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Evaluation of the SD Bioline Syphilis 3.0 rapid immunochromatographic test for syphilis screening in Burkina Faso

Oumar TRAORÉ[1,2], Dissinviel Stéphane KPODA[3,4*], Adama Patrice SOUBEIGA[4], Rokiatou Henry-SANGARÉ[4], Abraham AJAYI[5], Casimir OUÉDRAOGO[6], Maxime Koiné DRABO[4], Elie KABRÉ[4] and Lassana SANGARÉ[6, 7]

[1]*Unité de Formation et de Recherche en Sciences Appliquées et Technologies (UFR/SAT), Université de Dédougou BP 76, Burkina Faso.*

[2]*Laboratoire de Biologie Moléculaire d'Epidémiologie et de Surveillance des bactéries et virus transmis par les aliments. CRSBAN/Département de Biochimie-Microbiologie, UFR/ SVT-Université Joseph KI-ZERBO, 03 B.P. 7021 Ouagadougou 03 ; Burkina Faso.*

[3]*Université Joseph Ki-Zerbo, Centre Universitaire de Ziniaré 03 BP 7021 Ouagadougou 03, Burkina Faso.*

[4]*Laboratoire National de Santé Publique ; 09 BP 24, Ouagadougou 09, Burkina Faso.*

[5]*Nigerian Institute of Medical Research Yaba, Lagos, Nigeria.*

[6]*Centre Hospitalier Universitaire Yalgado Ouedraogo, 03 BP 7022, Ouagadougou 03, Burkina Faso.*

[7]*Université Joseph Ki-Zerbo, 03 BP 7021 Ouagadougou 03, Burkina Faso.*

[*] *Corresponding author; E-mail: podadissin@yahoo.fr; Telephone: (226) 70077357.*

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ABSTRACT

Syphilis remains a global health problem. In Burkina Faso, cases of syphilis are still prevalent despite concerted effort in the fight against sexually transmitted infections. The availability of *Treponema pallidum* haemagglutination assay in the diagnosis of syphilis has not eliminated the challenges encountered in the diagnosis of syphilis in Burkina Faso, hence the difficulty in case management. This study evaluated the diagnostic performance of SD Bioline syphilis 3.0 test against the combination of venereal disease research laboratory (VDRL) and *Treponema pallidum* haemagglutination assay (TPHA) a reference test used routinely in Burkina Faso. A total of 633 serum samples collected from suspected syphilis infected participants were tested for syphilis using the combination of VDRL, TPHA and SD Bioline syphilis 3.0, a rapid immunochromatographic test (ICT). The sensitivity and specificity of SD Bioline syphilis 3.0 test were 100% and 92%, and the positive and negative predictive values were 85.95% and 100%, respectively, compared to the classical TPHA test used for screening/diagnosis of syphilis. The SD Bioline Syphilis 3.0 test gave good diagnostic accuracy compared to the VDRL and TPHA tests ($p<0.001$). SD Bioline syphilis ICT test could be used in health facilities for screening and diagnosis of syphilis in Burkina Faso.

Keywords: Diagnosis, SD Bioline syphilis 3.0, Burkina Faso, Syphilis.

