

Community Based Evaluation of Malaria Rapid Diagnostic Test (ICT) Comparing with Conventional Method of Microscopy

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ABSTRACT

Objective: to estimate the validity of immunochromatographic test (ICT) while comparing it with the conventional method of microscopy.

Study Design: Descriptive / cross sectional study

Place and Duration of Study: This study was conducted at the Community Medicine, Liaquat College of Medicine & Dentistry, Karachi from July 2015 to November 2015.

Materials and Methods: A sample of 296 community members of both sexes and above one year age was taken who were diagnosed clinically as a suspected case of malaria through Community based surveillance in katchi abadi, Karachi. Selected subjects were interviewed using a structured and pre-tested questionnaire regarding socio-demographic variables, their symptoms of malaria. A venous blood sample by the standard venipuncture procedure was collected from each subject and blood CP, ICT and microscopy was performed for Plasmodium Falciparum or Plasmodium Vivax malaria diagnosis and confirmation of the parasite. Data was analyzed on SPSS version 20. The validity of each test was calculated by OpenEpi software.

Results: Using a Wilson score method, the sensitivity of ICT was 82.14% and specificity was 97.01%. The Positive Predictive Value (PPV) for ICT was 74.19% whilst the Negative Predictive Value (NPV) was 98.11%.

Conclusion: Compared with the results of the direct microscopy, ICT gave almost perfect agreement and near-perfect sensitivities and specificities in the detection of the clinically most important species of Plasmodium.

Key Words: Malaria, Rapid diagnostic tests, Microscopy, Sensitivity, Specificity

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INTRODUCTION

Despite decades of malaria control efforts in tropical and subtropical regions of the world, Malaria is still remains a main reason of morbidity and mortality in these regions. According to WHO, the global burden of malaria in 2015 were 212 million new cases and 429,000 deaths.² Based on the reported data in 2012, it is estimated that 45% of the population of the Eastern Mediterranean Region are living in areas at risk of local malaria transmission.

In eastern Mediterranean regions 45% of the population living in areas at risk of local malaria transmission reported in 2012. EMRO region countries are currently in different phases of control of malaria. Malaria is endemic in Pakistan and in the control phase for both *P. falciparum* and *P. vivax*. In 2013 WHO reported total estimated population at risk of malaria transmission in Pakistan, with local transmission is 98.3% of the total population.³ In 2015, National malaria disease surveillance system reported 202,013 confirmed malaria cases in country and in the same year 3.1 million cases were clinically diagnosed and treated at public sector outpatient health care facilities.⁴ Rapid and accurate diagnosis is the key to effective disease management and one of the basic technical elements of the strategy for malaria control.³ So far the light microscopic examination (ME) of the stained blood smears have been considered as the standard gold test for the diagnosis of malaria. ME however, requires well trained and experienced malaria microscopists and it is also rather time consuming. Therefore, the recent introduction of rapid diagnostic tests for malaria is of considerable interest. Such tests are based on antigen capture assay and application of the immunochromato-

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graphy (ICT) method for detection of Plasmodium specific antigen in a finger prick blood sample prepared from suspected malaria patients.^{5,6}

Rapid antigen assays is a valuable tool for the detection of malaria in symptomatic patients. The diagnosis of falciparum malaria with parasitemias of $> \text{or} = 500$ trophozoites/microL through ICT Malaria Pf/Pv test showed 100% sensitivity and 99.7% specificity in previous studies.⁷ The performance of Rapid diagnostic tests (RDTs) was measured against microscopy and showed a 97% and 100% specificity and sensitivity, respectively. ICT was 97% sensitive and 98.3% specific for *P. falciparum* and 89.7% sensitive and 97.9% specific for *P. vivax*.⁸ Khurshid et al also reported that ICT tests are simple to use and effective diagnostic tool for detection of malaria but expensive than other tests.⁹ ICT is very helpful for the remote areas as well as for clinics and health centers where the necessary facilities for ME are not accessible for the prompt diagnosis of falciparum infection, particularly in patients with severe and complicated malaria.⁵

MATERIALS AND METHODS

A sample of 296 community members of both sexes and above one year age was taken who were diagnosed clinically as a suspected case of malaria through Community based surveillance in katchi abadi, Karachi. The subjects were selected cases (male or female) of suspected malaria (defined as presentation with fever or headache or chills), attending health camps for an initial visit and who consented to participate. Patients attending the health camps for follow-up visits, severely ill patients needing referral, patients with an obvious non-malarial fever, and pregnant women were excluded. Written informed consent was obtained from each subject. Selected subjects were interviewed using a structured and pre-tested questionnaire regarding socio-demographic variables, their symptoms of malaria (high grade intermittent fever, headache, body ache), if they were using any medication, about pregnancy in married women and history of recent blood transfusion. A venous blood sample by the standard venipuncture procedure was collected was from each subject and blood CP, ICT and microscopy was performed for Plasmodium falciparum and Plasmodium vivax malaria diagnosis and confirmation of the parasite. The procedure was pre-tested on a small sub sample. Data was analyzed on SPSS version 20. Qualitative variables were presented as frequency and percentages while quantitative mean and standard deviation. Sensitivity and of specificity of each test was calculated and predictability was calculated by Open Epi software.

