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Comparative Study of Rapid Diagnostic Test (RDT) and Microscopic Diagnosis of Malaria Infection among Patients Attending General Hospital Minna, Niger State

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Abstract

Malaria is a global public health problem known to be a common cause of under five children mortality in the tropical area of Africa. The aim of this study was to compare rapid diagnostic test (RDT) and microscopy technique of malaria infection among patients attending General Hospital Minna, Niger State. A convenience sampling qualitative study was carried out on 300 consenting outpatients of general hospital, Minna in Niger state. Results of the study showed that most of the respondents were females 212(71%) and Most of the participants were within the age bracket of 11-20 years (41%). This demonstrated that transmission was higher among the young age than the elderly. Microscopy was positive in 179(59%) patients and RDT was positive in 185(61%) of the total study population while 6(3%) of those negative by microscopy were also positive with RDT. There was no significant difference when the efficacy of both tests was compared. The RDT used had a sensitivity of 87%, a specificity of 98% while microscopy had sensitivity of 95% and specificity of 72%. The RDT performance was extremely high compared to microscopy in this study. RDT can still serve as the first screening test for malaria diagnosis. However, the gold standard for confirmation of clinical diagnosis for malaria is microscopy examination. Rapid diagnostic test (RDT) offers rapid, timely, accurate and accessible detection of malaria parasites which is important for prevention and treatment.

Keywords*: Rapid diagnostic test, microscopic diagnosis of Malaria, Malaria fever.*

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Introduction

Malaria is a parasitic disease spread by infected vector Anopheles mosquitoes. Globally there are more than 60 species of anophelines which are recognized vectors. Malaria is caused by four parasite species in humans: Plasmodium falciparum, *P. vivax, P. malariae*and *P. Ovale* [1]. According to reports by World Health Organization [2] estimates, malaria kills more than 600,000 people every year, most of them children under five years of age. About 97 countries are facing the malaria disease burden especially in sub-Saharan Africa. Poor and vulnerable communities living in rural areas with limited access to health facilities suffer the most. Four out of Ten people who died of malaria live in the two highest burden countries: the Democratic Republic of the Congo and Nigeria [1]. Among all the human malaria parasites, *Plasmodium falciparum* is the most pathogenic and deadly if not treated early [3]. In Nigeria, malaria causes about 50% of out-patient visits, 40% of hospital admissions and 30% of mortalities out of about 30 million children under the age of five years [4]. Moreover, it was found that 11% of maternal mortality and about N132 billion is lost to the disease annually [5].

In 2015, the World Health Organization reported a decline of 18% in the prevalence of malaria globally from an estimated 262 million in the year 2000 to 214 million in the year 2015. [6]. According to the [6] malaria report, there was an estimated global decline in malaria related deaths from 839 000 in 2000 (range: 653 000–1.1 million) with most deaths in the WHO African Region (90%). The malaria mortality rate was estimated to have decreased by 60% globally between 2000 and 2015.

The epidemiology of malaria in Nigeria is divided in to an endemic and perennial transmission zone, an endemic and seasonal transmission zone and epidemic and strongly seasonal zone. The difficulty in diagnosing malaria becomes an impediment to treatment adherence [1]. Misdiagnosis of malaria will result in over diagnosis, over prescription of antimalaria drugs, under diagnosis, and inappropriate treatment of non-malaria febrile patients [7]. WHO recommends that there should always be a microscopy confirmation or alternatively by the rapid diagnostic test before treatment is concerned [5]. Clinical diagnosis of malaria by doctors using patient sign and symptoms should be discouraged [4]. Microscopy is so reliable confirmation test for malaria. [8]. Rapid diagnostic tests (RDTs), animmuno chromatographic capture procedure is used to improve timeless sensitivity and objectivity of malaria diagnosis especially where microscopy test is not available [9].

