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Full Length Research Paper

Comparison of CARE START HRP2 rapid malaria test with light microscopy for guiding patient's treatment of fever in Nigerian endemic areas

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ABSTRACT

To compare the diagnostic performance of CARE START malaria rapid diagnostic test (RDT) with reference to light microscopy. Microscopy remains the gold standard for malaria diagnosis. However, its accuracy under operational conditions in Africa where malaria is highly endemic is often low. This study is therefore to test the performance of the CARE START rapid diagnostic test with light microscopy. Field stain A and B Manufactured by PARK Scientific ltd, UK were used for the Light Microscopy. The CARE START rapid test manufactured by ACCESS BIO INC, USA was used for the rapid test. Of the 263 patients tested, 139 (52.9%) were positive for malaria parasites with the Light Microscopy and 112 (42.6%) were positive for malaria parasite by RDT CARE START HRP_2. The sensitivity and specificity of the RDT was found to be 78.4% and 97.6% respectively while the Positive Predictive Value (PPV) and the Negative Predictive Value (NPV) were found to be 97.3% and 80.1%respectively. The CareStart™ RDT test showed good sensitivity and specificity with a good agreement to the reference light microscopy. The RDT could therefore be used in place of light microscopy, which in poor set-ups cannot be used routinely.

Keywords: CareStart ^{TM} HRP_2, RDT, Light Microscopy, Malaria, Field'stain, Sensitivity, Specificity, Treatment.

INTRODUCTION

Malaria is one of the most important killer disease specifically affecting African countries including Nigeria. Over 500 million people are infected by malaria globally with over a million pediatrics dead each year (Azikiwe *et al*., 2012). Malaria is the most common single diagnosis made in most countries in Africa where the disease is highly endemic (Huge *et al*., 2007), but the accuracy of clinical diagnosis is limited by the low specificity of symptoms and signs of malaria (Chandramohan *et al.,* 2002). In most rural areas in Africa, presumptive treatment is endorsed because light microscopy, which for decades has been the standard for malaria diagnosis, remains inaccessible to most patients because of the laboratory infrastructure and technical expertise it requires (Bloland *et al*., 2003). Moreover, microscopy is time consuming, requires trained personnel and needs careful preparation and application of reagents to ensure quality results (WHO, 2000; Haditsch, 2004). For a better and sustainable control, malaria diagnosis requires a more rapid, easy, sensitive and specific method (Beyene *et al*., 2012).

The advent of immunodiagnostic techniques have enhanced the detection of malaria infections as an adjunct to thick blood stained by either Giemsa or Field's stain technique. The principle of RDT is to capture malaria antigen from peripheral blood flowing across a membrane containing specific anti-malaria antibodies. The antibodies available in these test kits detect antigens derived from malaria parasites. Such immunologic tests often use a dipstick or cassette format and provide results in 2 to 20 minutes (Woyessa *et al*., 2013). Malaria rapid diagnostic test (RDT) was introduced in the 1990s

Table 1. Sex distribution of malaria parasites obtained from the Light microscopy and Rapid test.

Sex	No tested	No (%) positive Light microscopy	No (%) positive RDT
Male	136	68 (50%)	54 (39.7%)
Female	127	71 (55.9%)	58 (45.7%)
Total	263	139 (52.9%)	112 (42.6%)

and has undergone many improvements (Moody, 2002; Bell *et al*., 2006), but is yet to be seen in many community in Africa (Azikiwe *et al*., 2012).

Plasmodium falciparum has been the major causes of high case fatality. Since 2005, the National Malaria Control Programme intensified the deployment of key malaria interventions including artemisinin-combination therapy (ACT), malaria rapid diagnostic tests (RDTs), and vector control measures (WHO, 2008). The Care Start™ Malaria HRP-2 Test is a two-band RDT detecting Histidine Rich Protein 2 (HRP-2). It is a new tool for the rapid qualitative determination of malaria HRP2 in human blood, aiding the diagnosis of malaria infection. This study was conducted to evaluate the sensitivity and specificity of Care Start™ rapid malaria test in reference to the conventional Light microscopy.

METHODOLOGY

The Study Area: The study was conducted in Zaria, Kaduna state, Nigeria, using Hajiya Gambo Sawaba General Hospital (HGSGH) where patients from Zaria and environ routinely attain for medical attention. The samples were collected between February and April, 2013 after ethical approval from the hospital management.

Sample Size: Two hundred and thirty six (236) blood samples each 3ml were collected and thick films were immediately made.

Light microscopy: The Light Microscopy followed a standard procedure (Mendiratta *et al*., 2006). Thick films were stained using average of 10µl of whole blood. The thick films were air dried. Field's stain was applied by dipping the slides into Field's stain A for 3 seconds, then into tap water for 3 seconds with gentle agitation and into Field's stain B for a further 3 seconds and then washing gently in slow running tap water to remove excess stain. The slides were then air dried for at least 30 minutes. The slides were observed under oil immersion objective.

