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Original article

Evaluation of 9 rapid diagnostic tests for screening HIV infection, in Lomé, Togo

Performance de 9 tests rapides de diagnostic de l'infection VIH, à Lomé, Togo

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Abstract

Purpose. – HIV rapid diagnostic tests (RDT) could be greatly contributive for a universal access to HIV diagnosis. However, according to the WHO, these tests need to be assessed before they can be used in routine.

Method and results. – We assessed 9 RDT in routine clinical use between 2009 and 2013. The sensitivity and specificity observed for 7 tests were ≥ 99% and ≥ 98%, respectively: FIRST RESPONSE HIV1-2-O PMC Medical, India, GENIE Fast HIV 1-2 and GENIE™ III HIV$^{1/2}$ Bio-Rad, France, HIV TRI-DOT + Ag; J. Mitra, INDIA; SD BIOLINE HIV$^{1/2}$ 3.0 and SD BIOLINE HIV/SYPHILIS DUO Standard Diagnostic, Korea; and VIKIA HIV$^{1/2}$; BioMérieux, France. Two tests had performances inferior to WHO recommendations: INSTI HIV1/2 Biolytical Canada; sensitivity = 97.8% and HEXAGON HIV HUMAN GmbH Germany; specificity = 94.8%.

Conclusion. – Seven of 9 RDT had excellent performances. Nevertheless, they can be used only after training staff, and taking into account national algorithm for their safe use.

Keywords: Rapid diagnostic test; HIV; Screening

Résumé

Introduction. – L'utilisation des tests de diagnostic rapide (TDR) du virus de l'immunodéficience humaine (VIH) est importante pour l'accès universel au diagnostic du VIH. Cependant, selon l'Organisation Mondiale de la santé, leur évaluation est indispensable avant la mise à disposition des prestataires.

Méthode et résultats. – Nous avons évalué en routine 9 TDR entre 2009–2013. La sensibilité et la spécificité observées pour 7 tests (FIRST RESPONSE HIV1-2-O PMC Medical, India, GENIE FAST HIV 1-2 et GENIE™ III HIV$^{1/2}$ Bio-Rad, France, HIV TRI-DOT + Ag ; J. Mitra, INDIA ; SD BIOLINE HIV-1/2 3.0 et SD BIOLINE HIV/SYPHILIS DUO Standard Diagnostic, Korea ; et VIKIA HIV$^{1/2}$; Bio Mérieux, France) étaient respectivement ≥ 99 % et ≥ 98 %. Deux tests avaient des performances en dessous de celles recommandées par l'OMS (INSTI HIV1/2 Biolytical Canada ; sensibilité = 97,8 % et HEXAGON HIV HUMAN GmbH Germany ; spécificité = 94,8 %)

Conclusion. – La performance observée pour 7 des 9 TDR est excellente. Cependant, leur utilisation nécessite la formation des prestataires et le respect de l'algorithme national.

Mots clés : HIV ; Tests de diagnostic rapide ; Dépistage

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1. Introduction

The diagnosis of human immunodeficiency virus (HIV) infection is a crucial step in the therapeutic management, blood transfusion safety, and decrease of mother to child virus transmission. Enzyme immunoassays (ELISA) and Western blotting are used for the diagnosis of HIV in Europe and in the United States. Only a few laboratories use these tests in countries with limited resources, which limit universal access to HIV testing. The introduction of rapid diagnostic tests (RDTs) in these countries over the past 15 years has significantly increased access to HIV diagnosis in many countries [1,2]. This is because RDT requires neither highly technical nor additional laboratory equipment. Thus they can be performed by personnel without any qualification in laboratory techniques. However, as with ELISA, RDTs should be regularly assessed because of genetic diversity, especially in sub-Saharan Africa, and this may have an impact on their performance; strains used to manufacture these tests are those commonly encountered in the Northern countries [3–6]. It is thus recommended to regularly assess RDTS and systematically evaluate new tests before introducing them in national algorithms. In Togo, the HIV diagnosis algorithm includes 3 tests used consecutively: a first test called screening test (ELISA or RDT), a second test called confirmation test (RDTs are always discriminating) which is used when the first test is positive, and a third test (Western or dot blot) in case of discordant results for the first 2 tests. The patient is considered as HIV-negative if the first test is negative; he is considered as HIV-positive if the first 2 tests are positive.

We report the performance of 9 RDTs for the diagnosis of HIV, in Togo.

