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**Original Research Article**

# Efficacy of rapid test as an aid in rapid diagnosis of malaria at bed side in an endemic region in comparison to conventional microscopy

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## ABSTRACT

**Background:** The routine and commonly used test for malaria diagnosis is obtaining thick and thin smears and examining it under microscope. This test required skilled laboratory and skilled staff. Hence rapid diagnostic kits have been developed. Present study attempts to study the efficacy of this optical test in the diagnosis of malaria among children. Objectives of present study was to study efficacy of rapid test in rapid diagnosis of malaria at bed side in an endemic region.
**Methods:** Hospital based cross sectional diagnostic evaluation study was carried out at SVS Medical College, Mahabubnagar, Telangana, India from September 2015 to September 2016. 100 in-patients with fever from pediatric ward belonging to 1-14 years of age were included in the present study after applying the inclusion and exclusion criteria.
**Results:** Maximum children belonged to 1-5 years of age. All patients presented with fever. Splenomegaly, convulsions and pallor was seen in most of the children. Diagnostic accuracy of rapid test was near 100% as it missed only one case of P. falciparum. For vivax malaria there was 100% sensitivity and specificity of the rapid test. For falciparum malaria, it was 97.8% and 100% respectively. Statistically this was significant.
**Conclusions:** Rapid test can be considered as diagnostic test in areas where laboratory facilities are not available. It is cost effective. It takes little time. It can be done anywhere.

**Keywords:** Children, Conventional microscopy, Rapid test, Thick smear, Thin smear

## INTRODUCTION

Even today malaria is a health hazard. Globally it has been estimated that 1600 million population are living in malaria endemic areas. Every year it has been estimated that 100 million malaria cases occur globally. Nearly 1-2 billion people die every year due to malaria all over the world. Under five children are the major victims of malaria deaths. P. falciparum has been incriminated as the sole cause of all these deaths among children. Among the list of countries affected on a vast scale, India stands in the list of those global countries.[1] India reported 1.64 million cases of malaria in 2003. Majority of these cases were caused by P. vivax. But P. falciparum contributed to the occurrence of 0.74 million cases of malaria. Around 1000 deaths were reported from India during the same period.[2]

Malaria is easily preventable disease. Effective vector control is very important. Early diagnosis and rapid treatment in the secondary prevention of malaria is useful which will prevent morbidity and mortality due to malaria. Complications can also be prevented if we can diagnose malaria rapidly and treat it effectively. Alternating fever i.e. tertian fever, cold stage, hot stage and sweating stage are classical clinical features of malaria. But due to mal-treatment like taking analgesics for fever can alter this classical clinical picture of

malaria. More over malaria can present in various other forms like low grade fever, upper respiratory tract features or urinary tract infection features or as diarrhea. Hence any fever should be suspected as malaria, screened and treated if found positive.[3]

Among the two species of plasmodium causing almost 99% of cases of malaria, falciparum contributes to less than one third cases but is fatal as it causes cerebral malaria. Hence its rapid detection is very important.[4] The case fatality rate of cerebral malaria even when treated in hospital can reach to around 30-40%.[5]

Routinely for diagnosis of malaria, thick and thin smears are prepared and observed under the microscope. The thick smear helps to identify the parasite of malaria. The thin smear is useful to identify the species of the malaria parasite. It is the gold standard in detection of malaria parasite.[6] But strictly speaking, this microscopy procedure requires the presence of laboratory, a skilled technician who is experienced in microscopy. This procedure is time consuming and puts cost burden.

Time wasted is life wasted.[7] The places where these lab facilities are present, malaria incidence seems to be low. The places where these lab facilities are absent, malaria incidence is more. The smears from these areas need to be sent to the nearest primary health centre for diagnosis.[8]

Hence rapid diagnostic kits have been developed to overcome this problem for detection of falciparum malaria so that treatment can be initiated at the earliest and complications can be prevented.[4]

Hence present study was carried out to study the efficacy of rapid test as an aid in rapid diagnosis of malaria at bed side in an endemic region.

## METHODS

A hospital based cross sectional study was carried out in the department of pediatrics. The in-patients of the department of pediatrics SVS Medical College, Mahabubnagar, Telangana, India were the cases for the present study. Present study was carried out from September 2015 to September 2016. Present study was a diagnostic evaluation study to evaluate the efficacy of the rapid malaria test kits in comparison to conventional microscopy.

### *Inclusion criteria*

- Children in the age group of 1-14 years
- Admitted to pediatric ward with fever, jaundice, convulsions, pallor and splenomegaly

### *Exclusion criteria*

- Children found to be suffering from infective hepatitis
- Known cases of anemia.

During the study period it was possible to study 100 eligible children.

