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The Performance of Rapid Diagnostic Test for Malaria Parasite Diagnosis Compared to Microscopic Test in Meru South Sub-County, Tharaka-Nithi County, Kenya

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Abstract
Despite intensive worldwide attempt to control malaria, it remains one of the most fatal and widespread protozoan infection of mankind. About 2.4 billon people inhabit malaria prone regions which is about forty percentage of the world population in over 90 countries of Sub-Saharan Africa are affected. Prompt accurate, diagnosis and treatment is important to avert suffering of patients and malaria infection is a serious global challenge in the affected countries. The rapid diagnosis test of malaria is a recent diagnostic technique whose performance has not been evaluated in Meru South Sub-County. The main purpose of this research study was to perform immunosurveillance and evaluate performance rapid diagnosis test for malaria parasites in Meru South Sub-County, Tharaka-Nithi County. The study design was hospital based cross-sectional study in the laboratory at Chuka Level Five Hospital. Three hundred and eighty four blood specimens were used from febrile patients with clinical manifestation of malaria infection. The blood specimens were used for thin, thick smear and rapid diagnosis test. The results were analyzed by t-test to compare the mean of the two methods. A P –value of 0.953 was obtained which is greater than 0.05, therefore we accept the null hypothesis that there is no difference in performance between the Rapid Diagnostic Test (RDT) and microscopic test. The results indicated that RDT had similar performance with microscopy for both positive and negative cases of malaria infection. In conclusion RDT is appropriate for malaria diagnosis since the incidence rate of malaria was found to be high and the predominant *Plasmodium falciparum* was high in the study area. The researcher recommends the use of RDTs in mass screening for malaria infection, adopt or intensify protective measures during dry seasons and monitoring antimalaria drug resistance or tolerance in all counties in Kenya.

1. Introduction

Rapid diagnostic test for malaria diagnosis is an immune chromatographic assay for initial detection, identification and confirmation of *Plasmodium* species. The method involves the dynamic flow liquid on the surface of strip paper. Parasite antigen is react with antibodies of superficial blood collected in the specimen prepared against a malaria antigen target conjugated to either selenium dye or gold particles in a mobile phase. The *Plasmodium* Lactate Dehydrogenase (PLDH) enzyme disintegrates almost immediately there is effective treatment of malaria therefore absent in the patient's bloodstream but if treatment fails the enzyme persists. (WHO, 2013).The movement of antigen-antibody complex in the mobile phase along a nitrocellose tape allows the labeled antigen to be accurately captured by monoclonal antibodies of immobile phase to form macro-complex molecule. It can detect presence or absence of *Plasmodium* lactase dehydrogenase (PLDH), a 33kD De-oxyreductase enzyme. The lack or presence of PLDH after treatment implies that test may be important in determination of effective treatment or inadequate treatment possibly due to drug resistance and other factors or failure. The results are visible in the reader's window by observing one coloured line for negative test results and two coloured lines for positive test results plus species identified. The RDTs have been improved and modified in various diagnostic test designs. In some RDT kit, they have one well where blood sample is placed followed by the buffer solution which causes the components to be dynamic along the nitrocellose tape. The blood specimen is usually about one drop obtained from the patient third finger is pricked then placed in the first well and a buffer solution placed in the second well that contains a hemolyzing reagent and a specific antibody that is labeled with a visually detectable marker likes colloidal gold particle. In some kits, labeled antibody is incorporated in the reagent and lysing washing buffer introduced. If the target antigen is present in the blood, a labeled antigen/antibody complex is formed and it moves up the nitrocellose tape to be captured by the incorporated antibodies specific against the antigens and against the labeled antibody (as in user guide manual). A rinsing buffer solution is then put to clear remains of the hemoglobin and allow observation of the colored lines developed along the tape the antigen-antibody reaction complex. The pLDH enzyme and aldolase are designed to detect a parasitemia of greater than 100 to 200 parasites/µL and some of the PfHRP2 protein identifies asexual phase parasites reproduction at very low parasitemia of below 40 parasites/µL. The RDT and microscopic diagnosis have high sensitivity and specificity for malaria test followed by treatment in endemic areas. If diagnosis of interested groups of people is found necessary, then, rapid diagnostic test or microscopy may be applied for symptomatic and asymptomatic infections. The microscopic diagnosis is the standard gold test for malaria infection but the most effective and appropriate test for mass diagnosis would be RDTS since it is easy to use without skilled personnel. It should be realized that the life of child or expectant

woman is threated from *P. falciparum* malaria infection which likely to cause death that diagnosis must not be miss out (WHO, 2009). Figure 2.2 shows a flow diagram on how RDT works.