The conventional staining of peripheral blood microscopy is the gold standard in laboratory of malaria diagnosis. However, it is not only discouraging in poor power supply settings but also time-consuming and requiring a lot of training and expertise. Microscopy tests in Africa are usually available in very large hospitals [3]. Rapid diagnostic tests (RDTs) are commercially available kits containing all the necessary reagents with easy procedures which do not require extensive training or equipments to perform and interpret the results within 12-15 minutes [8]. RDTs could be considered for most patients in endemic regions especially in poor settings and shortage of power supply and qualified manpower are experienced. However, there is very little evidence, especially from malaria endemic areas to guide decision makers on its use. The old practice of treating presumptively based on fever history and other related symptoms lead to wastage of considerable number of drugs [9]. This archaic practice of wasting time of getting microscopy diagnosis as lead to increase child mortality in some places. WHO has tentatively recommended microscopy diagnosis in all suspected cases of malaria except in serious children's emergency cases in high prevalence malaria areas [10]. For this recommendation to be adhered to obviously, rapid and accurate

laboratory finding, or demonstration of malaria parasite should be established [11].

Research on malaria diagnosis has so far been neglected [12]. Accurate diagnosis is important to effective malaria treatment as this will prevent drug misuse and death [7].

Statement of Problem

Despite the decline in malaria prevalence as reported by [6] malaria is still endemic in Nigeria and still the leading cause of morbidity (41%) and mortality (43%). According to the National Malaria Control Program (NMCP), malaria accounts for 50–56% of morbidity and 40% of deaths among children less than five years of age. Malaria constitutes a heavy burden on the health care system and economy as it is responsible for 40–50% of medical consultations and 30–47% of hospitalizations, as well as 40% of household health expenditure and 26% of work and school absenteeism. The consequent health care costs and loss in productivity result in an estimated annual loss of 1.3% GDP to the national economy. Despite the implementation of malaria prevention and treatment strategies since 2002, coverage of malaria services and commodities in Nigeria lag goals for universal coverage.

Malaria infection occurs in tropical and subtropical Latin America [13]. An estimated 95% of cases and deaths are being reported to occur in sub-Saharan Africa [14]. It is a disease that is associated with poverty and can affect the economics of a country negatively [15]. The disease has caused many countries in Africa to incur losses of US$12 billion a year [16]. There are about 10,000 malaria cases per year in Western Europe, and 1300–1500 in the United States [17]. About 900 people died from the disease in Europe between 1993 and 2003 [18]. Pregnant women in sub-Saharan Africa are at higher risk of infection due maternal malaria which is associated with 200,000 infant deaths yearly [19]. In the United States malaria eradication is a major public health concern in year 1951 though some small outbreaks persist [20]. According to the WHO and UNICEF, deaths attributable to malaria in 2015 were reduced by 60% from a 2000 estimate of 985,000, largely due to the widespread use of insecticide-treated nets and artemisinin-based combination therapies [21]. In the year 2012, there were reported cases of malaria of about 207 million cases of malaria. In the same year, the disease is estimated to have killed between 473,000 and 789,000 people, many of whom were children in Africa. [22].

The aim of this study is to determine the comparative study of rapid diagnostic test (RDT) and microscopy diagnosis of malaria infection among patients attending General Hospital Minna, Niger State.

Methodology

The study was carried out in General Hospital Minna, Niger State, Nigeria. Minna, the capital city of Niger State Nigeria, with a population of 3,950,249 and land mass of 29,484sqm, lies at latitude of 3.20’ and longitude 8 and 11.3’, roughly 150 km away from Abuja. It is occupied majorly by the Nupes, Hausas and Gbagyis whose main occupation are farming, fishing, and trading. Islam and Christianity are the two major religion of practice. The state is bounded at the north by Kebbi, Sokoto and Kaduna, Federal Capital Territory (FCT) to the East, Benin Republic to the West, Kwara and Kogi to the South. The metropolis spreads across two Local Government Areas namely: Bosso and Chanchaga LGA. The mean annual rainfall of Minna is 1334 mm with August and September recording the highest monthly rainfall of about 300 mm. the highest monthly temperature is recorded in March with an average daily temperature of 30°C and the lowest in August at about 22°C. Minna has a tropical wet and dry climate with a pronounced dry season.

A study was carried out between July 2022 and September 2022 at the General Hospital Minna, Niger State, Nigeria to provide baseline data on comparative performance of RDT and

microscopy diagnostic techniques of malaria infection among patients attending general hospital Minna.

The study population comprises all outpatients five years and ≤ sixty-five years who presents who present as suspected malaria cases are referred to do microscopy test.