CareStart^{Tm} Malaria HRP_2 One Step Rapid Test (RDT): Whole blood (5µl) was added into sample wells and 60µl of assay buffer were added into assay buffer wells. The blood -buffer mixture were allowed to run toward the test and control window. Result was read within 20 minutes. The present of two color bands indicated positive result. The present of only one band (the control line) within the result window indicated negative result.

RESULTS

The result revealed that 139 (52.9%) were positive for malaria parasites with the Light microscopy and 112 (42.6%) were positive with the CareStar^{Tm} HRP_2 rapid test. The males had 68 (50%) positive and the females 71 (55.9%) positive for the light microscopy. For the RDT, 54 (39.7%) were positive for males and 58 (45.7%) were positive for females (Table 1).

The age group of ≤ 20 years had the highest prevalence of 89 (70%) malaria parasites infection with the Light microscopy and 67 (40%) with the RDT followed by 21-40 age group with 35 (55.6%) for Light microscopy and 32 (50.8%) for RDT (Table 2). The 41-60 age group had the lowest prevalence of 12 (50%) for Light microscopy and 10 (41.7%) for RDT.

Taking the Light Microscopy as a standard test for malaria, the sensitivity and specificity of CareStart™ RDT was found to be 78.4% and 97.6% respectively. The positive predictive value (PPV) and the negative predictive value (NPV) were found to be 97.3% and 80.1%respectively (Table 3).

DISCUSSION

This study compared the conventionally accepted Light Microscopy of peripheral blood slides with Care Start^{Tm} Malaria HRP_2 Rapid diagnostic test (RDT). Overall, more infections were detected by blood slide microscopy, 139 (52.9%) than by Care Start ^{Tm} Malaria HRP2 Test, 112 (42.6%). The finding in the current study was slightly higher than the 104 (40.9%) for Light Microscopy and 100(39.4%) for CareStart^{TM} RDT reported by (Bayene *et al*., 2012). Another study by Xiaodong *et al*. (2013) indicated strong similarities with our study where (52.28%) malaria cases were detected by microscopy compared to (47.72%) CareStart™ kit. However, in both studies the Light microscopy shows more detection of parasites than the RDT.

Table 2. Age distribution of malaria parasites as obtain from Light microscopy and RDT

Age	NO Test	No (%) positive Light microscopy	No (%) positive RDT
≤ 20	172	89 (70%)	67 (40%)
21-40	63	35 (55.6%)	32 (50.8%)
41-60	24	12 (50%)	10 (41.7%)
61-60	4	4 (100%)	3 (75%)
Total	263	140 (53.2%)	112 (42.6%)

Table 3. Result of CareStart™ HRP_2 Rapid test (RDT) Against Light Microscopy

Rapid diagnostic test (RDT)	Light Microscopy		
	Positive	**Negative**	**Total**
Positive	TP = 109	FN = 30	139
Negative	FP = 3	TN = 121	124
Total	112	151	263

TP = True Positive TN = True Negative FP = False Negative FN = False Negative.
Sensitivity = 78.4% Specificity = 97.6% Positive predictive value =97.3% Negative predictive value =80.1%

Considering the Light Microscopy as gold standard, this study revealed a sensitivity of 78.4%, Specificity of 97.6%, The RDT had high Positive predictive value (97.3%), meaning that patients will be correctly diagnosed as positive for malaria and avoids unnecessary treatment. The higher Negative predictive value (80.1%) means that it was reliable in ruling out malaria. This CareStart™ RDT kit showed no need of sophisticated equipment and facilities, and was easy to operate. Its applicability and rapidity in diagnosis could be of additional value for *Plasmodium falciparum* malaria detection and prompt case management as well as cross borders malaria monitoring in Nigerian endemic areas in the National Malaria Elimination programme. The traditional method of microscopic identification of parasite however, is not only daunting in poor power setting, but also time consuming and requiring a lot of expertise and training. Thus microscopy in Africa is generally, limited to larger clinics and tertiary centers. The limitation of CareStart™ HRP_2 RDT for detecting only *Plasmodium falciparum* malaria would not affect it usage in Nigeria where other species of malaria are rarely found. More also the most serious and sometimes fatal type of malaria is caused by *Plasmodium falciparum*. The other human malaria species, *P. vivax*, *P. ovale*, *P. malariae*, and sometimes *P. knowlesi* can cause acute, severe illness but mortality rates are low (Tangpukdee *et al.*, 2009).

CONCLUSION

The CareStart™ HRP2 Rapid Diagnostic Test (RDT) kit had good sensitivity and specificity when compared with the gold standard Light Microscopy. It also had high positive predictive value and high negative predictive value indicating that it can be favorably use in poor settings for guiding patients treatment of febrile illness in Nigeria especially where Light Microscopy and expertise is not obtainable.

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