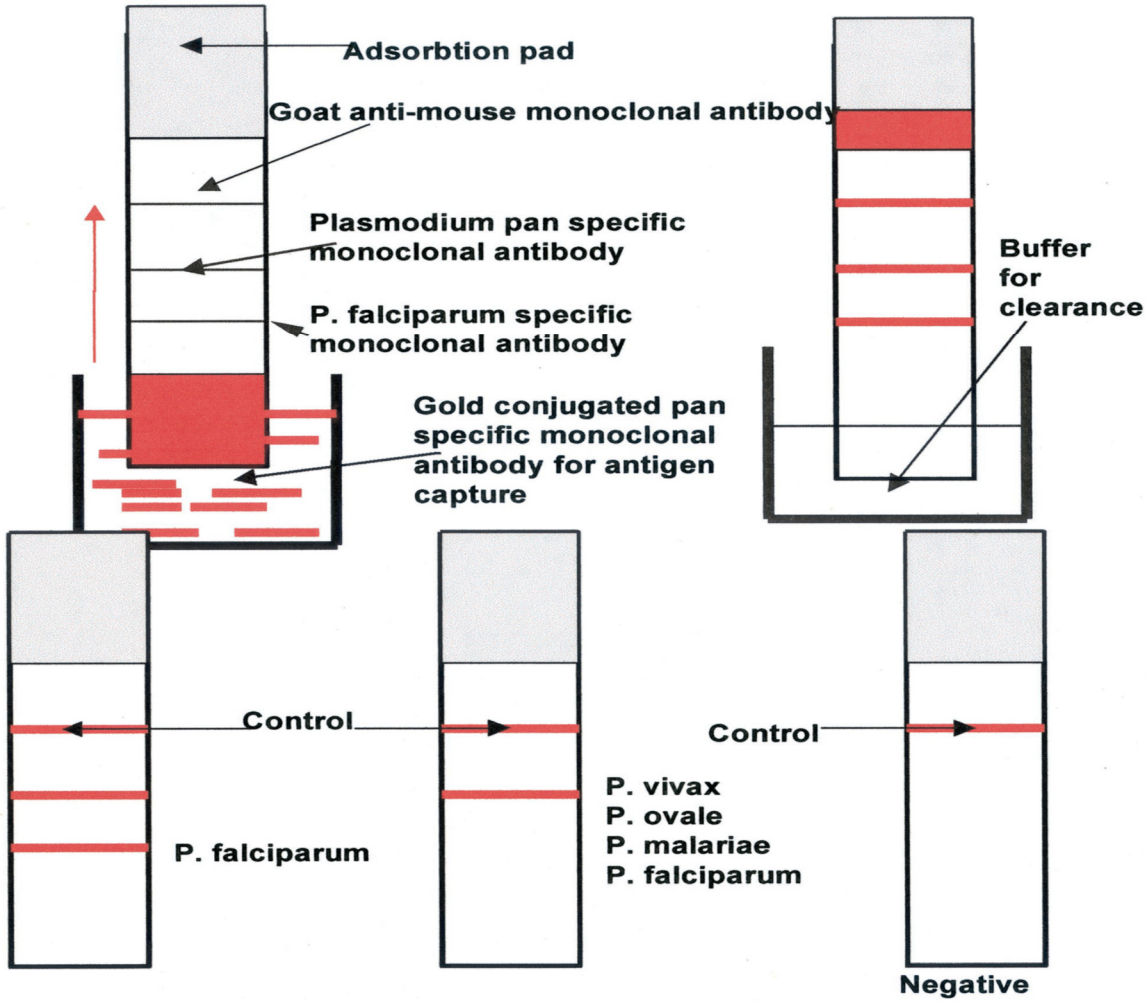

Figure 2.2: Sample RDT Strips Showing Test Results (Farcas *et al*., 2009)