Sampling Technique

A convenience sampling qualitative study was carried out on all malaria suspected cases that participated in the study and sent to the laboratory for confirmation test (microscopy and Rapid Diagnostic Test).

The materials used in this study include Giemsa stain reagent, microscopic glass slides, EDTA bottles, syringe and needles, microscope, and staining racks.

All patients five years and ≤ sixty-five years that were clinically suspected to have malaria and had malaria test request were enrolled in the study.

Sample Size Determination

The sample size was calculated using 50% prevalence of malaria in children and prevalence data of 50.0%, precision 0.05(5%) and 95% confidence level in the study area using the formula described in a manual by centre for Disease Control.

The sample size was determined using the formula for sample size determination for large population greater than 10,000.

$$n = \frac{Z^2 P(1-p)q}{d^2}$$

Where:

n = the desired sample size when the population is greater than 10,000,

Z^2 = the standard normal deviation, set at 1.96 which corresponds to 95% confidence interval,

P = is % of the target population estimated,

q = 0.5.

d = degree of accuracy, set at 0.05. calculated from the formular.

If applied then,

$$n = \frac{1.96^2 \times (0.5 \times 0.5)}{(0.05)^2} = 384.16 \; or \; 385$$

This brings the required minimum sample size for the study to **385**.

Sample Collection and Processing

Using standard phlebotomy procedure about 2ml of venous blood was drawn and dispensed into ethylene diamine-tetraacetic acid anticoagulant (EDTA) tubes. The samples were taken to the laboratory and were used for the rapid diagnostic test and microscopy testing. The quality assurance process was carried out.

Accuracy of the quality of malaria microscopy was evaluated based on full satisfaction of all the following criteria.

The proportion of well- prepared and/or stained blood films. Slide positivity rate (SPR): The proportion of smears that were positive for malaria parasites among all the examined slides.

Data Collection Tools

An open-ended questionnaire was divided into three sections under the following subheadings: Socio-demographic data where the age, sex, ethnicity, occupation, and educational status of the respondents were captured. The second section addressed the clinical details which include microscopy test result and RDT test result and the third section addressed the efficacy and comparative study between the two methods.

Data Collection Technique/Procedures

An interviewer-administered questionnaire was used for data collection. The questionnaires were administered by the researcher and trained research assistants. The research assistants were trained for one day on how to elicit responses from the respondents based on the questionnaire and to record same. Five laboratory technicians were also engaged to help collect samples of the patient at the time of the study. Before the actual study, the questionnaire was pre-tested to determine the

effectiveness and clarity of the questionnaire and necessary adjustments made.

Data Analysis

The results obtained from the comparative study of rapid diagnostic test (RDT) and microscopy diagnosis of malaria infection among patients attending general hospital Minna, Niger State were analyzed using Statistical Package for Social Science (SPSS) Version 21.

Results

Three hundred and eighty five respondents participated in the study out of which data for this analysis was obtained from 300 respondents, giving a response rate of 78%. The respondents were asked questions concerning their socio-demographic data, clinical examination, and their knowledge on malaria test method. In this study the overall prevalence rate of malaria infection according to two diagnostic methods had microscopy (59%) and RDT (53%). There was no significant difference between the diagnostic test methods ($p<0.05$). The mean SD age of the respondent was 26 ± 2 years. Their ages range from 5-65 years. Over two thirds 123(41%) of the respondents were young adults (11-20 years), 24% were 5-10 years and 1% were ≤ 65 years. More than half of the respondents were of Niger; Nupe 77(26%), Gbagyi 49(16%), Hausa 38(13%) while Igbo 16(5%), Yoruba 12(4%) and others 108(36%) had least respondents. Majority of the respondent were Muslims 234(78%) while remaining were Christians 65(22%). Most of the respondents had formal education, with 92% having no knowledge of malaria test methods. The majority of the respondents were married 202(67%) while 98(33%) were single. Out of the 300 respondents that present with sign and symptoms of malaria infection, 234(88%) present with acute/mild symptoms while severe conditions account to 76(32%).

A total of 300 respondents of different age participated in the study of whom 212(71%) were female and male 88(29%) with the least percentage. Most of the respondents in the study population, 202(67%) were married while 98(33%) were not married.

