ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

# Efficacy of Malarial Ag Rapid Test Kit (RDT) in Diagnosis of Malaria.

**Savetha P*, and Kiarn M.**

Department of Microbiology, Sree Balaji Medical College & hospital, Chromepet, Chennai, Tamil Nadu, India.

**ABSTRACT**

Malaria rapid diagnostic tests (RDTs) are a useful tool in for quick detection of malaria in endemic malaria countries. This present study aims to compare the efficiency of Aleretrueline rapid test for malaria Ag pf/pan (HRP-11/pLDH) falciparum with microscopy. Blood samples were collected during a six-month period from 2014 February to July in patients suspected to have malaria from Chennai. The samples were examined by light microscopy and RDT. Sensitivity, specificity, positive predictive value and negative predictive value were used to evaluate the performance of RDT. Samples of 453 patients were included. The Aleretrueline rapid test had a sensitivity of 92.59% and specificity of 99.30%. The RDT performs similar to microscopy for the detection of *P.falciparum/p.vivax* making it a valuable tool for routine diagnosis of malaria.

**Keywords:** Malaria; Diagnosis, Rapid diagnostic test, Microscopy, Sensitivity/specificity.

***Corresponding author***

ISSN: 0975-8585

## INTRODUCTION

The mosquito borne diseases such as dengue fever, malaria, filariasis and yellow fever are vigorously spreading worldwide and affecting millions of people. Among this malaria presents a diagnostic challenge and it is a major threat to human kind causing nearly one million deaths annually [1].Urban malaria is considered to be one of the most significant infectious diseases due to varied socioeconomic problems especially in tropical countries like India. Among these south Indian cities, Chennai is endemic for malaria [2].And it is also noted that that till date there is no specific antimalarail therapy available to control the incidence of this disease. According to the WHO guidelines treatment is recommend only to those patients who have done their parasitological confirmation. Early diagnosis is therefore essential to the treatment success and eradication of the disease. Microscopy is considered as the gold standard diagnostic procedure for malaria detection since it is inexpensive to perform, can differentiate malarial parasite species, and also can be used to quantify parasites. However, microscopy requires well-trained personnel and methodical maintenance of functional infrastructures and quality assurance (QA). In comparison to expert microscopy, a wide range of false positive and false negative results were also reported in many local laboratories [3]. The traditional method of microscopic identification of parasite is not only difficult procedure but also time consuming so it is of limited use to larger clinics/tertiary Centre [4]. This challenge has led manufactures and scientist to develop antigen-detecting malaria rapid diagnostic tests (RDTs) in many malaria endemic countries.RDTS are commercially available in kit forms and easy and quicker to perform, does not require extensive training or equipments to perform or to interpret results. However, the efficiency of these RDTs compared to different malarial diagnostic procedures such as microscopy, QBC and PCR is not completely evaluated. The quality assurance of the RDT method is necessary for making these RDTs for routine malaria confirmatory tests. WHO recommends for RDT QA to monitor the tests in field use monthly, by comparing the RDT results to microscopy done in reference labs. However, the reports on the specificity and sensitivity of these RDTs in the diagnosis of malaria were scant especially in South Indian population which is a high risk ethnic group for malaria.

On considering this we hypothesized that Rapid malarial test kit (RDT) can be an alternative to microscopy in the diagnosis of malaria. The aim of this study therefore, was to monitor the performance of RDT based on reference microscopy. This study was therefore designed to find out efficacy of RDT with “gold standard” microscopic method of malaria diagnosis.

## METHODS

The study was conducted at a tertiary referral hospital in Chennai, Tamilnadu. The patients referred to the hospital either with fever associated with rigor and/or with microscopic diagnosis of malaria were included in the study.

The samples were collected in six months periods from February 2014 to July 2014. Patients suspected of malaria (N=453) were recruited, a medical history was obtained, a physical examination was undertaken and blood sample were collected for both microscopic and RDT analysis. Blood samples were collected from patients using a lancet and placed in the appropriate well on the RDT and from the same finger prick 2-3 drops of blood collected and used for thick and thin blood smears preparation on a clean slide and stained with field stain after fixing the thin smear with methanol.

Data were entered in Microsoft Excel and analyzed in SPSS 174 statistical package (Version 20.0; SPSS, Chicago, IL) and P value less than 0.05 was considered significant. Smears were considered negative when no parasites are detected after examination of 100 microscopic fields. The RDT kit used in the study was Aleretrueline rapid test for malaria Ag pf/pan (HRP-11/pLDH) falciparum which could detect HRP-II specific to plasmodium falciparum and PLDH specific to plasmodium species(p.malariae, p.ovale and p. vivax) in finger-prick samples. The microscopic blood smear analysis was taken as standard and sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of RDT were calculated.