2. Materials and methods

The study was conducted at the national reference center for HIV/STI testing in Lome (NRC/HIV/STI/NACP), Togo. One of the laboratory's activities, required by the Ministry of Health, is to evaluate RDTs. The samples used for test evaluation were collected in the same laboratory and stored at −20 °C. They were harvested from patients coming for voluntary testing, or patients suspected of HIV infection according to the criteria defining the WHO AIDS stage. The following tests (Table 1) were evaluated: FIRST RESPONSE HIV1-2-O test card (PMC Medical, Nani Daman, India), 1-2 GENIE Fast HIV and HIV$^{1/2}$ GENIETM III (Bio-Rad, Marnes-la-Coquette, France), HEXAGON HIV (HUMAN GmbH- 65205 Wiesbaden - Germany), HIV TRI-DOT + Ag (J. Mitra & Pvt Ltd. New Delhi-110-India Co.), INSTI HIV-1/2 (bioLytical, Canada). SD BIOLINE HIV-1/2 3.0 and SD BIOLINE HIV/SYPHILIS DUO (Standard Diagnostics, Inc., Yongin-si, Kyonggi-do, Korea) and VIKIA HIV$^{1/2}$ (BioMérieux, Marcy-Étoile, France). All the evaluated tests were third generation based on recombinant HIV antigens except for the Ag + TRI-DOT test which was a 4th generation based on recombinant antigen and monoclonal antibodies for the detection of the P24 antigen (Table 1). SD BIOLINE HIV/SYPHILIS DUO can detect HIV and syphilis, but the assessment in this study concerned only HIV testing. The tests were performed according to the manufacturer's protocol. Two reference tests were used to assess the performance of RDTs; an enzyme immunoassay, Vironostika HIV Uniform II Micro ELISA (BioMérieux, Geneva, Switzerland), and a combined test antigen/antibody systematically performed on all samples: if the test was negative, the sample was considered as negative and included as such for evaluation; a dot blot assay, INNO-LIATM HIV I/II Score (Innogenetics NV Belgium) was performed to confirm all positive ELISA results. If the test was positive, the sample was considered as positive and included for evaluation. Two groups of sample were used for the evaluation: HIV-negative samples (Vironostika negative) and positive samples (INNO-LIA Vironostika and positive). Five positive HIV-2 samples were included in the group of HIV-positive samples for the evaluation of each test. The reference tests (INNO-LIA and Vironostika) and evaluated tests were systematically retrieved in case of discordant results between reference tests and evaluated tests, to avoid the impact of sample preservation on the results. The results of each RDT were compared to the results of reference tests to determine the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). The Epi-info software was used to determine the confidence interval (CI) at 95%.

3. Results

The evaluations were made between 2009 and 2013. Samples were collected from the population with the following characteristics: 65% of patients were < 40 years of age, 54.6% were female patients, and 20% to 23.6% depending on the year had already been tested in the previous 2 years. Between 149 and 310, samples were included in the study depending on the number of available tests (Table 2). The PPV was 100% for the following tests, INSTI HIV-1/2, GENIE IIITMHIV1/2 VIKIA HIV1/2 and SD BIOLINE HIV/SYPHILIS DUO. The NPV was 100% for HEXAGON HIV, SD BIOLINE HIV1/2 3.0, TRI-DOT Ag, GENIE Fast, SD BIOLINE HIV/Syphilis HIV DUO and VIKIA. The sensitivity of SD BIOLINE HIV1/2 3.0 was 100% for the 98 HIV-1 or HIV-2 positive samples tested (Table 2). The INNO-LIA test results for these 98 samples revealed HIV-1 ($n = 93$) and HIV-2 ($n = 5$) infection. The SD BIOLINE HIV1/2 3.0 result for 12 (12.2%) samples positive for HIV-1 and HIV-2 (double profile) which could mimic HIV-1/HIV-2 coinfection. The intensity among bands was not similar in case of dual reactivity; it was very high for the type of virus involved and very low (pale) for false positivity. This possibility was described in the package notice. The same observations were made for the HIV1-2-O FIRST RESPONSE test for 9 (8.8%) of the 102 positive samples evaluated.

Five false negative results (Table 3) were recorded for 3 tests: INSTI HIV-1/2 ($n = 2$), FIRST RESPONSE HIV1-2-O ($n = 2$), and GENIETM HIV$^{1/2}$ ($n = 1$). The INNO-LIA test allowed classifying these 5 samples as 4 samples positive for HIV-1 and 1 sample positive for HIV- 2. All the tests detected 5 samples as positive for HIV- 2 except for INSTI HIV1/2 and-O HIV1-2 FIRST RESPONSE for which one sample was falsely negative. The reactivity of the FIRST RESPONSE HIV1-2-O test for this