



The Efficacy of Rapid Diagnostic Test in the Diagnosis of Malaria among Adults as Compared to Microscopy in a Hospital in Imo State, South Eastern Nigeria

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Abstract

Malaria has been noted to be one of the most prevalent diseases affecting mankind. Diagnosis is based on clinical assessment using microscopy and recently by rapid diagnostic tests (RDTs). The objective of this study was to ascertain the efficacy of RDT to microscopy in the identification of malaria parasite among adults attending a hospital in Owerri, Imo State. A cross-sectional study was carried out using 110 consenting outpatients of a hospital in Imo state, Nigeria. Results of the study showed that more respondents were females 63 (57.3%). Microscopy was positive in 97.3% (107) patients, and RDT was positive in 100% (32) of the adult, while 2.7% of those negative by microscopy were also negative with RDT. There was no significant difference when the accuracy of both tests was compared ($P = 0.261$, $\chi^2 = 1.262$). The RDT used had a sensitivity of 29.9%, a specificity of 100%. The positive predictive value was 100% and the negative predictive value 3.85%. The microscopy performance was extremely high compared to RDT in the diagnosis of malaria in adults. Microscopy is recommended, if available to be done for all patients suspected of having malaria with negative RDT in other not to miss out people with the disease as it remains the gold standard for malaria diagnosis.

Subject Areas

Epidemiology

Keywords

Malaria, Efficacy, Rapid Diagnostic Test, Microscopy

1. Introduction

Malaria has been noted to be one of the most infectious diseases affecting mankind which differs in its epidemiology and clinical manifestations in various parts of the globe. Variable factors including mosquito vector efficiency and distribution, climate, environmental and climatic conditions as well as state of acquired immunity of the exposed individuals contribute to wide distribution of malaria [1]. Early and accurate identification of malaria diagnosis is a key to the successful control of malaria which will in turn reduce malarial illness and death while avoiding the unnecessary use of antimalarial drug. Worldwide effect of malaria has led to increased interest in the development of effective diagnostic strategies both in developing countries where the burden of malaria is high as well as developed countries where expertise in malaria diagnosis is relatively scarce [2].

World Health Organization in 2010 suggested patients that are suspected to have malaria should be tested for malaria prior to treatment. Microscopy or malaria Rapid Diagnostic Tests can be used, however in rural African settings microscopy is often unavailable. The process of diagnosis is based on fever detection, often people were presumably administered antimalarial drugs. Because of this, conducting a more rapid diagnostic test that can achieve fast and early diagnosis is recommended as a first step and active surveillance to the control of malaria [3]. The acceptance and use of rapid diagnostic test by community health workers may ease diagnosis process in local malaria-endemic areas characterized by limited facilities and health workers [4]. However, there is very few evidence and studies carried in malaria endemic areas to inform policy makers on the specificity and sensitivity of these RDTs. In aged patients, increase in malaria transmission and lack of symptoms were suggested to affect specificity and sensitivity of RDTs. This in other words can give rise to over- or under-diagnosis of the malaria disease [2] [5]-[10]. As a result, there is little information on the efficacy of rapid diagnostic tests in malaria diagnosis of adults. Therefore this study assessed the efficacy of rapid diagnostic test in the diagnosis of malaria among adults as compared to microscopy in a hospital in Imo state, south eastern Nigeria.

2. Materials and Methods

2.1. Study Design

The study was conducted from August to September 2018 using a cross sectional study design.

2.2. Area of Study

This study was conducted in Umezurike hospital located in Owerri municipal

local government area of Imo State. The hospital is a private hospital that provides a wide range of medical and support services. Owerri is a commercial city in the south-East of Nigeria. The people are farmers and small scale industrial activities dominate the socio-economy of the inhabitants in the area. Owerri is lying between latitude of 5.483 and longitude of 7.033. It is also bordered by the Otamiri River to the east and Nworie River to the south. Owerri is located in the humid tropical climate with a mean annual rainfall of about 2500 mm and mean annual temperature of 29°C. Relative humidity is high during the rainy season and malaria is endemic in these areas during this period.

