Biotechnology in Malaria Management: A Case Study in a Semi-urban Nigerian Clinic

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Abstract: Until recently, in areas of high malaria transmission such as Nigeria, malaria treatment has been based mainly on clinical diagnosis which was presumptive, because malaria was considered one of the commonest causes of fever. With the availability of new tools such as parasite–based rapid diagnostic kits, a product of biotechnology, which complements the standard microscopy, it is imperative to provide targeted treatment on accurate estimation of true malaria cases. To proffer solution to the limitations of microscopy, this study was carried out to ascertain the reliability of SD Bioline HRP-2-Based RDTs in malaria case management. A parasite based diagnosis of malaria was carried out on the total 1,276 patients attending an out-clinic in a Semi-urban area (Amukoko) of Lagos State, South West Nigeria to evaluate specific performance characteristics of SD Bioline HRP-2 RDT in malaria case management using microscopy as a gold standard. Only 15.4% and 14.6% was positive for P. falciparum by HRP- 2-RDT (Rapid Diagnostic Testing) and microscopy respectively and the sensitivity, specificity, PPV and NPV are 94%, 98.5%, 91.4% and 98.2% respectively. Using RDT, fever has a sensitivity of 79.7% and specificity of 60.5%. Patients have fever but no HRP-2 in their blood (fever + Neg. RDT). Since symptoms of malaria are not only peculiar to *P. falciparum* infection, parasite based diagnosis must be performed. The performance characteristics of the SD Bioline HRP-2 RDT generated from this study indicated that the tool is reliable and fast in generating the test result. Similarly, parasite based diagnosis is required to eliminate other causes of fever symptoms.

***Key words*:** Malaria, Biotechnology, Microscopy, Case management.

Introduction

Malaria case is defined as a person presenting to the clinic with a history of fever and concurrent parasitaemia. Malaria transmission in Nigeria takes place all year round in the south but

is more seasonal in the northern regions. About 25% of all estimated malaria cases in the WHO African Region occur in Nigeria [1]. Almost all cases are caused by *P. falciparum*, but only a small fraction is tested parasite based. Until recently, in areas of high malaria transmission such as Nigeria, malaria treatment has been based mainly on clinical diagnosis which was presumptive, because malaria was considered one of the commonest causes of fever. With the availability of new tools such as parasite–based rapid diagnostic kits, a product of biotechnology, which complements the standard microscopy, it is imperative to provide targeted treatment on accurate estimation of true malaria cases [2]. However, in cases where parasitological confirmation is not available, highly vulnerable groups (including children under five years and those suspected with severe malaria) can be treated on a clinical basis [2].

A new generation of easy to perform Rapid Diagnostic Tests (RDTs) has been developed to diagnose *P. falciparum* rapidly and reliably without the need of a microscope. This is based on the immunochromatographic detection of antigen histidine–rich protein II (HRP-2) or specific plasmodium lactate dehydrogenase (pLDH). Both HRP-2 and pLDH are produced by the parasite during their growth and multiplication in red cells. In Nigeria, Parasight TML ICT and OptiMAL became commercially available in 2000. More recently, others like SD Bioline were also introduced into the Nigerian market. Studies to evaluate the efficacy of these RDTs in Nigeria [3-5], have reported efficacy similar to expert microscopy.

In addition, RDTs have been shown to be cost effective in malaria case management in Nigeria [6] and potentially saves the cost and time wasted on presumptive treatment [3]. This of course is essential in effective malaria case management, which entails early diagnosis and prompt treatment with effective antimalarial medicines recommended for use in the Country. Unfortunately, this has received a major setback in the past years because of the high level of resistance to the first and second line antimalarial medicines; Chloroquine and Sulphadoxine–pyrimethamine [2]. Despite the observed changes in parasite sensitivity to artemisinins, the clinical and parasitological efficacy of artemisinin based combination therapies (ACTs) has not yet been compromised [7], until recently when the drug efficacy studies have detected resistance of *Plasmodium falciparum* to artemisinins in the South-East Asia. *P. falciparum* resistance to artemisinins has not been detected outside of the Greater Mekong sub-region [8].