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INTRODUCTION

Syphilis is a sexually transmitted infection (STI) caused by the bacterium *Treponema pallidum* subspecies *pallidum* (*T. pallidum*) which is contracted through sexual exposure or vertical transmission during pregnancy (Peeling et al., 2017). The global burden of syphilis is 36 million cases and 11 million new infection per year of which maternal syphilis in sub-Saharan Africa makes up 63% of this burden (Parker et al., 2016; Perez and Mayaud, 2019). Syphilis remains a major public health problem in Africa. The disease is categorized into primary, secondary, latent and tertiary syphilis base on the duration of infection and identified signs and symptoms associated with each stage (CDC, 2017). There is paucity of information on syphilis in Burkina Faso, however 160 cases were reported in 2011 by the Ministry of Health (2011). Bisseye et al. (2013) in an epidemiological study of syphilis in regional blood transfusion centers in Burkina Faso reported a 1.5% seroprevalence of syphilis among first time blood donors using regain rapid test and *Treponema pallidum* haemagglutination test (TPHA). In a study conducted in Chad among blood donors, out of 789 donors, the prevalence of syphilis was 4.9%, where donors were 96.1% male and 3.9% female and the prevalence was higher in subjects aged [21-30] years (Dungous et al., 2020). In Gabon, syphilis fell significantly between 2009 and 2015, from 4.6% to 2.1% among blood donors (Mba et al., 2017). In the diagnosis of syphilis in sub-Saharan Africa, serology (treponemal and non-treponemal test) is greatly relayed upon because of the difficulty in culturing and investigating the pathogen in vitro since it is an obligate human pathogen (Peeling et al., 2017; Lafond et al., 2006, Rakotoarisa et al., 2017). Although, other methods including microscopy (dark field microscopy), nucleic acid amplification test, direct fluorescent antibody test and cerebrospinal fluids examination exist (WHO, 2016). Early and proper diagnosis of syphilis remains a key strategy for the control and possible eradication of the disease. Thus, this study evaluated the diagnostic performance of SD Bioline Syphilis 3.0, a rapid immunochromatographic test for the detection of syphilis in human serum.

MATERIALS AND METHODS

Study Design and Sample Collection

This study was a prospective study that involved suspected syphilis infected participants with clinical characteristics including fever, headache, fatigue, swollen lymph glands, weight loss, and hair loss attending health facilities at Ouagadougou and Bobo Dioulasso regions of Burkina Faso between 1 September 2011 and 31 July 2012. Blood samples were collected from participants who were randomly selected after administration of a structured questionnaire.

Initial screening was done on serum obtained from collected blood samples using the venereal disease research laboratory test (VDRL) and TPHA test according to manufacturer's instruction by trained laboratory personnel at the various laboratories of health centers before serum samples were transported to laboratory of Bacteriology and Virology Unit of Centre Hospitalier Universitaire Yalgado Ouedraogo (CHU-YO) a national reference laboratory for HIV/AIDS and STI. VDRL test was done by first inactivating serum samples by heating at 56ºC for 30 minutes. A 50 µL aliquot of the inactivated serum was mixed with 1/60 mL of VDRL antigen on a slide and rocked for 4 minutes for agglutination to occur. Slides were read immediately under the microscope with low power objective. Medium and large clumps were indicative of a positive result while slight or absence of clumps were considered as negative.

For the TPHA test, 190 µL of diluent was dispensed into row 1 and 10 µL of serum was added and mixed. One hundred and fifty microliters of the mix in row 1 was pipetted out and 25 µL of the mix in row 1 was transferred to row 2. Seventy-five microliter of well mixed test cells were added to row 1 and 75 µL of well mixed control cells were added to row 2. The

microliter plates were gently tapped to facilitate mixing, covered and incubated at room temperature for 45 to 60 minutes after which they were observed for agglutination. Agglutination observed in test cells but not in control cells was considered as positive, absence of agglutination was considered as negative while agglutination in both test and control cells were considered to be invalid.

Serum was stored at -20˚C until SD Bioline syphilis 3.0 test was performed according to the manufacturer's instructions. SD Bioline syphilis 3.0 test is a solid phase immunochromatographic assay test that detects immunoglobulin variants including IgA, IgG and IgM against *T. pallidum*. Test device were removed from pouch and 10 µL of serum was dispensed into sample wells. Four drops of assay diluent were added and then incubated for 5 - 20 minutes at room temperature. The presence of "T" and "C" band within the result window was considered positive and the presence of a single purple color band within the result window was indicative of a negative result. Samples with no purple color band visible within the result window were considered as invalid.

