spastic paraplasia. Various studies have reported a close association of PPK with oesophageal carcinoma[18,25–29] lymphoma/sarcoma[19] squamous cell carcinoma, skin malignancy[20,24,30] and melanoma/sarcoma[21,29,31]. PPK sometimes is also found to be lethal[13–15,18]. No such symptoms could be observed in the present study.

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Field evaluation of HRP-2 antigen detection test kit for *Plasmodium falciparum* malaria

Malaria has emerged as the major disease in the north-eastern region of India and is detrimental to socio-economic development of the region. Transmission of malaria is perennial and persistent, and outbreaks are frequent amounting to high morbidity and mortality largely due to *Plasmodium falciparum* infections (the dreaded form of malaria)[1]. Its control has become a complex enterprise and requires a more skilled and integrated approach based on local intervention strategies and understanding of transmission dynamics[2]. Taking into account the worsening situation, a global malaria control strategy is currently under implementation with the ultimate goal to prevent mortality and reduce morbidity[3]. One of the key components of this strategy is to ensure early diagnosis and prompt treatment (EDPT).

Definite diagnosis of malaria is currently based on microscopic examination of whole blood but this method is time consuming, labour intensive and requires considerable technical skill. It is also rather impractical in remote inaccessible areas with poor health infrastructure. These population groups are worst affected and contribute bulk of *P. falciparum* infections transmitted by the most efficient vectors, i.e. *Anopheles minimus*, *An. fluviatilis* and *An. dirus*[4]. In such pockets, EDPT is all the more important to prevent mortality, and to contain the spread of often drug-resistant varieties of *P. falciparum* (the killer parasite).

In this context, the development of rapid on-the-spot diagnosis of *P. falciparum* infection is very timely.

Presently, two diagnostic test kits namely ParaSight^{TM}-F, a dipstick antigen-

capture assay (Becton Dickinson, Sparks, MD), and immunochromatographic test (ICT Malaria Pf™, ICT Diagnostics, Brookvale, NSW, Australia) are available for rapid diagnosis of *P. falciparum* infection. Both these tests are based on detection of circulating antigen *P. falciparum* histidine-rich protein-2 (Pf HRP-2) in whole blood. It is a water soluble protein synthesized by the parasite and released from the *P. falciparum* infected erythrocytes[5].

Both the tests utilize two antibodies specific for Pf HRP-2 antigen. One of the antibodies is attached to visible colloidal gold and impregnated into an absorbent pad while the second antibody is immobilized in a line across the test strip. Ten microlitre of whole blood is added to the absorbent pad where lysis occurs and Pf HRP-2 if present binds to the colloidal gold-labelled antibody. On adding the buffer to the absorbent pad, both blood and the labelled antibody migrate up the test strip crossing the second antibody. In a positive sample, Pf HRP-2 complexed with gold labelled antibody is captured by the antibody on the test strip and a pink line is formed. In the negative sample, no pink line is seen in the test line area. These kits have a built-in procedural control line to ensure the validity of the test performed.

Both these diagnostic test kits (based on same test principle) were subjected to field evaluation in malaria endemic districts of Assam for their comparative sensitivity and specificity for diagnosis of *P. falciparum* malaria in comparison to routine microscopy by examination of thick and thin blood smears. As many as 119 subjects (comprising all age groups) reporting fever were examined for malaria parasite employing ICT Malaria Pf™ test as well as by microscope for confirmation of test results. Of these, 95 cases were confirmed *P. falciparum* positive by both these methodologies except a lone case of a carrier of mature gametocytes which was concluded to be negative using ICT-Pf kit; thus the overall sensitivity was 98.75%. All *P. vivax* cases diagnosed by microscopic method were recorded negative by ICT-Pf test kit; thus it was 100% specific for *P. falciparum* malaria.

For comparative evaluation of the two test kits, the other kit, i.e. ParaSight-F™ was also field evaluated. Using this kit, 53 subjects reporting fever were tested in parallel with microscopic diagnosis. Of these, 34 cases were diagnosed as *P. falciparum* and one case as mixed infection (Pf + Pv) by microscopy, while all the 35 cases were recorded as *P. falciparum* infections using this kit. Thus, this kit was also highly specific and 100% sensitive to *P. falciparum* infections. All malaria positive cases were administered radical treatment, and of these 9 cases were followed on subsequent days till the subjects were recorded to be parasite/antigen negative by the respective methods. It was observed that the parasitaemia (ranging between 800 and 51,200 per microlitre of blood) was cleared within 3 days of initiation of curative antimalarial chemotherapy while antigenaemia persisted till day 7 as determined by the dipstic method.

Both these test kits are qualitative test methods based on presence or absence of *P. falciparum*-specific antigen in the blood, and results may not always correlate well with the other methods which detect presence of parasite in the peripheral blood. However, these kits are simple to use for on-the-spot diagnosis of *P. falciparum* infection and do not require special equipment and can be performed with minimum skill. It takes less than 8 min to get a definite diagnosis so that treatment can begin without any delay; the latter being the prime cause of mortality due to malaria.

It was concluded that both the kits were equally good as diagnostic tools in this geo-epidemiological setting, but ICT Malaria Pf™ kit was much simpler to perform, involving only a few steps which are well-illustrated in the small-sized kit. Nevertheless, both these kits are much superior to other new approaches, viz. quantitative buffycoat analysis (QBC), polymerase chain reaction (PCR), enzyme linked immunosorbent assay (ELISA), being simpler and cost-effective while working in the field conditions. These kits were also field evaluated in other geo-epidemiological regions and the results were found to be comparable[6–10]. Indeed, the development of these kits will go a long way to achieve the targets in the context of roll back malaria[11].

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