2.3. Sample Size

A total of 110 consenting patients comprising of both males and females who were attending the outpatient of Umezurike hospital within the period of the study (August-September 2018) were recruited for the study.

2.3.1. Inclusion Criteria

Adult patients (≥ 18 years) that were clinically suspected to have malaria, that requested for a malaria test and given consent were enrolled in the study. The criteria for the guess of clinical malaria included fever, headache, weakness/body ache and vomiting/nausea.

2.3.2. Exclusion Criteria

Patients were excluded if they declined to participate. Also, patients with history of anti-malaria drugs or herbal remedies in the preceding two weeks were excluded from the study. Participants with severe clinical condition needing urgent care were also excluded from the study.

2.4. Method of Data Collection

Blood samples were collected from the participants by a trained laboratory scientist for RDT testing and microscopy examination.

2.4.1. RDT Procedure

The patient's number was written on the cassette. The finger that was pricked was cleaned using alcohol swab and allowed to dry. Blood was obtained with a capillary tube for testing malaria parasite using SD Bioline malaria HRP-2. 5 μ of blood collected from the patient was deposited on the RDT cassette and 4 drops of buffer was added to facilitate the blood flow through the nitrocellulose. The result was obtained after 15 minutes following the manufacturer's instructions. The cassette had two lines comprising of a control line that showed the validity of the test, and HRP-2 line that indicated an infection with *Plasmodium falciparum*. Absence of the infection line with the appearance of control line only indicated no infection with the parasite (**Figure 1**).

2.4.2. Microscopy Procedure

Smears for Thick films were made from the fresh blood samples collected from

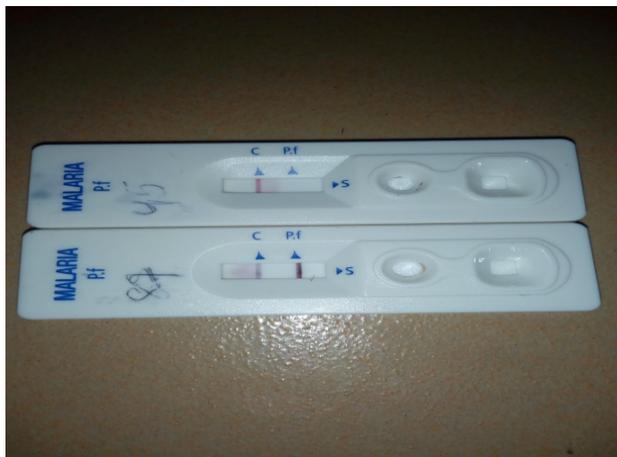


Figure 1. Blood analysis with SD Bioline malaria HRP-2 RDT.

all patients. The slides samples were air dried, and marked with Giemsa stain before the smears were examined for the presence of malaria parasites under light microscopy at a magnification of $\times 100$ by a laboratory scientist (**Figure 2**).

2.5. Method of Data Analysis

Descriptive statistics (frequency distribution and percentage) were used. Data generated were analyzed using Chi-square test at 5% level of significant using Statistical Package for Social Sciences (SPSS) Version 21.

2.6. Ethical Approval

Permission to conduct the study was obtained from the Chief Medical Director of the Hospital. During the data collection, Respondents were assured of confidentiality of information. A verbal informed consent was obtained from each of the respondents before collecting their sample.

3. Results

Socio-demographic characteristics of the patients

A total of 110 adults of different ages were recruited for the study. There were 63 (57.3%) females and 47 (42.7%) males. Their ages scaled from 18 - 79 years and the mean age was 37.2 ± 15.3 . As shown in **Table 1**, those in the age range of 18 - 33 constituted the highest number (49%).

