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Short Communication

Performance of OptiMAL-IT® compared to microscopy, for malaria detection in Burkina Faso

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Summary

OBJECTIVE To compare the performance of OptiMAL-IT®, a rapid diagnostic test for malaria, with that of microscopy in Burkina Faso.

METHOD Finger-prick blood samples of 464 children attending hospital for suspected malaria were tested for malaria by microscopy and OptiMAL-IT®.

RESULTS The sensitivity and specificity of OptiMAL-IT® were 98.7% (CI 95% = 97.6–99.8) and 96.2% (CI 95% = 94.3–98.1) respectively, with a high positive likelihood ratio (25.97).

CONCLUSION OptiMAL-IT® can be considered a good method to diagnose malaria in Burkina Faso, particularly in remote areas with little or no access to microscopy services.

keywords malaria, diagnosis, rapid test, Burkina Faso

Misdiagnosis of malaria cases is a major challenge for control programs, possibly resulting in delayed diagnosis and treatment followed by substantial mortality and morbidity in Sub-Saharan countries (Amexo *et al.* 2004). A rapid and accurate method for detecting malaria parasitaemia is essential to address this issue (WHO 2003). Microscopy is currently considered as the golden standard for malaria diagnosis but, despite its apparent simplicity, requires some conditions not always accessible for many peripheral health facilities in Africa (Haditsch 2004). In this context, the rapid diagnostic tests (RDTs) might be a possible alternative. National Malaria Control Programs are being encouraged to include RDTs in the algorithms designed for malaria case management. Nevertheless, choosing a particular RDT is not easy as several brands are available on the market. In addition, little information on the performance of RDTs in Africa is available (Vanderjagt *et al.* 2005). In this study, we evaluated the OptiMAL-IT® (DiaMed Basel, Switzerland), an RDT recently registered by Burkina Faso's Drugs Authorities.

The study was conducted in 2005 in Nanoro, Burkina Faso, where malaria is hyperendemic and the entomological inoculation rate (EIR) is estimated at around 50–60 infecting bites/man/year (T. Baldet, personal communication). Children 6–59 months old attending the local hospital and with suspected malaria were recruited if a parent or guardian gave informed consent. For each patient, two drops of blood were collected by finger prick and used to determine the presence of peripheral parasitaemia (thick/thin blood film) and to perform the RDT. The parasite density was determined according to published methods (Warhurst & Williams 1996). The OptiMAL-IT® test was performed according to the manufacturer's recommendations (Ratsimbasoa *et al.* 2007). The microscopic reader was blinded to the RDT's results. Considering the results of the microscopy as the 'golden standard', we categorised each RDT result as a true-positive, true-negative, false-positive or false-negative. The test's sensitivity, specificity, positive predictive value (PPV), negative predictive value (NNV) and likelihood ratio of a positive test (LR) were then calculated according to published methods (Mboera *et al.* 2006). For each value, the 95% confidence interval (95%CI) ($\alpha = 0.05$) was calculated.

A total of 82.8% (384) of the 464 patients recruited had microscopically detectable peripheral parasitaemia with a

Table 1 Prevalences of malarial infection among the study population as determined by the OptiMAL-IT® and by microscopy

	Microscopy		
	Positive *n* (%)	Negative *n* (%)	Total *n* (%)
OptiMAL-IT Positive	379 (81.68)	3 (0.65)	382 (82.33)
OptiMAL-IT Negative	5 (1.08)	77 (16.59)	82 (17.67)
Total	384 (82.76)	80 (17.24)	464

geometric mean density of 5 237 parasites/μl (SD = 1 576, range = 40–234 280 parasites/μl), mostly *P. falciparum* (94.3%; 362/384). The percentage of children positive to the RDT was slightly lower (82.3%; 382/464) than the percentage detected by microscopy, also mostly *P. falciparum* (97.1%; 371/382) infections. The 379 true positive cases had a geometric mean-parasite density of 4 268 parasites/μl (SD = 740, range = 40–234 280). There were three false-positives and five false-negatives, the latter with a low parasite density (geometric mean = 225.3, SD = 112.8, range = 80–720 parasites/μl) (Table 1). The test's sensitivity, specificity, PPV and NNV were, 98.70 [97.56–99.84], 96.25 [94.35–98.15], 99.21 [98.32–100.0] and 93.90 [69.96–96.29] respectively. OptiMAL-IT® performed very well with an LR of 25.97 [21.98–29.96]. However, its sensitivity falls with the level of parasite density (Table 2).

OptiMAL-IT® RDT is based on the detection of a specific antigens produced by the malaria parasites, the plasmodium lactate dehydrogenase (pLDH) (Makler *et al.* 1998), present in the blood of currently or recently infected people. OptiMAL-IT® performs relatively well, with a false negative result only in children with a low-parasite density. Its sensitivity reported is higher than the 95% recommended by WHO (2003), but drops significantly when parasitaemia is less than 500 parasites/μl, a result consistent with earlier studies in Guyana and Thailand (Palmer *et al.* 1999).

Table 2 Sensitivity of OptiMAL-IT® at different levels of parasitemia

Microscopy parasitemia ranges	*n*	OptiMAL-IT® positive	Sensitivity (%)
<500	51	47	92.2
501–1000	24	23	95.8
1001–5000	85	85	100
5001–10000	59	59	100
>10000	157	157	100

False positives represented less than 1% of all positive by OptiMAL-IT®. This may be due to the cross-reactions with heterophile antibodies in patient's plasma (Ghosh *et al.* 2001; Bell *et al.* 2005) or to parasite density below the microscopy threshold of detection (50–100 parasites/μl) (WHO 1998). Indeed, malaria infection can be detected by PCR in samples negative for microscopy but positive by RDT (Tham *et al.* 1999; Moody & Chiodini 2002).

The RDTs used in this study were permanently stored in individual packages at a temperature below 30 °C. These conditions may not be respected if the tests were stored and made available in peripheral health facilities and might result in a much higher percentage of false positive than described here. Stability is often mentioned when the percentage of false positive is higher than expected, for example in Thailand, where the percentage of false positives was 8% (Pattanasin *et al.* 2003).

In conclusion, in Burkina Faso, OptiMAL-IT® could be a useful alternative to microscopy, although the issue of conservation in peripheral health facilities should be carefully considered before their implementation. The high cost (2.5€) is another reason limiting their scaling up and use in most health facilities. Adequate diagnosis is considered an important component of malaria case management. However, in many African countries microscopy is not available in most peripheral health facilities, even after the change of antimalarial drug policy to artemisinin-based combination treatments. RDT could be a useful tool to overcome this limitation but need to be made more accessible in terms of cost and availability.

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