ORIGINAL ARTICLE

Evaluationof ParaSight F Test in Dignosis of Plasmodium Falciparum Infection

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Abstract

P. falciparum malaria is a severe form of disease which requires urgent diagnosis and treatment to save the life of patient. Blood smear examination is the commonest method used for diagnosis. The present study was done to evaluate ParaSight F test in patients of P. falciparum infection.The study was performed on 100 patients who where clinically diagnosed as cases of P. falciparum infection. ParaSight F test and Leishman stained blood smear examination was done in all 100 patients (50 patients of cerebral malaria + 50 patients of acute malaria).ParaSight F test was positive in 45 patients and blood smear positive in 28 patients of cerebral malaria. 35 patients of acute malaria were positive by ParaSight F test while blood smear was positive in 15 patients. Sensitivity, specificity, positive and negative predictive values of ParaSight F test are 95.7%, 100%, 100%, 100%, 60% in cerebral malaria and 100% each in acute malaria. ParaSight F test can be used as diagnostic tool in cases of P. falciparum infections, where blood smear is negative.

Key Words

ParSight F Test, P Falciparum, Cerebral Malaria

Introduction

Malaria is one of the most important parasitic disease, which kills between 1.1 to 2.7 million people worldwide each year (1). P. falciparum is responsible for severe form of infection and is associated with high mortality and morbidity if not diagnosed and treated early. Since decades definite diagnosis is based on clinical criteria supported by blood smear examination under light microscope (2). Nothing is found to be better than the direct examination of parasite, but it is time consuming, requires infrastructure and single negative smear does not rule out malarial infection.

Newer diagnostic test like ParaSight F test can be used as an adjunct to microscopy in suspected P. falciparum infection, for early treatment. ParaSight F test is an immunochromatographic test to detect histidine rich protein (HRP-2) antigen secreted by P. falciparum throughout erythrocytic cycle (3). This study was designed to evaluate the effectiveness of ParaSight F test and to compare it with standard blood smear examination in patients of P. falciparum infection.

Material and Methods

Study Group: Comprised of patients admitted in Paediatric and Medicine wards of J.N. Medical College Hospital, Aligarh, India. They are divided into two groups.

Group I: Comprised of 50 patients who were clinically diagnosed as cases of cerebral malaria.

Group II: Comprised of 50 patients diagnosed as cases of acute malaria (history of fever with chills and rigors) complications associated withP. falciparum infection other then cerebral involvement, clinically suggestive of P. falciparum infection.

Control Groups: Comprised healthy individuals

Group I: Comprised of 10 healthy individuals. There was no history suggestive of malaria or anti-malarial treatment in past 6 months in all individuals included in this group

Group II: Comprised of 10 patients whose blood smear was positive for P. vivax, to rule out cross-reactivity in ParaSight F test.

Leishman's stained blood smear examinations were performed in all patients of study groups and both thick and thin blood smears were examined under 100x. ParaSight F test was performed by pricking a finger and taking 50ml of blood in heparinized capillary tube and transferred to a dispensing tube containing haemolysing agent. One drop of haemolysed blood was transferred from dispensing tube into a well on plastic plate provided with the kit. The dipstick was placed vertically into the haemolysed blood sample. One drop of detection reagent containing a rabbit polyclonal antibody raised against PfHRP-II labeled with sulforhodamine B, was added. Once absorption was complete, one or two drops of washing reagent were added to clear the haemolysed blood. If the blood sample was positive for P. falciparum, a pink line developed almost simultaneously at monoclonal antibody deposit site and a pink broken line above it as reagent control. In negative cases, only the pink broken line developed.

Statistical Analysis

It was carried out using tests of significance such as Z test. Sensitivity, specificity, positive and negative predictive values of ParaSight F Test was calculated keeping in consideration, clinical diagnosis and response to anti-malarial treatment.

Results

The study group comprised of 100 patients (50 in each group I, and group II). In group I, all patients presented with affected level of consciousness fever and convulsions were present in 10(20%), renal complaints in 8(16%) and loose stools in 1(2%) cases. In group II all patients presented withfever 50 (100%), vomiting 28(56%), headache 21(42%), loose stools 3(6%),

Yellowish discoloration of eyes 1(2%) and renal complaints 1(2%) were also present *(Table I)*.

Out of 50 patients 28 patients in group I and 15 in group II were positive by Leishman's stained blood smear examination. ParaSight F test was positive in 45 and 35 cases in group I and group II respectively *(Table II)*.

On comparing ParaSight F test with blood smear examination for diagnosis of P. falciparum infection we have applied Z-test for statistical analysis $Z = 3.8$ (p value <0.001) in study group I and $Z = 4.4$ (p values <0.001) which are statistically significant.

Taking into consideration clinical diagnosis & response to anti-malarial treatment in patients of both study groups sensitivity, specificity, positive and negative predictive values were calculated.Leishman's stained blood smear examination was positive in 28 patients and 15 in study group I and II and ParaSight F test was positive in 45 in group I and 35 in group II. In study group II out of 50 patients 15 were positive for P. falciparum and 12 were positive for P vivax *(Table II)*. *Table 1* shows distribution of symptoms in study groups.

