SPECIFICITY AND SENSITIVITY FOR MALARIA DETECTION BY RAPID (PARAHIT) DETECTION TEST AND MICROSCOPIC METHOD

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ABSTRACT

Malaria continues to be a major killer of mankind, especially in developing countries.¹ It is a disease of antiquity, has proved to be a formidable deterrent to the cultural and socio-economic progress of man in tropical, subtropical and monsoon prone zones of world.² One of the most pronounced problems in controlling the morbidity and mortality caused by malaria is limited access to effective diagnosis and treatment in areas where malaria is endemic.³ 100 cases were analyzed in respect of clinical presentation by routine microscopic methods and the immune assay techniques namely pLDH antigen detection for rapid P. falciparum and P. vivax detection. More than two third (67%) positivity rate for P. falciparum blood smear. The pLDH antigen detection was positive in 58% of P. falciparum cases while 22% of P. vivax cases. Also pLDH antigen detection immunoassay gives 100% specificity and 85.42% sensitivity.

Key Words: Malaria detection, Specificity and sensitivity of rapid test, ParaHIT

INTRODUCTION

Malaria continues to be a major killer of mankind, especially in developing countries.¹ It is a disease of antiquity, has proved to be a formidable deterrent to the cultural and socioeconomic progress of man in tropical, subtropical and monsoon prone zones of world.²

The Causative agents in humans are four species of plasmodium protozoa-P.falciparum, P.ovale and P.Malariae. Of these, P.Falciparum account for majority of morbidity and is most lethal.

The disease now occurs in more than 90 countries worldwide. It is estimated that there are over 500 million clinical cases and 2.7 million malaria –caused deaths per year. Being associated with most serious complications, diagnosis of P.falsiparum malaria constitutes a

medical emergency. One of the most pronounced problems in controlling the morbidity and mortality caused by malaria is limited access to effective diagnosis and treatment in areas where malaria is endemic.³

Microscopic examination of blood smears is the widely used routine method for detection of malaria parasite and remains the gold standard for malaria diagnosis. But microscopic laborious examination is and requires considerable expertise for its interpretation, particularly at low levels of parasitaemia. In with addition, in patients plasmodium falciparum malaria, sometimes the parasites can be sequestered and are not present in peripheral blood. Thus, a P. falciparum infection could be missed due to absence of the parasite in the peripheral blood film. Besides these, majority of

malaria cases occur in rural areas where there is little of no access to reference laboratories and in many areas, microscopy is not available. Because of the non-specific nature of the symptoms and signs of malaria, this results in considerable mistreatment, both over-treatment with antimalarial agents and under-treatment of those with non-malarial illness. Keeping all these in mind, the World Health Organization has recently reiterated.⁴ The urgent need for simple and cost effective diagnostic tests for malaria to overcome the deficiencies of light microscopy and clinical diagnosis.

Recently, rapid non-microscopic tests for the detection of plasmodium falciparum infection have been introduced to overcome problems associated with time constraint and low sensitivity in diagnosing malaria infections with a low level of parasitaemia by microscopy. These rapid tests are based on the detection of antigens released from parasitezed erythrocytes.⁵ One of them is paraHIT f test. This test utilizes the detection of Histidine Rich Protine II which is species specific test for P.falciparum malaria.1 The other is Plasma Dehydrogenase Lactate (pLDH) antigen produced by all four species of genus plasmodium which infect humans.6

Similar test for P.Vivax is also available now commercially in developing countries like ours, if the cost becomes reasonable then it can be beneficially used as an adjunct to microscopy especially in endemic areas, peripheral and tertiary centers and for rational use of antimalarials.

MATERIALS AND METHOD

The present study has been carried out from April 2006 to October 2006 in Sir Sayajirav Gyakwad Hospital, Vadodara. The study was done on the cases of fever admitted in the hospital & suspicious of having fever on the basis of clinical findings. The study included 100 Rapid dipstick test and cases. smear examination were done. The cases with smear positive for P.falciparum and P.vivax malaria were used for calculation of sensitivity and specificity. Positivity of thick and thin smear & positive ParaHIT test are compared for sensitivity and specificity. Data entry and analysis was undertaken by EpiInfo software (version 6.04).

RESULTS

During the present study 100 cases were analyzed in respect of clinical presentation by routine microscopic methods and the immune assay techniques namely pLDH antigen detection for rapid P. falciparum and P. vivax detection.

| Table 1: Distribution of malarial cases according |
|--|
| to their result by Dipstick with Microscopy |

| Results | Positive | Positive | |
|---------------|------------|-----------|-----------|
| | cases by | cases by | Negative |
| | Microscopy | Dipstick | cases by |
| | (%) | (%) | Dipstick |
| P. falciparum | 67 (69.8) | 58 (70.8) | 09 (64.3) |
| P. vivax | 27 (28.1) | 22 (26.8) | 05 (35.7) |
| Mixed | 02 (2.1) | 02 (2.4) | 00 (Nil) |
| Total | 96 | 82 | 14 |

The careful thick and thin peripheral blood smear examination made it easy, with the fact that, it was correlated well with serological marker i.e. pLDH antigen detection. Our casestudy showed 67% positivity rate for P. falciparum blood smear. The pLDH antigen detection was positive in 58% of P. falciparum cases while 22% of P. vivax cases were positive by same technique.

| Table 2: Dipstick and microscopic result wise |
|---|
| comparison of cases |

| Dipstick | Microscopy | | | |
|----------|------------|------------|------------|--|
| Test | Positive | Negative | Total | |
| Positive | 82 (a) | 00 (b) | 82 (a + b) | |
| Negative | 14 (c) | 04 (d) | 18 (c + d) | |
| Total | 96 (a + c) | 04 (b + d) | 100 | |

The present study evaluates the comparison of methodology used for definite diagnosis of specific parasite by conventional method such as the thick and thin blood smear examination with the serological marker viz. pLDH antigen detection immunoassay which gives 100% specificity and 85.42% sensitivity along with its other merits explained earlier and documented.

DISCUSSION

Newer, more advanced malaria diagnostics based on fluorescent microscopy and detecting of nucleic acid (PCR) are well known, but there are limitations for these newer techniques viz. require skill, equipments and are it universally available in many malaria-endemic countries. Recently introduced diagnostic tests based on immune assays solve this problem, since they are easy to run and interpret and do not require complex equipment or technical support. They are also rapid (20 min / test) and at least having comparable sensitivity with traditional microscopy⁷.

The present study evaluates the comparison of methodology used for definite diagnosis of specific parasite by conventional method such as the thick and thin blood smear examination with the serological marker viz. pLDH antigen detection immunoassay which gives 100% specificity and 85.42% sensitivity along with its other merits explained earlier and documented.

CONCLUSION

Comparing ParaHIT Total test with microscopy the sensitivity is 85.42% and specificity of test is 100%. Positive predictive value is 100% and Negative predictive value is 63.16%.

Thus, concluding that in contrast to light microscopy, the ParaHIT Total test is rapid and technically easy to perform. It takes approximately 10 minutes to perform a single test and we can perform many tests simultaneously. Minimal training is required to perform the assy. No equipment is required. It require little space and no electricity supply. As it is rapid method, it helps in management of sever cases of malaria particularly at peripheral health centres. Both specificity and sensitivity of this test is comparable to the microscopy which is considered as 'Gold standard' currently. So, this test is very useful in rapid diagnosis of complicated falciparum cases, partially treated cases, at peripheral health centers, was microscopy is not feasible.

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