Perceived fever is the sign most health workers use to diagnose clinical malaria. However, studies in areas of intense transmission have

found reported fever or a history of fever to be an unreliable indicator of clinical malaria. It is reported that clinical diagnosis of malaria has led to over–diagnosis and over–consumption of anti-malarial since malaria presentation is not specific [9-10] and have, therefore, not been helpful in improving malaria diagnosis. Hence, prompt parasitological confirmation by microscopy or with RDT is recommended for all patients with suspected malaria before treatment is started [7]. In addition, treatment solely on clinical suspicion should only be considered when a parasitological diagnosis is not accessible [2]. This then took us into the study of SD Bioline HRP-2-Based RDTs in malaria case management.

The objective of this work is thus:

(a) To validate the SD-Bioline HRP-2-based RDT diagnostic performance using microscopy as a standard.

(b) To ascertain the performance characteristics of clinical diagnosis using SD–Bioline HRP– 2–Based RDTs as a standard in malaria case management.

Materials and Methods

Study Area: The study site was at St. Matthew Primary Health Care Centre, situated at No. 3 Mayegun–Oro St., Amukoko in Ajiromi–Ifelodun Local Government Area, on the Longitude $6^0$27' 52"N and Latitude $3^0$20'44" E. It is 14 km from Lagos center. It is bounded on the North by Apapa Local Government Area and on the East by Amuwo–Odofin Local Government Area. Amukoko is one of the 50 communities found in Ajeromi–Ifelodun LGA of Lagos state and it is densely populated with population density of 687,316 (Nigeria Census, 2006). The laboratory work was carried out at The International Center for Malaria Microscopy and Malaria Rapid Diagnostic Tests Quality Assurance Programme, Department of Medical Microbiology and Parasitology, College of Medicine University of Lagos (CMUL), Idi–Araba. The "Standard for reporting diagnostic accuracy recommendations" was followed [11].

Ethical approval for this study was obtained from the Ethics Committee of the College of Medicine of the University of Lagos and Lagos University Teaching Hospital, Lagos, Nigeria.

Study Procedures

Participants were administered with the consent form and the intending patients were given case report form (CRF) for any history of febrile illness or malaria, anti malaria treatment in the past 2 weeks, taking temperature with mercury thermometer (Goshen ^{CE} 0483,), age and other relevant data were also recorded (Appendix A & B). Samples were collected from individuals of all ages from infants to the old who attended St. Matthew Primary Health Care Center.

Venous blood of 5ml was collected from peripheral vein of each

participant and shared into EDTA and plain bottles. The EDTA blood was diluted in the ratio 1:20 against turk solution for WBC count using "Neubauer ruled chamber (Germany(R)) and recorded.

Study Sample: The criteria for inclusion included the complaints of fever and malaise at the time of survey or in the past 48 hours and other malaria related symptoms like headache, body weakness, chills, joint pains, diarrhoea, cough and vomiting. Patients on admission were excluded from the research. The study area is a rural settlement composed of artisans and traders that deal in trade ranging from Carpentry & Upholstery, Transportation to Site labour.

A total of 1,276 subjects, which cover all age groups, were selected for this study using random sampling method of the patient attending outpatient department (OPD) of the primary health center. The recruitment was based on the presentation of symptoms and previous clinical history as narrated by the patient. It was a prospective study in which data collection was done before reference standard were performed.

The patients' whole blood was collected by vein puncture to test for the presence of *P. falciparum* malaria antigen (HRP-2) and for microscopic identification.

Description and Interpretation of MRDTs

The procedure of the test was strictly adhered to according to manufacturer's instructions.

Standard Diagnostic Bioline HRP-2 Based RDT: The test device had a LOT number 082048 and an expiry date of 31st March 2012. Quality assurance testing was carried out on the RDTs used for the test by "The International Center for Malaria Microscopy and Malaria Rapid Diagnostic Tests Quality Assurance Programme. Department of Medical Microbiology and Parasitology, CMUL, Idi–Araba", before use. The device was seen to contain a cassette, an applicator loop stick, lancet, a buffer solution and desiccant. The cassette had two wells on the surface as shown in Picture 2. The labeling was done on the RDT cassette using glass marker and placed on a smooth flat dry surface. 5µl of blood (one loop-full) was added to the smaller sample well on the cassette with the aid of the applicator loop stick, 4 drops of the buffer was added into the second sample well, which is larger. As the test began to work, a pinkish–red color was seen moving across the result window in the center of the test device. Test result was interpreted within 15 minutes.

