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Original Research Article

# A Hospital Based Assessment of the Diagnostic Efficacy of Two Different Approaches in the Diagnosis of Malaria

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**Abstract**

**Aim:** Evaluation of Rapid diagnostic tests compared to peripheral smear in the diagnosis of malaria.

**Methods and Materials:** This is a retrospective hospital-based study was conducted in the Department of pathology, NMCH, Patna, Bihar, India for 9 months. During this period, 1835 blood samples were received for malaria diagnosis from clinically suspected cases. Blood samples were collected in EDTA vacutainer tube. Peripheral smears were made on a clean glass slide with a drop of blood, air dried and stained with Leishman stain. Smears were thoroughly examined under oil immersion for the presence of malaria parasite. Of 1835 samples, 600 samples were randomly selected and Rapid Diagnostic test was performed using Antigen based Pf (HRP-II) and PV (pLDH) specific kit. Procedure was performed as per manufacturer's instructions.

**Results:** Of the 600 Peripheral smears studied, 175 showed positive for malarial parasite. Plasmodium Vivax (Pv) was diagnosed in 173 Cases, Plasmodium Falciparum (Pf) was identified in one case and one smear showed mixed infection with both Plasmodium Vivax and Plasmodium Falciparum. Rapid Diagnostic test showed 189 positive cases, of which 178 were plasmodium Vivax, four cases were Plasmodium Falciparum and seven cases showed mixed infection with Falciparum and Vivax. Sensitivity, specificity, Positive Predictive Value and Negative Predictive value were 100%, 96.7%, 92.5% and 100% respectively.

**Conclusions:** Peripheral smears are considered to be gold standard for diagnosis of malaria. RDTs can be more sensitive and specific than peripheral smears. Newer Pf /Pv specific antigen card can distinguish mixed and PF infections. However further studies are required to assess cost effectiveness and efficiency of different RDTs.

**Keywords:** Malaria diagnosis, Rapid Diagnostic test, Diagnostic accuracy



## Introduction

Malaria, a life-threatening disease caused by Plasmodium parasites, remains a significant public health challenge, particularly in tropical and subtropical regions. Accurate and timely diagnosis is crucial for effective treatment and control of malaria. Traditionally, the microscopic examination of blood smears, known as the peripheral smear, has been the gold standard for malaria diagnosis. However, rapid diagnostic tests (RDTs) have emerged as an alternative diagnostic tool, providing quicker results and requiring less technical expertise. The peripheral smear involves staining a blood sample with Giemsa stain and examining it under a microscope to identify and quantify Plasmodium parasites. This method allows for the differentiation of Plasmodium species and assessment of parasite density, which is important for monitoring treatment efficacy and disease severity . Despite its advantages, the peripheral smear has limitations, including the need for well-trained personnel, time-consuming procedures, and reduced sensitivity in low-parasite-density infections. [1,2] RDTs detect specific antigens derived from malaria parasites in a blood sample, offering a simple, rapid, and reliable diagnostic alternative to microscopy. The most commonly used RDTs target histidine-rich protein 2 (HRP2) produced by Plasmodium falciparum and Plasmodium lactate dehydrogenase (pLDH), which is present in all Plasmodium species . These tests can produce results in 15-20 minutes and do not require extensive laboratory infrastructure or highly trained personnel, making them suitable for use in remote and resource-limited settings. Studies comparing the effectiveness of RDTs and peripheral smears have shown mixed results. Some research indicates that RDTs have high sensitivity and specificity for P. falciparum, making them a valuable tool in areas

with a high prevalence of this species . However, the performance of RDTs can vary based on factors such as parasite density, species, and the quality of the test kits. In contrast, peripheral smears, while more labour-intensive, provide more comprehensive diagnostic information, including species identification and parasite quantification, which are crucial for patient management and epidemiological studies. [3,4] Despite the advantages of RDTs, several challenges remain. False-negative results can occur due to genetic variations in the HRP2 gene, leading to undetected P. falciparum infections . Additionally, RDTs may produce false positives due to persistent antigenemia after parasite clearance, potentially resulting in unnecessary treatment . Quality control and assurance are critical for both RDTs and peripheral smears to ensure accurate and reliable diagnoses. Regular training and proficiency testing of laboratory personnel are essential to maintain the diagnostic accuracy of peripheral smears. [5,6]

## Methods and Materials

This is a retrospective hospital-based study was conducted in the Department of pathology, NMCH, Patna, Bihar, India for 9 moths. During this period, 1835 blood samples were received for malaria diagnosis from clinically suspected cases. Blood samples were collected in EDTA vacutainer tube. Peripheral smears were made on a clean glass slide with a drop of blood, air dried and stained with Leishman stain. Smears were thoroughly examined under oil immersion for the presence of malaria parasite. Of 1835 samples, 600 samples were randomly selected and Rapid Diagnostic test was performed using Antigen based Pf (HRP-II) and PV (pLDH) specific kit. Procedure was performed as per manufacturer's instructions. About 5 µl of blood was put in sample well with the help of disposable loop provided with the kit. 4 drops of assay diluent provided with the kit was added to second well. Results were interpreted after 15 -20 minutes. Results were interpreted as negative when only control band appeared with two negative test bands and as mixed infection when control band and two test bands appeared. It was interpreted as Plasmodium Vivax infection when PV band appeared along with control band. Plasmodium Falciparum was diagnosed when Pf band and control band appeared. Clinically suspected cases of malaria which had both peripheral smear and Rapid diagnostic tests performed on the same blood sample.

