



CHAPTER IV

DISCUSSION

This study evaluated a new formulation of OptiMAL called OptiMAL-IT (OptiMAL Individual Test). Global sensitivity and global specificity of OptiMAL-IT for *P.falciparum* was 88.1% and 91.8% respectively. Global sensitivity and global specificity of OptiMAL-IT for *non-P.falciparum* was 65.1% and 98.9% respectively. Global sensitivity and global specificity of Paracheck was 89.9% and 95.7% respectively.

The overall validity of pLDH detecting assay (OptiMAL-IT) and HRP-II detecting assay for *Plasmodium falciparum* detection was not significantly different (sensitivity ($p = 0.76$), specificity ($p = 0.10$), PPV ($p = 0.15$), NPV ($p = 0.71$)). The sensitivity of both tests decreased dramatically when the parasitaemia level go down. As the results showed the sensitivity of OptiMAL-IT and Paracheck Pf were 100% when parasitaemia $500 / \mu\text{L}$ of blood (0.01%) but at the parasitaemia level of $100-500 / \mu\text{L}$ of blood ($0.001-0.01\%$) the sensitivity of OptiMAL- IT and Paracheck Pf were 70% and 90% respectively. At the level of parasitaemia $<100 / \mu\text{L}$ of blood ($< 0.002\%$) the sensitivity of OptiMAL-IT and Paracheck Pf were only 20% when compared to microscopy.

To compare the effectiveness of these two rapid diagnostic tests with the conventional microscopy as considered as gold standard, the results demonstrated that at the high level of parasitaemia $500 / \mu\text{L}$ of blood (0.01%) the both rapid tests perform as good as experienced microscopist but when the parasitaemia less than $100 / \mu\text{L}$ of blood ($< 0.002\%$) both tests cannot perform comparable with a microscopist.

When compared the results of this study with the results of previous OptiMAL studies (1,2,4,7,9) we found that sensitivity of OptiMAL-IT in this study is lower. The explanation would be in this Karen community living on the western border of Thailand is an area of low malaria transmission (approximate one infection per person per year), asymptomatic malaria is unusual (C Luxemburger et al., 1997). From this study, 33% (47/141) of positive samples by microscopy had parasitaemia $< 500/\mu\text{L}$ of blood (0.01%), which may decrease a global sensitivity and global specificity of OptiMAL-IT and Paracheck.

Global sensitivity and global specificity of Paracheck in this study was not different from the study by Proux S et al., 2001. The sensitivity at various level of parasitaemia, the results from this study was not different from previous studies (2,4,5,6,8), for *P.falciparum* both tests were found less sensitive when parasitaemia $< 500/\mu\text{L}$ of blood ($< 0.01\%$). For *non-P.falciparum*, OptiMAL-IT sensitivity started to decrease when parasitaemia $< 5,000/\mu\text{L}$ of blood ($< 0.1\%$).

The results obtained from primary and secondary microscopy do not show the difference in species identification so the PCR result for tertiary confirmation at

DiaMed Switzerland is not necessary. In the future, to avoid bias from the company, I would like to suggest to use the laboratory facilities of the Department of Medical Science, Ministry of Health as the reference.

The OptiMAL-IT is designed in an individual device test, which has more advantages above the old OptiMAL because the new test can be kept from humidity for long time after result was read. The new test is also more suitable whether to perform single test or many tests together at the same time. The OptiMAL-IT is presented as a device individually packed in aluminium-coated packets containing a desiccant. Thus, the problem of loss of sensitivity under tropical conditions (temperature > 30°C and humidity > 70 %) reported with the OptiMAL first generation has been solved. The new plastic device is well designed: guides maintain the test strip at a fixed angle in the well and at the end of the procedure the test strip is inserted into a clear plastic cover for a safe storage and permanent record. Strong and intermediate reactive lines are still visible for weeks and allows quality control of the tests. Finally there is a 10 µl mark on the pipette for a calibrated blood collection and a clear schematic procedure is provided with each test. We found both tests, Paracheck and OptiMAL-IT, easy to perform and to teach, however Paracheck procedure has fewer steps.

In the areas of low transmission with multidrug resistant malaria, laboratory confirmation for malaria is necessary for disease management and control whereas in remote areas the health services are usually hardly possible for people to reach as well as reliable microscopy confirmation for malaria is also unavailable. Thus, rapid diagnostic tests (RDTs) for malaria offer the great alternative way to combat with

malaria though the sensitivity at the low parasitaemia level (<100 parasites/ μL of blood) is less than desirable level but RDTs can be performed and diagnosed by local health volunteer in the community then the patient can be treated immediately the incidence of severe malaria could be reduced.



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