-100
Total	100.00 (115)	100.00 (115)	-	Negative Predictive Value for HIV-1	100	95.31-100
				Diagnostic Accuracy	100	96.44-100