A RDT result was interpreted as positive when both the test line and control line showed pink (Picture 3), negative when only the control line showed pink or invalid when the control line did not appear regardless of the test line (Picture 4). Four independent readings were graded based on visual assessment as "3+ or high" if the test line is darker than the control, " 2+ or moderate" if the

test line was as intense as the control line, "1+ or light" if the result was a line that could only be seen in good light for reactive tests and " – or negative" for non-reactive ones, where no line is seen but for the control.

Grading was also used to determine the source of variability in results reported by two independent readers. Any invalid RDT test was repeated. Two scientists read RDT cassettes independently. Temperature and humidity for the storage conditions for RDTs during study period were maintained.

***Microscopy*:** This entails film preparation, staining process, and mounting of the slide on the stage as well as counting and identification.

Malaria Blood Film (MBF) Preparation

Two (2) malaria blood films (MBF) were prepared for each patient, one is marked "R" for "read" and "A" for "archive" on the glass slide. On the frosted end of the grease free slides, the identification number and date for each participant were written using a glassmaker. A 12 µl of blood was spread over a diameter of 15 mm for a thick blood film while 2 µl of blood was used for a thin blood film on the same slide. Another clean slide was used to spread the blood drops to get a thin film by placing at an angle of 45^0 at the edge of the blood drop and then pulled forward to make an even spread with a tail end. The thin film was fixed in absolute methanol for 2 seconds to prevent lysis of the red blood cells and air dried on the rack [12]. The dried slides were kept in the incubator already set at 35^0C for 48 hours, EDTA blood took longer time to dry.

The blood films were stained after 48 hours with 3% Giemsa stain solution at pH 7.2. The stain was left for 45 minutes and then gently rinsed off with buffered solution of pH 7.2 until the flooding became clear to sight [12]. The slides were then placed vertically in a slide rack and allowed to dry and later arranged into the slide box.

Microscopic examinations of stained blood films were done using X100 oil immersion objectives. A minimum of 100 fields was carefully examined horizontally down on the thick film to ascertain the slide negative for malaria parasites. A definitive diagnosis of malaria by microscopy was made when a reddish chromatin dot with a purple or blue cytoplasm of the malaria parasites are seen together.

Malaria parasites seen on the slides were counted against 200 WBC or 500 if the parasite count is less than 100 parasites/200 WBC. The number of asexual parasitic forms (trophozoites and schizonts) and sexual (gametocytes) present in these microscopic fields was recorded separately. The slides were adjusted to read the thin film for parasite identification, concentration and clarity was observed at the tail end of the film. The calculation of the total number of parasite/µl of blood required the input of total white

blood cell (WBC) count and the formula is computed as:

The stained slides were read by myself and a competent microscopist as Reader-1 and Reader- 2. The parasite density was calculated for each of the reader and the mean parasite density was obtained from the two readers by adding the two parasite density and divided by 2.

Microscopy was considered the gold standard reference level for positivity or negativity for the RDT device and SD Bioline HRP –2–Based RDT as the standard for the clinical symptoms. The age grouping was done to the nearest whole number, no gap is included nor any group excluded. All data were entered and analyzed using Statistical Package for Social Sciences for Windows V 17 (SPSS Inc., Chicago, IL). The comparism was done at 95% confidence intervals.

$$\text{Sensitivity} = \frac{\text{True Positive}}{\text{True positive + False Negative}}$$

$$\text{Specificity} = \frac{\text{True Negative}}{\text{True positive + False Positive}}$$

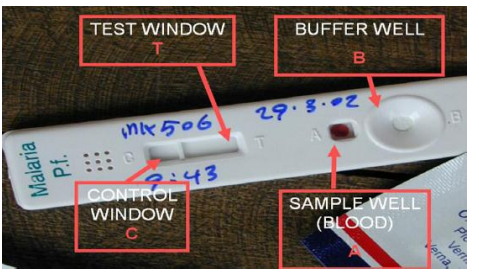
$$\text{PPV} = \frac{\text{True Positive}}{\text{True Positive + False Positive}}$$

$$\text{NPV} = \frac{\text{True Negative}}{\text{False Negative + True Negative}}$$

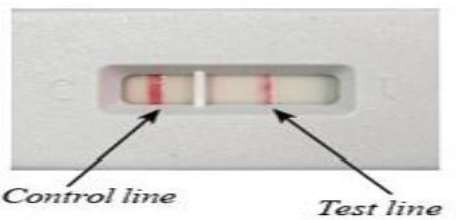
Performance Characteristics

The sensitivity, specificity, PPV, NPV and test efficiency of clinical symptoms was calculated using 1273 whole–blood samples and SD-Bioline HRP-2 RDT as the reference test. The formula is as follows [13].