RESULTS

A total of two hundred and ninety six (296) participants were involved in this study. Out of this 145(49%) were

females and 151(51%) were males. The mean age of study participants was 24 ± 11 and ranged from 1 to 46 years (Table 1). Whilst 112 (37.8%) of the study participants were mohajirs, 76 (25.6%) were Pathans, 59 (19.9%) were Sindhi, 26 (8.7%) were Punjabi and 23 (8%) were from other ethnic groups (Figure 1). Microscopy and ICT malaria test were done for all 296 study participants. Using a Wilson score method, the sensitivity of ICT was 82.14% (95%CI: 64.41, 92.12) and specificity was 97.01% (95%CI: 94.22, 98.48). The Positive Predictive Value (PPV) for ICT was 74.19% (95%CI: 56.75, 86.3) whilst the Negative Predictive Value (NPV) was 98.11% (95%CI: 95.66, 99.19) (Table 2). In terms of the identification of the Plasmodium species present, the ICT gave generally good agreement ($k = 0.76$) with the results of the direct microscopy.

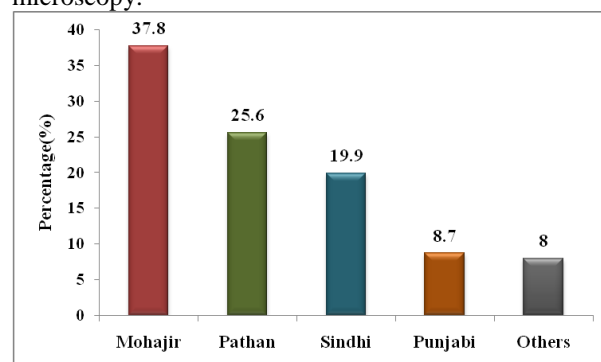


Figure No.1: Ethnicity wise distribution of study participants (n=296)

Table No.1: Characteristics of study participants

Characteristic	n(%)
Age (yrs)	
Range	1 – 46
Median	23.8
Gender	
Male	145(%)
Female	151(%)
Presence of fever	198
Presence of chills	67
Presence of sweating	72
Presence of headache	103

Table No.2: Validity test results for ICT

Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Diagnostic Accuracy
82.14% (64.41, 92.12)	97.01% (94.22, 98.48)	74.19% (56.75, 86.3)	98.11% (95.66, 99.19)	95.61%

DISCUSSION

Malaria remains a noteworthy issue all through the tropics following 50 years of annihilation endeavors. In many parts of the world, doctors regularly diagnose malaria determination in light of clinical manifestations and signs. This strategy has poor specificity and

positive predictive value. It doesn't permit separation of various types of malaria.¹⁰ So far, the light microscopic examination (ME) of the stained blood smear has been considered as the best quality level test and gold standard for the diagnosis of malaria. Microscopic examination of blood smear notwithstanding requires very much trained and experienced microbiologist and it is likewise time consuming.¹¹

Moody revealed ICT technique is a straightforward, fast and reliable tool for recognition of malarial parasite.¹² In the present study, we discovered all age groups ranging from 1-46 years were affected by malaria. Comparative discoveries were found by an investigation in 2016 from Egypt where mean age of patients affected by malaria was 23.7 ± 17.9 (range 6-42 years).¹³ In the present study, we discovered 28(60.20%) were test positive by microscopic examination of peripheral blood film, 31(58.16%) were positive by ICT in the clinically presumed cases. In a study by Khan et al. in 2004 from Pakistan discovered 45.5% positive by microscopic examination of peripheral blood film and 43.2% positive by ICT for antigen.¹⁴ In another investigation done by Iqbal et al. in 2003 from Pakistan discovered 42% were positive by microscopy and 32 % were positive by ICT for antigen.¹⁵

In the present study, we found sensitivity of 93.22% and specificity of 94.87% by ICT for antigen, when compared with microscopic examination of peripheral blood film. In studies that verified RDTs with microscopy, tests that used a *P. vivax* specific antibody line to identify *P. vivax* had a pooled sensitivity of 95% (95% CI 86% to 99%) and a pooled specificity of 99% (95% CI 99% to 100%). Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries.¹⁶ Mohammad et al reported that ICT yielded a very high sensitivity (96.1%) and Specificity (95.7%) for Malaria.¹⁷ In another study Iqbal et al found The overall sensitivity of ICT was 99%, while specificity was 98%, with a PPV of 96% and NPV of 99%. Test efficiency was calculated as 98%.¹⁸ Previous studies and systematic reviews also reported the sensitivity and specificity of ICT ranging from 92-100% and 90-99% respectively.^{13,19,20}

However, this study could not measure the sensitivity of ICT to detect parasitaemia <100 parasites/ μ l of blood. More studies are needed to assess the accuracy of the ICT designed to detect *Plasmodium* species specifically, particularly in areas with low prevalence.

CONCLUSION

Compared with the results of the direct microscopy, ICT gave almost perfect agreement and near-perfect sensitivities and specificities in the detection of *P. falciparum*, the clinically most important species of *Plasmodium*. ICT may be useful in areas where the

majority of malaria is caused by *P. falciparum* or *vivax* and where good quality microscopy is not available at community level.

Author's Contribution:

Concept & Design of Study:	Dr. Riaz Arshad Warriach
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Final Approval of version:	Dr. Riaz Arshad Warriach

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