3.1. Efficacy of RDT in the Diagnosis of Malaria Using Microscopy as a Standard

Table 2 displayed the accuracy of RDT in the diagnosis of malaria using microscopy as a gold standard. Microscopy was positive in 107 (97.3%), and RDT was positive in 32 (100%) of the adult, while 3 (2.7%) of those negative by microscopy were also negative by RDT. The accuracy of microscopy and RDT when compared was not significant ($P = 0.261$, $\chi^2 = 1.262$). False positive was 0.0% while false negative was 96.2%.

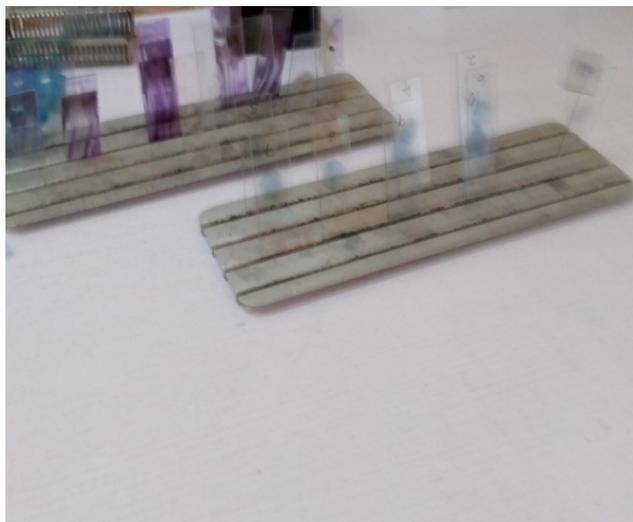


Figure 2. Blood analysis with Giemsa stain ready to be examined under microscope.

Table 1. Sex and age distribution of the respondents.

Sex	Frequency	Percentage (%)
Female	63	57.3
Male	47	42.7
Total	110	100.0
Age group (years)		
18 - 33	54	49.1
34 - 48	33	30.0
49 - 63	14	12.7
64 - 79	9	8.2
Total	110	100

Table 2. Comparison between rapid diagnostic test and microscopy results.

	Microscopy n (%)		Total
	Positive	Negative	
RDT n (%)			
Positive	32 (100.0)	0 (0.0)	32 (100.0%)
Negative	75 (96.2)	3 (3.8)	78 (100.0%)
Total	107 (97.3)	3 (2.7)	110 (100.0%)

$P = 0.261, \chi^2 = 1.262.$

3.2. The Validity of RDT Using Microscopy as a Standard

When compared with the microscopy, RDT had a sensitivity of 29.9% (32/107) and a specificity of 100% (3/3). The positive predictive value was 100% (32/32) and negative predictive value of 3.85% (3/78) as shown in (Table 3).

Table 3. Diagnostic performance of RDTs compared with microscopy.

Test characteristics	SD Bioline (<i>for P. falciparum</i>) %
Sensitivity	29.9
Specificity	100
Positive predictive value	100
Negative predictive value	3.85

4. Discussion

This study investigated the test performance of two routine malaria diagnostic methods (microscopy technique and Rapid Diagnostic Test (RDT)). The patients were dominated by female gender. This indicated that female participants were highly infected with malaria parasite than their male counterpart. This is in congruent with previous studies conducted by Kalu [11] and Ibekwe [12] in South-Eastern Nigeria, where females were observed to be more infected than males. Olatunji [13] also recorded more prevalence of malaria infection in females than in males. However, the results contradict reports of Adeyemo *et al.* [14] and Ruquayyah *et al.* [15] that showed more prevalence of malaria infection among male participants than the female. More than half of the participants were within the age bracket of 18 - 33 years. This demonstrated that transmission was higher among the youths than the elderly. This is in line with the study of Enitan *et al.* [16] who reported higher prevalence of *P. falciparum* malaria infection in subjects within 16 - 25 years age bracket. In similar study, Adesina [17] reported a higher rate of malaria in 17 - 19 years age bracket of students of University of Maiduguri, North-Eastern Nigeria.