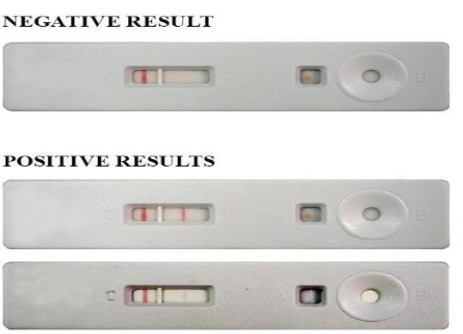
Sensitivity was calculated as:



Picture 2: The pictorial view of the labelled SD Bioline HRP-2 RDT cassette. *(T, test window; C, control window; A, sample well; and B, buffer well)*



Picture 3: The RDT cassette with the result Lines



Picture 4: The pictorial view of the cassette indicating the test result after 15 minutes of applying the sample.

Results

This research was done between the month of November 2010 and August, 2011. The demographic characteristics of the study participants are shown in Table 1. A total of 1,276 people were included in the analysis, which is composed of

60.2% female, and the overall mean age was 26.30 years with the range from 0.083 to 80 years.

Table 1. The malaria parasite prevalence by blood slide microscopy was 14.6% (186/1273) and 15.4 % (197/1273) by SD Bioline HRP-2-Based RDT. This put the HRP-2 RDT to the sensitivity value of 94%, specificity value of 98.5%, PPV of 91.4% and NPV of 98.2%. The older children age group "6-11years" presented the highest prevalence of 19.3% followed by adolescent by children ≤5 years with 13.7% (Table I).

Table 2. The distribution of symptoms with respect to age is represented on Table 2, fever is higher in children ≤ 5years (11.1%) than in older children "6–11" (6.8%) and in adolescent "12–16" (3.2%). Also high in the younger children ≤5 are chills, headache and febrile fever compared to older children and adolescent. The rate of vomiting is the same in the younger children and older children (19.6%) than in the other age groups. Adolescent presented the highest rate of loss of appetite (17.6%) but lowest in the adult group age "17 years and above". Adult group presented more diarrhoea than adolescent, followed by children ≤5years, older children have no diarrhoea. Children ≤5 years rated highest for cough (21.8%) followed by adult (14.3%), adolescent (13.4%) and older children (12.5%). Sleeplessness and dizziness are for adult while older children "6–11 years" presented highest level of yellow urine (51.8%) followed by adult (47.6%), adolescent has 41.8% and children ≤5 years have 39.7%. Diagnosing with febrile fever (tempt. $\geq 37.5^0$C) gave 18.1% prevalence and fever complaints by the patient rated highest even among other symptoms at 63.5%. Only 12 patients had had convulsion before attending the health center and are found negative by RDT. 18.3% of total male and 13.5% of total female were positive for HRP-2. There is statistical significant difference between the age and infection ($P<0.05$).

The relationship between various symptoms and infection using RDT and microscopy are also captured on Table 3.

Table 3. There was no much difference in the percentage occurrence of the symptoms in the two diagnostic methods. It is observed that 79.7% of the patients was having HRP-2 in their peripheral blood and presenting fever at the same time (Pos RDT + Fever) which is higher than (Pos. microscopy + fever) at 74.7%. So also (Neg. RDT + No fever) at 25.3% is higher than (Neg. microscopy + No fever) at 20.3%. (Pos. microscopy + joint ache) at 46.2% is higher than (Pos. RDT + Joint ache) at 40%. (Fever + Neg. RDT) was at 60.5%.

45.8% of the patients recruited for this study had access to medicines. Of the total 584 patients having access to medicine (ATM), 52% had taken herbal remedy "Agbo", 43% took paracetamol/pain reliever

(PCM) and 36% took ACT. The drug chart is represented in Fig. 1 and 2.