Statistical analysis of data

The data obtained were entered into Microsoft Excel sheet. The sensitivity and specificity of the SD Bioline Syphilis 3.0 for the detection of syphilis in comparison to the VDRL and TPHA was determined using the formula;

Sensitivity (%) = True Positive/(True Positive + False Negative) × 100, Specificity (%) = True Negative/(True Negative + False Positive) × 100, Positive Predictive Value (PPV) (%) = True Positive/(True positive + False positive) × 100, and Negative Predictive Value (NPV) (%) = True Negative/(True negative + False negative) × 100. True positive is defined as those correctly diagnosed with the disease while false positive is defined as those incorrectly diagnosed with the disease. True negatives are those correctly diagnosed as not having the disease while false negatives are those incorrectly diagnosed as not having the disease. Statistical analysis was done with GraphPad Prism version 5.04 (GraphPad Software Inc., LA Jolla, CA, USA). Chi-square test was used for the comparison of the diagnostic values $p < 0.05$ is used as significant.

RESULTS

Sociodemographic characteristics of participants

Patients enrolled for this study (from whom blood samples were collected) were aged between 17 and 47 years (Table 1). Sixty seven percent (67%; 425/633) of the participants were females and 33% (208/633) were males. The average age was 25.2 years. The age group 20-25 years were most represented 51.0% (323/633), while the least represented was 40 years and above (2.4%; 15). Singles were 54.8% (347/633), secondary school students made up 25% (163/633) and 0.6% (4/633) were from the liberal profession as shown in Table 2.

Results of SD Bioline, VDRL and TPHA tests

From the results in Table 3, the number of serum samples positive on the SD Bioline Syphilis 3.0 was 242/633 (38.2%), VDRL was 264/633 (41.7%) and TPHA test was 208/633 (32.9%).

Comparison of the SD Bioline Syphilis 3.0 test performance with VDRL

The sensitivity of the SD Bioline Syphilis 3.0 test compared to the VDRL test in this study was 81.4% (215/264, 95% CI = 76.31-85.67) and the specificity was 92.6% (342/369, 95% CI = 89.56-94.92). The positive and negative predictive values were 88.8% (215/242, 95% CI= 84.25-92.22) and 87.4% (342/391, 95% CI = 83.82-90.39) respectively (Table 3). The difference between diagnostic accuracy of the SD Bioline Syphilis 3.0 test and the VDRL test was statistically significant ($p \leq 0.001$), implying that SD Bioline Syphilis 3.0 had a good diagnostic accuracy over VDRL test.

Comparison of the SD Bioline Syphilis 3.0 test performance with the TPHA test (classical test)

The sensitivity of the SD Bioline Syphilis 3.0 test compared to the conventional TPHA test was 100% (208/208, 95% CI = 98. 19-100) and the specificity was 92% (391/425 95% CI = 89.03-94.22). The positive predictive value was 85.95% (208/242, 95% CI = 81.01-89.77) and the negative predictive value was 100% (391/391, 95% CI = 99.03-100) (Table 3). The difference between performance of SD Bioline Syphilis 3.0 test and the conventional TPHA test is statistically significant (p <0.001). The SD Bioline Syphilis 3.0 test is better than the TPHA test, and the 34 biological samples tested positive results in the SD Bioline Syphilis 3.0 test but negative in the TPHA test. These results could be considered as false negatives (Table 3).

Table 1: Sociodemographic characteristics of all enrolled participants.

Variables	All participants n (%)
Gender	
Female	425 (67.0)
Male	208 (33.0)
Age group (years)	
≤ 20	167 (26.4)
20-25	233 (36.8)
25-30	111 (17.5)
30-35	73 (11.5)
35-40	34 (5.4)
>40	15 (2.4)
Marital status	
Single	347 (54.8)
Married	131 (20.7)
Unmarried couple	155 (24.5)
Socioeconomic occupations	
Trader	92 (14.5)
Farmer	125 (19.7)
Secondary school student (SSS)	163 (25.7)
University student	73 (11.5)
Housewife	117 (18.4)
Civil servant	59 (9.3)
Liberal profession	4 (0.6)

Table 2: Results of the three tests according to the socioeconomic occupations and the marital status.