## Results

In the present study six hundred samples were evaluated for the presence of malaria parasite by conventional peripheral smear examination and Rapid Diagnostic Test. Of the 600 Peripheral smears studied, 175 showed positive for malarial parasite. Plasmodium Vivax (Pv) was diagnosed in 173 Cases, Plasmodium Falciparum (Pf) was identified in one case and one smear showed mixed infection with both Plasmodium Vivax and Plasmodium Falciparum. Rapid Diagnostic test showed 189 positive cases, of which 178 were plasmodium Vivax, four cases were Plasmodium Falciparum and seven cases showed mixed infection with Falciparum and Vivax. Sensitivity, specificity, Positive Predictive Value and Negative Predictive value were 100%, 96.7%, 92.5% and 100% respectively.

**Table-1: Showing comparison of Peripheral smears and Rapid Diagnostic Tests diagnoses**

| Results | Peripheral smears | Rapid Diagnostic tests |
|---|---|---|
| Positive cases | 175 /600 (29.1%) | 189/600 (31.5%) |
| Plasmodium Vivax | 173 | 178 |
| Plasmodium Falciparum | 01 | 04 |
| Mixed infection | 01 | 07 |
| Negative | 425/600 (70.9%) | 411/600 (68.5%) |
| Total cases | 600 | 600 |

## Discussion

Accurate diagnosis and early treatment of malaria is essential to reduce mortality and morbidity due to malaria. The various modalities to diagnose malaria are conventional peripheral smear, Quantitative Buffy coat, antigen based Rapid diagnostic kits and Molecular studies (PCR). As per 2011 WHO report, the sensitivity of microscopic examination is less than 75%. It is a common practice in many parts of India to treat febrile patients with antimalarial drugs even after negative microscopic examination which has resulted in resistance to commonly used drug chloroquine. Now the concern is emergence of drug resistance to artemisinin therapy if empirical therapy is followed and this may not be cost effective also as artemisinin is more expensive than chloroquine.[3] There are more than 60 brands of RDTS in the market based on different combination of antigen specificity. Previous studies have shown RDTs that detects Histidine Rich Protein type 2 (HRP-2) are more sensitive in diagnosing Plasmodium falciparum whereas those detecting lactate dehydrogenase (LDH) enzyme are more specific for

P.Vivax diagnosis. [4] In the present study RDT with Pf (HRP 2) and PV (pLDH) specificity were used. Past studies have also proven that the cost of malaria treatment can be reduced by 24% by using RDT and 46% by microscopy against presumptive treatment. [5] In the present study out of 600 patients 189 (31.5%) were positive and 411 (68.5%) were negative to RDT whereas 175 (21.1%) were positive and 425 (70.9%) were negative on microscopic examination. Similar findings were also reported in a study conducted by Rajini Kurup. [6] Previous studies have shown sensitivity and specificity ranging from 84 to 100% for RDT. [7-9] In the present study we found 100% and 96.7% respectively. In our study peripheral smear were negative in 14 cases that showed positivity with RDT. These peripheral smears were retrieved and studied again. In few cases parasite density was very low and occasional parasite was noted after careful screening of the smears and few cases were partially treated cases before visiting this hospital. Compared to Peripheral smear RDTs are more sensitive and specific for diagnosis of P Falciparum and mixed infections. This is important because Falciparum causes severe disease and has high mortality requiring urgent intervention, whereas P. Vivax needs to be treated with primaquine to prevent relapses of malaria. The advantages of RDTs are that it is simple, easy to perform, no instruments or electricity required and interpretation is also easy. But the disadvantage is parasite density cannot be assessed and cannot be used to assess response to treatment as it can be positive for 7-14 days after treatment. [10] > 60 brands being marketed in India there is always confusion about which RDT kit to use. Pf /Pan specific RDTs cannot differentiate mixed infection (Pf with Pv) from P. Falciparum infections. But recently it is found P.Vivax also can lead to serious disease and no longer can be considered as benign malaria.[2] Hence when Pv/Pan specific RDT kit is used, mixed infections are to be confirmed with peripheral smear examination. However, newer Pf/Pv specific RDT kits can differentiate mixed from P. falciparum infections. Peripheral smear though inexpensive of the two is laborious to perform, less sensitive, requires electricity, microscope and skilled technician to interpret. Results depend on quality of the smears. [11] But the advantages of peripheral smears are it is cheaper than RDT, parasite density can be assessed and it can also be used as quality control measure to check efficiency of RDTs.

## Conclusions

Peripheral smears are considered to be gold standard for diagnosis of malaria. RDTs can be more sensitive and specific than peripheral smears. Newer Pf /Pv specific antigen card can distinguish mixed and PF infections. However further studies are required to assess cost effectiveness and efficiency of different RDTs.

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