Scientific Research Publishing

Open Journal of Medical Microbiology, 2024, 14, 1-10
https://www.scirp.org/journal/ojmm
ISSN Online: 2165-3380
ISSN Print: 2165-3372

Seroprevalence of HBV and HCV among People Living with HIV in Burkina Faso and Diagnostic Performance of HIV/HCV/HBsAg Combined Rapid Test in Comparison with Architect Assays

Serge Theophile Soubeiga[1,2*], Albert Theophane Yonli[2,3], Alain Megabtche Nantchouang[4], Jacques Simpore[2,3]

[1]Department of Biomedical and Public Health, Research Institute for Health Sciences (IRSS), Ouagadougou, Burkina Faso
[2]Pietro Annigoni Biomolecular Research Centre (CERBA), Ouagadougou, Burkina Faso
[3]Laboratory of Molecular Biology and Genetics (LABIOGENE), University Joseph Ki-Zerbo, Ouagadougou, Burkina Faso
[4]BIOMEX Laboratory, Heidelberg, Germany
Email: *theo.soubeiga@gmail.com

How to cite this paper: Soubeiga, S.T., Yonli, A.T., Nantchouang, A.M. and Simpore, J. (2024) Seroprevalence of HBV and HCV among People Living with HIV in Burkina Faso and Diagnostic Performance of HIV/HCV/HBsAg Combined Rapid Test in Comparison with Architect Assays. *Open Journal of Medical Microbiology*, **14**, 1-10.
https://doi.org/10.4236/ojmm.2024.141001

Received: May 31, 2023
Accepted: March 25, 2024
Published: March 28, 2024

Abstract

Background: The diagnosis of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) remains a constraint for some populations in sub-Saharan Africa. This study aimed to determine the prevalence of HBV and HCV in people living with HIV and to evaluate the performance of a combined rapid test for the simultaneous detection of HIV, HBV, and HCV. **Methods**: This is a cross-sectional study that took place from February 2017 to November 2018 and included 139 HIV-infected individuals followed up at different medical centers in Ouagadougou, Burkina Faso. HBV and HCV serology tests were performed on-site using finger prick whole blood with HIV/HCV/HBsAg combined rapid test and then serum with two reference tests "Architect HBsAg Qualitative" and "Architect HIV Ag/Ab Combo". **Results**: The mean age of the participants was 57 ± 8 years. Of the 139 participants, 10% (14/139) were HIV-1 positive, 71.9% (100/139) were HIV-2 positive, and 18.0% (25/139) were HIV-1/HIV-2 coinfected. The sensitivity and specificity of the HIV/HCV/HBsAg combined rapid test were 33.33% vs 99.11% and 20% vs 99.25% compared to Architect HBsAg Qualitative and Architect HIV Ag/Ab Combo, respectively. The Kappa and Youden Index values were 0.4262 and 0.3244 and 0.2707 and 0.1925, respectively, compared to each of the two reference tests. **Conclusion**: The results show that the HIV/HCV/HBsAg combined rapid test has poor diagnostic efficiency and should not be recommended for the diagnosis of these viruses.

Keywords

HIV, HBV, HCV, Prevalence, Diagnosis, Burkina Faso

1. Introduction

Human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) are viruses with common risk factors and modes of transmission [1] [2] and remain high in prevalence in sub-Saharan Africa [3]. However, many populations remain underdiagnosed or unaware of their positive status, and they can transmit the virus to others [4] [5]. Early identification of people with HIV, HBV, or HCV infection not only allows them to receive the care and treatment needed to prevent or delay disease progression but also reduces transmission [3] [6]. Serological testing for each virus is more expensive in resource-limited settings than multiplex testing. HIV/HBV/HCV multiplex serology tests offer advantages in terms of cost reduction, speed, and reduction in the number of blood draws and can be used in peripheral health care settings due to the ability to use serum, plasma or whole blood samples [7] [8]. However, they would be more accessible to populations and would favor the simultaneous screening of these three viruses. However, their difficulty may lie in their performance in terms of sensitivity and specificity. Currently, several serological tests exist and offer the possibility of performing HIV-1/2, HBsAg, and HCV antibody serology simultaneously. Only their validation is necessary before they can be introduced into routine use. The HIV/HCV/HBsAg rapid combination test is a rapid immunochromatographic assay for the qualitative detection of anti-HCV antibodies, HIV1/2 antibodies, and HBsAg in whole blood, plasma, or human serum samples. The results are read within a maximum of 15 minutes. Usually, rapid diagnostic tests are not evaluated before their commercialization in the local market. In Burkina Faso, there is no commercialized simultaneous detection rapid test for these three viruses. This study aimed to determine the prevalence of HBV and HCV in people living with HIV and to evaluate the performance of a combined rapid test for the simultaneous detection of HIV, HBV, and HCV.