Institutional Ethic Committee permission was obtained after submitting the proposal. After approval from the Institutional Ethic Committee the study was initiated. Based on extensive review of literature on malaria among pediatric age group, a well-designed, semi structured questionnaire was prepared. It was tested on 10 children. It was found to be feasible with this study questionnaire to carry out the study. Thus, data was collected from all eligible children as per the inclusion and exclusion criteria laid down for the present study after obtaining informed verbal consent from the parents of these selected children. The information was collected in the pre-designed, pre tested, semi structured study questionnaire for the present study.

After obtaining basic demographic and clinical data from each child, the blood sample from each child was collected using standardized methods taking all universal precautions.

Each sample was tested for malaria by two tests. One with peripheral smear and one with the rapid diagnostic kits. For peripheral smears, the thick and thin smears were prepared. The staining and other procedures were done as per the standard protocol for laboratory methods. The results of both the tests were recorded and compared.

Each sample was also tested for type of anemia and other necessary things depending upon the need for the child.

All cases received treatment as follows:

- Cerebral malaria cases were treated with intra venous Quinine with cardiac and glucose monitoring with supportive therapy. IV quinine was changed to oral after patient is stabilized for total of 7 days. For non-responsive cases intra muscular Artimether was used OD for 5 days.
- Uncomplicated cases of malaria were treated with oral chloroquine for 3 days.
- Radical therapy with Primaquine is given for 14 days in vivax infection.
- Smears were prepared every 24 hours to detect the rate of parasitemia. Child was declared cured when smears were negative for ring forms. Follow up smears were repeated on day 7, day 14, and day 28 for any persistent parasitemia.

### *Statistical analysis*

Chi square test/Fisher Exact test has been used to find the significant association of findings. Diagnostic statistics viz. Sensitivity, Specificity, PPV, NPV, Diagnostic Accuracy were obtained.

## RESULTS

Table 1 shows age wise distribution of children. The mean age was 7.22 years.

Maximum cases were in the age group of 6-10 years i.e. 39% followed by children in the age group of 1-5 years i.e. 36%.

**Table 1: Age wise distribution of children.**

| Age group (years) | Number | Percentage |
|---|---|---|
| 1-5 | 36 | 36.0 |
| 6-10 | 39 | 39.0 |
| 11-15 | 25 | 25.0 |
| Total | 100 | 100.0 |
| Mean±SD | 7.22±3.74 | |

**Table 2: Clinical findings symptoms in children with suspected malaria.**

| Presenting symptoms | Number (n=100) | % | 90%CI |
|---|---|---|---|
| Fever | 100 | 100.0 | 97.37-100.00 |
| Splenomegaly | 74 | 74.0 | 66.22-80.62 |
| Pallor | 67 | 67.0 | 58.91-74.20 |
| Convulsion | 42 | 42.0 | 34.20-50.22 |
| Jaundice | 12 | 12.0 | 7.63-18.37 |

Table 2 shows clinical findings symptoms in children with suspected malaria all children presented with fever to the pediatrician.

The prevalence of splenomegaly was very high i.e. 74% and this was followed by pallor in 67% of the cases. 42% of the children had convulsions. While 12% children developed jaundice.

**Table 3: Diagnosis of malaria by conventional microscopy and rapid method.**

| Findings | Microscopy (n=100) | | Rapid method (n=100) | |
|---|---|---|---|---|
| | No. | % | No. | % |
| Negative for malaria | 47 | 47.0 | 48 | 48.00 |
| *Plasmodium falciparum* | 45 | 45.0 | 44 | 44.00 |
| *Plasmodium vivax* | 8 | 8.0 | 8 | 8.0 |

Table 3 shows diagnosis of Malaria by Conventional microscopy and Rapid method.

In present study in 100 clinically suspected cases 45 cases were positive for P. falciparum by microscopy, and 44 were positive by Rapid method. 8 cases were positive for P. vivax by both the methods.

**Table 4: Age wise distribution of malaria positive children.**

| Age in years | Number | Percentage |
|---|---|---|
| 1-5 | 16 | 30.2 |
| 6-10 | 17 | 32.1 |
| 11-15 | 20 | 37.8 |
| Total | 53 | 100.0 |

Table 4 shows age wise distribution of malaria positive children. In 53 proved cases of malaria 16 were in 1 to 5 year age, 17 were in 6 to 10 years age and 20 were in 11 to 15 year age.

**Table 5: Sex distribution among the proved malaria cases.**

| Sex | Number | Percentage |
|---|---|---|
| Male | 31 | 58.5 |
| Female | 22 | 41.5 |
| Total | 53 | 100.0 |

Table 5 shows sex distribution among the proved malaria cases in present study 58.5% of males and 41.95% of females were positive for Malaria.