In study group I 5 patients who were negative by ParaSight F test 3 were later found to be suffering from pyogenic meningitis other 2 patients whose ParaSight F test was negative were found positive by Leishman's stained blood smear examination.

On comparing ParaSight F test with blood smear examination for diagnosis of P. falciparum infection we have applied Z-test for statistical analysis $Z = 3.8$ (P<0.001) in study group I which is statistically significant. $Z = 4.4$ (P<0.001) in study group II which is also statistically significant. Sensitivity, specificity, positive and negative predictive values of ParaSight F test in group I are 95.7%, 100%, 100%, 60% respectively, in group II are values are 100% each.

ParaSight F test was more costly, less time consuming, technical expertise are not required, no laboratory or microscope is required. For Leishman stained blood smear examination we need laboratory, more time consuming expert microscopist is required, but is a cheaper. No cross reactivity with P. vivax was observed in control group II.

Table I: Distribution of Clinical Symptoms in Study Group

S.No.	Group I (n = 50) Cases of Cerebral Malaria		Group II (n = 50) Case of Acute Malaria	
	Symptoms	No. of Cases	Symptoms	No. of Cases
1.	Fever	50 (100%)	Fever	50 (100%)
2.	Affected Consciousness	50 (100%)	Vomiting	28 (56%)
3.	Convulsion	10 (20%)	Headache	21(42%)
4.	Renal complaints	8 (16%)	Renal complaints	3 (6%)
5.	Loose stools	1 (2%)	Loose stool	1 (2%)
6.	Yellow discoloration	9 (0%)	Yellowish discoloration	1 (2%)

Table –II: Comparison of Blood Smear with ParaSight F Test

S.No. Diagnostic test	Cases Positive for P. falciparum	
	Study group I (n=50)	Study group II (n=50)
1. Leishman's stained Blood Smear Examination	28	15
2. ParaSight F test	45	35

 Z = 3.8 (Group I), Z = 4.4 (Group II)

Discussion

The majority of cases of malaria worldwide are treated on the basis of clinical diagnosis and microscopy. Although microscopic examination of blood smear continues to be the gold standard, it has a drawback that it is time consuming and requires an expert microscopist and results are poor in cases of low parasitaemia. Several studies have shown that ability to diagnose malaria by blood film examination alone is about 75% for P. falciparum.

In this study, we have compared ParaSight F test with Leishman stained blood smear examination. In study group I 28(59.57%) patients were positive for P. falciparum on blood smear examination either due to low parasitaemia or improperly treated cases 45(90%) patient were positive by ParaSight F test, 3 were of pyogenic meningitis, so only 47 patients had cerebral malaria in group I. That means (40.42%) of patients could not be diagnosed by this conventional method of blood smear examination ini study group I. In study group 12 patients were positive by blood smear examination but negative by ParaSight F test. Similar problem of false negative results were found by other workers. Plausible explanation include deletion of HRP-2 gene, antigen variation in HRP-2, the presence of blocking antibodies or immune complex formation (4).

In study group II all 38 patients who had P. falciparum infection showed ParaSight F test positive. No case was detected which showed false positive ParaSight F test in our study as reported by other workers (5) due to cross reactivity with rheumatoid factor.

Our results are in agreement with results reported by Lema *et al* (4). Basis of this study the ParaSight F test is a rapid antigen detection assay with very high sensitivity and specificity with even better performance then conventional blood smear examination in cases were parasitaemia is low, in partially treated cases or where there is urgent need for diagnosis. This is in concordance with other hospital based field studies done by other workers (6-13).

Mengesha *et al* (6)1999 in their study in Ethiopia found sensitivity, specificity, positive and negative predictive values as 92.5%, 93%, 82% and 995 respectively Ficci *et al* (8) 2000 showed sensitivity of ParaSight F test to be 94% in comparison with light microscopy.Recently also one of our study (14) also recorded sensitivity and specificity of ParaSight-F test to be 96.6 and 94%. Sensitivity specificity positive and negative predictive values are higher in our study due selection of patients, we have carried out study in patients where there was very high suspicion of P. falciparum infection.Recent metaanalysis suggested that overall, the Parasight-F test demonstrated 0.90 (95%, confidence intervals 0.88-0.93) sensitivity and 0.94 (0.92-0.96) specificity.The Parasight-F test is a simple and accurate test for the diagnosis of P. falciparum infection. The test could be of particular value in the diagnosis of malaria in travelers returning from endemic areas (15).

Conclusion

ParaSight F test was found to be highly sensitive and specific for diagnosis of P. falciparum infection. It can be used as an effective tool for rapid diagnosis, to prevent mortality and morbidity associated with P. falciparum, and in areas where expert microscopists are not available and in partially or improperly treated cases where blood smear is negative.

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