About 104(35%) of the respondent were self-employed, fulltime housewife 95(32%), unemployed 60(20%), 28(9%) Civil Servants while 13(4%) were company workers.

On knowledge of Malaria test method, most of the respondents, 276(92%) have no knowledge of malaria test methods while 22(7%) said they have knowledge of malaria test method before.

Figure 1 showed the Distribution of Malaria Infection Among Patients Attending General Hospital Minna, Niger State based on Diagnostic Test Methods.

Distribution of malaria across age groups shows that 123(53%) were 11-20 years which had the highest positive cases while above 60 years 2(1%) with the least positive cases.

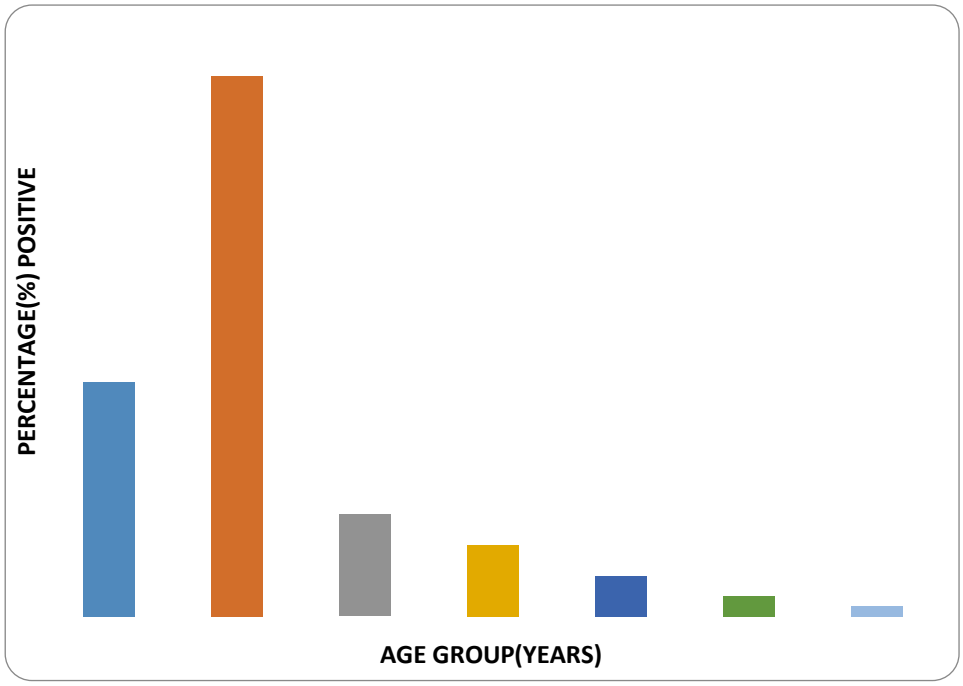

Figure 1. Distribution of Malaria Infection based on Age Group (Years)

The below, showed as the distribution of malaria according to sex, 185(62%) were positive for malaria out of which 212(79%) were females and 88(21%) positive were males.