The study also measured the discriminatory accuracy of the RDTs against microscopy using sensitivity and specificity of the apparatuses. The sensitivity and specificity were 29.9% and 100% respectively. Lower rate of sensitivity of RDT was shown in this study compared to its stated value suggesting a high level of false negative result which was not anticipated [18]. Lower sensitivity was observed for the RDT when compared to 88.6% sensitivity reported by Mahende *et al.* [19] in Tanzania. The reading was also lower than that reported in a similar study in Nigeria by Ojurongbe *et al.* [20] which had 62.3%. However, Garba *et al.* [21] observed a very low sensitivity (9.09%) in a study conducted in Gusau Nigeria in infants under the age of five. The accuracy of RDTs diagnosis can be affected by numerous factors ranging from storage humidity, temperature, product quality and end users' operation [22]. This low sensitivity recorded in this study can be disadvantageous as it will hinder control intervention due to some portion of the infected population being left untreated especially when RDT is the only available malaria diagnosis tool. This may result in critical implications in transmission, health and possibly mortality. Good sensitivity and a negative RDT result would allow malaria to be ruled out, hence avoiding unnecessary presumptive treatment in any area where this technique is used [23] [24].

As recommended by [25], appropriate and suitable outcome of mRDT should demonstrate high sensitivity of 95%. Higher (100%) specificity recorded in this study is in line with the study of Ilesanmi *et al.* [26] in Ibadan Nigeria where 99.6% specificity was observed. The specificity rating of 100% was also reported in the study of Awortu *et al.* [27] in Port Harcourt, Nigeria. Lower specificities of 56.26% and 46.7% were however reported in Nigeria and western Uganda by Enebeli *et al.* [28] and Murungi *et al.* [29] respectively.

However, although microscopy is regarded as the gold standard, there could still possibility of human error which could be the reason for the gap. Thus the high specificity will make the cost of malaria affordable and thereby enhancing the number of non-infected individuals who would have been miss-out, hence the need for proper case definition and care.

The RDT gave positive and negative predictive value of 100% and 3.98% respectively. The positive predictive value of 100% obtained in this study is the same with [30] findings, and this outcome implies that any individual who tested positive using this RDT is expected to be malaria positive when tested with microscopy. Nevertheless, the prevalence of malaria disease among the tested population influence positive and negative predictive values. Also the reason why high positive predictive value was recorded in this study may be because of the prevalence of malaria in the study area.

Compared to microscopic test, the RDT used in this study has the potential of detecting more negative cases and less positive cases. According to [30] the cause of lower positivity rates could be as result of external factors which might affect the stability of the RDT. These factors include exposure to extreme temperatures which has been reported to be an utmost contributor to poor performance of rapid diagnosis tests, particularly during conveyance and storage.

5. Conclusion

The study showed that microscopy performance is extremely high compared to RDT in the diagnosis of malaria in adults. Therefore, microscopy remains the standard for malaria testing. However, the drawbacks of this method may affect the pace of distribution of standard services to the patients. Thus, RDT can still serve as the first screening test for malaria diagnosis in rural areas.

Recommendations

Microscopy is recommended, if available to be done for every patient suspected of having malaria with negative RDT in other not to miss out people with the disease as it remains the gold standard for malaria diagnosis. More studies using a large sample size with this specific RDT brand are also recommended to be carried out in the diagnosis of malaria while comparing it with microscopy.

Limitations of the Study

The sample size enrolled for this study was determined within the short period

of recruitment which was one month. The pattern of the outcome may have a slight difference change with an increased number of participants. Furthermore, the choice of a study area as a result of the availability of required health facilities may be doubted as not being a characteristic of the population as a whole.

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Competing Interests

The authors declare that they have no competing interests.

Consent for Publication

Not applicable.

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