2. Material and Methods

2.1. Type and Population Study

This was a cross-sectional study that took place from February 2017 to November 2021 in Ouagadougou, Burkina Faso, West Africa. This long period was due to the COVID-19 pandemic that stopped the process of the study. The study population consisted of HIV-positive diagnosed patients on antiretroviral (ARV) treatment who were followed-up at different medical centers in Ouagadougou, the capital city of Burkina Faso. Given the very low prevalence of HIV-2, all adult HIV-2-infected people followed-up were recruited. Participants were selected through a questionnaire. The selection criteria were as follows: age (≤18

years), HIV-2 confirmed status, enrollment in a medical center and written informed consent.

2.2. Serological Test with HIV/HCV/HBsAg Combined Rapid Test

HBV and HCV serology was performed on-site with the "HIV/HCV/HBsAg combined rapid test" (Mexacare GmbH, Germany) following the manufacturer's procedure from whole blood obtained by finger prick with lancets. This is an immunochromatographic rapid assay for the qualitative detection of HCV antibodies, HIV-1/2 antibodies, and HBsAg in whole blood, serum and plasma samples, respectively. This test contains three parts for each target and control line "C". The result must be read within 15 minutes.

2.3. Serological Analysis with Reference Tests

A total of 139 participants were included. After inclusion, venous blood samples were taken from each patient and collected in a dry tube. Sera were used to perform HBV and HCV serology tests using two reference tests, "Architect HBsAg Qualitative" and "Architect Anti-HCV", in the BIOMEX laboratory in Germany.

HBV serology was performed using the "Architect HBsAg Qualitative" assay (Abbott Laboratories, Germany) following the manufacturer's protocol. The ARCHITECT HBsAg Qualitative assay is a CMIA for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma.

HCV serology was performed using the Architect Anti-HCV assay on Architect 1000 SR (Abbott Laboratories, Germany) following the manufacturer's instructions. The Architect Anti-HCV assay is a two-step immunoassay that uses chemiluminescent microparticle immunoassay (CMIA) technology for the qualitative detection of anti-HCV antibodies in human serum/plasma. It uses the HCr43 protein composed of two noncontiguous coding regions of the HCV genome (33c and core) and the c100-3 protein (putative nonstructural NS3 and NS4).

2.4. Data Analysis

Data were entered into Excel and analyzed using OpenEpi software (http://www.openepi.com). The sensitivity (VP)/(VP + FN) and diagnostic specificity (VN)/(VN + FP) of each test were estimated with their 95% confidence intervals. In addition to the two main characteristics (sensitivity and specificity) of the diagnostic performance of the test, other test-specific parameters, such as positive (PPV) and negative (NPV) predictive values (PPV = VP/VP + FP and NPV = VN/VN + FN), positive (RV+) and negative (RV−) likelihood ratios, and the Kappa coefficient of agreement between the antigenic RDT and the RT-PCR test, were calculated and interpreted. The Kappa coefficient of agreement was interpreted according to the criteria of Landis and Koch [9] as follows: Kappa < 0, no agreement; 0 < kappa ≤ 0.2 = mild agreement; 0.2 < kappa < 0.4, moderate agreement; 0.4 < kappa ≤ 0.6; moderate agreement; 0.6 < kappa ≤ 0.8 = substan-

tial agreement; 0.8 < kappa ≤ 1, near perfect agreement. Youden's J index was calculated using the following formula: Youden's J index = sensitivity + specificity − 1.

2.5. Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. This study received approval from the Ethics Committee for Health Sciences of the Ministry of Health (Deliberation n˚2016-04-75).

3. Results

3.1. Distribution of the Study Population

The mean age of the participants was 57 ± 8 years, and the majority were women (61.9%, 86/139). The sex ratio of men to women was 0.62. Of the 139 participants, 10% (14/139) were HIV-1 positive, 71.9% (100/139) were HIV-2, and 18.0% (25/139) were HIV-1/HIV-2 coinfected (Table 1).

Table 1. Seroprevalence of HBV and HCV.