## RESULTS

Table 1 shows the demographic characteristics of the 453 suspected malaria cases, by age, sex. The slide positivity rate (SPR) from microscopic examination was significantly in the age group 41–50 years. The overall SPR for men was significantly higher than that of females (data not shown).

On comparing RDT with microscopic examination out of 453 fever cases included in the study 28 (6.1%) fever patients tested positive for malaria by RDT whereas 25 (5.5%) tested positive from microscopic examination.Out of these 25 fever cases positive by microscopy, RDT was positive in 23 cases. Out of 28 RDT positive cases, all tested positive by microscopy (no false positive cases detected).

**Table 1: Demographic distribution and blood smear slide positivity rates (SPR) of 453 fever cases tested**

| Age(years) | Number Tested | M/F | SPR | p-value |
|---|---|---|---|---|
| ≤10 | 24 | 13/11 | 0 | >0.05 |
| 11-20 | 44 | 25/19 | 6.81 | >0.05 |
| 21-30 | 172 | 91/81 | 4.65 | >0.05 |
| 31-40 | 62 | 31/31 | 4.83 | >0.05 |
| 41-50 | 62 | 31/31 | 14.51 | <0.05 |
| 51-60 | 59 | 31/28 | 1.69 | >0.05 |
| ≥60 | 74 | 45/29 | 2.70 | >0.05 |

*Z test.* Statistically significant differences are indicated in bold type

Validity indicators were calculated for RDT for diagnosis of malaria taking blood smear examination as the gold standard. The sensitivity of RDT for the diagnosis of malaria was (92.59%; 95% CI: 75.67% - 98.88%).The specificity of RDT for the diagnosis was(99.30%; 95% CI: 97.98 % -99.85 %)whereas the positive likelihood and negative likely hood ratio were 133.02%and 0.07%.The positive predictive value (PPV) and negative predictive value (NPV) for RDT for the diagnosis of malaria was (89.29 % ; 95% CI: 71.75 % - 97.61 %)and (99.53 % ; 95% CI: 98.33 % - 99.93 %)respectively.

## DISCUSSION

The significance of using microscopy as routine for diagnosis of malaria in clinical settings cannot be overly emphasized due to various reason such as requirement of expert technician, time consumption, accuracy etc. The present study assessed the performance of a RDT for detecting malarial infection (*P. falciparum and other plasmodium species* infection) versus light microscopy as gold standard. Major result includes: 1.The specificity and sensitivity of RDT on comparing with microscopy was found to be 92.59% and 99.30% respectively.

The overall SPR was 5.5 % among the fever cases included in the present studyduring the period February to July is corresponded with the high transmission season for malaria in Chennai city. In the present study we observed a significantly higher number of malarial patients among males compared to females. This is in agreement with Aditya P. Dash et al., who reported the deaths due to malaria follow a male: female ratio of 1:0.56[5].The present study found the sensitivity and specificity of the RDT for malarial parasite detection was 92.59% and 99.30% respectively. This is in line with Morankar Set al.,who reported the sensitivity and specificity of RDT 93.02% and 99.44% [6]. The PPV for malaria in the present study was 89.29 % .However, in another study conducted in India it was ranged between 63.0% [7].

## CONCLUSION

The Aleretrueline rapid test for malaria Ag pf/pan (HRP-11/pLDH) falciparum RDT performed well for the diagnosis of malaria. High sensitivity of malaria diagnosis is important in setting up the treatment soon for the people especially in south Indian population who all are more vulnerable for malaria infection that can rapidly progress to death. Microscopy, RDT,OBC and PCR diagnostic methods are the present diagnostic procedure for this disease. However, the practical easiness and less duration of test time makes RDTs more useful than microscopic studies .The present study suggests RDT procedure can be used as routine screening test for detection of malarial infections.

## REFERENCES

[1] Tolle MA. Curr Probl Pediatr Adolesc Health Care 2009;39(4):97-140.

[2] Kumar DS, et al. Malar J 13:14.
[3] Wongsrichanalai C, et al. Am J Trop Med Hyg, 2007;77(6 Suppl):119-27.
[4] Cancrini G, and A Iori. Parassitologia 2004;46(1-2):173-6.
[5] Kumar A, et al. Am J Trop Med Hyg 2007;77(6 Suppl): 69-78.
[6] Morankar S, et al. Ethiop Med J. 49(2):131-8.
[7] Vyas S, et al. East Mediterr Health J 20(4):236-41.