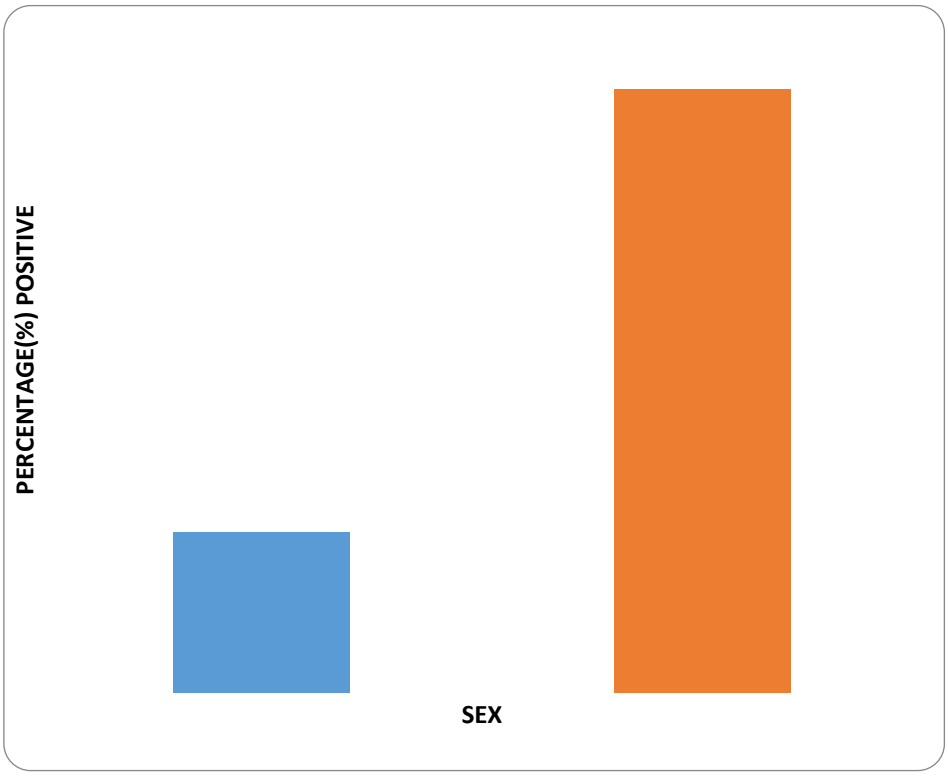

Figure 2. The Distribution of Malaria According to Sex

Out of the respondents that present with acute/mild malaria 234(88%) were positive while those with severe cases 76(12%) were positive according to diagnostic methods.

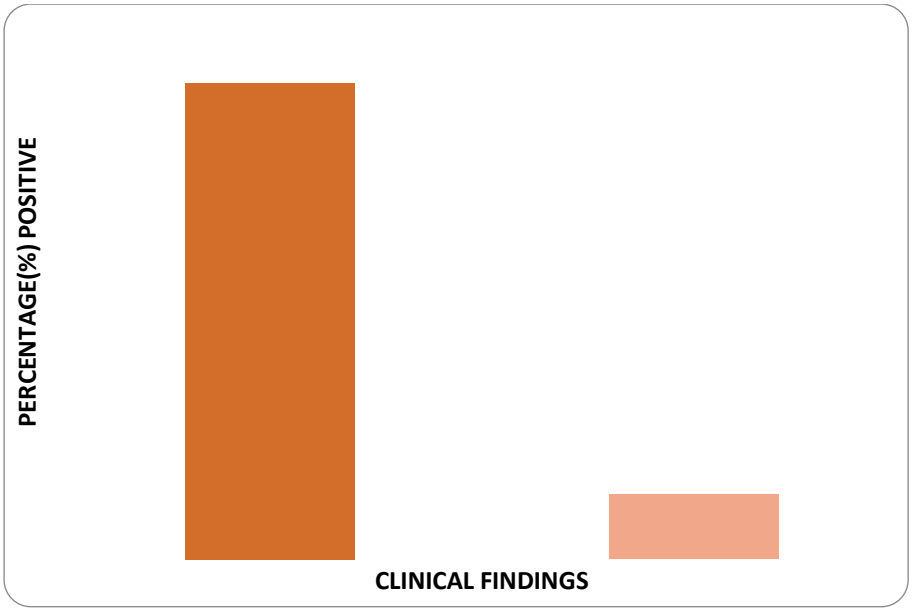

Figure 3. The Distribution According to Clinical Findings

Table 1 shows malaria distribution based on the two diagnostic tests method shows that out of the 185 positive cases, 179(97%) were positive using microscopy while 185(100%) were positive for RDT while 6(3%) of those negative by microscopy were positive with RDT.

Table 1. Distribution of Malaria in the Study Population based on Diagnostic Test Methods

Diagnostic method	No. of positive Cases (n=185)	Percentage positive (%)
Microscopy	179	97
Rapid Diagnostic Test (RDT)	185	100

Table 2 above compares indicators in relation to diagnostic techniques in the detection of malaria infection shows a sensitivity and specificity value of 87(29%) and 98(33%) with RDT when compared to microscopy (gold standard) of 95(32%) and 72(24%) respectively of all cases. There were no significant differences between microscopy and RDT sensitivity, thus RDT 98(33%) had higher specificity than microscopy 72(24%).