**Table 6: Distribution of malaria positive children as per clinical findings.**

| Presenting symptoms | Number (n=53) | Percentage |
|---|---|---|
| Fever | 53 | 100.0 |
| Splenomegaly | 46 | 86.8 |
| Convulsions | 23 | 43.4 |
| Pallor | 37 | 69.8 |
| Jaundice | 10 | 18.9 |

**Table 7: Performance of rapid method in comparison with conventional microscopy in diagnosis of malaria.**

| Rapid vs. Microscopy | Malaria Species | | Combined |
|---|---|---|---|
| | *Plasmodium falciparum* | *Plasmodium vivax* | |
| True positive (n) | 44 | 8 | 52 |
| False Positive (n) | 0 | 0 | 0 |
| False negative(n) | 1 | 0 | 1 |
| True negative (n) | 47 | 47 | 47 |
| Sensitivity (%) | 97.78 | 100.00 | 98.11 |
| Specificity (%) | 100.00 | 100.00 | 100.00 |
| PPV (%) | 100.00 | 100.00 | 100.00 |
| NPV (%) | 97.82 | 100.00 | 97.92 |
| Accuracy (%) | 98.91 | 100.00 | 99.00 |
| P value | <0.001** | <0.001** | <0.001** |

Table 6 shows distribution of malaria positive children as per clinical findings. The Table 6 shows that all malaria cases had fever (100%), 86.8% had splenomegaly, 69.8% had pallor, 43.4% had convulsions and 10% had jaundice.

Table 7 shows performance of rapid method in comparison with conventional microscopy in diagnosis of malaria. Present study has showed that rapid method had excellent sensitivity and specificity (100%) for detecting plasmodium vivax, very good sensitivity and specificity (97.8%, 100%) for detecting *Plasmodium falciparum*. Rapid test had positive predictive value of 100%, negative predictive value of 98.9% and accuracy of 98.9% with p value <0.001.

## DISCUSSION

Out of 100 clinically suspected cases of malaria majority were in 1 to 5 year age group. All the clinically suspected cases of malaria had fever; majority of them had splenomegaly, pallor, and convulsions. 45% cases were positive for *P. falciparum* by microscopy, and 44 were positive by rapid method. 8 cases were positive for P. vivax by both the methods. 58.5% of males and 41.95% of females were positive for Malaria. Rapid method had excellent sensitivity and specificity (100%) for detecting plasmodium vivax, very good sensitivity and specificity (97.8%, 100%) for detecting *Plasmodium falciparum*. Rapid test had positive predictive value of 100%, negative predictive value of 98.9% and accuracy of 98.9% with p value <0.001.

The incidence of malaria was 53% in the present study among children with clinically suspected malaria. Falciparum dominated with a huge number of cases of 45 i.e. 84.9% and vivax contributing to only eight cases i.e. 15.1% of the cases. This is totally in contrast to the picture depicted in India, where vivax contributes to nearly 70% of the total cases and falciparum contributes to nearly 25-30% of the total cases. This contrast may be due to the fact that present study is a hospital-based study and done among the children who were admitted in the pediatric wards. Only complicated cases will be admitted to the hospitals and complicated cases are only caused by falciparum and not by vivax. Hence, we got typical hospital-based study picture. This does not represent the status of malaria in community at all.

Rapid test was able to detect all vivax cases. Rapid test was also able to detect all but one falciparum cases. On detailed history it was found that the one patient who was negative for falciparum had received the anti-malaria treatment before coming to hospital. Thus, rapid test has established itself as the equivalent or even we can say equal status compared to the gold standard test i.e. smear examination under microscope.

Present study showed 97.8%, 100% sensitivity for pf and Pv respectively. 100% specificity for both pf and Pv. The positive and negative predictive values were 100% and 98.9% respectively. The accuracy of Rapid test was 98.91% with p value <0.001.

**Table 8: Comparison of present study with other studies.**

| | Present study | Palmer CJ et al study | Singh N et al Study |
|---|---|---|---|
| Sensitivity | 97.8% (Pf)<br>100% (Pv) | 98% | 100% |
| Specificity | 100% (Pf)<br>100% (Pv) | 100% | 97% |
| Positive predictive value | 100% | 100% | 98% |
| Negative predictive value | 98.9% | 99% | 100% |
| Accuracy | 98.9% | 99% | 99% |

Thus, from Table 8 we can say that the findings of the present study are similar with the findings with study by Palmer CJ et al and study by Singh N et al.[4,9]

Thus, rapid test has established itself as the equivalent or even we can say equal status compared to the gold standard test i.e. smear examination under microscope.

In present study group there was one death, case of cerebral Malaria which occurred on the day of admission who could not afford for ventilatory support.

The rapid test is bit costlier than the conventional microscopy. But it is cost effective though not cost beneficial. Because any one can use it, rapid diagnosis and prompt treatment is possible with this kit at the remote place also. It saves lives and prevents life threatening complications.

## CONCLUSION

Thus, rapid test has established itself as the equivalent or even we can say equal status compared to the gold standard test i.e. smear examination under microscope. The rapid test is bit costlier than the conventional microscopy. But it is cost effective though not cost beneficial. Because any one can use it, rapid diagnosis and prompt treatment is possible with this kit at the remote place also. It saves lives and prevents life threatening complications.

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