1.1 Sensitivity of Rapid Diagnostic Test for Malaria

WHO (2009) guidelines and protocol on malaria case treatment must be based on appropriate diagnostic test and not clinical signs and symptoms. However, in high malaria transmission settings, this protocol may limit the commitment to the guidelines where resources are inadequate or absent. The application immunochromatographic assay using rapid diagnostic test provides important approach for management of malaria in situations where microscopy may not be possible. The limited resources may be complicated by low budgetary allocation due to other emerging tropical diseases requiring immediate attention. Sensitivity of RDTs refers to their ability to demonstrate reliable identification of malaria parasites at moderate parasite densities (200parasites/µl). The RDTs are not affected by tropical temperatures hence easy to use, store and above all identify the *Plasmodium* species.

Recommended sensitivity for RDTs is 95% at 100 parasites /µl of blood. Sensitivity is mainly associated with the amount of target antigen available, thus change slightly parasitemia. Similar diagnosis could attain a high sensitivity in a group of people in which all sick individuals have high parasitemia greater than 1000 parasites/µl and attain low sensitivity and specificity in regions with parasitemia less than 50 parasites/ µl. The sensitivity and specificity of RDTs are stated in the manufacturers user guide although slight variation may occur due to parasite density in the study area. The RDTs must be sensitive and specific enough to accurately and reliably diagnosise malaria at moderate parasitemia. The sensitivity of RDTs in diagnosis of malaria is affected manufactures guide, type of species of malaria, parasite density and storage conditions. The most important approach is the adherence to the manufacture's guide in performing the test and recording. This study sought to determine the sensitivity and specificity of RDTs used for malaria diagnosis in Chuka Level five Hospital, Tharaka-Nithi County.

2. Objectives

The objectiove of this study was to determine the Performance of Rapid Diagnostic Test for malaria parasite

diagnosis in Meru South Sub-County, Tharaka-Nithi County, Kenya.

3. Methodology

This research study was carried out at Chuka Level Five Referral Hospital in the hospital laboratory, Meru South Sub-County, Tharaka-Nithi County. The hospital serves as a referral for patients from the following dispensaries; Mpukoni, Consolata Cottage, Chera, Chogoria, Nkaanwa, Kajuki, Kambandi, Magumoni, Igambang'ombe and private health clinics in the district. The divisions covered were Chuka, Magumoni, Maara, Igambang'ombe and Kajuki which are endemic to malaria. The study design was hospital based cross sectional study. The young children less than five years and expectant females were examined by clinicians and those with febrile illness were referred to the laboratory. The data of the first three children and one expectant female referred by clinicians to the laboratory was collected per day and analyzed for a period of six months to achieve target sample size. The samples were collected by myself and assisted by laboratory technician for analysis. The permission to carry out study was granted by Kenyatta University, District Medical officer of Health (MOH), Ministry of Education Science and Technology, the administration and leaders of Meru South Sub-County, Tharaka -Nithi County

4. Results and Discussions

The following are the results and discussions of the study

4.1 Socio-Demographic Characteristics of the Participants

In this study, a total of 384 samples were analyzed from enrolled participants. These comprised 154 male children and 206 female children and 24 expectant women. Approximately 360 (93.7 %) patients were children aged below 5 years and 24 (6.3 %) patients were expectant women. In this study 59.9% of patients with malaria were females, and 44.1% were males.