Table I: The prevalence of malaria by HRP–2 RDT in different age categories

	HRP2 RDT		
Age Group	Neg. (%)	Pos. (%)	Total (%)
0-5yrs	152 (14.1%)	27 (13.7%)	179 (14.0%)
6-11yrs	74 (6.9%)	38 (19.3%)	112 (8.8%)
12-16yrs	45 (4.2%)	22 (11.2%)	67 (5.3%)
17yrs and above	808 (74.9%)	110 (55.8%)	918 (71.9%)
Total	1079 (84.6%)	197 (15.4%)	1276 (100.0%)

Table II: The distribution of the signs and symptoms with respect to age

Clinical signs &Symptoms	"0 – 5" years (%)	"6 – 11" years (%)	"12 – 16" years (%)	17 Years & above (%)	Total (%)	Mean value
Fever:						
1. Body hotness.	141	87 (6.8%)	41 (3.2%)	541 (42.4%)	810	0.63
2. Febrile fever	(11.1%)	39 (3.1%)	12 (0.9%)	115 (9.0%)	(63.5%)	1.1813
(≥37^{0}C)	63 (4.9%)				229	
					(17.9%)	
Chills (feeling cold & rigors)	57 (4.5%)	41 (3.2%)	23 (1.8%)	299 (23.4%)	420 (32.9%)	0.33
Headache	55 (4.3%)	36 (2.8%)	23 (1.8%)	329 (25.8%)	443 (34.7%)	0.35
Joint weakness	36 (2.8%)	37 (2.9%)	30 (2.4%)	446 (35.0%)	549 (43.0%)	0.43
Digestive problems:						
1. Vomiting	35 (19.6%)	22 (19.6%)	12 (17.9%)	77 (8.4%)	146	0.11
2. Nausea	6 (14%)	5 (11.6%)	1 (2.3%)	31 (72.1%)	(11.4%)	0.03
3. Diarrhoea	2 (11.8%)	0	3 (17.6%)	12 (70.6%)	43 (3.37%)	0.01
4. Loss of	37 (20.7%)	22 (19.6%)	15 (22.4%)	148 (16.1%)	17 (1.3%)	0.17
appetite	17 (9.5)	9 (8.0%)	8 (11.9%)	161 (17.5%)	222	0.15
5. Stomach ache					(17.4%)	
					195	
					(15.3%)	
Respiratory problems:						
1. Cough	39 (21.8%)	14(12.5%)	9 (13.4%)	131 (14.3%)	193	0.15
2. Chest pain	2 (7.1%)	2 (7.1%)	3 (10.7%)	21 (75.0%)	(15.1%)	0.02
					21 (1.6%)	
Itching	1 (6.3%)	4 (25.0%)	1 (6.3%)	10 (62.5%)	16 (1.25%)	0.01
Sleeplessness	3 (1.7%)	3 (2.7%)	1 (1.5%)	42 (4.6%)	49 (3.8%)	0.04
Dizziness	10 (5.6%)	8 (7.1%)	3 (4.5%)	86 (9.4%)	107 (8.4%)	0.08
Yellow urine	17 (39.7%)	58 (51.8%)	28 (41.8%)	437 (47.6%)	594 (46.4%)	0.47

Discussion

The prevalence of malaria from this study is 15.4% with a highly sensitive SD Bioline HRP-2- Based RDT (sensitivity= 94%, specificity=98.5%, PPV=91.4% and NPV=98.2) when compared with the gold standard microscopy.

This result is consistent with other published studies showing that the sensitivity and specificity of HRP-2-based tests usually are > 90% for *P. falciparum* [14-15].

Comparing the two diagnostic methods, prevalence by RDT is higher than microscopy. This is contrary to the report by [16}, where the prevalence of malaria parasites by slide microscopy was higher than prevalence by RDT though the different was not statistically significant. This is further confirmed in reports by [17] that RDTs have shown a comparable level of accuracy to microscopy in clinical setting. This is not surprising as the quality assurance studies have been conducted on all the RDTs used for this research work by "The International Center for Malaria Microscopy and Malaria Rapid Diagnostic Tests Quality Assurance Programme, Department of Medical Microbiology and Parasitology, College of Medicine University of Lagos, Idi–Araba".