Socioeconomic Occupations	VDRL Test result		TPHA Test result		SD Bioline Test result	
	Negative n (%)	Positive n (%)	Negative n (%)	Positive n (%)	Negative n (%)	Positive n (%)
Trader	51 (55.4)	41 (44.6)	59 (64.1)	33 (35.9)	55 (59.8)	37 (40.2)
Farmer	34 (27.2)	91 (72.8)	47 (37.6)	78 (62.4)	38 (30.4)	87 (69.6)
Sec. Sch. student	82 (50.3)	81 (49.7)	105 (64.4)	58 (35.6)	100 (61.3)	63 (38.7)
University student	44 (60.3)	29 (39.7)	51 (69.9)	22 (30.1)	49 (67.1)	24 (32.9)
Housewife	114 (97.4)	3 (2.6)	115 (98.3)	2 (1.7)	106 (90.6)	11 (9.4)
Official	40 (67.8)	19 (32.2)	44 (74.6)	15 (25.4)	39 (66.1)	20 (33.9)
Liberal profession	4 (100.0)	-	4 (100.0)	-	4 (100.0)	-
Marital status						
Single	166 (7.8)	181 (52.2)	208 (59.9)	139 (40.1)	196 (56.5)	151 (443, 5)
Married	92 (70.2)	39 (29.8)	97 (74.0)	34 (26. 0)	85 (64.9)	46 (35, 1)
Unmarried couple	111 (71. 6)	44 (28.4)	120 (77.4)	35 (22.6)	110 (71.0)	45 (29, 0)

Table 3: Positive and negative concordance of the SD Bioline 3.0 Rapid test compared to TPHA and VDRL tests.

Results		VDRL		TPHA		SD Bioline 3.0	
		Positive	Negative	Positive	Negative	Positive	Negative
VDRL	Positive	264	-	208	56	215	49
	Negative	-	369	-	369	27	342
TPHA	Positive	208	-	208	-	208	-
	Negative	56	369	-	425	34	391
SD Bioline 3.0	Positive	215	27	208	34	242	-
	Negative	49	342	-	391	-	391

DISCUSSION

Despite the reported decrease in the seroprevalence of syphilis in Burkina Faso (Kirakoya et al., 2010), the disease remains a threat, particularly to pregnant women and their unborn. This underscores the need for a rapid, reliable and affordable test for screening and diagnosis of the disease. Of the 633 serum samples tested with SD Bioline syphilis 3.0, VDRL and TPHA, SD Bioline syphilis 3.0 showed high sensitivity (100%) and specificity (92%) compared to the classical TPHA test used for screening/confirmation of syphilis, implying that it can be used for both screening test and as an alternative to TPHA, particularly in health centers located in remote regions of sub-Saharan Africa. This is in line with the report of Gliddon et al. (2017) on the diagnostic accuracy of SD Bioline HIV/syphilis duo test, where the sensitivity of the method was between 89% and 100%, while specificity values for syphilis diagnosis was between 91% and 100%. Early and proper diagnosis of syphilis is key to effective treatment and possible eradication of the disease. However, the cost of testing, expertise and distance to laboratory poses barriers to the treatment and management of syphilis at community level in Burkina Faso (Bocoum et al., 2014). SD Bioline Syphilis 3.0 comes in handy as a point-of-care-testing alternative because of its cost effectiveness and accuracy. The test does not require any pretreatment of specimens or qualified technical personnel to perform. This makes the test an ideal on-site option for screening in health facilities without laboratory facilities.

Conclusion

Rapid point of care syphilis diagnostic tests kits can help in the diagnosis of syphilis in remote health care centers that lack adequate laboratory facilities. This study show that SD Bioline syphilis 3.0 rapid test kit is a reliable diagnostic method of syphilis in Burkina Faso. Further study on the feasibility and acceptability of this rapid syphilis test in first-level healthcare centers is advocated.

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

OT and DSK had the original idea for the study and, with all co-authors carried out the design, sampling and the analyses and drafted the manuscript, APS, RHS, AA, CO, MKD, EK and LS participated in writing the manuscript. All authors read and approved the final version of the manuscript.

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