4.2 Performance of RDT and Microscopy for Malaria Parasite Diagnosis

The study evaluated the performance of RDTs in terms of accuracy and reliability compared to microscopy for detecting *Plasmodium falciparum* parasites in the blood. The results of tests using RDT and Microscopy are shown in Table 4.2

Performance of RDT and Microscopy Tests for Malaria Diagnosis

Cases	Microscopy	Percentage %	RDT	Percentage %
Positive cases	**274**	**71.35**	**272**	**70.83**
Negative cases	**110**	**28.65**	**112**	**29.17**
Total	**384**	**100**	**384**	**100**

The results show 274 cases tested positive accounting for 71.35% with microscopy test as compared with 272 cases (70.83%) with RDT. The study also compares the negative cases of microscopic test which was 28.65% and 29.17% for RDT test. Further analysis was done by use of t-paired test for microscopic and RDT and the results are shown in table 1

Table 1: t-Paired Test Analysis of Microscopic and RDT tests

Tests		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Microscope (+ve)	46.67	274	12.242	4.998
	Microscope (-ve)	18.33	110	7.528	3.073
Pair 2	RDT (+ve)	45.33	272	13.307	5.432
	RDT (-ve)	18.67	112	7.659	3.127

From the results on table 1 microscopic tests for both negative and positive cases, the positive cases had the highest mean of 46.67 and standard deviation of 12.242, compared to RDT (+ve) which had mean of 45.33 and standard deviation of 13.307. On the other hand, microscopic tests (-ve) had mean of 18.33 and standard deviation 7.528 compared to RDT (-ve) which had mean of 18.67 and standard deviation 7.659. To determine whether there was significance difference microscopic tests for both negative and positive cases and RDT (+VE) and RDT (-VE) case a t- test analysis was carried out and results shown in table 2

Table 2: t-Test Analysis of Microscopic +ve and RDT +ve Tests Results

	Test Value = 46.67					
					95% Confidence Interval of the Difference	
Tests	t-values	N	Sig. (2-tailed)	Mean Difference	Lower	Upper
Microsco (+ve)	0.333	274	0.752	1.667	-11.18	14.51
RDT (+ve)	0.061	272	0.953	0.333	-13.63	14.30

Since p=0.953 is greater than 0.05 we accept the null hypothesis and conclude that the hypothesized population mean (46.67) in Microscope (+ve) is equal to the RDT (+ve) 45.53 mean and conclude that the mean of Microscope (+ve) is not significantly different than that of RDT (+ve).

Table 3. t-Test Analysis of Microscopic –ve and RDT –ve Tests Results

	Test Value = 18.33					
					95% Confidence Interval of the Difference	
Test	t-value	N	Sig. (2-tailed)	Mean Difference	Lower	Upper
Microscope (-ve)	0.434	110	0.682	1.333	-6.57	9.23
RDT (-ve)	0.533	112	0.617	1.667	-6.37	9.70

Since p = 0.617 is greater than 0.05 we accept the null hypothesis and conclude that the hypothesized population mean (18.33) in Microscopic (-ve) is equal to the RDT (-ve) mean 18.67 and conclude that the mean of Microscopic (-ve) is not significantly different than that of RDT (-ve).

Table 4: Results of RDT and Microscopic Tests

Diagnostic method (n)	Parameter for Assessment							
	TP	FP	TN	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
RDT	380	12	404	4	98.9	97.1	96.9	99.0
Microscopy	384	0	416	0	100	100	100	100

TP: true positive; FP: false positive; TN: true negative; FN: false negative; Sample size for determination of performance of RDT was eight hundred, (n=800).

Malaria Rapid Diagnostic Tests showed 98.9% sensitivity, 97.1% specificity, 96.9% positive predictive value and 99.0% negative predictive value. The microscopy based test showed 100% sensitivity, 100% specificity, 100% positive predictive value and 100% negative predictive value. (WHO, 2005), recommends that diagnostic test should have performance above 95% in terms of sensitivity, specificity and predictive values. Tests below 90% are considered inferior and unacceptable. Malaria was noted in 384 (48%) of the 800 samples.

5. Conclusion

Rapid Diagnostic Test (RDT) is appropriate in large scale screening for malaria parasites and interventions in the management and control of malaria in Meru South Sub-County. The RDTs may be used in a mobile clinic and can be performed conveniently at patients comfort or diagnosis is done by the patient.

6. Recommendations

Based on the study findings it was recommended that RDT may be used in malaria surveillance and mass screening of patients during outbreak of epidemics. Malaria immunosurveillance to be conducted in all Counties in Kenya.

References

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