Table III: Relationship between clinical symptoms and infection by RDT and microscopy

S/N	SYMPTOMS	HRP-2 RDT		MICROSCOPY	
		POS. (%)	NEG. (%)	POS. (%)	NEG. (%)
1	Fever	157 (79.7%)	653 (60.5%)	139 (74.7%)	670 (61.6%)
	No Fever	40 (20.3%)	426 (39.5%)	47 (25.3%)	417 (38.4%)
2	Chills	84 (42.6%)	336 (31%)	71 (38.2%)	349 (32.1%)
	No Chills	113 (57.4%)	743 (69%)	115 (61.3%)	738 (67.9%)
3	Joint ache	79 (40%)	470 (43.6%)	86 (46.2%)	462 (42.5%)
	No Joint ache	118 (60%)	609 (56.4%)	100 (53.8%)	625 (57.5%)
4	Headache	76 (38.6%)	367 (34%)	69 (37.1%)	373 (34.3%)
	No headache	121 (61.4%)	712 (66%)	117 (62.9%)	714 (65.7%)
5	Febrile fever (Temp.≥37.5^{0}C)	62 (31.6%)	167 (15.7%)	52 (28%)	177 (16.5%)
	Temp. <37.5^{0}C	134 (68.4%)	900 (84.3%)	134 (72%)	897 (83.5%)
6	Body weakness	52 (26.4%)	269 (24.9%)	52 (28%)	269 (24.7%)
	No Body weakness	145 (73.62%)	810 (75.1%)	134 (72%)	818 (75.3%)
7	Vomiting	24 (12.2%)	122 (11.3%)	21 (11.3%)	124 (11.4%)
	No vomiting	173 (87.8%)	957 (88.7%)	165 (88.7%)	963 (88.6%)
8	Cough	22 (11.2%)	171 (15.8%)	23 (12.4%)	170 (15.6%)
	No cough	175 (88.8%)	908 (84.2%)	163 (87.6%)	917 (84.4%)

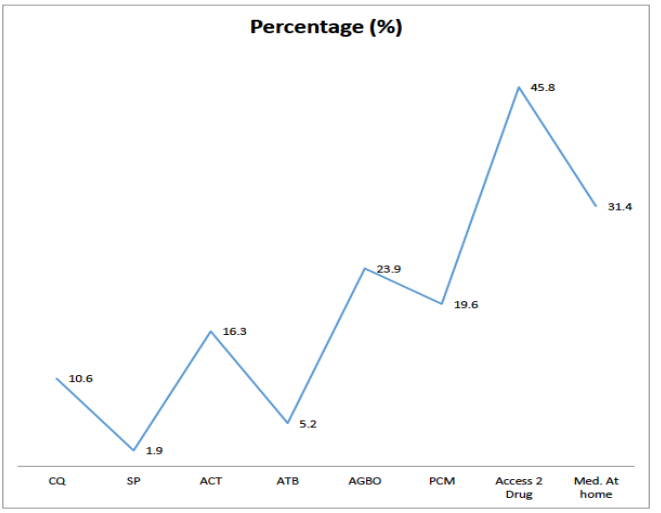


Fig. 1 (Right): Chart indicating percentage patient and disposition to drug before attending Clinic *(CQ-chloroquin; SP-sulphadoxine pyrimethamine, ACT-artemisinin-based combination therapy; ATB-antibiotics; AGBO-herbal remedy for malaria; PCM-paracetamol*

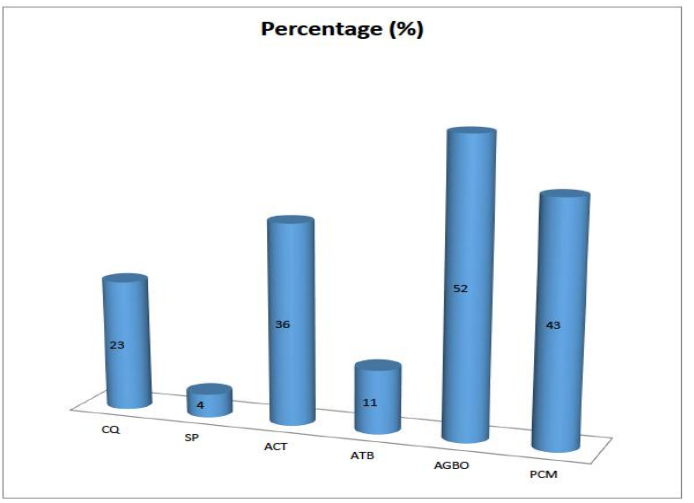


Fig. 2: The percentage of drug taken by those having access to medicine only

The prevalence of malaria in this study contrast sharply with the prevalence reported in the North Western Nigeria of prevalence rate of 27.29% [18], this is attributed to the fact that most of the sampling collection was done in the early part of the year when the transmission is usually low due to dry season period of the year.