Table 2. Comparing Indicators for Microscopy and Rapid Diagnostic Test.

Microscopy RDT	No. of Rate	Percentage (%)	No. of Rate	Percentage (%)
Positive Sample	179	59	185	61
Negative Sample	6	2	0	0
True Positive (TP)	98	33	103	34
True Negative (TN)	51	17	76	25
Agreement	149	50	169	56
False Positive (FP)	19	6	11	4
False Negative (FN)	5	2	15	5
Sensitivity	95	32	87	29
Specificity	72	24	98	33

Key: TP= True Positive, TN= True Negative, FP= False Positive, FN= False Negative. n =300, * Sensitivity = TP/ (TP + FN) X 100. *Specificity = TN/ (TN + FP) X 100. * Positive Predictive Value = TP/TP + FP X 100. * Negative Predictive Value = TN/TN + FN X 100.

Table 3 above compares the performance in relation to diagnostic techniques in the detection of malaria infection shows the prevalence of malaria using microscopy in this study was 59% while using RDT was 53%. There was no significant difference between microscopy (86%) and RDT (87%) in relation to test efficiency.

Table 3. Comparing the Performances of Microscopy and Rapid Diagnostic Test

Microscopy RDT	No. of Rate	Percentage (%)	No. of Rate	Percentage (%)
Prevalence of malaria	179	59	185	53
Efficiency	179	86	185	87
Sensitivity	95	32	87	29
Specificity	72	24	98	33

Key: TP= True Positive, TN= True Negative, FP= False Positive, FN= False Negative. n =300, * Sensitivity = TP/ (TP + FN) X 100. *Specificity = TN/ (TN + FP) X 100. * Positive Predictive Value = TP/TP + FP X 100. * Negative Predictive Value = TN/TN + FN X 100. Efficiency = TP + TN/TP + FN + FP +TN X 100. Prevalence of Malaria = TP + FN/TP+FP+FN +TN X 100

Discussion

This study determines the comparison of two routine malaria diagnostic between microscopy technique and Rapid Diagnostic Test (RDT) among patients attending general hospital Minna, Niger State. The socio-demographic characteristics of the study population revealed that out of the 300 respondents, 123(41%) were in the age range of 11-20 years while those that were above 60 years were the least (1%). The mean age of the respondents was 26 years. Most of the participants were within the age bracket of 11-20 years. This demonstrated that transmission was higher among the young age than the elderly. This is in line with the study carried out by Enitan *et al*., 2019 who reported higher prevalence of *P. falciparum* malaria infection in subjects within the 12-22 years age bracket. In similar study, [23] reported a higher rate of malaria in 17-19 years age bracket of students in University of Maiduguri, North-Eastern Nigeria.

In this study the respondents were dominated by female gender 212 (71%) than male gender 88(21%). This indicated that female participants were highly infected with malaria parasite than their male counterpart. This agrees with previous studies conducted by [24] and [25] in South-Eastern Nigeria, where females were observed to be more infected than males. [26] also recorded more prevalence of malaria infection in females than in males. However, the results contradict reports of [27] and [28] that showed more prevalence of malaria infection among male participants than the female.

The respondents cut across several ethnic groups, but Nupe, as a single ethnic group had the highest value of respondents 77(26%) while Yoruba 12(4%) with least number of respondents. The high value of Nupe ethnicity in the study population can be attributed to their dominant in the study area. In this study Islamic religion account to 234(78%) had the highest value of respondent while Christianity 65(22%) and others 0%.

The high value recorded was attributed to Islam being the dominant religious group in the region. About 104 (35%) of the respondent were self-employed, 95(32%) were fulltime housewives, 60(20%) were unemployed, and 13(4%) were company workers, while 28(9%) were Civil Servants. In this study 146(49%) of the respondents had secondary education or the other, while only 5(2%) had other forms of education. This certainly must have contributed to their level of awareness and health-seeking behavior.

The knowledge about malaria test methods in this study is low 22(7%), majority of the respondents 276(92%) said they had no

knowledge of malaria test methods. Most respondent who have heard of malaria tests were not able to correctly identify the methods. A major hurdle is the fact that malaria test method is not perceived as a problem.