	Number (%)
Mean age (years)	57 ± 8
Gender (n = 139)	
Male	53 (38.1)
Female	86 (61.9)
HIV status (n = 139)	
HIV-1	14 (10.1)
HIV-2	100 (71.9)
Coinfected HIV-1/2	25 (18.0)
Hepatitis virus infection status (n = 139)	
HBV	27 (19.6)
HCV	5 (3.6)
Coinfected HBV/HCV	2 (1.4)
Coinfections HIV and HBV (n = 139)	
HBV/VIH-1	4 (2.9)
HBV/VIH-2	4 (2.9)
HBV/VIH-1/2	17 (12.2)
Coinfections HIV and HCV (n = 139)	
HCV/VIH-1	0 (0.0)
HCV/VIH-2	4 (2.9)
HCV/VIH-1/2	0 (0.0)

3.2. HBV and HCV Seroprevalence among PLWHIV

The seroprevalence was 19.6% (27/139) for HBV and 3.6% (5/139) for HCV (Table 1) among PLWHIV. Women were most affected by HBV and HCV infection, with rates of 51.9% and 60.0%, respectively. However, there was no statistically significant difference (p = 0.232 and p = 0.930). It is also noted that people aged between 45 and 60 years were the most affected by HBV and HCV infection at 48.1% and 60%, respectively, but there was no statistically significant difference (p = 0.831 and p = 0.4) (Table 2).

3.3. Analytical Performance of the HIV/HCV/HBsAg Test

The number of false positives for the HIV/HCV/HBsAg test was 1 for each of the two tests, Architect HBsAg Qualitative and Architect Anti-HCV. On the other hand, the number of false negatives was higher with the Architect HBsAg Qualitative II test (FN = 18) than with the Architect Anti-HCV test (FN = 4) (Table 3). The HIV/HCV/HBsAg test had lower sensitivity compared to Architect HBsAg Qualitative and Architect Anti-HCV (33.33% and 20%) but good specificity (99.11% and 99.25%). The positive predictive value was better for HIV/HCV/HBsAg vs Architect HBsAg Qualitative (90%) than for HIV/HCV/HBsAg vs Architect Anti-HCV (50%). However, the negative predictive value was better for HIV/HCV/HBsAg vs Architect Anti-HCV (97.08%) than for HIV/HCV/HBsAg vs Architect HBsAg Qualitative (86.05%). The diagnostic accuracy was better for anti-HCV detection (96.4%) than HBsAg detection (86.33%). The low values of the Kappa coefficient show that the HIV/HCV/HBsAg test has low reliability. The Youden indices are all very low (far from 1) (Table 4).

Table 2. Relation between HBV and HCV infections.

	HBV		p value	HCV		p value
	Positive	Negative		Positive	Negative	
Sex						
Male	13 (48.1)	40 (35.7)	0.232	2 (40)	51 (38.1)	0.930
Female	14 (51.9)	72 (64.3)		3 (60)	83 (61.9)	
Age (years)						
<35	0 (0.0)	1 (0.9)	0.831	0 (0.0)	1 (0.7)	0.4
35 - 45	2 (7.4)	5 (4.5)		1 (20)	6 (4.5)	
45 - 60	13 (48.1)	61 (54.5)		3 (60)	71 (53)	
≥60	12 (44.4)	45 (40.2)		1 (20)	56 (41.8)	

Table 3. Results of serological tests.

HIV/HCV/HBsAg	Architect HBsAg qualitative II		Architect anti-HCV	
	Positive	Negative	Positive	Negative
Positive	9	1	1	1
Negative	18	111	4	133

Table 4. Performance of HIV/HCV/HBsAg test.

	HIV/HCV/HBsAg vs architect HBsAg qualitative % (95% CI)	HIV/HCV/HBsAg vs architect anti-HCV % (95% CI)
Sensibility	33.33 (18.64 - 52.18)	20 (3.62 - 62.45)
Specificity	99.11 (95.12 - 99.84)	99.25 (95.89 - 99.87)
Positive predictive value	90 (59.58 - 98.21)	50 (9.45 - 90.55)
Negative predictive value	86.05 (79.02 - 90.99)	97.08 (92.73 - 98.86)
Accuracy of diagnosis	86.33 (79.64 - 91.07)	96.4 (91.86 - 98.45)
Positive likelihood ratio	37.33 (3.402 - 409.7)	26.8 (0.0015 - 483.3)
Negative likelihood ratio	0.6727 (0.6032 - 0.7502)	0.806 (1.75 - 632)
Kappa coefficient	0.4262 (0.2836 - 0.5689)	0.2707 (0.1212 - 0.4202)
Youden's Index	0.3244	0.1925