Children are still more vulnerable, but there is now a shift from the ≤5 years which was at 16% in Nigeria as reported in the World Malaria Report [7] to 19.3% of the older children of age group "6-11years" as observed from this study. The drop in the prevalence is not surprising

because of the various intervention strategies adopted for the Country in the last one decade that focuses on all age group in the country which include the disbursement of insecticide treated nets/ long lasting insecticide nets (ITNs/LLINs) in 2009 [1].

The prevalence is observed to be higher by RDTs than microscopy basically due to the fact that some patients are fond of self-medication as indicated in the case report form (CRF). Some of the patients had taken anti-malaria, which has the ability to bring down the level of parasitaemia, but *P. falciparum* antigens HRP-2 still persist in the peripheral blood. In Fig. 1, 45.8% of the patients had access to drug, 31.4% actually kept the medicine at home. 16.3% had taken

ACT and 23.9% had taken "Agbo" before coming to the clinic. From Fig. 2, 52% of those having access to medicine had taken herbal remedy "Agbo" before attending the clinic while 32% had actually taken artemisinin based combination therapies (ACTs). Among many plants used for herbal remedy "Agbo" for malaria are lemon grass, bitter leaf, brimstone leaf, pawpaw leaf and mango tree bark which have been proved effective (Adodo, 2008), this is the reason for low or no parasitaemia compared to HRP-2 positive.

There was no statistical significant different between the symptoms and age (Table 2) except for Nausea and Diarrhoea ($p<0.05$). From this study, it can be said that 157 (79.7%) of the total patients having HRP-2 in their peripheral blood and presenting fever are actually regarded as having malaria case, this is higher than what is observed with microscopy 139 (74.4%), 653 (60.5%) patients have fever but no HRP- 2 in their blood (fever + Neg. RDT) as represented on Table 4, meaning there are other aetiologies of fever other than *P. falciparum* which may include influenza, shigella, salmonella, cholera etc, which could have been the causative agents in these negative results. This is therefore in agreement with the report of a work done in a similar endemic region that stated that clinical diagnosis has little utility in malaria case management [19].

18.1% prevalence by febrile fever (tempt. $\geq 37.5^0$C) is lower compared to the findings reported by [20] in Senegal at 49.7% though theirs was calculated from 38^0C and above. The fever complaints in this study were 63.5%, which is also lower, compared to 80.4% found in Senegal. The twelve (12) patients that had had convulsion before attending the health center were cleared from malaria by presenting a negative RDT result. The severe presentation of convulsion may be because of the poor ventilation of the residence houses of the patients. Based on the high sensitivity coupled with the rapid availability of the test result which is practicable in twenty (20) minutes, SD Bioline HRP-2-Based RDT is hereby preferred to

microscopy this is in line with the requirements documented by [21] which also include technical simplicity of the test and training needs, ease of interpretation and absence of any need for electricity to operate the assay. Further criteria essential for selecting appropriate RDTs by an operational manual on universal access to malaria diagnostic testing [22] are the supplier's production capacity and lead times, storage conditions, delivery schedules, shelf-life as well as registration and budget requirements. With the availability of the quality assured sole distributors in Nigeria such as Codix Pharma Ltd. and others, SD Bioline HRP-2-Based RDTs should be advocated for use in every level of health care facilities.

Conclusion

The performance characteristics of the SD Bioline HRP-2 RDT gotten from this study indicated that it is reliable in the parasite based diagnosis of malaria, but clinical symptoms are not reliable yet, the parasite based diagnosis must always be done to eliminate other causes of the symptoms. Based on the high sensitivity coupled with the rapid availability of the test result which is practicable in twenty (20) minutes from this study, SD Bioline HRP-2-Based RDT is hereby preferred to microscopy. The low prevalence rate from this study indicated the effect of the intervention put in place by the national malaria control programme (NMCP).

With the availability of the quality assured distributors of SD Bioline HRP-2-Based RDTs in Nigeria like Codix Pharma Ltd. and others, I hereby recommend that the continuous effort by national and international organization on the malaria control should be strengthened with a continuous advocate for the use of HRP-2-Based RDT in the malaria case management for all level of health facilities, so that Nigeria can also be enlisted one day with malaria-free Countries.

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