In this study the distribution of malaria infection among patients attending general hospital Minna, Niger state base on diagnostic technique shows higher positivity rate of RDTs (61%) and microscopy (59%) was observed out of 300 respondents that participated in the study while prevalence rate of malaria infection using RDTs (57%), and microscopy (53%) was recorded.

The distribution of malaria infection across age groups with 11-20 years 97(53%) out of 185 positive cases while above 60 years 2(1%) had the least positive cases. Similar study by Perkin *et al*., 2017 were observed in other parts of Nigeria. Respondents with lower age group (<20) had a prevalence of 57.4% and asserted that, there is slow acquisition of active immunity to malaria; this could be the reason why respondents of lower age groups were susceptible to malaria in this study. Male 38(21%) respondents showed a lower positive case of malaria infection while female respondent had 147(79%).

The reason for the differences cannot be empirically traced to any reason, it may have occurred by chance. [29] reported that there is no scientific evidence that susceptibility to malaria is gender based. In this study the distribution of malaria infection according to clinical findings shows that most of the respondents presented with acute/mild had 163(88%) positive cases while severe cases had 22(12%) out the total study population. The reason for the differences can be attributed to clinical manifestation of malaria shown by the respondents. The study also measured the discriminatory accuracy of the RDTs against microscopy using sensitivity and specificity of the apparatuses.

The sensitivity and specificity values for RDT and microscopy in this study shows sensitivity and specificity using RDT were 87% and 98% while microscopy had 95% and 72% respectively. The lower rate of sensitivity for RDT shown in this study compared to microscopy techniques (gold standard) were like findings reported by [30] in tertiary healthcare facility in Rivers State, Nigeria. Also, a similar study conducted in Akure by [31] which showed a sensitivity of (65%) RDT compared to microscopy (71.4%). This could be attributed to the age of the strips, different manufacturers and methods employed in the study. Lower sensitivity was observed for the RDT can be attributed to greater value of false negative result which was not anticipated. The accuracy of RDTs diagnosis can be affected by numerous factors ranging from storage, humidity, temperature, product quality and end users' operation. However, the sensitivity recorded in this study can be advantageous as it will not hinder control intervention especially when RDT is the only available malaria diagnosis tool. 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.

Microscopy had 72% specificity while RDT (98%) specificity recorded in this study is in line with the study of [32] in Ibadan Nigeria where 99.6% specificity was observed. The specificity rating of 100% was also reported in the study of [33] in Port Harcourt, Nigeria. There was no significant difference in the efficacy rate between RDT (87%) and microscopy (86%). However, although microscopy is regarded as the gold standard, there could still be the possibility of human error. Thus, the high specificity of RDT will make the cost of malaria affordable and thereby enhance the number of non-infected individuals who would have missed out, hence the need for proper case definition and care.

Conclusion

The finding from this study showed that the overall prevalence of malaria infection according to diagnostic methods had microscopy (59%) and RDT (53%). This shows no significant difference ($p<0.05$) between the methods.

The mean SD age of the respondent was 26 ± 2 years. Over two thirds 123(41%) of the respondents were young adults (11-20 years) and 1% were ≤ 65 years and present with clinical sign and symptoms of malaria infection from acute/mild (88%) to severe cases (32%). Malaria infection distribution shows that out of the 185 positive cases, 179(97%) were positive for microscopy while 185(100%) were positive for RDT while 6(3%) of those negative by microscopy were positive with RDT.

The high specificity observed for RDT (98%) when compared to microscopy (72%) will make the cost of malaria affordable. Rapid diagnostic test (RDT) offers rapid, timely, accurate and accessible detection of malaria parasites and it's important for prevention, treatment, reduced malaria mortality, morbidity, and transmission.

Conflict of Interest

The authors declare there is no conflict of interest while producing this article.

Acknowledgment

We acknowledged the participation of the laboratory staff and the secretary that participated in seem that this work was successfully completed.

Recommendation

Microscopy is recommended to be done for every patient suspected of having malaria with negative RDT in order not to miss out people with the disease as it remains the gold standard for malaria diagnosis. It is suggested that further research be carried out using two different clinical facilities with this specific RDT brand in the diagnosis of malaria infection while comparing it with microscopy (gold standard).

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