4. Discussion

This study revealed a high prevalence of HBV (19.6%), HCV (3.6%), and HBV/HCV coinfection (1.4%) among people living with HIV (PLWHIV). These prevalence values are higher than those found in the general population [10]. Another study showed a high prevalence of 21.1% of HBV among HIV-infected individuals before their initial ARV treatment [11] in Burkina Faso. Our results confirm those found in a systematic review and meta-analysis that revealed high HBV, HCV, and HBV/HCV coinfection seroprevalences of 10.5% [95% CI = 9.6 - 11.3], 5.4% [95% CI = 4.6 - 6.2], and 0.7% [95% CI = 0.3 - 1.0], respectively, among PLWHIV living in Africa [12]. This large difference could be explained by the fact that PLWHIV are at higher risk concerning their common modes of transmission and immune system failure (WHO, 2017). Indeed, the common routes of these viruses are sexual and injecting drugs [13]. People living with HIV are frequently infected with HBV and/or HCV [13] [14]. One of the causes of death among PLWHIV remains HBV- and HCV-related liver disease [15] [16] as they rapidly progress to AIDS [17] and experience high liver toxicity related to ARV treatment [18]. To this end, measures must be taken in terms of prevention, awareness, increased diagnostic capacity, and treatment of viral hepatitis to reduce HBV and HCV transmission in the general population and in particular in at-risk populations such as those living with HIV [12] [19]. Most

countries in sub-Saharan Africa have not integrated HBV and/or HCV into their HIV/AIDS programs, yet the high prevalence of HBV and HCV among PLWHIV found in this and other studies indicates the need to integrate actions against these two viruses into these country programs. In Africa, most HBV infections occur perinatally and in early childhood [20]. The risks of progression to chronicity are also very high in children compared to adults. HIV, on the other hand, is mainly acquired in Africa through sexual intercourse in adulthood [12]. There is a hypothesis that in Africa, most of the HBV/HIV coinfected subjects come from an infection of HBV monoinfected subjects acquired in childhood who will become HIV coinfected in adulthood through the sexual route [12].

In addition, longitudinal studies to understand the factors associated with the high morbidity and/or mortality of HBV and/or HCV among PLWHIV in Africa would further assist in effectively addressing these infections [21]. Evaluation of the analytical performance of the combined HIV/HCV/HBsAg rapid diagnostic test (RDT) compared to the reference tests Architect HBsAg Qualitative and Architect Anti-HCV showed low sensitivities of 33.33% and 20%, respectively. This demonstrates its poor ability to detect the infection among sick people. Nevertheless, the specificity was good (≥99%). The performance found in this study shows that the combined HIV/HCV/HBsAg rapid test does not meet the acceptance criteria for rapid tests defined by the WHO, especially in terms of sensitivity (sensitivity ≥ 99% for detection of anti-HIV antibodies; sensitivity ≥ 98% for detection of anti-HCV antibodies; sensitivity = 100% for HBsAg detection) [22]. The positive predictive value was better for HIV/HCV/HBsAg vs Architect HBsAg Qualitative (90%) than for HIV/HCV/HBsAg vs Architect Anti-HCV (50%). However, the negative predictive value was better for HIV/HCV/HBsAg vs Architect Anti-HCV (97.08%) than for HIV/HCV/HBsAg vs Architect HBsAg Qualitative (86.05%). The positive predictive value and negative predictive value reflect the proportion of positive and negative results that are true positives and true negatives, respectively [23]. That means in this study, the probability is 90% for the participant to have HBV disease if the test is positive and only 50% for the participant to have HCV disease if the test is positive. In addition, the probability is 97.08% for the participant to not have HCV disease if the test is negative and 86.05% for the participant to not have HBV disease if the test is negative. The diagnostic accuracy was better for anti-HCV detection (96.4%) than HBsAg detection (86.33%). The low Kappa and Youden index values demonstrate that the diagnostic efficiency of the combined HIV/HCV/HBsAg rapid test is not good and should not be used for the diagnosis of these three viruses. False negatives for HCV may result from decreased HCV-specific antibody levels and/or very low affinity of HCV-specific antibodies for their antigens [24]. In contrast, false negatives for HBV would likely be due to the poor ability of the test to detect HBsAg mutants [25]. Thus, better tests must be developed to make the diagnosis of the three viruses (HIV, HBV, and HCV) more accessible, especially in resource-limited countries. This study has a few limitations. First, the combined HIV/HCV/HBsAg rapid test was performed using whole blood ob-

tained by finger prick, while the reference tests were performed with serum. Second, the sample size is still small, and further studies with a larger sample size would allow a better appreciation of the results.

5. Conclusion

This study reported a high prevalence of HBV and HCV in PLWHIV, confirming their high risk of infection with these two viruses. Management of HBV and HCV is therefore necessary to avoid their complications in PHAs. The combined HIV/HCV/HBsAg rapid test is less effective in the diagnosis of HBV and HCV and should not be used for the diagnosis of these viruses.

Acknowledgements

All authors want to thank all medical staff of hospitals included in this study for their support and the BIOMEX laboratory for their support in the realization of serological tests.

Conflicts of Interest

The authors have no relevant financial or nonfinancial interests to disclose.

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